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(iii) The sum of packers' reported estimates of the total number of swine committed by contract for delivery during the next 6 and 12 months beginning with the month the report is published. The report will indicate the number of swine committed by geographic reporting region and by contract type.

(iv) The types of conditions or circumstances as reported by packers that could result in expansion in the numbers of swine to be delivered under the terms of expansion clauses in the contracts at any time during the following 12 calendar months.

(v) The sum of packers' reported estimates of the maximum total number of swine that potentially could be delivered during each of the next 6 and 12 months if all expansion clauses in current contracts are executed. The report will indicate the sum of estimated maximum potential deliveries by geographic reporting region and by contract type.

(Approved by the Office of Management and Budget under control number 0580–0021)

CHAPTER III—FOOD SAFETY AND INSPECTION SERVICE, DEPARTMENT OF AGRICULTURE

SUBCHAPTER A—AGENCY ORGANIZATION AND TERMINOLOGY; MANDATORY MEAT AND POULTRY PRODUCTS INSPECTION AND VOLUNTARY INSPECTION AND CERTIFICATION

Part		*Page*
300	Agency mission and organization	81
301	Definitions	82
302	Application of inspection and other requirements	89
303	Exemptions	89
304	Application for inspection; grant of inspection	98
305	Official numbers; inauguration of inspection; withdrawal of inspection; reports of violation	99
306	Assignment and authorities of program employees	100
307	Facilities for inspection	101
308	[Reserved]	
309	Ante-mortem inspection	106
310	Post-mortem inspection	113
311	Disposal of diseased or otherwise adulterated carcasses and parts	130
312	Official marks, devices and certificates	139
313	Humane slaughter of livestock	144
314	Handling and disposal of condemned or other inedible products at official establishments	150
315	Rendering or other disposal of carcasses and parts passed for cooking	153
316	Marking products and their containers	154
317	Labeling, marking devices, and containers	159
318	Entry into official establishments; reinspection and preparation of products	235
319	Definitions and standards of identity or composition	301
320	Records, registration, and reports	320
321	Cooperation with States and territories	322
322	Exports	323
325	Transportation	325
327	Imported products	336

Part		Page
329	Detention; seizure and condemnation; criminal offenses	354
331	Special provisions for designated States and Territories; and for designation of establishments which endanger public health and for such designated establishments	356
335	Rules of practice governing proceedings under the Federal Meat Inspection Act	362
350	Special services relating to meat and other products	362
351	Certification of technical animal fats for export	365
352	Exotic animals; voluntary inspection	371
354	Voluntary inspection of rabbits and edible products thereof	379
355	Certified products for dogs, cats, and other carnivora; inspection, certification, and identification as to class, quality, quantity, and condition	404
362	Voluntary poultry inspection regulations	415
381	Poultry products inspection regulations	419

SUBCHAPTERS B–C [RESERVED]

SUBCHAPTER D—FOOD SAFETY AND INSPECTION SERVICE ADMINISTRATIVE PROVISIONS

390	Freedom of information and public information	620
391	Fees and charges for inspection services and laboratory accreditation	622

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

416	Sanitation	624
417	Hazard Analysis and Critical Control Point (HACCP) Systems	628
424	Preparation and Processing Operations	632
430	Requirements for specific classes of product	658
441	Consumer Protection Standards: Raw Products	661
500	Rules of Practice	663

SUBCHAPTER I—EGG PRODUCTS INSPECTION

590	Inspection of eggs and egg products (Egg Products Inspection Act)	666
592	Voluntary inspection of egg products	712

SUBCHAPTER A—AGENCY ORGANIZATION AND TERMINOLOGY; MANDATORY MEAT AND POULTRY PRODUCTS INSPECTION AND VOLUNTARY INSPECTION AND CERTIFICATION

PART 300—AGENCY MISSION AND ORGANIZATION

Sec.
300.1 Purpose.
300.2 FSIS responsibilities.
300.3 FSIS organization.
300.6 Access to establishments and other places of business.

AUTHORITY: 21 U.S.C. 451–470, 601–695, 1031–1056; 7 U.S.C. 138–138i, 450, 1621–1627, 1901–1906; 7 CFR 2.7, 2.18, 2.53.

SOURCE: 63 FR 72354, Dec. 31, 1998, unless otherwise noted.

§ 300.1 Purpose.

This part describes the duties and organization of the Food Safety and Inspection Service (FSIS), an agency of the United States Department of Agriculture (USDA).

§ 300.2 FSIS responsibilities.

(a) [Reserved]

(b) *Implementing regulations.* This chapter of title 9 of the Code of Federal Regulations (9 CFR chapter III) includes, in addition to administrative rules, rules and regulations that implement provisions of the following statutes:

(1) The Federal Meat Inspection Act, as amended (FMIA) (21 U.S.C. 601 *et seq.*), except provisions pertaining to the inspection and certification of the condition of animals for export, and related legislation;

(2) The Poultry Products Inspection Act, as amended (PPIA) (21 U.S.C. 451 *et seq.*);

(3) The Egg Products Inspection Act, as amended (EPIA) (21 U.S.C. 1031 *et seq.*), except for the shell egg surveillance program, voluntary laboratory analyses of egg products, and the voluntary grading program;

(4) The Humane Slaughter Act (7 U.S.C. 1901–1906);

(5) The Talmadge-Aiken Act (7 U.S.C. 450), with respect to cooperation with States in the administration of the Federal Meat Inspection Act and the Poultry Products Inspection Act;

(6) The Agricultural Marketing Act of 1946, as amended (7 U.S.C. 1621–1627), relating to voluntary inspection of poultry and edible products thereof; voluntary inspection and certification of technical animal fat; certified products for dogs, cats, and other carnivora; voluntary inspection of rabbits and edible products thereof; and voluntary inspection and certification of edible meat and other products; and

(7) The National Laboratory Accreditation Program (7 U.S.C. 138–138i) with respect to laboratories accredited only for pesticide residue analysis in meat and poultry products.

§ 300.3 FSIS organization.

(a) *General.* The organization of FSIS reflects the agency's primary regulatory responsibilities: implementation of the FMIA, the PPIA, and the EPIA.

(b) *Headquarters.* FSIS has four principal components or offices, each of which is under the direction of a Deputy Administrator. The Deputy Administrators, along with their staffs, and the Administrator, along with the Office of the Administrator and three staff offices that report to the Administrator, are located at U.S. Department of Agriculture headquarters in Washington, DC.

(1) *Program offices.* FSIS's headquarters offices are the Office of Public Health and Science, which provides scientific analysis, advice, data, and recommendations on matters involving public health and science; the Office of Management, which provides centralized administrative and support services; the Office of Policy, Program Development and Evaluation, which develops and recommends domestic and international policy activities; and the Office of Field Operations, which manages regulatory oversight and inspection (see paragraph (c) of this section).

(2) *Staff offices.* The Administrator's staff offices are the Food Safety Executive Management and Coordination Staff, the Legislative Liaison Staff, and the Food Safety Education and Communications Staff.

(c) *Field.* FSIS's field structure consists of eighteen district offices and a technical center.

(1) *District offices.* Each district office, under the direction of a District Manager, manages a farm-to-table food safety program of regulatory oversight and inspection in a district consisting of a State or several States and territories.

The locations of the district offices and the districts' geographic boundaries are as follows:

Alameda, CA	California.
Salem, OR	Alaska, American Samoa, Guam, Hawaii, Idaho, Northern Mariana Islands, Oregon, and Washington.
Boulder, CO	Arizona, Colorado, Nevada, New Mexico, Utah.
Minneapolis, MN	Minnesota, Montana, North Dakota, South Dakota, and Wyoming.
Des Moines, IA	Iowa and Nebraska.
Lawrence, KS	Kansas and Missouri.
Springdale, AR	Arkansas, Louisiana, and Oklahoma.
Dallas, TX	Texas.
Madison, WI	Michigan and Wisconsin.
Chicago, IL	Illinois and Indiana.
Pickerington, OH	Kentucky, Ohio, and West Virginia.
Philadelphia, PA	Pennsylvania.
Albany, NY	New Jersey and New York.
Boston, MA	Connecticut, Maine, Massachusetts, New Hampshire, Puerto Rico, Rhode Island, Vermont, and Virgin Islands.
Greenbelt, MD	Delaware, District of Columbia, Maryland, and Virginia.
Raleigh, NC	North Carolina and South Carolina.
Atlanta, GA	Florida and Georgia.
Jackson, MS	Alabama, Mississippi, and Tennessee.

(2) *Technical Service Center.* The Technical Service Center, which is located in Omaha, Nebraska, provides technical guidance, review, and training on the interpretation and application of regulatory requirements.

§ 300.6 Access to establishments and other places of business.

(a) *General.* Upon presentation of credentials—

(1) Persons subject to provisions of the FMIA or the PPIA must afford representatives of the Secretary access to establishments that slaughter or otherwise prepare livestock products or process poultry products and to other places of business subject to regulation thereunder; and

(2) Persons subject to provisions of the EPIA must afford representatives of the Secretary access as specified in part 590 of this chapter.

(b) [Reserved]

PART 301—DEFINITIONS

Sec.
301.1 Meaning of terms.
301.2 Definitions.

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

§ 301.1 Meaning of terms.

As used in this subchapter, unless otherwise required by the context, the singular form shall also import the plural and the masculine form shall also import the feminine, and vice versa.

[35 FR 15554, Oct. 3, 1970]

§ 301.2 Definitions.

As used in this subchapter, unless otherwise required by the context, the following terms shall be construed, respectively, to mean:

The Act. The Federal Meat Inspection Act, as amended, (34 Stat. 1260, as amended, 81 Stat. 584, 84 Stat. 438, 92 Stat. 1069, 21 U.S.C., sec. 601 *et seq.*).

Administrator. The Administrator of the Food Safety and Inspection Service or any officer or employee of the Department to whom authority has heretofore been delegated or may hereafter be delegated to act in his/her stead.

Adulterated. This term applies to any carcass, part thereof, meat or meat food product under one or more of the following circumstances:

(1) If it bears or contains any such poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance, such article shall not be considered adulterated under this clause if the quantity of such substance in or on such article does not ordinarily render it injurious to health;

(2)(i) If it bears or contains (by reason of administration of any substance to the live animal or otherwise) any added poisonous or added deleterious substance (other than one which is:

(A) A pesticide chemical in or on a raw agricultural commodity;

(B) A food additive; or

(C) A color additive which may, in the judgment of the Administrator, make such article unfit for human food;

(ii) If it is, in whole or in part, a raw agricultural commodity and such commodity bears or contains a pesticide chemical which is unsafe within the meaning of section 408 of the Federal Food, Drug, and Cosmetic Act;

(iii) If it bears or contains any food additive which is unsafe within the meaning of section 409 of the Federal Food, Drug, and Cosmetic Act;

(iv) If it bears or contains any color additive which is unsafe within the meaning of section 706 of the Federal Food, Drug, and Cosmetic Act: *Provided,* That an article which is not deemed adulterated under paragraphs (aa)(2) (ii), (iii), or (iv) of this section shall nevertheless be deemed adulterated if use of the pesticide chemical food additive, or color additive in or on such article is prohibited by the regulations in this subchapter in official establishments;

(3) If it consists in whole or in part of any filthy, putrid, or decomposed substance or is for any other reason unsound, unhealthful, unwholesome, or otherwise unfit for human food;

(4) If it has been prepared, packed, or held under unsanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health;

(5) If it is, in whole or in part, the product of an animal which has died otherwise than by slaughter;

(6) If its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health;

(7) If it has been intentionally subjected to radiation, unless the use of the radiation was in conformity with a regulation or exemption in effect pursuant to section 409 of the Federal Food, Drug, and Cosmetic Act;

(8) If any valuable constituent has been in whole or in part omitted or abstracted therefrom; or if any substance has been substituted, wholly or in part therefor; or if damage or inferiority has been concealed in any manner; or if any substance has been added thereto or mixed or packed therewith so as to increase its bulk or weight, or reduce its quality or strength, or make it appear better or of greater value than it is; or,

(9) If it is margarine containing animal fat and any of the raw material used therein consisted in whole or in part of any filthy, putrid, or decomposed substance, or is otherwise adulterated.

Anesthesia. Loss of sensation or feeling.

Animal food. Any article intended for use as food for dogs, cats, or other animals derived wholly, or in part, from the carcass or parts or products of the carcass of any livestock, except that the term animal food as used herein does not include:

(1) Processed dry animal food or

(2) Livestock or poultry feeds manufactured from processed livestock byproducts (such as meatmeal tankage, meat and bonemeal, bloodmeal, and feed grade animal fat).

Animal food manufacturer. Any person engaged in the business of manufacturing or processing animal food.

Area. One or more circuits under the supervision of an area supervisor.

Area Supervisor. The official in charge of an area.

Artificial coloring. A coloring containing any dye or pigment, which dye or pigment was manufactured by a process of synthesis or other similar artifice, or a coloring which was manufactured by extracting a natural dye or natural pigment from a plant or other material in which such dye or pigment was naturally produced.

Artificial flavoring. A flavoring containing any sapid or aromatic constituent, which constituent was manufactured by a process of synthesis or other similar artifice.

Biological residue. Any substance, including metabolites, remaining in livestock at time of slaughter or in any of its tissues after slaughter as the result of treatment or exposure of the livestock to a pesticide, organic or inorganic compound, hormone, hormone-like substance, growth promoter, antibiotic, anthelmintic, tranquilizer, or other therapeutic or prophylactic agent.

Capable of use as human food. This term applies to any carcass, or part or product of a carcass, of any livestock, unless it is denatured or otherwise identified as required by the applicable provisions of §§ 314.3, 314.10, 325.11, and 325.13 of this subchapter to deter its use as a human food, or it is naturally inedible by humans; e.g., hoofs or horns in their natural state.

Captive bolt. A stunning instrument which when activated drives a bolt out of a barrel for a limited distance.

Carbon dioxide. A gaseous form of the chemical formula CO_2.

Carbon dioxide concentration. Ratio of carbon dioxide gas and atmospheric air.

Carcass. All parts, including viscera, of any slaughtered livestock.

Chemical preservative. Any chemical that, when added to a meat or meat food product, tends to prevent or retard deterioration thereof, but does not include common salt, sugars, vinegars, spices, or oils extracted from spices or substances added to meat and meat food products by exposure to wood smoke.

Other definitions, if any, that are applicable only for purposes of a specific part of the regulations in this subchapter, are set forth in such part.

Circuit. One or more official establishments included under the supervision of a circuit supervisor.

Circuit supervisor. The supervisor of a circuit.

Commerce. Commerce between any State, any Territory, or the District of Columbia, and any place outside thereof; or within any Territory not organized with a legislative body, or the District of Columbia.

Consciousness. Responsiveness of the brain to the impressions made by the senses.

Cutting up. Any division of any carcass or part thereof, except that the trimming of carcasses or parts thereof to remove surface contaminants is not considered as cutting up.

Dead livestock. The body (cadaver) of livestock which has died otherwise than by slaughter.

The Department. The United States Department of Agriculture.

Dying, diseased, or disabled livestock. Livestock which has or displays symptoms of having any of the following:

(1) Central nervous system disorder;

(2) Abnormal temperature (high or low);

(3) Difficult breathing;

(4) Abnormal swellings;

(5) Lack of muscular coordination;

(6) Inability to walk normally or stand;

(7) Any of the conditions for which livestock is required to be condemned on ante-mortem inspection in accordance with the regulations in part 309 of this subchapter.

Edible. Intended for use as human food.

Experimental animal. Any animal used in any research investigation involving the feeding or other administration of, or subjection to, an experimental biological product, drug, or chemical or any nonexperimental biological product, drug, or chemical used in a manner for which it was not intended.

Exposure time. The period of time an animal is exposed to an anesthesia-producing carbon dioxide concentration.

Federal Food, Drug, and Cosmetic Act. The Act so entitled, approved June 25, 1938 (52 Stat. 1040), and Acts amendatory thereof or supplementary thereto.

Firm. Any partnership, association, or other unincorporated business organization.

Food Safety and Inspection Service. The Food Safety and Inspection Service of the Department.

Further processing. Smoking, cooking, canning, curing, refining, or rendering in an official establishment of product previously prepared in official establishments.

Immediate container. The receptacle or other covering in which any product is directly contained or wholly or partially enclosed.

Import Field Office (IFO). The office of the supervisor of import inspection activities for a particular importing field area. The areas are as follows:

IFO #1. Boston, MA—Covering the States of Massachusetts, New York (excluding New York City), Connecticut, Rhode Island, Vermont, New Hampshire and Maine.

IFO #2. New York, NY—Covering the areas of New York City and northern New Jersey.

IFO #3. Philadelphia, PA—Covering the State of Pennsylvania and the area of southern New Jersey.

IFO #4. Baltimore, MD—Covering the States of Maryland, Delaware, West Virginia, Virginia and Kentucky.

IFO #5. Charleston, SC—Covering the States of Tennessee, North Carolina, South Carolina, Georgia and Florida (excluding south Florida).

1IFO #6. Miami, FL—Covering the areas of southern Florida, Puerto Rico and the Virgin Islands.

1IFO #7. New Orleans, LA—Covering the States of Louisiana, Mississippi, Alabama, Arkansas, Texas, Oklahoma, Kansas, New Mexico and Colorado.

1IFO #8. San Pedro, CA—Covering the States of Hawaii, Arizona, Utah, Nevada, the area of southern California, American Samoa, Guam, and the Northern Marianas.

1IFO #9. Tacoma, WA—Covering the States of Washington, Oregon, Idaho, Montana, Wyoming, North Dakota, South Dakota, Alaska, and Nebraska, and the area of northern California.

1IFO #10. Detroit, MI—Covering the States of Michigan, Wisconsin, Minnesota, Iowa, Missouri, Illinois, Indiana and Ohio.

Import Supervisor. The official in charge of import inspection activities within each of the import field offices.

Inedible. Adulterated, uninspected, or not intended for use as human food.

Inhumane slaughter or handling in connection with slaughter. Slaughter or handling in connection with slaughter not in accordance with the Act of August 27, 1958 (72 Stat. 862; 7 U.S.C. 1901 through 1906, as amended by the Humane Methods of Slaughter Act of 1978, 92 Stat. 1069) and part 313 of this subchapter.

''Inspected and passed'' or ''U.S. Inspected and Passed'' or ''U.S. Inspected and Passed by Department of Agriculture'' (or any authorized abbreviation thereof). This term means that the product so identified has been inspected and passed under the regulations in this subchapter, and at the time it was inspected, passed, and identified, it was found to be not adulterated.

Inspector. An inspector of the Program.

Inspector in charge. A designated program employee who is in charge of one or more official establishments within a circuit and is responsible to the circuit supervisor or his/her designee.

Label. A display of written, printed, or graphic matter upon the immediate container (not including package liners) of any article.

Labeling. All labels and other written, printed, or graphic matter:

(1) Upon any article or any of its containers or wrappers, or

(2) Accompanying such article.

Livestock. Cattle, sheep, swine, goat, horse, mule, or other equine.

Meat. (1) The part of the muscle of any cattle, sheep, swine, or goats, which is skeletal or which is found in the tongue, in the diaphragm, in the heart, or in the esophagus, 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. It does not include the muscle found in the lips, snout, or ears. This term, as applied to products of equines, shall have a meaning comparable to that provided in this paragraph with respect to cattle, sheep, swine, and goats.

(2) The product derived from the mechanical separation of the skeletal muscle tissue from the bones of livestock using the advances in mechanical meat/bone separation machinery and meat recovery systems that do not crush, grind, or pulverize bones, and

from which the bones emerge comparable to those resulting from hand-deboning (i.e., essentially intact and in natural physical conformation such that they are recognizable, such as loin bones and rib bones, when they emerge from the machinery) which meets the criteria of no more than 0.15 percent or 150 mg/100 gm of product for calcium (as a measure of bone solids content) within a tolerance of 0.03 percent or 30 mg.

Meat broker. Any person engaged in the business of buying or selling carcasses, parts of carcasses, meat or meat food products of livestock on commission, or otherwise negotiating purchases or sales of such articles other than for his/her own account or as an employee of another person.

Meat byproduct. Any part capable of use as human food, other than meat, which has been derived from one or more cattle, sheep, swine, or goats. This term, as applied to products of equines, shall have a meaning comparable to that provided in this paragraph with respect to cattle, sheep, swine, and goats.

Meat food product. Any article capable of use as human food which is made wholly or in part from any meat or other portion of the carcass of any cattle, sheep, swine, or goats, except those exempted from definition as a meat food product by the Administrator in specific cases or by the regulations in part 317 of this subchapter, upon a determination that they contain meat or other portions of such carcasses only in a relatively small proportion or historically have not been considered by consumers as products of the meat food industry, and provided that they comply with any requirements that are imposed in such cases or regulations as conditions of such exemptions to assure that the meat or other portions of such carcasses contained in such articles are not adulterated and that such articles are not represented as meat food products. This term, as applied to food products of equines, shall have a meaning comparable to that provided in this paragraph with respect to cattle, sheep, swine, and goats.

Misbranded. This term applies to any carcass, part thereof, meat or meat food product under one or more of the following circumstances:

(1) If its labeling is false or misleading in any particular;

(2) If it is offered for sale under the name of another food;

(3) If it is an imitation of another food, unless its label bears, in type of uniform size and prominence, the word ''imitation'' and immediately thereafter, the name of the food imitated;

(4) If its container is so made, formed, or filled as to be misleading;

(5) If in a package or other container unless it bears a label showing:

(i) The name and place of business of the manufacturer, packer, or distributor; and

(ii) An accurate statement of the quantity of the contents in terms of weight, measure, or numerical count; except as otherwise provided in part 317 of this subchapter with respect to the quantity of contents;

(6) If any word, statement, or other information required by or under authority of the Act to appear on the label or other labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use;

(7) If it purports to be or is represented as a food for which a definition and standard of identity or composition has been prescribed by the regulations in part 319 of this subchapter unless:

(i) It conforms to such definition and standard, and

(ii) Its label bears the name of the food specified in the definition and standard and, insofar as may be required by such regulations, the common names of optional ingredients (other than spices, flavoring, and coloring) present in such food;

(8) If it purports to be or is represented as a food for which a standard or standards of fill of container have been prescribed by the regulations in part 319 of this subchapter, and it falls below the standard of fill of container applicable thereto, unless its label bears, in such manner and form as such

regulations specify, a statement that it falls below such standard;

(9) If it is not subject to the provisions of paragraph (vv)(7)(ii) of this section unless its label bears:

(i) The common or usual name of the food, if any there be, and

(ii) In case it is fabricated from two or more ingredients, the common or usual name of each such ingredient, except as otherwise provided in part 317 of this subchapter;

(10) If it purports to be or is represented for special dietary uses, unless its label bears such information concerning its vitamin, mineral, and other dietary properties as is required by the regulations in part 317 of this subchapter.

(11) If it bears or contains any artificial flavoring, artificial coloring, or chemical preservative, unless it bears a label stating that fact; except as otherwise provided by the regulations in part 317 of this subchapter; or

(12) If it fails to bear, directly thereon or on its containers, when required by the regulations in part 316 or 317 of this subchapter, the inspection legend and, unrestricted by any of the foregoing, such other information as the Administrator may require in such regulations to assure that it will not have false or misleading labeling and that the public will be informed of the manner of handling required to maintain the article in a wholesome condition.

Nonfood compound. Any substance proposed for use in official establishments, the intended use of which will not result, directly or indirectly, in the substance becoming a component or otherwise affecting the characteristics of meat food and meat products, excluding labeling and packaging materials as covered in part 317 of the subchapter.

Official certificate. Any certificate prescribed by the regulations in this subchapter for issuance by an inspector or other person performing official functions under the Act.

Official device. Any device prescribed by the regulations in part 312 of this subchapter for use in applying any official mark.

Official establishment. Any slaughtering, cutting, boning, meat canning, curing, smoking, salting, packing, rendering, or similar establishment at which inspection is maintained under the regulations in this subchapter.

Official import inspection establishment. This term means any establishment, other than an official establishment as defined in paragraph (zz) of this section, where inspections are authorized to be conducted as prescribed in § 327.6 of this subchapter.

Official inspection legend. Any symbol prescribed by the regulations in this subchapter showing that an article was inspected and passed in accordance with the Act.

Official mark. The official inspection legend or any other symbol prescribed by the regulations in this subchapter to identify the status of any article or animal under the Act.

Packaging material. Any cloth, paper, plastic, metal, or other material used to form a container, wrapper, label, or cover for meat products.

Person. Any individual, firm, or corporation.

Pesticide chemical, food additive, color additive, raw agricultural commodity. These terms shall have the same meanings for purposes of the Act and the regulations in this subchapter as under the Federal Food, Drug, and Cosmetic Act.

Prepared. Slaughtered, canned, salted, rendered, boned, cut up, or otherwise manufactured or processed.

Process authority. A person or organization with expert knowledge in meat production process control and relevant regulations. This definition does not apply to subpart G of part 318.

Process schedule. A written description of processing procedures, consisting of any number of specific, sequential operations directly under the control of the establishment employed in the manufacture of a specific product, including the control, monitoring, verification, validation, and corrective action activities associated with production. This definition does not apply to subpart G of part 318.

Product. Any carcass, meat, meat byproduct, or meat food product, capable of use as human food.

Program. The organizational unit within the Department having the responsibility for carrying out the provisions of the Act.

Program employee. Any inspector or other individual employed by the Department or any cooperating agency who is authorized by the Secretary to do any work or perform any duty in connection with the Program.

Regional Director. The official[1] in charge of the program within each of the following regions:

Northeastern Region—Connecticut, Delaware, District of Columbia, Maine, Maryland, Massachusetts, New Hampshire, New Jersey, New York, Pennsylvania, Rhode Island, Vermont, and Virginia (except for Northwestern part).

Southeastern Region— Alabama, Florida, Georgia, Kentucky, Mississippi, North Carolina, South Carolina, Tennessee, Virginia (Northwestern), West Virginia, Puerto Rico, and the Virgin Islands.

North Central Region— Illinois, Indiana, Iowa, Michigan, Minnesota, Ohio, and Wisconsin.

Southwestern Region— Arkansas, Kansas, Louisiana, Missouri, Nebraska, New Mexico, Oklahoma, and Texas.

Western Region— Alaska, Arizona, California, Colorado, Hawaii, Idaho, Montana, Nevada, North Dakota, Oregon, South Dakota, Utah, Washington, and Wyoming, American Samoa, Guam, and the Northern Mariana Islands.

Renderer. Any person engaged in the business of rendering carcasses or parts or products of the carcasses of any livestock except rendering conducted under inspection or exemption under Title I of the Act.

Secretary. The Secretary of Agriculture of the United States or his/her delegate.

Shipping container. The outside container (box, bag, barrel, crate, or other receptacle or covering) containing or wholly or partly enclosing any product packed in one or more immediate containers.

State. Any State of the United States or the Commonwealth of Puerto Rico.

Supervision. The controls, as prescribed in instructions to Program employees, to be exercised by them over particular operations to insure that such operations are conducted in compliance with the Act and the regulations in this subchapter.

Surgical anesthesia. A state of unconsciousness measured in conformity with accepted surgical practices.

Territory. Guam, the Virgin Islands of the United States, American Samoa, and any other territory or possession of the United States, excluding the Canal Zone.

U.S. Condemned. This term means that the livestock so identified has been inspected and found to be in a dying condition, or to be affected with any other condition or disease that would require condemnation of its carcass.

U.S. Inspected and Condemned (or any authorized abbreviation thereof). This term means that the carcass, viscera, other part of carcass, or other product so identified has been inspected, found to be adulterated, and condemned under the regulations in this subchapter.

U.S. Passed for Cooking. This term means that the meat or meat byproduct so identified has been inspected and passed on condition that it be cooked or rendered as prescribed by the regulations in part 315 of this chapter.

U.S. Passed for Refrigeration. This term means that the meat or meat byproduct so identified has been inspected and passed on condition that it be refrigerated or otherwise handled as prescribed by the regulations in part 311 of this subchapter.

U.S. Retained. This term means that the carcass, viscera, other part of carcass, or other product, or article so identified is held for further examination by an inspector to determine its disposal.

U.S. Suspect. This term means that the livestock so identified is suspected of being affected with a disease or condition which may require its condemnation, in whole or in part, when slaughtered, and is subject to further examination by an inspector to determine its disposal.

[1] The addresses of the Regional Directors are as follows:

Northeastern Region—Seventh Floor, 1421 Cherry Street, Philadelphia, PA 19102.

Southeastern Region—Room 299 South, 1718 Peachtree Street, NW., Atlanta, GA 30309.

North Central Region—607 East Second Street, Des Moines, IA 50309.

Southwestern Region—Room 5–F41, 1100 Commerce Street, Dallas, TX 75201.

Western Region—Room 620 Central Avenue, Building 2C, Alameda, CA 94501.

United States. The States, the District of Columbia, and the Territories of the United States.

[35 FR 15554, Oct. 3, 1970]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting §301.2, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and on GPO Access.

PART 302—APPLICATION OF INSPECTION AND OTHER REQUIREMENTS

Sec.
302.1 Establishments requiring inspection.
302.2 Application of requirements in designated States or Territories; and to designated plants endangering public health.
302.3 Livestock and products entering official establishments.

AUTHORITY: 21 U.S.C. 601–695; 7 CFR 2.17, 2.55.

§302.1 Establishments requiring inspection.

(a) Inspection under the regulations in this subchapter is required at:

(1) Every establishment, except as provided in §303.1 (a) and (b), or (c) of this subchapter, in which any livestock are slaughtered for transportation or sale as articles of commerce, or in which any products of, or derived from, carcasses of livestock are, wholly or in part, prepared for transportation or sale as articles of commerce, which are intended for use as human food;

(2) Every establishment, except as provided in §303.1 (a) and (b), or (d) of this subchapter, within any State or organized Territory which is designated pursuant to paragraph 301(c) of the Act, at which any livestock are slaughtered or any products of any livestock are prepared, for use as human food solely for distribution within such jurisdiction; and

(3) Every establishment, except as provided in §303.1 (a) and (b) of this subchapter, that is designated by the Administrator pursuant to paragraph 301(c) of the Act as one producing adulterated products which would clearly endanger the public health.

[35 FR 15556, Oct. 3, 1970, as amended at 36 FR 12002, June 24, 1971]

§302.2 Application of requirements in designated States or Territories; and to designated plants endangering public health.

Special provisions with respect to establishments and their operations and transactions by any persons in designated States and Territories and with respect to establishments designated as producing adulterated products which clearly endanger public health, and the operators thereof, in any State or Territory appear in part 331 of this subchapter, and apply to such establishments, operations and transactions in lieu of the regulations elsewhere in this subchapter except insofar as such regulations are made applicable by the provisions in part 331 of this subchapter.

[35 FR 15556, Oct. 3, 1970, as amended at 51 FR 29909, Aug. 21, 1986]

§302.3 Livestock and products entering official establishments.

All livestock and all products entering any official establishment and all products prepared, in whole or in part, therein, shall be inspected, handled, stored, prepared, packaged, marked, and labeled as required by the regulations in this subchapter.

[35 FR 15556, Oct. 3, 1970]

PART 303—EXEMPTIONS

Sec.
303.1 Exemptions.
303.2 Experimentation: Intensity of inspection coverage.

AUTHORITY: 21 U.S.C. 601–695; 7 CFR 2.17, 2.55.

§303.1 Exemptions.

(a) The requirements of the Act and the regulations in this subchapter for inspection of the preparation of products do not apply to:

(1) The slaughtering by any individual of livestock of his own raising, and the preparation by him and transportation in commerce of the carcasses, parts thereof, meat and meat food products of such livestock exclusively for use by him and members of his household and his nonpaying guests and employees;

(2) The custom slaughter by any person of cattle, sheep, swine, or goats delivered by the owner thereof for such slaughter, and the preparation by such slaughterer and transportation in commerce of the carcasses, parts thereof, meat and meat food products of such livestock, exclusively for use, in the household of such owner, by him and members of his household and his nonpaying guests and employees; nor to the custom preparation by any person of carcasses, parts thereof, meat or meat food products derived from the slaughter by any individual of cattle, sheep, swine, or goats of his own raising or from game animals, delivered by the owner thereof for such custom preparation, and transportation in commerce of such custom prepared articles, exclusively for use in the household of such owner, by him and members of his household and his nonpaying guests and employees: *Provided,* That the following requirements are met by such custom operator;

(i) Establishments that conduct custom operations must be maintained and operated in accordance with the provisions of §§416.1 through 416.6, except for: §416.2(g)(2) through (6) of this chapter, regarding water reuse and any provisions of part 416 of this chapter relating to inspection or supervision of specified activities or other action by a Program employee. If custom operations are conducted in an official establishment, however, all of the provisions of Part 416 of this chapter of shall apply to those operations.

(ii) If the custom operator prepares or handles any products for sale, they are kept separate and apart from the custom prepared products at all times while the latter are in his custody;

(iii) The custom prepared products are plainly marked ''Not for Sale'' as provided in §316.16 of this subchapter, immediately after being prepared and are kept so identified until delivered to the owner; and

(iv) If exempted custom slaughtering or other preparation of products is conducted in an official establishment, all facilities and equipment in the official establishment used for such custom operations shall be thoroughly cleaned and sanitized before they are used for preparing any products for sale.

(b)(1) The exempted custom prepared products shall be prepared and handled in accordance with the provisions of §§318.5, 318.6, 318.7, 318.10, and 318.300 through 318.311 of this subchapter and shall not be adulterated as defined in paragraph 1(m) of the Act: *Provided,* That the provisions of §§318.5, 318.6, 318.10, and 318.300 through 318.311 relating to inspection or supervision of specified activities or other action by a Program inspector, and the provisions of §318.6(b)(9) and (10), shall not apply to the preparation and handling of such exempted products.

(2) The exempted custom prepared products shall comply with the requirements of §§316.16 and 317.16 of this subchapter.

(3) The custom operators claiming exemption under paragraph (a)(2) of this section shall keep records, in addition to records otherwise required by part 320 of this subchapter, showing the numbers and kinds of livestock slaughtered on a custom basis, the quantities and types of products prepared on a custom basis, and the names and addresses of the owners of the livestock and products.

(4) Articles capable of use as human food, resulting from the exempted custom slaughter or other preparation of products shall be promptly denatured or otherwise identified in accordance with §325.13 of this subchapter and not removed from the establishment where the custom operations are conducted until so identified, unless they are delivered to the owner of the articles for use in accordance with paragraph (a)(2) of this section.

(c) It has been determined that it is impracticable to provide inspection of the preparation of products at establishments in any unorganized Territory at which livestock are slaughtered or their products are prepared for distribution solely within such jurisdiction and that exempting such establishments from requirements of the Act for such inspections under the conditions stated in this section will otherwise facilitate enforcement of the Act. Therefore, such inspection requirements of the Act and of the regulations in this subchapter shall not apply at such establishments if they are operated in accordance with the

regulations in part 416, §§ 416.1 through 416.5 of this chapter. However, the Administrator may refuse, withdraw, or modify any exemption under this paragraph when he determines in any specific case in accordance with the applicable rules of practice that such action is necessary to effectuate the purposes of this Act.

(d)(1) The requirements of the Act and the regulations in this subchapter for inspection of the preparation of products do not apply to operations of types traditionally and usually conducted at retail stores and restaurants, when conducted at any retail store or restaurant or similar retail-type establishment for sale in normal retail quantities or service of such articles to consumers at such establishments.

(2) For purposes of paragraph (d)(1) of this section:

(i) Operations of types traditionally and usually conducted at retail stores and restaurants are the following:

(*a*) Cutting up, slicing, and trimming carcasses, halves, quarters, or wholesale cuts into retail cuts such as steaks, chops, and roasts, and freezing such cuts;

(*b*) Grinding and freezing products made from meat;

(*c*) Curing, cooking, smoking, rendering or refining of livestock fat, or other preparation of products, except slaughtering or the retort processing of canned products;

(*d*) Breaking bulk shipments of products;

(*e*) Wrapping or rewrapping products.

(ii) Any quantity or product purchased by a consumer from a particular retail supplier shall be deemed to be a normal retail quantity if the quantity so purchased does not in the aggregate exceed one-half carcass. The following amounts of product will be accepted as representing one-half carcass of the species identified:

	One-half carcass pounds
Cattle	300
Calves	37.5
Sheep	27.5
Swine	100
Goats	25

(iii) A retail store is any place of business where:

(*a*) The sales of product are made to consumers only;

(*b*) At least 75 percent, in terms of dollar value, of total sales of product represents sales to household consumers and the total dollar value of sales of product to consumers other than household consumers does not exceed the dollar limitation per calendar year set by the Administrator. This dollar limitation is a figure which will automatically be adjusted during the first quarter of each calendar year, upward or downward, whenever the Consumer Price Index, published by the Bureau of Labor Statistics, Department of Labor, indicates a change in the price of this same volume of product which exceeds $500. Notice of the adjusted dollar limitation will be published in the FEDERAL REGISTER.[1]

(*c*) Only federally or State inspected and passed product is handled or used in the preparation of any product, except that product resulting from the custom slaughter or custom preparation of product may be handled or used in accordance with paragraph (a)(2) and (b) of this section but not for sale;

(*d*) No sale of product is made in excess of a normal retail quantity as defined in paragraph (d)(2)(ii) of this section;

(*e*) The preparation of products for sale to household consumers is limited to traditional and usual operations as defined in paragraph (d)(2)(i) of this section; and

(*f*) The preparation of products for sale to other than household consumers is limited to traditional and usual operations as defined in paragraph (d)(2)(i) (*a*), (*b*), (*d*), and (*e*) of this section. (A retail store at which custom slaughtering or preparation of products is conducted is not thereby disqualified from exemption as a retail store under this paragraph (d).)

(iv) *Restaurants.* (*a*) A restaurant is any establishment where:

[1] The dollar limitation currently in effect may be obtained by contacting Director, Slaughter Inspection Standards and Procedures Division, Technical Services, Food and Safety Inspection Service, U.S. Department of Agriculture, Washington, DC 20250 (202) 447–3219.

(*1*) Product is prepared only for sale or service in meals or as entrees directly to individual consumers at such establishments;

(*2*) Only federally or State inspected and passed product or such product prepared at a retail store exempted under paragraph (d)(2)(iii) of this section is handled or used in the preparation of any product;

(*3*) No sale of product is made in excess of a normal retail quantity as defined in paragraph (d)(2)(ii) of this section; and

(*4*) The preparation of product is limited to traditional and usual operations as defined in paragraph (d)(2)(i) of this section.

(*b*) The definition of a restaurant includes a caterer which delivers or serves product in meals, or as entrees, only to individual consumers and otherwise meets the requirements of this paragraph.

(*c*) For purposes of this paragraph, operations conducted at a restaurant central kitchen facility shall be considered as being conducted at a restaurant if the restaurant central kitchen prepares meat or meat food products that are ready to eat when they leave such facility (i.e., no further cooking or other preparation is needed, except that they may be reheated prior to serving if chilled during transportation), transported directly to a receiving restaurant by its own employees, without intervening transfer or storage, maintained in a safe, unadulterated condition during transportation, and served in meals or as entrees only to customers at restaurants, or through vending machines, owned or operated by the same person that owns or operates such facility, and which otherwise meets the requirements of this paragraph: *Provided,* That the requirements of §§ 320.1 through 320.4 of this subchapter apply to such facility. *Provided further,* That the exempted facility may be subject to inspection requirements under the Act for as long as the Administrator deems necessary, if the Administrator determines that the sanitary conditions or practices of the facility or the processing procedures or methods at the facility are such that any of its meat or meat food products are rendered adulterated. When the Administrator has made such determination and subjected a restaurant central kitchen facility to such inspection requirements, the operator of such facility shall be afforded an opportunity to dispute the Administrator's determination in a hearing pursuant to rules of practice which will be adopted for this proceeding.

(v) Similar retail-type establishment: Any establishment which is a combination retail store and restaurant; any delicatessen which meets the requirements for a retail store or restaurant as prescribed in paragraphs (d)(2) (iii) or (iv) of this section; or other establishment as determined by the Administrator in specific cases.

(vi) Consumer: Any household consumer, hotel, restaurant, or similar institution as determined by the Administrator in specific cases.

(3) Whenever any complaint is received by the Administrator from any person alleging that any retail store claiming exemption under this paragraph (d), in any designated State or organized Territory that is identified under section 205 of the Act (as one that does not have or is not exercising adequate authority with respect to recordkeeping requirements) has been operated in violation of the conditions prescribed in this section for exemption, and the Administrator, upon investigation of the complaint, has reason to believe that any such violation has occurred, he shall so notify the operator of the retail store and afford him reasonable opportunity to present his views informally with respect to the matter. Thereafter, if the Administrator still has reason to believe that such a violation has occurred, and that a requirement that the operator keep records concerning the operations of the retail store would effectuate the purposes of the Act, the Administrator shall order the operator to maintain complete, accurate, and legible records of total monthly purchases and of total monthly sales of meat, meat byproducts, and meat food products, in terms of dollar values of the products involved. Such records shall separately show total sales to household consumers and total sales to other consumers and shall be maintained for the

period prescribed in § 320.3 of this subchapter. If the operator maintains copies of bills of lading, receiving and shipping invoices, warehouse receipts, or similar documents which give the information required herein, additional records are not required by this subparagraph.

(e)(1) The requirements of the Act and the regulations in this subchapter for inspection of the preparation of products do not apply to meat pizzas containing meat food product ingredients which were prepared, inspected, and passed in a cured or cooked form as ready-to-eat (i.e., no further cooking or other preparation is needed) in compliance with the requirements of the Act and these regulations; and the meat pizzas are to be served in public or private nonprofit institutions, provided that the meat pizzas are ready-to-eat (i.e., no further cooking or other preparation is needed, except that they may be reheated prior to serving if chilled during transportation), transported directly to the receiving institution by employees of the preparing firm, receiving institution, or a food service management company contracted to conduct food service at the public or private nonprofit institution, without intervening transfer or storage.

(2) The definitions at Chapter 1, 1–102, except 1–102(z) and the provisions of Chapters 2 through 8, except sections 2–102(a) and (b), 2–302(d), 2–403(a), 2–403(c), 2–404, 2–405, 2–407, 2–502 through 2–506, 2–508, 2–509, 4–105, 4–201(c), 4–208, 5–101(a), 5–103, 5–104, 5–202(c), 5–203, and 6–105, part IV, of the Food and Drug Administration's Food Service Sanitation Manual (1976 Recommendations), DHEW Publication No. (FDA) 78–2081, which is incorporated by reference, shall apply to the facilities and operations of businesses claiming this exemption. (These materials are incorporated as they exist on the date of approval. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be purchased from the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402. It is also available for inspection at the Office of the Federal Register Information Center, suite 700, 800 North Capitol Street, NW., Washington, DC, or the FSIS Hearing Clerk, room 3171, South Building, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250.)

(3) Facilities and operations of businesses claiming this exemption shall also conform to the following requirements:

(i) *Manual cleaning and sanitizing.* (A) For manual washing, rinsing and sanitizing of utensils and equipment, a sink with not fewer than three compartments shall be provided and used. Sink compartments shall be large enough to permit the accommodation of the equipment and utensils, and each compartment of the sink shall be supplied with hot and cold potable running water. Fixed equipment and utensils and equipment too large to be cleaned in sink compartments shall be washed manually or cleaned through pressure spray methods.

(B) Drain boards or easily movable dish tables of adequate size shall be provided for proper handling of soiled utensils prior to washing and for cleaned utensils following sanitizing and shall be located so as not to interfere with the proper use of the dishwashing facilities.

(C) Equipment and utensils shall be preflushed or prescraped and, when necessary, presoaked to remove gross food particles and soil.

(D) Except for fixed equipment and utensils too large to be cleaned in sink compartments, manual washing, rinsing and sanitizing shall be conducted in the following sequence:

(*1*) Sinks shall be cleaned prior to use.

(*2*) Equipment and utensils shall be thoroughly washed in the first compartment with a hot detergent solution that is kept clean.

(*3*) Equipment and utensils shall be rinsed free of detergent and abrasives with clean water in the second compartment.

(*4*) Equipment and utensils shall be sanitized in the third compartment according to one of the methods prescribed in paragraph (e)(3)(i)(E) (*1*) through (*4*) of this section.

(E) The food-contact surfaces of all equipment and utensils shall be sanitized by:

(*1*) Immersion for at least ½ minute in clean, hot water at a temperature of at least 170 °F; or

(*2*) Immersion for at least 1 minute in a clean solution containing at least 50 parts per million of available chlorine as a hypochlorite and at a temperature of at least 75 °F; or

(*3*) Immersion for at least 1 minute in a clean solution containing at least 12.5 parts per million of available iodine and having a pH not higher than 5.0 and at a temperature of at least 75 °F; or

(*4*) Immersion in a clean solution containing any other chemical sanitizing agent allowed under 21 CFR 178.1010 that will provide the equivalent bactericidal effect of a solution containing at least 50 parts per million of available chlorine as a hypochlorite at a temperature of at least 75 °F for 1 minute; or

(*5*) Treatment with steam free from materials or additives other than those specified in 21 CFR 173.310 in the case of equipment too large to sanitize by immersion, but in which steam can be confined; or

(*6*) Rinsing, spraying, or swabbing with a chemical sanitizing solution of at least twice the strength required for that particular sanitizing solution under paragraph (e)(3)(i)(E)(*4*) of this section in the case of equipment too large to sanitize by immersion.

(F) When hot water is used for sanitizing, the following facilities shall be provided and used:

(*1*) An integral heating device or fixture installed in, on, or under the sanitizing compartment of the sink capable of maintaining the water at a temperature of at least 170 °F; and

(*2*) A numerically scaled indicating thermometer, accurate to ±3 °F, convenient to the sink for frequent checks of water temperature; and

(*3*) Dish baskets of such size and design to permit complete immersion of the tableware, kitchenware, and equipment in the hot water.

(G) When chemicals are used for sanitization, they shall not have concentrations higher than the maximum permitted under 21 CFR 178.1010 and a test kit or other device that accurately measures the parts per million concentration of the solution shall be provided and used.

(ii) *Mechanical cleaning and sanitizing.* (A) Cleaning and sanitizing may be done by spray-type or immersion dishwashing machines or by any other type of machine or device if it is demonstrated that it thoroughly cleans and sanitizes equipment and utensils. These machines and devices shall be properly installed and maintained in good repair.

Machines and devices shall be operated in accordance with manufacturers' instructions, and utensils and equipment placed in the machine shall be exposed to all dishwashing cycles. Automatic detergent dispensers, wetting agent dispensers, and liquid sanitizer injectors, if any, shall be properly installed and maintained.

(B) The pressure of final rinse water supplied to spray-type dishwashing machines shall not be less than 15 nor more than 25 pounds per square inch measured in the water line immediately adjacent to the final rinse control valve. A ¼–inch IPS valve shall be provided immediately up stream from the final rinse control valve to permit checking the flow pressure of the final rinse water.

(C) Machine or water line mounted numerically scaled indicating thermometers, accurate to ±3 °F, shall be provided to indicate the temperature of the water in each tank of the machine and the temperature of the final rinse water as it enters the manifold.

(D) Rinse water tanks shall be protected by baffles, curtains, or other effective means to minimize the entry of wash water into the rinse water. Conveyors in dishwashing machines shall be accurately timed to assure proper exposure times in wash and rinse cycles in accordance with manufacturers' specifications attached to the machines.

(E) Drain boards shall be provided and be of adequate size for the proper handling of soiled utensils prior to washing and of cleaned utensils following sanitization and shall be so located and constructed as not to interfere with the proper use of the dishwashing facilities. This does not preclude the use of easily movable dish tables for the storage of soiled utensils or

the use of easily movable dishtables for the storage of clean utensils following sanitization.

(F) Equipment and utensils shall be flushed or scraped and, when necessary, soaked to remove gross food particles and soil prior to being washed in a dishwashing machine unless a prewashcycle is a part of the dishwashing machine operation. Equipment and utensils shall be placed in racks, trays, or baskets, or on conveyors, in a way that food-contact surfaces are exposed to the unobstructed application of detergent wash and clean rinse waters and that permits free draining.

(G) Machines (single-tank, stationary-rack, door-type machines and spray-type glass washers) using chemicals for sanitization may be used: *Provided, That,*

(*1*) The temperature of the wash water shall not be less than 120 °F.

(*2*) The wash water shall be kept clean.

(*3*) Chemicals added for sanitization purposes shall be automatically dispensed.

(*4*) Utensils and equipment shall be exposed to the final chemical sanitizing rinse in accordance with manufacturers' specifications for time and concentration.

(*5*) The chemical sanitizing rinse water temperature shall be not less than 75 °F nor less than the temperature specified by the machine's manufacturer.

(*6*) Chemical sanitizers used shall meet the requirements of 21 CFR 178.1010.

(*7*) A test kit or other device that accurately measures the parts per million concentration of the solution shall be available and used.

(H) Machines using hot water for sanitizing may be used provided that wash water and pumped rinse water shall be kept clean and water shall be maintained at not less than the following temperatures:

(*1*) Single-tank, stationary-rack, dual-temperature machine:

Wash temperature .....150 °F
Final rinse temperature .....180 °F

(*2*) Single-tank, stationary-rack, single-temperature machine:

Wash temperature .....165 °F
Final rinse temperature .....165 °F

(*3*) Single-tank, conveyor machine:

Wash temperature .....160 °F
Final rinse temperature .....180 °F

(*4*) Multitank, conveyor machine:

Wash temperature .....150 °F
Pumped rinse temperature .....160 °F
Final rinse temperature .....180 °F

(*5*) Single-tank, pot, pan, and utensil washer (either stationary or moving-rack):

Wash temperature .....140 °F
Final rinse temperature .....180 °F

(I) All dishwashing machines shall be thoroughly cleaned at least once a day or more often when necessary to maintain them in a satisfactory operating condition.

(iii) *Steam.* Steam used in contact with food or food-contact surfaces shall be free from any materials or additives other than those specified in 21 CFR 173.310.

(4) For purposes of this paragraph, the term ''private nonprofit institution'' means ''a corporation, and any community chest, fund, or foundation, organized and operated exclusively for religious, charitable, scientific, testing for public safety, literary, or educational purposes, or to foster national or international amateur sports competition (but only if no part of its activities involve the provision of athletic facilities or equipment), or for the prevention of cruelty to children or animals, no part of the net earnings of which inures to the benefit of any private shareholder or individual, no substantial part of the activities of which is carrying on propaganda, or otherwise attempting, to influence legislation, and which does not participate in, or intervene in (including the publishing or distribution of statements), any political campaign on behalf of (or in opposition to) any candidate for public office.''

(5) The Administrator may withdraw or modify the exemption set forth in § 303.1(e)(1) for a particular establishment when he or she determines that such action is necessary to ensure food safety and public health. Before such action is taken, the owner or operator of the particular establishment shall be notified, in writing, of the reasons for

the proposed action and shall be given an opportunity to respond, in writing, to the Administrator within 20 days after notification of the proposed action. The written notification shall be served on the owner or operator of the establishment in the manner prescribed in section 1.147(b) of the Department's Uniform Rules of Practice (7 CFR 1.147(b)). In those instances where there is conflict of any material fact, the owner or operator of the establishment, upon request, shall be afforded an opportunity for a hearing with respect to the disputed fact, in accordance with rules of practice which shall be adopted for the proceeding. However, such withdrawal or modification shall become effective pending final determination in the proceeding when the Administrator determines that an imminent threat to food safety or public health exists, and that such action is, therefore, necessary to protect the public health, interest or safety. Such withdrawal or modification shall be effective upon oral or written notification, whichever is earlier, to the owner or operator of the particular establishment as promptly as circumstances permit. In the event of oral notification, written confirmation shall be given to the owner or operator of the establishment as promptly as circumstances permit. This withdrawal or modification shall continue in effect ending the completion of the proceeding and any judicial review thereof, unless otherwise ordered by the Administrator.

(f) The adulteration and misbranding provisions of the Act and the regulations in this subchapter, other than the requirement of the official inspection legend, apply to articles which are exempted from inspection or not required to be inspected under this section. This includes the requirement that any pork and any product containing pork be prepared only in compliance with any applicable requirement for the destruction of trichina as provided in § 318.10 of this subchapter.

(g) The Administrator may extend the requirements of titles I and IV of the Act to any establishment in any State or organized Territory at which products are prepared for distribution solely within such jurisdiction, if he determines in accordance with the provisions of paragraph 301(c)(1) of the Act that it is producing adulterated products which would clearly endanger the public health.

(h) The Administrator may in specific classes of cases waive for limited periods any provisions of the regulations in this subchapter in order to permit appropriate and necessary action in the event of a public health emergency or to permit experimentation so that new procedures, equipment, and/or processing techniques may be tested to facilitate definite improvements: *Provided,* That such waivers of the provisions of such regulations are not in conflict with the purposes or provisions of the Act.

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

[35 FR 15558, Oct. 3, 1970, as amended at 36 FR 12002, 12004, June 24, 1971; 45 FR 27922, Apr. 25, 1980; 46 FR 46288, Sept. 18, 1981; 47 FR 746, Jan. 7, 1982; 51 FR 29909, Aug. 21, 1986; 52 FR 10032, Mar. 30, 1987; 52 FR 48091, Dec. 18, 1987; 53 FR 24679, June 30, 1988; 57 FR 34182, Aug. 3, 1992; 64 FR 56415, Oct. 20, 1999]

§ 303.2 Experimentation: Intensity of inspection coverage.

(a) Pursuant to the Processed Products Inspection Improvement Act of 1986, Title IV of the Futures Trading Act of 1986 (Pub. L. 99–641), in establishments preparing products at which inspection under the Act and regulations is required, the frequency with which and the manner in which meat food products made from livestock previously slaughtered in official establishments are examined and inspected by Program employees is to be based on considerations relevant to effective regulation of meat food products and protection of the health and welfare of consumers. In order to test procedures for use in making such determinations and, in particular, for determining whether and, is so, to what extent the intensity of inspection coverage exceeds that which should be considered necessary pursuant to section 6 of the Act, as amended by section 403(a) of the Futures Trading Act of 1986, the Administrator is initiating experimentation of a new system of inspection

for reviewing the performance of establishments and for designing the supervision and other conditions and methods of inspection coverage. For the period of such experimentation, the Administrator shall identify establishments for review, and the frequency and the manner of inspection by Program employees shall be determined on the basis of the results of those reviews and be otherwise in accordance with this section.

(b) The determinations referred to in paragraph (a) of this section shall be made by the program and shall reflect evaluations of the performance and the characteristics and such establishments.

(1) In assessing the performance of an establishment, the following factors are appropriate for consideration:

(i) The history of compliance with applicable regulatory requirements by the person conducting operations at such establishment or by anyone responsibly connected with the business conducting operations at such establishment, as ''responsibly connected'' is defined in section 401(g) of the Act,

(ii) The competence of the person conducting operations at such establishment, as indicated by:

(A) Knowledge of appropriate manufacturing practices and applicable regulatory requirements,

(B) Demonstrated ability to apply such knowlege in a timely and consistent manner, and

(C) Commitment to correcting deficiencies noted by Program employees and otherwise assuring compliance with applicable regulatory requirements, and

(iii) The procedures used in such establishment to control the production process, environment, and resulting product in order to assure and monitor compliance with the requirements of the Act and the rules and regulations promulgated thereunder.

(2) In assessing the characteristics of an establishment, the following factors are appropriate for consideration:

(i) The complexity of the processing operation(s) conducted at such establishment,

(ii) The frequency with which each such operation is conducted at such establishment,

(iii) The volume of product resulting from each such operation at such establishment,

(iv) Whether and to what extent slaughter operations also are conducted at such establishment,

(v) What, if any, food products not regulated under this Act or the Poultry Products Inspection Act also are prepared at such establishment, and

(vi) The size of such establishment.

(c)(1) For the period of experimentation described in paragraph (a) of this section, the frequency of inspection by Program employees of operations other than slaughter may be reduced in an establishment in which the procedures referred to therein are being tested if and only if the evaluation of the performance of such establishment described in paragraph (b)(1) indicates that there are:

(i) No instances, documented in records compiled no earlier than 10 years before, of substantial and recent noncompliance with applicable regulatory requirements (taking into account both the nature and frequency of any such noncompliance), and

(ii) The competence and control procedures needed to assure and monitor compliance with applicable regulatory requirements.

(2)(i) The frequency of Federal inspection and other conditions and methods of inspection coverage in any establishment in which the frequency of Federal inspection is reduced shall be based on:

(A) The evaluation of the characteristics of such establishment described in paragraph (b)(2) of this section,[1]

(B) The significance of potential public health consequences of noncompliance, and

(C) The availability of Program employees.

(ii) To the extent that such frequency of inspection or other conditions and

[1] These evaluations will be based upon guidelines developed by FSIS and the complexity categorization in FSIS Directive 1030.2 (Documentation of Processing and Combination Assignments, 4/22/85). The guidelines and Directive will be available for public inspection and copying in the Policy Office, Room 3168, South Agriculture Building, 14th Street and Independence Avenue, SW., Washington, DC.

methods of inspection coverage are identified as conflicting with provisions of the regulations in this subchapter, the Administrator will waive such provisions for the period of experimentation, in accordance with §303.1(g) of this subchapter.

[52 FR 10032, Mar. 30, 1987 and 52 FR 48091, Dec. 18, 1987]

PART 304—APPLICATION FOR INSPECTION; GRANT OF INSPECTION

Sec.

304.1 Application for inspection.
304.2 Information to be furnished; grant or refusal of inspection.
304.3 Conditions for receiving inspection.

AUTHORITY: 21 U.S.C. 601–695; 7 CFR 2.18, 2.53.

§304.1 Application for inspection.

(a) Before the inspection is granted, each person conducting operations at an establishment subject to the Act, whether tenant, subsidiary, or landlord, shall make application therefor to the Administrator as provided for in this part.

(b) Every application under this section shall be made on an official form furnished by the Program, available from any Regional Director identified in §301.2(kkk) of this subchapter, and shall be completed to include all information requested. Trade names of the applicant for labeling purposes, shall be inserted in the appropriate blank in the application. Each applicant for inspection will be held responsible for compliance with the Act and the regulations in this subchapter if inspection is granted. Preparation of product and other operations at the establishment for which inspection is granted may be conducted only by the applicant named in the application.

(c) In cases of change of ownership or location, a new application shall be made.

[40 FR 2575, Jan. 14, 1975, as amended at 53 FR 49848, Dec. 12, 1988]

§304.2 Information to be furnished; grant or refusal of inspection.

(a) FSIS shall give notice in writing to each applicant granted inspection and shall specify in the notice the establishment, including the limits of the establishment's premises, to which the grant pertains.

(b) The Administrator is authorized to grant inspection upon his determination that the applicant and the establishment are eligible therefor and to refuse to grant inspection at any establishment if he determines that it does not meet the requirements of this part or the regulations in parts 305, 307, and part 416, §§416.1 through 416.6 of this chapter or that the applicant has not received approval of labeling and containers to be used at the establishment as required by the regulations in parts 316 and 317. Any application for inspection may be refused in accordance with the rules of practice in part 500 of this chapter.

(c)(1) Any applicant for inspection at an establishment where the operations thereof may result in any discharge into the navigable waters in the United States is required by subsection 21(b) of the Federal Water Pollution Control Act, as amended (84 Stat. 91), to provide the Administrator with a certification as prescribed in said subsection that there is reasonable assurance that such activity will be conducted in a manner which will not violate the applicable water quality standards. No grant of inspection can be issued after April 3, 1970 (the date of enactment of the Water Quality Improvement Act), unless such certification has been obtained, or is waived because of failure or refusal of the State, interstate agency or the Secretary of the Interior to act on a request for certification within a reasonable period (which shall not exceed 1 year after receipt of such request).

(2) However, certification is not initially required in connection with an application for inspection granted after April 3, 1970, for facilities existing or under construction on April 3, 1970, although certification for such facilities is required to be obtained within the 3-year period immediately following April 3, 1970. Failure to obtain such certification and meet the other requirements of subsection 21(b) prior to April 3, 1973, will result in the termination of inspection at such facilities on that date.

Further, any application for inspection pending on April 3, 1970, and granted within 1 year thereafter shall not require certification for 1 year following the grant of inspection but such grant of inspection shall terminate at the end of 1 year after its issuance unless prior thereto such certification has been obtained and the other requirements of subsection 21(b) are met.

[35 FR 15558, Oct. 3, 1970, as amended at 41 FR 4889, Feb. 3, 1976; 44 FR 68813, Nov. 30, 1979; 62 FR 45024, Aug. 25, 1997; 64 FR 56415, Oct. 20, 1999; 64 FR 66545, Nov. 29, 1999; 65 FR 2284, Jan. 14, 2000]

§304.3 Conditions for receiving inspection.

(a) Before being granted Federal inspection, an establishment shall have developed written sanitation Standard Operating Procedures, as required by part 416 of this chapter.

(b) Before being granted Federal inspection, an establishment shall have conducted a hazard analysis and developed and validated a HACCP plan, as required by §§417.2 and 417.4 of this chapter. A conditional grant of inspection shall be issued for a period not to exceed 90 days, during which period the establishment must validate its HACCP plan.

(c) Before producing new product for distribution in commerce, an establishment shall have conducted a hazard analysis and developed a HACCP plan applicable to that product in accordance with §417.2 of this chapter. During a period not to exceed 90 days after the date the new product is produced for distribution in commerce, the establishment shall validate its HACCP plan, in accordance with §417.4 of this chapter.

[61 FR 38864, July 25, 1996]

PART 305—OFFICIAL NUMBERS; INAUGURATION OF INSPECTION; WITHDRAWAL OF INSPECTION; REPORTS OF VIOLATION

Sec.

305.1 Official numbers; subsidiaries and tenants.
305.2 Separation of official establishments.
305.3 Sanitation and adequate facilities.
305.4 Inauguration of inspection.
305.6 Reports of violations.

AUTHORITY: 21 U.S.C. 601–695; 7 CFR 2.17, 2.55.

SOURCE: 35 FR 15559, Oct. 3, 1970, unless otherwise noted.

§305.1 Official numbers; subsidiaries and tenants.

(a) An official number shall be assigned to each establishment granted inspection. Such number shall be used to identify all inspected and passed products prepared in the establishment. More than one number shall not be assigned to an establishment.

(b) Two or more official establishments under the same ownership or control may be granted the same official number, provided a serial letter is added in each case to identify each establishment and the products thereof.

(c) When inspection has been granted to any applicant at an establishment, it shall not be granted to any other person at the same establishment. However, persons operating as separate entities in the same building or structure may operate separate establishments therein only under their own grant of inspection. All such persons operating separate establishments in the same building or structure shall be responsible for compliance with the Act and regulations in their own establishments, which shall include common areas, e.g., hallways, stairways, and elevators.

[35 FR 15559, Oct. 3, 1970, as amended at 40 FR 2576, Jan. 14, 1975]

§305.2 Separation of official establishments.

(a) Each official establishment shall be separate and distinct from any unofficial establishment except a poultry products processing establishment operated under Federal inspection under the Poultry Products Inspection Act or under State inspection.

(b) The slaughter or other preparation of products of horses, mules, or other equines required to be conducted under inspection pursuant to the regulations in this subchapter shall be done in establishments separate from any establishment in which cattle, sheep, swine, or goats are slaughtered or their products are prepared.

(c) Inspection shall not be inaugurated in any building, any part of

which is used as living quarters, unless the part for which inspection is requested is separated from such quarters by floors, walls, and ceilings of solid concrete, brick, wood, or similar material, and the floors, walls, and ceilings are without openings that directly or indirectly communicate with any part of the building used as living quarters.

§ 305.3 Sanitation and adequate facilities.

Inspection shall not be inaugurated if an establishment is not in a sanitary condition nor unless the establishment agrees to maintain a sanitary condition and provides adequate facilities for conducting such inspection.

§ 305.4 Inauguration of inspection.

When inspection is granted, the circuit supervisor shall, at or prior to the inauguration of inspection, inform the operator of the establishment of the requirements of the regulations in this subchapter. If the establishment, at the time inspection is inaugurated, contains any product which has not theretofore been inspected, passed, and marked in compliance with the regulations in this subchapter, the identity of the same shall be maintained, and it shall not be distributed in commerce, or otherwise subject to the requirements of such regulations, or dealt with as inspected and passed under the regulations. The establishment shall adopt and enforce all necessary measures and shall comply with all such directions as the circuit supervisor may prescribe, for carrying out the purposes of this section.

§ 305.6 Reports of violations.

Program employees shall report, in a manner prescribed by the Administrator, all violations of the Act or regulations in this subchapter of which they have information.

PART 306—ASSIGNMENT AND AUTHORITIES OF PROGRAM EMPLOYEES

Sec.

306.1 Designation of circuit supervisor and assistants.
306.2 Program employees to have access to establishments.
306.3 Badge as identification of inspectors.
306.4 Assignment of Program employees where members of family employed; soliciting employment; procuring product from official establishments.
306.5 Appeals.

AUTHORITY: 21 U.S.C. 601–695; 7 CFR 2.18, 2.53.

SOURCE: 35 FR 15559, Oct. 3, 1970, unless otherwise noted.

§ 306.1 Designation of circuit supervisor and assistants.

The Administrator shall designate a circuit supervisor of the inspection in each circuit, and assign to said inspector such assistants as may be necessary.

§ 306.2 Program employees to have access to establishments.

For the purpose of any examination or inspection necessary to prevent the use in commerce of any adulterated product, Program employees shall have access at all times, by day or night, whether the establishment is operated or not, to every part of any official establishment to which they are assigned. Access to establishments is also authorized in accordance with section 202 of the Act and the regulations in part 320 of this subchapter.

§ 306.3 Badge as identification of inspectors.

Each inspector will be furnished with a numbered official badge, which he shall not allow to leave his possession, and which he shall wear in such manner and at such times as the Administrator may prescribe. This badge shall be sufficient identification to entitle him to admittance at all regular entrances and to all parts of the establishment and premises to which he is assigned.

§ 306.4 Assignment of Program employees where members of family employed; soliciting employment; procuring product from official establishments.

(a) Except as specifically authorized by the Administrator, no Program employee shall be detailed for duty at an establishment where any member of his family is employed by the operator

of the establishment, or any tenant or subsidiary of such operator nor shall any circuit supervisor or other employee acting in a supervisory capacity be continued on duty at a circuit where any member of his family is so employed at any establishment under his jurisdiction. Program employees are forbidden to solicit, for any person, employment at any official establishment, or by any officer, manager, or employee thereof.

(b) Program employees shall not procure product from any official establishment or any other establishment if its operations or products are inspected or regulated under the Poultry Products Inspection Act or the Agricultural Marketing Act of 1946, as amended, or any other law administered by the Department unless the store or outlet from which the purchase is made is open to the general public and the price paid by such employee is the same as the price paid by the general public. Program employees must pay, and obtain receipts for money paid to such establishments for all such product and keep such receipts subject to inspection by supervisory employees or other authorized Department employees.

§306.5 Appeals.

Any appeal from a decision of any Program employee shall be made to his/her immediate supervisor having jurisdiction over the subject matter of the appeal, except as otherwise provided in the applicable rules of practice.

[48 FR 11418, Mar. 18, 1983, as amended at 60 FR 67454, Dec. 29, 1995]

PART 307—FACILITIES FOR INSPECTION

Sec.

307.1 Facilities for Program employees.
307.2 Other facilities and conditions to be provided by the establishment.
307.3 Inspectors to furnish and maintain implements in a sanitary condition.
307.4 Schedule of operations.
307.5 Overtime and holiday inspection service.
307.6 Basis of billing for overtime and holiday services.
307.7 Safety requirements for electrical stimulating (EST) equipment.

AUTHORITY: 7 U.S.C. 394, 21 U.S.C. 601–695; 7 CFR 2.17, 2.55.

SOURCE: 35 FR 15560, Oct. 3, 1970, unless otherwise noted.

§307.1 Facilities for Program employees.

Office space, including necessary furnishings, light, heat, and janitor service, shall be provided by official establishments, rent free, for the exclusive use for official purposes of the inspector and other Program employees assigned thereto. The space set aside for this purpose shall meet with approval of the circuit supervisor and shall be conveniently located, properly ventilated and provided with lockers suitable for the protection and storage of Program supplies and with facilities suitable for Program employees to change clothing if such clothes changing facilities are deemed necessary by the circuit supervisor. At the discretion of the Administrator, small plants requiring the services of less than one full time inspector need not furnish facilities for Program employees as prescribed in this section, where adequate facilities exist in a nearby convenient location. Laundry service for inspectors' outer work clothing shall be provided by each establishment.

§307.2 Other facilities and conditions to be provided by the establishment.

When required by the circuit supervisor, the following facilities and conditions, and such others as may be found to be essential to efficient conduct of inspection and maintenance of sanitary conditions, shall be provided by each official establishment:

(a) Satisfactory pens, equipment, and assistants for conducting ante-mortem inspection and for separating, marking and holding apart from passed livestock those marked ''U.S. suspect'' and those marked ''U.S. condemned'' (pens, alleys, and runways shall be paved, drained, and supplied with adequate hose connections for cleanup purposes);

(b) Sufficient light to be adequate for proper conduct of inspection;

(c) Racks, receptacles, or other suitable devices for retaining such parts as the head, tongue, tail, thymus gland, and viscera, and all parts and blood to

be used in the preparation of meat food products or medical products, until after the post-mortem examination is completed, in order that they may be identified in case of condemnation of the carcass; equipment, trucks, and receptacles for the handling of viscera of slaughtered animals so as to prevent contact with the floor; and trucks, racks, marked receptacles, tables, and other necessary equipment for the separate and sanitary handling of carcasses or parts passed for cooking;

(d) Tables, benches, and other equipment on which inspection is to be performed, of such design, material, and construction as to enable Program employees to conduct their inspection in a ready, efficient and clean manner;

(e) Watertight metal trucks or receptacles for holding and handling diseased carcasses and parts, so constructed as to be readily cleaned; such trucks or receptacles to be marked in a conspicuous manner with the phrase ''U.S. condemned'' in letters not less than 2 inches high, and, when required by the circuit supervisor, to be equipped with facilities for locking or sealing;

(f) Adequate arrangements, including liquid soap and cleansers, for cleansing and disinfecting hands, for sterilizing all implements used in dressing diseased carcasses, floors, and such other articles and places as may be contaminated by diseased carcasses or otherwise;

(g) In establishments in which slaughtering is done, rooms, compartments, or specially prepared open places, to be known as ''final inspection places,'' at which the final inspection of retained carcasses may be conducted (competent assistants for handling retained carcasses and parts shall be provided by the establishment; final inspection places shall be adequate in size and their rail arrangement and other equipment shall be sufficient to prevent carcasses and parts passed for food or cooking, from being contaminated by contact with condemned carcasses or parts; they shall be equipped with hot water, lavatory, sterilizer, tables, and other equipment required for ready, efficient, and sanitary conduct of the inspection; the floors shall be of such construction as to facilitate the maintenance of sanitary conditions and shall have proper drainage connections, and when the final inspection place is part of a larger floor, it shall be separated from the rest of the floor by a curb, railing, or otherwise);

(h) Retention rooms, cages, or other compartments, and receptacles in which carcasses and product may be held for further inspection (these shall be in such number and in such locations as the needs of the inspection in the establishment may require; they shall be equipped for secure locking or sealing and shall be held under locks or official seals furnished by the Department; the keys of such locks shall not leave the custody of Program employees. Every such room, compartment, or receptacle shall be marked conspicuously with the phrase ''U.S. retained'' in letters not less than 2 inches high; rooms or compartments for these purposes shall be secure and susceptible of being kept clean, including a sanitary disposal of the floor liquids; establishment employees shall not enter any retention rooms or compartments or open any retention receptacles unless authorized by Program employees);

(i) Adequate facilities, including denaturing materials, for the proper disposal of condemned articles in accordance with the regulations in this subchapter (tanks or other rendering equipment which, under the regulations in this subchapter, must be sealed, shall be properly equipped for sealing as specified by the regulations in part 314 of this subchapter or by the circuit supervisor in specific cases);

(j) Docks and receiving rooms, to be designated by the operator of the official establishment, with the circuit supervisor, for the receipt and inspection of all products as provided in § 318.3 of this subchapter.

(k) Suitable lockers in which brands bearing the official inspection legend and other official devices (excluding labels) and official certificates shall be kept when not in use (all such lockers shall be equipped for sealing or locking with locks or seals to be supplied by the Department; the keys of such locks shall not leave the custody of Program employees);

(l) Sanitary facilities and accommodations as prescribed by §416.2(c), (d), (e), (f), and (h) of this chapter.

(m) In addition to any facilities required to accomplish sanitary dressing procedures, the following inspection station facilities for cattle and swine slaughter lines described in §310.1(b) of this subchapter are required:

(1) An inspection station consisting of 5 feet of unobstructed line space for each head or carcass inspector and, for viscera table kills, 8 feet for each viscera inspector on the inspector's side of the table.

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

(3) A handwash lavatory (other than one which is hand operated), furnished with soap, towels, and hot and cold water, and located adjacent to the inspector's work area. In addition, for each head and viscera inspector on cattle slaughter lines, and each head inspector on swine slaughter lines, a sterilizer located adjacent to the inspector's work area.

(4) For mechanized operations, a line control switch located adjacent to each inspection station.

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

(6) For swine slaughter lines requiring three or more inspectors, and for those one- and two-inspector configurations where the establishment installs a mirror: At the carcass inspection station one glass or plastic, distortion-free mirror, at least 5 feet × 5 feet, mounted far enough away from the vertical axis of the moving line to allow the carcass to be turned, but not over 3 feet away, and so mounted that any inspector standing at the carcass inspection station can readily view the back of the carcass.

[35 FR 15560, Oct. 3, 1970, as amended at 47 FR 33676, Aug. 4, 1982; 50 FR 19902, May 13, 1985; 64 FR 56415, Oct. 20, 1999]

§307.3 Inspectors to furnish and maintain implements in a sanitary condition.

Inspectors shall furnish their own work clothing and implements, such as flashlights and triers, for conducting inspection and shall maintain their implements in sanitary condition as prescribed by §416.3(a) of this chapter.

[64 FR 56415, Oct. 20, 1999]

§307.4 Schedule of operations.

(a) No operations requiring inspection shall be conducted except under the supervision of a Program employee. All slaughtering of animals and preparation of products shall be done with reasonable speed, considering the official establishment's facilities.

(b) A shift is a regularly scheduled operating period, exclusive of mealtime. One lunch period is the only official authorized interruption in the inspector's tour of duty once it begins. Lunch periods may be 30 minutes, 45 minutes, or in any case may not exceed one hour in duration. Once established, the lunch period must remain relatively constant as to time and duration. Lunch periods for inspectors shall not, except as provided herein, occur prior to 4 hours after the beginning of scheduled operations nor later than 5 hours after operations begin. In plants where a company rest break of not less than 30 minutes is regularly observed, approximately midpoint between start of work and the lunch period, and the inspector is allowed this time to meet his personal needs, the lunch period may be scheduled as long as 5½ hours after the beginning of scheduled operations.

(c) Official establishments, importers, and exporters shall be provided inspection service, without charge, up to 8 consecutive hours per shift during the basic workweek subject to the provisions of §307.5: *Provided*, That any additional shifts meet requirements as determined by the Administrator or his designee. The basic workweek shall consist of 5 consecutive 8-hour days within the administrative workweek Sunday through Saturday, excluding the lunch period; except that, when possible, the Department shall schedule the basic workweek so as to consist of 5 consecutive 8-hour days Monday through Friday, excluding lunch period. The Department may depart from the basic workweek in those cases where maintaining such a schedule

would seriously handicap the Department in carrying out its function. These provisions are applicable to all official establishments except in certain cases as provided in § 318.4(h) of this subchapter.

(d)(1) Each official establishment shall submit a work schedule to the area supervisor for approval. In consideration of whether the approval of an establishment work schedule shall be given, the area supervisor shall take into account the efficient and effective use of inspection personnel. The work schedule must specify daily clock hours of operation and lunch periods for all departments of the establishment requiring inspection.

(2) Establishments shall maintain consistent work schedules. Any request by an establishment for a change in its work schedule involving an addition or elimination of shifts shall be submitted to the area supervisor at least 2 weeks in advance of the proposed change. Frequent requests for change shall not be approved: *Provided,* however, minor deviations from a daily operating schedule may be approved by the inspector in charge, if such request is received on the day preceding the day of change.

(3) Request for inspection service outside an approved work schedule shall be made as early in the day as possible for overtime work to be performed within that same workday; or made prior to the end of the day's operation when such a request will result in overtime service at the start of the following day: *Provided,* That an inspector may be recalled to his assignment after completion of his daily tour of duty under the provisions of § 307.6(b).

[40 FR 45799, Oct. 3, 1975, as amended at 40 FR 50719, Oct. 31, 1975; 41 FR 15401, Apr. 13, 1976; 48 FR 6893, Feb. 16, 1983; 51 FR 32304, Sept. 11, 1986]

§ 307.5 Overtime and holiday inspection service.

(a) The management of an official establishment, an importer, or an exporter shall reimburse the Program, at the rate specified in § 391.3, for the cost of the inspection service furnished on any holiday as specified in paragraph (b) of this section; or for more than 8 hours on any day, or more than 40 hours in any administrative workweek Sunday through Saturday.

(b) Holidays for Federal employees shall be New Year's Day, January 1; Birthday of Martin Luther King, Jr., the third Monday in January; Washington's Birthday, the third Monday in February; Memorial Day, the last Monday in May; Independence Day, July 4; Labor Day, the first Monday in September; Columbus Day, the second Monday in October; Veterans' Day, November 11; Thanksgiving Day, the fourth Thursday in November; Christmas Day, December 25. When any of the above-listed holidays falls outside the basic workweek, the nearest workday within that week shall become a holiday.

[40 FR 45800, Oct. 3, 1975, as amended at 43 FR 51754, Nov. 7, 1978; 50 FR 724, Jan. 7, 1985; 50 FR 51513, Dec. 18, 1985; 52 FR 4, Jan. 2, 1987; 53 FR 13397, Apr. 22, 1988; 54 FR 6389, Feb. 10, 1989]

§ 307.6 Basis of billing for overtime and holiday services.

(a) Each recipient of overtime or holiday inspection service, or both, shall be billed as provided for in § 307.5(a) and at the rates specified in § 391.3, in increments of quarter hours. For billing purposes, 8 or more minutes shall be considered a full quarter hour. Billing will be for each quarter hour of service rendered by each Program employee.

(b) Official establishments, importers, or exporters requesting and receiving the services of a Program employee after he has completed his day's assignment and left the premises, or called back to duty during any overtime or holiday period, shall be billed for a minimum of 2 hours overtime or holiday inspection service at the established rate.

(c) Bills are payable upon receipt and become delinquent 30 days from the date of the bill. Overtime or holiday inspection will not be performed for anyone having a delinquent account.

[40 FR 45800, Oct. 3, 1975, as amended at 54 FR 6389, Feb. 10, 1989]

§ 307.7 Safety requirements for electrical stimulating (EST) equipment.

(a) *General.* Electrical stimulating (EST) equipment is equipment that provides electric shock treatment to

carcasses for the purpose of accelerating rigor mortis of facilitating blood removal. These provisions do not apply to electrical equipment used to stun and/or slaughter animals or to facilitate hide removal. Electrical stimulating equipment consists of two separate pieces—the control system and the applicator. The EST control system contains the circuitry to generate pulsed DC or AC voltage for stimulation and is separate from the equipment used to apply the voltage to the carcass. The voltage is applied by inserting a probe that penetrates the carcass or is inserted in the rectum, placing a clamp in the nose, a carcass rubbar, a conveyor with energized surfaces traveling with the carcass, or any other acceptable method.

(b) *Safety requirements*—(1) *Circuits, grounding.* Either a bonded grounding conductor shall lead from each section of the carcass rail within the stimulating enclosure to the service ground, or the secondary voltage (stimulating circuit) shall be insulated from the service ground. If the stimulating section of the carcass rail and carcass drive mechanisms are insulated from the service ground then the stimulating rail or the return path shall be electrically bonded to the transformer secondary to isolate the stimulation voltage.

(2) *Enclosure.* Electrical stimulation shall occur in an area that will prevent persons from contacting an energized surface. If the area is surrounded by physical barriers, the enclosure shall be either electrically grounded or it shall be made of materials that do not conduct electricity. The interior of the stimulating area shall be visible from the start switch so the operator can be assured that there is no person, equipment or material present that should not be there prior to starting the stimulating sequence. If light or sound beam sensors form the enclosure, the stimulating equipment shall be automatically shut off when the sensor signals are broken.

(3) *Mandatory Warning Devices and Signals.* The following warning devices or signals shall be installed at each opening to the stimulating area through which a person would normally enter:

(i) A red light that flashes distinctly during the operating cycle of the stimulating equipment.

(ii) An ANSI Z53.1-Color Code sign reading (a) ''Danger Electrical Hazard'' for stimulating voltage below 50 or (b) ''Danger High Voltage'' for stimulating voltage above 50.

(iii) An emergency stop button.

(4) *Optional Warning Device—Horn or Bell.* If a warning horn or bell is installed, the signal shall be audible above background noises in the vicinity, and it shall sound for at least 1 second before each manual stimulation or before the carcass chain is started in an automatic system.

(c) Operation—

(1) *Training.* Only persons who have received safety instruction by the equipment manufacturer or designee may operate electrical stimulating equipment.

(2) *Cleaning and Maintenance.* To prevent an electrical shock to personnel, the electricity supplied to the stimulating surfaces shall be locked-off when cleaning, mechanical inspection, maintenance or testing are performed.

(3) *Water.* To prevent an electrical shock, personnel shall not spray streams of water on energized carcasses or on energized stimulating surfaces.

(d) Special provisions for manually operated equipment.

(1) Stimulating probes or clamps shall be stored in a sanitary container which is insulated with a material approved by the Administrator.[1]

(2) The electric wires attached to a clamp or probe shall not allow for contact between the probe or clamp and an electrical ground and shall not extend outside the enclosure.

[53 FR 46432, Nov. 17, 1988, as amended at 64 FR 56415, Oct. 20, 1999]

PART 308 [RESERVED]

[1] A list of approved insulation materials is available upon request from the Facilities, Equipment and Sanitation Division, Technical Services, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250.

PART 309—ANTE-MORTEM INSPECTION

Sec.
309.1 Ante-mortem inspection in pens of official establishments.
309.2 Livestock suspected of being diseased or affected with certain conditions; identifying suspects; disposition on post-mortem inspection or otherwise.
309.3 Dead, dying, disabled, or diseased and similar livestock.
309.4 Livestock showing symptoms of certain metabolic, toxic, nervous, or circulatory disturbances, nutritional imbalances, or infectious or parasitic diseases.
309.5 Swine; disposal because of hog cholera.
309.6 Epithelioma of the eye.
309.7 Livestock affected with anthrax; cleaning and disinfection of infected livestock pens and driveways.
309.8 Cattle affected with anasarca and generalized edema.
309.9 Swine erysipelas.
309.10 Onset of parturition.
309.11 Vaccine livestock.
309.12 Emergency slaughter; inspection prior to.
309.13 Disposition of condemned livestock.
309.14 Brucellosis-reactor goats.
309.15 Vesicular diseases.
309.16 Livestock suspected of having biological residues.
309.17 Livestock used for research.
309.18 Official marks and devices for purposes of ante-mortem inspection.

AUTHORITY: 21 U.S.C. 601–695; 7 CFR 2.17, 2.55.

SOURCE: 35 FR 15563, Oct. 3, 1970, unless otherwise noted.

§309.1 Ante-mortem inspection in pens of official establishments.

(a) All livestock offered for slaughter in an official establishment shall be examined and inspected on the day of and before slaughter unless, because of unusual circumstances, prior arrangements acceptable to the Administrator have been made in specific cases by the circuit supervisor for such examination and inspection to be made on a different day before slaughter.

(b) Such ante-mortem inspection shall be made in pens on the premises of the establishment at which the livestock are offered for slaughter before the livestock shall be allowed to enter into any department of the establishment where they are to be slaughtered or dressed or in which edible products are handled. When the holding pens of an official establishment are located in a public stockyard and are reserved for the exclusive use of the establishment, such pens shall be regarded as part of the premises of that establishment and the operator of the establishment shall be responsible for compliance with all requirements of the regulations in this subchapter with respect to such pens.

§309.2 Livestock suspected of being diseased or affected with certain conditions; identifying suspects; disposition on post-mortem inspection or otherwise.

(a) Any livestock which, on ante-mortem inspection, do not clearly show, but are suspected of being affected with any disease or condition that, under part 311 of this subchapter, may cause condemnation of the carcass on post-mortem inspection, and any livestock which show, on ante-mortem inspection, any disease or condition that, under part 311 of this subchapter would cause condemnation of only part of the carcass on post-mortem inspection, shall be so handled as to retain its identity as a suspect until it is given final post-mortem inspection, when the carcass shall be marked and disposed of as provided in parts 310 and 311 of this subchapter, or until it is disposed of as otherwise provided in this part.

(b) All seriously crippled animals and animals commonly termed ''downers,'' shall be identified as U.S. Suspects and disposed of as provided in §311.1 of this subchapter unless they are required to be classed as condemned under §309.3.

(c) Livestock which have reacted to a test for leptospirosis, or anaplasmosis, but which show no symptoms of the disease, shall be identified as U.S. Suspects and disposed of as provided in §311.10 of this subchapter.

(d) Livestock which are known to have reacted to the tuberculin test shall be identified as U.S. Suspects and disposed of as provided in §311.2 of this subchapter, except that livestock bearing an official ''USDA Reactor'' or similar State reactor tag shall not be tagged as U.S. Suspects.

(e) Any cattle found on ante-mortem inspection to be affected with epithelioma of the eye or of the orbital region to a lesser extent than as described in §309.6 shall be identified as a

U.S. Suspect and disposed of as provided in § 311.12 of this subchapter.

(f) Cattle found on ante-mortem inspection to be affected with anasarca to a lesser extent than as described in § 309.8 shall be identified as U.S. Suspects and disposed of as provided in § 311.8 of this subchapter or paragraph (g) of this section.

(g) Any livestock suspected of being affected with anasarca may be set apart and held for treatment under Program or other responsible official supervision approved by the area supervisor. If at the expiration of the treatment period the livestock upon examination is found to be free from disease, it may be released for any purpose. Otherwise, it shall be identified as U.S. Suspect and disposed of as provided in § 311.8 of this subchapter or condemned and disposed of as provided in § 309.8, whichever is appropriate.

(h) All hogs suspected on ante-mortem inspection of being affected with swine erysipelas shall be identified as U.S. Suspects and disposed of as provided in § 311.5 of this subchapter or paragraph (i) of this section.

(i) A hog suspected of being affected with swine erysipelas may be set apart and held for treatment under Program or other responsible official supervision approved by the area supervisor. If at the expiration of the treatment period the animal upon examination is found to be free from disease, it may be released for any purpose. Otherwise, it shall be identified as U.S. Suspect and disposed of as provided in § 311.5 of this subchapter, or condemned and disposed of as provided in § 309.13, whichever is appropriate.

(j) Any livestock which is affected with vesicular exanthema or vesicular stomatitis, but which has recovered to the extent that the lesions are in process of healing, the temperature is within normal range, and the livestock shows a return to normal appetite and activity, shall be identified as U.S. Suspect and disposed of as provided in § 311.32 of this subchapter, except that if desired, such livestock may be set apart and held under supervision of a Program employee or other official designated by the area supervisor for treatment. If the livestock is set aside for treatment, the U.S. Suspect identification device will be removed by a Program employee, following such treatment, if the livestock is found to be free from any such disease. Such livestock found to be free from any such disease may be released for slaughter or for purposes other than slaughter, provided that in the latter instance, the operator of the official establishment or the owner of the animal shall first obtain permission from the local, State, or Federal livestock sanitary official having jurisdiction over the movement of such livestock.

(k) Livestock which are offered for ante-mortem inspection under this part, and which are regarded by the inspector as immature, shall be identified as U.S. Suspects and, if slaughtered, the disposition of their carcasses shall be determined by the post-mortem findings in connection with the ante-mortem conditions. If not slaughtered as suspects, such livestock shall be held under supervision of a Program employee or other official designated by the area supervisor, and after sufficient development may be released for slaughter or may be released for any other purpose, provided they have not been exposed to any infectious or contagious disease. If such exposure occurs, permission should be obtained from the nearest Veterinary Services unit of the Animal and Plant Health Inspection Service prior to release of such livestock.

(l) Livestock previously condemned for listeriosis, if released for slaughter under § 309.13(b) shall be identified as a U.S. Suspect in accordance with § 309.13(c).

(m) Each animal required by this part to be treated as a U.S. Suspect shall be identified as such by or under the supervision of a Program employee with an official device in accordance with § 309.18. No such device shall be removed except by a Program employee.

(n) Each animal identified as a U.S. Suspect on ante-mortem inspection shall be set apart and shall be slaughtered separately from other livestock at that establishment unless disposed of as otherwise provided in this part.

(o) Each animal identified as a U.S. Suspect on ante-mortem inspection, when presented for slaughter shall be accompanied with a form MP 402–2 on

which the inspector at the establishment shall record the U.S. Suspect identification number and any other identifying tag numbers present and a brief description of the animal and of the disease or condition for which the animal was classed as a suspect, including its temperature when the temperature of such animal might have a bearing on the disposition of the carcass on post-mortem inspection.

(p) When any animal identified as a U.S. Suspect is released for any purpose or reason, as provided in this part, the official identification device shall be removed only by a Program employee and he shall report his action to the area supervisor. When a suspect is to be released under the provisions of this part for a purpose other than slaughter, the operator of the official establishment or the owner of the animal shall first obtain permission for the removal of such animal from the local, State or Federal livestock sanitary official having jurisdiction.

[35 FR 15563, Oct. 3, 1970, as amended at 38 FR 29214, Oct. 23, 1973; 39 FR 36000, Oct. 17, 1974]

§ 309.3 Dead, dying, disabled, or diseased and similar livestock.

(a) Livestock found to be dead or in a dying condition on the premises of an official establishment shall be identified as U.S. Condemned and disposed of in accordance with § 309.13.

(b) Livestock plainly showing on ante-mortem inspection any disease or condition that, under part 311 of this subchapter, would cause condemnation of their carcasses on post-mortem inspection shall be identified as U.S. Condemned and disposed of in accordance with § 309.13.

(c) Any swine having a temperature of 106 °F. or higher and any cattle, sheep, goats, horses, mules, or other equines having a temperature of 105 °F. or higher shall be identified as U.S. Condemned. In case of doubt as to the cause of the high temperature, or when for other reasons a Program employee deems such action warranted, any such livestock may be held for a reasonable time under the supervision of a Program employee for further observation and taking of temperature before final disposition of such livestock is determined. Any livestock so held shall be reinspected on the day it is slaughtered. If, upon such reinspection, or when not held for further observation and taking of temperature, then on the original inspection, the animal has a temperature of 106 °F. or higher in the case of swine, or 105 °F. or higher in the case of other livestock, it shall be condemned and disposed of in accordance with § 309.13.

(d) Any livestock found in a comatose or semicomatose condition or affected with any condition not otherwise covered in this part, which would preclude release of the animal for slaughter for human food, shall be identified ''U.S. Condemned'' and disposed of in accordance with § 309.13, except that such animal may be set apart and held for further observation or treatment under supervision of a Program employee or other official designated by the area supervisor and for final disposition in accordance with this part.

§ 309.4 Livestock showing symptoms of certain metabolic, toxic, nervous, or circulatory disturbances, nutritional imbalances, or infectious or parasitic diseases.

(a) All livestock showing, on antemortem inspection, symptoms of anaplasmosis, ketosis, leptospirosis, listeriosis, parturient paresis, pseudorabies, rabies, scrapie, tetanus, grass tetany, transport tetany, strangles, purpura hemorrhagica, azoturia, infectious equine encephalomyelitis, toxic encephalomyelitis (forage poisoning), dourine, acute influenza, generalized osteoporosis, glanders (farcy), acute inflammatory lameness or extensive fistula shall be identified as U.S. Condemned and disposed of in accordance with § 309.13.

(b) If any equine is suspected on antemortem inspection of being infected with glanders or dourine, the nearest Veterinary Services unit of the Animal and Plant Health Inspection Service shall be so informed by a Program employee. Tests shall be performed by said unit to determine whether the animal is, in fact, infected with such disease. If it is found on such tests to be infected, the animal shall be disposed of in accordance with paragraph (a) of this section. Otherwise, the animal shall be identified as a U.S. Suspect

and disposed of as provided in §311.10 of this subchapter.

[35 FR 15563, Oct. 3, 1970 as amended at 38 FR 29214, Oct. 23, 1973]

§309.5 Swine; disposal because of hog cholera.

(a) All swine found by an inspector to be affected with hog cholera shall be identified as U.S. Condemned and disposed of in accordance with §309.13. Immediate notification shall be given by the inspector to the official in the Veterinary Services unit of the Animal and Plant Health Inspection Service who has responsibility for the control of swine diseases in the State where the swine are located.

(b) All swine, even though not themselves identified as U.S. Suspects, which are of lots in which one or more animals have been condemned or identified as U.S. Suspect for hog cholera, shall, as far as possible, be slaughtered separately and apart from all other livestock passed on ante-mortem inspection.

[40 FR 27225, June 27, 1975]

§309.6 Epithelioma of the eye.

Any animal found on ante-mortem inspection to be affected with epithelioma of the eye and the orbital region in which the eye has been destroyed or obscured by neoplastic tissue and which shows extensive infection, suppuration, and necrosis, usually accompanied with foul odor, or any animal affected with epithelioma of the eye or of the orbital region which, regardless of extent, is accompanied with cachexia shall be identified as U.S. Condemned and disposed of in accordance with §309.13.

§309.7 Livestock affected with anthrax; cleaning and disinfection of infected livestock pens and driveways.

(a) Any livestock found on ante-mortem inspection to be affected with anthrax shall be identified as U.S. Condemned and disposed of in accordance with §309.13.

(b) No other livestock of a lot in which anthrax is found on ante-mortem inspection shall be slaughtered and presented for post-mortem inspection until it has been determined by a careful ante-mortem inspection that no anthrax infected livestock remains in the lot.

(c) Apparently healthy livestock (other than hogs) from a lot in which anthrax is detected, and any apparently healthy livestock which have been treated with anthrax biologicals which do not contain living anthrax organisms, may be slaughtered and presented for post-mortem inspection if they have been held not less than 21 days following the last treatment or the last death of any livestock in the lot. Alternatively, if desired, all apparently healthy livestock of the lot may be segregated and held for treatment by a State licensed veterinarian under supervision of a Program employee or other official designated by the area supervisor. No anthrax vaccine (live organisms) shall be used on the premises of an official establishment.

(d) Livestock which have been injected with anthrax vaccines (live organisms) within 6 weeks, and those bearing evidence of reaction to such treatment, such as inflammation, tumefaction, or edema at the site of the injection, shall be condemned on ante-mortem inspection, or such animals may be held under supervision of a Program employee or other official designated by the area supervisor until the expiration of the 6-week period and the disappearance of any evidence of reaction to the treatment.

(e) When livestock are found on ante-mortem inspection to be affected with anthrax, all exposed livestock pens and driveways of the official establishment shall be cleaned and disinfected by promptly and thoroughly removing and burning all straw, litter, and manure. This shall be followed immediately by a thorough disinfection of the exposed premises by soaking the ground, fences, gates, and all exposed material with a 5 percent solution of sodium hydroxide or commercial lye prepared as outlined in §310.9(e)(1) of this subchapter, or other disinfectant that may be approved in specific cases by the Administrator specifically for this purpose.

§ 309.8 Cattle affected with anasarca and generalized edema.

All cattle found on ante-mortem inspection to be affected with anasarca in advanced stages and characterized by an extensive and generalized edema shall be identified as U.S. Condemned and disposed of in accordance with § 309.13.

§ 309.9 Swine erysipelas.

All hogs plainly showing on ante-mortem inspection that they are affected with acute swine erysipelas shall be identified as U.S. Condemned and disposed of in accordance with § 309.13.

§ 309.10 Onset of parturition.

Any livestock showing signs of the onset of parturition shall be withheld from slaughter until after parturition and passage of the placenta. Slaughter or other disposition may then be permitted if the animal is otherwise acceptable.

§ 309.11 Vaccine livestock.

Vaccine livestock with unhealed lesions of vaccinia, accompanied with fever, which have not been exposed to any other infectious or contagious disease, are not required to be slaughtered and may be released for removal from the premises.

§ 309.12 Emergency slaughter; inspection prior to.

In all cases of emergency slaughter, except as provided in § 311.27 of this subchapter, the animals shall be inspected immediately before slaughter, whether theretofore inspected or not. When the necessity for emergency slaughter exists, the establishment shall notify the inspector in charge so that such inspection may be made.

§ 309.13 Disposition of condemned livestock.

(a) Except as otherwise provided in this part, livestock identified as U.S. Condemned shall be killed by the official establishment, if not already dead. Such animals shall not be taken into the official establishment to be slaughtered or dressed; nor shall they be conveyed into any department of the establishment used for edible products; but they shall be disposed of in the manner provided for condemned carcasses in part 314 of this subchapter. The official U.S. Condemned tag shall not be removed from, but shall remain on the carcass until it goes into the tank, or is otherwise disposed of as prescribed in part 314 of this subchapter, at which time such tag may be removed by a Program employee only. The number of such tag shall be reported to the veterinary medical officer by the inspector who affixed it, and also by the inspector who supervised the tanking of the carcass.

(b) Any livestock condemned on account of ketosis, swine erysipelas, vesicular diseases, grass tetany, transport tetany, parturient paresis, anasarca, anaplasmosis, leptospirosis, listeriosis, or inflammatory condition including pneumonia, enteritis, and peritonitis may be set apart and held for treatment under supervision of a Program employee or official designated by the area supervisor. The U.S. Condemned identification tag will be removed by a Program employee following treatment under such supervision if the animal is found to be free from any such disease.

(c) Livestock previously affected with listeriosis, including those released for slaughter after treatment under paragraph (b) of this section, shall be identified as U.S. Suspect.

(d) When livestock under the provisions of this section is to be released for a purpose other than slaughter, the operator of the official establishment or the owner of the livestock shall first obtain permission for the movement of such livestock from the local, State, or Federal livestock sanitary official having jurisdiction.

§ 309.14 Brucellosis-reactor goats.

Goats which have reacted to a test for brucellosis shall not be slaughtered in an official establishment.

§ 309.15 Vesicular diseases.

(a) Immediate notification shall be given by the inspector to the local, State, and Federal livestock sanitary officials having jurisdiction when any livestock is found to be affected with a vesicular disease.

(b) No livestock under quarantine by State or Federal livestock sanitary officials on account of a vesicular disease will be given ante-mortem inspection. If no quarantine is invoked, or if quarantine is invoked and later removed, upon ante-mortem inspection, any animal found to be affected with vesicular exanthema or vesicular stomatitis in the acute stages, as evidenced by acute and active lesions or an elevated temperature, shall be identified as U.S. Condemned and disposed of in accordance with §309.13.

§309.16 Livestock suspected of having biological residues.

(a) Except as provided by paragraph (d) of this section, livestock suspected of having been treated with or exposed to any substance that may impart a biological residue which would make the edible tissues unfit for human food or otherwise adulterated shall be handled in compliance with the provisions of this paragraph. They shall be identified at official establishments as ''U.S. Condemned.'' These livestock may be held under the custody of a Program employee, or other official designated by the Administrator, until metabolic processes have reduced the residue sufficiently to make the tissues fit for human food and otherwise not adulterated. When the required time has elapsed, the livestock, if returned for slaughter, must be re-examined on ante-mortem inspection. To aid in determining the amount of residue present in the tissues, officials of the Program may permit the slaughter of any such livestock for the purpose of collecting tissues for analysis for the residue. Such analysis may include the use of inplant screening procedures designed to detect the presence of antimicrobial residues in any species of livestock.

(b) All carcasses and edible organs and other parts thereof, in which are found any biological residues which render such articles adulterated, shall be marked as ''U.S. Condemned'' and disposed of in accordance with §314.1 or §314.3 of this chapter.

(c) [Reserved]

(d) Calves shall not be presented for ante-mortem inspection in an official establishment except under the provisions of this paragraph.

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

(i) *Calf.* A calf up to 3 weeks of age or up to 150 pounds.

(ii) *Certified calf.* A calf that the producer and all other subsequent custodians of the calf certify in writing has not been treated with any animal drug while in his or her custody or has been treated with one or more drugs in accordance with FDA approved label directions while in his or her custody and has been withheld from slaughter for the period(s) of time specified by those label directions.

(iii) *Healthy calf.* A calf that an inspector determines shows no visual signs of disease or treatment of disease at ante-mortem inspection.

(iv) *Producer.* The owner of the calf at the time of its birth.

(v) *Sick calf.* A calf that an inspector on ante-mortem inspection determines has either signs of treatment or signs of disease.

(vi) *Veterinary medical officer.* An inspector of the Program that has obtained a Doctor of Veterinary Medicine degree which is recognized by the Program.

(2) *General requirements.* (i) The identity of the producer of each calf presented for ante-mortem inspection shall be made available by the official establishment to the inspection prior to the animal being presented for ante-mortem inspection.

(ii) The inspector shall segregate the calves presented for ante-mortem inspection at the establishment and identify each calf as one of the following: (a) Certified, (B) noncertified, or (C) previous residue condemnation.

(3) *Certified group.* (i) For a calf to be considered certified, the producer and all other subsequent custodians of the calf must certify in writing that while the calf was in his or her custody, the calf was not treated with animal drugs or was treated with one or more drugs in accordance with FDA approved label directions and was withheld from slaughter for the period(s) of time specified by those label directions. All prior certifications must be presented with the animal at the time of slaughter.

The certifications shall contain a list of the calves with accompanying identification numbers, as required by paragraph (d)(3)(ii) of this section, followed by the following language:

I hereby certify that, while in my custody, from _____ to _____ (time period of custody), the above-listed calf or calves have not been treated with drugs, or have been treated with one or more drugs in accordance with FDA approved label directions and have been withheld from slaughter for the period(s) of time specified by those label directions. I certify that, to the best of my knowledge and belief, all information contained herein is true, that the information may be relied upon at the official establishment, and that I understand that any willful falsification of this certification is a felony and may result in a fine of up to $250,000 for an individual or up to $500,000 for an organization, or imprisonment for not more than 5 years, or both (21 U.S.C. 677, 18 U.S.C. 1001 and 3571).

Executed on _____
(date of certification)

_____
(signature of certifier)

_____
(typed or printed name and address of certifier)

_____
(business of certifier)

(ii) Each calf must be identified by use of backtag, eartag, or other type of secure identification which displays a number which shall be recorded on all written certifications.

(iii) The inspector shall have segregated for veterinary medical officer examination any certified calf which he or she determines to show any sign of disease or which is not identified individually. Such animal will be tagged as ''U.S. Suspect'' and its carcass will be retained on post-mortem inspection and handled in accordance with § 310.21 (c) and (d).

(iv) The inspector shall handle the remaining carcasses of healthy animals in accordance with § 310.21(c) and (d).

(4) *Noncertified group.* On ante-mortem inspection, the inspector shall have segregated for veterinary medical officer examination any calf which he or she determines to show any sign of disease. Such animal will be tagged as ''U.S. Suspect'' and its carcass will be retained on post-mortem inspection and handled in accordance with § 310.21(c). The inspector shall handle the remaining carcasses of healthy animals in accordance with § 310.21(c).

(5) *Calves from producers with previous residue condemnation.* On ante-mortem inspection, the inspector shall have segregated for veterinary medical officer examination any calf which he or she determines to show any sign of disease. Such animal will be tagged as ''U.S. Suspect'' and its carcass will be retained on post-mortem inspection and handled in accordance with § 310.21(e). The inspector shall handle the remaining carcasses of healthy animals in accordance with § 310.21(e).

(e) The name of each and all person(s) who sold or consigned each swine to the establishment shall be made available by the establishment to any Program employee or other authorized employee of the United States Department of Agriculture upon that employee's request and presentation of his or her official credentials. Swine identification, by means approved by the Animal and Plant Health Inspection Service, USDA, under part 71 of this title, must be maintained throughout post-mortem inspection, in accordance with § 310.23(a) of this subchapter.

(Recordkeeping requirements approved by the Office of Management and Budget under control number 0583–0053)

[36 FR 24928, Dec. 24, 1971, as amended at 44 FR 45606, Aug. 3, 1979; 44 FR 59499, Oct. 16, 1979; 47 FR 746, Jan. 7, 1982; 47 FR 41336, Sept. 20, 1982; 50 FR 32164, Aug. 9, 1985; 50 FR 53127, Dec. 30, 1985; 52 FR 2104, Jan. 20, 1987; 53 FR 40387, Oct. 14, 1988; 55 FR 7474, Mar. 2, 1990]

§ 309.17 Livestock used for research.

(a) No livestock used in any research investigation involving an experimental biological product, drug, or chemical shall be eligible for slaughter at an official establishment unless:

(1) The operator of such establishment, the sponsor of the investigation, or the investigator has submitted to the Program, or the Veterinary Services unit of the Animal and Plant Health Inspection Service of the Department of Agriculture or to the Environmental Protection Agency or to the Food and Drug Administration of the Department of Health, Education, and Welfare, data or a summary evaluation of the data which demonstrates that

the use of such biological product, drug, or chemical will not result in the products of such livestock being adulterated, and a Program employee has approved such slaughter;

(2) Written approval by the Deputy Administrator, Meat and Poultry Inspection Field Operations is furnished the area supervisor prior to the time of slaughter;

(3) In the case of an animal administered any unlicensed, experimental veterinary biologic product regulated under the Virus-Serum Toxin Act (21 U.S.C. 151 et seq.), the product was prepared and distributed in compliance with Part 103 of the regulations issued under said Act (part 103 of this title), and used in accordance with the labeling approved under said regulations;

(4) In the case of an animal administered any investigational drug regulated under the Federal Food, Drug, and Cosmetic Act, as amended (21 U.S.C. 301 et seq.), the drug was prepared and distributed in compliance with the applicable provisions of part 135 of the regulations issued under said Act (21 CFR part 135), and used in accordance with the labeling approved under said regulations;

(5) In the case of an animal subjected to any experimental economic poison under section 2(a) of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended (7 U.S.C. 135 et seq.), the product was prepared and distributed in accordance with §362.17 of the regulations issued under said Act (7 CFR 362.17), and used in accordance with the labeling approved under said regulations.

(6) In the case of an animal administered or subjected to any substance that is a food additive or pesticide chemical under the Federal Food, Drug, and Cosmetic Act, supra, there has been compliance with all tolerance limitations established by said Act and the regulations promulgated thereunder (21 CFR 1.1 et seq.), and all other restrictions and requirements imposed by said Act and said regulations will be complied with at the time of slaughter.

(b) The inspector in charge may deny or withdraw the approval for slaughter of any livestock subject to the provision of this section when he deems it necessary to assure that all products prepared at the official establishment are free from adulteration.

§309.18 Official marks and devices for purposes of ante-mortem inspection.

(a) All livestock required by this part to be identified as U.S. Suspects shall be tagged with a serially numbered metal ear tag bearing the term ''U.S. Suspect,'' except as provided in §309.2(d) and except that cattle affected with epithelioma of the eye, antinomycosis, or actinobacillosis to such an extent that the lesions would be readily detected on post-mortem inspection, need not be individually tagged on ante-mortem inspection with the U.S. Suspect tag, provided that such cattle are segregated and otherwise handled as U.S. Suspects.

(b) In addition, identification of U.S. Suspect swine must include the use of tattoos specified by the inspector to maintain the identity of the animals through the dehairing equipment when such equipment is used.

(c) All livestock required by this part to be identified as U.S. Condemned shall be tagged with a serially numbered metal ear tag bearing the term ''U.S. Condemned.''

(d) The devices described in paragraphs (a), (b), and (c) of this section shall be the official devices for identification of livestock required to be identified as U.S. Suspect or U.S. Condemned as provided in this part.

PART 310—POST-MORTEM INSPECTION

Sec.

310.1 Extent and time of post-mortem inspection; post-mortem inspection staffing standards.
310.2 Identification of carcass with certain severed parts thereof and with animal from which derived.
310.3 Carcasses and parts in certain instances to be retained.
310.4 Identification of carcasses and parts; tagging.
310.5 Condemned carcasses and parts to be so marked; tanking; separation.
310.6 Carcasses and parts passed for cooking; marking.
310.7 Removal of spermatic cords, pizzles and preputial diverticuli.
310.8 Passing and marking of carcasses and parts.

310.9 Anthrax; carcasses not to be eviscerated; disposition of affected carcasses; hides, hoofs, horns, hair, viscera and contents, and fat; handling of blood and scalding vat water; general cleanup and disinfection.
310.10 Carcasses with skin or hide on; cleaning before evisceration; removal of larvae of Hypodermae, external parasites and other pathological skin conditions.
310.11 Cleaning of hog carcasses before incising.
310.12 Sternum to be split; abdominal and thoracic viscera to be removed.
310.13 Inflating carcasses or parts thereof; transferring caul or other fat.
310.14 Handling of bruised parts.
310.15 Disposition of thyroid glands and laryngeal muscle tissue.
310.16 Disposition of lungs.
310.17 Inspection of mammary glands.
310.18 Contamination of carcasses, organs, or other parts.
310.19 Inspection of kidneys.
310.20 Saving of blood from livestock as an edible product.
310.21 Carcasses suspected of containing sulfa and antibiotic residues; sampling frequency; disposition of affected carcasses and parts.
310.22 [Reserved]
310.23 Identification of carcasses and parts of swine.
310.24 [Reserved]
310.25 Contamination with microorganisms; process control verification criteria and testing; pathogen reduction standards.

AUTHORITY: 21 U.S.C. 601–695; 7 CFR 2.18, 2.53.

SOURCE: 35 FR 15567, Oct. 3, 1970, unless otherwise noted.

§ 310.1 Extent and time of post-mortem inspection; post-mortem inspection staffing standards.

(a) A careful post-mortem examination and inspection shall be made of the carcasses and parts thereof of all livestock slaughtered at official establishments. Such inspection and examination shall be made at the time of slaughter unless, because of unusual circumstances, prior arrangements acceptable to the Administrator have been made in specific cases by the circuit supervisor for making such inspection and examination at a later time.

(b)(1) The staffing standards on the basis of the number of carcasses to be inspected per hour are outlined in the following tables. Standards for multiple inspector lines are based on inspectors rotating through the different types of inspection stations during each shift to equalize the workload. The inspector in charge shall have the authority to require the establishment to reduce slaughter line speeds where, in his judgment, the inspection procedure cannot be adequately performed at the current line speed because of particular deficiencies in carcass preparation and presentation by the plant at the higher speed, or because the health condition of the particular animals indicates a need for more extensive inspection.

(2) *Cattle inspection.* For all cattle staffing standards, an ''a'' in the ''Number of Inspectors by Stations'' column means that one inspector performs the entire inspection procedure and a ''b'' means that one inspector performs the head and lower carcass inspection and a second inspector performs the viscera and upper carcass inspection.[1]

(i) Inspection Using the Viscera Truck.

STEERS AND HEIFERS

Maximum slaughter rates (head per hour)	Number of inspectors by stations		
	Head	Viscera	Carcass
1 to 27	a	a	a
28 to 56	b	b	b
57 to 84	1	1	1
85 to 86	1	2	1
87 to 143	2	2	1

COWS AND BULLS

Maximum slaughter rates (head per hour)	Number of inspectors by stations		
	Head	Viscera	Carcass
1 to 27	a	a	a
28 to 55	b	b	b
56 to 77	1	1	1
78 to 81	1	2	1
82 to 134	2	2	1

[1] The ''Maximum Slaughter Rates'' figures listed in paragraph (b)(2)(i) of this section for one (a) and two (b) inspector kills are overstated because the time required to walk from one inspection station to another is not included. To determine the proper adjusted maximum slaughter line speed, paragraph (b)(2)(i)(A) of this section for one inspector kills or paragraph (b)(2)(i)(B) of this section for two inspector kills must be used along with their accompanying rules.

(A) Rules for determining adjusted maximum slaughter rates for single-inspector kills considering walking distance according to the table in this subdivision: Determine the distances the inspector actually walks between the points shown in columns 2 through 14 of the following table. For each column, determine the deduction figure opposite the appropriate number of feet in column 1. Compute the total of the deduction figures for columns 2 through 14. The adjusted maximum rate is the maximum rate in paragraph (b)(2)(i) of this section minus total of the deduction figures. If the resultant number is not a whole number, it must be rounded off to the next *lowest* whole number.

ONE-INSPECTOR CATTLE KILL—VISCERA TRUCK

[Table of deductions from maximum slaughter rates for each 2 feet between points (in tenths of cattle per hour)]

1 Number of feet between points	2 Head rack and high rail		3 Viscera and low rail		4 Low rail and head rack		5 Head rack and carcass [2]		6 Carcass [2] and washbasin		7 Tags—brands and low rail		8 Viscera and washbasin		9 Viscera and high rail		10 Low rail and high rail		11 Head rack and closest washbasin		12 Washbasin and high rail [1]		13 Head rack and wash-basin [1]		14 Viscera and tags—brands	
	Strs. Hfrs.	Cows Bulls	Strs. Hfrs.	Cows Bulls	Strs. Hfrs.	Cows Bulls	Strs. Hfrs.	Cows Bulls	Strs. Hfrs.	Cows Bulls	Strs. Hfrs.	Cows Bulls	Strs. Hfrs.	Cows Bulls	Strs. Hfrs.	Cows Bulls	Strs. Hfrs.	Cows Bulls	Strs. Hfrs.	Cows Bulls	Strs. Hfrs.	Cows Bulls	Strs. Hfrs.	Cows Bulls	Strs. Hfrs.	Cows Bulls
1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
3	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0.1	0
5	0	0	0.1	0	0	0	0	0	0	0	0	0	0	0.1	0.1	0.1	0	0	0	0	0	0	0	0	0.2	0.1
7	0	0	0.1	0.1	0.1	0.1	0	0	0	0	0.1	0.1	0.1	0.2	0.2	0.2	0.1	0.1	0	0	0	0	0	0	0.3	0.3
9	0	0	0.2	0.1	0.1	0.1	0	0	0	0	0.1	0.1	0.1	0.3	0.3	0.3	0.1	0.1	0	0	0.1	0.1	0.1	0.1	0.4	0.4
11	0.1	0.1	0.2	0.2	0.2	0.2	0	0	0	0	0.1	0.2	0.2	0.4	0.4	0.4	0.2	0.2	0	0	0.1	0.1	0.1	0.1	0.5	0.6
13	0.1	0.1	0.3	0.2	0.2	0.2	0	0	0	0	0.2	0.2	0.2	0.5	0.5	0.5	0.2	0.2	0	0	0.1	0.1	0.1	0.1	0.6	0.7
15	0.1	0.1	0.4	0.3	0.3	0.3	0	0	0	0	0.2	0.3	0.3	0.5	0.6	0.6	0.3	0.3	0	0	0.2	0.2	0.2	0.2	0.7	0.9
17	0.1	0.1	0.4	0.3	0.3	0.3	0	0	0	0	0.3	0.3	0.3	0.6	0.7	0.7	0.3	0.3	0	0.1	0.2	0.2	0.2	0.2	0.9	1.0
19	0.1	0.1	0.5	0.4	0.4	0.4	0	0	0	0	0.3	0.4	0.4	0.7	0.8	0.8	0.4	0.4	0	0.1	0.2	0.2	0.2	0.2	1.0	1.1
21	0.2	0.2	0.5	0.4	0.4	0.4	0	0	0	0	0.3	0.4	0.4	0.8	0.9	0.8	0.4	0.4	0	0.1	0.3	0.2	0.3	0.2	1.1	1.3
23	0.2	0.2	0.6	0.5	0.5	0.5	0	0	0	0	0.4	0.5	0.5	0.9	1.0	0.9	0.5	0.5	0	0.1	0.3	0.3	0.3	0.3	1.2	1.4
25	0.2	0.2	0.7	0.5	0.5	0.5	0	0	0	0	0.4	0.5	0.5	1.0	1.1	1.0	0.5	0.5	0	0.1	0.3	0.3	0.3	0.3	1.3	1.5
27	0.2	0.2	0.7	0.5	0.6	0.5	0	0	0	0	0.4	0.5	0.6	1.1	1.2	1.1	0.6	0.6	0	0.1	0.3	0.3	0.3	0.3	1.4	1.7
29	0.2	0.2	0.8	0.6	0.6	0.6	0	0	0	0	0.5	0.6	0.6	1.2	1.3	1.2	0.6	0.6	0	0.1	0.4	0.3	0.4	0.3	1.5	1.8
31	0.3	0.2	0.8	0.6	0.7	0.6	0	0	0	0	0.5	0.6	0.7	1.3	1.3	1.4	0.7	0.7	0	0.1	0.4	0.4	0.4	0.4	1.6	1.9
33	0.3	0.3	0.9	0.7	0.7	0.7	0	0	0	0	0.6	0.7	0.7	1.3	1.4	1.4	0.7	0.7	0	0.1	0.4	0.4	0.4	0.4	1.7	2.1
35	0.3	0.3	1.0	0.7	0.8	0.7	0	0	0	0	0.6	0.7	0.8	1.4	1.5	1.5	0.8	0.8	0	0.2	0.5	0.4	0.5	0.4	1.8	2.2
37	0.3	0.3	1.0	0.8	0.8	0.8	0	0	0	0	0.6	0.8	0.8	1.5	1.6	1.6	.0.8	0.8	0	0.2	0.5	0.5	0.5	0.5	1.9	2.3
39	0.3	0.3	1.1	0.8	0.9	0.8	0	0	0	0	0.7	0.8	0.9	1.6	1.7	1.7	0.9	0.9	0	0.2	0.5	0.5	0.5	0.5	2.0	2.4
41	0.4	0.3	1.1	0.9	0.9	0.9	0	0.1	0	0.1	0.7	0.9	0.9	1.7	1.7	1.8	0.9	0.9	0	0.2	0.6	0.5	0.6	0.5	2.1	2.6
43	0.4	0.4	1.2	0.9	1.0	0.9	0	0.1	0	0.1	0.7	0.9	1.0	1.8	1.8	1.9	1.0	1.0	0.1	0.2	0.6	0.5	0.6	0.5	2.2	2.7
45	0.4	0.4	1.2	0.9	1.0	0.9	0	0.1	0	0.1	0.8	0.9	1.0	1.8	1.9	2.0	1.0	1.0	0.1	0.2	0.6	0.6	0.6	0.6	2.3	2.8
47	0.4	0.4	1.3	1.0	1.1	1.0	0	0.1	0	0.1	0.8	1.0	1.1	1.9	2.0	2.1	1.1	1.1	0.1	0.2	0.6	0.6	0.6	0.6	2.4	2.9
49	0.4	0.4	1.4	1.0	1.1	1.0	0	0.1	0	0.1	0.8	1.0	1.1	2.0	2.1	2.2	1.1	1.1	0.1	0.2	0.7	0.6	0.7	0.6	2.5	3.1
51	0.5	0.5	1.4	1.1	1.2	1.1	0	0.1	0	0.1	0.9	1.1	1.2	2.1	2.2	2.2	1.2	1.2	0.1	0.3	0.7	0.7	0.7	0.7	2.6	3.2
53	0.5	0.5	1.5	1.1	1.2	1.1	0	0.1	0	0.1	0.9	1.1	1.2	2.2	2.3	2.3	1.2	1.2	0.1	0.3	0.7	0.7	0.7	0.7	2.7	3.3
55	0.5	0.5	1.5	1.2	1.2	1.2	0	0.1	0	0.1	1.0	1.2	1.2	2.3	2.3	2.4	1.3	1.3	0.1	0.3	0.8	0.7	0.8	0.7	2.8	3.4
57	0.5	0.5	1.6	1.2	1.3	1.2	0	0.1	0	0.1	1.0	1.2	1.3	2.3	2.4	2.5	1.3	1.3	0.1	0.3	0.8	0.7	0.8	0.7	2.9	3.5
59	0.5	0.5	1.6	1.3	1.3	1.3	0	0.1	0	0.1	1.0	1.3	1.3	2.4	2.5	2.6	1.4	1.4	0.1	0.3	0.8	0.8	0.8	0.8	3.0	3.6

[1] The washbasin referred to here is the one the inspector uses while enroute from the head rack to high rail inspection.
[2] This refers to the carcass in the bleeding area.

(B) Rules for determining adjusted maximum slaughter rates for two-inspector kills considering walking distance according to the table in this subdivision: Determine the distances the inspectors actually walk between the points shown in columns 2 through 9 of the following table. Column 9 is used only if the condemned brands and tags the viscera inspector uses are kept at a location other than at the wash-basin-sterilizer. For each column, determine the deduction figure opposite the appropriate number of feet in column 1. Compute the total of the deduction figures for columns 2 through 9. Divide this total by 2. The adjusted maximum rate is the maximum rate in paragraph (b)(2)(i) of this section minus the number calculated above. If the resultant number is not a whole number, it must be rounded off to the next *lowest* whole number.

TWO-INSPECTOR CATTLE KILL—VISCERA TRUCK

[Table of deductions from maximum slaughter rates for each 2 feet between points (in tenths of cattle per hour)]

	Heads and low rail inspection								Viscera and high rail inspection							
1	2		3		4		5		6		7		8		9[1]	
Number of feet between points	Head rack and washbasin		Head rack and carcasses[2]		Washbasin and low rail		Head rack and low rail		Viscera and brands tags (washbasin)		Viscera and high rail		High rail and washbasin		Viscera and washbasin	
	Strs. Hfrs.	Cows Bulls	Strs. Hfrs.	Cows Bulls	Strs. Hfrs.	Cows Bulls	Strs. Hfrs.	Cows Bulls	Strs. Hfrs.	Cows Bulls	Strs. Hfrs.	Cows Bulls	Strs. Hfrs.	Cows Bulls	Strs. Hfrs.	Cows Bulls
1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
3	0.1	0	0.1	0	0.1	0	0	0	0	0	0	0	0	0	0.1	0.2
5	0.1	0.1	0.1	0.1	0.1	0.1	0.8	0.7	0.4	0.5	0.5	0.5	0.1	0.2	0.2	0.3
7	0.1	0.2	0.1	0.1	0.1	0.1	1.5	1.4	0.7	0.9	1.0	0.9	0.3	0.3	0.3	0.4
9	0.2	0.2	0.1	0.2	0.1	0.2	2.2	2.0	1.1	1.3	1.5	1.3	0.4	0.5	0.4	0.5
11	0.2	0.3	0.1	0.2	0.2	0.2	2.8	2.7	1.4	1.7	1.9	1.8	0.5	0.6	0.4	0.6
13	0.2	0.4	0.1	0.3	0.2	0.2	3.5	3.3	1.7	2.1	2.4	2.2	0.6	0.7	0.5	0.8
15	0.3	0.4	0.1	0.3	0.2	0.3	4.1	3.9	2.0	2.5	2.9	2.6	0.7	0.9	0.6	0.9
17	0.3	0.5	0.1	0.4	0.2	0.3	4.8	4.5	2.4	2.9	3.3	3.0	0.8	1.0	0.7	1.0
19	0.3	0.6	0.2	0.4	0.3	0.4	5.4	5.1	2.7	3.3	3.7	3.4	0.9	1.2	0.7	1.2
21	0.3	0.6	0.2	0.4	0.3	0.4	6.0	5.7	3.0	3.7	4.2	3.7	1.0	1.3	0.8	1.3
23	0.4	0.7	0.2	0.5	0.3	0.5	6.6	6.3	3.3	4.0	4.6	4.1	1.2	1.4	0.9	1.4
25	0.4	0.7	0.2	0.5	0.3	0.5	7.2	6.8	3.6	4.4	5.0	4.5	1.3	1.6	1.0	1.6
27	0.4	0.8	0.2	0.6	0.4	0.5	7.8	7.4	3.9	4.7	5.4	4.9	1.4	1.7	1.0	1.7
29	0.5	0.9	0.2	0.6	0.4	0.6	8.3	7.9	4.2	5.1	5.8	5.2	1.5	1.8	1.1	1.8
31	0.5	0.9	0.2	0.7	0.4	0.6	8.9	8.5	4.5	5.4	6.2	5.6	1.6	2.0	1.2	2.0
33	0.5	1.0	0.2	0.7	0.4	0.7	9.4	9.0	4.8	5.8	6.5	5.9	1.7	2.1	1.3	2.1
35	0.6	1.1	0.3	0.8	0.5	0.7	10.0	9.5	5.0	6.1	6.9	6.3	1.8	2.2	1.3	2.3
37	0.6	1.1	0.3	0.8	0.5	0.7	10.5	10.0	5.3	6.4	7.3	6.6	1.9	2.4	1.4	2.4
39	0.6	1.2	0.3	0.9	0.5	0.8	11.0	10.5	5.6	6.8	7.6	6.9	2.0	2.5	1.5	2.5
41	0.7	1.2	0.3	0.9	0.6	0.8	11.5	11.0	5.9	7.1	8.0	7.2	2.1	2.6	1.5	2.6
43	0.7	1.3	0.3	0.9	0.6	0.9	12.0	11.4	6.1	7.4	8.3	7.6	2.2	2.8	1.6	2.8
45	0.7	1.4	0.3	1.0	0.6	0.9	12.5	11.9	6.4	7.7	8.7	7.9	2.4	2.9	1.7	2.9
47	0.8	1.4	0.3	1.0	0.6	1.0	13.0	12.4	6.7	8.0	9.0	8.2	2.5	3.0	1.8	3.0
49	0.8	1.5	0.3	1.1	0.7	1.0	13.4	12.8	6.9	8.3	9.4	8.5	2.6	3.2	1.8	3.1
51	0.8	1.6	0.3	1.1	0.7	1.0	13.9	13.3	7.2	8.6	9.7	8.8	2.7	3.3	1.9	3.3
53	0.9	1.6	0.4	1.2	0.7	1.1	14.4	13.7	7.4	8.9	10.0	9.1	2.8	3.4	2.0	3.4
55	0.9	1.7	0.4	1.2	0.7	1.1	14.8	14.1	7.7	9.2	10.3	9.4	2.9	3.5	2.0	3.5
57	0.9	1.7	0.4	1.3	0.8	1.2	15.2	14.6	7.9	9.5	10.6	9.7	3.0	3.7	2.1	3.6
59	0.9	1.8	0.4	1.3	0.8	1.2	15.7	15.0	8.2	9.7	10.9	9.9	3.1	3.8	2.2	3.8

[1] This column to be used only if brands and tags are not located at the washbasin.
[2] This refers to the carcasses in the bleeding area.

(ii) Inspection Using Viscera Table, Tongue-In Presentation of Heads.

STEERS AND HEIFERS

Maximum slaughter rates (head per hour)	Number of inspectors by stations		
	Head	Viscera	Carcass
1 to 32	a	a	a
33 to 58	b	b	b
59 to 84	1	1	1
85 to 86	1	2	1
87 to 143	2	2	1
144 to 171	3	2	1
172 to 198	3	3	1
199 to 226	3	3	2
227 to 253	4	3	2
254 to 280	4	4	2
281 to 306	5	4	2
307 to 333	5	5	2

COWS AND BULLS

Maximum slaughter rates (head per hour)	Number of inspectors by stations		
	Head	Viscera	Carcass
1 to 29	a	a	a
30 to 56	b	b	b
57 to 77	1	1	1
78 to 81	1	2	1
82 to 134	2	2	1
135 to 159	2	3	1
160 to 187	3	3	1
188 to 213	3	4	1
214 to 234	3	4	2
235 to 264	4	4	2
265 to 289	5	4	2
290 to 314	5	5	2

(iii) Inspection Using Viscera Table, Tongue-Out Presentation of Heads.

STEERS AND HEIFERS

Maximum slaughter rates (head per hour)	Number of inspectors by stations		
	Head	Viscera	Carcass
1 to 32	a	a	a
33 to 58	b	b	b
59 to 86	1	1	1
87 to 103	1	2	1
104 to 156	2	2	1
157 to 186	2	3	1
187 to 216	3	3	1
217 to 246	3	3	2
247 to 275	3	4	2
276 to 304	4	4	2
305 to 333	4	5	2
334 to 362	5	5	2
363 to 390	5	6	2

COWS AND BULLS

Maximum slaughter rates (head per hour)	Number of inspectors by stations		
	Head	Viscera	Carcass
1 to 29	a	a	a
30 to 56	b	b	b
57 to 79	1	1	1
80 to 98	1	2	1
99 to 147	2	2	1
148 to 174	2	3	1
175 to 205	3	3	1
206 to 233	3	4	1
234 to 256	3	4	2
257 to 288	4	4	2
289 to 316	5	4	2
317 to 343	5	5	2

(3) *Swine Inspection.* The following inspection staffing standards are applicable to swine slaughter configurations. The inspection standards for all slaughter lines are based upon the observation rather than palpation, at the viscera inspection station, of the spleen, liver, heart, lungs, and mediastinal lymph nodes. In addition, for one- and two-inspector lines, the standards are based upon the distance walked (in feet) by the inspector between work stations; and for three or more inspector slaughter lines, upon the use of a mirror, as described in § 307.2(m)(6), at the carcass inspection station. Although not required in a one- or two-inspector slaughter configuration, except in certain cases as determined by the inspection service, if a mirror is used, it must comply with the requirements of § 307.2(m)(6).

TABLE 1—ONE INSPECTOR—STAFFING STANDARDS FOR SWINE

Distance walked[1] in feet is—	Maximum inspection rates (head per hour)			
	Market hogs (heads attached or detached)		Sows and boars (heads detached)	
	Without mirror	With mirror	Without mirror	With mirror
0 to 5	140	150	131	143
6 to 10	134	144	126	137
11 to 15	129	137	122	132
16 to 20	124	132	117	127
21 to 35	120	127	113	122
26 to 30	116	122	110	118
31 to 35	112	118	106	114
36 to 40	108	114	103	110
41 to 45	105	110	100	106
46 to 50	101	107	97	103
51 to 55	98	103	94	100
56 to 60	96	100	91	97
61 to 65	93	97	89	94
66 to 70	90	95	87	92

TABLE 1—ONE INSPECTOR—STAFFING STANDARDS FOR SWINE—Continued

Distance walked[1] in feet is—	Maximum inspection rates (head per hour)			
	Market hogs (heads attached or detached)		Sows and boars (heads detached)	
	Without mirror	With mirror	Without mirror	With mirror
71 to 75	88	92	85	89
76 to 80	86	89	82	87
81 to 85	84	87	80	85
86 to 90	82	85	79	83
91 to 95	80	83	77	81
96 to 100	78	81	75	79

[1] Distance walked is the total distance that the inspector will have to walk between work stations during one inspection cycle (e.g., between viscera, carcass, head, and wash-basin).

TABLE 2—TWO INSPECTORS—STAFFING STANDARDS FOR MARKET HOGS

Distance walked[1] in feet by inspector B is—	Maximum inspection rates (head per hour with heads attached or detached)		
	Line configuration		
	Carcass,[2] head viscera[3]	Viscera,[2] head carcass[3]	Head,[2] viscera carcass[3]
Without Mirror			
0 to 5	151–253	151–271	151–296
6 to 10	151–239	151–255	151–277
11 to 15	151–226	151–240	151–260
16 to 20	151–214	151–227	151–244
21 to 25	151–204	151–215	151–231
With Mirror			
0 to 5	151–253	151–303	151–318
6 to 10	151–239	151–283	151–304
11 to 15	151–226	151–265	151–289
16 to 20	151–214	151–249	151–270
21 to 25	151–204	151–235	151–254

[1] Distance walked is the total distance that Inspector B will have to walk between work stations during one inspection cycle (e.g., between viscera, carcass, and washbasin).
[2] Inspector A.
[3] Inspector B.

NOTE: In multiple-inspector plants, the inspectors must rotate between all inspection positions *during each shift* to equalize the workload.

TABLE 3—TWO INSPECTORS—STAFFING STANDARDS FOR SOWS AND BOARS

Distance walked[1] in feet by inspector B is—	Maximum inspection rates (head per hour)			
	Line Configuration			
	Carcass,[2] head viscera,[3] heads detached	Viscera,[2] head carcass,[3] heads detached	Head,[2] viscera carcass,[3] heads detached	Head,[2] viscera carcass,[3] heads attached
Without Mirror				
0 to 5	144–248	144–254	144–267	144–267
6 to 10	144–235	144–240	144–253	144–253
11 to 15	144–222	144–227	144–239	144–239
16 to 20	144–211	144–215	144–226	144–226
21 to 25	144–201	144–205	144–214	144–214
With Mirror				
0 to 5	144–248	144–292	144–305	144–292
6 to 10	144–235	144–273	144–291	144–280
11 to 15	144–222	144–256	144–272	144–268
16 to 20	144–211	144–241	144–255	144–255
21 to 25	144–201	144–228	144–240	144–240

[1] Distance walked is the total distance that Inspector B will have to walk between work stations during one inspection cycle (e.g., between viscera, carcass, and washbasin).
[2] Inspector A.
[3] Inspector B.

NOTE: In multiple-inspector plants, the inspectors must rotate between all inspection positions *during each shift* to equalize the workload.

TABLE 4—THREE INSPECTORS OR MORE—STAFFING STANDARDS FOR SWINE

Maximum inspection rates (head per hour with heads attached)	Number of inspectors by station			
	Head	Viscera	Carcass	Total
Market hogs:				
319 to 506	1	1	1	3
507 to 540	1	2	1	4
541 to 859	2	2	1	5
860 to 1,022	2	3	1	6
1,023 to 1,106	3	3	1	7
Sows and boars:				
306 to 439	1	1	1	3
306 to 462[1]	1	1	1	3
440 to 475	2	1	1	4
476 to 752	2	2	1	5
753 to 895	3	2	1	6
896 to 964	3	3	1	7

[1] This rate applies if the heads of sows and boars are *detached* from the carcasses at the time of inspection.

NOTE: In multiple-inspector plants, the inspectors must rotate between all inspection positions *during each shift* to equalize the workload.

[35 FR 15567, Oct. 3, 1970, as amended at 47 FR 33676, Aug. 4, 1982; 50 FR 19903, May 13, 1985]

§310.2 Identification of carcass with certain severed parts thereof and with animal from which derived.

(a) The head, tail, tongue, thymus gland, and all viscera of each slaughtered animal, and all blood and other parts of such animal to be used in the preparation of meat food products or medical products, shall be handled in such a manner as to identify them with the rest of the carcass and as being derived from the particular animal involved, until the post-mortem examination of the carcass and parts thereof has been completed. Such handling shall include the retention of ear tags, backtags, implants, and other identifying devices affixed to the animal, in such a way to relate them to the carcass until the post-mortem examination has been completed.

(b) The official State-Federal Department backtag on any carcass shall:

(1)(i) Be removed from the hide of the animal by an establishment employee and placed in a clear plastic bag. The bag containing the tag shall be affixed to the corresponding carcass.

(ii) The bag containing the tag shall be removed from the carcass by an establishment employee and presented with the viscera to the Program inspector at the point where such inspector conducts the viscera inspection.

(2)(i) Brucellosis and tuberculosis ear tags, herd identification ear tags, sales tags, ear bangles, and similar identification devices shall be removed from the animal's hide or ear by an establishment employee and shall be placed in a clear plastic bag and affixed to the corresponding carcass.

(ii) The bag containing the tag shall be removed from the carcass by an establishment employee and presented with the viscera to the Program inspector at the point where such inspector conducts the viscera inspection.

(3) In cases where both types of devices described in paragraphs (b)(1) and (2) of this section are present on the same animal, both types may be placed in the same plastic bag or in two separate bags.

(4) The circuit supervisor may allow the use of any alternate method proposed by the operator of an official establishment for handling the type of devices described in paragraph (b)(2) of this section if such alternate method would provide a ready means of identifying a specific carcass with the corresponding devices by a Program inspector during the post-mortem inspection.

(5) Disposition and use of identifying devices.

(i) The official State-Federal Department backtags will be collected by a Program inspector and used to obtain traceback information necessary for proper disposition of the animal or carcass and otherwise handled according to instructions issued to the inspectors.

(ii) The devices described in paragraph (b)(2) of this section shall be collected by the Program inspector when required to obtain traceback information necessary for proper disposition of the animal or carcass and for controlling the slaughter of reactor animals. Devices not collected for these purposes shall be discarded after the post-mortem examination is complete.

(6) Plastic bags used by the establishment for collecting identifying devices will be furnished by the Department.

[35 FR 15567, Oct. 3, 1970; 36 FR 12004, June 24, 1971]

§310.3 Carcasses and parts in certain instances to be retained.

Each carcass, including all detached organs and other parts, in which any lesion or other condition is found that might render the meat or any part unfit for food purposes, or otherwise adulterated, and which for that reason would require a subsequent inspection, shall be retained by the Program employee at the time of inspection. The identity of every such retained carcass, detached organ, or other part shall be maintained until the final inspection has been completed. Retained carcasses shall not be washed or trimmed unless authorized by the Program employee.

§310.4 Identification of carcasses and parts; tagging.

Such devices and methods as may be approved by the Administrator may be used for the temporary identification of retained carcasses, organs, and other parts. In all cases, the identification shall be further established by affixing

''U.S. Retained'' tags as soon as practicable and before final inspection. These tags shall not be removed except by a Program employee.

§ 310.5 Condemned carcasses and parts to be so marked; tanking; separation.

Each carcass or part which is found on final inspection to be unsound, unhealthful, unwholesome, or otherwise adulterated shall be conspicuously marked, on the surface tissues thereof, by a Program employee at the time of inspection, as ''U.S. Inspected and Condemned.'' Condemned detached organs and other parts of such character that they cannot be so marked shall be placed immediately in trucks or receptacles which shall be kept plainly marked ''U.S. Condemned,'' in letters not less than 2 inches high. All condemned carcasses and parts shall remain in the custody of a Program employee and shall be disposed of as required in the regulations in part 314 of this subchapter at or before the close of the day on which they are condemned.

§ 310.6 Carcasses and parts passed for cooking; marking.

Carcasses and parts passed for cooking shall be marked conspicuously on the surface tissues thereof by a Program employee at the time of inspection, ''U.S. Passed for Cooking.'' All such carcasses and parts shall be cooked in accordance with part 315 of this subchapter, and until so cooked shall remain in the custody of a Program employee.

§ 310.7 Removal of spermatic cords, pizzles and preputial diverticuli.

Spermatic cords and pizzles shall be removed from all carcasses. Preputial diverticuli shall be removed from hog carcasses.

§ 310.8 Passing and marking of carcasses and parts.

Carcasses and parts found to be sound, healthful, wholesome, and otherwise not adulterated shall be passed and marked as provided in part 316 of this subchapter. In all cases where carcasses showing localized lesions are passed for food or for cooking and ''U.S. Retained'' tags are attached to the carcasses, the affected tissues shall be removed and condemned before the tags are removed. ''U.S. Retained'' tags shall be removed only by a Program employee.

§ 310.9 Anthrax; carcasses not to be eviscerated; disposition of affected carcasses; hides, hoofs, horns, hair, viscera and contents, and fat; handling of blood and scalding vat water; general cleanup and disinfection.

(a) Carcasses found before evisceration to be affected with anthrax shall not be eviscerated but shall be retained, condemned, and immediately tanked or otherwise disposed of as provided in part 314 of this subchapter.

(b) All carcasses and all parts, including hides, hoofs, horns, hair, viscera and contents, blood, and fat of any livestock found to be affected with anthrax shall be condemned and immediately disposed of as provided in part 314 of this subchapter, except that the blood may be handled through the usual blood cooking and drying equipment.

(c) Any part of any carcass that is contaminated with anthrax-infected material through contact with soiled instruments or otherwise shall be immediately condemned and disposed of as provided in part 314 of this subchapter.

(d) The scalding vat water through which hog carcasses affected with anthrax have passed shall be immediately drained into the sewer and all parts of the scalding vat shall be cleaned and disinfected as provided in paragraph (e) of this section.

(e)(1) That portion of the slaughtering department, including the bleeding area, scalding vat, gambrelling bench, floors, walls, posts, platforms, saws, cleavers, knives, and hooks, as well as employees' boots and aprons, contaminated through contact with anthrax-infected material, shall, except as provided in paragraph (e)(2) of this section be cleaned immediately and disinfected with one of the following

disinfectants or other disinfectant[1] approved specifically for this purpose by the Administrator:

(i) A 5 percent solution of sodium hydroxide or commercial lye containing at least 94 percent of sodium hydroxide. The solution shall be freshly prepared immediately before use by dissolving 2½ pounds of sodium hydroxide or lye in 5½ gallons of hot water and shall be applied as near scalding hot as possible to be most effective. (Owing to the extremely caustic nature of sodium hydroxide solution, precautionary measures such as the wearing of rubber gloves and boots to protect the hands and feet, and goggles to protect the eyes, should be taken by those engaged in the disinfection process. It is also advisable to have an acid solution, such as vinegar, in readiness in case any of the sodium hydroxide solution should come in contact with any part of the body.)

(ii) A solution of sodium hypochlorite containing approximately one-half of 1 percent (5,000 parts per million) of available chlorine. The solution shall be freshly prepared.

(iii) When a disinfectant solution has been applied to equipment which will afterwards contact product, the equipment shall be rinsed with clean water before such contact.

(2) In case anthrax infection is found in the hog slaughtering department, an immediate preliminary disinfection shall be made from the head-dropper's station to the point where the disease is detected and the affected carcasses shall be cut down from the rail and removed from the room. Upon completion of the slaughtering of the lot of hogs of which the anthrax-infected animals were a part, slaughtering operations shall cease, and a thorough cleanup and disinfection shall be made, as provided in paragraph (e)(1) of this section. If the slaughter of the lot has not been completed by the close of the day on which anthrax was detected, the cleanup and disinfection shall not be deferred beyond the close of that day.

(3) The first and indispensable precautionary step for persons who have handled anthrax material is thorough cleansing of the hands and arms with liquid soap and running hot water. It is important that this step be taken immediately after exposure, before vegetative anthrax organisms have had time to form spores. In the cleansing, a brush or other appropriate appliance shall be used to insure the removal of all contaminating material from under and about the fingernails. This process of cleansing is most effective when performed in repeated cycles of lathering and rinsing rather than in spending the same amount of time in scrubbing with a single lathering. After the hands have been cleansed thoroughly and rinsed free of soap, they may, if desired, be immersed for about 1 minute in a 1:1,000 solution of bichloride of mercury, followed by thorough rinsing in clean running water. Supplies of bichloride of mercury for the purpose must be held in the custody of the veterinary medical officer. (As a precautionary measure, all persons exposed to anthrax infection should report promptly any suspicious condition (sore or carbuncle) or symptom to a physician, in order that anti-anthrax serum or other treatment may be administered as indicated.)

[35 FR 15567, Oct. 3, 1970; 36 FR 11903, June 23, 1971]

§310.10 Carcasses with skin or hide on; cleaning before evisceration; removal of larvae of Hypodermae, external parasites and other pathological skin conditions.

When a carcass is to be dressed with the skin or hide left on, the skin or hide shall be thoroughly washed and cleaned before any incision is made for the purpose of removing any part thereof or evisceration, except that where calves are slaughtered by the kosher method, the heads shall be removed from the carcasses, before washing of the carcasses. The skin shall be removed at the time of post-mortem inspection from any calf carcass infested with the larvae of the ''oxwarble'' fly (Hypoderma lineata and Hypoderma bovis), or external parasites, or affected with other pathological skin conditions.

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

§ 310.11 Cleaning of hog carcasses before incising.

All hair, scurf, dirt, hoofs and claws shall be removed from hog carcasses, and the carcasses shall be thoroughly washed and cleaned before any incision is made for inspection or evisceration.

§ 310.12 Sternum to be split; abdominal and thoracic viscera to be removed.

The sternum of each carcass shall be split and the abdominal and thoracic viscera shall be removed at the time of slaughter in order to allow proper inspection.

§ 310.13 Inflating carcasses or parts thereof; transferring caul or other fat.

(a)(1) Establishments shall not inflate carcasses or parts of carcasses with air, except as set forth in paragraph (a)(2) of this section.

(2)(i) Any establishment slaughtering livestock that wishes to inflate carcasses or parts thereof with air, using procedures other than the approved methods listed below, shall submit a request for approval for experimental testing to the Administrator. Such a request shall include the purpose of the use of air, a detailed description of the procedure for injecting the air and evidence that the procedure can be performed in a sanitary manner.

(ii) The Administrator shall evaluate newly submitted procedures for the use of air. If the Administrator determines that any such procedure will likely result in wholesome, unadulterated meat product, then the Administrator shall approve experimental testing of the new procedure. In any situation where the Administrator finds a submitted procedure to be unlikely to result in wholesome, unadulterated meat product, the Administrator shall send written notification to the establishment of the denial of such approval. The establishment may re-submit for evaluation a testing procedure that has been denied, provided that modifications have been made to address the original reason for denial. The establishment also shall be afforded an opportunity to submit a written statement in response to the notification of denial. In those instances where there is a conflict of facts, a hearing, under applicable rules of practice, will be held to resolve the conflict.

(iii) Final approval of an acceptable new proposed method shall be effectuated by modifying, through rulemaking procedures, the Federal regulations to include the new method.

(iv) Uses for which approval is granted are:

(A) Compressed air injection of cattle feet to facilitate removal of hair from feet intended for human consumption;

(B) Compressed air injection under the skin of cattle heads to facilitate head skinning;

(C) Compressed air injection into the skull in conjunction with a captive bolt stunner to hold the animal still for dressing operations; or

(D) Compressed air injected into the abdominal cavity of swine to facilitate the skinning operation and to minimize the loss of body fat.

The method of compressed air injection shall be a sanitary procedure that includes air filtration and injection needle disinfection. Air filtration shall consist of not less than two stages. An initial stage of filtration shall occur at or near the use point and shall consist of an aerosol or coalescing filter, capable of filtration to not more than 0.75 micron, for the removal of oil and water. A subsequent stage of filtration shall occur at or near the point of needle hose attachment to the air line and shall be a particulate filter, capable of filtration to not more than 0.3 micron. The filters shall be maintained by inspecting regularly to assure they are working properly, and cleaned or replaced when necessary. The injection needle shall be disinfected by placement in water that is not less than 180 °F. for at least 10 seconds immediately prior to each injection.

(b) Transferring the caul or other fat from a fat to a lean carcass is prohibited.

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

[54 FR 36756, Sept. 5, 1989, as amended at 55 FR 29565, July 20, 1990]

§ 310.14 Handling of bruised parts.

When only a portion of a carcass is to be condemned on account of slight

bruises, either the bruised portion shall be removed immediately and disposed of in accordance with part 314 of this subchapter, or the carcass shall be promptly placed in a retaining room and kept until chilled and the bruised portion shall then be removed and disposed of as provided in part 314 of this subchapter.

§310.15 Disposition of thyroid glands and laryngeal muscle tissue.

(a) Livestock thyroid glands and laryngeal muscle tissue shall not be used for human food.

(b) Livestock thyroid glands and laryngeal muscle tissue may be distributed to pharmaceutical manufacturers for pharmaceutical use in accordance with §314.9 or §325.19(c) of this subchapter, if they are labeled in accordance with §316.13(f) of this subchapter. Otherwise, they shall be disposed of at the official establishment in accordance with §314.1 or §314.3 of this subchapter.

[53 FR 45890, Nov. 15, 1988]

§310.16 Disposition of lungs.

(a) Livestock lungs shall not be saved for use as human food.

(b) Lungs found to be affected with disease or pathology and lungs found to be adulterated with chemical or biological residue shall be condemned and identified as ''U.S. Inspected and Condemned.'' Condemned lungs may not be saved for pet food or other nonhuman food purposes. They shall be maintained under inspectional control and disposed of in accordance with §§314.1 and 314.3 of this subchapter.

(c) Lungs not condemned under paragraph (b) of this section may be used in the preparation of pet food or for other nonhuman food purposes at the official establishment, provided they are handled in the manner prescribed in §318.12 of this subchapter, or they may be distributed from the establishment in commerce, or otherwise, in accordance with the conditions prescribed in §325.8 of this subchapter for nonhuman food purposes or they may be so distributed to pharmaceutical manufacturers for pharmaceutical use in accordance with §§314.9 and 325.19(b) of this subchapter, if they are labeled as ''Inedible [SPECIES] Lungs—for Pharmaceutical Use Only.'' Otherwise, they shall be disposed of at the official establishment, in accordance with §§314.1 and 314.3 of this subchapter.

[36 FR 11639, June 17, 1971]

§310.17 Inspection of mammary glands.

(a) Lactating mammary glands and diseased mammary glands of cattle, sheep, swine, and goats shall be removed without opening the milk ducts or sinuses. If pus or other objectionable material is permitted to come in contact with the carcass, the parts of the carcass thus contaminated shall be removed and condemned.

(b) Nonlactating cow udders may be saved for food purposes provided suitable facilities for handling and inspecting them are provided. Examination of udders by palpation shall be done by a Program employee. When necessary, in the judgment of the Program employee for adequate inspection, the official establishment employees shall incise udders in sections no greater than 2 inches in thickness. All udders showing disease lesions shall be condemned by a Program employee. Each udder shall be properly identified with its respective carcass and kept separate and apart from other udders until its disposal has been accomplished in accordance with the provisions of part 311 of this subchapter.

(c) Lactating mammary glands of cattle, sheep, swine, and goats shall not be saved for edible purposes.

(d) The udders from cows officially designated as ''Brucellosis reactors'' or as ''Mastitis elimination cows'' shall be condemned.

§310.18 Contamination of carcasses, organs, or other parts.

(a) Carcasses, organs, and other parts shall be handled in a sanitary manner to prevent contamination with fecal material, urine, bile, hair, dirt, or foreign matter; however, if contamination occurs, it shall be promptly removed in a manner satisfactory to the inspector.

(b) Brains, cheek meat, and head trimmings from animals stunned by lead, sponge iron, or frangible bullets shall not be saved for use as human food but shall be handled as described in §314.1 or §314.3 of this subchapter.

§ 310.19 Inspection of kidneys.

An employee of the establishment shall open the kidney capsule and expose the kidneys of all livestock at the time of slaughter for the purpose of examination by a Program employee.

§ 310.20 Saving of blood from livestock as an edible product.

Blood may be saved for edible purposes at official establishments provided it is derived from livestock, the carcasses of which are inspected and passed, and the blood is collected, defibrinated, and handled in a manner so as not to render it adulterated under the Federal Meat Inspection Act and regulations issued pursuant thereto. The defibrination of blood intended for human food purposes shall not be done with the hands. Anticoagulants may be used in accordance with 21 CFR Chapter I, Subchapter A and Subchapter B, or by regulation in 9 CFR Chapter III, Subchapter A or Subchapter E.

[64 FR 72174, Dec. 23, 1999]

§ 310.21 Carcasses suspected of containing sulfa and antibiotic residues; sampling frequency; disposition of affected carcasses and parts.

(a) Calf carcasses from animals suspected of containing biological residues under § 309.16(d) of this subchapter shall, on post-mortem inspection, be handled in accordance with the provisions of this section.

(b) For purposes of this section, the following definitions shall apply:

(1) *Calf.* A calf up to 3 weeks of age or up to 150 pounds.

(2) *Certified calf.* A calf that the producer and all other subsequent custodians of the calf certify in writing has not been treated with any animal drug while in his or her custody or has been treated with one or more drugs in accordance with FDA approved label directions while in his or her custody and has been withheld from slaughter for the period(s) of time specified by those label directions.

(3) *Healthy carcass.* A carcass that an inspector determines shows no lesions of disease or signs of disease treatment at post-mortem inspection

(4) *Producer.* The owner of the calf at the time of its birth.

(5) *Sick calf carcass.* A calf carcass that an inspector on post-mortem inspection determines has either signs of disease treatment or lesions of disease or was from an animal identified as sick on ante-mortem.

(6) *Sign of treatment.* Sign of treatment of a disease is indicated by leakage around jugular veins, subcutaneous, intramuscular or intraperitoneal injection lesions, or discoloration from particles or oral treatment in any part of the digestive tract.

(7) *Veterinary medical officer.* An inspector of the Program that has obtained a Doctor of Veterinary Medicine degree which is recognized by the Program.

(c) *Selection of carcasses for testing.* The inspector shall perform a swab bioassay test [1] on:

(1) Any carcass from a calf tagged as ''U.S. Suspect'' at the time of ante-mortem inspection, except that calves whose carcasses are condemned for pathology shall not be tested for drug residues.

(2) Any carcass which he/she finds has either lesions of disease which is not condemned because of these lesions or a sign of treatment of disease at the time of post-mortem inspection,

(3) Any carcass of a calf from a producer whose calf or calves have previously been condemned for residues as prescribed in paragraph (e) of this section, and

(4) Carcasses from healthy-appearing certified and noncertified calves, as determined by the veterinary medical officer during ante-mortem inspection, will be selected for testing as set forth below:

Testing level	Sampling Rate (percent of estimated day's slaughter)	
	Certified	Noncertified
A	100	100

[1] The procedures for performing the swab bioassay test are set forth in one of two self–instructional guides: ''Performing the CAST'' or ''Fast Antimicrobial Screen Test.'' These guides are available for review in the office of the FSIS Docket Clerk, Room 4352 South, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250.

Testing level	Sampling Rate (percent of estimated day's slaughter)	
	Certified	Noncertified
B	50	50
C	20	30
(Start) D	5	10
E	2	5
F	1	2

(d) *Testing of carcasses:*

(1) The inspector shall test all carcasses as prescribed in paragraph (c) of this section.

(2) Upon initiation of this program at an establishment, the inspector shall begin the testing rate for carcasses from healthy-appearing certified and noncertified calves at Level D as prescribed in paragraph (c)(4) of this section. The inspector shall increase the testing rate to the next higher level the following business day when three carcasses in 100 or less consecutively tested show a positive test result for a drug residue. The inspector shall decrease it to the next lower level when no more than two calves show a positive test result for a drug residue in either 500 calves consecutively tested or all calves tested over a 60 working day period.

(3) Test results shall be determined by the veterinary medical officer.

(4) The establishment may designate one or more of its employees to aid the inspector in performing the swab bioassay test under the supervision of the veterinary medical officer who shall interpret the results, maintain animal identification with the test unit, and ensure integrity of the testing program.

(5) All carcasses and parts thereof from calves selected for testing shall be retained until all test results are complete.

(6) The veterinary medical officer shall condemn all carcasses and parts thereof for which there are positive test results and release for human consumption all carcasses and parts thereof for which there are negative test results.

(7) If there is a positive test result, subsequent calves from the producer of the calf shall be tested in accordance with paragraph (e) of this section. These test results will not be included in computations to determine an establishment's compliance record.

(8) The veterinary medical officer may reduce inspection line rates when, in his/her judgment, the prescribed testing cannot be adequately performed within the time available because the establishment's compliance history dictates a need for extensive testing.

(e) *Calves from producers with a previous residue condemnation.* The inspector shall perform a swab bioassay test on all carcasses of all calves in the group. The veterinary medical officer shall determine the test results and shall condemn any carcass and parts thereof for which there is a positive test result and pass for human consumption any such carcass and parts thereof for which there is a negative test result. All subsequent calves from the same producer which has previously sold or delivered to official establishments any carcass that was condemned because of drug residues must be tested according to this paragraph until five consecutive animals test completely free of animal drug residues.

(f) If the owner or operator of an official establishment disagrees with the veterinary medical officer's disposition of carcasses and parts thereof, the owner or operator may appeal as provided in section 306.5 of this chapter.

[50 FR 32164, Aug. 9, 1985, as amended at 52 FR 2104, Jan. 20, 1987; 55 FR 7475, Mar. 2, 1990; 60 FR 66483, Dec. 22, 1995]

§310.22 [Reserved]

§310.23 Identification of carcasses and parts of swine.

(a) The identification of the carcasses and parts of swine identified in accordance with part 71 of this title shall be made available to the inspector upon the inspector's request throughout post-mortem inspection.

(b) If the establishment fails to provide required swine identification, the inspector shall order the retention of swine caracasses at the establishment until the completion of tests to confirm that the carcasses are not adulterated.

[53 FR 40387, Oct. 14, 1988]

§ 310.24 [Reserved]

§ 310.25 Contamination with microorganisms; process control verification criteria and testing; pathogen reduction standards.

(a) Criteria for verifying process control; *E. coli* testing. (1) Each official establishment that slaughters livestock must test for *Escherichia coli* Biotype 1 (*E.coli*) Establishments that slaughter more than one type of livestock or both livestock and poultry, shall test the type of livestock or poultry slaughtered in the greatest number. The establishment shall:

(i) Collect samples in accordance with the sampling techniques, methodology, and frequency requirements in paragraph (a)(2) of this section;

(ii) Obtain analytic results in accordance with paragraph (a)(3) of this section; and

(iii) Maintain records of such analytic results in accordance with paragraph (a)(4) of this section.

(2) Sampling requirements.

(i) *Written procedures.* Each establishment shall prepare written specimen collection procedures which shall identify employees designated to collect samples, and shall address location(s) of sampling, how sampling randomness is achieved, and handling of the sample to ensure sample integrity. The written procedure shall be made available to FSIS upon request.

(ii) *Sample collection.* The establishment must collect samples from all chilled livestock carcasses, except those boned before chilling (hot-boned), which must be sampled after the final wash. Samples must be collected in the following manner;

(A) For cattle, establishments must sponge or excise tissue from the flank, brisket and rump, except for hide-on calves, in which case establishments must take samples by sponging from inside the flank, inside the brisket, and inside the rump.

(B) For sheep, goat, horse, mule, or other equine carcasses, establishments must sponge from the flank, brisket and rump, except for hide-on carcasses, in which case establishments must take samples by sponging from inside the flank, inside the brisket, and inside the rump.

(C) For swine carcasses, establishments must sponge or excise tissue from the ham, belly and jowl areas.

(iii) *Sampling frequency.* Slaughter establishments, except very low volume establishments as defined in parag®aph (a)(2)(v) of this section, must take samples at a frequency proportional to the volume of production at the following rates:

(A) Cattle, sheep, goas, horses, mules, and other equines: 1 test per 300 carcasses, but, a minimum of one sample during each week of operation.

Swine: 1 test per 1,000 carcasses, but a minimum of one sample during each week of operation.

(iv) *Sampling frequency alternatives.* An establishment operating under a validated HACCP plan in accordance with § 417.2(b) of this chapter may substitute an alternative frequency for the frequency of sampling required under paragraph (a)(2)(iii) of this section if,

(A) The alternative is an integral part of the establishment's verification procedures for its HACCP plan and,

(B) FSIS does not determine, and notify the establishment in writing, that the alternative frequency is inadequate to verify the effectiveness of the establishment's processing controls.

(v) *Sampling in very low volume establishments.*

(A) Very low volume establishments annually slaughter no more than 6,000 cattle, 6,000 sheep, 6,000 goats, 6,000 horses, mules or other equines, 20,000 swine, or a combination of livestock not exceeding 6,000 cattle and 20,000 total of all livestock. Very low volume establishments that collect samples by sponging shall collect at least one sample per week, starting the first full week of operation after June 1 of each year, and continue sampling at a minimum of once each week the establishment operates until June 1 of the following year or until 13 samples have been collected, whichever comes first. Very low volume establishments collecting samples by excising tissue from carcasses shall collect one sample per week, starting the first full week of operation after June 1 of each year, and continue sampling at a minimum of once each week the establishment operates until one series of 13 tests meets

the criteria set forth in paragraph (a)(5)(i) of this section.

(B) Upon the establishment's meeting requirements of paragraph (a)(2)(v)(A) of this section, weekly sampling and testing is optional, unless changes are made in establishment facilities, equipment, personnel or procedures that may affect the adequacy of existing process control measures, as determined by the establishment or FSIS. FSIS determinations that changes have been made requiring resumption of weekly testing shall be provided to the establishment in writing.

(3) *Analysis of samples.* Laboratories may use any quantitative method for analysis of *E. coli* that is approved as an AOAC Official Method of the AOAC International (formerly the Association of Official Analytical Chemists)[2] or approved and published by a scientific body and based on the results of a collaborative trial conducted in accordance with an internationally recognized protocol on collaborative trials and compared against the three tube Most Probable Number (MPN) method and agreeing with the 95 percent upper and lower confidence limit of the appropriate MPN index.

(4) *Recording of test results.* The establishment shall maintain accurate records of all test results, in terms of CFU/cm^2 of surface area sponged or excised. Results shall be recorded onto a process control chart or table showing at least the most recent 13 test results, by type of livestock slaughtered. Records shall be retained at the establishment for a period of 12 months and shall be made available to FSIS upon request.

(5) *Criteria for evaluation of test results.*

(i) An establishment excising samples from carcasses is operating within the criteria when the most recent *E. coli* test result does not exceed the upper limit (M), and the number of samples, if any, testing positive at levels above (m) is three or fewer out of the most recent 13 samples (n) taken, as follows:

TABLE 1—EVALUATION OF E. COLI TEST RESULTS

Type of livestock	Lower limit of marginal range (m)	Upper limit of marginal range (M)	Number of sample tested (n)	Maximum number permitted in marginal range (c)
Cattle	Negative[a]	100 CFU/cm^2	13	3
Swine	10 CFU/cm^2	10,000 CFU/cm^2	13	3

[a] Negative is defined by the sensitivity of the method used in the baseline study with a limit of sensitivity of at least 5 cfu/cm^2 carcass surface area.

(ii) Establishments sponging carcasses shall evaluate *E. coli* test results using statistical process control techniques.

(6) *Failure to meet criteria.* Test results that do not meet the criteria described in paragraph (a)(5) of this section are an indication that the establishment may not be maintaining process controls sufficient to prevent fecal contamination. FSIS shall take further action as appropriate to ensure that all applicable provisions of the law are being met.

(7) *Failure to test and record.* Inspection shall be suspended in accordance with rules of practice that will be adopted for such proceedings upon a finding by FSIS that one or more provisions of paragraphs (a) (1)–(4) of this section have not been complied with and written notice of same has been provided to the establishment.

(b) Pathogen reduction performance standard; *Salmonella.*

[2] A copy of the current edition/revision of the ''Official Methods of AOAC International,'' 16th edition, 3rd revision, 1997, is on file with the Director, Office of the Federal Register, and may be purchased from the Association of Official Analytical Chemists International, Inc., 481 North Frederick Ave., Suite 500, Gaithersburg, MD 20877–2417.

(1) *Raw meat product performance standards for Salmonella.* An establishment's raw meat products, when sampled and tested by FSIS for *Salmonella,* as set forth in this section, may not test positive for *Salmonella* at a rate exceeding the applicable national pathogen reduction performance standard, as provided in Table 2:

TABLE 2—SALMONELLA PERFORMANCE STANDARDS

Class of product	Performance Standard (percent positive for *Salmonella*)[a]	Number of samples tested (n)	Maximum number of positives to achieve Standard (c)
Steers/heifers	1.0%	82	1
Cows/bulls	2.7%	58	2
Ground beef	7.5%	53	5
Hogs	8.7%	55	6
Fresh pork sausages	[b] N.A.	N.A.	N.A.

[a] Performance Standards are FSIS's calculation of the national prevalence of *Salmonella* on the indicated raw product based on data developed by FSIS in its nationwide microbiological data collection programs and surveys. Copies of Reports on FSIS's Nationwide Microbiological Data Collection Programs and Nationwide Microbiological Surveys used in determining the prevalence of *Salmonella* on raw products are available in the FSIS Docket Room.

[b] Not available; values for fresh pork sausage will be added upon completion data collection programs for those products.

(2) *Enforcement.* FSIS will sample and test raw meat products in an individual establishment on an unannounced basis to determine prevalence of *Salmonella* in such products to determine compliance with the standard. The frequency and timing of such testing will be based on the establishment's previous test results and other information concerning the establishment's performance. In an establishment producing more than one class of product subject to the pathogen reduction standard, FSIS may sample any or all such classes of products.[3]

(3) *Noncompliance and establishment response.* When FSIS determines that an establishment has not met the performance standard:

(i) The establishment shall take immediate action to meet the standard.

(ii) If the establishment fails to meet the standard on the next series of compliance tests for that product, the establishment shall reassess its HACCP plan for that product and take appropriate corrective actions.

(iii) Failure by the establishment to act in accordance with paragraph (b)(3)(ii) of this section, or failure to meet the standard on the third consecutive series of FSIS-conducted tests for that product, constitutes failure to maintain sanitary conditions and failure to maintain an adequate HACCP plan, in accordance with part 417 of this chapter, for that product, and will cause FSIS to suspend inspection services. Such suspension will remain in effect until the establishment submits to the FSIS Administrator or his/her designee satisfactory written assurances detailing the action taken to correct the HACCP system and, as appropriate, other measures taken by the establishment to reduce the prevalence of pathogens.

[61 FR 38864, July 25, 1996, as amended at 62 FR 26217, May 13, 1997; 63 FR 1735, Jan. 12, 1998;64 FR 66553, Nov. 29, 1999]

[3] A copy of FSIS's ''Sample Collection Guidelines and Procedure for Isolation and Identification of *Salmonella* from Meat and Poultry Products'' is available for inspection in the FSIS Docket Room.

PART 311—DISPOSAL OF DISEASED OR OTHERWISE ADULTERATED CARCASSES AND PARTS

Sec.
311.1 Disposal of diseased or otherwise adulterated carcasses and parts; general.
311.2 Tuberculosis.
311.3 Hog cholera.
311.5 Swine erysipelas.
311.6 Diamond-skin disease.
311.7 Arthritis.
311.8 Cattle carcasses affected with anasarca or generalized edema.
311.9 Actinomycosis and actinobacillosis.
311.10 Anaplasmosis, anthrax, babesiosis, bacillary hemoglobinuria in cattle,

blackleg, bluetongue, hemorrhagic septicemia, icterohematuria in sheep, infectious bovine rhinotracheitis, leptospirosis, malignant epizootic catarrh, strangles, purpura hemorrhagica, azoturia, infectious equine encephalomyelitis, toxic encephalomyelitis (forage poisoning), infectious anemia (swamp fever), dourine, acute influenza, generalized osteoporosis, glanders (farcy), acute inflammatory lameness, extensive fistula, and unhealed vaccine lesions.
311.11 Neoplasms.
311.12 Epithelioma of the eye.
311.13 Pigmentary conditions; melanosis, xanthosis, ochronosis, etc.
311.14 Abrasions, bruises, abscesses, pus, etc.
311.15 Brucellosis.
311.16 Carcasses so infected that consumption of the meat may cause food poisoning.
311.17 Necrobacillosis, pyemia, and septicemia.
311.18 Caseous lymphadenitis.
311.19 Icterus.
311.20 Sexual odor of swine.
311.21 Mange or scab.
311.22 Hogs affected with urticaria, tinea tonsurans, demodex follicurlorum, or erythema.
311.23 Tapeworm cysts (cysticercus bovis) in cattle.
311.24 Hogs affected with tapeworm cysts.
311.25 Parasites not transmissible to man; tapeworm cysts in sheep; hydatid cysts; flukes; gid bladder-worms.
311.26 Emaciation.
311.27 Injured animals slaughtered at unusual hours.
311.28 Carcasses of young calves, pigs, kids, lambs, and foals.
311.29 Unborn and stillborn animals.
311.30 Livestock suffocated and hogs scalded alive.
311.31 Livers affected with carotenosis; livers designated as ''telangiectatic,'' ''sawdust,'' or ''spotted.''
311.32 Vesicular diseases.
311.33 Listeriosis.
311.34 Anemia.
311.35 Muscular inflammation, degeneration, or infiltration.
311.36 Coccidioidal granuloma.
311.37 Odors, foreign and urine.
311.38 Meat and meat byproducts from livestock which have been exposed to radiation.
311.39 Biological residues.

AUTHORITY: 21 U.S.C. 601–695; 7 CFR 2.17, 2.55.

SOURCE: 35 FR 15569, Oct. 3, 1970, unless otherwise noted.

§311.1 Disposal of diseased or otherwise adulterated carcasses and parts; general.

(a) The carcasses or parts of carcasses of all animals slaughtered at an official establishment and found at the time of slaughter or at any subsequent inspection to be affected with any of the diseases or conditions named in this part shall be disposed of according to the section pertaining to the disease or condition: *Provided,* That no product shall be passed for human food under any such section unless it is found to be otherwise not adulterated. Products passed for cooking or refrigeration under this part must be so handled at the official establishment where they are initially prepared unless they are moved to another official establishment for such handling or in the case of products passed for refrigeration are moved for such refrigeration to a freezing facility approved by the Administrator in specific cases: *Provided,* That when so moved the products are shipped in containers sealed in accordance with §318.10(c) of this subchapter or in a sealed means of conveyance as provided in §325.7 of this subchapter. Owning to the fact that it is impracticable to formulate rules covering every case and to designate at just what stage a disease process or a condition results in adulteration of a product, the decision as to the disposal of all carcasses, organs, or other parts not specifically covered in this part shall be left to the veterinary medical officer. The veterinary medical officer shall exercise his judgment regarding the disposition of all carcasses or parts of carcasses under this part in a manner which will insure that only wholesome, unadulterated product is passed for human food.

(b) In cases of doubt as to a condition, a disease, or the cause of a condition, or to confirm a diagnosis, representative specimens of the affected tissues, properly prepared and packaged, shall be sent for examination to one of the laboratories of the Biological Control Section of the Program.

§311.2 Tuberculosis.

The following principles shall apply to the disposition of carcasses of livestock based on the difference in the

pathogenesis of tuberculosis in swine, cattle, sheep, goats, and equines.

(a) *Carcasses condemned.* The entire carcass of swine, cattle, sheep, goats, and equines shall be condemned if any of the following conditions occur:

(1) When the lesions of tuberculosis are generalized (tuberculosis is considered to be generalized when the lesions are distributed in a manner made possible only by entry of the bacilli into the systemic circulation);

(2) When on ante mortem inspection the animal is observed to have a fever found to be associated with an active tuberculosis lesion on post mortem inspection;

(3) When there is an associated cachexia;

(4) When a tuberculosis lesion is found in any muscle or intermuscular tissue, or bone, or joint, or abdominal organ (excluding the gastrointestinal tract) or in any lymph node as a result of draining a muscle, bone, joint, or abdominal organ (excluding the gastrointestinal tract);

(5) When the lesions are extensive in tissues of either the thoracic or the abdominal cavity;

(6) When the lesions are multiple, acute, and actively progressive; or

(7) When the character or extent of the lesions otherwise is not indicative of a localized condition.

(b) *Organs or other parts condemned.* An organ or other part of a swine, cattle, sheep, goat, or equine carcass affected by localized tuberculosis shall be condemned when it contains lesions of tuberculosis or when the corresponding lymph node contains lesions of tuberculosis.

(c) *Carcasses of cattle passed without restriction for human food.* Carcasses of cattle may be passed without restriction for human food only when the carcass of an animal not identified as a reactor to a tuberculin test administered by an Animal and Plant Health Inspection Service, State, or accredited veterinarian[1] is found free of tuberculosis lesions during postmortem inspection.

(d) *Portions of carcasses and carcasses of cattle passed for cooking.* (1) When a cattle carcass reveals a tuberculosis lesion or lesions not so severe or so numerous as the lesions described in paragraph (a) of this section, the unaffected portion of the carcass may be passed for cooking in accordance with part 315 of this chapter; if the character and extent of the lesions indicate a localized condition, and if the lesions are calcified or encapsulated, and provided the affected organ or other part is condemned.

(2) When the carcass of a cattle identified as a reactor to a tuberculin test administered by an Animal and Plant Health Inspection Service, State or accredited veterinarian is found free of lesions of tuberculosis, the carcass may be passed for cooking in accordance with part 315 of this chapter.

(e) *Portions of carcasses and carcasses of swine passed without restriction for human food.* Swine carcasses found free of tuberculosis lesions during post mortem inspection may be passed for human food without restriction. When tuberculosis lesions in any swine carcass are localized and confined to one primary seat of infection, such as the cervical lymph nodes, the mesenteric lymph nodes, or the mediastinal lymph nodes, the unaffected portion of the carcass may be passed for human food without restriction after the affected organ or other part is condemned.

(f) *Portions of carcasses of swine passed for cooking.* When the carcass of any swine reveals lesions more severe or more numerous than those described in paragraph (e) of this section, but not so severe or so numerous as the lesions described in paragraph (a) of this section, the unaffected portions of such carcass may be passed for cooking in accordance with part 315 of this chapter; if the character and extent of the lesions indicate a localized condition, and if the lesions are calcified or encapsulated, and provided the affected organ or other part is condemned.

(g) *Carcasses of sheep, goats, and equines passed without restriction for human food.* Carcasses of sheep, goats, and equines may be passed without restriction for human food only if found free of tuberculosis lesions during post mortem inspection.

[1] Such testing is conducted in the tuberculosis eradication program of the Animal and Plant Health Inspection Service, U.S. Department of Agriculture.

(h) *Portions of carcasses of sheep, goats, and equines passed for cooking.* If a carcass of any sheep, goat, or equine reveals a tuberculosis lesion or lesions that are not so severe or so numerous as the lesions described in paragraph (a) of this section, the unaffected portion of the carcass may be passed for cooking in accordance with part 315 of this chapter; if the character and extent of the lesions indicate a localized condition, and if the lesions are calcified or encapsulated, and provided the affected organ or other part is condemned.

[37 FR 2661, Feb. 4, 1972; 38 FR 29214, Oct. 23, 1973]

§311.3 Hog cholera.

(a) The carcasses of all hogs affected with hog cholera shall be condemned.

(b) Inconclusive but suspicious symptoms of hog cholera observed during the ante-mortem inspection of a U.S. suspect shall be duly considered in connection with post-mortem findings and when the carcass of such a suspect shows lesions in the kidneys and the lymph nodes which resemble lesions of hog cholera, they shall be regarded as those of hog cholera and the carcass shall be condemned.

(c) When lesions resembling those of hog cholera occur in kidneys and lymph nodes of carcasses of hogs which appeared normal on ante-mortem inspection, further inspection of such carcasses shall be made for corroborative lesions. If on such further inspection, characteristic lesions of hog cholera are found in some organ or tissue in addition to those in the kidneys or in the lymph nodes or in both, then all lesions shall be regarded as those of hog cholera and the carcass shall be condemned. Immediate notification shall be given by the inspector to the official in the Veterinary Services unit of the Animal and Plant Health Inspection Service who has responsibility for control of swine diseases in the State where the swine are located.

[35 FR 15569, Oct. 3, 1970, as amended at 40 FR 27225, June 27, 1975]

§311.5 Swine erysipelas.

Carcasses affected with swine erysipelas which is acute or generalized, or which show systemic change, shall be condemned.

§311.6 Diamond-skin disease.

Carcasses of hogs affected with diamond-skin disease when localized and not associated with systemic change may be passed for human food after removal and condemnation of the affected parts, provided such carcasses are otherwise healthy.

§311.7 Arthritis.

(a) Carcasses affected with arthritis which is localized and not associated with systemic change may be passed for human food after removal and condemnation of all affected parts. Affected joints with corresponding lymph nodes shall be removed and condemned. In order to avoid contamination of the meat which is passed, a joint capsule shall not be opened until after the affected joint is removed.

(b) Carcasses affected with arthritis shall be condemned when there is evidence of systemic involvement.

§311.8 Cattle carcasses affected with anasarca or generalized edema.

(a) Carcasses of cattle found on post-mortem inspection to be affected with anasarca in advanced stages and characterized by an extensive or well-marked generalized edema shall be condemned.

(b) Carcasses of cattle, including their detached organs and other parts, found on post-mortem inspection to be affected with anasarca to a lesser extent than as described in paragraph (a) of this section may be passed for human food after removal and condemnation of the affected tissues, provided the lesion is localized.

§311.9 Actinomycosis and actinobacillosis.

(a) The definition of generalization as outlined for tuberculosis in §311.2(a) shall apply for actinomycosis and actinobacillosis, and carcasses of livestock with generalized lesions of either such disease shall be condemned.

(b) Carcasses of livestock in a well-nourished condition showing uncomplicated localized lesions of actinomycosis or actinobacillosis may be passed

for human food after the infected organs or other infected parts have been removed and condemned, except as provided in paragraphs (c) and (d) of this section.

(c) Heads affected with actinomycosis or actinobacillosis, including the tongue, shall be condemned, except that when the disease of the jaw is slight, strictly localized, and without suppuration, fistulous tracts, or lymph node involvement, the tongue, if free from disease, may be passed, or, when the disease is slight and confined to the lymph nodes, the head including the tongue, may be passed for human food after the affected nodes have been removed and condemned.

(d) When the disease is slight and confined to the tongue, with or without involvement of the corresponding lymph nodes, the head may be passed for human food after removal and condemnation of the tongue and corresponding lymph nodes.

§ 311.10 Anaplasmosis, anthrax, babesiosis, bacillary hemoglobinuria in cattle, blackleg, bluetongue, hemorrhagic septicemia, icterohematuria in sheep, infectious bovine rhinotracheitis, leptospirosis, malignant epizootic catarrh, strangles, purpura hemorrhagica, azoturia, infectious equine encephalomyelitis, toxic encephalomyelitis (forage poisoning), infectious anemia (swamp fever), dourine, acute influenza, generalized osteoporosis, glanders (farcy), acute inflammatory lameness, extensive fistula, and unhealed vaccine lesions.

(a) Carcasses of livestock affected with or showing lesions of any of the following named diseases or conditions shall be condemned:

(1) Anthrax.
(2) Blackleg.
(3) Unhealed vaccine lesions (vaccinia).
(4) Strangles.
(5) Purpura hemorrhagica.
(6) Azoturia.
(7) Infectious equine encephalomyelitis.
(8) Toxic encephalomyelitis (forage poisoning).
(9) Infectious anemia (swamp fever).
(10) Dourine.
(11) Acute influenza.
(12) Generalized osteoporosis.
(13) Glanders (farcy).
(14) Acute inflammatory lameness.
(15) Extensive fistula.

(b) Carcasses of livestock affected with or showing lesions of any of the following named diseases or conditions shall be condemned, except when recovery has occurred to the extent that only localized lesions persist, in which case the carcass may be passed for human food after removal and condemnation of the affected organs or other parts:

(1) Anaplasmosis.
(2) Bacillary hemoglobinuria in cattle.
(3) Babesiosis (piroplasmosis).
(4) Bluetongue.
(5) Hemorrhagic septicemia.
(6) Icterohematuria in sheep.
(7) Infectious bovine rhinotracheitis.
(8) Leptospirosis.
(9) Malignant epizootic catarrh.

[35 FR 15569, Oct. 3, 1970, as amended at 36 FR 12004, June 24, 1971]

§ 311.11 Neoplasms.

(a) An individual organ or other part of a carcass affected with a neoplasm shall be condemned. If there is evidence of metastasis or that the general condition of the animal has been adversely affected by the size, position, or nature of the neoplasm, the entire carcass shall be condemned.

(b) Carcasses affected with malignant lymphoma shall be condemned.

§ 311.12 Epithelioma of the eye.

(a) Carcasses of animals affected with epithelioma of the eye, or the orbital region shall be condemned in their entirety if one of the following three conditions exists:

(1) The affection has involved the osseous structures of the head with extensive infection, suppuration, and necrosis;

(2) There is metastasis from the eye, or the orbital region, to any lymph node including the parotid lymph node, internal organs, muscles, skeleton, or other structures, regardless of the extent of the primary tumor; or

(3) The affection, regardless of extent, is associated with cachexia or evidence of absorption or secondary changes.

(b) Carcasses of animals affected with epithelioma of the eye, or the orbital region, to a lesser extent than as described in paragraph (a) of this section may be passed for human food after removal and condemnation of the head, including the tongue, provided the carcass is otherwise normal.

§311.13 Pigmentary conditions; melanosis, xanthosis, ochronosis, etc.

(a) Except as provided in §311.19, carcasses of livestock showing generalized pigmentary deposits shall be condemned.

(b) The affected parts of carcasses showing localized pigmentary deposits of such character as to be unwholesome or otherwise adulterated shall be removed and condemned.

§311.14 Abrasions, bruises, abscesses, pus, etc.

All slight, well-limited abrasions on the tongue and inner surface of the lips and mouth, when without lymph node involvement, shall be carefully excised, leaving only sound, normal tissue, which may be passed for human food. Any organ or other part of a carcass which is badly bruised or which is affected by an abscess, or a suppurating sore shall be condemned; and when the lesions are of such character or extent as to affect the whole carcass, the whole carcass shall be condemned. Portions of carcasses which are contaminated by pus or other diseased material shall be condemned.

§311.15 Brucellosis.

Carcasses affected with localized lesions of brucellosis may be passed for human food after the affected parts are removed and condemned.

§311.16 Carcasses so infected that consumption of the meat may cause food poisoning.

(a) All carcasses of animals so infected that consumption of the products thereof may give rise to food poisoning shall be condemned. This includes all carcasses showing signs of:

(1) Acute inflammation of the lungs, pleura, pericardium, peritoneum, or meninges.

(2) Septicemia or pyemia, whether puerperal, traumatic, or without any evident cause.

(3) Gangrenous or severe hemorrhagic enteritis or gastritis.

(4) Acute diffuse metritis or mammitis.

(5) Phlebitis of the umbilical veins.

(6) Septic or purulent traumatic pericarditis.

(7) Any acute inflammation, abscess, or suppurating sore, if associated with acute nephritis, fatty and degenerated liver, swollen soft spleen, marked pulmonary hyperemia, general swelling of lymph nodes, diffuse redness of the skin, cachexia, icteric discoloration of the carcass or similar condition, either singly or in combination.

(8) Salmonellosis.

(b) Implements contaminated by contact with carcasses affected with any of the disease conditions mentioned in this section shall be thoroughly cleaned and sanitized as prescribed in part 308 of this subchapter. The equipment used in the dressing of such carcasses, such as viscera trucks or inspection tables, shall be sanitized with hot water having a minimum temperature of 180 °F. Carcasses or parts of carcasses contaminated by contact with such diseased carcasses shall be condemned unless all contaminated tissues are removed within 2 hours.

§311.17 Necrobacillosis, pyemia, and septicemia.

From the standpoint of meat inspection, necrobacillosis may be regarded as a local infection at the beginning, and carcasses in which the lesions are localized may be passed for human food if in a good state of nutrition, after those portions affected with necrotic lesions are removed and condemned. However, when emaciation, cloudy swelling of the parenchymatous tissue of organs or enlargement of the lymph nodes is associated with the infection, it is evident that the disease has progressed beyond the condition of localization to a state of toxemia, and the entire carcass shall therefore be condemned as both unwholesome and noxious. Pyemia or septicemia may intervene as a complication of the local necrosis, and when present the carcass

shall be condemned in accordance with § 311.16.

§ 311.18 Caseous lymphadenitis.

(a) A thin carcass showing well-marked lesions in the viscera and the skeletal lymph nodes, or a thin carcass showing extensive lesions in any part shall be condemned.

(b) A thin carcass showing well-marked lesions in the viscera with only slight lesions elsewhere or showing well-marked lesions in the skeletal lymph nodes with only slight lesions elsewhere may be passed for cooking.

(c) A thin carcass showing only slight lesions in the skeletal lymph nodes and in the viscera may be passed for human food without restriction.

(d) A well-nourished carcass showing well-marked lesions in the viscera and with only slight lesions elsewhere or showing well-marked lesions confined to the skeletal lymph nodes with only slight lesions elsewhere may be passed for human food without restriction.

(e) A well-nourished carcass showing well-marked lesions in the viscera and the skeletal lymph nodes may be passed for cooking; but where the lesions in a well-nourished carcass are both numerous and extensive, it shall be condemned.

(f) All affected organs and nodes of carcasses passed for human food without restriction or passed for cooking shall be removed and condemned.

(g) As used in this section, the term ''thin'' does not apply to a carcass which is anemic or emaciated; and the term ''lesions'' refers to lesions of caseous lymphadenitis.

§ 311.19 Icterus.

Carcasses showing any degree of icterus shall be condemned. Yellow fat conditions caused by nutritional factors or characteristic of certain breeds of livestock and yellow fat sometimes seen in sheep shall not be confused with icterus. Such carcasses should be passed for human food, if otherwise normal.

§ 311.20 Sexual odor of swine.

(a) Carcasses of swine which give off a pronounced sexual odor shall be condemned.

(b) The meat of swine carcasses which give off a sexual odor less than pronounced may be passed for use in comminuted cooked meat food product or for rendering. Otherwise it shall be condemned.

§ 311.21 Mange or scab.

Carcasses of livestock affected with mange or scab in advanced stages, showing cachexia or extensive inflammation of the flesh, shall be condemned. When the disease is slight, the carcass may be passed after removal of the affected portion.

§ 311.22 Hogs affected with urticaria, tinea tonsurans, demodex follicurlorum, or erythema.

Carcasses of hogs affected with urticaria (nettle rash), tinea tonsurans, demodex folliculorum, or erythema may be passed for human food after detaching and condemning the affected skin, if the carcass is otherwise not adulterated.

§ 311.23 Tapeworm cysts (cysticercus bovis) in cattle.

(a) Except as provided in paragraph (b) of this section, carcasses of cattle affected with lesions of cysticercus bovis shall be disposed of as follows:

(1) Carcasses of cattle displaying lesions of cysticercus bovis shall be condemned if the infestation is extensive or if the musculature is edematous or discolored. Carcasses shall be considered extensively infested if in addition to finding lesions in at least two of the usual inspection sites, namely the heart, diaphragm and its pillars, muscles of mastication, esophagus, tongue, and musculature exposed during normal dressing operations, they are found in at least two of the sites exposed by (i) an incision made into each round exposing the musculature in cross section, and (ii) a transverse incision into each forelimb commencing 2 or 3 inches above the point of the olecranon and extending to the humerus.

(2) Carcasses of cattle showing one or more tapeworm lesions of cysticercus bovis but not so extensive as indicated in paragraph (a)(1) of this section, as determined by a careful examination, including examination of, but not limited to, the heart, diaphragm and its

pillars, muscles of mastication, esophagus, tongue, and musculature exposed during normal dressing operations, may be passed for human food after removal and condemnation of the lesions with surrounding tissues: *Provided,* That the carcasses, appropriately identified by retained tags, are held in cold storage under positive control of a USDA Food Inspector at a temperature not higher than 15 °F. continuously for a period of not less than 10 days, or in the case of boned meat derived from such carcasses, the meat, when in boxes, tierces, or other containers, appropriately identified by retained tags, is held under positive control of a Program Inspector at a temperature of not higher than 15 °F. continuously for a period of not less than 20 days. As an alternative to retention in cold storage as provided in this subparagraph, such carcasses and meat may be heated throughout to a temperature of at least 140 °F. under positive control of a Program Inspector.

(b) Edible viscera and offal shall be disposed of in the same manner as the rest of the carcass from which they were derived unless any lesion of cysticercus bovis is found in these byproducts, in which case they shall be condemned.

[36 FR 4591, Mar. 10, 1971]

§311.24 Hogs affected with tapeworm cysts.

Carcasses of hogs affected with tapeworm cysts (Cysticercus cellulosae) may be passed for cooking, unless the infestation is excessive, in which case the carcass shall be condemned.

§311.25 Parasites not transmissible to man; tapeworm cysts in sheep; hydatid cysts; flukes; gid bladder-worms.

(a) In the disposal of carcasses, edible organs, and other parts of carcasses showing evidence of infestation with parasites not transmissible to man, the following general rules shall govern except as otherwise provided in this section: If the lesions are localized in such manner and are of such character that the parasites and the lesions caused by them can be completely removed, the nonaffected portion of the carcass, organ, or other part of the carcass may be passed for human food after the removal and condemnation of the affected portions. If an organ or other part of a carcass shows numerous lesions caused by parasites, or if the character of the infestation is such that complete extirpation of the parasitic infestation or invasion renders the part in any way unfit for human food, the affected part shall be condemned. If parasites are found to be distributed in a carcass in such a manner or to be of such character that their removal and the removal of the lesions caused by them is impracticable, no part of the carcass shall be passed for human food. If the infestation is excessive, the carcass shall be condemned. If the infestation is moderate, the carcass may be passed for cooking, but in case such carcass is not cooked as required by part 315 of this subchapter, it shall be condemned.

(b) In the case of sheep carcasses affected with tapeworm cysts (Cysticercus ovis, so-called sheep measles, not transmissible to man), such carcasses may be passed for human food after the removal and condemnation of the affected portions: *Provided, however,* That if, upon the final inspection of sheep carcasses retained on account of measles, the total number of cysts found embedded in muscular tissue, or in immediate relation with muscular tissue, excluding the heart, exceeds five, the entire carcass shall be condemned, or such carcass shall be heated throughout to a temperature of at least 140 °F. After removal and condemnation of all affected portions.

(c) Carcasses found infested with gid bladder-worms (Coenurus cerebralis, Multiceps multiceps) may be passed for human food after condemnation of the affected organ (brain or spinal cord).

(d) Organs or other parts of carcasses infested with hydatid cysts (echinococus) shall be condemned.

(e) Livers infested with flukes or fringed tapeworms shall be condemned.

§311.26 Emaciation.

Carcasses of livestock too emaciated to produce wholesome meat, and carcasses which show a serous infiltration of muscle tissues, or a serous or mucoid degeneration of the fatty tissue, shall be condemned. A gelatinous

change of the fat of the heart and kidneys of well-nourished carcasses and mere leanness shall not be classed as emaciation.

[35 FR 15569, Oct. 3, 1970; 36 FR 11903, June 23, 1971]

§ 311.27 Injured animals slaughtered at unusual hours.

When it is necessary for humane reasons to slaughter an injured animal at night or on Sunday or a holiday when the inspector cannot be obtained, the carcass and all parts shall be kept for inspection, with the head and all viscera except the stomach, bladder, and intestines held by the natural attachments. If all parts are not so kept for inspection, the carcass shall be condemned. If, on inspection of a carcass slaughtered in the absence of an inspector, any lesion or other evidence is found indicating that the animal was sick or diseased, or affected with any other condition requiring condemnation of the animal on ante-mortem inspection, or if there is lacking evidence of the condition which rendered emergency slaughter necessary, the carcass shall be condemned.

§ 311.28 Carcasses of young calves, pigs, kids, lambs, and foals.

Carcasses of young calves, pigs, kids, lambs, and foals are unwholesome and shall be condemned if (a) the meat has the appearance of being water-soaked, is loose, flabby, tears easily, and can be perforated with the fingers; or (b) its color is grayish-red; or (c) good muscular development as a whole is lacking, especially noticeable on the upper shank of the leg, where small amounts of serous infiltrates or small edematous patches are sometimes present between the muscles; or (d) the tissue which later develops as the fat capsule of the kidneys is edematous, dirty yellow, or grayish-red, tough, and intermixed with islands of fat.

§ 311.29 Unborn and stillborn animals.

All unborn and stillborn animals shall be condemned and no hide or skin thereof shall be removed from the carcass within a room in which edible products are handled.

§ 311.30 Livestock suffocated and hogs scalded alive.

All livestock which have been suffocated in any way and hogs which have entered the scalding vat alive shall be condemned.

§ 311.31 Livers affected with carotenosis; livers designated as "telangiectatic," "sawdust," or "spotted."

(a) Livers affected with carotenosis shall be condemned.

(b) Cattle livers and calf livers showing the conditions sometimes designated as ''telangiectatic,'' ''sawdust,'' or ''spotted'' shall be disposed of as follows:

(1) When any or all of the conditions are slight in the organ, the whole organ shall be passed for human food without restriction.

(2) When any or all of the conditions are more severe than slight and involve less than one-half of the organ, while in the remainder of the organ the conditions are slight or nonexistent, the remainder shall be passed for human food without restriction and the other portion shall be condemned.

(3) When any or all of the conditions are more severe than slight and involve one-half or more of the organ, the whole organ shall be condemned.

(4) The divisions of an organ into two parts as contemplated in this paragraph for disposition, shall be accomplished by one cut through the organ. This, of course, does not prohibit incisions which are necessary for inspection.

(c) ''Telangiectatic,'' ''sawdust,'' or ''spotted'' livers and parts of livers which are condemned for human food may be shipped from an official establishment for purposes other than human food in accordance with § 314.10 of this subchapter.

§ 311.32 Vesicular diseases.

(a) Any carcass affected with vesicular disease shall be condemned if the condition is acute and if the extent of the condition is such that it affects the entire carcass or there is evidence of absorption or secondary change.

(b) Any carcass affected with vesicular disease to a lesser extent than as

described in paragraph (a) of this section may be passed for human food after removal and condemnation of the affected parts, if the carcass is otherwise healthy.

§ 311.33 Listeriosis.

Carcasses of livestock identified as U.S. Suspects because of a history of listeriosis shall be passed for human food after condemnation of the head if the carcass is otherwise normal.

§ 311.34 Anemia.

Carcasses of livestock too anemic to produce wholesome meat shall be condemned.

§ 311.35 Muscular inflammation, degeneration, or infiltration.

(a) If muscular lesions are found to be distributed in such a manner or to be of such character that removal is impractical, the carcass shall be condemned.

(b) If muscular lesions are found to be distributed in such a manner or to be of such character that removal is practical, the following rules shall govern the disposal of the carcasses, edible organs, and other parts of carcasses showing such muscular lesions. If the lesions are localized in such a manner and are of such a character that the affected tissues can be removed, the non-affected parts of the carcass may be passed for human food after the removal and condemnation of the affected portion. If a part of the carcass shows numerous lesions, or if the character of the lesion is such that complete extirpation is difficult and uncertainly accomplished, or if the lesion renders the part in any way unfit for human food, the part shall be condemned.

(c) If the lesions are slight or of such character as to be insignificant from a standpoint of wholesomeness, the carcass or parts may be passed for use in the manufacture of comminuted cooked product, after removal and condemnation of the visibly affected portions.

§ 311.36 Coccidioidal granuloma.

(a) Carcasses which are affected with generalized coccidioidal granuloma or which show systemic changes because of such disease shall be condemned.

(b) Carcasses affected with localized lesions of this disease may be passed for human food after the affected parts are removed and condemned.

§ 311.37 Odors, foreign and urine.

(a) Carcasses which give off a pronounced odor of medicinal, chemical, or other foreign substance shall be condemned.

(b) Carcasses which give off a pronounced urine odor shall be condemned.

(c) Carcasses, organs, or parts affected by odor to a lesser degree than as described in paragraphs (a) and (b) of this section and in which the odor can be removed by trimming or chilling may be passed for human food, after removal of affected parts or dissipation of the condition.

§ 311.38 Meat and meat byproducts from livestock which have been exposed to radiation.

Meat and meat byproducts from livestock which have been administered radioactive material shall be condemned unless the use of the radiation was in conformity with a regulation or exemption in effect pursuant to section 409 of the Federal Food, Drug, and Cosmetic Act.

§ 311.39 Biological residues.

Carcasses, organs, or other parts of carcasses of livestock shall be condemned if it is determined that they are adulterated because of the presence of any biological residues.

PART 312—OFFICIAL MARKS, DEVICES AND CERTIFICATES

Sec.

312.1 General.
312.2 Official marks and devices to identify inspected and passed products of cattle, sheep, swine, or goats.
312.3 Official marks and devices to identify inspected and passed equine products.
312.4 Official ante-mortem inspection marks and devices.
312.5 Official seals for transportation of products.
312.6 Official marks and devices in connection with post–mortem inspection and

identification of adulterated products and insanitary equipment and facilities.
312.7 [Reserved]
312.8 Official export inspection marks, devices, and certificates.
312.9 Official detention marks and devices.
312.10 Official mark for maintaining the identity and integrity of samples.

AUTHORITY: 21 U.S.C. 601–695; 7 CFR 2.17, 2.55.

SOURCE: 35 FR 15573, Oct. 3, 1970, unless otherwise noted.

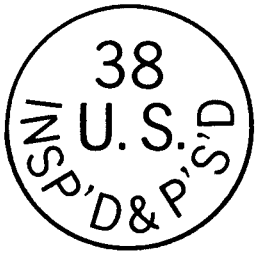
§ 312.1 General.

The marks, devices, and certificates prescribed or referenced in this part shall be official marks, devices, and certificates for purposes of the Act, and shall be used in accordance with the provisions of this part and the regulations cited therein.

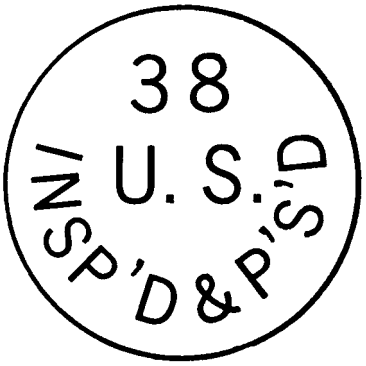
§ 312.2 Official marks and devices to identify inspected and passed products of cattle, sheep, swine, or goats.

(a) The official inspection legend required by part 316 of this subchapter to be applied to inspected and passed carcasses and parts of carcasses of cattle, sheep, swine and goats, meat food products in animal casings, and other products as approved by the Administrator, shall be in the appropriate form as hereinafter specified:[1]

For application to sheep carcasses, the loins and ribs of pork, beef tails, and the smaller varieties of sausage and meat food products in animal casings.



For application to calf and goat carcasses and on the larger varieties of sausage and meat food products in animal casings.



For application to beef and hog carcasses primal parts and cuts therefrom, beef livers, beef tongues, beef hearts, and smoked meats not in casings.

[1] The number ''38'' is given as an example only. The establishment number of the official establishment where the product is prepared shall be used in lieu thereof.

For application to burlap, muslin, cheesecloth, heavy paper, or other acceptable material that encloses carcasses or parts of carcasses.

(b)(1) The official inspection legend required by part 317 of this subchapter to be shown on all labels for inspected and passed products of cattle, sheep, swine, and goats shall be in the following form [1] except that it need not be of the size illustrated, provided that it is a sufficient size and of such color as to be conspicuously displayed and readily legible and the same proportions of letter size and boldness are maintained as illustrated:

(2) This official mark shall be applied by mechanical means and shall not be applied by a hand stamp.

(3) The official inspection legend described in paragraph (b)(1) of this section may also be used for purposes of part 316 of this subchapter on shipping containers, band labels, artificial casings, and other articles with the approval of the Administrator.

(c) Any brand, stamp, label, or other device approved by the Administrator and bearing any official mark prescribed in paragraphs (a) or (b) of this section shall be an official device for purposes of the Act.

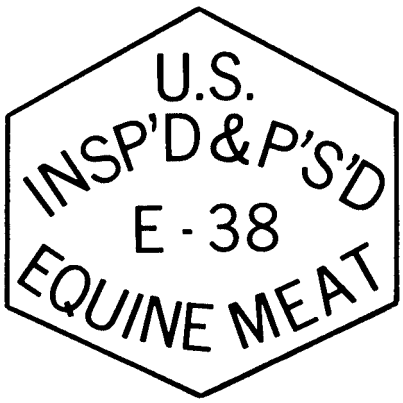
[35 FR 15573, Oct. 3, 1970; 36 FR 12002, June 24, 1971]

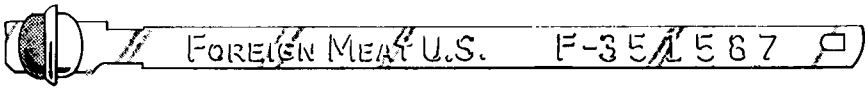
§312.3 Official marks and devices to identify inspected and passed equine products.

(a) The official inspection legend required by §316.12 or §317.2 of this subchapter to identify inspected and passed horse carcasses and parts of carcasses, or horse meat food products shall be in the appropriate form as hereinafter specified: [1]

(b) The official inspection legend required by §316.12 or §317.2 of this subchapter to identify inspected and passed mule and other (nonhorse) equine carcasses and parts of carcasses, or equine meat food products shall be

in whichever of the following form, is appropriate:[1]





(c) Any brand, stamp, label, or other device approved by the Administrator and bearing any official mark prescribed in paragraphs (a) or (b) of this section shall be an official device for purposes of the Act.

§ 312.4 Official ante-mortem inspection marks and devices.

The official marks and devices used in connection with ante-mortem inspection are those prescribed in § 309.18 of this subchapter.

§ 312.5 Official seals for transportation of products.

The official mark for use in sealing railroad cars or other means of conveyance as prescribed in part 325 of this subchapter shall be the inscription and a serial number as hereinafter shown[2] and any seal approved by the Administrator for applying such mark shall be an official device for purposes of the Act. This seal shall be attached to the means of conveyance only by a Program employee and he shall also affix thereto a ''Warning Tag'' (Form MP–408–3).

[35 FR 15573, Oct. 3, 1970, as amended at 39 FR 36000, Oct. 7, 1974; 51 FR 37707, Oct. 24, 1986]

[1] The number ''38'' is given as an example only. The establishment number of the official establishment where the product is prepared shall be used in lieu thereof.

[2] The number ''2135202'' is given as an example only. The serial number of the specific seal will be shown in lieu thereof.

§312.6 Official marks and devices in connection with post-mortem inspection and identification of adulterated products and insanitary equipment and facilities.

(a) The official marks required by parts 310 and 416 of this chapter for use in post-mortem inspection and identification of adulterated products and insanitary equipment and facilities are:

(1) The tag (Form MP–427) which is used to retain carcasses and parts of carcasses in the slaughter department; it is black and white, and bears the legend ''U.S. Retained.''

(2) The ''U.S. Retained'' mark which is applied to products and articles as prescribed in part 310 of this subchapter by means of a paper tag (Form MP–35) bearing the legend ''U.S. Retained.''

(3) The ''U.S. Rejected'' mark which is used to identify insanitary buildings, rooms, or equipment as prescribed in part 416, section 6, of this chapter and is applied by means of a paper tag (Form MP–35) bearing the legend ''U.S. Rejected.''

(4) The ''U.S. Passed for Cooking'' mark is applied on products passed for cooking as prescribed in part 310 of this subchapter by means of a brand and is in the following form:

U.S. PASSED
FOR COOKING

(5) The ''U.S. Inspected and Condemned'' mark shall be applied to products condemned as prescribed in part 310 by means of a brand and is in the following form:

U.S. INSP'D AND
CONDEMNED

(b) The ''U.S. Retained'' and ''U.S. Rejected'' tags, and all other brands, stamps, labels, and other devices approved by the Administrator and bearing any official mark prescribed in paragraph (a) of this section, shall be official devices for purposes of the Act.

[35 FR 15573, Oct. 3, 1970, as amended at 38 FR 29214, Oct. 23, 1973; 39 FR 36000; Oct. 7, 1974; 43 FR 29268, July 7, 1978; 64 FR 36415, Oct. 20, 1999; 65 FR 2284, Jan. 14, 2000]

§312.7 [Reserved]

§312.8 Official export inspection marks, devices, and certificates.

(a) The official export meat inspection mark required by part 322 of this subchapter shall be in the following form as hereinafter specified:[1]

Any rubber stamp approved by the Administrator, in the manner provided for in part 317 of this subchapter, and bearing the official mark prescribed in this paragraph shall be an official device for the purposes of the Act.

(b) The official export certificate required by part 322 of this subchapter is a paper certificate form for signature by a Program employee, bearing a letterhead and the seal of the United States Department of Agriculture, with a certification that meat or meat food products described on the form is from animals that received antemortem and post-mortem inspection and were found sound and healthy and that it has been inspected and passed as provided by law and the regulations of the Department of Agriculture and is sound and wholesome. The certificate also bears a serial number such as ''No. 184432.''

[35 FR 15573, Oct. 3, 1970, as amended at 42 FR 11825, Mar. 1, 1977; 47 FR 29823, July 9, 1982]

[1] The number ''529893'' is given as an example only. The number of the offical export certificate will be shown in lieu thereof.

§ 312.9 Official detention marks and devices.

The official mark for articles and livestock detained under part 329 of this subchapter shall be the designation ''U.S. Detained'' and the official device for applying such mark shall be the official ''U.S. Detained'' tag (FSIS Form 8400–2) as prescribed in § 329.2 of this subchapter.

[55 FR 47842, Nov. 16, 1990]

§ 312.10 Official mark for maintaining the identity and integrity of samples.

The official mark for use in sealing containers of samples submitted under any requirements in this subchapter and section 202 of the Federal Meat Inspection Act shall bear the designation ''Sample Seal'' accompanied by the official USDA logo as shown below. Any seal approved by the Administrator for applying such mark shall be deemed an official device for purposes of the Act. Such device shall be supplied to inspectors, compliance officers, and other designated Agency officials by the United States Department of Agriculture.

[52 FR 41958, Nov. 2, 1987]

PART 313—HUMANE SLAUGHTER OF LIVESTOCK

Sec.
313.1 Livestock pens, driveways and ramps.
313.2 Handling of livestock.
313.5 Chemical; carbon dioxide
313.15 Mechanical; captive bolt.
313.16 Mechanical; gunshot.
313.30 Electrical; stunning or slaughtering with electric current.
313.50 Tagging of equipment, alleyways, pens or compartments to prevent inhumane slaughter or handling in connection with slaughter.
313.90 [Reserved]

AUTHORITY: 7 U.S.C. 1901–1906; 21 U.S.C. 601–695; 7 CFR 2.17, 2.55.

SOURCE: 44 FR 68813, Nov. 30, 1979, unless otherwise noted.

§ 313.1 Livestock pens, driveways and ramps.

(a) Livestock pens, driveways and ramps shall be maintained in good repair. They shall be free from sharp or protruding objects which may, in the opinion of the inspector, cause injury or pain to the animals. Loose boards, splintered or broken planking, and unnecessary openings where the head, feet, or legs of an animal may be injured shall be repaired.

(b) Floors of livestock pens, ramps, and driveways shall be constructed and maintained so as to provide good footing for livestock. Slip resistant or waffled floor surfaces, cleated ramps and the use of sand, as appropriate, during winter months are examples of acceptable conctruction and maintenance.

(c) U.S. Suspects (as defined in § 301.2(xxx)) and dying, diseased, and disabled livestock (as defined in § 301.2(y)) shall be provided with a covered pen sufficient, in the opinion of the inspector, to protect them from the adverse climatic conditions of the locale while awaiting disposition by the inspector.

(d) Livestock pens and driveways shall be so arranged that sharp corners and direction reversal of driven animals are minimized.

[44 FR 68813, Nov. 30, 1979, as amended at 53 FR 49848, Dec. 12, 1988]

§ 313.2 Handling of livestock.

(a) Driving of livestock from the unloading ramps to the holding pens and from the holding pens to the stunning area shall be done with a minimum of excitement and discomfort to the animals. Livestock shall not be forced to move faster than a normal walking speed.

(b) Electric prods, canvas slappers, or other implements employed to drive animals shall be used as little as possible in order to minimize excitement

and injury. Any use of such implements which, in the opinion of the inspector, is excessive, is prohibited. Electrical prods attached to AC house current shall be reduced by a transformer to the lowest effective voltage not to exceed 50 volts AC.

(c) Pipes, sharp or pointed objects, and other items which, in the opinion of the inspector, would cause injury or unnecessary pain to the animal shall not be used to drive livestock.

(d) Disabled livestock and other animals unable to move.

(1) Disabled animals and other animals unable to move shall be separated from normal ambulatory animals and placed in the covered pen provided for in §313.1(c).

(2) The dragging of disabled animals and other animals unable to move, while conscious, is prohibited. Stunned animals may, however, be dragged.

(3) Disabled animals and other animals unable to move may be moved, while conscious, on equipment suitable for such purposes; e.g., stone boats.

(e) Animals shall have access to water in all holding pens and, if held longer than 24 hours, access to feed. There shall be sufficient room in the holding pen for animals held overnight to lie down.

(f) Stunning methods approved in §313.30 shall be effectively applied to animals prior to their being shackled, hoisted, thrown, cast, or cut.

§313.5 Chemical; carbon dioxide.

The slaughtering of sheep, calves and swine with the use of carbon dioxide gas and the handling in connection therewith, in compliance with the provisions contained in this section, are hereby designated and approved as humane methods of slaughtering and handling of such animals under the Act.

(a) *Administration of gas, required effect; handling.* (1) The carbon dioxide gas shall be administered in a chamber in accordance with this section so as to produce surgical anesthesia in the animals before they are shackled, hoisted, thrown, cast, or cut. The animals shall be exposed to the carbon dioxide gas in a way that will accomplish the anesthesia quickly and calmly, with a minimum of excitement and discomfort to the animals. In swine, carbon dioxide may be administered to induce death in the animals before they are shackled, hoisted, thrown, cast, or cut.

(2) The driving or conveying of the animals to the carbon dioxide chamber shall be done with a minimum of excitement and discomfort to the animals. Delivery of calm animals to the anesthesia chamber is essential since the induction, or early phase, of anesthesia is less violent with docile animals. Among other things this requires that, in driving animals to the anesthesia chamber, electrical equipment be used as little as possible and with the lowest effective voltage.

(3) On emerging from the carbon dioxide tunnel, the animals shall be in a state of surgical anaesthesia and shall remain in this condition throughout shackling, sticking, and bleeding, except for swine in which death has been induced by the administration of carbon dioxide. Asphyxia or death from any cause shall not be produced in animals before bleeding, except for swine in which death has been induced by the administration of carbon dioxide.

(b) *Facilities and procedures*—(1) *General requirements for gas chambers and auxiliary equipment; operator.* (i) The carbon dioxide gas shall be administered in a tunnel which is designed to permit the effective exposure of the animal. Two types of tunnels, based on the same principle, are in common use for carbon dioxide anesthesia. They are the ''U'' type tunnel and the ''Straight Line'' type tunnel, and are based on the principle that carbon dioxide gas has a higher specific gravity than air. The tunnels are open at both ends for entry and exit of animals and have a depressed central section. Anesthetizing, or, in the case of swine, death-inducing, carbon dioxide concentrations are maintained in the central sections of the tunnels. Effective anaesthetization is produced in these central sections. Animals are driven from holding pens through pathways constructed of large-diameter pipe or smooth metal and onto continuous conveyor devices that move the animals through the tunnels. The animals are either compartmentalized on the conveyors by mechanical impellers synchronized with the conveyor or they are otherwise prevented from

crowding. While impellers are used to compartmentalize the animals, mechanically or manually operated gates are used to move the animals onto the conveyors. Surgically anaesthetized animals, or killed swine, are moved out of the tunnels by the same continuous conveyors that moved them into and through the carbon dioxide gas.

(ii) Flow of animals into and through the carbon dioxide chamber is dependent on one operator. The operation or stoppage of the conveyor is entirely dependent upon this operator. It is necessary that he be skilled, attentive, and aware of his responsibility. Overdosages and death of animals can be brought about by carelessness of this individual.

(2) *Special requirements for gas chamber and auxiliary equipment.* The ability of anesthetizing equipment to perform with maximum efficiency is dependent on its proper design and efficient mechanical operation. Pathways, compartments, gas chambers, and all other equipment used must be designed to accommodate properly the species of animals being anesthetized. They shall be free from pain-producing restraining devices. Injury of animals must be prevented by the elimination of sharp projections or exposed wheels or gears. There shall be no unnecessary holes, spaces or openings where feet or legs of animals may be injured. Impellers or other devices designed to mechanically move or drive animals or otherwise keep them in motion or compartmentalized shall be constructed of flexible or well padded rigid material. Power activated gates designed for constant flow of animals to anesthetizing equipment shall be so fabricated that they will not cause injury. All equipment involved in anesthetizing animals shall be maintained in good repair.

(3) *Gas.* Maintenance of a uniform carbon dioxide concentration and distribution in the anesthesia chamber is a vital aspect of producing surgical anesthesia. This may be assured by reasonably accurate instruments which sample and analyze carbon dioxide gas concentration within the chamber throughout anesthetizing operations. Gas concentration shall be maintained uniform so that the degree of anesthesia in exposed animals will be constant. Carbon dioxide gas supplied to anesthesia chambers may be from controlled reduction of solid carbon dioxide or from a controlled liquid source. In either case the carbon dioxide shall be supplied at a rate sufficient to anesthetize adequately and uniformly the number of animals passing through the chamber. Sampling of gas for analysis shall be made from a representative place or places within the chamber and on a continuing basis. Gas concentrations and exposure time shall be graphically recorded throughout each day's operation. Neither carbon dioxide nor atmospheric air used in the anesthesia chambers shall contain noxious or irritating gases. Each day before equipment is used for anesthetizing animals, proper care shall be taken to mix adequately the gas and air within the chamber. All gas producing and control equipment shall be maintained in good repair and all indicators, instruments, and measuring devices must be available for inspection by Program inspectors during anesthetizing operations and at other times. An exhaust system must be provided so that, in case of equipment failure, non-uniform carbon dioxide concentrations in the gas tunnel or contamination of the ambient air of the establishment will be prevented.

[44 FR 68813, Nov. 30, 1979, as amended at 59 FR 21640, Apr. 26, 1994]

§ 313.15 Mechanical; captive bolt.

The slaughtering of sheep, swine, goats, calves, cattle, horses, mules, and other equines by using captive bolt stunners and the handling in connection therewith, in compliance with the provisions contained in this section, are hereby designated and approved as humane methods of slaughtering and handling of such animals under the Act.

(a) *Application of stunners, required effect; handling.* (1) The captive bolt stunners shall be applied to the livestock in accordance with this section so as to produce immediate unconsciousness in the animals before they are shackled, hoisted, thrown, cast, or cut. The animals shall be stunned in such a manner that they will be rendered unconscious with a minimum of excitement and discomfort.

(2) The driving of the animals to the stunning area shall be done with a minimum of excitement and discomfort to the animals. Delivery of calm animals to the stunning areas is essential since accurate placement of stunning equipment is difficult on nervous or injured animals. Among other things, this requires that, in driving animals to the stunning areas, electrical equipment be used as little as possible and with the lowest effective voltage.

(3) Immediately after the stunning blow is delivered the animals shall be in a state of complete unconsciousness and remain in this condition throughout shackling, sticking and bleeding.

(b) *Facilities and procedures*—(1) *General requirements for stunning facilities; operator.* (i) Acceptable captive bolt stunning instruments may be either skull penetrating or nonpenetrating. The latter type is also described as a concussion or mushroom type stunner. Penetrating instruments on detonation deliver bolts of varying diameters and lengths through the skull and into the brain. Unconsciousness is produced immediately by physical brain destruction and a combination of changes in intracranial pressure and acceleration concussion. Nonpenetrating or mushroom stunners on detonation deliver a bolt with a flattened circular head against the external surface of the animal's head over the brain. Diameter of the striking surface of the stunner may vary as conditions require. Unconsciousness is produced immediately by a combination of acceleration concussion and changes in intracranial pressures. A combination instrument utilizing both penetrating and nonpenetrating principles is acceptable. Energizing of instruments may be accomplished by detonation of measured charges of gunpowder or accurately controlled compressed air. Captive bolts shall be of such size and design that, when properly positioned and activated, immediate unconsciousness is produced.

(ii) To assure uniform unconsciousness with every blow, compressed air devices must be equipped to deliver the necessary constant air pressure and must have accurate, constantly operating air pressure gauges. Gauges must be easily read and conveniently located for use by the stunning operator and the inspector. For purposes of protecting employees, inspectors, and others, it is desirable that any stunning device be equipped with safety features to prevent injuries from accidental discharge. Stunning instruments must be maintained in good repair.

(iii) The stunning area shall be so designed and constructed as to limit the free movements of animals sufficiently to allow the operator to locate the stunning blow with a high degree of accuracy. All chutes, alleys, gates and restraining mechanisms between and including holding pens and stunning areas shall be free from pain-producing features such as exposed bolt ends, loose boards, splintered or broken planking, and protruding sharp metal of any kind. There shall be no unnecessary holes or other openings where feet or legs of animals may be injured. Overhead drop gates shall be suitably covered on the bottom edge to prevent injury on contact with animals. Roughened or cleated cement shall be used as flooring in chutes leading to stunning areas to reduce falls of animals. Chutes, alleys, and stunning areas shall be so designed that they will comfortably accommodate the kinds of animals to be stunned.

(iv) The stunning operation is an exacting procedure and requires a well-trained and experienced operator. He must be able to accurately place the stunning instrument to produce immediate unconsciousness. He must use the correct detonating charge with regard to kind, breed, size, age, and sex of the animal to produce the desired results.

(2) *Special requirements.* Choice of instrument and force required to produce immediate unconsciousness varies, depending on kind, breed, size, age, and sex of the animal. Young swine, lambs, and calves usually require less stunning force than mature animals of the same kind. Bulls, rams, and boars usually require skull penetration to produce immediate unconsciousness. Charges suitable for smaller kinds of livestock such as swine or for young animals are not acceptably interchanged for use on larger kinds or older livestock, respectively.

§ 313.16 Mechanical; gunshot.

The slaughtering of cattle, calves, sheep, swine, goats, horses, mules, and other equines by shooting with firearms and the handling in connection therewith, in compliance with the provisions contained in this section, are hereby designated and approved as humane methods of slaughtering and handling of such animals under the Act.

(a) *Utilization of firearms, required effect; handling.* (1) The firearms shall be employed in the delivery of a bullet or projectile into the animal in accordance with this section so as to produce immediate unconsciousness in the animal by a single shot before it is shackled, hoisted, thrown, cast, or cut. The animal shall be shot in such a manner that they will be rendered unconscious with a minimum of excitement and discomfort.

(2) The driving of the animals to the shooting areas shall be done with a minimum of excitement and discomfort to the animals. Delivery of calm animals to the shooting area is essential since accurate placement of the bullet is difficult in case of nervous or injured animals. Among other things, this requires that, in driving animals to the shooting areas, electrical equipment be used as little as possible and with the lowest effective voltage.

(3) Immediately after the firearm is discharged and the projectile is delivered, the animal shall be in a state of complete unconsciousness and remain in this condition throughout shackling, sticking and bleeding.

(b) *Facilities and procedure*—(1) *General requirements for shooting facilities; operator.* (i) On discharge, acceptable firearms dispatch free projectiles or bullets of varying sizes and diameters through the skull and into the brain. Unconsciousness is produced immediately by a combination of physical brain destruction and changes in intracranial pressure. Caliber of firearms shall be such that when properly aimed and discharged, the projectile produces immediate unconsciousness.

(ii) To assure uniform unconsciousness of the animal with every discharge where small-bore firearms are employed, it is necessary to use one of the following type projectiles: Hollow pointed bullets; frangible iron plastic composition bullets; or powdered iron missiles. When powdered iron missiles are used, the firearms shall be in close proximity with the skull of the animal when fired. Firearms must be maintained in good repair. For purposes of protecting employees, inspectors and others, it is desirable that all firearms be equipped with safety devices to prevent injuries from accidental discharge. Aiming and discharging of firearms should be directed away from operating areas.

(iii) The provisions contained in § 313.15(b)(1)(iii) with respect to the stunning area also apply to the shooting area.

(iv) The shooting operation is an exacting procedure and requires a well-trained and experienced operator. He must be able to accurately direct the projectile to produce immediate unconsciousness. He must use the correct caliber firearm, powder charge and type of ammunition to produce the desired results.

(2) *Special requirements.* Choice of firearms and ammunition with respect to caliber and choice of powder charge required to produce immediate unconsciousness of the animal may vary depending on age and sex of the animal. In the case of bulls, rams, and boars, small bore firearms may be used provided they are able to produce immediate unconsciousness of the animals. Small bore firearms are usually effective for stunning other cattle, sheep, swine, and goats, and calves, horses, and mules.

§ 313.30 Electrical; stunning or slaughtering with electric current.

The slaughtering of swine, sheep, calves, cattle, and goats with the use of electric current and the handling in connection therewith, in compliance with the provisions contained in this section, are hereby designated and approved as humane methods of slaughtering and handling of such animals under the Act.

(a) *Administration of electric current, required effect; handling.* (1) The electric current shall be administered so as to produce, at a minimum, surgical anesthesia, i.e., a state where the animal feels no painful sensation. The animals shall be either stunned or killed before

they are shackled, hoisted, thrown, cast, or cut. They shall be exposed to the electric current in a way that will accomplish the desired result quickly and effectively, with a minimum of excitement and discomfort.

(2) The driving or conveying of the animals to the place of application of electric current shall be done with a minimum of excitement and discomfort to the animals. Delivery of calm animals to the place of application is essential to ensure rapid and effective insensibility. Among other things, this requires that, in driving animals to the place of application, electrical equipment be used as little as possible and with the lowest effective voltage.

(3) The quality and location of the electrical shock shall be such as to produce immediate insensibility to pain in the exposed animal.

(4) The stunned animal shall remain in a state of surgical anesthesia through shackling, sticking, and bleeding.

(b) *Facilities and procedures; operator*—(1) *General requirements for operator.* It is necessary that the operator of electric current application equipment be skilled, attentive, and aware of his or her responsibility.

(2) *Special requirements for electric current application equipment.* The ability of electric current equipment to perform with maximum efficiency is dependent on its proper design and efficient mechanical operation. Pathways, compartments, current applicators, and all other equipment used must be designed to properly accommodate the species of animals being anesthetized. Animals shall be free from pain-producing restraining devices. Injury of animals must be prevented by the elimination of sharp projections or exposed wheels or gears. There shall be no unnecessary holes, spaces or openings where feet or legs of animals may be injured. Impellers or other devices designed to mechanically move or drive animals or otherwise keep them in motion or compartmentalized shall be constructed of flexible or padded material. Power activated gates designed for constant flow of animals shall be so fabricated that they will not cause injury. All equipment used to apply and control the electrical current shall be maintained in good repair, and all indicators, instruments, and measuring devices shall be available for inspection by Program inspectors during the operation and at other times.

(3) *Electric current.* Each animal shall be given a sufficient application of electric current to ensure surgical anesthesia throughout the bleeding operation. Suitable timing, voltage and current control devices shall be used to ensure that each animal receives the necessary electrical charge to produce immediate unconsciousness. The current shall be applied so as to avoid the production of hemorrhages or other tissue changes which could interfere with inspection procedures.

[44 FR 68813, Nov. 30, 1979, as amended at 50 FR 25202, June 18, 1985]

§313.50 Tagging of equipment, alleyways, pens, or compartments to prevent inhumane slaughter or handling in connection with slaughter.

When an inspector observes an incident of inhumane slaughter or handling in connection with slaughter, he/she shall inform the establishment operator of the incident and request that the operator take the necessary steps to prevent a recurrence. If the establishment operator fails to take such action or fails to promptly provide the inspector with satisfactory assurances that such action will be taken, the inspector shall follow the procedures specified in paragraph (a), (b), or (c) of this section, as appropriate.

(a) If the cause of inhumane treatment is the result of facility deficiencies, disrepair, or equipment breakdown, the inspector shall attach a ''U.S. Rejected'' tag thereto. No equipment, alleyway, pen or compartment so tagged shall be used until made acceptable to the inspector. The tag shall not be removed by anyone other than an inspector. All livestock slaughtered prior to such tagging may be dressed, processed, or prepared under inspection.

(b) If the cause of inhumane treatment is the result of establishment employee actions in the handling or moving of livestock, the inspector shall attach a ''U.S. Rejected'' tag to the alleyways leading to the stunning area.

After the tagging of the alleyway, no more livestock shall be moved to the stunning area until the inspector receives satisfactory assurances from the establishment operator that there will not be a recurrence. The tag shall not be removed by anyone other than an inspector. All livestock slaughtered prior to the tagging may be dressed, processed, or prepared under inspection.

(c) If the cause of inhumane treatment is the result of improper stunning, the inspector shall attach a ''U.S. Rejected'' tag to the stunning area. Stunning procedures shall not be resumed until the inspector receives satisfactory assurances from the establishment operator that there will not be a recurrence. The tag shall not be removed by anyone other than an inspector. All livestock slaughtered prior to such tagging may be dressed, processed, or prepared under inspection.

§ 313.90 [Reserved]

PART 314—HANDLING AND DISPOSAL OF CONDEMNED OR OTHER INEDIBLE PRODUCTS AT OFFICIAL ESTABLISHMENTS

Sec.

314.1 Disposition of condemned products at official establishments having tanking facilities; sealing of tanks.
314.2 Tanking and other facilities for inedible products to be separate from edible product facilities.
314.3 Disposition of condemned products at official establishments having no tanking facilities.
314.4 Suppression of odors in preparing inedible products.
314.5 Inedible rendered fats prepared at official establishments.
314.6 Inedible fats from outside official establishments.
314.7 Carcasses of livestock condemned on ante-mortem inspection not to pass through edible product areas.
314.8 Dead animal carcasses.
314.9 Specimens for educational, research, and other nonfood purposes; permits for, required.
314.10 Livers condemned because of parasitic infestation and for other causes; conditions for disposal for purposes other than human food.
314.11 Handling of certain condemned products for purposes other than human food.

AUTHORITY: 21 U.S.C. 601–695; 7 CFR 2.17, 2.55.

SOURCE: 35 FR 15575, Oct. 3, 1970, unless otherwise noted.

§ 314.1 Disposition of condemned products at official establishments having tanking facilities; sealing of tanks.

(a) Carcasses, parts of carcasses, and other products condemned at official establishments having facilities for tanking shall, except as provided in paragraph (c) of this section or elsewhere in this part, be disposed of by tanking as follows:

(1) The lower opening of the tank shall first be sealed securely by a Program employee, except when permanently connected with a blow line; then the condemned products shall be placed in the tank in his presence, after which the upper opening shall also be sealed securely by such employee, who shall then see that the contents of the tank are subjected to sufficient heating for sufficient time to effectively destroy the contents for human food purposes.

(2) The use of equipment such as crushers or hashers for pretanking preparation of condemned products in the inedible products department has been found to give inedible character and appearance to the material. Accordingly, if condemned products are so crushed or hashed, conveying systems, rendering tanks, and other equipment used in the further handling of crushed or hashed material need not be locked or sealed during the tanking operations. If the rendering tanks or other equipment contain condemned material not so crushed or hashed, the equipment shall be sealed as prescribed in paragraph (a)(1) of this section. If the crushed or hashed material is not rendered in the establishment where produced, it shall be denatured as provided for in § 314.3 before leaving such establishment.

(b) The seals of tanks shall be broken only by a Program employee and only after the contents of the tanks have been treated as provided in paragraph (a) of this section. The rendered fat derived from condemned material shall be held until a Program employee shall have had an opportunity to determine

whether it conforms with the requirements of this section. Samples shall be taken by Program employees as often as is necessary to determine whether the rendered fat is effectually denatured.

(c) Carcasses of animals condemned under §309.3 of this subchapter may be disposed of as provided in §314.3, in lieu of tanking, with the approval of the inspector.

§314.2 Tanking and other facilities for inedible products to be separate from edible product facilities.

All tanks and equipment used for rendering, otherwise preparing, or storing inedible products must be in rooms or compartments separate from those used for preparing or storing edible products. There may be a connection between rooms or compartments containing inedible products and those containing edible products as long as it does not cause the adulteration of edible product or create insanitary conditions.

[64 FR 56416, Oct. 20, 1999]

§314.3 Disposition of condemned products at official establishments having no tanking facilities.

(a) Carcasses, parts of carcasses, and other products condemned at an official establishment which has no facilities for tanking shall, except as provided in paragraph (b) of this section or elsewhere in this part, be destroyed in the presence of an inspector by incineration, or denatured with crude carbolic acid, or cresylic disinfectant, or a formula consisting of one part FD&C No. 3 green coloring, 40 parts water, 40 parts liquid detergent, and 40 parts oil of citronella or any other proprietary material approved by the Administrator in specific cases. When such product is to be denatured, it shall be freely slashed before the denaturing agent is applied, except that, in the case of dead animals that have not been dressed, the denaturant may be applied by injection. The denaturant must be deposited in all portions of the carcass or product to the extent necessary to preclude its use for food purposes.

(b) All carcasses and parts condemned on account of anthrax, as identified in §310.9(b) of this subchapter, at official establishments which are not equipped with tanking facilities shall be disposed of by (1) complete incineration, or (2) by thorough denaturing with crude carbolic acid, or cresylic disinfectant, and then disposed of in accordance with the requirements of the particular State or municipal authorities, who shall be notified immediately by the area supervisor.

§314.4 Suppression of odors in preparing inedible products.

Tanks, fertilizer driers, and other equipment used in the preparation of inedible product must be operated in a manner that will suppress odors incident to such preparation which could adulterate edible product or create insanitary conditions.

[64 FR 56416, Oct. 20, 1999]

§314.5 Inedible rendered fats prepared at official establishments.

Except as provided in §325.11(b) of this subchapter, rendered animal fat derived from condemned or other inedible materials at official establishments shall be denatured to effectually distinguish it from an edible product, either with low grade offal during the rendering or by adding to, and mixing thoroughly with, such fat, denaturing oil, No. 2 fuel oil, or brucine dissolved in a mixture of alcohol and pine oil or oil of rosemary, and may be shipped in commerce in accordance with §325.11(c) of this subchapter.

[35 FR 15575, Oct. 3, 1970, as amended at 53 FR 24679, June 30, 1988]

§314.6 Inedible fats from outside official establishments.

Except as provided in §325.11(b) of this subchapter, inedible fats from outside the premises of any official establishment shall not be received into an official establishment except into the tank room provided for inedible products, and then only when they have been denatured in accordance with §314.5 and are marked in accordance with §316.15 of this subchapter, and when their receipt into the tank room produces no insanitary condition on the premises; nor shall such fats be received in such volume as interferes

with prompt disposal of condemned or other inedible material produced at the establishment. When received, they shall not enter any room or compartment used for edible products.

[35 FR 15575, Oct. 3, 1970, as amended at 53 FR 24679, June 30, 1988]

§ 314.7 Carcasses of livestock condemned on ante-mortem inspection not to pass through edible product areas.

Carcasses of livestock which have been condemned on ante-mortem inspection shall not be taken through rooms or compartments in which an edible product is prepared, handled, or stored.

§ 314.8 Dead animal carcasses.

(a) With the exception of dead livestock which have died en route and are received with livestock for slaughter at an official establishment, no dead animal or part of the carcass of any livestock that died otherwise than by slaughter may be brought on the premises of an official establishment unless advance permission therefore is obtained from the circuit supervisor.

(b) Under no circumstances shall the carcasses of any animal which has died otherwise than by slaughter, or any part thereof, be brought into any room or compartment in which any edible product is prepared, handled, or stored.

§ 314.9 Specimens for educational, research, and other nonfood purposes; permits for, required.

(a) Specimens of condemned or other inedible materials, including embryos and specimens of animal parasites, may be released for educational, research, or other nonfood purposes under permit issued by the inspector in charge: *Provided,* That the person desiring such specimens makes a written application to the inspector in charge for such permit on Form MP–403–10 and arranges with and receives permission from the official establishment to obtain the specimens. Permits shall be issued for a period not longer than 1 year. The permit may be revoked by the inspector in charge if the specimens are not used as stated in the application, or if the collection or handling of the specimens interferes with inspection or the maintenance of sanitary conditions in the establishment.

(b) The specimens referred to in paragraph (a) of this section shall be collected and handled only at such time and place and in such manner as not to interfere with the inspection or to cause any objectionable condition and shall be identified as inedible when they leave the establishment.

[35 FR 15575, Oct. 3, 1970, as amended at 38 FR 18665, July 13, 1973; 39 FR 36000, Oct. 7, 1974]

§ 314.10 Livers condemned because of parasitic infestation and for other causes; conditions for disposal for purposes other than human food.

(a) Livers condemned on account of hydatid cysts shall be disposed of by tanking pursuant to the provisions of § 314.1 of this subchapter if condemned at official establishments having facilities for tanking; otherwise they shall be destroyed pursuant to the provisions of § 314.3 of this subchapter.

(b) Livers condemned because of parasites other than hydatid cysts; and livers condemned because of telangiectasis, angioma, ''sawdust'' condition, cirrhosis, carotenosis, or other nonmalignant change, benign abscesses, or contamination, when these conditions are not associated with infectious diseases in the carcasses, may be shipped from an official establishment only for purposes other than human food, and only if all tissue affected with abscesses is removed and destroyed within the establishment, and all livers are processed and denatured, with any agent prescribed in § 325.13(a)(1) or (2) or (5), and in accordance with § 325.13(a)(6) of this subchapter. This provision for movement from an official establishment is made solely under the Federal Meat Inspection Act and is not intended to relieve or modify any other applicable requirements under any other law regarding the movement of such articles, for purposes other than use as human food.

(c) Livers condemned because of conditions described in paragraph (b) of this section shall be in containers plainly marked ''inedible''.

[41 FR 23701, June 11, 1976]

§314.11 Handling of certain condemned products for purposes other than human food.

Condemned carcasses of animals affected with one or more of the following conditions may be shipped from an official establishment only for purposes other than human food and only if permission therefor is obtained from the circuit supervisor: Anasarca, Ocular Squamous Cell Carcinoma (after removal of neoplastic tissue), emaciation, eosinophilic myositis, immaturity, nonseptic bruises and injuries, and sarcosporidiosis. This provision also applies to unborn calves and to products such as paunches and udders when they have not been handled as required under this subchapter for products for human food purposes; provided, such articles have not been condemned for other pathological reasons. Such permission will be granted only if all parts to be so used will be promptly handled, freely slashed and adequately identified as required by §325.13(a)(2) of this subchapter. The slashing, identification and packing of the product shall be accomplished in an inedible product area under the supervision of an inspector. Facilities must be adequate so that the carcasses or parts saved under these provisions are not contaminated with pus, manure, septic, or toxic materials, or similar substances. The operation must not result in insanitary conditions within the establishment.

[35 FR 15575, Oct. 3, 1970, as amended at 36 FR 11639, June 17, 1971; 36 FR 11903, June 23, 1971]

PART 315—RENDERING OR OTHER DISPOSAL OF CARCASSES AND PARTS PASSED FOR COOKING

Sec.

315.1 Carcasses and parts passed for cooking; rendering into lard or tallow.
315.2 Carcasses and parts passed for cooking; utilization for food purposes after cooking.
315.3 Disposal of products passed for cooking if not handled according to this part.

AUTHORITY: 21 U.S.C. 601–695; 7 CFR 2.17, 2.55.

§315.1 Carcasses and parts passed for cooking; rendering into lard or tallow.

Carcasses and parts passed for cooking may be rendered into lard in accordance with §319.702 of this subchapter or rendered into tallow, provided such rendering is done in the following manner:

(a) When closed rendering equipment is used, the lower opening, except when permanently connected with a blowline, shall first be sealed securely by a Program employee; then the carcasses or parts shall be placed in such equipment in his presence, after which the upper opening shall be securely sealed by such employee. When the product passed for cooking in the tank does not consist of a carcass or whole primal part, the requirements for sealing shall be at the discretion of the circuit supervisor. Such carcasses and parts shall be cooked for a time sufficient to render them effectually into lard or tallow, provided all parts of the products are heated to a temperature not lower than 170 °F. for a period of not less than 30 minutes.

(b) At establishments not equipped with closed rendering equipment for rendering carcasses and parts passed for cooking into lard and tallow, such carcasses or parts may be rendered in open kettles under the direct supervision of a Program employee. Such rendering shall be done during regular hours of work and in compliance with the requirements as to temperature and time specified in paragraph (a) of this section.

[35 FR 15577, Oct. 3, 1970, as amended at 43 FR 25420, June 13, 1978]

§315.2 Carcasses and parts passed for cooking; utilization for food purposes after cooking.

Carcasses and parts passed for cooking may be used for the preparation of meat food products, provided all such carcasses or parts are heated to a temperature not lower than 170 °F. for a period of not less than 30 minutes either before being used in or during the preparation of the finished product.

[37 FR 2661, Feb. 4, 1972]

§ 315.3 Disposal of products passed for cooking if not handled according to this part.

Products passed for cooking if not handled and processed in accordance with the provisions of this part, shall be disposed of in accordance with § 314.1 or § 314.3 of this subchapter.

[35 FR 15577, Oct. 3, 1970. Redesignated at 37 FR 2661, Feb. 4, 1972]

PART 316—MARKING PRODUCTS AND THEIR CONTAINERS

Sec.

316.1 Authorization required to make devices bearing official marks.
316.2 Approval required for official marks.
316.3 Use of official marks prohibited except under supervision of Program employee; removal of official marks, when required.
316.4 Marking devices; to be furnished by official establishments; control of.
316.5 Branding ink; to be furnished by official establishments; approval by Program; color.
316.6 Products not to be removed from official establishments unless marked in accordance with the regulations.
316.7 Marking devices not to be false or misleading; style and size of lettering; approval required.
316.8 Unmarked inspected products; moved between official establishments; moved in commerce.
316.9 Products to be marked with official marks.
316.10 Marking of meat food products with official inspection legend and ingredient statement.
316.11 Special markings for certain meat food products.
316.12 Marking of equine carcasses and parts thereof.
316.13 Marking of outside containers.
316.14 Marking tank cars and tank trucks used in transportation of edible products.
316.15 Marking outside containers of inedible grease, etc.
316.16 Custom prepared products to be marked ''Not for Sale.''

AUTHORITY: 21 U.S.C. 601–695; 7 CFR 2.17, 2.55.

SOURCE: 35 FR 15577, Oct. 3, 1970, unless otherwise noted.

§ 316.1 Authorization required to make devices bearing official marks.

No brand manufacturer, printer or other person shall cast, print, lithograph, or otherwise make or cause to be made any device containing any official mark or simulation thereof without prior written authority therefor from the Administrator as provided for in part 317 of this subchapter.

§ 316.2 Approval required for official marks.

No device containing any official mark shall be made or caused to be made for use on any product until it has been approved by the Administrator as provided for in part 317 of this subchapter.

§ 316.3 Use of official marks prohibited except under supervision of Program employee; removal of official marks, when required.

(a) No person shall affix or place, or cause to be affixed or placed, the official inspection legend or any other official mark, or any abbreviation or simulation of any official mark, to or on any product, or container thereof, except under the supervision of a Program employee, or as authorized by part 317 of this subchapter in connection with the manufacture of containers.

(b) No person shall fill, or cause to be filled, in whole or in part, with any product, any container bearing or intended to bear any official mark, or any abbreviation or simulation of any official mark, except under the supervision of a Program employee.

(c) Product bearing any official mark shall not be canned, cooked, cured, smoked, salted, packed, rendered, or otherwise prepared by any person for commercial purposes unless:

(1) Such preparation is performed at an official establishment; or

(2) Such preparation is conducted under State or other governmental inspection and the prepared product is marked to show that fact; or

(3) The official marks are removed, defaced, or otherwise destroyed before or during such preparation; or

(4) The preparation of the product consists solely of cutting up operations at any establishment exempted from inspection under paragraph 301(c)(2) of the Act or equal provisions of a law of a State or organized Territory or at any establishment in an unorganized Territory exempted under paragraph 23(b) of the Act.

§316.4 Marking devices; to be furnished by official establishments; control of.

(a) The operator of each official establishment or official import inspection establishment shall furnish such ink brands, burning brands, and any other device for marking products with official marks as the Administrator may determine is necessary for marking products at such establishment. The official inspection legend on such a device shall be as prescribed in part 312 of this subchapter.

(b) All official devices for marking products with the official inspection legend, or other official inspection marks, including self-locking seals, shall be used only under supervision of a Program employee, and, when not in use for marking shall be kept locked in properly equipped locks or compartments, the keys of which shall not leave the possession of a Program employee, or the locker or compartment shall be sealed with an official seal of the Department as prescribed in part 312 of this subchapter.

[35 FR 15577, Oct. 3, 1970, as amended at 36 FR 12004, June 24, 1971; 46 FR 38072, July 24, 1981]

§316.5 Branding ink; to be furnished by official establishments; approval by Program; color.

(a) The operator of each official establishment shall furnish all ink for marking products with the official marks at such establishment. Such ink must be made with harmless ingredients that are approved for the purpose by the Administrator. Samples of inks shall be submitted to the Program laboratory from time to time as may be deemed necessary by the inspector in charge.

(b) Only ink approved for the purpose shall be used to apply ink brands bearing official marks to carcasses of cattle, sheep, swine, or goats and fresh meat cuts derived therefrom. Any ink containing F.D. & C. Violet No. 1 shall not be considered an approved ink within the meaning of this paragraph.

(c) Green ink shall not be used to apply marks to carcasses of cattle, sheep, swine, or goats or fresh meat cuts derived therefrom.

(d) Except as provided in paragraphs (b) and (c) of this section, branding ink of any color, approved for the purpose by the Administrator in specific cases, may be used to apply ink brands, bearing official marks, to processed meat cuts derived from cattle, sheep, swine, or goats.

(e) Only green ink approved for the purpose shall be used to apply ink brands bearing official marks to carcasses and parts of carcasses and meat cuts derived from horses, mules, and other equines.

(f) Ink used must assure legibility and permanence of the markings and the color of ink shall provide acceptable contrast with the color of the product to which it is applied.

[35 FR 15577, Oct. 3, 1970, as amended at 38 FR 9088, Apr. 10, 1973]

§316.6 Products not to be removed from official establishments unless marked in accordance with the regulations.

No person shall remove or cause to be removed from an official establishment any products which the regulations in this subchapter require to be marked in any way unless they are clearly and legibly marked in compliance with such regulations.

§316.7 Marking devices not to be false or misleading; style and size of lettering; approval required.

No brand or other marking device shall be false or misleading. The letters and figures thereon shall be of such style and type as will make a clear and legible impression. All markings to be applied to products in an official establishment shall be approved prior to use by the Administrator as provided for in §317.3 of this subchapter, except that official markings prescribed by the Federal meat grading regulations (7 CFR 53.19) need not be submitted to the Administrator for approval.

§316.8 Unmarked inspected products; moved between official establishments; moved in commerce.

(a) Unmarked products which have been inspected and passed but do not bear the official inspection legend may be transported in compliance with part 325 of this subchapter from one official establishment to another official establishment, for further processing, in

a railroad car, truck, or other closed container, if the railroad car, truck, or container is sealed with an official seal of the Department (as prescribed in part 312 of this subchapter) bearing the official inspection legend.

(b) Products which have been inspected and passed but do not bear the official inspection legend may be removed from an official establishment in closed containers bearing the official inspection legend and all other information required by this part and part 317 of this subchapter: *Provided,* That upon removal from such closed container the product may not be further transported in commerce unless such removal is made under the supervision of a Program employee and such product is reinspected by a Program employee and packed under his supervision in containers bearing the official inspection legend and all other information required by this part and part 317 of this subchapter: *And provided further,* That unmarked product shall not be brought into an official establishment in an open container.

§ 316.9 Products to be marked with official marks.

(a) Each carcass which has been inspected and passed in an official establishment shall be marked at the time of inspection with the official inspection legend containing the number of the official establishment.

(b) Except as provided otherwise in § 316.8, each primal part of a carcass and each liver, beef tongue, and beef heart which has been inspected and passed shall be marked with the official inspection legend containing the number of the official establishment before it leaves the establishment in which it is first inspected and passed, and each such inspected and passed product shall be marked with the official inspection legend containing the number of the official establishment where it was last prepared. Additional official marks of inspection may be applied to products as desired to meet local conditions. Primal parts are the wholesale cuts of carcasses as customarily distributed to retailers. The round, flank, loin, rib, plate, brisket, chuck, and shank are primal parts of beef carcasses. Veal, mutton, and goat primal parts are the leg; flank, loin, rack, breast, and shoulder. The ham, belly, loin, shoulder, and jowl are pork primal parts. Equine primal parts are the round, flank, loin, rib, plate, brisket, chuck, and shank.

(c) Beef livers shall be marked with the official inspection legend containing the number of the official establishment, at which the cattle involved were slaughtered, on the convex surface of the thickest portion of the organ.

(d) Inspected and passed parts of carcasses which are not marked with the official inspection legend under this section shall not enter any official establishment or be sold, transported, or offered for sale or transportation, in commerce, except as provided in § 316.8.

[35 FR 15577, Oct. 3, 1970, as amended at 36 FR 23720, Dec. 14, 1971]

§ 316.10 Marking of meat food products with official inspection legend and ingredient statement.

(a) Inspected and passed sausages and other products in casings or in link form, of the ordinary ''ring'' variety or larger shall be marked with the official inspection legend and list of ingredients in accordance with part 317 of this subchapter. The official marks required by this section shall be branded near each end of the sausage or similar product prepared in casings when the product is of a size larger than that customarily sold at retail intact.

(b) Inspected and passed sausage and other products, in casings or in link form, of the smaller varieties, shall bear one or more official inspection legends and one or more lists of ingredients in accordance with part 317 of this subchapter on each kilogram (2.205 lbs.) of product, except where such products leave the official establishment completely enclosed in properly labeled immediate containers having a capacity of 5 kilograms (11.025 lbs.) or less and containing a single kind of product: *Provided,* That such products in properly labeled closed containers exceeding 5 kilograms (11.025 lbs.) capacity, when shipped to another official establishment for further processing or to a governmental agency, need only have the official inspection legend and list of ingredients shown

twice throughout the contents of the container. When such products are shipped to another official establishment for further processing, the inspector in charge at the point of origin shall identify the shipment to the inspector in charge at destination by means of Form MP 408–1.

(c) The list of ingredients may be applied by stamping, printing, using paper bands, tags, or tissue strips, or other means approved by the Administrator in specific cases.

(d) All cured products shall be marked with the list of ingredients in accordance with part 317 of this subchapter.

[35 FR 15577, Oct. 3, 1970, as amended at 37 FR 16863, Aug. 22, 1972; 38 FR 4385, Feb. 14, 1973; 39 FR 36000, Oct. 7, 1974; 44 FR 67088, Nov. 23, 1979]

§316.11 Special markings for certain meat food products.

(a) Meat food products prepared in casing or link form (whether or not thereafter subdivided), other than sausage, which possess the characteristics of or resemble sausage, shall bear on each link or piece the word ''imitation'' prominently displayed: *Provided*, That the following need not be so marked if they bear on each link or piece the name of the product in accordance with §317.2 of this subchapter: Such products as coppa, capocollo, lachschinken, bacon, pork loins, pork shoulder butts, and similar cuts of meat which are prepared without added substance other than curing materials or condiments; meat rolls, bockwurst, and similar products which do not contain cereal or vegetables; headcheese, souse, sulze, scrapple, blood pudding, and liver pudding; and other products such as loaves, chili con carne, and meat and cheese products when prepared with sufficient cheese to give definite characteristics to the finished products: *And provided further*, That imitation sausage packed in properly labeled containers having a capacity of 3 pounds or less and of a kind usually sold at retail intact, need not bear the word ''imitation'' on each link or piece if no other marking or labeling is applied directly to the product.

(b) When cereal, vegetable starch, starchy vegetable flour, soy flour, soy protein concentrate, isolated soy protein, dried milk, nonfat dry milk, or calcium reduced dried skim milk is added to sausage in casing or in link form within the limits prescribed in part 319 of this subchapter, the products shall be marked with the name of each added ingredient, as for example ''cereal added,'' ''potato flour added,'' ''cereal and potato flour added,'' ''soy flour added,'' ''isolated soy protein added,'' ''nonfat dry milk added,'' ''calcium reduced dried skim milk added,'' or ''cereal and nonfat dry milk added,'' as the case may be.

(c)(1) When product is placed in a casing to which artificial coloring is thereafter applied, as permitted in part 318 of this subchapter, the product shall be legibly and conspicuously marked by stamping or printing on the casing the words ''artificially colored.''

(2) If a casing is removed from product at an official establishment and there is evidence of artificial coloring on the surface of the product, the product from which the casing has been removed shall be marked by stamping directly thereon the words ''artificially colored.''

(3) The casing containing product need not be marked to show that it is colored if it is colored prior to its use as a covering for the product, and the coloring is of a kind and so applied as not to be transferable to the product and not to be misleading or deceptive in any respect.

(d) When an approved artificial smoke flavoring or an approved smoke flavoring is added to the formula of any meat food product as permitted in part 318 of this subchapter, the product shall be legibly and conspicuously marked with the words ''Artificial Smoke Flavoring Added'' or ''Smoke Flavoring Added,'' whichever may be applicable.

(e) Subject to the provisions in paragraph (a) of this section, in the case of sausage of the smaller varieties, the markings prescribed in this section may be limited to links bearing the official inspection legend, and such markings shall not be required if the sausages are packed in properly labeled containers having a capacity of 3 pounds or less and of a kind usually

sold at retail intact. Further, all markings otherwise required by this section (except those required by paragraph (a) of this section) may be omitted from the casings of sausage and other meat food products when these products are to be processed in sealed metal containers properly labeled in accordance with the requirements in part 317 of this subchapter.

(f) When an approved antioxidant is added to any meat food product as permitted in parts 318 and 319 of this subchapter, the products shall be legibly and conspicuously marked in an approved manner identifying the specific antioxidant used by its common name or approved abbreviation and the purpose for which it is added, such as, ''BHA, BHT, and Propylgallate added to help protect flavor.''

(g) Sausage of the dry varieties treated with potassium sorbate or propylparaben (propyl p-hydroxybenzoate) as permitted by part 318 of this subchapter shall be marked as prescribed in § 317.8(b)(28) of this subchapter).

§ 316.12 Marking of equine carcasses and parts thereof.

(a) All inspected and passed equine carcasses and parts thereof prepared at any establishment shall be conspicuously marked at the time of inspection with the official inspection legend as prescribed in § 312.3 of this subchapter and with other information prescribed for marking products in this part.

(b) All equine carcasses and meat and other parts thereof shall be marked to show the kinds of animals from which they were derived, before the products are sold, transported, offered for sale or transportation, or received for transportation in commerce.

§ 316.13 Marking of outside containers.

(a) Except as otherwise provided in part 325 of this subchapter, when any inspected and passed product for domestic commerce is moved from an official establishment, the outside container shall bear an official inspection legend as prescribed in part 312 of this subchapter.

(b) When any product prepared in an official establishment for domestic commerce has been inspected and passed and is enclosed in a cloth or other wrapping, such wrapping shall bear the official inspection legend and official establishment number applied by the approved 2½-inch rubber brand in the form prescribed in part 312 of this subchapter: *Provided,* That the rubber brand may be omitted if the official inspection legend and official establishment number on the product itself are clearly legible through the wrapping or the wrapping is labeled in accordance with part 317 of this subchapter: *Provided further,* That plain unprinted wrappings, such as stockinettes, cheesecloth, paper, and crinkled paper bags, for properly marked products, which are used solely to protect the product against soiling or excessive drying during transportation or storage, need not bear the official inspection legend.

(c) The outside containers of products for export shall be marked in compliance with part 322 of this subchapter as well as this part.

(d) Slack barrels used as outside containers of products shall have a cloth or paper top covering bearing the official inspection legend containing the official establishment number. At the time of removal of the covering, the official inspection legend shall be destroyed.

(e) The outside containers of any product which has been inspected and passed for cooking, pork which has been refrigerated as provided in § 318.10(c) of this subchapter, and beef which has been inspected and passed for refrigeration shall bear the markings and tag prescribed in § 325.7(b) of this subchapter.

(f) The outside containers of glands and organs which are not used for human food purposes, such as those described in § 325.19 of this subchapter, shall be plainly marked with the phrase ''For pharmaceutical purposes,'' ''For organotherapeutic purposes'' or ''For technical purposes,'' as appropriate, with no reference to inspection, and need not bear other markings otherwise required under the regulations in this subchapter.

(g) Stencils, box dies, labels, and brands may be used on shipping containers of properly labeled products and on such immediate containers, of

properly marked products, as tierces, barrels, drums, boxes, crates, and large-size fiber-board containers, without approval as provided for in §317.3 of this subchapter: *Provided,* That the stencils, box dies, labels, and brands are not false or misleading and are approved by the inspector in charge. The official inspection legend for use with such markings shall be approved by the Administrator as provided for in part 317 of this subchapter.

(h) The outside containers of livers prepared as described in §314.10(b), shall be marked as prescribed in §314.10(c) of this subchapter.

(i) The outside containers of any equine product shall be marked to show the kinds of animals from which derived, when the products are sold, transported, offered for sale or transported, or received for transportation in commerce.

[35 FR 15577, Oct. 3, 1970, as amended at 43 FR 29268, July 7, 1978]

§316.14 Marking tank cars and tank trucks used in transportation of edible products.

Each tank car and each tank truck carrying inspected and passed product from an official establishment shall bear a label containing the name of the product in accordance with §317.2 of this subchapter, the official inspection legend containing the number of the official establishment and the words ''date of loading,'' followed by a suitable space in which the date the tank car or tank truck is loaded shall be inserted. The label shall be located conspicuously and shall be printed on material of such character and so affixed as to preclude detachment or effacement upon exposure to the weather. Before the car or truck is removed from the place where it is unloaded, the carrier shall remove or obliterate such label.

[53 FR 28634, July 29, 1988]

§316.15 Marking outside containers of inedible grease, etc.

(a) Outside containers of inedible grease, inedible tallow, or other inedible animal fat, or mixture of any such articles, resulting from operations at any official establishment shall be marked conspicuously with the word ''inedible'' prior to removal from the point of filling. Containers, such as tierces, barrels, and half barrels shall have both ends painted white with durable paint, if necessary, to provide a contrasting background, and the word ''inedible'' shall be marked thereon in letters not less than 2 inches high, while on tank cars and tank trucks the letters shall be not less than 4 inches high.

(b) Inspected rendered animal fat which is intended not to be used for human food may also be marked ''inedible'' if handled as provided in paragraph (a) of this section and part 314 of this subchapter.

§316.16 Custom prepared products to be marked "Not for Sale."

Carcasses and parts therefrom that are prepared on a custom basis under §303.1(a)(2) of this subchapter shall be marked at the time of preparation with the term ''Not for Sale'' in letters at least three-eighths inch in height, except that such products need not be so marked if in immediate containers properly labeled in accordance with the regulations in §317.16 of this subchapter. Ink used for marking such products must comply with the requirements of §316.5.

[35 FR 15577, Oct. 3, 1970, as amended at 38 FR 29214, Oct. 23, 1973]

PART 317—LABELING, MARKING DEVICES, AND CONTAINERS

Subpart A—General

Sec.

317.1 Labels required; supervision by Program employee.
317.2 Labels: definition; required features.
317.3 Approval of abbreviations of marks of inspection; preparation of marking devices bearing inspection legend without advance approval prohibited; exception.
317.4 Labeling approval.
317.5 Generically approved labeling.
317.6 Approved labels to be used only on products to which they are applicable.
317.7 Products for foreign commerce; printing labels in foreign language permissible; other deviations.
317.8 False or misleading labeling or practices generally; specific prohibitions and requirements for labels and containers.
317.9 Labeling of equine products.

317.10 Reuse of official inspection marks; reuse of containers bearing official marks, labels, etc.
317.11 Labeling, filling of containers, handling of labeled products to be only in compliance with regulations.
317.12 Relabeling products; requirements.
317.13 Storage and distribution of labels and containers bearing official marks.
317.14–317.15 [Reserved]
317.16 Labeling and containers of custom prepared products.
317.17 Interpretation and statement of labeling policy for cured products; special labeling requirements concerning nitrate and nitrite.
317.18 Quantity of contents labeling.
317.19 Definitions and procedures for determining net weight compliance.
317.20 Scale requirements for accurate weights, repairs, adjustments, and replacement after inspection.
317.21 Scales: testing of.
317.22 Handling of failed product.
317.23 [Reserved]
317.24 Packaging materials.

Subpart B—Nutrition Labeling

317.300 Nutrition labeling of meat or meat food products.
317.301 [Reserved]
317.302 Location of nutrition information.
317.303–317.307 [Reserved]
317.308 Labeling of meat or meat food products with number of servings.
317.309 Nutrition label content.
317.310–317.311 [Reserved]
317.312 Reference amounts customarily consumed per eating occasion.
317.313 Nutrient content claims; general principles.
317.314–317.342 [Reserved]
317.343 Significant participation for voluntary nutrition labeling.
317.344 Identification of major cuts of meat products.
317.345 Guidelines for voluntary nutrition labeling of single-ingredient, raw products.
317.346–317.353 [Reserved]
317.354 Nutrient content claims for ''good source,'' ''high,'' and ''more''.
317.355 [Reserved]
317.356 Nutrient content claims for ''light'' or ''lite''.
317.357–317.359 [Reserved]
317.360 Nutrient content claims for calorie content.
317.361 Nutrient content claims for the sodium content.
317.362 Nutrient content claims for fat, fatty acids, and cholesterol content.
317.363 Nutrient content claims for ''healthy''.
317.364–317.368 [Reserved]
317.369 Labeling applications for nutrient content claims.
317.370–317.379 [Reserved]
317.380 Label statements relating to usefulness in reducing or maintaining body weight.
317.381–317.399 [Reserved]
317.400 Exemption from nutrition labeling.

AUTHORITY: 21 U.S.C. 601–695; 7 CFR 2.18, 2.53.

SOURCE: 35 FR 15580, Oct. 3, 1970, unless otherwise noted.

Subpart A—General

§ 317.1 Labels required; supervision by Program employee.

(a) When, in an official establishment, any inspected and passed product is placed in any receptacle or covering constituting an immediate container, there shall be affixed to such container a label as described in § 317.2 except that the following do not have to bear such a label.

(1) Wrappings of dressed carcasses and primal parts in an unprocessed state, bearing the official inspection legend, if such wrappings are intended solely to protect the product against soiling or excessive drying during transportation or storage, and the wrappings bear no information except company brand names, trade marks, or code numbers which do not include any information required by § 317.2;

(2) Uncolored transparent coverings, such as cellophane, which bear no written, printed, or graphic matter and which enclose any unpackaged or packaged product bearing all markings required by part 316 of this subchapter which are clearly legible through such coverings;

(3) Animal and transparent artificial casings bearing only the markings required by part 316 of this subchapter;

(4) Stockinettes used as ''operative devices'', such as those applied to cured meats in preparation for smoking, whether or not such stockinettes are removed following completion of the operations for which they were applied;

(5) Containers such as boil-in bags, trays of frozen dinners, and pie pans which bear no information except company brand names, trademarks, code numbers, directions for preparation and serving suggestions, and which are

enclosed in a consumer size container that bears a label as described in §317.2;

(6) Containers of products passed for cooking or refrigeration and moved from an official establishment under §311.1 of this subchapter.

(b) Folders and similar coverings made of paper or similar materials, whether or not they completely enclose the product and which bear any written, printed, or graphic matter, shall bear all features required on a label for an immediate container.

(c) No covering or other container which bears or is to bear a label shall be filled, in whole or in part, except with product which has been inspected and passed in compliance with the regulations in this subchapter, which is not adulterated and which is strictly in accordance with the statements on the label. No such container shall be filled, in whole or in part, and no label shall be affixed thereto, except under supervision of a Program employee.

§317.2 Labels: definition; required features.

(a) A label within the meaning of this part shall mean a display of any printing, lithographing, embossing, stickers, seals, or other written, printed, or graphic matter upon the immediate container (not including package liners) of any product.

(b) Any word, statement, or other information required by this part to appear on the label must be prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use. In order to meet this requirement, such information must appear on the principal display panel except as otherwise permitted in this part. Except as provided in §317.7, all words, statements, and other information required by or under authority of the Act to appear on the label or labeling shall appear thereon in the English language: *Provided, however,* That in the case of products distributed solely in Puerto Rico, Spanish may be substituted for English for all printed matter except the USDA inspection legend.

(c) Labels of all products shall show the following information on the principal display panel (except as otherwise permitted in this part), in accordance with the requirements of this part or, if applicable, part 319 of this subchapter:

(1) The name of the product, which in the case of a product which purports to be or is represented as a product for which a definition and standard of identity or composition is prescribed in part 319 of this subchapter, shall be the name of the food specified in the standard, and in the case of any other product shall be the common or usual name of the food, if any there be, and if there is none, a truthful descriptive designation, as prescribed in paragraph (e) of this section;

(2) If the product is fabricated from two or more ingredients, the word ''ingredients'' followed by a list of the ingredients as prescribed in paragraph (f) of this section;

(3) The name and place of business of the manufacturer, packer, or distributor for whom the product is prepared, as prescribed in paragraph (g) of this section;

(4) An accurate statement of the net quantity of contents, as prescribed in paragraph (h) of this section;

(5) An official inspection legend and, except as otherwise provided in paragraph (i) of this section, the number of the official establishment, in the form required by part 312 of this subchapter;

(6) Any other information required by the regulations in this part or part 319 of this subchapter.

(d) The principal display panel shall be the part of a label that is most likely to be displayed, presented, shown, or examined under customary conditions of display for sale. Where packages bear alternate principal display panels, information required to be placed on the principal display panel shall be duplicated on each principal display panel. The principal display panel shall be large enough to accommodate all the mandatory label information required to be placed thereon by this part and part 319 of this subchapter with clarity and conspicuousness and without obscuring of such information by

designs or vignettes or crowding. In determining the area of the principal display panel, exclude tops, bottoms, flanges at tops and bottoms of cans, and shoulders and necks of bottles or jars. The principal display panel shall be:

(1) In the case of a rectangular package, one entire side, the area of which is at least the product of the height times the width of that side.

(2) In the case of a cylindrical or nearly cylindrical container:

(i) An area that is 40 percent of the product of the height of the container times the circumference of the container, or

(ii) A panel, the width of which is one-third of the circumference and the height of which is as high as the container: *Provided, however,* That if there is immediately to the right or left of such principal display panel, a panel which has a width not greater than 20 percent of the circumference and a height as high as the container, and which is reserved for information prescribed in paragraphs (c) (2), (3), and (5), such panel shall be known as the ''20 percent panel'' and such information may be shown on that panel in lieu of showing it on the principal display panel.

(3) In the case of a container of any other shape, 40 percent of the total surface of the container.

(e) Any descriptive designation used as a product name for a product which has no common or usual name shall clearly and completely identify the product. Product which has been prepared by salting, smoking, drying, cooking, chopping, or otherwise shall be so described on the label unless the name of the product implies, or the manner of packaging shows that the product was subjected to such preparation. The unqualified terms ''meat,'' ''meat byproduct,'' ''meat food product,'' and terms common to the meat industry but not common to consumers such as ''picnic,'' ''butt,'' ''cala,'' ''square,'' ''loaf,'' ''spread,'' ''delight,'' ''roll,'' ''plate,'' ''luncheon,'' and ''daisy'' shall not be used as names of a product unless accompanied with terms descriptive of the product or with a list of ingredients, as deemed necessary in any specific case by the Administrator in order to assure that the label will not be false or misleading.

(f)(1) The list of ingredients shall show the common or usual names of the ingredients arranged in the descending order of predominance, except as otherwise provided in this paragraph.

(i) The terms spice, natural flavor, natural flavoring, flavor and flavoring may be used in the following manner:

(A) The term ''spice'' means any aromatic vegetable substance in the whole, broken, or ground form, with the exceptions of onions, garlic and celery, whose primary function in food is seasoning rather than nutritional and from which no portion of any volatile oil or other flavoring principle has been removed. Spices include the spices listed in 21 CFR 182.10, and 184.

(B) The term ''natural flavor,'' ''natural flavoring,'' ''flavor'' or ''flavoring'' means the essential oil, oleoresin, essence or extractive, protein hydrolysate, distillate, or any product or roasting, heating or enzymolysis, which contains the flavoring constituents derived from a spice, fruit or fruit juice, vegetable or vegetable juice, edible yeast, herb, bark, bud, root, leaf or any other edible portion of a plant, meat, seafood, poultry, eggs, dairy products, or fermentation products thereof, whose primary function in food is flavoring rather than nutritional. Natural flavors include the natural essence or extractives obtained from plants listed in 21 CFR 182.10, 182.20, 182.40, 182.50 and 184, and the substances listed in 21 CFR 172.510. The term natural flavor, natural flavoring, flavor or flavoring may also be used to designate spices, powered onion, powdered garlic, and powdered celery.

(ii) The term ''corn syrup'' may be used to designate either corn syrup or corn syrup solids.

(iii) The term ''animal and vegetable fats'' or ''vegetable and animal fats'' may be used to designate the ingredients of mixtures of such edible fats in product designated ''compound'' or ''shortening.'' ''Animal fats'' as used herein means fat derived from inspected and passed cattle, sheep, swine, or goats.

(iv) When a product is coated with pork fat, gelatin, or other approved

substance and a specific declaration of such coating appears contiguous to the name of the product, the ingredient statement need not make reference to the ingredients of such coating.

(v) When two meat ingredients comprise at least 70 percent of the meat and meat byproduct ingredients of a formula and when neither of the two meat ingredients is less than 30 percent by weight of the total meat and meat byproducts used, such meat ingredients may be interchanged in the formula without a change being made in the ingredients statement on labeling materials: *Provided,* That the word ''and'' in lieu of a comma shall be shown between the declaration of such meat ingredients in the statement of ingredients.

(vi)(A) Product ingredients which are present in individual amounts of 2 percent or less by weight may be listed in the ingredients statement in other than descending order of predominance: *Provided,* That such ingredients are listed by their common or usual names at the end of the ingredients statement and preceded by a quantifying statement, such as ''Contains _____ percent of _____,'' ''Less than _____percent of _____.'' The percentage of the ingredient(s) shall be filled in with a threshold level of 2 percent, 1.5 percent, 1.0 percent, or 0.5 percent, as appropriate. No ingredient to which the quantifying statement applies may be present in an amount greater than the stated threshold. Such a quantifying statement may also be utilized when an ingredients statement contains a listing of ingredients by individual components. Each component listing may utilize the required quantifying statement at the end of each component ingredients listing.

(B) Such ingredients may be adjusted in the product formulation without a change being made in the ingredients statement on the labeling, provided that the adjusted amount complies with § 318.7(c)(4) and part 319 of this subchapter, and does not exceed the amount shown in the quantifying statement. Any such adjustments to the formulation shall be provided to the inspector-in-charge.

(2) On containers of frozen dinners, entrees, pizzas, and similar consumer packaged products in cartons the ingredient statement may be placed on the front riser panel: *Provided,* That the words ''see ingredients'' followed immediately by an arrow is placed on the principal display panel immediately above the location of such statement without intervening print or designs.

(3) The ingredient statement may be placed on the 20 percent panel adjacent to the principal display panel and reserved for required information, in the case of a cylindrical or nearly cylindrical container.

(4) The ingredients statement may be placed on the information panel, except as otherwise permitted in this subchapter.

(g)(1) The name or trade name of the person that prepared the product may appear as the name of the manufacturer or packer without qualification on the label. Otherwise the name of the distributor of the product shall be shown with a phrase such as ''Prepared for * * *''. The place of business of the manufacturer, packer, or distributor shall be shown on the label by city, State, and postal ZIP code when such business is listed in a telephone or city directory, and if not listed in such directory, then the place of business shall be shown by street address, city, State, and postal ZIP code.

(2) The name and place of business of the manufacturer, packer, or distributor may be shown:

(i) On the principal display panel, or

(ii) On the 20 percent panel adjacent to the principal display panel and reserved for required information, in the case of a cylindrical or nearly cylindrical container, or

(iii) On the front riser panel of frozen food cartons, or

(iv) On the information panel.

(h)(1) The statement of net quantity of contents shall appear on the principal display panel of all containers to be sold at retail intact, in conspicuous and easily legible boldface print or type in distinct contrast to other matter on the container, and shall be declared in accordance with the provisions of this paragraph.

(2) The statement as it is shown on a label shall not be false or misleading and shall express an accurate statement of the quantity of contents of the container. Reasonable variations caused by loss or gain of moisture during the course of good distribution practices or by unavoidable deviations in good manufacturing practices will be recognized. Variations from stated quantity of contents shall be as provided in § 317.19. The statement shall not include any term qualifying a unit of weight, measure, or count such as ''jumbo quart,'' ''full gallon,'' ''giant quart,'' ''when packed,'' ''minimum,'' or words of similar importance.

(3) The statement shall be placed on the principal display panel within the bottom 30 percent of the area of the panel in lines generally parallel to the base: *Provided,* That on packages having a principal display panel of 5 square inches or less, the requirement for placement within the bottom 30 percent of the area of the label panel shall not apply when the statement meets the other requirements of this paragraph (h). In any case, the statement may appear in more than one line. The terms ''net weight'' or ''net wt.'' shall be used when stating the net quantity of contents in terms of weight, and the term ''net contents'' or ''content'' when stating the net quantity of contents in terms of fluid measure.

(4) Except as provided in § 317.7, the statement shall be expressed in terms of avoirdupois weight or liquid measure. Where no general consumer usage to the contrary exists, the statement shall be in terms of liquid measure, if the product is liquid, or in terms of weight if the product is solid, semisolid viscous or a mixture of solid and liquid. For example, a declaration of ¾-pound avoirdupois weight shall be expressed as ''Net Wt. 12 oz.'' except as provided for in paragraph (h)(5) of this section for random weight packages; a declaration of 1½ pounds avoirdupois weight shall be expressed as ''Net Wt. 24 oz. (1 lb. 8 oz.),'' ''Net Wt. 24 oz. (1½ lb.),'' or ''Net Wt. 24 oz. (1.5 lbs.).''

(5) On packages containing 1 pound or 1 pint and less than 4 pounds or 1 gallon, the statement shall be expressed as a dual declaration both in ounces and (immediately thereafter in parentheses) in pounds, with any remainder in terms of ounces or common or decimal fraction of the pound, or in the case of liquid measure, in the largest whole units with any remainder in terms of fluid ounces or common or decimal fractions of the pint or quart, except that on random weight packages the statement shall be expressed in terms of pounds and decimal fractions of the pound, for packages over 1 pound, and for packages which do not exceed 1 pound the statement may be in decimal fractions of the pound in lieu of ounces. Paragraph (h)(9) of this section permits certain exceptions from the provisions of this paragraph for margarine packages, random weight consumer size packages, and packages of less than ½ ounce net weight. Pargraph (h)(12) of this section permits certain exceptions from the provision of this paragraph for multi-unit packages.

(6) The statement shall be in letters and numerals in type size established in relationship to the area of the principal display panel of the package and shall be uniform of all packages of substantially the same size by complying with the following type specifications:

(i) Not less than one-sixteenth inch in height on packages, the principal display panel of which has an area of 5 square inches or less;

(ii) Not less than one-eighth inch in height on packages, the principal display panel of which has an area of more than 5 but not more than 25 square inches;

(iii) Not less than three-sixteenths inch in height on packages, the principal display panel of which has an area of more than 25 but not more than 100 square inches;

(iv) Not less than one-quarter inch in height on packages, the principal display panel of which has an area of more than 100 but not more than 400 square inches.

(v) Not less than one-half inch in height on packages, the principal display panel of which has an area of more than 400 square inches.

(7) The ratio of height to width of letters and numerals shall not exceed a differential of 3 units to 1 unit (no more than 3 times as high as it is wide). Heights pertain to upper case or

capital letters. When upper and lower case or all lower case letters are used, it is the lower case letter ''o'' or its equivalent that shall meet the minimum standards. When fractions are used, each component numeral shall meet one-half the height standards.

(8) The statement shall appear as a distinct item on the principal display panel and shall be separated by a space at least equal to the height of the lettering used in the statement from other printed label information appearing above or below the statement and by a space at least equal to twice the width of the letter ''N'' of the style of type used in the quantity of contents statement from other printed label information appearing to the left or right of the statement. It shall not include any term qualifying a unit of weight, measure, or count such as, ''jumbo quart,'' ''full gallon,'' ''giant quart,'' ''when packed,'' ''Minimum'' or words of similar import.

(9) The following exemptions from the requirements contained in this paragraph (h) are hereby established:

(i) Individually wrapped, random weight consumer size packages shipped in bulk containers (as specified in paragraph (h)(11) of this section) and meat products that are subject to shrinkage through moisture loss during good distribution practices and are designated as gray area type of products as defined under § 317.19 need not bear a net weight statement when shipped from an official establishment, provided that a net weight shipping statement which meets the requirements of paragraph (h)(2) of this section is applied to their shipping container prior to shipping it from the official establishment. Net weight statements so applied to the shipping container are exempt from the type size, dual declaration, and placement requirements of this paragraph, if an accurate statement of net weight is shown conspicuously on the principal display panel of the shipping container. The net weight also shall be applied directly to random weight consumer size packages prior to retail display and sale. The net weight statement on random weight consumer size packages for retail sale shall be exempt from the type size, dual declaration, and placement requirements of this paragraph, if an accurate statement of net weight is shown conspicuously on the principal display panel of the package.

(ii) Individually wrapped and labeled packages of less than ½ ounce net weight and random weight consumer size packages shall be exempt from the requirements of this paragraph if they are in a shipping container and the statement of net quantity of contents on the shipping container meets the requirements of paragraph (h)(2) of this section;

(iii) Individually wrapped and labeled packages of less than ½ ounce net weight bearing labels declaring net weight, price per pound, and total price, shall be exempt from the type size, dual declaration, and placement requirements of this paragraph, if an accurate statement of net weight is shown conspicuously on the principal display panel of the package.

(iv) Margarine in 1 pound rectangular packages (except packages containing whipped or soft margarine or packages that contain more than four sticks) is exempt from the requirements of paragraphs (h) (3) and (5) of this section regarding the placement of the statement of the net quantity of contents within the bottom 30 percent of the principal display panel and that the statement be expressed both in ounces and in pounds, if the statement appears as ''1 pound'' or ''one pound'' in a conspicuous manner on the principal display panel.

(v) Sliced shingle packed bacon in rectangular packages is exempt from the requirements of paragraphs (h)(3) and (h)(5) of this section regarding the placement of the statement of the net quantity of contents within the bottom 30 percent of the principal display panel, and that the statement be expressed both in ounces and in pounds, if the statement appears in a conspicuous manner on the principal display panel.

(10) Labels for containers which bear any representation as to the number of servings contained therein shall bear, contiguous to such representation, and in the same size type as is used for such representation, a statement of the net quantity of each such serving.

(11) As used in this section, a ''random weight consumer size package'' is

one which is one of a lot, shipment or delivery of packages of the same product with varying weights and with no fixed weight pattern.

(12) On a multiunit retail package, a statement of the net quantity of contents shall appear on the outside of the package and shall include the number of individual units, the quantity of each individual unit, and in parentheses, the total net quantity of contents of the multiunit package in terms of avoirdupois or fluid ounces, except that such declaration of total quantity need not be followed by an additional parenthetical declaration in terms of the largest whole units and subdivisions thereof, as required by paragraph (h)(5) of this section. For the purposes of this section, ''multiunit retail package'' means a package containing two or more individually packaged units of the identical commodity and in the same quantity, with the individual packages intended to be sold as part of the multiunit retail package but capable of being individually sold in full compliance with all requirements of the regulations in this part. Open multiunit retail packages that do not obscure the number of units and the labeling thereon are not subject to this paragraph if the labeling of each individual unit complies with the requirements of paragraphs (h) (2), (3), (6), and (8) of this section.

(i) The official establishment number of the official establishment in which the product was processed under inspection shall be placed as follows:

(1) Within the official inspection legend in the form required by part 312 of this subchapter; or

(2) Outside the official inspection legend elsewhere on the exterior of the container or its labeling, e.g., the lid of a can, if shown in a prominent and legible manner in a size sufficient to insure easy visibility and recognition and accompanied by the prefix ''EST''; or

(3) Off the exterior of the container, e.g., on a metal clip used to close casings or bags, or on the back of a paper label of a canned product, or on other packaging or labeling material in the container, e.g., on aluminum pans and trays placed within containers, when a statement of its location is printed contiguous to the official inspection legend, such as ''EST. No. on Metal Clip'' or ''Est. No. on Pan'', if shown in a prominent and legible manner in a size sufficient to insure easy visibility and recognition; or

(4) On an insert label placed under a transparent covering if clearly visible and legible and accompanied by the prefix ''EST''.

(j) Labels of any product within any of the following paragraphs shall show the information required by such paragraph for such product:

(1) A label for product which is an imitation of another food shall bear the word ''imitation'' immediately preceding the name of the food imitated and in the same size and style of lettering as in that name and immediately thereafter the word ''ingredients:'' and the names of the ingredients arranged in the order of their predominance.

(2) If a product purports to be or is represented for any special dietary use by man, its label shall bear a statement concerning its vitamin, mineral, and other dietary properties upon which the claim for such use is based in whole or in part and shall be in conformity with regulations (21 CFR part 125) established pursuant to sections 403, and 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343, 371).

(3) When an artificial smoke flavoring or an smoke flavoring is added as an ingredient in the formula of a meat food product, as permitted in part 318 of this subchapter, there shall appear on the label, in prominent letters and contiguous to the name of the product, a statement such as ''Artificial Smoke Flavoring Added'' or ''Smoke Flavoring Added,'' as may be applicable, and the ingredient statement shall identify any artificial smoke flavoring or smoke flavoring so added as an ingredient in the formula of the meat food product.

(4) When any other artificial flavoring is permitted under part 318 of this subchapter to be added to a product, the ingredient statement shall identify it as ''Artificial Flavoring.''

(5) When artificial coloring is added to edible fats as permitted under part 318 of this subchapter such substance shall be declared on the label in a prominent manner and contiguous to

the name of the product by the words ''Artificially colored'' or ''Artificial coloring added'' or ''With added artificial coloring.'' When natural coloring such as annatto is added to edible fats as permitted under part 318 of this subchapter, such substance shall be declared on the label in the same manner by a phrase such as ''Colored with annatto.''

(6) When product is placed in a casing to which artificial coloring is applied as permitted under part 318 of this subchapter, there shall appear on the label, in a prominent manner and contiguous to the name of the product, the words, ''Artificially colored.''

(7) If a casing is removed from product at an official establishment and there is evidence of artificial coloring on the surface of the product, there shall appear on the label, in a prominent manner and contiguous to the name of product, the words ''Artificially colored.''

(8) When a casing is colored prior to its use as a covering for product and the color is not transferred to the product enclosed in the casing, no reference to color need appear on the label but no such casing may be used if it is misleading or deceptive with respect to color, quality, or kind of product, or otherwise.

(9) Product which bears or contains any other artificial coloring, as permitted under part 318 of this subchapter, shall bear a label stating that fact on the immediate container or if there is none, on the product.

(10) When an antioxidant is added to product as permitted under part 318 of this subchapter, there shall appear on the label in prominent letters and contiguous to the name of the product, a statement identifying the officially approved specific antioxidant by its common name or abbreviation thereof and the purpose for which it is added, such as, ''BHA, BHT, and Propylgallate added to help protect flavor.''

(11) Containers of meat packed in borax or other preservative for export to a foreign country which permits the use of such preservative shall, at the time of packing, be marked ''for export,'' followed on the next line by the words ''packed in preservative,'' or such equivalent statement as may be approved for this purpose by the Administrator and directly beneath this there shall appear the word ''establishment'' or abbreviation thereof, followed by the number of the establishment at which the product is packed. The complete statement shall be applied in a conspicuous location and in letters not less than 1 inch in height.

(12) Containers of other product packed in, bearing, or containing any chemical preservative shall bear a label stating that fact.

(13)(i) On the label of any ''Mechanically Separated (Species)'' described in § 319.5(a) of this subchapter, the name of such product shall be followed immediately by the phrase ''for processing'' unless such product has a protein content of not less than 14 percent and a fat content of not more than 30 percent.

(ii) When any ''Mechanically Separated (Species)'' described in § 319.5 of this subchapter is used as an ingredient in the preparation of a meat food product and such ''Mechanically Separated (Species)'' contributes 20 mg or more of calcium to a serving of such meat food product, the label of such meat food product shall state the calcium content of such meat food product, determined and expressed as the percentage of the U.S. Recommended Daily Allowance (U.S. RDA) in a serving in accordance with 21 CFR 101.9(b)(1), (c)(7) (i) and (iv), and (e), as part of any nutrition information included on such label, or if such meat food product does not bear nutrition labeling information, as part of a prominent statement in immediate conjunction with the list of ingredients, as follows: ''A ——— serving contains ——% of the U.S. RDA of calcium'', with the blanks to be filled in, respectively, with the quantity of such product that constitutes a serving and the amount of calcium provided by such serving: *Provided*, That, calcium content need not be stated where (*a*) the percent of the U.S. RDA of calcium to be declared would not differ from the percent of the U.S. RDA that would be declared if the meat food product contained only hand deboned ingredients or (*b*) the calcium content of a serving of the meat food product would be 20 percent of the U.S. RDA or more

if the meat food product contained only hand deboned ingredients.

(k) Packaged products which require special handling to maintain their wholesome condition shall have prominently displayed on the principal display panel of the label the statement: ''Keep Refrigerated,'' ''Keep Frozen,'' ''Perishable Keep Under Refrigeration,'' or such similar statement as the Administrator may approve in specific cases. Products that are distributed frozen during distribution and thawed prior to or during display for sale at retail shall bear the statement on the shipping container: ''Keep Frozen.'' The consumer-size containers for such products shall bear the statement ''Previously Handled Frozen for Your Protection, Refreeze or Keep Refrigerated.'' For all perishable canned products the statement shall be shown in upper case letters one-fourth inch in height for containers having a net weight of 3 pounds or less, and for containers having a net weight over 3 pounds, the statement shall be in upper case letters at least one-half inch in height.

(l) Safe handling instructions shall be provided for: All meat and meat products of cattle, swine, sheep, goat, horse, other equine that do not meet the requirements contained in § 318.17, or that have not undergone other processing that would render them ready-to-eat; and all comminuted meat patties not heat processed in a manner that conforms to the time and temperature combinations in the Table for Permitted Heat-Processing Temperature/Time Combinations For Fully-Cooked Patties in § 318.23, except as exempted under paragraph (l)(4) of this section.

(1)(i) Safe handling instructions shall accompany every meat or meat product, specified in this paragraph (l) destined for household consumers, hotels, restaurants, or similar institutions and shall appear on the label. The information shall be in lettering no smaller than one-sixteenth of an inch in size and shall be prominently placed with such conspicuousness (as compared with other words, statements, designs or devices in the labeling) as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(ii) The safe handling information shall be presented on the label under the heading ''Safe Handling Instructions'' which shall be set in type size larger than the print size of the rationale statement and handling statements as discussed in paragraphs (l)(2) and (l)(3) of this section. The safe handling information shall be set off by a border and shall be one color type printed on a single color contrasting background whenever practical.

(2) The labels of the meat and meat products specified in this paragraph (l) shall include the following rationale statement as part of the safe handling instructions, ''This product was prepared from inspected and passed meat and/or poultry. Some food products may contain bacteria that could cause illness if the product is mishandled or cooked improperly. For your protection, follow these safe handling instructions.'' This statement shall be placed immediately after the heading and before the safe handling statements.

(3) Meat and meat products, specified in this paragraph (l), shall bear the labeling statements:

(i) Keep refrigerated or frozen. Thaw in refrigerator or microwave. (Any portion of this statement that is in conflict with the product's specific handling instructions, may be omitted, e.g., instructions to cook without thawing.) (A graphic illustration of a refrigerator shall be displayed next to the statement.);

(ii) Keep raw meat and poultry separate from other foods. Wash working surfaces (including cutting boards), utensils, and hands after touching raw meat or poultry. (A graphic illustration of soapy hands under a faucet shall be displayed next to the statement.);

(iii) Cook thoroughly. (A graphic illustration of a skillet shall be displayed next to the statement.); and

(iv) Keep hot foods hot. Refrigerate leftovers immediately or discard. (A graphic illustration of a thermometer shall be displayed next to the statement.)

(4) Meat or meat products intended for further processing at another official establishment are exempt from the requirements prescribed in paragraphs (l)(1) through (l)(3) of this section.

(m)(1) The information panel is that part of a label that is the first surface to the right of the principal display panel as observed by an individual facing the principal display panel, with the following exceptions:

(i) If the first surface to the right of the principal display panel is too small to accommodate the required information or is otherwise unusable label space, e.g., folded flaps, tear strips, opening flaps, heat-sealed flaps, the next panel to the right of this part of the label may be used.

(ii) If the package has one or more alternate principal display panels, the information panel is to the right of any principal display panel.

(iii) If the top of the container is the principal display panel and the package has no alternate principal display panel, the information panel is any panel adjacent to the principal display panel.

(2) (i) Except as otherwise permitted in this part, all information required to appear on the principal display panel or permitted to appear on the information panel shall appear on the same panel unless there is insufficient space. In determining the sufficiency of the available space, except as otherwise prescribed in this part, any vignettes, designs, and any other nonmandatory information shall not be considered. If there is insufficient space for all required information to appear on a single panel, it may be divided between the principal display panel and the information panel, provided that the information required by any given provision of this part, such as the ingredients statement, is not divided and appears on the same panel.

(ii) All information appearing on the information panel pursuant to this section shall appear in one place without intervening material, such as designs or vignettes.

[35 FR 15580, Oct. 3, 1970]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting §317.2, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and on GPO Access.

§317.3 Approval of abbreviations of marks of inspection; preparation of marking devices bearing inspection legend without advance approval prohibited; exception.

(a) The Administrator may approve and authorize the use of abbreviations of marks of inspection under the regulations in this subchapter. Such abbreviations shall have the same force and effect as the respective marks for which they are authorized abbreviations.

(b) Except for the purposes of preparing and submitting a sample or samples of the same to the Administrator for approval, no brand manufacturer, printer, or other person shall cast, print, lithograph, or otherwise make any marking device containing any official mark or simulation thereof, or any label bearing any such mark or simulation, without the written authority therefor of the Administrator. However, when any such sample label, or other marking device, is approved by the Administrator, additional supplies of the approved label, or marking device, may be made for use in accordance with the regulations in this subchapter, without further approval by the Administrator. The provisions of this paragraph apply only to labels, or other marking devices, bearing or containing an official inspection legend shown in §312.2(b), §312.3(a) (only the legend appropriate for horse meat food products) or §312.3(b) (only the legend appropriate for other (nonhorse) equine meat food products), or any abbreviations, copy or representation thereof.

(c) No brand manufacturer or other person shall cast or otherwise make, without an official certificate issued in quadruplicate by a Program employee, a brand or other marking device containing an official inspection legend, or simulation thereof, shown in §312.2(a), §312.3(a) (only the legend appropriate for horse carcasses and parts of horse carcasses), §312.3(b) (only the legend appropriate for other equine (nonhorse) carcasses and parts of other (nonhorse) equine carcasses) or §312.7(a).

(1) The certificate is a Food Safety and Inspection Service form for signature by a Program employee and the

official establishment ordering the brand or other marking device, bearing a certificate serial number and a letterhead and the seal of the United States Department of Agriculture. The certificate authorizes the making of only the brands or other marking devices of the type and quantity listed on the certificate.

(2) After signing the certificate, the Program employee and the establishment shall each keep a copy, and the remaining two copies shall be given to the brand or other marking device manufacturer.

(3) The manufacturer of the brands or other marking devices shall engrave or otherwise mark each brand or other marking device with a permanent identifying serial number unique to it. The manufacturer shall list on each of the two copies of the certificate given to the manufacturer the number of each brand or other marking device authorized by the certificate. The manufacturer shall retain one copy of the certificate for the manufacturer's records and return the remaining copy with the brands or other marking devices to the Program employee whose name and address are given on the certificate as the recipient.

(4) In order that all such brands or other marking devices bear identifying numbers, within one year after June 24, 1985, an establishment shall either replace each such brand or other marking device which does not bear an identifying number, or, under the direction of the inspector-in-charge, mark such brand or other marking device with a permanent identifying number.

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

[35 FR 15580, Oct. 3, 1970, as amended at 50 FR 21422, May 24, 1985]

§ 317.4 Labeling approval.

(a) No final labeling shall be used on any product unless the sketch labeling of such final labeling has been submitted for approval to the Food Labeling Division, Regulatory Programs, Food Safety and Inspection Service, and approved by such division, accompanied by FSIS form, Application for Approval of Labels, Marking, and Devices, except for generically approved labeling authorized for use in § 317.5(b). The management of the official establishment or establishment certified under a foreign inspection system, in accordance with part 327 of this subchapter, must maintain a copy of all labeling used, along with the product formulation and processing procedure, in accordance with part 320 of this subchapter. Such records shall be made available to any duly authorized representative of the Secretary upon request.

(b) The Food Labeling Division shall permit submission for approval of only sketch labeling, as defined in § 317.4(d), for all products, except as provided in § 317.5(b) (2)–(9) and except for temporary use of final labeling as prescribed in paragraph (f) of this section.

(c) All labeling required to be submitted for approval as set forth in § 317.4(a) shall be submitted in duplicate to the Food Labeling Division, Regulatory Programs, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250. A parent company for a corporation may submit only one labeling application (in duplicate form) for a product produced in other establishments that are owned by the corporation.

(d) ''Sketch'' labeling is a printer's proof or equivalent which clearly shows all labeling features, size, location, and indication of final color, as specified in § 317.2. FSIS will accept sketches that are hand drawn, computer generated or other reasonable facsimiles that clearly reflect and project the final version of the labeling. Indication of final color may be met by: submission of a color sketch, submission of a sketch which indicates by descriptive language the final colors, or submission with the sketch of previously approved final labeling that indicates the final colors.

(e) Inserts, tags, liners, pasters, and like devices containing printed or graphic matter and for use on, or to be placed within, containers and coverings of product shall be submitted for approval in the same manner as provided for labeling in § 317.4(a), except that such devices which contain no reference to product and bear no misleading feature shall be used without

submission for approval as prescribed in §317.5(b)(7).

(f)(1) Consistent with the requirements of this section, temporary approval for the use of a final label or other final labeling that may otherwise be deemed deficient in some particular may be granted by the Food Labeling Division. Temporary approvals may be granted for a period not to exceed 180 calendar days, under the following conditions:

(i) The proposed labeling would not misrepresent the product;

(ii) The use of the labeling would not present any potential health, safety, or dietary problems to the consumer;

(iii) Denial of the request would create undue economic hardship; and

(iv) An unfair competitive advantage would not result from the granting of the temporary approval.

(2) Extensions of temporary approvals may also be granted by the Food Labeling Division provided that the applicant demonstrates that new circumstances, meeting the above criteria, have developed since the original temporary approval was granted.

(g) The inspector-in-charge shall approve meat carcass ink brands and meat food product ink and burning brands, which comply with parts 312 and 316 of this subchapter.

[60 FR 67454, Dec. 29, 1995]

§317.5 Generically approved labeling.

(a)(1) An official establishment or an establishment certified under a foreign inspection system, in accordance with part 327 of this subchapter, is authorized to use generically approved labeling, as defined in paragraph (b) of this section, without such labeling being submitted for approval to the Food Safety and Inspection Service in Washington or the field, provided the labeling is in accordance with this section and shows all mandatory features in a prominent manner as required in §317.2, and is not otherwise false or misleading in any particular.

(2) The Food Safety and Inspection Service shall select samples of generically approved labeling from the records maintained by official establishments and establishments certified under foreign inspection systems, in accordance with part 327 of this subchapter, as required in §317.4, to determine compliance with labeling requirements. Any finding of false or misleading labeling shall institute the proceedings prescribed in §335.12.

(b) Generically approved labeling is labeling which complies with the following:

(1) Labeling for a product which has a product standard as specified in part 319 of this subchapter or the Standards and Labeling Policy Book and which does not contain any special claims, such as quality claims, nutrient content claims, health claims, negative claims, geographical origin claims, or guarantees, or which is not a domestic product labeled in a foreign language;

(2) Labeling for single-ingredient products (such as beef steak or lamb chops) which does not contain any special claims, such as quality claims, nutrient content claims, health claims, negative claims, geographical origin claims, or guarantees, or which is not a domestic product labeled with a foreign language;

(3) Labeling for containers of products sold under contract specifications to Federal Government agencies, when such product is not offered for sale to the general public, provided that the contract specifications include specific requirements with respect to labeling, and are made available to the inspector-in-charge;

(4) Labeling for shipping containers which contain fully labeled immediate containers, provided such labeling complies with §316.13;

(5) Labeling for products not intended for human food, provided they comply with part 325 of this subchapter;

(6) Meat inspection legends, which comply with parts 312 and 316 of this subchapter;

(7) Inserts, tags, liners, pasters, and like devices containing printed or graphic matter and for use on, or to be placed within containers, and coverings of products, provided such devices contain no reference to product and bear no misleading feature;

(8) Labeling for consumer test products not intended for sale; and

(9) Labeling which was previously approved by the Food Labeling Division

as sketch labeling, and the final labeling was prepared without modification or with the following modifications:

(i) All features of the labeling are proportionately enlarged or reduced, provided that all minimum size requirements specified in applicable regulations are met and the labeling is legible;

(ii) The substitution of any unit of measurement with its abbreviation or the substitution of any abbreviation with its unit of measurement, e.g., ''lb.'' for ''pound,'' or ''oz.'' for ''ounce,'' or of the word ''pound'' for ''lb.'' or ''ounce'' for ''oz.'';

(iii) A master or stock label has been approved from which the name and address of the distributor are omitted and such name and address are applied before being used (in such case, the words ''prepared for'' or similar statement must be shown together with the blank space reserved for the insertion of the name and address when such labels are offered for approval);

(iv) Wrappers or other covers bearing pictorial designs, emblematic designs or illustrations, e.g., floral arrangements, illustrations of animals, fireworks, etc. are used with approved labeling (the use of such designs will not make necessary the application of labeling not otherwise required);

(v) A change in the language or the arrangement of directions pertaining to the opening of containers or the serving of the product;

(vi) The addition, deletion, or amendment of a dated or undated coupon, a cents-off statement, cooking instructions, packer product code information, or UPC product code information;

(vii) Any change in the name or address of the packer, manufacturer or distributor that appears in the signature line;

(viii) Any change in the net weight, provided the size of the net weight statement complies with § 317.2;

(ix) The addition, deletion, or amendment of recipe suggestions for the product;

(x) Any change in punctuation;

(xi) Newly assigned or revised establishment numbers for a particular establishment for which use of the labeling has been approved by the Food Labeling Division, Regulatory Programs;

(xii) The addition or deletion of open dating information;

(xiii) A change in the type of packaging material on which the label is printed;

(xiv) Brand name changes, provided that there are no design changes, the brand name does not use a term that connotes quality or other product characteristics, the brand name has no geographic significance, and the brand name does not affect the name of the product;

(xv) The deletion of the word ''new'' on new product labeling;

(xvi) The addition, deletion, or amendment of special handling statements, provided that the change is consistent with § 317.2(k);

(xvii) The addition of safe handling instructions as required by § 317.2(l);

(xviii) Changes reflecting a change in the quantity of an ingredient shown in the formula without a change in the order of predominance shown on the label, provided that the change in quantity of ingredients complies with any minimum or maximum limits for the use of such ingredients prescribed in parts 318 and 319 of this subchapter;

(xix) Changes in the color of the labeling, provided that sufficient contrast and legibility remain;

(xx) A change in the product vignette, provided that the change does not affect mandatory labeling information or misrepresent the content of the package;

(xxi) A change in the establishment number by a corporation or parent company for an establishment under its ownership;

(xxii) Changes in nutrition labeling that only involve quantitative adjustments to the nutrition labeling information, except for serving sizes, provided the nutrition labeling information maintains its accuracy and consistency;

(xxiii) Deletion of any claim, and the deletion of non-mandatory features or non-mandatory information; and

(xxiv) The addition or deletion of a direct translation of the English language into a foreign language for products marked ''for export only.''

[60 FR 67455, Dec. 29, 1995]

§317.6 Approved labels to be used only on products to which they are applicable.

Labels shall be used only on products for which they are approved, and only if they have been approved for such products in accordance with §317.3: *Provided,* That existing stocks of labels approved prior to the effective date of this section and the quantity of which has been identified to the circuit supervisor as being in storage on said date at the official establishment or other identified warehouse for the account of the operator of the official establishment may be used until such stocks are exhausted, but not later than 1 year after the effective date of this section unless such labels conform to all the requirements of this part and part 319 of this subchapter. The Administrator may upon the show of good cause grant individual extension of time as he deems necessary.

§317.7 Products for foreign commerce; printing labels in foreign language permissible; other deviations.

Labels to be affixed to packages of products for foreign commerce may be printed in a foreign language and may show the statement of the quantity of contents in accordance with the usage of the country to which exported and other deviations from the form of labeling required under this part may be approved for such product by the Administrator in specific cases: *Provided,*

(a) That the proposed labeling accords to the specifications of the foreign purchaser,

(b) That it is not in conflict with the laws of the country to which the product is intended for export, and

(c) That the outside container is labeled to show that it is intended for export; but if such product is sold or offered for sale in domestic commerce, all the requirements of this subchapter apply. The inspection legend and the establishment number shall in all cases appear in English but in addition, may appear literally translated in a foreign language.

§317.8 False or misleading labeling or practices generally; specific prohibitions and requirements for labels and containers.

(a) No product or any of its wrappers, packaging, or other containers shall bear any false or misleading marking, label, or other labeling and no statement, word, picture, design, or device which conveys any false impression or gives any false indication of origin or quality or is otherwise false or misleading shall appear in any marking or other labeling. No product shall be wholly or partly enclosed in any wrapper, packaging, or other container that is so made, formed, or filled as to be misleading.

(b) The labels and containers of product shall comply with the following provisions, as applicable:

(1) Terms having geographical significance with reference to a locality other than that in which the product is prepared may appear on the label only when qualified by the word ''style,'' ''type,'' or ''brand,'' as the case may be, in the same size and style of lettering as in the geographical term, and accompanied with a prominent qualifying statement identifying the country, State, Territory, or locality in which the product is prepared, using terms appropriate to effect the qualification. When the word ''style'' or ''type'' is used, there must be a recognized style or type of product identified with and peculiar to the area represented by the geographical term and the product must possess the characteristics of such style or type, and the word ''brand'' shall not be used in such a way as to be false or misleading: *Provided,* That a geographical term which has come into general usage as a trade name and which has been approved by the Administrator as being a generic term may be used without the qualifications provided for in this paragraph. The terms ''frankfurter,'' ''vienna,'' ''bologna,'' ''lebanon bologna,'' ''braunschweiger,'' ''thuringer,'' ''genoa,'' ''leona,'' ''berliner,'' ''holstein,'' ''goteborg,'' ''milan,'' ''polish,'' ''italian,'' and their modifications, as applied to sausages, the terms ''brunswick'' and ''irish'' as applied to stews

and the term ''boston'' as applied to pork shoulder butts need not be accompanied with the word ''style,'' ''type,'' or ''brand,'' or a statement identifying the locality in which the product is prepared.

(2) Such terms as ''farm'' or ''country'' shall not be used on labels in connection with products unless such products are actually prepared on the farm or in the country: *Provided,* That if the product is prepared in the same way as on the farm or in the country these terms, if qualified by the word ''style'' in the same size and style of lettering, may be used: *Provided further,* That the term ''farm'' may be used as part of a brand designation when qualified by the word ''brand'' in the same size and style of lettering, and followed with a statement identifying the locality in which the product is prepared: *And Provided further,* That the provisions of this paragraph shall not apply to products prepared in accordance with § 319.106 of this subchapter. Sausage containing cereal shall not be labeled ''farm style'' or ''country style,'' and lard not rendered in an open kettle shall not be designated as ''farm style'' or ''country style.''

(3) The requirement that the label shall contain the name and place of business of the manufacturer, packer, or distributor shall not relieve any establishment from the requirement that its label shall not be misleading in any particular.

(4) The term ''spring lamb'' or ''genuine spring lamb'' is applicable only to carcasses of new-crop lambs slaughtered during the period beginning in March and terminating not beyond the close of the week containing the first Monday in October.

(5)(i) Coverings shall not be of such color, design, or kind as to be misleading with respect to color, quality, or kind of product to which they are applied. For example, transparent or semitransparent coverings for such articles as sliced bacon or fresh (uncooked) meat and meat food products shall not bear lines or other designs of red or other color which give a false impression of leanness of the product. Transparent or semitransparent wrappers, casings, or coverings for use in packaging cured, cured and smoked, or cured and cooked sausage products, and sliced ready-to-eat meat food products may be color tinted or bear red designs on 50 percent of such wrapper or covering: *Provided,* That the transparent or semitransparent portion of the principal display panel is free of color tinting and red designs: *And provided further,* That the principal display panel provides at least 20 percent unobstructed clear space, consolidated in one area so that the true nature and color of the product is visible to the consumer.

(ii) Packages for sliced bacon that have a transparent opening shall be designed to expose, for viewing, the cut surface of a representative slice. Packages for sliced bacon which meet the following specifications will be accepted as meeting the requirements of this subparagraph provided the enclosed bacon is positioned so that the cut surface of the representative slice can be visually examined:

(*a*) For shingle-packed sliced bacon, the transparent window shall be designed to reveal at least 70 percent of the length (longest dimension) of the representative slice, and this window shall be at least 1½ inches wide. The transparent window shall be located not more than five-eighths inch from the top or bottom edge of a 1-pound or smaller package and not more than three-fourths inch from either the top or bottom edge of a package larger than 1 pound.

(*b*) For stack-packed sliced bacon, the transparent window shall be designed to reveal at least 70 percent of the length (longest dimension) of the representative slice and be at least 1½ inches wide.

(6) The word ''fresh'' shall not be used on labels to designate product which contains any sodium nitrate, sodium nitrite, potassium nitrate, or potassium nitrite, or which has been salted for preservation.

(7)(i) No ingredient shall be designated on the label as a spice, flavoring, or coloring unless it is a spice, flavoring, or coloring, as the case may be. An ingredient that is both a spice and a coloring, or both a flavoring and a coloring, shall be designated as

''spice and coloring'', or ''flavoring and coloring'', as the case may be, unless such ingredient is designated by its common or usual name.

(ii) Any ingredient not designated in § 317.2(f)(1)(i) of this part whose function is flavoring, either in whole or in part, must be designated by its common or usual name. Those ingredients which are of livestock and poultry origin must be designated by names that include the species and livestock and poultry tissues from which the ingredients are derived.

(8) As used on labels of product, the term ''gelatin'' shall mean (i) the jelly prepared in official establishments by cooking pork skins, tendons, or connective tissue from inspected and passed product, and (ii) dry commercial gelatin or the jelly resulting from its use.

(9) Product (other than canned product) labeled with the term ''loaf'' as part of its name:

(i) If distributed from the official establishment in consumer size containers may be in any shape;

(ii) If distributed in a container of a size larger than that sold intact at retail the product shall be prepared in rectangular form, or as in paragraph (b)(9)(iii) of this section;

(iii) If labeled as an ''Old Fashioned Loaf'' shall be prepared in a traditional form, such as rectangular with rounded top or circular with flat bottom and rounded top.

(10) The term ''baked'' shall apply only to product which has been cooked by the direct action of dry heat and for a sufficient time to permit the product to assume the characteristics of a baked article, such as the formation of a brown crust on the surface, rendering out of surface fat, and the caramelization of the sugar if applied. Baked loaves shall be heated to a temperature of at least 160 °F. and baked pork cuts shall be heated to an internal temperature of at least 170 °F.

(11) When products such as loaves are browned by dipping in hot edible oil or by a flame, the label shall state such fact, e.g., by the words ''Browned in Hot Cottonseed Oil'' or ''Browned by a Flame,'' as the case may be, appearing as part of the product name.

(12) The term ''meat'' and the names of particular kinds of meat, such as beef, veal, mutton, lamb, and pork, shall not be used in such manner as to be false or misleading.

(13) The word ''ham,'' without any prefix indicating the species of animal from which derived, shall be used in labeling only in connection with the hind legs of swine. Ham shanks as such or ham shank meat as such or the trimmings accruing in the trimming and shaping of hams shall not be labeled ''ham'' or ''ham meat'' without qualification. When used in connection with a chopped product the term ''ham'' or ''ham meat'' shall not include the skin.

(14) The terms ''shankless'' and ''hockless'' shall apply only to hams and pork shoulders from which the shank or hock has been completely removed, thus eliminating the entire tibia and fibula, or radius and ulna, respectively, together with the overlying muscle, skin, and other tissue.

(15) Such terms as ''meat extract'' or ''extract of beef'' without qualification shall not be used on labels in connection with products prepared from organs or other parts of the carcass, other than fresh meat. Extracts prepared from any parts of the carcass other than fresh meat may be properly labeled as extracts with the true name of the parts from which prepared. In the case of extract in fluid form, the word ''fluid'' shall also appear on the label, as, for example, ''fluid extract of beef.''

(16) [Reserved]

(17) When any product is enclosed in a container along with a packing substance such as brine, vinegar, or agar jelly, a declaration of the packing substance shall be printed prominently on the label as part of the name of the product, as for example, ''frankfurts packed in brine,'' ''lamb tongue packed in vinegar,'' or ''beef tongue packed in agar jelly,'' as the case may be. The packing substance shall not be used in such a manner as will result in the container being so filled as to be misleading.

(18) ''Leaf lard'' is lard prepared from fresh leaf fat.

(19) When lard or hardened lard is mixed with rendered pork fat or hardened rendered pork fat, the mixture

shall be designated as ''rendered pork fat'' or ''hardened rendered pork fat,'' as the case may be.

(20) Oil, stearin, or stock obtained from beef or mutton fats rendered at a temperature above 170 °F. shall not be designated as ''oleo oil,'' ''oleo stearin,'' or ''oleo stock,'' respectively.

(21) When not more than 20 percent of beef fat, mutton fat, oleo stearin, vegetable stearin, or hardened vegetable fat is mixed with lard or with rendered pork fat, there shall appear on the label, contiguous to and in the same size and style of lettering as the name of the product, the words ''beef fat added,'' ''mutton fat added,'' ''oleo stearin added,'' ''vegetable stearin added,'' or ''hardened vegetable fat added,'' as the case may be. If more than 20 percent is added, the product name shall refer to the particular animal fat or fats used, such as, ''Lard and Beef Fat.'' The designation ''vegetable fat'' is applicable to vegetable oil, vegetable stearin, or a combination of such oil and stearin, whereas the designations ''vegetable oil'' and ''vegetable stearin'' shall be applicable only to the oil and the stearin respectively, when used in meat food products.

(22) Cooked, cured, or pickled pigs feet, pigs knuckles, and similar products, shall be labeled to show that the bones remain in the product, if such is the case. The designation ''semi-boneless'' shall not be used if less than 50 percent of the total weight of bones has been removed.

(23) When monoglycerides, diglycerides, and/or polyglycerol esters of fatty acids are added to rendered animal fat or a combination of such fat and vegetable fat, there shall appear on the label in a prominent manner and contiguous to the name of the product a statement such as ''With Monoglycerides and Diglycerides Added,'' or ''With Diglycerides and Monoglycerides,'' or ''With Polyglycerol Esters of Fatty Acids'' as the case may be.

(24) Section 407 of the Federal Food, Drug, and Cosmetic Act contains provisions with respect to colored margarine or colored oleomargarine (21 U.S.C. 347) which are set forth herein as footnote.[1]

[1] ''Sec. 407(a) Colored oleomargarine or colored margarine which is sold in the same State or Territory in which it is produced shall be subject in the same manner and to the same extent to the provisions of this Act as if it had been introduced in interstate commerce.

(b) No person shall sell, or offer for sale, colored oleomargarine or colored margarine unless—

(1) Such oleomargarine or margarine is packaged,

(2) The net weight of the contents of any package sold in a retail establishment is one pound or less,

(3) There appears on the label of the package (A) The word 'oleomargarine' or 'margarine' in type or lettering at least as large as any other type or lettering on such label, and (B) A full and accurate statement of all the ingredients contained in such oleomargarine, or margarine, and

(4) Each part of the contents of the package is contained in a wrapper which bears the word 'oleomargarine' or 'margarine' in type or lettering not smaller than 20-point type.

The requirements of this subsection shall be in addition to and not in lieu of any of the other requirements of this Act.

(c) No person shall possess in a form ready for serving colored oleomargarine or colored margarine at a public eating place unless a notice that oleomargarine or margarine is served is displayed prominently and conspicuously in such place and in such manner as to render it likely to be read and understood by the ordinary individual being served in such eating place or is printed or is otherwise set forth on the menu in type or lettering not smaller than that normally used to designate the serving of other food items. No person shall serve colored oleomargarine or colored margarine at a public eating place, whether or not any charge is made therefor, unless (1) each separate serving bears or is accompanied by labeling identifying it as oleomargarine or margarine, or (2) each separate serving thereof is triangular in shape.

(d) Colored oleomargarine or colored margarine when served with meals at a public eating place shall at the time of such service be exempt from the labeling requirements of section 343 of this Act (except subsection (a) and (f) of section 343 of this title) if it complies with the requirements of subsection (b) of this section.

(e) For the purpose of this section colored oleomargarine or colored margarine is oleomargarine or margarine having a tint or shade containing more than one and six tenths degrees of yellow or of yellow and red

(25) When approved proteolytic enzymes as permitted in part 318 of this subchapter are used on steaks or other raw meat cuts, there shall appear on the label, in a prominent manner, contiguous to the product name, the statement, ''Tenderized with [approved enzyme],'' to indicate the use of such enzymes. Any other approved substance which may be used in the solution shall also be included in the statement.

When approved inorganic chlorides as permitted in part 318 of this subchapter are used on steaks or other raw meat cuts there shall appear on the label in a prominent manner, contiguous to the product name, the statement, ''Tenderized with (names of approved inorganic chloride(s))'' to indicate the use of such inorganic chlorides. Any other approved substance which may be in the solution shall also be included in the statement.

(26) When dimethylpolysiloxan is added as an antifoaming agent to rendered fats, its presence shall be declared on the label contiguous to the name of the product. Such declaration shall read ''Dimethylpolysiloxan Added.''

(27) When pizzas are formulated with crust containing calcium propionate or sodium propionate, there shall appear on the label contiguous to the name of the product the statement ''_____ added to retard spoilage of crust'' preceded by the name of the preservative.

(28) Sausage of the dry varieties treated with potassium sorbate or propylparaben (propyl p-hydroxybenzoate) as permitted by part 318 of this subchapter, shall be marked or labeled with a statement disclosing such treatment and the purpose thereof, such as ''dipped in a potassium sorbate solution to retard mold growth.''

(29) Meat of goats shall be identified as goat meat or chevon.

(30) The term ''Chitterlings'' shall apply to the large intestines of swine, or young bovine animals when preceded with the word ''Calf'' or ''Veal.'' Meat food products that contain chitterlings or calf or veal chitterlings, in accordance with § 318.6(b)(8) of this subchapter shall be identified with product names that refer to such ingredients, as for instance, ''Chitterling Loaf,'' ''Chitterling Pie,'' or ''Calf Chitterlings and Gravy,'' and shall be packed in containers having a capacity of 3 pounds or less and of a kind usually sold at retail intact and bearing such other information as is required by this part.

(31) Products that contain blood from livestock as permitted by part 318 of this subchapter shall be labeled with a name that includes the term ''blood,'' and the specific kind of blood shall be declared in the ingredient statement, e.g., ''Swine blood,'' in the manner required by this part.

(32) A calendar date may be shown on labeling when declared in accordance with the provisions of this subparagraph:

(i) The calendar date shall express the month of the year and the day of the month for all products and also the year in the case of products hermetically sealed in metal or glass containers, dried or frozen products, or any other products that the Administrator finds should be labeled with the year because the distribution and marketing practices with respect to such products may cause a label without a year identification to be misleading.

(ii) Immediately adjacent to the calendar date shall be a phrase explaining the meaning of such date, in terms of ''packing'' date, ''sell by'' date, or ''use before'' date, with or without a further qualifying phrase, e.g., ''For Maximum Freshness'' or ''For Best Quality'', and such phrases shall be approved by the Administrator as prescribed in § 317.4.

(33) [Reserved]

(34) The terms ''All,'' ''Pure,'' ''100%,'' and terms of similar connotation shall not be used on labels for products to identify ingredient content, unless the product is prepared solely from a single ingredient.

(35) When agar-agar is used in canned jellied meat food products, as permitted in part 318 of this subchapter, there shall appear on the label in a prominent manner, contiguous to the product name, a statement to indicate the use of agar-agar.

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collectively, but with an excess of yellow over red, measured in terms of Lovibond tintometer scale or its equivalent'' (21 U.S.C. 347).

(36) When sodium alginate, calcium carbonate, and lactic acid and calcium carbonate (or glucono delta-lactone) are used together in a dry binding matrix in restructured, formed meat food products, as permitted in part 318 of this subchapter, there shall appear on the label contiguous to the product name, a statement to indicate the use of sodium alginate, calcium carbonate and lactic acid and calcium carbonate (or glucono delta-lactone).

(37) The labels of sausages encased in natural casings made from meat or poultry viscera shall identify the type of meat or poultry from which the casings were derived, if the casings are from a different type of meat or poultry than the encased meat or poultry. The identity of the casing, if required, may be placed on the principal display panel or in the ingredient statement. Establishments producing, manufacturing, or using natural sausage casings are to maintain records documenting the meat or poultry source in accordance with part 320 of this chapter.

(38) The labels of sausages encased in regenerated collagen casings shall disclose this fact on the product label. The fact that the sausage is encased in collagen may be placed on the principal display panel or in the ingredient statement.

(39) When transglutaminase enzyme is used to bind pieces of meat to form a cut of meat, or to reform a piece of meat from a multiple cuts, there shall appear on the label, as part of the product name, a statement that indicates that the product has been ''formed'' or ''reformed,'' in addition to other preparation steps, e.g., ''Formed Beef Tenderloin'' or ''Reformed and Shaped Beef Tenderloin.''

(40) Products identified as ''pizza'' that list a meat component as part of the product name must bear a parenthetical statement contiguous to the ingredients statement that conveys the percent of the cooked, cured, or dried meat component in the product. This paragraph shall expire on October 30, 2006.

[35 FR 15580, Oct. 3, 1970]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 317.8, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and on GPO Access.

EFFECTIVE DATE NOTE: At 68 FR 44870, July 31, 2003, § 317.8 was amended by adding paragraph (b)(40), effective Oct. 22, 2003, through Oct. 24, 2006.

§ 317.9 Labeling of equine products.

The immediate containers of any equine products shall be labeled to show the kinds of animals from which derived when the products are sold, transported, offered for sale or transportation or received for transportation in commerce.

§ 317.10 Reuse of official inspection marks; reuse of containers bearing official marks, labels, etc.

(a) No official inspection legend or other official mark which has been previously used shall be used again for the identification of any product, except as provided for in paragraph (b) of this section.

(b) All stencils, marks, labels, or other labeling on previously used containers, whether relating to any product or otherwise, shall be removed or obliterated before such containers are used for any product, unless such labeling correctly indicates the product to be packed therein and such containers are refilled under the supervision of a Program employee.

§ 317.11 Labeling, filling of containers, handling of labeled products to be only in compliance with regulations.

(a) No person shall in any official establishment apply or affix, or cause to be applied or affixed, any label to any product prepared or received in such establishment, or to any container thereof, or fill any container at such an establishment, except in compliance with the regulations in this subchapter.

(b) No covering or other container shall be filled, in whole or in part, at any official establishment with any product unless it has been inspected and passed in compliance with the regulations in this subchapter, is not adulterated, and is strictly in accordance with the statements on the label, and such filling is done under the supervision of a Program employee.

(c) No person shall remove, or cause to be removed from an official establishment any product bearing a label unless such label is in compliance with the regulations in this subchapter, or any product not bearing a label required by such regulations.

§317.12 Relabeling products; requirements.

When it is claimed by an official establishment that any of its products which bore labels bearing official marks has been transported to a location other than an official establishment, and it is desired to relabel the product because the labels have become mutilated or otherwise damaged, a request for relabeling the product shall be sent to the Administrator, accompanied with a statement of the reasons therefor. Labeling material intended for relabeling inspected and passed product shall not be transported from an official establishment until permission has been received from the Administrator. The relabeling of inspected and passed product with labels bearing any official marks shall be done under the supervision of a Program inspector. The official establishment shall reimburse the Program, in accordance with the regulations of the Department, for any cost involved in supervising the relabeling of such product.

§317.13 Storage and distribution of labels and containers bearing official marks.

Labels, wrappers, and containers bearing any official marks, with or without the establishment number, may be transported from one official establishment to any other official establishment provided such shipments are made with the prior authorization of the inspector in charge at point of origin, who will notify the inspector in charge at destination concerning the date of shipment, quantity, and type of labeling material involved. No such material shall be used at the establishment to which it is shipped unless such use conforms with the requirements of this subchapter.

§§317.14–317.15 [Reserved]

§317.16 Labeling and containers of custom prepared products.

Products that are custom prepared under §303.1(a)(2) of this subchapter must be packaged immediately after preparation and must be labeled (in lieu of information otherwise required by this part 317) with the words ''Not For Sale'' in lettering not less than three-eighth inch in height. Such exempted custom prepared products or their containers may bear additional labeling provided such labeling is not false or misleading.

[37 FR 4071, Feb. 26, 1972]

§317.17 Interpretation and statement of labeling policy for cured products; special labeling requirements concerning nitrate and nitrite.

(a) With respect to sections 1(n) (7), (9), and (12) of the Act and §317.2, any substance mixed with another substance to cure a product must be identified in the ingredients statement on the label of such product. For example, curing mixtures composed of such ingredients as water, salt, sugar, sodium phosphate, sodium nitrate, and sodium nitrite or other permitted substances which are added to any product, must be identified on the label of the product by listing each such ingredient in accordance with the provisions of §317.2.

(b) Any product, such as bacon and pepperoni, which is required to be labeled by a common or usual name or descriptive name in accordance with §317.2(c)(1) and to which nitrate or nitrite is permitted or required to be added may be prepared without nitrate or nitrite and labeled with such common or usual name or descriptive name when immediately preceded with the term ''Uncured'' as part of the product name in the same size and style of lettering as the product name, provided that the product is found by the Administrator to be similar in size, flavor, consistency, and general appearance to such product as commonly prepared with nitrate or nitrite, or both.

(c)(1) Products described in paragraph (b) of this section or §319.2 of

this subchapter, which contain no nitrate or nitrite shall bear the statement ''No Nitrate or Nitrite Added.'' This statement shall be adjacent to the product name in lettering of easily readable style and at least one-half the size of the product name.

(2) Products described in paragraph (b) of this section and § 319.2 of this subchapter shall bear, adjacent to the product name in lettering of easily readable style and at least one-half the size of the product name, the statement ''Not Preserved—Keep Refrigerated Below 40 °F. At All Times'' unless they have been thermally processed to F_o 3 or more; they have been fermented or pickled to pH of 4.6 or less; or they have been dried to a water activity of 0.92 or less.

(3) Products described in paragraph (b) of this section and § 319.2 of this subchapter shall not be subject to the labeling requirements of paragraphs (b) and (c) of this section if they contain an amount of salt sufficient to achieve a brine concentration of 10 percent or more.

[37 FR 16863, Aug. 22, 1972, as amended at 44 FR 48961, Aug. 21, 1979]

§ 317.18 Quantity of contents labeling.

Sections 317.18 through 317.22 of this part prescribe the procedures to be followed for determining net weight compliance and prescribe the reasonable variations from the declared net weight on the labels of immediate containers of products in accordance with § 317.2(h) of this part.

[55 FR 49834, Nov. 30, 1990]

§ 317.19 Definitions and procedures for determining net weight compliance.

(a) For the purpose of §§ 317.18 through 317.22 of this part, the reasonable variations allowed, definitions, and procedures to be used in determining net weight and net weight compliance are described in the National Institute of Standards and Technology (NIST) Handbook 133, ''Checking the Net Contents of Packaged Goods,'' Third Edition, September 1988, and Supplements 1, 2, 3, and 4 dated September 1990, October 1991, October 1992, and October 1994, respectively, which are incorporated by reference, with the exception of the NIST Handbook 133 and Supplements 1, 3, and 4 requirements listed in paragraphs (b) and (c) of this section. Those provisions incorporated by reference herein, are considered mandatory requirements. This incorporation was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. (These materials are incorporated as they exist on the date of approval.) A notice of any change in the Handbook cited herein will be published in the FEDERAL REGISTER. Copies may be purchased from the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402. It is also available for inspection at the Office of the Federal Register Information Center, 800 North Capitol Street NW., suite 700, Washington, DC 20408.

(b) The following NBS Handbook 133 requirements are not incorporated by reference.

Chapter 2—General Considerations

2.13.1 Polyethylene Sheeting and Film
2.13.2 Textiles
2.13.3 Mulch

Chapter 3—Methods of Test for Packages Labeled by Weight

3.11. Aerosol Packages
3.14. Glazed Raw Seafood and Fish
3.15. Canned Coffee
3.16. Borax
3.17. Flour

CHAPTER 4—METHODS OF TEST FOR PACKAGES LABELED BY VOLUME

4.7. Milk
4.8. Mayonnaise and Salad Dressing
4.9. Paint, Varnish, and Lacquers—Nonaerosol
4.11. Peat Moss
4.12. Bark Mulch
4.15. Ice Cream Novelties

CHAPTER 5—METHODS OF TEST FOR PACKAGES LABELED BY COUNT, LENGTH, AREA, THICKNESS, OR COMBINATIONS OF QUANTITIES

5.4. Polyethylene Sheeting
5.5. Paper Plates
5.6. Sanitary Paper Products
5.7. Pressed and Blown Glass Tumblers and Stemware

APPENDIX D: PACKAGE NET CONTENTS REGULATIONS

D.1.1. U.S. Department of Health and Human Services, Food and Drug Administration

D.1.2. Department of Agriculture, Food Safety and Inspection Service
D.1.3. Federal Trade Commission
D.1.4. Environmental Protection Agency
D.1.5. U.S. Department of the Treasury, Bureau of Alcohol, Tobacco, and Firearms

(c) The following requirements of Supplement 1, dated September 1990, Supplement 3, dated October 1992, and Supplement 4, dated 1994, of NIST Handbook 133 are not incorporated by reference.

Supplement 1

Chapter 2 General Considerations

2.13.1. Polyethylene Sheeting and Film
2.13.2. Textiles
2.13.3. Mulch

Chapter 3 Methods of Test for Packages Labeled by Weight

3.11.4. Exhausting the Aerosol Container

Chapter 4 Methods of Test for Packages Labeled by Volume

4.6.4. Method D: Determining the Net Contents of Compressed Gas in Cylinders
4.7. Milk
4.16. Fresh Oysters Labeled by Volume

Chapter 5 Methods of Test for Packages Labeled by Count, Length, Area, Thickness, or Combinations of Quantities

5.4. Polyethylene Sheeting

Supplement 3

Chapter 3 Methods of Test for Packages Labeled by Weight

3.17. Flour and Dry Pet Food

Chapter 5 Methods of Test for Packages Labeled by Count, Length, Area, Thickness, or Combination of Quantities

5.4. Polyethylene Sheeting
5.5. Paper Plates
5.8. Baler Twine

Appendix A. Forms and Worksheets

Supplement 4

3.11 Aerosol Packages
3.11.1 Equipment
3.11.2 Preparation for Test
3.11.3 The Determination of Net Contents: Part 1
3.11.4 Exhausting the Aerosol Container
3.11.5 The Determination of Net Contents: Part 2

Appendix A. Report Forms

[55 FR 49834, Nov. 30, 1990, as amended at 60 FR 12884, March 9, 1995]

§317.20 Scale requirements for accurate weights, repairs, adjustments, and replacement after inspection.

(a) All scales used to weigh meat products sold or otherwise distributed in commerce in federally inspected meat establishments shall be installed, maintained and operated to insure accurate weights. Such scales shall meet the applicable requirements contained in National Institute of Standards and Technology Handbook 44, ''Specifications, Tolerances, and Other Technical Requirements for Weighing and Measuring Devices'', 1999 Edition, November 1998, which is incorporated by reference. This incorporation was approved by the Director of the Federal Register in accordance with 5 U.S.C.. 552(a) and 1 CFR part 51. (These materials are incorporated as they exist on the date of approval.) Copies may be purchased from the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402. It is also available for inspection at the Office of the Federal Register Information Center, 800 North Capitol Street NW., suite 700, Washington, DC 20408.

(b) All scales used to weigh meat products sold or otherwise distributed in commerce or in States designated under section 301(c) of the Federal Meat Inspection Act, shall be of sufficient capacity to weigh the entire unit and/or package.

(c) No scale shall be used at a federally inspected establishment to weigh meat products unless it has been found upon test and inspection, as specified in NIST Handbook 44, to provide accurate weight. If a scale is reinspected or retested and found to be inaccurate, or if any repairs, adjustments or replacements are made to a scale, it shall not be used until it has been inspected and tested by a USDA official, or a State or local government weights and measures official, or State registered or licensed scale repair firm or person, and it must meet all accuracy requirements as specified in NIST Handbook 44. If a USDA inspector has put a retain tag on a scale it can only be removed by a USDA inspector. As long as the tag is on the scale, it shall not be used.

[55 FR 49834, Nov. 30, 1990, as amended at 60 FR 12884, Mar. 9, 1995; 64 FR 53187, Oct. 1, 1999]

§ 317.21 Scales: testing of.

(a) The operator of each official establishment that weighs meat food products shall cause such scales to be tested for accuracy, in accordance with the technical requirements of NIST Handbook 44, at least once during the calendar year. In cases where the scales are found not to maintain accuracy between tests, more frequent tests may be required and monitored by an authorized USDA program official.

(b) The operator of each official establishment shall display on or near each scale a valid certification of the scale's accuracy from a State or local government's weights and measures authority or from a State registered or licensed scale repair firm or person, or shall have alternative documented procedures showing that the scale has been tested for accuracy in accordance with the requirements of NIST Handbook 44.

[55 FR 49834, Nov. 30, 1990, as amended at 62 FR 45024, Aug. 25, 1997; 65 FR 34389, May 30, 2000; 66 FR 52486, Oct. 16, 2001]

§ 317.22 Handling of failed product.

Any lot of product which is found to be out of compliance with net weight requirements upon testing in accordance with § 317.19 shall be handled as follows:

(a) A lot tested in an official establishment and found not to comply with net weight requirements may be reprocessed and must be reweighed and remarked to satisfy the net weight requirements of this section and be reinspected, in accordance with the requirements of this part.

(b) A lot tested outside of an official establishment and found not to comply with net weight requirements must be reweighed and remarked with a proper net weight statement, provided that such reweighing and remarking shall not deface, cover, or destroy any other marking or labeling required under this subchapter and the net quantity of contents is shown with the same prominence as the most conspicuous feature of a label.

[55 FR 49834, Nov. 30, 1990]

§ 317.23 [Reserved]

§ 317.24 Packaging materials.

(a) Edible products may not be packaged in a container which is composed in whole or in part of any poisonous or deleterious substances which may render the contents adulterated or injurious to health. All packaging materials must be safe for their intended use within the meaning of section 409 of the Federal Food, Drug, and Cosmetic Act, as amended (FFDCA).

(b) Packaging materials entering the official establishment must be accompanied or covered by a guaranty, or statement of assurance, from the packaging supplier under whose brand name and firm name the material is marketed to the official establishment. The guaranty shall state that the material's intended use complies with the FFDCA and all applicable food additive regulations. The guaranty must identify the material, e.g., by the distinguishing brand name or code designation appearing on the packaging material shipping container; must specify the applicable conditions of use, including temperature limits and any other pertinent limits specified under the FFDCA and food additive regulations; and must be signed by an authorized official of the supplying firm. The guaranty may be limited to a specific shipment of an article, in which case it may be part of or attached to the invoice covering such shipment, or it may be general and continuing, in which case, in its application to any article or other shipment of an article, it shall be considered to have been given at the date such article was shipped by the person who gives the guaranty. Guaranties consistent with the Food and Drug Administration's regulations regarding such guaranties (21 CFR 7.12 and 7.13) will be acceptable. The management of the establishment must maintain a file containing guaranties for all food contact packaging materials in the establishment. The file shall be made available to Program inspectors or other Department officials upon request. While in the official establishment, the identity of all packaging materials must be traceable to the applicable guaranty.

(c) The guaranty by the packaging supplier will be accepted by Program inspectors to establish that the use of material complies with the FFDCA and all applicable food additive regulations.

(d) The Department will mmnitor the use of packaging material in official establishments to assure that the requirements of paragraph (a) of this section are met, and may question the basis for any guaranty described under paragraph (b) of this section. Official establishments and packaging suppliers providing written guaranties to those official establishments will be permitted an opportunity to provide information tm designated Department officials as needed to verify the basis for any such guaranty. The required information will include, but is not limited to, manufacturing firm's name, trade name or code designation for the material, complete chemical composition, and use. Selection of a material for review does not in itself affect a material's acceptability. Materials may continue to be used during the review period. However, if information requested from the supplier is not provided within the time indicated in the request—a minimum of 30 days—any applicable guaranty shall cease to be effective, and approval to continue using the specified packaging material in official establishments may be denied. The Administrator may extend this time where reasonable grounds for extension are shown, as, for example, where data must be obtained from suppliers.

(e) The Administrator may disapprove for use in official establishmelts packaging materials whose use cannot be confirmed as complying with FFDCA and applicable food additive regulations. Before approval to use a packaging material is finally denied by the Administrator, the affected official establishment and the supplier of the material shall be given notice and the opportunity to present their views to the Administrator. If the official establishment and the supplier do not accept the Administrator's determination, a hearing in accordance with applicable rules of practice will be held to resolve such dispute. Approval to use the materials pending the outcome of the presentation of views or hearing shall be denied if the Administrator determines that such use may present an imminent hazard to public health.

(f) Periodically, the Administrator will issue to inspectors a listing, by distinguishing brand name or code designation, of packaging materials that have been reviewed and that fail to meet the requirements of paragraph (a) of this section. Listed materials will not be permitted for use in official establishments. If a subsequent review of any material indicates that it meets the requirements of paragraph (a), the material will be deleted from the listing.

(g) Nothing in this section shall affect the authority of Program inspectors to refuse a specific material if he/she determines the material may render products adulterated or injurious to health.

[49 FR 2235, Jan. 19, 1984. Redesignated at 55 FR 49833, Nov. 30, 1990]

Subpart B—Nutrition Labeling

SOURCE: 58 FR 664, Jan. 6, 1993, unless otherwise noted.

§ 317.300 Nutrition labeling of meat or meat food products.

(a) Nutrition labeling shall be provided for all meat or meat food products intended for human consumption and offered for sale, except single-ingredient, raw products, in accordance with the requirements of § 317.309; except as exempted under § 317.400 of this subpart.

(b) Nutrition labeling may be provided for single-ingredient, raw meat or meat food products in accordance with the requirements of §§ 317.309 and 317.345. Significant participation in voluntary nutrition labeling shall be measured by the Agency in accordance with §§ 317.343 and 317.344 of this subpart.

[58 FR 664, Jan. 6, 1993, as amended at 60 FR 176, Jan. 3, 1995]

§ 317.301 [Reserved]

§ 317.302 Location of nutrition information.

(a) Nutrition information on a label of a packaged meat or meat food product shall appear on the label's principal display panel or on the information panel, except as provided in paragraphs (b) and (c) of this section.

(b) Nutrition information for gift packs may be shown at a location other than on the product label, provided that the labels for these products bear no nutrition claim. In lieu of on the product label, nutrition information may be provided by alternate means such as product label inserts.

(c) Meat or meat food products in packages that have a total surface area available to bear labeling greater than 40 square inches but whose principal display panel and information panel do not provide sufficient space to accommodate all required information may use any alternate panel that can be readily seen by consumers for the nutrition information. In determining the sufficiency of available space for the nutrition information, the space needed for vignettes, designs, and other nonmandatory label information on the principal display panel may be considered.

[58 FR 664, Jan. 6, 1993, as amended at 59 FR 40213, Aug. 8, 1994; 60 FR 176, Jan. 3, 1995]

§§ 317.303–317.307 [Reserved]

§ 317.308 Labeling of meat or meat food products with number of servings.

The label of any package of a meat or meat food product that bears a representation as to the number of servings contained in such package shall meet the requirements of § 317.2(h)(10).

[58 FR 664, Jan. 6, 1993, as amended at 60 FR 176, Jan. 3, 1995]

§ 317.309 Nutrition label content.

(a) All nutrient and food component quantities shall be declared in relation to a serving as defined in this section.

(b)(1) The term ''serving'' or ''serving size'' means an amount of food customarily consumed per eating occasion by persons 4 years of age or older, which is expressed in a common household measure that is appropriate to the product. When the product is specially formulated or processed for use by infants or by toddlers, a serving or serving size means an amount of food customarily consumed per eating occasion by infants up to 12 months of age or by children 1 through 3 years of age, respectively.

(2) Except as provided in paragraphs (b)(8), (b)(12), and (b)(14) of this section and for products that are intended for weight control and are available only through a weight-control or weight-maintenance program, serving size declared on a product label shall be determined from the ''Reference Amounts Customarily Consumed Per Eating Occasion—General Food Supply'' (Reference Amount(s)) that appear in § 317.312(b) using the procedures described in this paragraph (b). For products that are both intended for weight control and available only through a weight-control program, a manufacturer may determine the serving size that is consistent with the meal plan of the program. Such products must bear a statement, ''for sale only through the _____ program'' (fill in the blank with the name of the appropriate weight-control program, e.g., Smith's Weight Control), on the principal display panel. However, the Reference Amounts in § 317.312(b) shall be used for purposes of evaluating whether weight-control products that are available only through a weight-control program qualify for nutrition claims.

(3) The declaration of nutrient and food component content shall be on the basis of the product ''as packaged'' for all products, except that single-ingredient, raw products may be declared on the basis of the product ''as consumed'' as set forth in § 317.345(a)(1). In addition to the required declaration on the basis of ''as packaged'' for products other than single-ingredient, raw products, the declaration may also be made on the basis of ''as consumed,'' provided that preparation and cooking instructions are clearly stated.

(4) For products in discrete units (e.g., hot dogs, and individually packaged products within a multi-serving package), and for products which consist of two or more foods packaged and

presented to be consumed together where the ingredient represented as the main ingredient is in discrete units (e.g., beef fritters and barbecue sauce), the serving size shall be declared as follows:

(i) If a unit weighs 50 percent or less of the Reference Amount, the serving size shall be the number of whole units that most closely approximates the Reference Amount for the product category.

(ii) If a unit weighs more than 50 percent but less than 67 percent of the Reference Amount, the manufacturer may declare one unit or two units as the serving size.

(iii) If a unit weighs 67 percent or more but less than 200 percent of the Reference Amount, the serving size shall be one unit.

(iv) If a unit weighs 200 percent or more of the Reference Amount, the manufacturer may declare one unit as the serving size if the whole unit can reasonably be consumed at a single eating occasion.

(v) For products that have Reference Amounts of 100 grams (or milliliter) or larger and are individual units within a multi-serving package, if a unit contains more than 150 percent but less than 200 percent of the Reference Amount, the manufacturer may decide whether to declare the individual unit as 1 or 2 servings.

(vi) For products which consist of two or more foods packaged and presented to be consumed together where the ingredient represented as the main ingredient is in discrete units (e.g., beef fritters and barbecue sauce), the serving size may be the number of discrete units represented as the main ingredient plus proportioned minor ingredients used to make the Reference Amount for the combined product as determined in § 317.312(c).

(vii) For packages containing several individual single-serving containers, each of which is labeled with all required information including nutrition labeling as specified in this section (i.e., are labeled appropriately for individual sale as single-serving containers), the serving size shall be 1 unit.

(5) For products in large discrete units that are usually divided for consumption (e.g., pizza), for unprepared products where the entire contents of the package is used to prepare large discrete units that are usually divided for consumption (e.g. pizza kit), and for products which consist of two or more foods packaged and presented to be consumed together where the ingredient represented as the main ingredient is a large discrete unit usually divided for consumption, the serving size shall be the fractional slice of the ready-to-eat product (e.g., ⅛ quiche, ¼ pizza) that most closely approximates the Reference Amount for the product category. The serving size may be the fraction of the package used to make the Reference Amount for the unprepared product determined in § 317.312(d) or the fraction of the large discrete unit represented as the main ingredient plus proportioned minor ingredients used to make the Reference Amount of the combined product determined in § 317.312(c). In expressing the fractional slice, manufacturers shall use ½, ⅓, ¼, ⅕, ⅙, or smaller fractions that can be generated by further division by 2 or 3.

(6) For nondiscrete bulk products (e.g., whole roast beef, marinated beef tenderloin, large can of chili), and for products which consist of two or more foods packaged and presented to be consumed together where the ingredient represented as the main ingredient is a bulk product (e.g., roast beef and gravy), the serving size shall be the amount in household measure that most closely approximates the Reference Amount for the product category and may be the amount of the bulk product represented as the main ingredient plus proportioned minor ingredients used to make the Reference Amount for the combined product determined in § 317.312(c).

(7) For labeling purposes, the term ''common household measure'' or ''common household unit'' means cup, tablespoon, teaspoon, piece, slice, fraction (e.g., ¼ pizza), ounce (oz), or other common household equipment used to package food products (e.g., jar or tray). In expressing serving size in household measures, except as specified in paragraphs (b)(7)(iv), (v), and (vi) of this section, the following rules shall be used:

(i) Cups, tablespoons, or teaspoons shall be used wherever possible and appropriate. Cups shall be expressed in ¼- or ⅓-cup increments, tablespoons in whole number of tablespoons for quantities less than ¼ cup but greater than or equal to 2 tablespoons (tbsp), 1, 1⅓, 1½, or 1 ⅔ tbsp for quantities less than 2 tbsp but greater than or equal to 1 tbsp, and teaspoons in whole number of teaspoons for quantities less than 1 tbsp but greater than or equal to 1 teaspoon (tsp), and in ¼-tsp increments for quantities less than 1 tsp.

(ii) If cups, tablespoons or teaspoons are not applicable, units such as piece, slice, tray, jar, and fraction shall be used.

(iii) If cups, tablespoons and teaspoons, or units such as piece, slice, tray, jar, or fraction are not applicable, ounces may be used. Ounce measurements shall be expressed in 0.5-ounce increments most closely approximating the Reference Amount with rounding indicated by the use of the term ''about'' (e.g., about 2.5 ounces).

(iv) A description of the individual container or package shall be used for single-serving containers and meal-type products and for individually packaged products within multi-serving containers (e.g., can, box, package, meal, or dinner). A description of the individual unit shall be used for other products in discrete units (e.g., chop, slice, link, or patty).

(v) For unprepared products where the entire contents of the package is used to prepare large discrete units that are usually divided for consumption (e.g., pizza kit), the fraction or portion of the package may be used.

(vi) For products that consist of two or more distinct ingredients or components packaged and presented to be consumed together (e.g., ham with a glaze packet), the nutrition information may be declared for each component or as a composite. The serving size may be provided in accordance with the provisions of paragraphs (b)(4), (b)(5), and (b)(6) of this section.

(vii) For nutrition labeling purposes, a teaspoon means 5 milliliters (mL), a tablespoon means 15 mL, a cup means 240 mL, and 1 oz in weight means 28 grams (g).

(viii) When a serving size, determined from the Reference Amount in § 317.312(b) and the procedures described in this section, falls exactly half way between two serving sizes (e.g., 2.5 tbsp), manufacturers shall round the serving size up to the next incremental size.

(8) A product that is packaged and sold individually and that contains less than 200 percent of the applicable Reference Amount shall be considered to be a single-serving container, and the entire content of the product shall be labeled as one serving, except for products that have Reference Amounts of 100 g (or mL) or larger, manufacturers may decide whether a package that contains more than 150 percent but less than 200 percent of the Reference Amount is 1 or 2 servings. Packages sold individually that contain 200 percent or more of the applicable Reference Amount may be labeled as a single-serving if the entire content of the package can reasonably be consumed at a single-eating occasion.

(9) A label statement regarding a serving shall be the serving size expressed in common household measures as set forth in paragraphs (b)(2) through (b)(8) of this section and shall be followed by the equivalent metric quantity in parenthesis (fluids in milliliters and all other foods in grams), except for single-serving containers.

(i) For a single-serving container, the parenthetical metric quantity, which will be presented as part of the net weight statement on the principal display panel, is not required except where nutrition information is required on a drained weight basis according to paragraph (b)(11) of this section. However, if a manufacturer voluntarily provides the metric quantity on products that can be sold as single-servings, then the numerical value provided as part of the serving size declaration must be identical to the metric quantity declaration provided as part of the net quantity of contents statement.

(ii) The gram or milliliter quantity equivalent to the household measure should be rounded to the nearest whole number except for quantities that are less than 5 g (mL). The gram (mL) quantity between 2 and 5 g (mL) should

be rounded to the nearest 0.5 g (mL) and the g (mL) quantity less than 2 g (mL) should be expressed in 0.1-g (mL) increments.

(iii) In addition, serving size may be declared in ounce, in parenthesis, following the metric measure separated by a slash where other common household measures are used as the primary unit for serving size, e.g., 1 slice (28 g/1 oz) for sliced bologna. The ounce quantity equivalent to the metric quantity should be expressed in 0.1-oz increments.

(iv) If a manufacturer elects to use abbreviations for units, the following abbreviations shall be used: tbsp for tablespoon, tsp for teaspoon, g for gram, mL for milliliter, and oz for ounce.

(10) Determination of the number of servings per container shall be based on the serving size of the product determined by following the procedures described in this section.

(i) The number of servings shall be rounded to the nearest whole number except for the number of servings between 2 and 5 servings and random weight products. The number of servings between 2 and 5 servings shall be rounded to the nearest 0.5 serving. Rounding should be indicated by the use of the term ''about'' (e.g., about 2 servings; about 3.5 servings).

(ii) When the serving size is required to be expressed on a drained solids basis and the number of servings varies because of a natural variation in unit size (e.g., pickled pigs feet), the manufacturer may state the typical number of servings per container (e.g., usually 5 servings).

(iii) For random weight products, a manufacturer may declare ''varied'' for the number of servings per container provided the nutrition information is based on the Reference Amount expressed in ounces. The manufacturer may provide the typical number of servings in parenthesis following the ''varied'' statement (e.g., varied (approximately 8 servings per pound)).

(iv) For packages containing several individual single-serving containers, each of which is labeled with all required information including nutrition labeling as specified in this section (i.e., are labeled appropriately for individual sale as single-serving containers), the number of servings shall be the number of individual packages within the total package.

(v) For packages containing several individually packaged multi-serving units, the number of servings shall be determined by multiplying the number of individual multi-serving units in the total package by the number of servings in each individual unit.

(11) The declaration of nutrient and food component content shall be on the basis of product as packaged or purchased with the exception of products that are packed or canned in water, brine, or oil but whose liquid packing medium is not customarily consumed. Declaration of the nutrient and food component content of products that are packed in liquid which is not customarily consumed shall be based on the drained solids.

(12) Serving size for meal-type products as defined in § 317.313(l) shall be the entire content (edible portion only) of the package.

(13) Another column of figures may be used to declare the nutrient and food component information in the same format as required by § 317.309(e),

(i) Per 100 grams, 100 milliliters, or 1 ounce of the product as packaged or purchased.

(ii) Per one unit if the serving size of a product in discrete units in a multi-serving container is more than one unit.

(14) If a product consists of assortments of meat or meat food products (e.g., variety packs) in the same package, nutrient content shall be expressed on the entire package contents or on each individual product.

(15) If a product is commonly combined with other ingredients or is cooked or otherwise prepared before eating, and directions for such combination or preparations are provided, another column of figures may be used to declare the nutrient contents on the basis of the product as consumed for the product alone (e.g., a cream soup mix may be labeled with one set of Daily Values for the dry mix (per serving), and another set for the serving of the final soup when prepared (e.g., per serving of cream soup mix and 1 cup of vitamin D fortified whole milk)): *Provided,* That the type and quantity of

the other ingredients to be added to the product by the user and the specific method of cooking and other preparation shall be specified prominently on the label.

(c) The declaration of nutrition information on the label or in labeling of a meat or meat food product shall contain information about the level of the following nutrients, except for those nutrients whose inclusion, and the declaration of amounts, is voluntary as set forth in this paragraph. No nutrients or food components other than those listed in this paragraph as either mandatory or voluntary may be included within the nutrition label. Except as provided for in paragraph (f) or (g) of this section, nutrient information shall be presented using the nutrient names specified and in the following order in the formats specified in paragraph (d) or (e) of this section.

(1) ''Calories, total,'' ''Total calories,'' or ''Calories'': A statement of the caloric content per serving, expressed to the nearest 5-calorie increment up to and including 50 calories, and 10-calorie increment above 50 calories, except that amounts less than 5 calories may be expressed as zero. Energy content per serving may also be expressed in kilojoule units, added in parenthesis immediately following the statement of the caloric content.

(i) Caloric content may be calculated by the following methods. Where either specific or general food factors are used, the factors shall be applied to the actual amount (i.e., before rounding) of food components (e.g., fat, carbohydrate, protein, or ingredients with specific food factors) present per serving.

(A) Using specific Atwater factors (i.e., the Atwater method) given in Table 13, page 25, ''Energy Value of Foods—Basis and Derivation,'' by A. L. Merrill and B. K. Watt, United States Department of Agriculture (USDA), Agriculture Handbook No. 74 (Slightly revised February 1973), which is incorporated by reference. Table 13 of the ''Energy Value of Foods—Basis and Derivation,'' Agriculture Handbook No. 74 is incorporated as it exists on the date of approval. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. It is available for inspection at the Office of the Federal Register, suite 700, 800 North Capitol Street, NW., Washington, DC, or at the office of the FSIS Docket Clerk, Room 3171, South Building, 14th and Independence Avenue, SW., Washington, DC. Copies of the incorporation by reference are available from the Product Assessment Division, Regulatory Programs, Food Safety and Inspection Service, U.S. Department of Agriculture, Room 329, West End Court Building, Washington, DC 20250–3700;

(B) Using the general factors of 4, 4, and 9 calories per gram for protein, total carbohydrate, and total fat, respectively, as described in USDA's Agriculture Handbook No. 74 (Slightly revised February 1973), pages 9–11, which is incorporated by reference. Pages 9–11, Agriculture Handbook No. 74 is incorporated as it exists on the date of approval. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. (The availability of this incorporation by reference is given in paragraph (c)(1)(i)(A) of this section.);

(C) Using the general factors of 4, 4, and 9 calories per gram for protein, total carbohydrate less the amount of insoluble dietary fiber, and total fat, respectively, as described in USDA's Agriculture Handbook No. 74 (Slightly revised February 1973), pages 9–11, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. (The availability of this incorporation by reference is given in paragraph (c)(1)(i)(A) of this section.); or

(D) Using data for specific food factors for particular foods or ingredients approved by the Food and Drug Administration (FDA) and provided in parts 172 or 184 of 21 CFR, or by other means, as appropriate.

(ii) ''Calories from fat'': A statement of the caloric content derived from total fat as defined in paragraph (c)(2) of this section per serving, expressed to the nearest 5-calorie increment, up to and including 50 calories, and the nearest 10-calorie increment above 50 calories, except that label declaration of ''calories from fat'' is not required on products that contain less than 0.5

gram of fat per serving and amounts less than 5 calories may be expressed as zero. This statement shall be declared as provided in paragraph (d)(5) of this section.

(iii) ''Calories from saturated fat'' or ''Calories from saturated'' (VOLUNTARY): A statement of the caloric content derived from saturated fat as defined in paragraph (c)(2)(i) of this section per serving may be declared voluntarily, expressed to the nearest 5-calorie increment, up to and including 50 calories, and the nearest 10-calorie increment above 50 calories, except that amounts less than 5 calories may be expressed as zero. This statement shall be indented under the statement of calories from fat as provided in paragraph (d)(5) of this section.

(2) ''Fat, total'' or ''Total fat'': A statement of the number of grams of total fat per serving defined as total lipid fatty acids and expressed as triglycerides. Amounts shall be expressed to the nearest 0.5 (½)-gram increment below 5 grams and to the nearest gram increment above 5 grams. If the serving contains less than 0.5 gram, the content shall be expressed as zero.

(i) ''Saturated fat'' or ''Saturated'': A statement of the number of grams of saturated fat per serving defined as the sum of all fatty acids containing no double bonds, except that label declaration of saturated fat content information is not required for products that contain less than 0.5 gram of total fat per serving if no claims are made about fat or cholesterol content, and if ''calories from saturated fat'' is not declared. Saturated fat content shall be indented and expressed as grams per serving to the nearest 0.5 (½)-gram increment below 5 grams and to the nearest gram increment above 5 grams. If the serving contains less than 0.5 gram, the content shall be expressed as zero.

(A) ''Stearic Acid'' (VOLUNTARY): A statement of the number of grams of stearic acid per serving may be declared voluntarily, except that when a claim is made about stearic acid, label declaration shall be required. Stearic acid content shall be indented under saturated fat and expressed to the nearest 0.5 (½)-gram increment below 5 grams and the nearest gram increment above 5 grams. If the serving contains less than 0.5 gram, the content shall be expressed as zero.

(B) [Reserved]

(ii) ''Polyunsaturated fat'' or ''Polyunsaturated'' (VOLUNTARY): A statement of the number of grams of polyunsaturated fat per serving defined as *cis,cis*-methylene-interrupted polyunsaturated fatty acids may be declared voluntarily, except that when monounsaturated fat is declared, or when a claim about fatty acids or cholesterol is made on the label or in labeling of a product other than one that meets the criteria in § 317.362(b)(1) for a claim for ''fat free,'' label declaration of polyunsaturated fat is required. Polyunsaturated fat content shall be indented and expressed as grams per serving to the nearest 0.5 (½)-gram increment below 5 grams and to the nearest gram increment above 5 grams. If the serving contains less than 0.5 gram, the content shall be expressed as zero.

(iii) ''Monounsaturated fat'' or ''Monounsaturated'' (VOLUNTARY): A statement of the number of grams of monounsaturated fat per serving defined as *cis*-monounsaturated fatty acids may be declared voluntarily, except that when polyunsaturated fat is declared, or when a claim about fatty acids or cholesterol is made on the label or in labeling of a product other than one that meets the criteria in § 317.362(b)(1) for a claim for ''fat free,'' label declaration of monounsaturated fat is required. Monounsaturated fat content shall be indented and expressed as grams per serving to the nearest 0.5 (½)-gram increment below 5 grams and to the nearest gram increment above 5 grams. If the serving contains less than 0.5 gram, the content shall be expressed as zero.

(3) ''Cholesterol'': A statement of the cholesterol content per serving expressed in milligrams to the nearest 5-milligram increment, except that label declaration of cholesterol information is not required for products that contain less than 2 milligrams of cholesterol per serving and make no claim about fat, fatty acids, or cholesterol content, or such products may state the cholesterol content as zero. If the product contains 2 to 5 milligrams of cholesterol per serving, the content

may be stated as ''less than 5 milligrams.''

(4) ''Sodium'': A statement of the number of milligrams of sodium per serving expressed as zero when the serving contains less than 5 milligrams of sodium, to the nearest 5-milligram increment when the serving contains 5 to 140 milligrams of sodium, and to the nearest 10-milligram increment when the serving contains greater than 140 milligrams.

(5) ''Potassium'' (VOLUNTARY): A statement of the number of milligrams of potassium per serving may be declared voluntarily, except that when a claim is made about potassium content, label declaration shall be required. Potassium content shall be expressed as zero when the serving contains less than 5 milligrams of potassium, to the nearest 5-milligram increment when the serving contains 5 to 140 milligrams of potassium, and to the nearest 10-milligram increment when the serving contains greater than 140 milligrams.

(6) ''Carbohydrate, total'' or ''Total carbohydrate'': A statement of the number of grams of total carbohydrate per serving expressed to the nearest gram, except that if a serving contains less than 1 gram, the statement ''Contains less than 1 gram'' or ''less than 1 gram'' may be used as an alternative, or, if the serving contains less than 0.5 gram, the content may be expressed as zero. Total carbohydrate content shall be calculated by subtraction of the sum of the crude protein, total fat, moisture, and ash from the total weight of the product. This calculation method is described in USDA's Agriculture Handbook No. 74 (Slightly revised February 1973), pages 2 and 3, which is incorporated by reference. Pages 2 and 3, Agriculture Handbook No. 74 is incorporated as it exists on the date of approval. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. (The availability of this incorporation by reference is given in paragraph (c)(1)(i)(A) of this section.)

(i) ''Dietary fiber'': A statement of the number of grams of total dietary fiber per serving, indented and expressed to the nearest gram, except that if a serving contains less than 1 gram, declaration of dietary fiber is not required, or, alternatively, the statement ''Contains less than 1 gram'' or ''less than 1 gram'' may be used, and if the serving contains less than 0.5 gram, the content may be expressed as zero.

(A) ''Soluble fiber'' (VOLUNTARY): A statement of the number of grams of soluble dietary fiber per serving may be declared voluntarily except when a claim is made on the label or in labeling about soluble fiber, label declaration shall be required. Soluble fiber content shall be indented under dietary fiber and expressed to the nearest gram, except that if a serving contains less than 1 gram, the statement ''Contains less than 1 gram'' or ''less than 1 gram'' may be used as an alternative, and if the serving contains less than 0.5 gram, the content may be expressed as zero.

(B) ''Insoluble fiber'' (VOLUNTARY): A statement of the number of grams of insoluble dietary fiber per serving may be declared voluntarily except when a claim is made on the label or in labeling about insoluble fiber, label declaration shall be required. Insoluble fiber content shall be indented under dietary fiber and expressed to the nearest gram, except that if a serving contains less than 1 gram, the statement ''Contains less than 1 gram'' or ''less than 1 gram'' may be used as an alternative, and if the serving contains less than 0.5 gram, the content may be expressed as zero.

(ii) ''Sugars'': A statement of the number of grams of sugars per serving, except that label declaration of sugars content is not required for products that contain less than 1 gram of sugars per serving if no claims are made about sweeteners, sugars, or sugar alcohol content. Sugars shall be defined as the sum of all free mono- and disaccharides (such as glucose, fructose, lactose, and sucrose). Sugars content shall be indented and expressed to the nearest gram, except that if a serving contains less than 1 gram, the statement ''Contains less than 1 gram'' or ''less than 1 gram'' may be used as an alternative, and if the serving contains less than 0.5 gram, the content may be expressed as zero.

(iii) ''Sugar alcohol'' (VOLUNTARY): A statement of the number of grams of sugar alcohols per serving may be declared voluntarily on the label, except that when a claim is made on the label or in labeling about sugar alcohol or sugars when sugar alcohols are present in the product, sugar alcohol content shall be declared. For nutrition labeling purposes, sugar alcohols are defined as the sum of saccharide derivatives in which a hydroxyl group replaces a ketone or aldehyde group and whose use in the food is listed by FDA (e.g., mannitol or xylitol) or is generally recognized as safe (e.g., sorbitol). In lieu of the term ''sugar alcohol,'' the name of the specific sugar alcohol (e.g., ''xylitol'') present in the product may be used in the nutrition label, provided that only one sugar alcohol is present in the product. Sugar alcohol content shall be indented and expressed to the nearest gram, except that if a serving contains less than 1 gram, the statement ''Contains less then 1 gram'' or ''less than 1 gram'' may be used as an alternative, and if the serving contains less than 0.5 gram, the content may be expressed as zero.

(iv) ''Other carbohydrate'' (VOLUNTARY): A statement of the number of grams of other carbohydrate per serving may be declared voluntarily. Other carbohydrate shall be defined as the difference between total carbohydrate and the sum of dietary fiber, sugars, and sugar alcohol, except that if sugar alcohol is not declared (even if present), it shall be defined as the difference between total carbohydrate and the sum of dietary fiber and sugars. Other carbohydrate content shall be indented and expressed to the nearest gram, except that if a serving contains less than 1 gram, the statement ''Contains less than 1 gram'' or ''less than 1 gram'' may be used as an alternative, and if the serving contains less than 0.5 gram, the content may be expressed as zero.

(7) ''Protein'': A statement of the number of grams of protein per serving expressed to the nearest gram, except that if a serving contains less than 1 gram, the statement ''Contains less than 1 gram'' or ''less than 1 gram'' may be used as an alternative, and if the serving contains less than 0.5 gram, the content may be expressed as zero. When the protein in products represented or purported to be for adults and children 4 or more years of age has a protein quality value that is a protein digestibility-corrected amino acid score of less than 20 expressed as a percent, or when the protein in a product represented or purported to be for children greater than 1 but less than 4 years of age has a protein quality value that is a protein digestibility-corrected amino acid score of less than 40 expressed as a percent, either of the following shall be placed adjacent to the declaration of protein content by weight: The statement ''not a significant source of protein,'' or a listing aligned under the column headed ''Percent Daily Value'' of the corrected amount of protein per serving, as determined in paragraph (c)(7)(ii) of this section, calculated as a percentage of the Daily Reference Value (DRV) or Reference Daily Intake (RDI), as appropriate, for protein and expressed as percent of Daily Value. When the protein quality in a product as measured by the Protein Efficiency Ratio (PER) is less than 40 percent of the reference standard (casein) for a product represented or purported to be for infants, the statement ''not a significant source of protein'' shall be placed adjacent to the declaration of protein content. Protein content may be calculated on the basis of the factor of 6.25 times the nitrogen content of the food as determined by appropriate methods of analysis in accordance with § 317.309(h), except when the procedure for a specific food requires another factor.

(i) A statement of the corrected amount of protein per serving, as determined in paragraph (c)(7)(ii) of this section, calculated as a percentage of the RDI or DRV for protein, as appropriate, and expressed as percent of Daily Value, may be placed on the label, except that such a statement shall be given if a protein claim is made for the product, or if the product is represented or purported to be for infants or children under 4 years of age. When such a declaration is provided, it shall be placed on the label adjacent to the statement of grams of protein and aligned under the column headed ''Percent Daily Value,'' and expressed

to the nearest whole percent. However, the percentage of the RDI for protein shall not be declared if the product is represented or purported to be for infants and the protein quality value is less than 40 percent of the reference standard.

(ii) The corrected amount of protein (grams) per serving for products represented or purported to be for adults and children 1 or more years of age is equal to the actual amount of protein (grams) per serving multiplied by the amino acid score corrected for protein digestibility. If the corrected score is above 1.00, then it shall be set at 1.00. The protein digestibility-corrected amino acid score shall be determined by methods given in sections 5.4.1, 7.2.1, and 8 in ''Protein Quality Evaluation, Report of the Joint FAO/WHO Expert Consultation on Protein Quality Evaluation,'' Rome, 1990, which is incorporated by reference. Sections 5.4.1, 7.2.1, and 8 of the ''Report of the Joint FAO/WHO Expert Consultation on Protein Quality Evaluation,'' as published by the Food and Agriculture Organization of the United Nations/World Health Organization, is incorporated as it exists on the date of approval. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. It is available for inspection at the Office of the Federal Register, suite 700, 800 North Capitol Street, NW., Washington, DC, or at the office of the FSIS Docket Clerk, Room 3171, South Building, 14th and Independence Avenue, SW., Washington, DC. Copies of the incorporation by reference are available from the Product Assessment Division, Regulatory Programs, Food Safety and Inspection Service, U.S. Department of Agriculture, Room 329, West End Court Building, Washington, DC 20250–3700. For products represented or purported to be for infants, the corrected amount of protein (grams) per serving is equal to the actual amount of protein (grams) per serving multiplied by the relative protein quality value. The relative protein quality value shall be determined by dividing the subject product's protein PER value by the PER value for casein. If the relative protein value is above 1.00, it shall be set at 1.00.

(iii) For the purpose of labeling with a percent of the DRV or RDI, a value of 50 grams of protein shall be the DRV for adults and children 4 or more years of age, and the RDI for protein for children less than 4 years of age, infants, pregnant women, and lactating women shall be 16 grams, 14 grams, 60 grams, and 65 grams, respectively.

(8) Vitamins and minerals: A statement of the amount per serving of the vitamins and minerals as described in this paragraph, calculated as a percent of the RDI and expressed as percent of Daily Value.

(i) For purposes of declaration of percent of Daily Value as provided for in paragraphs (d) through (g) of this section, products represented or purported to be for use by infants, children less than 4 years of age, pregnant women, or lactating women shall use the RDI's that are specified for the intended group. For products represented or purported to be for use by both infants and children under 4 years of age, the percent of Daily Value shall be presented by separate declarations according to paragraph (e) of this section based on the RDI values for infants from birth to 12 months of age and for children under 4 years of age. Similarly, the percent of Daily Value based on both the RDI values for pregnant women and for lactating women shall be declared separately on products represented or purported to be for use by both pregnant and lactating women. When such dual declaration is used on any label, it shall be included in all labeling, and equal prominence shall be given to both values in all such labeling. All other products shall use the RDI for adults and children 4 or more years of age.

(ii) The declaration of vitamins and minerals as a percent of the RDI shall include vitamin A, vitamin C, calcium, and iron, in that order, and shall include any of the other vitamins and minerals listed in paragraph (c)(8)(iv) of this section when they are added, or when a claim is made about them. Other vitamins and minerals need not be declared if neither the nutrient nor the component is otherwise referred to

on the label or in labeling or advertising and the vitamins and minerals are:

(A) Required or permitted in a standardized food (e.g., thiamin, riboflavin, and niacin in enriched flour) and that standardized food is included as an ingredient (i.e., component) in another product; or

(B) Included in a product solely for technological purposes and declared only in the ingredients statement. The declaration may also include any of the other vitamins and minerals listed in paragraph (c)(8)(iv) of this section when they are naturally occurring in the food. The additional vitamins and minerals shall be listed in the order established in paragraph (c)(8)(iv) of this section.

(iii) The percentages for vitamins and minerals shall be expressed to the nearest 2-percent increment up to and including the 10-percent level, the nearest 5-percent increment above 10 percent and up to and including the 50-percent level, and the nearest 10-percent increment above the 50-percent level. Amounts of vitamins and minerals present at less than 2 percent of the RDI are not required to be declared in nutrition labeling but may be declared by a zero or by the use of an asterisk (or other symbol) that refers to another asterisk (or symbol) that is placed at the bottom of the table and that is followed by the statement ''Contains less than 2 percent of the Daily Value of this (these) nutrient (nutrients).'' Alternatively, if vitamin A, vitamin C, calcium, or iron is present in amounts less than 2 percent of the RDI, label declaration of the nutrient(s) is not required if the statement ''Not a significant source of _____ (listing the vitamins or minerals omitted)'' is placed at the bottom of the table of nutrient values.

(iv) The following RDI's and nomenclature are established for the following vitamins and minerals which are essential in human nutrition:

Vitamin A, 5,000 International Units
Vitamin C, 60 milligrams
Calcium, 1.0 gram
Iron, 18 milligrams
Vitamin D, 400 International Units
Vitamin E, 30 International Units
Thiamin, 1.5 milligrams
Riboflavin, 1.7 milligrams
Niacin, 20 milligrams
Vitamin B_6, 2.0 milligrams
Folate, 0.4 milligram
Vitamin B_{12}, 6 micrograms
Biotin, 0.3 milligram
Pantothenic acid, 10 milligrams
Phosphorus, 1.0 gram
Iodine, 150 micrograms
Magnesium, 400 milligrams
Zinc, 15 milligrams
Copper, 2.0 milligrams

(v) The following synonyms may be added in parenthesis immediately following the name of the nutrient or dietary component:

Vitamin C—Ascorbic acid
Thiamin—Vitamin B_1
Riboflavin—Vitamin B_2
Folate—Folacin
Calories—Energy

(vi) A statement of the percent of vitamin A that is present as *beta*-carotene may be declared voluntarily. When the vitamins and minerals are listed in a single column, the statement shall be indented under the information on vitamin A. When vitamins and minerals are arrayed horizontally, the statement of percent shall be presented in parenthesis following the declaration of vitamin A and the percent of Daily Value of vitamin A in the product (e.g., ''Percent Daily Value: Vitamin A 50 (90 percent as *beta*-carotene)''). When declared, the percentages shall be expressed in the same increments as are provided for vitamins and minerals in paragraph (c)(8)(iii) of this section.

(9) For the purpose of labeling with a percent of the DRV, the following DRV's are established for the following food components based on the reference caloric intake of 2,000 calories:

Food component	Unit of measurement	DRV
Fat	grams (g)	65
Saturated fatty acids	do	20
Cholesterol	milligrams (mg)	300
Total carbohydrate	grams (g)	300
Fiber	do	25
Sodium	milligrams (mg)	2,400
Potassium	do	3,500
Protein	grams (g)	50

(d)(1) Nutrient information specified in paragraph (c) of this section shall be presented on products in the following format, except on products on which dual columns of nutrition information

are declared as provided for in paragraph (e) of this section, on those products on which the simplified format is permitted to be used as provided for in paragraph (f) of this section, on products for infants and children less than 4 years of age as provided for in § 317.400(c), and on products in packages that have a total surface area available to bear labeling of 40 or less square inches as provided for in paragraph (g) of this section.

(i) The nutrition information shall be set off in a box by use of hairlines and shall be all black or one color type, printed on a white or other neutral contrasting background whenever practical.

(ii) All information within the nutrition label shall utilize:

(A) A single easy-to-read type style,

(B) Upper and lower case letters,

(C) At least one point leading (i.e., space between two lines of text) except that at least four points leading shall be utilized for the information required by paragraphs (d)(7) and (d)(8) of this section, and

(D) Letters should never touch.

(iii) Information required in paragraphs (d)(3), (d)(5), (d)(7), and (d)(8) of this section shall be in type size no smaller than 8 point. Except for the heading ''Nutrition Facts,'' the information required in paragraphs (d)(4), (d)(6), and (d)(9) of this section and all other information contained within the nutrition label shall be in type size no smaller than 6 point. When provided, the information described in paragraph (d)(10) of this section shall also be in type no smaller than 6 point.

(iv) The headings required by paragraphs (d)(2), (d)(4), and (d)(6) of this section (i.e., ''Nutrition Facts,'' ''Amount per Serving,'' and ''% Daily Value*''), the names of all nutrients that are not indented according to requirements of paragraph (c) of this section (i.e., Calories, Total fat, Cholesterol, Sodium, Potassium, Total carbohydrate, and Protein), and the percentage amounts required by paragraph (d)(7)(ii) of this section shall be highlighted by bold or extra bold type or other highlighting (reverse printing is not permitted as a form of highlighting) that prominently distinguishes it from other information. No other information shall be highlighted.

(v) A hairline rule that is centered between the lines of text shall separate ''Amount Per Serving'' from the calorie statements required in paragraph (d)(5) of this section and shall separate each nutrient and its corresponding percent of Daily Value required in paragraphs (d)(7)(i) and (d)(7)(ii) of this section from the nutrient and percent of Daily Value above and below it.

(2) The information shall be presented under the identifying heading of ''Nutrition Facts'' which shall be set in a type size larger than all other print size in the nutrition label and, except for labels presented according to the format provided for in paragraph (d)(11) of this section, unless impractical, shall be set the full width of the information provided under paragraph (d)(7) of this section.

(3) Information on serving size shall immediately follow the heading. Such information shall include:

(i) ''Serving Size'': A statement of the serving size as specified in paragraph (b)(9) of this section.

(ii) ''Servings Per Container'': The number of servings per container, except that this statement is not required on single-serving containers as defined in paragraph (b)(8) of this section.

(4) A subheading ''Amount Per Serving'' shall be separated from serving size information by a bar.

(5) Information on calories shall immediately follow the heading ''Amount Per Serving'' and shall be declared in one line, leaving sufficient space between the declaration of ''Calories'' and ''Calories from fat'' to allow clear differentiation, or, if ''Calories from saturated fat'' is declared, in a column with total ''Calories'' at the top, followed by ''Calories from fat'' (indented), and ''Calories from saturated fat'' (indented).

(6) The column heading ''% Daily Value,'' followed by an asterisk (e.g., ''% Daily Value*''), shall be separated from information on calories by a bar. The position of this column heading shall allow for a list of nutrient names and amounts as described in paragraph (d)(7) of this section to be to the left of, and below, this column heading. The

column headings ''Percent Daily Value,'' ''Percent DV,'' or ''% DV'' may be substituted for ''% Daily Value.''

(7) Except as provided for in paragraph (g) of this section, and except as permitted by § 317.400(d)(2), nutrient information for both mandatory and any voluntary nutrients listed in paragraph (c) of this section that are to be declared in the nutrition label, except vitamins and minerals, shall be declared as follows:

(i) The name of each nutrient, as specified in paragraph (c) of this section, shall be given in a column and followed immediately by the quantitative amount by weight for that nutrient appended with a ''g'' for grams or ''mg'' for milligrams.

(ii) A listing of the percent of the DRV as established in paragraphs (c)(7)(iii) and (c)(9) of this section shall be given in a column aligned under the heading ''% Daily Value'' established in paragraph (d)(6) of this section with the percent expressed to the nearest whole percent for each nutrient declared in the column described in paragraph (d)(7)(i) of this section for which a DRV has been established, except that the percent for protein may be omitted as provided in paragraph (c)(7) of this section. The percent shall be calculated by dividing either the amount declared on the label for each nutrient or the actual amount of each nutrient (i.e., before rounding) by the DRV for the nutrient, except that the percent for protein shall be calculated as specified in paragraph (c)(7)(ii) of this section. The numerical value shall be followed by the symbol for percent (i.e., %).

(8) Nutrient information for vitamins and minerals shall be separated from information on other nutrients by a bar and shall be arrayed horizontally (e.g., Vitamin A 4%, Vitamin C 2%, Calcium 15%, Iron 4%) or may be listed in two columns, except that when more than four vitamins and minerals are declared, they may be declared vertically with percentages listed under the column headed ''% Daily Value.''

(9) A footnote, preceded by an asterisk, shall be placed beneath the list of vitamins and minerals and shall be separated from that list by a hairline.

(i) The footnote shall state: Percent Daily Values are based on a 2,000 calorie diet. Your daily values may be higher or lower depending on your calorie needs.

	Calories:	2,000	2,500
Total fat	Less than	65 g	80 g
Saturated fat	Less than	20 g	25 g
Cholesterol	Less than	300 mg	300 mg
Sodium	Less than	2,400 mg	2,400 mg
Total carbohydrate.		300 g	375 g
Dietary fiber		25 g	30 g

(ii) If the percent of Daily Value is given for protein in the Percent of Daily Value column as provided in paragraph (d)(7)(ii) of this section, protein shall be listed under dietary fiber, and a value of 50 g shall be inserted on the same line in the column headed ''2,000'' and value of 65 g in the column headed ''2,500.''

(iii) If potassium is declared in the column described in paragraph (d)(7)(i) of this section, potassium shall be listed under sodium and the DRV established in paragraph (c)(9) of this section shall be inserted on the same line in the numeric columns.

(iv) The abbreviations established in paragraph (g)(2) of this section may be used within the footnote.

(10) Caloric conversion information on a per-gram basis for fat, carbohydrate, and protein may be presented beneath the information required in paragraph (d)(9), separated from that information by a hairline. This information may be presented horizontally (i.e., ''Calories per gram: Fat 9, Carbohydrate 4, Protein 4'') or vertically in columns.

(11)(i) If the space beneath the information on vitamins and minerals is not adequate to accommodate the information required in paragraph (d)(9) of this section, the information required in paragraph (d)(9) may be moved to the right of the column required in paragraph (d)(7)(ii) of this section and set off by a line that distinguishes it and sets it apart from the percent of Daily Value information. The caloric conversion information provided for in paragraph (d)(10) of this section may be presented beneath either side or along the full length of the nutrition label.

(ii) If the space beneath the mandatory declaration of iron is not adequate

to accommodate any remaining vitamins and minerals to be declared or the information required in paragraph (d)(9) of this section, the remaining information may be moved to the right and set off by a line that distinguishes it and sets it apart from the percent of Daily Value information given to the left. The caloric conversion information provided for in paragraph (d)(10) of this section may be presented beneath either side or along the full length of the nutrition label.

(iii) If there is not sufficient continuous vertical space (i.e., approximately 3 inches) to accommodate the required components of the nutrition label up to and including the mandatory declaration of iron, the nutrition label may be presented in a tabular display in which the footnote required by paragraph (d)(9) of the section is given to the far right of the label, and additional vitamins and minerals beyond the four that are required (i.e., vitamin A, vitamin C, calcium, and iron) are arrayed horizontally following declarations of the required vitamins and minerals.

(12) The following sample label illustrates the provisions of paragraph (d) of this section:

Nutrition Facts

Serving Size 1 cup (228g)
Servings Per Container 2

Amount Per Serving	
Calories 260 Calories from Fat 120	
	% Daily Value*
Total Fat 13g	**20%**
Saturated Fat 5g	**25%**
Cholesterol 30mg	**10%**
Sodium 660mg	**28%**
Total Carbohydrate 31g	**10%**
Dietary Fiber 0g	**0%**
Sugars 5g	
Protein 5g	

Vitamin A 4%	•	Vitamin C 2%
Calcium 15%	•	Iron 4%

* Percent Daily Values are based on a 2,000 calorie diet. Your daily values may be higher or lower depending on your calorie needs:

	Calories:	2,000	2,500
Total Fat	Less than	65g	80g
Sat Fat	Less than	20g	25g
Cholesterol	Less than	300mg	300mg
Sodium	Less than	2,400mg	2,400mg
Total Carbohydrate		300g	375g
Dietary Fiber		25g	30g

Calories per gram:
Fat 9 • Carbohydrate 4 • Protein 4

(13)(i) Nutrition labeling on the outer label of packages of meat or meat food products that contain two or more products in the same packages (e.g., variety packs) or of packages that are used interchangeably for the same type of food (e.g., meat salad containers) may use an aggregate display.

(ii) Aggregate displays shall comply with format requirements of paragraph

(d) of this section to the maximum extent possible, except that the identity of each food shall be specified to the right of the ''Nutrition Facts'' title, and both the quantitative amount by weight (i.e., g/mg amounts) and the percent Daily Value for each nutrient shall be listed in separate columns under the name of each food.

(14) When nutrition labeling appears in a second language, the nutrition information may be presented in a separate nutrition label for each language or in one nutrition label with the information in the second language following that in English. Numeric characters that are identical in both languages need not be repeated (e.g., ''Protein/Proteinas 2 g''). All required information must be included in both languages.

(e) Nutrition information may be presented for two or more forms of the same product (e.g., both ''raw'' and ''cooked'') or for common combinations of foods as provided for in paragraph (b) of this section, or for different units (e.g., per 100 grams) as provided for in paragraph (b) of this section, or for two or more groups for which RDI's are established (e.g., both infants and children less than 4 years of age) as provided for in paragraph (c)(8)(i) of this section. When such dual labeling is provided, equal prominence shall be given to both sets of values. Information shall be presented in a format consistent with paragraph (d) of this section, except that:

(1) Following the subheading of ''Amount Per Serving,'' there shall be two or more column headings accurately describing the forms of the same product (e.g., ''raw'' and ''roasted''), the combinations of foods, the units, or the RDI groups that are being declared. The column representing the product as packaged and according to the label serving size based on the Reference Amount in § 317.312(b) shall be to the left of the numeric columns.

(2) When the dual labeling is presented for two or more forms of the same product, for combinations of foods, or for different units, total calories and calories from fat (and calories from saturated fat, when declared) shall be listed in a column and indented as specified in paragraph (d)(5) of this section with quantitative amounts declared in columns aligned under the column headings set forth in paragraph (e)(1) of this section.

(3) Quantitative information by weight required in paragraph (d)(7)(i) of this section shall be specified for the form of the product as packaged and according to the label serving size based on the Reference Amount in § 317.312(b).

(i) Quantitative information by weight may be included for other forms of the product represented by the additional column(s) either immediately adjacent to the required quantitative information by weight for the product as packaged and according to the label serving size based on the Reference Amount in § 317.312(b) or as a footnote.

(A) If such additional quantitative information is given immediately adjacent to the required quantitative information, it shall be declared for all nutrients listed and placed immediately following and differentiated from the required quantitative information (e.g., separated by a comma). Such information shall not be put in a separate column.

(B) If such additional quantitative information is given in a footnote, it shall be declared in the same order as the nutrients are listed in the nutrition label. The additional quantitative information may state the total nutrient content of the product identified in the second column or the nutrient amounts added to the product as packaged for only those nutrients that are present in different amounts than the amounts declared in the required quantitative information. The footnote shall clearly identify which amounts are declared. Any subcomponents declared shall be listed parenthetically after principal components (e.g., ½ cup skim milk contributes an additional 40 calories, 65 mg sodium, 6 g total carbohydrate (6 g sugars), and 4 g protein).

(ii) Total fat and its quantitative amount by weight shall be followed by an asterisk (or other symbol) (e.g., ''Total fat (2 g)*'') referring to another asterisk (or symbol) at the bottom of the nutrition label identifying the form(s) of the product for which quantitative information is presented.

(4) Information required in paragraphs (d)(7)(ii) and (d)(8) of this section shall be presented under the subheading ''% DAILY VALUE'' and in columns directly under the column headings set forth in paragraph (e)(1) of this section.

(5) The following sample label illustrates the provisions of paragraph (e) of this section:

Nutrition Facts

Serving Size 1/12 package
(44g, about 1/4 cup dry mix)
Servings Per Container 12

Amount Per Serving	Mix	Baked
Calories	190	280
Calories from Fat	45	140
	% Daily Value**	
Total Fat 5g*	**8%**	**24%**
Saturated Fat 2g	**10%**	**13%**
Cholesterol 0mg	**0%**	**23%**
Sodium 300mg	**13%**	**13%**
Total Carbohydrate 34g	**11%**	**11%**
Dietary Fiber 0g	**0%**	**0%**
Sugars 18g		
Protein 2g		
Vitamin A	0%	0%
Vitamin C	0%	0%
Calcium	6%	8%
Iron	2%	4%

* Amount in Mix

** Percent Daily Values are based on a 2,000 calorie diet. Your daily values may be higher or lower depending on your calorie needs:

	Calories:	2,000	2,500
Total Fat	Less than	65g	80g
Sat Fat	Less than	20g	25g
Cholesterol	Less than	300mg	300mg
Sodium	Less than	2,400mg	2,400mg
Total Carbohydrate		300g	375g
Dietary Fiber		25g	30g

Calories per gram:
Fat 9 • Carbohydrate 4 • Protein 4

(f)(1) Nutrition information may be presented in a simplified format as set forth herein when any required nutrients, other than the core nutrients

(i.e., calories, total fat, sodium, total carbohydrate, and protein), are present in insignificant amounts. An insignificant amount shall be defined as that amount that may be rounded to zero in nutrition labeling, except that for total carbohydrate, dietary fiber, sugars and protein, it shall be an amount less than 1 gram.

(2) The simplified format shall include information on the following nutrients:

(i) Total calories, total fat, total carbohydrate, sodium, and protein;

(ii) Any of the following that are present in more than insignificant amounts: Calories from fat, saturated fat, cholesterol, dietary fiber, sugars, vitamin A, vitamin C, calcium, and iron; and

(iii) Any vitamins and minerals listed in paragraph (c)(8)(iv) of this section when they are added in fortified or fabricated foods.

(3) Other nutrients that are naturally present in the product in more than insignificant amounts may be voluntarily declared as part of the simplified format.

(4) Any required nutrient, other than a core nutrient, that is present in an insignificant amount may be omitted from the tabular listing, provided that the following statement is included at the bottom of the nutrition label, ''Not a significant source of _____.'' The blank shall be filled in with the appropriate nutrient or food component. Alternatively, amounts of vitamins and minerals present in insignificant amounts may be declared by the use of an asterisk (or symbol) that is placed at the bottom of the table of nutrient values and that is followed by the statement ''Contains less than 2 percent of the Daily Value of this (these) nutrient (nutrients).''

(5) Except as provided for in paragraph (g) of this section and in § 317.400(c) and (d), nutrient information declared in the simplified format shall be presented in the same manner as specified in paragraphs (d) or (e) of this section, except that the footnote required in paragraph (d)(9) of this section is not required. When the footnote is omitted, an asterisk shall be placed at the bottom of the label followed by the statement ''Percent Daily Values are based on a 2,000 calorie diet'' and, if the term ''Daily Value'' is not spelled out in the heading, a statement that ''DV'' represents ''Daily Value.''

(g) Foods in packages that have a total surface area available to bear labeling of 40 or less square inches may modify the requirements of paragraphs (c) through (f) of this section and § 317.302(a) by one or more of the following means:

(1)(i) Presenting the required nutrition information in a tabular or linear (i.e., string) fashion, rather than in vertical columns if the product has a total surface area available to bear labeling of less than 12 square inches, or if the product has a total surface area available to bear labeling of 40 or less square inches and the package shape or size cannot accommodate a standard vertical column or tabular display on any label panel. Nutrition information may be given in a linear fashion only if the package shape or size will not accommodate a tabular display.

(ii) When nutrition information is given in a linear display, the nutrition information shall be set off in a box by the use of a hairline. The percent Daily Value is separated from the quantitative amount declaration by the use of parenthesis, and all nutrients, both principal components and subcomponents, are treated similarly. Bolding is required only on the title ''Nutrition Facts'' and is allowed for nutrient names for ''Calories,'' ''Total fat,'' ''Cholesterol,'' ''Sodium,'' ''Total carbohydrate,'' and ''Protein.''

(2) Using any of the following abbreviations:

Serving size—Serv size
Servings per container—Servings
Calories from fat—Fat cal
Calories from saturated fat—Sat fat cal
Saturated fat—Sat fat
Monounsaturated fat—Monounsat fat
Polyunsaturated fat—Polyunsat fat
Cholesterol—Cholest
Total carbohydrate—Total carb
Dietary fiber—Fiber
Soluble fiber—Sol fiber
Insoluble fiber—Insol fiber
Sugar alcohol—Sugar alc
Other carbohydrate—Other carb

(3) Omitting the footnote required in paragraph (d)(9) of this section and

placing another asterisk at the bottom of the label followed by the statement ''Percent Daily Values are based on a 2,000 calorie diet'' and, if the term ''Daily Value'' is not spelled out in the heading, a statement that ''DV'' represents ''Daily Value.''

(4) Presenting the required nutrition information on any other label panel.

(h) Compliance with this section shall be determined as follows:

(1) A production lot is a set of food production consumer units that are from one production shift. Alternatively, a collection of consumer units of the same size, type, and style produced under conditions as nearly uniform as possible, designated by a common container code or marking, constitutes a production lot.

(2) The sample for nutrient analysis shall consist of a composite of a minimum of six consumer units, each from a production lot. Alternatively, the sample for nutrient analysis shall consist of a composite of a minimum of six consumer units, each randomly chosen to be representative of a production lot. In each case, the units may be individually analyzed and the results of the analyses averaged, or the units would be composited and the composite analyzed. In both cases, the results, whether an average or a single result from a composite, will be considered by the Agency to be the nutrient content of a composite. All analyses shall be performed by appropriate methods and procedures used by the Department for each nutrient in accordance with the ''Chemistry Laboratory Guidebook,'' or, if no USDA method is available and appropriate for the nutrient, by appropriate methods for the nutrient in accordance with the 1990 edition of the ''Official Methods of Analysis'' of the AOAC International, formerly Association of Official Analytical Chemists, 15th ed., which is incorporated by reference, unless a particular method of analysis is specified in § 317.309(c), or, if no USDA, AOAC, or specified method is available and appropriate, by other reliable and appropriate analytical procedures as so determined by the Agency. The ''Official Methods of Analysis'' is incorporated as it exists on the date of approval. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be purchased from the AOAC International, 2200 Wilson Blvd., suite 400, Arlington, VA 22201. It is also available for inspection at the Office of the Federal Register Information Center, suite 700, 800 North Capitol Street, NW., Washington, DC.

(3) Two classes of nutrients are defined for purposes of compliance:

(i) Class I. Added nutrients in fortified or fabricated foods; and

(ii) Class II. Naturally occurring (indigenous) nutrients. If any ingredient which contains a naturally occurring (indigenous) nutrient is added to a food, the total amount of such nutrient in the final food product is subject to Class II requirements unless the same nutrient is also added, which would make the total amount of such nutrient subject to Class I requirements.

(4) A product with a label declaration of a vitamin, mineral, protein, total carbohydrate, dietary fiber, other carbohydrate, polyunsaturated or monounsaturated fat, or potassium shall be deemed to be misbranded under section 1(n) of the Federal Meat Inspection Act (21 U.S.C. 601(n)(1)) unless it meets the following requirements:

(i) Class I vitamin, mineral, protein, dietary fiber, or potassium. The nutrient content of the composite is at least equal to the value for that nutrient declared on the label.

(ii) Class II vitamin, mineral, protein, total carbohydrate, dietary fiber, other carbohydrate, polyunsaturated or monounsaturated fat, or potassium. The nutrient content of the composite is at least equal to 80 percent of the value for that nutrient declared on the label; *Provided*, That no regulatory action will be based on a determination of a nutrient value which falls below this level by an amount less than the variability generally recognized for the analytical method used in that product at the level involved, and inherent nutrient variation in a product.

(5) A product with a label declaration of calories, sugars, total fat, saturated fat, cholesterol, or sodium shall be deemed to be misbranded under section 1(n) of the Federal Meat Inspection Act

(21 U.S.C. 601(n)(1)) if the nutrient content of the composite is greater than 20 percent in excess of the value for that nutrient declared on the label; *Provided*, That no regulatory action will be based on a determination of a nutrient value which falls above this level by an amount less than the variability generally recognized for the analytical method used in that product at the level involved, and inherent nutrient variation in a product.

(6) The amount of a vitamin, mineral, protein, total carbohydrate, dietary fiber, other carbohydrate, polyunsaturated or monounsaturated fat, or potassium may vary over labeled amounts within good manufacturing practice. The amount of calories, sugars, total fat, saturated fat, cholesterol, or sodium may vary under labeled amounts within good manufacturing practice.

(7) Compliance will be based on the metric measure specified in the label statement of serving size.

(8) The management of the establishment must maintain records to support the validity of nutrient declarations contained on product labels. Such records shall be made available to the inspector or any duly authorized representative of the Agency upon request.

(9) The compliance provisions set forth in paragraph (h) (1) through (8) of this section shall not apply to single-ingredient, raw meat (including ground beef) products, including those that have been previously frozen, when nutrition labeling is based on the most current representative data base values contained in USDA's National Nutrient Data Bank or its published form, the Agriculture Handbook No. 8 series available from the Government Printing Office.

(Paperwork requirements were approved by the Office of Management and Budget under control number 0583–0088)

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§§ 317.310–317.311 [Reserved]

§ 317.312 Reference amounts customarily consumed per eating occasion.

(a) The general principles followed in arriving at the reference amounts customarily consumed per eating occasion (Reference Amount(s)), as set forth in paragraph (b) of this section, are:

(1) The Reference Amounts are calculated for persons 4 years of age or older to reflect the amount of food customarily consumed per eating occasion by persons in this population group. These Reference Amounts are based on data set forth in appropriate national food consumption surveys.

(2) The Reference Amounts are calculated for an infant or child under 4 years of age to reflect the amount of food customarily consumed per eating occasion by infants up to 12 months of age or by children 1 through 3 years of age, respectively. These Reference Amounts are based on data set forth in appropriate national food consumption surveys. Such Reference Amounts are to be used only when the product is specially formulated or processed for use by an infant or by a child under 4 years of age.

(3) An appropriate national food consumption survey includes a large sample size representative of the demographic and socioeconomic characteristics of the relevant population group and must be based on consumption data under actual conditions of use.

(4) To determine the amount of food customarily consumed per eating occasion, the mean, median, and mode of the consumed amount per eating occasion were considered.

(5) When survey data were insufficient, FSIS took various other sources of information on serving sizes of food into consideration. These other sources of information included:

(i) Serving sizes used in dietary guidance recommendations or recommended by other authoritative systems or organizations;

(ii) Serving sizes recommended in comments;

(iii) Serving sizes used by manufacturers and grocers; and

(iv) Serving sizes used by other countries.

(6) Because they reflect the amount customarily consumed, the Reference Amount and, in turn, the serving size declared on the product label are based on only the edible portion of food, and not bone, seed, shell, or other inedible components.

(7) The Reference Amount is based on the major intended use of the product (e.g., a mixed dish measurable with a cup as a main dish and not as a side dish).

(8) The Reference Amounts for products that are consumed as an ingredient of other products, but that may also be consumed in the form in which they are purchased (e.g., ground beef), are based on use in the form purchased.

(9) FSIS sought to ensure that foods that have similar dietary usage, product characteristics, and customarily consumed amounts have a uniform Reference Amount.

(b) The following Product Categories and Reference Amounts shall be used as the basis for determining serving sizes for specific products:

TABLE 1—REFERENCE AMOUNTS CUSTOMARILY CONSUMED PER EATING OCCASION—INFANT AND TODDLER FOODS [1,2,3]

Product category	Reference amount
Infant & Toddler Foods:	
Dinner Dry Mix	15 g
Dinner, ready-to-serve, strained type	60 g
Dinner, soups, ready-to-serve junior type	110 g
Dinner, stew or soup ready-to-serve toddlers	170 g
Plain meats and meat sticks, ready-to-serve	55 g

[1] These values represent the amount of food customarily consumed per eating occasion and were primarily derived from the 1977–1978 and the 1987–1988 Nationwide Food Consumption Surveys conducted by the U.S. Department of Agriculture.

[2] Unless otherwise noted in the Reference Amount column, the Reference Amounts are for the ready-to-serve or almost ready-to-serve form of the product (i.e., heat and serve). If not listed separately, the Reference Amount for the unprepared form (e.g., dehydrated cereal) is the amount required to make one Reference Amount of the prepared form.

[3] Manufacturers are required to convert the Reference Amount to the label serving size in a household measure most appropriate to their specific product using the procedures established by regulation.

TABLE 2—REFERENCE AMOUNTS CUSTOMARILY CONSUMED PER EATING OCCASION—GENERAL FOOD SUPPLY [1,2,3,4,5]

Product category	Reference amount	Reference amount
	Ready-to-serve	Ready-to-cook
Egg mixtures, (western style omelet, souffle, egg foo young	110 g	n/a.
Lard, margarine, shortening	1 tbsp	n/a.
Salad and potato toppers; e.g., bacon bits	7 g	n/a.
Bacon (bacon, beef breakfast strips, pork breakfast strips, pork rinds)	15 g	54 g=bacon. 30 g = breakfast strips.
Dried; e.g., jerky, dried beef, Parma ham sausage products with a moisture/protein ratio of less than 2:1; e.g., pepperoni.	30 g	n/a.
Snacks; e.g., meat snack food sticks	30 g	n/a.
Luncheon meat, bologna, Canadian style bacon, pork pattie crumbles, beef pattie crumbles, blood pudding, luncheon loaf, old fashioned loaf, berlinger, bangers, minced luncheon roll, thuringer, liver sausage, mortadella, uncured sausage (franks), ham and cheese loaf, P&P loaf, scrapple souse, head cheese, pizza loaf, olive loaf, pate, deviled ham, sandwich spread, teawurst, cervelet, Lebanon bologna, potted meat food product, taco fillings, meat pie fillings.	55 g	n/a.
Linked meat sausage products, Vienna sausage, frankfurters, pork sausage, imitation frankfurters, bratwurst, kielbasa, Polish sausage, summer sausage, mettwurst, smoked country sausage, smoked sausage, smoked or pickled meat, pickled pigs feet.	55 g	n/a. 75 g=uncooked sausage.
Entrees without sauce, cuts of meat including marinated, tenderized, injected cuts of meat, beef patty, corn dog, croquettes, fritters, cured ham, dry cured ham, dry cured cappicola, corned beef, pastrami, country ham, pork shoulder picnic, meatballs, pureed adult foods.	85 g	114 g.
Canned meats, canned beef, canned pork. [4]	55 g	n/a.
Entrees with sauce, barbecued meats in sauce	140 g	n/a.
Mixed dishes NOT measurable with a cup; [5] e.g., burrito, egg roll, enchilada, pizza, pizza roll, quiche, all types of sandwiches, cracker and meat lunch type packages, gyro, stromboli, burger on a bun, frank on a bun, calzone, taco, pockets stuffed with meat, foldovers, stuffed vegetables with meat, shish kabobs, empanada.	140 g (plus 55 g for products with sauce toppings)	n/a.
Mixed dishes measurable with a cup; e.g., meat casserole, macaroni and cheese with meat, pot pie, spaghetti with sauce, meat chili, chili with beans, meat hash, creamed chipped beef, beef ravioli in sauce, beef stroganoff, Brunswick stew, goulash, meat stew, ragout, meat lasagna, meat filled pasta.	1 cup	n/a.
Salads—pasta or potato, potato salad with bacon, macaroni and meat salad	140 g	n/a.
Salads—all other meat, salads, ham salad	100 g	n/a.

TABLE 2—REFERENCE AMOUNTS CUSTOMARILY CONSUMED PER EATING OCCASION—GENERAL FOOD SUPPLY [1,2,3,4,5]—Continued

Product category	Reference amount	Reference amount
	Ready-to-serve	Ready-to-cook
Soups—all varieties	245 g	n/a.
Major main entree type sauce; e.g., spaghetti sauce with meat, spaghetti sauce with meatballs.	125 g	n/a.
Minor main entree sauce; e.g., pizza sauce with meat, gravy	¼ cup	n/a.
Seasoning mixes dry, bases, extracts, dried broths and stock/juice, freeze dry trail mix products with meat..		
As reconstituted:		
Amount to make one Reference Amount of the final dish; e.g.,		
Gravy	¼ cup	n/a.
Major main entree type sauce	125 g	n/a.
Soup	245 g	n/a.
Entree measurable with a cup	1 cup	n/a.

[1] These values represent the amount of food customarily consumed per eating occasion and were primarily derived from the 1977–78 and the 1987–88 Nationwide Food Consumption Surveys conducted by the U.S. Department of Agriculture.
[2] Manufacturers are required to convert the Reference Amounts to the label serving size in a household measure most appropriate to their specific product using the procedures established by regulation.
[3] Examples listed under Product Category are not all inclusive or exclusive. Examples are provided to assist manufacturers in identifying appropriate product Reference Amount.
[4] If packed or canned in liquid, the Reference Amount is for the drained solids, except for products in which both the solids and liquids are customarily consumed.
[5] Pizza sauce is part of the pizza and is not considered to be sauce topping.

(c) For products that have no Reference Amount listed in paragraph (b) of this section for the unprepared or the prepared form of the product and that consist of two or more foods packaged and presented to be consumed together (e.g., lunch meat with cheese and crackers), the Reference Amount for the combined product shall be determined using the following rules:

(1) For bulk products, the Reference Amount for the combined product shall be the Reference Amount, as established in paragraph (b) of this section, for the ingredient that is represented as the main ingredient plus proportioned amounts of all minor ingredients.

(2) For products where the ingredient represented as the main ingredient is one or more discrete units, the Reference Amount for the combined product shall be either the number of small discrete units or the fraction of the large discrete unit that is represented as the main ingredient that is closest to the Reference Amount for that ingredient as established in paragraph (b) of this section plus proportioned amounts of all minor ingredients.

(3) If the Reference Amounts are in compatible units, they shall be summed (e.g., ingredients in equal volumes such as tablespoons). If the Reference Amounts are in incompatible units, the weights of the appropriate volumes should be used (e.g., grams of one ingredient plus gram weight of tablespoons of a second ingredient).

(d) If a product requires further preparation, e.g., cooking or the addition of water or other ingredients, and if paragraph (b) of this section provides a Reference Amount for the product in the prepared form, then the Reference Amount for the unprepared product shall be determined using the following rules:

(1) Except as provided for in paragraph (d)(2) of this section, the Reference Amount for the unprepared product shall be the amount of the unprepared product required to make the Reference Amount for the prepared product as established in paragraph (b) of this section.

(2) For products where the entire contents of the package is used to prepare one large discrete unit usually divided for consumption, the Reference Amount for the unprepared product shall be the amount of the unprepared product required to make the fraction of the large discrete unit closest to the Reference Amount for the prepared product as established in paragraph (b) of this section.

(e) The Reference Amount for an imitation or substitute product or altered product as defined in § 317.313(d), such

as a ''low calorie'' version, shall be the same as for the product for which it is offered as a substitute.

(f) The Reference Amounts set forth in paragraphs (b) through (e) of this section shall be used in determining whether a product meets the criteria for nutritional claims. If the serving size declared on the product label differs from the Reference Amount, and the product meets the criteria for the claim only on the basis of the Reference Amount, the claim shall be followed by a statement that sets forth the basis on which the claim is made. That statement shall include the Reference Amount as it appears in paragraph (b) of this section followed, in parentheses, by the amount in common household measure if the Reference Amount is expressed in measures other than common household measures.

(g) The Administrator, on his or her own initiative or on behalf of any interested person who has submitted a labeling application, may issue a proposal to establish or amend a Product Category or Reference Amount identified in paragraph (b) of this section.

(1) Labeling applications and supporting documentation to be filed under this section shall be submitted in quadruplicate, except that the supporting documentation may be submitted on a computer disc copy. If any part of the material submitted is in a foreign language, it shall be accompanied by an accurate and complete English translation. The labeling application shall state the applicant's post office address.

(2) Pertinent information will be considered as part of an application on the basis of specific reference to such information submitted to and retained in the files of the Food Safety and Inspection Service. However, any reference to unpublished information furnished by a person other than the applicant will not be considered unless use of such information is authorized (with the understanding that such information may in whole or part be subject to release to the public) in a written statement signed by the person who submitted it. Any reference to published information should be accompanied by reprints or photostatic copies of such references.

(3) The availability for public disclosure of labeling applications, along with supporting documentation, submitted to the Agency under this section will be governed by the rules specified in subchapter D, title 9.

(4) Data accompanying the labeling application, such as food consumption data, shall be submitted on separate sheets, suitably identified. If such data has already been submitted with an earlier labeling application from the applicant, the present labeling application must provide the data.

(5) The labeling application must be signed by the applicant or by his or her attorney or agent, or (if a corporation) by an authorized official.

(6) The labeling application shall include a statement signed by the person responsible for the labeling application, that to the best of his or her knowledge, it is a representative and balanced submission that includes unfavorable information, as well as favorable information, known to him or her pertinent to the evaluation of the labeling application.

(7) Labeling applications for a new Reference Amount and/or Product Category shall be accompanied by the following data which shall be submitted in the following form to the Director, Food Labeling Division, Regulatory Programs, Food Safety and Inspection Service, Washington, DC 20250:

(Date)

The undersigned, _____ submits this labeling application pursuant to 9 CFR 317.312 with respect to Reference Amount and/or Product Category.

Attached hereto, in quadruplicate, or on a computer disc copy, and constituting a part of this labeling application, are the following:

(i) A statement of the objective of the labeling application;

(ii) A description of the product;

(iii) A complete sample product label including nutrition label, using the format established by regulation;

(iv) A description of the form in which the product will be marketed;

(v) The intended dietary uses of the product with the major use identified (e.g., ham as a luncheon meat);

(vi) If the intended use is primarily as an ingredient in other foods, list of foods or food categories in which the product will be used

as an ingredient with information on the prioritization of the use;

(vii) The population group for which the product will be offered for use (e.g., infants, children under 4 years of age);

(viii) The names of the most closely-related products (or in the case of foods for special dietary use and imitation or substitute foods, the names of the products for which they are offered as substitutes);

(ix) The suggested Reference Amount (the amount of edible portion of food as consumed, excluding bone, skin or other inedible components) for the population group for which the product is intended with full description of the methodology and procedures that were used to determine the suggested Reference Amount. In determining the Reference Amount, general principles and factors in paragraph (a) of this section should be followed.

(x) The suggested Reference Amount shall be expressed in metric units. Reference Amounts for foods shall be expressed in grams except when common household units such as cups, tablespoons, and teaspoons are more appropriate or are more likely to promote uniformity in serving sizes declared on product labels. For example, common household measures would be more appropriate if products within the same category differ substantially in density such as mixed dishes measurable with a cup.

(A) In expressing the Reference Amount in grams, the following general rules shall be followed:

(*1*) For quantities greater than 10 grams, the quantity shall be expressed in nearest 5 grams increment.

(*2*) For quantities less than 10 grams, exact gram weights shall be used.

(B) [Reserved]

(xi) A labeling application for a new subcategory of food with its own Reference Amount shall include the following additional information:

(A) Data that demonstrate that the new subcategory of food will be consumed in amounts that differ enough from the Reference Amount for the parent category to warrant a separate Reference Amount. Data must include sample size, and the mean, standard deviation, median, and modal consumed amount per eating occasion for the product identified in the labeling application and for other products in the category. All data must be derived from the same survey data.

(B) Documentation supporting the difference in dietary usage and product characteristics that affect the consumption size that distinguishes the product identified in the labeling application from the rest of the products in the category.

(xii) In conducting research to collect or process food consumption data in support of the labeling application, the following general guidelines should be followed.

(A) Sampled population selected should be representative of the demographic and socioeconomic characteristics of the target population group for which the food is intended.

(B) Sample size (i.e., number of eaters) should be large enough to give reliable estimates for customarily consumed amounts.

(C) The study protocol should identify potential biases and describe how potential biases are controlled for or, if not possible to control, how they affect interpretation of results.

(D) The methodology used to collect or process data including study design, sampling procedures, materials used (e.g., questionnaire, interviewer's manual), procedures used to collect or process data, methods or procedures used to control for unbiased estimates, and procedures used to correct for nonresponse, should be fully documented.

(xiii) A statement concerning the feasibility of convening associations, corporations, consumers, and other interested parties to engage in negotiated rulemaking to develop a proposed rule.

Yours very truly,

Applicant _____

By _____

(Indicate authority)

(8) Upon receipt of the labeling application and supporting documentation, the applicant shall be notified, in writing, of the date on which the labeling application was received. Such notice shall inform the applicant that the labeling application is undergoing Agency review and that the applicant shall subsequently be notified of the Agency's decision to consider for further review or deny the labeling application.

(9) Upon review of the labeling application and supporting documentation, the Agency shall notify the applicant, in writing, that the labeling application is either being considered for further review or that it has been summarily denied by the Administrator.

(10) If the labeling application is summarily denied by the Administrator, the written notification shall state the reasons therefor, including why the Agency has determined that the proposed Reference Amount and/or Product Category is false or misleading. The notification letter shall inform the applicant that the applicant may submit a written statement by way of answer to the notification, and that the applicant shall have the right to request a hearing with respect to

the merits or validity of the Administrator's decision to deny the use of the proposed Reference Amount and/or Product Category.

(i) If the applicant fails to accept the determination of the Administrator and files an answer and requests a hearing, and the Administrator, after review of the answer, determines the initial determination to be correct, the Administrator shall file with the Hearing Clerk of the Department the notification, answer, and the request for a hearing, which shall constitute the complaint and answer in the proceeding, which shall thereafter be conducted in accordance with the Department's Uniform Rules of Practice.

(ii) The hearing shall be conducted before an administrative law judge with the opportunity for appeal to the Department's Judicial Officer, who shall make the final determination for the Secretary. Any such determination by the Secretary shall be conclusive unless, within 30 days after receipt of notice of such final determination, the applicant appeals to the United States Court of Appeals for the circuit in which the applicant has its principal place of business or to the United States Court of Appeals for the District of Columbia Circuit.

(11) If the labeling application is not summarily denied by the Administrator, the Administrator shall publish in the FEDERAL REGISTER a proposed rule to amend the regulations to authorize the use of the Reference Amount and/or Product Category. The proposal shall also summarize the labeling application, including where the supporting documentation can be reviewed. The Administrator's proposed rule shall seek comment from consumers, the industry, consumer and industry groups, and other interested persons on the labeling application and the use of the proposed Reference Amount and/or Product Category. After public comment has been received and reviewed by the Agency, the Administrator shall make a determination on whether the proposed Reference Amount and/or Product Category shall be approved for use on the labeling of meat food products.

(i) If the Reference Amount and/or Product Category is denied by the Administrator, the Agency shall notify the applicant, in writing, of the basis for the denial, including the reason why the Reference Amount and/or Product Category on the labeling was determined by the Agency to be false or misleading. The notification letter shall also inform the applicant that the applicant may submit a written statement by way of answer to the notification, and that the applicant shall have the right to request a hearing with respect to the merits or validity of the Administrator's decision to deny the use of the proposed Reference Amount and/or Product Category.

(A) If the applicant fails to accept the determination of the Administrator and files an answer and requests a hearing, and the Administrator, after review of an answer, determines the initial determination to be correct, the Administrator shall file with the Hearing Clerk of the Department the notification, answer, and the request for a hearing, which shall constitute the complaint and answer in the proceeding, which shall thereafter be conducted in accordance with the Department's Uniform Rules of Practice.

(B) The hearing shall be conducted before an administrative law judge with the opportunity for appeal to the Department's Judicial Officer, who shall make the final determination for the Secretary. Any such determination by the Secretary shall be conclusive unless, within 30 days after receipt of the notice of such final determination, the applicant appeals to the United States Court of Appeals for the circuit in which the applicant has its principal place of business or to the United States Court of Appeals for the District of Columbia Circuit.

(ii) If the Reference Amount and/or Product Category is approved, the Agency shall notify the applicant, in writing, and shall also publish in the FEDERAL REGISTER a final rule amending the regulations to authorize the

use of the Reference Amount and/or Product Category.

(Paperwork requirements were approved by the Office of Management and Budget under control number 0583–0088)

[58 FR 664, Jan. 6, 1993; 58 FR 43788, Aug. 18, 1993 as amended at 58 FR 47627, Sept. 10, 1993; 59 FR 45196, Sept. 1, 1994; 60 FR 186, Jan. 3, 1995]

§ 317.313 Nutrient content claims; general principles.

(a) This section applies to meat or meat food products that are intended for human consumption and that are offered for sale.

(b) A claim which, expressly or by implication, characterizes the level of a nutrient (nutrient content claim) of the type required in nutrition labeling pursuant to § 317.309, may not be made on a label or in labeling of that product unless the claim is made in accordance with the applicable provisions in this subpart.

(1) An expressed nutrient content claim is any direct statement about the level (or range) of a nutrient in the product, e.g., ''low sodium'' or ''contains 100 calories.''

(2) An implied nutrient content claim is any claim that:

(i) Describes the product or an ingredient therein in a manner that suggests that a nutrient is absent or present in a certain amount (e.g., ''high in oat bran''); or

(ii) Suggests that the product, because of its nutrient content, may be useful in maintaining healthy dietary practices and is made in association with an explicit claim or statement about a nutrient (e.g., ''healthy, contains 3 grams (g) of fat'').

(3) Except for claims regarding vitamins and minerals described in paragraph (q)(3) of this section, no nutrient content claims may be made on products intended specifically for use by infants and children less than 2 years of age unless the claim is specifically provided for in subpart B of this part.

(4) Reasonable variations in the spelling of the terms defined in applicable provisions in this subpart and their synonyms are permitted provided these variations are not misleading (e.g., ''hi'' or ''lo'').

(c) Information that is required or permitted by § 317.309 to be declared in nutrition labeling, and that appears as part of the nutrition label, is not a nutrient content claim and is not subject to the requirements of this section. If such information is declared elsewhere on the label or in labeling, it is a nutrient content claim and is subject to the requirements for nutrient content claims.

(d) A ''substitute'' product is one that may be used interchangeably with another product that it resembles, i.e., that it is organoleptically, physically, and functionally (including shelf life) similar to, and that it is not nutritionally inferior to unless it is labeled as an ''imitation.''

(1) If there is a difference in performance characteristics that materially limits the use of the product, the product may still be considered a substitute if the label includes a disclaimer adjacent to the most prominent claim as defined in paragraph (j)(2)(iii) of this section, informing the consumer of such difference (e.g., ''not recommended for frying'').

(2) This disclaimer shall be in easily legible print or type and in a size no less than that required by § 317.2(h) for the net quantity of contents statement, except where the size of the claim is less than two times the required size of the net quantity of contents statement, in which case the disclaimer statement shall be no less than one-half the size of the claim but no smaller than 1/16-inch minimum height, except as permitted by § 317.400(d)(2).

(e)(1) Because the use of a ''free'' or ''low'' claim before the name of a product implies that the product differs from other products of the same type by virtue of its having a lower amount of the nutrient, only products that have been specially processed, altered, formulated, or reformulated so as to lower the amount of the nutrient in the product, remove the nutrient from the product, or not include the nutrient in the product, may bear such a claim (e.g., ''low sodium beef noodle soup'').

(2) Any claim for the absence of a nutrient in a product, or that a product is low in a nutrient when the product has not been specially processed, altered,

formulated, or reformulated to qualify for that claim shall indicate that the product inherently meets the criteria and shall clearly refer to all products of that type and not merely to the particular brand to which the labeling attaches (e.g., ''lard, a sodium free food'').

(f) A nutrient content claim shall be in type size and style no larger than two times that of the statement of identity and shall not be unduly prominent in type style compared to the statement of identity.

(g) Labeling information required in §§ 317.313, 317.354, 317.356, 317.360, 317.361, 317.362, and 317.380, whose type size is not otherwise specified, is required to be in letters and/or numbers no less than 1/16 inch in height, except as permitted by § 317.400(d)(2).

(h) [Reserved]

(i) Except as provided in § 317.309 or in paragraph (q)(3) of this section, the label or labeling of a product may contain a statement about the amount or percentage of a nutrient if:

(1) The use of the statement on the product implicitly characterizes the level of the nutrient in the product and is consistent with a definition for a claim, as provided in subpart B of this part, for the nutrient that the label addresses. Such a claim might be, ''less than 10 g of fat per serving;''

(2) The use of the statement on the product implicitly characterizes the level of the nutrient in the product and is not consistent with such a definition, but the label carries a disclaimer adjacent to the statement that the product is not ''low'' in or a ''good source'' of the nutrient, such as ''only 200 milligrams (mg) sodium per serving, not a low sodium product.'' The disclaimer must be in easily legible print or type and in a size no less than required by § 317.2(h) for the net quantity of contents, except where the size of the claim is less than two times the required size of the net quantity of contents statement, in which case the disclaimer statement shall be no less than one-half the size of the claim but no smaller than 1/16-inch minimum height, except as permitted by § 317.400(d)(2);

(3) The statement does not in any way implicitly characterize the level of the nutrient in the product and it is not false or misleading in any respect (e.g., ''100 calories'' or ''5 grams of fat''), in which case no disclaimer is required.

(4) ''Percent fat free'' claims are not authorized by this paragraph. Such claims shall comply with § 317.362(b)(6).

(j) A product may bear a statement that compares the level of a nutrient in the product with the level of a nutrient in a reference product. These statements shall be known as ''relative claims'' and include ''light,'' ''reduced,'' ''less'' (or ''fewer''), and ''more'' claims.

(1) To bear a relative claim about the level of a nutrient, the amount of that nutrient in the product must be compared to an amount of nutrient in an appropriate reference product as specified in this paragraph (j).

(i)(A) For ''less'' (or ''fewer'') and ''more'' claims, the reference product may be a dissimilar product within a product category that can generally be substituted for one another in the diet or a similar product.

(B) For ''light,'' ''reduced,'' and ''added'' claims, the reference product shall be a similar product, and

(ii)(A) For ''light'' claims, the reference product shall be representative of the type of product that includes the product that bears the claim. The nutrient value for the reference product shall be representative of a broad base of products of that type; e.g., a value in a representative, valid data base; an average value determined from the top three national (or regional) brands, a market basket norm; or, where its nutrient value is representative of the product type, a market leader. Firms using such a reference nutrient value as a basis for a claim, are required to provide specific information upon which the nutrient value was derived, on request, to consumers and appropriate regulatory officials.

(B) For relative claims other than ''light,'' including ''less'' and ''more'' claims, the reference product may be the same as that provided for ''light'' in paragraph (j)(1)(ii)(A) of this section or it may be the manufacturer's regular product, or that of another manufacturer, that has been offered for sale to the public on a regular basis for a

substantial period of time in the same geographic area by the same business entity or by one entitled to use its trade name, provided the name of the competitor is not used on the labeling of the product. The nutrient values used to determine the claim when comparing a single manufacturer's product to the labeled product shall be either the values declared in nutrition labeling or the actual nutrient values, provided that the resulting labeling is internally consistent (i.e., that the values stated in the nutrition information, the nutrient values in the accompanying information, and the declaration of the percentage of nutrient by which the product has been modified are consistent and will not cause consumer confusion when compared), and that the actual modification is at least equal to the percentage specified in the definition of the claim.

(2) For products bearing relative claims:

(i) The label or labeling must state the identity of the reference product and the percent (or fraction) of the amount of the nutrient in the reference product by which the nutrient has been modified, (e.g., ''50 percent less fat than 'reference product'' or ''⅓fewer calories than 'reference product'''); and

(ii) This information shall be immediately adjacent to the most prominent claim in easily legible boldface print or type, in distinct contrast to other printed or graphic matter, that is no less than that required by § 317.2(h) for net quantity of contents, except where the size of the claim is less than two times the required size of the net quantity of contents statement, in which case the referral statement shall be no less than one-half the size of the claim, but no smaller than 1/16-inch minimum height, except as permitted by § 317.400(d)(2).

(iii) The determination of which use of the claim is in the most prominent location on the label or labeling will be made based on the following factors, considered in order:

(A) A claim on the principal display panel adjacent to the statement of identity;

(B) A claim elsewhere on the principal display panel;

(C) A claim on the information panel; or

(D) A claim elsewhere on the label or labeling.

(iv) The label or labeling must also bear:

(A) Clear and concise quantitative information comparing the amount of the subject nutrient in the product per labeled serving size with that in the reference product; and

(B) This statement shall appear adjacent to the most prominent claim or to the nutrition information.

(3) A relative claim for decreased levels of a nutrient may not be made on the label or in labeling of a product if the nutrient content of the reference product meets the requirement for a ''low'' claim for that nutrient.

(k) The term ''modified'' may be used in the statement of identity of a product that bears a relative claim that complies with the requirements of this part, followed immediately by the name of the nutrient whose content has been altered (e.g., ''modified fat 'product'''). This statement of identity must be immediately followed by the comparative statement such as ''contains 35 percent less fat than 'reference product'.'' The label or labeling must also bear the information required by paragraph (j)(2) of this section in the manner prescribed.

(l) For purposes of making a claim, a ''meal-type product'' shall be defined as a product that:

(1) Makes a significant contribution to the diet by weighing at least 6 ounces, but no more than 12 ounces per serving (container), and

(2) Contains ingredients from two or more of the following four food groups:

(i) Bread, cereal, rice and pasta group,

(ii) Fruits and vegetables group,

(iii) Milk, yogurt, and cheese group, and

(iv) Meat, poultry, fish, dry beans, eggs, and nuts group, and

(3) Is represented as, or is in a form commonly understood to be a breakfast, lunch, dinner, meal, main dish, entree, or pizza. Such representations may be made either by statements, photographs, or vignettes.

(m) [Reserved]

(n) Nutrition labeling in accordance with § 317.309, shall be provided for any food for which a nutrient content claim is made.

(o) Compliance with requirements for nutrient content claims shall be in accordance with § 317.309(h).

(p)(1) Unless otherwise specified, the reference amount customarily consumed set forth in § 317.312(b) through (e) shall be used in determining whether a product meets the criteria for a nutrient content claim. If the serving size declared on the product label differs from the reference amount customarily consumed, and the amount of the nutrient contained in the labeled serving does not meet the maximum or minimum amount criterion in the definition for the descriptor for that nutrient, the claim shall be followed by the criteria for the claim as required by § 317.312(f) (e.g., ''very low sodium, 35 mg or less per 55 grams'').

(2) The criteria for the claim shall be immediately adjacent to the most prominent claim in easily legible print or type and in a size that is no less than that required by § 317.2(h) for net quantity of contents, except where the size of the claim is less than two times the required size of the net quantity of contents statement, in which case the criteria statement shall be no less than one-half the size of the claim but no smaller than 1/16-inch minimum height, except as permitted by § 317.400(d)(2).

(q) The following exemptions apply:

(1) Nutrient content claims that have not been defined by regulation and that appear as part of a brand name that was in use prior to November 27, 1991, may continue to be used as part of that brand name, provided they are not false or misleading under section 1(n) of the Act (21 U.S.C. 601(n)(1)).

(2) [Reserved]

(3) A statement that describes the percentage of a vitamin or mineral in the food, including foods intended specifically for use by infants and children less than 2 years of age, in relation to a Reference Daily Intake (RDI) as defined in § 317.309 may be made on the label or in the labeling of a food without a regulation authorizing such a claim for a specific vitamin or mineral.

(4) The requirements of this section do not apply to infant formulas and medical foods, as described in 21 CFR 101.13(q)(4).

(5) [Reserved]

(6) Nutrient content claims that were part of the name of a product that was subject to a standard of identity as of November 27, 1991, are not subject to the requirements of paragraph (b) of this section whether or not they meet the definition of the descriptive term.

(7) Implied nutrient content claims may be used as part of a brand name, provided that the use of the claim has been authorized by FSIS. Labeling applications requesting approval of such a claim may be submitted pursuant to § 317.369.

[58 FR 664, Jan. 6, 1993; 58 FR 43788, Aug. 18, 1993, as amended at 58 FR 47627, Sept. 10, 1993; 59 FR 40213, Aug. 8, 1994; 59 FR 45196, Sept. 1, 1994; 60 FR 187, Jan. 3, 1995]

§§ 317.314–317.342 [Reserved]

§ 317.343 Significant participation for voluntary nutrition labeling.

(a) In evaluating significant participation for voluntary nutrition labeling, FSIS will consider only the major cuts of single-ingredient, raw meat products, as identified in § 317.344, including those that have been previously frozen.

(b) FSIS will judge a food retailer to be participating at a significant level if the retailer provides nutrition labeling information for at least 90 percent of the major cuts of single-ingredient, raw meat products, listed in § 317.344, that it sells, and if the nutrition label is consistent in content and format with the mandatory program, or nutrition information is displayed at point-of-purchase in an approriate manner.

(c) To determine whether there is significant participation by retailers under the voluntary nutrition labeling guidelines, FSIS will select a representative sample of companies allocated by type and size.

(d) FSIS will find that significant participation by food retailers exists if at least 60 percent of all companies that are evaluated are participating in accordance with the guidelines.

(e) FSIS will evaluate significant participation of the voluntary program every 2 years beginning in May 1995.

(1) If significant participation is found, the voluntary nutrition labeling guidelines shall remain in effect.

(2) If significant participation is not found, FSIS shall initiate rulemaking to require nutrition labeling on those products under the voluntary program.

§317.344 Identification of major cuts of meat products.

The major cuts of single-ingredient, raw meat products are: Beef chuck blade roast, beef loin top loin steak, beef rib roast large end, beef round eye round steak, beef round top round steak, beef round tip roast, beef chuck arm pot roast, beef loin sirloin steak, beef round bottom round steak, beef brisket (whole, flat half, or point half), beef rib steak small end, beef loin tenderloin steak, ground beef regular without added seasonings, ground beef about 17% fat, pork loin chop, pork loin country style ribs, pork loin top loin chop boneless, pork loin rib chop, pork spareribs, pork loin tenderloin, pork loin sirloin roast, pork shoulder blade steak, pork loin top roast boneless, ground pork, lamb shank, lamb shoulder arm chop, lamb shoulder blade chop, lamb rib roast, lamb loin chop, lamb leg (whole, sirloin half, or shank half), veal shoulder arm steak, veal shoulder blade steak, veal rib roast, veal loin chop, and veal cutlets.

[58 FR 664, Jan. 6, 1993, as amended at 59 FR 45196, Sept. 1, 1994]

§317.345 Guidelines for voluntary nutrition labeling of single-ingredient, raw products.

(a) Nutrition information on the cuts of single-ingredient, raw meat products, including those that have been previously frozen, shall be provided in the following manner:

(1) If a retailer or manufacturer chooses to provide nutrition information on the label of these products, these products shall be subject to all requirements of the mandatory nutrition labeling program, except that nutrition labeling may be declared on the basis of either ''as consumed'' or ''as packaged.'' In addition, the declaration of the number of servings per container need not be included in nutrition labeling of single-ingredient, raw meat products (including ground beef), including those that have been previously frozen.

(2) A retailer may choose to provide nutrition information at the point-of-purchase, such as by posting a sign, or by making the information readily available in brochures, notebooks, or leaflet form in close proximity to the food. The nutrition labeling information may also be supplemented by a video, live demonstration, or other media. If a nutrition claim is made on point-of-purchase materials all of the requirements of the mandatory nutrition labeling program apply. However, if only nutrition information—and not a nutrition claim—is supplied on point-of-purchase materials:

(i) The requirements of the mandatory nutrition labeling program apply, but the nutrition information may be supplied on an ''as packaged'' or ''as consumed,'' basis;

(ii) The listing of percent of Daily Value for the nutrients (except vitamins and minerals specified in §317.309(c)(8)) and footnote required by §317.309(d)(9) may be omitted; and

(iii) The point-of-purchase materials are not subject to any of the format requirements.

(b) [Reserved]

(c) The declaration of nutrition information may be presented in a simplified format as specified in §317.309(f) for the mandatory nutrition labeling program.

(d) The nutrition label data should be based on either the raw or cooked edible portions of meat cuts with external cover fat at trim levels reflecting current marketing practices. If data are based on cooked portions, the methods used to cook the products must be specified and should be those which do not add nutrients from other ingredients such as flour, breading, and salt. Additional nutritional data may be presented on an optional basis for the raw or cooked edible portions of the separable lean of meat cuts.

(e) Nutrient data that are the most current representative data base values contained in USDA's National Nutrient Data Bank or its published form, the Agriculture Handbook No. 8 series, may be used for nutrition labeling of single-ingredient, raw meat products (including ground beef), including

those that have been previously frozen. These data may be composite data that reflect different quality grades of beef or other variables affecting nutrient content. Alternatively, data that reflect specific grades or other variables may be used, except that if data are used on labels attached to a product which is labeled as to grade of meat or other variables, the data must represent the product in the package when such data are contained in the representative data base. When data are used on labels attached to a product, the data must represent the edible meat tissues present in the package.

(f) If the nutrition information is in accordance with paragraph (e) of this section, a nutrition label or labeling will not be subject to the Agency compliance review under §317.309(h), unless a nutrition claim is made on the basis of the representative data base values.

(g) Retailers may use data bases that they believe reflect the nutrient content of single-ingredient, raw meat products (including ground beef), including those that have been previously frozen; however, such labeling shall be subject to the compliance procedures of paragraph (e) of this section and the requirements specified in this subpart for the mandatory nutrition labeling program.

[58 FR 664, Jan. 6, 1993, as amended at 58 FR 47627, Sept. 10, 1993; 60 FR 189, Jan. 3, 1995]

§§ 317.346–317.353 [Reserved]

§ 317.354 Nutrient content claims for "good source," "high," and "more."

(a) *General requirements.* Except as provided in paragraph (e) of this section, a claim about the level of a nutrient in a product in relation to the Reference Daily Intake (RDI) or Daily Reference Value (DRV) established for that nutrient (excluding total carbohydrate) in §317.309(c), may only be made on the label or in labeling of the product if:

(1) The claim uses one of the terms defined in this section in accordance with the definition for that term;

(2) The claim is made in accordance with the general requirements for nutrient content claims in §317.313; and

(3) The product for which the claim is made is labeled in accordance with §317.309.

(b) *''High'' claims.* (1) The terms ''high,'' ''rich in,'' or ''excellent source of'' may be used on the label or in labeling of products, except meal-type products as defined in §317.313(l), provided that the product contains 20 percent or more of the RDI or the DRV per reference amount customarily consumed.

(2) The terms defined in paragraph (b)(1) of this section may be used on the label or in labeling of a meal-type product as defined in §317.313(l), provided that:

(i) The product contains a food that meets the definition of ''high'' in paragraph (b)(1) of this section; and

(ii) The label or labeling clearly identifies the food that is the subject of the claim (e.g., ''the serving of broccoli in this meal is high in vitamin C'').

(c) *''Good Source'' claims.* (1) The terms ''good source,'' ''contains,'' or ''provides'' may be used on the label or in labeling of products, except meal-type products as described in §317.313(l), provided that the product contains 10 to 19 percent of the RDI or the DRV per reference amount customarily consumed.

(2) The terms defined in paragraph (c)(1) of this section may be used on the label or in labeling of a meal-type product as defined in §317.313(l), provided that:

(i) The product contains a food that meets the definition of ''good source'' in paragraph (c)(1) of this section; and

(ii) The label or labeling clearly identifies the food that is the subject of the claim (e.g., ''the serving of sweet potatoes in this meal is a good source of fiber'').

(d) *Fiber claims.* (1) If a nutrient content claim is made with respect to the level of dietary fiber, i.e., that the product is high in fiber, a good source of fiber, or that the product contains ''more'' fiber, and the product is not ''low'' in total fat as defined in §317.362(b)(2) or, in the case of a meal-type product, is not ''low'' in total fat as defined in §317.362(b)(3), then the labeling shall disclose the level of total

fat per labeled serving size (e.g., ''contains 12 grams (g) of fat per serving''); and

(2) The disclosure shall appear in immediate proximity to such claim and be in a type size no less than one-half the size of the claim.

(e) *''More'' claims.* (1) A relative claim using the terms ''more'' and ''added'' may be used on the label or in labeling to describe the level of protein, vitamins, minerals, dietary fiber, or potassium in a product, except meal-type products as defined in § 317.313(l), provided that:

(i) The product contains at least 10 percent more of the RDI or the DRV for protein, vitamins, minerals, dietary fiber, or potassium (expressed as a percent of the Daily Value) per reference amount customarily consumed than an appropriate reference product as described in § 317.313(j)(1); and

(ii) As required in § 317.313(j)(2) for relative claims:

(A) The identity of the reference product and the percent (or fraction) that the nutrient is greater relative to the RDI or DRV are declared in immediate proximity to the most prominent such claim (e.g., ''contains 10 percent more of the Daily Value for fiber than 'reference product' ''); and

(B) Quantitative information comparing the level of the nutrient in the product per labeled serving size with that of the reference product that it replaces is declared adjacent to the most prominent claim or to the nutrition information (e.g., ''fiber content of 'reference product' is 1 g per serving; 'this product' contains 4 g per serving'').

(2) A relative claim using the terms ''more'' and ''added'' may be used on the label or in labeling to describe the level of protein, vitamins, minerals, dietary fiber, or potassium in meal-type products as defined in § 317.313(l), provided that:

(i) The product contains at least 10 percent more of the RDI or the DRV for protein, vitamins, minerals, dietary fiber, or potassium (expressed as a percent of the Daily Value) per 100 g of product than an appropriate reference product as described in § 317.313(j)(1); and

(ii) As required in § 317.313(j)(2) for relative claims:

(A) The identity of the reference product and the percent (or fraction) that the nutrient is greater relative to the RDI or DRV are declared in immediate proximity to the most prominent such claim (e.g., ''contains 10 percent more of the Daily Value for fiber per 3 ounces (oz) than does 'reference product' ''), and

(B) Quantitative information comparing the level of the nutrient in the meal-type product per specified weight with that of the reference product that it replaces is declared adjacent to the most prominent claim or to the nutrition information (e.g., ''fiber content of 'reference product' is 2 g per 3 oz; 'this product' contains 5 g per 3 oz'').

[60 FR 189, Jan. 3, 1995]

§ 317.355 [Reserved]

§ 317.356 Nutrient content claims for "light" or "lite."

(a) *General requirements.* A claim using the terms ''light'' or ''lite'' to describe a product may only be made on the label or in labeling of the product if:

(1) The claim uses one of the terms defined in this section in accordance with the definition for that term;

(2) The claim is made in accordance with the general requirements for nutrient content claims in § 317.313; and

(3) The product for which the claim is made is labeled in accordance with § 317.309.

(b) *''Light'' claims.* The terms ''light'' or ''lite'' may be used on the label or in labeling of products, except meal-type products as defined in § 317.313(l), without further qualification, provided that:

(1) If the product derives 50 percent or more of its calories from fat, its fat content is reduced by 50 percent or more per reference amount customarily consumed compared to an appropriate reference product as described in § 317.313(j)(1); or

(2) If the product derives less than 50 percent of its calories from fat:

(i) The number of calories is reduced by at least one-third (33⅓ percent) per reference amount customarily consumed compared to an appropriate reference product as described in § 317.313(j)(1); or

(ii) Its fat content is reduced by 50 percent or more per reference amount customarily consumed compared to the appropriate reference product as described in § 317.313(j)(1); and

(3) As required in § 317.313(j)(2) for relative claims:

(i) The identity of the reference product and the percent (or fraction) that the calories and the fat were reduced are declared in immediate proximity to the most prominent such claim (e.g., ''⅓fewer calories and 50 percent less fat than the market leader''); and

(ii) Quantitative information comparing the level of calories and fat content in the product per labeled serving size with that of the reference product that it replaces is declared adjacent to the most prominent claim or to the nutrition information (e.g., ''lite 'this product'—200 calories, 4 grams (g) fat; regular 'reference product'—300 calories, 8 g fat per serving''); and

(iii) If the labeled product contains less than 40 calories or less than 3 g fat per reference amount customarily consumed, the percentage reduction for that nutrient need not be declared.

(4) A ''light'' claim may not be made on a product for which the reference product meets the definition of ''low fat'' and ''low calorie.''

(c)(1)(i) A product for which the reference product contains 40 calories or less and 3 g fat or less per reference amount customarily consumed may use the terms ''light'' or ''lite'' without further qualification if it is reduced by 50 percent or more in sodium content compared to the reference product; and

(ii) As required in § 317.313(j)(2) for relative claims:

(A) The identity of the reference product and the percent (or fraction) that the sodium was reduced are declared in immediate proximity to the most prominent such claim (e.g., ''50 percent less sodium than the market leader''); and

(B) Quantitative information comparing the level of sodium per labeled serving size with that of the reference product it replaces is declared adjacent to the most prominent claim or to the nutrition information (e.g., ''lite 'this product'—500 milligrams (mg) sodium per serving; regular 'reference product'—1,000 mg sodium per serving'').

(2)(i) A product for which the reference product contains more than 40 calories or more than 3 g fat per reference amount customarily consumed may use the terms ''light in sodium'' or ''lite in sodium'' if it is reduced by 50 percent or more in sodium content compared to the reference product, provided that ''light'' or ''lite'' is presented in immediate proximity with ''in sodium'' and the entire term is presented in uniform type size, style, color, and prominence; and

(ii) As required in § 317.313(j)(2) for relative claims:

(A) The identity of the reference product and the percent (or fraction) that the sodium was reduced are declared in immediate proximity to the most prominent such claim (e.g., ''50 percent less sodium than the market leader''); and

(B) Quantitative information comparing the level of sodium per labeled serving size with that of the reference product it replaces is declared adjacent to the most prominent claim or to the nutrition information (e.g., or ''lite 'this product'—170 mg sodium per serving; regular 'reference product'—350 mg per serving'').

(3) Except for meal-type products as defined in § 317.313(l), a ''light in sodium'' claim may not be made on a product for which the reference product meets the definition of ''low in sodium.''

(d)(1) The terms ''light'' or ''lite'' may be used on the label or in labeling of a meal-type product as defined in § 317.313(l), provided that:

(i) The product meets the definition of:

(A) ''Low in calories'' as defined in § 317.360(b)(3); or

(B) ''Low in fat'' as defined in § 317.362(b)(3); and

(ii)(A) A statement appears on the principal display panel that explains whether ''light'' is used to mean ''low fat,'' ''low calories,'' or both (e.g., ''Light Delight, a low fat meal''); and

(B) The accompanying statement is no less than one-half the type size of the ''light'' or ''lite'' claim.

(2)(i) The terms ''light in sodium'' or ''lite in sodium'' may be used on the label or in labeling of a meal-type

product as defined in § 317.313(l), provided that the product meets the definition of ''low in sodium'' as defined in § 317.361(b)(5)(i); and

(ii) ''Light'' or ''lite'' and ''in sodium'' are presented in uniform type size, style, color, and prominence.

(3) The term ''light'' or ''lite'' may be used in the brand name of a product to describe the sodium content, provided that:

(i) The product is reduced by 50 percent or more in sodium content compared to the reference product;

(ii) A statement specifically stating that the product is ''light in sodium'' or ''lite in sodium'' appears:

(A) Contiguous to the brand name; and

(B) In uniform type size, style, color, and prominence as the product name; and

(iii) As required in § 317.313(j)(2) for relative claims:

(A) The identity of the reference product and the percent (or fraction) that the sodium was reduced are declared in immediate proximity to the most prominent such claim; and

(B) Quantitative information comparing the level of sodium per labeled serving size with that of the reference product it replaces is declared adjacent to the most prominent claim or to the nutrition information.

(e) Except as provided in paragraphs (b) through (d) of this section, the terms ''light'' or ''lite'' may not be used to refer to a product that is not reduced in fat by 50 percent, or, if applicable, in calories by ⅓ or, when properly qualified, in sodium by 50 percent unless:

(1) It describes some physical or organoleptic attribute of the product such as texture or color and the information (e.g., ''light in color'' or ''light in texture'') so stated, clearly conveys the nature of the product; and

(2) The attribute (e.g., ''color'' or ''texture'') is in the same style, color, and at least one-half the type size as the word ''light'' and in immediate proximity thereto.

(f) If a manufacturer can demonstrate that the word ''light'' has been associated, through common use, with a particular product to reflect a physical or organoleptic attribute to the point where it has become part of the statement of identity, such use of the term ''light'' shall not be considered a nutrient content claim subject to the requirements in this part.

(g) The term ''lightly salted'' may be used on a product to which has been added 50 percent less sodium than is normally added to the reference product as described in § 317.313(j)(1)(i)(B) and (j)(1)(ii)(B), provided that if the product is not ''low in sodium'' as defined in § 317.361(b)(4), the statement ''not a low sodium food,'' shall appear adjacent to the nutrition information and the information required to accompany a relative claim shall appear on the label or labeling as specified in § 317.313(j)(2).

[60 FR 189, Jan. 3, 1995]

§§ 317.357–317.359 [Reserved]

§ 317.360 Nutrient content claims for calorie content.

(a) *General requirements.* A claim about the calorie or sugar content of a product may only be made on the label or in labeling of the product if:

(1) The claim uses one of the terms defined in this section in accordance with the definition for that term;

(2) The claim is made in accordance with the general requirements for nutrient content claims in § 317.313; and

(3) The product for which the claim is made is labeled in accordance with § 317.309.

(b) *Calorie content claims.* (1) The terms ''calorie free,'' ''free of calories,'' ''no calories,'' ''zero calories,'' ''without calories,'' ''trivial source of calories,'' ''negligible source of calories,'' or ''dietarily insignificant source of calories'' may be used on the label or in labeling of products, provided that:

(i) The product contains less than 5 calories per reference amount customarily consumed and per labeled serving size; and

(ii) If the product meets this condition without the benefit of special processing, alteration, formulation, or reformulation to lower the caloric content, it is labeled to clearly refer to all products of its type and not merely to the particular brand to which the label attaches.

(2) The terms ''low calorie,'' ''few calories,'' ''contains a small amount of calories,'' ''low source of calories,'' or ''low in calories'' may be used on the label or in labeling of products, except meal-type products as defined in § 317.313(l), provided that:

(i)(A) The product has a reference amount customarily consumed greater than 30 grams (g) or greater than 2 tablespoons (tbsp) and does not provide more than 40 calories per reference amount customarily consumed; or

(B) The product has a reference amount customarily consumed of 30 g or less or 2 tbsp or less and does not provide more than 40 calories per reference amount customarily consumed and per 50 g (for dehydrated products that must be reconstituted before typical consumption with water or a diluent containing an insignificant amount, as defined in § 317.309(f)(1), of all nutrients per reference amount customarily consumed, the per-50-g criterion refers to the ''as prepared'' form).

(ii) If the product meets these conditions without the benefit of special processing, alteration, formulation, or reformulation to lower the caloric content, it is labeled to clearly refer to all products of its type and not merely to the particular brand to which the label attaches.

(3) The terms defined in paragraph (b)(2) of this section may be used on the label or in labeling of a meal-type product as defined in § 317.313(l), provided that:

(i) The product contains 120 calories or less per 100 g of product; and

(ii) If the product meets this condition without the benefit of special processing, alteration, formulation, or reformulation to lower the calorie content, it is labeled to clearly refer to all products of its type and not merely to the particular brand to which it attaches.

(4) The terms ''reduced calorie,'' ''reduced in calories,'' ''calorie reduced,'' ''fewer calories,'' ''lower calorie,'' or ''lower in calories'' may be used on the label or in labeling of products, except meal-type products as defined in § 317.313(l), provided that:

(i) The product contains at least 25 percent fewer calories per reference amount customarily consumed than an appropriate reference product as described in § 317.313(j)(1); and

(ii) As required in § 317.313(j)(2) for relative claims:

(A) The identity of the reference product and the percent (or fraction) that the calories differ between the two products are declared in immediate proximity to the most prominent such claim (e.g., lower calorie 'product'—''33⅓ percent fewer calories than our regular 'product' ''); and

(B) Quantitative information comparing the level of calories in the product per labeled serving size with that of the reference product that it replaces is declared adjacent to the most prominent claim or to the nutrition information (e.g., ''calorie content has been reduced from 150 to 100 calories per serving'').

(iii) Claims described in paragraph (b)(4) of this section may not be made on the label or in labeling of products if the reference product meets the definition for ''low calorie.''

(5) The terms defined in paragraph (b)(4) of this section may be used on the label or in labeling of a meal-type product as defined in § 317.313(l), provided that:

(i) The product contains at least 25 percent fewer calories per 100 g of product than an appropriate reference product as described in § 317.313(j)(1); and

(ii) As required in § 317.313(j)(2) for relative claims:

(A) The identity of the reference product and the percent (or fraction) that the calories differ between the two products are declared in immediate proximity to the most prominent such claim (e.g., ''calorie reduced 'product', 25% less calories per ounce (oz) (or 3 oz) than our regular 'product' ''); and

(B) Quantitative information comparing the level of calories in the product per specified weight with that of the reference product that it replaces is declared adjacent to the most prominent claim or to the nutrition information (e.g., ''calorie content has been reduced from 110 calories per 3 oz to 80 calories per 3 oz'').

(iii) Claims described in paragraph (b)(5) of this section may not be made on the label or in labeling of products

if the reference product meets the definition for ''low calorie.''

(c) *Sugar content claims.* (1) Terms such as ''sugar free,'' ''free of sugar,'' ''no sugar,'' ''zero sugar,'' ''without sugar,'' ''sugarless,'' ''trivial source of sugar,'' ''negligible source of sugar,'' or ''dietarily insignificant source of sugar'' may reasonably be expected to be regarded by consumers as terms that represent that the product contains no sugars or sweeteners, e.g., ''sugar free,'' or ''no sugar,'' as indicating a product which is low in calories or significantly reduced in calories. Consequently, except as provided in paragraph (c)(2) of this section, a product may not be labeled with such terms unless:

(i) The product contains less than 0.5 g of sugars, as defined in § 317.309(c)(6)(ii), per reference amount customarily consumed and per labeled serving size or, in the case of a meal-type product, less than 0.5 g of sugars per labeled serving size;

(ii) The product contains no ingredient that is a sugar or that is generally understood by consumers to contain sugars unless the listing of the ingredient in the ingredients statement is followed by an asterisk that refers to the statement below the list of ingredients, which states: ''Adds a trivial amount of sugar,'' ''adds a negligible amount of sugar,'' or ''adds a dietarily insignificant amount of sugar;'' and

(iii)(A) It is labeled ''low calorie'' or ''reduced calorie'' or bears a relative claim of special dietary usefulness labeled in compliance with paragraphs (b)(2), (b)(3), (b)(4), or (b)(5) of this section; or

(B) Such term is immediately accompanied, each time it is used, by either the statement ''not a reduced calorie product,'' ''not a low calorie product,'' or ''not for weight control.''

(2) The terms ''no added sugar,'' ''without added sugar,'' or ''no sugar added'' may be used only if:

(i) No amount of sugars, as defined in § 317.309(c)(6)(ii), or any other ingredient that contains sugars that functionally substitute for added sugars is added during processing or packaging;

(ii) The product does not contain an ingredient containing added sugars such as jam, jelly, or concentrated fruit juice;

(iii) The sugars content has not been increased above the amount present in the ingredients by some means such as the use of enzymes, except where the intended functional effect of the process is not to increase the sugars content of a product, and a functionally insignificant increase in sugars results;

(iv) The product that it resembles and for which it substitutes normally contains added sugars; and

(v) The product bears a statement that the product is not ''low calorie'' or ''calorie reduced'' (unless the product meets the requirements for a ''low'' or ''reduced calorie'' product) and that directs consumers' attention to the nutrition panel for further information on sugar and calorie content.

(3) Paragraph (c)(1) of this section shall not apply to a factual statement that a product, including products intended specifically for infants and children less than 2 years of age, is unsweetened or contains no added sweeteners in the case of a product that contains apparent substantial inherent sugar content, e.g., juices.

(4) The terms ''reduced sugar,'' ''reduced in sugar,'' ''sugar reduced,'' ''less sugar,'' ''lower sugar,'' or ''lower in sugar'' may be used on the label or in labeling of products, except meal-type products as defined in § 317.313(l), provided that:

(i) The product contains at least 25 percent less sugars per reference amount customarily consumed than an appropriate reference product as described in § 317.313(j)(1); and

(ii) As required in § 317.313(j)(2) for relative claims:

(A) The identity of the reference product and the percent (or fraction) that the sugars differ between the two products are declared in immediate proximity to the most prominent such claim (e.g., ''this product contains 25 percent less sugar than our regular product''); and

(B) Quantitative information comparing the level of the sugar in the product per labeled serving size with that of the reference product that it replaces is declared adjacent to the most prominent claim or to the nutrition information (e.g., ''sugar content has

been lowered from 8 g to 6 g per serving'').

(5) The terms defined in paragraph (c)(4) of this section may be used on the label or in labeling of a meal-type product as defined in § 317.313(l), provided that:

(i) The product contains at least 25 percent less sugars per 100 g of product than an appropriate reference product as described in § 317.313(j)(1); and

(ii) As required in § 317.313(j)(2) for relative claims:

(A) The identity of the reference product and the percent (or fraction) that the sugars differ between the two products are declared in immediate proximity to the most prominent such claim (e.g., ''reduced sugar 'product'—25% less sugar than our regular 'product' ''); and

(B) Quantitative information comparing the level of the nutrient in the product per specified weight with that of the reference product that it replaces is declared adjacent to the most prominent claim or to the nutrition information (e.g., ''sugar content has been reduced from 17 g per 3 oz to 13 g per 3 oz'').

[60 FR 191, Jan. 3, 1995]

§ 317.361 Nutrient content claims for the sodium content.

(a) *General requirements.* A claim about the level of sodium in a product may only be made on the label or in labeling of the product if:

(1) The claim uses one of the terms defined in this section in accordance with the definition for that term;

(2) The claim is made in accordance with the general requirements for nutrient content claims in § 317.313; and

(3) The product for which the claim is made is labeled in accordance with § 317.309.

(b) *Sodium content claims.* (1) The terms ''sodium free,'' ''free of sodium,'' ''no sodium,'' ''zero sodium,'' ''without sodium,'' ''trivial source of sodium,'' ''negligible source of sodium,'' or ''dietarily insignificant source of sodium'' may be used on the label or in labeling of products, provided that:

(i) The product contains less than 5 milligrams (mg) of sodium per reference amount customarily consumed and per labeled serving size or, in the case of a meal-type product, less than 5 mg of sodium per labeled serving size;

(ii) The product contains no ingredient that is sodium chloride or is generally understood by consumers to contain sodium unless the listing of the ingredient in the ingredients statement is followed by an asterisk that refers to the statement below the list of ingredients, which states: ''Adds a trivial amount of sodium,'' ''adds a negligible amount of sodium'' or ''adds a dietarily insignificant amount of sodium''; and

(iii) If the product meets these conditions without the benefit of special processing, alteration, formulation, or reformulation to lower the sodium content, it is labeled to clearly refer to all products of its type and not merely to the particular brand to which the label attaches.

(2) The terms ''very low sodium'' or ''very low in sodium'' may be used on the label or in labeling of products, except meal-type products as defined in § 317.313(l), provided that:

(i)(A) The product has a reference amount customarily consumed greater than 30 grams (g) or greater than 2 tablespoons (tbsp) and contains 35 mg or less sodium per reference amount customarily consumed; or

(B) The product has a reference amount customarily consumed of 30 g or less or 2 tbsp or less and contains 35 mg or less sodium per reference amount customarily consumed and per 50 g (for dehydrated products that must be reconstituted before typical consumption with water or a diluent containing an insignificant amount, as defined in § 317.309(f)(1), of all nutrients per reference amount customarily consumed, the per-50-g criterion refers to the ''as prepared'' form); and

(ii) If the product meets these conditions without the benefit of special processing, alteration, formulation, or reformulation to lower the sodium content, it is labeled to clearly refer to all products of its type and not merely to the particular brand to which the label attaches.

(3) The terms defined in paragraph (b)(2) of this section may be used on the label or in labeling of a meal-type product as defined in § 317.313(l), provided that:

(i) The product contains 35 mg or less of sodium per 100 g of product; and

(ii) If the product meets this condition without the benefit of special processing, alteration, formulation, or reformulation to lower the sodium content, it is labeled to clearly refer to all products of its type and not merely to the particular brand to which the label attaches.

(4) The terms ''low sodium,'' ''low in sodium,'' ''little sodium,'' ''contains a small amount of sodium,'' or ''low source of sodium'' may be used on the label and in labeling of products, except meal-type products as defined in § 317.313(l), provided that:

(i)(A) The product has a reference amount customarily consumed greater than 30 g or greater than 2 tbsp and contains 140 mg or less sodium per reference amount customarily consumed; or

(B) The product has a reference amount customarily consumed of 30 g or less or 2 tbsp or less and contains 140 mg or less sodium per reference amount customarily consumed and per 50 g (for dehydrated products that must be reconstituted before typical consumption with water or a diluent containing an insignificant amount, as defined in § 317.309(f)(1), of all nutrients per reference amount customarily consumed, the per-50-g criterion refers to the ''as prepared'' form); and

(ii) If the product meets these conditions without the benefit of special processing, alteration, formulation, or reformulation to lower the sodium content, it is labeled to clearly refer to all products of its type and not merely to the particular brand to which the label attaches.

(5) The terms defined in paragraph (b)(4) of this section may be used on the label or in labeling of a meal-type product as defined in § 317.313(l), provided that:

(i) The product contains 140 mg or less sodium per 100 g of product; and

(ii) If the product meets these conditions without the benefit of special processing, alteration, formulation, or reformulation to lower the sodium content, it is labeled to clearly refer to all products of its type and not merely to the particular brand to which the label attaches.

(6) The terms ''reduced sodium,'' ''reduced in sodium,'' ''sodium reduced,'' ''less sodium,'' ''lower sodium,'' or ''lower in sodium'' may be used on the label or in labeling of products, except meal-type products as defined in § 317.313(l), provided that:

(i) The product contains at least 25 percent less sodium per reference amount customarily consumed than an appropriate reference product as described in § 317.313(j)(1); and

(ii) As required in § 317.313(j)(2) for relative claims:

(A) The identity of the reference product and the percent (or fraction) that the sodium differs between the two products are declared in immediate proximity to the most prominent such claim (e.g., ''reduced sodium 'product', 50 percent less sodium than regular 'product' ''); and

(B) Quantitative information comparing the level of sodium in the product per labeled serving size with that of the reference product that it replaces is declared adjacent to the most prominent claim or to the nutrition information (e.g., ''sodium content has been lowered from 300 to 150 mg per serving'').

(iii) Claims described in paragraph (b)(6) of this section may not be made on the label or in labeling of a product if the nutrient content of the reference product meets the definition for ''low sodium.''

(7) The terms defined in paragraph (b)(6) of this section may be used on the label or in labeling of a meal-type product as defined in § 317.313(l), provided that:

(i) The product contains at least 25 percent less sodium per 100 g of product than an appropriate reference product as described in § 317.313(j)(1); and

(ii) As required in § 317.313(j)(2) for relative claims:

(A) The identity of the reference product and the percent (or fraction) that the sodium differs between the two products are declared in immediate proximity to the most prominent such claim (e.g., ''reduced sodium 'product'—30% less sodium per 3 oz than our 'regular product' ''); and

(B) Quantitative information comparing the level of sodium in the product per specified weight with that of

the reference product that it replaces is declared adjacent to the most prominent claim or to the nutrition information (e.g., ''sodium content has been reduced from 220 mg per 3 oz to 150 mg per 3 oz'').

(iii) Claims described in paragraph (b)(7) of this section may not be made on the label or in labeling of products if the nutrient content of the reference product meets the definition for ''low sodium.''

(c) The term ''salt'' is not synonymous with ''sodium.'' Salt refers to sodium chloride. However, references to salt content such as ''unsalted,'' ''no salt,'' ''no salt added'' are potentially misleading.

(1) The term ''salt free'' may be used on the label or in labeling of products only if the product is ''sodium free'' as defined in paragraph (b)(1) of this section.

(2) The terms ''unsalted,'' ''without added salt,'' and ''no salt added'' may be used on the label or in labeling of products only if:

(i) No salt is added during processing;

(ii) The product that it resembles and for which it substitutes is normally processed with salt; and

(iii) If the product is not sodium free, the statement, ''not a sodium free product'' or ''not for control of sodium in the diet'' appears adjacent to the nutrition information of the product bearing the claim.

(3) Paragraph (c)(2) of this section shall not apply to a factual statement that a product intended specifically for infants and children less than 2 years of age is unsalted, provided such statement refers to the taste of the product and is not false or otherwise misleading.

[60 FR 192, Jan. 3, 1995]

§ 317.362 Nutrient content claims for fat, fatty acids, and cholesterol content.

(a) *General requirements.* A claim about the level of fat, fatty acid, and cholesterol in a product may only be made on the label or in labeling of products if:

(1) The claim uses one of the terms defined in this section in accordance with the definition for that term;

(2) The claim is made in accordance with the general requirements for nutrient content claims in § 317.313; and

(3) The product for which the claim is made is labeled in accordance with § 317.309.

(b) *Fat content claims.* (1) The terms ''fat free,'' ''free of fat,'' ''no fat,'' ''zero fat,'' ''without fat,'' ''nonfat,'' ''trivial source of fat,'' ''negligible source of fat,'' or ''dietarily insignificant source of fat'' may be used on the label or in labeling of products, provided that:

(i) The product contains less than 0.5 gram (g) of fat per reference amount customarily consumed and per labeled serving size or, in the case of a meal-type product, less than 0.5 g of fat per labeled serving size;

(ii) The product contains no added ingredient that is a fat or is generally understood by consumers to contain fat unless the listing of the ingredient in the ingredients statement is followed by an asterisk that refers to the statement below the list of ingredients, which states: ''Adds a trivial amount of fat,'' ''adds a negligible amount of fat,'' or ''adds a dietarily insignificant amount of fat''; and

(iii) If the product meets these conditions without the benefit of special processing, alteration, formulation, or reformulation to lower the fat content, it is labeled to clearly refer to all products of its type and not merely to the particular brand to which the label attaches.

(2) The terms ''low fat,'' ''low in fat,'' ''contains a small amount of fat,'' ''low source of fat,'' or ''little fat'' may be used on the label and in labeling of products, except meal-type products as defined in § 317.313(l), provided that:

(i)(A) The product has a reference amount customarily consumed greater than 30 g or greater than 2 tablespoons (tbsp) and contains 3 g or less of fat per reference amount customarily consumed; or

(B) The product has a reference amount customarily consumed of 30 g or less or 2 tbsp or less and contains 3 g or less of fat per reference amount customarily consumed and per 50 g (for dehydrated products that must be reconstituted before typical consumption with water or a diluent containing an

insignificant amount, as defined in § 317.309(f)(1), of all nutrients per reference amount customarily consumed, the per-50-g criterion refers to the ''as prepared'' form).

(ii) If the product meets these conditions without the benefit of special processing, alteration, formulation, or reformulation to lower the fat content, it is labeled to clearly refer to all products of its type and not merely to the particular brand to which the label attaches.

(3) The terms defined in paragraph (b)(2) of this section may be used on the label or in labeling of a meal-type product as defined in § 317.313(l), provided that:

(i) The product contains 3 g or less of total fat per 100 g of product and not more than 30 percent of calories from fat; and

(ii) If the product meets these conditions without the benefit of special processing, alteration, formulation, or reformulation to lower the fat content, it is labeled to clearly refer to all products of its type and not merely to the particular brand to which the label attaches.

(4) The terms ''reduced fat,'' ''reduced in fat,'' ''fat reduced,'' ''less fat,'' ''lower fat,'' or ''lower in fat'' may be used on the label or in labeling of products, except meal-type products as defined in § 317.313(l), provided that:

(i) The product contains at least 25 percent less fat per reference amount customarily consumed than an appropriate reference product as described in § 317.313(j)(1); and

(ii) As required in § 317.313(j)(2) for relative claims:

(A) The identity of the reference product and the percent (or fraction) that the fat differs between the two products are declared in immediate proximity to the most prominent such claim (e.g., ''reduced fat—50 percent less fat than our regular 'product' ''); and

(B) Quantitative information comparing the level of fat in the product per labeled serving size with that of the reference product that it replaces is declared adjacent to the most prominent claim or to the nutrition information (e.g., ''fat content has been reduced from 8 g to 4 g per serving'').

(iii) Claims described in paragraph (b)(4) of this section may not be made on the label or in labeling of a product if the nutrient content of the reference product meets the definition for ''low fat.''

(5) The terms defined in paragraph (b)(4) of this section may be used on the label or in labeling of a meal-type product as defined in § 317.313(l), provided that:

(i) The product contains at least 25 percent less fat per 100 g of product than an appropriate reference product as described in § 317.313(j)(1); and

(ii) As required in § 317.313(j)(2) for relative claims:

(A) The identity of the reference product and the percent (or fraction) that the fat differs between the two products are declared in immediate proximity to the most prominent such claim (e.g., ''reduced fat 'product', 33 percent less fat per 3 oz than our regular 'product' ''); and

(B) Quantitative information comparing the level of fat in the product per specified weight with that of the reference product that it replaces is declared adjacent to the most prominent such claim or to the nutrition information (e.g., ''fat content has been reduced from 8 g per 3 oz to 5 g per 3 oz'').

(iii) Claims described in paragraph (b)(5) of this section may not be made on the label or in labeling of a product if the nutrient content of the reference product meets the definition for ''low fat.''

(6) The term ''_____percent fat free'' may be used on the label or in labeling of products, provided that:

(i) The product meets the criteria for ''low fat'' in paragraph (b)(2) or (b)(3) of this section;

(ii) The percent declared and the words ''fat free'' are in uniform type size; and

(iii) A ''100 percent fat free'' claim may be made only on products that meet the criteria for ''fat free'' in paragraph (b)(1) of this section, that contain less than 0.5 g of fat per 100 g, and that contain no added fat.

(iv) A synonym for ''_____percent fat free'' is ''_____percent lean.''

(c) *Fatty acid content claims.* (1) The terms ''saturated fat free,'' ''free of saturated fat,'' ''no saturated fat,''

''zero saturated fat,'' ''without saturated fat,'' ''trivial source of saturated fat,'' ''negligible source of saturated fat,'' or ''dietarily insignificant source of saturated fat'' may be used on the label or in labeling of products, provided that:

(i) The product contains less than 0.5 g of saturated fat and less than 0.5 g *trans* fatty acids per reference amount customarily consumed and per labeled serving size or, in the case of a meal-type product, less than 0.5 g of saturated fat and less than 0.5 g *trans* fatty acids per labeled serving size;

(ii) The product contains no ingredient that is generally understood by consumers to contain saturated fat unless the listing of the ingredient in the ingredients statement is followed by an asterisk that refers to the statement below the list of ingredients, which states: ''Adds a trivial amount of saturated fat,'' ''adds a negligible amount of saturated fat,'' or ''adds a dietarily insignificant amount of saturated fat;'' and

(iii) If the product meets these conditions without the benefit of special processing, alteration, formulation, or reformulation to lower saturated fat content, it is labeled to clearly refer to all products of its type and not merely to the particular brand to which the label attaches.

(2) The terms ''low in saturated fat,'' ''low saturated fat,'' ''contains a small amount of saturated fat,'' ''low source of saturated fat,'' or ''a little saturated fat'' may be used on the label or in labeling of products, except meal-type products as defined in § 317.313(l), provided that:

(i) The product contains 1 g or less of saturated fat per reference amount customarily consumed and not more than 15 percent of calories from saturated fat; and

(ii) If the product meets these conditions without benefit of special processing, alteration, formulation, or reformulation to lower saturated fat content, it is labeled to clearly refer to all products of its type and not merely to the particular brand to which the label attaches.

(3) The terms defined in paragraph (c)(2) of this section may be used on the label or in labeling of a meal-type product as defined in § 317.313(l), provided that:

(i) The product contains 1 g or less of saturated fat per 100 g and less than 10 percent calories from saturated fat; and

(ii) If the product meets these conditions without the benefit of special processing, alteration, formulation, or reformulation to lower saturated fat content, it is labeled to clearly refer to all products of its type and not merely to the particular brand to which the label attaches.

(4) The terms ''reduced saturated fat,'' ''reduced in saturated fat,'' ''saturated fat reduced,'' ''less saturated fat,'' ''lower saturated fat,'' or ''lower in saturated fat'' may be used on the label or in labeling of products, except meal-type products as defined in § 317.313(l), provided that:

(i) The product contains at least 25 percent less saturated fat per reference amount customarily consumed than an appropriate reference product as described in § 317.313(j)(1); and

(ii) As required in § 317.313(j)(2) for relative claims:

(A) The identity of the reference product and the percent (or fraction) that the saturated fat differs between the two products are declared in immediate proximity to the most prominent such claim (e.g., ''reduced saturated fat 'product', contains 50 percent less saturated fat than the national average for 'product' ''); and

(B) Quantitative information comparing the level of saturated fat in the product per labeled serving size with that of the reference product that it replaces is declared adjacent to the most prominent claim or to the nutrition information (e.g., ''saturated fat reduced from 3 g to 1.5 g per serving'').

(iii) Claims described in paragraph (c)(4) of this section may not be made on the label or in labeling of a product if the nutrient content of the reference product meets the definition for ''low saturated fat.''

(5) The terms defined in paragraph (c)(4) of this section may be used on the label or in labeling of a meal-type product as defined in § 317.313(l), provided that:

(i) The product contains at least 25 percent less saturated fat per 100 g of

product than an appropriate reference product as described in § 317.313(j)(1); and

(ii) As required in § 317.313(j)(2) for relative claims:

(A) The identity of the reference product and the percent (or fraction) that the saturated fat differs between the two products are declared in immediate proximity to the most prominent such claim (e.g., ''reduced saturated fat 'product','' ''50 percent less saturated fat than our regular 'product' ''); and

(B) Quantitative information comparing the level of saturated fat in the product per specified weight with that of the reference product that it replaces is declared adjacent to the most prominent claim or to the nutrition information (e.g., ''saturated fat content has been reduced from 2.5 g per 3 oz to 1.5 g per 3 oz'').

(iii) Claims described in paragraph (c)(5) of this section may not be made on the label or in labeling of a product if the nutrient content of the reference product meets the definition for ''low saturated fat.''

(d) *Cholesterol content claims.* (1) The terms ''cholesterol free,'' ''free of cholesterol,'' ''zero cholesterol,'' ''without cholesterol,'' ''no cholesterol,'' ''trivial source of cholesterol,'' ''negligible source of cholesterol,'' or ''dietarily insignificant source of cholesterol'' may be used on the label or in labeling of products, provided that:

(i) The product contains less than 2 milligrams (mg) of cholesterol per reference amount customarily consumed and per labeled serving size or, in the case of a meal-type product as defined in § 317.313(l), less than 2 mg of cholesterol per labeled serving size;

(ii) The product contains no ingredient that is generally understood by consumers to contain cholesterol, unless the listing of the ingredient in the ingredients statement is followed by an asterisk that refers to the statement below the list of ingredients, which states: ''Adds a trivial amount of cholesterol,'' ''adds a negligible amount of cholesterol,'' or ''adds a dietarily insignificant amount of cholesterol'';

(iii) The product contains 2 g or less of saturated fat per reference amount customarily consumed or, in the case of a meal-type product as defined in § 317.313(l), 2 g or less of saturated fat per labeled serving size; and

(iv) If the product meets these conditions without the benefit of special processing, alteration, formulation, or reformulation to lower cholesterol content, it is labeled to clearly refer to all products of its type and not merely to the particular brand to which it attaches; or

(v) If the product meets these conditions only as a result of special processing, alteration, formulation, or reformulation, the amount of cholesterol is reduced by 25 percent or more from the reference product it replaces as described in § 317.313(j)(1) and for which it substitutes as described in § 317.313(d) that has a significant (e.g., 5 percent or more of a national or regional market) market share. As required in § 317.313(j)(2) for relative claims:

(A) The identity of the reference product and the percent (or fraction) that the cholesterol was reduced are declared in immediate proximity to the most prominent such claim (e.g., ''cholesterol free 'product', contains 100 percent less cholesterol than 'reference product' ''); and

(B) Quantitative information comparing the level of cholesterol in the product per labeled serving size with that of the reference product that it replaces is declared adjacent to the most prominent claim or to the nutrition information (e.g., ''contains no cholesterol compared with 30 mg in one serving of 'reference product' '').

(2) The terms ''low in cholesterol,'' ''low cholesterol,'' ''contains a small amount of cholesterol,'' ''low source of cholesterol,'' or ''little cholesterol'' may be used on the label or in labeling of products, except meal-type products as defined in § 317.313(l), provided that:

(i)(A) If the product has a reference amount customarily consumed greater than 30 g or greater than 2 tbsp:

(*1*) The product contains 20 mg or less of cholesterol per reference amount customarily consumed; and

(*2*) The product contains 2 g or less of saturated fat per reference amount customarily consumed; or

(B) If the product has a reference amount customarily consumed of 30 g or less or 2 tbsp or less:

(*1*) The product contains 20 mg or less of cholesterol per reference amount customarily consumed and per 50 g (for dehydrated products that must be reconstituted before typical consumption with water or a diluent containing an insignificant amount, as defined in §317.309(f)(1), of all nutrients per reference amount customarily consumed, the per-50-g criterion refers to the ''as prepared'' form); and

(*2*) The product contains 2 g or less of saturated fat per reference amount customarily consumed.

(ii) If the product meets these conditions without the benefit of special processing, alteration, formulation, or reformulation to lower cholesterol content, it is labeled to clearly refer to all products of its type and not merely to the particular brand to which the label attaches; or

(iii) If the product contains 20 mg or less of cholesterol only as a result of special processing, alteration, formulation, or reformulation, the amount of cholesterol is reduced by 25 percent or more from the reference product it replaces as described in §317.313(j)(1) and for which it substitutes as described in §317.313(d) that has a significant (e.g., 5 percent or more of a national or regional market) market share. As required in §317.313(j)(2) for relative claims:

(A) The identity of the reference product and the percent (or fraction) that the cholesterol has been reduced are declared in immediate proximity to the most prominent such claim (e.g., ''low cholesterol 'product', contains 85 percent less cholesterol than our regular 'product' ''); and

(B) Quantitative information comparing the level of cholesterol in the product per labeled serving size with that of the reference product that it replaces is declared adjacent to the most prominent claim or to the nutrition information (e.g., ''cholesterol lowered from 30 mg to 5 mg per serving'').

(3) The terms defined in paragraph (d)(2) of this section may be used on the label or in labeling of a meal-type product as defined in §317.313(l), provided that:

(i) The product contains 20 mg or less of cholesterol per 100 g of product;

(ii) The product contains 2 g or less of saturated fat per 100 g of product; and

(iii) If the product meets these conditions without the benefit of special processing, alteration, formulation, or reformulation to lower cholesterol content, it is labeled to clearly refer to all products of its type and not merely to the particular brand to which the label attaches.

(4) The terms ''reduced cholesterol,'' ''reduced in cholesterol,'' ''cholesterol reduced,'' ''less cholesterol,'' ''lower cholesterol,'' or ''lower in cholesterol'' may be used on the label or in labeling of products or products that substitute for those products as specified in §317.313(d), excluding meal-type products as defined in §317.313(l), provided that:

(i) The product has been specifically formulated, altered, or processed to reduce its cholesterol by 25 percent or more from the reference product it replaces as described in §317.313(j)(1) and for which it substitutes as described in §317.313(d) that has a significant (e.g., 5 percent or more of a national or regional market) market share;

(ii) The product contains 2 g or less of saturated fat per reference amount customarily consumed; and

(iii) As required in §317.313(j)(2) for relative claims:

(A) The identity of the reference product and the percent (or fraction) that the cholesterol has been reduced are declared in immediate proximity to the most prominent such claim (e.g., ''25 percent less cholesterol than 'reference product' ''); and

(B) Quantitative information comparing the level of cholesterol in the product per labeled serving size with that of the reference product that it replaces is declared adjacent to the most prominent claim or to the nutrition information (e.g., ''cholesterol lowered from 55 mg to 30 mg per serving'').

(iv) Claims described in paragraph (d)(4) of this section may not be made on the label or in labeling of a product if the nutrient content of the reference product meets the definition for ''low cholesterol.''

(5) The terms defined in paragraph (d)(4) of this section may be used on the label or in labeling of a meal-type

product as defined in §317.313(l), provided that:

(i) The product has been specifically formulated, altered, or processed to reduce its cholesterol by 25 percent or more from the reference product it replaces as described in §317.313(j)(1) and for which it substitutes as described in §317.313(d) that has a significant (e.g., 5 percent or more of a national or regional market) market share;

(ii) The product contains 2 g or less of saturated fat per 100 g of product; and

(iii) As required in §317.313(j)(2) for relative claims:

(A) The identity of the reference product and the percent (or fraction) that the cholesterol has been reduced are declared in immediate proximity to the most prominent such claim (e.g., ''25% less cholesterol than 'reference product' ''); and

(B) Quantitative information comparing the level of cholesterol in the product per specified weight with that of the reference product that it replaces is declared adjacent to the most prominent claim or to the nutrition information (e.g., ''cholesterol content has been reduced from 35 mg per 3 oz to 25 mg per 3 oz).

(iv) Claims described in paragraph (d)(5) of this section may not be made on the label or in labeling of a product if the nutrient content of the reference product meets the definition for ''low cholesterol.''

(e) *''Lean'' and ''Extra Lean'' claims.* (1) The term ''lean'' may be used on the label or in labeling of a product, provided that the product contains less than 10 g of fat, 4.5 g or less of saturated fat, and less than 95 mg of cholesterol per 100 g of product and per reference amount customarily consumed for individual foods, and per 100 g of product and per labeled serving size for meal-type products as defined in §317.313(l).

(2) The term ''extra lean'' may be used on the label or in labeling of a product, provided that the product contains less than 5 g of fat, less than 2 g of saturated fat, and less than 95 mg of cholesterol per 100 g of product and per reference amount customarily consumed for individual foods, and per 100 g of product and per labeled serving size for meal-type products as defined in §317.313(l).

[60 FR 193, Jan. 3, 1995]

§317.363 Nutrient content claims for "healthy."

(a) The term ''healthy,'' or any other derivative of the term ''health,'' may be used on the labeling of any meat or meat food product, provided that the product is labeled in accordance with §317.309 and §317.313.

(b)(1) The product shall meet the requirements for ''low fat'' and ''low saturated fat,'' as defined in §317.362, except that single-ingredient, raw products may meet the total fat and saturated fat criteria for ''extra lean'' in §317.362.

(2) The product shall not contain more than 60 milligrams (mg) of cholesterol per reference amount customarily consumed, per labeled serving size, and, only for foods with reference amounts customarily consumed of 30 grams (g) or less or 2 tablespoons (tbsp) or less, per 50 g, and, for dehydrated products that must be reconstituted with water or a diluent containing an insignificant amount, as defined in §317.309(f)(1), of all nutrients, the per-50-g criterion refers to the prepared form, except that:

(i) A meal-type product, as defined in §317.313(l), and including meal-type products that weigh more than 12 ounces (oz) per serving (container), shall not contain more than 90 mg of cholesterol per labeled serving size; and

(ii) Single-ingredient, raw products may meet the cholesterol criterion for ''extra lean''in §317.362.

(3) The product shall not contain more than 360 mg of sodium, except that it shall not contain more than 480 mg of sodium effective through January 1, 2006, per reference amount customarily consumed, per labeled serving size, and, only for foods with reference amounts customarily consumed of 30 g or less or 2 tbsp or less, per 50 g, and, for dehydrated products that must be reconstituted with water or a diluent containing an insignificant amount, as defined in §317.309(f)(1), of all nutrients, the per-50-g criterion refers to the prepared form, except that:

(i) A meal-type product, as defined in § 317.313(l), and including meal-type products that weigh more than 12 oz per serving (container), shall not contain more than 480 mg of sodium, except that it shall not contain more than 600 mg of sodium effective through January 1, 2006, per labeled serving size; and

(ii) The requirements of this paragraph (b)(3) do not apply to single-ingredient, raw products.

(4) The product shall contain 10 percent or more of the Reference Daily Intake or Daily Reference Value as defined in § 317.309 for vitamin A, vitamin C, iron, calcium, protein, or fiber per reference amount customarily consumed prior to any nutrient addition, except that:

(i) A meal-type product, as defined in § 317.313(l), and including meal-type products that weigh at least 6 oz but less than 10 oz per serving (container), shall meet the level for two of the nutrients per labeled serving size; and

(ii) A meal-type product, as defined in § 317.313(l), and including meal-type products that weigh 10 oz or more per serving (container), shall meet the level for three of the nutrients per labeled serving size.

[59 FR 24228, May 10, 1994, as amended at 60 FR 196, Jan. 3, 1995; 63 FR 7281, Feb. 13, 1998; 64 FR 72492, Dec. 28, 1999; 68 FR 463, Jan. 6, 2003]

§§ 317.364–317.368 [Reserved]

§ 317.369 Labeling applications for nutrient content claims.

(a) This section pertains to labeling applications for claims, express or implied, that characterize the level of any nutrient required to be on the label or in labeling of product by this subpart.

(b) Labeling applications included in this section are:

(1) Labeling applications for a new (heretofore unauthorized) nutrient content claim,

(2) Labeling applications for a synonymous term (i.e., one that is consistent with a term defined by regulation) for characterizing the level of a nutrient, and

(3) Labeling applications for the use of an implied claim in a brand name.

(c) Labeling applications and supporting documentation to be filed under this section shall be submitted in quadruplicate, except that the supporting documentation may be submitted on a computer disc copy. If any part of the material submitted is in a foreign language, it shall be accompanied by an accurate and complete English translation. The labeling application shall state the applicant's post office address.

(d) Pertinent information will be considered as part of an application on the basis of specific reference to such information submitted to and retained in the files of the Food Safety and Inspection Service. However, any reference to unpublished information furnished by a person other than the applicant will not be considered unless use of such information is authorized (with the understanding that such information may in whole or part be subject to release to the public) in a written statement signed by the person who submitted it. Any reference to published information should be accompanied by reprints or photostatic copies of such references.

(e) If nonclinical laboratory studies accompany a labeling application, the applicant shall include, with respect to each nonclinical study included with the application, either a statement that the study has been, or will be, conducted in compliance with the good laboratory practice regulations as set forth in part 58 of chapter 1, title 21, or, if any such study was not conducted in compliance with such regulations, a brief statement of the reason for the noncompliance.

(f) If clinical investigations accompany a labeling application, the applicant shall include, with respect to each clinical investigation included with the application, either a statement that the investigation was conducted in compliance with the requirements for institutional review set forth in part 56 of chapter 1, title 21, or was not subject to such requirements in accordance with § 56.194 or § 56.105, and that it was conducted in compliance with the requirements for informed consents set forth in part 50 of chapter 1, title 21.

(g) The availability for public disclosure of labeling applications, along

with supporting documentation, submitted to the Agency under this section will be governed by the rules specified in subchapter D, title 9.

(h) The data specified under this section to accompany a labeling application shall be submitted on separate sheets, suitably identified. If such data has already been submitted with an earlier labeling application from the applicant, the present labeling application must provide the data.

(i) The labeling application must be signed by the applicant or by his or her attorney or agent, or (if a corporation) by an authorized official.

(j) The labeling application shall include a statement signed by the person responsible for the labeling application, that to the best of his or her knowledge, it is a representative and balanced submission that includes unfavorable information, as well as favorable information, known to him or her pertinent to the evaluation of the labeling application.

(k)(1) Labeling applications for a new nutrient content claim shall be accompanied by the following data which shall be submitted in the following form to the Director, Food Labeling Division, Regulatory Programs, Food Safety and Inspection Service, Washington, DC 20250.

(Date)

The undersigned, _____, submits this labeling application pursuant to 9 CFR 317.369 with respect to (statement of the claim and its proposed use).

Attached hereto, in quadruplicate, or on a computer disc copy, and constituting a part of this labeling application, are the following:

(i) A statement identifying the nutrient content claim and the nutrient that the term is intended to characterize with respect to the level of such nutrient. The statement shall address why the use of the term as proposed will not be misleading. The statement shall provide examples of the nutrient content claim as it will be used on labels or labeling, as well as the types of products on which the claim will be used. The statement shall also specify the level at which the nutrient must be present or what other conditions concerning the product must be met for the appropriate use of the term in labels or labeling, as well as any factors that would make the use of the term inappropriate.

(ii) A detailed explanation supported by any necessary data of why use of the food component characterized by the claim is of importance in human nutrition by virtue of its presence or absence at the levels that such claim would describe. This explanation shall also state what nutritional benefit to the public will derive from use of the claim as proposed and why such benefit is not available through the use of existing terms defined by regulation. If the claim is intended for a specific group within the population, the analysis shall specifically address nutritional needs of such group, and scientific data sufficient for such purpose, and data and information to the extent necessary to demonstrate that consumers can be expected to understand the meaning of the term under the proposed conditions of use.

(iii) Analytical data that demonstrates the amount of the nutrient that is present in the products for which the claim is intended. The assays should be performed on representative samples in accordance with 317.309(h). If no USDA or AOAC methods are available, the applicant shall submit the assay method used, and data establishing the validity of the method for assaying the nutrient in the particular food. The validation data shall include a statistical analysis of the analytical and product variability.

(iv) A detailed analysis of the potential effect of the use of the proposed claim on food consumption, and any corresponding changes in nutrient intake. The analysis shall specifically address the intake of nutrients that have beneficial and negative consequences in the total diet. If the claim is intended for a specific group within the population, the analysis shall specifically address the dietary practices of such group, and shall include data sufficient to demonstrate that the dietary analysis is representative of such group.

Yours very truly,

Applicant _____

By _____

(Indicate authority)

(2) Upon receipt of the labeling application and supporting documentation, the applicant shall be notified, in writing, of the date on which the labeling application was received. Such notice shall inform the applicant that the labeling application is undergoing Agency review and that the applicant shall subsequently be notified of the Agency's decision to consider for further review or deny the labeling application.

(3) Upon review of the labeling application and supporting documentation, the Agency shall notify the applicant,

in writing, that the labeling application is either being considered for further review or that it has been summarily denied by the Administrator.

(4) If the labeling application is summarily denied by the Administrator, the written notification shall state the reasons therefor, including why the Agency has determined that the proposed nutrient content claim is false or misleading. The notification letter shall inform the applicant that the applicant may submit a written statement by way of answer to the notification, and that the applicant shall have the right to request a hearing with respect to the merits or validity of the Administrator's decision to deny the use of the proposed nutrient content claim.

(i) If the applicant fails to accept the determination of the Administrator and files an answer and requests a hearing, and the Administrator, after review of the answer, determines the initial determination to be correct, the Administrator shall file with the Hearing Clerk of the Department the notification, answer, and the request for a hearing, which shall constitute the complaint and answer in the proceeding, which shall thereafter be conducted in accordance with the Department's Uniform Rules of Practice.

(ii) The hearing shall be conducted before an administrative law judge with the opportunity for appeal to the Department's Judicial Officer, who shall make the final determination for the Secretary. Any such determination by the Secretary shall be conclusive unless, within 30 days after receipt of notice of such final determination, the applicant appeals to the United States Court of Appeals for the circuit in which the applicant has its principal place of business or to the United States Court of Appeals for the District of Columbia Circuit.

(5) If the labeling application is not summarily denied by the Administrator, the Administrator shall publish in the FEDERAL REGISTER a proposed rule to amend the regulations to authorize the use of the nutrient content claim. The proposal shall also summarize the labeling application, including where the supporting documentation can be reviewed. The Administrator's proposed rule shall seek comment from consumers, the industry, consumer and industry groups, and other interested persons on the labeling application and the use of the proposed nutrient content claim. After public comment has been received and reviewed by the Agency, the Administrator shall make a determination on whether the proposed nutrient content claim shall be approved for use on the labeling of meat and meat food products.

(i) If the claim is denied by the Administrator, the Agency shall notify the applicant, in writing, of the basis for the denial, including the reason why the claim on the labeling was determined by the Agency to be false or misleading. The notification letter shall also inform the applicant that the applicant may submit a written statement by way of answer to the notification, and that the applicant shall have the right to request a hearing with respect to the merits or validity of the Administrator's decision to deny the use of the proposed nutrient content claim.

(A) If the applicant fails to accept the determination of the Administrator and files an answer and requests a hearing, and the Administrator, after review of the answer, determines the initial determination to be correct, the Administrator shall file with the Hearing Clerk of the Department the notification, answer, and the request for a hearing, which shall constitute the complaint and answer in the proceeding, which shall thereafter be conducted in accordance with the Department's Uniform Rules of Practice.

(B) The hearing shall be conducted before an administrative law judge with the opportunity for appeal to the Department's Judicial Officer, who shall make final determination for the Secretary. Any such determination by the Secretary shall be conclusive unless, within 30 days after receipt of the notice of such final determination, the applicant appeals to the United States Court of Appeals for the circuit in which the applicant has its principal place of business or to the United States Court of Appeals for the District of Columbia Circuit.

(ii) If the claim is approved, the Agency shall notify the applicant, in

writing, and shall also publish in the FEDERAL REGISTER a final rule amending the regulations to authorize the use of the claim.

(l)(1) Labeling applications for a synonymous term shall be accompanied by the following data which shall be submitted in the following form to the Director, Food Labeling Division, Regulatory Programs, Food Safety and Inspection Service, Washington, DC 20250:

_____

(Date)

The undersigned, _____ submits this labeling application pursuant to 9 CFR 317.369 with respect to (statement of the synonymous term and its proposed use in a nutrient content claim that is consistent with an existing term that has been defined under subpart B of part 317).

Attached hereto, in quadruplicate, or on a computer disc copy, and constituting a part of this labeling application, are the following:

(i) A statement identifying the synonymous term, the existing term defined by a regulation with which the synonymous term is claimed to be consistent, and the nutrient that the term is intended to characterize the level of. The statement shall address why the use of the synonymous term as proposed will not be misleading. The statement shall provide examples of the nutrient content claim as it will be used on labels or labeling, as well as the types of products on which the claim will be used. The statement shall also specify whether any limitations not applicable to the use of the defined term are intended to apply to the use of the synonymous term.

(ii) A detailed explanation supported by any necessary data of why use of the proposed term is requested, including whether the existing defined term is inadequate for the purpose of effectively characterizing the level of a nutrient. This explanation shall also state what nutritional benefit to the public will derive from use of the claim as proposed, and why such benefit is not available through the use of existing terms defined by regulation. If the claim is intended for a specific group within the population, the analysis shall specifically address nutritional needs of such group, scientific data sufficient for such purpose, and data and information to the extent necessary to demonstrate that consumers can be expected to understand the meaning of the term under the proposed conditions of use.

Yours very truly,

Applicant _____

By _____

(Indicate authority)

(2) Upon receipt of the labeling application and supporting documentation, the applicant shall be notified, in writing, of the date on which the labeling application was received. Such notice shall inform the applicant that the labeling application is undergoing Agency review and that the applicant shall subsequently be notified of the Agency's decision to consider for further review or deny the labeling application.

(3) Upon review of the labeling application and supporting documentation, the Agency shall notify the applicant, in writing, that the labeling application is either being considered for further review or that it has been summarily denied by the Administrator.

(4) If the labeling application is summarily denied by the Administrator, the written notification shall state the reasons therefor, including why the Agency has determined that the proposed synonymous term is false or misleading. The notification letter shall inform the applicant that the applicant may submit a written statement by way of answer to the notification, and that the applicant shall have the right to request a hearing with respect to the merits or validity of the Administrator's decision to deny the use of the proposed synonymous term.

(i) If the applicant fails to accept the determination of the Administrator and files an answer and requests a hearing, and the Administrator, after review of the answer, determines the initial determination to be correct, the Administrator shall file with the Hearing Clerk of the Department the notification, answer, and the request for a hearing, which shall constitute the complaint and answer in the proceeding, which shall thereafter be conducted in accordance with the Department's Uniform Rules of Practice.

(ii) The hearing shall be conducted before an administrative law judge with the opportunity for appeal to the Department's Judicial Officer, who shall make the final determination for the Secretary. Any such determination by the Secretary shall be conclusive unless, within 30 days after receipt of notice of such final determination, the applicant appeals to the United States Court of Appeals for the circuit in which the applicant has its principal

place of business or to the United States Court of Appeals for the District of Columbia Circuit.

(5) If the claim is approved, the Agency shall notify the applicant, in writing, and shall publish in the FEDERAL REGISTER a notice informing the public that the synonymous term has been approved for use.

(m)(1) Labeling applications for the use of an implied nutrient content claim in a brand name shall be accompanied by the following data which shall be submitted in the following form to the Director, Food Labeling Division, Regulatory Programs, Food Safety and Inspection Service, Washington, DC 20250:

_____

(Date)

The undersigned, _____ submits this labeling application pursuant to 9 CFR 317.369 with respect to (statement of the implied nutrient content claim and its proposed use in a brand name).

Attached hereto, in quadruplicate, or on a computer disc copy, and constituting a part of this labeling application, are the following:

(i) A statement identifying the implied nutrient content claim, the nutrient the claim is intended to characterize, the corresponding term for characterizing the level of such nutrient as defined by a regulation, and the brand name of which the implied claim is intended to be a part. The statement shall address why the use of the brand-name as proposed will not be misleading. The statement shall provide examples of the types of products on which the brand name will appear. It shall also include data showing that the actual level of the nutrient in the food would qualify the label of the product to bear the corresponding term defined by regulation. Assay methods used to determine the level of a nutrient shall meet the requirements stated under labeling application format in paragraph (k)(1)(iii) of this section.

(ii) A detailed explanation supported by any necessary data of why use of the proposed brand name is requested. This explanation shall also state what nutritional benefit to the public will derive from use of the brand name as proposed. If the branded product is intended for a specific group within the population, the analysis shall specifically address nutritional needs of such group and scientific data sufficient for such purpose.

Yours very truly,

Applicant _____

By _____

(2) Upon receipt of the labeling application and supporting documentation, the applicant shall be notified, in writing, of the date on which the labeling application was received. Such notice shall inform the applicant that the labeling application is undergoing Agency review and that the applicant shall subsequently be notified of the Agency's decision to consider for further review or deny the labeling application.

(3) Upon review of the labeling application and supporting documentation, the Agency shall notify the applicant, in writing, that the labeling application is either being considered for further review or that it has been summarily denied by the Administrator.

(4) If the labeling application is summarily denied by the Administrator, the written notification shall state the reasons therefor, including why the Agency has determined that the proposed implied nutrient content claim is false or misleading. The notification letter shall inform the applicant that the applicant may submit a written statement by way of answer to the notification, and that the applicant shall have the right to request a hearing with respect to the merits or validity of the Administrator's decision to deny the use of the proposed implied nutrient content claim.

(i) If the applicant fails to accept the determination of the Administrator and files an answer and requests a hearing, and the Administrator, after review of the answer, determines the initial determination to be correct, the Administrator shall file with the Hearing Clerk of the Department the notification, answer, and the request for a hearing, which shall constitute the complaint and answer in the proceeding, which shall thereafter be conducted in accordance with the Department's Uniform Rules of Practice.

(ii) The hearing shall be conducted before an administrative law judge with the opportunity for appeal to the Department's Judicial Officer, who shall make the final determination for the Secretary. Any such determination by the Secretary shall be conclusive unless, within 30 days after receipt of notice of such final determination, the applicant appeals to the United States Court of Appeals for the circuit in

which the applicant has its principal place of business or to the United States Court of Appeals for the District of Columbia Circuit.

(5) If the labeling application is not summarily denied by the Administrator, the Administrator shall publish a notice of the labeling application in the FEDERAL REGISTER seeking comment on the use of the implied nutrient content claim. The notice shall also summarize the labeling application, including where the supporting documentation can be reviewed. The Administrator's notice shall seek comment from consumers, the industry, consumer and industry groups, and other interested persons on the labeling application and the use of the implied nutrient content claim. After public comment has been received and reviewed by the Agency, the Administrator shall make a determination on whether the implied nutrient content claim shall be approved for use on the labeling of meat food products.

(i) If the claim is denied by the Administrator, the Agency shall notify the applicant, in writing, of the basis for the denial, including the reason why the claim on the labeling was determined by the Agency to be false or misleading. The notification letter shall also inform the applicant that the applicant may submit a written statement by way of answer to the notification, and that the applicant shall have the right to request a hearing with respect to the merits or validity of the Administrator's decision to deny the use of the proposed implied nutrient content claim.

(A) If the applicant fails to accept the determination of the Administrator and files an answer and requests a hearing, and the Administrator, after review of the answer, determines the initial determination to be correct, the Administrator shall file with the Hearing Clerk of the Department the notification, answer, and the request for a hearing, which shall thereafter be conducted in accordance with the Department's Uniform Rules of Practice.

(B) The hearing shall be conducted before an administrative law judge with the opportunity for appeal to the Department's Judicial Officer, who shall make the final determination for the Secretary. Any such determination by the Secretary shall be conclusive unless, within 30 days after receipt of the notice of such final determination, the applicant appeals to the United States Court of Appeals for the circuit in which the applicant has its principal place of business or to the United States Court of Appeals for the District of Columbia Circuit.

(ii) If the claim is approved, the Agency shall notify the applicant, in writing, and shall also publish in the FEDERAL REGISTER a notice informing the public that the implied nutrient content claim has been approved for use.

(Paperwork requirements were approved by the Office of Management and Budget under control number 0583–0088)

[58 FR 664, Jan. 6, 1993, as amended at 59 FR 45196, Sept. 1, 1994; 60 FR 196, Jan. 3, 1995]

§§ 317.370–317.379 [Reserved]

§ 317.380 Label statements relating to usefulness in reducing or maintaining body weight.

(a) *General requirements.* Any product that purports to be or is represented for special dietary use because of usefulness in reducing body weight shall bear:

(1) Nutrition labeling in conformity with § 317.309 of this subpart, unless exempt under that section, and

(2) A conspicuous statement of the basis upon which the product claims to be of special dietary usefulness.

(b) *Nonnutritive ingredients.* (1) Any product subject to paragraph (a) of this section that achieves its special dietary usefulness by use of a nonnutritive ingredient (i.e., one not utilized in normal metabolism) shall bear on its label a statement that it contains a nonnutritive ingredient and the percentage by weight of the nonnutritive ingredient.

(2) A special dietary product may contain a nonnutritive sweetener or other ingredient only if the ingredient is safe for use in the product under the applicable law and regulations of this chapter. Any product that achieves its special dietary usefulness in reducing or maintaining body weight through the use of a nonnutritive sweetener shall bear on its label the statement

required by paragraph (b)(1) of this section, but need not state the percentage by weight of the nonnutritive sweetener. If a nutritive sweetener(s) as well as nonnutritive sweetener(s) is added, the statement shall indicate the presence of both types of sweetener; e.g., ''Sweetened with nutritive sweetener(s) and nonnutritive sweetener(s).''

(c) *''Low calorie'' foods.* A product purporting to be ''low calorie'' must comply with the criteria set forth for such foods in § 317.360.

(d) *''Reduced calorie'' foods and other comparative claims.* A product purporting to be ''reduced calorie'' or otherwise containing fewer calories than a reference food must comply with the criteria set forth for such foods in § 317.360(b) (4) and (5).

(e) *''Label terms suggesting usefulness as low calorie or reduced calorie foods''.* (1) Except as provided in paragraphs (e)(2) and (e)(3) of this section, a product may be labeled with terms such as ''diet,'' ''dietetic,'' ''artificially sweetened,'' or ''sweetened with nonnutritive sweetener'' only if the claim is not false or misleading, and the product is labeled ''low calorie'' or ''reduced calorie'' or bears another comparative calorie claim in compliance with the applicable provisions in this subpart.

(2) Paragraph (e)(1) of this section shall not apply to any use of such terms that is specifically authorized by regulation governing a particular food, or, unless otherwise restricted by regulation, to any use of the term ''diet'' that clearly shows that the product is offered solely for a dietary use other than regulating body weight, e.g., ''for low sodium diets.''

(3) Paragraph (e)(1) of this section shall not apply to any use of such terms on a formulated meal replacement or other product that is represented to be of special dietary use as a whole meal, pending the issuance of a regulation governing the use of such terms on foods.

(f) *''Sugar free'' and ''no added sugar''.* Criteria for the use of the terms ''sugar free'' and ''no added sugar'' are provided for in § 317.360(c).

[58 FR 664, Jan. 6, 1993; 58 FR 43788, Aug. 18, 1993, as amended at 58 FR 47627, Sept. 10, 1993; 58 FR 66075, Dec. 17, 1993; 60 FR 196, Jan. 3, 1995]

§§ 317.381–317.399 [Reserved]

§ 317.400 Exemption from nutrition labeling.

(a) The following meat or meat food products are exempt from nutrition labeling:

(1) Food products produced by small businesses provided that the labels for these products bear no nutrition claims or nutrition information,

(i) A food product, for the purposes of the small business exemption, is defined as a formulation, not including distinct flavors which do not significantly alter the nutritional profile, sold in any size package in commerce.

(ii) For purposes of this paragraph, a small business is any single-plant facility or multi-plant company/firm that employs 500 or fewer people and produces no more than the following amounts of pounds of the product qualifying the firm for exemption from this subpart:

(A) During the first year of implementation of nutrition labeling, from July 1994 to July 1995, 250,000 pounds or less,

(B) During the second year of implementation of nutrition labeling, from July 1995 to July 1996, 175,000 pounds or less, and

(C) During the third year of implementation and subsequent years thereafter, 100,000 pounds or less.

(iii) For purposes of this paragraph, calculation of the amount of pounds shall be based on the most recent 2-year average of business activity. Where firms have been in business less than 2 years or where products have been produced for less than 2 years, reasonable estimates must indicate that the annual pounds produced will not exceed the amounts specified.

(2) Products intended for further processing, provided that the labels for these products bear no nutrition claim or nutrition information,

(3) Products that are not for sale to consumers, provided that the labels for these products bear no nutrition claims or nutrition information,

(4) Products in small packages that are individually wrapped packages of less than ½ ounce net weight, provided that the labels for these products bear

no nutrition claims or nutrition information,

(5) Products custom slaughtered or prepared,

(6) Products intended for export, and

(7) The following products prepared and served or sold at retail provided that the labels or the labeling of these products bear no nutrition claims or nutrition information:

(i) Ready-to-eat products that are packaged or portioned at a retail store or similar retail-type establishment; and

(ii) Multi-ingredient products (e.g., sausage) processed at a retail store or similar retail-type establishment.

(b) Restaurant menus generally do not constitute labeling or fall within the scope of these regulations.

(c)(1) Foods represented to be specifically for infants and children less than 2 years of age shall bear nutrition labeling as provided in paragraph (c)(2) of this section, except such labeling shall not include calories from fat, calories from saturated fat, saturated fat, stearic acid, polyunsaturated fat, monounsaturated fat, and cholesterol.

(2) Foods represented or purported to be specifically for infants and children less than 4 years of age shall bear nutrition labeling except that:

(i) Such labeling shall not include declarations of percent of Daily Value for total fat, saturated fat, cholesterol, sodium, potassium, total carbohydrate, and dietary fiber;

(ii) Nutrient names and quantitative amounts by weight shall be presented in two separate columns;

(iii) The heading ''Percent Daily Value'' required in §317.309(d)(6) shall be placed immediately below the quantitative information by weight for protein;

(iv) The percent of the Daily Value for protein, vitamins, and minerals shall be listed immediately below the heading ''Percent Daily Value''; and

(v) Such labeling shall not include the footnote specified in §317.309(d)(9).

(d)(1) Products in packages that have a total surface area available to bear labeling of less than 12 square inches are exempt from nutrition labeling, provided that the labeling for these products bear no nutrition claims or other nutrition information. The manufacturer, packer, or distributor shall provide, on the label of packages that qualify for and use this exemption, an address or telephone number that a consumer can use to obtain the required nutrition information (e.g., ''For nutrition information call 1–800–123–4567'').

(2) When such products bear nutrition labeling, either voluntarily or because nutrition claims or other nutrition information is provided, all required information shall be in a type size no smaller than 6 point or all upper case type of 1/16-inch minimum height, except that individual serving-size packages of meat products that have a total area available to bear labeling of 3 square inches or less may provide all required information in a type size no smaller than 1/32-inch minimum height.

[58 FR 664, Jan. 6, 1993, as amended at 58 FR 47627, Sept. 10, 1993; 59 FR 45196, Sept. 1, 1994; 60 FR 196, Jan. 3, 1995]

PART 318—ENTRY INTO OFFICIAL ESTABLISHMENTS; REINSPECTION AND PREPARATION OF PRODUCTS

Subpart A—General

Sec.

318.1 Products and other articles entering official establishments.
318.2 Reinspection, retention, and disposal of meat and poultry products at official establishments.
318.3 Designation of places of receipt of products and other articles for reinspection.
318.4 Preparation of products to be officially supervised; responsibilities of official establishments; plant operated quality control.
318.5 Requirements concerning procedures.
318.6 Requirements concerning ingredients and other articles used in preparation of products.
318.8 Preservatives and other substances permitted in product for export only; handling; such product not to be used for domestic food purposes.
318.9 Samples of products, water, dyes, chemicals, etc., to be taken for examination.
318.10 Prescribed treatment of pork and products containing pork to destroy trichinae.
318.11 [Reserved]

318.12 Manufacture of dog food or similar uninspected article at official establishments.
318.13 Mixtures containing product but not amendable to the Act.
318.14 Adulteration of product by polluted water; procedure for handling.
318.15 Tagging chemicals, preservatives, cereals, spices, etc., ''U.S. retained.''
318.16 Pesticide chemicals and other residues in products.
318.17 Requirements for the production of cooked beef, roast beef, and cooked corned beef products.
318.18 Handling of certain material for mechanical processing.
318.19 Compliance procedure for cured pork products.
318.20 Use of animal drugs.
318.21 Accreditation of chemistry laboratories.
318.22 Determination of added water in cooked sausages.
318.23 Heat-processing and stabilization requirements for uncured meat patties.
318.24 Compliance procedures for meat derived from advanced meat/bone separation machinery and recovery systems.

Subparts B–F [Reserved]

Subpart G—Canning and Canned Products

318.300 Definitions.
318.301 Containers and closures.
318.302 Thermal processing.
318.303 Critical factors and the application of the process schedule.
318.304 Operations in the thermal processing area.
318.305 Equipment and procedures for heat processing systems.
318.306 Processing and production records.
318.307 Record review and maintenance.
318.308 Deviations in processing.
318.309 Finished product inspection.
318.310 Personnel and training.
318.311 Recall procedure.

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) To ensure the safe use of preparations used in hog scalding water or in

the denuding of tripe, the label or labeling on containers of such preparations shall bear adequate directions to ensure use in compliance with any limitations prescribed in 21 CFR Chapter I, Subchapter A or Subchapter B, or 9 CFR Chapter III, Subchapter A or Subchapter E.

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

(f) [Reserved]

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

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

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

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

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

[35 FR 15586, Oct. 3, 1970, as amended at 36 FR 11639, June 17, 1971; 38 FR 5152, Feb. 26, 1973; 48 FR 6091, Feb. 10, 1983; 49 FR 32055, Aug. 10, 1984; 64 FR 72174, Dec. 23, 1999]

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

(a) All products and all slaughtered poultry and poultry products brought

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

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

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

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

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

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

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

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

(a) All processes used in curing, pickling, rendering, canning, or otherwise

[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.

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

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

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

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

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

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

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

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

(d) [Reserved]

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

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

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

(f) *Labeling Logo.* Owners and operators of official establishments having a total plant quality control system approved under the provisions of paragraph (c) of this section, may only use, as a part of any 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; 65 FR 34389, May 30, 2000]

§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]

§318.8 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

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

Diameter of casing at time of stuffing[1]	Days in drying room[2]
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

TABLE 4—REDUCED SALT CONTENT—DRYING ROOM TIMES—Continued

[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]
3.1	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

TABLE 4—REDUCED SALT CONTENT—DRYING ROOM TIMES—Continued

[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]
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.

$(3.56 \times 100)/(127.872 - 3.56 - 2 - .8 - .012) = 356/121.5 = 2.93$

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

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

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

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

(a) Cooked beef, roast beef, and cooked corned beef products must be produced using processes ensuring that the products meet the following performance standards:

(1) *Lethality.* A 6.5-$\log_{10}$ reduction of *Salmonella* or an alternative lethality that achieves an equivalent probability

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

that no viable *Salmonella* organisms remain in the finished product, as well as the reduction of other pathogens and their toxins or toxic metabolites necessary to prevent adulteration, must be demonstrated to be achieved throughout the product. The lethality process must include a cooking step. Controlled intermediate step(s) applied to raw product may form part of the basis for the equivalency.

(2) *Stabilization.* There can be no multiplication of toxigenic microorganisms such as *Clostridium botulinum,* and no more than 1-$\log_{10}$ multiplication of *Clostridium perfringens* within the product.

(b) For each product produced using a process other than one conducted in accordance with the Hazard Analysis and Critical Control Point (HACCP) system requirements in part 417 of this chapter, an establishment must develop and have on file and available to FSIS, a process schedule, as defined in §301.2 of this chapter. Each process schedule must be approved in writing by a process authority for safety and efficacy in meeting the performance standards established for the product in question. A process authority must have access to the establishment in order to evaluate and approve the safety and efficacy of each process schedule.

(c) Under the auspices of a processing authority, an establishment must validate new or altered process schedules by scientifically supportable means, such as information gleaned from the literature or by challenge studies conducted outside the plant.

[64 FR 744, Jan. 6, 1999]

§318.18 Handling of certain material for mechanical processing.

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

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

§318.19 Compliance procedure for cured pork products.

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

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

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

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

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

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

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

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

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

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

(b) *Normal Compliance Procedures.* The Department shall collect samples of cured pork products and analyze them for their PFF content. Analyses shall be conducted in accordance with the ''Official Methods of Analysis of the Association of Official Analytical Chemists §§950.46, and 928.08 (Chapter

39).[1] The ''Official Methods of Analysis of the Association of Official Analytical Chemists,'' 15th edition, 1990, is incorporated by reference with the approval of the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Each analytical result shall be recorded and evaluated to determine whether future sampling of product Groups within an official establishment shall be periodic or daily under the provisions of paragraph (b)(1) of this section, and if the affected lot and subsequent production of like product shall be U.S. retained, or administratively detained, as appropriate, as provided in paragraph (b)(2) of this section.[2]

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

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

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

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

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

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

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

(2) *Criteria for U.S. retention or administrative detention of cured pork products*

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

[2] Rules for Rounding:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

[3] If the processor does not wish to have the product evaluated in this manner, alternate

Continued

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

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

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

(iii) The lot is one that has been prepared subsequent to preparation of the lot which, under the provisions of paragraph (c)(2) of this section, resulted in discontinuance of U.S. retention of new lots of like product. Such lot may be released for entry into commerce prior to receipt of analytical results for which sampling has been conducted. Upon receipt of such results, they shall be subjected to the provisions of paragraphs (b)(2)(i) and (c)(2) of this section.

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

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

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

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

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

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

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

(3) For purposes of this section, the plant owner or operator shall have the option of temporarily removing a product from its Product Group, provided product lots are being U.S. retained, as produced, and provided further that the average production rate of the product, over the 8-week period preceding the week in which the first U.S. retained lot was prepared, is not greater than 20 percent of the production rate of its Group. When a product is thus removed from its Group, analytical results of

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sampling plans may be used provided such plans have been formulated by the processor and approved by the Administrator prior to evaluation by the three-sample criteria, and provided the analyses specified in such plans are performed at the expense of the processor.

product samples shall not cause daily sampling of the Group. When pursuant to paragraph (c)(2)(vi) of this section, new lots of the product are no longer being U.S. retained, the product shall again be considered with its Group.

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

(e) *Quality control.* Cured pork products bearing on their labeling the statement ''X% of Weight is Added Ingredients'' shall be prepared only under a quality control system or program in accordance with §318.4 of this subchapter. With respect to any other cured pork product, official establishments may institute quality control procedures under §318.4 of this subchapter. Cured pork products produced in such establishments may be exempt from the requirements of this section, provided 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.

[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.

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 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
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.

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

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 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.]

[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.

(*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, 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.

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[6] *See* footnote 3.

(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 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.

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

(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, 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.

[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.

(*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, 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:

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[12] *See* footnote 11.

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

(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, 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.

[15] *See* footnote 11.

[16] *See* footnote 11.

(*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 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

[17] *See* footnote 13.

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

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.

(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]

[1] The equation for the narrative description of the calculation for added water is as follows: AW=TW-(TP-(P-1.0))4, Where

Continued

§ 318.23 Heat-processing and stabilization requirements for uncured meat patties.

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

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

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

(3) *Partially-cooked patties.* Meat patties that have been heat processed for less time or using lower internal temperatures than are prescribed by paragraph (b)(1) of this section.

(4) *Char-marked patties.* Meat patties that have been marked by a heat source and that have been heat processed for less time or using lower internal temperatures than are prescribed by paragraph (b)(1) of this section.

(b) *Heat-processing procedures for fully-cooked patties.* (1) Official establishments which manufacture fully-cooked patties shall use one of the following heat-processing procedures:

PERMITTED HEAT-PROCESSING TEMPERATURE/TIME COMBINATIONS FOR FULLY-COOKED PATTIES

Minimum internal temperature at the center of each patty (Degrees)		Minimum holding time after required internal temperature is reached (Time)	
Fahrenheit	Or centigrade	Minutes	Or seconds
151	66.1	.68	41
152	66.7	.54	32
153	67.2	.43	26
154	67.8	.34	20
155	68.3	.27	16
156	68.9	.22	13
157 (and up)	69.4 (and up)	.17	10

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

(3) Requirements for handling heating deviations. (i) If for any reason a heating deviation has occurred, the official establishment shall investigate and identify the cause; take steps to assure that the deviation will not recur; and place on file in the official establishment, available to any duly authorized FSIS program employee, a report of the investigation, the cause of the deviation, and the steps taken to prevent recurrence.

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

(c) *Stabilization.* (1) Fully cooked, partially cooked, and char-marked meat patties must be produced using processes ensuring no multiplication of toxigenic microorganisms such as *Clostridium botulinum,* and no more than a 1 $\log_{10}$ multiplication of *Clostridium perfringens,* within the product.

(2) For each meat patty product produced using a stabilization process other than one conducted in accordance with the Hazard Analysis and Critical Control Point (HACCP) system requirements in part 417 of this chapter, an establishment must develop and have on file, available to FSIS, a process schedule, as defined in § 301.2 of this chapter. Each process schedule must be approved in writing by a process authority for safety and efficacy in meeting the performance standards established for the product in question. A process authority must have access to an establishment in order to evaluate

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.

and approve the safety and efficacy of each process schedule.

(3) Under the auspices of a processing authority, an establishment must validate new or altered process schedules by scientifically supportable means, such as information gleaned from the literature or by challenge studies conducted outside the plant.

(4) Partially cooked patties must bear the labeling statement ''Partially cooked: For Safety Cook Until Well Done (Internal Meat Temperature 160 degrees F.).'' The labeling statement must be adjacent to the product name, and prominently placed with such conspicuousness (as compared with other words, statements, designs or devices in the labeling) as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

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

[64 FR 744, Jan. 6, 1999]

§318.24 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.

[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.

(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]

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.

(h) *Critical factor.* Any characteristic, condition or aspect of a product, container, or procedure that affects the adequacy of the process schedule. Critical factors are established by processing authorities.

(i) *Headspace.* That portion of a container not occupied by the product.

(1) *Gross headspace.* The vertical distance between the level of the product (generally the liquid surface) in an upright rigid container and the top edge of the container (i.e., the flange of an unsealed can, the top of the double seam on a sealed can, or the top edge of an unsealed jar).

(2) *Net headspace.* The vertical distance between the level of the product (generally the liquid surface) in an upright rigid container and the inside surface of the lid.

(j) *Hermetically sealed containers.* Airtight containers which are designed and intended to protect the contents against the entry of microorganisms during and after thermal processing.

(1) *Rigid container.* A container, the shape or contour of which, when filled and sealed, is neither affected by the enclosed product nor deformed by external mechanical pressure of up to 10 pounds per square inch gauge (0.7 kg/cm^2) (i.e., normal firm finger pressure).

(2) *Semirigid container.* A container, the shape or contour of which, when filled and sealed, is not significantly affected by the enclosed product under normal atmospheric temperature and pressure, but can be deformed by external mechanical pressure of less than 10 pounds per square inch gauge (0.7 kg/cm^2) (i.e., normal firm finger pressure).

(3) *Flexible container.* A container, the shape or contour of which, when filled and sealed, is significantly affected by the enclosed product.

(k) *Incubation tests.* Tests in which the thermally processed product is kept at a specific temperature for a

specified period of time in order to determine if outgrowth of microorganisms occurs.

(l) *Initial temperature.* The temperature, determined at the initiation of a thermal process cycle, of the contents of the coldest container to be processed.

(m) *Low acid product.* A canned product in which any component has a pH value above 4.6.

(n) *Process schedule.* The thermal process and any specified critical factors for a given canned product required to achieve shelf stability.

(o) *Process temperature.* The minimum temperature(s) of the heating medium to be maintained as specified in the process schedule.

(p) *Process time.* The intended time(s) a container is to be exposed to the heating medium while the heating medium is at or above the process temperature(s).

(q) *Processing authority.* The person(s) or organization(s) having expert knowledge of thermal processing requirements for foods in hermetically sealed containers, having access to facilities for making such determinations, and designated by the establishment to perform certain functions as indicated in this subpart.

(r) P*rogram employee.* Any inspector or other individual employed by the Department or any cooperating agency who is authorized by the Secretary to do any work or perform any duty in connection with the Program (see § 301.2(f)).

(s) *Retort.* A pressure vessel designed for thermal processing of product packed in hermetically sealed containers.

(t) *Seals.* Those parts of a semirigid container and lid or of a flexible container that are fused together in order to hermetically close the container.

(u) *Shelf stability.* The condition achieved by application of heat, sufficient, alone or in combination with other ingredients and/or treatments, to render the product free of microorganisms capable of growing in the product at nonrefrigerated conditions (over 50 °F or 10 °C) at which the product is intended to be held during distribution and storage. Shelf stability and shelf stable are synonymous with commercial sterility and commercially sterile, respectively.

(v) *Thermal process.* The heat treatment necessary to achieve shelf stability as determined by the establishment's processing authority. It is quantified in terms of:

(1) Time(s) and temperature(s); or

(2) Minimum product temperature.

(w) *Venting.* The removal of air from a retort before the start of process timing.

(x) *Water activity.* The ratio of the water vapor pressure of the product to the vapor pressure of pure water at the same temperature.

§ 318.301 Containers and closures.

(a) *Examination and cleaning of empty containers.* (1) Empty containers, closures, and flexible pouch roll stock shall be evaluated by the establishment to ensure that they are clean and free of structural defects and damage that may affect product or container integrity. Such an examination should be based upon a statistical sampling plan.

(2) All empty containers, closures, and flexible pouch roll stock shall be stored, handled, and conveyed in such a manner that will prevent soiling and damage that could affect the hermetic condition of the sealed container.

(3) Just before filling, rigid containers shall be cleaned to prevent incorporation of foreign matter into the finished product. Closures, semirigid containers, preformed flexible pouches, and flexible pouch roll stock contained in original wrappings do not need to be cleaned before use.

(b) *Closure examinations for rigid containers (cans)*—(1) *Visual examinations.* A closure technician shall visually examine the double seams formed by each closing machine head. When seam defects (e.g., cutovers, sharpness, knocked down flanges, false seams, droops) are observed, necessary corrective actions, such as adjusting or repairing the closing machine, shall be taken. In addition to the double seams, the entire container shall be examined for product leakage or obvious defects. A visual examination shall be performed on at least one container from each closing machine head, and the observations, along with any corrective

actions, shall be recorded. Visual examinations shall be conducted with sufficient frequency to ensure proper closure and should be conducted at least every 30 minutes of continuous closing machine operation. Additional visual examinations shall be made by the closure technician at the beginning of production, immediately following every jam in the closing machine and after closing machine adjustment (including adjustment for changes in container size).

(2) *Teardown examinations.* Teardown examinations of double seams formed by each closing machine head shall be performed by a closure technician at a frequency sufficient to ensure proper closure. These examinations should be made at intervals of not more than 4 hours of continuous closing machine operation. At least one container from each closing head shall be examined on the packer's end during each regular examination period. Examination results along with any necessary corrective actions, such as adjusting or repairing the closing machine, shall be promptly recorded by the closure technician. The establishment shall have container specification guidelines for double seam integrity on file and available for review by Program employees. A teardown examination of the can maker's end shall be performed on at least one container selected from each closing machine during each examination period except when teardown examinations are made on incoming empty containers or when, in the case of self-manufactured containers, the containers are made in the vicinity of the establishment and the container plant records are made available to Program employees. Additional teardown examinations on the packer's end should be made at the beginning of production, immediately following every jam in a closing machine and after closing machine adjustment (including adjustment for a change in container size). The following procedures shall be used in teardown examinations of double seams:

(i) One of the following two methods shall be employed for dimensional measurements of the double seam.

(*a*) *Micrometer measurement.* For cylindrical containers, measure the following dimensions (Figure 1) at three points approximately 120 degrees apart on the double seam excluding and at least one-half inch from the side seam juncture:

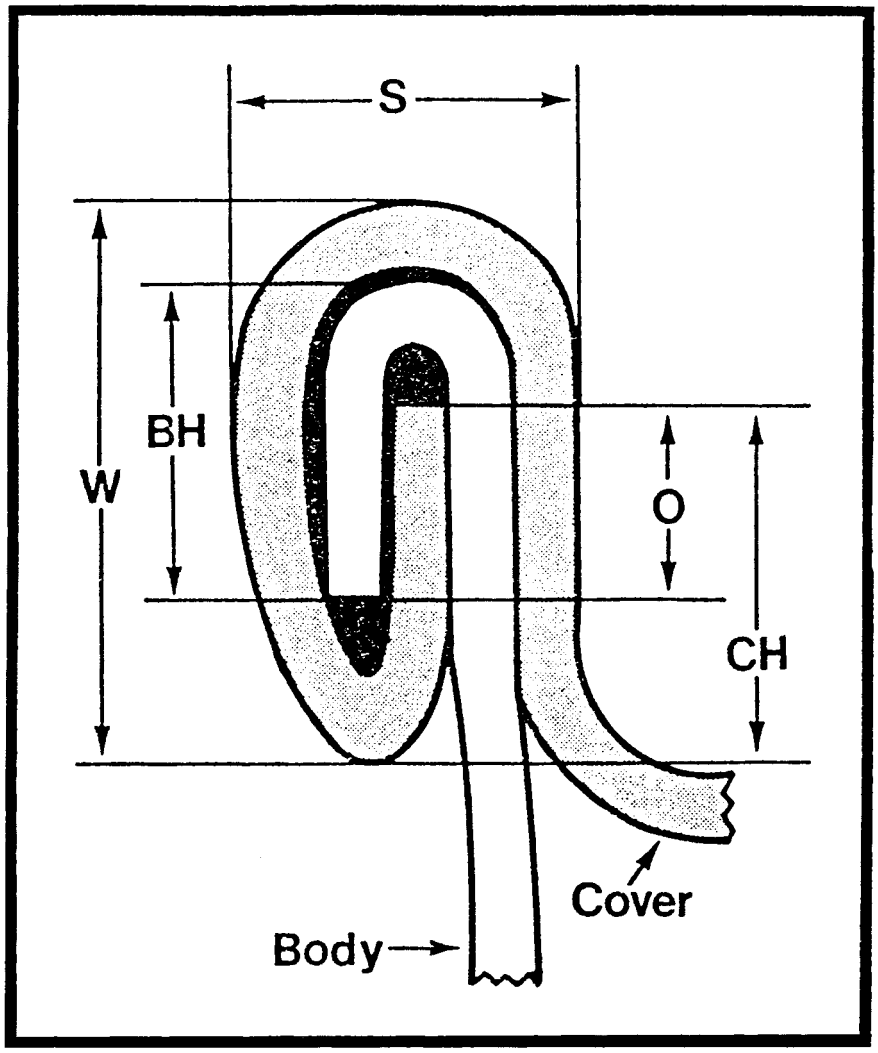
(*1*) Double seam length—W;

(*2*) Double seam thickness—S;

(*3*) Body hook length—BH; and

(*4*) Cover hook length—CH.

Maximum and minimum values for each dimensional measurement shall be recorded by the closure technician.



(*b*) *Seamscope or seam projector.* Required measurements of the seam include thickness, body hook, and overlap. Seam thickness shall be obtained by micrometer. For cylindrical containers, at least two locations, excluding the side seam juncture, shall be used to obtain the required measurements.

(ii) *Seam tightness.* Regardless of the dimensional measurement method used to measure seam dimensions, at a minimum, the seam(s) examined shall be stripped to assess the degree of wrinkling.

(iii) *Side seam juncture rating.* Regardless of the dimensional measurement method used to measure seam dimensions, the cover hook shall be stripped to examine the cover hook droop at the juncture for containers having side seams.

(iv) *Examination of noncylindrical containers.* Examination of noncylindrical

containers (e.g., square, rectangular, ''D''-shaped, and irregularly-shaped) shall be conducted as described in paragraphs (b)(2) (i), (ii), and (iii) of this section except that the required dimensional measurements shall be made on the double seam at the points listed in the establishment's container specification guidelines.

(c) *Closure examinations for glass containers*—(1) *Visual examinations.* A closure technician shall visually assess the adequacy of the closures formed by each closing machine. When closure defects, such as loose or cocked caps, fractured or cracked containers and low vacuum jars, are observed, necessary corrective actions, such as adjusting or repairing the closing machine shall be taken and recorded. In addition to the closures, the entire container shall be examined for defects. Visual examinations shall be made with sufficient frequency to ensure proper closure and should be conducted at least every 30 minutes of continuous closing machine operation. Additional visual examinations shall be made by the closure technician and the observations recorded at the beginning of production, immediately following every jam in the closing machine, and after closing machine adjustment (including adjustment for a change in container size).

(2) *Closure examinations and tests.* Depending upon the container and closure, tests shall be performed by a closure technician at a frequency sufficient to ensure proper closure. These examinations should be made either before or after thermal processing and at intervals of not more than 4 hours of continuous closing machine operation. At least one container from each closing machine shall be examined during each regular examination period. Examination results along with any necessary corrective actions, such as adjusting or repairing the closing machine, shall be promptly recorded by the closure technician. The establishment shall have specification guidelines for closure integrity on file and available for review by Program employees. Additional closure examinations should be made at the beginning of production, immediately following every jam in the closing machine, and after closing machine adjustment (including adjustment for a change in container size).

(d) *Closure examinations for semirigid and flexible containers*—(1) *Heat seals*—(i) *Visual examinations.* A closure technician shall visually examine the seals formed by each sealing machine. When sealing defects are observed, necessary corrective actions, such as adjusting or repairing the sealing machine, shall be taken and recorded. In addition to examining the heat seals, the entire container shall be examined for product leakage or obvious defects. Visual examinations shall be performed before and after the thermal processing operation and with sufficient frequency to ensure proper closure. These examinations should be conducted at least in accordance with a statistical sampling plan. All defects noted and corrective actions taken shall be promptly recorded.

(ii) *Physical tests.* Tests determined by the establishment as necessary to assess container integrity shall be conducted by the closure technician at a frequency sufficient to ensure proper closure. These tests shall be performed after the thermal processing operation and should be made at least every 2 hours of continuous production. The establishment's acceptance guidelines for each test procedure shall be on file and available for review by Program employees. Test results along with any necessary corrective actions, such as adjusting or repairing the sealing machine, shall be recorded.

(2) Double seams on semirigid or flexible containers shall be examined and the results recorded as provided in paragraph (b) of this section. Any additional measurements specified by the container manufacturer shall also be made and recorded.

(e) *Container coding.* Each container shall be marked with a permanent, legible, identifying code mark. The mark shall, at a minimum, identify in code the product (unless the product name lithographed or printed elsewhere on the container) and the day and year the product was packed.

(f) *Handling of containers after closure.* (1) Containers and closures shall be protected from damage which may cause defects that are likely to affect

the hermetic condition of the containers. The accumulation of stationary containers on moving conveyors should be minimized to avoid damage to the containers.

(2) The maximum time lapse between closing and initiation of thermal processing shall be 2 hours. However, the Administrator may specify a shorter period of time when considered necessary to ensure product safety and stability. A longer period of time between closing and the initiation of thermal processing may be permitted by the Administrator.

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

§ 318.302 Thermal processing.

(a) *Process schedules.* Prior to the processing of canned product for distribution in commerce, an establishment shall have a process schedule (as defined in § 318.300(n) of this subpart) for each canned meat product to be packed by the establishment.

(b) *Source of process schedules.* (1) Process schedules used by an establishment shall be developed or determined by a processing authority.

(2) Any change in product formulation, ingredients, or treatments that are not already incorporated in a process schedule and that may adversely affect either the product heat penetration profile or sterilization value requirements shall be evaluated by the establishment's processing authority. If it is determined that any such change adversely affects the adequacy of the process schedule, the processing authority shall amend the process schedule accordingly.

(3) Complete records concerning all aspects of the development or determination of a process schedule, including any associated incubation tests, shall be made available by the establishment to the Program employee upon request.

(c) *Submittal of process information.* (1) Prior to the processing of canned product for distribution in commerce, the establishment shall provide the inspector at the establishment with a list of the process schedules (including alternate schedules) along with any additional applicable information, such as the retort come-up operating procedures and critical factors.

(2) Letters or other written communications from a processing authority recommending all process schedules shall be maintained on file by the establishment. Upon request by Program employees, the establishment shall make available such letters or written communications (or copies thereof). If critical factors are identified in the process schedule, the establishment shall provide the inspector with a copy of the procedures for measuring, controlling, and recording these factors, along with the frequency of such measurements, to ensure that the critical factors remain within the limits used to establish the process schedule. Once submitted, the process schedules and associated critical factors and the procedures for measuring (including the frequency), controlling, and recording of critical factors shall not be changed without the prior written submittal of the revised procedures (including supporting documentation) to the inspector at the establishment.

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

§ 318.303 Critical factors and the application of the process schedule.

Critical factors specified in the process schedule shall be measured, controlled and recorded by the establishment to ensure that these factors remain within the limits used to establish the process schedule. Examples of factors that are often critical to process schedule adequacy may include:

(a) *General.* (1) Maximum fill-in weight or drained weight;

(2) Arrangement of pieces in the container;

(3) Container orientation during thermal processing;

(4) Product formulation;

(5) Particle size;

(6) Maximum thickness for flexible, and to some extent semirigid containers during thermal processing;

(7) Maximum pH;

(8) Percent salt;

(9) Ingoing (or formulated) nitrite level (ppm);

(10) Maximum water activity; and

(11) Product consistency or viscosity.

(b) *Continuous rotary and batch agitating retorts.* (1) Minimum headspace; and

(2) Retort reel speed.

(c) *Hydrostatic retorts.* (1) Chain or conveyor speed.

(d) *Steam/air retorts.* (1) Steam/air ratio; and

(2) Heating medium flow rate.

§ 318.304 Operations in the thermal processing area.

(a) *Posting of processes.* Process schedules (or operating process schedules) for daily production, including minimum initial temperatures and operating procedures for thermal processing equipment, shall be posted in a conspicuous place near the thermal processing equipment. Alternatively, such information shall be available to the thermal processing system operator and the inspector.

(b) *Process indicators and retort traffic control.* A system for product traffic control shall be established to prevent product from bypassing the thermal processing operation. Each basket, crate or similar vehicle containing unprocessed product, or at least one visible container in each vehicle, shall be plainly and conspicuously marked with a heat sensitive indicator that will visually indicate whether such unit has been thermally processed. Exposed heat sensitive indicators attached to container vehicles shall be removed before such vehicles are refilled with unprocessed product. Container loading systems for crateless retorts shall be designed to prevent unprocessed product from bypassing the thermal processing operation.

(c) *Initial temperature.* The initial temperature of the contents of the coldest container to be processed shall be determined and recorded by the establishment at the time the processing cycle begins to assure that the temperature of the contents of every container to be processed is not lower than the minimum initial temperature specified in the process schedule. Thermal processing systems which subject the filled and sealed containers to water at any time before process timing begins shall be operated to assure that such water will not lower the temperature of the product below the minimum initial temperature specified in the process schedule.

(d) *Timing devices.* Devices used to time applicable thermal processing operation functions or events, such as process schedule time, come-up time and retort venting, shall be accurate to assure that all such functions or events are achieved. Pocket watches and wrist watches are not considered acceptable timing devices. Analog and digital clocks are considered acceptable. If such clocks do not display seconds, all required timed functions or events shall have at least a 1-minute safety factor over the specified thermal processing operation times. Temperature/time recording devices shall correspond within 15 minutes to the time of the day recorded on written records required by § 318.306.

(e) *Measurement of pH.* Unless other methods are approved by the Administrator, potentiometric methods using electronic instruments (pH meters) shall be used for making pH determinations when a maximum pH value is specified as a critical factor in a process schedule.

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

§ 318.305 Equipment and procedures for heat processing systems.

(a) *Instruments and controls common to different thermal processing systems*—(1) *Indicating temperature devices.* Each retort shall be equipped with at least one indicating temperature device that measures the actual temperature within the retort. The indicating temperature device, not the temperature/time recording device, shall be used as the reference instrument for indicating the process temperature.

(i) *Mercury-in-glass thermometers.* A mercury-in-glass thermometer shall have divisions that are readable to 1F °(or 0.5C°) and whose scale contains not more than 17F°/inch (or 4.0C°/cm) of graduated scale. Each mercury-in-glass thermometer shall be tested for accuracy against a known accurate standard upon installation and at least once a year to ensure its accuracy. Records that specify the date, standard used, test method, and the person or testing authority performing the test shall be

maintained on file by the establishment and made available to Program employees. A mercury-in-glass thermometer that has a divided mercury column or that cannot be adjusted to the standard shall be repaired and tested for accuracy before further use, or replaced.

(ii) *Other devices.* Temperature-indicating devices, such as resistance temperature detectors, used in lieu of mercury-in-glass thermometers, shall meet known, accurate standards for such devices when tested for accuracy. The records of such testing shall be available to FSIS program employees.

(2) *Temperature/time recording devices.* Each thermal processing system shall be equipped with at least one temperature/time recording device to provide a permanent record of temperatures within the thermal processing system. This recording device may be combined with the steam controller and may be a recording/controlling instrument. When compared to the known accurate indicating temperature device, the recording accuracy shall be equal to or better than 1F °(or 0.5C°) at the process temperature. The temperature recording chart should be adjusted to agree with, but shall never be higher than, the known accurate indicating temperature device. A means of preventing unauthorized changes in the adjustment shall be provided. For example, a lock or a notice from management posted at or near the recording device warning that only authorized persons are permitted to make adjustments, are satisfactory means for preventing unauthorized changes. Air-operated temperature controllers shall have adequate filter systems to ensure a supply of clean, dry air. The recorder timing mechanism shall be accurate.

(i) *Chart-type devices.* Devices using charts shall be used only with the correct chart. Each chart shall have a working scale of not more than 55F°/inch (or 12C°/cm) within a range of 20F °(or 11C°) of the process temperature. Chart graduations shall not exceed 2F degrees (or 1C degree) within a range of 10F degrees (or 5C degrees) of the process temperature. Multipoint plotting chart-type devices shall print temperature readings at intervals that will assure that the parameters of the process time and process temperature have been met. The frequency of recording should not exceed 1-minute intervals.

(ii) *Other devices.* Temperature/time recording devices or procedures used in lieu of chart-type devices must meet known accurate standards for such devices or procedures when tested for accuracy. Such a device must be accurate enough for ensuring that process time and temperature parameters have been met.

(3) *Steam controllers.* Each retort shall be equipped with an automatic steam controller to maintain the retort temperature. This may be a recording/controlling instrument when combined with a temperature/time recording device.

(4) *Air valves.* All air lines connected to retorts designed for pressure processing in steam shall be equipped with a globe valve or other equivalent-type valve or piping arrangement that will prevent leakage of air into the retort during the process cycle.

(5) *Water valves.* All retort water lines that are intended to be closed during a process cycle shall be equipped with a globe valve or other equivalent-type valve or piping arrangement that will prevent leakage of water into the retort during the process cycle.

(b) *Pressure processing in steam*—(1) *Batch still retorts.* (i) The basic requirements and recommendations for indicating temperature devices and temperature/time recording devices are described in paragraphs (a) (1) and (2) of this section. Additionally, bulb sheaths or probes of indicating temperature devices and probes of temperature/time recording devices shall be installed either within the retort shell or in external wells attached to the retort. External wells shall be connected to the retort through at least a ¾ inch (1.9 cm) diameter opening and equipped with a 1/16 inch (1.6 mm) or larger bleeder opening so located as to provide a constant flow of steam past the length of the bulb or probe. The bleeder for external wells shall emit steam continuously during the entire thermal processing period.

(ii) Steam controllers are required as described under paragraph (a)(3) of this section.

(iii) *Steam inlet.* The steam inlet to each retort shall be large enough to provide steam for proper operation of the retort, and shall enter at a point to facilitate air removal during venting.

(iv) *Crate supports.* Vertical still retorts with bottom steam entry shall employ bottom retort crate supports. Baffle plates shall not be used in the bottom of retorts.

(v) *Steam spreader.* Perforated steam spreaders, if used, shall be maintained to ensure they are not blocked or otherwise inoperative. Horizontal still retorts shall be equipped with perforated steam spreaders that extend the full length of the retort unless the adequacy of another arrangement is documented by heat distribution data or other documentation from a processing authority. Such information shall be maintained on file by the establishment and made available to Program employees for review.

(vi) *Bleeders and condensate removal.* Bleeders, except those for external wells of temperature devices, shall have ⅛ inch (or 3 mm) or larger openings and shall be wide open during the entire process, including the come-up time. For horizontal still retorts, bleeders shall be located within approximately 1 foot (or 30 cm) of the outermost locations of containers at each end along the top of the retort. Additional bleeders shall be located not more than 8 feet (2.4 m) apart along the top. Bleeders may be installed at positions other than those specified above, as long as the establishment has heat distribution data or other documentation from the manufacturer or from a processing authority demonstrating that the bleeders accomplish removal of air and circulate the steam within the retort. This information shall be maintained on file by the establishment and made available to Program employees for review. All bleeders shall be arranged in a way that enables the retort operator to observe that they are functioning properly. Vertical retorts shall have at least one bleeder opening located in the portion of the retort opposite the steam inlet. All bleeders shall be arranged so that the retort operator can observe that they are functioning properly. In retorts having a steam inlet above the level of the lowest container, a bleeder shall be installed in the bottom of the retort to remove condensate. The condensate bleeder shall be so arranged that the retort operator can observe that it is functioning properly. The condensate bleeder shall be checked with sufficient frequency to ensure adequate removal of condensate. Visual checks should be performed at intervals of not more than 15 minutes and the results recorded. Intermittent condensate removal systems shall be equipped with an automatic alarm system that will serve as a continuous monitor of condensate bleeder functioning. The automatic alarm system shall be tested at the beginning of each shift for proper functioning and the results recorded. If the alarm system is not functioning properly, it must be repaired before the retort is used.

(vii) *Stacking equipment—(a) Equipment for holding or stacking containers in retorts.* Crates, trays, gondolas, carts, and other vehicles for holding or stacking product containers in the retort shall be so constructed to ensure steam circulation during the venting, come-up, and process times. The bottom of each vehicle shall have perforations at least 1 inch (2.5 cm) in diameter on 2 inch (or 5 cm) centers or the equivalent unless the adequacy of another arrangement is documented by heat distribution data or other documentation from a processing authority and such information is maintained on file by the establishment and made available to Program employees for review.

(*b*) *Divider plates.* Whenever one or more divider plates are used between any two layers of containers or placed on the bottom of a retort vehicle, the establishment shall have on file documentation that the venting procedure allows the air to be removed from the retort before timing of the thermal process is started. Such documentation shall be in the form of heat distribution data or documentation from a processing authority. This information shall be made available to Program employees for review.

(viii) *Bleeder and vent mufflers.* If mufflers are used on bleeders or vent systems, the establishment shall have on file documentation that the mufflers

do not impede the removal of air from the retort. Such documentation shall consist of either heat distribution data or documentation from the muffler manufacturer or from a processing authority. This information shall be made available to Program employees for review.

(ix) *Vents—(a)* Vents shall be located in that portion of the retort opposite the steam inlet and shall be designed, installed, and operated in such a way that air is removed from the retort before timing of the thermal process is started. Vents shall be controlled by a gate, plug cock, or other full-flow valve which shall be fully opened to permit rapid removal of air from retorts during the venting period.

(*b*) Vents shall not be connected to a closed drain system without an atmospheric break in the line. Where a retort manifold connects several pipes from a single retort, the manifold shall be controlled by a gate, plug cock, or other full-flow valve and the manifold shall be of a size such that the cross-sectional area of the manifold is larger than the total cross-sectional area of all connecting vents. The discharge shall not be connected to a closed drain without an atmospheric break in the line. A manifold header connecting vents or manifolds from several still retorts shall lead to the atmosphere. The manifold header shall not be controlled by a valve and shall be of a size such that the cross-sectional area is at least equal to the total cross-sectional area of all connecting retort manifold pipes from the maximum number of retorts to be vented simultaneously.

(*c*) Some typical installations and operating procedures are described below. Other retort installations, vent piping arrangements, operating procedures or auxiliary equipment such as divider plates may be used provided there is documentation that the air is removed from the retort before the process is started. Such documentation shall be in the form of heat distribution data or other documentation from the equipment manufacturer or processing authority. This information shall be maintained on file by the establishment and made available to Program employees for review.

(*d*) For crateless retort installations, the establishment shall have heat distribution data or other documentation from the equipment manufacturer or from a processing authority that demonstrates that the venting procedure used accomplishes the removal of air and condensate. This information shall be maintained on file by the establishment and made available to Program employees for review.

(*e*) Examples of typical installations and operating procedures that comply with the requirements of this section are as follows:

(*1*) Venting horizontal retorts.

(*i*) Venting through multiple 1 inch (2.5 cm) vents discharging directly to the atmosphere.

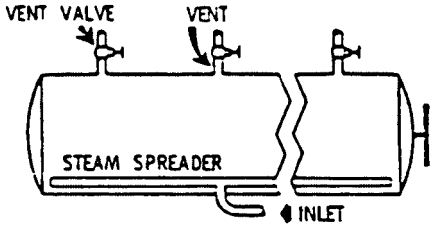


Figure 1.

Specifications (Figure 1): One, 1-inch (2.5 cm) vent for every 5 feet (1.5 m) of retort length, equipped with a gate, plug cock, or other full-flow valve and discharging to atmosphere. The end vents shall not be more than 2½ feet (or 75 cm) from ends of retort. *Venting method (Figure 1):* Vent valves shall be wide open for at least 5 minutes and to at least 225°F (or 107°C), or at least 7 minutes and to at least 220°F (or 104.5°C).

(*ii*) Venting through multiple 1 inch (2.5 cm) vents discharging through a manifold to the atmosphere.

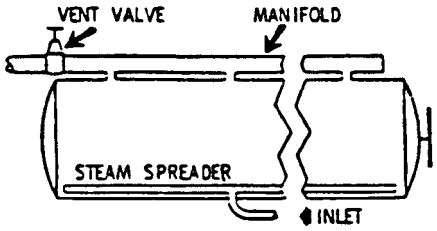


Figure 2.

Specifications (Figure 2): One, 1-inch (2.5 cm) vent for every 5 feet (1.5 m) of retort length; vents not over 2½ feet (or 75 cm) from ends of retort; size of manifold for retorts less than 15 feet (4.6 m) in length, 2½ inches (6.4

cm), and for retorts 15 feet (4.6 m) and over in length, 3 inches (7.6 cm).

Venting method (Figure 2): The manifold vent gate, plug cock, or other full-flow valve shall be wide open for at least 6 minutes and to at least 225°F (or 107°C) or for at least 8 minutes and to at least 220°F (or 104.5°C).

(*iii*) Venting through water spreaders.

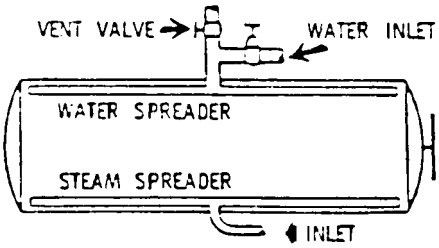


Figure 3.

Specifications (Figure 3): Size of vent and vent valve. For retorts less than 15 feet (4.6 m) in length, 2 inches (or 5 cm); for retorts 15 feet (4.6 m) and over in length, 2½ inches (6.4 cm).

Size of water spreader (Figure 3): For retorts less than 15 feet (4.6 m) in length, 1½ inches (3.8 cm); for retorts 15 feet (4.6 m) and over in length, 2 inches (or 5 cm). The number of holes shall be such that their total cross-sectional area is equal to the cross-sectional area of the vent pipe inlet.

Venting method (Figure 3): The gate, plug cock, or other full-flow valve on the water spreader vent shall be wide open for at least 5 minutes and to at least 225°F (or 107°C), or for at least 7 minutes and to at least 220°F (or 104.5°C).

(*iv*) Venting through a single 2½ inch (6.4 cm) top vent for retorts not exceeding 15 feet (4.6 m) in length.

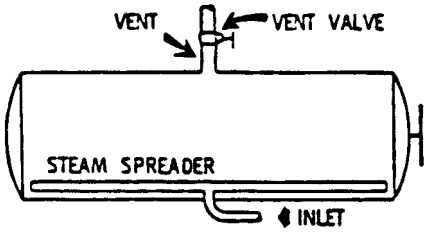


Figure 4.

Specifications (Figure 4): A 2½ inch (6.4 cm) vent equipped with a 2½ inch (6.4 cm) gate, plug cock, or other full-flow valve and located within 2 feet (61 cm) of the center of the retort.

Venting method (Figure 4): The vent valve shall be wide open for at least 4 minutes and to at least 220°F (or 104.5°C).

(*2*) Venting vertical retorts.

(*i*) Venting through a 1½ inch (3.8 cm) overflow.

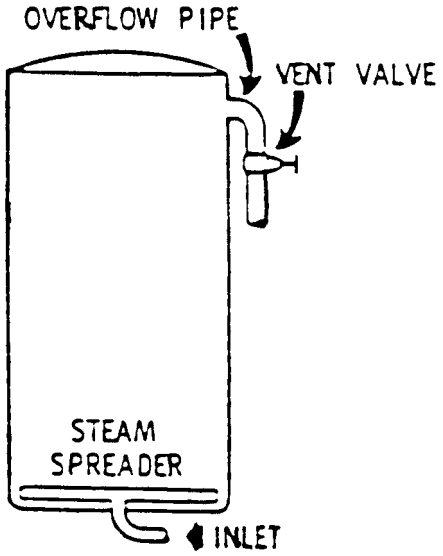


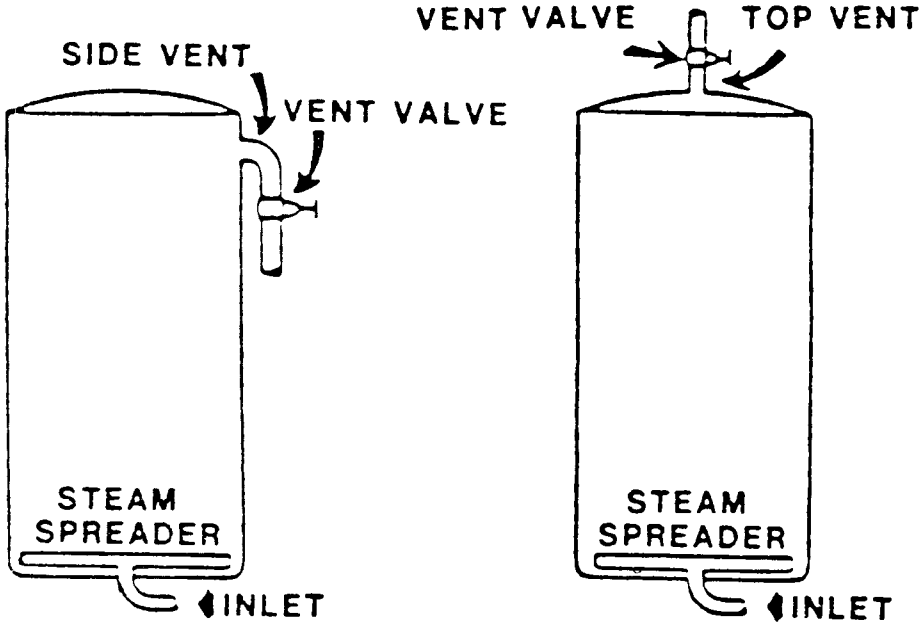
Figure 5.

FIGURE 5

Specifications (Figure 5): A 1½ inch (3.8 cm) overflow pipe equipped with a 1½ inch (3.8 cm) gate, plug cock, or other full-flow valve and with not more than 6 feet (1.8 m) of 1½ inch (3.8 cm) pipe beyond the valve before a break to the atmosphere or to a manifold header.

Venting method (Figure 5): The vent valve shall be wide open for at least 4 minutes and to at least 218°F (or 103.5°C), or for at least 5 minutes and to at least 215°F (or 101.5°C).

(*ii*) Venting through a single 1 inch (2.5 cm) side or top vent.



Specifications (Figure 6 or 7): A 1 inch (2.5 cm) vent in lid or top side, equipped with a gate, plug cock, or other full-flow valve and discharging directly into the atmosphere or to a manifold header.

Venting method (Figure 6 or 7): The vent valve shall be wide open for at least 5 minutes and to at least 230 °F (110 °C), or for at least 7 minutes and to at least 220 °F (or 104.5 °C).

(2) *Batch agitating retorts.* (i) The basic requirements for indicating temperature devices and temperature/time recording devices are described in paragraphs (a) (1) and (2) of this section. Additionally, bulb sheaths or probes of indicating temperature devices and probes of temperature/time recording devices shall be installed either within the retort shell or in external wells attached to the retort. External wells shall be connected to the retort through at least a ¾ inch (1.9 cm) diameter opening and equipped with a 1/16 (1.6 mm) or larger bleeder opening so located as to provide a constant flow of steam past the length of the bulbs or probes. The bleeder for external wells shall emit steam continuously during the entire thermal processing period.

(ii) Steam controllers are required as described in paragraph (a)(3) of this section.

(iii) *Steam inlet.* The steam inlet to each retort shall be large enough to provide steam for proper operation of the retort and shall enter at a point(s) to facilitate air removal during venting.

(iv) *Bleeders.* Bleeders, except those for external wells of temperature devices, shall be ⅛ inch (or 3 mm) or larger and shall be wide open during the entire process including the come-up time. Bleeders shall be located within approximately 1 foot (or 30 cm) of the outermost location of containers, at each end along the top of the retort. Additional bleeders shall be located not more than 8 feet (2.4 m) apart along the top. Bleeders may be installed at positions other than those specified above, as long as the establishment has heat distribution data or other documentation from the manufacturer or from a processing authority that the bleeders accomplish removal of air and circulate the steam within the retort. This information shall be maintained on file by the establishment and made

available to Program employees for review. All bleeders shall be arranged in a way that enables the retort operator to observe that they are functioning properly.

(v) *Venting and condensate removal.* The air in the retort shall be removed before processing is started. Heat distribution data or other documentation from the manufacturer or from the processing authority who developed the venting procedure shall be kept on file by the establishment and made available to Program employees for review. At the time the steam is turned on, the drain shall be opened to remove steam condensate from the retort. A bleeder shall be installed in the bottom of the retort to remove condensate during retort operation. The condensate bleeder shall be so arranged that the retort operator can observe that it is functioning properly. The condensate bleeder shall be checked with sufficient frequency to ensure adequate removal of condensate. Visual checks should be performed at intervals of not more than 15 minutes and the results recorded. Intermittent condensate removal systems shall be equipped with an automatic alarm system that will serve as a continuous monitor of condensate bleeder functioning. The automatic alarm system shall be tested at the beginning of each shift for proper functioning and the results recorded. If the alarm system is not functioning properly, it must be repaired before the retort is used.

(vi) *Retort or reel speed timing.* The retort or reel speed shall be checked before process timing begins and, if needed, adjusted as specified in the process schedule. In addition, the rotational speed shall be determined and recorded at least once during process timing of each retort load processed. Alternatively, a recording tachometer can be used to provide a continuous record of the speed. The accuracy of the recording tachometer shall be determined and recorded at least once per shift by checking the retort or reel speed using an accurate stopwatch. A means of preventing unauthorized speed changes on retorts shall be provided. For example, a lock or a notice from management posted at or near the speed adjustment device warning that only authorized persons are permitted to make adjustments are satisfactory means of preventing unauthorized changes.

(vii) *Bleeder and vent mufflers.* If mufflers are used on bleeders or vent systems, the establishment shall have documentation that the mufflers do not impede the removal of air from the retort. Such documentation shall consist of either heat distribution data or documentation from the muffler manufacturer or from a processing authority. This information shall be maintained on file by the establishment and made available to Program employees for review.

(3) *Continuous rotary retorts.* (i) The basic requirements for indicating temperature devices and temperature/time recording devices are described in paragraphs (a) (1) and (2) of this section. Additionally, bulb sheaths or probes of indicating temperature devices and probes of temperature/time recording devices shall be installed either within the retort shell or in external wells attached to the retort. External wells shall be connected to the retort through at least a ¾ inch (1.9 cm) diameter opening and equipped with a 1/16 inch (1.6 mm) or larger bleeder opening so located as to provide a constant flow of steam past the length of the bulbs or probes. The bleeder for external wells shall emit steam continuously during the entire thermal processing period.

(ii) Steam controllers are required as described in paragraph (a)(3) of this section.

(iii) *Steam inlet.* The steam inlet to each retort shall be large enough to provide steam for proper operation of the retort, and shall enter at a point(s) to facilitate air removal during venting.

(iv) *Bleeders.* Bleeders, except those for external wells of temperature devices, shall be ⅛ inch (3.2 mm) or larger and shall be wide open during the entire process, including the come-up time. B!eeders shall be located within approximately 1 foot (or 30 cm) of the outermost location of containers at each end along the top of the retort. Additional bleeders shall be located not more than 8 feet (2.4 m) apart along the top of the retort. Bleeders may be installed at positions other than those

specified above, as long as the establishment has heat distribution data or other documentation from the manufacturer or a processing authority that the bleeders accomplish removal of air and circulate the steam within the retort. This information shall be maintained on file by the establishment and made available to Program employees for review. All bleeders shall be arranged so that the retort operator can observe that they are functioning properly.

(v) *Venting and condensate removal.* The air in the retort shall be removed before processing is started. Heat distribution data or other documentation from the manufacturer or from the processing authority who deve!oped the venting procedure shall be kept on file by the establishment and made available to Program employees for review. At the time the steam is turned on, the drain shall be opened to remove steam condensate from the retort. A bleeder shall be installed in the bottom of the shell to remove condensate during the retort operation. The condensate bleeder shall be so arranged that the retort operator can observe that it is functioning properly. The condensate bleeder shall be checked with sufficient frequency to ensure adequate removal of condensate. Visual checks should be performed at intervals of not more than 15 minutes and the results recorded. Intermittent condensate removal systems shall be equipped with an automatic alarm system that will serve as a continuous monitor of condensate bleeder functioning. The automatic alarm system shall be tested at the beginning of each shift for proper functioning and the results recorded. If the alarm system is not functioning properly, it must be repaired before the retort is used.

(vi) *Retort speed timing.* The rotational speed of the retort shall be specified in the process schedule. The speed shall be adjusted as specified, and recorded by the establishment when the retort is started, and checked and recorded at intervals not to exceed 4 hours to ensure that the correct retort speed is maintained. Alternatively, a recording tachometer may be used to provide a continuous record of the speed. If a recording tachometer is used, the speed shall be manually checked against an accurate stopwatch at least once per shift and the results recorded. A means of preventing unauthorized speed changes on retorts shall be provided. For example, a lock or a notice from management posted at or near the speed adjustment device warning that only authorized persons are permitted to make adjustments are satisfactory means of preventing unauthorized changes.

(vii) *Bleeders and vent mufflers.* If mufflers are used on bleeders or vent systems, the establishment shall have documentation that the mufflers do not impede the removal of air from the retort. Such documentation shall consist of either heat distribution data or other documentation from the muffler manufacturer or from a processing authority. This information shall be maintained on file by the establishment and made available to Program employees for review.

(4) *Hydrostatic retorts.* (i) The basic requirements for indicating temperature devices and temperature/time recording devices are described in paragraphs (a) (1) and (2) of this section. Additionally, indicating temperature devices shall be located in the steam dome near the steam/water interface. Where the process schedule specifies maintenance of particular water temperatures in the hydrostatic water legs, at least one indicating temperature device shall be located in each hydrostatic water leg so that it can accurately measure water temperature and be easily read. The temperature/time recorder probe shall be installed either within the steam dome or in a well attached to the dome. Each probe shall have a 1/16 inch (1.6 mm) or larger bleeder opening which emits steam continuously during the processing period. Additional temperature/time recorder probes shall be installed in the hydrostatic water legs if the process schedule specifies maintenance of particular temperatures in these water legs.

(ii) Steam controllers are required as described in paragraph (a)(3) of this section.

(iii) *Steam inlet.* The steam inlets shall be large enough to provide steam for proper operation of the retort.

(iv) *Bleeders.* Bleeder openings ¼ inch (or 6 mm) or larger shall be located in the steam chamber(s) opposite the point of steam entry. Bleeders shall be wide open and shall emit steam continuously during the entire process, including the come-up time. All bleeders shall be arranged in such a way that the operator can observe that they are functioning properly.

(v) *Venting.* Before the start of processing operations, the retort steam chamber(s) shall be vented to ensure removal of air. Heat distribution data or other documentation from the manufacturer or from a processing authority demonstrating that the air is removed from the retort prior to processing shall be kept on file at the establishment and made available to Program employees for review.

(vi) *Conveyor speed.* The conveyor speed shall be calculated to obtain the required process time and recorded by the establishment when the retort is started. The speed shall be checked and recorded at intervals not to exceed 4 hours to ensure that the correct conveyor speed is maintained. A recording device may be used to provide a continuous record of the conveyor speed. When a recording device is used, the speed shall be manually checked against an accurate stopwatch at least once per shift by the establishment. A means of preventing unauthorized speed changes of the conveyor shall be provided. For example, a lock or a notice from management posted at or near the speed adjustment device warning that only authorized persons are permitted to make adjustments are satisfactory means of preventing unauthorized changes.

(vii) *Bleeders and vent mufflers.* If mufflers are used on bleeders or vent systems, the establishment shall have documentation that the muffler do not impede the removal of air from the retort. Such documentation shall consist of either heat distribution data or other documentation from the muffler manufacturer or from a processing authority. This information shall be maintained on file by the establishment and made available to Program employees for review.

(c) *Pressure processing in water*—(1) *Batch still retorts.* (i) The basic requirements for indicating temperature devices and temperature/time recording devices are described in paragraphs (a)(1) and (2) of this section. Additionally, bulbs or probes of indicating temperature devices shall be located in such a position that they are beneath the surface of the water throughout the process. On horizontal retorts, the indicating temperature device bulb or probe shall be inserted directly into the retort shell. In both vertical and horizontal retorts, the indicating temperature device bulb or probe shall extend directly into the water a minimum of 2 inches (or 5 cm) without a separable well or sleeve. In vertical retorts equipped with a recorder/controller, the controller probe shall be located at the bottom of the retort below the lowest crate rest in such a position that the steam does not strike it directly. In horizontal retorts so equipped, the controller probe shall be located between the water surface and the horizontal plane passing through the center of the retort so that there is no opportunity for direct steam impingement on the controller probe. Air-operated temperature controllers shall have filter systems to ensure a supply of clean, dry air.

(ii) *Pressure recording device.* Each retort shall be equipped with a pressure recording device which may be combined with a pressure controller.

(iii) *Steam controllers* are required as described in paragraph (a)(3) of this section.

(iv) *Heat distribution.* Heat distribution data or other documentation from the equipment manufacturer or a processing authority demonstrating uniform heat distribution within the retort shall be kept on file at the establishment and made available to Program employees for review.

(v) *Crate supports.* A bottom crate support shall be used in vertical retorts. Baffle plates shall not be used in the bottom of the retort.

(vi) *Stacking equipment.* For filled flexible containers and, where applicable, semirigid containers, stacking equipment shall be designed to ensure that the thickness of the filled containers does not exceed that specified in the process schedule and that the containers do not become displaced and

overlap or rest on one another during the thermal process.

(vii) *Drain valve.* A nonclogging, water-tight drain valve shall be used. Screens shall be installed over all drain openings.

(viii) *Water level.* There shall be a means of determining the water level in the retort during operation (i.e., by using a gauge, electronic sensor, or sight glass indicator). For retorts requiring complete immersion of containers, water shall cover the top layer of containers during the entire come-up time and thermal processing periods and should cover the top layer of containers during cooling. For retorts using cascading water or water sprays, the water level shall be maintained within the range specified by the retort manufacturer or processing authority during the entire come-up, thermal processing, and cooling periods. A means to ensure that water circulation continues as specified throughout the come-up, thermal processing, and cooling periods shall be provided. The retort operator shall check and record the water level at intervals to ensure it meets the specified processing parameters.

(ix) *Air supply and controls.* In both horizontal and vertical still retorts, a means shall be provided for introducing compressed air or steam at the pressure required to maintain container integrity. Compressed air and steam entry shall be controlled by an automatic pressure control unit. A nonreturn valve shall be provided in the air supply line to prevent water from entering the system. Overriding air or steam pressure shall be maintained continuously during the come-up, thermal processing, and cooling periods. If air is used to promote circulation, it shall be introduced into the steam line at a point between the retort and the steam control valve at the bottom of the retort. The adequacy of the air circulation for maintaining uniform heat distribution within the retort shall be documented by heat distribution data or other documentation from a processing authority, and such data shall be maintained on file by the establishment and made available to Program employees for review.

(x) *Water recirculation.* When a water recirculation system is used for heat distribution, the water shall be drawn from the bottom of the retort through a suction manifold and discharged through a spreader that extends the length or circumference of the top of the retort. The holes in the water spreader shall be uniformly distributed. The suction outlets shall be protected with screens to keep debris from entering the recirculation system. The pump shall be equipped with a pilot light or a similar device to warn the operator when it is not running, and with a bleeder to remove air when starting operations. Alternatively, a flow-meter alarm system can be used to ensure proper water circulation. The adequacy of water circulation for maintaining uniform heat distribution within the retort shall be documented by heat distribution or other documentation from a processing authority and such data shall be maintained on file by the establishment and made available to Program employees for review. Alternative methods for recirculation of water in the retort may be used, provided there is documentation in the form of heat distribution data or other documentation from a processing authority maintained on file by the establishment and made available to Program employees for review.

(xi) *Cooling water entry.* In retorts for processing product packed in glass jars, the incoming cooling water should not directly strike the jars, in order to minimize glass breakage by thermal shock.

(2) *Batch agitating retorts.* (i) The basic requirements and recommendations for indicating temperature devices and temperature/time recording devices are described in paragraphs (a)(1) and (2) of this section. Additionally, the indicating temperature device bulb or probe shall extend directly into the water without a separable well or sleeve. The recorder/controller probe shall be located between the water surface and the horizontal plane passing through the center of the retort so that there is no opportunity for steam to directly strike the controller bulb or probe.

(ii) *Pressure recording device.* Each retort shall be equipped with a pressure

recording device which may be combined with a pressure controller.

(iii) Steam controllers are required as described in paragraph (a)(3) of this section.

(iv) *Heat distribution.* Heat distribution data or other documentation from the equipment manufacturer or a processing authority shall be kept on file by the establishment and made available to Program employees for review.

(v) *Stacking equipment.* All devices used for holding product containers (e.g., crates, trays, divider plates) shall be so constructed to allow the water to circulate around the containers during the come-up and thermal process periods.

(vi) *Drain valve.* A nonclogging, water-tight drain valve shall be used. Screens shall be installed over all drain openings.

(vii) *Water level.* There shall be a means of determining the water level in the retort during operation (i.e., by using a gauge, electronic sensor, or sight glass indicator). Water shall completely cover all containers during the entire come-up, thermal processing, and cooling periods. A means to ensure that water circulation continues as specified throughout the come-up, thermal processing, and cooling periods shall be provided. The retort operator shall check and record the adequacy of the water level with sufficient frequency to ensure it meets the specified processing parameters.

(viii) *Air supply and controls.* Retorts shall be provided with a means for introducing compressed air or steam at the pressure required to maintain container integrity. Compressed air and steam entry shall be controlled by an automatic pressure control unit. A nonreturn valve shall be provided in the air supply line to prevent water from entering the system. Overriding air or steam pressure shall be maintained continuously during the come-up, thermal processing, and cooling periods. If air is used to promote circulation, it shall be introduced into the steam line at a point between the retort and the steam control valve at the bottom of the retort. The adequacy of the air circulation for maintaining uniform heat distribution within the retort shall be documented by heat distribution data or other documentation from a processing authority, and such data shall be maintained on file by the establishment and made available to Program employees for review.

(ix) *Retort or reel speed timing.* The retort or reel speed timing shall be checked before process timing begins and, if needed, adjusted as specified in the process schedule. In addition, the rotational speed shall be determined and recorded at least once during process timing of each retort load processed. Alternatively, a recording tachometer can be used to provide a continuous record of the speed. The accuracy of the recording tachometer shall be determined and recorded at least once per shift by the establishment by checking the retort or reel speed using an accurate stopwatch. A means of preventing unauthorized speed changes on retorts shall be provided. For example, a lock or a notice from management posted at or near the speed adjustment device warning that only authorized persons are permitted to make adjustments are satisfactory means of preventing unauthorized changes.

(x) *Water recirculation.* If a water recirculation system is used for heat distribution, it shall be installed in such a manner that water will be drawn from the bottom of the retort through a suction manifold and discharged through a spreader which extends the length of the top of the retort. The holes in the water spreader shall be uniformly distributed. The suction outlets shall be protected with screens to keep debris from entering the recirculation system. The pump shall be equipped with a pilot light or a similar device to warn the operator when it is not running and with a bleeder to remove air when starting operations. Alternatively, a flow-meter alarm system can be used to ensure proper water circulation. The adequacy of water circulation for maintaining uniform heat distribution within the retort shall be documented by heat distribution data or other documentation from a processing authority, and such data shall be maintained on file by the establishment and made available to Program employees for review. Alternative methods for recirculation of water in the retort may be used provided there is documentation

in the form of heat distribution data or other documentation from a processing authority maintained on file by the establishment and made available to Program employees for review.

(xi) *Cooling water entry.* In retorts for processing product packed in glass jars, the incoming cooling water should not directly strike the jars, in order to minimize glass breakage by thermal shock.

(d) *Pressure processing with steam/air mixtures in batch retorts.* (1) The basic requirements for indicating temperature devices and temperature/time recording devices are described in paragraphs (a) (1) and (2) of this section. Additionally, bulb sheaths or probes for indicating temperature devices and temperature/time recording devices or controller probes shall be inserted directly into the retort shell in such a position that steam does not strike them directly.

(2) Steam controllers are required as described in paragraph (a)(3) of this section.

(3) *Recording pressure controller.* A recording pressure controller shall be used to control the air inlet and the steam/air mixture outlet.

(4) *Circulation of steam/air mixtures.* A means shall be provided for the circulation of the steam/air mixture to prevent formation of low-temperature pockets. The efficiency of the circulation system shall be documented by heat distribution data or other documentation from a processing authority, and such data shall be maintained on file by the establishment and made available to Program employees for review. The circulation system shall be checked to ensure its proper functioning and shall be equipped with a pilot light or a similar device to warn the operator when it is not functioning. Because of the variety of existing designs, reference shall be made to the equipment manufacturer for details of installation, operation, and control.

(e) *Atmospheric cookers*—(1) *Temperature/time recording device.* Each atmospheric cooker (e.g., hot water bath) shall be equipped with at least one temperature/time recording device in accordance with the basic requirements described in paragraph (a)(2) of this section.

(2) *Heat distribution.* Each atmospheric cooker shall be equipped and operated to ensure uniform heat distribution throughout the processing system during the thermal process. Heat distribution data or other documentation from the manufacturer or a processing authority demonstrating uniform heat distribution within the cooker shall be kept on file by the establishment and made available to Program employees for review.

(f) *Other systems.* All other systems not specifically delineated in this section and used for the thermal processing of canned product shall be adequate to produce shelf-stable products consistently and uniformly.

(g) *Equipment maintenance.* (1) Upon installation, all instrumentation and controls shall be checked by the establishment for proper functioning and accuracy and, thereafter, at any time their functioning or accuracy is suspect.

(2) At least once a year each thermal processing system shall be examined by an individual not directly involved in daily operations to ensure the proper functioning of the system as well as all auxiliary equipment and instrumentation. In addition, each thermal processing system should be examined before the resumption of operation following an extended shutdown.

(3) Air and water valves that are intended to be closed during thermal processing shall be checked by the establishment for leaks. Defective valves shall be repaired or replaced as needed.

(4) Vent and bleeder mufflers shall be checked and maintained or replaced by the establishment to prevent any reduction in vent or bleeder efficiency.

(5) When water spreaders are used for venting, a maintenance schedule shall be developed and implemented to assure that the holes are maintained at their original size.

(6) Records shall be kept on all maintenance items that could affect the adequacy of the thermal process. Records shall include the date and type of maintenance performed and the person conducting the maintenance.

(h) *Container cooling and cooling water.* (1) Potable water shall be used

for cooling except as provided for in paragraphs (h) (2) and (3) of this section.

(2) Cooling canal water shall be chlorinated or treated with a chemical approved by the Administrator as having a bactericidal effect equivalent to chlorination. There shall be a measurable residual of the sanitizer in the water at the discharge point of the canal. Cooling canals shall be cleaned and replenished with potable water to prevent the buildup of organic matter and other materials.

(3) Container cooling waters that are recycled or reused shall be handled in systems that are so designed, operated, and maintained so there is no buildup of microorganisms, organic matter, and other materials in the systems and in the waters. System equipment, such as pipelines, holding tanks and cooling towers, shall be constructed and installed so that they can be cleaned and inspected. In addition, the establishment shall maintain, and make available to Program employees for review, information on at least the following:

(i) System design and construction;

(ii) System operation including the rates of renewal with fresh, potable water and the means for treating the water so that there is a measurable residual of an acceptable sanitizer, per paragraph (h)(2) of this section, in the water at the point where the water exits the container cooling vessel;

(iii) System maintenance including procedures for the periodic cleaning and sanitizing of the entire system; and

(iv) Water quality standards, such as microbiological, chemical and physical, monitoring procedures including the frequency and site(s) of sampling, and the corrective actions taken when water quality standards are not met.

(i) *Post-process handling of containers* Containers shall be handled in a manner that will prevent damage to the hermetic seal area. All worn and frayed belting, can retarders, cushions, and the like shall be replaced with nonporous materials. To minimize container abrasions, particularly in the seal area, containers should not remain stationary on moving conveyors. All post-process container handling equipment should be kept clean so there is no buildup of microorganisms on surfaces in contact with the containers.

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[51 FR 45619, Dec. 19, 1986, as amended at 65 FR 34389, May 30, 2000]

§ 318.306 Processing and production records.

At least the following processing and production information shall be recorded by the establishment: date of production; product name and style; container code; container size and type; and the process schedule, including the minimum initial temperature. Measurements made to satisfy the requirements of § 318.303 regarding the control of critical factors shall be recorded. In addition, where applicable, the following information and data shall also be recorded:

(a) *Processing in steam*—(1) *Batch still retorts.* For each retort batch, record the retort number or other designation, the approximate number of containers or the number of retort crates per retort load, product initial temperature, time steam on, the time and temperature vent closed, the start of process timing, time steam off, and the actual processing time. The indicating temperature device and the temperature recorder shall be read at the same time at least once during process timing and the observed temperatures recorded.

(2) *Batch agitating retorts.* In addition to recording the information required for batch, still steam retorts in paragraph (a)(1) of this section, record the functioning of the condensate bleeder(s) and the retort or reel speed.

(3) *Continuous rotary retorts.* Record the retort system number, the approximate total number of containers retorted, product initial temperature, time steam on, the time and temperature vent closed, time process temperature reached, the time the first can enters and the time the last can exits the retort. The retort or reel speed shall be determined and recorded at intervals not to exceed 4 hours. Readings of the indicating temperature device(s) and temperature recorder(s) shall be made and recorded at the time the first container enters the retort and thereafter with sufficient frequency to ensure

compliance with the process schedule. These observations should be made and recorded at intervals not exceeding 30 minutes of continuous retort operation. Functioning of the condensate bleeder(s) shall be observed and recorded at the time the first container enters the retort and thereafter as specified in § 318.305(b)(3)(v).

(4) *Hydrostatic retorts.* Record the retort system number, the approximate total number of containers retorted, product initial temperature, time steam on, the time and temperature vent(s) closed, time process temperature reached, time first containers enter the retort, time last containers exit the retort, and, if specified in the process schedule, measurements of temperatures in the hydrostatic water legs. Readings of the temperature indicating device, which is located in the steam/water interface, and the temperature recording device shall be observed and the temperatures recorded at the time the first containers enter the steam dome. Thereafter, these instruments shall be read and the temperatures recorded with sufficient frequency to ensure compliance with the temperature specified in the process schedule and should be made at least every hour of continuous retort operation. Container conveyor speed, and for agitating hydrostatic retorts, the rotative chain speed, shall be determined and recorded at intervals of sufficient frequency to ensure compliance with the process schedule and should be performed at least every 4 hours.

(b) *Processing in water*—(1) *Batch still retorts.* For each retort batch, record the retort number or other designation, the approximate number of containers or number of retort crates per retort load, product initial temperature, time steam on, the start of process timing, water level, water recirculation rate (if critical), overriding pressure maintained, time steam off, and actual processing time. The indicating temperature device and the temperature recorder shall be read at the same time at least once during process timing and the observed temperatures recorded.

(2) *Batch agitating retorts.* In addition to recording the information required in paragraph (b)(1) of this section, record the retort or reel speed.

(c) *Processing in steam/air mixtures.* For each retort batch, record the retort number or other designation, the approximate number of containers or number of retort crates per retort load, product initial temperature, time steam on, venting procedure, if applicable, the start of process timing, maintenance of circulation of the steam/air mixture, air flow rate or forced recirculation flow rate (if critical), overriding pressure maintained, time steam off, and actual processing time. The indicating temperature device and the temperature recorder shall be read at the same time at least once during process timing and the observed temperatures recorded.

(d) *Atmospheric cookers*—(1) *Batch-type systems.* For each cooker batch, record the cooker number or other designation and the approximate number of containers. In addition, record all critical factors of the process schedule such as cooker temperature, initial temperature, the time the thermal process cycle begins and ends, hold time, and the final internal product temperature.

(2) *Continuous-type systems.* Record the cooker number or other designation, the time the first containers enter and the last containers exit a cooker, and the approximate total number of containers processed. In addition, record all critical factors of the process schedule such as the initial temperature, cooker speed, and final internal product temperature.

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§ 318.307 Record review and maintenance.

(a) *Process records.* Charts from temperature/time recording devices shall be identified by production date, container code, processing vessel number or other designation, and other data as necessary to enable correlation with the records required in § 318.306. Each entry on a record shall be made at the time the specific event occurs, and the recording individual shall sign or initial each record form. No later than 1 working day after the actual process, the establishment shall review all

processing and production records to ensure completeness and to determine if all product received the process schedule. All records, including the temperature/time recorder charts and critical factor control records, shall be signed or initialed and dated by the person conducting the review. All processing and production records required in this subpart shall be made available to Program employees for review.

(b) *Automated process monitoring and recordkeeping.* Automated process monitoring and recordkeeping systems shall be designed and operated in a manner that will ensure compliance with the applicable requirements of § 318.306.

(c) *Container closure records.* Written records of all container closure examinations shall specify the container code, the date and time of container closure examination, the measurement(s) obtained, and any corrective actions taken. Records shall be signed or initialed by the container closure technician and shall be reviewed and signed by the establishment within 1 working day after the actual production to ensure that the records are complete and that the closing operations have been properly controlled. All container closure examination records required in this subpart shall be made available to Program employees for review.

(d) *Distribution of product.* Records shall be maintained by the establishment identifying initial distribution of the finished product to facilitate, if necessary, the segregation of specific production lots that may have been contaminated or are otherwise unsound for their intended use.

(e) *Retention of records.* Copies of all processing and production records required in § 318.306 shall be retained for no less than 1 year at the establishment, and for an additional 2 years at the establishment or other location from which the records can be made available to Program employees within 3 working days.

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[51 FR 45619, Dec. 19, 1986, as amended at 65 FR 34389, May 30, 2000]

§ 318.308 Deviations in processing.

(a) Whenever the actual process is less than the process schedule or when any critical factor does not comply with the requirements for that factor as specified in the process schedule, it shall be considered a deviation in processing.

(b) Deviations in processing (or process deviations) must be handled according to:

(1)(i) A HACCP plan for canned product that addresses hazards associated with microbial contamination, or,

(ii) Alternative documented procedures that will ensure that only safe and stable product is shipped in commerce; or

(iii) Paragraph (d) of this section.

(c) [Reserved]

(d) Procedures for handling process deviations where the HACCP plan for thermally processed/commercially sterile product does not address food safety hazards associated with microbial contamination, where there is no approved total quality control system, or where the establishment has no alternative documented procedures for handling process deviations.

(1) *Deviations identified in-process.* If a deviation is noted at any time before the completion of the intended process schedule, the establishment shall:

(i) Immediately reprocess the product using the full process schedule; or

(ii) Use an appropriate alternate process schedule provided such a process schedule has been established in accordance with § 318.302 (a) and (b) and is filed with the inspector in accordance with § 318.302(c); or

(iii) Hold the product involved and have the deviation evaluated by a processing authority to assess the safety and stability of the product. Upon completion of the evaluation, the establishment shall provide the inspector the following:

(*a*) A complete description of the deviation along with all necessary supporting documentation;

(*b*) A copy of the evaluation report; and

(*c*) A description of any product disposition actions, either taken or proposed.

(iv) Product handled in accordance with paragraph (d)(1)(iii) of this section

shall not be shipped from the establishment until the Program has reviewed all of the information submitted and approved the product disposition actions.

(v) If an alternate process schedule is used that is not on file with the inspector or if an alternate process schedule is immediately calculated and used, the product shall be set aside for further evaluation in accordance with paragraphs (d)(1)(iii) and (iv) of this section.

(vi) When a deviation occurs in a continuous rotary retort, the product shall be handled in accordance with paragraphs (d)(1)(iii) and (iv) of this section or in accordance with the following procedures:

(*a*) Emergency stops.

(*1*) When retort jams or breakdowns occur during the processing operations, all containers shall be given an emergency still process (developed per § 318.302(b)) before the retort is cooled or the retort shall be cooled promptly and all containers removed and either reprocessed, repacked and reprocessed, or destroyed. Regardless of the procedure used, containers in the retort intake valve and in transfer valves between retort shells at the time of a jam or breakdown shall be removed and either reprocessed, repacked and reprocessed and or destroyed. Product to be destroyed shall be handled as ''U.S. Inspected and Condemned'', as defined in § 301.2(ttt) of this subchapter, and disposed of in accordance with part 314 of this subchapter.

(*2*) The time the retort reel stopped and the time the retort is used for an emergency still retort process shall be noted on the temperature/time recording device and entered on the other production records required in § 318.306.

(*b*) Temperature drops. When the retort temperature drops below the temperature specified in the process schedule, the reel shall be stopped and the following actions shall be taken:

(*1*) For temperature drops of less than 10 °F (or 5.5 °C) either, (*i*) all containers in the retort shall be given an emergency still process (developed per § 318.302(b)) before the reel is restarted; (*ii*) container entry to the retort shall be prevented and an emergency agitating process (developed per § 318.302(b)) shall be used before container entry to the retort is restarted; or (*iii*) container entry to the retort shall be prevented and the reel restarted to empty the retort. The discharged containers shall be reprocessed, repacked and reprocessed, or destroyed. Product to be destroyed shall be handled as ''U.S. Inspected and Condemned'', as defined in § 318.2(ee) of this subchapter, and disposed of in accordance with part 314 of this subchapter.

(*2*) For temperature drops of 10 °F (or 5.5 °C) or more, all containers in the retort shall be given an emergency still process (developed per § 318.302(b)). The time the reel was stopped and the time the retort was used for a still retort process shall be marked on the temperature/time recording device by the establishment and entered on the other production records required in § 318.306. Alternatively, container entry to the retort shall be prevented and the reel restarted to empty the retort. The discharged containers shall be either reprocessed, repacked and reprocessed, or destroyed. Product to be destroyed shall be handled as ''U.S. Inspected and Condemned'', as defined in § 301.2(ee) of this subchapter, and disposed of in accordance with part 314 of this subchapter.

(2) *Deviations identified through record review.* Whenever a deviation is noted during review of the processing and production records required by § 318.307 (a) and (b), the establishment shall hold the product involved and the deviation shall be handled in accordance with paragraphs (d)(1) (iii) and (iv) of this section.

(e) Process deviation file. The establishment shall maintain full records regarding the handling of each deviation. Such records shall include, at a minimum, the appropriate processing and production records, a full description of the corrective actions taken, the evaluation procedures and results, and the disposition of the affected product. Such records shall be maintained in a separate file or in a log that contains the appropriate information. The file or log shall be retained in accordance with § 318.307(e) and shall be made

available to Program employees upon request.

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§ 318.309 Finished product inspection.

(a) Finished product inspections must be handled according to:

(1) A HACCP plan for canned product that addresses hazards associated with microbiological contamination;

(2) An FSIS-approved total quality control system;

(3) Alternative documented procedures that will ensure that only safe and stable product is shipped in commerce; or

(4) Paragraph (d) of this section.

(b)–(c) [Reserved]

(d) Procedures for handling finished product inspections where the HACCP plan for thermally processed/commercially sterile product does not address food safety hazards associated with microbial contamination, where there is no approved total quality control system, or where the establishment has no alternative documented procedures for handling process deviations.

(1) *Incubation of shelf stable canned product*—(i) *Incubator.* The establishment shall provide incubation facilities which include an accurate temperature/time recording device, an indicating temperature device, a means for the circulation of the air inside the incubator to prevent temperature variations, and a means to prevent unauthorized entry into the facility. The Program is responsible for the security of the incubator.

(ii) *Incubation temperature.* The incubation temperature shall be maintained at 95±5 °F (35±2.8 °C). If the incubation temperature falls below 90 °F (or 32 °C) or exceeds 100 °F (or 38 °C) but does not reach 103 °F (or 39.5 °C), the incubation temperature shall be adjusted within the required range and the incubation time extended for the time the sample containers were held at the deviant temperature. If the incubation temperature is at or above 103 °F (or 39.5 °C) for more than 2 hours, the incubation test(s) shall be terminated, the temperature lowered to within the required range, and new sample containers incubated for the required time.

(iii) *Product requiring incubation.* Shelf stable product requiring incubation includes:

(*a*) Low acid products as defined in § 318.300(m); and

(*b*) Acidified low acid products as defined in § 318.300(b).

(iv) *Incubation samples.* (*a*) From each load of product processed in a batch-type thermal processing system (still or agitation), the establishment shall select at least one container for incubation.

(*b*) For continuous rotary retorts, hydrostatic retorts, or other continuous-type thermal processing systems, the establishment shall select at least one container per 1,000 for incubation.

(*c*) Only normal-appearing containers shall be selected for incubation.

(v) *Incubation time.* Canned product requiring incubation shall be incubated for not less than 10 days (240 hours) under the conditions specified in paragraph (d)(1)(ii) of this section.

(vi) *Incubation checks and record maintenance.* Designated establishment employees shall visually check all containers under incubation each working day and the inspector shall be notified when abnormal containers are detected. All abnormal containers should be allowed to cool before a final decision on their condition is made. For each incubation test the establishment shall record at least the product name, container size, container code, number of containers incubated, in and out dates, and incubation results. The establishment shall retain such records, along with copies of the temperature/time recording charts, in accordance with § 318.307(e).

(vii) *Abnormal containers.* The finding of abnormal containers (as defined in § 318.300(a)) among incubation samples is cause to officially retain at least the code lot involved.

(viii) *Shipping.* No product shall be shipped from the establishment before the end of the required incubation period except as provided in this paragraph or paragraph (b) or (c) of this section. An establishment wishing to ship product prior to the completion of

the required incubation period shall submit a written proposal to the area supervisor. Such a proposal shall include provisions that will assure that shipped product will not reach the retail level of distribution before sample incubation is completed and that product can be returned promptly to the establishment should such action be deemed necessary by the incubation test results. Upon receipt of written approval from the area supervisor, product may be routinely shipped provided the establishment continues to comply with all requirements of this subpart.

(2) *Container condition*—(i) *Normal containers.* Only normal-appearing containers shall be shipped from an establishment as determined by an appropriate sampling plan or other means acceptable to Program employees.

(ii) *Abnormal containers.* When abnormal containers are detected by any means other than incubation, the establishment shall inform the inspector, and the affected code lot(s) shall not be shipped until the Program has determined that the product is safe and stable. Such a determination will take into account the cause and level of abnormals in the affected lot(s) as well as any product disposition actions either taken or proposed by the establishment.

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§ 318.310 Personnel and training.

All operators of thermal processing systems specified in § 318.305 and container closure technicians shall be under the direct supervision of a person who has successfully completed a school of instruction that is generally recognized as adequate for properly training supervisors of canning operations.

[51 FR 45619, Dec. 19, 1986]

§ 318.311 Recall procedure.

Establishments shall prepare and maintain a current procedure for the recall of all canned product covered by this subpart. Upon request, the recall procedure shall be made available to Program employees for review.

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PART 319—DEFINITIONS AND STANDARDS OF IDENTITY OR COMPOSITION

Subpart A—General

Sec.
319.1 Labeling and preparation of standardized products.
319.2 Products and nitrates and nitrites.
319.5 Mechanically Separated (Species).
319.6 Limitations with respect to use of Mechanically Separated (Species).

Subpart B—Raw Meat Products

319.15 Miscellaneous beef products.
319.29 Miscellaneous pork products.

Subpart C—Cooked Meats

319.80 Barbecued meats.
319.81 Roast beef parboiled and steam roasted.

Subpart D—Cured Meats, Unsmoked and Smoked

319.100 Corned beef.
319.101 Corned beef brisket.
319.102 Corned beef round and other corned beef cuts.
319.103 Cured beef tongue.
319.104 Cured pork products.
319.105 ''Ham patties,'' ''Chopped ham,'' ''Pressed ham,'' ''Spiced ham,'' and similar products.
319.106 ''Country Ham,'' ''Country Style Ham,'' ''Dry Cured Ham,'' ''Country Pork Shoulder,'' ''Country Style Pork Shoulder,'' and ''Dry Cured Pork Shoulder.''
319.107 Bacon.

Subpart E—Sausage Generally: Fresh Sausage

319.140 Sausage.
319.141 Fresh pork sausage.
319.142 Fresh beef sausage.
319.143 Breakfast sausage.
319.144 Whole hog sausage.
319.145 Italian sausage products.

Subpart F—Uncooked, Smoked Sausage

319.160 Smoked pork sausage.

Subpart G—Cooked Sausage

319.180 Frankfurter, frank, furter, hotdog, weiner, vienna, bologna, garlic bologna, knockwurst, and similar products.
319.181 Cheesefurters and similar products.
319.182 Braunschweiger and liver sausage or liverwurst.

Subpart H [Reserved]

Subpart I—Semi-Dry Fermented Sausage [Reserved]

Subpart J—Dry Fermented Sausage [Reserved]

Subpart K—Luncheon Meat, Loaves and Jellied Products

319.260 Luncheon meat.
319.261 Meat loaf.

Subpart L—Meat Specialties, Puddings and Nonspecific Loaves

319.280 Scrapple.
319.281 Bockwurst.

Subpart M—Canned, Frozen, or Dehydrated Meat Food Products

319.300 Chili con carne.
319.301 Chili con carne with beans.
319.302 Hash.
319.303 Corned beef hash.
319.304 Meat stews.
319.305 Tamales.
319.306 Spaghetti with meatballs and sauce, spaghetti with meat and sauce, and similar products.
319.307 Spaghetti sauce with meat.
319.308 Tripe with milk.
319.309 Beans with frankfurters in sauce, sauerkraut with wieners and juice, and similar products.
319.310 Lima beans with ham in sauce, beans with ham in sauce, beans with bacon in sauce, and similar products.
319.311 Chow mein vegetables with meat, and chop suey vegetables with meat.
319.312 Pork with barbecue sauce and beef with barbecue sauce.
319.313 Beef with gravy and gravy with beef.

Subpart N—Meat Food Entree Products, Pies, and Turnovers

319.500 Meat pies.

Subpart O—Meat Snacks, Hors d'Oeuvres, Pizza, and Specialty Items

319.600 [Reserved]

Subpart P—Fats, Oils, Shortenings

319.700 Margarine or oleomargarine.
319.701 Mixed fat shortening.
319.702 Lard, leaf lard.
319.703 Rendered animal fat or mixture thereof.

Subpart Q—Meat Soups, Soup Mixes, Broths, Stocks, Extracts

319.720 Meat extract.
319.721 Fluid extract of meat.

Subpart R—Meat Salads and Meat Spreads

319.760 Deviled ham, deviled tongue, and similar products.
319.761 Potted meat food product and deviled meat food product.
319.762 Ham spread, tongue spread, and similar products.

Subpart S—Meat Baby Foods [Reserved]

Subpart T—Dietetic Meat Foods [Reserved]

Subpart U—Miscellaneous

319.880 Breaded products.
319.881 Liver meat food products.

AUTHORITY: 7 U.S.C. 450, 1901–1906; 21 U.S.C. 601–695; 7 CFR 2.17, 2.55.

SOURCE: 35 FR 15597, Oct. 3, 1970, unless otherwise noted.

Subpart A—General

§ 319.1 Labeling and preparation of standardized products.

(a) Labels for products for which standards of identity or composition are prescribed in this part shall show the appropriate product name, an ingredient statement, and other label information in accordance with the special provisions, if any, in this part, and otherwise in accordance with the general labeling provisions in part 317 of this subchapter, and such products shall be prepared in accordance with the special provisions, if any, in this part and otherwise in accordance with the general provisions in this subchapter. Any product for which there is a common or usual name must consist of ingredients and be prepared by the use of procedures common or usual to such products insofar as specific ingredients or procedures are not prescribed or prohibited by the provisions of this subchapter.

(b) Any binder or antimicrobial agent that has been found to be safe and suitable by the Food and Drug Administration and the Food Safety and Inspection Service may be used in the production of meat products with standards of identity in this part, where the product standards and applicable Federal regulations already permit the use of these types of ingredients.

[35 FR 15597, Oct. 3, 1970, as amended at 68 FR 22578, Apr. 29, 2003]

§319.2 Products and nitrates and nitrites.

Any product, such as frankfurters and corned beef, for which there is a standard in this part and to which nitrate or nitrite is permitted or required to be added, may be prepared without nitrate or nitrite and labeled with such standard name when immediately preceded with the term ''Uncured'' in the same size and style of lettering as the rest of such standard name: *Provided,* That the product is found by the Administrator to be similar in size, flavor, consistency, and general appearance to such product as commonly prepared with nitrate and nitrite: *And provided further,* That labeling for such product complies with the provisions of §317.17(c) of this subchapter.

[44 FR 48961, Aug. 21, 1979]

§319.5 Mechanically Separated (Species).

(a) Mechanically Separated (Species) is any finely comminuted product resulting from the mechanical separation and removal of most of the bone from attached skeletal muscle of livestock carcasses and parts of carcasses and meeting the other provisions of this paragraph. Examples of such product are ''Mechanically Separated Beef'', ''Mechanically Separated Veal'', ''Mechanically Separated Pork'', and ''Mechanically Separated Lamb''. At least 98 percent of the bone particles present in such product shall have a maximum size no greater than 0.5 millimeter in their greatest dimension and there shall be no bone particles larger than 0.85 millimeter in their greatest dimension. The product resulting from the separating process shall not have a calcium content exceeding 0.75 percent, as a measure of a bone solids content of not more than 3 percent, and shall have a minimum PER of 2.5 (except as modified in paragraph (e)(1) of this section). Such product also shall have a protein content of not less than 14 percent and a fat content of not more than 30 percent, or it shall be deemed to be product for processing. Such product failing to meet the bone particle size, calcium, or PER requirements of this paragraph shall only be used in producing animal fats. Where such product meets the bone particle size, calcium, and PER requirements of this paragraph, it may also be used in the formulation of meat food products in accordance with §319.6.

(b)–(d) [Reserved]

(e)(1) An essential amino acid content of at least 33 percent of the total amino acids presents in ''Mechanically Separated (Species)'' shall be accepted as evidence of compliance with the protein quality requirement set forth in paragraph (a) of this section. For purposes of this paragraph, essential amino acid content includes isoleucine, leucine, lysine, methionine, phenylalanine, threonine, and valine content, and the total amino acids present include isoleucine, leucine, lysine, methionine, phenylalanine, threonine, valine, tyrosine, arginine, histidine, alanine, aspartic acid, glutamic acid, glycine, proline, serine, and hydroxyproline content.

(2) Analytical methods used by establishments in verifying the fat, protein, and calcium content of product consisting of or containing Mechanically Separated (Species) shall be among those listed in ''Official Methods of Analysis of the Association of Official Analytical Chemists (AOAC),'' 16th edition, 1995, §§960.39, 976.21, 928.08 (Chapter 39), and 940.33 (Chapter 45), which is incorporated by reference, or, if no AOAC method is available, in the ''Chemistry Laboratory Guidebook,'' U.S. Department of Agriculture, Washington, D.C., March 1986 edition, sections 6.011–6.013, Revised June 1987 (pages 6–35 through 6–65), or by appropriate methods validated by scientific

bodies in collaborative trials. The ''Official Methods of Analysis of the Association of Official Analytical Chemists,'' Chapter 39 and Chapter 45, subsection 45.2.06 (AOAC Official Method 940.33), 16th edition, 1995, are incorporated by reference with the approval of the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR Part 51.

[47 FR 28256, June 29, 1982, as amended at 54 FR 40631, Oct. 3, 1989; 59 FR 33642, June 30, 1994; 62 FR 45026, Aug. 25, 1997; 65 FR 34389, May 30, 2000]

§ 319.6 Limitations with respect to use of Mechanically Separated (Species).

(a) Meat food products required to be prepared from one species shall not contain Mechanically Separated (Species) of any other species.

(b) Mechanically Separated (Species) described in § 319.5 that has a protein content of not less than 14 percent and a fat content of not more than 30 percent may constitute up to 20 percent of the livestock and poultry product portion of any meat food product except those listed in paragraph (d) of this section.

(c) Mechanically Separated (Species) for processing described in § 319.5 may constitute up to 20 percent of the livestock and poultry product portion of any meat food product that is subject to a definition and standard of identity or composition in part 319 which establishes a maximum limit on the fat content of such meat food product except those listed in paragraph (d) of this section.

(d) Mechanically Separated (Species) and Mechanically Separated (Species) for processing described in § 319.5 shall not be used in baby, junior, or toddler foods, ground beef, hamburger, fabricated steaks (§ 319.15 (a), (b), and (d)), barbecued meats (§ 319.80), roast beef-parboiled and steam roasted (§ 319.81), corned (cured) beef cuts (§§ 319.100—319.103), certain cured pork products (§§ 319.104 (a)–(e) and 319.106), tripe with milk (§ 319.308), lima beans with ham and similar products (§ 319.310), beef with gravy and gravy with beef (§ 319.313), and meat pies (§ 319.500).

[47 FR 28257, June 29, 1982]

Subpart B—Raw Meat Products

§ 319.15 Miscellaneous beef products.

(a) *Chopped beef, ground beef.* ''Chopped Beef'' or ''Ground Beef'' shall consist of chopped fresh and/or frozen beef with or without seasoning and without the addition of beef fat as such, shall not contain more than 30 percent fat, and shall not contain added water, phosphates, binders, or extenders. When beef cheek meat (trimmed beef cheeks) is used in the preparation of chopped or ground beef, the amount of such cheek meat shall be limited to 25 percent; and if in excess of natural proportions, its presence shall be declared on the label, in the ingredient statement required by § 317.2 of this subchapter, if any, and otherwise contiguous to the name of the product.

(b) *Hamburger.* ''Hamburger'' shall consist of chopped fresh and/or frozen beef with or without the addition of beef fat as such and/or seasoning, shall not contain more than 30 percent fat, and shall not contain added water, phosphates, binders, or extenders. Beef cheek meat (trimmed beef cheeks) may be used in the preparation of hamburger only in accordance with the conditions prescribed in paragraph (a) of this section.

(c) *Beef patties.* ''Beef Patties'' shall consist of chopped fresh and/or frozen beef with or without the addition of beef fat as such and/or seasonings. Binders or extenders, Mechanically Separated (Species) used in accordance with § 319.6, and/or partially defatted beef fatty tissue may be used without added water or with added water only in amounts such that the product characteristics are essentially that of a meat pattie.

(d) *Fabricated steak.* Fabricated beef steaks, veal steaks, beef and veal steaks, or veal and beef steaks, and similar products, such as those labeled ''Beef Steak, Chopped, Shaped, Frozen,'' ''Minute Steak, Formed, Wafer Sliced, Frozen,'' ''Veal Steaks, Beef Added, Chopped—Molded—Cubed—Frozen, Hydrolyzed Plant Protein, and Flavoring'' shall be prepared by comminuting and forming the product from fresh and/or frozen meat, with or

without added fat, of the species indicated on the label. Such products shall not contain more than 30 percent fat and shall not contain added water or extenders. Transglutaminase enzyme at levels of up to 65 ppm may be used as a binder. Beef cheek meat (trimmed beef cheeks) may be used in the preparation of fabricated beef steaks only in accordance with the conditions prescribed in paragraph (a) of this section.

(e) *Partially defatted beef fatty tissue.* ''Partially Defatted Beef Fatty Tissue'' is a beef byproduct derived from the low temperature rendering (not exceeding 120 °F.) of fresh beef fatty tissue. Such product shall have a pinkish color and a fresh odor and appearance.

[35 FR 15597, Oct. 3, 1970, as amended at 38 FR 29215, Oct. 23, 1973; 43 FR 26424, June 20, 1978; 47 FR 10784, Mar. 12, 1982; 47 FR 28257, June 29, 1982; 66 FR 54916, Oct. 31, 2001]

§ 319.29 Miscellaneous pork products.

(a) *Partially defatted pork fatty tissue.* ''Partially Defatted Pork Fatty Tissue'' is a pork byproduct derived from the low temperature rendering (not exceeding 120 °F.) of fresh pork fatty tissue, exclusive of skin. Such product shall have a pinkish color and a fresh odor and appearance.

Subpart C—Cooked Meats

§ 319.80 Barbecued meats.

Barbecued meats, such as product labeled ''Beef Barbecue'' or ''Barbecued Pork,'' shall be cooked by the direct action of dry heat resulting from the burning of hard wood or the hot coals therefrom for a sufficient period to assume the usual characteristics of a barbecued article, which include the formation of a brown crust on the surface and the rendering of surface fat. The product may be basted with a sauce during the cooking process. The weight of barbecued meat shall not exceed 70 percent of the weight of the fresh uncooked meat.

§ 319.81 Roast beef parboiled and steam roasted.

''Roast Beef Parboiled and Steam Roasted'' shall be prepared so that the weight of the finished product, excluding salt and flavoring material, shall not exceed 70 percent of the fresh beef weight. Transglutaminase enzyme at levels of up to 65 ppm may be used as a binder in such product. Beef cheek meat and beef head meat from which the overlying glandular and connective tissues have been removed, and beef heart meat, exclusive of the heart cap may be used individually or collectively to the extent of 5 percent of the meat ingredients in the preparation of canned product labeled ''Roast Beef Parboiled and Steam Roasted.'' When beef cheek meat, beef head meat, or beef heart meat is used in the preparation of this product, its presence shall be reflected in the statement of ingredients required by part 317 of this subchapter.

[35 FR 15597, Oct. 3, 1970, as amended at 38 FR 29215, Oct. 23, 1973; 66 FR 54916, Oct. 31, 2001]

Subpart D—Cured Meats, Unsmoked and Smoked

§ 319.100 Corned beef.

''Corned Beef'' shall be prepared from beef briskets, navels, clods, middle ribs, rounds, rumps, or similar cuts using one or a combination of the curing ingredients specified in a regulation permitting that use in this subchapter or 9 CFR Chapter III, Subchapter E, or in 21 CFR Chapter I, Subchapter A or Subchapter B. Canned product labeled ''Corned Beef'' shall be prepared so that the weight of the finished product, excluding cure, salt, and flavoring material, shall not exceed 70 percent of the fresh beef weight. Corned beef other than canned shall be cured in pieces weighing not less than 1 pound, and if cooked, its weight shall not exceed the weight of the fresh uncured beef. Beef cheek meat, beef head meat and beef heart meat may be used to the extent of 5 percent of the meat ingredient in preparation of this product when trimmed as specified in § 319.81. When beef cheek meat, beef head meat, or beef heart meat is used in preparation of this product, its presence shall be reflected in the statement of ingredients required by part 317 of this subchapter. The application of curing solution to beef cuts, other than briskets, which are intended for bulk corned beef shall not result in an increase in the weight of the finished

cured product of more than 10 percent over the weight of the fresh uncured meat.

[35 FR 15597, Oct. 3, 1970; 36 FR 11903, June 23, 1971, as amended at 38 FR 29215, Oct. 23, 1973; 64 FR 72174, Dec. 23, 1999]

§ 319.101 Corned beef brisket.

In preparing ''Corned Beef Brisket,'' the application of curing solution to the beef brisket shall not result in an increase in the weight of the finished cured product of more than 20 percent over the weight of the fresh uncured brisket. If the product is cooked, the weight of the finished product shall not exceed the weight of the fresh uncured brisket.

§ 319.102 Corned beef round and other corned beef cuts.

In preparing ''Corned Beef Round'' and other corned beef cuts, except ''Corned Beef Briskets,'' the curing solution shall be applied to pieces of beef weighing not less than one pound and such application shall not result in an increased weight of the cured beef product of more than 10 percent over the weight of the fresh uncured beef cut. If the product is cooked, the weight of the finished product shall not exceed the weight of the fresh uncured beef cut.

§ 319.103 Cured beef tongue.

In preparing ''Cured Beef Tongue,'' the application of curing solution to the fresh beef tongue shall not result in an increase in the weight of the cured beef tongue of more than 10 percent over the weight of the fresh uncured beef tongue.

§ 319.104 Cured pork products.

(a) Cured pork products, including hams, shoulders, picnics, butts and loins, shall comply with the minimum meat Protein Fat Free (PFF) percentage requirements set forth in the following chart:

Type of cured pork product	Minimum meat PFF percentage[1]	Product name and qualifying statements
Cooked ham, loin[2].	20.5	(Common and usual).
	18.5	(Common and usual) with natural juices.
	17.0	(Common and usual) water added.
	<17.0	(Common and usual) and water product—X% of weight is added ingredients.[3]
Cooked shoulder, butt, picnic[2].	20.0	(Common and usual).
	18.0	(Common and usual) with natural juices.
	16.5	(Common and usual) water added.
	<16.5	(Common and usual) and water product—X% of weight is added ingredients.[3]
Uncooked cured ham, loin.	18.0	Uncooked (common and usual).
	<18.0	Uncooked (common and usual) and water product—X% of weight is added ingredients.[3]
Uncooked cured shoulder, butt, picnic.	17.5	Uncooked (common and usual).
	<17.5	Uncooked (common and usual) and water product—X% of weight is added ingredients.[3]

[1] The minimum meat PFF percentage shall be the minimum meat protein which is indigenous to the raw unprocessed pork expressed as a percent of the non-fat portion of the finished product; and compliance shall be determined under § 318.19 of this subchapter for domestic cured pork product and § 327.23 of this subchapter for imported cured pork product.

[2] The term ''cooked'' is not appropriate for use on labels of cured pork products heated only for the purpose of destruction of possible live trichinae.

[3] Processors may immediately follow this qualifying statement with a list of the ingredients in descending order of predominance rather than having the traditional ingredients statement. In any case, the maximum percent of added substances in the finished product on a total weight percentage basis would be inserted as the X value; e.g., Ham and Water Product—20% of Weight is Added Ingredients.

(b) Cured pork products for which there is a qualifying statement required in paragraph (a) of this section shall bear that statement as part of the product name in lettering not less than ⅜ inch in height, or in lettering not less than one-third the size of the largest letter in the product name if it is in the same color and style of print and on the same color background as the product name. However, the Administrator may approve smaller lettering for labeling of packages of 1 pound or less, provided such lettering is at least one-third the size and of the same color and style as the product name.

(c) Cured pork product prepared pursuant to this section shall be subject to the compliance procedures in § 318.19 of this subchapter.

(d) The binders provided for use in cured pork products in a regulation in this subchapter, in 9 CFR Chapter III, Subchapter E, or in 21 CFR Chapter I, Subchapter A or Subchapter B, may be used singly in those cured pork products labeled as ''Ham Water Added,'' ''Ham and Water Product-X% of Weight is Added Ingredients,'' and ''Ham with Natural Juices.'' In addition to the binders referred to in the preceding sentence, the following substances are permitted for use as binders and may be used singly in those cured pork products labeled as ''Ham Water Added,'' ''Ham and Water Product-X% of Weight is Added Ingredients,'' and ''Ham with Natural Juices'': pork collagen at up to 3.5% of the product formulation. Unless their use is provided for in a regulation in this subchapter, in 9 CFR Chapter III, Subchapter E, or in 21 CFR Chapter I, Subchapter A or Subchapter B, or in this paragraph, these binders are not permitted to be used in combination with another such binder listed for use in cured pork products. When any such substance is added to these products, the substance shall be declared in the ingredients statement by its common or usual name in order of predominance.

[49 FR 14879, Apr. 13, 1984, as amended at 50 FR 9792, Mar. 12, 1985; 53 FR 5151, Feb. 22, 1988; 57 FR 42888, Sept. 17, 1992; 62 FR 45026, Aug. 25, 1997; 63 FR 148, Jan. 5, 1998; 64 FR 27904, May 24, 1999; 65 FR 34389, May 30, 2000; 66 FR 54916, Oct. 31, 2001]

§ 319.105 "Ham patties," "Chopped ham," "Pressed ham," "Spiced ham," and similar products.

(a) Finely divided (chopped, ground, flaked, chipped) cured ham products such as ''Ham patties,'' ''Chopped ham,'' ''Pressed ham,'' and ''Spiced ham'' shall comply with minimum meat Protein Fat Free (PFF) percentage requirements set forth in the following chart:

Type of cured pork product	Minimum meat PFF percentage [1]	Product name and qualifying statements
''Ham Patties,'' ''Chopped Ham,'' ''Pressed Ham,'' and ''Spiced Ham''	19.5	(Common and usual).
''Ham Patties,'' ''Chopped Ham,'' ''Pressed Ham,'' and ''Spiced Ham''	17.5	(Common and usual) with natural juices.
''Ham Patties,'' ''Chopped Ham,'' ''Pressed Ham,'' and ''Spiced Ham''	16.0	(Common and usual) water added.
''Ham Patties,'' ''Chopped Ham,'' ''Pressed Ham,'' and ''Spiced Ham''	<16.0	(Common and usual) and water product—(x)% of weight is added ingredients. [2]

[1] The minimum meat PFF percentage shall be the minimum meat protein which is indigenous to the raw, unprocessed pork expressed as a percent of the nonfat portion of the finished product; and compliance shall be determined under section 318.19 of this subchapter.

[2] Processors may immediately follow this qualifying statement with a list of the ingredients in descending order of predominance rather than having the traditional ingredients statement. In any case, the maximum percent of added substances in the finished product on a total weight percentage basis would be inserted as the X value; e.g., Ham and Water Product—20% of Weight is Added Ingredients.

(b) Cured pork products prepared under this section except ''Ham patties'' may contain finely chopped ham shank meat to the extent of 25 percent over that normally present in boneless ham. Mechanically Separated (Species) Product may be used in accordance with § 319.6.

(c) Cured pork product prepared pursuant to this section shall be subject to the compliance procedures in § 318.19 of this subchapter, and those cured pork products prepared under this section for which there is a qualifying statement required shall comply with the requirements of § 319.104(b) of this subchapter.

(d) In addition to the other requirements of this section, ''Ham Patties'' may not contain more than 35 percent fat, by analysis.

[49 FR 14880, Apr. 13, 1984, as amended at 53 FR 5151, Feb. 22, 1988; 62 FR 45026, Aug. 25, 1997; 65 FR 34389, May 30, 2000]

§ 319.106 "Country Ham," "Country Style Ham," "Dry Cured Ham," "Country Pork Shoulder," "Country Style Pork Shoulder," and "Dry Cured Pork Shoulder."

(a) ''Country Ham,'' ''Country Style Ham,'' or ''Dry Cured Ham,'' and ''Country Pork Shoulder,'' ''Country Style Pork Shoulder,'' or ''Dry Cured

Pork Shoulder.'' are the uncooked, cured, dried, smoked or unsmoked meat food products made respectively from a single piece of meat conforming to the definition of ''ham,'' as specified in § 317.8(b)(13) of this subchapter, or from a single piece of meat from a pork shoulder. They are prepared in accordance with paragraph (c) of this section by the dry application of salt (NaCl), or by the dry application of salt (NaCl) and one or more of the optional ingredients as specified in paragraph (d) of this section. They may not be injected with curing solutions nor placed in curing solutions.

(b) The product must be treated for the destruction of possible live trichinae in accordance with such methods as may be approved by the Administrator upon request in specific instances and none of the provisions of this standard can be interpreted as discharging trichinae treatment requirements.

(c)(1) The entire exterior of the ham or pork shoulder shall be coated by the dry application of salt or by the dry application of salt combined with other ingredients as permitted in paragraph (d) of this section.

(2) Additional salt, or salt mixed with other permitted ingredients, may be reapplied to the product as necessary to insure complete penetration.

(3) When sodium or potassium nitrate, or sodium or potassium nitrite, or a combination thereof, is used, the application of salt shall be in sufficient quantity to insure that the finished product has an internal salt content of at least 4 percent.

(4) When no sodium nitrate, potassium nitrate, sodium nitrite, potassium nitrite or a combination thereof is used, the application of salt shall be in sufficient quantity to insure that the finished product has a brine concentration of not less than 10 percent or a water activity of not more than 0.92.

(5) For hams or pork shoulders labeled ''country'' or ''country style,'' the combined period for curing and salt equalization shall not be less than 45 days for hams, and shall not be less than 25 days for pork shoulders; the total time for curing salt equalization, and drying shall not be less than 70 days for hams, and shall not be less than 50 days for pork shoulders. During the drying and smoking period, the internal temperature of the product must not exceed 95 °F., provided that such temperature requirement shall not apply to product dried or smoked under natural climatic conditions.

(6) For hams or pork shoulders labeled ''dry cured,'' the combined period for curing and salt equalization shall not be less than 45 days for hams, and shall not be less than 25 days for pork shoulders; and the total time for curing, salt equalization, and drying shall not be less than 55 days for hams and shall not be less than 40 days for pork shoulders.

(7) The weight of the finished hams and pork shoulders covered in this section shall be at least 18 percent less than the fresh uncured weight of the article.

(d) The optional ingredients for products covered in this section are:

(1) Nutritive sweeteners, spices, seasonings and flavorings.

(2) Sodium or potassium nitrate and sodium or potassium nitrite if used as prescribed in this section and in accordance with a regulation permitting that use in this subchapter or 9 CFR Chapter III, Subchapter E, or in 21 CFR Chapter I, Subchapter A or Subchapter B.

[42 FR 3299, Jan. 18, 1977, as amended at 64 FR 72174, Dec. 23, 1999]

EFFECTIVE DATE NOTE: At 46 FR 1257, Jan. 6, 1981, the Department announced that the temperature and time period provisions of § 319.106 (c)(5) and (c)(6) have not been in effect since November 17, 1980, and will not be enforced pending future Agency action in the matter. However, ham and pork shoulders must continue to be prepared in compliance with all other provisions of § 319.106 in order to be labeled ''country ham,'' ''country style ham,'' or ''dry cured ham,'' and ''country pork shoulder,'' ''country style pork shoulder,'' or ''dry cured pork shoulder.''

§ 319.107 Bacon.

The weight of cured pork bellies ready for slicing and labeling as ''Bacon'' shall not exceed the weight of the fresh uncured pork bellies.

[49 FR 14880, Apr. 13, 1984]

Subpart E—Sausage Generally: Fresh Sausage

§319.140 Sausage.

Except as otherwise provided in this section, or under the Poultry Products Inspection Act with respect to products consisting partly of poultry, sausage is the coarse or finely comminuted meat food product prepared from one or more kinds of meat or meat and meat byproducts, containing various amounts of water as provided for elsewhere in this part, and usually seasoned with condimented proportions of condimental substances, and frequently cured. Certain sausage as provided for elsewhere in this part may contain binders and extenders as provided in a regulation permitting that use in this subchapter or in 9 CFR Chapter III, Subchapter E, or in 21 CFR Chapter I, Subchapter A or Subchapter B. In addition to the binders and extenders referred to in the preceding sentence, the following two substances may also be used as binders in those sausages in which the use of such class of substances is permitted: pork collagen at up to 3.5% of the product formulation and transglutaminase enzyme at up to 65 ppm of the product formulation. Sausage may not contain phosphates except that phosphates listed in a regulation permitting that use in this subchapter or in 9 CFR Chapter III, Subchapter E, or in 21 CFR Chapter I, Subchapter A or Subchapter B may be used in cooked sausage. To facilitate chopping or mixing or to dissolve the usual curing ingredients, water or ice may be used in the preparation of sausage which is not cooked in an amount not to exceed 3 percent of the total ingredients in the formula. Cooked sausages such as Polish sausage, cotto salami, braunschweiger, liver sausage, and similar cooked sausage products may contain no more than 10 percent of added water in the finished product. Sausage may contain Mechanically Separated (Species) used in accordance with §319.6.

[55 FR 34683, Aug. 24, 1990, as amended at 64 FR 72175, Dec. 23, 1999; 66 FR 54916, Oct. 31, 2001]

§319.141 Fresh pork sausage.

''Fresh Pork Sausage'' is sausage prepared with fresh pork or frozen pork or both, but not including pork byproducts, and may contain Mechanically Separated (Species) in accordance with §319.6, and may be seasoned with condimental substances as permitted under part 318 of this subchapter. The finished product shall not contain more than 50 percent fat. To facilitate chopping or mixing, water or ice may be used in an amount not to exceed 3 percent of the total ingredients used.

[35 FR 15597, Oct. 3, 1970, as amended at 43 FR 26424, June 20, 1978; 47 FR 28257, 28258, June 29, 1982]

§319.142 Fresh beef sausage.

''Fresh Beef Sausage'' is sausage prepared with fresh beef or frozen beef, or both, but not including beef byproducts, and may contain Mechanically Separated (Species) used in accordance with §319.6, and may be seasoned with condimental substances as permitted under part 318 of this subchapter. The finished product shall not contain more than 30 percent fat. To facilitate chopping or mixing, water or ice may be used in an amount not to exceed 3 percent of the total ingredients used.

[35 FR 15597, Oct. 3, 1970, as amended at 43 FR 26424, June 20, 1978; 47 FR 28257, June 29, 1982]

§319.143 Breakfast sausage.

''Breakfast sausage'' is sausage prepared with fresh and/or frozen meat; or fresh and/or frozen meat and meat byproducts, and may contain Mechanically Separated (Species) in accordance with §319.6, and may be seasoned with condimental substances as permitted in part 318 of this subchapter. The finished product shall not contain more than 50 percent fat. To facilitate chopping or mixing, water or ice may be used in an amount not to exceed 3 percent of the total ingredients used. Binders or extenders may be added as provided in §319.140 of this part.

[55 FR 34683, Aug. 24, 1990, as amended at 66 FR 54916, Oct. 31, 2001]

§319.144 Whole hog sausage.

''Whole Hog Sausage'' is sausage prepared with fresh and/or frozen meat from swine in such proportions as are

normal to a single animal, and may include any Mechanically Separated (Species) produced from the animal and used in accordance with § 319.6, and may be seasoned with condimental substances as permitted under part 318 of this subchapter. The finished product shall not contain more than 50 percent fat. To facilitate chopping or mixing, water or ice may be used in an amount not to exceed 3 percent of the total ingredients used.

[35 FR 15597, Oct. 3, 1970, as amended at 43 FR 26424, June 20, 1978; 47 FR 28257, 28258, June 29, 1982]

§ 319.145 Italian sausage products.

(a) Italian sausage products are cured or uncured sausages containing at least 85 percent meat, or combination of meat and fat, with the total fat content constituting not more than 35 percent of the finished product. Such products shall be prepared in accordance with the provisions of paragraph (a) (1), (2) or (3) of this section, and shall contain salt, pepper, and either fennel or anise, or a combination of fennel and anise. Such products may contain any or all of the optional ingredients listed in paragraph (b) of this section.

(1) ''Italian Sausage'' shall be prepared with fresh or frozen pork, or pork and pork fat, and may contain Mechanically Separated (Species) in accordance with § 319.6.

(2) ''Italian Sausage with Beef,'' ''Italian Sausage with Veal,'' or ''Italian Sausage with Beef and Veal,'' shall be prepared so that fresh or frozen pork constitutes the major portion of the meat content requirement of this paragraph. Mechanically Separated (Species) may be used in accordance with § 319.6. When pork muscle tissue is combined with beef or veal, or both, in the preparation of bulk-packed products, or patties, it shall be treated for the destruction of possible live trichinae in accordance with § 318.10 of this subchapter.

(3) ''Italian Beef Sausage'' or ''Kosher Italian Beef Sausage'' shall be prepared with fresh or frozen beef or beef and beef fat. ''Italian Veal Sausage'' or ''Kosher Italian Veal Sausage'' shall be prepared with fresh or frozen veal or veal and veal fat. Mechanically Separated (Species) may be used in accordance with § 319.6.

(4) Italian sausage products made in conformance with the provisions of paragraphs (a) (1), (2), and (3) of this section, and with paragraphs (b) and (c) of this section, may contain sodium nitrite or potassium nitrite in amounts not to exceed those allowed in a regulation permitting that use in this subchapter or in 9 CFR Chapter III, Subchapter E, or in 21 CFR Chapter I, Subchapter A or Subchapter B, provided that such products are labeled with the word ''cured'' in the product name, such as ''Cured Italian Sausage.'' The word ''cured'' shall be displayed on the product label in the same size and style of lettering as other words in the product name.

(b) Optional ingredients permitted in Italian sausage products include:

(1) Spices (including paprika) and flavorings.

(2) Water or ice to facilitate chopping or mixing, but not to exceed 3 percent of the total weight of all ingredients including the water.

(3) Red or green peppers, or both.

(4) Dehydrated or fresh onions, garlic, and parsley.

(5) Sugar, dextrose, corn syrup, corn syrup solids, and glucose syrup.

(6) Monosodium glutamate and antioxidants in accordance with the chart of substances a regulation permitting that use in this subchapter or in 9 CFR Chapter III, Subchapter E, or in 21 CFR Chapter I, Subchapter A or Subchapter B.

(c) If Italian sausage products are cooked or smoked, determination of compliance with the provisions of paragraphs (a) and (b) of this section shall be based on the uncooked or unsmoked product. The product before cooking or smoking shall contain no more than 3 percent water as specified in paragraph (b)(2) of this section. Product which is cooked shall be labeled with the word ''cooked'' in the product name, such as ''Cooked Italian Sausage'' or ''Cooked Cured Italian Sausage.'' Product which is smoked shall be labeled with the word ''smoked'' in the product name, such as ''Smoked Italian Sausage'' or ''Smoked Cured Italian Sausage.'' The words ''cooked'' and ''smoked'' shall be displayed on the product label in the

same size and style of lettering as other words in the product name.

[41 FR 2630, Jan. 19, 1976, as amended at 43 FR 26424, June 20, 1978; 47 FR 28257, 28258, June 29, 1982; 49 FR 46533, Nov. 27, 1984; 64 FR 72175, Dec. 23, 1999]

Subpart F—Uncooked, Smoked Sausage

§319.160 Smoked pork sausage.

''Smoked Pork Sausage'' is pork sausage that is smoked with hardwood or other approved nonresinous materials. It may be seasoned with condimental substances as permitted in part 318 of this subchapter. The finished product shall not contain more than 50 percent fat. To facilitate chopping or mixing, water, or ice may be used in an amount not to exceed 3 percent of the total ingredients used.

[35 FR 15597, Oct. 3, 1970, as amended at 47 FR 28258, June 29, 1982]

Subpart G—Cooked Sausage

§319.180 Frankfurter, frank, furter, hotdog, weiner, vienna, bologna, garlic bologna, knockwurst, and similar products.

(a) Frankfurter, frank, furter, hotdog, wiener, vienna, bologna, garlic bologna, knockwurst and similar cooked sausages are comminuted, semisolid sausages prepared from one or more kinds of raw skeletal muscle meat or raw skeletal muscle meat and raw or cooked poultry meat, and seasoned and cured, using one or more of the curing agents in accordance with a regulation permitting that use in this subchapter or in 9 CFR Chapter III, Subchapter E, or in 21 CFR Chapter I, Subchapter A or Subchapter B. They may or may not be smoked. The finished products shall not contain more than 30 percent fat. Water or ice, or both, may be used to facilitate chopping or mixing or to dissolve the curing ingredients but the sausage shall contain no more than 40 percent of a combination of fat and added water. These sausage products may contain only phosphates approved under part 318 of this chapter. Such products may contain raw or cooked poultry meat and/or Mechanically Separated (Kind of Poultry) without skin and without kidneys and sex glands used in accordance with §381.174, not in excess of 15 percent of the total ingredients, excluding water, in the sausage, and Mechanically Separated (Species) used in accordance with §319.6. Such poultry meat ingredients shall be designated in the ingredient statement on the label of such sausage in accordance with the provisions of §381.118 of this chapter.

(b) Frankfurter, frank, furter, hotdog, wiener, vienna, bologna, garlic bologna, knockwurst and similar cooked sausages that are labeled with the phrase ''with byproducts'' or ''with variety meats'' in the product name are comminuted, semisolid sausages consisting of not less than 15 percent of one or more kinds of raw skeletal muscle meat with raw meat byproducts, or not less than 15 percent of one or more kinds of raw skeletal muscle meat with raw meat byproducts and raw or cooked poultry products; and seasoned and cured, using one or more of the curing ingredients in accordance with a regulation permitting that use in this subchapter or in 9 CFR Chapter III, Subchapter E, or in 21 CFR Chapter I, Subchapter A or Subchapter B. They may or may not be smoked. Partially defatted pork fatty tissue or partially defatted beef fatty tissue, or a combination of both, may be used in an amount not exceeding 15 percent of the meat and meat byproducts or meat, meat byproducts, and poultry products ingredients. The finished products shall not contain more than 30 percent fat. Water or ice, or both, may be used to facilitate chopping or mixing to dissolve the curing and seasoning ingredients, the sausage shall contain no more than 40 percent of a combination of fat and added water. These sausage products may contain only phosphates approved under part 318 of this chapter. These sausage products may contain poultry products and/or Mechanically Separated (Kind of Poultry) used in accordance with §381.174, individually or in combination, not in excess of 15 percent of the total ingredients, excluding water, in the sausage, and may contain Mechanically Separated (Species) used in accordance with §319.6. Such poultry products shall not contain kidneys or sex glands. The amount of poultry skin

present in the sausage must not exceed the natural proportion of skin present on the whole carcass of the kind of poultry used in the sausage, as specified in § 381.117(d) of this chapter. The poultry products used in the sausage shall be designated in the ingredient statement on the label of such sausage in accordance with the provisions of § 381.118 of this chapter. Meat byproducts used in the sausage shall be designated individually in the ingredient statement on the label for such sausage in accordance with § 317.2 of this chapter.

(c) A cooked sausage as defined in paragraph (a) of this section shall be labeled by its generic name, e.g., frankfurter, frank, furter, hotdog, wiener, vienna, bologna, garlic bologna, or knockwurst. When such sausage products are prepared with meat from a single species of cattle, sheep, swine, or goats they shall be labeled with the term designating the particular species in conjunction with the generic name, e.g., ''Beef Frankfurter,'' and when such sausage products are prepared in part with Mechanically Separated (Species) in accordance with § 319.6, they shall be labeled in accordance with § 317.2(j)(13) of this subchapter.

(d) A cooked sausage as defined in paragraph (b) of this section shall be labeled by its generic name, e.g., frankfurter, frank, furter, hotdog, wiener, vienna, bologna, garlic bologna, or knockwurst, in conjunction with the phrase ''with byproducts'' or ''with variety meats'' with such supplemental phrase shown in a prominent manner directly contiguous to the generic name and in the same color on an identical background.

(e) Binders and extenders as provided in § 319.140 of this part may be used in cooked sausage that otherwise comply with paragraph (a) or (b) of this section. When any such substance is added to these products, the substance shall be declared in the ingredients statement by its common or usual name in order of predominance.

(f) Cooked sausages shall not be labeled with terms such as ''All Meat'' or ''All (Species),'' or otherwise to indicate they do not contain nonmeat ingredients or are prepared only from meat.

(g) For the purposes of this section: Poultry meat means deboned chicken meat or turkey meat, or both, without skin or added fat; poultry products mean chicken or turkey, or chicken meat or turkey meat as defined in § 381.118 of this chapter, or poultry byproducts as defined in § 381.1 of this chapter; and meat byproducts (or variety meats), mean pork stomachs or snouts; beef, veal, lamb, or goat tripe; beef, veal, lamb, goat, or pork hearts, tongues, fat, lips, weasands, and spleens; and partially defatted pork fatty tissue, or partially defatted beef fatty tissue.

[38 FR 14742, June 5, 1973; 38 FR 22621, Aug. 23, 1973; 38 FR 24640, Sept. 10, 1973, as amended at 43 FR 26424, June 20, 1978; 45 FR 10318, Feb. 15, 1980; 47 FR 10784, Mar. 12, 1982; 47 FR 26374, June 18, 1982; 47 FR 28257, June 29, 1982; 53 FR 8428, Mar. 15, 1988; 55 FR 34683, Aug. 24, 1990; 56 FR 41448, Aug. 21, 1991; 60 FR 55982, Nov. 3, 1995; 64 FR 72175, Dec. 23, 1999; 66 FR 54916, Oct. 31, 2001]

§ 319.181 Cheesefurters and similar products.

''Cheesefurters'' and similar products are products in casings which resemble frankfurters except that they contain sufficient cheese to give definite characteristics to the finished article. They may contain binders and extenders as provided in § 318.7(c)(4) of this subchapter. Limits on use as provided in § 318.7 are intended to be exclusive of the cheese constituent. When any such substance is added to these products, the substance shall be designated in the ingredients statement by its common or usual name in order of predominance. These products shall contain no more than 40 percent of a combination of fat and added water, and no more than 30 percent fat and shall comply with the other provisions for cooked sausages that are in this subchapter.

[55 FR 34683, Aug. 24, 1990, as amended at 56 FR 41448, Aug. 21, 1991]

§ 319.182 Braunschweiger and liver sausage or liverwurst.

(a) ''Braunschweiger'' is a cooked sausage made from fresh, cured, and/or frozen pork, beef, and/or veal and at least 30 percent pork, beef, and/or veal livers computed on the weight of the fresh livers. It may also contain pork

and/or beef fat. Mechanically Separated (Species) may be used in accordance with §319.6. Binders and extenders may be used as permitted in §319.140. The product may have a smoked taste characteristic, which may be imparted by use of smoked meats, smoke flavoring or smoking. If prepared from components of a single species, the product name may reflect the species, e.g., ''Beef Braunschweiger.'' Braunschweiger may also be labeled as any of the following: ''Braunschweiger—A Liver Sausage,'' ''Braunschweiger—A Liverwurst,'' or ''Braunschweiger (Liver Sausage)'' or ''Braunschweiger (Liverwurst).''

(b) ''Liver Sausage'' or ''Liverwurst'' is a cooked sausage made from fresh, cured, and/or frozen pork, beef, and/or veal and at least 30 percent pork, beef, veal, sheep, and/or goat livers computed on the weight of the fresh livers. It may also contain pork and/or beef byproducts. Mechanically Separated (Species) may be used in accordance with §319.6. Binders and extenders maybe used as permitted in §319.140. If prepared from components of a single species, the product name may reflect that species, e.g., ''Pork Liver Sausage.''

[47 FR 36108, Aug. 19, 1982]

Subpart H [Reserved]

Subpart I—Semi-Dry Fermented Sausage [Reserved]

Subpart J—Dry Fermented Sausage [Reserved]

Subpart K—Luncheon Meat, Loaves and Jellied Products

§319.260 Luncheon meat.

''Luncheon Meat'' is a cured, cooked meat food product made from comminuted meat. Mechanically Separated (Species) may be used in accordance with §319.6. To facilitate chopping or mixing or to dissolve the usual curing ingredients, water or ice may be used in the preparation of luncheon meat in an amount not to exceed 3 percent of the total ingredients.

[35 FR 15597, Oct. 3, 1970, as amended at 43 FR 26425, June 20, 1978; 47 FR 28257, June 29, 1982]

§319.261 Meat loaf.

''Meat Loaf'' is a cooked meat food product in loaf form made from comminuted meat. Mechanically Separated (Species) may be used in accordance with §319.6. To facilitate chopping or mixing, water or ice may be used in an amount not to exceed 3 percent of the total ingredients used.

[35 FR 15597, Oct. 3, 1970, as amended at 43 FR 26425, June 20, 1978; 47 FR 28257, June 29, 1982]

Subpart L—Meat Specialties, Puddings and Nonspecific Loaves

§319.280 Scrapple.

''Scrapple'' shall contain not less than 40 percent meat and/or meat byproducts computed on the basis of the fresh weight, exclusive of bone. Mechanically Separated (Species) may be used in accordance with §319.6. The meal or flour used may be derived from grain and/or soybeans.

[35 FR 15597, Oct. 3, 1970, as amended at 43 FR 26425, June 20, 1978; 47 FR 28257, June 29, 1982]

§319.281 Bockwurst.

(a) Bockwurst is an uncured, comminuted meat food product which may or may not be cooked. It contains meat, milk or water or a combination thereof, eggs, vegetables, and any of the optional ingredients listed in paragraph (b) of this section; and is prepared in accordance with the provisions of paragraphs (a)(1), (2), (3), and (4) of this section.

(1) Meat shall constitute not less than 70 percent of the total weight of the product and shall consist of pork or a mixture of pork and veal, pork and beef, or pork, veal, and beef. Such meat shall be fresh or fresh frozen meat. Pork may be omitted when the specie or species of meat used in the product is identified in the product name (e.g., Veal Bockwurst, Beef Bockwurst, or Beef and Veal Bockwurst). Mechanically Separated (Species) may be used in accordance with §319.6.

(2) The ''milk'' may be fresh whole milk, dried milk, nonfat dry milk, calcium reduced dried skim milk, enzyme (rennet) treated calcium reduced dried skim milk and calcium lactate, or any combination thereof.

(3) ''Eggs'' refer to whole eggs that are fresh, frozen, or dried.

(4) ''Vegetables'' refer to onions, chives, parsley, and leeks, alone or in any combination.

(b) Bockwurst may contain one or more of the following optional ingredients:

(1) Pork fat.

(2) Celery, fresh or dehydrated.

(3) Spices, flavorings.

(4) Salt.

(5) Egg whites, fresh, frozen, or dried.

(6) Corn syrup solids, corn syrup, or glucose syrup with a maximum limit of 2 percent individually or collectively, calculated on a dry basis. The maximum quantities of such ingredients shall be computed on the basis of the total weight of the ingredients.

(7) Autolyzed yeast extract, hydrolyzed plant protein, milk protein hydrolysate, and monosodium glutamate.

(8) Sugars (sucrose and dextrose).

(9) Binders and extenders may be added as provided in § 318.7(c)(4) of this subchapter. When any such substance is added to bockwurst, the substance shall be designated in the ingredients statement by its common or usual name in order of predominance.

(c) If bockwurst is cooked or partially cooked, the composition of the raw mix from which it is prepared shall be used in determining whether it meets the requirements of this section.

[40 FR 18542, Apr. 29, 1975, as amended at 41 FR 18089, Apr. 30, 1976; 43 FR 26425, June 20, 1978; 45 FR 10318, Feb. 15, 1980; 47 FR 26374, June 18, 1982; 47 FR 28257, 28258, June 29, 1982; 55 FR 34683, Aug. 24, 1990; 56 FR 41448, Aug. 21, 1991]

Subpart M—Canned, Frozen, or Dehydrated Meat Food Products

§ 319.300 Chili con carne.

''Chili con carne'' shall contain not less than 40 percent of meat computed on the weight of the fresh meat. Mechanically Separated (Species) may be used in accordance with § 319.6. Head meat, cheek meat, and heart meat exclusive of the heart cap may be used to the extent of 25 percent of the meat ingredients under specific declaration on the label. The mixture may contain binders and extenders as provided in § 318.7(c)(4) of this subchapter.

[55 FR 34684, Aug. 24, 1990]

§ 319.301 Chili con carne with beans.

Chili con carne with beans shall contain not less than 25 percent of meat computed on the weight of the fresh meat. Mechanically Separated (Species) may be used in accordance with § 319.6. Head meat, cheek meat, or heart meat exclusive of the heart cap may be used to the extent of 25 percent of the meat ingredients, and its presence shall be reflected in the statement of ingredients required by part 317 of this subchapter. The mixture may contain binders and extenders as provided in § 318.7(c)(4) of this subchapter.

[55 FR 34684, Aug. 24, 1990]

§ 319.302 Hash.

''Hash'' shall contain not less than 35 percent of meat computed on the weight of the cooked and trimmed meat. The weight of the cooked meat used in this calculation shall not exceed 70 percent of the weight of the uncooked fresh meat. Mechanically Separated (Species) may be used in accordance with § 319.6.

[35 FR 15597, Oct. 3, 1970, as amended at 43 FR 26425, June 20, 1978; 47 FR 28257, June 29, 1982]

§ 319.303 Corned beef hash.

(a) ''Corned Beef Hash'' is the semi-solid food product in the form of a compact mass which is prepared with beef, potatoes, curing agents, seasonings, and any of the optional ingredients listed in paragraph (b) of this section, in accordance with the provisions of paragraphs (a) (1), (2), (3) and (4) of this section and the provisions of paragraph (c) of this section.

(1) Either fresh beef, cured beef, or canned corned beef or a mixture of two or more of these ingredients, may be used, and the finished product shall contain not less than 35 percent of beef computed on the weight of the cooked and trimmed beef. The weight of the cooked meat used in this calculation

shall not exceed 70 percent of the weight of the uncooked fresh meat.

(2) ''Potatoes'' refers to fresh potatoes, dehydrated potatoes, cooked dehydrated potatoes, or a mixture of two or more of these ingredients.

(3) The curing agents that may be used are salt, sodium nitrate, sodium nitrite, potassium nitrate, or potassium nitrite, or a combination of two or more of these ingredients. When sodium nitrate, or sodium nitrite, potassium nitrate, or potassium nitrite is used it shall be used in amounts not exceeding those specified in a regulation permitting that use in this subchapter or in 9 CFR Chapter III, Subchapter E, or in 21 CFR Chapter I, Subchapter A or Subchapter B.

(4) The seasonings that may be used, singly or in combination, are salt, sugar (sucrose or dextrose), spice, and flavoring, including essential oils, oleoresins, and other spice extractives.

(b) Corned beef hash may contain one or more of the following optional ingredients:

(1) Beef cheek meat and beef head meat from which the overlying glandular and connective tissues have been removed, and beef heart meat, exclusive of the heart cap, may be used individually or collectively to the extent of 5 percent of the meat ingredients;

(2) Onions, including fresh onions, dehydrated onions, or onion powder;

(3) Garlic, including fresh garlic, dehydrated garlic, or garlic powder;

(4) Water;

(5) Beef broth or beef stock;

(6) Monosodium glutamate;

(7) Hydrolyzed plant protein;

(8) Beef fat;

(9) Mechanically Separated (Species) when derived from carcasses of cattle may be used in accordance with §319.6.

(c) The finished product shall not contain more than 15 percent fat nor more than 72 percent moisture.

(d)(1) When any ingredient specified in paragraph (b)(1) of this section is used, the label shall bear the following applicable statement: ''Beef cheek meat constitutes 5 percent of the meat ingredient,'' or ''Beef head meat constitutes 5 percent of the meat ingredient,'' or ''Beef heart meat constitutes 5 percent of the meat ingredient.'' When two or more of the ingredients are used, the words ''Constitutes 5 percent of meat ingredient'' need only appear once.

(2) Whenever the words ''corned beef hash'' are featured on the label so conspicuously as to identify the contents, the statements prescribed in paragraph (d)(1) of this section shall immediately and conspicuously precede or follow such name without intervening written, printed, or other graphic matter.

[35 FR 15597, Oct. 3, 1970, as amended at 43 FR 26425, June 20, 1978; 47 FR 28257, June 29, 1982; 64 FR 72175, Dec. 23, 1999]

§319.304 Meat stews.

Meat stews such as ''Beef Stew'' or ''Lamb Stew'' shall contain not less than 25 percent of meat of the species named on the label, computed on the weight of the fresh meat. Mechanically Separated (Species) may be used in accordance with §319.6.

[35 FR 15597, Oct. 3, 1970, as amended at 43 FR 26425, June 20, 1978; 47 FR 28257, June 29, 1982]

§319.305 Tamales.

''Tamales'' shall be prepared with at least 25 percent meat computed on the weight of the uncooked fresh meat in relation to all ingredients of the tamales. When tamales are packed in sauce or gravy, the name of the product shall include a prominent reference to the sauce or gravy; for example, ''Tamales With Sauce'' or ''Tamales With Gravy.'' Product labeled ''Tamales With Sauce'' or ''Tamales With Gravy'' shall contain not less than 20 percent meat, computed on the weight of the uncooked fresh meat in relation to the total ingredients making up the tamales and sauce or the tamales and gravy. Mechanically Separated (Species) may be used in accordance with §319.6.

[35 FR 15597, Oct. 3, 1970, as amended at 43 FR 26425, June 20, 1978; 47 FR 28257, 28258, June 29, 1982]

§319.306 Spaghetti with meatballs and sauce, spaghetti with meat and sauce, and similar products.

''Spaghetti with Meatballs and Sauce'' and ''Spaghetti with Meat and Sauce,'' and similar products shall contain not less than 12 percent of meat computed on the weight of the fresh

meat. Mechanically Separated (Species) may be used in accordance with § 319.6. The presence of the sauce or gravy constituent shall be declared prominently on the label as part of the name of the product. Meatballs may be prepared with farinaceous material and with other binders and extenders as provided in § 318.7(c)(4) of this subchapter.

[55 FR 34684, Aug. 24, 1990]

§ 319.307 Spaghetti sauce with meat.

''Spaghetti Sauce with Meat'' shall contain not less than 6 percent of meat computed on the weight of the fresh meat. Mechanically Separated (Species) may be used in accordance with § 319.6.

[35 FR 15597, Oct. 3, 1970, as amended at 43 FR 26425, June 20, 1978; 47 FR 28257, June 29, 1982]

§ 319.308 Tripe with milk.

''Tripe with Milk'' shall be prepared so that the finished canned article, exclusive of the cooked-out juices and milk, will contain at least 65 percent tripe. The product shall be prepared with not less than 10 percent milk.

§ 319.309 Beans with frankfurters in sauce, sauerkraut with wieners and juice, and similar products.

''Beans with Frankfurters in Sauce,'' ''Sauerkraut with Wieners and Juice,'' and similar products shall contain not less than 20 percent frankfurters or wieners computed on the weight of the smoked and cooked sausage prior to its inclusion with the beans or sauerkraut.

§ 319.310 Lima beans with ham in sauce, beans with ham in sauce, beans with bacon in sauce, and similar products.

''Lima Beans with Ham in Sauce,'' ''Beans with Ham in Sauce,'' ''Beans with Bacon in Sauce,'' and similar products shall contain not less than 12 percent ham or bacon computed on the weight of the smoked ham or bacon prior to its inclusion with the beans and sauce.

§ 319.311 Chow mein vegetables with meat, and chop suey vegetables with meat.

''Chow Mein Vegetables with Meat'' and ''Chop Suey Vegetables with Meat'' shall contain not less than 12 percent meat computed on the weight of the uncooked fresh meat prior to its inclusion with the other ingredients. Mechanically Separated (Species) may be used in accordance with § 319.6.

[35 FR 15597, Oct. 3, 1970; 36 FR 11903, June 23, 1971, as amended at 43 FR 26425, June 20, 1978; 47 FR 28257, June 29, 1982]

§ 319.312 Pork with barbecue sauce and beef with barbecue sauce.

''Pork with Barbecue Sauce'' and ''Beef with Barbecue Sauce'' shall contain not less than 50 percent meat of the species specified on the label, computed on the weight of the cooked and trimmed meat. Mechanically Separated (Species) may be used in accordance with § 319.6. The weight of the cooked meat used in this calculation shall not exceed 70 percent of the uncooked weight of the meat. If uncooked meat is used in formulating the products, they shall contain at least 72 percent meat computed on the weight of the fresh uncooked meat.

[51 FR 32059, Sept. 9, 1986]

§ 319.313 Beef with gravy and gravy with beef.

''Beef with Gravy'' and ''Gravy with Beef'' shall not be made with beef which, in the aggregate for each lot contains more than 30 percent trimmable fat, that is, fat which can be removed by thorough, practicable trimming and sorting.

Subpart N—Meat Food Entree Products, Pies, and Turnovers

§ 319.500 Meat pies.

Meat pies such as ''Beef Pie,'' ''Veal Pie,'' and ''Pork Pie'' shall contain meat of the species specified on the label, in an amount not less than 25 percent of all ingredients including crust and shall be computed on the basis of the fresh uncooked meat.

Subpart O—Meat Snacks, Hors d'Oeuvres, Pizza, and Specialty Items

§ 319.600 [Reserved]

Subpart P—Fats, Oils, Shortenings

§ 319.700 Margarine or oleomargarine.[1]

(a) Margarine or oleomargarine is the food in plastic form or liquid emulsion, containing not less than 80 percent fat determined by the method prescribed under § 938.06 (Chapter 33) of the ''Indirect Methods'' in ''Official Methods of Analysis of the Association of Official Analytical Chemists'', 15th edition, 1990.[2] The ''Official Methods of Analysis of the Association of Official Analytical Chemists,'' 15th edition, 1990, is incorporated by reference with the approval of the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. It is produced from one or more of the ingredients designated in paragraph (a)(1) of this section, and one or more of the ingredients designated in paragraph (a)(2) of this section, to which may be added one or more of the optional ingredients designated in paragraph (b) of this section. Margarine or oleomargarine contains Vitamin A as provided for in paragraph (a)(3) of this section.

(1) Edible fats and oils or mixtures of these, whose origin is vegetable or rendered animal fats from cattle, sheep, swine or goats.

(2)(i) Water; milk; milk products including, but not limited to, the liquid, condensed, or dry form of whey, reduced lactose whey, reduced minerals whey, or whey protein concentrate, non-lactose-containing whey components, casein, or caseinate; or other suitable edible protein, including albumin, vegetable proteins, or soy protein isolate; or any mixture of two or more of the articles designated in this subparagraph, in amounts not greater than reasonably required to accomplish the desired effect.

(ii) The articles designated in this subparagraph shall be pasteurized and then may be subjected to the action of harmless bacterial starters. One or more of the articles designated in this subparagraph is intimately mixed with the edible fat or oil ingredients, or both, to form a solidified or liquid emulsion.

(3) Vitamin A in such quantity that the finished margarine or oleomargarine contains not less than 15,000 International Units (IU) of ViTamin A per pound or 33,000 IU per kilogram.

(b)(1) Vitamin D in such quantity that the finished margarine or oleomargarine contains not less than 1,500 IU of Vitamin D per pound or 3,300 IU per kilogram.

(2) Salt (sodium chloride); or potassium chloride for dietary margarine or oleomargarine.

(3) Nutritive carbohydrate sweeteners.

(4) Emulsifiers identified in a regulation permitting that use in this subchapter or a regulation permitting that use in this subchapter or in 9 CFR Chapter III, Subchapter E, or in 21 CFR Chapter I, Subchapter A or Subchapter B, within these maximum amounts in percent by weight of the finished food: Mono- and diglycerides of fatty acids esterified with any or all of the following acids: acetic, acetyltartaric, citric, lactic, tartaric, and their sodium and calcium salts, 0.5 percent; such mono- and diglycerides in combination with the sodium sulfoacetate derivatives thereof, 0.5 percent; polyglycerol esters of fatty acids, 0.5 percent; 1,2-propylene glycol esters of fatty acids, 2 percent; lecithin, 0.5 percent.

(5) Preservatives identified in a regulation permitting that use in this subchapter or in 9 CFR Chapter III, Subchapter E, or in 21 CFR Chapter I, Subchapter A or Subchapter B, within these maximum amounts in percent by weight of the finished food: Sorbic

[1] Insofar as the standard contains provisions relating to margarine or oleomargarine which does not contain any meat food products, such provisions merely reflect the applicable standard under the Federal Food, Drug, and Cosmetic Act.

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

acid, benzoic acid and their sodium, potassium, and calcium salts, individually, 0.1 percent, or in combination, 0.2 percent, expressed as the acids; calcium disodium EDTA, 0.0075 percent; stearyl citrate, 0.15 percent; isopropyl citrate mixture, 0.02 percent.

(6) Antioxidants identified in a regulation permitting that use in this subchapter or in 9 CFR Chapter III, Subchapter E, or in 21 CFR Chapter I, Subchapter A or Subchapter B, within these maximum amounts in percent by weight of the finished food: propyl, octyl and dodecyl gallates, BHT (butylated hydroxytoluene), BHA (butylated hydroxyanisole), ascorbyl palmitate, ascorbyl stearate, all individually or in combination, 0.02 percent. Instead of these antioxidants, TBHQ (tertiary butylhydroquinone), alone or in combination only with BHT and/or BHA, with a maximum 0.02 percent by weight of the fat and oil content.

(7) Coloring agents identified in a regulation permitting that use in this subchapter or in 9 CFR Chapter III, Subchapter E, or in 21 CFR Parts 73, 74, 81, or 82, in amounts sufficient for purpose.[3] For the purpose of this subparagraph, provitamine A (beta-carotene) shall also be deemed to be a coloring agent.

(8) Flavoring substances in amounts sufficient for purpose.

(9) Acidulants identified in a regulation permitting that use in this subchapter or in 9 CFR Chapter III, Subchapter E, or in 21 CFR Chapter I, Subchapter A or Subchapter B, in amounts sufficient for purpose: adipic acid; citric and lactic acids and their potassium and sodium salts; phosphoric acid; L-tartaric acid and its sodium and sodium-potassium salts; and hydrochloric acid.

(10) Alkalizers identified in a regulation permitting that use in this subchapter or in 9 CFR Chapter III, Subchapter E, or in 21 CFR Chapter I, Subchapter A or Subchapter B, in amounts sufficient for purpose: potassium bicarbonate, potassium carbonate, sodium bicarbonate, sodium carbonate, and sodium hydroxide.

(11) For the purposes of this section, the term ''milk'' unqualified means milk from cows. If any milk other than cow's milk is used in whole or in part, the animal source shall be identified in conjunction with the word ''milk'' in the ingredient statement.

[48 FR 52697, Nov. 22, 1983, as amended at 50 FR 3739, Jan. 28, 1985; 54 FR 40632, Oct. 3, 1989; 59 FR 33642, June 30, 1994; 64 FR 72175, Dec. 23, 1999]

§ 319.701 Mixed fat shortening.

Shortening prepared with a mixture of meat fats and vegetable oils may be identified either as ''Shortening Prepared with Meat Fats and Vegetable Oils'' or ''Shortening Prepared with Vegetable Oils and Meat Fats'' depending on the predominance of the fat and oils used, or the product may be labeled ''Shortening'' when accompanied by an ingredient statement with ingredients listed in descending order of predominance.

§ 319.702 Lard, leaf lard.

(a) Lard is the fat rendered from clean and sound edible tissues from swine. The tissues may be fresh, frozen, cooked, or prepared by other processes approved by the Administrator in specific cases, upon his determination that the use of such processes will not result in the adulteration or misbranding of the lard. The tissues shall be reasonably free from blood, and shall not include stomachs, livers, spleens, kidneys, and brains, or settlings and skimmings. ''Leaf Lard'' is lard prepared from fresh leaf (abdominal) fat.

(b) Lard (when properly labeled) may be hardened by the use of lard stearin or hydrogenated lard or both and may contain refined lard and deodorized lard, but the labels of such lard shall state such facts, as applicable.

(c) Products labeled ''Lard'' or ''Leaf Lard'' must have the following identity and quality characteristics to insure good color, odor, and taste of finished product:

(1) Color	White when solid, Maximum 3.0 red units in a 5¼ inch cell on the Lovibond scale.
(2) Odor and taste	Characteristic and free from foreign odors and flavors.

[3] Colored margarine or oleomargarine is also subject to the provisions of section 407 of the Federal Food, Drug, and Cosmetic Act, as amended (21 U.S.C. 347), as reflected in § 317.8(h)(24) of this subchapter.

(3) Free fatty acid	Maximum 0.5 percent (as oleic) or 1.0 acid value, as milligrams KOH per gram of sample.
(4) Peroxide value	Maximum 5.0 (as milliequivalents of peroxide per kilogram fat).
(5) Moisture and volatile matter.	Maximum 0.2 percent.
(6) Insoluble impurities	By appearance of liquid, fat or maximum 0.05 percent.

(d) Product found upon inspection not to have the characteristics specified in paragraph (c) of this section but found to be otherwise sound and in compliance with paragraph (a) of this section may be further processed for the purpose of achieving such characteristics.

[43 FR 25420, June 13, 1978]

§ 319.703 Rendered animal fat or mixture thereof.

''Rendered Animal Fat,'' or any mixture of fats containing edible rendered animal fat, shall contain no added water, except that ''Puff Pastry Shortening'' may contain not more than 10 percent of water.

[35 FR 15597, Oct. 3, 1970, as amended at 43 FR 25420, June 13, 1978]

Subpart Q—Meat Soups, Soup Mixes, Broths, Stocks, Extracts

§ 319.720 Meat extract.

Meat extract (e.g., ''Beef Extract'') shall contain not more than 25 percent of moisture.

§ 319.721 Fluid extract of meat.

Fluid extract of meat (e.g., ''Fluid Extract of Beef'') shall contain not more than 50 percent of moisture.

Subpart R—Meat Salads and Meat Spreads

§ 319.760 Deviled ham, deviled tongue, and similar products.

(a) ''Deviled Ham'' is a semiplastic cured meat food product made from finely comminuted ham and containing condiments. Mechanically Separated (Species) may be used in accordance with § 319.6. Deviled ham may contain added ham fat: *Provided,* That the total fat content shall not exceed 35 percent of the finished product. The moisture content of deviled ham shall not exceed that of the fresh unprocessed meat.

(b) The moisture content of ''Deviled Tongue'' and similar products shall not exceed that of the fresh, unprocessed meat.

[35 FR 15597, Oct. 3, 1970, as amended at 43 FR 26425, June 20, 1978; 47 FR 28257, June 29, 1982]

§ 319.761 Potted meat food product and deviled meat food product.

''Potted Meat Food Product'' and ''Deviled Meat Food Product'' shall not contain cereal, vegetable flour, nonfat dry milk, or similar substances. The amount of water added to potted meat food product and deviled meat food product shall be limited to that necessary to replace moisture lost during processing.

§ 319.762 Ham spread, tongue spread, and similar products.

''Ham Spread,'' ''Tongue Spread,'' and similar products shall contain not less than 50 percent of the meat ingredient named, computed on the weight of the fresh meat. Other meat and fat may be used to give the desired spreading consistency provided it does not detract from the character of the spreads named. Mechanically Separated (Species) may be used in accordance with § 319.6.

[35 FR 15597, Oct. 3, 1970, as amended at 43 FR 26425, June 20, 1978; 47 FR 28257, June 29, 1982]

Subpart S—Meat Baby Foods [Reserved]

Subpart T—Dietetic Meat Foods [Reserved]

Subpart U—Miscellaneous

§ 319.880 Breaded products.

The amount of batter and breading used as a coating for breaded product shall not exceed 30 percent of the weight of the finished breaded product.

§ 319.881 Liver meat food products.

Meat food products characterized and labeled as liver products such as liver loaf, liver cheese, liver spread, liver mush, liver paste, and liver pudding shall contain not less than 30 percent

of pork, beef, sheep, or goat livers computed on the fresh weight of the livers.

[36 FR 12004, June 24, 1971]

PART 320—RECORDS, REGISTRATION, AND REPORTS

Sec.
320.1 Records required to be kept.
320.2 Place of maintenance of records.
320.3 Record retention period.
320.4 Access to and inspection of records, facilities and inventory; copying and sampling.
320.5 Registration.
320.6 Information and reports required from official establishment operators.
320.7 Reports by consignees of allegedly adulterated or misbranded products; sale or transportation as violations.

AUTHORITY: 21 U.S.C. 601–695; 7 CFR 2.18, 2.53.

SOURCE: 35 FR 15603, Oct. 3, 1970, unless otherwise noted.

§ 320.1 Records required to be kept.

(a) Every person (including every firm or corporation) within any of the classes specified in paragraph (a) (1), (2), or (3) of this section is required by the Act to keep records which will fully and correctly disclose all transactions involved in his or its business subject to the Act:

(1) Any person that engages, for commerce, in the business of slaughtering any cattle, sheep, swine, goats, horses, mules, or other equines, or preparing, freezing, packaging, or labeling any carcasses, or parts or products of carcasses, of any such animals, for use as human food or animal food;

(2) Any person that engages in the business of buying or selling (as a meat broker, wholesaler, or otherwise), or transporting in commerce, or storing in or for commerce, or importing, any carcasses, or parts or products of carcasses, of any such animals;

(3) Any person that engages in business, in or for commerce, as a renderer, or engages in the business of buying, selling, or transporting in commerce, or importing, any dead, dying, disabled, or diseased cattle, sheep, swine, goats, horses, mules, or other equines, or parts of the carcasses of any such animals that died otherwise than by slaughter.

(b) The required records are:

(1) Records, such as bills of sale, invoices, bills of lading, and receiving and shipping papers, giving the following information with respect to each transaction in which any livestock or carcass, part thereof, meat or meat food product is purchased, sold, shipped, received, transported, or otherwise handled by said person in connection with any business subject to the Act:

(i) The name or description of the livestock or article;

(ii) The net weight of the livestock or article;

(iii) The number of outside containers (if any);

(iv) The name and address of the buyer of livestock or article sold by such person, and the name and address of the seller of livestock or articles purchased by such person;

(v) The name and address of the consignee or receiver (if other than the buyer);

(vi) The method of shipment;

(vii) The date of shipment; and

(viii) The name and address of the carrier.

(ix) In the case of a person belonging to the class specified in paragraph (a)(1), and engaged, for commerce, in the business of slaughtering any swine for use as human or animal food, the name and address (including the city and state, or the township, county, and state) of each person from whom the person belonging to the class so specified purchased or otherwise obtained each swine, and the telephone number, if available, of the person from whom the swine were purchased or otherwise obtained, and all serial numbers and other approved means of identification appearing on all test swine selected at antemortem inspection by FSIS representatives for residue testing.

(2) Shipper's certificates and permits required to be kept by shippers and carriers of articles under part 325 of this subchapter.

(3) A record of seal numbers required to be kept by consignees of inedible products shipped under unofficial seals under § 325.11(b) or (e) of this subchapter, and a record of new consignees of inedible products diverted under § 325.11(e) of this subchapter.

(4) [Reserved]

(5) Guaranties provided by suppliers of packaging materials under §317.20.

(6) Records of canning as required by subpart G of this subchapter A, 9 CFR chapter III.

(7) Sample results and calculation results as required by processing procedures to destroy trichinae in §318.10(c)(3)(iv) (Methods 5 and 6).

(8) Records of nutrition labeling as required by subpart B, part 317, of this subchapter.

(9) Records as required in §318.23(b) and (c).

(10) Records of calcium content in meat derived from advanced meat/bone separation machinery and meat recovery systems as required by §318.24 of this subchapter.

(11) Records of all labeling, along with the product formulation and processing procedures, as prescribed in §317.4 and §317.5.

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

[35 FR 15603, Oct. 3, 1970, as amended at 36 FR 12004, June 24, 1971; 37 FR 1229, Jan. 27, 1972; 43 FR 30793, July 18, 1978; 47 FR 746, Jan. 7, 1982; 47 FR 17274, Apr. 22, 1982; 49 FR 2235, Jan. 19, 1984; 51 FR 45633, Dec. 19, 1986; 53 FR 40387, Oct. 14, 1988; 57 FR 27877, June 22, 1992; 58 FR 675, Jan. 6, 1993; 58 FR 41152, Aug. 2, 1993; 59 FR 6897, Feb. 14, 1994; 59 FR 62562, Dec. 6, 1994; 60 FR 67456, Dec. 29, 1995; 64 FR 745, Jan. 6, 1999]

§320.2 Place of maintenance of records.

Every person engaged in any business described in §320.1 and required by this part to keep records shall maintain such records at the place where such business is conducted except that if such person conducts such business at multiple locations, he may maintain such records at his headquarters' office. When not in actual use, all such records shall be kept in a safe place at the prescribed location in accordance with good commercial practices.

§320.3 Record retention period.

(a) Every record required to be maintained under this part shall be retained for a period of 2 years after December 31 of the year in which the transaction to which the record relates has occurred and for such further period as the Administrator may require for purposes of any investigation or litigation under the Act, by written notice to the person required to keep such records under this part.

(b) Records of canning as required in subpart G of this subchapter A, 9 CFR chapter III, shall be retained as required in §318.307(e); except that records required by §318.302 (b) and (c) shall be retained as required by those sections.

[35 FR 15603, Oct. 3, 1970, as amended at 51 FR 45633, Dec. 19, 1986]

§320.4 Access to and inspection of records, facilities and inventory; copying and sampling.

Every person (including every firm or corporation) within any of the classes specified in §320.1 shall upon the presentation of official credentials by any duly authorized representative of the Secretary, during ordinary business hours, permit such representative to enter his or its place of business and examine the records required to be kept by §320.1 and the process schedules, facilities and inventory pertaining to the business of such person subject to the Act, and to copy all such records and to take reasonable samples of the inventory upon payment of the fair market value therefor. Any necessary facilities (other than reproduction equipment) for such examination and copying of records and for such examination and sampling of inventory shall be afforded to such authorized representative of the Secretary.

[35 FR 15603, Oct. 3, 1970, as amended at 64 FR 745, Jan. 6, 1999]

§320.5 Registration.

(a) Except as provided in paragraph (c) of this section, every person that engages in business in or for commerce, as a meat broker, renderer, or animal food manufacturer, or engages in business in commerce as a wholesaler of any carcasses, or parts or products of the carcasses, or any livestock, whether intended for human food or other purposes, or engages in business as a public warehouseman storing any such articles in or for commerce, or engages in the business of buying, selling, or

transporting in commerce, or importing, any dead, dying, disabled, or diseased livestock, or parts of the carcasses of any such livestock that died otherwise than by slaughter, shall register with the Administrator, giving such information as is required, including his name, and the address of each place of business at which, and all trade names under which he conducts such business, by filing with the Administrator, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250, a form containing such information within 90 days after the effective date hereof or after such later date as he begins to engage in such business if not engaged therein upon said effective date. All information submitted shall be current and correct. The registration form shall be obtained from the Compliance Programs, Regulatory Programs, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250.

(b) Whenever any change is made in the name of, or address of any place of business at which, or any trade name under which a registrant conducts his business, he shall report such change in writing to the Administrator within 15 days after making the change.

(c) The registration requirements prescribed in this section shall not apply to persons conducting any of the businesses specified in this section only at an official establishment.

[35 FR 15603, Oct. 3, 1970, as amended at 57 FR 53982, Nov. 16, 1992]

§ 320.6 Information and reports required from official establishment operators.

(a) The operator of each official establishment shall furnish to Program employees accurate information as to all matters needed by them for making their daily reports of the amount of products prepared or handled in the departments of the establishment to which they are assigned and such reports concerning sanitation, mandatory microbiological testing, and other aspects of the operations of the establishment and the conduct of inspection, as may be required by the Administrator in special cases.

(b) The operator of each official establishment shall report quarterly the number of pounds of meat and meat food product produced at that establishment. The report shall be made on a form furnished by the Administrator and shall be submitted to an inspector at the establishment. Each report shall cover a calendar quarter and shall be filed within 15 days after the end of each quarter.

(c) The operator of each official establishment shall also make such other reports as the Administrator may from time to time require under the Act.

[35 FR 15603, Oct. 3, 1970, as amended at 45 FR 76968, Nov. 21, 1980; 61 FR 38866, July 25, 1996]

§ 320.7 Reports by consignees of allegedly adulterated or misbranded products; sale or transportation as violations.

Whenever the consignee of any product which bears an official inspection legend refuses to accept delivery of such product on the grounds that it is adulterated or misbranded, the consignee shall notify the Inspector in Charge, Meat and Poultry Inspection Program, Food Safety and Inspection Service, U.S. Department of Agriculture, of the kind, quantity, source, and present location of the product and the respects in which it is alleged to be adulterated or misbranded, and it will be a violation of the Act for any person to sell or transport, or offer for sale or transportation, or receive for transportation, in commerce, any such product which is capable of use as human food and is adulterated or misbranded at the time of such sale, transportation, offer, or receipt: *Provided, however,* That any such allegedly adulterated or misbranded product may be transported to the official establishment from which it had been transported, in accordance with § 325.10 of this subchapter.

PART 321—COOPERATION WITH STATES AND TERRITORIES

Sec.

321.1 Assistance to State and Territorial programs.
321.2 Cooperation of States in Federal programs.

AUTHORITY: 21 U.S.C. 601–695; 7 CFR 2.17, 2.55.

§321.1 Assistance to State and Territorial programs.

(a) The Administrator is authorized under paragraph (a) of section 301 of the Act, when he determines it would effectuate the purposes of the Act, to cooperate with any State (including Puerto Rico) or any organized Territory in developing and administering the meat inspection program of such jurisdiction with a view to assuring that it imposes and enforces requirements at least equal to those under Titles I and IV of the Act, with respect to establishments at which products are prepared for use as human food solely for distribution within such jurisdiction, and with respect to the products of such establishments. Such cooperation is authorized if the jurisdiction has enacted a law imposing mandatory ante-mortem and post-mortem inspection, reinspection, and sanitation requirements at least equal to the Federal requirements with respect to all or certain classes of persons engaged in slaughtering livestock or otherwise preparing products solely for distribution within such jurisdiction.

(b) The Administrator is also authorized under paragraph (a) of section 301 of the Act to cooperate with any State (including Puerto Rico) or any organized Territory in developing and administering programs under the laws of such jurisdiction containing authorities at least equal to those in Title II of the Act (relating to records; registration of specified classes of operators; dead, dying, disabled, or diseased livestock; and products not intended for human food), when he determines that such cooperation would effectuate the purposes of the Act.

(c) Such cooperation may include advisory assistance, technical and laboratory assistance and training, and financial aid. The Federal contribution to any State (or Territory) may not exceed 50 percent of the estimated total cost of the cooperative State (or Territorial) program. A cooperative program under this section is called a State-Federal program.

[35 FR 15604, Oct. 3, 1970]

§321.2 Cooperation of States in Federal programs.

Under the ''Talmadge-Aiken Act'' of September 28, 1962 (7 U.S.C. 450), the Administrator is authorized to utilize employees and facilities of any State in carrying out Federal functions under the Federal Meat Inspection Act. A cooperative program for this purpose is called a Federal-State program.

[35 FR 15604, Oct. 3, 1970]

PART 322—EXPORTS[1]

Sec.
322.1 Manner of affixing stamps and marking products for export.
322.2 Export certificates; instructions concerning issuance.
322.3 Transferring products for export.
322.4 Clearance of vessels and transportation without certificate prohibited; exceptions.
322.5 Uninspected tallow, stearin, oleo oil, etc., not to be exported unless certified as prescribed.

AUTHORITY: 21 U.S.C. 601–695; 7 CFR 2.17, 2.55.

SOURCE: 35 FR 15604, Oct. 3, 1970, unless otherwise noted.

§322.1 Manner of affixing stamps and marking products for export.

(a) The outside container (including cloth wrappings) of any inspected and passed product for export, except ship stores, small quantities exclusively for the personal use of the consignee and not for sale or distribution, and shipments by and for the U.S. Armed Forces, shall be marked with an official export stamp, as shown in §312.8 of this subchapter, bearing the number of the export certificate.

(b) Each tank car of inspected and passed lard or similar edible product, and each door of each railroad car or other closed means of conveyance, containing inspected and passed loose product shipped directly to a foreign country, shall be marked with an official export stamp, as shown in §312.8 of

[1] Attention is directed to the requirements of part 325 of this subchapter, governing transportation, and to the requirements of §318.8 of this subchapter that products prepared under that section for export be destroyed for food purposes before being sold or offered for sale for domestic use.

this subchapter, bearing the number of the export certificate.

[42 FR 11825, Mar. 1, 1977, as amended at 50 FR 25204, June 18, 1985]

§ 322.2 Export certificates; instructions concerning issuance.

(a) Upon application of the exporter, the inspector in charge is authorized to issue official export certificates for shipments of inspected and passed product to any foreign country. Certificates should be issued at the time the products leave the official establishment; if not issued at that time they may be issued later only after identification and reinspection of the products.

(b) Official export certificates shall be issued with serial numbers and in triplicate form. Quadruplicate certificates may be issued for any exportation on request of the exporter. Each certificate shall show the names of the exporter and the consignee, the destination, the number and types of packages, the shipping marks, the kinds of products, and the weight of the products in accordance with § 317.2 of this subchapter.

(c) Only one certificate shall be issued for each consignment, except that for sufficient reasons new certificates in lieu of the original certificates may be issued. A certificate issued in lieu of another shall show in the left hand margin the notation ''Issued in lieu of * * *'', and the number of the certificate which is superseded. The certificate that is superseded when another is issued in lieu thereof, shall if available, be surrendered to the inspector in charge and marked by him to show in the left hand margin the number of the certificate which supersedes it, as follows: ''Superseded by No. ____''.

(d) The original of the certificate shall be delivered to the shipper and may be furnished by him to the consignee for purposes of effecting the entry of product into the foreign country of destination.

(e) The duplicate of the certificate shall be delivered to the shipper and shall be delivered by the shipper to the agent of the railroad or other carrier which transports the consignment from the United States otherwise than by water, or to the chief officer of the vessel on which the export shipment is made, or to the vessel's agent and shall be used only by such carrier and only for the purpose of effecting the transportation of the consignment certified. The chief officer of the vessel or the vessel's agent, shipper or shipper's agent shall file such duplicate with the Customs officer within four (4) business days of the clearance of the vessel at the time of filing the complete manifest. In the interim period, the vessel will be cleared by Customs on the basis of a statement, under the shipper's or agent's letterhead, containing the number of boxes, the number of pounds, the product name and the USDA export certificate number that covers the shipment of the product. No clearance shall be given to a vessel carrying meat products unless either the duplicate of the certificate or the prescribed statement referencing the certificate has been presented to Customs.

(f) The triplicate of the certificate shall be retained in the circuit file.

(g) Under no circumstances shall the original or the triplicate of such certificate be used for the purpose prescribed by paragraph (e) of this section for the duplicate.

(h) Upon request, official export certificates may be issued by inspectors for export consignments of product of official establishments not under their supervision, provided the consignments are first identified as having been ''U.S. inspected and passed'' and are found to be neither adulterated nor misbranded, and marked as required by § 322.1.

[35 FR 15604, Oct. 3, 1970, as amended at 42 FR 11826, Mar. 1, 1977; 51 FR 31938, Sept. 8, 1986]

§ 322.3 Transferring products for export.

When inspected and passed products for export are transferred from tank cars to other containers on vessels, such transfer shall be done in accordance with the provisions of part 350 of subchapter B of this chapter.

§ 322.4 Clearance of vessels and transportation without certificate prohibited; exceptions.

No clearance shall be given to any vessel having on board any product

destined to any foreign country, and no person operating any vessel, and no railroad or other carrier, shall receive for transportation or transport from the United States to any foreign country, any products, unless and until an official export certificate covering the same has been issued and delivered as provided in this part; except in the case of inspected and passed ship stores and not more than 50 pounds of inspected and passed product for the exclusive personal use of the consignee and not for sale or distribution, and except for exempted product eligible for exportation under the provisions of the Act and the regulations in this subchapter and inedible product that is not capable of use as human food and is eligible for exportation under other provisions of said regulations.

[38 FR 18868, July 16, 1973]

§322.5 Uninspected tallow, stearin, oleo oil, etc., not to be exported unless certified as prescribed.

No tallow, stearin, oleo oil, or the rendered fat derived from the carcasses of livestock, that has not been inspected and passed, and so marked in compliance with the regulations in this subchapter shall be exported, unless the product has been denatured as required by §314.5 or §325.13 of this subchapter or identified and marked as prescribed by §325.11 of this subchapter.

[35 FR 15604, Oct. 3, 1970, as amended at 47 FR 17274, Apr. 22, 1982]

PART 325—TRANSPORTATION

Sec.

325.1 Transactions in commerce prohibited without official inspection legend or certificate when required; exceptions; and vehicle sanitation requirements.
325.2 Parcel post and ferries deemed carriers.
325.3 Product transported within the United States as part of export movement.
325.4 [Reserved]
325.5 Unmarked inspected product transported under official seal between official establishments for further processing; certificate.
325.6 Shipment of paunches between official establishments under official seal; certificate.
325.7 Shipment of products requiring special supervision between official establishments under official seal; certificate.
325.8 Transportation and other transactions concerning certain undenatured lungs or lung lobes from official establishments or in commerce; provisions and restrictions.
325.9 [Reserved]
325.10 Handling of products which may have become adulterated or misbranded; authorization and other requirements.
325.11 Inedible articles: denaturing and other means of identification; exceptions.
325.12 [Reserved]
325.13 Denaturing procedures.
325.14 Certificates, retention by carrier.
325.15 Evidence of proper certification required on waybills; transfer bills, etc., for shipment by connecting carrier; forms of statement.
325.16 Official seals; forms, use, and breaking.
325.17 Loading or unloading products in sealed railroad cars, trucks, etc., en route prohibited; exception.
325.18 Diverting of shipments, breaking of seals, and reloading by carrier in emergency; reporting to Regional Director.
325.19 Provisions inapplicable to specimens for laboratory examination, etc., or to naturally inedible articles.
325.20 Transportation and other transactions concerning dead, dying, disabled, or diseased livestock, and parts of carcasses of livestock that died otherwise than by slaughter.
325.21 Means of conveyance in which dead, dying, disabled, or diseased livestock and parts of carcasses thereof shall be transported.

AUTHORITY: 7 U.S.C. 450, 1901–1906; 21 U.S.C. 601–695; 7 CFR 2.17, 2.55.

SOURCE: 35 FR 15605, Oct. 3, 1970, unless otherwise noted.

§325.1 Transactions in commerce prohibited without official inspection legend or certificate when required; exceptions; and vehicle sanitation requirements.

(a) No person shall sell, transport, offer for sale or transportation, or receive for transportation, in commerce, any product which is capable of use as human food unless the product and its container, if any, bear the official inspection legend as required under parts 316 and 317 of this subchapter or such product is exempted from the requirement of inspection under part 303 of this subchapter.

(b)(1) No carrier shall transport or receive for transportation in commerce (including transportation in the course of importation) and no person shall offer for transportation any carcass, part thereof, meat or meat food product until a certificate, if required for such transportation by this part, is made and furnished to the carrier in one of the forms prescribed in this part.

(2) Product imported into the United States may be transported and offerred or received for transportation if such product is conveyed in railroad cars, trucks or other means of conveyance, prior to inspection, to an authorized place of inspection, as provided in § 327.6 of this part.

(c) No person, engaged in the business of buying, selling, freezing, storing, or transporting, in or for commerce, meat or meat food products capable of use as human food, or importing such articles, shall transport, offer for transportation, or receive for transportation in commerce or in any State designated under § 331.2 of this subchapter, any such meat or meat food product which is capable of use as human food and is not wrapped, packaged, or otherwise enclosed to prevent adulteration by airborne contaminants, unless the railroad car, truck, or other means of conveyance in which the product is contained or transported is completely enclosed with tight fitting doors or other covers for all openings. In all cases, the means of conveyance shall be reasonably free of foreign matter (such as dust, dirt, rust, or other articles or residues), and free of chemical residues, so that product placed therein will not become adulterated. Any cleaning compound, lye, soda solution, or other chemical used in cleaning the means of conveyance must be thoroughly removed from the means of conveyance prior to its use. Such means of conveyance onto which product is loaded, being loaded, or intended to be loaded, shall be subject to inspection by an inspector at any official establishment. The decision whether or not to inspect a means of conveyance in a specific case, and the type and extent of such inspection shall be at the Program's discretion and shall be adequate to determine if product in such conveyance is, or when moved could become, adulterated. Circumstances of transport that can be reasonably anticipated shall be considered in making said determination. These include, but are not limited to, weather conditions, duration and distance of trip, nature of product covering, and effect of restowage at stops en route. Any means of conveyance found upon such inspection to be in such condition that product placed therein could become adulterated shall not be used until such condition which could cause adulteration is corrected. Product placed in any means of conveyance that is found by the inspector to be in such condition that the product may have become adulterated shall be removed from the means of conveyance and handled in accordance with § 318.2(d) of this subchapter.

[35 FR 15605, Oct. 3, 1970, as amended at 41 FR 23700, June 11, 1976; 47 FR 17274, Apr. 22, 1982; 56 FR 65180, Dec. 16, 1991]

§ 325.2 Parcel post and ferries deemed carriers.

(a) For the purposes of this subchapter, the United States parcel post shall be deemed a carrier, and the provisions of this subchapter relating to transportation by carrier shall apply, so far as they may be applicable, to transportation by parcel post.

(b) For the purposes of this subchapter, the operator of every ferry shall be deemed a carrier, and the provisions of this subchapter relating to transportation by carrier shall apply to transportation by ferry of any products loaded on a truck or other vehicle, or otherwise moved by such ferry.

§ 325.3 Product transported within the United States as part of export movement.

When any shipment of any product is offered to any carrier for transportation within the United States as a part of an export movement, the same certificate shall be required as if the shipment were destined to a point within the United States.

§325.4 [Reserved]

§325.5 Unmarked inspected product transported under official seal between official establishments for further processing; certificate.

(a) Any product which has been inspected and passed may be transported from one official establishment to another for further processing without each article being marked with the official inspection legend, if it is so transported in a railroad car, motortruck, or other means of conveyance which is sealed by a Program employee with an official seal of the Department prescribed in §312.5(a) of this subchapter. Unless 25 percent or more of the contents of each car or other means of conveyance consists of product not marked with the inspection legend, transportation will not be permitted under this paragraph.

(b) When articles are offered for transportation under paragraph (a) of this section, the initial carrier shall require, and the shipper shall make in duplicate and deliver to the carrier, one copy of a certificate in the following form:[1]

Date _____, 19__

Name of carrier _____

Establishment number of consignor _____

Point of shipment _____

Establishment number of consignee _____

Destination _____

Car number and initials _____

License number of other means of conveyance _____

I hereby certify that the following described product has been U.S. inspected and passed by the U.S. Department of Agriculture; and that it is not marked ''U.S. inspected and passed,'' but has been placed in the means of conveyance specified above under the supervision of an employee of the Meat and Poultry Inspection Programs of said Department, and the means of conveyance has been sealed by him with official U.S. Government seals Nos. —— and ——.

Kind of product	Amount and weight

_____

(Signature of shipper)

(Address of shipper)

When paunches are offered for transportation under this paragraph, the initial carrier shall require, and the shipper shall make in duplicate and deliver to the carrier, one copy of a certificate in duplicate in the form set out in §325.5(b), appropriately modified. Certificates in this form or copies thereof need not be forwarded to any official or office of the Department, but the original of the certificate shall be retained by the carrier and a copy shall be retained by the shipper in accordance with part 320 of this subchapter. If the shipper is also the carrier, he shall nevertheless execute and retain the certificate in accordance with part 320 of this subchapter.

(c) The signature of the shipper or his agent shall be written in full. This certificate may be stamped upon or incorporated in any form ordinarily used in the transportation of product. Certificates in this form or copies thereof need not be forwarded to any official or office of the Department. The original of the certificate required by this section shall be retained by the carrier and a copy shall be retained by the shipper in accordance with part 320 of this subchapter. If the shipper is also the carrier, he shall nevertheless execute and retain the certificate in accordance with part 320 of this subchapter.

§325.6 Shipment of paunches between official establishments under official seal; certificate.

Cattle and sheep paunches which have been made clean and from which the mucous membrane has not been removed may be transported from one official establishment to another official establishment for further processing, only under an official seal of the Department as prescribed in §312.5(a) of this subchapter.

§325.7 Shipment of products requiring special supervision between official establishments under official seal; certificate.

(a) Products passed for cooking, pork that has been refrigerated to destroy

[1] For convenience in filing, it is requested that these certificates be made on paper 5½×8 inches in size.

trichinae, and beef that is to be refrigerated to destroy cysticerci, may be shipped loose from one official establishment to any other official establishment, for further handling in accordance with part 318 of this subchapter, in railroad cars, trucks, or other means of conveyance sealed with the official seal of the Department as prescribed in § 325.16: *Provided*, That in the case of railroad cars, the receiving establishment has railroad facilities for unloading the products directly into the establishment.

(b) When such restricted product is shipped from one official establishment to another official establishment in the same railroad car or other means of conveyance with other product, such restricted product shall be packed in individual closed containers as hereinafter provided. Containers shall be sealed by firmly applying a pressure sensitive tape around each container in two directions and stamping the intersection of the tape with the marking device described in § 312.2(a) of this subchapter for use on burlap, muslin, etc. (2½-inch rubber brand). Such tape must possess the adhesive property to actually remove a portion of the container surface when the tape is removed. Alternatively, an inelastic, nonmetallic strap which will retain a legible imprint of the marking device (2½-inch rubber brand) may be used. The imprint of the marking device shall be placed partially on the strap and partially on the container. Such restricted product shall be marked ''U.S. passed for cooking'' or ''pork product —— °F. ——days refrigeration'' or ''beef passed for refrigeration,'' as the case may be. In addition, a ''U.S. retained'' tag shall be securely affixed to each container of product passed for cooking and of beef passed for refrigeration. The means of conveyance shall not be sealed unless at least 25 percent of the other product in the vehicle is unmarked. For each consignment there shall be promptly issued and forwarded by the inspector to the inspector in charge at destination, a report on the form entitled ''Notice of Unmarked Meats Shipped in Sealed Cars,'' appropriately modified to show the character of the containers, and that the contents are restricted. A duplicate copy shall be retained in the program files.

(c) When products are offered for transportation under this section, the initial carrier shall require and the shipper shall make in duplicate and deliver to the carrier one copy of a certificate in the form set out in § 325.5(b). Certificates in this form or copies thereof need not be forwarded to any official or office of the Department, but the original of the certificate shall be retained by the carrier and a copy shall be retained by the shipper in accordance with part 320 of this subchapter. If the shipper is also the carrier, he shall nevertheless execute and retain the certificate in accordance with part 320 of this subchapter.

[35 FR 15605, Oct. 3, 1970, as amended at 39 FR 20187, June 7, 1974]

§ 325.8 Transportation and other transactions concerning certain undenatured lungs or lung lobes from official establishments or in commerce; provisions and restrictions.

(a) Lungs or lung lobes, other than those condemned under § 310.16(b) of this subchapter, that are prepared at any official establishment, may be sold, transported, offered for sale or transportation, or received for transportation from the establishment, in commerce or otherwise, without denaturing as prescribed in § 314.1 or § 314.3 of this subchapter: *Provided:*

(1) The lungs or lung lobes are sold, transported, or offered for sale or transportation to, or received for transportation by: An animal food manufacturer for use in manufacturing animal food; a zoo, mink farm, or other establishment for use as animal food without further processing; a warehouse in the United States for storage and subsequent movement to such a manufacturer or establishment in the United States, or from one warehouse to another for the account of and subsequent movement to such a manufacturer or establishment, or for export, for nonhuman food purposes.

(2) The boxes or other containers used for shipping the undenatured lungs or lung lobes are closed with nylon filament tape, metallic on nonmetallic straps, round wire, or other

similar materials that securely effect closure of such containers, and the containers are permanently identified in at least 2-inch (5 cm) high lettering with the statement ''(Species) Lungs—Not Intended for Human Food.'' In lieu of securely closing the immediate container with any of the above materials, a 1-inch (2.5 cm) wide bright orange band, imprinted around the length and width of the container may be used.

(3) The name and place of business of the packer or distributor shall be shown on the immediate container of the product. In addition, the country of origin shall be shown on the immediate container of imported lungs or lung lobes.

(b) Lungs or lung lobes, other than those condemned under a State law or regulation at least equal to §310.16(b) of this subchapter, that are prepared at any State inspected establishment may be sold, transported, offered for sale, or transportation or received for transportation from that establishment, in commerce, without denaturing as prescribed under section 201 of the Act, provided the State law or regulations permit such disposition and provided there is compliance with the provisions of paragraph (a) of this section.

(c) Foreign establishments shall be eligible to export lungs or lung lobes, other than those condemned for reasons set forth in §310.16(b) of this subchapter, to the United States from such foreign country under this section, only if such establishments are certified and approved for export of products to the United States under part 327 of this subchapter, and such product complies with the applicable regulations for preventing the introduction into the United States of diseases (9 CFR 94), in addition to the requirements of paragraph (a) of this section.

(d) All such lungs or lung lobes, if intended for animal food, are subject to the Federal Food, Drug, and Cosmetic Act.

[43 FR 43445, Sept. 26, 1978]

§325.9 [Reserved]

§325.10 Handling of products which may have become adulterated or misbranded; authorization and other requirements.

(a) When it is claimed that any inspected and passed product, marked with an inspection legend, has become adulterated or misbranded after it has been transported from an official establishment, such product may be transported in commerce to an official establishment after oral permission is obtained from the area supervisor of the area in which that offical establishment is located. The transportation of the product may be to the official establishment from which it had been transported or to another official establishment designated by the person desiring to handle the product. The transportation shall be authorized only for the purpose of officially determining if the product has become adulterated or misbranded and making the appropriate disposition. The area supervisor shall make a record of the authorization and such other information which will effectively identify the shipment and shall provide a copy of the record to the inspector at the establishment receiving the product. The shipper shall be furnished a copy of the authorization record upon request.

(b) Upon the arrival of the shipment at the official establishment, a careful inspection shall be made of the product by a Program inspector, and if it is found that the article is not adulterated, the same may be received into the establishment; but if the article is found to be adulterated, it shall at once be stamped ''U.S. inspected and condemned'' and disposed of in accordance with part 314 of this subchapter, and if it is found to be misbranded, it shall be handled in accordance with §318.2(d) of this subchapter: *Provided,* That when a product is found to be affected with one of the correctable conditions specified in §318.2(d) of this subchapter, in respect to which rehandling is permitted, it may be transported from the official establishment to another official establishment for such

rehandling as is necessary to assure that the product is not adulterated or misbranded when finally released. The transportation of such a product from an official establishment shall be done in a manner prescribed in each specific case by the Administrator.

[35 FR 15605, Oct. 3, 1970, as amended at 47 FR 17274, Apr. 22, 1982]

§ 325.11 Inedible articles: denaturing and other means of identification; exceptions.

(a) Except as provided in § 325.8 and § 325.10, no carcass, part of a carcass, rendered grease, tallow, or other fat derived from the carcasses of livestock, or other meat food product, that has not been inspected and passed at an official establishment under the provisions of this subchapter and is not exempted from such inspection, and no carcass, part of a carcass, fat or other meat food product that is adulterated or misbranded, shall be offered for transportation in commerce by any person unless it is handled in accordance with paragraph (b), (c), (d), or (e) of this section or is denatured or otherwise identified as prescribed in § 325.13, § 314.1, § 314.3, § 314.9, § 314.10, or § 314.11 of this subchapter.

(b) Inedible rendered animal fats from official or other establishments in the United States having the physical characteristics of a meat food product fit for human food may be transported in commerce without denaturing, if the following conditions are met:

(1) Such inedible rendered fat shall not be bought, sold, transported, or offered for sale or offered for transportation in commerce, or imported, except by rendering companies, dealers, brokers, or others who obtain a numbered permit for such activities from the Regional Director.

(2) Such inedible rendered animal fat may be so distributed only if consigned to a domestic manufacturer of technical articles other than for human food or to an export terminal for exportation or storage for exportation as an inedible article, and provided, in the case of such fat consigned to a domestic manufacturer, the product is for use solely by the consignee for manufacturing purposes of nonhuman food articles and may not be further sold or shipped without first receiving approval of the Regional Director: *And provided further,* That such fat intended for export and stored at a terminal point prior to export will be subject to review by Program employees to assure that it is exported as inedible.

(3) When transported in commerce, or imported, such inedible rendered fat shall be marked conspicuously with the words ''technical animal fat not intended for human food'' on the ends of the shipping containers, in letters not less than 2 inches high; in the case of shipping containers such as drums, tierces, barrels, and half barrels, and not less than 4 inches high in the case of tank cars and trucks. All shipping containers shall have both ends painted with a durable paint, if necessary, to provide a contrasting background for the required marking.

(4) Such inedible rendered fat shall be transported only in sealed shipping containers bearing unofficial seals applied by the shipper, which shall include the identification number assigned by said Director for the permit holder. The number shall appear on the bill of lading or other transportation documents for the shipment. The consignees in the United States must retain the seals in their records as prescribed in part 320 of this subchapter.

(5) Any diversion or effort to divert inedible rendered fat contrary to the provisions of this paragraph (b) or other violation of the provisions of this section may result in the revocation of the permit for shipment of technical animal fat at the discretion of the Administrator.

(c) Inedible rendered animal fat derived from condemned or other inedible materials at official or other establishments in the United States may be transported in commerce if mixed with low grade offal or other materials which render the fat readily distinguishable from an article of human food, and if the outside container bears the word ''inedible.''

(d)(1) Except as provided in paragraphs (d)(2), (3), and (4) of this section, or in §§ 314.10 and 314.11 of this subchapter, no animal food prepared, in whole or in part, from materials derived from the carcasses of livestock in an official establishment or elsewhere,

shall be bought, sold, transported, offered for sale or transportation, or received for transportation, in commerce, or imported, unless:

(i) It is properly identified as animal food;

(ii) It is not represented as being a human food; and

(iii) It has been denatured as prescribed in § 325.13(a)(2) so as to be readily distinguishable from an article of human food.

(2) Notwithstanding the provisions of paragraph (d)(1) of this section, an animal food that consists of less than 5 percent of parts or products of the carcasses of livestock and that is not represented by labeling or appearance or otherwise as being a human food or as a product of the meat food industry need not be denatured in accordance with § 325.13(a)(2).

(3) Notwithstanding the provisions of paragraph (d)(1) of this section, animal food packed in hermetically sealed, retort processed, conventional retail-size containers, and retail-size packages of semi-moist animal food need not be denatured in accordance with § 325.13(a)(2) if the name of the article clearly conveys the article's intended use for animal food and appeared on the label in a conspicuous manner.

(i) Except as provided in paragraph (ii) of paragraph (d)(3), the name of the article must be stated on the label as ''Animal Food,'' ''Pet Food,'' or ''(name of species) Food'' (e.g., ''Dog Food'' or ''Cat Food''). To be considered conspicuous, the name of the article, wherever it appears on the label, must be in letters at least twice as high, wide, and thick as the letters indicating the presence in the article of any ingredients derived from the carcasses of livestock.

(ii) Notwithstanding the provisons of paragraph (i) of this paragraph (d)(3), the article's name may be stated on the label to show that it is or contains livestock-source material and that the article is for animals; e.g., ''Horsemeat for Pets'' or ''Beef Stew for Dogs'': *Provided,* That the entire name of the article is stated, wherever it appears on the label, as an individual, contiguous unit, whether stated on a single line or more than one line, and the letters denoting the article's intended use for animal food are at least as high, wide, and thick as the letters indicating the presence of material derived from any livestock carcass. However, when the label bears on its principal display panel a vignette which pictures, in clearly recognizable form and size, one or more animals of the species for which the article's name indicates the article is intended, the letters used to state the article's intended use shall be at least one-half as high, wide, and thick as the letters used in the article's name or other letters indicating the presence of material derived from any livestock carcass, but shall not be less than ⅛ inches high. The letters used to state the article's intended use may be separated from the article's name by the vignette.

(iii) Letters used to denote the intended use of the article must contrast as markedly with their background as the letters indicating the presence in the article of livestock carcass-source material contrast with their background.

(4) The requirements of this part do not apply to livestock or poultry feeds manufactured from processed livestock byproducts (such as meat meal tankage, meat and bone meal, blood meal, and feed grade animal fat), or to processed dry animal food.

(e) Except for inedible rendered animal fats and lungs or lung lobes, inedible products (including condemned products only if condemned for causes specified in § 314.11 of this subchapter) which were prepared at any official establishment, or at any State inspected establishment in any State not listed in § 331.2 of this subchapter, and which have the physical characteristics of a product fit for human food, may be transported from an official establishment or in commerce, without denaturing as required by this subchapter, if the following conditions are met:

(1) The shipper must have obtained a numbered permit for such activity from the appropriate Regional Director, as identified in § 301.2 of this subchapter. Such permit may be obtained upon written application to the appropriate Regional Director and his determination that the proposed transportation would be authorized under this paragraph (e). The application shall

state the name and address of the applicant, a description of the type of his business operations, and the purpose of making such application.

(2) Such inedible products may be transported under this paragraph (e) only if consigned to a manufacturer in the United States of articles other than for human food and if the product is for use solely by the consignee for manufacturing articles not for human food. Such products may not be transported in commerce to any consignee other than the one to which they were originally shipped unless prior notice of the diversion is given to the appropriate Regional Director and a record identifying the new consignee is maintained by the shipper as required by § 320.1 of this subchapter.

(3) When transported from an official establishment or in commerce under this paragraph (e), the outside container of such inedible products shall be marked conspicuously with the words ''Inedible—Not Intended for Human Food'' in letters not less than 2 inches high, in the case of containers, such as cartons, drums, tierces, barrels, and half barrels, and not less than 4 inches high in the case of tank cars and trucks used to transport such products not in other containers.

(4) Such inedible products shall be transported from an official establishment or in commerce under this paragraph (e) only in railroad cars, trucks, or containers which bear unofficial seals applied by the shipper, which shall include the identification number assigned to the permit holder and an individual seal serial number assigned by the shipper; and the product so transported shall be accompanied by an invoice or bill of lading specifying the permit holder's identification number. The consignee in the United States must retain a record of the identification and serial numbers shown on the seals in his records as prescribed in part 320 of this subchapter.

(5) Any diversion, or effort to divert, undenatured, inedible product contrary to the provisions of this paragraph (e) or other violation of the provisions of this section may result in the revocation of the permit for shipment of inedible products under this paragraph (e), at the discretion of the Administrator.

[47 FR 17274, Apr. 22, 1982, as amended at 49 FR 47478, Dec. 5, 1984]

§ 325.12 [Reserved]

§ 325.13 Denaturing procedures.

(a) Carcasses, parts thereof, meat and meat food products (other than rendered animal fats) that have been treated in accordance with the provisions of this paragraph shall be considered denatured for the purposes of the regulations in this part, except as otherwise provided in part 314 of this subchapter for articles condemned at official establishments.

(1) The following agents are prescribed for denaturing carcasses, parts thereof, meat or meat food products which are affected with any condition that would result in their condemnation and disposal under part 314 of this subchapter if they were at an official establishment: Crude carbolic acid; cresylic disinfectant; a formula consisting of 1 part FD&C green No. 3 coloring, 40 parts water, 40 parts liquid detergent, and 40 parts oil of citronella, or other proprietary substance approved by the Administrator in specific cases.[3]

(2) Except as provided in paragraphs (a)(3), (4), and (5) of this section, the following agents are prescribed for denaturing other carcasses, parts thereof, meat and meat food products, for which denaturing is required by this part: FD&C green No. 3 coloring; FD&C blue No. 1 coloring; FD&C blue No. 2 coloring; finely powdered charcoal; or other proprietary substance approved by the Administrator in specific cases.[3]

(3) Tripe may be denatured by dipping it in a 6 percent solution of tannic acid for 1 minute followed by immersion in a water bath, then immersing it for 1 minute in a solution of 0.022 percent FD&C yellow No. 5 coloring;

(4) Meat may be denatured by dipping it in a solution of 0.0625 percent tannic

[3] Information as to approval of any proprietary denaturing substance may be obtained from the Technical Services, Meat and Poultry Inspection, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250.

acid, followed by immersion in a water bath, then dipping it in a solution of 0.0625 percent ferric acid; and

(5) When meat, meat byproducts, or meat food products are in ground form, 4 percent by weight of coarsely ground hard bone, which shall be in pieces no smaller than the opening size specified for No. 5 mesh in the standards issued by the U.S. Bureau of Standards or 6 percent by weight of coarsely ground hard bone, which shall be in pieces no smaller than the opening size specified for No. 8 mesh in said Standards, uniformly incorporated with the product may be used in lieu of the agents prescribed in paragraph (a)(2) of this section.

(6) Before the denaturing agents are applied to articles in pieces more than 4 inches in diameter, the pieces shall be freely slashed or sectioned. (If the articles are in pieces not more than 4 inches in diameter, slashing or sectioning will not be necessary.) The application of any of the denaturing agents listed in paragraph (a)(1) or (2) of this section to the outer surface of molds or blocks of boneless meat, meat byproducts, or meat food products shall not be adequate. The denaturing agent must be mixed intimately with all of the material to be denatured, and must be applied in such quantity and manner that it cannot easily and readily be removed by washing or soaking. A sufficient amount of the appropriate agent shall be used to give the material a distinctive color, odor, or taste so that such material cannot be confused with an article of human food.

(7) Carcasses (other than viscera), parts thereof, cuts of meat, and unground pieces of meat darkened by charcoal or other black dyes shall be deemed to be denatured pursuant to this section only if they contain at least that degree of darkness depicted by diagram 1 of the Meat Denaturing Guide (MP Form 91).[1]

(b) Inedible rendered animal fats shall be denatured by thoroughly mixing therein denaturing oil, No. 2 fuel oil, brucine dissolved in a mixture of alcohol and pine oil or oil of rosemary, finely powdered charcoal, or any proprietary denaturing agent approved for the purpose by the Administrator in specific cases. The charcoal shall be used in no less quantity than 100 parts per million and shall be of such character that it will remain suspended indefinitely in the liquid fat. Sufficient of the chosen identifying agents shall be used to give the rendered fat so distinctive a color, odor, or taste that it cannot be confused with an article of human food.

[35 FR 15605, Oct. 3, 1970, as amended at 41 FR 22930, June 8, 1976; 44 FR 67626, Nov. 27, 1979]

§325.14 Certificates, retention by carrier.

All original certificates delivered to a carrier in accordance with this part shall be filed separate and apart from all its other papers and records or identified in such a manner as to be readily checked by Department employees. Every certificate required to be maintained under this part shall be retained for a period of 2 years after December 31 of the year in which the transaction has occurred.

§325.15 Evidence of proper certification required on waybills; transfer bills, etc., for shipment by connecting carrier; forms of statement.

(a) All waybills, transfer bills, running slips, conductor's cards, or other papers accompanying a shipment, in the course of importation or otherwise in commerce, of any product shall have embodied therein, stamped thereon, or attached thereto a signed statement which shall be evidence to connecting carriers that the proper shipper's certificate, as required by §325.5, §325.6, or §325.7, is on file with the initial carrier. No connecting carrier shall receive for transportation or transport in the course of importation or otherwise in

[1] Copies of MP Form 91 may be obtained, without charge, by writing to the Administrative Operations Branch, Food Safety and Inspection Service, U.S. Department of Agriculture, 123 East Grant Street, Minneapolis, Minnesota 55403. Diagrams 2 and 3 of the Meat Denaturing Guide are for comparison purposes only. The Meat Denaturing Guide has been approved for incorporation by reference by the Director, Office of the Federal Register, and is on file at the Federal Register library.

commerce any product unless the waybill, transfer bill, running slip, conductor's card, or other papers accompanying the same includes the signed statement in the following form:

(Name of transportation company)
U.S. inspected and passed, as evidenced by shipper's certificate on file with initial carrier.
(signed) _____
Agent

(b) Signatures of agents to statements required under this section shall be written in full.

[47 FR 17276, Apr. 22, 1982]

§ 325.16 Official seals; forms, use, and breaking.

(a) The official seals required by this part shall be those prescribed in § 312.5(a) of this subchapter.

(b) Except as provided in § 325.18(b), official seal affixed under this part shall be affixed or broken only by Program employees, and no person other than a Program employee shall affix, detach, break, change, or tamper with any such seal in any way whatever. Commission of any such acts contrary to this regulation is a criminal offense.

§ 325.17 Loading or unloading products in sealed railroad cars, trucks, etc., en route prohibited; exception.

Unloading any product from an officially sealed railroad car, truck, or other means of conveyance containing any unmarked product or loading any product or any other commodity in the means of conveyance while en route from one official establishment to another official establishment is not permitted, except that product transported under § 325.5 from one official establishment to another for further processing may be unloaded and stored in transit at any approved warehouse which is operated under the identification service provided under the regulations in part 350 of subchapter B of this chapter and which has railroad facilities or a receiving dock for unloading the product directly into such warehouse: *Provided,* That the product is stored in rooms which are of such size and type as will not result in adulteration or misbranding of the product: *And provided further,* That the product is transported to and from such warehouse, and under official seal as provided in § 325.5 and stored in such rooms at such warehouse.

§ 325.18 Diverting of shipments, breaking of seals, and reloading by carrier in emergency; reporting to Regional Director.

(a) Shipments of inspected and passed product that bear the inspection legend may be diverted from the original destination without a reinspection of the articles, provided the waybills, transfer bills, running slips, conductor's card, or other papers accompanying the shipments are marked, stamped, or have attached thereto signed statements in accordance with § 325.15.

(b) In case of wreck or similar extraordinary emergency, the Department seals on a railroad car or other means of conveyance containing any inspected and passed product may be broken by the carrier, and if necessary, the articles may be reloaded into another means of conveyance, or the shipment may be diverted from the original destination, without another shipper's certificate; but in all such cases the carrier shall immediately report the facts by telephone or telegraph to the Regional Director in the area in which the emergency occurs. Such report shall include the following information:

(1) Nature of the emergency.

(2) Place where seals were broken.

(3) Original points of shipment and destination.

(4) Number and initial of the original car or truck.

(5) Number and initials of the car or truck into which the articles are reloaded.

(6) New destination of the shipment.

(7) Kind and amount of articles.

[35 FR 15605, Oct. 3, 1970, as amended at 42 FR 39087, Aug. 2, 1977]

§ 325.19 Provisions inapplicable to specimens for laboratory examination, etc., or to naturally inedible articles.

The provisions of this part do not apply:

(a) To specimens of product sent to or by the Department of Agriculture or

divisions thereof in Washington, DC, or elsewhere, for laboratory examination, exhibition purposes, or other official use;

(b) To material released for educational, research and other nonfood purposes, as prescribed in §314.9 of this subchapter;

(c) To glands and organs for use in preparing pharmaceutical, organotherapeutic, or technical products and not used for human food, as described in §318.1(g) of this subchapter;

(d) To material or specimens of product for laboratory examination, research, or other nonhuman food purposes, when authorized by the Administrator, and under conditions prescribed by him in specific cases; and

(e) To articles that are naturally inedible by humans, such as hoofs, horns, and hides in their natural state.

§325.20 Transportation and other transactions concerning dead, dying, disabled, or diseased livestock, and parts of carcasses of livestock that died otherwise than by slaughter.

No person engaged in the business of buying, selling, or transporting in commerce, or importing any dead, dying, disabled or diseased animals or parts of the carcasses of any animals that died otherwise than by slaughter shall:

(a) Buy, sell, transport, or offer for sale or transportation, in commerce, or import any dead livestock if its hide or skin has been removed;

(b) Sell, transport, offer for sale or transportation, or receive for transportation, in commerce, any dead, dying, disabled, or diseased livestock, or parts of the carcasses of any livestock that died otherwise than by slaughter, unless such livestock and parts are consigned and delivered, without avoidable delay, to establishments of animal food manufacturers, renderers, or collection stations that are registered as required by part 320 of this subchapter, or to official establishments that operate under Federal inspection, or to establishments that operate under a State or Territorial inspection system approved by the Secretary as one that imposes requirements at least equal to the Federal requirements for purposes of paragraph 301(c) of the Act;[4]

(c) Buy in commerce or import any dead, dying, disabled, or diseased livestock or parts of the carcasses of any livestock that died otherwise than by slaughter, unless he is an animal food manufacturer or renderer and is registered as required by part 320 of this subchapter, or is the operator of an establishment inspected as required by paragraph (b) of this section and such livestock or parts of carcasses are to be delivered to establishments eligible to receive them under paragraph (b) of this section;

(d) Unload en route to any establishment eligible to receive them under paragraph (b) of this section, any dead, dying, disabled, or diseased livestock or parts of the carcasses of any livestock that died otherwise than by slaughter, which are transported in commerce or imported by any such person: *Provided,* That any such dead, dying, disabled, or diseased livestock, or parts of carcasses may be unloaded from a means of conveyance en route where necessary in case of a wreck or otherwise extraordinary emergency, and may be reloaded into another means of conveyance; but in all such cases, the carrier shall immediately report the facts by telegraph or telephone to the Compliance Staff, Meat and Poultry Inspection Field Operations, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250.

(e) Load into any means of conveyance containing any dead, dying, disabled, or diseased livestock, or parts of the carcasses of any livestock that died otherwise than by slaughter, while in the course of importation or other transportation in commerce any livestock or parts of carcasses not within

[4] A list of such registrants, States, and amendments thereof, will be published in the Federal Register, and information concerning the registration status of particular animal food manufacturers, renderers, or collection stations, or the status of particular States or Territories may also be obtained from the Director, Administrative Management Staff, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250.

the foregoing description or any other products or other commodities.

[35 FR 15605, Oct. 3, 1970, as amended at 42 FR 42309, Aug. 23, 1977]

§ 325.21 Means of conveyance in which dead, dying, disabled, or diseased livestock and parts of carcasses thereof shall be transported.

All vehicles and other means of conveyance used by persons subject to § 325.20 for transporting in commerce or importing, any dead, dying, disabled, and diseased livestock or parts of carcasses of livestock that died otherwise than by slaughter shall be leak-proof and so constructed and equipped as to permit thorough cleaning and sanitizing. The means of conveyance so used in conveying such livestock, or parts thereof, shall be cleaned and disinfected prior to use in the transportation of any product intended for use as human food. The cleaning procedure shall include the complete removal from the means of conveyance of any fluid, parts, or product of such dead, dying, disabled, or diseased livestock and the thorough application of a disinfectant to the interior surfaces of the cargo space. Substances permitted for such use are:

(a) ''Liquified phenol'' (U.S.P. strength 87 percent phenol) in the proportion of at least 6 fluid ounces to 1 gallon of water.

(b) ''Cresylic disinfectant'' in the proportion of not less than 4 fluid ounces to 1 gallon of water; and such other disinfectants as are approved by the Administrator in specific cases. The use of ''cresylic disinfectant'' is permitted subject to the conditions prescribed in § 71.10(b) of this title.

PART 327—IMPORTED PRODUCTS

Sec.

327.1 Definitions; application of provisions.
327.2 Eligibility of foreign countries for importation of products into the United States.
327.3 No product to be imported without compliance with applicable regulations.
327.4 Imported products; foreign certificates required.
327.5 Importer to make application for inspection of products for entry; information required; ''streamlined'' inspection procedures for Canadian product.
327.6 Products for importation; program inspection, time, and place; application for approval of facilities as official import inspection establishment; refusal or withdrawal of approval; official numbers.
327.7 Products for importation; movement prior to inspection; handling; bond; assistance.
327.8 Import products; equipment and means of conveyance used in handling to be maintained in sanitary condition.
327.9 Burlap wrapping for foreign meat.
327.10 Samples; inspection of consignments; refusal of entry; marking.
327.11 Receipts to importers for import product samples.
327.12 Foreign canned or packaged products bearing trade labels; sampling and inspection.
327.13 Foreign products offered for importation; reporting of findings to customs; handling of articles refused entry.
327.14 Marking of products and labeling of immediate containers thereof for importation.
327.15 Outside containers of foreign products; marking and labeling; application of official inspection legend.
327.16 Small importations for importer's own consumption; requirements.
327.17 Returned U.S. inspected and marked products.
327.18 Products offered for entry and entered to be handled and transported as domestic; exception.
327.19 Specimens for laboratory examination and similar purposes.
327.20 Importation of foreign inedible fats.
327.21 Inspection procedures for chilled fresh and frozen boneless manufacturing meat.
327.22 [Reserved]
327.23 Compliance procedure for cured pork products offered for entry.
327.24 Appeals; how made.
327.25 Disposition procedures for product condemned or ordered destroyed under import inspection.
327.26 Official import inspection marks and devices.

AUTHORITY: 21 U.S.C. 601–695; 7 CFR 2.18, 2.53.

SOURCE: 35 FR 15610, Oct. 3, 1970, unless otherwise noted.

§ 327.1 Definitions; application of provisions.

(a) When used in this part, the following terms shall be construed to mean:

(1) *Import (imported).* To bring within the territorial limits of the United States whether that arrival is accomplished by land, air, or water.

(2) For product from eligible countries other than Canada:

(i) *Offer(ed) for entry.* The point at which the importer presents the imported product to the Program for reinspection.

(ii) *Entry (entered).* The point at which imported product offered for entry receives reinspection and is marked with the offical mark of inspection in accordance with §327.26 of this subchapter.

(3) For product from Canada:

(i) *Offer(ed) for entry* from establishments participating in the ''streamlined'' inspection procedures. The point at which an official of the Canadian meat inspection system contacts the Import Field Office for an inspection assignment.

(ii) *Offer(ed) for entry* from nonparticipating establishments. The point at which the importer presents the imported product to the Program for reinspection.

(iii) *Entry (entered)* for product not subject to reinspection. When the containers or the products themselves if not in containers are marked with the Canadian port stamp and upon the filing of Customs Form 7533 at the port of entry or at the nearest customhouse in accordance with 19 CFR part 123.

(iv) *Entry (entered)* for product subject to reinspection. When the containers or the products themselves if not in containers are marked with the Canadian export stamp and the foreign inspection certificate accompanying the product is stamped as ''Inspected and Passed'' by the import inspector.

(b) The provisions of this part shall apply to products derived from cattle, sheep, swine, goats, horses, mules, and other equines, if capable of use as human food. Compliance with the conditions for importation of products under this part does not excuse the need for compliance with applicable requirements under other laws, including the provisions in parts 94, 95, and 96 of chapter I of this title.

[35 FR 15610, Oct. 3, 1970, as amended at 36 FR 12004, June 24, 1971; 54 FR 41048, Oct. 5, 1989]

§327.2 Eligibility of foreign countries for importation of products into the United States.

(a)(1) Whenever it shall be determined by the Administrator that the system of meat inspection maintained by any foreign country, with respect to establishments preparing products in such country for export to the United States, insures compliance of such establishments and their products with requirements equivalent to all the inspection, building construction standards, and all other provisions of the Act and the regulations in this subchapter which are applied to official establishments in the United States, and their products, and that reliance can be placed upon certificates required under this part from authorities of such foreign country, notice of that fact will be given by including the name of such foreign country in paragraph (b) of this section. Thereafter, products prepared in such establishments which are certified and approved in accordance with paragraph (a)(3) of this section, shall be eligible so far as this subchapter is concerned for importation into the United States from such foreign country after applicable requirements of this subchapter have been met.

(2) The determination of acceptability of a foreign meat inspection system for purposes of this section shall be based on an evaluation of the foreign program in accordance with the following requirements and procedures:

(i) The system shall have a program organized and administered by the national government of the foreign country. The system as implemented must provide standards equivalent to those of the Federal system of meat inspection in the United States with respect to:

(A) Organizational structure and staffing, so as to insure uniform enforcement of the requisite laws and regulations in all establishments throughout the system at which products are prepared for export to the United States;

(B) Ultimate control and supervision by the national government over the official activities of all employees or licensees of the system;

(C) The assignment of competent, qualified inspectors;

(D) Authority and responsibility of national inspection officials to enforce the requisite laws and regulations governing meat inspection and to certify or refuse to certify products intended for export;

(E) Adequate administrative and technical support;

(F) The inspection, sanitation, quality, species verification, and residue standards applied to products produced in the United States.

(G) Other requirements of adequate inspection service as required by the regulations in this subchapter.

(ii) The legal authority for the system and the regulations thereunder shall impose requirements equivalent to those governing the system of meat inspection organized and maintained in the United States with respect to:

(A) Ante-mortem inspection of animals for slaughter and inspection of methods of slaughtering and handling in connection with slaughtering which shall be performed by veterinarians or by other employees or licensees of the system under the direct supervision of the veterinarians;

(B) Post-mortem inspection of carcasses and parts thereof at time of slaughter, performed by veterinarians or other employees or licensees of the system under the direct supervision of veterinarians;

(C) Official controls by the national government over establishment construction, facilities, and equipment;

(D) Direct and continuous official supervision of slaughtering and preparation of product, by the assignment of inspectors to establishments certified under paragraph (a)(3) of this section, to assure that adulterated or misbranded product is not prepared for export to the United States;

(E) Complete separation of establishments certified under subparagraph (3) of this paragraph from establishments not certified and the maintenance of a single standard of inspection and sanitation throughout all certified establishments;

(F) Requirements for sanitation at certified establishments and for sanitary handling of product;

(G) Official controls over condemned material until destroyed or removed and thereafter excluded from the establishment;

(H) A Hazard Analysis and Critical Control Point (HACCP) system, as set forth in part 417 of this chapter.

(I) Other matters for which requirements are contained in the Act or regulations in this subchapter.

(iii) Countries desiring to establish eligibility for importation of product into the United States may request a determination of eligibility by presenting copies of the laws and regulations on which the foreign meat inspection system is based and such other information as the Administrator may require with respect to matters enumerated in paragraphs (a)(2) (i) and (ii) of this section. Determination of eligibility is based on a study of the documents and other information presented and an initial review of the system in operation by a representative of the Department using the criteria listed in paragraphs (a)(2) (i) and (ii) of this section. Maintenance of eligibility of a country for importation of products into the United States depends on the results of periodic reviews of the foreign meat inspection system in operation by a representative of the Department, and the timely submission of such documents and other information related to the conduct of the foreign inspection system, including information required by paragraph (e) of section 20 of the Act, as the Administrator may find pertinent to and necessary for the determinations required by this section of the regulations.

(iv) The foreign inspection system must maintain a program to assure that the requirements referred to in this section, equivalent to those of the Federal system of meat inspection in the United States, are being met. The program as implemented must provide for the following:

(A) Periodic supervisory visits by a representative of the foreign inspection system not less frequent than one such visit per month to each establishment certified in accordance with paragraph (a)(3) of this section to assure that requirements referred to in (A) through (H) of paragraph (a)(2)(ii) of this section are being met: *Provided,* That such

visits are not required with respect to any establishment during a period when the establishment is not operating or is not engaged in producing products for exportation to the United States;

(B) Written reports prepared by the representative of the foreign inspection system who has conducted a supervisory visit, documenting his or her findings with respect to the requirements referred to in (A) through (H) of paragraph (a)(2)(ii) of this section, copies of which shall be made available to the representative of the Department at the time of that representative's review upon request by that representative to a responsible foreign meat inspection official: *Provided,* That such reports are not required with respect to any establishment during a period when the establishment is not operating or is not engaged in producing products for exportation to the United States; and

(C) Random sampling of internal organs and fat of carcasses at the point of slaughter and the testing of such organs and fat, for such residues having been identified by the exporting country's meat inspection authorities or by this Agency as potential contaminants, in accordance with sampling and analytical techniques approved by the Administrator: *Provided,* That such testing is required only on samples taken from carcasses from which meat or meat food products intended for importation into the United States are produced.

(3) Only those establishments that are determined and certified to the Department by a responsible official of the foreign meat inspection system as fully meeting the requirements of paragraphs (a)(2) (i) and (ii) of this section are eligible to have their products imported into the United States. Eligibility of certified establishments is subject to review by the Department (including observations of the establishments by Program representatives at times prearranged with the officials of the foreign meat inspection system). Certifications of establishments must be renewed annually. Notwithstanding certification by a foreign official, the Administrator may, at his discretion, terminate the eligibility of any foreign establishment for importation of its products into the United States if he has information that such establishment does not comply with the requirements listed in paragraphs (a)(2) (i) and (ii) of this section or if he cannot obtain current information concerning such establishment. The Administrator will provide reasonable notice to the foreign government of the proposed termination of eligibility of any foreign establishment for importation of its products into the United States unless, in his judgment, delay in terminating its eligibility could result in the importation of adulterated or misbranded product. Certifications of official establishments by the responsible official of the foreign meat inspection system shall be in the following form:

FOREIGN OFFICIAL MEAT ESTABLISHMENT CERTIFICATE

I hereby certify that the establishment(s) listed below fully comply (complies) with requirements of (specify foreign country) equivalent to all the inspection, building construction standards, and other requirements for the slaughter and preparation of the carcasses, parts thereof, meat and meat food products of cattle, sheep, swine, goats, and equines applied to official establishments in the United States under the Federal Meat Inspection Act and otherwise meet (meets) the requirements of §327.2(a) of the regulations governing meat inspection of the U.S. Department of Agriculture.

Control numbers	Name	Address

Date _____

Signature _____

Official Title _____

(4) Product of cattle, sheep, swine, and goats from foreign countries not listed in paragraph (b) of this section and product of equines from countries not listed in paragraph (c) of this section is not eligible for importation into the United States, except as provided by §327.16 or §327.17. The listing of any foreign country under this section may be withdrawn whenever it shall be determined by the Administrator that the system of meat inspection maintained by such foreign country does not assure compliance with requirements equivalent to all the inspection,

building construction standards, and other requirements of the Act and the regulations in this subchapter as applied to official establishments in the United States; or that reliance cannot be placed upon certificates required under this part from authorities of such foreign country; or that, for lack of current information concerning the system of meat inspection being maintained by such foreign country, such foreign country should be required to reestablish its eligibility for listing.

(b) It has been determined that product of cattle, sheep, swine, and goats from the following countries covered by foreign meat inspection certificates of the country of origin as required by § 327.4, except fresh, chilled, or frozen or other product ineligible for importation into the United States from countries in which the contagious and communicable disease of rinderpest or of foot-and-mouth disease or of African swine fever exists as provided in part 94 of this title, is eligible under the regulations in this subchapter for entry into the United States after inspection and marking as required by the applicable provisions of this part.

Argentina, Australia, Austria, Belgium, Belize, Brazil, Canada, Costa Rica, Czech Republic, Denmark, Dominican Republic, El Salvador, England and Wales, Finland, France, Germany (Federal Republic), Guatemala, Honduras, Hungary, Iceland, Ireland (Eire), Italy, Japan, Mexico, Netherlands, New Zealand, Nicaragua, Northern Ireland, Norway, Paraguay, Poland, Republic of China, (Taiwan), Republic of Croatia, Republic of Slovenia, Romania, Scotland, Spain, Sweden, Switzerland, Uruguay, Venezuela, Yugoslavia.

(c) It has been determined that product of equines from the following countries, covered by foreign meat inspection certificates of the country of origin as required by § 327.4, is eligible under the regulations in this subchapter for importation into the United States after inspection and marking as required by the applicable provisions of this part.

Argentina, Canada, New Zealand, Paraguay.

[35 FR 15610, Oct. 3, 1970]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 327.2, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and on GPO Access.

§ 327.3 No product to be imported without compliance with applicable regulations.

(a) No product offered for importation from any foreign country shall be admitted into the United States if it is adulterated or misbranded or does not comply with all the requirements of this subchapter that would apply to it if it were a domestic product.

(b) No cooked or partially cooked meat or meat trimmings, either in separable pieces or molded into larger forms, shall be permitted entry except under the following conditions:

(1) A complete procedure for preparing and handling the product in the foreign country and en route to the United States shall be submitted by the exporter or his authorized agent to the Administrator and determined by the Administrator to be adequate to assure that the product will not be adulterated or misbranded at the time of offer for entry.

(2) A system acceptable to the Administrator (upon his determination that the system will provide a reliable indication of the kinds and numbers of microorganisms present) for the microbiological testing of the finished product shall be installed by the processor, the product is subjected to such testing, and the results thereof are furnished to the Administrator and are acceptable to him as showing that the product has been prepared and handled in a sanitary manner.

(c) [Reserved]

[35 FR 15610, Oct. 3, 1970, as amended at 38 FR 29215, Oct. 23, 1973; 54 FR 41048, Oct. 5, 1989; 56 FR 38335, Aug. 13, 1991; 57 FR 27906, June 23, 1992]

§ 327.4 Imported products; foreign certificates required.

(a) Except as provided in § 327.16, each consignment containing any fresh meat or fresh meat byproducts consigned to the United States from a foreign country shall be accompanied by a foreign-meat-inspection certificate for fresh meat and meat byproducts in the following form:

ORIGINAL

OFFICIAL MEAT-INSPECTION CERTIFICATE FOR FRESH MEAT AND MEAT BYPRODUCTS

Place _____ (City) _____ (Country) Date _____

I hereby certify that the meat and meat byproducts herein described were derived from livestock which received ante-mortem and post-mortem veterinary inspections at time of slaughter in plants certified for importation of their products into the United States and are not adulterated or misbranded as defined by the regulations governing meat inspection of the U.S. Department of Agriculture; and that said products have been handled in a sanitary manner in this country and are otherwise in compliance with requirements equivalent to those in the Federal Meat Inspection Act and said regulations.

Kind of product	Species of livestock derived from	Number of pieces or containers	Weight

Identification marks on products and containers _____

Consignor _____
Address _____
Establishment number _____
Consignee _____
Destination _____
Shipping marks _____
(Signature) _____
(Name of official authorized by the national foreign government to issue inspection certificates for meat and meat byproducts exported to the United States)
(Official title) _____

(b) Except as provided in § 327.16, each consignment containing any meat food product consigned to the United States from a foreign country shall be accompanied by a foreign-meat-inspection certificate for meat food products in the following form:

ORIGINAL

OFFICIAL MEAT-INSPECTION CERTIFICATE FOR MEAT FOOD PRODUCTS

Place _____ (City) _____ (Country) _____ Date _____

I hereby certify that the meat food products herein described were derived from livestock which received ante-mortem and post-mortem veterinary inspections at time of slaughter in plants certified for importation of their products into the United States, were handled in a sanitary manner, and were prepared under the continuous supervision of an inspector under control of the national meat inspection system and that said meat food products are not adulterated or misbranded as defined by the regulations governing meat inspection of the U.S. Department of Agriculture, and are otherwise in compliance with requirements equivalent to those in the Federal Meat Inspection Act and said regulations.

I further certify that all products herein described that are prepared customarily to be eaten without cooking and contain muscle tissue of pork were treated for destruction of trichnae as prescribed in § 318.10 of the Meat Inspection Regulations of the U.S. Department of Agriculture.

Kind of product	Species of livestock derived from	Number of pieces or containers	Weight

Identification marks on products and containers _____

Consignor _____
Address _____
Establishment number _____
Consignee _____
Destination _____
Shipping marks _____
(Signature) _____
(Name of official authorized by the national foreign government to issue inspection certificates for meat food product exported to the United States)
(Official title) _____

(c) Each foreign meat-inspection certificate shall bear the official seal of the national government agency responsible for the inspection of the product and be signed and issued by an official authorized to sign and issue such certificates by the national government of the foreign country in which the product is inspected.

(d) Each foreign meat-inspection certificate shall be in both the English language and the language of the foreign country of origin.

(e) Except for product subject to procedures in § 327.5(d)(l), the foreign meat inspection certificate required by this section to accompany each consignment containing any product shall be delivered by the consignee, or his

agent, in the United States to the Program import inspector at the place of inspection, and inspection of the product will not be commenced prior to such delivery.

[35 FR 15610, Oct. 3, 1970, as amended at 54 FR 274, Jan. 5, 1989; 60 FR 38668, July 28, 1995]

§ 327.5 Importer to make application for inspection of products for entry; information required; "streamlined" inspection procedures for Canadian product.

(a) Except for importers of Canadian products, each importer shall apply for inspection of any product offered for entry by contacting the Import Field Office covering the location where import inspection will take place. The Import Field Office will provide specific application instructions (See § 301.2 (yyy)).

(b) The application should be made as long as possible in advance of the anticipated arrival of each consignment, except in case of consignments of products expressly exempted from inspection by §§ 327.16 and 327.17, and in the case of product imported from Canada.

(c) Except in the case of product imported from Canada, each application shall state the approximate date on which the consignment is due to arrive at such port in the United States, the name of the ship or other carrier transporting it, the name of the country from which the product was, or is to be, shipped, the place where inspection is desired in accordance with § 327.6, the quantity and kind of product, and whether it is fresh, cured, canned or otherwise prepared. In case of consignments arriving in the United States by water, the application shall also state the port of first arrival in the United States.

(d) For participating Canadian establishments, an official of the Canadian meat inspection system shall contact the participating Import Field Office for an inspection assignment (See § 301.2 (yyy)).

(1) If the Automated Import Information System (AIIS) does not designate the consignment for reinspection, the consignment may be transported to its consignee for further distribution.

(2) If the AIIS designates the consignment for reinspection, the representative shall:

(i) Select samples in accordance with USDA sampling tables.[3]

(ii) Identify and place samples in the vehicle for easy removal and reinspection by an import inspector.

(3) In the event that any one of the requirements provided in (d)(2) of this section is not met, reinspection of the consignment shall be conducted by a Program import inspector in accordance with established procedures provided in the regulations for other imported products.

[54 FR 274, Jan. 5, 1989, as amended at 54 FR 41048, Oct. 5, 1989]

§ 327.6 Products for importation; program inspection, time and place; application for approval of facilities as official import inspection establishment; refusal or withdrawal of approval; official numbers.

(a)(1) Except as provided in §§ 327.5(d)(1), 327.16 and 327.17, all products offered for entry from any foreign country shall be reinspected by a Program inspector before they shall be allowed entry into the United States.

(2) Every lot of product shall routinely be given visual inspection by a Program import inspector for appearance and condition, and checked for certification and label compliance, except as provided in 327.5(d)(1).

(3) The computerized Automated Import Information System (AIIS) shall be consulted for reinspection instructions. The AIIS will assign reinspection levels and procedures based on established sampling plans or established sampling plans and established product and plant history.

(4) When the inspector deems it necessary, the inspector may sample and inspect lots not designated by AIIS.

(b) All products, required by this part to be inspected, shall be inspected only at an official establishment or at an official import inspection establishment

[3] A copy of the sampling tables is available, upon request, from the Import Inspection Division, International Programs, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250.

approved by the Administrator as provided in this section. Such approved official import inspection establishments will be listed in the Directory of Meat and Poultry Inspection Program Establishments, Circuits and Officials, published by the Food Safety and Inspection Service. The listing will categorize the kind or kinds of product[2] which may be inspected at each official import inspection establishment, based on the adequacy of the facilities for making such inspections and handling such products in a sanitary manner.

(c) Owners or operators of establishments, other than official establishments, who want to have import inspections made at their establishments, shall apply to the Administrator for approval of their establishments for such purpose. Application shall be made on a form furnished by the Program, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC, and shall include all information called for by that form.

(d) Approval for Federal import inspection shall be in accordance with part 304 of this subchapter.

(e) Owners or operators of establishments at which import inspections of product are to be made shall furnish adequate sanitary facilities and equipment for examination of such product. The requirements of §§ 304.2(e), 307.1, 307.2 (b), (d), (f), (h), (k), and (l) and 416.1 through 416.6 of this chapter shall apply as conditions for approval of establishments as official import inspection establishments to the same extent and in the same manner as they apply with respect to official establishments.

(f) The Administrator is authorized to approve any establishment as an official import inspection establishment provided that an application has been filed and drawings have been submitted in accordance with the requirements of paragraphs (c) and (d) of this section and he determines that such establishment meets the requirements under paragraph (e) of this section. Any application for inspection under this section may be denied or refused in accordance with the rules of practice in part 500 of this chapter.

(g) Approval of an official import inspection establishment may be withdrawn in accordance with applicable rules of practice if it is determined that the sanitary conditions are such that the product is rendered adulterated, that such action is authorized by section 21(b) of the Federal Water Pollution Control Act, as amended (84 Stat. 91), or that the requirements of paragraph (e) of this section were not complied with. Approval may also be withdrawn in accordance with section 401 of the Act and applicable rules of practice.

(h) A special official number shall be assigned to each official import inspection establishment. Such number shall be used to identify all products inspected and passed for entry at the establishment.

(i) A sampling inspection shall be made, as provided in paragraph (a) of this section, of foreign chilled fresh or frozen fresh meat, including defrosting if necessary to determine its condition. Inspection standards for foreign chilled fresh or frozen fresh meat shall be the same as those used for domestic chilled fresh or frozen fresh meat. (See § 327.21)

(j) Imported canned products are required to be sound, healthful, properly labeled, wholesome, and otherwise not adulterated at the time the products are offered for importation into the United States. Provided other requirements of this part are met, the determination of the acceptability of the product and the condition of the containers shall be based on the results of an examination of a statistical sample drawn from the consignment as provided in paragraph (a) of this section. If the inspector determines, on the basis of the sample examination, that the product does not meet the requirements of the Act and regulations thereunder, the consignment shall be refused entry. However, a consignment rejected for container defects but otherwise acceptable may be reoffered for inspection under the following conditions:

(1) If the defective containers are not indicative of an unsafe and unstable product as determined by the Administrator;

[1] [Reserved]

[2] For example: Canned product, boneless meat, carcasses and cuts.

(2) If the number and kinds of container defects found in the original sample do not exceed the limits specified for this purpose in FSIS guidelines; and

(3) If the defective containers in the consignment have been sorted out and exported or destroyed under the supervision of an inspector.

(k) Program inspectors or Customs officers at border or seaboard ports shall report the sealing of cars, trucks, or other means of conveyance, and the sealing or identification of containers of foreign product on Form MP–410 to Program area supervisors at points where such product is to be inspected.

(l) Representative samples of canned product designated by the Administrator in instructions to inspectors shall be incubated under supervision of such inspectors in accordance with § 318.309 (d)(1)(ii), (d)(1)(iii), (d)(1)(iv)(*c*), (d)(1)(v), (d)(1)(vii) and (d)(1)(viii) of this subchapter. The importers or his/her agent shall provide the necessary incubation facilities in accordance with § 318.309(d)(1)(i) of this subchapter.

(m) Sampling plans and acceptance levels as prescribed in paragraphs (j) and (l) of this section may be obtained, upon request, from International Programs, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250.

[35 FR 15610, Oct. 3, 1970, as amended at 37 FR 21927, Oct. 17, 1972; 38 FR 29215, Oct. 23, 1973; 49 FR 36818, Sept. 20, 1984; 51 FR 37707, Oct. 24, 1986; 51 FR 45633, Dec. 19, 1986; 54 FR 274, Jan. 5, 1989; 54 FR 41048, Oct. 5, 1989; 62 FR 45026, Aug. 25, 1997; 64 FR 56416, Oct. 20, 1999; 64 FR 66545, Nov. 29, 1999; 65 FR 2284, Jan. 14, 2000]

§ 327.7 Products for importation; movement prior to inspection; handling; bond; assistance.

(a) No product required by this part to be inspected shall be moved, prior to inspection from any port, or, if arriving by water from the wharf where first unloaded, to any place other than the place designated by, or in accordance with, this part as the place where the same shall be inspected.

(b) No product required by this part to be inspected shall be conveyed, prior to inspection, from any port, or, if arriving by water, from the wharf where first unloaded, in any manner other than in compliance with this part.

(c) No product required by this part to be inspected shall be delivered to the consignee or his agent prior to inspection, unless the consignee shall furnish a bond, in form prescribed by the Secretary of the Treasury, conditioned that the product shall be returned, if demanded, to the collector of the port where the same is offered for clearance through the customs.

(d) The consignee or his agent shall provide such assistance as Program inspectors may require for the handling and marking of product offered for entry.

[35 FR 15610, Oct. 3, 1970, as amended at 37 FR 21928, Oct. 17, 1972; 51 FR 37707, Oct. 24, 1986; 56 FR 65180, Dec. 16, 1991]

§ 327.8 Import products; equipment and means of conveyance used in handling to be maintained in sanitary condition.

Compartments of steamships, sailing vessels, railroad cars, and other means of conveyance transporting any product to the United States, and all trucks, chutes, platforms, racks, tables, tools, utensils, and all other devices used in moving and handling any product offered for importation into the United States, shall be maintained in a sanitary condition.

§ 327.9 Burlap wrapping for foreign meat.

Burlap shall not be used as a wrapping for foreign meat unless the meat is first wrapped with a good grade of paper or cloth of a kind which will prevent contamination with lint or other foreign material.

§ 327.10 Samples; inspection of consignments; refusal of entry; marking.

(a) Program inspectors may take, without cost to the United States, for laboratory examination, samples of any product which is subject to analysis, from each consignment offered for importation, except that such samples shall not be taken of any product offered for importation under § 327.16.

(b) Except for product offered for entry from Canada, the outside containers of all products offered for entry

from any foreign country and accompanied with a foreign inspection certificate as required by this part, which, upon reinspection by import inspectors are found not to be adulterated or misbranded and are otherwise eligible for entry into the United States under this part, or the products themselves if not in containers, shall be marked with the official inspection legend prescribed in §327.26 of this part. Except for Canadian product, all other products so marked, in compliance with this part, shall be entered into the United States, insofar as such entry is regulated under the Act.

(c) Product which is inspected and rejected shall be marked ''U.S. Refused Entry'' as shown in §327.26(c). Such marks shall be applied to the shipping container or the product itself if not in a container.

(d) The inspection legend may be placed on containers of product before completion of official import inspection if the containers are being inspected by an import inspector who reports directly to an Import Field Office Supervisor; the product is not required to be held at the establishment pending the receipt of laboratory test results; and a written procedure for controlled stamping, submitted by the import establishment and approved by the Director, Import Inspection Division, is on file at the import inspection facility where the inspection is to be performed.

(1) The written procedure for controlled pre-stamping should be in the form of a letter and shall include the following:

(i) That stamping under this part will be limited to those lots of product which can be inspected on the day that certificates for the product are examined;

(ii) That all product which has been pre-stamped will be stored in the facility where the import inspection will occur;

(iii) That inspection marks applied under this part will be removed from any lot of product subsequently refused entry on the day the product is rejected; and

(iv) That the establishment will maintain a daily stamping log containing the following information for each lot of product: the date of inspection, the country of origin, the foreign establishment number, the product name, the number of units, the shipping container marks, and the MP–410 number covering the product to be inspected. The daily stamping log must be retained by the establishment in accordance with the requirements of §320.3.

(2) An establishment's controlled pre-stamping privilege may be cancelled orally or in writing by the inspector who is supervising its enforcement whenever the inspector finds that the establishment has failed to comply with the provisions of this part or any conditions imposed pursuant thereto. If the cancellation is oral, the decision and the reasons therefor shall be confirmed in writing, as promptly as circumstances allow. Any person whose controlled pre-stamping privilege has been cancelled may appeal the decision to the Administrator, in writing, within ten (10) days after receiving written notification of the cancellation. The appeal shall state all of the facts and reasons upon which the person relies to show that the controlled pre-stamping privilege was wrongfully cancelled. The Administrator shall grant or deny the appeal, in writing, stating the reasons for such decision, as promptly as circumstances allow. If there is a conflict as to any material fact, a hearing shall be held to resolve such conflict. Rules of practice concerning such a hearing will be adopted by the Administrator. The cancellation of the controlled pre-stamping privilege will be in effect until there is a final determination of the proceeding.

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

[35 FR 15610, Oct. 3, 1970, as amended at 53 FR 17014, May 13, 1988; 54 FR 41048, Oct. 5, 1989]

§327.11 Receipts to importers for import product samples.

In order that importers may be assured that samples of foreign products collected for laboratory examination are to be used exclusively for that purpose, official receipts shall be issued and delivered to importers, or their agents, by inspectors for all samples of foreign products collected. The official receipt shall be prepared in duplicate,

over the signature of the inspector who collects the samples, and shall show the name of the importer, country of origin, quantity and kind of product collected, date of collection, and that the sample was collected for laboratory examination. The duplicate copy of the receipt shall be retained by the inspectors as their office record.

[35 FR 15610, Oct. 3, 1970, as amended at 51 FR 37707, Oct. 24, 1986]

§ 327.12 Foreign canned or packaged products bearing trade labels; sampling and inspection.

(a) Samples of foreign canned or packaged products bearing on their immediate containers trade labels which have not been approved under § 317.3 of this subchapter shall be collected and forwarded to the laboratory by the Program inspector for examination, and the products shall be held pending receipt of the report of the laboratory findings and the results of the examination of trade labels and the marks on shipping containers.

(b) Foreign canned or packaged products bearing trade labels and other markings which have been approved under § 317.3 of this subchapter shall be inspected for soundness and checked for net weight. Samples may be collected for laboratory examination, but the products may be released under customs' bond pending the report of laboratory findings.

(c) Samples shall be taken from foreign canned products or packaged products as required by § 327.6 (a) and (j) of this part.

[35 FR 15610, Oct. 3, 1970, as amended at 49 FR 36818, Sept. 20, 1984]

§ 327.13 Foreign products offered for importation; reporting of findings to customs; handling of articles refused entry.

(a)(1) Program inspectors shall report their findings as to any product which has been inspected in accordance with this part, to the Director of Customs at the original port of entry where the same is offered for clearance through Customs inspection.

(2) When product has been identified as ''U.S. refused entry, '' the inspector shall request the Director of Customs to refuse admission to such product and to direct that it be exported by the owner or consignee within the time specified in this section, unless the owner or consignee, within the specified time, causes it to be destroyed by disposing of it under the supervision of a Program employee so that the product can no longer be used as human food, or by converting it to animal food uses, if permitted by the Food and Drug Administration. The owner or consignee of the refused entry product shall not transfer legal title to such product, except to a foreign consignee for direct and immediate exportation, or to an end user, e.g., an animal food manufacturer or a renderer, for destruction for human food purposes. ''Refused entry'' product must be delivered to and used by the manufacturer or renderer within the 45-day time limit. Even if such title is illegally transferred, the subsequent purchaser will still be required to export the product or have it destroyed as specified in the notice under paragraph (a)(5) of this section.

(3) No lot of product which has been refused entry may be subdivided during disposition pursuant to paragraph (a)(2) of this section, except that removal and destruction of any damaged or otherwise unsound product from a lot destined for reexportation is permitted under supervision of USDA prior to exportation. Additionally, such refused entry lot may not be shipped for export from any port other than that through which the product came into the United States, without the expressed consent of the Administrator based on full information concerning the product's disposition, including the name of the vessel and the date of export. For the purposes of this paragraph, the term ''lot'' shall refer to that product indentified on MP Form 410 in the original request for inspection for importation pursuant to § 327.5.

(4) Product which has been refused entry solely because of misbranding, in lieu of exportation or destruction pursuant to paragraph (a)(2) of this section, may be brought into compliance with the requirements of this part, under supervision of an authorized representative of the Administrator.

(5) The owner or consignee shall have 45 days after notice is given by FSIS to the Director of Customs at the original port of entry to take the action required in paragraph (a)(2) of this section for ''refused entry'' product. Extension beyond the 45-day period may be granted by the Administrator when extreme circumstances warrant it; e.g., a dock workers' strike or an unforeseeable vessel delay.

(6) If the owner or consignee fails to take the required action within the time specified under paragraph (a)(5) of this section, the Department will take such action as may be necessary to effectuate its order to have the product destroyed for human food purposes. The Department shall seek court costs and fees, storage, and proper expense in the appropriate legal forum.

(7) No product which has been refused entry and exported to another country pursuant to paragraph (a)(2) of this section may be returned to the United States under any circumstance. Any such product so returned to the United States shall be subject to administrative detention in accordance with section 402 of the Act and seizure and condemnation in accordance with section 403 of the Act.

(b) Upon the request of the Director of Customs at the port where a product is offered for clearance through the customs, the consignee of the product shall, at the consignee's own expense, immediately return to the Director any product which has been delivered to consignee under §327.7 and subsequently designated ''U.S. Refused Entry'' or found in any respect not to comply with the requirements in this part.

(c) All charges for storage, cartage, and labor with respect to any product which was imported contrary to the Act shall be paid by the owner or consignee, and in default of such payment shall constitute a lien against such product and any other product thereafter imported by or for such owner or consignee.

[35 FR 15610, Oct. 3, 1970, as amended at 48 FR 15889, Apr. 13, 1983; 49 FR 29568, July 23, 1984; 50 FR 19907, May 13, 1985; 53 FR 17015, May 13, 1988; 54 FR 50735, Dec. 11, 1989]

§327.14 Marking of products and labeling of immediate containers thereof for importation.

(a) Product which is offered for importation, and which is susceptible of marking, shall, whether or not enclosed in an immediate container, bear the name of the country of origin, preceded by the words ''product of''; the establishment number assigned by the foreign meat inspection system and certified to the Program; and such other markings as are necessary for compliance with part 316 of this subchapter. When such markings are imprints of stamps or brands made with branding ink, such ink shall be harmless and shall create permanent imprints. In case the name of the country of origin appears as part of an official mark of the national foreign government and such name is prominently and legibly displayed, the words ''product of'' may be omitted.

(b) In addition to the marking of products required under paragraph (a) of this section, the immediate container of any product offered for importation:

(1) Shall bear a label showing in accordance with §317.2 of this subchapter all information required by that section (except that the establishment number assigned by the foreign meat inspection system and certified to the Program and the official inspection mark of the foreign meat inspection system shall be shown instead of the official inspection legend of the United States) and in addition the name of the country of origin preceded by the words ''product of,'' immediately under the name or descriptive designation of the product as required by §317.2: *Provided,* That such establishment number may be omitted from a label lithographed directly on a can if said number is lithographed or embossed elsewhere on the can; and

(2) Shall, if such immediate container is a sealed metal container, have the establishment number assigned by the foreign meat inspection authority and certified by the Program embossed or lithographed on the sealed metal container, and such establishment number shall not be covered or obscured by any label or other means.

(c) All marks and other labeling for use on or with immediate containers, as well as private brands on carcasses or parts of carcasses, shall be approved by the Food Safety and Inspection Service in accordance with part 317 of this subchapter before products bearing such marks, labeling, or brands will be entered into the United States. The marks of inspection of foreign systems embossed on metal containers or branded on carcasses or parts thereof need not be submitted to the Food Safety and Inspection Service for approval, and such marks of inspection put on stencils, box dies, labels, and brands may be used on such immediate containers as tierces, barrels, drums, boxes, crates, and large-size fiberboard containers of foreign products without such marks of inspection being submitted for approval, provided the markings made by such articles are applicable to the product and are not false or misleading.

[35 FR 15610, Oct. 3, 1970, as amended at 51 FR 37707, Oct. 24, 1986; 60 FR 67456, Dec. 29, 1995]

§ 327.15 Outside containers of foreign products; marking and labeling; application of official inspection legend.

(a) The outside container in which any immediate container of foreign product is shipped to the United States shall bear, in English, in a prominent and legible manner:

(1) The name or descriptive designation of the product in accordance with § 317.2 of this subchapter;

(2) The name of the country of origin; and

(3) The establishment number assigned by the foreign meat inspection system and certified to the Program.

(b) All labeling used with an outside container of foreign product must be approved in accordance with part 317 of this subchapter.

(c) Except for product offered for entry from Canada, all outside containers of products which have been inspected and passed in accordance with this part shall be marked by a Program import inspector or under a Program import inspector's supervision with the official import meat inspection mark prescribed in § 327.26.

[35 FR 15610, Oct. 3, 1970, as amended at 51 FR 37707, Oct. 24, 1986; 54 FR 41048, Oct. 5, 1989]

§ 327.16 Small importations for importer's own consumption; requirements.

Any product in a quantity of 50 pounds or less which was purchased by the importer outside the United States for his/her own consumption, is eligible to be imported into the United States from any country without compliance with the provisions in other sections of this part but subject to applicable requirements under other laws, including the regulations in part 94 of this title. However, Program employees may inspect any product imported under this section to determine whether it is within the class eligible to be imported under this paragraph.

[54 FR 41048, Oct. 5, 1989]

§ 327.17 Returned U.S. inspected and marked products.

U.S. inspected and passed and so marked products exported to and returned from foreign countries will be admitted into the United States without compliance with this part upon notification to and approval of the Deputy Administrator, International Programs, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250, in specific cases.

[35 FR 15610, Oct. 3, 1970, as amended at 51 FR 37707, Oct. 24, 1986]

§ 327.18 Products offered for entry and entered to be handled and transported as domestic; exception.

(a) All products, after entry into the United States, shall be deemed and treated as domestic products and shall be subject to the applicable provisions of the Act and the regulations in this subchapter and the applicable requirements under the Federal Food, Drug and Cosmetic Act, except that products imported under § 327.16 are required to comply only with the requirements of that Act and § 327.16 of this subchapter.

(b) Products entered in accordance with this part may, subject to the provisions of part 318 of this subchapter,

be taken into official establishments and be mixed with or added to any product in such establishments which has been inspected and passed therein.

(c) Imported product which has been inspected, passed, and marked under this part may be transported in the course of importation or subsequently in commerce only upon compliance with part 325 of this subchapter.

[35 FR 15610, Oct. 3, 1970, as amended at 41 FR 18089, Apr. 30, 1976; 54 FR 41049, Oct. 5, 1989]

§327.19 Specimens for laboratory examination and similar purposes.

The provisions in this part do not apply to specimens of products for laboratory examination, research, or similar purposes when authorized importation by the Administrator under conditions specified by him in specific cases, including requirements of denaturing or other identification to deter their use for human food. Authorization will not be given for the importation of any products contrary to the provisions of part 94 of this chapter.

§327.20 Importation of foreign inedible fats.

No inedible grease, inedible tallow, or other inedible rendered fat shall be imported into the United States unless it has been first denatured as prescribed in §327.25 of this part and the containers marked as prescribed by §316.15 of this subchapter or unless it is identified and handled as prescribed by §325.11 (b) or (c) of this subchapter.

[54 FR 41049, Oct. 5, 1989]

§327.21 Inspection procedures for chilled fresh and frozen boneless manufacturing meat.

(a) *Definitions; sampling; standards.* (1) Frozen boneless manufacturing meat is meat, frozen in the fresh state from cattle, sheep, swine, goats, horses, mules, or other equines that has all bone removed and is cut into pieces or trimmings, frozen into a compact block of any shape and suitable for slicing or chopping in the manufacturing of meat food products. As used in this section, the term ''frozen'' includes ''chilled fresh,'' and ''lot'' means any amount of frozen boneless manufacturing meat of one species, similarly packaged, shipped from one establishment, and offered for import inspection under one or more foreign inspection certificates.

(2) Imported frozen boneless manufacturing meat shall be sampled as required by §327.6(a) of this part, and the samples defrosted for inspection. The Program import inspector, or in the case of Canadian product subject to procedures described in §327.5(d)(1), the Canadian representative will select from a lot the appropriate number of cartons specified by the table of sampling plans. The total sample for inspection will consist of the necessary number of 12-pound units drawn from these cartons. The 12-pound units selected will be completely defrosted and examined.

(b) *Lots refused entry.* Reinspection (including resampling) will be provided for any lot of frozen boneless manufacturing meat which was refused entry under this section on the basis of the original evaluation of the sample thereof, upon appeal from the inspector's initial decision.

[35 FR 15610, Oct. 3, 1970, as amended at 49 FR 36819, Sept. 20, 1984; 51 FR 44901, Dec. 15, 1986; 54 FR 275, Jan. 5, 1989; 57 FR 27906, June 23, 1992]

§327.22 [Reserved]

§327.23 Compliance procedure for cured pork products offered for entry.

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

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

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

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

(ii) Group II, consisting of cured pork products which have been water cooked. Any product that does not fit

into Group I but does fit into Group II shall be placed into Group II regardless of any other considerations.

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

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

(3) *Protein Fat-Free Percentage, Protein Fat-Free Content, PFF Percentage, PFF Content or PFF* of a product means the meat protein (indigenous to the raw, unprocessed pork cut) content expressed as a percent of the non-fat portion of the finished product.

(4) A *PFF Standardized Difference* is the PFF of the sample minus the minimum PFF requirement, set forth in § 319.104 and § 319.105 of this subchapter, for the product being analyzed, divided by the Appropriate Standard Deviation for the product group.

(5) The *Absolute Minimum PFF Requirement* is that no laboratory result of an individual sample for PFF content be below the applicable minimum requirement of § 319.104 or § 319.105 of this subchapter by 2.3 or more percentage points for a Group I or II product or 2.7 or more percentage points for a Group III or IV product.

(6) A *PFF Standardized Arithmetic Average of the Country's Products* is the arithmetic average of PFF Standardized Differences from either 36 or 100 consecutively sampled lots of product entering the United States from a given producing country.

(7) A *PFF Standardized Weighted Average of the Country's Products* is an estimate of the average of the PFF Standardized Differences from either 36 or 100 consecutively sampled lots, adjusted for the size of the lot, of different types of cured pork product entering the United States from a given producing country. A Standardized Weighted Average is computed by multiplying the PFF Standardized Difference calculated for each lot by the number of pounds of product in each lot, adding those results together, and dividing the sum by the total weight of product from all the lots making up the average.

(8) The *Appropriate Standard Deviation* is based on within lot variability. That assigned to Groups I and II = 0.75 percent PFF and that assigned to Groups III and IV = 0.91 percent PFF.

(9) A *Lot* is all product of one type from one establishment presented by an importer as the unit for inspection at the Port of Entry.

(b) *Normal monitoring procedures.* Except for product imported from Canada, the Department shall collect sample(s) of cured pork product on a random basis from lots offered for entry at the Port of Entry and, after analyzing the sample for fat and indigenous protein content, calculate the PFF percentage. The product shall not be held pending laboratory results during the monitoring phase. The PFF percentage for each sample shall be considered along with the cumulative results of prior samples to assess the effectiveness of a country's overall compliance program and to determine the course of action for subsequent lots of product.

(1) Factors determining whether a country's inspection system is functioning adequately:

(i) The PFF percentage for each sample must not be below the minimum PFF requirement by 2.3 percentage points for cured pork products in Groups I and II or 2.7 percentage points for cured pork products in Groups III and IV.

(ii) Both of the PFF Standardized Averages, Arithmetic and Weighted, for the last 100 consecutive lots of all cured pork products from the country must be equal to or greater than zero. The count for the 100 consecutive lots starts with the lots arriving from that country after April 15, 1985.

(iii) Both of the PFF Standardized Averages, Arithmetic and Weighted, for the last 36 consecutive lots of all cured pork products from the country must be above the lowest 5 percent of the Normal distribution. This minimum value is minus 0.28 (−0.28) for the Arithmetic Average and depends on the production volume for the Weighted Average.

(2) Actions when calculations indicate that processing procedures in a country are out-of-compliance:

(i) If the PFF level of a sample taken during normal monitoring procedures is found to be as low as the Absolute Minimum PFF Requirement, the country of origin shall be notified; the lot involved shall be retained if still available in an official establishment or subject to detention or other actions pursuant to the Act; and all subsequently presented lots of that cured pork product from the same foreign establishment shall be held under retention until the provisions of paragraph (c) are satisfied.

(ii) If either of the PFF Standardized Averages, Arithmetic or Weighted, for the last 100 consecutive lots falls below zero or either of the PFF Standardized Averages for the last 36 consecutive lots falls below the upper 95 percent of the Normal distribution, all available cured pork product from the foreign country shall be subject to administrative retention and all subsequently presented lots of cured pork product from the foreign country shall be held under retention until the provisions of paragraph (c) are satisfied. The country of origin shall be notified, and shall be subject to other actions pursuant to the Act.

(c) *Retention*. When lots of cured pork product are under retention they shall be refused entry and reexported in accordance with § 327.13 of this subchapter unless they can be released in accordance with the provisions of paragraph (c)(1), establishments may be returned to normal monitoring procedures in accordance with paragraph (c)(2), and countries may be returned to normal monitoring procedures in accordance with paragraph (c)(3).

(1) If a lot is subject to retention procedures under this section, the Department shall collect five randomly selected sample units from each lot and determine the PFF of each sample unit. The lot may be released into commerce if:

(i) The average PFF percentage of the five randomly selected sample units is equal to or greater than the applicable minimum PFF percentage required by § 319.104 or § 319.105 of this subchapter, or

(ii) The product is relabeled under the supervision of a program employee so that it conforms to the provisions of § 319.104 or § 319.105 of this subchapter.

(2) If product from a foreign establishment is subject to retention procedures under this section, the foreign establishment may be returned to normal monitoring procedures when:

(i) Ten consecutively presented lots of that cured pork product from that establishment have been sampled as provided in paragraph (c)(1) of this section and the average of each set of five sample units representing each lot have been found to be equal to or greater than the required minimum PFF percentage; and

(ii) The PFF percentage of each sample unit (50 in all) is above the Absolute Minimum PFF Percentage.

(3) If a country is subject to retention procedures under this section, the country shall be returned to normal monitoring procedures when:

(i) Twenty-five consecutively presented lots of cured pork product have been sampled as required in paragraph (c)(1) of this section and the average of each set of five sample units representing each lot have been found to be equal to or greater than the required minimum PFF percentage; and

(ii) The PFF percentage of each sample unit (125 in all) is above the Absolute Minimum PFF Percentage; and

(iii) Both of the PFF Standardized Averages for 36 consecutive lots are in the required percentage of the Normal distribution; and

(iv) Both of the PFF Standardized Averages for 100 consecutive lots are zero or higher.

(4) The sample units collected under retention procedures as provided in paragraph (c)(2) of this section will not be included in the PFF standardized averages for 36 and 100 consecutive lots.

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

(e) Activities requiring additional inspectional supervision, such as relabeling, shall be at the importer's expense. In addition, if the importer wishes, he or she may have samples analyzed at an accredited laboratory.

[50 FR 9792, Mar. 12, 1985, as amended at 54 FR 41049, Oct. 5, 1989]

§ 327.24 Appeals; how made.

Any appeal from a decision of any program employee shall be made to his/her immediate supervisor having jurisdiction over the subject matter of the appeal, except as otherwise provided in the applicable rules of practice.

[51 FR 37707, Oct. 24, 1986, as amended at 60 FR 67456, Dec. 29, 1995]

§ 327.25 Disposition procedures for product condemned or ordered destroyed under import inspection.

(a) Carcasses, parts thereof, meat and meat food products (other than rendered animal fats) that have been treated in accordance with the provisions of this section shall be considered denatured for the purposes of the regulations in this part, except as otherwise provided in part 314 of this subchapter for articles condemned at official establishments or at official import inspection establishments.

(1) The following agents are prescribed for denaturing carcasses, parts thereof, meat or meat food products which are affected with any condition that would result in their condemnation and disposal under part 314 of this subchapter if they were at an official establishment or at an official import inspection establishment: Crude carbolic acid; cresylic disinfectant; a formula consisting of 1 part FD&C green No. 3 coloring, 40 parts water, 40 parts liquid detergent, and 40 parts oil of citronella, or other proprietary substance approved by the Administrator in specific cases.[1]

(2) Meat may be denatured by dipping it in a solution of 0.0625 percent tannic acid, followed by immersion in a water bath, then dipping it in a solution of 0.0625 percent ferric acid; and except as provided in paragraphs (a) (3) and (5) of this section, the following agents are prescribed for denaturing other carcasses, parts thereof, meat and meat food products, for which denaturing is required by this part: FD&C green No. 3 coloring; FD&C blue No. 1 coloring; FD&C blue No. 2 coloring; finely powdered charcoal; or other proprietary substance approved by the Administrator in specific cases.[1] Carcasses (other than viscera), parts thereof, cuts of meat, and unground pieces of meat darkened by charcoal or other black dyes shall be deemed to be denatured pursuant to this section only if they contain at least that degree of darkness depicted by diagram 1 of the Meat Denaturing Guide (MP Form 91).[2]

(3) Tripe may be denatured by dipping it in a 6 percent solution of tannic acid for 1 minute followed by immersion in a water bath, then immersing it for 1 minute in a solution of 0.022 percent FD&C yellow No. 5 coloring.

(4) When meat, meat byproducts, or meat food products are in ground form, 4 percent by weight of coarsely ground hard done, which shall be in pieces no smaller than the opening size specified for No. 5 mesh in the standards issued by the U.S. Bureau of Standards or 6 percent by weight of coarsely ground hard bone, which shall be in pieces no smaller than the opening size specified for No. 8 mesh in said Standards, uniformly incorporated with the product, may be used in lieu of the agents prescribed in paragraph (a)(2) of this section.

(5) Before the denaturing agents are applied to articles in pieces more than 4 inches in diameter, the pieces shall be freely slashed or sectioned. (If the articles are in pieces not more than 4

[1] Information as to approval of any proprietary denaturing substance may be obtained from the Meat and Poultry Inspection Technical Services, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250.

[2] Copies of MP Form 91 may be obtained, without charge, by writing to the Administrative Operations Branch, Food Safety and Inspection Service, U.S. Department of Agriculture, 123 East Grant Street, Minneapolis, Minnesota 55403. Diagrams 2 and 3 of the Meat Denaturing Guide are for comparison purposes only. The Meat Denaturing Guide has been approved for incorporation by reference by the Director, Office of the Federal Register, and is on file at the Federal Register Library.

inches in diameter, slashing or sectioning will not be necessary.) The application of any of the denaturing agents listed in paragraph (a) (1) or (2) of this section to the outer surface of molds or blocks or boneless meat, meat by-products, or meat food products shall not be adequate. The denaturing agent must be mixed intimately with all the material to be denatured, and must be applied in such quantity and manner that it cannot easily and readily be removed by washing or soaking. A sufficient amount of the appropriate agent shall be used to give the material a distinctive color, odor, or taste so that such material cannot be confused with an article of human food.

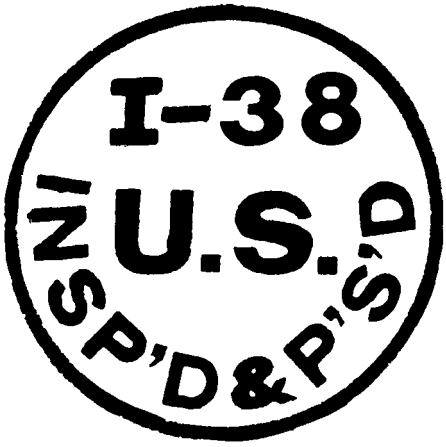
(b) Inedible rendered animal fats shall be denatured by thoroughly mixing therein denaturing oil, No. 2 fuel oil, brucine dissolved in a mixture of alcohol and pine oil or oil of rosemary, finely powdered charcoal, or any proprietary denaturing agent approved for the purpose by the Administrator in specific cases. The charcoal shall be used in no less quantity than 100 parts per million and shall be of such character that it will remain suspended indefinitely in the liquid fat. Sufficient of the chosen identifying agents shall be used to give the rendered fat so distinctive a color, odor, or taste that it cannot be confused with an article of human food.

[51 FR 37707, Oct. 24, 1986]

§327.26 Official import inspection marks and devices.

(a) When import inspections are performed in official import inspection establishments, the official inspection legend to be applied to imported meat and meat food products shall be in the appropriate form[1] as herein specified.

For application to cattle, sheep, swine, and goat carcasses, primal parts, and cuts, not in containers.

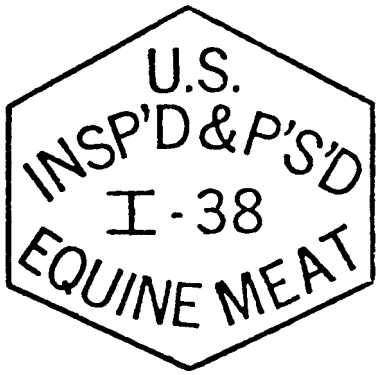


For application to outside containers of meat and meat food products prepared from cattle, sheep, swine, and goats.

[1] The number ''I–38'' is given as an example only. The establishment number of the official import inspecton establishment where the imported product is inspected shall be used in lieu thereof.

For application to horse carcasses, primal parts, and cuts, not in containers.

For application to outside containers of horsemeat food products.



For application to mule and other (nonhorse) equine carcasses, primal parts, and cuts, not in containers.

For application to outside containers of equine meat food products.

(b) Except for product offered for entry from Canada, when import inspections are performed in official establishments the official inspection legend to be applied to meat and meat food products offered for entry shall be the appropriate form as specified in §§312.2 and 312.3 of this subchapter.

(c) When products are refused entry into the United States, the official mark to be applied to the products refused entry shall be in the following form:

UNITED STATES
REFUSED ENTRY

(d) Devices for applying ''United States Refused Entry'' marks shall be furnished to Program inspectors by the Department.

(e) The ordering and manufacture of brands containing official inspection legends shall be in accordance with the provisions contained in §317.3(c) of the Federal meat inspection regulations.

[51 FR 37708, Oct. 24, 1986, as amended at 54 FR 41049, Oct. 5, 1989]

PART 329—DETENTION; SEIZURE AND CONDEMNATION; CRIMINAL OFFENSES

Sec.

329.1 Article or livestock subject to administrative detention.

329.2 Method of detention; form of detention tag.
329.3 Notification of detention to the owner of the article or livestock detained, or the owner's agent, and person having custody.
329.4 Notification of governmental authorities having jurisdiction over article or livestock detained; form of written notification.
329.5 Movement of article or livestock detained; removal of official marks.
329.6 Articles or livestock subject to judicial seizure and condemnation.
329.7 Procedure for seizure, condemnation and disposition.
329.8 Authority for condemnation or seizure under other provisions of law.
329.9 Criminal offenses.

AUTHORITY: 21 U.S.C. 601–695; 7 CFR 2.17, 2.55.

SOURCE: 35 FR 15617, Oct. 3, 1970, unless otherwise noted.

§329.1 Article or livestock subject to administrative detention.

Any carcass, part of a carcass, meat or meat food product of livestock, or article exempted from the definition of meat food product, or any dead, dying, disabled, or diseased livestock is subject to detention for a period not to exceed 20 days when found by any authorized representative of the Secretary upon any premises where it is held for the purposes of, or during or after distribution in, commerce or it is otherwise subject to Title I or II of the Act, and there is reason to believe that:

(a) Any such article is adulterated or misbranded and is capable of use as human food; or

(b) Any such article has not been inspected, in violation of the provisions of Title I of the Act, any other Federal law, or the laws of any State or Territory, or the District of Columbia; or

(c) Any such article or livestock has been or is intended to be, distributed in violation of the provisions of Title I of the Act, any other Federal law, or the laws of any State or Territory, or the District of Columbia.

§329.2 Method of detention; form of detention tag.

An authorized representative of the Secretary shall detain any article or livestock to be detained under this part, by affixing an official ''U.S. Detained'' tag (FSIS Form 8400–2) to such article or livestock.

[55 FR 47842, Nov. 16, 1990]

§329.3 Notification of detention to the owner of the article or livestock detained, or the owner's agent, and person having custody.

(a) When any article or livestock is detained under this part, an authorized representative of the Secretary shall:

(1) Orally notify the immediate custodian of the article or livestock detained, and

(2) Promptly furnish a copy of a completed ''Notice of Detention'' (FSIS Form 8080–1) to the immediate custodian of the detained article or livestock.

(b) If the owner of the detained article or livestock, or the owner's agent, is not the immediate custodian at the time of detention and if the owner, or owner's agent, can be ascertained and notified, an authorized representative of the Secretary shall furnish a copy of the completed ''Notice of Detention'' to the owner or the owner's agent. Such copy shall be served, as soon as possible, by delivering the notification to the owner, or the owner's agent, or by certifying and mailing the notification to the owner, or the owner's agent, at his or her last known residence or principal office or place of business.

[55 FR 47842, Nov. 16, 1990]

§329.4 Notification of governmental authorities having jurisdiction over article or livestock detained; form of written notification.

Within 48 hours after the detention of any livestock or article pursuant to this part, an authorized representative of the Secretary shall give oral or written notification of such detention to any Federal authorities not connected with the Program, and any State or other governmental authorities, having jurisdiction over such livestock or article. In the event notification is given orally, it shall be confirmed in writing, as promptly as circumstances permit.

§329.5 Movement of article or livestock detained; removal of official marks.

(a) No article or livestock detained in accordance with the provisions in this

part shall be moved by any person from the place at which it is located when so detained, until released by an authorized representative of the Secretary: *Provided*, That any such article or livestock may be moved from the place at which it is located when so detained, for refrigeration, freezing, or storage purposes if such movement has been approved by an authorized representative of the Secretary: *And provided further*, That the article or livestock so moved will be detained by an authorized representative of the Secretary after such movement until such time as the detention is terminated.

(b) Upon terminating the detention of such article or livestock, an authorized representative of the Secretary shall:

(1) Orally notify the immediate custodian of the released article or livestock, and

(2) Furnish copies of a completed ''Notice of Termination of Detention'' (FSIS Form 8400–1) to the persons notified when the article or livestock was detained. The notice shall be served by either delivering the notice to such persons or by certifying and mailing the notice to such persons at their last known residences or principal offices or places of business.

(c) All official marks may be required by such representative to be removed from such article or livestock before it is released unless it appears to the satisfaction of the representative that the article or livestock is eligible to retain such marks.

[35 FR 15617, Oct. 3, 1970, as amended at 36 FR 12004, June 24, 1971; 39 FR 36000, Oct. 7, 1974; 55 FR 47842, Nov. 16, 1990]

§ 329.6 Articles or livestock subject to judicial seizure and condemnation.

Any carcass, part of a carcass, meat or meat food product, or any dead, dying, disabled, or diseased livestock, that is being transported in commerce or is otherwise subject to Title I or II of the Act, or is held for sale in the United States after such transportation, is subject to seizure and condemnation, in a judicial proceeding pursuant to section 403 of the Act if such article or livestock:

(a) Is or has been prepared, sold, transported, or otherwise distributed or offered or received for distribution in violation of the Act, or

(b) Is capable of use as human food and is adulterated or misbranded, or

(c) In any other way is in violation of the Act.

§ 329.7 Procedure for seizure, condemnation, and disposition.

Any article or livestock subject to seizure and condemnation under this part shall be liable to be proceeded against and seized and condemned, and disposed of, at any time, on an appropriate pleading in any United States district court, or other proper court specified in section 404 of the Act, within the jurisdiction of which the article or livestock is found.

§ 329.8 Authority for condemnation or seizure under other provisions of law.

The provisions of this part relating to seizure, condemnation and disposition of articles or livestock do not derogate from authority for condemnation or seizure conferred by other provisions of the Act, or other laws.

§ 329.9 Criminal offenses.

The Act contains criminal provisions with respect to numerous offenses specified in the Act, including but not limited to bribery of Program employees, receipt of gifts by Program employees, and forcible assaults on, or other interference with, Program employees while engaged in, or on account of, the performance of their official duties under the Act.

PART 331—SPECIAL PROVISIONS FOR DESIGNATED STATES AND TERRITORIES; AND FOR DESIGNATION OF ESTABLISHMENTS WHICH ENDANGER PUBLIC HEALTH AND FOR SUCH DESIGNATED ESTABLISHMENTS

Sec.

331.1 Definition of ''State.''
331.2 Designation of States under paragraph 301(c) of the Act.
331.3 States designated under paragraph 301(c) of the Act; application of regulations.

331.4 Control and disposal of non-federally-inspected products in States designated under paragraph 301(c) of the Act.
331.5 Criteria and procedure for designating establishments with operations which would clearly endanger the public health; disposition of products; application of regulations.
331.6 Designation of States under section 205 of the Act; application of sections of the Act and the regulations.

AUTHORITY: 21 U.S.C. 601–695; 7 CFR 2.17, 2.55.

SOURCE: 35 FR 19667, Dec. 29, 1970, unless otherwise noted.

§331.1 Definition of "State".

For purposes of this part, the term ''State'' means any State (including the Commonwealth of Puerto Rico) or organized Territory.

§331.2 Designation of States under paragraph 301(c) of the Act.

Each of the following States has been designated, under paragraph 301(c) of the Act, as a State in which the provisions of Titles I and IV of the Act shall apply to operations and transactions wholly within such State. The Federal provisions apply, effective on the dates shown below:

State	Effective date of application of Federal provisions
Alaska	July 31, 1999.
Arkansas	June 1, 1981.
California	Apr. 1, 1976.
Colorado	July 1, 1975.
Connecticut	Oct. 1, 1975.
Florida	Dec. 2, 1997.
Guam	Jan. 21, 1972.
Hawaii	Nov. 1, 1995.
Idaho	July 1, 1981.
Kentucky	Jan. 14, 1972.
Maryland	March 31, 1991
Massachusetts	Jan. 12, 1976.
Michigan	Oct. 3, 1981.
Nebraska	Oct. 1, 1971.
Nevada	July 1, 1973.
New Hampshire	Aug. 6, 1978.
New Jersey	July 1, 1975.
New York	July 16, 1975.
Northern Mariana Islands	Oct. 29, 1979.
Oregon	July 1, 1972.
Pennsylvania	July 17, 1972.
Puerto Rico	June 18, 1971.
Rhode Island	Oct. 1, 1981.
Tennessee	Oct. 1, 1975.
Virgin Islands of the U.S	Nov. 27, 1971.
Washington	June 1, 1973.

[35 FR 19667, Dec. 29, 1970]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting §331.2, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and on GPO Access.

§331.3 States designated under paragraph 301(c) of the Act; application of regulations.

The provisions of the regulations in this subchapter apply to operations and transactions wholly within each State designated in §331.2 under paragraph 301(c) of the Act, except as otherwise provided in this section. (The provisions of the regulations apply in all respects to operations and transactions in or for commerce.)

(a) Each establishment located in such a designated State shall be granted inspection required under §302.1(a)(2) of this subchapter only if it is found, upon a combined evaluation of its premises, facilities, and operating procedures, to be capable of producing products that are not adulterated or misbranded.

(b) Section 305.2 of this subchapter will apply to establishments required to have inspection under §302.1(a)(2) of this subchapter, except that existing interconnections between official and unofficial establishments will be permitted if it is determined in specific cases that the interconnections are such that transfer of inedible product into the official establishment would be difficult or unusual, and any such transfers are strictly prohibited, except as permitted under other provisions of this subchapter. It is essential that separation of facilities be maintained to the extent necessary to assure that inedible product does not enter the official establishment contrary to the regulations in this subchapter.

(c) Sections 416.2(c), (d), (e), (f), and (h) of this chapter shall apply to such establishments.

(d) Section 314.2 of this subchapter shall apply to such establishments, except that a separate room or compartment need not be provided for inedible products if they can be handled so that they do not create insanitary conditions in any room or compartment used for edible products or otherwise render any edible products adulterated and do not interfere with the conduct of inspection. For example, intestines, paunch contents, feet, and hides might be accumulated on the kill floor in

clean, watertight drums with close fitting covers if there is sufficient space to store them out of the way until the close of the day's operation.

(e) Sections 316.7, 317.3, and 317.4 of this subchapter shall apply to such establishments, except as provided in this paragraph (e).

(1) The operator of each such establishment shall, prior to the inauguration of inspection, identify all labeling and marking devices in use, or proposed for use (upon the date of inauguration of inspection) to the circuit supervisor of the circuit in which the establishment is located. Temporary approval, pending formal approval under §§316.7, 317.3, and 317.4 of this subchapter, will be granted by the circuit supervisor for labeling and marking devices that he determines are neither false nor misleading, provided the official inspection legend bearing the official establishment number is applied to the principal display panel of each label, either by a mechanical printing device or a self-destructive pressure sensitive sticker, and provided the label shows the true product name, an accurate ingredient statement, the name and address of the manufacturer, packer, or distributor, and any other features required by paragraph 1(n) of the Act.

(2) The circuit supervisor will forward one copy of each item of labeling and a description of each marking device for which he has granted temporary approval to the Washington, DC, office of the Labeling and Packaging Staff and will retain one copy in a temporary approval file for the establishment.

(3) The operator of the official establishment shall promptly forward a copy of each item of labeling and a description of each marking device for which temporary approval has been granted by the circuit supervisor (showing any modifications required by the circuit supervisor) to the Labels and Packaging Staff, Meat and Poultry Inspection, Food Safety and Inspection Service, USDA, Washington, DC 20250, accompanied by the formula and details of preparation and packaging for each product. Within 90 days after inauguration of inspection, all labeling material and marking devices temporarily approved by the circuit supervisor must receive approval as required by §§316.7, 317.3, and 317.4, of this subchapter or their use must be discontinued.

(4) The circuit supervisor will also review all shipping containers to insure that they do not have any false or misleading labeling and are otherwise not misbranded. Modifications of unacceptable information on labeling material by the use of self-destructive pressure sensitive tape or by blocking out with an ink stamp will be authorized on a temporary basis to permit the maximum allowable use of all labeling materials on hand. All unacceptable labeling material which is not modified to comply with the requirements of this subchapter must be destroyed or removed from the official establishment.

(f) Sections 320.1, 320.2, 320.3, 320.4, 320.5, 325.20, and 325.21 apply to operations and transactions not in or for commerce in a State designated under paragraph 301(c) only if the State is also designated under section 205 of the Act and if such provisions are applicable as shown in §331.6.

(g) Section 321.1(a) of this subchapter will not apply to States designated under paragraph 301(c) of the Act.

(h) Parts 322 and 327 and §325.3 of this subchapter relating to exports and imports do not apply to operations and transactions solely in or for intrastate commerce.

(i) Part 325 of this subchapter will apply to establishments required to have inspection under §302.1(a)(2) of this subchapter and to operations and transactions solely in or for intrastate commerce, except as provided in paragraphs (h) and (j) of this section.

(j) Sections 325.4, 325.15, and 325.1(b) of this subchapter will not apply to require a certificate, or evidence thereof, for the distribution solely within any designated State of products that are U.S. inspected and passed and so marked.

[35 FR 19667, Dec. 29, 1970, as amended at 36 FR 12004, June 24, 1971; 41 FR 18089, Apr. 30, 1976; 62 FR 45026, Aug. 25, 1997; 64 FR 56416, Oct. 20, 1999]

§331.4 Control and disposal of non-federally-inspected products in States designated under paragraph 301(c) of the Act.

Upon the effective date of designation of a State under paragraph 301(c) of the Act, no products can be prepared within the State unless they are prepared under inspection pursuant to the regulations in this subchapter or are exempted from the requirement of inspection under §303.1 of this subchapter, and no unexempted products which were prepared without any inspection can lawfully be distributed within the State. For a period of 90 days from the effective date of such designation, products which were prepared and inspected and passed under the supervision of a responsible State or local inspection agency can be distributed solely within the State, provided they are not adulterated or misbranded, except that the official inspection legend is not required. Within the 90-day period, products that have been inspected by the State or local inspection agency may be further prepared and otherwise handled in official establishments required to have inspection under §302.1(a)(2) of this subchapter or at establishments exempted from the requirements of such inspection under §303.1 of this subchapter, and may be distributed as provided in this section but otherwise shall be handled in accordance with §305.4 of this subchapter. Such products shall not bear any [Federal] official inspection legends. After said 90–day period, only federally inspected and passed products may be distributed within the designated State, except as provided in §303.1 of this subchapter.

§331.5 Criteria and procedure for designating establishments with operations which would clearly endanger the public health; disposition of products; application of regulations.

(a) An establishment preparing products solely for distribution within any State shall be designated as one producing adulterated products which would clearly endanger the public health, if:

(1) Any meat or meat food product prepared at the establishment is adulterated in any of the following respects:

(i) It bears or contains a pesticide chemical, food additive, or color additive, that is ''unsafe'' within the meaning of sections 408, 409, or 706 of the Federal Food, Drug, and Cosmetic Act or was intentionally subjected to radiation in a manner not permitted under section 409 of said Act; or if it bears or contains any other added poisonous or added deleterious substance which may render it injurious to health or make it unfit for human food; or

(ii) It consists in whole or in part of any filthy, putrid, or decomposed substance or is for any other reason unsound, unhealthful, or unwholesome or otherwise unfit for human food (for example, it was prepared from meat or other ingredients exhibiting spoilage characteristics; or it is, or was prepared from, a carcass affected with a disease transmissible to humans and its condemnation would be required under part 309 or 310 of the Federal Meat Inspection regulations (9 CFR parts 309, 310) at federally inspected establishments; or it is a ready-to-eat pork product which has not been treated to destroy trichinae as prescribed in §318.10 of this subchapter for products at federally inspected establishments); or

(iii) It has been prepared, packed or held under insanitary conditions whereby it may have become contaminated with filth or may have been rendered injurious to health (for example if insects or vermin are not effectively controlled at the establishments, or insanitary water is used in preparing meat or meat food products for human food); or

(iv) It is, in whole or in part, the product of an animal that died otherwise than by slaughter; or

(v) Its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health; and

(2) Such adulterated articles are intended to be or are distributed from the establishment while capable of use as human food.

(b) When any such establishment is identified by a Program Inspector as one producing adulterated product,

which would clearly endanger public health under the criteria in paragraph (a) of this section, the following procedure will be followed:

(1) The Program Inspector will informally advise the operator of the establishment concerning the deficiencies found by him and report his findings to the appropriate Regional Director for the Program. When it is determined by the Regional Director that any establishment preparing products solely for distribution within any State is producing adulterated products for distribution within such State which would clearly endanger the public health, written notification thereof will be issued to the appropriate State officials, including the Governor of the State and the appropriate Advisory Committee, for effective action under State or local law to prevent such endangering of the public health. Such written notification shall clearly specify the deficiencies deemed to result in the production of adulterated products and shall specify a reasonable time for such action under State or local law.

(2) If effective action is not taken under State or local law within the specified time, written notification shall be issued by the Regional Director to the operator of the establishment, specifying the deficiencies involved and allowing him ten days to present his views or make the necessary corrections, and notifying him that failure to correct such deficiencies may result in designation of the establishment and operator thereof as subject to the provisions of titles I and IV of the Act as though engaged in commerce.

(3) Thereafter the Program Inspector shall survey the establishment and designate it if he determines, in consultation with the Regional Director, that it is producing adulterated products, which would clearly endanger the public health, and formal notice of such designation will be issued to the operator of the establishment by the Regional Director.

(c) Products on hand at the time of designation of an establishment under this section are subject to detention, seizure and condemnation in accordance with part 329 of this subchapter: *Provided,* That products that have been federally inspected and so identified and that have not been further prepared at any nonfederally inspected establishment may be released for distribution if the products appear to be not adulterated or misbranded at the time of such release.

(d) No establishment designated under this section can lawfully prepare any products unless it first obtains inspection or qualifies for exemption under § 303.1 of this subchapter. All of the provisions of the regulations shall apply to establishments designated under this section, except that the exceptions provided for in § 331.3 of this part shall apply to such establishments.

§ 331.6 Designation of States under section 205 of the Act; application of sections of the Act and the regulations.

Each of the following States has been designated, effective on the date shown below, under section 205 of the Act, as a State in which the provisions of the sections of the Act and regulations specified below shall apply to operators engaged, other than in or for commerce, in the kinds of business indicated below:

Sections of act and regulations	Classes of operators	State	Effective date of designation
Act, section 202; §§ 320.1, 320.2, 320.3, and 320.4.	Persons engaged (not in or for commerce) in (1) the business of slaughtering any livestock or preparing, freezing, packaging or labeling any livestock carcasses or parts or products thereof, for use as human food or animal food; (2) the business of buying or selling (as a meat broker, wholesaler, or otherwise), transporting or storing any livestock carcasses or parts or products thereof; or (3) business as a renderer, or in the business of buying, selling, or transporting any dead, dying, disabled, or diseased livestock or parts of carcasses of any livestock that died otherwise than by slaughter.	Alaska	July 31, 1999.
		Arkansas	Mar. 29, 1982.
		California	Apr. 1, 1976.
		Colorado	July 1, 1975.
		Connecticut	Oct. 1, 1975.
		Guam	Nov. 19, 1976.
		Idaho	Mar. 29, 1982.
		Kentucky	Apr. 18, 1973.
		Maryland	Mar. 31, 1991.
		Massachusetts	Jan. 12, 1976.
		Michigan	Mar. 29, 1982.
		Nebraska	Jan. 31, 1975.
		Nevada	Jan. 31, 1975.

Sections of act and regulations	Classes of operators	State	Effective date of designation
		New Hampshire	Oct. 29, 1979.
		New Jersey	July 1, 1975.
		New York	July 16, 1975.
		Northern Mariana Islands.	Oct. 29, 1979.
		Oregon	Jan. 31, 1975.
		Pennsylvania	May 2, 1974.
		Puerto Rico	Nov. 19, 1976.
		Rhode Island	Mar. 29, 1982.
		Tennessee	Oct. 1, 1975.
		Virgin Islands	Nov. 19, 1976.
		Washington	Jan. 31, 1975.
Act, 203; § 320.5	Persons engaged (not in or for commerce) in business as a meat broker; renderer; animal food manufacturer; wholesaler or public warehouseman of livestock carcasses, or parts or products thereof; or buying, selling, or transporting any dead, dying, disabled, or diseased livestock, or parts of carcasses of any such livestock that dies otherwise than by slaughter.	Alaska	July 31, 1999.
		Arkansas	Mar. 29, 1982.
		California	Apr. 1, 1976.
		Colorado	July 1, 1975.
		Connecticut	Oct. 1, 1973.
		Guam	Nov. 19, 1976.
		Idaho	Mar. 29, 1982.
		Kentucky	Apr. 18, 1976.
		Maryland	Mar. 31, 1991.
		Massachusetts ..	Jan. 12, 1975.
		Michigan	Mar. 29, 1982.
		Nebraska	Jan. 31, 1975.
		Nevada	Jan. 31, 1975.
		New Hampshire	Oct. 29, 1979.
		New Jersey	July 1, 1975.
		New York	July 16, 1973.
		Northern Mariana Islands.	Oct. 29, 1979.
		Oregon	Jan. 31, 1974.
		Pennsylvania	May 2, 1975.
		Puerto Rico	Nov. 19, 1976.
		Rhode Island	Mar. 29, 1982.
		Tennessee	Oct. 1, 1975.
		Virgin Islands	Nov. 19, 1976.
		Washington	Jan. 31, 1975.
Act, 204; §§ 325.20 and 325.21.	Persons engaged (not in or for commerce) in the business of buying, selling or transporting any dead, dying, disabled or diseased animals, or parts of carcasses of any animals that died otherwise than by slaughter.	Alaska	July 31, 1999.
		Arkansas	Mar. 29, 1982.
		Connecticut	Oct. 1, 1975.
		Guam	Nov. 19, 1976.
		Idaho	Mar. 29, 1982.
		Kentucky	Apr. 18, 1973.
		Maryland	Mar. 31, 1991.
		Massachusetts ..	Jan. 12, 1976.
		Michigan	Mar. 29, 1982.
		Nevada	Jan. 31, 1975.
		New Hampshire	Oct. 29, 1979.
		New Jersey	July 1, 1975.
		New York	July 16, 1975.
		Northern Mariana Islands.	Oct. 29, 1979.
		Oregon	Jan. 31, 1975.
		Pennsylvania	May 2, 1974.
		Puerto Rico	Nov. 19, 1976.
		Rhode Island	Mar. 29, 1982.
		Virgin Islands	Nov. 19, 1976.
		Washington	Jan. 31, 1975.

[35 FR 19667, Dec. 29, 1970]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 331.6, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and on GPO Access.

PART 335—RULES OF PRACTICE GOVERNING PROCEEDINGS UNDER THE FEDERAL MEAT INSPECTION ACT

Subpart A—Criminal Violations

Sec.
335.40 Opportunity for presentation of views before report of criminal violations.

AUTHORITY: 21 U.S.C. 601–695; 7 CFR 2.17, 2.55.

SOURCE: 42 FR 10960, Feb. 25, 1977, unless otherwise noted.

Subpart A—Criminal Violations

AUTHORITY: Sec. 406, Pub. L. 99–641, 100 Stat. 3571; 21 U.S.C. 606 note.

[42 FR 10960, Feb. 25, 1977. Redesignated at 64 FR 66545, Nov. 29, 1999]

§ 335.40 Opportunity for presentation of views before report of criminal violations.

(a) Except as provided in paragraphs (a)(1) through (5) of this section, before any violation of the Federal Meat Inspection Act is reported to the Department of Justice by the Secretary for criminal prosecution the Secretary must give reasonable notice to the suspected violator that the Secretary intends to report the violation for prosecution and give the suspected violator an opportunity to present the violator's views to the Secretary with respect to such proceeding.

(1) Notice and opportunity need not be provided if the Secretary has any reason to believe that providing such notice and opportunity could result in the alteration or destruction of evidence, or where disclosure could result in injury to persons or property.

(2) Notice and opportunity need not be provided if the Secretary has any reason to believe that providing such notice and opportunity could result in flight of a suspected violator to avoid prosecution.

(3) Notice and opportunity need not be provided if the Secretary has any reason to believe that providing such notice and opportunity could result in compromising special investigative techniques, such as undercover or other covert operations.

(4) Notice and opportunity need not be provided when the impending criminal referral involves suspicion of bribery and related offenses, or clandestine slaughtering and/or processing operations.

(5) Notice and opportunity need not be provided when the impending referral is part of an investigation involving non-Act violations, and the Act and non-Act violations are jointly referred for prosecution.

(b) A notice of opportunity to present views will be sent by registered or certified mail, summarize the violations that constitute the basis of the contemplated prosecution, and describe the procedures for presentation of views. Any information given by a respondent, orally or in writing, shall become part of the Department's official record concerning the matter. The Department is under no obligation to disclose evidence to the suspected violator.

[52 FR 13828, Apr. 27, 1987]

PART 350—SPECIAL SERVICES RELATING TO MEAT AND OTHER PRODUCTS

Sec.
350.1 Meaning of words.
350.2 Definitions.
350.3 Types and availability of service.
350.4 [Reserved]
350.5 Application for service.
350.6 Denial or withdrawal of service.
350.7 Fees and charges.
350.8 Scope and applicability of rules of practice.

AUTHORITY: 7 U.S.C. 1622, 1624; 7 CFR 2.17, 2.55.

SOURCE: 23 FR 9982, Dec. 23, 1958. Redesignated at 30 FR 4195, Mar. 31, 1965, and at 35 FR 15554, Oct. 3, 1970.

§ 350.1 Meaning of words.

Words used in this part in the singular form shall be deemed to import the plural, and vice versa, as the case may demand.

§ 350.2 Definitions.

For the purposes of the regulations in this part, unless the context otherwise requires, the following terms shall be construed, respectively, to mean:

(a) *Department.* The United States Department of Agriculture.

(b) *Service.* The Food Safety and Inspection Service of the Department.

(c) *Administrator.* The Administrator of the Service or any officer or employee of the Department to whom authority has heretofore been delegated, or to whom authority may hereafter be delegated, to act in his stead.

(d) [Reserved]

(e) *Inspector.* Any officer or employee of the Department authorized to perform any duties under the regulations in this part.

(f) *Person.* Any individual, corporation, company, association, firm, partnership, society, or joint stock company, or other organized group of any of the foregoing.

(g) *Federally inspected and passed.* Inspected and passed under the Meat Inspection Act, as amended (21 U.S.C. 71 et seq.) or under the provisions in paragraphs 306 (b) and (c) of the Tariff Act of 1930 (19 U.S.C. 1306 (b) and (c)).

(h) *Official establishment.* An establishment operated under Federal meat inspection pursuant to the Meat Inspection Act, as amended (21 U.S.C. 71 et seq.).

(i) *Food article.* Any article of human food derived wholly or in part from meat, meat byproducts, or meat food products, which is not subject to the Federal meat inspection laws, and animal casings, for which the mark of Federal meat inspection is requested: *Provided,* That such articles and casings are derived from federally inspected and passed carcasses.

(j) [Reserved]

(k) *Secretary.* The Secretary of Agriculture of the United States, or any officer or employee of the Department to whom authority has heretofore been delegated, or may hereafter be delegated, to act in his stead in connection with the function involved.

[23 FR 9982, Dec. 23, 1958, as amended at 25 FR 9642, Oct. 7, 1960; 30 FR 258, Jan. 9, 1965. Redesignated and amended at 30 FR 4195, Mar. 31, 1965; 32 FR 6021, Apr. 15, 1967; 32 FR 13115, Sept. 15, 1967. Further redesignated at 35 FR 15554, Oct. 3, 1970, and amended at 43 FR 11147, Mar. 17, 1978; 54 FR 1329, Jan. 13, 1989]

§350.3 Types and availability of service.

Upon application in accordance with §350.5 the following types of service may be furnished under the regulations in this part:

(a) *Identification service.* (1) Meat or other product that is federally inspected and passed at an official establishment, or upon importation, under the meat inspection laws, is officially marked to identify it as federally inspected and passed. In order to facilitate the division of such meat or other product into smaller portions or its combination into larger units and still maintain its identity as product which has been federally inspected and passed and so marked, inspectors may supervise the handling of the product and mark such portions or units with the marks of Federal inspection when they determine that the identity has been maintained.

(2) At the time service is furnished product must be sound, wholesome and fit for human food. The service will be available only on premises other than those of an official establishment. The sanitation of the plant or area where service is furnished must comply with applicable provisions of part 416, §§416.1 through 416.6 of this chapter.

(3) The mark of inspection shall be applied only under the immediate supervision of an inspector.

(4) The service will be available for products moved in tank cars and tank trucks from an official establishment or from a location operating under this service only if such tank cars or tank trucks bear a label before leaving such official establishment or such other location, in accordance with 9 CFR §§316.14 and 317.2.

(b) *Certification service.* At the request of a purchaser, supplier, exporter, or others, inspectors may make certification regarding livestock products for human food purposes (including casings), to be exported, as meeting conditions or standards that are not imposed or are in addition to those imposed by the regulations in parts 301 through 331 of this chapter and the laws under which such regulations were issued.

(c) *Food inspection service.* An inspection and certification service for

wholesomeness relating to the manufacture of a food article may be furnished upon application. All applicable provisions of this chapter shall apply to the preparation, labeling and certification of the food article prepared under this food inspection service.

(d) [Reserved]

[25 FR 9642, Oct. 7, 1960, as amended at 30 FR 258, Jan. 9, 1965. Redesignated at 30 FR 4195, Mar. 31, 1965, and amended at 30 FR 8675, July 9, 1965. Further redesignated at 35 FR 15554, Oct. 3, 1970, and amended at 38 FR 29215, Oct. 23, 1973; 53 FR 28634, July 29, 1988; 54 FR 1329, Jan. 13, 1989; 64 FR 56416, Oct. 20, 1999; 65 FR 2284, Jan. 14, 2000]

§ 350.4 [Reserved]

§ 350.5 Application for service.

Any person who desires to receive service under the regulations in this part for meat or other product eligible therefor under such regulations may make application for service to the Administrator, upon an application form which will be furnished by the Administrator upon request.

(Approved by the Office of Management and Budget under control number 0583–0036)

[23 FR 9982, Dec. 23, 1958. Redesignated at 30 FR 4195, Mar. 31, 1965, and at 35 FR 15554, Oct. 3, 1970, and amended at 47 FR 746, Jan. 7, 1982]

§ 350.6 Denial or withdrawal of service.

(a) If any person has applied for service for meat or other product not eligible therefor under the regulations in this part, or has failed to make proper application for service or to pay fees and charges due for service furnished or to be furnished to him under the regulations in this part, or if the service cannot be furnished to any person applying therefor because of lack of available inspectors or other administrative reasons, the service may be denied to such person by the Administrator until the condition justifying such denial is corrected.

(b) Service under the regulations in this part may also be denied to any person by the Secretary for such period as he may deem proper, if it is determined, after opportunity for hearing before a proper official in the Department, that such person has been responsible for any willful misrepresentation to the Department concerning any meat or other product for which service has been requested under the regulations, in this part, or that such person has been responsible for the use without authority, or the imitation, of any marks or certificates of Federal meat inspection on or with respect to any meat or other product, or has otherwise been responsible for any fraudulent or deceptive practice with respect to such service, or that such person has interfered with or obstructed any inspector in the performance of his duties under the regulations in this part, or attempted to do so. When the Administrator determines that the public interest so requires, he may deny or withdraw service provided for in this part, without a hearing, pending final determination of the matter. The applicant or recipient of service involved shall be notified of the Administrator's decision to deny or suspend service and the reasons therefor, in writing, in the manner prescribed in § 1.147(b) of the rules of practice (7 CFR 1.147(b)), or orally. The Administrator's decision to deny or suspend the service shall be effective upon such oral or written notification, whichever is earlier, to the applicant or recipient of service. If such notification is oral, the Administrator shall confirm such decision and the reasons therefor, in writing, as promptly as circumstances permit, and such written confirmation shall be served upon the applicant or recipient of service, in the manner prescribed in § 1.147(b) of the rules of practice (7 CFR 1.147(b)). In other cases prior to the institution of proceedings for denial of service under this paragraph, the facts or conduct which may warrant such action shall be called to the attention of the person involved, in writing, and he shall be given an opportunity to demonstrate or achieve compliance with all applicable requirements.

[23 FR 9982, Dec. 23, 1958; 25 FR 9642, Oct. 7, 1960. Redesignated at 30 FR 4195, Mar. 31, 1965, and 35 FR 15554, Oct. 3, 1970, and amended at 43 FR 11147, Mar. 17, 1978]

§ 350.7 Fees and charges.

(a) Fees and charges for service under the regulations in this part shall be paid by the applicant for the service in

accordance with this section, and, if required by the Administrator, the fees and charges shall be paid in advance.

(b) The fees and charges provided for in this section shall be paid by check, draft, or money order payable to the Treasurer of the United States and shall be remitted promptly to the Administrator upon furnishing to the applicant of a statement as to the amount due.

(c) The fees to be charged and collected for service under the regulations in this part shall be at the rates specified in §§391.2, 391.3, and 391.4 respectively for base time; for overtime including Saturdays, Sundays, and holidays; and for certain laboratory services which are not covered under the base time, overtime, and/or holiday costs. Such fees shall cover the costs of the service and shall be charged for the time required to render such services. Where appropriate, this time will include, but will not be limited to, the time required for travel of the inspector or inspectors in connection therewith during the regularly scheduled administrative workweek.

(d) Charges may also be made to cover the cost of travel and other expenses incurred by the Service in connection with the furnishing of the service.

[23 FR 9982, Dec. 23, 1958, as amended at 53 FR 13397, Apr. 22, 1988; 54 FR 6389, Feb. 10, 1989]

§350.8 Scope and applicability of rules of practice.

The rules of practice of the Department of Agriculture in subpart H of part I, subtitle A, title 7 of the Code of Federal Regulations, are the rules of practice applicable to adjudicatory, administrative proceedings under the regulations in this part (9 CFR part 350).

[43 FR 11147, Mar. 17, 1978]

PART 351—CERTIFICATION OF TECHNICAL ANIMAL FATS FOR EXPORT

DEFINITIONS

Sec.
351.1 Meaning of words.
351.2 Terms defined.

SCOPE OF CERTIFICATION SERVICE

351.3 Kind of service.

PROCEDURE FOR OBTAINING SERVICE: ADMINISTRATION OF PROGRAM

351.4 Application for certification service.
351.5 Conditions of eligibility for certification service; review of applications.
351.6 Official number.
351.7 Administration of certification service program.

FEES

351.8 Charges for surveys of plants.
351.9 Charges for examinations.

FACILITIES AND OPERATIONS

351.10 Facilities.
351.11 Identification and separation of technical animal fats for certification and materials for use therein; removal of wrappers, etc.; cleaning of equipment.
351.12 Circuit supervisor to be informed when plant operates.
351.13 Inspectors to have access to certified plants at all times.
351.14 Processes to be supervised; extent of examinations.
351.15 Reports of violations.

TRANSPORTATION AND EXPORTATION OF CERTIFIED TECHNICAL ANIMAL FAT

351.16 Certificate required for shipments of technical animal fat.
351.17 Identification required.

PROHIBITIONS

351.18 Official identifications; unauthorized use.

REMEDIES; PENALTIES

351.19 Refusal of certification for specific lots.
351.20 Withdrawal of service from certified plants.

APPEALS

351.21 Appeals.

RECORDS AND REPORTS

351.22 Certified plants to maintain records and make reports; access to records.

AUTHORITY: 7 U.S.C. 1622, 1624; 7 CFR 2.17 (g) and (i), 2.55.

SOURCE: 40 FR 58627, Dec. 18, 1975, unless otherwise noted.

DEFINITIONS

§351.1 Meaning of words.

Words used in this part in the singular form shall be deemed to import

the plural, and vice versa, as the case may demand.

§ 351.2 Terms defined.

When used in this part, unless the context otherwise requires:

(a) *Department* means the United States Department of Agriculture.

(b) *Program* means the Meat and Poultry Inspection Program of the Food Safety and Inspection Service of the Department.

(c) *Administrator* means the Administrator of the Food Safety and Inspection Service of the Department, or any officer or employee of the Department to whom authority has heretofore been delegated or may hereafter be delegated to act in his stead.

(d) *Circuit supervisor* means an employee of the Program assigned to supervise and perform official work in a circuit. Such employee is assigned by and reports directly to the Administrator or person designated by him.

(e) *Inspector* means an employee of the Program or a cooperating State.

(f) *Circuit* means one or more inspected plants assigned to a circuit supervisor.

(g) *Recognized State* means any State not designated in § 331.2 of this chapter.

(h) *Cooperating State* means any State cooperating under § 351.7 in administration of the regulations in this part.

(i) *Inspection* means ante-mortem and post-mortem inspection by Program inspectors or inspectors of a Meat Inspection Service of a recognized State.

(j) *Animals* means cattle, sheep, swine, goats, horses, mules and other equines.

(k) *Technical animal fat* means animal fat eligible for exportation, or storage for exportation, in accordance with § 325.11 of this chapter.

(l) *Certified technical animal fat* means technical animal fat certified for export or storage for export under the regulations in this part.

(m) *Tallow* means technical animal fat with a minimum titre of 40 °C.

(n) *Certified plant* means any plant or storage facility preparing or storing certified technical animal fat for export, or for transfer to another certified plant or storage facility for ultimate export, and at which certification service is provided under the regulations in this part.

(o) *Inspected and Passed* means inspected and passed under the Federal Meat Inspection Act (21 U.S.C. 601 *et seq.*) or the meat inspection laws of a recognized State.

SCOPE OF CERTIFICATION SERVICE

§ 351.3 Kind of service.

(a) Certification, in the form set forth in paragraph (b), is available under the regulations in this part for specific lots of technical animal fat for export, if the fat was rendered from materials derived from carcasses, or parts of carcasses, that had been inspected and passed and came from animals that did not die otherwise than by slaughter under inspection. The certification will be made by a Program employee when he determines, upon the basis of examinations made by him or other inspectors, as provided in § 351.14, and information obtained by him or them from the exporter or other sources, as provided in the regulations in this part, that the technical animal fat is eligible for certification under this section and therefore the statements to be certified are correct. The service will be available upon a voluntary fee basis in accordance with said regulations.

(b)(1) The form of Certificate for Export of Technical Animal Fats is as follows:

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE
MEAT AND POULTRY INSPECTION PROGRAM
WASHINGTON, D.C. 20250

CERTIFICATE FOR EXPORT OF TECHNICAL ANIMAL FATS

1. KIND OF PRODUCT

2. NET WEIGHT OF PRODUCT *(From Bill of Lading)*

3. NAME AND ADDRESS OF PLANT MAKING SHIPMENT

CERTIFIED PLANT NO.

4. NAME AND ADDRESS OF TRANSPORTING COMPANY

5. NAME OF VESSEL

6. COUNTRY OF DESTINATION

7. VESSEL NUMBER

8. NAME OF CITY WHERE LOADED

9. DATE LOADED

The Undersigned Certifies In Accordance With 9 CFR 351.3 That:

a. The product described above has been obtained by rendering raw materials, none of which were diseased, suspected of being diseased, or from dead animals.

b. The product covered by this certification has not been rendered under the continuous Federal inspection provided in the Federal Meat Inspection Act. For compliance with this certification, the plant equipment, plant conditions, and processing operations of the rendering plant(s) supplying the product certified by this certification are subject to Federal inspection on a periodic basis as authorized by the Agricultural Marketing Act and regulations thereunder *(9 CFR Part 351)*.

10. ISSUED AT *(Name of City)*

11. DATE ISSUED

12. SIGNATURE OF USDA INSPECTOR

MP FORM 87
NOV. 1975

(2) Certified technical animal fat may be described on the certificate as ''technical animal fat''; or if it is tallow, it may be described on the certificate as ''Tallow'' and the description may include the statement ''titre not less than 40 °C.''

PROCEDURE FOR OBTAINING SERVICE: ADMINISTRATION OF PROGRAM

§351.4 Application for certification service.

Application for certification service under the regulations in this part may be made to the Administrator by the operator of any rendering plant or storage facility at which technical animal fat is prepared or stored for export. In case of a change of ownership or change of location, a new application shall be made. Applications shall be made on forms[1] available from the Administrator and provide all information called for thereon relating to the identity of the applicant and the plant, and the nature of the plant operations, and a certification of specified facts and an agreement to comply with specified requirements.

(Approved by the Office of Management and Budget under control number 0583–0036)

[40 FR 58627, Dec. 18, 1975, as amended at 47 FR 746, Jan. 7, 1982]

§351.5 Conditions of eligibility for certification service; review of applications.

(a) To be eligible for certification service under the regulations in this part, the operator of a rendering plant must demonstrate that:

(1) He operates a rendering plant which will receive materials derived from inspected and passed carcasses, or parts of carcasses, of animals that did not die otherwise than by slaughter under inspection, (i.e., not ''dead animals''); and such source materials will be rendered at the plant into technical animal fat eligible for export, or storage for export, in accordance with the regulations in this part;

(2) The source materials and the rendered technical animal fat described in paragraph (a)(1) will be identified and kept separated at all times from other products; and

[1] Copy filed as part of the original document.

(3) He will comply with the applicable regulations in this part.

(b) To be eligible for certification service under the regulations in this part, the operator of a storage facility must demonstrate that:

(1) He operates a storage facility that will receive for storage certified technical animal fat shipped directly from a certified rendering plant for storage for export and he will keep such shipments identified and separated from other products that are not certified, and he will receive such fat only if it is accompanied by MP Form 85, as required by § 351.17.

(2) He will comply with the applicable regulations in this part.

(c) Each applicant for certification service must file with the Administrator, with the application for service, a written description of the procedures to be used for receiving, identifying, processing, storing, and otherwise handling technical animal fat, and materials for use in the preparation thereof, at the plant or storage facility involved, and for shipping technical animal fat from the plant or facility and storing and exporting such technical animal fat, and a written description of the shipping, receiving, and inventory records maintained for technical animal fat.

(d) The Administrator will determine, on the basis of all information available to him, whether the arrangements at the plant or storage facility are such as will assure that certifications of technical animal fat will be correct, and, if so, will grant the application for certification service. An applicant will be given an opportunity to present his views prior to refusal of the service.

(Approved by the Office of Management and Budget under control number 0583–0036)

[40 FR 58627, Dec. 18, 1975, as amended at 41 FR 12637, Mar. 26, 1976; 47 FR 746, Jan. 7, 1982]

§ 351.6 Official number.

The Administrator will assign a certified technical animal fat plant number to each plant granted service. Such number shall be preceded by the letter ''C'' and be used to identify all certified technical animal fat prepared or stored by the plant.

§ 351.7 Administration of certification service program.

(a) The regulations in this part shall be administered by the circuit supervisor for the jurisdiction in which is located the certified plant or plants for which application for certification service is made, and such assistants as may be necessary will be assigned by the Administrator.

(b) The Administrator may enter into a cooperative agreement with any recognized State for the conduct by State employees of any surveys, examinations, and other activities involved in the administration of the regulations in this part. However, certifications under these regulations may be issued only by Program employees, as provided in § 351.3.

FEES

§ 351.8 Charges for surveys of plants.

Applicants for the certification service shall pay the Department for salary costs at the rates specified in §§ 391.2 and 391.3 respectively for base time, and for overtime, travel, and per diem allowances at rates currently allowed by the Federal Travel Regulations, and other expenses incidental to the initial survey of the rendering plants or storage facilities for which certification service is requested.

[54 FR 6389, Feb. 10, 1989]

§ 351.9 Charges for examinations.

(a) The fees to be charged and collected by the Administrator for examination shall be at the rates specified in §§ 391.2, 391.3, and 391.4 respectively for base time; for overtime including Saturdays, Sundays, and holidays, as provided for in § 351.14; and for certain laboratory services which are not covered under the base time, overtime, and/or holiday costs and which are required to determine the eligibility of any technical animal fat for certification under the regulations in this Part. Such fees shall be charged for the time required to render such service, including, but not limited to, the time required for the travel of the inspector or inspectors in connection therewith.

(b) Charges may also be made to cover the actual cost of travel and per

diem allowance at rates currently allowed by the General Services Administration, and other expenses incurred by the Department in connection with such examinations and laboratory service.

[40 FR 58627, Dec. 18, 1975, as amended at 53 FR 13397, Apr. 22, 1988; 54 FR 6389, Feb. 10, 1989]

FACILITIES AND OPERATIONS

§351.10 Facilities.

(a) Facilities for the preparation, identification, and storage of the technical animal fat to be certified shall be furnished and maintained by the certified plant in accordance with this section.

(b) The operator of the certified plant shall provide at the plant, rooms, compartments, and equipment needed to maintain the identity of certified technical animal fats and materials used in their preparation, and separation of such articles from other products. Such rooms, compartments, and equipment shall be conspicuously marked with the phrase ''Certified Technical Animal Fat'' whenever they contain these fats.

§351.11 Identification and separation of technical animal fats for certification and materials for use therein; removal of wrappers, etc.; cleaning of equipment.

(a) All technical animal fat to be offered for certification under this part and materials to be used in the preparation of such fat, and all certified technical animal fat, shall be identified and kept separate from other products from the time of receipt at a certified plant and throughout processing or handling at such plant. All wrappers and packaging shall be removed from the source materials to the fullest extent practicable before the materials are rendered at the plant.

(b) If a plant's operations are within the provisions of §351.14(b)(3), all equipment shall be cleaned before it is used for receiving, preparation, or storage of certified technical animal fats or material to be used in preparation of such fats. Such cleaning shall be done in such manner as to prevent contamination of such certified fats or source material with materials that are unacceptable under §351.3.

§351.12 Circuit supervisor to be informed when plant operates.

The operator of each certified plant shall inform the circuit supervisor, in advance, when the plant's work schedule will include preparing technical animal fats for certification and identify the approximate days and hours when operations will begin and end.

§351.13 Inspectors to have access to certified plants at all times.

For the purpose of administering the regulations in this part, inspectors shall have access at all times by day or night to every part of a certified plant.

§351.14 Processes to be supervised; extent of examinations.

(a) All processes used in the preparation of certified technical animal fats at any certified plant shall be subject to supervision by an inspector. Certified plants shall not prepare any technical animal fat for certification under the regulations in this part, except in accordance with such regulations.

(b) Supervision, ranging from full-time coverage of an entire process to one or more reviews per month, to determine a plant's compliance with the regulations in this part will be maintained. A circuit supervisor may increase the frequency of reviews whenever he deems necessary to assure the validity of certifications under the regulations in this part. Usual coverage of individual rendering plants will be as follows:

(1) Coverage shall be at least once a month if the plant consistently handles only raw materials acceptable under §351.3 for the preparation of certified technical animal fat and the plant operator, in writing, certifies that he is maintaining this procedure.

(2) Coverage shall be at least once a week if the plant consistently handles some raw materials that are acceptable, and some that are unacceptable, under §351.3, for the preparation of certified technical animal fat, uses separate equipment for processing, and uses separate rooms, compartments, and equipment for receiving and storing

the respective types of raw materials and technical animal fats, and the plant operator, in writing, certifies that he is maintaining this complete physical separation procedure.

(3) Coverage shall be fulltime during receiving of raw materials and their preparation into certified technical animal fat, if the plant handles some raw materials that are acceptable, and some that are unacceptable, under § 351.3, for the preparation of certified technical animal fat, and uses the same rooms, compartments, and equipment, with only time separation between receiving, processing, and storing the respective types of raw materials and technical animal fats.

§ 351.15 Reports of violations.

Inspectors shall report to the circuit supervisor any apparent violations of the regulations in this part or the Federal Meat Inspection Act or regulations thereunder (subchapter A of this chapter) which occur at certified plants, or elsewhere, within their knowledge. The circuit supervisor shall report such actions to the Administrator through appropriate channels.

TRANSPORTATION AND EXPORTATION OF CERTIFIED TECHNICAL ANIMAL FAT

§ 351.16 Certificate required for shipments of technical animal fat.

No certified plant shall export any certified technical animal fat unless the shipment is accompanied by a certificate issued under § 351.3.

§ 351.17 Identification required.

Certified technical animal fats being exported directly from a certified plant or transferred between certified plants for storage for export are subject to the requirements of § 325.11 of this chapter. In addition, such shipments between certified plants shall be accompanied by MP Form 85 (Declaration to Accompany Technical Animal Fats Between Certified Technical Animal Fat Plants)[2] prepared by the operator of the certified plant from which shipment is made, certifying that the product has been obtained by rendering raw materials derived from federally or State inspected and passed carcasses, or parts of carcasses. Technical animal fat described on MP Form 85 as tallow must meet the definition of ''Tallow'' in § 351.2.

PROHIBITIONS

§ 351.18 Official identifications; unauthorized use.

(a) The form of certification set forth in § 351.3 and the term ''Certified Technical Animal Fat'' are official identifications for purposes of the Agricultural Marketing Act of 1946, as amended, and shall not be falsely made, issued, altered, forged, or counterfeited, or used for purpose of misrepresentation or deception.

(b) No container which bears or is to bear any designation as certified technical animal fat shall be filled in whole or in part, except with technical animal fats which have been certified and identified in compliance with this part.

REMEDIES; PENALTIES

§ 351.19 Refusal of certification for specific lots.

If an inspector has reason to believe that a lot of technical animal fat is ineligible for certification under § 351.3, or any materials to be used in a lot of technical animal fat would make the technical animal fat ineligible for such certification, certification of the lot shall be withheld pending final determination by the circuit supervisor. The operator of the plant shall be afforded an opportunity to demonstrate the eligibility of the lot for certification before the final determination is made.

§ 351.20 Withdrawal of service from certified plants.

(a) After opportunity for hearing has been accorded the operator of a certified plant, the certification service, provided for in this part, may be withdrawn from such plant in accordance with the applicable rules of practice, if it is determined that:

(1) The operator, or his employee or agent:

(i) Has made any willful misrepresentation or engaged in any fraudulent or deceptive practice in connection with the service;

[2] Copy filed as part of the original document.

(ii) Has interfered with or obstructed any Program employee or other inspector in the performance of his duties, under the regulations in this part, by intimidation, threats, or other improper means; or

(iii) Has violated section 203(h) of the Agricultural Marketing Act of 1946, as amended (7 U.S.C. 1622(h)), or any regulation in this part; or

(2) Facilities or procedures at the certified plant do not conform to the arrangements approved by the Administrator under §351.5.

(b) Pending final determination of the matter, the Administrator may summarily suspend the certification service at any certified plant when he has reason to believe that there is cause for withdrawal of the service under paragraph (a). The operator of the certified plant shall be notified of the Administrator's decision to suspend summarily the certification service at such plant and the reasons therefor, in writing, in the manner prescribed in §1.147(b) of the rules of practice (7 CFR 1.147(b)), or orally. The Administrator's decision to suspend summarily the certification service shall be effective upon such oral or written notification, whichever is earlier, to the operator of the certified plant. If such notification is oral, the Administrator shall confirm such decision, and the reasons therefor, in writing, as promptly as circumstances permit, and such written confirmation shall be served upon the operator of the certified plant, in the manner prescribed in §1.147(b) of the rules of practice (7 CFR 1.147(b)).

(c) The rules of practice of the Department of Agriculture in subpart H of part I, subtitle A, title 7 of the Code of Federal Regulations, are the rules of practice applicable to adjudicatory, administrative proceedings under the regulations in this part (9 CFR part 351).

[40 FR 58627, Dec. 18, 1975, as amended at 43 FR 11148, Mar. 17, 1978]

APPEALS

§351.21 Appeals.

Any decision by an employee of the Program may be appealed by any adversely affected person to the immediate supervisor of such employee. Decisions of other inspectors may be appealed to the circuit supervisor.

RECORDS AND REPORTS

§351.22 Certified plants to maintain records and make reports; access to records.

(a) Each day a certified plant prepares, receives, or ships certified technical animal fat or receives material for use in such product, the operator of the plant shall prepare records identifying the kinds and quantities of such materials and technical animal fats received, the number of pounds of certified technical animal fat prepared or shipped, and an up-to-date inventory of certified technical animal fats in storage. The operator of each certified plant shall include in the records required by this section all MP Forms 85 which he receives with shipments of certified technical animal fat from any other certified plant. These records shall be maintained by the operator of each certified plant and made available to an inspector, upon request, for examination and copying, for a period of 1 year after the date of the transaction involved.

(b) The operator of each certified plant shall provide such relevant information as any inspector may request to enable him to determine whether any technical animal fats are eligible for certification and whether the plant is eligible for certification service under the regulations in this part.

(Approved by the Office of Management and Budget under control number 0583–0036)

[40 FR 58627, Dec. 18, 1975, as amended at 47 FR 746, Jan. 7, 1982]

PART 352—EXOTIC ANIMALS; VOLUNTARY INSPECTION

Sec.

352.1 Definitions.
352.2 Type of service available.
352.3 Application by official exotic animal establishment for inspection service.
352.4 Application for ante-mortem inspection service in the field.
352.5 Fees and charges.
352.6 Denial or withrawal of inspection service.
352.7 Marking inspected products.
352.8 Time of inspection in the field and in an official exotic animal establishment.

352.9 Report of inspection work.
352.10 Ante-mortem inspection.
352.11 Post-mortem inspection.
352.12 Disposal of diseased or otherwise adulterated carcasses and parts.
352.13 Handling and disposal of condemned or other inedible exotic animal products at official exotic animal establishments.
352.14 Entry into official establishments; reinspection and preparation of products.
352.15 Records, registration and reports.
352.16 Exports.
352.17 Transportation.
352.18 Cooperation of States in Federal programs.

AUTHORITY: 7 U.S.C. 1622, 1624; 7 CFR 2.17 (g) and (i), 2.55.

SOURCE: 50 FR 41847, Oct. 16, 1985, unless otherwise noted.

§ 352.1 Definitions.

The definitions in § 301.2, not otherwise defined in this part, are incorporated into this part. In addition to those definitions, the following definitions will be applicable to the regulations in this part.

(a) *Act* means the applicable provisions of the Agricultural Marketing Act of 1946, as amended (60 Stat. 1087, as amended; 7 U.S.C. 1621 *et seq.*).

(b) *Acceptable* means suitable for the purpose intended and acceptable to the Food Safety and Inspection Service.

(c) *Antelope* means any animal belonging to the antelope family.

(d) *Applicant* means any interested party who requests any inspection service.

(e) *Bison* means any American bison or catalo or cattalo.

(f) *Buffalo* means any animal belonging to the buffalo family.

(g) *Catalo* or *Cattalo* means any hybrid animal with American bison appearance resulting from direct crossbreeding of American bison and cattle.

(h) *Condition* means any condition, including, but not limited to, the state of preservation, cleanliness, or soundness of any product or the processing, handling, or packaging which may affect such product.

(i) *Condition and wholesomeness* means the condition of any product, its healthfulness and fitness for human food.

(j) *Deer* means any member of the deer family.

(k) *Exotic animal* means any reindeer, elk, deer, antelope, water buffalo or bison.

(l) *Elk* means any American elk.

(m) *Exotic animal inspection service* means the personnel who are engaged in the administration, application, and direction of exotic animal inspection programs and services pursuant to the regulations in this part.

(n) *Exotic animal producer* means any interested party that engages in the raising and/or marketing of an exotic animal for commercial purposes.

(o) *Field ante-mortem inspection* means the ante-mortem inspection of an exotic animal away from the official exotic animal establishment's premises.

(p) *Field designated area* means any designated area on the applicant's premises, approved by the Regional Director, where field ante-mortem inspection is to be performed.

(q) *Identify* means to apply official identification to products or containers.

(r) *Inspection* means any inspection by an inspector to determine, in accordance with regulations in this part, (1) the condition and wholesomeness of an exotic animal, or (2) the condition and wholesomeness of edible product of an exotic animal at any state of the preparation or packaging in the official plant where inspected and certified, or (3) the condition and wholesomeness of any previously inspected and certified product of an exotic animal if such product has not lost its identity as an inspected and certified product.

(s) *Interested party* means any person financially interested in a transaction involving any inspection.

(t) *Official exotic animal establishment* means any slaughtering, cutting, boning, curing, smoking, salting, packing, rendering, or similar establishment at which inspection is maintained under the regulations in this part.

(u) *Official device* means a stamping appliance, branding device, stencil printed label, or any other mechanically or manually operated tool that is approved by the Administrator for the purpose of applying any official mark or other identification to any product or packaging material.

(v) *Official identification* means any symbol, stamp, label or seal indicating that the product has been officially inspected and/or indicating the condition of the product approved and authorized by the Administrator to be affixed to any product, or affixed to or printed on the packaging material of any product.

(w) *Program* means the Voluntary Exotic Animal Inspection Program of the Food Safety and Inspection Service.

(x) *Reindeer* means any reindeer commonly referred to as caribou.

(y) *Transport vehicle* means any vehicle used to transport an exotic animal.

(z) *Veterinarian* means an authorized veterinarian of the Program employed by the Department or any cooperating State who is authorized by the Secretary to do any work or perform any duty in connection with the Program.

(aa) *Water buffalo* means any Asiatic water buffalo, commonly referred to as carabao; and the water buffalo of India, commonly referred to as the Indian buffalo.

[54 FR 1330, Jan. 13, 1989]

§352.2 Type of service available.

Upon application, in accordance with §352.3, §352.4, and §352.5, the following type of service may be furnished under the regulations in this part:

(a) Voluntary Inspection Service. An inspection and certification service for wholesomeness relating to the slaughter and processing of exotic animals and the processing of exotic animal products. All provisions of this part shall apply to the slaughter of exotic animals, and the preparation, labeling, and certification of the exotic animal meat and exotic animal products processed under this exotic animal inspection service.

(b) Only exotic animals which have had ante–mortem inspection as described under this part and which are processed in official exotic animal establishments in accordance with this part may be marked inspected and passed.

(c) Exotic animals, exotic animal meat and meat food products shall be handled in an official exotic animal establishment to ensure separation and identity of the exotic animal or exotic animal meat and meat food products until they are shipped from the official exotic animal establishment to prevent commingling with other species.

[54 FR 1330, Jan. 13, 1989]

§352.3 Application by official exotic animal establishment for inspection services.

(a) Any person desiring to process an exotic animal, exotic animal carcasses, exotic animal meat and meat food products in an establishment under exotic animal inspection service must receive approval of such establishment and facilities as an official exotic animal establishment prior to the rendition of such service. An application for inspection service to be rendered in an official exotic animal establishment shall be approved in accordance with the provisions contained in §§304.1 and 304.2 of subchapter A of this chapter.

(b) Initial survey. When an application has been filed for exotic animal inspection service, the Regional Director or designee, shall examine the establishment, premises, and facilities.

[54 FR 1331, Jan. 13, 1989]

§352.4 Application for ante-mortem inspection service in the field.

Any exotic animal producer desiring field ante-mortem exotic animal inspection service must receive approval of the field ante-mortem designated area from the Regional Director or designee prior to the rendition of such service. An application seeking approval of the designated area for ante-mortem inspection shall be obtained from the Regional Director, and completed and submitted to the Regional Director.

(a) An initial application for field ante-mortem exotic animal inspection service shall be made by an official exotic animal establishment to the Regional Director. Subsequent requests shall be made by the official exotic animal establishment on behalf of an exotic animal producer to the Regional Director in one of the following manners: (1) telephone, (2) telegraph, (3) mail, or (4) in person as determined by the Regional Director.

(b) Upon receipt of the completed application, the Regional Director or designee shall examine the field ante-

mortem designated area and facilities for approval of the designated area.

(c) All fees involved for the approval of the designated area, including but not limited to any travel, per diem costs, and time required to perform such approval services, shall be paid directly by the applicant to the Regional Director.

[54 FR 1331, Jan. 13, 1989]

§ 352.5 Fees and charges.

(a) Fees and charges for service under the regulations in this part shall be paid by the applicant for the service in accordance with this section.

(b) The fees and charges provided for in this section shall be paid by check, draft, or money order payable to the ''Treasurer of the United States'' and shall be remitted promptly to the Regional Director upon furnishing to the applicant a statement as to the amount due.

(c) The fees to be charged and collected for service under the regulations in this part shall be at the rates specified in §§ 391.2, 391.3, and 391.4 respectively for base time; for overtime including Saturdays, Sundays, and holidays; and for certain laboratory services which are not covered under the base time, overtime, and/or holiday costs. Such fees shall cover the costs of the service and shall be charged for the time required to render such service, including, but not limited to, the time required for the travel of the inspector or inspectors in connection therewith during the regularly scheduled administrative workweek.

(d) Charges may also be made to cover other expenses incurred by the Service in connection with the furnishing of the service.

(e) Fees and charges for any inspection pursuant to a cooperative agreement with any State shall be paid in accordance with the terms of such cooperative agreement.

[50 FR 41847, Oct. 16, 1988, as amended at 53 FR 13398, Apr. 22, 1988; 54 FR 6390, Feb. 10, 1989]

§ 352.6 Denial or withdrawal of inspection service.

(a) *For miscellaneous reasons.* An application or a request for service may be rejected, or the benefits of the service may be otherwise denied to, or withdrawn from, any person, without a hearing by the appropriate Regional Director: (1) for administrative reasons such as the nonavailability of personnel to perform the service; (2) for the failure of payment for service; (3) in case the application or request relates to exotic animals or exotic animal products which are not eligible for service under this part; (4) for failure to maintain the designated area or the plant in a state of repair approved by the Service; (5) for the use of operating procedures which are not in accordance with the regulations of this part; (6) for alterations of buildings, facilities, or equipment which cannot be approved under the regulations in this part. Notice of such rejection, denial, or withdrawal, and the reasons therefore, shall promptly be given to the person involved. The applicant or recipient shall be notified of such decision to reject an application or request for service or to deny or withdraw the benefits of the service, and the reasons therefor, in writing in the manner prescribed in § 1.147(b) of the rules of practice (7 CFR 1.147(b)), or orally. Such decision shall be effective upon such oral or written notification, whichever is earlier, to the applicant or recipient. If such notification is oral, the person making such decision shall confirm such decision, and the reasons therefor, in writing, as promptly as circumstances permit, and such written confirmation shall be served upon the applicant or recipient in the manner prescribed in § 1.147(b) of the rules of practice (7 CFR 1.147(b)).

(b) *For disciplinary reasons—Basis for denial or withdrawal.* An application or request for service may be denied, or the benefits of the service may be withdrawn from, any person or entity who, or whose officer, employee or agent in the scope of his employment or agency: (1) Has willfully made any misrepresentation or has committed any other fraudulent or deceptive practice in connection with any application or request for service under this part; (2) has given or attempted to give, as a loan or for any other purpose, any money, favor or other thing of value, to any employee or agent of the Department

or a cooperating State authorized to perform any function under this part; (3) has interfered with or obstructed, or attempted to interfere with or to obstruct, any employee or agent of the Department or cooperating State in the performance of his or her duties under this part by intimidation, threats, assaults, abuse, or any other improper means; (4) has knowingly represented that any exotic animal carcass, or exotic animal product, has been officially inspected and passed by an authorized inspector under this part, when it had not, in fact, been so inspected; (5) has been convicted of more than one misdemeanor under any law based upon the acquiring, handling, or distributing of adulterated, mislabeled, or deceptively packaged good, or fraud in connection with transactions in food, or any felony; *Provided*, an application or a request for service made in the name of a person or entity otherwise eligible for service under the regulations may be denied, or the benefits of the service may be withdrawn, from such a person or entity in case the service is or would be performed at a location operated by a person or entity, from whom the benefits of the service are currently being denied or have been withdrawn under this part; or by a person or entity having an officer, director, partner, manager or substantial investor from whom the benefits of service under this part are currently being denied or have been withdrawn under this part, and who has any authority with respect to the location where service is or would be performed; or in case the service is or would be performed with respect to any exotic animal or exotic animal product in which any person or entity, from whom the benefits of service are currently being denied or have been withdrawn under this part, has contract or other financial interest.

(c) *Procedure.* (1) An application or request for service may be denied or benefits of the service may be withdrawn by the Secretary, as provided by paragraph (b) of this section, after notice and opportunity for hearing before a designated official of the Department. The Administrator may suspend service under this paragraph without hearing, pending final determination of the matter, when he determines that the public health, interest or safety so requires. The applicant or recipient shall be notified of the Administrator's decision to suspend service, and the reasons therefor, in writing or orally. The Administrator's decision to suspend service under this part shall be effective upon such an oral or written notification, whichever is earlier, to the applicant or recipient. If such notification is oral, the Administrator shall confirm such decision, and the reasons therefor, in writing, as promptly as circumstances permit, and such written confirmation shall be served upon the applicant or recipient in the manner prescribed in 1.147(b) of Departmental rules of practice (7 CFR 1.147(b)).

(2) The written notification specified in paragraph (c) of this section, which shall constitute the complaint in the proceeding, shall briefly set forth the reason for the denial or withdrawal of service, including allegations of fact which constitute a basis for the action. After the complaint is served upon the respondent, as provided in §1.147(b) of Departmental rules of practice (7 CFR 1.147(b)), the proceeding shall thereafter be conducted in accordance with rules of practice which shall be adopted for the proceeding.

[50 FR 41847, Oct. 16, 1985, as amended at 54 FR 1331, Jan. 13, 1989]

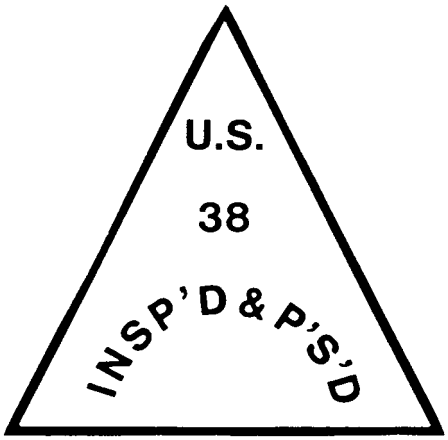
§352.7 Marking inspected products.

Wording and form of inspection mark. Except as otherwise authorized by the Administrator, the inspection mark applied to inspected and passed exotic animal carcasses, meat or meat food products under this part shall include wording as follows: ''Inspected and Passed by U.S. Department of Agriculture.'' This wording shall be contained within a triangle in the form and arrangement shown in this section. The establishment number of the official establishment shall be included in the triangle unless it appears elsewhere on the packaging material. Ordering and manufacture of the triangle brand shall be in accordance with the provisions in 9 CFR 317.3(c) of the Federal meat inspection regulations. The Administrator may approve the use of abbreviations of such inspection mark, and such approved abbreviations shall

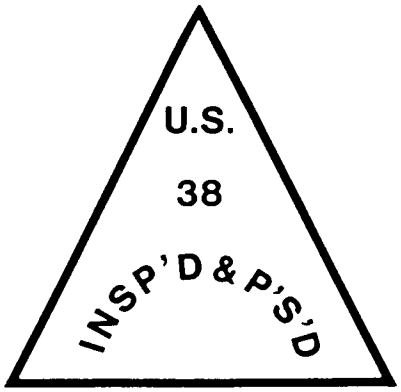
have the same force and effect as the inspection mark. The inspection mark or approved abbreviation shall be applied, under the supervision of the inspector, to the inspected and passed edible product, packaging material, immediate container or shipping container. When the inspection mark or approved abbreviation is used on packaging material, immediate container or shipping container, it shall be printed on such material or container or on a label to be affixed to the packaging material or container. The name and address of the packer or distributor of such product shall be printed on the packaging material or label. The inspection marks may be stenciled on the container, and when the inspection mark is so stenciled, the name and address of the packer or distributor may be applied by the use of a stencil or rubber stamp. The name and address of the packer or distributor, if prominently shown elsewhere on the packaging material or container, may be omitted from insert labels which bear an official identification if the applicable establishment number is shown.

(a) The inspection mark to be applied to inspected and passed carcasses and parts of carcasses of an exotic animal, and products as therefrom approved by the Administrator, shall be in the form and arrangement as indicated in the example below.[1] The establishment number of the official establishment shall be set forth if it does not appear on the packaging material or container.

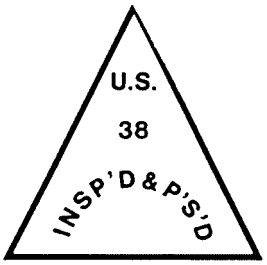
(1) For application to exotic animal carcasses, primal parts and cuts therefrom, exotic animal livers, exotic animal tongues, and exotic animal hearts.



(2) For application to exotic animal calf carcasses.

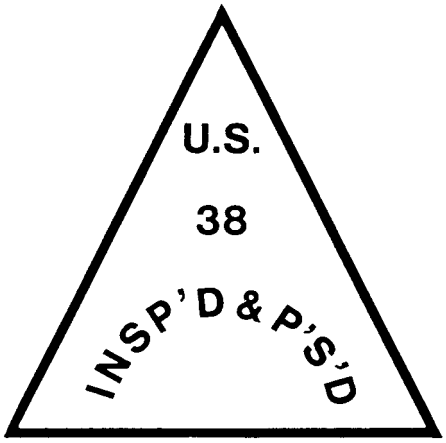


(3) For application to exotic animal tails.

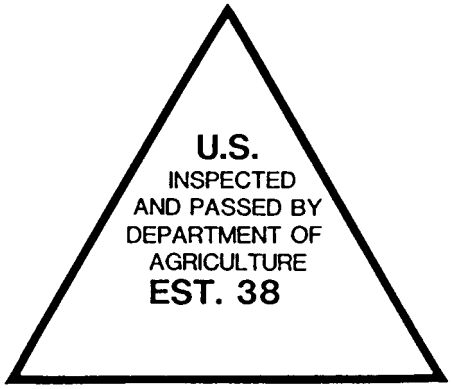


[1] The number ''38'' is given as an example only. The establishment number of the official exotic animal establishment where the product is prepared shall be used in lieu thereof.

(4) For application to burlap, muslin, cheesecloth, heavy paper, or other acceptable material that encloses carcasses or parts of carcasses.



(b) The official inspection mark to be shown on all labels.[1] (1) For inspected and passed products of an exotic animal shall be in the following form, except that it need not be of the size illustrated, provided that it is a sufficient size and of such color as to be conspicuously displayed and readily legible and the same proportions of letter size and boldness are maintained as illustrated:



[1] The number ''38'' is given as an example only. The establishment number of the official exotic animal establishment where the product is prepared shall be used in lieu thereof.

(2) This official mark shall be applied by mechanical means and shall not be applied by a hand stamp.

(3) The official inspection legend described in paragraph (b)(1) of this section shall also be used on shipping containers, bond labels, artificial casings, and other articles with the approval of the Administrator.

(c) Any brand, stamp, label or other device approved by the Administrator and bearing any official mark prescribed in paragraph (a) or (b) of this section shall be an official device for purposes of the Act.

[50 FR 41847, Oct. 16, 1985, as amended at 54 FR 1331, Jan. 13, 1989]

§352.8 Time of inspection in the field and in an official exotic animal establishment.

The official exotic animal establishment on behalf of the applicant shall notify the Regional Director or designee, in advance, of the hours when such inspection is desired. Inspection personnel shall have access at all times to every part of any field ante-mortem inspection area and/or official exotic animal establishment to which they are assigned.

[54 FR 1332, Jan. 13, 1989]

§352.9 Report of inspection work.

Reports of the work of inspection carried on within the field ante-mortem inspection area of an exotic animal producer's premises and/or official exotic animal establishment shall be forwarded to the Administrator by the ante-mortem inspector. The applicant for such inspection shall furnish to the Administrator such information as may be required on forms provided by the Administrator.

[54 FR 1333, Jan. 13, 1989]

§352.10 Ante-mortem inspection.

An ante-mortem inspection of an exotic animal shall, where and to the extent considered necessary by the Administrator and under such instructions as he may issue from time to time, be made on the day of slaughter of an exotic animal, in one of the following listed ways or as determined by the Administrator. Humane handling of an exotic animal during ante-

mortem inspection shall be in accordance with the provisions contained in 9 CFR 313.2. Immediately after the animal is stunned or killed, it shall be shackled, hoisted, stuck and bled.

(a) To be performed on an exotic animal in the field in a designated area of an exotic animal producer's premises.

(1) Reindeer, elk, deer, antelope, bison and water buffalo are eligible for field ante-mortem inspection. The field ante-mortem designated area must be approved by the Regional Director or designee prior to rendition of the service.

(2) Any person who desires to receive field ante-mortem inspection must provide:

(i) Notification from an official exotic animal establishment to the Regional Director or designee.

(ii) A field ante-mortem designated area.

(iii) A stunning/slaughtering area which is in a condition that minimizes the possibility of soiling the animal when stunned/slaughtered and bled as determined by the inspector.

(iv) A transport vehicle that is as sanitary as practicable as determined by the inspector.

(3) The ante-mortem inspector shall determine the acceptableness and safety of performing field ante-mortem inspection. If, in the opinion of the ante-mortem inspector, an unsafe circumstance exists at the time of field ante-mortem inspection, the service shall be denied.

(4) An exotic animal that, in the ante-mortem inspector's opinion, does not pass ante-mortem inspection must be withheld from slaughter.

(5) Stunning to render the animal unconscious shall be in accordance with 9 CFR 313.15 or 313.16.

(6) All stunned/slaughtered and bled exotic animals shall be tagged with a ''U.S. Suspect'' tag in an ear by the ante-mortem inspector or designee prior to loading on the transport vehicle.

(7) The transport of intact exotic animal carcasses to an official exotic animal establishment for post-mortem inspection shall be as expedient as possible, and must be within the same day as field slaughter.

(8) Ante-mortem cards (Form MP 402–2) shall be filled out by the ante-mortem inspector. One copy is to be retained by the ante-mortem inspector. The other copy shall accompany the transport vehicle to the official exotic animal establishment and shall be delivered to the post-mortem veterinarian.

(9) The ante-mortem inspector shall supervise all phases of field ante-mortem inspection.

(b) To be performed on exotic animals that are inside of the transport vehicle at an official exotic animal establishment.

(1) Reindeer, elk, deer, antelope, bison, and water buffalo are eligible for transport vehicle inspection.

(2) The ante-mortem inspector shall remain outside the transport vehicle while performing ante-mortem inspection.

(3) The person requesting transport vehicle inspection must provide a transport vehicle that is as sanitary as practicable and that would safely and thoroughly permit the inspection of an exotic animal from outside of the transport vehicle as determined by the inspector.

(4) The ante-mortem inspector shall determine the adequacy and safety of performing ante-mortem inspection. If, in the ante-mortem inspector's opinion, the transport vehicle is not adequate or safe to perform ante-mortem inspection, the service shall be denied.

(c) To be performed in pens at official exotic animal establishments. The inspection shall be conducted in accordance with the provisions contained in 9 CFR part 309.

[54 FR 1333, Jan. 13, 1989]

§ 352.11 Post-mortem inspection.

(a) Post-mortem inspection of reindeer, elk, deer, antelope, bison and water buffalo shall be conducted in accordance with the provisions contained in 9 CFR part 310 or as determined by the Administrator.

(b) The post-mortem examination of field ante-mortem-inspected exotic animals must occur in the shortest length of time practicable and on the day that field ante-mortem inspection is performed to minimize the changes in the carcass which can affect the post-

mortem examination, disposition and wholesomeness of the carcass and its parts.

(c) The post-mortem veterinarian shall inspect and make the disposition of all incoming ''U.S. Suspect'' tagged exotic animals.

[54 FR 1333, Jan. 13, 1989]

§ 352.12 Disposal of diseased or otherwise adulterated carcasses and parts.

This shall be conducted in accordance with the provisions contained in 9 CFR part 311.

§ 352.13 Handling and disposal of condemned or other inedible exotic animal products at official exotic animal establishments.

This shall be conducted in accordance with the provisions contained in 9 CFR part 314.

§ 352.14 Entry into official establishments; reinspection and preparation of products.

This shall be conducted in accordance with the provisions contained in 9 CFR 318.1, 318.2, and 318.3.

§ 352.15 Records, registration, and reports.

This shall be conducted or maintained in accordance with the provisions contained in 9 CFR 320.1 through 320.7.

§ 352.16 Exports.

This shall be conducted in accordance with the provisions contained in 9 CFR 322.1 through 322.5.

§ 352.17 Transportation.

This shall be conducted in accordance with the provisions contained in §§ 325.1 through 325.21.

§ 352.18 Cooperation of States in Federal programs.

Under the ''Talmadge-Aiken Act'' of September 28, 1962 (7 U.S.C. 450), the Administrator is authorized to utilize employees and facilities of States in carrying out Federal functions.

PART 354—VOLUNTARY INSPECTION OF RABBITS AND EDIBLE PRODUCTS THEREOF

GENERAL

Sec.
354.1 Definitions.
354.2 Designation of official certificates, memoranda, marks, other identifications, and devices for purposes of the Agricultural Marketing Act.

ADMINISTRATION

354.3 Administration.

BASIS OF SERVICE

354.10 Inspection service.
354.12 Eligibility.
354.13 Supervision.
354.14 Authority to waive provisions of § 354.12.

PERFORMANCE OF SERVICES

354.20 Licensed or authorized inspectors.
354.21 Suspension of license; revocation.
354.22 Surrender of license.
354.23 Identification.
354.24 Financial interest of inspectors.
354.25 Political activity.
354.26 Schedule of operation of official plants.

APPLICATION FOR INSPECTION SERVICE

354.30 Who may obtain inspection service.
354.31 How application for service may be made; conditions of resident service.
354.32 Filing of application.
354.33 Authority of applicant.
354.34 Application for inspection service in official plants; approval.
354.35 Rejection of application.
354.36 Withdrawal of application.
354.38 Suspension of plant approval.

VIOLATIONS

354.45 Denial of service.
354.46 Misrepresentation; deceptive or fraudulent acts or practices.
354.47 Use of facsimile forms.
354.48 Willful violation of the regulations.
354.49 Interfering with an inspector or employee of Service.
354.51 Miscellaneous.

OTHER APPLICABLE REGULATIONS

354.53 Other applicable regulations.

IDENTIFYING AND MARKING PRODUCTS

354.60 Approval of official identification.
354.62 Inspection mark with respect to product.
354.63 Marking inspected products.
354.64 Form of official identification.

354.65 Form of inspection mark.

SUPERVISION OF MARKING AND PACKAGING

354.70 Evidence of label approval.
354.71 Affixing of official identification.
354.72 Packaging.
354.73 Retention labels.
354.74 Prerequisites to inspection.
354.75 Accessibility of products.
354.76 Time of inspection in an official plant.

REPORTS

354.90 Report of inspection work.
354.91 Information to be furnished to inspectors.
354.92 Reports of violations.

FEES AND CHARGES

354.100 Payment of fees and charges.
354.101 On a fee basis.
354.105 Fees for additional copies of inspection certificates.
354.106 Travel expenses and other charges.
354.107 Continuous inspection performed on a resident basis.
354.109 Fees or charges for inspection service performed under cooperative agreement.
354.110 Disposition of fees for inspection made under cooperative agreement.

INSPECTION PROCEDURES; ANTE-MORTEM INSPECTIONS

354.120 Manner of handling products in an official plant.
354.121 Ante-mortem inspection.
354.122 Condemnation on ante-mortem inspection.
354.123 Segregation of suspects on ante-mortem inspection.
354.124 Quarantine of diseased rabbits.

POST-MORTEM INSPECTION

354.125 Evisceration.
354.126 Carcasses held for further examination.
354.127 Condemnation and treatment of carcasses.
354.128 Certification of carcasses.

DISPOSITION OF DISEASED RABBIT CARCASSES AND PARTS

354.129 General.
354.130 Diseases or conditions evident which require condemnation.
354.131 Decomposition.
354.132 Disposal of condemned carcasses and parts.

REINSPECTION AND INGREDIENTS

354.133 Reinspection of edible products; ingredients.

APPEALS

354.134 Appeal inspections; how made.

INSPECTION CERTIFICATES

354.140 Forms of inspection certificates.
354.141 Issuance and disposition of rabbits inspection certificates.
354.142 Food product inspection certificates; issuance and disposition.
354.143 Export certificates; issuance and disposition.
354.144 Advance information.

BASIS OF ACCEPTABILITY OF OTHER OFFICIAL INSPECTION SYSTEMS

354.160 General.
354.161 Requirements as to manner of inspection.
354.162 Determining compliance with § 354.161.

SANITARY REQUIREMENTS

GENERAL

354.210 Minimum standards for sanitation, facilities, and operating procedures in official plants.

BUILDINGS AND PLANT FACILITIES

354.220 Buildings.
354.221 Rooms and compartments.
354.222 Floors, walls, ceilings, etc.
354.223 Drainage and plumbing.
354.224 Water supply.
354.225 Lavatory accommodations.
354.226 Lighting and ventilation.

EQUIPMENT AND UTENSILS

354.230 Equipment and utensils.
354.231 Accessibility.
354.232 Restrictions on use.

MAINTENANCE OF SANITARY CONDITIONS AND PRECAUTIONS AGAINST CONTAMINATION OF PRODUCTS

354.240 General.
354.241 Cleaning of rooms and compartments.
354.242 Cleaning of equipment and utensils.
354.243 Operations and procedures.
354.244 Temperatures and cooling and freezing procedures.
354.245 Vermin.
254.246 Exclusion of diseased persons.
354.247 Table showing types of materials.
354.248 Scope and applicability of rules of practice.

AUTHORITY: 7 U.S.C. 1622, 1624; 7 CFR 2.17 (g) and (i), 2.55.

SOURCE: 41 FR 23702, June 11, 1976, unless otherwise noted.

GENERAL

§354.1 Definitions.

Unless the context otherwise requires, the following terms shall have the following meaning:

(a) *Act* means the applicable provisions of the Agricultural Marketing Act of 1946 (60 Stat. 1087; 7 U.S.C. 1621 et seq.) or any other act of Congress conferring like authority.

(b) *Acceptable* means suitable for the purpose intended and acceptable to the Service.

(c) *Administrator* means the Administrator of the Food Safety and Inspection Service of the Department or any other officer or employee of the Department to whom there has heretofore been delegated, or to whom there may hereafter be delegated the authority to act in his stead.

(d) *Applicant* means any interested party who requests any inspection service.

(e) *Area supervisor* means any employee of the Department in charge of rabbit inspection service in a designated geographical area.

(f) *Carcass* means any rabbit carcass.

(g) *Circuit supervisor* or *technical supervisor* means the officer in charge of the rabbit inspection service in a circuit consisting of a group of stations within an area.

(h) *Class* means any subdivision of a product based on essential physical characteristics that differentiate between major groups of the same kind.

(i) *Condition* means any condition, including, but not being limited to, the state of preservation, cleanliness, or soundness, of any product or the processing, handling, or packaging which may affect such product.

(j) *Condition and wholesomeness* means the condition of any product, its healthfulness and fitness for human food.

(k) *Department* means the United States Department of Agriculture.

(l) *Edible product* means any product derived from ready-to-cook domestic rabbits.

(m) *Giblets* means the liver from which the bile sac has been removed and the heart from which the pericardial sac has been removed.

(n) *Holiday* or *legal holiday* shall mean the legal public holidays specified by the Congress in paragraph (a) of section 6103, Title 5, of the United States Code.

(o) *Identify* means to apply official identification to products or to containers thereof.

(p) *Inspected and certified* or *certified* means, with respect to any product, that it has undergone an inspection and was found, at the time of such inspection, to be sound, wholesome, and fit for human food.

(q) *Inspection, inspection service,* or *inspection of products for condition and wholesomeness* means any inspection by an inspector to determine, in accordance with the regulations in this part, (1) the condition and wholesomeness of rabbits, or (2) the condition and wholesomeness of any edible product at any state of the preparation or packaging thereof in the official plant where inspected and certified, or (3) the condition and wholesomeness of any previously inspected and certified product if such product has not lost its identity as an inspected and certified product.

(r) *Inspection certificate* means a statement, either written or printed, issued by an inspector, pursuant to the regulations in this part, relative to the condition and wholesomeness of products.

(s) *Inspector* means any person who is licensed by the Secretary to investigate and certify, in accordance with the regulations in this part, the condition and wholesomeness of products. An inspector is an employee of the Department or of a State; he may be a graduate veterinarian or a layman.

(t) *Interested party* means any person financially interested in a transaction involving any inspection.

(u) *National supervisor* means (1) the officer in charge of the rabbit inspection service of the Food Safety and Inspection Service, and (2) other officers or employees of the Department designated by the officer in charge of the rabbit inspection service of the Food Safety and Inspection Service.

(v) *Official plant* means one or more buildings or parts thereof, comprising a single plant in which the facilities and methods of operation therein have been

approved by the Administrator as suitable and adequate for operation under inspection service and in which inspection is carried on in accordance with the regulations in this part.

(w) *Person* means any individual, partnership, association, business trust, corporation, or any organized group of persons, whether incorporated or not.

(x) *Potable water* means water that has been approved by the State health authority as safe for drinking and suitable for food processing.

(y) *Product* means ready-to-cook cooked rabbits, or edible products derived therefrom.

(z) *Rabbit* means any domesticated rabbit, whether live or dead.

(aa) *Rabbit inspection service* means the personnel who are engaged in the administration, application, and direction of rabbit inspection programs and services pursuant to the regulations in this part.

(bb) *Ready-to-cook domestic rabbit* means any rabbit which has been slaughtered for human food, from which the head, blood, skin, feet, and inedible viscera have been removed, that is ready to cook without need of further processing. Ready-to-cook rabbit also means any cut-up or disjointed portion of rabbit or any edible part thereof, as described in this paragraph.

(cc) *Regulations* means the provisions of this entire part as may be in effect at the time inspection is performed.

(dd) *Secretary* means the Secretary of the Department, or any other officer or employee of the Department to whom there has heretofore been delegated, or to whom there may hereafter be delegated, the authority to act in his stead.

(ee) *Service* means the Food Safety and Inspection Service of the Department.

(ff) *Station supervisor* means any authorized individual who is designated to supervise rabbit inspection service in a large official plant or in a group of several small plants.

§ 354.2 Designation of official certificates, memoranda, marks, other identifications, and devices for purposes of the Agricultural Marketing Act.

Subsection 203(h) of the Agricultural Marketing Act of 1946, as amended by Pub. L. 272, 84th Congress, provides criminal penalties for various specified offenses relating to official certificates, memoranda, marks or other identifications, and devices for making such marks or identifications, issued or authorized under section 203 of said Act, and certain misrepresentations concerning the inspection of agricultural products under said section. For the purposes of said subsection and the provisions in this part, the terms listed in this section shall have the respective meanings specified:

(a) *Official certificate* means any form of certification, either written or printed, used under this part to certify with respect to the inspection or class or condition of products.

(b) *Official memorandum* means any initial record of findings made by an authorized person in the process of inspecting or sampling, pursuant to this part, any processing or plant operation report made by an authorized person in connection with inspecting or sampling under this part, and any report made by an authorized person of services performed pursuant to this part.

(c) *Official mark* means the inspection mark, and any other mark, or any variations in such marks, approved by the Administrator and authorized to be affixed to any product, or affixed to or printed on the packaging material of any product, stating that the product was inspected, or indicating the condition of the product, or for the purpose of maintaining the identity of products inspected under this part, including, but not limited to, that set forth in § 354.65.

(d) *Official identification* means any symbol, stamp, label, or seal indicating that the product has been officially inspected and/or indicating the class or condition of the product approved by the Administrator and authorized to be affixed to any product, or affixed to or printed on the packaging material of any product.

(e) *Official device* means a stamping appliance, branding device, stencil, printed label, or any other mechanically or manually operated tool that is approved by the Administrator for the purpose of applying any official mark or other identification to any product or the packaging material thereof.

ADMINISTRATION

§354.3 Administration.

The Administrator shall perform, for and under the supervision of the Secretary, such duties as are prescribed in the regulations in this part and as the Secretary may require in the administration of the regulations in this part. The Administrator is authorized to waive for limited periods any particular provisions of the regulations to permit experimentation so that new procedures, equipment, and processing techniques may be tested to facilitate definite improvements and, at the same time, to assure full compliance with the spirit and intent of the regulations. The Food Safety and Inspection Service and its officers and employees shall not be liable in damages through acts of commission or omission in the administration of this part.

BASIS OF SERVICE

§354.10 Inspection service.

Any inspection service in accordance with the regulations in this part shall be for condition and wholesomeness.

§354.12 Eligibility.

(a) Only rabbits which are processed in official plants in accordance with the regulations in this part may be inspected.

(b) All rabbits that are eviscerated in an official plant where inspection service is maintained shall be inspected for condition and wholesomeness and no dressed rabbits or uninspected products shall be brought into such official plant.

§354.13 Supervision.

All inspection service shall be subject to supervision at all times by the station supervisor, circuit supervisor, area supervisor, and national supervisor. Such service shall be rendered where the facilities and conditions are satisfactory for the conduct of the service and the requisite inspectors are available.

§354.14 Authority to waive provisions of §354.12.

The Administrator is authorized to waive the provisions of §354.12 which pertain to the entry of uninspected edible products into official plants in specific instances where rabbits are to be brought into compliance with a law under the provisions of a court order. Such rabbits shall be handled in an official plant in accordance with such procedures as the Administrator may prescribe to insure proper segregation and identity of the rabbits or rabbit products until they are shipped from the official plant.

PERFORMANCE OF SERVICES

§354.20 Licensed or authorized inspectors.

(a) Any person who is a Federal or State employee or the employee of a local jurisdiction possessing proper qualifications as determined by an examination for competency, and who is to perform inspection service under this part may be licensed or otherwise authorized by the Secretary as an inspector.

(b) All licenses issued by the Secretary shall be countersigned by the officer in charge of the rabbit inspection service of the Animal and Plant Health Inspection Service or any other designated officer of such Service.

§354.21 Suspension of license; revocation.

Pending final action by the Secretary, any person authorized to countersign a license to perform inspection service may, whenever he deems such action necessary to assure that any inspection service is properly performed, suspend any license to perform inspection service issued pursuant to this part, by giving notice of such suspension to the respective licensee, accompanied by a statement of the reasons therefor. Within 7 days after the receipt of the aforesaid notice and statement of reasons, the licensee may file an appeal in writing, with the Secretary, supported by any argument or evidence that he may wish to offer as to why his license should not be further suspended or revoked. After the expiration of the aforesaid 7–day period and consideration of such argument and evidence, the Secretary will take such action as he deems appropriate

with respect to such suspension or revocation. When no appeal is filed within the prescribed 7 days, the license to perform inspection service is revoked.

§ 354.22 Surrender of license.

Each license which is suspended, or revoked, or has expired shall promptly be surrendered by the licensee to his immediate superior. Upon termination of the services of a licensed inspector, the licensee shall promptly surrender his license to his immediate superior.

§ 354.23 Identification.

Each inspector shall have in his possession at all times, and present upon request while on duty, the means of identification furnished by the Department to such person.

§ 354.24 Financial interest of inspectors.

No inspector shall render service on any product in which he is financially interested.

§ 354.25 Political activity.

All inspectors are forbidden, during the period of their respective appointments or licenses, to take an active part in political management or in political campaigns. Political activity in city, county, State, or national elections, whether primary or regular, or in behalf of any party or candidate, or any measure to be voted upon, is prohibited. This applies to all appointees, including, but not being limited to, temporary and cooperative employees and employees on leave of absence with or without pay. Willful violation of §§ 354.20 to 354.25 will constitute grounds for dismissal in the case of appointees and revocation of licenses in the case of licensees.

§ 354.26 Schedule of operation of official plants.

Inspection operating schedules for services performed pursuant to § 354.107 shall be requested in writing and be approved by the Administrator. Normal operating schedules for a full week consist of a continuous 8-hour period per day (excluding not to exceed 1 hour for lunch), 5 consecutive days per week, within the period of Monday through Saturday, for each shift required. Less than 8-hour schedules may be requested and will be approved if an inspector is available. Sundays may not be approved in any tour of duty. Clock hours of daily operations need not be specified in the request, although as a condition of continued approval, the hours of operation shall be reasonably uniform from day to day. Inspectors are to be notified by management 1 day in advance of any change in the hours inspection service is requested.

APPLICATION FOR INSPECTION SERVICE

§ 354.30 Who may obtain inspection service.

An application for inspection service may be made by any interested person, including, but not being limited to, the United States, any State, county, municipality, or common carrier, and any authorized agent of the foregoing.

§ 354.31 How application for service may be made; conditions of resident service.

(a) On a fee basis. An application for any inspection service on a fee basis may be made in any office of inspection or with any inspector at or nearest the place where the service is desired. Such application may be made orally (in person or by telephone), in writing, or by telegraph. If the application for inspection service is made orally, the office of inspection or the inspector with whom the application is made, or the Administrator, may require that the application be confirmed in writing.

(b) On a resident inspection basis. An application for resident inspection service must be made in writing on forms approved by the Administrator and filed with the Administrator. Such forms may be obtained at the national, area, or State inspection office. In making application, the applicant agrees to comply with the terms and conditions of the regulations (including, but not being limited to, such instructions governing inspection of products as may be issued from time to time by the Administrator). No member of or delegate to Congress or Resident Commissioner shall be admitted to any benefit that may arise from such service unless derived through

service rendered a corporation for its general benefit.

§354.32 Filing of application.

An application for inspection service shall be regarded as filed only when made pursuant to the regulations in this part.

§354.33 Authority of applicant.

Proof of the authority of any person applying for inspection service may be required at the discretion of the Administrator.

§354.34 Application for inspection service in official plants; approval.

Any person desiring to process and pack products in a plant under inspection service must receive approval of such plant and facilities as an official plant prior to the rendition of such service. An application for inspection service to be rendered in an official plant shall be approved according to the following procedure:

(a) Initial survey. When application has been filed for inspection service as aforesaid, the area supervisor, or his assistant, shall examine the plant, premises, and facilities and shall specify any additional facilities required for the service. Appeals with respect to any such specification may be made to the national supervisor.

(b) Drawings and specifications to be furnished in advance of construction or alterations.

(1) Four copies of drawings or blueprints showing the features specified herein shall be submitted to the Administrator. The drawings or blueprints shall be legible, made with sharp, clear lines, and properly drawn to scale, and shall consist of floor plans and a plot plan.

(2) The plot plan shall show such features as the limits of the plant's premises, locations in outline of buildings on the premises, one point of the compass, and roadways and railroads serving the plant.

(3) The floor plan shall show all space to be included in the official plant. If rooms or compartments shown on the drawings or blueprints are not to be included as part of the official plant, this shall be clearly indicated thereon.

(4) The sheets of paper on which drawings or blueprints are made shall not exceed a size 34″ × 44″. The drawings other than of the plot plan shall be made to a scale of ⅛″ per foot, except that additional plans for some areas showing detail may be drawn to a scale of ¼″ per foot. The plot plan may be drawn to a scale of not less than 1/32″ per foot. The drawings shall indicate the scale used and shall also indicate the floor shown (e.g., basement, first, or second).

(c) Features required to be shown on floor plan. The following features shall be shown on the floor plan:

(1) The principal pieces of equipment drawn to scale in the proper locations.

(2) The name of the firm and the address of the plant by street and street number, or by other means properly identifying the location of the plant.

(3) One point of the compass.

(4) The doors and openings for passageways, designating those which are self-closing or permanently closed.

(5) All floor drain openings and gutter drains.

(6) Lavatories in toilet and processing rooms (lavatories which are other than hand-operated shall be so designated on the drawings or blueprints).

(7) All steam and hot and cold water outlets for cleanup purposes.

(8) Ice-making and storage facilities.

(9) The point at which live rabbits are hung on the conveyor line, the point at which the ready-to-cook rabbits are removed, and any intermediate transfer points.

(10) The routes of the edible and inedible products.

(11) The location of fresh air inlets, exhaust fans, and hoods.

(d) Specifications. Specifications covering the following items shall accompany the drawings:

(1) Height of ceilings.

(2) Type of ceilings—open or closed.

(3) Finish of ceilings; for example—cement plaster, metal, marine plywood, cement, asbestos board, etc.

(4) Finish of walls; for example—cement plaster, glazed tile, glaze brick, glass blocks, etc.

(5) Screens—indicate whether all outside openings are screened or provided

with other suitable devices against entrance of flies or other insects.

(6) Finish of floors—concrete, brick, mastic material, etc.

(7) Drainage—indicate the amount of slope of floors to the drains in processing rooms, coolers, toilets, and refuse rooms, and give description of trapping and venting of drainage lines and of floor drain openings. Indicate size of drainage lines and whether house drainage lines and toilet soil lines are separate to a point outside of buildings.

(8) Heating—indicate type.

(9) Water supply—indicate whether public or private water supply, or both, and specify in terms of gallons of water available per minute for the processing needs of the plant. Also indicate whether or not a nonpotable water supply is used for any purpose in the plant and, if so, specify such uses.

(10) Hot water facilities—specify facilities such as boilers, storage tanks, mixing valves, etc., and indicate the size and number of boilers and storage tanks.

(11) Specify number of men and number of women who will use each toilet room.

(12) Sewage disposal—indicate whether city sewer, cesspool, sedimentation tank, etc.

(13) Approximate rate of production—indicate hourly rate of slaughter and evisceration for rabbits.

(e) Rooms and compartments which must be included in the official plant. The official plant shall include employees' toilet and dressing rooms, office space for the inspectors, storerooms for supplies, refuse rooms, and rooms, compartments, or passageways where rabbits or any ingredients to be used in the preparation of products under inspection will be handled or kept. It also may include other rooms or compartments located in the buildings comprising the official plant.

(f) Changes in drawings or blueprints. When changes are proposed in areas for which drawings or blueprints have been previously approved, one of the following types of revised drawings or blueprints shall be submitted for review and consideration.

(1) A completely revised sheet or sheets showing proposed alterations or additions, or

(2) Approved pasters of the proposed changes which may be affixed to the affected areas on the previously approved drawings or blueprints in a manner not obscuring essential data. Paster drawings and blueprints shall be prepared to the same scale and presented on a background similar to that of the originally approved drawing or blueprint.

(g) Final survey and plant approval. Prior to the inauguration of the inspection service, a final survey of the plant and premises shall be made by the area supervisor or his assistant to determine if the plant is constructed and facilities are installed in accordance with the approved drawings and the regulations in this part. The plant may be approved by the Administrator only when these requirements have been met, except that conditional approval for a specified limited time may be granted only under emergency conditions of restricted availability of facilities and construction materials, provided practices suitable to the Administrator are employed to effect adequate sanitary conditions in the plant.

(Approved by the Office of Management and Budget under control number 0583–0036)

[41 FR 23702, June 11, 1976, as amended at 47 FR 746, Jan. 7, 1982]

§ 354.35 Rejection of application.

Any application for inspection service may be rejected by the Administrator:

(a) Whenever the applicant fails to meet the requirements of the regulations prescribing the conditions under which the service is made available;

(b) Whenever the product is owned by or located on the premises of a person currently denied the benefits of the Act;

(c) Where any individual holding office or a responsible position with or having a substantial financial interest or share in the applicant is currently denied the benefits of the Act or was responsible in whole or in part for the current denial of the benefits of the Act to any person;

(d) Where the Administrator determines that the application is an attempt on the part of a person currently denied the benefits of the Act to obtain inspection service;

(e) Whenever the applicant, after an initial survey has been made in accordance with §354.34(a), fails to bring the plant, facilities, and operating procedures into compliance with the regulations within a reasonable period of time; or

(f) Notwithstanding any prior approval whenever, before inauguration of service, the applicant fails to fulfill commitments concerning the inauguration of the service. Each such applicant shall be promptly notified by registered mail of the reasons for the rejection. A written petition for reconsideration of such rejection may be filed by the applicant with the Administrator if postmarked or delivered within 10 days after the receipt of notice of the rejection. Such petition shall state specifically the errors alleged to have been made by the Administrator in rejecting the application. Within 20 days following the receipt of such a petition for reconsideration, the Administrator shall approve the application or notify the applicant by registered mail of the reasons for the rejection thereof.

§354.36 Withdrawal of application.

Any application for inspection service may be withdrawn by the applicant at any time before the service is performed upon payment, by the applicant, of all expenses incurred by the Service in connection with such application.

§354.38 Suspension of plant approval.

(a) Any plant approval given pursuant to the regulations in this part may be suspended by the Administrator for:

(1) Failure to maintain plant and equipment in a satisfactory state of repair;

(2) The use of operating procedures which are not in accordance with the regulations in this part; or

(3) Alterations of buildings, facilities, or equipment which cannot be approved in accordance with the regulations in this part.

(b) During such period of suspension, inspection service shall not be rendered. However, the other provisions of the regulations pertaining to providing service on a resident basis will remain in effect unless such service is terminated in accordance with the provisions of this part. If the plant facilities or methods of operation are not brought into compliance within a reasonable period of time, to be specified by the Administrator, the service shall be terminated. Upon termination of inspection service in an official plant pursuant to the regulations in this part, the plant approval shall also become terminated, and all labels, seals, tags or packaging material bearing official identification shall, under the supervision of a person designated by the Service, either be destroyed, or the official identification completely obliterated, or sealed in a manner acceptable to the Service.

VIOLATIONS

§354.45 Denial of service.

(a) The acts or practices set forth in §§354.46 through 354.51 or the causing thereof may be deemed sufficient cause, for the debarment, by the Secretary, of any person, including any agents, officers, subsidiaries, or affiliates of such person, from any or all benefits of the Act for a specified period after notice and opportunity for hearing has been afforded.

(b) Whenever the Administrator has reason to believe that any person or his employee, agent, or representative has flagrantly or repeatedly committed any of the acts or practices specified in §§354.46 to 354.51, he may, without hearing, direct that the benefits of the Act be denied such person, including any agents, officers, subsidiaries, or affiliates of such person, pending investigation and hearing, and shall give notice thereof to any such person in the manner prescribed in §1.147(b) of the rules of practice (7 CFR 1.147(b)). The Administrator's decision to deny the benefits of the Act to any such person, including any agents, officers, subsidiaries, or affiliates of such person, shall be effective upon service of such notice. A written petition for reconsideration of such interim denial may be filed with

the Administrator by any person so denied the benefits of the Act within 10 days after notice of the interim denial. Such petition shall state specifically the errors alleged to have been made by the Administrator in denying the benefits of the Act pending investigation and hearing. Within 20 days following the receipt of such petition for reconsideration, the Administrator shall reinstate the benefits of the Act or notify the petitioner of the reasons for continued interim denial.

[41 FR 23702, June 11, 1976, as amended at 43 FR 11148, Mar. 17, 1978]

§ 354.46 Misrepresentation; deceptive or fraudulent acts or practices.

Any willful misrepresentation or any deceptive or fraudulent act or practice made or committed by any person in connection with:

(a) The making or filing of any application for any inspection service;

(b) The making of the product accessible for inspection;

(c) The making, issuing, or using, or attempting to issue or use any inspection certificate, symbol, stamp, label, seal or identification, authorized pursuant to the regulations in this part;

(d) The use of the terms ''U.S. Inspected'' or ''Government Inspected'', or any term of similar import in the labeling or advertising of any product.

§ 354.47 Use of facsimile forms.

Using or attempting to use a form which simulates, in whole or in part, any certificate, symbol, stamp, label, seal or identification authorized to be issued or used under the regulations in this part.

§ 354.48 Willful violation of the regulations.

Any willful violation of the regulations in this part or the Act.

§ 354.49 Interfering with an inspector or employee of Service.

Any interference with or obstruction or any attempted interference or obstruction of or assault upon any inspector or employee of the Service in the performance of his duties. The giving or offering directly or indirectly of any money, loan, gift, or anything of value to an employee of the Service or the making or offering of any contribution to or in any way supplementing the salary, compensation, or expenses of an employee of the Service, or the offering or entering into a private contract or agreement with an employee of the Service for any services to be rendered while employed by the Service.

§ 354.51 Miscellaneous.

The existence of any of the conditions set forth in § 354.35 constituting a basis for the rejection of an application for inspection service.

OTHER APPLICABLE REGULATIONS

§ 354.53 Other applicable regulations.

Compliance with the regulations in this part shall not excuse failure to comply with any other Federal or any State or municipal applicable laws or regulations.

IDENTIFYING AND MARKING PRODUCTS

§ 354.60 Approval of official identification.

(a) Any label or packaging material which bears any official identification shall be used only in such manner as the Administrator may prescribe. No label or packaging material bearing official identification may be used unless finished copies or samples of such labels and packaging material have been approved by the Administrator. No label bearing official identification shall be printed for use until the printer's final proof has been approved by the Administrator, and no label, other than labels for shipping containers or containers for institutional packs, bearing any official identification shall be used until finished copies or samples of such labels have been approved by the Administrator. Final approval may be given to printer's final proof or photostatic copies of labels for shipping containers or containers for institutional packs, and no such labels shall be used until such proofs or copies have been approved by the Administrator. A label which bears official identification shall not bear any statement that is false or misleading, and if labels in the name of the same packer or distributor, or bearing the same brand

name, are used on the same or similar products which are prepared from products which are not inspected, the diameter of the inspection mark used on labels for inspected products shall be equal to at least one-tenth of the length of the label, plus at least one-tenth of the width of the label. If the labeling is printed or otherwise applied directly to the container, the principal display panel of such container shall, for this purpose, be considered as the label.

§354.62 Inspection mark with respect to product.

The Administrator is authorized to prescribe and approve the form of the inspection mark that may be used.

§354.63 Marking inspected products.

(a) *Wording and form of inspection mark.* Except as otherwise authorized, the inspection mark permitted to be used with respect to inspected and certified edible products shall include wording as follows: ''Inspected for Wholesomeness by U.S. Department of Agriculture.'' This wording shall be contained within a circle in the form and arrangement shown in §354.65. The appropriate plant number of the official plant shall be included in the circle unless it appears elsewhere on the packaging material. The Administrator may approve the use of abbreviations of such inspection mark, and such approved abbreviations shall have the same force and effect as the inspection mark. The inspection mark or approved abbreviation thereof, as the case may be, may be applied to the inspected and certified edible product or to the packaging material of such product. When the inspection mark, or the approved abbreviation thereof, is used on packaging material, it shall be printed on such material or on a label to be affixed to the packaging material and the name of the packer or distributor of such product shall be printed on the packaging material or label, as the case may be, except that on shipping containers and containers for institutional packs, the inspection marks may be stenciled on the container and, when the inspection mark is so stenciled, the name and address of the packer or distributor may be applied by the use of a stencil or a rubber stamp. Notwithstanding the foregoing, the name and address of the packer or distributor, if appropriately shown elsewhere on the packaging material, may be omitted from insert labels which bear an official identification if the applicable plant number is shown.

(b) *Wording on labels.* Each trade label to be approved for use pursuant to §§354.60 to 354.64 with respect to any inspected and certified edible product shall bear the true name of the edible product, the name and address of the packer or distributor thereof, and in prominent letters and figures of uniform size, the inspection mark, as aforesaid, and the label shall also bear, in such manner as may be prescribed or approved by the Administrator, the plant number, if any, of the official plant in which such product was inspected and certified. The class of the rabbits shall be shown on the label. The appropriate designation ''young'', ''mature'', or ''old'' may be used as a prefix to the word ''rabbit'' in lieu of the class name.

(c) *Labels in foreign languages.* Any trade label to be affixed to a container of any edible products for foreign commerce may be printed in a foreign language. However, the inspection mark shall appear on the label in English, but, in addition, may be literally translated into such foreign language. Each such trade label which is to be printed in a foreign language must be approved pursuant to §§354.60 to 354.64.

(d) *Unauthorized use or disposition of approved labels.* (1) Labels approved for use pursuant to §§354.60 to 354.64 shall be used only for the purpose for which approved and shall not otherwise be disposed of from the plant for which approved except with written approval of the Administrator. Any unauthorized use or disposition of approved labels or labels bearing official identification may result in cancellation of the approval and denial of the use of labels bearing official identification or denial of the benefits of the Act pursuant to the provisions of §354.60.

(2) The use of simulations or imitations of any official identification by any person is prohibited.

(e) *Rescindment of approved labels.* Once a year, or more often if requested,

each applicant shall submit to the Administrator a list in triplicate of approved labels that have become obsolete, accompanied with a statement that such approvals are no longer desired. The approvals shall be identified by the date of approval and the name of product or other designation showing the class of material.

§ 354.64 Form of official identification.

The form prescribed in § 354.65 is subject to the requirements of §§ 354.60 to 354.64, Identifying and Marking Products.

§ 354.65 Form of inspection mark.

The inspection mark approved for use on inspected and certified edible products shall be contained within a circle and include the following wording: ''Inspected for Wholesomeness by U.S. Department of Agriculture.'' The form and arrangement of such wording shall be as indicated in the example below. The plant number of the official plant shall be set forth if it does not appear on the packaging material.

SUPERVISION OF MARKING AND PACKAGING

§ 354.70 Evidence of label approval.

No inspector shall authorize the use of official identification for any inspected product unless he has on file evidence that such official identification or packaging material bearing such official identification has been approved in accordance with the provisions of §§ 354.60 to 354.64.

§ 354.71 Affixing of official identification.

(a) No official identification or any abbreviation, copy, or representation thereof may be affixed to or placed on or caused to be affixed to or placed on any product or container thereof except by an inspector or under the supervision of an inspector. All such products shall have been inspected and certified. The inspector shall have supervision over the use and handling of all material bearing any official identification.

(b) Each container of inspected and certified products to be shipped from one official plant to another official plant for further processing shall be marked for identification and shall show the following information:

(1) The name of the inspected and certified products in the container;

(2) The name and address of the packer or distributor of such products;

(3) The net weight of the container;

(4) The inspection mark permitted to be used pursuant to the regulations in this part unless the containers are sealed or otherwise identified in such manner as may be approved by the Administrator; and

(5) The plant number of the official plant where the products were packed.

§ 354.72 Packaging.

No container which bears or may bear any official identification or any abbreviation or copy or representation thereof may be filled in whole or in part except with edible products which were inspected and certified and are, at the time of such filing, sound, wholesome, and fit for human food. All such filling of containers shall be under the supervision of an inspector.

§ 354.73 Retention labels.

An inspector may use such labels, devices, and methods as may be approved by the Administrator for the identification of:

(a) Products which are held for further examination, and

(b) All equipment and utensils which are to be held for proper cleaning.

§ 354.74 Prerequisites to inspection.

Inspection of products shall be rendered pursuant to the regulations in

this part and under such conditions and in accordance with such methods as may be prescribed or approved by the Administrator.

§ 354.75 Accessibility of products.

Each product for which inspection service is requested shall be so arranged so as to permit adequate determination of its class, quantity, and condition as the circumstances may warrant.

§ 354.76 Time of inspection in an official plant.

The inspector who is to perform the inspection in an official plant shall be informed, in advance, by the applicant of the hours when such inspection is desired. Inspectors shall have access at all times to every part of any official plant to which they are assigned.

REPORTS

§ 354.90 Report of inspection work.

Reports of the work of inspection carried on within official plants shall be forwarded to the Administrator by the inspector in such manner as may be specified by the Administrator.

§ 354.91 Information to be furnished to inspectors.

When inspection service is performed within an official plant, the applicant for such inspection shall furnish to the inspector rendering such service such information as may be required for the purposes of §§ 354.90 to 354.92.

(Approved by the Office of Management and Budget under control number 0583–0036)

[41 FR 23702, June 11, 1976, as amended at 47 FR 746, Jan. 7, 1982]

§ 354.92 Reports of violation.

Each inspector shall report, in the manner prescribed by the Administrator, all violations of and noncompliance with the Act and the regulations in this part of which he has knowledge.

FEES AND CHARGES

§ 354.100 Payment of fees and charges.

(a) Fees and charges for any inspection shall be paid by the applicant for the service in accordance with the applicable provisions of §§ 354.100 to 354.110, both inclusive. If so required by the inspector, such fees and charges shall be paid in advance.

(b) Fees and charges for any inspection service shall, unless otherwise required pursuant to paragraph (c) of this section, be paid by check, draft, or money order payable to the Food Safety and Inspection Service and remitted promptly to the Service.

(c) Fees and charges for any inspection pursuant to a cooperative agreement with any State or person shall be paid in accordance with the terms of such cooperative agreement.

§ 354.101 On a fee basis.

(a) Unless otherwise provided in this part, the fees to be charged and collected for any service performed, in accordance with this part, on a fee basis shall be based on the applicable rates specified in this section.

(b) The charges for inspection service will be based on the time required to perform such services. The hourly rates shall be as specified in §§ 391.2 and 391.3 respectively for base time and for overtime or holiday work.

(c) Charges for certain laboratory analysis or laboratory examination of rabbits under this part related to inspection service shall be at the rate specified in § 391.4 for that part which is not covered under the base time, overtime, and/or holiday costs.

[41 FR 23702, June 11, 1976, as amended at 53 FR 13398, Apr. 22, 1988; 54 FR 6390, Feb. 10, 1989]

§ 354.105 Fees for additional copies of inspection certificates.

Additional copies, other than those provided for in §§ 354.141, 354.142, and 354.143, of any inspection certificates may be supplied to any interested party upon payment of a fee of $2.00 for each set of five or fewer copies.

§ 354.106 Travel expenses and other charges.

Charges are to be made to cover the cost of travel and other expenses incurred by the Service in connection with rendering inspection service. Such charges shall include the costs of transportation, per diem, and any other expenses.

§ 354.107 Continuous inspection performed on a resident basis.

The charges for inspection of rabbits and products thereof shall be those provided for in § 354.101(b) and specified by hourly rates in §§ 391.2 and 391.3 when the inspection service is performed on a continuous year-round resident basis and the services of an inspector or inspectors are required 4 or more hours per day. When the services of an inspector are required on an intermittent basis, the charges shall be those provided for in § 354.101(b) and specified by hourly rates in §§ 391.2 and 391.3 plus the travel expense and other charges provided for in § 354.106.

[54 FR 6390, Feb. 10, 1989]

§ 354.109 Fees or charges for inspection service performed under cooperative agreement.

Fees or charges to be made to an applicant for any inspection service which differ from those listed in §§ 354.100 through 354.107 shall be provided for by a cooperative agreement.

§ 354.110 Disposition of fees for inspection made under cooperative agreement.

Fees for inspection under a cooperative agreement with any State or person shall be disposed of in accordance with the terms of such agreement. Such portion of the fees collected under a cooperative agreement as may be due the United States shall be remitted to the Service.

INSPECTION PROCEDURES; ANTE-MORTEM INSPECTIONS

§ 354.120 Manner of handling products in an official plant.

Unless otherwise specified in the regulations in this part or by the Administrator, products which are to be further processed under inspection in an official plant shall be prepared and handled in such official plant under the supervision of an inspector.

§ 354.121 Ante-mortem inspection.

An ante-mortem inspection of rabbits shall, where and to the extent considered necessary by the Administrator and under such instructions as he may issue from time to time, be made of rabbits on the day of slaughter in any official plant processing rabbits under inspection pursuant to the regulations in this part.

§ 354.122 Condemnation on ante-mortem inspection.

Rabbits found in a dying condition on premises of an official plant shall be immediately destroyed and, together with any rabbits found dead on such premises, shall be disposed of in accordance with § 354.132. Rabbits plainly showing, on ante-mortem inspection, any disease or condition, that under §§ 354.129 to 354.131, inclusive, would cause condemnation of their carcasses on post-mortem inspection, shall be condemned. Rabbits which, on ante-mortem inspection, are condemned shall not be dressed, nor shall they be conveyed into any department of the plant where rabbit products are prepared or held. Rabbits which have been condemned on ante-mortem inspection and have been killed shall, under the supervision of an inspector of the Inspection Service, receive treatment as provided in § 354.132.

§ 354.123 Segregation of suspects on ante-mortem inspection.

All rabbits which, on ante-mortem inspection, do not plainly show, but are suspected of being affected with any disease or condition that under §§ 354.129 to 354.131, inclusive, may cause condemnation in whole or in part on post-mortem inspection, shall be segregated from the other rabbits and held for separate slaughter, evisceration, and post-mortem inspection. The inspector shall be notified when such segregated lots are presented for post-mortem inspection and inspection of such rabbits shall be conducted separately. Such procedure for the correlation of ante-mortem and post-mortem findings by the inspector, as may be prescribed or approved by the Administrator, shall be carried out.

§ 354.124 Quarantine of diseased rabbits.

If live rabbits, which are affected by any contagious disease which is transmissible to man, are brought into an official establishment, such rabbits shall be segregated. The slaughtering

of such rabbits shall be deferred and they shall be dealt with in one of the following ways:

(a) If it is determined by a veterinary inspector that further handling of the rabbits will not create a health hazard, the lot shall be subject to ante-mortem and post-mortem inspection pursuant to the regulations in this part.

(b) If it is determined by a veterinary inspector that further handling of the rabbits will not create a health hazard, such rabbits may be released for treatment under the control of an appropriate State or Federal agency. If the circumstances are such that release for treatment is impracticable, a careful rabbit-by-rabbit ante-mortem inspection shall be made, and all rabbits found to be, or which are suspected of being, affected with the contagious disease transmissible to man shall be condemned.

POST-MORTEM INSPECTION

§ 354.125 Evisceration.

No viscera or any part thereof shall be removed from any rabbits which are to be processed under inspection in any official plant, except at the time of evisceration and inspection. Each carcass to be eviscerated shall be opened so as to expose the organs and the body cavity for proper examination by the inspector and shall be prepared immediately after inspection as ready-to-cook rabbit.

§ 354.126 Carcasses held for further examination.

Each carcass, including all parts thereof, in which there is any lesion of disease or other condition, which might render such carcass or any part thereof unfit for human food, and with respect to which a final decision cannot be made on first examination by the inspector, shall be held for further examination. The identity of each such carcass, including all parts thereof, shall be maintained until a final examination has been completed.

§ 354.127 Condemnation and treatment of carcasses.

Each carcass, or any part thereof, which is found to be unsound, unwholesome, or otherwise unfit for human food shall be condemned by the inspector and shall receive such treatment, under the supervision of the inspector, as will prevent its use for human food and preclude dissemination of disease through consumption by animals.

§ 354.128 Certification of carcasses.

Each carcass and all parts and organs thereof which are found by the inspector to be sound, wholesome, and fit for human food shall be certified as provided in this part.

DISPOSITION OF DISEASED RABBIT CARCASSES AND PARTS

§ 354.129 General.

The carcasses or parts of carcasses of all rabbits inspected at an official establishment and found at the time of post-mortem inspection, or at any subsequent inspection, to be affected with any of the diseases or conditions named in other sections in this part, shall be disposed of in accordance with the section pertaining to the disease or condition. Owing to the fact that it is impracticable to formulate rules for each specific disease or condition and to designate at just what stage a disease process results in an unwholesome product, the decision as to the disposal of all carcasses, parts, or organs not specifically covered by the regulations, or by instructions of the Administrator issued pursuant thereto, shall be left to the inspector in charge, and if the inspector in charge is in doubt concerning the disposition to be made, specimens from such carcasses shall be forwarded to the laboratory for diagnosis.

§ 354.130 Diseases or conditions evident which require condemnation.

(a) Carcasses of rabbits affected with or showing lesions of any of the following named diseases or conditions shall be condemned: Tularemia, anthrax, hemorrhagic septicemia, pyemia, septicemia, leukemia, acute enteritis, peritonitis, sarcomatosis, metritis, necrobacillosis (Smorl's Disease), tuberculosis, emaciation, streptobacillary pseudotuberculosis,

and advanced stages of snuffles. Rabbits from pathological laboratories shall be condemned.

(b) Any organ or part of a rabbit carcass affected with a tumor shall be condemned and when there is evidence that the general condition of the rabbit has been affected by the size, position, or nature of the tumor, the whole carcass shall be condemned. In cases of malignant neoplasms involving any internal organ to a marked extent, or affecting the muscles, skeleton, or body lymph glands, even primarily, the whole carcass shall be condemned.

(c) Carcasses of rabbits showing any disease such as generalized melanosis, pseudoleukemia, and the like, which systemically affect the rabbit, shall be condemned.

(d) Any organ or part of a carcass which is badly bruised or which is affected by an abscess, or a suppurating sore, shall be condemned. Parts or carcasses which are contaminated by pus shall be condemned.

(e) Carcasses of rabbits contaminated by volatile oils, paints, poisons, gases, or other substances which affect the wholesomeness of the carcass shall be condemned.

(f) All carcasses of rabbits so infected that consumption of the meat or meat food products thereof may give rise to meat poisoning shall be condemned. This includes all carcasses showing signs of any of the following diseases: Acute inflammation of the lungs, pleura, pericardium, peritoneum or meninges; septicemia or pyemia, whether traumatic, or without evident cause; gangrenous or severe hemorrhagic enteritis or gastritis; polyarthritis and acute nephritis. Immediately after the slaughter of any rabbit so infected, the infected premises and implements used shall be thoroughly sanitized. The part or parts of any carcass coming into contact with the carcass or any part of the carcass of any rabbit covered by this section other than those affected with acute inflammation of the lungs, pleura, pericardium, peritoneum or meninges, shall be condemned.

(g) Carcasses showing any degree of icterus with a parenchymatous degeneration of organs, the result of infection or intoxication, and those which, as a result of a pathological condition, show an intense yellow or greenish-yellow discoloration without evidence of infection or intoxication shall be condemned.

(h) Carcasses of rabbits affected with mange or scab in advanced stages, or showing emaciation or extension of the inflammation to the flesh, shall be condemned. When the diseased condition is slight, the carcass may be passed for food after removal and condemnation of the affected parts.

(i) In the disposal of carcasses and parts of carcasses showing evidence of infestation with parasites not transmissible to man, the following general rules shall govern: If the lesions are localized in such manner and are of such character that the parasites and the lesions caused by them may be radically removed, the non-affected portion of the carcass, or part of the carcass, may be certified for food after the removal and condemnation of the affected portions. Where a part of a carcass shows numerous lesions caused by parasites, or the character of the infestation is such that complete extirpation of the parasites and lesions is difficult and uncertainly accomplished, or if the parasitic infestation or invasion renders the organ or part in any way unfit for food, the affected organ or part shall be condemned. Where parasites are found to be distributed in a carcass in such a manner or to be of such a character that their removal and the removal of the lesions caused by them are impracticable, no part of the carcass shall be certified for food and the entire carcass shall be condemned. Carcasses infested with a hydatid cyst or cysts (Echinococcus granulosis), transmissible to dogs and from dogs to man, shall in all cases be condemned regardless of the degree of infestation.

(j) Carcasses of rabbits showing such degree of emaciation or anemic condition as would render the meat unwholesome, and carcasses which show a slimy degeneration of the fat or a serious infiltration of the muscles shall be condemned.

§ 354.131 Decomposition.

Carcasses of rabbits deleteriously affected by post-mortem changes shall be disposed of as follows:

(a) Carcasses which have reached a state of putrefaction or stinking fermentation shall be condemned.

(b) [Reserved]

(c) Carcasses affected by types of post-mortem change which are superficial in nature may be certified for food after removal and condemnation of affected parts.

§ 354.132 Disposal of condemned carcasses and parts.

All condemned carcasses, or parts of carcasses, shall be disposed of by one of the following methods, under the supervision of an inspector of the Inspection Service: (Facilities and materials for carrying out the requirements in this section shall be furnished by the official establishment.)

(a) Steam treatment (which shall be accomplished by processing the condemned product in a pressure tank under at least 40 pounds of steam pressure) or thorough cooking in a kettle or vat for a sufficient time to effectively destroy the product for human food purposes and preclude dissemination of disease through consumption by animals. Tanks and equipment used for this purpose or for rendering or preparing inedible products shall be in rooms or compartments separate from those used for the preparation of edible products. There shall be no direct connection, by means of pipes or otherwise, between tanks containing inedible products and those containing edible products.

(b) Incineration or complete destruction by burning.

(c) Chemical denaturing, which shall be accomplished by the liberal application to all carcasses and parts thereof, of:

(1) Crude carbolic acid,

(2) Kerosene, fuel oil, or used crank case oil,

(3) Any phenolic disinfectant conforming to commercial standards CS 70–41 or CS 71–41 which shall be used in at least 2 percent emulsion or solution, or

(4) Any other substance that the Administrator approves which will decharacterize the carcasses or parts to the extent necessary to accomplish the purposes of this section.

REINSPECTION AND INGREDIENTS

§ 354.133 Reinspection of edible products; ingredients.

(a) Any inspected and certified edible product may be brought into an official plant only if the container of such product is marked for identification in the manner prescribed in § 354.71(b) and the product is reinspected by an inspector at the time it is brought into such plant. Upon reinspection, if any such product or portion thereof is found to be unsound, unwholesome, or otherwise unfit for human food, such product, or portion thereof, shall be condemned and shall receive treatment as provided in § 354.127.

(b) Any product which is prepared under inspection in an official plant shall be inspected in such plant as often as the inspector deems it necessary in order to ascertain whether such product is sound, wholesome, and fit for human food at the time such product leaves such plant. Upon any such inspection, if any such product or portion thereof is found to be unsound, unwholesome, or otherwise unfit for human food, such product or portion thereof shall be condemned and shall receive treatment as provided in § 354.127.

(c) All substances and ingredients used in the manufacture or preparation of any edible product shall be clean, sound, wholesome, and fit for human food. Liquid and frozen egg products used in the preparation of any edible product shall have been prepared under continuous inspection of the Department.

APPEALS

§ 354.134 Appeal inspections; how made.

Any person receiving inspection service may, if dissatisfied with any decision of an inspector relating to any inspection, file an appeal from such decision: *Provided,* That such appeal is filed within 48 hours from the time the decision was made. Any such appeal from a decision of an inspector shall be made to his immediate superior having jurisdiction over the subject matter of the appeal. Review of such appeal findings, when requested, shall be made by the

immediate superior of the employee of the Department making the appeal inspection. The cost of any such appeal shall be borne by the applicant if the Administrator determines that the appeal is frivolous. The charges for such frivolous appeal shall be based on the hourly rates as specified in § 354.101(b).

INSPECTION CERTIFICATES

§ 354.140 Forms of inspection certificates.

Each inspection certificate issued pursuant to the regulations in this part shall be approved by the Administrator as to form, and:

(a) Each rabbit inspection certificate shall show the class or classes of rabbits, the quantity of product contained in the respective lot, and all pertinent information concerning the condition and wholesomeness thereof;

(b) Each food product inspection certificate shall show the names of the edible products covered by such certificate, the quantity of each such product, such shipping marks as are necessary to identify such products, and all pertinent information concerning the condition and wholesomeness thereof;

(c) Each export certificate shall show the respective names of the exporter and the consignee, the destination, the shipping marks, the numbers of the export stamps attached to the edible products to be exported and covered by the certificate, and the names of such products and the total net weight thereof.

§ 354.141 Issuance and disposition of rabbits inspection certificates.

(a) Upon the request of an interested party, any inspector is authorized to issue a rabbit inspection certificate with respect to any lot of rabbits inspected by him. Each certificate shall be signed by the inspector who made the inspection covered by the certificate, and if more than one inspector participated in the inspection of the lot of rabbits, each such inspector shall sign the certificate with respect to such lot.

(b) The original and a copy of each inspection certificate, issued pursuant to §§ 354.140 to 354.144, and not to exceed two additional copies thereof if requested by the applicant prior to issuance, shall, immediately upon issuance, be delivered or mailed to the applicant or person designated by him. One copy shall be filed in the office of the area supervisor serving the area in which the inspection was performed, and the remaining copies shall be disposed of in such manner as the Administrator may approve. Additional copies of any such certificate may be furnished to any interested party as provided in § 354.105.

§ 354.142 Food product inspection certificates; issuance and disposition.

(a) Upon the request of an interested party, any inspector is authorized to issue a food product inspection certificate with respect to any inspected and certified edible product after suitable examination of the product has been made by the inspector.

(b) The original of each food product inspection certificate, and not to exceed two copies thereof, if requested, shall, immediately upon issuance, be delivered or mailed to the applicant or person designated by him. Another copy shall be filed in the office of the regional supervisor serving the area in which such certificate was issued, and one copy shall be forwarded to the Administrator. The last named two copies shall be retained until otherwise ordered by the Administrator.

§ 354.143 Export certificates; issuance and disposition.

(a) Upon the request of an exporter, any inspector is authorized to issue an export certificate with respect to the shipment to any foreign country of any inspected and certified edible product after suitable examination of the product has been made by the inspector.

(b) Each export certificate shall be issued in quintuplicate; the original shall be delivered to the exporter who requested such certificate, and the duplicate copy shall be delivered to the agent of the railroad or other carrier transporting such products from the United States. The triplicate copy of such export certificate shall be forwarded to the Administrator; the quadruplicate copy shall be filed in the office of the regional supervisor serving

the area in which such export certificate was issued, and the memorandum copy shall be retained by the inspector for filing. The last named three copies shall be retained until otherwise ordered by the Administrator.

§ 354.144 Advance information.

Upon the request of an applicant, all or part of the contents of any inspection certificate issued to such applicant may be telephoned or telegraphed to him, or to any person designated by him, at his expense.

BASIS OF ACCEPTABILITY OF OTHER OFFICIAL INSPECTION SYSTEMS

§ 354.160 General.

Any rabbit inspection system may be deemed to be acceptable to the Administrator which:

(a) Is conducted under the authority of laws, ordinances, or similar enactments of the State, county, city, or other political subdivision in which is located the official plant at which the ready-to-cook rabbits are prepared and

(b) Imposes at least the requirements set forth in § 354.161: *Provided,* That no such inspection shall be deemed acceptable to the Administrator with respect to any official plant in which ready-to-cook rabbits are prepared if he finds at any time that such requirements are not adequately enforced.

§ 354.161 Requirements as to manner of inspection.

(a) The inspection shall be conducted by an inspector who is a qualified veterinarian or under the supervision of a qualified veterinarian. All such inspectors shall be employed by the State, county, city, or other political subdivision in which the official plant is located.

(b) The inspection shall include postmortem examination of each rabbit carcass during the evisceration operation.

(c) All carcasses which show evidence of disease or any other condition which may render them unwholesome or unfit for food shall be condemned and shall be destroyed for food purposes under the supervision of an inspector. Each carcass and part thereof which has been inspected and passed or containers of carcasses or parts thereof shall bear the identifying inspection symbol of the official inspection system and the marking devices or labels shall be in the custody of the inspector at all times.

§ 354.162 Determining compliance with § 354.161.

A qualified veterinary supervisor of the rabbit inspection service shall investigate the manner of operation of the inspection system to determine the adequacy of the post-mortem examination and the compliance with the requirements contained in §§ 354.160 to 354.162 prior to approving the official plant for the inspection of ready-to-cook rabbits. This supervisor, as well as any official graders who may be stationed in the official plant, shall periodically observe the inspection operations in the official plant to determine that the requirements of §§ 354.160 to 354.162 are being met.

SANITARY REQUIREMENTS

GENERAL

§ 354.210 Minimum standards for sanitation, facilities, and operating procedures in official plants.

The provisions of §§ 354.210 to 354.247 shall apply with respect to inspection service in all official plants. The table set forth in § 354.247 indicates some of the types of material which may be used in the construction of equipment, utensils, and facilities for use in the plant.

BUILDINGS AND PLANT FACILITIES

§ 354.220 Buildings.

The buildings shall be of sound construction and kept in good repair, and shall be of such construction as to prevent the entrance or harboring of vermin.

(a) Outside openings. (1) The doors, windows, skylights, and other outside openings of the plant, except receiving rooms and live rabbit holding rooms, shall be protected by properly fitted screens or other suitable devices against the entrance of flies and other insects.

(2) Outside doors, except in receiving rooms and live rabbit holding rooms,

shall be self-closing and so hung that not over ¼–inch clearance remains when closed. Screen doors shall open toward the outside of the building.

§ 354.221 Rooms and compartments.

Rooms and compartments used for edible products shall be separate and distinct from inedible products departments and from rooms where rabbits are slaughtered and skinned. Separate rooms shall be provided when required for conducting processing operations in a sanitary manner, and all rooms shall be of sufficient size to permit the installation of the necessary equipment for processing operations and the conduct of such operations in a sanitary manner.

(a) Rooms for separate operation. The official plant should have separate rooms for each of the following operations depending upon the various types of operations conducted, but, in no case, shall the receiving or holding of live rabbits or killing operations be permitted in rooms in which eviscerating operations are performed:

(1) The receiving and feeding of live rabbits.

(2) Killing and skinning operations.

(3) Eviscerating, chilling, and packing operations for ready-to-cook rabbits.

(4) Inedible products departments.

(5) Refuse room.

(b) Rooms for holding carcasses for further inspection. Rooms and compartments in which carcasses or parts thereof are held for further inspection shall be in such number and such location as the needs of the inspection in the plant may require. They shall be equipped with locks and keys and the keys shall not leave the custody of the inspector in charge of the plant. All such rooms and compartments shall be marked conspicuously with the word ''retained'' in letters not less than 2 inches high.

(c) Coolers and freezers. Coolers and freezers of adequate size and capacity shall be provided to reduce the internal temperature of ready-to-cook rabbits prepared and otherwise handled in the plant to 36 °F. within 24 hours unless other cooling facilities are available.

(d) Refuse rooms. Refuse rooms shall be entirely separate from other rooms in the plant, and shall have tight fitting doors and be properly ventilated.

(e) Storage and supply rooms. The storage and supply rooms shall be in good repair, kept dry, and maintained in a sanitary condition.

(f) Boiler room. The boiler room shall be a separate room, if necessary, to prevent its being a source of dirt and objectionable odors entering any room where ready-to-cook rabbits are prepared, processed, handled, and stored.

(g) Inspector's office. Furnished office space, including, but not being limited to, light, heat, and janitor service shall be provided rent free in the official plant for the exclusive use for official purposes of the inspector and the Administration. The room or rooms set apart for this purpose must meet with the approval of the regional supervisor and be conveniently located, properly ventilated, and provided with lockers or cabinets suitable for the protection and storage of supplies and with facilities suitable for inspectors to change clothing.

(h) Toilet rooms. Toilet rooms opening directly into rooms where rabbit products are exposed shall have self-closing doors and shall be ventilated to the outside of the building.

§ 354.222 Floors, walls, ceilings, etc.

(a) Floors. All floors in rooms where exposed products are prepared or handled shall be constructed of or finished with materials impervious to moisture, so they can be readily and thoroughly cleaned. The floors in killing, ice cooling, ice packing, eviscerating, cooking, boning, and cannery rooms shall be graded for complete runoff with no standing water.

(b) Walls, posts, partitions, doors. All walls, posts, partitions, and doors in rooms where exposed products are prepared or handled shall be smooth and constructed of materials impervious to moisture to a height of 6 feet above the floor to enable thorough cleaning. All surfaces above this height must be smooth and finished with moisture-resistant material.

(c) Ceilings. Ceilings must be moisture-resistant in rooms where exposed products are prepared or handled, and finished and sealed to prevent collection of dirt or dust that might sift

through flooring above or fall from collecting surfaces on equipment or exposed product.

§ 354.223 Drainage and plumbing.

There shall be an efficient drainage and plumbing system for the plant and premises.

(a) Drains and gutters. All drains and gutters shall be properly installed with approved traps and vents. The drainage and plumbing system must permit the quick runoff of all water from plant buildings, and surface water around the plant and on the premises, and all such water shall be disposed of in such a manner as to prevent a nuisance or health hazard.

(b) Sewage and plant wastes. (1) The sewerage system shall have adequate slope and capacity to remove readily all waste from the various processing operations and to minimize, and if possible to prevent, stoppage and surcharging of the system.

(2) Grease traps which are connected with the sewerage system shall be suitably located but not near any edible products department or in any area where products are unloaded from or loaded into vehicles. To facilitate cleaning, such traps shall have inclined bottoms and be provided with suitable covers.

(3) Toilet soil lines shall be separate from house drainage lines to a point outside the buildings unless they are positively trapped to prevent backing up. Drainage from toilet bowls and urinals shall not be discharged into a grease catch basin.

(4) All floor drains shall be equipped with traps, constructed so as to minimize clogging, and the plumbing shall be so installed as to prevent sewerage from backing up and from flooding the floor.

(5) Floor drainage lines should be of metal and at least 4 inches in diameter and open into main drains of at least 6 inches in diameter and shall be properly vented to outside air.

(6) Where refrigerators are equipped with drains, such drains should be properly trapped and should discharge through an air gap into the sewer system. All new installations, and all replacements, or refrigerators equipped with drains shall meet these requirements.

§ 354.224 Water supply.

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

(a) Hot water at a temperature not less than 180 °F. shall be available for sanitation purposes.

(b) Hose connections with steam and water mixing valves or hot water hose connections shall be provided at convenient locations throughout the plant for cleaning purposes.

(c) The refuse rooms shall be provided with adequate facilities for washing refuse cans and other equipment in the rooms; the rooms, cans, and equipment shall be cleaned after each day's use.

§ 354.225 Lavatory accommodations.

Modern lavatory accommodations and properly located facilities for cleaning utensils and hands shall be provided.

(a) Adequate lavatory and toilet accommodations, including, but not being limited to, running hot water and cold water, soap, and towels, shall be provided. Such accommodations shall be in or near toilet and locker rooms and also at such other places in the plant as may be essential to the cleanliness of all personnel handling products.

(b) Sufficient metal containers shall be provided for used towels and other wastes.

(c) An adequate number of hand washing facilities serving areas where dressed rabbits and edible products are prepared shall be operated by other than hand-operated controls, or shall be of a continuous flow type which provides an adequate flow of water for washing hands.

(d) Durable signs shall be posted conspicuously in each toilet room and locker room directing employees to wash their hands before returning to work.

(e) Toilet facilities shall be provided according to the following formula:

Persons of same sex	Toilet bowls required
1 to 15, inclusive	1
16 to 35, inclusive	2
36 to 55, inclusive	[1] 3
56 to 80, inclusive	[1] 4
For each additional 30 persons in excess of 80	[1] 1

[1] Urinals may be substituted for toilet bowls but only to the extent of ⅓ of the total number of bowls stated.

§ 354.226 Lighting and ventilation.

There shall be ample light, either natural or artificial or both, of good quality and well distributed, and sufficient ventilation for all rooms and compartments to insure sanitary conditions.

(a) All rooms in which rabbits are killed, eviscerated, or otherwise processed shall have at least 30 foot candles of light intensity on all working surfaces except that at the inspection stations such light intensity shall be of 50 foot candles. In all other rooms, there shall be provided at least 5 foot candles of light intensity when measured at distance of 30 inches from the floor.

(b) All rooms shall be adequately ventilated to eliminate objectionable odors and minimize moisture condensation.

EQUIPMENT AND UTENSILS

§ 354.230 Equipment and utensils.

Equipment and utensils used for the preparation, processing, or other handling of any product in the plant shall be suitable for the purpose intended and shall be of such material and construction as will facilitate their thorough cleaning and insure cleanliness in the preparation and handling of products.

(a) Live rabbit holding pens shall be so constructed as to allow satisfactory ante-mortem examination and to permit proper cleaning.

(b) Metal refuse containers shall be provided, and such containers shall be kept covered.

(c) Insofar as it is practical, equipment and utensils shall be made of metal or other impervious material. Trucks and receptacles used for handling inedible products shall be of similar construction and shall be conspicuously and distinctly marked and shall not be used for handling any edible products.

(d) Chilling vats or tanks used for chilling ready-to-cook rabbits shall be made of metal or other hard-surfaced impervious material.

(e) Where grading bins are used for ready-to-cook rabbits, they shall be of sufficient number and capacity to handle the grading adequately without the use of makeshift bins and all ready-to-cook rabbits shall be kept off the floor. Grading bins may be made of metal or enameled wood and shall be constructed and maintained in such a manner as to allow easy and thorough cleaning. All replacements of such bins shall, however, be of metal.

(f) Except as otherwise provided herein, all equipment and utensils used in the killing, skinning, eviscerating, chilling, and packing rooms shall be of metal or other impervious material and constructed so as to permit proper and complete cleaning.

(g) Conveyors: (1) Conveyors used in the preparation of ready-to-cook rabbits shall be of metal or other acceptable material and of such construction as to permit thorough and ready cleaning and easy identification of viscera with its carcass.

(2) Overhead conveyors shall be so constructed and maintained that they do not allow grease, oil, or dirt to accumulate on the drop chain or shackle, which shall be of noncorrosive metal.

(3) Nonmetallic belt-type conveyors used in moving edible products shall be of water-proof composition.

(h) Inspection, eviscerating, and cutting tables shall be made of metal and have coved corners and be so constructed and placed to permit thorough cleaning.

(i) In plants where no conveyors are used, each carcass shall be eviscerated in an individual metal tray of seamless construction.

(j) Water spray washing equipment shall be used for washing carcasses inside and out.

(k) Watertight metal receptacles shall be used for entrails and other waste resulting from preparation of ready-to-cook rabbits.

(l) Watertight trucks and receptacles for holding or handling diseased carcasses and diseased parts of carcasses

shall be so constructed as to be readily and thoroughly cleaned; such trucks and receptacles shall be marked in a conspicuous manner with the word ''condemned'' in letters not less than 2 inches high and, when required by the inspector in charge, shall be equipped with facilities for locking and sealing.

(m) Freezing rooms should be adequately equipped to freeze ready-to-cook rabbits solid in less than 48 hours. Ready-to-cook rabbits should be frozen at temperatures of −10 °F. to −40 °F. and should be stored at 0 °F. or below, with the temperature maintained as constant as possible. Freezing room should be equipped with floor racks or pallets and fans to insure air circulation.

(n) Cooling racks should be made of metal and be readily accessible for thorough washing and cleaning. All replacements of cooling racks shall be made of metal.

(o) Trucks and receptacles in which carcasses or parts thereof are held for further inspection shall be in such number and such location as the needs of the inspection in the plant may require. They shall be equipped for locking by means of lock and key and the key shall not leave the custody of the inspector in charge of the plant. Such trucks and receptacles shall be marked conspicuously with the word ''retained'' in letters not less than 2 inches high.

§ 354.231 Accessibility.

All equipment shall be so placed as to be readily accessible for all processing and cleaning operations.

§ 354.232 Restrictions on use.

Equipment and utensils used in the official plant shall not be used outside the official plant except under such conditions as may be prescribed or approved by the national supervisor, and equipment used in the preparation of any article (including, but not being limited to, animal food) from inedible material shall not be used outside of the inedible products department except under such conditions as may be prescribed or approved by the national supervisor.

MAINTENANCE OF SANITARY CONDITIONS AND PRECAUTIONS AGAINST CONTAMINATION OF PRODUCTS

§ 354.240 General.

The premises shall be kept free from refuse, waste materials, and all other sources of objectionable odors and conditions.

§ 354.241 Cleaning of rooms and compartments.

Rooms, compartments, or other parts of the official plant shall be kept clean and in sanitary condition.

(a) All blood, offal, rabbits or parts of rabbits too severely damaged to be salvaged and all discarded containers and other materials shall be completely disposed of daily.

(b) All windows, doors, and light fixtures in the official plant shall be kept clean.

(c) All docks and rooms shall be kept clean and free from debris and unused equipment and utensils.

(d) Live rabbit receiving docks and receiving rooms shall be of such construction as readily to permit their thorough cleaning, and such docks and rooms should be kept clean at all times.

(e) Floors in live rabbit holding rooms shall be cleaned with such regularity as may be necessary to maintain them in a sanitary condition.

(f) The killing and skinning room shall be kept clean and free from offensive odors at all times.

(g) The walls, floors, and all equipment and utensils used in the killing and skinning room shall be thoroughly washed and cleaned after each day's operation.

(h) The floor in the killing and skinning rooms shall be cleaned frequently during killing and skinning operations and be kept reasonably free from accumulated blood, offal, water, and dirt.

(i) All equipment in the toilet room and locker room, as well as the room itself, shall be kept clean, sanitary, and in good repair.

(j) Cooler and freezer rooms shall be free from objectionable odors of any kind and shall be maintained in a sanitary condition (including, but not being limited to, the prevention of

drippings from refrigerating coils onto products).

§ 354.242 Cleaning of equipment and utensils.

Equipment and utensils used for preparing or otherwise handling any product shall be kept clean and in a sanitary condition and in good repair.

(a) Pens shall be cleaned regularly and the manure removed from the plant daily.

(b) All equipment and utensils used in the killing and skinning rooms shall be thoroughly washed and cleaned after each day's operation. The eviscerating, chilling, and packing room and equipment and utensils used therein shall be maintained in a clean and sanitary condition.

(c) Graders' and packers' gloves and grading bins shall be washed daily and used only for grading or packing, as the case may be.

(d) All crates or pens used for transporting live rabbits to the plant shall be cleaned regularly.

(e) Chilling vats or tanks, if practicable, shall be emptied after each use. They shall be thoroughly cleaned once daily and, after each cleaning operation, they shall be sanitized with such compounds or by such methods as may be approved or prescribed by the Administrator.

(f) When synchronized overhead conveyors and tray conveyors are used, the trays shall be completely washed and sanitized after being automatically emptied of inedible viscera.

(g) When a conveyor tray operation is used, each carcass shall be eviscerated in an individual metal tray of seamless construction, and such trays shall be completely washed and sanitized after each use.

(h) Tables, shelves, bins, trays, pans, knives, and all other tools and equipment used in the preparation of ready-to-cook rabbits shall be kept clean and sanitary at all times. Cleaned equipment and utensils shall be drained on racks and shall not be nested.

(i) Drums, cans, tanks, vats, and other receptacles used to hold or transport ready-to-cook rabbits shall be kept in a clean and sanitary condition.

§ 354.243 Operations and procedures.

Operations and procedures involving the preparation, storing, or handling of any product shall be strictly in accord with clean and sanitary methods.

(a) There shall be no handling or storing of materials which create an objectionable condition in rooms, compartments, or other places in the plant where any product is prepared, stored, or otherwise handled.

(b) Blood from the killing operation shall be confined to a relatively small area and kept from being splashed about the room.

(c) In the final washing, the carcass shall be passed through a system of sprays providing an abundant supply of fresh clean water.

(d) The floors in the eviscerating room shall be kept clean and reasonably dry during eviscerating operations and free of all refuse.

(e) Conveyors shall be operated at such speeds as will permit a sanitary eviscerating operation and will permit adequate inspection for condition and wholesomeness.

(f) Mechanized packaging equipment shall be maintained in good sanitary condition.

(g) All offal resulting from the eviscerating operation shall be removed as often as necessary to prevent the development of a nuisance.

(h) Paper and other material used for lining containers in which products are packaged shall be of such kinds as do not tear readily during use, but remain intact when moistened by the product. Wooden containers to be used for packaging ready-to-cook rabbits shall be fully lined except when the individual carcasses to be packaged therein are fully wrapped.

(i) Protective coverings shall be used for the product in the plant and as it is distributed from the plant, as will afford adequate protection for the product against contamination by any foreign substance (including, but not being limited to, dust, dirt, and insects), considering the means intended to be employed in transporting the product from the plant.

(j) Refuse may be moved directly to loading docks only for prompt removal.

(k) Cleanliness and hygiene of personnel: (1) All employees coming in

contact with exposed edible products or edible products handling equipment shall wear clean garments and should wear caps or hair nets, and shall keep their hands clean at all times while thus engaged.

(2) Hands of employees handling edible products or edible products handling equipment shall be free of infected cuts, boils, and open sores at all times while thus engaged.

(3) Every person, after each use of toilet or change of garments, shall wash his hands thoroughly before returning to duties that require the handling of edible products or containers therefor or edible products handling equipment.

(4) Neither smoking nor chewing of tobacco shall be permitted in any room where exposed edible products are prepared, processed, or otherwise handled.

§ 354.244 Temperatures and cooling and freezing procedures.

Temperatures and procedures which are necessary for cooling and freezing of rabbits in accordance with sound commercial practice shall be maintained in the coolers and freezers, and chilling temperatures and procedures shall also be in accordance with sound commercial practice.

(a) *Cooling.* Immediately after evisceration and washing of the carcass, it shall be placed in a cooling tank containing running cold tap water to remove the animal heat from the carcass. Carcasses shall not be allowed to remain in the cooling tank for longer than 1 hour.

(b) *Air chilling.* Immediately after the initial water chilling, the carcasses shall be placed in cooling racks and thereupon placed in a refrigerated cooler with moderate air movements and a temperature which will reduce the internal temperature of the carcasses to from 36 °F. to 40 °F., both inclusive, within 24 hours.

(c) *Freezing.* (1) When ready-to-cook rabbits are packaged in bulk or shipping containers, the carcasses should be individually wrapped or packaged in water-vapor resistant cartons or the containers should be lined with heavy water-vapor resistant paper so as to assure adequate overlapping of the lining to completely surround the carcasses and to permit unsealed closure or sealing in such a manner that water-vapor loss from the product is considerably retarded or prevented. The rabbit carcasses should receive an initial rapid freezing under such packaging, temperature, air circulation, and stacking conditions which will result in freezing the carcasses solid in less than 48 hours.

(2) Frozen ready-to-cook rabbits shall be held under conditions which will maintain the product in a solidly frozen state with temperature maintained as constant as possible.

(d) *Refrigeration.* Immediately after packaging, all ready-to-cook rabbits, other than those which are shipped from the plant in a refrigerated carrier, should be moved into the freezer, except that a period not exceeding 72 hours will be permitted for transportation and temporary holding before placing in the freezer provided such rabbits are held at not above 36 °F.

§ 354.245 Vermin.

Every practicable precaution shall be taken to exclude flies, rats, mice, and other vermin from the official plant. Dogs, cats, and other pets shall be excluded from rooms where edible products are processed, handled, or stored.

§ 354.246 Exclusion of diseased persons.

No person affected with any communicable disease (including, but not being limited to, tuberculosis) in a transmissible stage shall be permitted in any room or compartment where exposed or unpacked edible products are prepared, processed, or otherwise handled.

§ 354.247 Table showing types of materials.

Equipment, utensils, and facilities	Iron	Stainless steel and monel metal	Aluminum	Galvanized iron
Holding pens	A	A	A	A

Equipment, utensils, and facilities	Iron	Stainless steel and monel metal	Aluminum	Galvanized iron
Overhead conveyors	A	A	A	A
Conveyor track	A	A	.....	A
Shackles	.....	A	.....	A
Shackle chain	A	A	.....	A
Eviscerating pans	.....	A	A	A
Inspection table	.....	A	A	A
Inside and outside washer	.....	A	A	A
Cooling tanks and racks	.....	A	A	A
Utensils for handling edible products	.....	A	A	A
Framework (of equipment)	A	.....	.....	.....

Key: A—Acceptable.

§ 354.248 Scope and applicability of rules of practice.

The rules of practice of the Department of Agriculture in subpart H of part I, subtitle A, title 7 of the Code of Federal Regulations, are the rules of practice applicable to adjudicatory, administrative proceedings under the regulations in this part (9 CFR part 354).

[43 FR 11148, Mar. 17, 1978]

PART 355—CERTIFIED PRODUCTS FOR DOGS, CATS, AND OTHER CARNIVORA; INSPECTION, CERTIFICATION, AND IDENTIFICATION AS TO CLASS, QUALITY, QUANTITY, AND CONDITION

DEFINITIONS

Sec.
355.1 Meaning of words.
355.2 Terms defined.

SCOPE OF INSPECTION SERVICE

355.3 Plants eligible for inspection.

APPLICATION FOR INSPECTION, CERTIFICATION, AND IDENTIFICATION

355.4 Application.
355.5 Drawings.
355.6 Review of applications.

INAUGURATION OF INSPECTION

355.7 Inauguration of inspection.
355.8 Official number.
355.9 Numbers granted same ownership or control.
355.10 Assignment of inspectors.

FEES

355.11 Charge for survey.
355.12 Charge for service.

SANITATION AND FACILITIES

355.13 Sanitation.
355.14 Facilities.
355.15 Inedible material operating and storage rooms; outer premises, docks, driveways, etc.; fly-breeding material; nuisances.
355.16 Control of flies, rats, mice, etc.
355.17 Tagging equipment ''U.S. rejected.''
355.18 Drawings and specifications to be furnished.

INSPECTION PROCEDURE

355.19 Inspector to be informed when plant operates.
355.20 Inspector to have access to plant at all times.
355.21 Products entering inspected plants.
355.22 Designation of place of receipt of returned products.
355.23 Tagging products ''U.S. retained.''
355.24 Processes to be supervised.
355.25 Canning with heat processing and hermetically sealed containers; closures; code marking; heat processing; incubation.
355.26 Samples of certified products, ingredients, etc., to be taken for examination.
355.27 Reports of violations of regulations.

DISPOSAL OF CONDEMNED MATERIAL

355.28 Unfit material to be condemned.

COMPOSITION OF CERTIFIED PRODUCTS

355.29 Composition of certified products for dogs, cats, and other carnivora.

SUPERVISION

355.31 Supervision by inspector.

LABELING

355.32 Labeling required.
355.33 Plant number to be embossed on metal containers.
355.34 Labels, approval of, by Administrator.
355.35 Label information to be displayed on principal panel.
355.36 Obsolete labels.
355.37 Alteration or limitation of statement of certification.

PENALTIES

355.38 Withdrawal of service.

APPEALS

355.39 Appeals from decisions made under this part.

REPORTS

355.40 Plants to furnish information for reports.

MULE MEAT AND ANIMAL FOOD, MULE MEAT BY-PRODUCT

355.41 Antemortem and postmortem inspection for mules.
355.42 Marking of mule meat and animal food mule meat by-product.
355.43 Scope and applicability of rules of practice.

AUTHORITY: 7 U.S.C. 1622, 1624; 7 CFR 2.17 (g) and (i), 2.55.

SOURCE: 23 FR 10107, Dec. 23, 1958, unless otherwise noted. Redesignated at 30 FR 4195, Mar. 31, 1965.

DEFINITIONS

§355.1 Meaning of words.

Words used in this part in the singular form shall be deemed to import the plural, and vice versa, as the case may demand.

§355.2 Terms defined.

When used in this part unless otherwise distinctly expressed or manifestly incompatible with the intent thereof:

(a) *Person* means any individual, partnership, association, business trust, corporation, or any organized group of persons, whether incorporated or not.

(b) *Program* means the Meat and Poultry Inspection Program of the Food Safety and Inspection Service of the United States Department of Agriculture.

(c) *Circuit supervisor* means an inspector of the Program assigned to supervise and perform official work at a circuit. Such inspector is assigned by and reports directly to the Administrator or other person designated by him.

(d) *Inspector* means an inspector of the Program.

(e) *Inspected plant* means any plant preparing certified products for dogs, cats, or other carnivora at which inspection is maintained under the regulations contained in this part.

(f) *Circuit* means one or more inspected plants assigned to a circuit supervisor.

(g) *Animal protein supplement* means a product containing animal protein and other elements normal to the component for use in compounding a maintenance food for dogs, cats, and other carnivora.

(h) *Products* means the products for dogs, cats, and other carnivora marked, or to be marked, with the certification provided in this part.

(i) *Meat* means the U.S. inspected and passed and so identified clean, wholesome muscle tissue of cattle, sheep, swine, or goats which is skeletal or which is found in the tongue, in the diaphragm, in the heart, or in the esophagus with or without the accompanying and overlying fat and the portions of skin, sinews, nerves, and blood vessels which normally accompany the muscle tissue and which are not separated from it in the process of dressing. It does not include the muscle found in the lips, snout, or ears.

(j) *Animal food meat by-product* means the part other than meat which has been derived from one or more cattle, sheep, swine or goats that have been U.S. Inspected and Passed and is fit for use as animal food.

(k) *Horse meat* means the U.S. inspected and passed and so identified clean, wholesome muscle tissue of horses which is skeletal or which is found in the tongue, in the diaphragm, in the heart, or in the esophagus, with or without the accompanying and overlying fat and the portions of sinews, nerves, and blood vessels which normally accompany the muscle tissue and which are not separated from it in the process of dressing.

(l) *Animal food horse meat by-product* means the part other than meat which has been derived from one or more horses that have been U.S. Inspected and Passed and is fit for use as animal food.

(m) *Mule meat* means the clean, sound, healthful, wholesome muscle tissue derived from mules as determined by antemortem and postmortem inspection by an inspector in accordance with §355.41. It includes muscle tissue which is found in the tongue, in the diaphragm, in the heart or in the

esophagus, with or without the accompanying and overlying fat and the portions of sinews, nerves, and blood vessels which normally accompany the muscle tissue and which are not separated from it in the process of dressing.

(n) *Animal food mule meat by-product* means the part other than meat which has been derived from one or more mules that have been handled in accordance with § 355.41 and is fit for use as animal food.

(o) *Bone* means the U.S. inspected and passed and so identified clean, wholesome bone which has been derived from cattle, sheep, swine, goats or horses, or bone derived from mules slaughtered and passed under Program inspection in accordance with § 355.41.

(p) *Poultry* means any domesticated bird slaughtered in accordance with the Poultry Products Inspection Act, Public Law 85–172, 85th Congress, S. 1747, dated August 28, 1957 (21 U.S.C. 451 et seq.).

(q) *Poultry product* means any edible part of fresh poultry which have been slaughtered for human food and from which the blood, feathers, feet, head and viscera have been removed in accordance with rules and regulations promulgated by the Secretary of Agriculture.

(r) *Administrator.* The Administrator of the Food Safety and Inspection Service or any officer or employee of the Department to whom authority has heretofore been delegated or may hereafter be delegated to act in his stead.

(s) *Whale meat* means the muscle tissue of whales which is fit for use in animal food.

(t) *Fish* means the whole or part of any aquatic, water breathing vertebrates, commonly designated as fish, which is fit for use in animal food.

(u) *Animal food poultry byproduct* means any portion of carcasses of poultry slaughtered under inspection and passed in accordance with the Poultry Products Inspection Act which is fit for use in animal food.

[23 FR 10107, Dec. 23, 1958, as amended at 25 FR 1356, Feb. 1960; 29 FR 18418, Dec. 25, 1964. Redesignated and amended at 30 FR 4195, Mar. 31, 1965; 32 FR 13115, Sept. 15, 1967; 33 FR 6707, May 2, 1968]

SCOPE OF INSPECTION SERVICE

§ 355.3 Plants eligible for inspection.

Upon application, inspection may be granted at a plant where products are to be prepared, when the Administrator has determined that the application conforms to and the plant meets with the requirements of this part.

APPLICATION FOR INSPECTION, CERTIFICATION, AND IDENTIFICATION

§ 355.4 Application.

The owner or operator of any plant of the kind specified in § 355.3 may apply to the Administrator for inspection, certification, and identification. In cases of change of ownership or change of location, new applications shall be made.

(Approved by the Office of Management and Budget under control number 0583–0036)

[23 FR 10107, Dec. 23, 1958. Redesignated at 30 FR 4195, Mar. 31, 1965, and amended at 47 FR 746, Jan. 7, 1982]

§ 355.5 Drawings.

Triplicate copies of complete drawings with specifications, consisting of floor plans showing the locations of such features as the principal pieces of equipment, floor drains, principal drainage lines, hand-washing basins, and hose connections for cleanup purposes; elevations; roof plans when necessary to show size and location of skylights and the like; cross and longitudinal sections of the various buildings, showing such features as principal pieces of equipment, heights of ceilings, conveyor rails, and character of floors, walls, and ceilings; and a plot plan showing relationship of various departments and structures of the plants, properly drawn to scale, shall accompany applications. Where complete approved drawings and specifications are available in the files of the Meat and Poultry Inspection Program, Food Safety and Inspection Service, U.S. Department of Agriculture, covering a plant operating under the supervision of that Program, it will not be necessary that drawings and specifications accompany an application

made under this part for inspection at such plant.

[23 FR 10107, Dec. 23, 1958. Redesignated and amended at 30 FR 4195, Mar. 31, 1965; 32 FR 13115, Sept. 15, 1967]

§355.6 Review of applications.

The Administrator will determine whether applications shall be granted or refused.

INAUGURATION OF INSPECTION

§355.7 Inauguration of inspection.

When an application for inspection, certification, and identification is granted, the circuit supervisor shall, at or prior to the inauguration of inspection, inform the owner or operator of the plant of the requirements of the regulations contained in this part. Inspection shall not be begun if a plant is not in a sanitary condition. The applicant shall adopt and enforce all necessary measures and shall comply with all such directions as the circuit supervisor may prescribe for carrying out the purposes of this part.

§355.8 Official number.

To each plant granted inspection an official number shall be assigned. Such number shall be preceded by the letter ''A'' and used to identify all certified products prepared in the plant.

§355.9 Numbers granted same ownership or control.

Two or more official plants under the same ownership or control may be granted the same official number, provided a serial letter is added after the number in each case to identify the plant.

§355.10 Assignment of inspectors.

The Administrator shall designate a circuit supervisor of the inspection at each circuit and assign to him such assistants as may be necessary.

FEES

§355.11 Charge for survey.

Applicants for the inspection, certification, and identification shall reimburse the department for salary, travel cost, per diem allowance, and the like, expended incidental to any survey of the premises for which the inspection is requested, and in connection with any review of plans which may be made.

§355.12 Charge for service.

The fees to be charged and collected by the Administrator shall be at the rates specified in §§391.2, 391.3, and 391.4 respectively for base time; for overtime, including Saturdays, Sundays, and holidays; and for certain laboratory services which are not covered under the base time, overtime, and/or holiday costs. Such fees shall reimburse the Service for the cost of the inspection service furnished.

[54 FR 6390, Feb. 10, 1989]

SANITATION AND FACILITIES

§355.13 Sanitation.

Sanitary facilities and accommodations shall be furnished by every inspected plant. Of these the following are specifically required:

(a) Dressing rooms, toilet rooms, and urinals shall be sufficient in number, ample in size, and conveniently located. They shall be properly lighted and ventilated and of sanitary construction. They shall be separate from the rooms and compartments in which certified products are prepared, stored or handled.

(b) Modern hand-washing basins, including running hot and cold water, soap and towels shall be placed in or near toilet rooms.

(c) Toilet soil lines shall be separate from house drainage lines to a point outside the buildings and drainage from toilet soil lines shall not be discharged into a grease catchbasin.

(d) Properly located facilities shall be provided for cleansing utensils and hands of all persons handling or preparing any products to be certified.

(e) Equipment and utensils used for preparing any products to be certified shall be of such material and construction as will make them susceptible of being readily and thoroughly cleaned.

(f) Trucks and receptacles used for inedible materials shall be of such construction as to permit ready and thorough cleansing, shall bear a conspicuous and distinctive mark, and

shall be used exclusively for handling inedible material.

(g) Rooms, compartments, places, equipment and utensils used for preparing, storing or otherwise handling any certified products, and all other parts of the inspected plant, shall be kept clean. There shall be no handling or storing of materials which creates an objectionable condition in rooms, compartments or places where certified products are prepared, stored or otherwise handled.

§ 355.14 Facilities.

Adequate facilities for the preparation and inspection of the products to be certified shall be furnished and maintained by the inspected plant. Of these the following are specifically required:

(a) A room or compartment adequately equipped for locking or sealing shall be provided for holding products prepared for certification or material used in their preparation which are identified as ''U.S. retained,'' and such rooms and compartments shall be conspicuously marked with the phrase ''U.S. retained'' prominently displayed.

(b) Adequate facilities, including denaturing materials, for the proper disposal of condemned articles including carcasses, parts of carcasses and other materials, shall be provided.

(c) Rooms or compartments adequate in size and properly equipped for holding samples of canned products prepared for certification under incubation, shall be maintained at the temperature specified in § 355.25(i).

(d) Furnished office room, including light, heat, janitor, and laundry service shall be provided rent free for the exclusive use of the inspector. These facilities shall be set apart for this purpose and provided with lockers suitable for the protection and storage of program supplies. Laundering of inspectors' outer work clothing shall be provided by the management of inspected plants.

§ 355.15 Inedible material operating and storage rooms; outer premises, docks, driveways, etc.; fly-breeding material; nuisances.

All operating and storage rooms and departments of inspected plants used for inedible material shall be maintained in clean condition, and shall be separate and apart from rooms and departments where certified products are prepared, handled, or stored. Docks and areas where cars and vehicles are loaded, and driveways, approaches and alleyways shall be properly paved and drained and the outer premises of every inspected plant shall be kept in clean and orderly condition. All catchbasins on the premises shall be of such construction and location and shall be given such attention as will insure their being kept in acceptable condition as regards odors and cleanliness. The accumulation on the premises of any material in which flies may breed, or the maintenance of any nuisance on the premises shall not be allowed.

§ 355.16 Control of flies, rats, mice, etc.

Flies, rats, mice, and other vermin shall be excluded from inspected plants and premises.

§ 355.17 Tagging equipment "U.S. rejected."

When necessary, inspectors shall attach a ''U.S. rejected'' tag to any equipment or utensil which is unclean or the use of which would be in conflict with the provisions of this part. No equipment or utensil so tagged shall again be used until made acceptable under this part and until removal of the tag. Such tag shall not be removed from the equipment or utensil by anyone other than an inspector.

§ 355.18 Drawings and specifications to be furnished.

Triplicate copies of complete drawings and specifications for remodeling inspected plants or for new structures at such plants shall be submitted to the Administrator and approval obtained for the plans in advance of construction.

INSPECTION PROCEDURE

§ 355.19 Inspector to be informed when plant operates.

The management of an inspected plant shall inform the inspector or the circuit supervisor when work in each department has been concluded for the day, and the day and hour when work

will be resumed therein. There shall be no preparation of certified products at an inspected plant except under the supervision of an inspector.

§355.20 Inspector to have access to plant at all times.

For the purpose of examination or inspection necessary to enforce any of the provisions of this part, inspectors shall have access at all times by day or night, whether the plant is being operated or not, to every part of an inspected plant.

§355.21 Products entering inspected plants.

All products of a kind certified under this part or materials to be used in the preparation of such products when brought into an inspected plant shall be identified and inspected at the time of receipt and be subject to further inspection in such manner and at such time as may be deemed necessary. If, upon inspection, any such article is found to be unsound or otherwise unfit, it shall be handled as provided in §355.28.

§355.22 Designation of place of receipt of returned products.

Certified products returned to an inspected plant shall be received at a dock or place specifically designated for the purpose by the plant management with the approval of the circuit supervisor. Such returned products shall be inspected there by the inspector before further entering the plant.

§355.23 Tagging products "U.S. retained."

A ''U.S. Retained'' tag shall be placed by an inspector at the time of inspection on all certified products, materials to be used in the preparation of certified products, or containers thereof, whenever such certified products, materials, or containers are suspected of being unsound or otherwise unfit or not in conformity with the requirements contained in this part. Such tags so placed shall not be removed by anyone other than an inspector.

§355.24 Processes to be supervised.

All processes used in the preparation of the certified products shall be supervised by an inspector. All steps in the process of manufacture shall be conducted carefully and with strict cleanliness. Inspected plants shall not prepare products of a kind certified under this part unless they conform with the regulations contained in this part.

§355.25 Canning with heat processing and hermetically sealed containers; closures; code marking; heat processing; incubation.

(a) Containers shall be cleaned thoroughly immediately before filling, and precaution must be taken to avoid soiling the inner surfaces subsequently.

(b) The inside surfaces of containers of metal, glass, or other material shall be washed by spraying in an inverted position with running water at a temperature of at least 180 °F. The container washing equipment shall be provided with a thermometer to register the temperature of the water used for cleaning the containers.

(c) Perfect closure is required for hermetically sealed containers. Heat processing shall follow promptly after closing.

(d) Careful inspection shall be made of the containers by competent plant employees immediately after closing, and containers which are defectively filled or defectively closed, or which show inadequate vacuum, shall not be further processed until the defect has been corrected. The containers shall again be inspected by plant employees when they have cooled sufficiently for handling after processing by heating. The contents of defective containers shall be condemned unless correction of the defect is accomplished within six hours following the sealing of the containers or completion of the heat processing, as the case may be, except that (1) if the defective condition is discovered during an afternoon run the cans of product may be held in coolers at a temperature not exceeding 38 °F. under conditions that will promptly and effectively chill them until the following day when the defect may be corrected; and (2) short vacuum or overstuffed cans of products which have not been handled in accordance with the above

may be incubated as provided in paragraph (i) of this section in the inspected plant under Program supervision, after which the cans shall be opened and the sound products passed.

(e) Canned products shall not be passed unless, after cooling to atmospheric temperature, they show the external characteristic of sound cans; that is, the cans shall not be overfilled, the ends of the cans shall be concave, there shall be no bulging of the cans, the sides and ends of the cans shall conform to the products, and there shall be no slack or loose tin in the cans.

(f) All canned products shall be plainly and permanently marked on the containers by code or otherwise with the identity of the contents and date of canning. The code used and its meaning shall be on record in the office of the circuit supervisor before use.

(g) The canned products must be processed at such temperature and for such period of time as will assure keeping without refrigeration under usual conditions of storage and transportation as evidenced by the incubation test.

(h) Lots of canned products shall be identified during their handling preparatory to and during heat processing by tagging the baskets or cages in which the cans are being conveyed, with a tag which will change color on going through the heat processing or by other effective means so as to insure the proper channeling of the products for effective heat processing after closing the cans.

(i) Facilities shall be provided to incubate at least representative samples of the fully processed canned products. The incubation shall consist of holding the canned products for at least 10 days at about 98 °F. The extent to which incubation tests shall be required by inspectors depends on conditions such as the record of the inspected plant in conducting canning operations, the extent to which the plant furnishes competent supervision and inspection in connection with the canning operations, the character of the equipment used, and the degree to which such equipment is maintained at maximum efficiency. Such factors shall be considered by the circuit supervisor in determining the extent of incubation testing at a particular plant. In the event of failure by an inspected plant to provide suitable facilities for incubation of test samples, the circuit supervisor may require holding of the entire lot under such conditions and for such period of time as may, in his discretion, be necessary to establish the stability of the canned products. The circuit supervisor may permit lots of canned certified products to be shipped from the inspected plant prior to completion of sample incubation when he has no reason to suspect unsoundness in the particular lots, and under circumstances which will assure the return of the products to the plant for inspection should such action be indicated by the incubation results.

§ 355.26 Samples of certified products, ingredients, etc., to be taken for examination.

Samples of certified products, water, chemicals, flavorings or other articles in an inspected plant shall be taken without cost to the Program for an examination as often as may be deemed necessary for the efficient conduct of the inspection. The frequency of sampling shall be determined by the needs of the inspection.

§ 355.27 Reports of violations of regulations.

Inspectors shall report to the circuit supervisor violations of or failures to conform with these regulations which occur at inspected plants, and the circuit supervisor shall report the same to the Administrator.

DISPOSAL OF CONDEMNED MATERIAL

§ 355.28 Unfit material to be condemned.

Subject to § 355.41, any certified products, or ingredients intended for use therein, which are decomposed or adulterated or otherwise unsound or unfit for use shall be condemned and destroyed, except that if the adulteration is such as will not preclude their legitimate use for some purpose other than the preparation of the certified products, they may be released by authorized inspectors for such other purpose for disposition under the supervision of

the proper local, State, or Federal official. The operator of the inspected plant shall make such arrangement as may be necessary with the proper officials for the disposition of the article.

COMPOSITION OF CERTIFIED PRODUCTS

§355.29 Composition of certified products for dogs, cats, and other carnivora.

(a) *Composition of canned or semi-moist certified maintenance food.* (1) Only ingredients which are normal to canned or semi-moist food for dogs, cats, and other carnivora, which are favorable to adequate nutrition, and which are classed by the Administrator as conforming with requirements contained in this part shall be used in the preparation of certified maintenance food.

(2) Not less than 30 percent of meat or animal food meat byproduct or both, or of horse meat or animal food horse meat byproduct or both, or of mule meat or animal food mule meat byproduct or both, or of poultry products, shall be used in the preparation of canned or semimoist certified maintenance food. Upon specific approval of the Administrator, combinations of the above specified ingredients may be used. The uncooked weight of the meat or animal food meat byproduct or both, or of the horse meat or animal food horse meat byproduct or both, or of the mule meat or animal food mule meat byproduct or both, or of the poultry products, or of the combinations thereof, shall be used in the calculation, and the percentage shall be obtained by relating this weight to the total weight of the certified maintenance food.

(3) Certified maintenance food shall contain not less than 10 percent of protein.

(4) Certified maintenance food shall contain a level of minerals and vitamins generally recognized to be essential to the nutritional value of the food.

(5) Vegetables and grains and their derivatives, used as ingredients of certified maintenance food, shall be of good quality, shall be free from discoloration, mold, smut, and insect infestation, and shall be otherwise fit for use as animal food.

(6) Inedible material such as tankage, dried blood, bone meal, and the like shall not be used as ingredients of certified maintenance food.

(7) Semi-moist certified maintenance food shall have a soft granular consistency, shall be shelf stable, and shall be processed so that the moisture content thereof does not exceed 27 percent of the net weight of such food.

(b) *Composition of canned or fresh frozen certified supplemental animal foods.* (1) Certified animal protein supplement shall comply with the following requirements:

(i) Certified animal protein supplement shall contain not less than 95 percent of meat or animal food meat byproduct or both, or of horse meat or animal food horse meat byproduct or both, or of mule meat or animal food mule meat byproduct or both, or of poultry products. Upon specific approval of the Administrator, combinations of the above specified ingredients may be used;

(ii) Certified animal protein supplement shall have added thereto a sufficient amount of fresh ground bone or other acceptable agent to satisfy the requirements of the regulations promulgated under the Meat Inspection Act (34 Stat. 1260), as amended (21 U.S.C. 71 et seq.), and the Horse Meat Act (41 Stat. 241; 21 U.S.C. 96), in order to insure decharacterization of the product for human food purposes;

(iii) Certified animal protein supplement may contain not more than 3 percent wheat flour or other processing aid acceptable to the Administrator, which shall be of good quality, shall be free from insect infestation, and shall be otherwise fit for use as animal food;

(iv) Certified animal protein supplement shall contain not less than 15 percent protein; and

(v) Certified animal protein supplement shall contain not less than 3 percent fat.

(2) Certified pet food supplement shall comply with the following requirements:

(i) Certified pet food supplement shall contain not less than 50 percent of meat or animal food meat byproduct or both, or of horse meat or animal food horse meat byproduct or both, or of mule meat or animal food mule meat byproduct or both, or of poultry products. Upon specific approval of the

Administrator, combinations of the above specified ingredients may be used;

(ii) Certified pet food supplement shall have added thereto a sufficient amount of fresh ground bone or other acceptable agent to satisfy the requirements of the regulations promulgated under the Meat Inspection Act (34 Stat. 1260), as amended (21 U.S.C. 71 et seq.), and the Horse Meat Act (41 Stat. 241; 21 U.S.C. 96), in order to insure decharacterization of the product for human food purposes;

(iii) Certified pet food supplement may contain various cereals, flours, vegetables, flavorings, seasonings and other processing aids acceptable to the Administrator which shall be of good quality, shall be free from discoloration, mold, smut, and insect infestation, and shall be otherwise fit for use as animal food;

(iv) Certified pet food supplement shall contain not less than 11 percent protein;

(v) Certified pet food supplement shall contain not less than 3 percent fat; and

(vi) Certified pet food supplement may not contain more than 74 percent moisture.

(c) *Composition of canned certified variety pet food.* (1) Certified variety pet food shall contain not less than 25 percent of meat or animal food meat byproduct or both, or of horse meat or animal food horse meat byproduct or both, or of mule meat or animal food mule meat byproduct or both, or of poultry products. Upon specific approval of the Administrator, combinations of the above specified ingredients may be used.

(2) Certified variety pet food shall contain a variety of vegetables and may contain other ingredients which are favorable to adequate nutrition.

(3) Vegetables and grains and their derivatives used as ingredients of certified variety pet food shall be of good quality, shall be free from discoloration, mold, smut, and insect infestation, and shall be otherwise fit for use as animal food.

(4) Certified variety pet food shall contain not less than 8 percent protein.

(5) Certified variety pet food shall contain not less than 2 percent fat.

(6) Certified variety pet food may contain not more than 75 percent moisture.

(d) Certified products for dogs, cats, and other carnivora may contain whale meat, fish, and animal food poultry byproducts or combinations thereof as optional ingredients in lieu of some but not all of the ingredients named in paragraphs (a)(2), (b)(1)(i), and (c)(1) of this section, respectively, upon specific approval of the Administrator.

[26 FR 3984, May 9, 1961, as amended at 29 FR 9819, July 22, 1964; 29 FR 18419, Dec. 25, 1964. Redesignated at 30 FR 4195, Mar. 31, 1965, and amended at 30 FR 10284, Aug. 19, 1965; 32 FR 13115, Sept. 15, 1967; 33 FR 6707, May 2, 1968]

SUPERVISION

§ 355.31 Supervision by inspector.

No container which bears or is to bear a label as provided for under this part shall be filled in whole or in part except with certified products which have been inspected in compliance with this part, which are sound, healthful, wholesome, and otherwise fit for dogs, cats, and other carnivora, and which are strictly in accordance with the statements on the label. No such container shall be filled in whole or in part and no such label shall be affixed thereto except under the supervision of an inspector.

LABELING

§ 355.32 Labeling required.

Each container of inspected and certified product shall have affixed thereto a label bearing the following information, prominently displayed:

(a) The name of the product, class of product, ingredient statement, and the animal foods inspection legend in the manner provided by paragraphs (a) (1), (2), (3), (4), (5), and (6) of this section.

(1) The name of the canned or semimoist certified food shall include words such as ''dog food,'' ''cat food,'' ''dog and cat food,'' or ''fox food,'' accompanied with such references to optional ingredients as may be required by the Administrator under this part. Product names shall not be misleading in regard to class of canned or semimoist certified food for which label is intended.

(2) Class of product as outlined in paragraphs (a), (b), and (c) of §355.29 shall be declared on either the main display or 20 percent panel of the label.

(3) The word ''ingredients,'' followed by a complete list of ingredients of the food in the order of their predominance and by their common or usual names, shall appear on the label with the name of the food.

(4) The inspection legend for canned, semi-moist or frozen certified animal food shall appear on the label in the form shown herewith, except that the plant number need not appear with the legend when such number is embossed on the sealed metal container as provided in §355.33.

PLANT A

(5) When a product is prepared in whole from any of the items defined in §355.2 (i) through (n), its name shall identify the item and there shall appear contiguous to the name of the item the name of the decharacterizing agent used, followed by the word ''added'' as, for example, ''bone added.''

(6) When wheat flour or other processing aid is added to the product, there shall appear on the label, with the name of the decharacterizing agent, in predominating order, the name of the processing aid, as, for example, ''Wheat flour and bone added'' or ''Bone and wheat flour added.''

(b) A statement of the quantity of contents of the container, representing in terms of avoirdupois weight the quantity of product in the container.

(c) The name and place of business of the manufacturer, packer, or distributor. The name under which inspection is granted to a plant may appear without qualification on the label of a product prepared by that plant. When the certified product is not prepared by the person whose name appears on the label, the name shall be qualified by a phrase which reveals the connection such person has with the product as, for example, ''Prepared for _____.''

[23 FR 10107, Dec. 23, 1958, as amended at 25 FR 1357, Feb. 16, 1960; 26 FR 3984, May 9, 1961; 29 FR 9819, July 22, 1964. Redesignated at 30 FR 4195, Mar. 31, 1965, and amended at 32 FR 13115, Sept. 15, 1967]

§355.33 Plant number to be embossed on metal containers.

The official number assigned to an inspected plant under §355.8 shall be embossed on all sealed metal containers of certified products filled in such plant, except that such containers which bear labels lithographed directly on the container and in which the plant number is incorporated need not have the plant number embossed thereon. Labels and embossed code identification shall be affixed so as not to obscure the embossed plant number.

[23 FR 10107, Dec. 23, 1958. Redesignated and amended at 30 FR 4195, Mar. 31, 1965; 32 FR 13115, Sept. 15, 1967; 38 FR 29215, Oct. 23, 1973]

§355.34 Labels, approval of, by Administrator.

(a) Except as provided in paragraph (c) of this section, no label shall be used on any container of certified products until it has been approved by the Administrator. For the convenience of the inspected plant, sketches or proofs of proposed labels may be submitted in triplicate to the Administrator for approval, and the preparation of the finished labels deferred until such approval is obtained. All finished labels shall be submitted in quadruplicate to the Administrator for approval. In the case of lithographed labels, paper take-offs in lieu of sections of the metal containers shall be submitted for approval. Such paper take-offs shall not be in the form of a negative but shall be a complete reproduction of the label as it will appear on the package, including any color scheme involved.

(b) Inserts, tags, liners, pasters, and like devices containing printed or graphic matter for use on, or to be placed within, containers and coverings of certified products shall be submitted for approval in the same manner as provided for labels in paragraph (a) of this section, except that inspectors in charge may permit the use of such devices if they contain no reference to

the certified products and bear no misleading feature.

(c) Stencils, labels, box dies, and brands may be used on shipping containers, including tierces, barrels, drums, boxes, crates, and large-size fiberboard containers, without approval by the Administrator, provided the markings are applicable to the certified products, are not false or deceptive, and are used with the approval of the circuit supervisor.

(d) No certified product and no container thereof shall be labeled with any false or deceptive term, and no statement, word, picture, design, or device which conveys any false impression or gives any false indication of the origin, quality, or quantity of the product shall appear on any label.

§ 355.35 Label information to be displayed on principal panel.

The label information required by § 355.32 shall be displayed on the principal panel or panels of the label except that label information other than the name of the product and the ingredient statement may be displayed on a panel immediately adjacent to the principal panel or panels if such supplemental panel consists of at least 20 percent of the label and is reserved exclusively for required labeling information.

§ 355.36 Obsolete labels.

At least once each year, each inspected plant shall submit to the Administrator, in quadruplicate, a list of approvals for labels that have become obsolete, accompanied by a statement that such approvals are no longer desired. The approvals shall be identified by the number, the date of approval, and the name of the product.

§ 355.37 Alteration or limitation of statement of certification.

The statement of certification provided for by § 355.32(a)(4) shall not be altered, defaced, imitated, or simulated in any respect or used for the purpose of misrepresentation or deception.

[25 FR 1357, Feb. 16, 1960. Redesignated at 30 FR 4195, Mar. 31, 1965]

PENALTIES

§ 355.38 Withdrawal of service.

After opportunity for hearing before a proper official of the Department has been accorded the operator of an inspected plant, the inspection, certification, and identification provided for in this part may be withdrawn from such plant if the operator: (a) Persistently fails to comply with any provision of the regulations in this part or of instructions or directions issued thereunder; (b) makes any willful misrepresentation or engages in any fraudulent or deceptive practice in connection with the making of any application for service; (c) violates § 355.37; or (d) interferes with or obstructs any program employee in the performance of his duties under the regulations in this part by intimidation, threats, or other improper means. Pending final determination of the matter, the Administrator may suspend such inspection, certification, and identification without hearing in cases of willfulness or those in which the public health, interest, or safety requires such action. The operator of the inspected plant shall be notified of the Administrator's decision to suspend such inspection, certification or identification service, and the reasons therefor, in writing, in the manner prescribed in § 1.147(b) of the rules of practice (7 CFR 1.147(b)), or orally. The Administrator's decision to suspend such inspection, certification or identification service shall be effective upon such oral or written notification, whichever is earlier, to the operator of the plant. If such notification is oral, the Administrator shall confirm such decision and the reasons therefor, in writing, as promptly as circumstances permit, and such written confirmation shall be served upon the operator of the inspected plant, in the manner prescribed in § 1.147(b) of the rules of practice (7 CFR 1.147(b)). In other cases, prior to the institution of proceedings for any withdrawal or suspension, the facts or conduct which may warrant such action shall be called to the attention of the operator in writing and he shall be given an opportunity to demonstrate or achieve compliance with the requirements of

the regulations in this part and instructions and directions issued thereunder.

[23 FR 10107, Dec. 23, 1958. Redesignated at 30 FR 4195, Mar. 31, 1965, and amended at 43 FR 11148, Mar. 17, 1978]

APPEALS

§ 355.39 Appeals from decisions made under this part.

Any appeal from a decision by an employee of the Program shall be made to his immediate superior having jurisdiction over the subject matter of the appeal.

REPORTS

§ 355.40 Plants to furnish information for reports.

Each day the operator of every inspected plant shall furnish the inspector assigned to that plant with a statement of the number of pounds of product certified by the inspector.

(Approved by the Office of Management and Budget under control number 0583–0036)

[23 FR 10107, Dec. 23, 1958. Redesignated at 30 FR 4195, Mar. 31, 1965, and amended at 47 FR 746, Jan. 7, 1982]

MULE MEAT AND ANIMAL FOOD, MULE MEAT BY-PRODUCT

§ 355.41 Antemortem and postmortem inspection for mules.

(a)(1) An antemortem examination and inspection shall be made of all mules about to be slaughtered for use in the preparation of products under this part, before their slaughter shall be allowed for such use. Such inspection shall be made on the day of slaughter.

(2) Mules found on such inspection to show symptoms of disease shall be set apart and slaughtered separately. Those found to be affected with strangles, purpura hemorrhagica, azoturia, infectious equine encephalomyelitis, toxic encephalomyelitis (forage poisoning), infectious anemia (swamp fever), dourine, acute influenza, generalized osteoporosis, glanders, farcy, or other malignant disorder, acute inflammatory lameness or extensive fistula, shall be condemned and destroyed. Any mule which is suspected on antemortem inspection of being infected with glanders shall be tested with mallein, and any mule which on physical examination is suspected of being affected with dourine shall be held for further examination or for such test as the Administrator may prescribe.

(b)(1) A careful postmortem examination and inspection shall be made of all carcasses and parts thereof of all mules inspected under this section, at the time of slaughter. All carcasses and parts of mules found to be affected with any disease listed under paragraph (a) of this section shall be condemned and destroyed.

(2) Other carcasses and parts of mules found abnormal or diseased upon inspection under this section shall be disposed of in accordance with such provisions of the Meat Inspection Regulations (Subchapter A of this chapter) as are deemed applicable by the Administrator.

§ 355.42 Marking of mule meat and animal food mule meat by-product.

All mule meat and animal food mule meat by-product inspected under this part shall be marked and identified as the Administrator may require in any particular case.

[25 FR 1357, Feb. 16, 1960. Redesignated at 30 FR 4195, Mar. 31, 1965, and amended at 32 FR 13115, Sept. 15, 1967]

§ 355.43 Scope and applicability of rules of practice.

The rules of practice of the Department of Agriculture in subpart H of part I, subtitle A, title 7 of the Code of Federal Regulations, are the rules of practice applicable to adjudicatory, admininstrative proceedings under the regulations in this part (9 CFR part 355).

[43 FR 11148, Mar. 17, 1978]

PART 362—VOLUNTARY POULTRY INSPECTION REGULATIONS

Sec.

362.1 Definitions.
362.2 Types and availability of service.
362.3 Application for service.
362.4 Denial or withdrawal of service.
362.5 Fees and charges.

AUTHORITY: 7 U.S.C. 1622; 7 CFR 2.18 (g) and (i) and 2.53.

SOURCE: 41 FR 23715, June 11, 1976, unless otherwise noted.

§ 362.1 Definitions.

The definitions in § 381.1 are incorporated in this part except for the definitions excluded in § 362.2(a). In addition to those definitions, the following definitions will be applicable to the regulations in this part.

(a) *Act.* ''Act'' means the Agricultural Marketing Act of 1946, as amended (60 Stat. 1087, as amended; 7 U.S.C. 1621 et seq.).

(b) *Inspector.* ''Inspector'' means any officer or employee of the Department authorized to perform any duties under the regulations in this part.

(c) *Person.* ''Person'' means any individual, corporation, company, association, firm, partnership, society, or joint stock company, or other organized business unit.

(d) *Poultry.* ''Poultry'' means any migratory water fowl or game bird, whether dead or alive.

(e) *Poultry Product.* ''Poultry product'' means any poultry carcass or part thereof; or any human food product which is made wholly or in part from the carcass of any domesticated bird (as defined in § 381.1(b) of this chapter) and is excepted from the inspection requirements of the Poultry Products Inspection Act (21 U.S.C. 451 et seq.).

[66 FR 22905, May 7, 2001]

§ 362.2 Types and availability of service.

Upon application, in accordance with § 362.3, the following types of service may be furnished under the regulations in this part:

(a) *Inspection service.* An inspection and certification service for wholesomeness relating to the slaughter and processing of poultry and the processing of poultry products. All provisions of Part 381 and §§ 416.1 through 416.6 of this chapter shall apply to the slaughter of poultry, and the preparation, labeling, and certification of the poultry and poultry products processed under this poultry inspection service except for the following provisions: the definitions of ''Act,'' ''animal food manufacturer,'' ''Inspection Service,'' ''inspector,'' ''Inspector in Charge,'' ''poultry,'' ''poultry product,'' ''poultry food product,'' ''poultry products broker,'' ''renderer,'' and ''U.S. Refused Entry'' in §§ 381.1 (b), 381.3 (a), 381.6, 381.10, 381.13–381.17, 381.21, 381.29, 381.39–381.42, 381.175 (a)(2), 381.175 (a)(3), 381.179, 381.185–381.187, 381.192, and 381.195–381.225.

(b) *Export certification service.* At the request of any person intending to export any slaughtered poultry or poultry product, inspectors may make certification regarding products for human food purposes, to be exported, as meeting conditions or standards that are not imposed or are in addition to those imposed by the regulations in this chapter and the laws under which such regulations were issued.

(c) *Identification Service.* (1) Poultry or other product that is federally inspected and passed at an official establishment, or upon importation, under the Poultry Products Inspection Act, is officially marked to identify it as federally inspected and passed. In order to facilitate the division of such poultry or other product into smaller portions or its combination into larger units and still maintain its identify as product which has been federally inspected and passed and so marked, inspectors may supervise the handling and weighing of the product and mark such portions and units with the official mark of inspection when they determine that identify has been maintained.

(2) At the time service is furnished, product must be sound, wholesome, and fit for human food. The service will be available only on premises other than those of an official establishment. The sanitation of the place or area where service is furnished must comply with provisions of §§ 416.1 through 416.6 of this chapter.

(3) The mark of inspection shall be applied only under the immediate supervision of an inspector.

(4) This service does not cover further cutting and processing of products. These activities must take place at an official establishment.

(5) The registration and recordkeeping requirements enumerated in Part 381, subpart Q, of this chapter

shall apply to persons requesting voluntary identification service under this paragraph (c).

[66 FR 22905, May 7, 2001]

§362.3 Application for service.

Any person who desires to receive service under the regulations in this part for poultry or other product eligible therefor under such regulations may make application for service to the Administrator, upon an application form which will be furnished by the Administrator upon request to the Meat and Poultry Inspection Program, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250. The application must include all the information called for by that form. In case of change of name, ownership, management, or location, a new application shall be made.

(Approved by the Office of Management and Budget under control number 0583–0036)

[41 FR 23715, June 11, 1976, as amended at 47 FR 746, Jan. 7, 1982]

§362.4 Denial or withdrawal of service.

(a) *For disciplinary reasons*—(1) *Bases for denial or withdrawal.* An application or request for service may be rejected, or the benefits of the service may be otherwise denied to, or withdrawn from, any person who, or whose employee or agent in the scope of his employment or agency, (i) has willfully made any misrepresentation or has committed any other fraudulent or deceptive practice in connection with any application or request for service under the regulations in this chapter; (ii) has given or attempted to give, as a loan or for any other purpose, any money, favor, or other thing of value, to any employee of the Department authorized to perform any function under the regulations in this chapter; (iii) has interfered with or obstructed, or attempted to interfere with or to obstruct, any employee of the Department in the performance of his duties under the regulations in this chapter by intimidation, threats, assaults, abuse, or any other improper means; (iv) has knowingly falsely made, issued, altered, forged, or counterfeited any official certificate, memorandum, mark, or other identification, or device for making any such mark or identification authorized or issued under this chapter; (v) has knowingly uttered, published, or used as true any such falsely made, issued, altered, forged, or counterfeited certificate, memorandum, mark, identification, or device; (vi) has knowingly obtained or retained possession of any such falsely made, issued, altered, forged, or counterfeited certificate, memorandum, mark, identification, or device, or of any carcass or poultry or product bearing any such falsely made, issued, altered, forged or counterfeited certificate, memorandum, mark, or identification; (vii) has knowingly represented that any carcass, poultry, or product has been officially inspected and passed (by an authorized inspector) under this chapter, when it had not in fact been so inspected; (viii) has, within the previous ten years, been convicted of any felony or more than one misdemeanor under any law based upon the acquiring, handling, or distributing of adulterated, mislabeled, or deceptively packaged food, or fraud in connection with transactions in food, or any felony indicating a lack of the integrity needed for the conduct of operations affecting the public health; (ix) has in any manner not specified in this paragraph violated subsection 203(h) of the Act:

Provided, That paragraph (a)(1)(vi) of this section shall not be deemed to be violated if the person in possession of any item mentioned therein notifies the inspector without delay that he has possession of such item and, in the case of an official device, surrenders it to the inspector, and, in the case of any other item, surrenders it to the inspector or destroys it or brings it into compliance with the regulations by obliterating or removing the violative features under supervision of the inspector; *And provided further,* That an application or a request for service may be rejected, or the benefits of the service may be otherwise denied to, or withdrawn from any person who operates an establishment for which he has made application for service if, with the knowledge of such operator, any

other person conducting any operations in such establishment has committed any of the offenses specified in paragraphs (a)(1) (i) through (ix) of this section after such application was made. Moreover, an application or a request for service made in the name of a person otherwise eligible for service under the regulations may be rejected, or the benefits of the service may be otherwise denied to, or withdrawn from, such a person (a) in case the service is or would be performed at an establishment operated (1) by a corporation, partnership, or other person from whom the benefits of the service are currently being withheld under this chapter, or (2) by a corporation, partnership, or other person having an officer, director, partner, or substantial investor from whom the benefits of service under this chapter are currently being withheld and who has any authority with respect to the establishment where service is or would be performed, or (b) in case the service is or would be performed with respect to any poultry or product in which any corporation, partnership, or other person within (a)(1) of this section has a contract or other financial interest.

(2) *Procedure.* An application or request for service may be rejected, or benefits of the service may be otherwise denied to or withdrawn by the Secretary, as provided by this paragraph, after notice and opportunity for hearing before a proper official of the Department. The Administrator may reject an application or request for service or deny or withdraw service under this paragraph without hearing, pending final determination of the matter, when he determines that the public interest so requires. The operator or applicant of such plant shall be notified of the Administrator's decision to reject the application or request for service or to deny or withdraw such service, and the reasons therefor, in writing, in the manner prescribed in § 1.147(b) of the rules of practice (7 CFR 1.147(b)), or orally. The Administrator's decision to reject an application or request for service or to deny or withdraw the benefits of service under the Act shall be effective upon such oral or written notification, whichever is earlier, to the operator or applicant of such plant. If such notification is oral, the Administrator shall confirm such decision, and the reasons therefor, in writing, as promptly as circumstances permit, and such written confirmation shall be served upon the operator or applicant of such plant in the manner prescribed in § 1.147(b) of the rules of practice (7 CFR 1.147(b)).

(b) *For correctable cause*—(1) *Basis for denial or withdrawal.* An application or request for service may be rejected, or the benefits of the service may be otherwise denied to, or withdrawn from, any person whose establishment does not meet the requirements as to premises, facilities, and equipment, and the operation thereof, prescribed in the regulations to prevent the distribution of adulterated poultry or poultry products, or who has not received approval of labeling and containers to be used at the establishment as required by the regulations.

(2) *Procedure.* An application or request for service may be rejected, or benefits of the service may be otherwise denied to or withdrawn by the Secretary, as provided by this paragraph, after notice and opportunity for hearing before a proper official of the Department. The Administrator may reject an application or request for service or deny or withdraw service under this paragraph without hearing, pending final determination of the matter, when he determines that the public interest so requires. The operator or applicant of such plant shall be notified of the Administrator's decision to reject the application or request for service or to deny or withdraw such service, and the reasons therefor, in writing, in the manner prescribed in § 1.147(b) of the rules of practice (7 CFR 1.147(b)), or orally. The Administrator's decision to reject an application or request for service or to deny or withdraw the benefits of service under the Act shall be effective upon such oral or written notification, whichever is earlier, to the operator or applicant of such plant. If such notification is oral, the Administrator shall confirm such decision, and the reasons therefor, in writing, as promptly as circumstances permit, and such written confirmation shall be served upon the operator or applicant of such plant in

the manner prescribed in §1.147(b) of the rules of practice (7 CFR 1.147(b)).

(c) *For miscellaneous reasons.* An application or a request for service may be rejected, or the benefits of the service may be otherwise denied to, or withdrawn from, any person, without a hearing, by the official in charge of the appropriate regional office, with the concurrence of the Regional Director (1) for administrative reasons such as the nonavailability of personnel to perform the service; (2) for the failure to pay for service; (3) in case the application or request relates to birds or products which are not eligible for service under this part 362; or (4) in case the person is a partnership, corporation, or other person from whom the benefits of the service are currently being withheld under paragraph (a) of this section. Notice of such rejection, denial, or withdrawal, and the reasons therefor, shall promptly be given to the person involved. The operator or applicant of such plant shall be notified of such decisions to reject an application or request for service or to deny or withdraw the benefits of the service, and the reasons therefor, in writing, in the manner prescribed in §1.147(b) of the rules of practice (7 CFR 1.147(b)), or orally. Such decision shall be effective upon such oral or written notification, whichever is earlier, to the operator or applicant of such plant. If such notification is oral, the person making such decision shall confirm such decision, and the reasons therefor, in writing, as promptly as circumstances permit, and such written confirmation shall be served upon the operator or applicant of such plant in the manner prescribed in §1.147(b) of the rules of practice (7 CFR 1.147(b)).

(d) *Scope and applicability of rules of practice.* The rules of practice of the Department of Agriculture in subpart H of part I, subtitle A, title 7 of the Code of Federal Regulations, are the rules of practice applicable to adjudicatory, administrative proceedings under the regulations in this part (9 CFR part 362).

[41 FR 23715, June 11, 1976, as amended at 43 FR 11148, Mar. 17, 1978]

§362.5 Fees and charges.

(a) Fees and charges for service under the regulations in this part shall be paid by the applicant for the service in accordance with this section, and, if required by the Administrator, the fees and charges shall be paid in advance.

(b) The fees and charges provided for in this section shall be paid by check, draft, or money order payable to the Treasurer of the United States and shall be remitted promptly to the Administrator upon furnishing to the applicant a statement as to the amount due.

(c) The fees to be charged and collected for service under the regulations in this part shall be at the rates specified in §§391.2, 391.3, and 391.4 respectively for base time; for overtime including Saturdays, Sundays, and holidays; and for certain laboratory services which are not covered under the base time, overtime, and/or holiday costs. Such fees shall cover the costs of the services and shall be charged for the time required to render such service, including, but not limited to, the time required for the travel of the inspector or inspectors in connection therewith during the regularly scheduled administrative workweek.

(d) Charges may also be made to cover the cost of travel and other expenses incurred by the Service in connection with the furnishing of the service.

[41 FR 23715, June 11, 1976, as amended at 53 FR 13398, Apr. 22, 1988; 54 FR 6390, Feb. 10, 1989]

PART 381—POULTRY PRODUCTS INSPECTION REGULATIONS

Subpart A—Definitions

Sec.
381.1 Definitions.

Subpart B—Administration; Application of Inspection and Other Requirements

381.3 Administration.
381.4 Inspection in accordance with methods prescribed or approved.
381.5 Publications.
381.6 Establishments requiring inspection.
381.7 Coverage of all poultry and poultry products processed in official establishments.

Subpart C—Exemptions

381.10 Exemptions for specified operations.
381.11 Exemptions based on religious dietary laws.
381.12 Effect of religious dietary laws exemptions on other persons.
381.13 Suspension or termination of exemptions.
381.14 Inspection concerning purportedly exempted operations.
381.15 Exemption from definition of ''poultry product'' of certain human food products containing poultry.

Subpart D—Application for Inspection; Grant or Refusal of Inspection

381.16 How application shall be made.
381.17 Filing of application.
381.18 Authority of applicant.
381.20 Survey and grant of inspection.
381.21 Refusal of inspection.
381.22 Conditions for receiving inspection.

Subpart E—Inauguration of Inspection; Official Establishment Numbers; Separation of Establishments and Other Requirements; Withdrawal of Inspection

381.25 Official establishment numbers.
381.26 Separation of establishments.
381.27 Inauguration of service; notification concerning regulations; status of uninspected poultry products.
381.28 Report of violations.

Subpart F—Assignment and Authorities of Program Employees; Appeals

381.30–381.31 [Reserved]
381.32 Access to establishments.
381.33 Identification.
381.34 Financial interest of inspectors.
381.35 Appeal inspections; how made.

Subpart G—Facilities for Inspection; Overtime and Holiday Service; Billing Establishments

381.36 Facilities required.
381.37 Schedule of operations.
381.38 Overtime and holiday inspection service.
381.39 Basis of billing for overtime and holiday services.

Subpart H [Reserved]

Subpart I—Operating Procedures

381.65 Operations and procedures, generally.
381.66 Temperatures and chilling and freezing procedures.
381.67 Young chicken and squab slaughter inspection rate maximums under traditional inspection procedure.
381.68 Maximum inspection rates—New turkey inspection system.

Subpart J—Ante Mortem Inspection

381.70 Ante mortem inspection; when required; extent.
381.71 Condemnation on ante mortem inspection.
381.72 Segregation of suspects on ante mortem inspection.
381.73 Quarantine of diseased poultry.
381.74 Poultry suspected of having biological residues.
381.75 Poultry used for research.

Subpart K—Post Mortem Inspection; Disposition of Carcasses and Parts

381.76 Post-mortem inspection, when required; extent; traditional, Streamlined Inspection System (SIS), New Line Speed (NELS) Inspection System and the New Turkey Inspection (NTI) System; rate of inspection.
381.77 Carcasses held for further examination.
381.78 Condemnation of carcasses and parts: separation of poultry suspected of containing biological residues.
381.79 Passing of carcasses and parts.
381.80 General; biological residues.
381.81 Tuberculosis.
381.82 Diseases of the leukosis complex.
381.83 Septicemia or toxemia.
381.84 Airsacculitis.
381.85 Special diseases.
381.86 Inflammatory processes.
381.87 Tumors.
381.88 Parasites.
381.89 Bruises.
381.90 Cadavers.
381.91 Contamination.
381.92 Overscald.
381.93 Decomposition.
381.94 Contamination with Microorganisms; process control verification criteria and testing; pathogen reduction standards.

Subpart L—Handling and Disposal of Condemned or Other Inedible Products at Official Establishments

381.95 Disposal of condemned poultry products.

Subpart M—Official Marks, Devices and Certificates; Export Certificates; Certification Procedures

381.96 Wording and form of the official inspection legend.
381.97 [Reserved]
381.98 Official seal.
381.99 Official retention and rejection tags.
381.100 Official detention tag.
381.101 Official U.S. Condemned mark.

381.102 [Reserved]
381.103 Official poultry condemnation certificates; issuance and form.
381.104 Official export certificates, marks and devices.
381.105 Export certification; marking of containers.
381.106 Form of official export certificate.
381.107 Special procedures as to certification of poultry products for export to certain countries.
381.108 Official poultry inspection certificates; issuance and disposition.
381.109 Form of official poultry inspection certificate.
381.110 Erasures or alterations made on certificates.
381.111 Data to be entered in proper spaces.
381.112 Official mark for maintaining the identity and integrity of samples.

Subpart N—Labeling and Containers

381.115 Containers of inspected and passed poultry products required to be labeled.
381.116 Wording on labels of immediate containers.
381.117 Name of product and other labeling.
381.118 Ingredients statement.
381.119 Declaration of artificial flavoring or coloring.
381.120 Antioxidants; chemical preservatives; and other additives.
381.121 Quantity of contents.
381.121a Quantity of contents labeling.
381.121b Definitions and procedures for determining net weight compliance.
381.121c Scale requirements for accurate weights, repairs, adjustments, and replacement after inspection.
381.121d Scales; testing of.
381.121e Handling of failed product.
381.122 Identification of manufacturer, packer or distributor.
381.123 Official inspection mark; official establishment number.
381.124 Dietary food claims.
381.125 Special handling label requirements.
381.126 Date of packing and date of processing; contents of cans.
381.127 Wording on labels of shipping containers.
381.128 Labels in foreign languages.
381.129 False or misleading labeling or containers.
381.130 False or misleading labeling or containers; orders to withhold from use.
381.131 Preparation of labeling or other devices bearing official inspection marks without advance approval prohibited; exceptions.
381.132 Labeling approval.
381.133 Generically approved labeling.
381.134 Requirement of formulas.
381.136 Affixing of official identification.
381.137 Evidence of labeling and devices approval.
381.138 Unauthorized use or disposition of approved labeling or devices.
381.139 Removal of official identifications.
381.140 Relabeling poultry products.
381.141–381.143 [Reserved]
381.144 Packaging materials.

Subpart O—Entry of Articles Into Official Establishments; Processing Inspection and Other Reinspections; Processing Requirements

381.146 Sampling at official establishments.
381.148 Processing and handling requirements for frozen poultry products.
381.150 Requirements for the production of fully cooked poultry products and partially cooked poultry breakfast strips.
381.151 Adulteration of product by polluted water; procedure for handling.
381.152 Preparation in an official establishment of articles not for human food.
381.153 Accreditation of chemistry laboratories.

Subpart P—Definitions and Standards of Identity or Composition

381.155 General.
381.156 Poultry meat content standards for certain poultry products.
381.157 Canned boned poultry and baby or geriatric food.
381.158 Poultry dinners (frozen) and pies.
381.159 Poultry rolls.
381.160 (Kind) burgers; (Kind) patties.
381.161 ''(Kind) A La Kiev.''
381.162 ''(Kind) steak or fillet.''
381.163 ''(Kind) baked'' or ''(Kind) roasted.''
381.164 ''(Kind) barbecued.''
381.165 ''(Kind) barbecued prepared with moist heat.''
381.166 Breaded products.
381.167 Other poultry dishes and specialty items.
381.168 Maximum percent of skin in certain poultry products.
381.169 Ready-to-cook poultry products to which solutions are added.
381.170 Standards for kinds and classes, and for cuts of raw poultry.
381.171 Definition and standard for ''Turkey Ham.''
381.173 Mechanically Separated (Kind of Poultry).
381.174 Limitations with respect to use of Mechanically Separated (Kind of Poultry).

Subpart Q—Records, Registration, and Reports

381.175 Records required to be kept.
381.176 Place of maintenance of records.
381.177 Record retention period.

381.178 Access to and inspection of records, facilities and inventory; copying and sampling.
381.179 Registration.
381.180 Information and reports required from official establishment operators.
381.181 Reports by consignees of allegedly adulterated or misbranded products; sale or transportation as violations.
381.182 Reports of inspection work.

Subpart R—Cooperation With States and Territories; Certification of State and Territorial Programs as at Least Equal to Federal Program

381.185 Assistance to State and Territorial programs.
381.186 Cooperation of States and other jurisdictions in Federal programs.

Subpart S—Transportation; Exportation; or Sale of Poultry or Poultry Products

381.189 Provisions inapplicable to specimens for laboratory examination, etc., or to naturally inedible articles.
381.190 Transactions in slaughtered poultry and other poultry products restricted; vehicle sanitation requirements.
381.191 Distribution of inspected products to small lot buyers.
381.192 Penalties inapplicable to carriers.
381.193 Poultry carcasses, etc., not intended for human food.
381.194 Transportation and other transactions concerning dead, dying, disabled, or diseased poultry, and parts of carcasses of poultry that died otherwise than by slaughter.

Subpart T—Imported Poultry Products

381.195 Definitions; requirements for importation into the United States.
381.196 Eligibility of foreign countries for importation of poultry products into the United States.
381.197 Imported products; foreign inspection certificates required.
381.198 Importer to make application for inspection of poultry products offered for entry.
381.199 Inspection of poultry products offered for entry.
381.200 Poultry products offered for entry, retention in customs custody; delivery under bond; movement prior to inspection; handling; facilities and assistance.
381.201 Means of conveyance and equipment used in handling poultry products offered for entry to be maintained in sanitary condition.
381.202 Poultry products offered for entry; reporting of findings to customs; handling of articles refused entry; appeals, how made; denaturing procedures.
381.203 Products offered for entry; charges for storage, cartage, and labor with respect to products which are refused entry.
381.204 Marking of poultry products offered for entry; official import inspection marks and devices.
381.205 Labeling of immediate containers of poultry products offered for entry.
381.206 Labeling of shipping containers of poultry products offered for entry.
381.207 Small importations for consignee's personal use, display, or laboratory analysis.
381.208 Poultry products offered for entry and entered to be handled and transported as domestic; entry into official establishments; transportation.
381.209 Returned United States inspected and marked poultry products: exemption.

Subpart U—Detention; Seizure and Condemnation; Criminal Offenses

381.210 Poultry and other articles subject to administrative detention.
381.211 Method of detention; form of detention tag.
381.212 Notification of detention to the owner of the poultry or other article, or the owner's agent, and person having custody.
381.213 Notification of governmental authorities having jurisdiction over article detained; form of written notification.
381.214 Movement of poultry or other article detained; removal of official marks.
381.215 Poultry or other articles subject to judicial seizure and condemnation.
381.216 Procedure for judicial seizure, condemnation, and disposition.
381.217 Authority for condemnation or seizure under other provisions of law.
381.218 Criminal offenses.

Subpart V—Special Provisions for Designated States and Territories; Criteria and Procedure for Designating Establishments With Operations Which Would Clearly Endanger the Public Health; Disposition of Poultry Products Therein

381.220 Definition of ''State''.
381.221 Designation of States under paragraph 5(c) of the Act.
381.222 States designated under paragraph 5(c) of the Act; application of regulations.
381.223 Control and disposition of nonfederally inspected poultry products in States designated under paragraph 5(c) of the Act.
381.224 Designation of States under section 11 of the Act; application of sections of the Act and the regulations.
381.225 Criteria and procedure for designating establishments with operations

which would clearly endanger the public health; disposition of poultry products therein.

Subpart X—Canning and Canned Products

381.300 Definitions.
381.301 Containers and closures.
381.302 Thermal processing.
381.303 Critical factors and the application of the process schedule.
381.304 Operations in the thermal processing area.
381.305 Equipment and procedures for heat processing systems.
381.306 Processing and production records.
381.307 Record review and maintenance.
381.308 Deviations in processing.
381.309 Finished product inspection.
381.310 Personnel and training.
381.311 Recall procedure.

Subpart Y—Nutrition Labeling

381.400 Nutrition labeling of poultry products.
381.401 [Reserved]
381.402 Location of nutrition information.
381.403–381.407 [Reserved]
381.408 Labeling of poultry products with number of servings.
381.409 Nutrition label content.
381.410–381.411 [Reserved]
381.412 Reference amounts customarily consumed per eating occasion.
381.413 Nutrient content claims; general principles.
381.414–381.442 [Reserved]
381.443 Significant participation for voluntary nutrition labeling.
381.444 Identification of major cuts of poultry products.
381.445 Guidelines for voluntary nutrition labeling of single-ingredient, raw products.
381.446–381.453 [Reserved]
381.454 Nutrient content claims for ''good source,'' ''high,'' and ''more''.
381.455 [Reserved]
381.456 Nutrient content claims for ''light'' or ''lite''.
381.457–381.459 [Reserved]
381.460 Nutrient content claims for calorie content.
381.461 Nutrient content claims for the sodium content.
381.462 Nutrient content claims for fat, fatty acids, and cholesterol content.
381.463 Nutrient content claims for ''healthy.''
381.464–381.468 [Reserved]
381.469 Labeling applications for nutrient content claims.
381.470–381.479 [Reserved]
381.480 Label statements relating to usefulness in reducing or maintaining body weight.
381.481–381.499 [Reserved]
381.500 Exemption from nutrition labeling.

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Subpart A—Definitions

§381.1 Definitions.

(a) For the purposes of the regulations in this part, unless otherwise required by the context, the singular form shall also import the plural and the masculine form shall also import the feminine, and vice versa.

(b) For the purposes of such regulations, unless otherwise required by the context, the following terms shall be construed, respectively, to mean:

Acceptable. ''Acceptable'' means suitable for the purpose intended and acceptable to the Administrator.

Act. ''Act'' means the Poultry Products Inspection Act (71 Stat. 441, as amended by the Wholesome Poultry Products Act, 82 Stat. 791; 21 U.S.C. 451 et seq.).

Administrator. ''Administrator'' means the Administrator of the Food Safety and Inspection Service of the Department or any other officer or employee of the Department to whom there has heretofore been delegated, or to whom there may hereafter be delegated the authority to act in his stead.

Adulterated. ''Adulterated'' applies to any poultry product under one or more of the following circumstances:

(i) If it bears or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance, such article shall not be considered adulterated under this clause if the quantity of such substance in or on such article does not ordinarily render it injurious to health;

(ii)(*a*) If it bears or contains (by reason of administration of any substance to the live poultry or otherwise) any added poisonous or added deleterious substance (other than one which is a pesticide chemical in or on a raw agricultural commodity; a food additive; or a color additive) which may, in the judgment of the Administrator, make such article unfit for human food;

(*b*) If it is, in whole or part, a raw agricultural commodity and such commodity bears or contains a pesticide chemical which is unsafe within the meaning of section 408 of the Federal Food, Drug, and Cosmetic Act;

(*c*) If it bears or contains any food additive which is unsafe within the meaning of section 409 of the Federal Food, Drug, and Cosmetic Act;

(*d*) If it bears or contains any color additive which is unsafe within the meaning of section 706 of the Federal Food, Drug, and Cosmetic Act:

Provided, That an article which is not otherwise deemed adulterated under paragraphs (b)(4)(ii) (*b*), (*c*), or (*d*) of this section shall nevertheless be deemed adulterated if use of the pesticide chemical, food additive, or color additive in or on such article is prohibited by the regulations in this part in official establishments;

(iii) If it consists in whole or in part of any filthy, putrid, or decomposed substance or is for any other reason unsound, unhealthful, unwholesome, or otherwise unfit for human food;

(iv) If it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health;

(v) If it is, in whole or in part, the product of any poultry which has died otherwise than by slaughter;

(vi) If its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health;

(vii) If it has been intentionally subjected to radiation, unless the use of the radiation was in conformity with a regulation or exemption in effect pursuant to section 409 of the Federal Food, Drug, and Cosmetic Act; or

(viii) If any valuable constituent has been in whole or in part omitted or abstracted therefrom; or if any substance has been substituted, wholly or in part therefor; or if damage or inferiority has been concealed in any manner; or if any substance has been added thereto or mixed or packed therewith so as to increase its bulk or weight, or reduce its quality or strength, or make it appear better or of greater value than it is.

Animal food. Any article intended for use as food for dogs, cats, or other animals, derived wholly, or in part, from carcasses or parts or products of the carcass of poultry, except that the term animal food as used herein does not include (i) processed dry animal food or (ii) livestock or poultry feeds manufactured from processed poultry byproducts (such as poultry byproduct meal, hydrolyzed poultry feathers, and hydrolyzed poultry byproducts aggregate).

Animal food manufacturer. ''Animal Food Manufacturer'' means any person engaged in the business of manufacturing or processing animal food.

Applicant. ''Applicant'' means any person who requests inspection service, exemption, or other authorization under the regulations.

Biological residue. ''Biological Residue'' means any substance, including metabolites, remaining in poultry at the time of slaughter or in any of its tissues after slaughter, as the result of treatment or exposure of the live poultry to a pesticide, organic compound, metallic or other inorganic compound, hormone, hormone-like substance, growth promoter, antibiotic, anthelmintic, tranquilizer, or other agent that leaves a residue.

Capable of use as human food. The term ''capable of use as human food'' applies to any carcass, or part or product of a carcass of any poultry, unless it is denatured or otherwise identified as required by the regulations, or it is naturally inedible by humans.

Carcass. This term means all parts, including viscera, of any slaughtered poultry.

Circuit supervisor. This term refers to the official of the Inspection Service who is assigned responsibility for supervising the conduct of inspection at a specific group of official establishments.

Commerce. ''Commerce'' means commerce between any State, any territory, or the District of Columbia, and any place outside thereof; or within any territory not organized with a legislative body, or the District of Columbia.

Consumer package. ''Consumer package'' means any container in which a

poultry product is enclosed for the purpose of display and sale to household consumers.

Container. The term ''container'' includes any box, can, tin, cloth, plastic, or any other receptacle, wrapper, or cover.

Department. ''Department'' means the United States Department of Agriculture.

Edible. This term means that an article is intended for use as human food.

Egg Products Inspection Act. ''Egg Products Inspection Act'' means the Act so entitled, approved December 29, 1970 (84 Stat. 1620, 21 U.S.C. 1031 et seq.).

Federal Food, Drug, and Cosmetic Act. ''Federal Food, Drug, and Cosmetic Act'' means the Act so entitled, approved June 25, 1938 (52 Stat. 1040), and acts amendatory thereof or supplementary thereto (21 U.S.C. 301 et seq.).

Federal Meat Inspection Act. ''Federal Meat Inspection Act'' means the Act so entitled, approved March 4, 1907, 34 Stat. 1260, as amended by the Wholesome Meat Act, 81 Stat. 584 (21 U.S.C. 601 et seq.).

Free from protruding pinfeathers. ''Free from protruding pinfeathers'' means that the carcass is free from protruding pinfeathers which are visible to an inspector during an examination of the carcass at normal operating speeds. However, a carcass may be considered as being free from protruding pinfeathers if it has a generally clean appearance (especially on the breast), and if not more than an occasional protruding pinfeather is in evidence during a more careful examination of the carcass.

Giblets. ''Giblets'' means the liver from which the bile sac has been removed, the heart from which the pericardial sac has been removed, and the gizzard from which the lining and contents have been removed: *Provided,* That each such organ has been properly trimmed and washed.

Immediate container. ''Immediate container'' includes any consumer package; or any other container in which poultry products, not consumer packaged, are packed.

Import Field Office (IFO). The office of the supervisor of import inspection activities for a particular importing field area. The areas are as follows:

IFO #1. Boston, MA—Covering the States of Massachusetts, New York (excluding New York City), Connecticut, Rhode Island, Vermont, New Hampshire, and Maine.

IFO #2. New York, NY—Covering the areas of New York City and northern New Jersey.

IFO #3. Philadelphia, PA—Covering the State of Pennsylvania and the area of southern New Jersey.

IFO #4. Baltimore, MD—Covering the States of Maryland, Delaware, West Virginia, Virginia and Kentucky.

IFO #5. Charleston, SC—Covering the States of Tennessee, North Carolina, South Carolina, Georgia, and Florida (excluding south Florida).

IFO #6. Miami, FL—Covering the areas of southern Florida, Puerto Rico and the Virgin Islands.

IFO #7. New Orleans, LA—Covering the States of Louisiana, Mississippi, Alabama, Arkansas, Texas, Oklahoma, Kansas, New Mexico and Colorado.

IFO #8. San Pedro, CA—Covering the States of Hawaii, Arizona, Utah, Nevada, the area of southern California, American Samoa, Guam, and the Northern Marianas.

IFO #9. Tacoma, WA—Covering the States of Washington, Oregon, Idaho, Montana, Wyoming, North Dakota, South Dakota, Alaska, and Nebraska, and the area of northern California.

IFO #10. Detroit, MI—Covering the States of Michigan, Wisconsin, Minnesota, Iowa, Missouri, Illinois, Indiana and Ohio.

Import Supervisor. The official in charge of import inspection activities within each of the import field offices.

Inedible. This term means any carcass or any part of a carcass that is either naturally inedible by humans or is rendered unfit for human food by reason of adulteration or denaturing.

Inspected for wholesomeness. This term means that the poultry product so identified has been inspected and was found at the time of such inspection to be not adulterated.

Inspection. ''Inspection'' means any inspection required by the regulations to determine whether any poultry or poultry products comply with the requirements of the Act and the regulations.

Inspection Service. ''Inspection Service'' means the organizational unit within the Department having the responsibility for carrying out the provisions of the Act.

Inspection Service employee. This term refers to any employee of the Inspection Service who is authorized to perform any function under the regulations.

Inspection Service supervisor. This term refers to any employee of the Inspection Service who is delegated authority to exercise supervision over certain phases of the inspection program at a designated level.[1]

Inspector. ''Inspector'' means (*a*) an employee or official of the U.S. Government authorized by the Administrator to inspect poultry and poultry products under the authority of this Act, or (*b*) any employee or official of the government of any State or Territory or the District of Columbia authorized by the Administrator to inspect poultry and poultry products under the authority of this Act, under an agreement entered into between the Administrator and the appropriate State or other agency.

Inspector in Charge. This term means the inspector primarily responsible for the conduct of inspection at any particular official establishment.

Label. This term applies to any display of written, printed, or graphic matter upon any article or the immediate container (not including package liners) of any article.

Labeling. This term applies to all labels and other written, printed, or graphic matter (i) upon any article or any of its containers or wrappers, or (ii) accompanying such article.

Misbranded. This term applies to any poultry product under one or more of the following circumstances:

(i) If its labeling is false or misleading in any particular;

(ii) If it is offered for sale under the name of another food;

(iii) If it is an imitation of another food, unless its label bears, in type of uniform size and prominence, the word ''imitation'' and immediately thereafter, the name of the food imitated;

(iv) If its container is so made, formed, or filled as to be misleading;

(v) If in a package or other container, unless it bears a label showing:

(*a*) The name and place of business of the manufacturer, packer, or distributor; and

(*b*) An accurate statement of the quantity of the contents in terms of weight, measure, or numerical count; except as otherwise provided in § 381.121(a) with respect to the quantity of contents;

(vi) If any word, statement, or other information required by or under authority of the Act to appear on the label or other labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use;

(vii) If it purports to be or is represented as a food for which a definition and standard of identity or composition is prescribed by the regulations in subpart P of this part unless:

(*a*) It conforms to such definition and standard, and

(*b*) Its label bears the name of the food specified in the definition and standard, and insofar as may be required by such regulations, the common names of optional ingredients (other than spices, flavoring, and coloring) present in such food.

(viii) If it purports to be or is represented as a food for which a standard or standards of fill of container have been prescribed by regulations of the Secretary,[2] and falls below the standard of fill of container applicable thereto, unless its label bears, in such manner and form as such regulations specify, a statement that it falls below such standard;

(ix) If it is not subject to the provisions of paragraph (b)(vii) of this section, unless its label bears:

(*a*) The common or usual name of the food, if any there be, and

(*b*) In case it is fabricated from two or more ingredients, the common or

[1] Information identifying the employees who have been delegated such authority at various levels may be obtained from an inspector or from the Administrator, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250.

[2] No such standards are currently in effect. However, § 381.129 prohibits the use of false or misleading containers.

usual name of each ingredient, except as otherwise provided in § 381.118(c);

(x) If it purports to be or is represented for special dietary uses, unless the label bears such information concerning its vitamin, mineral, and other dietary properties as is required by § 381.124;

(xi) If it bears or contains any artificial flavoring, artificial coloring, or chemical preservative, unless it bears a label stating that fact; except as otherwise provided in § 381.119, or

(xii) If it fails to bear, directly thereon or on its containers, when required by § 381.123, the official inspection legend and the official establishment number of the establishment where the product was processed; and unrestricted by any of the foregoing; such other information as the Administrator may require in the regulations to assure that it will not have false or misleading labeling and that the public will be informed of the manner of handling required to maintain the article in a wholesome condition.

Nonfood compounds. Any substance proposed for use in official establishments, the intended use of which will not result, directly or indirectly, in the substance becoming a component or otherwise affecting the characteristics of poultry or poultry products, excluding labeling and packaging materials as covered in subpart N of this part.

Official certificate. This term means any certificate prescribed in subpart M of this part relating to poultry or poultry products.

Official device. This term means any label or other device prescribed in subpart M of this part for use in applying any official mark.

Official establishment. ''Official establishment'' means any establishment as determined by the Administrator at which inspection of the slaughter of poultry, or the processing of poultry products, is maintained pursuant to the regulations.

Official inspection legend. This term means the official inspection mark prescribed in § 381.96 or the official poultry identification mark prescribed in § 381.97, showing that an article was inspected for wholesomeness and passed in accordance with the Act.

Official mark. This term means any symbol prescribed in subpart M of this part to identify the status of any article or poultry under the Act.

Packaging material. Any cloth, paper, plastic, metal, or other material used to form a container, wrapper, label, or cover for poultry products.

Pesticide chemical, food additive, color additive, raw agricultural commodity. These terms shall have the same meanings for the purposes of the Act and the regulations as under the Federal Food, Drug, and Cosmetic Act.

Poultry. ''Poultry'' means any domesticated bird (chickens, turkeys, ducks, geese, guineas, ratites, or squabs, also termed young pigeons from one to about thirty days of age), whether live or dead.

Poultry product. (i) This term means any poultry carcass or part thereof; or any product which is made wholly or in part from any poultry carcass or part thereof, excepting those exempted from definition as a poultry product in § 381.15. Except where the context requires otherwise (e.g., in paragraph (b)(42) of this section), this term is limited to articles capable of use as human food.

(ii) *Poultry food product.* This term means any product capable of use as human food which is made in part from any poultry carcass or part thereof, excepting those exempted from definition as a poultry product in § 381.15.

Poultry products broker. ''Poultry products broker'' means any person engaged in the business of buying or selling poultry products on commission, or otherwise negotiating purchases or sales of such articles other than for his own account or as an employee of another person.

Process. Process used as a verb means to conduct any operation or combination of operations, whereby poultry is slaughtered, eviscerated, canned, salted, stuffed, rendered, boned, cut up, or otherwise manufactured or processed. The term ''process'' does not refer to freezing of poultry products, except when freezing is incidental to operations otherwise classed as ''processing'' under this paragraph.

Process authority. A person or organization with expert knowledge in poultry production process control and relevant regulations.

Process schedule. A written description of processing procedures, consisting of any number of specific, distinct, and ordered operations directly under control of the establishment employed in the manufacture of a specific product, including the control, monitoring, verification, validation, and corrective action activities associated with production.

Ready-to-cook poultry. ''Ready-to-cook poultry'' means any slaughtered poultry free from protruding pinfeathers and vestigial feathers (hair or down), from which the head, feet, crop, oil gland, trachea, esophagus, entrails, and lungs have been removed, and from which the mature reproductive organs and kidneys may have been removed, and with or without the giblets, and which is suitable for cooking without need of further processing. Ready-to-cook poultry also means any cut-up or disjointed portion of poultry or other parts of poultry, such as reproductive organs, head, or feet that are suitable for cooking without need of further processing.

Regulations. ''Regulations'' means the provisions of this entire part.

Renderer. ''Renderer'' means any person engaged in the business of rendering carcasses, or parts or products of the carcasses, of poultry, except rendering conducted under inspection or exemption pursuant to the regulations.

Secretary. ''Secretary'' means the Secretary of Agriculture of the United States or his delegate.

Shipping container. ''Shipping container'' means any container used or intended for use in packaging the product packed in an immediate container.

Slaughter. ''Slaughter'' means the act of killing poultry for human food.

State. Except as otherwise provided in § 381.220 ''State'' means any State of the United States and the Commonwealth of Puerto Rico.

Supervision. This term means the controls, as prescribed in instructions to Inspection Service employees, to be exercised by them over particular operations to insure that such operations are conducted in compliance with the Act and the regulations in this part.

Territory. The term ''territory'' means Guam, the Virgin Islands of the United States, American Samoa, and any other territory or possession of the United States, excluding the Canal Zone.

United States. This term means the States, the District of Columbia, and the territories of the United States.

U.S. Condemned. This term means that the poultry carcass, or part or product of a poultry carcass, so identified was inspected and found to be adulterated and is condemned.

U.S. Detained. This term is applicable to poultry, poultry products, and other articles which are held in official custody in accordance with section 19 of the Act and § 381.210, pending disposal as provided in said section 19.

U.S. Refused Entry. This term means that the slaughtered poultry or other poultry product so identified was presented for inspection for entry into the United States and was found not to comply with the requirements of the Act.

U.S. Rejected. This term means that the equipment or facility so identified is prohibited from being used in the processing of any poultry or poultry product until such equipment or facility is found by an inspector to be sanitary and otherwise eligible for use under the regulations.

U.S. Retained. This term means that the poultry or carcass, or part or product of a carcass, of poultry so identified is held at an official establishment by the inspection service for further determination as to its disposal.

(c) For the purposes of the standard for cooked, smoked sausage (§ 319.180 of this chapter), the term ''poultry byproduct'' means the skin, fat, gizzard, heart, or liver, or any combination thereof, of any poultry.

[37 FR 9706; May 16, 1972, as amended at 39 FR 4568, Feb. 5, 1974; 40 FR 42338, Sept. 12, 1975; 48 FR 6091, Feb. 10, 1983; 49 FR 2236, Jan. 19, 1984; 49 FR 3643, Jan. 30, 1984; 49 FR 47478, Dec. 5, 1984; 51 FR 37709, Oct. 24, 1986; 64 FR 745, Jan. 6, 1999; 64 FR 56416, Oct. 20, 1999; 66 FR 1770, Jan. 9, 2001; 66 FR 22905, May 7, 2001; 67 FR 13258, Mar. 22, 2002]

Subpart B—Administration; Application of Inspection and Other Requirements

§381.3 Administration.

(a) General authority to administer the Act has been delegated to the Administrator (29 FR 16210, as amended; 37 FR 6327, 6505).

(b) The Administrator may in specific classes of cases waive for limited periods any provisions of the regulations in order to permit appropriate and necessary action in the event of a public health emergency or to permit experimentation so that new procedures, equipment, and processing techniques may be tested to facilitate definite improvements: *Provided,* That such waivers of the provisions of the regulations are not in conflict with the purposes or provisions of the Act.

(c) Pursuant to section 6 of the Act, the Administrator believes that, in establishments processing poultry products at which inspection under the Act and regulations is required, the frequency with which and the manner in which poultry products made from poultry previously slaughtered and eviscerated in official establishments are reinspected by Inspection Service employees should be based on considerations relevant to effective regulation of poultry products and protection of the health and welfare of consumers. In order to test procedures for use in making such determinations and, in particular, for determining whether and, if so, to what extent the intensity of inspection coverage exceeds that which should be deemed necessary pursuant to section 6 of the Act, the Administrator is initiating experimentation of a new system of inspection for reviewing the performance of establishments and for designing the supervision and other conditions and methods of inspection coverage. For the period of such experimentation, the Administrator shall identify establishments for review, and the frequency and the manner of inspection by Inspection Service employees shall be determined on the basis of the results of those reviews and be otherwise in accordance with this section.

(d) The determinations referred to in paragraph (c) of this section shall be made by the Inspection Service and shall reflect evaluations of the performance and the characteristics of such establishments.

(1) In assessing the performance of an establishment, the following factors are appropriate for consideration:

(i) The history of compliance with applicable regulatory requirements by the person operating such establishment or by anyone responsibly connected with the business operating such establishment, as ''responsibly connected'' is defined in section 18(a) of the Act,

(ii) The competence of the person operating such establishment, as indicated by:

(A) Knowledge of appropriate manufacturing practices and applicable regulatory requirements,

(B) Demonstrated ability to apply such knowledge in a timely and consistent manner, and

(C) Commitment to correcting deficiencies noted by Inspection Service employees and otherwise assuring compliance with applicable regulatory requirements, and

(iii) The procedures used in such establishment to control the production process, environment, and resulting product in order to assure and monitor compliance with the requirements of the Act and the rules and regulations promulgated thereunder.

(2) In assessing the characteristics of an establishment, the following factors are appropriate for consideration:

(i) The complexity of the processing operation(s) conducted at such establishment,

(ii) The frequency with which each such operation is conducted at such establishment,

(iii) The volume of product resulting from each such operation at such establishment,

(iv) Whether and to what extent slaughter and evisceration operations also are conducted at such establishment,

(v) What, if any, food products not regulated under this Act or the Federal Meat Inspection Act also are processed at such establishment, and

(vi) The size of such establishment.

(e)(1) For the period of experimentation described in paragraph (c) of

this section, the frequency of inspection by Inspection Service employees of operations other than slaughter and evisceration may be reduced in an establishment in which the procedures referred to therein are being tested if and only if the evaluation of the performance of such establishment described in paragraph (d)(1) indicates that there are:

(i) No instances, documented in records compiled no earlier than 10 years before, of substantial and recent noncompliance with applicable regulatory requirements (taking into account both the nature and frequency of any such noncompliance), and

(ii) The competence and control procedures needed to assure and monitor compliance with applicable regulatory requirements.

(2)(i) The frequency of Federal inspection and other conditions and methods of inspection coverage in any establishment in which the frequency of Federal inspection is reduced shall be based on:

(A) The evaluation of the characteristics of such establishment described in paragraph (d)(2) of this section,[1]

(B) The significance of potential public health consequences of noncompliance, and

(C) The availability of Inspection Service employees.

(ii) To the extent that frequency of inspection or other conditions and methods of inspection coverage are identified as conflicting with provisions of the regulations in this part, the Administrator will waive such provisions for the period of experimentation, in accordance with paragraph (b) of this section.

[37 FR 9706, May 16, 1972, as amended at 52 FR 10033, Mar. 30, 1987]

[1] These evaluations will be based upon guidelines developed by FSIS and the complexity categorization in FSIS Directive 1030.2 (Documentation of Processing and Combination Assignments, 4/22/85). The guidelines and Directive will be available for public inspection and copying in the Policy Office, Room 3168, South Agriculture Building, 14th Street and Independence Avenue, SW., Washington, DC.

§ 381.4 Inspection in accordance with methods prescribed or approved.

Inspection of poultry products shall be rendered pursuant to the regulations and under such conditions and in accordance with such methods as may be prescribed or approved by the Administrator.

§ 381.5 Publications.

Publications under the Act and the regulations shall be made in the FEDERAL REGISTER and in such other media as the Administrator may designate.

§ 381.6 Establishments requiring inspection.

Inspection under the regulations is required at:

(a) Every establishment, except as provided in § 381.10 (a) and (b) or § 381.11, in which any poultry is slaughtered for transportation or sale in commerce, or in which any poultry products are wholly or in part, processed for transportation or sale in commerce, as articles intended for use as human food;

(b) Every establishment, except as provided in § 381.10 (a) and (b), (c), or (d), or § 381.11, within any State or organized territory which is designated in § 381.221 pursuant to section 5(c) of the Act, at which any poultry is slaughtered or any poultry products are processed, for use as human food solely for distribution within such jurisdiction; and

(c) Except as provided in § 381.10 (a) and (b), or (c), or § 381.11, every establishment designated by the Administrator pursuant to section 5(c) of the Act as one producing adulterated poultry products which would clearly endanger the public health.

§ 381.7 Coverage of all poultry and poultry products processed in official establishments.

All poultry and poultry products processed in an official establishment shall be inspected, handled, processed, marked, and labeled as required by the regulations.

Subpart C—Exemptions

§381.10 Exemptions for specified operations.

(a) The requirements of the Act and the regulations for inspection of the processing of poultry and poultry products shall not apply to:

(1) Any retail dealer with respect to poultry products sold in commerce directly to consumers in an individual retail store, if the only processing operation performed by such retail dealer is the cutting up of poultry products on the premises where such sales to consumers are made: *Provided,* That such operation is conducted under such sanitary standards, practices, and procedures as result in the preparation of poultry products that are not adulterated: *And provided further,* That the poultry products sold in commerce are derived from poultry inspected and passed under the Act and such poultry products are not adulterated or misbranded at the time of sale (except that the official inspection legend shall not be used). (For the purposes of this subparagraph, a retail dealer is any person who sells poultry products directly to consumers as defined in paragraph (d)(2)(vi) of this section and whose sales of poultry products to household consumers constitute, in terms of dollar value, at least 75 percent of his total sales of poultry products.)

(2) The slaughter of poultry, and the processing of poultry products, by any person in any territory not organized with a legislative body, solely for distribution within such territory: *Provided,* That such poultry is sound and healthy and is slaughtered under such sanitary standards, practices, and procedures as result in the preparation of poultry products that are not adulterated: *And provided further,* That the poultry products are not adulterated or misbranded when so distributed (except that the official inspection legend shall not be used).

(3) The slaughtering by any person of poultry of his own raising, and the processing by him and transportation in commerce of the poultry products exclusively for use by him and members of his household and his nonpaying guests and employees: *Provided,* That in lieu of complying with all the adulteration and misbranding provisions of the Act, such poultry is healthy and is slaughtered and processed under such sanitary standards, practices, and procedures as result in the preparation of poultry products that are sound, clean, and fit for human food, and the shipping containers of such poultry products bear the producer's name and address and the statement ''Exempted—P.L. 90–492.''

(4) The custom slaughter by any person of poultry delivered by the owner thereof for such slaughter, and the processing by such slaughterer and transportation in commerce of the poultry products exclusively for use, in the household of such owner, by him and members of his household and his nonpaying guests and the employees: *Provided,* That such custom slaughterer does not engage in the business of buying or selling any poultry products capable of use as human food: *And provided further,* That in lieu of complying with all the adulteration and misbranding provisions of the Act, such poultry is healthy and is slaughtered and processed under such sanitary standards, practices, and procedures as result in the preparation of poultry products that are sound, clean and fit for human food, and the shipping containers of such poultry products bear the owner's name and address and the statement ''Exempted—P.L. 90–492.''

(5) The slaughtering of sound and healthy poultry and processing of poultry products therefrom in any State or territory or the District of Columbia by any poultry producer on his own premises with respect to poultry raised on his premises, and the distribution by any person solely within such jurisdiction of the poultry products derived from such operations: *Provided,* That (i) in lieu of complying with all the adulteration provisions of the Act, such poultry is slaughtered and otherwise processed and handled under such sanitary standards, practices, and procedures as result in the preparation of poultry products that are sound, clean, and fit for human food when so distributed; (ii) such poultry products when so distributed, bear (in lieu of labeling that would otherwise be required) the producer's name and address and the

statement ''Exempted—P.L. 90–492'' and such poultry products are not otherwise misbranded; (iii) such producer and distributor do not engage in the current calendar year in the business of buying or selling any poultry or poultry products other than as specified in this paragraph (a) (5) or (6) of this section; and (iv) neither such producer or distributor slaughters or processes the products of more poultry than allowed by paragraph (b) of this section.

(6) The slaughtering of sound and healthy poultry or the processing of poultry products of such poultry in any State or territory or the District of Columbia by any poultry producer or other person for distribution by him solely within such jurisdiction directly to household consumers, restaurants, hotels, and boardinghouses, for use in their own dining rooms, or in the preparation of meals for sales direct to consumers: *Provided,* That (i) in lieu of complying with all the adulteration provisions of the Act, such poultry is slaughtered and otherwise processed and handled under such sanitary standards, practices, and procedures as result in the preparation of poultry products that are sound, clean, and fit for human food when distributed by such processor; (ii) such poultry products when so distributed bear (in lieu of labeling that would otherwise be required) the processor's name and address and the statement ''Exempted—P.L. 90–492'' and such poultry products are not otherwise misbranded; (iii) such processor does not engage in the current calendar year in the business of buying or selling any poultry or poultry products other than as specified in this paragraph (a) (6) or (5) of this section; and (iv) such processor does not exceed the volume limitation prescribed in paragraph (b) of this section.

(7) The operations and products of small enterprises (including poultry producers) not exempted under paragraphs (a) (1) through (6) of this section that are engaged in any State or territory or the District of Columbia in slaughtering and/or cutting up poultry for distribution as carcasses or parts thereof solely for distribution within such jurisdiction; *Provided,* That (i) such poultry is sound and healthy when slaughtered and is slaughtered and/or cut up and handled under such sanitary standards, practices and procedures as result in the preparation of poultry products that are not adulterated when so distributed; and (ii) when so distributed, such poultry products are not misbranded (except that the official inspection legend shall not be used).

(b) No person qualifies for any exemption specified in paragraph (a)(5), (6), or (7) of this section if, in the current calendar year, such person:

(1) Slaughters or processes the products of more than 20,000 poultry, or

(2) Slaughters or processes poultry products at a facility used for slaughtering or processing poultry products by any other person, except when the Administrator grants such exemption after determining, upon review of a person's application, that such an exemption will not impair effectuating the purposes of the Act.

(c) The provisions of the Act and the regulations do not apply to any poultry producer with respect to poultry, of his own raising on his own farm, which he slaughters if:

(1) Such producer slaughters not more than 1,000 poultry during the calendar year for which this exemption is being determined;

(2) Such poultry producer does not engage in buying or selling poultry products other than those produced from poultry raised on his own farm; and

(3) None of such poultry moves in ''commerce'' (as defined in § 381.1).

(d)(1) The requirements of the Act and the regulations for inspection of the processing of poultry and poultry products do not apply to operations of types traditionally and usually conducted at retail stores and restaurants, when conducted at any retail store or restaurant or similar-retail-type establishment for sale in normal retail quantities or service of such articles to consumers at such establishments.

(2) For the purposes of paragraph (d)(1) of this section:

(i) Operations of types traditionally and usually conducted at retail stores and restaurants include any processing of poultry products except canning of

poultry products and except slaughtering of poultry unless such slaughtering is conducted at a retail store with respect to live poultry purchased by the consumer at the retail store and processed by the retail store operator in accordance with the consumer's instructions.

(ii) A normal retail quantity is any quantity of a poultry product purchased by a household consumer from a retail supplier that in the aggregate does not exceed 75 pounds. A normal retail quantity sold by a retail supplier to other than a household consumer is any quantity that in the aggregate does not exceed 150 pounds.

(iii) A retail store is any place of business where:

(*a*) The sales of poultry products are made to consumers only;

(*b*) At least 75 percent, in terms of dollar value, of total sales of product represents sales to household consumers and the total dollar value of sales of product to consumers other than household consumers does not exceed the dollar limitation per calendar year set by the Administrator. This dollar limitation is a figure which will automatically be adjusted during the first quarter of each calendar year, upward or downward, whenever the Consumer Price Index, published by the Bureau of Labor Statistics, Department of Labor, indicates a change in the price of this same volume of product which exceeds $500. Notice of the adjusted dollar limitation will be published in the FEDERAL REGISTER.[1]

(*c*) Only federally or State inspected and passed, or exempted (or, as provided in § 381.223, State or local agency inspected and passed or exempted) poultry products are handled or used in the preparation of any poultry products;

(*d*) No sale of poultry products is made in excess of a normal retail quantity as defined in paragraph (d)(2)(ii) of this section; and

(*e*) The processing of poultry products for sale is limited to traditional and usual operations as defined in paragraph (d)(2)(i) of this section.

(iv) *Restaurants.* (*a*) A restaurant is any establishment where:

(*1*) Poultry products are processed only for sale or service in meals or as entrees directly to individual consumers at such establishments;

(*2*) Only federally inspected and passed, or exempted (or, as provided in § 381.223, State or local agency inspected and passed or exempted) poultry products are handled or used in the preparation of any poultry products;

(*3*) No sale of poultry products is made in excess of a normal retail quantity as defined in paragraph (d)(2)(ii) of this section; and

(*4*) The processing of poultry products is limited to traditional and usual operations as defined in paragraph (d)(2)(i) of this section.

(*b*) The definition of a restaurant includes a caterer which delivers or serves product in meals, or as entrees, only to individual consumers and otherwise meets the requirements of this paragraph.

(*c*) For purposes of this paragraph, operations conducted as a restaurant central kitchen facility shall be considered as being conducted at a restaurant if the restaurant central kitchen prepares poultry products that are ready to eat when they leave such facility (i.e., no further cooking or other preparation is needed, except that they may be reheated prior to serving if chilled during transportation), transported directly to a receiving restaurant by its own employees, without intervening transfer or storage, maintained in a safe, unadulterated condition during transportation, and served in meals or as entrees only to customers at restaurants, or through vending machines, owned or operated by the same person that owns or operates such facility, and which otherwise meets the requirement of this paragraph: *Provided,* That the requirements of §§ 381.175 through 381.178 of this subchapter apply to such facility. *Provided further,* That the exempted facility may be subject to inspection requirements under the Act for as long as the Administrator deems necessary if the

[1] The dollar limitation currently in effect may be obtained by contacting Director, Slaughter Inspection Standards and Procedures Division, Technical Services, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250 (202) 447–3219.

Administrator determines that the sanitary conditions or practices of the facility or the processing procedures or methods at the facility are such that any of its poultry products are rendered adulterated. When the Administrator has made such determination and subjected a restaurant central kitchen facility to such inspection requirements, the operator of such facility shall be afforded an opportunity to dispute the Administrator's determination in a hearing pursuant to rules of practice which will be adopted for this proceeding.

(v) A similar retail-type establishment is any establishment which is a combination retail store and restaurant; any delicatessen which meets the requirements for a retail store or restaurant as prescribed in paragraph (d)(2) (iii) or (iv) of this section; or other establishment as determined by the Administrator in specific cases.

(vi) A consumer is any household consumer, hotel, or restaurant, or similar institution as determined by the Administrator in specific cases.

(3) Whenever any complaint is received by the Administrator from any person alleging that any retail establishment or restaurant claiming exemption under this paragraph (d) in any designated State or organized territory listed in § 381.221 that is also identified in § 381.224 as a jurisdiction that does not have or is not exercising adequate authority with respect to recordkeeping requirements, has been operated in violation of the conditions prescribed in this paragraph (d) for such exemption, and the Administrator, upon investigation of the complaint, has reason to believe that any such violation has occurred, he shall so notify the operator of the retail establishment or restaurant and afford him reasonable opportunity to present his views informally with respect to the matter. Thereafter, if the Administrator determines that such a violation has occurred, and that a requirement that the operator keep records concerning the operations of the retail establishment or restaurant would effectuate the purposes of the Act, the Administrator shall order the operator to maintain complete, accurate, and legible records of his total monthly purchases and of his total monthly sales of poultry and poultry products. Such records shall separately show total sales to household consumers and total sales to other consumers, and shall be maintained for the period prescribed in § 381.177. If the operator maintains copies of bills of lading, receiving and shipping invoices, warehouse receipts, or similar documents which give the information required herein, additional records are not required by this subparagraph.

(4) The adulteration and misbranding provisions of the Act and the regulations other than the requirement of the official inspection legend, apply to articles which are exempted from inspection under this paragraph (d).

(e)(1) The requirements of the Act and the regulations in this subchapter for inspection of the preparation of products do not apply to poultry pizzas containing poultry product ingredients which were prepared, inspected, and passed in a cured or cooked form as ready-to-eat (i.e., no further cooking or other preparation is needed) in compliance with the requirements of the Act and these regulations; and the poultry pizzas are to be served in public or private nonprofit institutions, provided that the poultry pizzas are ready to eat (i.e., no further cooking or other preparation is needed, except that they may be reheated prior to serving if chilled during transportation), transported directly to the receiving institution by employees of the preparing firm, receiving institution, or a food service management company contracted to conduct food service at the public or private nonprofit institution, without intervening transfer or storage.

(2) The definitions at Chapter 1, 1–102, except 1–102(z) and the provisions of Chapters 2 through 8, except sections 2–102 (a) and (b), 2–302(d), 2–403(a), 2–403(c), 2–404, 2–405, 2–407, 2–502 through 2–506, 2–508, 2–509, 4–105, 4–201(c), 4–208, 5–101(a), 5–103, 5–104, 5–202(c), 5–203, and 6–105, Part IV, of the Food and Drug Administration's Food Service Sanitation Manual (1976 Recommendations), DHEW Publication No. (FDA) 78–2081, which is incorporated by reference,

shall apply to the facilities and operations of businesses claiming this exemption. (These materials are incorporated as they exist on the date of approval. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be purchased from the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402. It is also available for inspection at the Office of the Federal Register Information Center, Suite 700, 800 North Capitol Street, NW., Washington, DC, or the FSIS Hearing Clerk, room 3171, South Building, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250.)

(3) Facilities and operations of businesses claiming this exemption shall also conform to the following requirements:

(i) *Manual cleaning and sanitizing.* (A) For manual washing, rinsing and sanitizing of utensils and equipment, a sink with not fewer than three compartments shall be provided and used. Sink compartments shall be large enough to permit the accommodation of the equipment and utensils, and each compartment of the sink shall be supplied with hot and cold potable running water. Fixed equipment and utensils and equipment too large to be cleaned in sink compartments shall be washed manually or cleaned through pressure spray methods.

(B) Drain boards or easily movable dish tables of adequate size shall be provided for proper handling of soiled utensils prior to washing and for cleaned utensils following sanitizing and shall be located so as not to interfere with the proper use of the dishwashing facilities.

(C) Equipment and utensils shall be preflushed or prescraped and, when necessary, presoaked to remove gross food particles and soil.

(D) Except for fixed equipment and utensils too large to be cleaned in sink compartments, manual washing, rinsing and sanitizing shall be conducted in the following sequence:

(*1*) Sinks shall be cleaned prior to use.

(*2*) Equipment and utensils shall be thoroughly washed in the first compartment with a hot detergent solution that is kept clean.

(*3*) Equipment and utensils shall be rinsed free of detergent and abrasives with clean water in the second compartment.

(*4*) Equipment and utensils shall be sanitized in the third compartment according to one of the methods prescribed in paragraph (e)(3)(i)(E) (*1*) through (*4*) of this section.

(E) The food-contact surfaces of all equipment and utensils shall be sanitized by:

(*1*) Immersion for at least ½ minute in clean, hot water at a temperature of at least 170 °F; or

(*2*) Immersion for at least 1 minute in a clean solution containing at least 50 parts per million of available chlorine as a hypochlorite and at a temperature of at least 75 °F; or

(*3*) Immersion for at least 1 minute in a clean solution containing at least 12.5 parts per million of available iodine and having a pH not higher than 5.0 and at a temperature of at least 75 °F; or

(*4*) Immersion in a clean solution containing any other chemical sanitizing agent allowed under 21 CFR 178.1010 that will provide the equivalent bactericidal effect of a solution containing at least 50 parts per million of available chlorine as a hypochlorite at a temperature of at least 75 °F for 1 minute; or

(*5*) Treatment with steam free from materials or additives other than those specified in 21 CFR 173.310 in the case of equipment too large to sanitize by immersion, but in which steam can be confined; or

(*6*) Rinsing, spraying, or swabbing with a chemical sanitizing solution of at least twice the strength required for that particular sanitizing solution under paragraph (e)(3)(i)(E)(*4*) of this section in the case of equipment too large to sanitize by immersion.

(F) When hot water is used for sanitizing, the following facilities shall be provided and used:

(*1*) An integral heating device or fixture installed in, on, or under the sanitizing compartment of the sink capable of maintaining the water at a temperature of at least 170 °F; and

(*2*) A numerically scaled indicating thermometer, accurate to ±3 °F, convenient to the sink for frequent checks of water temperature; and

(*3*) Dish baskets of such size and design to permit complete immersion of the tableware, kitchenware, and equipment in the hot water.

(G) When chemicals are used for sanitization, they shall not have concentrations higher than the maximum permitted under 21 CFR 178.1010 and a test kit or other device that accurately measures the parts per million concentration of the solution shall be provided and used.

(ii) *Mechanical cleaning and sanitizing.* (A) Cleaning and sanitizing may be done by spray-type or immersion dishwashing machines or by any other type of machine or device if it is demonstrated that it thoroughly cleans and sanitizes equipment and utensils. These machines and devices shall be properly installed and maintained in good repair. Machines and devices shall be operated in accordance with manufacturers' instructions, and utensils and equipment placed in the machine shall be exposed to all dishwashing cycles. Automatic detergent dispensers, wetting agent dispensers, and liquid sanitizer injectors, if any, shall be properly installed and maintained.

(B) The pressure of final rinse water supplied to spray-type dishwashing machines shall not be less than 15 nor more than 25 pounds per square inch measured in the water line immediately adjacent to the final rinse control valve. A ¼-inch IPS valve shall be provided immediately upstream from the final rinse control valve to permit checking the flow pressure of the final rinse water.

(C) Machine or water line mounted numerically scaled indicating thermometers, accurate to ±3 °F, shall be provided to indicate the temperature of the water in each tank of the machine and the temperature of the final rinse water as it enters the manifold.

(D) Rinse water tanks shall be protected by baffles, curtains, or other effective means to minimize the entry of wash water into the rinse water. Conveyors in dishwashing machines shall be accurately timed to assure proper exposure times in wash and rinse cycles in accordance with manufacturers' specifications attached to the machines.

(E) Drain boards shall be provided and be of adequate size for the proper handling of soiled utensils prior to washing and of cleaned utensils following sanitization and shall be so located and constructed as not to interfere with the proper use of the dishwashing facilities. This does not preclude the use of easily movable dish tables for the storage of soiled utensils or the use of easily movable dishtables for the storage of clean utensils following sanitization.

(F) Equipment and utensils shall be flushed or scraped and, when necessary, soaked to remove gross food particles and soil prior to being washed in a dishwashing machine unless a prewashcycle is a part of the dishwashing machine operation. Equipment and utensils shall be placed in racks, trays, or baskets, or on conveyors, in a way that food-contact surfaces are exposed to the unobstructed application of detergent wash and clean rinse waters and that permits free draining.

(G) Machines (single-tank, stationary-rack, door-type machines and spray-type glass washers) using chemicals for sanitization may be used: Provided, That,

(*1*) The temperature of the wash water shall not be less than 120 °F.

(*2*) The wash water shall be kept clean.

(*3*) Chemicals added for sanitization purposes shall be automatically dispensed.

(*4*) Utensils and equipment shall be exposed to the final chemical sanitizing rinse in accordance with manufacturers' specifications for time and concentration.

(*5*) The chemical sanitizing rinse water temperature shall be not less than 75 °F nor less than the temperature specified by the machine's manufacturer.

(*6*) Chemical sanitizers used shall meet the requirements of 21 CFR 178.1010.

(*7*) A test kit or other device that accurately measures the parts per million concentration of the solution shall be available and used.

(H) Machines using hot water for sanitizing may be used provided that wash water and pumped rinse water shall be kept clean and water shall be maintained at not less than the following temperatures:

(*1*) Single-tank, stationary-rack, dual-temperature machine:

Wash temperature	150 °F
Final rinse temperature	180 °F

(*2*) Single-tank, stationary-rack, single-temperature machine:

Wash temperature	165 °F
Final rinse temperature	165 °F

(*3*) Single-tank, conveyor machine:

Wash temperature	160 °F
Final rinse temperature	180 °F

(*4*) Multitank, conveyor machine:

Wash temperature	150 °F
Pumped rinse temperature	160 °F
Final rinse temperature	180 °F

(*5*) Single-tank, pot, pan, and utensil washer (either stationary or moving-rack):

Wash temperature	140 °F
Final rinse temperature	180 °F

(I) All dishwashing machines shall be thoroughly cleaned at least once a day or more often when necessary to maintain them in a satisfactory operating condition.

(iii) *Steam*. Steam used in contact with food or food-contact surfaces shall be free from any materials or additives other than those specified in 21 CFR 173.310.

(4) For purposes of this paragraph, the term ''private nonprofit institution'' means ''a corporation, and any community chest, fund, or foundation, organized and operated exclusively for religious, charitable, scientific, testing for public safety, literary, or educational purposes, or to foster national or international amateur sports competition (but only if no part of its activities involve the provision of athletic facilities or equipment), or for the prevention of cruelty to children or animals, no part of the net earnings of which inures to the benefit of any private shareholder or individual, no substantial part of the activities of which is carrying on propaganda, or otherwise attempting, to influence legislation, and which does not participate in, or intervene in (including the publishing or distribution of statements), any political campaign on behalf of (or in opposition to) any candidate for public office.''

(5) The Administrator may withdraw or modify the exemption set forth in § 381.10(e)(1) for a particular establishment when he or she determines that such action is necessary to ensure food safety and public health. Before such action is taken, the owner or operator of the particular establishment shall be notified, in writing, of the reasons for the proposed action and shall be given an opportunity to respond, in writing, to the Administrator within 20 days after notification of the proposed action. The written notification shall be served on the owner or operator of the establishment in the manner prescribed in section 1.147(b) of the Department's Uniform Rules of Practice (7 CFR 1.147(b)). In those instances where there is conflict of any material fact, the owner or operator of the establishment, upon request, shall be afforded an opportunity for a hearing with respect to the disputed fact, in accordance with rules of practice which shall be adopted for the proceeding. However, such withdrawal or modification shall become effective pending final determination in the proceeding when the Administrator determines that an imminent threat to food safety or public health exists, and that such action is, therefore, necessary to protect the public health, interest or safety. Such withdrawal or modification shall be effective upon oral or written notification, whichever is earlier, to the owner or operator of the particular establishment as promptly as circumstances permit. In the event of oral notification, written confirmation shall be given to the owner or operator of the establishment as promptly as circumstances permit. This withdrawal or modification shall continue in effect pending the completion of the proceeding and any judicial review thereof, unless otherwise ordered by the Administrator.

(6) The adulteration and misbranding provisions of the Act and the regulations apply to articles which are exempted from inspection under § 381.10(e).

[37 FR 9706, May 16, 1972, as amended at 38 FR 16991, June 28, 1973; 45 FR 27922, Apr. 25, 1980; 46 FR 46288, Sept. 16, 1981; 48 FR 2959, Jan. 24, 1983; 51 FR 29909, Aug. 21, 1986; 53 FR 24679, June 30, 1988; 57 FR 34184, Aug. 3, 1992]

§ 381.11 Exemptions based on religious dietary laws.

(a) Any person who slaughters, processes, or otherwise handles poultry or poultry products which have been or are to be processed as required by recognized religious dietary laws may apply for exemption from specific provisions of the Act or regulations which are in conflict with such religious dietary laws. Any person desiring such an exemption shall apply in writing to the Meat and Poultry Inspection Program, Food Safety and Inspection Service, Department of Agriculture, Washington, DC 20250, setting forth the specific provisions of the Act and the regulations from which exemption is sought and setting forth the provisions of the religious dietary laws in support of the requested exemption. In addition, the applicant for such an exemption shall submit a statement from the clerical official having jurisdiction over the enforcement of the religious dietary laws with respect to the poultry or poultry products involved, which identifies the requirements of such laws pertaining to the slaughter of the poultry and the processing or other handling of the poultry products involved, and certifies that such requirements are in conflict with specific provisions of the Act and regulations from which the exemption is sought.

(b) The Administrator, upon a determination that an exemption should be granted, will grant such exemption to the extent necessary to avoid conflict with the religious requirements while still effectuating the purposes of the Act. He may impose such conditions as to sanitary standards, practices, and procedures in granting such exemption as he deems necessary to effectuate the purposes of the Act. Any person who processes poultry or poultry products under exemption from certain requirements as provided in this section shall be subject to all of the other applicable provisions of the Act and the regulations. Processing plants shall meet the sanitary requirements set forth in this part and unless exempted from inspection under the provisions of this subpart, shall be required to qualify for inspection and operate as official establishments. Slaughtered poultry which is prepared under an exemption authorizing the sale of noneviscerated poultry in commerce shall be individually identified with a label approved by the Administrator which identifies the clerical official under whose supervision the poultry was slaughtered.

§ 381.12 Effect of religious dietary laws exemptions on other persons.

Whenever a slaughterer or processor is granted an exemption under § 381.11 with respect to the slaughtering or processing of any poultry or poultry products under this part, under specified conditions, the sale, offer for sale, transportation and other handling in commerce by any person of such poultry and poultry products in accordance with such conditions is hereby authorized, except as restricted by the Act.

§ 381.13 Suspension or termination of exemptions.

(a) The Administrator may, by order, in accordance with the applicable rules of practice suspend or terminate any exemption under § 381.10(a) with respect to any person whenever he finds that such action will aid in effectuating the purposes of the Act. Failure to comply with the conditions of the exemption, including, but not limited to, failure to process poultry and poultry products under clean and sanitary conditions may result in termination of an exemption, in addition to any other penalties provided by law.

(b) Except as provided in § 381.10(c), the Administrator may extend the requirements of the Act to any establishment in any State or organized territory at which poultry products are processed for distribution solely within such jurisdiction if he determines in accordance with the provisions of subparagraph 5(c)(1) of the Act that the establishment is producing adulterated

poultry products which would clearly endanger the public health.

§381.14 Inspection concerning purportedly exempted operations.

Inspectors of the Inspection Service are authorized to make inspections in accordance with law to ascertain whether any of the provisions of the Act or the regulations applying to producers, retailers, or other persons purporting to be exempted from any requirements under this subpart have been violated.

§381.15 Exemption from definition of "poultry product" of certain human food products containing poultry.

The following articles contain poultry ingredients only in a relatively small proportion or historically have not been considered by consumers as products of the poultry food industry. Therefore said articles are exempted from the definition of ''poultry product'' and the requirements of the Act and the regulations applicable to poultry products, if they comply with the conditions specified in this section.

(a) Any human food product (in a consumer package) not provided for in paragraph (c) of this section, if:

(1) It contains less than 2 percent cooked poultry meat (deboned white or dark poultry meat, or both) and/or ''Mechanically Separated (Kind of Poultry)'' as defined in §381.173;

(2) It contains less than 10 percent of cooked poultry skins, giblets, or fat, separately, and less than 10 percent of cooked poultry skins, giblets, fat, and meat (as meat is limited in paragraph (a)(1) of this section) or ''Mechanically Separated (Kind of Poultry)'' as defined in §381.173, in any combination;

(3) The poultry ingredients used in the product were prepared under inspection as defined in §381.1, or were inspected under a foreign inspection system approved under §381.196(b) and imported in compliance with the Act and the regulations;

(4) The immediate container of the product bears a label which shows the name of the product in accordance with this section; and

(5) The product is not represented as a poultry product. The aforesaid percentages of ingredients shall be computed on the basis of the moist, deboned, cooked poultry in the ready-to-serve product when prepared according to the serving directions on the consumer package.

(b) Any human food product (in an institutional pack), not provided for in paragraph (c) of this section, if:

(1) It is prepared for sale only to institutional users, such as hotels, restaurants, and boardinghouses, for use as a soup base or flavoring;

(2) It contains less than 15 percent cooked poultry meat (deboned white or dark poultry meat or both) and/or ''Mechanically Separated (Kind of Poultry)'' as defined in §381.173, computed on the basis of the moist deboned, cooked poultry meat and/or ''Mechanically Separated (Kind of Poultry)'' in such product; and

(3) It complies with the provisions of paragraphs (a)(3), (4), and (5) of this section in all respects.

(c) Bouillon cubes, poultry broths, gravies, sauces, seasonings, and flavorings if:

(1) They contain poultry meat and/or ''Mechanically Separated (Kind of Poultry)'' as defined in §381.173 or poultry fat only in condimental quantities;

(2) They comply with the provisions of paragraphs (a)(3), (4), and (5) of this section in all respects; and

(3) In the case of poultry broth, it will not be used in the processing of any poultry product in any official establishment.

(d) Fat capsules and sandwiches containing poultry products if they comply with the provisions of paragraphs (a)(3), (4), and (5) of this section in all respects.

(e) Products of the types specified in this section except those specified in paragraphs (c) and (d) of this section will be deemed to be represented as poultry products if the kind name of the poultry (chicken, turkey, etc.) is used in the product name of the product without appropriate qualification. For example, a consumer-packaged noodle soup product containing less than 2 percent chicken meat on a ready-to-serve basis may not be labeled ''Chicken Noodle Soup'' but, when appropriate, could be labeled as ''Chicken Flavored Noodle Soup.'' Products exempted under this section are subject

to the requirements of the Federal Food, Drug, and Cosmetic Act.

[37 FR 9706, May 16, 1972, as amended at 60 FR 55982, Nov. 3, 1995]

Subpart D—Application for Inspection; Grant or Refusal of Inspection

§ 381.16 How application shall be made.

The operator of each establishment of the kind required by § 381.6 to have inspection shall make application to the Administrator for inspection service. In cases of change of name, ownership, or location, a new application shall be made.

§ 381.17 Filing of application.

Every application for inspection at any establishment shall be made by the operator on a form furnished by the Meat and Poultry Inspection Program, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250, and shall include all information called for by that form, including the name of any subsidiary corporation that will prepare any poultry product or conduct any other operation at the establishment for which inspection is requested. The applicant for inspection will be held responsible for compliance by all its subsidiaries with the requirements of the regulations at such establishments if inspection is granted. Processing of poultry products and other operations at the establishment for which inspection is granted may be conducted only by the applicant, except that such a subsidiary of the grantee, may conduct such operations at such establishment.

§ 381.18 Authority of applicant.

Any person applying for inspection service may be required at the discretion of the Administrator to demonstrate that the operator of the establishment authorized him to do so.

§ 381.20 Survey and grant of inspection.

(a) Before inspection is granted, FSIS shall survey the establishment to determine if the construction and facilities of the establishment are in accordance with the regulations. FSIS will grant inspection, subject to § 381.21, when these requirements are met.

(b) FSIS shall give notice in writing to each applicant granted inspection and shall specify in the notice the establishment, including the limits of the establishment's premises, to which the grant pertains.

[62 FR 45026, Aug. 25, 1997]

§ 381.21 Refusal of inspection.

(a) Any application for inspection in accordance with this part may be denied or refused in accordance with the rules of practice in part 500 of this chapter.

(b)(1) Any applicant for inspection at an establishment where the operations thereof may result in any discharge into the navigable waters of the United States is required by subsection 21(b) of the Federal Water Pollution Control Act, as amended, to provide the Administrator with a certification as prescribed in said subsection that there is reasonable assurance that such activity will be conducted in a manner which will not violate the applicable water quality standards. No grant of inspection can be issued after April 3, 1970 (the date of enactment of the Water Quality Improvement Act), unless such certification has been obtained, or is waived because of failure or refusal of the State, interstate agency, or the Administrator of the Environmental Protection Agency to act on a request for certification within 1 year after receipt of such request. Further, upon receipt of an application for inspection and a certification as required by subsection 21(b) of the Federal Water Pollution Control Act, the Administrator (as defined in § 381.1) is required by paragraph (2) of said subsection to notify the Administrator of the Environmental Protection Agency for proceedings in accordance with that paragraph. No grant of inspection can be made until the requirements of said paragraph (2) have been met.

(2) However, certification under subsection 21(b) of the Federal Water Pollution Control Act is not initially required in connection with an application for inspection granted after April 3, 1970, for facilities existing or under construction on April 3, 1970, although

certification for such facilities is required to be obtained within the 3–year period immediately following April 3, 1970. Failure to obtain such certification or to meet the other requirements of subsection 21(b) prior to April 3, 1973, will result in the termination of inspection at such facilities on that date.

(3) Further, any application for inspection pending on April 3, 1970, and granted within 1 year thereafter shall not require certification for 1 year following the grant of inspection but such grant of inspection shall terminate at the end of 1 year after its issuance unless prior thereto such certification has been obtained and the other requirements of subsection 21(b) are met.

(4) In the case of any activity which will affect water quality but for which there are no applicable water quality standards, no certification is required prior to the grant of inspection but such grant will be conditioned upon a requirement of compliance with the purpose of the Federal Water Pollution Control Act as provided in paragraph 21(b)(9) of said Act.

[37 FR 9706, May 16, 1972, as amended at 64 FR 66545, Nov. 29, 1999]

§381.22 Conditions for receiving inspection.

(a) Before being granted Federal inspection, an establishment shall have developed written sanitation Standard Operating Procedures, in accordance with part 416 of this chapter.

(b) Before being granted Federal inspection, an establishment shall have conducted a hazard analysis and developed and validated a HACCP plan, in accordance with §§417.2 and 417.4 of this chapter. A conditional grant of inspection shall be issued for a period not to exceed 90 days, during which period the establishment must validate its HACCP plan.

(c) Before producing new product for distribution in commerce, an establishment shall have conducted a hazard analysis and developed a HACCP plan applicable to that product in accordance with §417.2 of this chapter. During a period not to exceed 90 days after the date the new product is produced for distribution in commerce, the establishment shall validate its HACCP plan, in accordance with §417.4 of this chapter.

[61 FR 38866, July 25, 1996]

Subpart E—Inauguration of Inspection; Official Establishment Numbers; Separation of Establishments and Other Requirements; Withdrawal of Inspection

§381.25 Official establishment numbers.

An official establishment number shall be assigned to each establishment granted inspection service. Such number shall be used to identify all containers of inspected poultry products prepared in the establishment. An establishment shall not have more than one establishment number.

§381.26 Separation of establishments.

Each official establishment shall be separate and distinct from any other official establishment and from any unofficial establishment except an establishment preparing meat products under the Federal Meat Inspection Act or under State meat inspection. Further, doorways, or other openings, may be permitted between establishments at the discretion of the Administrator and under such conditions as he may prescribe.

§381.27 Inauguration of service; notification concerning regulations; status of uninspected poultry products.

The inspector in charge or his supervisor shall, upon or prior to the inauguration of service, inform the operator of the establishment of the requirements of the regulations. If the establishment at the time service is inaugurated contains any poultry product which has not been inspected and marked in compliance with the regulations, its identity shall be maintained, and it shall not be represented or dealt with as a product which has been inspected. Such products may not be shipped in commerce unless such products are eligible for such shipment under an exemption from inspection under subpart C and comply with all requirements of said subpart.

§ 381.28 Report of violations.

Each inspector, agent, representative, or employee of the Inspection Service shall report, in the manner prescribed by the Administrator, all violations of the Act and noncompliance with the regulations of which he has knowledge.

Subpart F—Assignment and Authorities of Program Employees; Appeals

§§ 381.30–381.31 [Reserved]

§ 381.32 Access to establishments.

Any duly authorized representative of the Secretary shall have access at all reasonable times, by day or night, whether the establishment is in operation or not, to the premises or any part thereof of an establishment engaged in processing poultry or poultry products for commerce, upon presentation of appropriate credentials.

§ 381.33 Identification.

Each inspector will be furnished with a numbered official inspection badge, which shall remain in his or her possession at all times, and which shall be worn in such manner and at such times as the Administrator may prescribe. This badge shall be sufficient identification to entitle the inspector to admittance at all regular entrances and to all parts of the establishment and premises to which the inspector is assigned.

[59 FR 42156, Aug. 17, 1994]

§ 381.34 Financial interest of inspectors.

(a) No inspector shall inspect any poultry or poultry product in which he, his spouse, minor child, partner, organization in which he is serving as officer, director, trustee, partner, or employee, or any person with whom he is negotiating or has any arrangement concerning prospective employment, is financially interested.

(b) All inspectors are subject to statutory restrictions with respect to political activities; e.g., 5 U.S.C. 7324 and 1502.

(c) Violation of the provisions of paragraph (a) of this section or the provisions of applicable statutes referenced in paragraph (b) of this section will constitute grounds for dismissal in the case of appointees and for revocation of licenses in the case of licensees.

(d) Inspectors are subject to all applicable provisions of law and regulations and instructions of the Department and the Food Safety and Inspection Service and other authority concerning employee responsibilities and conduct. The setting forth of certain prohibitions in this part in no way limits the applicability of such general or other regulations or instructions.

§ 381.35 Appeal inspections; how made.

Any person receiving inspection service may, if dissatisfied with any decision of an inspector relating to any inspection, file an appeal from such decision: *Provided*, That such appeal is filed within 48 hours from the time the decision was made. Any such appeal from a decision of an inspector shall be made to his immediate superior having jurisdiction over the subject matter of the appeal, and such superior shall determine whether the inspector's decision was correct. Review of such appeal determination, when requested, shall be made by the immediate superior of the employee of the Department making the appeal determination. The cost of any such appeal shall be borne by the appellant if the Administrator determines that the appeal is frivolous. The charges for such frivolous appeal shall be at the rate of $9.28 per hour for the time required to make the appeal inspection. The poultry or poultry products involved in any appeal shall be identified by U.S. retained tags and segregated in a manner approved by the inspector pending completion of an appeal inspection.

[48 FR 11419, Mar. 18, 1983, as amended at 60 FR 67456, Dec. 29, 1995]

Subpart G—Facilities for Inspection; Overtime and Holiday Service; Billing Establishments

§ 381.36 Facilities required.

(a) *Inspector's Office.* Office space, including, but not being limited to furnishings, light, heat, and janitor service, shall be provided rent free in the

official establishment, for the use of Government personnel for official purposes. The room or space set apart for this purpose must meet the approval of the Inspection Service and be conveniently located, properly ventilated, and provided with lockers or file cabinets suitable for the protection and storage of supplies and with facilities suitable for inspectors to change clothing. At the discretion of the Administrator, small plants requiring the services of less than one full-time inspector need not furnish facilities for Program employees as prescribed in this section, where adequate facilities exist in a nearby convenient location. Each official establishment shall provide commercial laundry service for inspectors' outer work clothing, or disposable outer work garments designed for one-time use, or uniform rental service garments which are laundered by the rental service.

(b) *Facilities for ante mortem inspection.* A suspect pen is required for adequate ratite inspection.

(c) Facilities for the Streamlined Inspection System (SIS). The following requirements for lines operating under SIS are in addition to the normal requirements to obtain a grant of inspection. The requirements for SIS in § 381.76(b) also apply.

(1) The following provisions shall apply to every inspection station:

(i) The conveyor line shall be level for the entire length of the inspection station. The vertical distance from the bottom of the shackles to the top of the adjustable platform (paragraph (c)(1)(iv) of this section) in its lowest position shall not be less than 60 inches.

(ii) Floor space shall consist of 4 feet along the conveyor line for the inspector, and 4 feet for the establishment helper. A total of at least 8 feet along the conveyor line shall be supplied for one inspection station and 16 feet for two-inspection stations.

(iii) Selectors or ''kickouts'' shall be installed in establishments with two inspection stations on a line so each inspector will receive birds on 12-inch centers with no intervening birds to impede inspection. The selector must move the bird to the edge of the trough for the inspector and establishment helper. The selectors must be smooth, steady, and consistent in moving the birds parallel and through the inspection station. Birds shall be selected and released smoothly to avoid swinging when entering the inspection station.

(iv) Each inspector's station shall have a platform that is slip-resistant and can be safely accessed by the inspector. The platform shall be designed so that it can be easily and rapidly adjusted for a minimum of 14 inches vertically while standing on the platform. The platform shall be a minimum length of 4 feet and have a minimum width of 2 feet; the platform shall be designed with a 42-inch high rail on the back side and with ½-inch foot bumpers on both sides and front to allow safe working conditions. The platform must have a safe lift mechanism and be large enough for the inspector to sit on a stool and to change stations during breaks or station rotation.

(v) Conveyor line stop/start switches shall be located within easy reach of each inspector.

(vi) A trough or other facilities shall extend beneath the conveyor at all places where processing operations are conducted from the point where the carcass is opened to the point where the trimming has been performed. The trough must be of sufficient width to preclude trimmings, drippage, and debris from accumulating on the floor or platforms. The clearance between the suspended carcasses and the trough must be sufficient to preclude contamination of carcasses by splash.

(vii) A minimum of 200-footcandles of shadow-free lighting with a minimum color rendering index value of 85 where the birds are inspected to facilitate inspection.

(viii) Online handrinsing facilities with a continuous flow of water must be provided for and within easy reach of each inspector and each establishment helper. The hand-contact element must be rinsed automatically with a sufficient volume of water to remove all fat, tissue, debris, and other extraneous material from the hand contact element after each use. Both hot and cold running water shall be available at each inspection station on the eviscerating line and shall be delivered

through a suitable mixing device controlled by the inspector. Alternatively, water for hand washing shall be delivered to such inspection stations at a minimum temperature of 65 degrees F.

(ix) Hangback racks shall be provided for and positioned within easy reach of the establishment helpers.

(x) Each inspection station shall be provided with receptacles for condemned carcasses and parts. Such receptacles shall comply with the performance standards in § 416.3(c) of this chapter.

(2) The following provisions shall apply only to prechill and postchill reinspection stations:

(i) Floor space shall consist of a minimum of 3 feet along each conveyor line and after each chiller to allow carcasses to be removed for evaluation. The space shall be level and protected from all traffic and overhead obstructions.

(ii) The vertical distance from the bottom of the shackles to the floor shall not be less than 48 inches.

(iii) A table, at least 2 feet wide, 2 feet deep, and 3 feet high designed to be readily cleanable and drainable shall be provided for reinspecting the sampled birds.

(iv) A minimum of 200-footcandles of shadow-free lighting with a minimum color rendering index of 85 on the table surface shall be provided.

(v) A separate clip board holder shall be provided for holding the recording sheets.

(vi) Handwashing facilities shall be provided for and shall be within easy access of persons working at the stations.

(vii) Hangback racks designed to hold 10 carcasses shall be provided for and positioned within easy reach of the person at the station.

(d) Facilities for the New Line Speed (NELS) inspection system. The following requirements for lines operating under the NELS inspection system are in addition to the normal requirements to obtain a grant of inspection and to the requirements for NELS in § 381.76 (b) and (c).

(1) The following provisions shall apply to every inspection station:

(i) The conveyor line shall be level for the entire length of the inspection station. The vertical distance from the bottom of the shackles to the top of the adjustable platform (paragraph (d)(1)(iv) of this section) in its lowest position shall not be less than 60 inches.

(ii) Floor space shall consist of 6 feet along the conveyor line for the establishment employee presenting the birds, 4 feet for the inspector, and 4 feet for the establishment helper. A total of at least 42 feet along the conveyor line shall be supplied for three inspection stations.

(iii) Selectors or ''kickouts'' shall be installed so the three inspection stations will receive birds on 18-inch centers with no intervening birds to impede inspection. The selector must move the bird to the end of the trough for the presenter, inspector, and establishment helper. The selectors must be smooth, steady, and consistent in moving the birds parallel and through the inspection station. Birds shall be selected and released smoothly to avoid splashing the mirror (paragraph (d)(1)(vii) of this section) and swinging when entering the inspection station. Guide bars shall not extend in front of the inspection station mirror to avoid obstructing the inspector's view.

(iv) Each inspector's station shall have an easily and rapidly adjustable platform, with a minimum of 14 inches of vertical adjustment, which covers the entire length of the station (4 feet) and has a minimum width of 2 feet. The platform shall be designed with a 42-inch high rail on the back side and with ½-inch foot bumpers on both sides and front to allow safe working conditions.

(v) Conveyor line stop/start switches shall be located within easy reach of each inspector.

(vi) A trough shall extend beneath the conveyor at all places where processing operations are conducted from the point where the carcass is opened to the point where the trimming has been performed. The trough must be of sufficient width to preclude trimmings, drippage, and debris from accumulating on the floor or platforms. The clearance between the suspended carcasses and the trough must be sufficient to preclude contamination of carcasses by splash.

(vii) A distortion-free mirror, at least 3 feet wide and 2 feet high, shall be mounted at each inspection station so that it can be adjusted between 5 and 15 inches behind the shackles, tilt up and down, tilt from side to side, and be raised and lowered. The mirror shall be positioned in relation to the inspection platform so that the inspector can position himself/herself opposite it 8 to 12 inches from the downstream edge. The mirror must be maintained abrasion free.

(viii) A minimum of 200-footcandles of shadow-free lighting with minimum color rendering index value of 85[1] where the birds are inspected to facilitate inspection. A light shall also be positioned above and slightly in front of the mirror to facilitate the illumination of the bird and mirror surfaces.

(ix) ''One-line'' handrinsing facilities with a continuous flow of water shall be provided for and within easy reach of each inspector and each establishment presenter and helper.

(x) Hangback racks shall be provided for and positioned within easy reach of the establishment helpers.

(xi) Each inspection station shall be provided with receptacle for condemned carcasses and parts. Such receptacles shall comply with the performance standards in § 416.3(c) of this chapter.

(2) The following provisions shall apply only to the reinspection station:

(i) Floor space shall consist of 6 feet along the conveyor line. The space shall be level and protected from all traffic and overhead obstructions.

(ii) The vertical distance from the bottom of the shackles to the floor shall not be less than 48 inches.

(iii) A table, at least 3 feet wide and 2 feet deep, shall be provided for reinspecting the sample birds.

(iv) A minimum of 200-footcandles of shows free lighting with a minimum color rendering index of 85[1] on the table surface.

(v) A separate clip board holder shall be provided for holding the recording sheets.

(vi) Handwashing facilities shall be provided for and shall be within easy reach of persons working at the station.

(vii) Hangback racks designed to hold 10 carcasses shall be provided for and positioned within easy reach of the person at the station.

(e) Facilities for the New Turkey Inspection (NTI) System. The following requirements for lines operating under the NTI System are in addition to the normal requirements to obtain a grant of inspection and to the requirements for the NTI System in § 381.76 (b) and (c).

(1) The following provisions apply to every inspection station:

(i) The conveyor line must be level for the entire length of the inspection station. The vertical distance from the bottom of the shackles to the top of the adjustable platform (paragraph (e)(1)(iii) of this section) in its lowest position shall not be less than 60 inches.

(ii) Floor space shall consist of 8 feet along the conveyor line; at least 4 feet for the inspector, and at least 4 feet for the establishment helper.

(iii) The inspector's station shall have an easily and rapidly adjustable platform with a minimum width of 2 feet which covers the entire length of the station (4 feet). The platform must adjust vertically a minimum of 14 inches, and must have a 42-inch rail on the back side and ½-inch foot bumpers on the sides and the front to allow safe working conditions.

(iv) Conveyor line stop/start switches shall be located within easy reach of each inspector.

(v) A trough or other facilities shall extend beneath the conveyor at all places where processing operations are conducted from the point where the carcass is opened to the point where the trimming has been performed. The trough must be wide enough to prevent trimmings, drippage, and debris from accumulation on the floor or platforms. The clearance between suspended carcasses and the trough must be sufficient to prevent contamination of carcasses by splash.

(vi) A minimum of 200 foot-candles of shadow-free lighting with a minimum

[1] This requirement may be met by deluxe cool white type of fluorescent lighting.

color rendering index value of 85[1] where the birds are inspected to facilitate inspection is required. The minimum lighting requirement for inspection stations in § 381.52(b) shall not apply.

(vii) On-line handrinsing facilities with a continuous flow of water shall be provided for and within easy reach of each inspector and each establishment helper.

(viii) Hangback racks shall be provided for and within easy reach of the establishment helper.

(ix) Each inspection station shall be provided with receptacles for condemned carcasses and parts. Such receptacles shall comply with the performance standards in § 416.3(c) of this chapter.

(2) The following provisions shall apply only to the reinspection station:

(i) Floor space shall consist of a minimum of 3 feet along the conveyor line so carcasses can be removed from each line for evaluation. The space shall be level and protected from all traffic and overhead obstructions.

(ii) The vertical distance from the bottom of the shackles to the floor must not be less than 48 inches.

(iii) A table at least 3 feet wide and 2 feet deep designed to be readily cleanable and drainable shall be provided for reinspecting the sampled birds.

(iv) A minimum of 200 foot-candles of shadow-free lighting with a minimum color rendering index of 85[1] at the table surface is required.

(v) A clipboard holder shall be provided for holding the recording sheets.

(vi) Handwashing facilities shall be provided for and within easy reach of persons working at the station.

(vii) Hangback racks designed to hold 10 carcasses shall be provided for and positioned within easy reach of the person at this station.

[37 FR 9706, May 16, 1972, as amended at 38 FR 9794, Apr. 20, 1973; 47 FR 23434, May 28, 1982; 49 FR 42554, Oct. 23, 1984; 50 FR 37512, Sept. 16, 1985; 52 FR 39209, Oct. 21, 1987; 64 FR 56416, Oct. 20, 1999; 66 FR 22905, May 7, 2001]

[1] This requirement may be met by deluxe cool white fluorescent lighting.

§ 381.37 Schedule of operations.

(a) No operations requiring inspection shall be conducted except under the supervision of an Inspection Service employee. All eviscerating of poultry and further processing shall be done with reasonable speed, considering the official establishment's facilities.

(b) A shift is a regularly scheduled operating period, exclusive of mealtime. One lunch period is the only official authorized interruption in the inspector's tour of duty once it begins. Lunch periods may be 30 minutes, 45 minutes, or in any case may not exceed one hour in duration. Once established, the lunch period must remain relatively constant as to time and duration. Lunch periods for inspectors shall not, except as provided herein, occur prior to 4 hours after the beginning of scheduled operations nor later than 5 hours after operations begin. In plants where a company rest break of not less than 30 minutes is regularly observed, approximately midpoint between start of work and the lunch period, and the inspector is allowed this time to meet his personal needs, the lunch period may be scheduled as long as 5½ hours after the beginning of scheduled operations.

(c) Official establishments, importers, and exporters shall be provided inspection service, without charge, up to 8 hours per shift during the basic workweek subject to the provisions of § 381.38: *Provided*, That any additional shifts meet requirements as determined by the Administrator or his designee. The basic workweek shall consist of 5 consecutive 8-hour days within the administrative workweek Sunday through Saturday, excluding the lunch period; except that, when possible, the Department shall schedule the basic workweek so as to consist of 5 consecutive 8-hour days Monday through Friday, excluding lunch period. The Department may depart from the basic workweek in those cases where maintaining such a schedule would seriously handicap the Department in carrying out its functions. These provisions are applicable to all official establishments except in certain cases as provided in § 381.145(h) of this subchapter.

(d)(1) Each official establishment shall submit a work schedule to the area supervisor for approval. In consideration of whether the approval of an establishment work schedule shall be given, the area supervisor shall take in account the efficient and effective use of inspection personnel. The work schedule must specify the workweek, daily clock hours of operation, and lunch periods for all departments of the establishment requiring inspection.

(2) Establishments shall maintain consistent work schedules. Any request by an establishment for a change in its work schedule involving changes in the workweek or an addition or elimination of shifts shall be submitted to the area supervisor at least 2 weeks in advance of the proposed change. Frequent requests for change shall not be approved: *Provided, however,* Minor deviations from a daily operating schedule may be approved by the inspector in charge if such request is received on the day preceding the day of change.

(3) Requests for inspection service outside an approved work schedule shall be made as early in the day as possible for overtime work to be performed within that same workday; or made prior to the end of the day's operation when such a request will result in overtime service at the start of the following day: *Provided,* That an inspector may be recalled to his assignment after the completion of his daily tour of duty under the provisions of §381.39(b).

[40 FR 45800, Oct. 3, 1975, as amended at 40 FR 50719, Oct. 31, 1975; 41 FR 15401, Apr. 13, 1976; 48 FR 6893, Feb. 16, 1983; 51 FR 32304, Sept. 11, 1986]

§381.38 Overtime and holiday inspection service.

(a) The management of an official establishment, an importer, or an exporter shall reimburse the Program, at the rate specified in §391.3, for the cost of the inspection service furnished on any holiday specified in paragraph (b) of this section; or for more than 8 hours on any day, or more than 40 hours in any administrative workweek Sunday through Saturday.

(b) Holidays for Federal employees shall be New Year's Day, January 1; Birthday of Martin Luther King, Jr., the third Monday in January; Washington's Birthday, the third Monday in February; Memorial Day, the last Monday in May; Independence Day, July 4; Labor Day, the first Monday in September; Columbus Day, the second Monday in October; Veterans' Day, November 11; Thanksgiving Day, the fourth Thursday in November; Christmas Day, December 25. When any of the above-listed holidays falls outside the basic workweek, the nearest workday within that week shall be the holiday.

[40 FR 45801, Oct. 3, 1975, as amended at 43 FR 51754, Nov. 7, 1978; 50 FR 51513, Dec. 18, 1985; 52 FR 5, Jan. 2, 1987; 53 FR 13398, Apr. 22, 1988; 54 FR 6390, Feb. 10, 1989]

§381.39 Basis of billing for overtime and holiday services.

(a) Each recipient of overtime or holiday inspection service, or both, shall be billed as provided for in §381.38(a) and at the rate specified in §391.3, in increments of quarter hours. For billing purposes, 8 or more minutes shall be considered a full quarter hour. Billing will be for each quarter hour of service rendered by each Inspection Service employee.

(b) Official establishments, importers, or exporters requesting and receiving the services of an Inspection Service employee after he has completed his day's assignment and left the premises, or called back to duty during any overtime or holiday period, shall be billed for a minimum of 2 hours overtime or holiday inspection service at the established rate.

(c) Bills are payable upon receipt and become delinquent 30 days from the date of the bill. Overtime or holiday inspection will not be performed for anyone having a delinquent account.

[40 FR 45801, Oct. 3, 1975, as amended at 54 FR 6390, Feb. 10, 1989]

Subpart H [Reserved]

Subpart I—Operating Procedures

§381.65 Operations and procedures, generally.

(a) Operations and procedures involving the processing, other handling, or storing of any poultry product must be

strictly in accord with clean and sanitary practices and must be conducted in a manner that will result in sanitary processing, proper inspection, and the production of poultry and poultry products that are not adulterated.

(b) Poultry must be slaughtered in accordance with good commercial practices in a manner that will result in thorough bleeding of the carcasses and ensure that breathing has stopped prior to scalding. Blood from the killing operation must be confined to a relatively small area.

(c) When thawing frozen ready-to-cook poultry in water, the establishment must use methods that prevent adulteration of, or net weight gain by, the poultry.

(d) The water used in washing the poultry must be permitted to drain freely from the body cavity.

(e) Poultry carcasses contaminated with visible fecal material shall be prevented from entering the chilling tank.

(f) Detached ova may be collected for human food and handled only in accordance with 9 CFR 590.44 and may leave the establishment only to be moved to an official egg product processing plant for processing. Ova from condemned carcasses must be condemned and treated as required in § 381.95.

[66 FR 1771, Jan. 9, 2001; 66 FR 19714, Apr. 17, 2001]

§ 381.66 Temperatures and chilling and freezing procedures.

(a) *General.* Temperatures and procedures that are necessary for chilling and freezing ready-to-cook poultry, including all edible portions thereof, must be in accordance with operating procedures that ensure the prompt removal of the animal heat, preserve the condition and wholesomeness of the poultry, and assure that the products are not adulterated.

(b) *General chilling requirements, except for ratites.* (1) All poultry that is slaughtered and eviscerated in the official establishment shall be chilled immediately after processing so that the internal temperature is reduced to 40 °F. or less, as provided in paragraph (b)(2) of this section unless such poultry is to be frozen or cooked immediately at the official establishment. Eviscerated poultry to be shipped from the establishment in packaged form shall be maintained at 40 °F. or less, except that during further processing and packaging operations, the internal temperature may rise to a maximum of 55 °F.: *Provided,* That immediately after packaging, the poultry is placed under refrigeration at a temperature that will promptly lower the internal temperature of the product to 40 °F. or less, or the poultry is placed in a freezer. Poultry which is to be held at the plant in packaged form in excess of 24 hours shall be held in a room at a temperature of 36 °F. or less.

(2) Major portions of poultry carcasses, as defined in § 381.170(b)(22), and poultry carcasses shall be chilled to 40 °F. or lower within the following specified times:

Weight of carcass	Time (hours)
Under 4 pounds	4
4 to 8 pounds	6
Over 8 pounds	8

(c) *Ice and water chilling.* (1) Only ice produced from potable water may be used for ice and water chilling, except that water and ice used for chilling may be reused in accordance with § 416.2(g). The ice must be handled and stored in a sanitary manner.

(2)(i) Poultry chilling equipment must be operated in a manner consistent with meeting the applicable pathogen reduction performance standards for raw poultry products as set forth in § 381.94 and the provisions of the establishment's HACCP plan.

(ii) Major portions of poultry carcasses, as defined in § 381.170(b)(22), may be chilled in water and ice.

(3) Previously chilled poultry carcasses and major portions must be maintained constantly at 40 °F or below until removed from the vats or tanks for immediate packaging. Such products may be removed from the vats or tanks prior to being cooled to 40 °F or below, for freezing or cooling in the official establishment. Such products must not be packed until after they have been chilled to 40 °F or below, except when the packaging will be followed immediately by freezing at the official establishment.

(4) Giblets must be chilled to 40 °F or below within 2 hours from the time they are removed from the inedible viscera, except that when they are cooled with the carcass, the requirements of paragraph (b)(2) of this section must apply. Any of the acceptable methods of chilling the poultry carcass may be followed in cooling giblets.

(d) *Water absorption and retention.* (1) Poultry washing, chilling, and draining practices and procedures must be such as will minimize water absorption and retention at time of packaging.

(2) The establishment must provide scales, weights, identification devices, and other supplies necessary to conduct water tests.

(e) *Air chilling.* In air chilling ready-to-cook poultry, the internal temperature of the carcasses shall be reduced to 40 °F. or less within 16 hours.

(f) *Freezing.* (1) Ready-to-cook poultry which is to be or is labeled with descriptive terms such as ''fresh frozen,'' ''quick frozen'' or ''frozen fresh'' or any other term implying a rapid change from a fresh state to a frozen state shall be placed into a freezer within 48 hours after initial chilling in accordance with paragraph (b) of this section. During this period, if such poultry is not immediately placed into a freezer after chilling and packaging, it shall be held at 36 °F. or lower.

(2) Ready-to-cook poultry shall be frozen in a manner so as to bring the internal temperature of the birds at the center of the package to 0 °F. or below within 72 hours from the time of entering the freezer. Such procedures shall not apply to raw poultry product described in §381.129(b)(6)(i) of this subchapter.

(3) Upon written request, and under such conditions as may be prescribed by the Administrator, in specific cases, ready-to-cook poultry which is to be frozen immediately may be moved from the official establishment prior to freezing: *Provided*, That the plant and freezer are so located and such necessary arrangements are made that the Inspection Service will have access to the freezing room and adequate opportunity to determine compliance with the time and temperature requirements specified in paragraph (f)(2) of this section.

(4) Warm packaged ready-to-cook poultry which is to be chilled by immediate entry into a freezer within the official establishment shall within 2 hours from time of slaughter be placed in a plate freezer or a freezer with a functioning circulating air system where a temperature of −10 °F. or lower is maintained.

(5) Frozen poultry shall be held under conditions which will maintain the product in a solidly frozen state with temperature maintained as constant as possible under good commercial practice.

[37 FR 9706, May 16, 1972, as amended at 39 FR 4568, 4569, Feb. 5, 1974; 40 FR 42338, Sept. 12, 1975; 49 FR 9411, Mar. 13, 1984; 60 FR 44412, Aug. 25, 1995; 63 FR 48960, Sept. 11, 1998; 66 FR 1771, Jan. 9, 2001; 66 FR 19714, Apr. 17, 2001; 66 FR 22905, May 7, 2001]

§381.67 Young chicken and squab slaughter inspection rate maximums under traditional inspection procedure.

The maximum number of birds to be inspected by each inspector per minute under the traditional inspection procedure for the different young chicken and squab slaughter line configurations are specified in the following table. These maximum rates will not be exceeded. The inspector in charge will be responsible for reducing production line rates where in the inspector's judgment the prescribed inspection procedure cannot be adequately performed within the time available, either because the birds are not presented by the official establishment in such a manner that the carcasses, including both internal and external surfaces and all organs, are readily accessible for inspection, or because the health conditions of a particular flock dictate a need for a more extended inspection procedure. The standards in 381.170(a) of this part specify which classes of birds constitute young chickens and squabs. Section 381.76(b) specifies when either the traditional inspection procedure or the modified traditional inspection procedure can or must be used.

MAXIMUM PRODUCTION LINE RATES—CHICKENS AND SQUABS-TRADITIONAL INSPECTION PROCEDURES

Line configuration [1]	Number of inspection stations	Birds per inspector per minute
6–1	1	25
12–1	2	23
12–2	2	21
18–1	3	19
18–2	3	19
18–3	3	18
24–1	4	16½
24–2	4	16
24–4	4	15½

[1] Birds are suspended on the slaughter line at 6–inch intervals. The first number indicates the interval in inches between the birds that each inspector examines. The second number indicates how many of the birds presented, the inspector is to inspect, i.e., ''1'' means inspect every bird. ''4'' means inspect every fourth bird, etc.

[47 FR 23435, May 28, 1982, as amended at 66 FR 22905, May 7, 2001]

§ 381.68 Maximum inspection rates—New turkey inspection system.

(a) The maximum inspection rates for one inspector New Turkey Inspection (NTI–1) and two inspector New Turkey Inspection (NTI–2) are listed in the table below. These line speeds are for lines using standard 9-inch shackles on 12-inch centers with birds hung on every shackle and opened with J-type or Bar-type opening cuts. Maximum rates for those establishments having varying configurations will be established by the Administrator but will not exceed those in the table. Neither the rates in the table nor those established for establishments with varying configurations shall be exceeded under any circumstances.

(b) There are two categories of turkeys for determining inspection rates, ''light turkeys'' and ''heavy turkeys''. Light turkeys are all turkeys weighing less than 16 pounds. Heavy turkeys are all turkeys weighing 16 pounds or more. The weights refer to the bird at the point of post-mortem inspection, with blood, feathers and feet removed.

(c) The inspector in charge may reduce inspection line rates when in his/her judgment the prescribed inspection procedure cannot be adequately performed within the time available because the health conditions of a particular flock dictate a need for a more extended inspection.

MAXIMUM TURKEY INSPECTION RATES

Inspection system	Line configuration	Number of inspectors	Birds/Minute			
			J-Type		Bar-Type	
			(<16#) light	(>16#)[1] heavy	(<#) light	(>16#)[1]) heavy
NTI–1	12–1	1	32	30	25	21
NTI–2	[2] 24–2	2	51	41	45	35

[1] This weight refers to the bird at the point of post-mortem inspection, without blood, feathers, or feet.
[2] The turkeys are suspended on the slaughter line at 12-inch intervals, with two inspectors each looking at alternating birds at 24-inch intervals.

[50 FR 37512, Sept. 16, 1985]

Subpart J—Ante Mortem Inspection

§ 381.70 Ante mortem inspection; when required; extent.

(a) An ante mortem inspection of poultry shall, where and to the extent considered necessary by the Administrator and under such instructions as he may issue from time to time, be made of poultry on the day of slaughter in any official establishment.

(b) The examination and inspection of ratites will be on the day of slaughter, except:

(1) When it is necessary for humane reasons to slaughter an injured animal at night or on a Sunday or holiday, and the FSIS veterinary medical officer cannot be obtained; or

(2) In low volume establishments, when ante mortem inspection cannot be done on the day of slaughter, and the birds to be slaughtered have received ante mortem inspection in the

last 24 hours, provided the establishment has an identification and control system over birds that have received ante mortem inspection.

[37 FR 9706, May 16, 1972, as amended at 66 FR 22906, May 7, 2001]

§381.71 Condemnation on ante mortem inspection.

(a) Birds plainly showing on ante mortem inspection any disease or condition, that under §§381.80 to 381.93, inclusive, would cause condemnation of their carcasses on post mortem inspection, shall be condemned. Birds which on ante mortem inspection are condemned shall not be dressed, nor shall they be conveyed into any department of the official establishment where poultry products are prepared or held. Poultry which has been condemned on ante mortem inspection and has been killed or died otherwise shall under the supervision of an inspector of the Inspection Service, be disposed of as provided in §381.95.

(b) Dead-on-arrival ratites and ratites condemned on ante mortem inspection will be tagged ''U.S. Condemned'' by an establishment employee under FSIS supervision and disposed of by one of the methods prescribed in §381.95.

(c) All seriously crippled ratites and non-ambulatory ratites, commonly termed ''downers,'' shall be identified as ''U.S. Suspects.''

(d) Ratites exhibiting signs of drug or chemical poisoning shall be withheld from slaughter.

(e) Ratites identified as ''U.S. Suspects'' or ''U.S. Condemned'' may be set aside for treatment. The ''U.S. Suspect'' or ''U.S. Condemned'' identification device will be removed by an establishment employee under FSIS supervision following treatment if the bird is found to be free of disease. Such a bird found to have recovered from the condition for which it was treated may be released for slaughter or for purposes other than slaughter, provided that in the latter instance permission is first obtained from the local, State, or Federal sanitary official having jurisdiction over movement of such birds.

(f) When it is necessary for humane reasons to slaughter an injured ratite at night or Sunday or a holiday, and the Agency veterinary medical officer cannot be obtained, the carcass and all parts shall be kept for inspection, with the head and all viscera except the gastrointestinal tract held by the natural attachment. If all parts are not so kept for inspection, the carcass shall be condemned. If on inspection of a carcass slaughtered in the absence of an inspector, any lesion or other evidence is found indicating that the bird was sick or diseased, or affected with any other condition requiring condemnation of the animal on ante mortem inspection, or if there is lacking evidence of the condition that rendered emergency slaughter necessary, the carcass shall be condemned. Ratites that are sick, dying, or that have been treated with a drug or chemical and presented for slaughter before the required withdrawal period, are not covered by emergency slaughter provisions.

[37 FR 9706, May 16, 1972, as amended at 66 FR 22906, May 7, 2001; 67 FR 13258, Mar. 22, 2002]

§381.72 Segregation of suspects on ante mortem inspection.

(a) All birds, except ratites, that on ante mortem inspection do not plainly show, but are suspected of being affected with, any disease or condition that under §§381.80 to 381.93 of this Part may cause condemnation in whole or in part on post mortem inspection, shall be segregated from the other poultry and held for separate slaughter, evisceration, and post mortem inspection. The inspector shall be notified when such segregated lots are presented for post mortem inspection, and inspection of such birds shall be conducted separately. Such procedure for the correlation of ante mortem and post mortem findings by the inspector, as may be prescribed or approved by the Administrator, shall be carried out.

(b) All ratites showing symptoms of disease will be segregated, individually tagged as ''U.S. Suspects'' by establishment personnel under FSIS supervision with a serially numbered metal or plastic leg band or tag bearing the term ''U.S. Suspect,'' and held for further examination by an FSIS veterinarian. Depending upon the findings of the veterinarian's examination, these birds

will either be passed for regular slaughter, slaughtered as suspects, withheld from slaughter, or condemned on ante mortem. Those ratites affected with conditions that would be readily detected on post mortem inspection need not be individually tagged on ante mortem inspection with the ''U.S. Suspect'' tag provided that such ratites are segregated and otherwise handled as ''U.S. Suspects.'' All ratites identified as ''U.S. Condemned'' shall be tagged by establishment personnel, under FSIS supervision, with a serially numbered metal or plastic leg band or tag bearing the term ''U.S. Condemned.''

[66 FR 22906, May 7, 2001]

§ 381.73 Quarantine of diseased poultry.

If live poultry, which is affected by any contagious disease which is transmissible to man, is brought into an official establishment, such poultry shall be segregated. The slaughtering of such poultry shall be deferred and the poultry shall be dealt with in one of the following ways:

(a) If it is determined by a veterinary inspector that further handling of the poultry will not create a health hazard, the lot shall be slaughtered separately, subject to ante mortem and post mortem inspection pursuant to the regulations.

(b) If it is determined by a veterinary inspector that further handling of the poultry will create a health hazard, such poultry may be released for treatment under the control of an appropriate State or Federal agency. If the circumstances are such that release for treatment is impracticable, a careful bird-by-bird ante mortem inspection shall be made, and all birds found to be, or which are suspected of being, affected with a contagious disease transmissible to man shall be condemned.

§ 381.74 Poultry suspected of having biological residues.

When any poultry at an official establishment is suspected of having been treated with or exposed to any substance that may impart a biological residue that would make their edible tissues adulterated, they shall, at the option of the operator of the establishment, be processed at the establishment and the carcasses and all parts thereof retained under U.S. Retained tags, pending final disposition in accordance with § 381.80, of this part, and other provisions in subpart K; or they shall be slaughtered at the establishment and buried or incinerated in a manner satisfactory to the inspector. Alternatively, such poultry may be returned to the grower, if further holding is likely to result in their not being adulterated by reason of any residue. The Inspection Service will notify the other Federal and State agencies concerned of such action. To aid in determining the amount of residue present in the poultry, officials of the Inspection Service may permit the slaughter of any such poultry for the purpose of collecting tissues for analysis of the residue. Such analysis may include the use of inplant screening procedures designed to detect the presence of antimicrobial residues in any species of poultry.

[47 FR 41336, Sept. 20, 1982]

§ 381.75 Poultry used for research.

(a) No poultry used in any research investigation involving an experimental biological product, drug, or chemical shall be eligible for slaughter at an official establishment unless the operator of such establishment, the sponsor of the investigation, or the investigator has submitted to the Inspection Service, or the Veterinary Biologics unit of Veterinary Services, Animal and Plant Health Inspection Service of the Department or the Environmental Protection Agency, or the Food and Drug Administration of the Department of Health, Education, and Welfare, data or a summary evaluation of the data which demonstrates that the use of such biological product, drug, or chemical will not result in the products of such poultry being adulterated, and the Administrator has approved such slaughter.

[37 FR 9706, May 16, 1972, as amended at 39 FR 4569, Feb. 5, 1974]

Subpart K—Post Mortem Inspection; Disposition of Carcasses and Parts

§381.76 Post-mortem inspection, when required; extent; traditional, Streamlined Inspection System (SIS), New Line Speed (NELS) Inspection System and the New Turkey Inspection (NTI) System; rate of inspection.

(a) A post-mortem inspection shall be made on a bird-by-bird basis on all poultry eviscerated in an official establishment. No viscera or any part thereof shall be removed from any poultry processed in any official establishment, except at the time of post-mortem inspection, unless their identify with the rest of the carcass is maintained in a manner satisfactory to the inspector until such inspection is made. Each carcass to be eviscerated shall be opened so as to expose the organs and the body cavity for proper examination by the inspector and shall be prepared immediately after inspection as ready-to-cook poultry. If a carcass is frozen, it shall be thoroughly thawed before being opened for examination by the inspector. Each carcass, or all parts comprising such carcass, shall be examined by the inspector, except for parts that are not needed for inspection purposes and are not intended for human food and are condemned.

(b)(1) There are five systems of post-mortem inspection: Streamlined Inspection System (SIS) and the New Line Speed (NELS) Inspection System, both of which shall be used only for broilers and cornish game hens; the New Turkey Inspection (NTI) System, which shall be used only for turkeys; Traditional Inspection; and Ratite Inspection.

(i) The SIS shall be used only for broilers and cornish game hens if:

(*a*) The Administrator determines that SIS will increase inspector efficiency; or

(*b*) The operator requests SIS and the Administrator determines that the system will result in no loss of inspection efficiency.

(ii) The NELS Inspection System shall be used only for broilers and cornish game hens if:

(*a*) The operator requests the NELS Inspection System, and

(*b*) The Administrator determines that the establishment has the intent and capability to operate at line speeds greater than 70 birds per minute, and meets all the facility requirements in §381.36(d).

(iii) The NTI System shall be used only for turkeys if:

(*a*) The operator requests it, and

(*b*) The Administrator determines that the establishment meets all the facility requirements in §381.36(e).

(iv) Traditional inspection shall be used for turkeys when the NTI System is not used. For other classes of poultry, Traditional Inspection shall be used when neither the SIS nor the NELS Inspection System is used.

(2) The requirements of paragraph (a) of this section are applicable to all four inspection systems.

(3) The following requirements are applicable to SIS:

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

(*a*) *Cumulative sum (CUSUM).* A statistical concept used by the establishment and monitored by the inspector whereby compliance is determined based on sample results collected over a period of time. For purposes of determining compliance with the finished product standards, the CUSUM is equal to the sum of prior test results plus the weighted result of the current test minus the tolerance, with the condition that the resulting CUSUM cannot go below zero.

(*b*) *Tolerance number.* A weighted measure that equates to product being produced at a national product quality level. See Table 2.

(*c*) *Action number.* A level reached by the CUSUM where the process is out of control and product action is required by the establishment or the inspector. See Table 2.

(*d*) ''Start number''. A value halfway between zero and the action number. The start number is used to determine the starting CUSUM for the first subgroup of a shift and to reset the CUSUM value if the CUSUM is equal to or greater than the action number. See Table 2.

(*e*) *Subgroup.* A 10-bird sample collected before product enters the chiller and after product leaves the chiller.

(*f*) *Subgroup absolute limit.* The tolerance number plus 5. See Table 2.

(*g*) *Prechill testing.* Testing conducted by the establishment to determine the CUSUM on consecutive 10-bird subgroup samples collected prior to product entering the chilling system.

(*h*) *Postchill testing.* Testing conducted by the establishment to determine the CUSUM on consecutive 10-bird subgroup samples collected as the product leaves the chilling system.

(*i*) *Rework.* Reprocessing the product to correct the condition or conditions causing the nonconformances listed in Table 1.

(ii) *General. (a*) Under SIS, one inspector inspects the outside, inside, and viscera of each bird. There may be two inspectors on one processing line, each inspecting every other bird. For the establishment to run its processing line(s) at maximum speed, optimal conditions must be maintained so that inspection may be conducted efficiently. The inspector in charge determines the speed at which each processing line may be operated to permit inspection. A variety of conditions may affect this determination including the health of each flock and the manner in which birds are being presented to the inspector for inspection.

(*b*) SIS may be performed by one inspector (SIS–1) or two inspectors (SIS–2). SIS–1 requires that the establishment provide one inspection station for each line and adequate reinspection facilities so carcasses can be removed from each line for evaluation. The maximum line speed for SIS–1 is 35 birds per minute. SIS–2 requires that the establishment provide two inspection stations for each line and adequate reinspection facilities so carcasses can be removed from each line for evaluation. The maximum line speed for SIS–2 is 70 birds per minute.

(*c*) Under all inspection systems, including SIS, inspectors conduct postmortem inspection and look for a number of conditions, as specified elsewhere in this subpart, which may indicate adulteration. Adulterated product is condemned and destroyed, except that carcasses and parts which may be made unadulterated by reprocessing (reworking) may be so reprocessed under the supervision of an inspector and reinspected. Under SIS, inspectors also reinspect product by sampling finished birds (both before and after chilling) for nonconformances with finished product standards (see Table 1). If such nonconformances are present at certain statistical levels, it may indicate process difficulties requiring corrective action by the establishment. If the establishment does not take adequate corrective action, the inspector shall initiate corrective actions such as conducting closer post-mortem inspections and requiring reprocessing and reinspection of previously processed carcasses and parts. Thus, SIS is conducted in two phases—a post-mortem inspection phase and a reinspection phase. The following paragraphs describe the inspection requirements (not addressed elsewhere in this subpart) under each.

(iii) *Post-mortem inspection. (a*) Facilities: Each inspection station must comply with the facility requirements in § 381.36(c).

(*b*) Presentation: Each inspector shall be flanked by an establishment employee assigned to be the inspector's helper. The one inspector on the SIS–1 line shall be presented every bird. Each inspector on the SIS–2 line shall be presented every other bird on the line. An establishment employee shall present each bird to the inspector properly eviscerated with the back side toward the inspector and the viscera uniformly trailing or leading. Each inspector shall inspect the inside, viscera, and outside of all birds presented.

(*c*) Disposition: The inspector shall determine which birds shall be salvaged, reprocessed, condemned, retained for disposition by the veterinarian, or allowed to proceed down the line as a passed bird subject to trim and reinspection. Carcasses with certain defects not requiring condemnation of the entire carcass shall be passed by the inspector, but shall be subject to reinspection to ensure the physical removal of the defects. The helper, under the supervision of the inspector, shall mark such carcasses for trim when the defects are not readily observable. Trimming of birds passed

subject to reinspection shall be performed by:

(*1*) The helper, time permitting, and

(*2*) One or more plant trimmers positioned after all giblets are harvested and prior to reinspection.

(iv) *Reinspection*. *(a*) Facilities: Reinspection stations are required at both the prechill and postchill locations. The Agency will determine the number of stations needed in those establishments having more than one processing line or more than one chiller. One or more prechill reinspection stations shall be conveniently located at the end of the line or lines prior to chilling. One or more postchill stations must be conveniently located at the end of the chiller or chillers. The prechill and postchill reinspection stations must meet the following provisions:

(*1*) Floor space shall consist of 3 feet along each conveyor line. The space shall be level and protected from all traffic and overhead obstructions.

(*2*) A table at least 2 feet wide and 2 feet deep and 3 feet in height designed to be readily cleanable and drainable shall be provided for reinspecting the sampled birds.

(*3*) A minimum of 200 foot-candles of shadow-free lighting with a minimum color rendering index of 85 on the table surface.

(*4*) A separate clip board holder shall be provided for holding the recording sheets.

(*5*) Hangback racks designed to hold 10 carcasses shall be provided for and positioned within easy reach of the person at the station.

(*b*) Disposition: An inspector shall monitor the establishment's application of the Finished Product Standards program and shall take corrective action including retaining product to prevent adulterated product from leaving the establishment when the inspector determines that the establishment has failed to apply the program as prescribed in paragraph (b)(3)(iv)(*c*) of this section).

(*c*) Finished Product Standards: Finished Product Standards (FPS) are criteria applied to processed birds before and after chill to ensure that the product being produced is consistently wholesome and unadulterated. These criteria consist of nonconformances (listed in Table 1), the incidence of which is determined from 10 bird subgroup samples, reduced to a CUSUM number, and measured against the standards (Table 2). The standards are applied to permit the Agency to estimate when the production process is in control and when it is out of control. The establishment is responsible for maintaining FPS which, in turn, is monitored by the inspector. FPS is applied in two separate parts. The first is called prechill testing. It is designed to ensure that the slaughter and evisceration procedures are in control. Compliance is measured by determining the CUSUM on consecutive 10-bird subgroup samples collected prior to product entering the chilling system. The second part of the FPS is called postchill testing. It is designed to monitor the production through the chill system to ensure that it meets the postchill FPS. This test is independent of the prechill test. Compliance is measured by determining the CUSUM on consecutive 10-bird subgroup samples as they exit the chilling system. When the system is operating within compliance, the establishment applies the FPS to product samples at the prechill reinspection station. Testing time and time between tests are such that birds represented by the test are still within the chiller. If an out-of-compliance condition is found, the product leaving the chiller is segregated for rework and retested before it may proceed into commerce. A second 10 bird subgroup sample of the birds is taken after they leave the chiller to ensure that the product meets the postchill FPS. Since the product is closer to the end of processing, the controls on releasing reworked product are stricter than controls under prechill testing, again to ensure that no adulterated product enters into commerce.

(*d*) *Prechill testing.* The prechill FPS have been divided into processing and trim categories. The processing category is designed to monitor the output of the dressing and evisceration

procedures. The trim category monitors the establishment's ability to remove unwholesome lesions and conditions from inspected and passed carcasses. Each category is monitored independently of the other category using a separate CUSUM for each category.

(*1*) *Actions to be taken when the process is in control.* If the CUSUM is less than the action number and the subgroup absolute limit is not exceeded, the process is judged to be in control.

(*i*) Establishment Actions. The establishment shall:

(*A*) Randomly select and record subgroup sampling times for each production unit of time before product reaches the prechill reinspection station on the production line. In no case shall the time between tests exceed 1 hour of production time.

(*B*) Conduct a 10-bird subgroup test at a random time on each poultry slaughter line. These times are preselected by the establishment and available to the inspector prior to the start of the shift/day's operations. All 10 samples of the subgroup shall be collected at the random time.

(*C*) Obtain the weighted value of each nonconformance by multiplying the number recorded for each nonconformance by the ''factor'' in Table 1, sum the total of all the nonconformances, and calculate the CUSUM value for that test.

(*ii*) Inspector Actions. The inspector shall:

(*A*) Select random times for monitoring subgroup tests for each half-shift on the evisceration line. In establishments that have multiple evisceration lines on a production shift, monitor all lines of product at the random times.

(*B*) Collect the subgroup samples to be monitored at preselected times. All 10 samples of the subgroup shall be collected at the random time selected in paragraph (b)(3)(iv)(*d*)(*1*)(*ii*)(*A*) of this section.

(*C*) Conduct the 10-bird monitoring subgroup test.

(*2*) *Actions to be taken when the subgroup absolute limit is exceeded.* If either an inspector or establishment subgroup test exceeds the subgroup absolute limit of tolerance plus 5 (T+5), the establishment shall determine if any of the immediate past 5 plant prechill subgroups for that category (processing or trim) resulted in a CUSUM above the start number.

(*i*) If all of the past 5 plant prechill subgroups are at or below the start number, the establishment shall immediately conduct a retest subgroup on that category of prechill to determine sample validity. If retest subgroup total equals tolerance or less, the establishment resumes random time testing. If the retest subgroup total exceeds tolerance, the establishment shall proceed as if CUSUM reaches the action number and shall begin process actions as set forth in paragraph (b)(3)(iv)(*d*)(*4*) of this section. In either case, the prechill retest results will be used to calculate CUSUM.

(*ii*) If any of the past 5 plant prechill subgroups resulted in a CUSUM above the start number, the establishment shall proceed as if CUSUM reaches the action number and shall begin process actions as set forth in paragraph (b)(3)(iv)(*d*)(*4*) of this section.

(*3*) *Actions to be taken when a trimmable lesion/condition is found.* If either inspection or plant monitoring finds any trimmable lesion or condition as specified in item B(7) of Table 1 during a prechill subgroup test, the establishment shall immediately conduct an additional prechill subgroup test for the same trimmable lesion/condition category. This is a requirement on the subgroup testing for the prechill trim nonconformance that is in addition to the CUSUM test described in paragraph (b)(3)(iv)(*d*)(*1*) of this section.

(*i*) If no additional item in the same category is found on retest, the establishment shall resume random time sampling.

(*ii*) If an additional item in the same category is found on retest, the establishment shall proceed as if CUSUM reaches the action number and shall initiate corrective action set forth in paragraph (b)(3)(iv)(*d*)(*4*) of this section for this category only.

(*4*) *Actions to be taken when the CUSUM reaches the action number.* Once CUSUM reaches the action number, the process is judged to be not in control.

(*i*) Establishment Actions. The establishment shall:

(*A*) Immediately notify the inspector in charge and the production supervisor responsible for the affected evisceration line.

(*B*) Suspend random time prechill testing of the affected nonconformance category (processing or trim). Suspend random time postchill subgroup testing when the processing category is the affected nonconformance category.

(*C*) Conduct subgroup retests on carcasses leaving the chill system. Apply the prechill criteria in Table 1 (A) or (B), depending upon which category caused the action, and apply prechill Finished Product Standards as listed in Table 2 to determine product compliance. In no case shall the time between retests exceed 30 minutes of production time. Apply prechill standard criteria at the postchill location after notifying the establishment's production supervisor. If any of these subgroup retests on product leaving the chill system result in a subgroup total exceeding tolerance, identify for rework subsequent product at the postchill location. All noncomplying product will be brought into compliance prior to release into commerce. Product from the chiller will continue accumulating for rework until a subsequent subgroup test results in a subgroup total equal to or less than tolerance.

(*D*) Conduct additional subgroup tests at the prechill reinspection station to determine the adequacy of production corrective action. If the prechill tests results in a subgroup total exceeding the tolerance, notify the production supervisor. The number of additional tests at the postchill reinspection station using prechill standards is increased as required to include the product in the chiller represented by this additional prechill test.

(*E*) After two consecutive additional prechill subgroup tests result in subgroup totals equal to or less than tolerance:

— Resume random time prechill subgroup testing as set forth in actions to be taken when the process is in control at paragraph (b)(3)(iv)(*d*)(*1*) of this section.

— Identify product entering the chill system that will mark the end of the retest action upon arrival at the postchill sampling location. Such identification may include tagging or empty space in chillers, depending upon the establishment's identification method.

— Once all product identified as needing retesting has arrived at the postchill sampling location, random time postchill FPS testing resumes.

— If two consecutive additional prechill subgroup tests demonstrate process control with subgroup totals equal to or less than tolerance, but they do not cause CUSUM to fall to the start line or below, reset CUSUM at the start number.

(*ii*) Inspector Actions. The inspector shall monitor product and process actions by making spot-check observations to ensure that all program requirements are met.

(*e*) *Postchill testing.* Postchill subgroups shall be collected after the product leaves the chiller but before the product is divided into separate processes. Each bird sampled shall be observed and its conformance measured against the postchill criteria. The subgroup nonconformance weights shall be totaled and the CUSUM calculated by subtracting the tolerance from the sum of the subgroup total and the starting CUSUM.

(*1*) *Actions to be taken when the process is in control.* If the CUSUM is less than the action number and the subgroup absolute limit is not exceeded, the process is judged to be in control.

(*i*) Establishment Actions. The establishment shall conduct a 10-bird subgroup test for each chiller system at a randomly selected time of production. In no case shall the time between tests exceed 2 hours of production time.

(*ii*) Inspector Actions. The inspector shall:

(*A*) Select random times for postchill monitoring.

(*B*) Monitor each chill system twice per shift.

(*C*) Conduct subgroup tests at preselected random times.

(*2*) *Actions to be taken when the subgroup absolute limit is exceeded.* If either an inspector or establishment subgroup test exceeds the subgroup absolute limit of tolerance plus 5(T+5), the establishment shall determine if any of

the last 5 postchill monitoring subgroups resulted in a CUSUM above the start number.

(*i*) If all of the past 5 postchill monitoring subgroups resulted in a CUSUM at or below the start number, the establishment shall immediately retest a subgroup to determine sample validity. If this retest subgroup total exceeds tolerance, the establishment shall proceed as if CUSUM reaches the action number and shall begin process actions as set forth in paragraph (b)(3)(iv)(*e*)(*3*) of this section.

(*ii*) If any of the past 5 postchill monitoring subgroups resulted in a CUSUM above the start number, the establishment shall proceed as if CUSUM reaches the action number and shall begin process actions as set forth in paragraph (b)(3)(iv)(*e*)(*3*) of this section.

(*3*) *Actions to be taken when the CUSUM reaches the action number.* Once CUSUM reaches the action number, the process is judged to be not in control.

(*i*) Establishment Actions. The establishment shall:

(*A*) Notify the inspector in charge and the production supervisor responsible for product in the chiller.

(*B*) Suspend random time postchill subgroup testing.

(*C*) Immediately conduct an additional postchill subgroup test. If the retest subgroup total exceeds tolerance, the establishment shall identify subsequent product for rework. Product will continue accumulating for rework until a subsequent subgroup test results in a subgroup total equal to or less than tolerance.

(*D*) After two consecutive additional postchill subgroup tests results in subgroup totals equal to or less than tolerance:

— Resume random time postchill subgroup testing as set forth in actions to be taken when the process is in control at paragraph (b)(3)(iv)(*e*)(*1*) of this section.

— If the two consecutive additional postchill subgroup totals equal to or less than tolerance do not cause CUSUM to fall to the start number or below, reset CUSUM at the start number.

(*ii*) Inspector Actions. The inspector shall monitor product and process actions to ensure that program requirements are met.

(v) When the prechill or postchill product has been identified as having been produced when the process was not in control, additional online subgroup testing by the establishment is required to determine its conformance to the standard. If any of the additional plant subgroup testing results in a subgroup total exceeding tolerance, offline product corrective actions must take place. The responsibilities of the establishment and the inspector change depending on the CUSUM.

All corrective actions such as identifying affected product, segregating product, and maintaining control through rework actions are the establishment's responsibility. Corrective actions by the inspector depends upon the establishment's ability to control rework of affected product. If the establishment fails in its responsibilities, the inspector will identify, segregate, and retain affected product to prevent adulterated product from reaching consumers.

(*a*) Offline product. The establishment shall identify the affected product so that it may be segregated and accumulated offline for rework. The inspector shall spot check the establishment's identification, segregation, and control of reworked product to ensure that program requirements are met.

(*b*) Reworked product. Reworked product must be tested by the establishment with a randomly selected subgroup test of the accumulated reworked lot. Before product is released, the random subgroup test must result in a subgroup total equal to or less than tolerance. If the subgroup test of a reworked lot results in a subgroup total exceeding tolerance, the lot must be reworked again before another subgroup is selected. The following actions are required.

(*1*) Establishment Actions. The establishment shall:

(*i*) Select the random subgroup from throughout the lot only after the total lot has been reworked.

(*ii*) Conduct the subgroup test using the same criteria (prechill or postchill) that resulted in the rework action.

(*iii*) Release the lot if the reworked subgroup test resulted in a subgroup total equal to or less than tolerance.

(*iv*) Identify and control the lot to be reworked if the reworked subgroup total again exceeds tolerance.

(*2*) Inspector Actions: The inspector shall spot check the rework procedure to ensure that plant monitoring and production meet the requirements of the program.

(vi) After the 10 bird subgroup tests are completed, the prechill and postchill processing nonconformances shall be corrected on all bird samples prior to returning the samples to the product flow. Samples with trim nonconformances shall be returned to the trim station for correction prior to their return to the product flow.

TABLE 1—DEFINITIONS OF NONCONFORMANCES

A Processing Nonconformances

1 Extraneous material ≤1/16″
—Include any specks, tiny smears, or stains of material that measure 1/16″ or less in the greatest dimension.
Examples: Ingesta, unattached feathers, grease, bile remnants, and/or whole gall bladder or spleen, embryonic yolk, etc.
—Factor is one.
—1 to 5=1 defect: 6 to 10=2 defects; 11 or more=3 defects. A maximum of three incidents per carcass.

2 Extraneous material >1/16″ to 1″
—The same material as line 1, but measuring >1/16″ to 1″ in the longest dimension.
—Factor is one.
—A maximum of three incidents per carcass.

3 Extraneous material >1″
—The same material as lines 1 to 2, but measuring greater than one inch.
—Factor is two.
—A maximum of two incidents per carcass.

4 Oil glands remnant—less than two whole glands
—Recognizable fragment(s) of one or both oil glands equals one incident.
—Factor is one.
—Maximum of one incident per carcass.

5 Oil glands—two whole glands
—Both whole oil glands with no missing fragments equals one incident. If the oil glands are cut, but no fragment is removed, consider them to be whole. But if even a small fragment is removed, use line 4.
—Factor is two.
—A maximum of one incident per carcass.

TABLE 1—DEFINITIONS OF NONCONFORMANCES—Continued

6 Lung ≥1/4″ whole
—Any portion less than a whole lung, and equal to or greater than 1/4″ at the greatest dimension, equals one incident.
—Factor is one.
—A maximum of two incidents per carcass.

7 Lung—whole
—Each whole lung equals one incident.
—Factor is two.
—A maximum of two incidents per carcass.

8 Intestine
—Any identifiable portion of the terminal portion of the intestinal tract with a lumen (closed circle) present, or split piece of intestine large enough to be closed to form a lumen.
—Factor is five.
—A maximum of one incident per carcass.

9 Cloaca
—Any identifiable portion of the terminal portion of the intestinal tract with mucosal lining.
—Factor is five.
—A maximum of one incident per carcass.

10 Bursa of Fabricius
—A whole rosebud, or identifiable portion with two or more mucosal folds.
—Factor is two.
—A maximum of one incident per carcass.

11 Esophagus
—Any portion of the esophagus with identifiable mocosal lining.
—Factor is two.
—A maximum of one incident per carcass.

12 Crop—partial—with mucosa
—Any portion of the crop that includes the mucosal lining.
—Factor is two.
—A maximum of one incident per carcass.

13 Crop—whole
—Any complete crop.
—Factor is five.
—A maximum of one incident per carcass.

14 Trachea ≤1″
—Identifiable portion of trachea less than or equal to one inch long.
—Factor is one.
—A maximum of one incident per carcass.

15 Trachea >1″
—Identifiable portion of trachea greater than one inch.
—Factor is two.
—A maximum of one incident per carcass.

TABLE 1—DEFINITIONS OF NONCONFORMANCES—Continued

16 Hair ≥¼″ 26 or more.
—Hair which is one-fourth inch long or longer measured from the top of the follicle to the end of the hair. 26 or more hairs equal one incident.
—Factor is one.
—A maximum of one incident per carcass.

17 Feather and/or Pinfeathers ≤1″
—Attached feathers or protruding pinfeathers less than or equal to one inch long. Scored 5 to 10 per carcass as one incident, 11 to 15 per carcass as two incidents, and 16 or more as three incidents.
—Factor is one.
—A maximum of three incidents per carcass.

18 Feathers >1″
—Attached feathers longer than one inch. Scored 1 to 3 per carcass as one incident 4 to 6 per carcass as two incidents, and 7 or more as three incidents.
—Factor is one.
—A maximum of three incidents per carcass.

19 Long Shank—both condyles covered
—If the complete tibiotarsal joint is covered, it equals one incident.
—Factor is two.
—A maximum of two incidents per carcass.

B Trim nonconformances

1 Breast blister
—Inflammatory tissue, fluid, or pus between the skin and keel must be trimmed if membrane ''slips'' or if firm nodule is greater than ½″ in diameter (dime size).
—Factor is two.
—A maximum of one incident per carcass.

2 Breast blister—partially trimmed
—All inflammatory tissue, including that which adheres tightly to the keel bone, must be removed.
—Factor is two.
—A maximum of one incident per carcass.

3 Bruise ½″ to 1″
—Blood clumps or clots in the superficial layers of tissue, skin, muscle or loose subcutaneous tissue may be slit and the blood completely washed out. When the bruise extends into the deeper layers of muscle, the affected tissue must be removed. Very small bruises less than ½″ (dime size) and areas showing only slight reddening need not be counted as defects.
—Factor is one.
—A maximum of five incidents per carcass.

TABLE 1—DEFINITIONS OF NONCONFORMANCES—Continued

4 Bruise >1″
—Same criteria as in line three, but greater than one inch in greatest dimension.
—Factor is two.
—A maximum of three incidents per carcass.

5 Bruise black/green ¼″ to 1″
—Bruises ¼″ to 1″ that have changed from red to a black/blue or green color due to age.
—Factor is two.
—A maximum of three incidents per carcass.

6 Bruise Black/green >1″
—Same as line 5, but measuring greater that 1″ in greatest dimension.
—Factor is five.
—A maximum of two incidents per carcass.

7 Trimmable lesions/Condition
—A trimmable tumor or identifiable portion of a tumor on any part of the carcass.
—Trimmable Synovitis/airsacculitis (saddle/frog) lesions that have not been removed.
—Lesion/condition subject to removal following an approved cleanout process. Examples: airsacculitis, salpingitis, nephritis, spleen, or liver conditions requiring removal of the kidneys.

Note: All establishments shall develop and maintain a permanent marking system that identifies carcasses with removable lesions/conditions on the inside surfaces. When removable lesions/conditions are identified inside the carcass by the inspector, the helper will be notified to apply the permanent mark. When removable inside lesions/conditions are found on a subgroup sample without the permanent mark, the error is not recorded in line 7. The affected carcass(s) will be hungback for IIC disposition and corrective action.
—Factor is five.
—A maximum of one incident per carcass.

8 Failure to complete task as indicated by marking system.
Example: Synovitis, airsacculitis, inflammatory process, contamination, etc.
—The helper, under the inspector's direction, will apply a mark to the carcass, indicating to the trimmer(s) that specific action must be taken on that carcass. When airsac and kidney cleanout, or synovitis part removal, or carcass removal from the line is not completed, or only partially completed, this occurrence is recorded as one defect.

TABLE 1—DEFINITIONS OF NONCONFORMANCES—Continued

—Factor is five. It will also be recorded as a line 7 defect for a total factor of 10.

—A maximum of one incident per carcass.

9 Compound fracture

—Any bone fracture (i.e., leg or wing) that has caused an opening through the skin. May be accompanied with a bruise, but not always. Do not count the bruise in line 3 or 4 if it is associated with the compound fracture.

—Factor is two.

—A maximum of three incidents per carcass.

10 Wingtip compound fracture

—Same criteria as line 9, but only for wingtips.

Note: Bruises not associated with the fracture should be recorded in the appropriate lines.

—Factor is one.

—A maximum of two incidents per carcass.

11 Untrimmed short hock

—When no cartilage of the hock surface is present and no tendons are attached to the bone.

—Factor is two.

—A maximum of two incidents per carcass.

12 Sores, scabs, inflammatory process, etc. ≤½″

—Any defects such as sores, abscesses, scabs, wounds, dermatitis, inflammatory process, that measure less than or equal to ½″ in the greatest dimension.

—Factor is two.

—A maximum of two incidents per carcass.

13 Sores, scabs, inflammatory process, etc. >½″

—Same as line 12, but greatest dimension is greater than ½″, or a cluster of smaller lesions in close proximity >½″, this category also includes turkey leg edema.

—Factor is five.

—A maximum of one incident per carcass.

14 External mutilation

—Mutilation to the skin and/or muscle that is caused by the slaughter, dressing or eviscerating processes. Skinned elbows (bucked wings) do not trim require unless affected wing joint capsule is also opened.

—Factor is one.

TABLE 1—DEFINITIONS OF NONCONFORMANCES—Continued

—A maximum of three incidents per carcass.

C Postchill nonconformances—(Designed to monitor those nonconformances added to product during the chilling process)

1 Extraneous material ≤1/16″

—Include specks, grease, or unidentifiable foreign material that measure 1/16″ or less in the greatest dimension.

—Example: Ingesta, grease, or unidentifiable foreign material.

—Factor is one.

—3 to 7=1 defect; 8 to 12=2 defects; 13 or more=3 defects. A maximum of three incidents per carcass.

2 Extraneous material >1/16″ to 1″

—This includes ingesta, grease, or unidentifiable foreign material measureing >1/16″ to 1″ longest dimension.

—Factor is one.

—A maximum of three incidents per carcass.

3 Extraneous material >1″

—The same material as line 2, but measuring greater than one inch.

—Factor is two.

—A maximum of two incidents per carcass.

TABLE 2—FINISHED PRODUCT STANDARDS

	SIS
Prechill Processing Nonconformance	
Tolerance number (T)	25
Subgroup Absolute Limit (T+5)	30
Action number	22
Start number	11
Prechill Trim Nonconformance	
Tolerance number (T)	12
Subgroup Absolute Limit (T+5)	17
Action number	15
Start number	8
Postchill Nonconformance	
Tolerance number (T)	5
Subgroup Absolute Limit (T+5)	10
Action number	10
Start number	5

(4) The following requirements are also applicable to NELS inspection:

(i) Inspection under NELS is conducted in two phases, as post-mortem inspection phase and a reinspection phase.

(*a*) *Post-mortem inspection*. The establishment shall provide three inspection stations on each eviscerating line in compliance with the facility requirements § 381.36(d)(1). The three inspectors shall inspect the inside, viscera, and outside of all birds presented. Each

inspector shall be flanked by two establishment employees—the presenter and the helper. The presenter shall ensure that the bird is properly eviscerated and presented for inspection and the viscera uniformly trailing or leading. The inspector shall determine which birds shall be salvaged, reprocessed, condemned, retained for disposition by the veterinarian, or allowed to proceed down the line as a passed bird subject to reinspection. Poultry carcasses with certain defects not requiring condemnation of the entire carcass shall be passed by the inspector, but shall be subject to reinspection to ensure the physical removal of the specified defects. The helper, under the supervision of the inspector, shall mark such carcasses for trim when the defects are not readily observable. Trimming or birds passed subject to reinspection shall be performed by:

(*1*) The helper, time permitting, and

(*2*) One or more plant trimmers positioned after giblet harvest and prior to reinspection.

(*b*) A reinspection station shall be located at the end of each line. This station shall comply with the facility requirements in § 381.36(d)(2). The inspector shall ensure that the establishment has performed the indicated trimming of carcasses passed subject to reinspection by visually monitoring, checking data, or gathering samples at the station or at other critical points on the line.

(ii)–(iii) [Reserved]

(iv) The maximum inspection rate for NELS shall be 91 birds per minute per eviscerating line.

(5) The following requirements are also applicable to the NTI System:

(i) Inspection under the NTI System is conducted in two phases, a post-mortem inspection phase and a reinspection phase. The NTI–1 Inspection System requires that the establishment provide one inspection station for each line and adequate reinspection facilitiates so carcasses can be removed from each line for evaluation. The NTI–2 Inspection System requires that the establishment provide two inspection stations for each line and adequate reinspection facilities so carcasses can be removed from each line for evaluation.

(*a*) *Post-mortem inspection*. Each inspection station must comply with the facility requirements in § 381.36(e)(1). Each inspector shall be flanked by and establishment employee assigned to be the inspector's helper. The one inspector on an NTI–1 Inspection System shall be presented every bird. Each inspector on an NTI–2 Inspection System line shall be presented every other bird on the line. An establishment employee shall present each bird to the inspector properly eviscerated with the back side toward the inspector and the viscera uniformly trailing or leading. Each inspector shall inspect the inside, viscera, and outside of all birds presented. The inspector shall determine which bird shall be salvaged, reprocessed, condemned, retained for disposition by a veterinarian, or allowed to proceed down the line as a passed bird subject to reinspection. Turkey carcasses with certain defects not requiring condemnation of the entire carcass shall be passed by the inspector, but shall be subject to reinspection to ensure the physical removal of the specified defects. The helper, under the supervision of the inspector, shall mark such carcasses for trim when the defects of birds passed subject to reinspection shall be performed by:

(*1*) The helper, time permitting, and

(*2*) One or more plant trimmers positioned after the giblet harvest and prior to reinspection.

(*b*) *Reinspection*. A reinspection station shall be located at the end of the lines. This station shall comply with the facility requirements in § 381.36(e)(2). The inspector shall ensure that establishments have performed the indicated trimming of each carcass passed subject to reinspection by visually monitoring, checking data, and/or sampling product at the reinspection station and, if necessary, at other points, critical to the wholesomeness of product, on the eviscerating line.

(ii)–(iii) [Reserved]

(Recordkeeping requirements approved by the Office of Management and Budget under control number 0583–0008)

[47 FR 23435, May 28, 1982, as amended at 49 FR 42555, Oct. 23, 1984; 50 FR 37513, Sept. 16, 1985; 50 FR 38097, Sept. 20, 1985; 51 FR 3574, Jan. 29, 1986; 53 FR 46861, Nov. 21, 1988; 62 FR 5143, Feb. 4, 1997; 65 FR 34390, May 30, 2000; 66 FR 22906, May 7, 2001]

§381.77 Carcasses held for further examination.

Each carcass, including all parts thereof, in which there is any lesion of disease, or other condition which might render such carcass or any part thereof adulterated and with respect to which a final decision cannot be made on first examination by the inspector, shall be held for further examination. The identity of each such carcass, including all parts thereof, shall be maintained until a final examination has been completed.

§381.78 Condemnation of carcasses and parts: separation of poultry suspected of containing biological residues.

(a) At the time of any inspection under this subpart each carcass, or any part thereof, which is found to be adulterated shall be condemned, except that any such articles which may be made not adulterated by reprocessing, need not be so condemned if so reprocessed under the supervision of an inspector and thereafter found to be not adulterated.

(b) When a lot of poultry suspected of containing biological residues is inspected in an official establishment, all carcasses and any parts of carcasses in such lot which are condemned shall be kept separate from all other condemned carcasses or parts.

[37 FR 9706, May 16, 1972, as amended at 48 FR 22899, May 23, 1983; 48 FR 23807, May 27, 1983]

§381.79 Passing of carcasses and parts.

Each carcass and all organs and other parts of carcasses which are found to be not adulterated shall be passed for human food.

§381.80 General; biological residues.

(a) The carcasses or parts of carcasses of all poultry inspected at an official establishment and found at the time of post mortem inspection, or at any subsequent inspection, to be affected with any of the diseases or conditions named in other sections in this subpart, shall be disposed of in accordance with the section pertaining to the disease or condition. Owing to the fact that it is impracticable to formulate rules for each specific disease or conditions and to designate at just what stage a disease process results in an adulterated article, the decision as to the disposal of all carcasses, organs or other parts not specifically covered by the regulations, or by instructions of the Administrator issued pursuant thereto, shall be left to the inspector in charge, and if the inspector in charge is in doubt concerning the disposition to be made, specimens from such carcasses shall be forwarded to the Inspection Service laboratory for diagnosis.

(b) All carcasses, organs, or other parts of carcasses of poultry shall be condemned if it is determined on the basis of a sound statistical sample that they are adulterated because of the presence of any biological residues.

§381.81 Tuberculosis.

Carcasses of poultry affected with tuberculosis shall be condemned.

§381.82 Diseases of the leukosis complex.

Carcasses of poultry affected with any one or more of the several forms of the avian leukosis complex shall be condemned.

§381.83 Septicemia or toxemia.

Carcasses of poultry showing evidence of any septicemic or toxemic disease, or showing evidence of an abnormal physiologic state, shall be condemned.

§381.84 Airsacculitis.

Carcasses of poultry with evidence of extensive involvement of the air sacs with airsacculitis or those showing airsacculitis along with systemic changes shall be condemned. Less affected carcasses may be passed for food

after complete removal and condemnation of all affected tissues including the exudate.

[40 FR 14297, Mar. 31, 1975]

§ 381.85 Special diseases.

Carcasses of poultry showing evidence of any disease which is characterized by the presence, in the meat or other edible parts of the carcass, or organisms or toxins dangerous to the consumer, shall be condemned.

§ 381.86 Inflammatory processes.

Any organ or other part of a carcass which is affected by an inflammatory process shall be condemned and, if there is evidence of general systemic disturbance, the whole carcass shall be condemned.

§ 381.87 Tumors.

Any organ or other part of a carcass which is affected by a tumor shall be condemned and when there is evidence of metastasis or that the general condition of the bird has been affected by the size, position, or nature of the tumor, the whole carcass shall be condemned.

§ 381.88 Parasites.

Organs or other parts of carcasses which are found to be infested with parasites, or which show lesions of such infestation shall be condemned and, if the whole carcass is affected, the whole carcass shall be condemned.

§ 381.89 Bruises.

Any part of a carcass which is badly bruised shall be condemned and, if the whole carcass is affected as a result of the bruise, the whole carcass shall be condemned. Parts of a carcass which show only slight reddening from a bruise may be passed for food.

§ 381.90 Cadavers.

Carcasses of poultry showing evidence of having died from causes other than slaughter shall be condemned.

§ 381.91 Contamination.

(a) Carcasses of poultry contaminated by volatile oils, paints, poisons, gases, scald vat water in the air sac system, or other substances which render the carcasses adulterated shall be condemned. Any organ or other part of a carcass which has been accidentally multilated in the course of processing shall be condemned, and if the whole carcass is affected, the whole carcass shall be condemned.

(b)(1) Any carcass of poultry accidentally contaminated during slaughter with digestive tract contents shall not be condemned if promptly reprocessed under the supervision of an inspector and thereafter found not to be adulterated. Contaminated surfaces that are cut shall be removed only by trimming. Contaminated inner surfaces that are not cut may be cleaned by trimming alone, or at an approved reprocessing station away from the main processing line, by any method that will remove the contamination, such as vacuuming, washing, and trimming, singly or in combination. All visible specks of contamination must be removed, and if the inner surfaces are reprocessed other than soley by trimming, all surfaces of the carcass shall be treated with chlorinated water containing 20 ppm available chlorine.

(2) An area will be designated as an approved reprocessing station only if the Administrator determines that reprocessing operations can be conducted in that area in accordance with all of the requirements of this part, and that the reprocessing methods to be utilized are capable of removing all visible specks of contamination on the inner surface of a carcass. Requests for such approval shall be submitted to the inspector in charge and shall describe the proposed area, proposed methods of reprocessing, and proposed equipment to be utilized. Whenever the Administrator finds that reprocessing operations cannot be conducted in such area in accordance with all of the requirements of this part or that the reprocessing methods utilized are not capable of removing all visible specks of contamination on the inner surface of a carcass, he may withdraw approval of such area, effective upon oral or written notification, whichever is earlier, to the operator of the establishment. In the event of oral notification, a written confirmation thereof shall be given to the operator as promptly as circumstances permit. The notification

shall specify the reasons for such withdrawal and shall afford the operator of the establishment an opportunity to present his views. In any instance where there is a conflict as to the facts, a hearing shall be held to resolve such conflict.

[37 FR 9706, May 16, 1972, as amended at 43 FR 12847, Mar. 28, 1978]

§381.92 Overscald.

Carcasses of poultry which have been overscalded, resulting in a cooked appearance of the flesh, shall be condemned.

§381.93 Decomposition.

Carcasses of poultry deleteriously affected by post mortem changes shall be disposed of as follows:

(a) Carcasses which have reached a state of putrefaction or stinking fermentation shall be condemned.

(b) Any part of a carcass which is green struck shall be condemned and, if the carcass is so extensively affected that removal of affected parts is impracticable, the whole carcass shall be condemned.

(c) Carcasses affected by types of post mortem change which are superficial in nature may be passed for human food after removal and condemnation of the affected parts.

§381.94 Contamination with Microorganisms; process control verification criteria and testing; pathogen reduction standards.

(a) Criteria for verifying process control; *E. coli* testing.

(1) Each official establishment that slaughters poultry shall test for *Escherichia coli* Biotype I (*E. coli*). Establishments that slaughter more than one type of poultry and/or poultry and livestock, shall test the type of poultry or livestock slaughtered in the greatest number. The establishment shall:

(i) Collect samples in accordance with the sampling techniques, methodology, and frequency requirements in paragraph (a)(2) of this section;

(ii) Obtain analytic results in accordance with paragraph (a)(3) of this section; and

(iii) Maintain records of such analytic results in accordance with paragraph (a)(4) of this section.

(2) Sampling requirements.

(i) *Written procedures.* Each establishment shall prepare written specimen collection procedures which shall identify employees designated to collect samples, and shall address location(s) of sampling, how sampling randomness is achieved, and handling of the sample to ensure sample integrity. The written procedure shall be made available to FSIS upon request.

(ii) *Sample collection.* A whole bird must be taken from the end of the chilling process. If this is impracticable, the whole bird can be taken from the end of the slaughter line. Samples must be collected by rinsing the whole carcass in an amount of buffer appropriate for that type of bird. Samples from turkeys or ratites also may be collected by sponging the carcass on the back and thigh.[1]

(iii) *Sampling frequency.* Slaughter establishments, except very low volume establishments as defined in paragraph (a)(2)(v) of this section, must take samples at a frequency proportional to the establishment's volume of production at the following rates:

(A) Chickens: 1 sample per 22,000 carcasses, but a minimum of one sample during each week of operation.

(B) Turkeys, Ducks, Geese, Guineas, Squabs, and Ratites: 1 sample per 3,000 carcasses, but at a minimum one sample each week of operation.

(iv) *Sampling frequency alternatives.* An establishment operating under a validated HACCP plan in accordance with §417.2(b) of this chapter may substitute an alternative frequency for the frequency of sampling required under paragraph (a)(2)(iii) of this section if,

(A) The alternative is an integral part of the establishment's verification procedures for its HACCP plan and,

(B) FSIS does not determine, and notify the establishment in writing, that the alternative frequency is inadequate to verify the effectiveness of the establishment's processing controls.

[1] A copy of FSIS's "Guidelines for *Escherichia coli* Testing for Process Control Verification in Poultry Slaughter Establishments," and "FSIS Turkey Microbiological Procedures for Sponge Sample Collection and Methods of Analysis" are available for inspection in the FSIS Docket Room.

(v) *Sampling in very low volume establishments.*

(A) Very low volume establishments annually slaughter no more than 440,000 chickens, 60,000 turkeys, 60,000 ducks, 60,000 geese, 60,000 guineas, 60,000 squabs, 6,000 ratites, or a combination of all types of poultry not exceeding 60,000 turkeys and 440,000 birds total. Very low volume establishments that slaughter turkeys, ducks, geese, guineas, squabs, or ratites in the largest number must collect at least one sample during each week of operation after June 1 of each year, and continue sampling at a minimum of once each week the establishment operates until June of the following year or until 13 samples have been collected, whichever comes first.

(B) Upon the establishment's meeting the requirements of paragraph (a)(2)(v)(A) of this section, weekly sampling and testing is optional, unless changes are made in establishment facilities, equipment, personnel or procedures that may affect the adequacy of existing process control measures, as determined by the establishment or by FSIS. FSIS determinations that changes have been made requiring resumption of weekly testing shall be provided to the establishment in writing.

(3) *Analysis of samples.* Laboratories may use any quantitative method for analysis of *E. coli* that is approved as an AOAC Official Method of the AOAC International (formerly the Association of Official Analytical Chemists)[2] or approved and published by a scientific body and based on the results of a collaborative trial conducted in accordance with an internationally recognized protocol on collaborative trials and compared against the three tube Most Probable Number (MPN) method and agreeing with the 95 percent upper and lower confidence limit of the appropriate MPN index.

(4) *Recording of test results.* The establishment shall maintain accurate records of all test results, in terms of CFU/ml of rinse fluid. Results shall be recorded onto a process control chart or table showing at least the most recent 13 test results, by type of poultry slaughtered. Records shall be retained at the establishment for a period of 12 months and shall be made available to FSIS upon request.

(5)(i) *Criteria for Evaluation of test results.* An establishment is operating within the criteria when the most recent *E. coli* test result does not exceed the upper limit (M), and the number of samples, if any, testing positive at levels above (m) is three or fewer out of the most recent 13 samples (n) taken, as follows:

TABLE 1—EVALUATION OF E. COLI TEST RESULTS

Types of poultry	Lower limit of marginal range (m)	Upper limit of marginal range (M)	Number of samples tested (n)	Maximum number permitted in marginal range (c)
Chickens	[1] 100	[1] 1,000	13	3
Turkeys	*NA	*NA	*NA	*NA
Ducks	*NA	*NA	*NA	*NA
Geese	*NA	*NA	*NA	*NA
Guineas	*NA	*NA	*NA	*NA
Squabs	*NA	*NA	*NA	*NA
Ratites	*NA	*NA	*NA	*NA

[1] CFU/ml.
*Values will be added upon completion of data collection programs.

(ii) For types of poultry appearing in paragraph (a)(5)(1) Table 1 of this section that do not have m/N criteria, establishments shall evaluate *E. coli* test results using statistical process control techniques.

[2] A copy of the current edition/revision of the ''Official Methods of AOAC International,'' 16th edition, 3rd revision, 1997, is on file with the Director, Office of the Federal Register, and may be purchased from the Association of Official Analytical Chemists International, Inc., 481 North Frederick Ave., Suite 500, Gaithersburg, MD 20877–2417.

(6) *Failure to meet criteria.* Test results that do not meet the criteria described in paragraph (a)(5) of this section are an indication that the establishment may not be maintaining process controls sufficient to prevent fecal contamination. FSIS shall take further action as appropriate to ensure that all applicable provisions of the law are being met.

(7) *Failure to test and record.* Inspection will be suspended in accordance with rules of practice that will be adopted for such proceeding, upon a finding by FSIS that one or more provisions of paragraphs (a) (1)–(4) of this section have not been complied with and written notice of same has been provided to the establishment.

(b) Pathogen reduction performance standards; *Salmonella.*

(1) *Raw poultry product performance standards for Salmonella.* (i) An establishment's raw poultry products, when sampled and tested by FSIS for *Salmonella* as set forth in this section, may not test positive for *Salmonella* at a rate exceeding the applicable national pathogen reduction performance standard, as provided in Table 2:

TABLE 2—SALMONELLA PERFORMANCE STANDARDS

Class of product	Performance Standard (percent positive for salmonella) [a]	Number of samples tested (n)	Maximum number of positives to achieve standard (c)
Broilers	20.0%	51	12
Ground chicken	44.6	53	26
Ground turkey	49.9	53	29
Turkeys	[b] NA	NA	NA
Squabs	[b] NA	NA	NA
Ratites	[b] NA	NA	NA

[a] Performance Standards are FSIS's calculation of the national prevalence of Salmonella on the indicated raw products based on data developed by FSIS in its nationwide microbiological baseline data collection programs and surveys. (Copies of Reports on FSIS's Nationwide Microbiological Data Collection Programs and Nationwide Microbiological Surveys used in determining the prevalence of Salmonella on raw products are available in the FSIS Docket Room.)

[b] Not available; baseline targets for turkeys, squabs, or ratites will be added upon completion of the data collection programs for that product.

(2) *Enforcement.* FSIS will sample and test raw poultry products in an individual establishment on an unannounced basis to determine prevalence of *Salmonella* in such products to determine compliance with the standard. The frequency and timing of such testing will be based on the establishment's previous test results and other information concerning the establishment's performance. In an establishment producing more than one class of product subject to the pathogen reduction standard, FSIS may sample any or all such classes of products.[3]

(3) *Noncompliance and establishment response.* When FSIS determines that an establishment has not met the performance standard:

(i) The establishment shall take immediate action to meet the standard.

(ii) If the establishment fails to meet the standard on the next series of compliance tests for that product, the establishment shall reassess its HACCP plan for that product.

(iii) Failure by the establishment to act in accordance with paragraph (b)(3)(ii) of this section, or failure to meet the standard on the third consecutive series of FSIS-conducted tests for that product, constitutes failure to maintain sanitary conditions and failure to maintain an adequate HACCP plan, in accordance with part 417 of this chapter, for that product, and will cause FSIS to suspend inspection services. Such suspension will remain in effect until the establishment submits to the FSIS Administrator or his/her designee satisfactory written assurances detailing the action taken to correct the HACCP system and, as appropriate,

[3] A copy of FSIS's ''Sample Collection Guidelines and Procedure for Isolation and Identification of *Salmonella* from Raw Meat and Poultry Products'' is available for inspection in the FSIS Docket Room.

other measures taken by the establishment to reduce the prevalence of pathogens.

[61 FR 38866, July 25, 1996, as amended at 62 FR 26218, May 13, 1997; 62 FR 61009, Nov. 14, 1997; 64 FR 66553, Nov. 29, 1999; 67 FR 13258, Mar. 22, 2002]

Subpart L—Handling and Disposal of Condemned or Other Inedible Products at Official Establishments

§ 381.95 Disposal of condemned poultry products.

All condemned carcasses, or condemned parts of carcasses, or other condemned poultry products, except those condemned for biological residues shall be disposed of by one of the following methods, under the supervision of an inspector of the Inspection Service. (Facilities and materials for carrying out the requirements in this section shall be furnished by the official establishment.)

(a) Steam treatment (which shall be accomplished by processing the condemned product in a pressure tank under at least 40 pounds of steam pressure) or thorough cooking in a kettle or vat, for a sufficient time to effectively destroy the product for human food purposes and preclude dissemination of disease through consumption by animals. (Tanks and equipment used for this purpose or for rendering or preparing inedible products shall be in rooms or compartments separate from those used for the preparation of edible products. There shall be no direct connection by means of pipes, or otherwise, between tanks containing inedible products and those containing edible products.)

(b) Incineration or complete destruction by burning.

(c) Chemical denaturing, which shall be accomplished by the liberal application to all carcasses and parts thereof, of:

(1) Crude carbolic acid,

(2) Kerosene, fuel oil, or used crankcase oil, or

(3) Any phenolic disinfectant conforming to commercial standards CS 70–41 or CS 71–41 which shall be used in at least 2 percent emulsion or solution.

(d) Any other substance or method that the Administrator approves in specific cases, which will denature the poultry product to the extent necessary to accomplish the purposes of this section.

(e) Carcasses and parts of carcasses condemned for biological residue shall be disposed of in accordance with paragraph (b) of this section or by burying under the supervision of an inspector.

Subpart M—Official Marks, Devices, and Certificates; Export Certificates; Certification Procedures

§ 381.96 Wording and form of the official inspection legend.

Except as otherwise provided in this subpart, the official inspection legend required to be used with respect to inspected and passed poultry products shall include wording as follows: ''Inspected for wholesomeness by U.S. Department of Agriculture.'' This wording shall be contained within a circle. The form and arrangement of such wording shall be exactly as indicated in the example in Figure 1, except that the appropriate official establishment number shall be shown, and if the establishment number appears elsewhere on the labeling material in the manner prescribed in § 381.123(b), it may be omitted from the inspection mark. The administrator may approve the use of abbreviations of such inspection mark; and such approved abbreviations shall have the same force and effect as the inspection mark. The official inspection legend, or the approved abbreviation thereof, shall be printed on consumer packages and other immediate containers of inspected and passed poultry products, or on labels to be securely affixed to such containers of such products and may be printed or stenciled thereon, but shall not be applied by rubber stamping. When applied by a stencil, the legend shall not be less than 4 inches in diameter. An official brand must be applied to inspected and passed carcasses and parts of ratites that are shipped unpacked.

FIGURE 1

[66 FR 22906, May 7, 2001]

§ 381.97 [Reserved]

§ 381.98 Official seal.

The official mark for use in sealing means of conveyance used in transporting poultry products under any requirement in this part shall be the inscription and a serial number as shown below, and any seals approved by the Administrator for applying such mark shall be an official device.

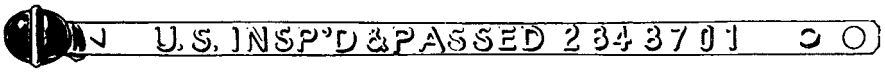

FIGURE 3

§ 381.99 Official retention and rejection tags.

The official marks for use in postmortem inspection and identification of adulterated products, insanitary equipment and facilities are:

(a) A paper tag (a portion of Form MP–35) bearing the legend ''U.S. Retained'' for use on poultry or poultry products under this section.

(b) A paper tag (another portion of Form C&MS 510) bearing the legend ''U.S. Rejected'' for use on equipment, utensils, rooms and compartments under this section.

[64 FR 56417, Oct. 20, 1999]

§ 381.100 Official detention tag.

The detention tag prescribed in § 381.211 is an official device.

§ 381.101 Official U.S. Condemned mark.

The term ''U.S. Condemned'' as shown below is an official mark and the devices used by the Department for applying such mark are official devices.

FIGURE 4

§ 381.102 [Reserved]

§ 381.103 Official poultry condemnation certificates; issuance and form.

Upon request by the operator of the establishment, the inspector in charge shall issue a poultry condemnation certificate (Form MP–514–1), showing the total number of poultry in the lot and the numbers condemned and the reasons for such condemnations.

The official poultry condemnation certificate authorized by this subpart is a paper certificate (Form MP–514–1), for signature by an inspector, bearing the legend

U.S. DEPARTMENT OF AGRICULTURE ANIMAL AND PLANT HEALTH INSPECTION SERVICE

POULTRY CONDEMNATION CERTIFICATE

and the seal of the United States Department of Agriculture, with a certification that the poultry enumerated on the form were inspected and condemned for the listed causes in compliance with the regulations of the Department. A statement to the effect that certain figures on the certificate were derived from information supplied by plant management, and a signature line for an authorized plant official is also shown.

§ 381.104 Official export certificates, marks and devices.

The form of certificate described in § 381.106 is an official export certificate, and the mark shown below is the official mark used on outside containers to identify inspected and passed poultry products for export. Devices used by the Department to apply such a mark are official devices.

[47 FR 29823, July 9, 1982]

§ 381.105 Export certification; marking of containers.

(a) Upon request or application by any person intending to export any poultry product, any inspector is authorized to issue an official export certificate as prescribed in § 381.107 with respect to the shipment to any foreign country of any inspected and passed poultry product, after adequate inspection of the product has been made by the inspector to determine its identity as inspected and passed and eligible for export: *Provided*, that the product is offered for inspection at an official establishment. Each shipping container covered by the export certificate, except ship stores, small quantities exclusively for the personal use of the consignee and not for sale or distribution, and shipments by and for the U.S. Armed Forces, shall be marked with an official export stamp as shown in § 381.104 bearing the number of the export certificate. Official export certificates will be issued only upon condition that the products covered thereby shall be subject to reinspection at any place and at any time prior to exportation to determine the identity of the products and their eligibility for certification, and such certificates shall become invalid if such reinspection is refused or discloses that the products are not eligible for certification. If reinspection discloses that any poultry products covered by an export certificate are not eligible for such certification, a superseding certificate setting forth such findings shall be issued and copies shall be furnished to interested persons.

(b) The original and a duplicate of each official export certificate shall be delivered to the person who requested such certificate or his agent. Such person may duplicate such numbers of exact copies of the original as he requires in connection with the exportation of the poultry products. Additional official file copies of the export certificates shall be prepared and distributed by the inspector in accordance with the instructions of the Administrator.

(c) Only one certificate shall be issued for each consignment, except in case of error in the certificate or loss of the certificate originally issued. A request for a new certificate, except in the case of a lost certificate, shall be accompanied by the original and all copies of the first certificate. The new certificate shall carry the following statement: ''This certificate supersedes certificate No. ——— Dated ————. The outside container of the poultry product covered by this certificate is

stamped with United States Department of Agriculture Certificate No. _____.''

[37 FR 9706, May 16, 1972, as amended at 50 FR 25204, June 18, 1985]

§ 381.106 Form of official export certificate.

The official export certificate authorized by this subpart is a paper certificate form for signature by an inspector, bearing a letterhead and the seal of the U.S. Department of Agriculture, with a certification that the slaughtered poultry and other poultry products described on the form came from birds that were officially given an ante-mortem and post-mortem inspection and passed in accordance with the regulations of the Department and that such products are wholesome and fit for human consumption. The certificate also bears a serial number, such as ''MPA 002805'', and shows the respective names of the exporter and consignee, the destination, the shipping marks, the names of such products, the total net weight thereof, and such other information as the Administrator may prescribe or approve in specific cases.

[47 FR 29823, July 9, 1982]

§ 381.107 Special procedures as to certification of poultry products for export to certain countries.

When export certificates are required by any foreign country for poultry products exported to such country, the Administrator shall in specific cases prescribe or approve the form of export certificate to be used and the methods and procedures he deems appropriate with respect to the processing of such products, in order to comply with requirements specified by the foreign country regarding the export products. Inspectors shall satisfy themselves that all such requirements are met before issuing such an export certificate. It shall be the responsibility of the exporter to provide any unofficial documentation needed to meet the foreign requirements, before the export certificate will be issued. Such certificates may also cover articles exempted from definition as a poultry product under § 381.15 if they have been inspected and are certified under the regulations in part 362 of this chapter.

[37 FR 9706, May 16, 1972, as amended at 39 FR 4569, Feb. 5, 1974; 41 FR 23702, June 11, 1976]

§ 381.108 Official poultry inspection certificates; issuance and disposition.

(a) Upon the request of an interested party, any veterinary inspector is authorized to issue an official poultry inspection certificate with respect to any lot of slaughtered poultry inspected by him. At any official establishment each such certificate shall be signed by the inspector who made the inspection covered by the certificate, and if more than one inspector participated in the inspection of the lot of poultry, each such inspector shall sign the certificate with respect to such lot. If the inspection of a lot covered by a certificate was made by a food inspector, such certificate shall also be signed by the inspector in charge when such inspection was made. Any inspector is authorized to issue a poultry inspection certificate with respect to any other poultry product inspected by him.

(b) The original and one copy of each poultry inspection certificate shall be issued to the applicant who requested such certificate, and one copy shall be retained by the inspector for filing. The inspector who issues any inspection certificate is authorized to furnish an additional copy of such certificate upon the request of an interested party. The person who sold the live poultry involved to the official establishment is an interested party for purposes of this section.

[37 FR 9706, May 16, 1972, as amended at 39 FR 36000, Oct. 7, 1974]

§ 381.109 Form of official poultry inspection certificate.

(a) The official poultry inspection certificate authorized by this subpart is a paper certificate (Form MP–505) for signature by an inspector, bearing the legend

U.S. DEPARTMENT OF AGRICULTURE ANIMAL AND PLANT HEALTH INSPECTION SERVICE MEAT AND POULTRY INSPECTION PROGRAM

POULTRY INSPECTION CERTIFICATE

and the seal of the U.S. Department of Agriculture, with a certification that the poultry described therein had been inspected in compliance with the Regulations of the Secretary of Agriculture Governing the Inspection of Poultry and Poultry Products.

(b) The certificate also bears a serial number such as ''B 3208'' and shows the respective name and address of the applicant, the shipper or seller and the receiver or buyer and the net weight in pounds of amount passed, amount rejected or condemned, type of poultry, lot number and class, and such other information as the Administrator may prescribe or approve in specific cases.

§ 381.110 Erasures or alterations made on certificates.

Erasures or alterations not initialed by the issuing inspector shall not be permitted on any official certificate or any copy thereof. All certificates rendered useless through clerical error or otherwise and all certificates canceled for whatever cause shall be voided and initialed, and one copy shall be retained in the inspector's file; and the original and all other copies shall be forwarded to the appropriate program supervisor.

§ 381.111 Data to be entered in proper spaces.

All certificates shall be so executed that the data entered thereon will appear in the proper spaces on each copy of the certificate.

§ 381.112 Official mark for maintaining the identity and integrity of samples.

The official mark for use in sealing containers of samples submitted under any requirements in this part and section 11(b) of the Poultry Products Inspection Act shall bear the designation ''Sample Seal'' accompanied by the official USDA logo as shown below. Any seal approved by the Administrator for applying such mark shall be deemed an official device for purposes of the Act. Such device shall be supplied to inspectors, compliance officers, and other designated Agency officials by the United States Department of Agriculture.

[52 FR 41958, Nov. 2, 1987]

Subpart N—Labeling and Containers

§ 381.115 Containers of inspected and passed poultry products required to be labeled.

Except as may be authorized in specific cases by the Administrator with respect to shipment of poultry products between official establishments, each shipping container and each immediate container of any inspected and passed poultry product shall at the time it leaves the official establishment bear a label which contains information, and has been approved, in accordance with this subpart.

§ 381.116 Wording on labels of immediate containers.

(a) Each label for use on immediate containers for inspected and passed poultry products shall bear on the principal display panel (except as otherwise permitted in the regulations), the items of information required by this subpart. Such items of information shall be in distinctly legible form. Except as provided in § 381.128, all words, statements and other information required by or under authority of the Act to appear on the label or labeling shall appear thereon in the English language: *Provided, however,* That in the case of products distributed solely in Puerto Rico, Spanish may be substituted for English for all printed matter except the USDA inspection legend.

(b) The principal display panel shall be the part of a label that is most likely to be displayed, presented, shown, or examined under customary conditions of display for sale. The principal display panel shall be large enough to accommodate all the mandatory label information required to be placed thereon by the regulations with clarity and conspicuousness and without being obscured by design or vignettes, or crowding. Where packages bear alternate principal display panels, information required to be placed on the principal display panel shall be duplicated on each principal display panel. The area that is to bear the principal display panel shall be:

(1) In the case of a rectangular package, one entire side, the area of which is the product of the height times the width of that side.

(2) In the case of a cylindrical or nearly cylindrical container:

(i) An area on the side of the container that is 40 percent of the product of the height of the container times the circumference, or

(ii) A panel, the width of which is one-third of the circumference and the height of which is as high as the container: *Provided, however,* That there is, immediately to the right or left of such principal display panel, a panel which has a width not greater than 20 percent of the circumference and a height as high as the container, and which is reserved for information prescribed in §§ 381.118, 381.122, and 381.123. Such panel shall be known as the ''20 percent panel'' and such information may be shown on that panel in lieu of showing it on the principal display panel as provided in this § 381.116.

(3) In the case of a container of any other shape, 40 percent of the total surface of the container.

In determining the area of the principal display panel, exclude tops, bottoms, flanges at tops and bottoms of cans, and shoulders and necks of bottles or jars.

(c) (1) The information panel is that part of a label that is the first surface to the right of the principal display panel as observed by an individual facing the principal display panel, with the following exceptions:

(i) If the first surface to the right of the principal display panel is too small to accommodate the required information or is otherwise unusable label space, e.g., folded flaps, tear strips, opening flaps, heat-sealed flaps, the next panel to the right of this part of the label may be used.

(ii) If the package has one or more alternate principal display panels, the information panel is to the right of any principal display panel.

(iii) If the top of the container is the principal display panel and the package has no alternate principal display panel, the information panel is any panel adjacent to the principal display panel.

(2) (i) Except as otherwise permitted in this part, all information required to appear on the principal display panel or permitted to appear on the information panel shall appear on the same panel unless there is insufficient space. In determining the sufficiency of the available space, except as otherwise prescribed in this part, any vignettes, designs, and any other nonmandatory information shall not be considered. If there is insufficient space for all required information to appear on a single panel, it may be divided between the principal display panel and the information panel, provided that the information required by any given provision of this part, such as the ingredients statement, is not divided and appears on the same panel.

(ii) All information appearing on the information panel pursuant to this section shall appear in one place without intervening material, such as designs or vignettes.

[37 FR 9706, May 16, 1972, as amended at 40 FR 11347, Mar. 11, 1975; 59 FR 40214, Aug. 8, 1994]

§ 381.117 Name of product and other labeling.

(a) The label shall show the name of the product, which, in the case of a poultry product which purports to be or is represented as a product for which a definition and standard of identity or composition is prescribed in subpart P, shall be the name of the food specified in the standard, and in the case of any other poultry product shall be the common or usual name of the food, if any

there be, and if there is none, a truthful descriptive designation.

(b) The name of the product required to be shown on labels for fresh or frozen raw whole carcasses of poultry shall be in either of the following forms: The name of the kind (such as chicken, turkey, or duck) preceded by the qualifying term ''young'' or ''mature'' or ''old'', whichever is appropriate; or the appropriate class name as described in § 381.170(a). The name of the kind may be used in addition to the class name, but the name of the kind alone without the qualifying age or class term is not acceptable as the name of the product, except that the name ''chicken'' may be used without such qualification with respect to a ready-to-cook pack of fresh or frozen cut-up young chickens, or a half of a young chicken, and the name ''duckling'' may be used without such qualification with respect to a ready-to-cook pack of fresh or frozen young ducks. The class name may be appropriately modified by changing the word form, such as using the term ''roasting chicken'', rather than ''roaster.'' The appropriate names for cut-up parts are set forth in § 381.170(b). When naming parts cut from young poultry, the identity of both the kind of poultry and the name of the part shall be included in the product name. The product name for parts or portions cut from mature poultry shall include, along with the part or portion name, the class name or the qualifying term ''mature.'' The name of the product for cooked or heat processed poultry products shall include the kind name of the poultry from which the product was prepared but need not include the class name or the qualifying term ''mature.''

(c) Poultry products containing light and dark chicken or turkey meat in quantities other than the natural proportions, as indicated in Table 1 in this paragraph, must have a qualifying statement in conjunction with the name of the product indicating, as shown in Table 1, the types of meat actually used, except that when the product contains less than 10 percent cooked deboned poultry meat or is processed in such a manner that the character of the light and dark meat is not distinguishable, the qualifying statement will not be required, unless the product bears a label referring to the light or dark meat content. In the latter case, the qualifying statement is required if the light and dark meat are not present in natural proportions. The qualifying statement must be in type at least one-half the size and of equal boldness as the name of the product; e.g., Boned Turkey (Dark Meat).

TABLE 1

Label terminology	Percent light meat	Percent dark meat
Natural proportions	50–65	50–35
Light or white meat	100	0
Dark meat	0	100
Light and dark meat	51–65	49–35
Dark and light meat	35–49	65–51
Mostly white meat	66 or more	34 or less
Mostly dark meat	34 or less	66 or more

(d) Boneless poultry products shall be labeled in a manner that accurately describes their actual form and composition. The product name shall specify the form of the product (e.g., emulsified, finely chopped, etc.), and the kind name of the poultry, and if the product does not consist of natural proportions of skin and fat, as they occur in the whole carcass, shall also include terminology that describes the actual composition. If the product is cooked, it shall be so labeled. For the purpose of this paragraph, natural proportions of skin, as found on a whole chicken or turkey carcass, will be considered to be as follows:

	Percent	
	Raw	Cooked
Chicken	20	25
Turkey	15	20

Boneless poultry product shall not have a bone solids content of more than 1 percent, calculated on a weight basis.

(e) On the label of any ''Mechanically Separated (Kind of Poultry) ''described in § 381.173, the name of such product shall be followed immediately by the phrase: ''with excess skin'' unless such product is made from poultry product that does not include skin in excess of the natural proportion of skin present on the whole carcass, as specified in paragraph (d) of this section. Appropriate terminology on the label shall

indicate if heat treatment has been used in the preparation of the product. The labeling information described in this paragraph shall be identified on the label before the product leaves the establishment at which it is manufactured.

(f) The labels of sausages encased in natural casings made from meat or poultry viscera shall identify the type of meat or poultry from which the casings were derived, if the casings are from a different type of meat or poultry than the encased meat or poultry. The identity of the casing, if required, may be placed on the principal display panel or in the ingredient statement. Establishments producing, manufacturing, or using natural sausage casings are to maintain records documenting the meat or poultry source in accordance with subpart Q of this part.

(g) The labels of sausages encased in regenerated collagen casings shall disclose this fact on the product label. The fact that the sausage is encased in collagen may be placed on the principal display panel or in the ingredient statement.

[37 FR 9706, May 16, 1972, as amended at 60 FR 55983, Nov. 3, 1995; 66 FR 40845, Aug. 6, 2001]

§ 381.118 Ingredients statement.

(a)(1) The label shall show a statement of the ingredients in the poultry product if the product is fabricated from two or more ingredients. Such ingredients shall be listed by their common or usual names in the order of their descending proportions, except as prescribed in paragraph (a)(2) of this section.

(2)(i) Product ingredients which are present in individual amounts of 2 percent or less by weight may be listed in the ingredients statement in other than descending order of predominance: *Provided,* That such ingredients are listed by their common or usual names at the end of the ingredients statement and preceded by a quantifying statement, such as ''Contains _____ percent or less of _____,'' or ''Less than _____ percent of _____.'' The percentage of the ingredient(s) shall be filled in with a threshold level of 2 percent, 1.5 percent, 1.0 percent, or 0.5 percent, as appropriate. No ingredient to which the quantifying statement applies may be present in an amount greater than the stated threshold. Such a quantifying statement may also be utilized when an ingredients statement contains a listing of ingredients by individual components. Each component listing may utilize the required quantifying statement at the end of each component ingredients listing.

(ii) Such ingredients may be adjusted in the product formulation without a change being made in the ingredients statement on the labeling, provided that the adjusted amount complies with § 381.147(f)(4) and subpart P of this part, and does not exceed the amount shown in the quantifying statement. Any such adjustments to the formulation shall be provided to the inspector-in-charge.

(b) For the purpose of this paragraph, the term ''chicken meat,'' unless modified by an appropriate adjective, is construed to mean deboned white and dark meat; whereas the term ''chicken'' may include other edible parts such as skin and fat not in excess of their natural proportions, in addition to the chicken meat. If the term ''chicken meat'' is listed and the product also contains skin, giblets, or fat, it is necessary to list each such ingredient. Similar principles shall be followed in listing ingredients of poultry products processed from other kinds of poultry.

(c) The terms spice, natural flavor, natural flavoring, flavor or flavoring may be used in the following manner:

(1) The term ''spice'' means any aromatic vegetable substance in the whole, broken, or ground form, with the exceptions of onions, garlic and celery, whose primary function in food is seasoning rather than nutritional and from which no portion of any volatile oil or other flavoring principle has been removed. Spices include the spices listed in 21 CFR 182.10, and 184.

(2) The term ''natural flavor,'' ''natural flavoring,'' ''flavor'' or ''flavoring'' means the essential oil, oleoresin, essence or extractive, protein hydrolysate, distillate, or any product of roasting, heating or enzymolysis, which contains the flavoring constituents derived from a spice, fruit or fruit

juice, vegetable or vegetable juice, edible yeast, herb, bark, bud, root, leaf or any other edible portions of a plant, meat, seafood, poultry, eggs, dairy products, or fermentation products thereof, whose primary function in food is flavoring rather than nutritional. Natural flavors include the natural essence or extractives obtained from plants listed in 21 CFR 182.10, 182.20, 182.40, 182.50 and 184, and the substances listed in 21 CFR 172.510. The term natural flavor, natural flavoring, flavor or flavoring may also be used to designate spices, powdered onion, powdered garlic, and powdered celery.

(i) Natural flavor, natural flavoring, flavor or flavoring as described in paragraph (c)(1) and (2) of this section, which are also colors shall be designated as ''natural flavor and coloring,'' ''natural flavoring and coloring,'' ''flavor and coloring'' or ''flavoring and coloring'' unless designated by their common or usual name.

(ii) Any ingredient not designated in paragraphs (c) (1) and (2) of this section whose function is flavoring, either in whole or in part, must be designated by its common or usual name. Those ingredients which are of livestock or poultry origin must be designated by names that include the species and livestock and poultry tissues from which the ingredients are derived.

(d) On containers of frozen dinners, entrees, and pizzas, and similarly packaged products in cartons, the ingredient statement may be placed on the front riser panel: *Provided*, That the words ''see ingredients,'' followed immediately by an arrow pointing to the front riser panel, are placed on the principal display panel immediately above the location of such statement, without intervening printing or designs.

(e) The ingredients statement may be placed on the information panel, except as otherwise permitted in this subchapter.

(f) Establishments may interchange the identity of two kinds of poultry (e.g., chicken and turkey, chicken meat and turkey meat) used in a product formulation without changing the product's ingredient statement or product name under the following conditions:

(1)(i) The two kinds of poultry used must comprise at least 70 percent by weight of the poultry and the poultry ingredients [e.g. giblets, skin or fat in excess of natural proportions, or mechanically separated (kind)] used; and,

(ii) Neither of the two kinds of poultry used can be less than 30 percent by weight of the total poultry and poultry ingredients used;

(2) The word ''and'' in lieu of a comma must be shown between the declaration of the two kinds of poultry in the ingredients statement and in the product name.

[37 FR 9706, May 16, 1972, as amended at 55 FR 7294, Mar. 1, 1990; 55 FR 26422, June 28, 1990; 58 FR 38049, July 15, 1993; 59 FR 40215, Aug. 8, 1994; 63 FR 11360, Mar. 9, 1998]

§ 381.119 Declaration of artificial flavoring or coloring.

(a) When an artificial smoke flavoring or a smoke flavoring is added as an ingredient in the formula of any poultry product, there shall appear on the label, in prominent letters and contiguous to the name of the product, a statement such as ''Artificial Smoke Flavoring Added'' or ''Smoke Flavoring Added,'' as applicable, and the ingredient statement shall identify any artificial smoke flavoring or smoke flavoring added as an ingredient in the formula of the poultry product.

(b) Any poultry product which bears or contains any artificial flavoring other than an artificial smoke flavoring or a smoke flavoring, or bears or contains any artificial coloring shall bear a statement stating that fact on the immediate container or, if there is none, on the product.

§ 381.120 Antioxidants; chemical preservatives; and other additives.

When an antioxidant is added to a poultry product, there shall appear on the label in prominent letters and contiguous to the name of the product, a statement showing the name of the antioxidant and the purpose for which it is added, such as ''BHA added to help protect the flavor.'' Immediate containers of poultry products packed in, bearing, or containing any chemical preservative shall bear a label stating that fact and naming the additive and

the purpose of its use. Immediate containers of poultry products packed in, bearing or containing any other chemical additive shall bear a label naming the additive and the purpose of its use when required by the Administrator in specific cases. When approved proteolytic enzymes as permitted in a regulation permitting that use in this subchapter or 9 CFR Chapter III, Subchapter E, or in 21 CFR Chapter I, Subchapter A or Subchapter B of this subchapter are used in mature poultry muscle tissue, there shall appear on the label, in a prominent manner, contiguous to the product name, the statement ''Tenderized with [approved enzyme],'' to indicate the use of such enzymes. Any other approved substance which may be used in the solution shall also be included in the statement. When approved inorganic chlorides as permitted in a regulation permitting that use in this subchapter or 9 CFR Chapter III, Subchapter E, or in 21 CFR Chapter I, Subchapter A or Subchapter B of this subchapter are used in mature poultry muscle tissue, there shall appear on the label, in a prominent manner, contiguous to the product name, the statement, ''Tenderized with (name of approved inorganic chloride(s))'' to indicate the use of such inorganic chlorides. Any other approved substance which may be used in the solution shall also be included in the statement.

[37 FR 9706, May 16, 1972, as amended at 45 FR 58820, Sept. 5, 1980; 49 FR 18999, May 4, 1984; 64 FR 72175, Dec. 23, 1999]

§ 381.121 Quantity of contents.

(a) The label shall bear a statement of the quantity of contents in terms of weight or measures as provided in paragraph (c)(5) of this section. However, the Administrator may approve the use of labels for certain types of consumer packages which do not bear a statement of the net weight that would otherwise be required under this subparagraph: *Provided,* That the shipping container bears a statement ''Net weight to be marked on consumer packages prior to display and sale'': *And provided further,* That the total net weight of the contents of the shipping container is marked on such container: *And provided further,* That the shipping container bears a statement ''Tare weight of consumer package'' and in close proximity thereto, the actual tare weight (weight of packaging material), weighed to the nearest one-eighth ounce or less, of the individual consumer package in the shipping container. The above-specified statements may be added to approved shipping container labels upon approval by the inspector in charge.

(b) When a poultry product and a nonpoultry product are separately wrapped and are placed in a single immediate container bearing the same name of both products, the net weight on such immediate container may be the total net weight of the products, or such immediate container may show the net weights of the poultry product and the nonpoultry product separately. Notwithstanding the other provisions of this paragraph, the label on consumer size retail packages of stuffed poultry and other stuffed poultry products must show the total net weight of the poultry product, and in close proximity thereto, a statement specifying the minimum weight of the poultry in the product.

(c)(1) The statement of net quantity of contents shall appear (except as otherwise permitted under this paragraph (c)), on the principal display panel of all containers to be sold at retail intact, in conspicuous and easily legible boldface print or type, in distinct contrast to other matter on the container, and shall be declared in accordance with the provisions of this paragraph (c). An unused tare weight, as defined in section 381.121b of this subchapter, may be printed adjacent to the statement of net quantity of contents when the product is packaged totally with impervious packaging material and is packed with a usable medium.

(2) The statement shall be placed on the principal display panel within the bottom 30 percent of the area of the panel, in lines generally parallel to the base: *Provided,* That on packages having a principal display panel of 5 square inches or less, the requirement for placement within the bottom 30 percent of the area of the label panel shall not apply when the statement meets

the other requirements of this paragraph. The declaration may appear in more than one line.

(3) The statement shall be in letters and numerals in type size established in relationship to the area of the principal display panel of the package and shall be uniform for all packages of substantially the same size by complying with the following type specifications:

(i) Not less than one-sixteenth inch in height on containers, the principal display panel of which has an area of 5 square inches or less;

(ii) Not less than one-eighth inch in height on containers, the principal display panel of which has an area of more than 5 but not more than 25 square inches;

(iii) Not less than three-sixteenth inch in height on containers, the principal display panel of which has an area of more than 25 but not more than 100 square inches;

(iv) Not less than one-quarter inch in height on containers, the principal display panel of which has an area of more than 100 but not more than 400 square inches;

(v) Not less than one-half inch in height on containers, the principal display panel of which has an area of more than 400 square inches.

(vi) The ratio of height to width of letters and numerals shall not exceed a differential of 3 units to 1 unit (no more than 3 times as high as it is wide). This height standard pertains to upper case or capital letters. When upper and lower case or all lower case letters are used, it is the lower case letter ''o'' or its equivalent that shall meet the minimum standards. When fractions are used, each component numeral shall meet one-half the height standards.

(4) The statement shall appear as a distinct item on the principal display panel and shall be separated, from other label information appearing to the left or right of the statement, by a space at least equal in width to twice the width of the letter ''N'' of the style of type used in the quantity of contents statement and shall be separated from other label information appearing above or below the statement by a space at least equal in height to the height of the lettering used in the statement.

(5) The terms ''net weight'' or ''net wt.'' shall be used when stating the net quantity of contents in terms of weight, and the term ''net contents'' or ''contents'' when stating the net quantity of contents in terms of fluid measure. Except as provided in § 381.128, the statement shall be expressed in terms of avoirdupois weight or liquid measure. Where no general consumer usage to the contrary exists, the statement shall be in terms of liquid measure, if the product is liquid, or in terms of weight if the product is solid, semi-solid, viscous or a mixture of solid and liquid. On packages containing less than 1 pound or 1 pint, the statement shall be expressed in ounces or fractions of a pint, respectively. On packages containing 1 pound or 1 pint or more, and less than 4 pounds or 1 gallon, the statement shall be expressed as a dual declaration both in ounces and (immediately thereafter in parenthesis) in pounds, with any remainder in terms of ounces or common or decimal fraction of the pound, or in the case of liquid measure, in the largest whole units with any remainder in terms of fluid ounces or common or decimal fraction of the pint or quart. For example, a declaration of three-fourths pound avoirdupois weight shall be expressed as ''Net Wt. 12 oz.''; a declaration of 1½ pounds avoirdupois weight shall be expressed as ''Net Wt. 24 oz. (1 lb. 8 oz.),'' ''Net Wt. 24 oz. (1½ lb.),'' or ''Net Wt. 24 oz. (1.5 lbs.).'' However, on random weight packages the statement shall be expressed in terms of pounds and decimal fractions of the pound, for packages over 1 pound, and for packages which do not exceed 1 pound the statement may be in decimal fractions of the pound in lieu of ounces. The numbers may be written in provided the unit designation is printed. Paragraphs (c) (8) and (9) of this section permit certain exceptions to this paragraph for multi-unit packages, and random weight consumer size and small packages (less than ½ ounce), respectively.

(6) The statement as it is shown on a label shall not be false or misleading and shall express an accurate statement of the quantity of contents of the

container. Reasonable variations caused by loss or gain of moisture during the course of good distribution practices or by unavoidable deviations in good manufacturing practices will be recognized. Variations from stated quantity of contents shall be as provided in section 381.121b of this subchapter. The statement shall not include any term qualifying a unit of weight, measure, or count such as ''jumbo quart,'' ''full gallon,'' ''giant quart,'' ''when packed,'' ''minimum,'' or words of similar importance except as provided in paragraph (b) of this section.

(7) Labels for containers which bear any representation as to the number of servings contained therein shall bear, contiguous to such representation, and in the same size type as is used for such representation, a statement of the net quantity of each such serving.

(8) On a multiunit retail package, a statement of the quantity of contents shall appear on the outside of the package and shall include the number of individual units, the quantity of each individual unit, and, in parentheses, the total quantity of contents of the multiunit package in terms of avoirdupois or fluid ounces, except that such declaration of total quantity need not be followed by an additional parenthetical declaration in terms of the largest whole units and subdivisions thereof, as otherwise required by this paragraph (c). ''A multiunit retail package'' is a package containing two or more individually packaged units of the identical commodity and in the same quantity, with the individual packages intended to be sold as part of the multiunit retail package but capable of being sold individually. Open multiunit retail packages that do not obscure the number of units and the labeling thereon are not subject to this paragraph (c)(8) if the labeling of each individual unit complies with the requirements of this paragraph (c).

(9) The following exemptions from the requirements contained in this section are hereby established:

(i) Individually wrapped, random weight consumer size packages of poultry products (as specified in paragraph (c)(10) of this section) and poultry products that are subject to shrinkage through moisture loss during good distribution practices and are designated as gray area type of products as defined in NBS handbook 133, section 3.18.2, need not bear a net weight statement when shipped from an official establishment provided a net weight shipping statement which meets the requirements of paragraph (c)(6) of this section is applied to the shipping container prior to shipping it from the official establishment. Net weight statements so applied to the shipping container are exempt from the type size, dual declaration, and placement requirements of this paragraph if an accurate statement of net weight is shown conspicuously on the principal display panel of the shipping container. The net weight also shall be applied directly to random weight consumer size packages prior to retail display and sale. The net weight statement of random weight consumer size packages for retail sale shall be exempt from the type size, dual declaration, and placement requirements of this paragraph if an accurate statement of net weight is shown conspicuously on the principal display panel of the package.

(ii) Individually wrapped and labeled packages of less than ½ ounce net weight and random weight consumer size packages shall be exempt from the requirements of this paragraph if they are in a shipping container and the statement of net quantity of contents on the shipping container meets the requirements of paragraph (c)(6) of this section;

(iii) Individually wrapped and labeled packages of less than ½ ounce net weight bearing labels declaring net weight, price per pound, and total price, shall be exempt from the type size, dual declaration, and placement requirements of this paragraph if an accurate statement of net weight is shown conspicuously on the principal display panel of the package.

(10) As used in this section a ''random weight consumer size package'' is one of a lot, shipment or delivery of packages of the same product, with varying weights and with no fixed weight pattern.

[37 FR 9706, May 16, 1972, as amended at 39 FR 4569, Feb. 5, 1974; 53 FR 28635, July 29, 1988; 55 FR 49835, Nov. 30, 1990]

§ 381.121a Quantity of contents labeling.

Sections 381.121a through 381.121e of this part prescribe the procedures to be followed for determining net weight compliance and prescribe the reasonable variations from the declared net weight on the labels of immediate containers of products in accordance with § 381.121 of this part.

[55 FR 49835, Nov. 30, 1990]

§ 381.121b Definitions and procedures for determining net weight compliance.

(a) For the purpose of § 381.121b of this part, the reasonable variations allowed, definitions, and procedures to be used in determining net weight and net weight compliance are described in the National Institute of Standards and Technology (NIST) Handbook 133, ''Checking the Net Contents of Packaged Goods,'' Third Edition, September 1988, and Supplements 1, 2, 3, and 4 dated September 1990, October 1991, October 1992, and October 1994, respectively, which are incorporated by reference, with the exception of the NIST Handbook 133 and Supplements 1 and 3 requirements listed in paragraphs (b) and (c) of this section. Those provisions, incorporated by reference herein, are considered mandatory requirements. This incorporation was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. (These materials are incorporated as they exist on the date of approval.) Copies may be purchased from the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402. It is also available for inspection at the Office of the Federal Register Information Center, 800 North Capitol Street NW., suite 700, Washington, DC 20408.

(b) The following NBS Handbook 133 requirements are not incorporated by reference.

Chapter 2—General Considerations

2.13.1 Polyethylene Sheeting and Film
2.13.2 Textiles
2.13.3 Mulch

Chapter 3—Methods of Test for Packages Labeled by Weight

3.11. Aerosol Packages
3.14. Glazed Raw Seafood and Fish
3.15. Canned Coffee
3.16. Borax
3.17. Flour

Chapter 4—Methods of Test for Packages Labeled by Volume

4.7. Milk
4.8. Mayonnaise and Salad Dressing
4.9. Paint, Varnish, and Lacquers—Nonaerosol
4.11. Peat Moss
4.12. Bark Mulch
4.15. Ice Cream Novelties

Chapter 5—Methods of Test for Packages Labeled by Count, Length, Area, Thickness, or Combinations of Quantities

5.4. Polyethlene Sheeting
5.5. Paper Plates
5.6. Sanitary Paper Products
5.7. Pressed and Blown Glass Tumblers and Stemware

Appendix D: Package Net Contents Regulations

D.1.1 U.S. Department of Health and Human Servcies, Food and Drug Administration
D.1.2 U.S. Department of Agriculture, Food Safety and Inspection Servcie
D.1.3 Federal Trade Commission
D.1.4 Environmental Protection Agency
D.1.5 U.S. Department of the Treasury, Bureau of Alcohol, Tobacco, and Firearms

(c) The following requirements of Supplement 1 dated September 1990, Supplement 3 dated October 1992, and Supplement 4 dated October 1994, of NIST Handbook 133 are not incorporated by reference.

Supplement 1

Chapter 2 General Considerations

2.13.1. Polyethylene Sheeting and Film
2.13.2. Textiles
2.13.3. Mulch

Chapter 3 Methods of Test for Packages Labeled by Weight

3.11.4. Exhausting the Aerosol Container

Chapter 4 Methods of Test for Packages Labeled by Volume

4.6.4. Method D: Determining the Net Contents of Compressed Gas in Cylinders
4.7. Milk
4.16. Fresh Oysters Labeled by Volume

Chapter 5 Methods of Test for Packages Labeled by Count, Length, Area, Thickness, or Combinations of Quantities

5.4. Polyethylene Sheeting

Supplement 3

Chapter 3 Methods of Test for Packages Labeled by Weight

3.17. Flour and Dry Pet Food

Chapter 5 Methods of Test for Packages Labeled by Count, Length, Area, Thickness, or Combinations of Quantities

5.4. Polyethylene Sheeting
5.5. Paper Plates
65.8. Baler Twine

Appendix A. Forms and Worksheets

Supplement 4

3.11 Aerosol Packages
3.11.1 Equipment
3.11.2 Preparation for Test
3.11.3 The Determination of Net Contents: Part 1
3.11.4 Exhausting the Aerosol Container
3.11.5 The Determination of Net Contents: Part 2

[55 FR 49835, Nov. 30, 1990, as amended at 60 FR 12885, Mar. 9, 1995]

§381.121c Scale requirements for accurate weights, repairs, adjustments, and replacement after inspection.

(a) All scales used to weight poultry products sold or otherwise distributed in commerce in federally inspected poultry plants shall be installed, maintained, and operated to insure accurate weights. Such scales shall meet the applicable requirements contained in National Institute of Standards and Technology (NIST) Handbook 44, ''Specifications, Tolerances, and Other Technical Requirements for Weighing and Measuring Devices'', 1999 Edition, November 1998, which is incorporated by reference. This incorporation was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. (These materials are incorporated as they exist on the date of approval.) A notice of any change in the Handbook cited herein will be published in the FEDERAL REGISTER. Copies may be purchased from the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402. It is also available for inspection at the Office of the Federal Register Information Center, 800 North Capitol Street NW., suite 700, Washington, DC 20408.

(b) All scales used to weigh poultry products sold or otherwise distributed in commerce or in State designated under section 5(c) of the Poultry Products Inspection Act, shall be of sufficient capacity to weigh the entire unit and/or package.

(c) No scale shall be used at a federally inspected establishment to weigh poultry products unless it has been found upon test and inspection as specified in NIST Handbook 44 to provide accurate weight. If a scale is inspected or tested and found to be inaccurate, or if any repairs, adjustments or replacements are made to a scale, it shall not be used until it has been reinspected and retested by a USDA official, or a State or local government weights and measures official, or a State registered or licensed scale repair firm or person, and it must meet all accuracy requirements as specified in NIST Handbook 44. If a USDA inspector has put a ''Retain'' tag on a scale it can only be removed by a USDA inspector. As long as the tag is on the scale, it shall not be used.

[55 FR 49836, Nov. 30, 1990, as amended at 60 FR 12885, Mar. 9, 1995; 64 FR 53188, Oct. 1, 1999]

§381.121d Scales; testing of.

(a) The operator of each official establishment that weighs poultry food products shall cause such scales to be tested for accuracy in accordance with the technical requirements of NIST Handbook 44, at least once during the calendar year. In cases where the scales are found not to maintain accuracy between tests, more fequent tests may be required and monitored by an authorized USDA program official.

(b) The operator of each official establishment shall display on or near each scale a valid certification of the scale's accuracy from a State or local government's weights and measures authority or from a State registered or licensed scale repair firm or person, or shall have alternative documented procedures showing that the scale has been tested for accuracy in accordance with the requirements of NIST Handbook 44.

[55 FR 49836, Nov. 30, 1990, as amended at 62 FR 45026, Aug. 25, 1997; 65 FR 34390, May 30, 2000; 66 FR 52486, Oct. 16, 2001]

§ 381.121e Handling of failed product.

Any lot of product which is found to be out of compliance with net weight requirements upon testing in accordance with § 381.121b of this subchapter shall be handled as follows:

(a) A lot tested in an official establishment and found not to comply with net weight requirements may be reprocessed and must be reweighed and remarked to satisfy the net weight requirements of this section, and be reinspected in accordance with the requirements of this part.

(b) A lot tested outside of an official establishment and found not to comply with net weight requirements must be reweighed and remarked with a proper net weight statement, provided that such reweighing and remarking shall not deface, cover, or destroy any other marking or labeling required under this subchapter and the net quantity of contents is shown with the same prominence as the most conspicuous feature of a label.

[55 FR 49836, Nov. 30, 1990]

§ 381.122 Identification of manufacturer, packer or distributor.

The name and address, including zip code, of the manufacturer, packer, or distributor shall be shown on the label and if only the name and address of the distributor is shown, it shall be qualified by such term as ''packed for,'' ''distributed by,'' or ''distributors.'' The name and place of business of the manufacturer, packer, or distributor may be shown on the principal display panel, on the 20-percent panel of the principal display panel reserved for required information, on the front riser panel of frozen food cartons, or on the information panel.

[37 FR 9706, May 16, 1972, as amended at 59 FR 40215, Aug. 8, 1994]

§ 381.123 Official inspection mark; official establishment number.

The immediate container of every inspected and passed poultry product shall bear:

(a) The official inspection legend; and

(b) The official establishment number of the official establishment in which the product was processed under inspection and placed as follows:

(1) Within the official inspection legend in the form required by subpart M of this part; or

(2) Outside the official inspection legend elsewhere on the exterior of the container or its labeling, e.g., the lid of a can, if shown in a prominent and legible manner in a size sufficient to insure easy visibility and recognition and accompanied by the prefix ''P''; or

(3) Off the exterior of the container, e.g., on a metal clip used to close casings or bags, or on the back of a paper label of a canned product, or on other packaging or labeling in the container, e.g., on aluminum pans and trays placed within containers, when a statement of its location is printed contiguous to the official inspection legend, such as ''Plant No. on Package Closure'' or ''Plant No. on Pan'', if shown in a prominent and legible manner in a size sufficient to ensure easy visibility and recognition; or

(4) On an insert label placed under a transparent covering if clearly visible and legible and accompanied by the prefix ''P''.

[47 FR 29515, July 7, 1982]

§ 381.124 Dietary food claims.

If a product purports to be or is represented for any special dietary use by man, its label shall bear a statement concerning its vitamin, mineral, and other dietary properties upon which the claim for such use is based in whole or in part and shall be in conformity with regulations (21 CFR part 125) established pursuant to sections 403 and 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343, 371).

§ 381.125 Special handling label requirements.

(a) Packaged products which require special handling to maintain their wholesome condition shall have prominently displayed on the principal display panel of the label the statement: ''Keep Refrigerated,'' ''Keep Frozen,'' ''Keep Refrigerated or Frozen,'' ''Perishable—Keep Under Refrigeration,'' or such similar statement as the Administrator may approve in specific cases. The immediate containers for products that are frozen during distribution and intended to be thawed prior to or during display for sale shall bear the

statement ''Shipped/Stored and Handled Frozen for Your Protection, Keep Refrigerated or Freeze.'' For all canned perishable products, the statement shall be shown in upper case letters one-fourth inch in height for containers having a net weight of 3 pounds or less, and for containers having a net weight over 3 pounds, the statement shall be shown in letters one-half inch in height.

(b) Safe handling instructions shall be provided for all poultry products not processed in accordance with the provisions of § 381.150(a) or that have not undergone other processing that would render them ready-to-eat, except as exempted under paragraph (b)(4) of this section.

(1) (i) Safe handling instructions shall accompany the poultry products, specified in this paragraph (b), destined for household consumers, hotels, restaurants, or similar institutions and shall appear on the label. The information shall be in lettering no smaller than one–sixteenth of an inch in size and shall be prominently placed with such conspicuousness (as compared with other words, statements, designs or devices in the labeling) as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(ii) The safe handling information shall be presented on the label under the heading ''Safe Handling Instructions'' which shall be set in type size larger than the print size of the rationale statement and handling statements as discussed in paragraphs (b)(2) and (b)(3) of this section. The safe handling information shall be set off by a border and shall be one color type printed on a single color contrasting background whenever practical.

(2) (i) The labels of the poultry products, specified in this paragraph (b) and prepared from inspected and passed poultry, shall include the following rationale statement as part of the safe handling instructions, ''This product was prepared from inspected and passed meat and/or poultry. Some food products may contain bacteria that could cause illness if the product is mishandled or cooked improperly. For your protection, follow these safe handling instructions.'' This statement shall be placed immediately after the heading and before the safe handling statements.

(ii) The labels of the poultry products, specified in this paragraph (b) and prepared pursuant to § 381.10(a) (2), (5), (6), and (7), shall include the following rationale statement as part of the safe handling instructions, ''Some food products may contain bacteria that could cause illness if the product is mishandled or cooked improperly. For your protection, follow these safe handling instructions.'' This statement shall be placed immediately after the heading and before the safe handling statements.

(3) Poultry products, specified in this paragraph (b), shall bear the labeling statements.

(i) Keep refrigerated or frozen. Thaw in refrigerator or microwave. (Any portion of this statement that is in conflict with the product's specific handling instructions may be omitted, e.g., instructions to cook without thawing.) (A graphic illustration of a refrigerator shall be displayed next to the statement.);

(ii) Keep raw meat and poultry separate from other foods. Wash working surfaces (including cutting boards), utensils, and hands after touching raw meat or poultry. (A graphic illustration of soapy hands under a faucet shall be displayed next to the statement.);

(iii) Cook thoroughly. (A graphic illustration of a skillet shall be displayed next to the statement.); and

(iv) Keep hot foods hot. Refrigerate leftovers immediately or discard. (A graphic illustration of a thermometer shall be displayed next to the statement.)

(4) Poultry products intended for further processing at another official establishment are exempt from the requirements prescribed in paragraphs (b)(1) through (b)(3) of this section.

[37 FR 9706, May 16, 1972, as amended at 39 FR 4569, Feb. 5, 1974; 59 FR 14540, Mar. 28, 1994; 64 FR 746, Jan. 6, 1999]

§ 381.126 Date of packing and date of processing; contents of cans.

(a) Either the immediate container or the shipping container of all poultry

food products shall be plainly and permanently marked by code or otherwise with the date of packing. If calendar dating is used, it must be accompanied by an explanatory statement, as provided in § 381.129(c)(2).

(b) The immediate container for dressed poultry shall be marked with a lot number which shall be the number of the day of the year on which the poultry was slaughtered or a coded number.

(c) All canned products shall be plainly and permanently marked, by code or otherwise, on the containers, with the identity of the contents and date of canning, except that canned products packed in glass containers are not required to be marked with the date of canning if such information appears on the shipping container. If calendar dating is used, it must be accompanied by an explanatory statement, as provided in § 381.129(c)(2).

(d) If any marking is by code, the inspector in charge shall be informed as to its meaning.

[37 FR 9706, May 16, 1972, as amended at 39 FR 28516, Aug. 8, 1974; 39 FR 35784, Oct. 4, 1974]

§ 381.127 Wording on labels of shipping containers.

(a) Each label for use on a shipping container for inspected and passed poultry products shall bear, in distinctly legible form, the following information:

(1) The official inspection legend.

(2) The official establishment number of the official establishment in which the poultry product was inspected, either within the official inspection mark, or elsewhere on the container clearly visible and in proximity to the official inspection mark.

§ 381.128 Labels in foreign languages.

Any label to be affixed to a container of any dressed poultry or other poultry product for foreign commerce may be printed in a foreign language. However, the official inspection legend and establishment number shall appear on the label in English, but in addition, may be literally translated into such foreign language. Each such label shall be subject to the applicable provisions of §§ 381.115 to 381.141, inclusive. Deviations from the form of labeling required under the regulations may be approved by the Administrator in specific cases and such modified labeling may be used for poultry products to be exported: *Provided,* (a) That the proposed labeling accords to the specifications of the foreign purchaser, (b) that it is not in conflict with the Act or the laws of the country to which it is intended for export, and (c) that the outside of the shipping container is labeled to show that it is intended for export; but if such product is sold or offered for sale in domestic commerce, all the requirements of the regulations shall apply.

§ 381.129 False or misleading labeling or containers.

(a) No poultry product subject to the Act shall have any false or misleading labeling or any container that is so made, formed, or filled as to be misleading. However, established trade names and other labeling and containers which are not false or misleading and which are approved by the Administrator in the regulations or in specific cases are permitted.

(b) No statement, word, picture, design, or device which is false or misleading in any particular or conveys any false impression or gives any false indication of origin, identity, or quality, shall appear on any label. For example:

(1) Official grade designations such as the letter grades A, B, and C may be used in labeling individual carcasses of poultry or containers of poultry products only if such articles have been graded by a licensed grader of the Federal or Federal-State poultry grading service and found to qualify for the indicated grade.

(2) Terms having geographical significance with reference to a particular locality may be used only when the product was produced in that locality.

(3) ''Fresh frozen'', ''quick frozen'', ''frozen fresh'', and terms of similar import apply only to ready-to-cook poultry processed in accordance with § 381.66(f)(1). Ready-to-cook poultry handled in any other manner and dressed poultry may be labeled ''frozen'' only if it is frozen in accordance

with § 381.66(f)(2) under Department supervision and is in fact in a frozen state. ''Individually quick frozen (Kind)'' and terms of similar import are applicable only to poultry products that are frozen as stated on the label and whose component parts can be easily separated at time of packing.

(4) Poultry products labeled with a term quoted in any paragraph of § 381.170(b) shall comply with the specifications in the applicable paragraph. However, parts of poultry may be cut in any manner the processor desires as long as the labeling appropriately reflects the contents of the container of such poultry.

(5) The terms ''All,'' ''Pure,'' ''100%,'' and terms of similar connotation shall not be used on labels for products to identify ingredient content, unless the product is prepared solely from a single ingredient.

(6)(i) Raw poultry product whose internal temperature has ever been below 26°F may not bear a label declaration of ''fresh.'' Raw poultry product bearing a label declaration of ''fresh'' but whose internal temperature has ever been below 26°F is mislabeled. The ''fresh'' designation may be deleted from such product in accordance with § 381.133(b)(9)(xxiv). The temperature of individual packages of raw poultry product within an official establishment may deviate below the 26°F standard by 1° (i.e., have a temperature of 25°F) and still be labeled ''fresh.'' The temperature of individual packages of raw poultry product outside an official establishment may deviate below the 26°F standard by 2° (i.e., have a temperature of 24°F) and still be labeled ''fresh.'' The average temperature of poultry product lots of each specific product type must be 26°F. Product described in this paragraph is not subject to the freezing procedures required in § 381.66(f)(2) of this subchapter.

(ii) Raw poultry product whose internal temperature has ever been at or below 0°F must be labeled with the descriptive term ''frozen,'' except when such labeling duplicates or conflicts with the labeling requirements in § 381.125 of this subchapter. The word ''previously'' may be placed next to the term ''frozen'' on an optional basis. The descriptive term must be prominently displayed on the principal display panel of the label. If additional labeling containing the descriptive term is affixed to the label, it must be prominently affixed to the label. The additional labeling must be so conspicuous (as compared with other words, statements, designs, or devices in the labeling) that it is likely to be read and understood by the ordinary individual under customary conditions of purchase and use. Product described in this paragraph is subject to the freezing procedures required in § 381.66(f)(2) of this subchapter.

(iii) Raw poultry product whose internal temperature has ever been below 26°F, but is above 0°F, is not required to bear any specific descriptive term. Raw poultry product whose internal temperature has ever been below 26°F, but is above 0°F, may bear labeling with an optional, descriptive term, provided the optional, descriptive term does not cause the raw poultry product to become misbranded. If used, an optional, descriptive term must be prominently displayed on the principal display panel of the label. If additional labeling containing the optional, descriptive term is affixed to the label, it must be prominently affixed on the label. The additional labeling must be so conspicuous (as compared with other words, statements, designs, or devices in the labeling) that it is likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(iv) Handling and relabeling of products. (A) Except as provided under paragraph (b)(6)(iii)(C) of this section, when any inspected and passed product has become misbranded under this subpart after it has been transported from an official establishment, such product may be transported in commerce to an official establishment after oral permission is obtained from the Area Supervisor of the area in which that official establishment is located. The transportation of the product may be to the official establishment from which it had been transported or to another official establishment designated by the person desiring to handle the product. The transportation shall be authorized only for the purpose of the

relabeling of the product. The Area Supervisor shall record the authorization and other information necessary to identify the product and shall provide a copy of the record to the inspector at the establishment receiving the product. The shipper shall be furnished a copy of the authorization record upon request.

(B) Upon the arrival of the shipment at the official establishment, a careful inspection shall be made of the product by the inspector, and if it is found that the product is not adulterated, it may be received into the establishment; but if the product is found to be adulterated, it shall at once be condemned and disposed of in accordance with § 381.95 of this subchapter. Wholesome product will be relabeled in accordance with paragraph (b)(6) (i) or (ii) of this section, as appropriate.

(C) When any inspected and passed product has become misbranded under this subpart after it has been transported from an official establishment, the owner may transport the product in commerce to a retail entity for relabeling in accordance with paragraph (b)(6) (i) or (ii) of this section, as appropriate, or to other end users, such as hotels, restaurants or similar institutions; or, relabel the product in accordance with paragraph (b)(6) (i) or (ii) of this section, as appropriate if the product is already at a retail entity. A hotel, restaurant or similar institution is not required to relabel product misbranded under this subpart; *Provided*, That the product is prepared in meals or as entrees only for sale or service directly to individual consumers at such institutions, and that the mark of inspection is removed or obliterated. Oral permission shall be obtained from the Area Officer-in-Charge of the Compliance Program for the area in which the product is located prior to such transportation or relabeling. The Area Officer-in-Charge shall record the authorization and other information necessary to identify the product, and shall furnish a copy of the authorization record upon request. Before being offered for sale at a retail entity, such product shall be relabeled.

(c) A calendar date may be shown on labeling when declared in accordance with the provisions of this paragraph:

(1) The calendar date shall express the month of the year and the day of the month for all products and also the year in the case of products hermetically sealed in metal or glass containers, dried or frozen products, or any other products that the Administrator finds should be labeled with the year because the distribution and marketing practices with respect to such products may cause a label without a year identification to be misleading.

(2) Immediately adjacent to the calendar date shall be a phrase explaining the meaning of such date in terms of ''packing'' date, ''sell by'' date, or ''use before'' date, with or without a further qualifying phrase, e.g., ''For Maximum Freshness'' or ''For Best Quality'', and such phrases shall be approved by the Administrator as prescribed in § 381.132.

(d) When sodium alginate, calcium carbonate, lactic acid, and calcium lactate are used together in a dry binding matrix in ground and formed poultry products, as permitted in § 381.147 of this subchapter, there shall appear on the label contiguous to the product name, a statement to indicate the use of sodium alginate, calcium carbonate, lactic acid, and calcium lactate.

(e) When transglutaminase enzyme is used to bind pieces of poultry to form a cut of poultry, or to reform a piece of poultry from a multiple cuts of poultry, there shall appear on the label, as part of the product name, a statement that indicates that the product has been ''formed'' or ''reformed,'' in addition to other preparation steps, e.g., ''Formed Turkey Thigh Roast'' or ''Reformed and Shaped Chicken Breast.''

(f) Products identified as ''pizza'' that list a poultry component as part of the product name must bear a parenthetical statement contiguous to the ingredients statement that conveys the percent of the cooked, cured, or dried poultry component in the product. This paragraph shall expire on October 30, 2006.

[37 FR 9706, May 16, 1972, as amended at 39 FR 28516, Aug. 8, 1974; 39 FR 42339, Dec. 5, 1974; 55 FR 5977, Feb. 21, 1990; 60 FR 44412, Aug. 25, 1995; 61 FR 66200, Dec. 17, 1996; 61 FR 68821, Dec. 30, 1996; 66 FR 54916, Oct. 31, 2001]

EFFECTIVE DATE NOTE: At 68 FR 44870, July 31, 2003, § 381.129 was amended by adding

paragraph (f), effective Oct. 22, 2003, through Oct. 24, 2006.

§ 381.130 False or misleading labeling or containers; orders to withhold from use.

If the Administrator has reason to believe that any marking or other labeling or the size or form of any container in use or proposed for use with respect to any article subject to the Act is false or misleading in any particular, he may direct that the use of the article be withheld unless it is modified in such manner as the Administrator may prescribe so that it will not be false or misleading. If the person using or proposing to use the labeling or container does not accept the determination of the Administrator, he may request a hearing, but the use of the labeling or container shall, if the Administrator so directs, be withheld pending hearing and final determination by the Secretary in accordance with applicable rules of practice. Any such determination with respect to the matter by the Secretary shall be conclusive unless, within 30 days after the receipt of notice of such final determination, the person adversely affected thereby appeals to the U.S. Court of Appeals for the Circuit in which he has his principal place of business, or to the U.S. Court of Appeals for the District of Columbia Circuit. The provisions of section 204 of the Packers and Stockyards Act of 1921, as amended, shall be applicable to appeals taken under this section.

§ 381.131 Preparation of labeling or other devices bearing official inspection marks without advance approval prohibited; exceptions.

(a) Except for the purposes of preparing and submitting a sample or samples of the same to the Administrator for approval, no brand manufacturer, printer, or other person shall cast, print, lithograph, or otherwise make any marking device containing any official mark or simulation thereof, or any label bearing any such mark or simulation, without the written authority therefor of the Administrator. However, when any such sample label, or other marking device, is approved by the Administrator, additional supplies of the approved label, or marking device, may be made for use in accordance with the regulations in this subchapter, without further approval by the Administrator. The provisions of this paragraph do not apply to marking devices containing the official inspection legend shown in Figure 5 of § 381.102.

(b) No brand manufacturer or other person shall cast or otherwise make, without an official certificate issued in quadruplicate by a Program employee, a marking device containing the official inspection legend shown in Figure 5 of § 381.102 or any simulation of that legend.

(1) The certificate is a Food Safety and Inspection Service form for signature by a Program employee and the official establishment ordering the marking device, bearing a certificate serial number and a letterhead and the seal of the United States Department of Agriculture. The certificate authorizes the making of only the devices of the type and quantity listed on the certificate.

(2) After signing the certificate, the Program employee and the establishment shall each keep a copy, and the remaining two copies shall be given to the marking device manufacturer.

(3) The manufacturer of the marking devices shall engrave or otherwise mark each marking device with a permanent identifying serial number unique to it. The manufacturer shall list on each of the two copies of the certificate given to the manufacturer the number of each marking device authorized by the certificate. The manufacturer shall retain one copy of the certificate for the manufacturer's records and return the remaining copy with the marking devices to the Program employee whose name and address are given on the certificate as the recipient.

(4) In order that all such marking devices bear identifying numbers, within one year after June 24, 1985, an establishment shall either replace each such marking device that does not bear an identifying number, or, under the direction of the inspector-in-charge,

mark such marking device with a permanent identifying number.

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

[50 FR 21423, May 24, 1985]

§ 381.132 Labeling approval.

(a) No final labeling shall be used on any product unless the sketch labeling of such final labeling has been submitted for approval to the Food Labeling Division, Regulatory Programs, Food Safety and Inspection Service, and approved by such division, accompanied by FSIS Form, Application for Approval of Labels, Marking, and Devices, except for generically approved labeling authorized for use in § 381.133(b) (2)–(9). The management of the official establishment or establishment certified under a foreign inspection system, in accordance with subpart T of this part, must maintain a copy of all labeling used, along with the product formulation and processing procedure, in accordance with subpart Q of this part. Such records shall be made available to any duly authorized representative of the Secretary upon request.

(b) The Food Labeling Division shall permit submission for approval of only sketch labeling, as defined in § 381.132(d), for all products, except as provided in § 381.133(b) (2)–(9) and except for temporary use of final labeling as prescribed in paragraph (f) of this section.

(c) All labeling required to be submitted for approval as set forth in § 381.132(b) shall be submitted in duplicate to the Food Labeling Division, Regulatory Programs, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250. A parent company for a corporation may submit only one labeling application (in duplicate) for a product produced in other establishments that are owned by the corporation.

(d) ''Sketch'' labeling is a printer's proof or equivalent which clearly shows all labeling features, size, location, and indication of final color, as specified in subpart N of this part. FSIS will accept sketches that are hand drawn, computer generated or other reasonable facsimiles that clearly reflect and project the final version of the labeling. Indication of final color may be met by: submission of a color sketch, submission of a sketch which indicates by descriptive language the final colors, or submission with the sketch of previously approved final labeling that indicates the final colors.

(e) Inserts, tags, liners, pasters, and like devices containing printed or graphic matter and for use on, or to be placed within, containers and coverings of product shall be submitted for approval in the same manner as provided for labeling in § 381.132(a), except that such devices which contain no reference to product and bear no misleading feature shall be used without submission for approval as prescribed in § 381.133(b)(9).

(f)(1) Consistent with the requirements of this section, temporary approval for the use of a final label or other final labeling that may otherwise be deemed deficient in some particular may be granted by the Food Labeling Division. Temporary approvals may be granted for a period not to exceed 180 calendar days under the following conditions:

(i) The proposed labeling would not misrepresent the product;

(ii) The use of the labeling would not present any potential health, safety, or dietary problems to the consumer;

(iii) Denial of the request would create undue economic hardship; and

(iv) An unfair competitive advantage would not result from the granting of the temporary approval.

(2) Extensions of temporary approvals may also be granted by the Food Labeling Division, provided that the applicant demonstrates that new circumstances, meeting the above criteria, have developed since the original temporary approval was granted.

[60 FR 67456, Dec. 29, 1995]

§ 381.133 Generically approved labeling.

(a)(1) An official establishment or an establishment certified under a foreign inspection system, in accordance with subpart T of this part, is authorized to use generically approved labeling, as defined in paragraph (b) of this section, without such labeling being submitted

for approval to the Food Safety and Inspection Service in Washington or the field, provided the labeling is in accord with this section and shows all mandatory features in a prominent manner as required in subpart N of this part, and is not otherwise false or misleading in any particular.

(2) The Food Safety and Inspection Service shall select samples of generically approved labeling from the records maintained by official establishments and establishments certified under foreign inspection systems, in accordance with subpart T of this part, as required in § 381.132, to determine compliance with labeling requirements. Any finding of false or misleading labeling shall institute the proceedings prescribed in § 381.233.

(b) Generically approved labeling is labeling which complies with the following:

(1) Labeling for a product which has a product standard as specified in subpart 381 of this subchapter or the Standards and Labeling Policy Book and which does not contain any special claims, such as quality claims, nutrient content claims, health claims, negative claims, geographical origin claims, or guarantees, or which is not a domestic product labeled in a foreign language;

(2) Labeling for single-ingredient products (such as chicken legs or turkey breasts) which does not contain any special claims, such as quality claims, nutrient content claims, health claims, negative claims, geographical origin claims, or guarantees, or which is not a domestic product labeled with a foreign language;

(3) Labeling for containers of products sold under contract specifications to Federal Government agencies, when such product is not offered for sale to the general public, provided that the contract specifications include specific requirements with respect to labeling, and are made available to the inspector-in-charge;

(4) Labeling for shipping containers which contain fully labeled immediate containers, provided such labeling complies with § 381.127;

(5) Labeling for products not intended for human food, provided they comply with §§ 381.152(c) and 381.193, and labeling for poultry heads and feet for export for processing as human food if they comply with § 381.190(b);

(6) Poultry inspection legends, which comply with subpart M of this part;

(7) Inserts, tags, liners, pasters, and like devices containing printed or graphic matter and for use on, or to be placed within containers, and coverings of products, provided such devices contain no reference to product and bear no misleading feature;

(8) Labeling for consumer test products not intended for sale; and

(9) Labeling which was previously approved by the Food Labeling Division as sketch labeling, and the final labeling was prepared without modification or with the following modifications:

(i) All features of the labeling are proportionately enlarged or reduced, provided that all minimum size requirements specified in applicable regulations are met and the labeling is legible;

(ii) The substitution of any unit of measurement with its abbreviation or the substitution of any abbreviation with its unit of measurement, e.g., ''lb.'' for ''pound,'' or ''oz.'' for ''ounce,'' or of the word ''pound'' for ''lb.'' or ''ounce'' for ''oz.'';

(iii) A master or stock label has been approved from which the name and address of the distributor are omitted and such name and address are applied before being used (in such case, the words ''prepared for'' or similar statement must be shown together with the blank space reserved for the insertion of the name and address when such labels are offered for approval);

(iv) Wrappers or other covers bearing pictorial designs, emblematic designs or illustrations, e.g., floral arrangements, illustrations of animals, fireworks, etc. are used with approved labeling (the use of such designs will not make necessary the application of labeling not otherwise required);

(v) A change in the language or the arrangement of directions pertaining to the opening of containers or the serving of the product;

(vi) The addition, deletion, or amendment of a dated or undated coupon, a cents-off statement, cooking instructions, packer product code information, or UPC product code information;

(vii) Any change in the name or address of the packer, manufacturer or distributor that appears in the signature line;

(viii) Any change in the net weight, provided that the size of the net weight statement complies with § 381.121;

(ix) The addition, deletion, or amendment of recipe suggestions for the product;

(x) Any change in punctuation;

(xi) Newly assigned or revised establishment numbers for a particular establishment for which use of the labeling has been approved by the Food Labeling Division, Regulatory Programs;

(xii) The addition or deletion of open dating information;

(xiii) A change in the type of packaging material on which the label is printed;

(xiv) Brand name changes, provided that there are no design changes, the brand name does not use a term that connotes quality or other product characteristics, the brand name has no geographic significance, and the brand name does not affect the name of the product;

(xv) The deletion of the word ''new'' on new product labeling;

(xvi) The addition, deletion, or amendment of special handling statements, provided that the change is consistent with § 381.125(a);

(xvii) The addition of safe handling instructions as required by § 381.125(b);

(xviii) Changes reflecting a change in the quantity of an ingredient shown in the formula without a change in the order of predominance shown on the label, provided that the change in quantity of ingredients complies with any minimum or maximum limits for the use of such ingredients prescribed in § 381.147 and subpart P of this part;

(xix) Changes in the color of the labeling, provided that sufficient contrast and legibility remain;

(xx) A change in the product vignette, provided that the change does not affect mandatory labeling information or misrepresent the content of the package;

(xxi) The addition, deletion, or substitution of the official USDA poultry grade shield; (xxii) A change in the establishment number by a corporation or parent company for an establishment under its ownership;

(xxiii) Changes in nutrition labeling that only involve quantitative adjustments to the nutrition labeling information, except for services sizes, provided the nutrition labeling information maintains its accuracy and consistency;

(xxiv) Deletion of any claim, and the deletion of non-mandatory features or non-mandatory information;

(xxv) The addition or deletion of a direct translation of the English language into a foreign language for products marked ''for export only''; and

(xxvi) The use of the descriptive term ''fresh'' in accordance with § 381.129(b)(6)(i) of this subchapter.

(xxvii) The use of the descriptive Term *frozen* as required by § 381.129(b)(6)(ii) of this subchapter.

[60 FR 67457, Dec. 29, 1995, as amended at 61 FR 66201, Dec. 17, 1996]

§ 381.134 Requirement of formulas.

Copies of each label submitted for approval, shall when the Administrator requires in any specific case, be accompanied by a statement showing, by their common or usual names, the kinds and percentages of the ingredients comprising the poultry product and by a statement indicating the method or preparation of the product with respect to which the label is to be used. Approximate percentages may be given in cases where the percentages of ingredients may vary from time to time, if the limits of variation are stated.

[37 FR 9706, May 16, 1972, as amended at 39 FR 4569, Feb. 5, 1974; 59 FR 45196, Sept. 1, 1994. Redesignated at 60 FR 67457, Dec. 29, 1995]

§ 381.136 Affixing of official identification.

(a) No official inspection legend or any abbreviation or other simulation thereof may be affixed to or placed on or caused to be affixed to or placed on any poultry product or container thereof, except by an inspector or under the supervision of an inspector or other person authorized by the Administrator, and no container bearing any such legend shall be filled except under such supervision.

(b) No official inspection legend shall be used on any poultry product or other article which does not qualify for such mark under the regulations.

§ 381.137 Evidence of labeling and devices approval.

No inspector shall authorize the use of any device bearing any official inspection legend unless he or she has on file evidence that such device has been approved in accordance with the provisions of this subpart.

[60 FR 67458, Dec. 29, 1995]

§ 381.138 Unauthorized use or disposition of approved labeling or devices.

(a) Labeling and devices approved for use pursuant to § 381.115 shall be used only for the purpose for which approved, and shall not be disposed of from the official establishment for which approved except with written approval of the Administrator. Any unauthorized use or disposition of approved labeling or devices bearing official inspection marks is prohibited and may result in cancellation of the approval.

(b) Labeling and containers bearing any official inspection marks, with or without the official establishment number, may be transported from one official establishment to any other official establishment, only if such shipments are made with the prior authorization of the inspector in charge at point of origin, who will notify the inspector in charge at destination concerning the date of shipment, quantity, and type of labeling material involved. Approved labeling and containers may be moved without restriction under this part between official establishments operated by the same person if such labeling and containers are approved for use at all such establishments. No such material shall be used at the establishment to which it is shipped unless such use conforms with the requirements of this subpart.

§ 381.139 Removal of official identifications.

(a) Every person who receives any poultry product in containers which bear any official inspection legend shall remove or deface such legend or destroy the containers upon removal of such articles from the containers.

(b) No person shall alter, detach, deface, or destroy any official identifications prescribed in subpart M that were applied pursuant to the regulations, unless he is authorized to do so by an inspector or this section; and no person shall fail to use any such official identification when required by this part.

§ 381.140 Relabeling poultry products.

When it is claimed by the operator of an official establishment that some of its labeled poultry product, which has been transported to a location other than an official establishment, is in need of relabeling because the labeling has become mutilated or damaged, or for some other reason needs relabeling, the requests for relabeling the poultry product shall be sent to the Administrator and accompanied with a statement of the reasons therefor and the quantity of labeling required. Labeling material intended for relabeling inspected and passed product shall not be transported from an official establishment until permission has been received from the Administrator. The relabeling of inspected and passed product with official labels shall be done under the supervision of an inspector pursuant to the regulations in part 362 of this chapter. The establishment shall reimburse the Inspection Service for any cost involved in supervising the relabeling of such product as provided in said regulations.

§§ 381.141–381.143 [Reserved]

§ 381.144 Packaging materials.

(a) Edible products may not be packaged in a container which is composed in whole or in part of any poisonous or deleterious substances which may render the contents adulterated or injurious to health. All packaging materials must be safe for the intended use within the meaning of section 409 of the Federal Food, Drug, and Cosmetic Act, as amended (FFDCA).

(b) Packaging materials entering the official establishment must be accompanied or covered by a guaranty, or statement of assurance, from the packaging supplier under whose brand name

and firm name the material is marketed to the official establishment. The guaranty shall state that the material's intended use complies with the FFDCA and all applicable food additive regulations. The guaranty must identify the material, e.g., by the distinguishing brand name or code designation appearing on the packaging material shipping container; must specify the applicable conditions of use, including temperature limits and other pertinent limits specified under the FFDCA and food additive regulations; and must be signed by an authorized official of the supplying firm. The guaranty may be limited to a specific shipment of an article, in which case it may be part of or attached to the invoice covering such shipment, or it may be general and continuing, in which case, in its application to any article or other shipment of an article, it shall be considered to have been given at the date such article was shipped by the person who gives the guaranty. Guaranties consistent with the Food and Drug Administration's regulations regarding such guaranties (21 CFR 7.12 and 7.13) will be acceptable. The management of the establishment must maintain a file containing guaranties for all food contact packaging materials in the establishment. The file shall be made available to Program inspectors or other Department officials upon request. While in the official establishment, the identity of all packaging materials must be traceable to the applicable guaranty.

(c) The guaranty by the packaging supplier will be accepted by Program inspectors to establish that the use of material complies with the FFDCA and all applicable food additive regulations.

(d) The Department will monitor the use of packaging materials in official establishments to assure that the requirements of paragraph (a) of this section are met, and may question the basis for any guaranty described under paragraph (b) of this section. Official establishments and packaging suppliers providing written guaranties to those official establishments will be permitted an opportunity to provide information to designated Department officials as needed to verify the basis for any such guaranty. The required information will include, but is not limited to, manufacturing firm's name, trade name or code designation for the material, complete chemical composition, and use. Selection of a material for review does not in itself affect a material's acceptability. Materials may continue to be used during the review period. However, if information requested from the supplier is not provided within the time indicated in the request—a minimum of 30 days—any applicable guaranty shall cease to be effective and approval to continue using the specified packaging material in official establishments may be denied. The Administrator may extend this time where reasonable grounds for extension are shown, as, for example, where data must be obtained from suppliers.

(e) The Administrator may disapprove for use in official establishments packaging materials whose use cannot be confirmed as complying with the FFDCA and applicable food additive regulations. Before approval to use a packaging material is finally denied by the Administrator, the affected official establishment and the supplier of the material shall be given notice and the opportunity to present their views to the Administrator. If the official establishment and the supplier do not accept the Administrator's determination, a hearing in accordance with applicable rules of practice will be held to resolve such dispute. Approval to use the materials pending the outcome of the presentation of views or hearing shall be denied if the Administrator determines that such use may present an imminent hazard to public health.

(f) Periodically, the Administrator will issue to inspectors a listing, by distinguishing brand name or code designation, of packaging materials that have been reviewed and that fail to meet the requirements of paragraph (a) of this section. Listed materials will not be permitted for use in official establishments. If a subsequent review of any material indicates that it meets the requirements of paragraph (a), the material will be deleted from the listing.

(g) Nothing in this section shall affect the authority of Program inspectors to refuse a specific material if he/she determines the material may render products adulterated or injurious to health.

[49 FR 2236, Jan. 19, 1984]

Subpart O—Entry of Articles Into Official Establishments; Processing Inspection and Other Reinspections; Processing Requirements

§ 381.145 Poultry products and other articles entering or at official establishments; examination and other requirements.

(a) No poultry product (including poultry broth for use in any poultry product in any official establishment) may be brought into any official establishment unless it has been processed in the United States only in an official establishment or imported from a foreign country listed in § 381.196(b), and inspected and passed, in accordance with the regulations; and unless the container of such product is marked so as to identify the product as so inspected and passed, in accordance with § 381.115 or § 381.205, except that poultry products inspected and passed and identified as such under the laws of an ''at least equal'' State or territory listed in § 381.187 may be brought into any official establishment solely for storage and distribution therefrom without repackaging, relabeling, or processing in such establishment. No carcass, part thereof, meat or meat food product of cattle, sheep, swine, goats, or equines may be brought into an official establishment unless it has been prepared in the United States only in an official meat packing establishment, or imported, and inspected and passed, in accordance with the Federal Meat Inspection Act, and the regulations under such Act (Subchapter A of this chapter) and is properly marked as so inspected and passed; or has been inspected and passed and is identified as such in accordance with the requirements of the law and regulations of a State not designated in § 331.2 of this chapter; or is present in the official establishment by reason of an exemption allowed in the Federal Meat Inspection Act and the regulations under such Act (Subchapter A of this chapter) or the law and regulations of a State not so designated. However, such exempted articles may enter only under conditions approved by the Administrator in specific cases, including but not limited to, complete separation of inspected poultry products and processing and other operations with respect thereto from the exempted articles and operations with respect thereto, complete cleanup of facilities and equipment between processing of inspected poultry products and the exempted articles and no commingling of inspected and exempted articles in receiving, holding or storage areas.

(b) All poultry products and all carcasses, parts thereof, meat and meat food products of cattle, sheep, swine, goats, or equines which enter any official establishment shall be identified by the operator of the official establishment at the time of receipt at the official establishment. All poultry products, and all carcasses, parts thereof, meat and meat food products of such animals, which are processed or otherwise handled at any official establishment shall be subject to examination by an inspector at the official establishment in such manner and at such times as may be deemed necessary by the inspector in charge to assure compliance with the regulations. Upon such examination, if any such article or portion thereof is found to be adulterated, such article or portion shall, in the case of poultry products, be condemned and disposed of as prescribed in § 381.95, unless by reprocessing they may be made not adulterated, and shall, in the case of such other articles be disposed of according to applicable law.

Such examination may be accomplished through use of statistically sound sampling plans that assure a high level of confidence. The inspector in charge shall designate the type of plan and the program employee shall select the specific plan to be used in

accordance with instructions issued by the Administrator.[1]

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

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

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

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

(4) Detailed information concerning the manner in which the system will function. Such information should include, but not necessarily be limited to, questions of raw material control, the critical check or control points, the nature and frequency of tests to be made, the nature of charts and other records that will be used, the length of time such charts and records will be maintained in the custody of the official establishment, the nature of deficiencies the quality control system is designed to identify and control, the parameters of limits which will be used and the points at which corrective action will occur, and the nature of such corrective action—ranging from the least to most severe: *Provided,* That subsequent to approval of the total plant quality control system by the Administrator, the official establishment may produce a new product for test marketing provided labeling for the product has been approved by the Administrator, the inspector in charge has determined that the procedures for preparing the product will assure that all Federal requirements are met, and the production for test marketing does not exceed 6 months. Such new product shall not be produced at that establishment after the 6-month period unless approval of the quality control system for that product has been received from the Administrator.

(d)–(e) [Reserved]

(f) *Labeling Logo.* Owners and operators of official establishments having a

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

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 subparts M and N of this part.

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

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

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

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

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

(4) If approval of a quality control system for irradiation facilities, as specified in section 381.149 of this subpart, has been terminated in accordance with the provisions of this section, a request for approval of the same or a modified quality control system will be evaluated by the Administrator upon receipt.

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

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

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

(iii) All immediate containers of products prepared and packaged shall bear code marks that are unique to any period of production beyond the 8 hours

of inspection. The form of such code marks will remain constant from day to day, and a facsimile of the code marks and their meaning shall be provided to the inspector.

(2) *Application.* Applications shall be submitted to the Regional Director and shall specify how the conditions in § 381.145(h)(1) have been or will be met.

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

(i) To ensure the safe use of preparations used in poultry scald water, the label or labeling on containers of such preparations shall bear adequate directions to ensure use in compliance with any limitations prescribed in 21 CFR Chapter I, Subchapter A or Subchapter B or 9 CFR Chapter III, Subchapter A or Subchapter E.

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

[37 FR 9706, May 16, 1972, as amended at 45 FR 54323, Aug. 15, 1980; 46 FR 48904, Oct. 5, 1981; 50 FR 6, Jan. 2, 1985; 51 FR 32304, Sept. 11, 1986; 57 FR 43598, Sept. 21, 1992; 62 FR 45026, Aug. 25, 1997; 62 FR 54759, Oct. 22, 1997; 64 FR 72175, Dec. 23, 1999; 65 FR 34390, May 30, 2000]

§ 381.146 Sampling at official establishments.

Inspectors may take, without cost to the Department, such samples as are necessary of any poultry product, or other article for use as an ingredient of any poultry product, at any official establishment to determine whether it complies with the requirements of the regulations.

§ 381.148 Processing and handling requirements for frozen poultry products.

Procedures with respect to processing of frozen ready-to-heat-and-eat poultry products or stuffed ready-to-roast poultry shall be in accordance with sound operating practices and carried out in a manner which will assure freedom from adulteration of the products. Products to be frozen shall be moved into the freezer promptly under such supervision by an inspector as is necessary to assure preservation of the products by prompt and efficient freezing. Adequate freezing facilities shall be provided within the official establishment where products to be frozen are prepared, except that, upon written request, and under such conditions as may be prescribed by the Administrator in specific cases, such products may be moved from the official establishment prior to freezing: *Provided,* That the official establishment and freezer are so located and the necessary arrangements are made so that the Inspection Service will have access to the freezing room and adequate opportunity to determine that the products are being properly handled and frozen.

§ 381.150 Requirements for the production of fully cooked poultry products and partially cooked poultry breakfast strips.

(a) Fully cooked poultry products must be produced using processes ensuring that the products meet the following performance standards:

(1) *Lethality.* A 7-$\log_{10}$ reduction of *Salmonella* or an alternative lethality that achieves an equivalent probability that no viable *Salmonella* organisms remain in the finished product, as well as the reduction of other pathogens and their toxins or toxic metabolites necessary to prevent adulteration, must be demonstrated to be achieved throughout the product. The lethality process must include a cooking step. Controlled intermediate step(s) applied to raw product may form part of the basis for the equivalency.

(2) *Stabilization.* There can be no multiplication of toxigenic microorganisms such as *Clostridium botulinum,* and no more than a 1 $\log_{10}$ multiplication of *Clostridium perfringens* within the product.

(b) Partially cooked poultry breakfast strips must be produced using processes ensuring that the products meet the performance standard listed in paragraph (a)(2) of this section. Labeling for these products must comply with § 381.125. In addition, the statement ''Partially Cooked: For Safety,

Cook Until Well Done'' must appear on the principal display panel in letters no smaller than ½ the size of the largest letter in the product name. Detailed cooking instructions shall be provided on the immediate container of the products.

(c) For each product produced using a process other than one conducted in accordance with the Hazard Analysis and Critical Control Point (HACCP) system requirements in part 417 of this chapter, an establishment must develop and have on file, available to FSIS, a process schedule, as defined in § 381.1(b). Each process schedule must be approved in writing by a process authority for safety and efficacy in meeting the performance standards established for the product in question. A process authority must have access to an establishment in order to evaluate and approve the safety and efficacy of each process schedule.

(d) Under the auspices of a processing authority, an establishment must validate new or altered process schedules by scientifically supportable means, such as information gleaned from the literature or by challenge studies conducted outside the plant.

[64 FR 746, Jan. 6, 1999]

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

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

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

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

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

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

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

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

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

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

[38 FR 34456, Dec. 14, 1973]

§ 381.152 Preparation in an official establishment of articles not for human food.

(a) *Requirements applicable when prepared in an edible products department.* When an article (including, but not being limited to, animal food) that is not for use as human food is prepared in any room or compartment, in an official establishment where poultry

[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.

products are prepared or handled (such room or compartment being herein referred to as an ''edible products department''), sufficient space and equipment shall be provided to assure that the preparation of the article in no way interferes with the preparation or other handling of the poultry products. Where necessary, separate equipment shall be provided for the preparation of the article. To assure the maintenance of the requisite sanitary conditions in the edible products department, the operations incident to the preparation of the article shall be subject to the same sanitary requirements as apply to the handling of poultry products in the edible products department. Preparation of the article shall be limited to those hours during which the official establishment operates under the supervision of an inspector. The ingredients used in the preparation of the article shall, unless otherwise approved by the Administrator in specific cases, be such as may be used in the preparation of a poultry product. The article may be stored in, and distributed from, the edible products department if the article is properly identified.

(b) *Requirements applicable when prepared in an inedible products department.* When an article (including, but not being limited to, animal food) that is not for use as human food, is prepared in any part of an official establishment other than an edible products department (such part of the establishment being herein referred to as the ''inedible products department''), the area in which such article is prepared shall be distinctly separated from all edible products departments. Poultry products and inedible products may be brought from any edible products department into any inedible products department, but no poultry product or inedible product may be brought from an inedible products department into an edible products department except that any such articles as are in sealed containers or are handled under conditions prescribed or approved by the Administrator in specific cases may be brought into an edible products department. Diseased carcasses or diseased parts of any carcass shall not be used in the preparation of any animal food unless they have been treated in the manner prescribed in § 381.95(a). Trucks or containers used for the transportation of poultry products or inedible products into an inedible products department shall be cleaned before being returned to or brought into an edible products department. Sufficient space shall be allotted and adequate equipment and facilities provided so that the preparation of the article does not interfere with the preparation of poultry products or the maintenance of the requisite sanitary conditions in the official establishment. The preparation of any such article shall be subject to supervision by an inspector.

(c) *Containers to be labeled.* The immediate container of any such article that is prepared in an official establishment shall be conspicuously labeled so as to distinguish it from human food. Such articles are also subject to the requirements under the Federal Food, Drug, and Cosmetic Act.

§ 381.153 Accreditation of chemistry laboratories.

(a) *Definitions:*

Accreditation—Determination by FSIS that a laboratory is qualified to analyze official samples of product subject to regulations in this subchapter and subchapter A 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 subchapter A 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.

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.

AOAC methods—Methods of chemical analysis, Chapter 39, Association of Official Analytical Chemists 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 multipled 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 of 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 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 systematic laboratory difference CUSUM (CUSUM–P)—monitors how consistently an accredited laboratory gets numerically greater results than the comparison mean;

(2) Negative systematic laboratory difference CUSUM (CUSUM–N)—monitors how consistently an accredited laboratory gets numerically smaller results than the comparison mean;

(3) Variability CUSUM (CUSUM–V)—monitors the average ''total 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.

[1] 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, 2200 Wilson Boulevard, Suite 400, Arlington, Virginia 22201. 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.

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 an inspector or inspection service 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 analyte)

Moisture	Protein [1]	Fat [2]	Salt [3]
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
Volatile Nitrosamine [2]	5 ppb	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 poultry and poultry 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 by 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 (b)(1) by January 13, 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 the 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 analyses of moisture, protein, fat, and salt content of poultry and poultry 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 AOAC 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

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

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 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, 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

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

[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 Analytical Chemists, Inc., 2200 Wilson Boulevard, Suite 400, Arlington, Virginia 22201.

criteria presented in this paragraph (b)(3)(ix).[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 2.4,
−2.0, if the standardized difference is less than −1.6,

or

the standardized difference minus 0.4, if the standardized difference lies between −1.6 and 2.4, inclusive.

(*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, 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:

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

[6] *See* footnote 3.

(*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 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 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 of 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 poultry and poultry 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 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 by 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 (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 the 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 poultry and poultry 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 and either the supervisor or the analyst assigned to analyze the sample has 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) of this section will only be determined when six or more analytical results with associated comparison means at or above the logarithm of the minimum proficiency level are available.] 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]

[7] All statistical computations are rounded to the nearest tenth, unless 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 to $1-(2.5/d)^4$.

(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 when there is any change in the laboratory's ownership, 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 on-site 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 below.[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

[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

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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, 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.

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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.

[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.

(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 Science Laboratory by certified mail or private carrier or, as an alternative, to an accredited laboratory accredited for this specific chemical residue. Mailing expenses 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 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 judgment of the inspector, 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

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

[15] *See* footnote 11.

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 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.

[16] *See* footnote 11.

[17] *See* footnote 13.

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

(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 will 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, unless written permission is granted by the Administrator to exceed the time limit.

(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) 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 2192, Jan. 20, 1987, as amended at 58 FR 65264, 65266–65268, Dec. 13, 1993; 59 FR 33642, 33643, June 30, 1994; 59 FR 66448, Dec. 27, 1994; 60 FR 10305, Feb. 24, 1995]

Subpart P—Definitions and Standards of Identity or Composition

§ 381.155 General.

(a) *Authorization to establish specifications.* (1) The Administrator is authorized to establish specifications or definitions and standards of identity or composition, covering the principal constituents of any poultry product with respect to which a specified name of the product or other labeling terminology may be used, whenever he determines such action is necessary to prevent sale of the product under false or misleading labeling. Further, the Administrator is authorized to prescribe definitions and standards of identity or composition for poultry products whenever he determines such action is otherwise necessary for the protection of the public. The requirements of this subpart are hereby found to be necessary for these purposes and standards are hereby established as set forth in this subpart.

(2) Where cooked poultry meat is specified in this subpart as an ingredient of poultry products, this means poultry meat derived from poultry

processed, cooked, and cooled in a manner approved by the Administrator in specific cases without use of liquid or moisture in direct contact with the poultry meat following the cooking and cooling of the poultry.

(3) If, following cooking and cooling of poultry meat to be used in poultry products, liquid or moisture is used in direct contact with such poultry meat and the percentage of solids, excluding salt, in the poultry meat is found to be below 34 percent when such poultry meat is tested by acceptable methods, the percentage of poultry meat required by this section for any poultry product shall be increased in proportion to the deficiency, or the meat shall be so processed as to raise the solids content, excluding salt, to 34 percent. The official establishment shall furnish adequate facilities for such testing.

(b) Any binder or antimicrobial agent that has been found to be safe and suitable by the Food and Drug Administration and the Food Safety and Inspection Service may be used in the production of poultry products with standards of identity in this part, where the product standards and applicable Federal regulations already permit the use of these types of ingredients.

[37 FR 9706, May 16, 1972, as amended at 68 FR 22578, Apr. 29, 2003]

§ 381.156 Poultry meat content standards for certain poultry products.

Poultry products with labeling terminology as set forth in Table I shall comply with the specifications for percent light meat and percent dark meat set forth in said table.

TABLE I

Label terminology	Percent light meat	Percent dark meat
Natural proportions	50–65	50–35.
Light or white meat	100	0.
Dark meat	0	100.
Light and dark meat	51–65	49–35.
Dark and light meat	35–49	65–51.
Mostly white meat	66 or more	34 or less.
Mostly dark meat	34 or less	66 or more.

[37 FR 9706, May 16, 1972, as amended at 39 FR 4569, Feb. 5, 1974]

§ 381.157 Canned boned poultry and baby or geriatric food.

(a) Canned boned poultry shall, unless otherwise specified in this section, be prepared from cooked deboned poultry meat and may contain skin and fat not in excess of natural whole carcass proportions. Gelatin, stabilizers, or similar solidifying or emulsifying agents shall not be added to product labeled ''Boned (Kind)—Solid Pack,'' but may be added in quantities not in excess of a total of 0.5 percent of the total ingredients in the preparation of other canned boned poultry products and in such cases the common name of the substance shall be included in the name of the product, e.g., ''Boned Chicken with Broth—Gelatin Added.''

(b) Canned boned poultry, except poultry within paragraph (c) of this section, shall meet the requirements set forth in Table II. The percentages in Table II shall be calculated on the basis of the total ingredients used in the preparation of the product.

(c) Canned boned poultry with natural juices (Boned (Kind) with natural juices) shall be prepared from either raw boned poultry or a mixture of raw boned poultry and cooked boned poultry and shall have no liquid added during the preparation of the product.

(d) Canned shredded poultry (Shredded Kind), consists of poultry meat reduced to a shredded appearance, from the kind of poultry indicated, with meat, skin, and fat not in excess of the natural whole carcass proportions. Canned shredded poultry from specific parts may include skin or fat in excess of the proportions normally found on a whole carcass, but not in excess of the proportions of skin and fat normal to the particular part or parts; and such product shall be labeled in accordance with § 381.117(d).

(e) Canned boned poultry shall be prepared as set forth in Table II, items 1, 2, 3, or 4, whichever is applicable.

TABLE II

Product name	Minimum percent cooked, deboned poultry meat of kind indicated, with skin, fat, and seasoning	Maximum percent liquid that may be added [1]
1. Boned (Kind)—solid pack	95	5
2. Boned (Kind)	90	10
3. Boned (Kind) with broth [2]	80	20
4. Boned (Kind) (——) percent broth [2, 3]	50	50

[1] Liquid may be in the form of, but is not limited to, broth or extractives.
[2] Alternatively, product may be prepared from raw boned poultry in combination with cooked boned poultry so long as the product complies with the specified standard.
[3] Total amount of liquid added shall be included in the name of the product; e.g., ''Boned Chicken with 25 percent broth.''

(f) Poultry products intended for infant or geriatric use and represented as having a ''high meat'' content shall contain not less than 18.75 percent cooked, deboned poultry meat of the kind indicated, with seasoning.

TABLE IIA

Product name	Minimum percent cooked, deboned, poultry meat of kind indicated, with seasoning	Maximum percent liquid that may be added [1]
1. Strained or chopped (Kind) with broth [2, 3]	43	57
2. High meat dinner [3]	18.75	

[1] Liquid may be in the form of, but not limited to, broth or extractives.
[2] Alternatively, product may be prepared from raw boned poultry meat in combination with cooked bone poultry meat so long as the product complies with the specified standard.
[3] Label must indicate in some manner that product is for infant or geriatric servings.

[37 FR 9706, May 16, 1972, as amended at 39 FR 4569, Feb. 5, 1974]

§ 381.158 Poultry dinners (frozen) and pies.

Poultry dinners (frozen) and pies shall meet the requirements set forth in Table III of this section and the percentage or weight specified therein shall be calculated on the basis of total ingredients used in the preparation of the poultry product.

TABLE III

	Minimum cooked deboned poultry meat of kind indicated		Minimum raw deboned poultry meat of kind indicated	
	Percent	Weight	Percent	Weight
(Kind) Pies	14	or 1⅛ oz. per 8-oz. pie [1]	25	or 2 oz. per 8-oz. pie. [1]
(Kind) Dinners	18	or 2 oz. [2, 3]		

[1] 14 percent or 1⅛ oz., whichever is greater; or 25 percent or 2 oz., whichever is greater.
[2] Excluding weight of appetizers, desserts, etc.
[3] 18 percent or 2 oz., whichever is greater. A minimum of 45 percent, or 5 ounces per dinner, whichever is greater, of cooked poultry including bone and breading may be used in lieu of minimum 18 percent or 2 ounces of cooked deboned poultry meat and the cooked poultry including bone and breading shall not contain more than 30 percent breading.

§ 381.159 Poultry rolls.

(a) Binders or extenders may be added in accordance with a regulation in this subchapter, in 9 CFR Chapter III, Subchapter E, or in 21 CFR Chapter I, Subchapter A or Subchapter B. In addition to the binders referred to in the preceding sentence, the following substances are permitted for use as binders in poultry rolls: transglutaminase enzyme at up to 65 ppm. When binding agents are added in excess of 3 percent for cooked rolls and 2 percent for raw rolls, the common name of the agent or the term ''Binders Added'' shall be included in the name of the product; e.g., ''Turkey Roll-Gelatin Added.''

(b) With respect to heat processed rolls, 2 percent or less liquid based on the weight of the finished product without liquid may remain with or be returned to product labeled as ''(Kind) Roll.''

(c) Heat processed rolls which have more than 2 percent liquid remaining with or returned to the product shall be labeled as ''(Kind) Roll with Natural Juices.'' If more than 2 percent of any liquid other than natural cookout juices is added, the product must be labeled to indicate that fact; e.g., ''Turkey Roll with Broth.'' Liquid shall not be returned or added to product within this paragraph graph in excess of the amount normally cooked out during preparation.

[37 FR 9706, May 16, 1972, as amended at 55 FR 34684, Aug. 24, 1990; 66 FR 54916, Oct. 31, 2001]

§ 381.160 (Kind) burgers; (Kind) patties.

Such product consists of 100 percent poultry of the kind indicated, with skin and fat not in excess of natural proportions. Product containing fillers or binders shall be named ''(Kind) Patties.''

§ 381.161 "(Kind) A La Kiev."

Such product consists of poultry meat of the kind indicated, stuffed with butter which may be seasoned and the product may be wrapped in sufficient skin to cover the meat. It may be dipped in batter, fried, and frozen.

§ 381.162 "(Kind) steak or fillet."

Such product consists of a boneless slice or strip of poultry meat of the kind indicated.

§ 381.163 "(Kind) baked" or "(Kind) roasted."

Such product consists of ready-to-cook poultry of the kind indicated, that has been cooked in dry source heat, e.g., oven roasted or oven baked.

§ 381.164 "(Kind) barbecued."

Such product consists of ready-to-cook poultry of the kind indicated, that has been cooked in dry heat and basted with a seasoned sauce.

§ 381.165 "(Kind) barbecued prepared with moist heat."

Such product consists of ready-to-cook poultry of the kind indicated that has been cooked by the action of moist heat in a barbecue sauce.

§ 381.166 Breaded products.

''Breaded'' is a term applicable to any poultry product which is coated with breading or a batter and breading in an amount not to exceed 30 percent of the weight of the finished breaded product.

§ 381.167 Other poultry dishes and specialty items.

Poultry dishes and specialty items listed in Table IV of this paragraph shall meet the requirements set forth in said table, irrespective of the type of packaging, and the percentages in Table IV shall be calculated on a ready-to-serve basis, except that soup bases in institutional packs which are prepared for sale to institutional users shall have a minimum of 15 percent cooked deboned poultry meat based on the weight of the soup base product.

TABLE IV

Product name [1]	Minimum percent cooked deboned poultry meat of kind indicated	Minimum percent cooked poultry of kind indicated, indicating bone
(Kind) Ravioli	2	.....
(Kind) Soup	2	.....
Chop Suey with (Kind)	2	.....
(Kind) Chop Suey	4	.....
(Kind) Chow Mein without noodles	4	.....
(Kind) Tamales	6	.....
Noodles or Dumplings with (Kind) [2]	6	.....
(Kind) Stew	12	.....
(Kind) Fricassee of Wings	.....	40
(Kind) Noodles or Dumplings [2]	15	30
(Kind) with Vegetables	15	.....
Gravy with sliced (Kind)	15	.....
(Kind) Tetrazzini	15	.....
(Kind) chili with beans	17	.....
Creamed (Kind)	20	.....
(Kind) Cacciatore	20	40
(Kind) Fricassee	20	40
(Kind) A-La-King	20	.....
(Kind) croquettes	25	.....
Slice (Kind) with Gravy and Dressing	25	.....
(Kind) Salad [3]	25	.....
(Kind) chili	28	.....
(Kind) Hash	30	.....
Sliced (Kind) with Gravy	35	.....
Minced (Kind) Barbecue	40	.....

[1] The product name may contain other appropriate descriptive terms such as ''noodle''; e.g., ''Chicken Noodle Soup.''
[2] This standard also applies to products named (Kind) with rice or similar starches.
[3] The 25 percent-standard listed includes poultry meat plus proportions of skin and fat natural to the poultry used.

[37 FR 9706, May 16, 1972, as amended at 39 FR 4569, Feb. 5, 1974]

§ 381.168 Maximum percent of skin in certain poultry products.

The poultry products listed in Table V shall have not more than the percent of skin specified in the table, when raw and when cooked.

TABLE V

Product name	Percent skin	
	Raw	Cooked
Boneless Turkey Breast or Boneless Turkey Breast Roll	14	

TABLE V—Continued

Product name	Percent skin	
	Raw	Cooked
Boneless Turkey Thigh or Boneless Turkey Thigh Roll	8	
Boneless Turkey or Turkey Roll	15	
Boneless Chicken Breast or Boneless Chicken Breast Roll	18	20
Boneless Chicken or Chicken Roll	20	25

§ 381.169 Ready-to-cook poultry products to which solutions are added.

(a) Butter alone, or solutions of poultry broth, poultry stock, water, or edible fats, or mixtures thereof, in which are included functional substances such as spices, flavor enhancers, emulsifiers, phosphates, coloring materials, or other substances, approved by the Administrator in specific cases, may be introduced by injection into the thick muscles (breast and legs) of ready-to-cook poultry carcasses and may be introduced by injection or marinating into any separate bone-in part therefrom, for the purpose of providing a basting medium or similar function. The ingredients of the added materials and the manner of addition to the products must be found acceptable by the Administrator, in all cases. The introduction of the added materials shall increase the weight of the processed product by approximately 3 percent over the weight of the raw product after washing and chilling in compliance with § 381.66. The weight of the added materials introduced into the poultry products as provided in this paragraph shall be included as part of the weight of the poultry for purposes of the net weight labeling provisions in § 381.121(b).

(b) A raw poultry product, into which added materials are introduced as provided in paragraph (a) of this section must be labeled with a conspicuous, legible, and descriptive name, including terms that concisely describe the method of addition and function of the added material. All major terms in the product name must be printed with the same prominence, except that the words which describe the function of the added materials (such as ''Injected for Flavored Basting'') may be more prominent, provided this does not detract from the conspicuousness of the other terms in the product name (such as ''Young Turkey''). The label must also bear a statement, in bold type, immediately below and adjacent to the product name, listing the common or usual names of the added materials in descending order of predominance. The first part of this statement must consist of terms adequate to inform consumers about the amount and manner of introduction of the solution (such as ''Injected with approximately 3 percent of a solution of ————''), and must be printed at least one-fourth the size of the most prominent letter in the product name, with a minimum size of one-fourth inch for a ready-to-cook turkey and proportionately smaller for other poultry products. The remainder of the solution ingredients shall be declared in type at least one-eighth inch in height. The entire statement must be printed in a color that contrasts with the background and be displayed on the principal display panel.

(c) Approval for use of a label for product under this section depends upon the ability of the processor to control the finished product, within a range of three-tenths of 1 percent accuracy, so that the average percent of basting material in each outgoing lot is not greater than 3.3 percent or less than 2.7 percent of basting material when tested by an approved plant control procedure would be in compliance. As used in this section, ''a lot'' may be any reasonable portion of production designated by the operator of the official establishment, with a maximum of an entire shift's production from one production line. The control procedures to be eligible for approval by the Administrator must:

(1) Assure compliance with all labeling requirements.

(2) Control the variability of the amount of added approved solution within the limits defined above.

(3) Provide for the disposition in accordance with the regulations of all products not in compliance with this section.

(4) Incorporate a system of raw weight identification of a sufficient

number of poultry and/or poultry parts to allow effective monitoring of the system by Federal inspectors and official establishment employees.

[37 FR 9706, May 16, 1972, as amended at 39 FR 36000, Oct. 7, 1974]

§ 381.170 Standards for kinds and classes, and for cuts of raw poultry.

(a) The following standards specify the various classes of the specified kinds of poultry, and the requirements for each class:

(1) *Chickens*—(i) *Rock Cornish game hen or Cornish game hen.* A Rock Cornish game hen or Cornish game hen is a young immature chicken (usually 5 to 6 weeks of age) weighing not more than 2 pounds ready-to-cook weight, which was prepared from a Cornish chicken or the progeny of a Cornish chicken crossed with another breed of chicken.

(ii) *Rock Cornish fryer, roaster, or hen.* A Rock Cornish fryer, roaster, or hen is the progeny of a cross between a purebred Cornish and a purebred Rock chicken, without regard to the weight of the carcass involved; however, the term ''fryer,'' ''roaster,'' or ''hen'' shall apply only if the carcasses are from birds with ages and characteristics that qualify them for such designation under paragraph (a)(1) (iii) or (iv) of this section.

(iii) *Broiler or fryer.* A broiler or fryer is a young chicken (usually under 13 weeks of age), of either sex, that is tender-meated with soft, pliable, smooth-textured skin and flexible breastbone cartilage.

(iv) *Roaster or roasting chicken.* A bird of this class is a young chicken (usually 3 to 5 months of age), of either sex, that is tender-meated with soft, pliable, smooth-textured skin and breastbone cartilage that may be somewhat less flexible than that of a broiler or fryer.

(v) *Capon.* A capon is a surgically unsexed male chicken (usually under 8 months of age) that is tender-meated with soft, pliable, smooth-textured skin.

(vi) *Hen, fowl, or baking or stewing.* A bird of this class is a mature female chicken (usually more than 10 months of age) with meat less tender than that of a roaster, or roasting chicken and nonflexible breastbone tip.

(vii) *Cock or rooster.* A cock or rooster is a mature male chicken with coarse skin, toughened and darkened meat, and hardened breastbone tip.

(2) *Turkeys*—(i) *Fryer-roaster turkey.* A fryer-roaster turkey is a young immature turkey (usually under 16 weeks of age), of either sex, that is tender-meated with soft, pliable, smooth-textured skin, and flexible breastbone cartilage.

(ii) *Young turkey.* A young turkey is a turkey (usually under 8 months of age) that is tender-meated with soft, pliable, smooth-textured skin, and breastbone cartilage that is somewhat less flexible than in a fryer-roaster turkey. Sex designation is optional.

(iii) *Yearling turkey.* A yearling turkey is a fully matured turkey (usually under 15 months of age) that is reasonably tender-meated and with reasonably smooth-textured skin. Sex designation is optional.

(iv) *Mature turkey or old turkey* (*hen or tom*). A mature or old turkey is an old turkey of either sex (usually in excess of 15 months of age) with coarse skin and toughened flesh.

(3) *Ducks*—(i) *Broiler duckling or fryer duckling.* A broiler duckling or fryer duckling is a young duck (usually under 8 weeks of age), of either sex, that is tender-meated and has a soft bill and soft windpipe.

(ii) *Roaster duckling.* A roaster duckling is a young duck (usually under 16 weeks of age), of either sex, that is tender-meated and has a bill that is not completely hardened and a windpipe that is easily dented.

(iii) *Mature duck or old duck.* A mature duck or an old duck is a duck (usually over 6 months of age), of either sex, with toughened flesh, hardened bill, and hardened windpipe.

(4) *Geese*—(i) *Young goose.* A young goose may be of either sex, is tender-meated, and has a windpipe that is easily dented.

(ii) *Mature goose or old goose.* A mature goose or old goose may be of either sex and has toughened flesh and hardened windpipe.

(5) *Guineas*—(i) *Young guinea.* A young guinea may be of either sex, is

tender-meated, and has a flexible breastbone cartilage.

(ii) *Mature guinea or old guinea.* A mature guinea or an old guinea may be of either sex, has toughened flesh, and a hardened breastbone.

(b) The following standards specify the requirements for the specified cuts of poultry:

(1) ''Breasts'' shall be separated from the back at the shoulder joint and by a cut running backward and downward from that point along the junction of the vertebral and sternal ribs. The ribs may be removed from the breasts, and the breasts may be cut along the breastbone to make two approximately equal halves; or the wishbone portion, as described in paragraph (b)(3) of this section, may be removed before cutting the remainder along the breastbone to make three parts. Pieces cut in this manner may be substituted for lighter or heavier pieces for exact weight-making purposes and the package may contain two or more of such parts without affecting the appropriateness of the labeling as e.g., ''chicken breasts.'' Neck skin shall not be included with the breasts, except that ''turkey breasts'' may include neck skin up to the whisker.

(2) ''Breasts with ribs'' shall be separated from the back at the junction of the vertebral ribs and back. Breasts with ribs may be cut along the breastbone to make two approximately equal halves; or the wishbone portion, as described in paragraph (b)(3) of this section, may be removed before cutting the remainder along the breastbone to make three parts. Pieces cut in this manner may be substituted for lighter or heavier pieces for exact weight-making purposes and the package may contain two or more of such parts without affecting the appropriateness of the labeling as ''breasts with ribs.'' Neck skin shall not be included, except that ''turkey breasts with ribs'' may include neck skin up to the whisker.

(3) ''Wishbones'' (Pulley Bones), with covering muscle and skin tissue, shall be severed from the breast approximately halfway between the end of the wishbone (hypocledium) and front point of the breastbone (cranial process of the sternal crest) to a point where the wishbone joins the shoulder. Neck skin shall not be included with the wishbone.

(4) ''Drumsticks'' shall be separated from the thigh by a cut through the knee joint (femorotibial and patellar joint) and from the hock joint (tarsal joint).

(5) ''Thighs'' shall be disjointed at the hip joint and may include the pelvic meat, but shall not include the pelvic bones. Back skin shall not be included.

(6) ''(Kind) legs'' shall be the poultry product which includes the thigh and the drumstick, i.e., the whole leg, and may include the pelvic meat, but shall not include the pelvic bones. Back skin shall not be included.

(7) ''Wings'' shall include the entire wing with all muscle and skin tissue intact, except that the wingtip may be removed.

(8) ''Backs'' shall include the pelvic bones and all the vertebrae posterior to the shoulder joint. The meat shall not be peeled from the pelvic bones. The vertebral ribs and/or scapula may be removed or included without affecting the appropriateness of the name. Skin shall be substantially intact.

(9) ''Stripped backs'' shall include the vertebrae from the shoulder joint to the tail, and include the pelvic bones. The meat may be stripped off of the pelvic bones.

(10) ''Necks'', with or without neck skin, shall be separated from the carcass at the shoulder joint.

(11) ''Halves'' are prepared by making a full-length back and breast split of an eviscerated poultry carcass so as to produce approximately equal right and left sides.

(12) ''Quarters'' consist of the entire eviscerated poultry carcass, which has been cut into four equal parts, but excluding the neck.

(13) ''Breast quarter'' consists of half a breast with the wing and a portion of the back attached.

(14) ''Breast quarter without wing'' consists of a front quarter of a poultry carcass, from which the wing has been removed.

(15) ''Leg quarter'' consists of a poultry thigh and drumstick, with a portion of the back attached.

(16) ''Thigh with back portion'' consists of a poultry thigh with back portion attached.

(17) ''Legs with pelvic bone'' consists of a poultry leg with adhering meat and skin and pelvic bone.

(18) ''Wing drummette'' consists of the humerus of a poultry wing with adhering skin and meat attached.

(19) ''Wing portion'' consists of a poultry wing except that the drummette has been removed.

(20) ''Cut-up Poultry'' is any cut-up or disjointed portion of poultry or any edible part thereof, as described in this section.

(21) ''Giblets'' consist of approximately equal numbers of hearts, gizzards, and livers, as determined on a count basis.

(22) ''Major portions'' of eviscerated poultry carcasses are either carcasses from which parts may be missing, or the front or rear portions of transversely-split carcasses.

[37 FR 9706, May 16, 1972, as amended at 39 FR 4569, Feb. 5, 1974; 63 FR 48960, Sept. 11, 1998]

§ 381.171 Definition and standard for "Turkey Ham."

(a) ''Turkey Ham'' shall be fabricated from boneless, turkey thigh meat with skin and the surface fat attached to the skin removed. The thighs shall be that cut of poultry described in § 381.170(b)(5) of this part.

(b) The product may or may not be smoked, and shall be cured using one or more of the approved curing agents as provided in a regulation permitting that use in this subchapter or 9 CFR Chapter III, Subchapter E, or in 21 CFR Chapter I, Subchapter A or Subchapter B. The product may also contain cure accelerators, phosphates, and flavoring agents as provided in a regulation permitting that use in this subchapter or 9 CFR Chapter III, Subchapter E, or in 21 CFR Chapter I, Subchapter A or Subchapter B; common salt, sugars, spices, spice extractives, dehydrated garlic, and dehydrated onions; and water for purpose of dissolving and dispersing the substances specified above.

(c) The cooked finished product weight shall be no more than the original weight of the turkey thigh meat used prior to curing.

(d) The product name on the label shall show the word ''Turkey'' in the same size, style, color, and with the same background as the word ''Ham'' and shall precede and be adjacent to it.

(e) The product name shall be qualified with the statement ''Cured Turkey Thigh Meat.'' The qualifying statement shall be contiguous to the product name, without intervening type or designs, shall be not less than one-half the size of the product name but not less than one-eighth inch in height, and shall be in the same style and color and with the same background as the product name.

(f) If the product is fabricated from pieces of turkey thigh meat that result from the cutting through the muscle (as opposed the whole thighs intact or whole thighs with some incidental separation of muscle tissue during removal of the bone), the product name shall be further qualified by a descriptive statement. The product name of product fabricated from such pieces of turkey thigh meat equivalent in size to a one-half inch cube or greater shall be further qualified to specify that the product is ''Chunked and Formed.'' The product name of product fabricated from such pieces of turkey thigh meat smaller than the equivalent of a one-half inch cube shall be further qualified to specify that the product is ''Ground and Formed'' or ''Chopped and Formed'' as appropriate. The qualifying statement shall immediately follow and be contiguous to the statement required in paragraph (e) of this section, and shall be not less than one-half the size of the product name but not less than one-eighth inch in height, and shall be in the same style and color and with the same background as the product name.

[44 FR 51190, Aug. 31, 1979; 64 FR 72175, Dec. 23, 1999]

§ 381.173 Mechanically Separated (Kind of Poultry).

(a) ''Mechanically Separated (Kind of Poultry)'' is any product resulting from the mechanical separation and removal of most of the bone from attached skeletal muscle and other tissue of poultry carcasses and parts of carcasses that has a paste-like form and

consistency, that may or may not contain skin with attached fat and meeting the other provisions of this section. Examples of such product are ''Mechanically Separated Chicken'' and ''Mechanically Separated Turkey.''

(b) ''Mechanically Separated (Kind of Poultry)'' shall not have a bone solids content of more than 1 percent. At least 98 percent of the bone particles present in ''Mechanically Separated (Kind of Poultry) ''shall have a maximum size no greater than 1.5 mm (millimeter) in their greatest dimension and there shall be no bone particles larger than 2.0 mm in their greatest dimension.

(c) ''Mechanically Separated (Kind of Poultry)'' shall not have a calcium content exceeding 0.235 percent when made from mature chickens or from turkeys as defined in § 381.170(a)(l)(vi) and (vii) and (a)(2), respectively, or 0.175 percent when made from other poultry, based on the weight of product that has not been heat treated, as a measure of a bone solids content of not more than 1 percent.

(d) ''Mechanically Separated (Kind of Poultry)'' may be used in the formulation of poultry products in accordance with § 381.174 and meat food products in accordance with subchapter A of this chapter.

(e) Product resulting from the mechanical separation process that fails to meet the bone particle size or calcium content requirements for ''Mechanically Separated (Kind of Poultry)'' shall be used only in producing poultry extractives, including fats, stocks, and broths and labeled as ''Mechanically Separated (Kind of Poultry) for Further Processing.''

[60 FR 55983, Nov. 3, 1995]

§ 381.174 Limitations with respect to use of Mechanically Separated (Kind of Poultry).

(a) A poultry product required to be prepared from a particular kind of poultry (e.g., chicken) shall not contain ''Mechanically Separated (Kind of Poultry)'' described in § 381.173, that is made from any other kind of poultry (e.g., Mechanically Separated Turkey).

(b) ''Mechanically Separated (Kind of Poultry)'' described in § 381.173 may be used in the formulation of any poultry or meat food product, provided such use conforms with any applicable requirements of the definitions and standards of identity or composition in this subchapter or part 319 of this chapter, and provided that it is identified as ''Mechanically Separated (Kind of Poultry).''

[60 FR 55983, Nov. 3, 1995]

Subpart Q—Records, Registration, and Reports

§ 381.175 Records required to be kept.

(a) Every person within any of the classes specified in paragraph (a) (1), (2), or (3) of this section is required by the Act to keep such records as are properly necessary for the effective enforcement of the Act:

(1) Any person that engages in the business of slaughtering any poultry or processing, freezing, packaging, or labeling any carcasses, or parts or products of carcasses, of any poultry, for commerce, for use as human food or animal food;

(2) Any person that engages in the business of buying or selling (as a poultry products broker, wholesaler, or otherwise) or transporting, in commerce, or storing in or for commerce, or importing, any carcasses, or parts or products of carcasses, of any poultry;

(3) Any person that engages in business, in or for commerce, as a renderer, or engages in the business of buying, selling, or transporting in commerce, or importing, any dead, dying, disabled, or diseased poultry or parts of the carcasses of any poultry that died otherwise than by slaughter.

(b) The required records are:

(1) Records, such as bills of sale, invoices, bills of lading, and receiving and shipping papers, giving the following information with respect to each transaction in which any poultry or poultry carcass, or part or product of a poultry carcass, is purchased, sold, shipped, received, transported, or otherwise handled by said person in connection with any business subject to the Act.

(i) The name or description of the poultry or other articles;

(ii) The net weight of the poultry or other articles;

(iii) The number of outside containers;

(iv) The name and address of the buyer of the poultry or other articles sold by such person, and the name and address of the seller of the poultry or other articles purchased by such person;

(v) The name and address of the consignee or receiver (if other than the buyer);

(vi) The method of shipment;

(vii) The date of shipment; and

(viii) The name and address of the carrier.

(2) Guaranties provided by suppliers of packaging materials under §381.144.

(3) Records of canning as required by subpart X of this part 381, of subchapter C, 9 CFR chapter III.

(4) Records of irradiation as required by sections 381.149 of this part.

(5) Records of nutrition labeling as required by subpart Y of this part.

(6) Records of all labeling, along with the product formulation and processing procedures, as prescribed in §§381.132 and 381.133.

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

[37 FR 9706, May 16, 1972, as amended at 47 FR 746, Jan. 7, 1982; 49 FR 2236, Jan. 19, 1984; 51 FR 45633, Dec. 19, 1986; 57 FR 43600, Sept. 21, 1992; 58 FR 675, Jan. 6, 1993; 60 FR 67458, Dec. 29, 1995]

§381.176 Place of maintenance of records.

Every person engaged in any business described in §381.175(a) shall maintain the records required by §381.175 at the place of business where such business is conducted, except that, if such person conducts such business at multiple locations, he may maintain such records at his headquarters' office. When not in actual use, all such records shall be kept in a safe place at the prescribed location in accordance with good commercial practices.

§381.177 Record retention period.

(a) Every record required to be maintained under this subpart shall be retained for a period not to exceed 2 years after December 31 of the year in which the transaction to which the record relates has occurred, and for such further period as the Administrator may require for purposes of any investigation or litigation under the Act, by written notice to the person required to keep such record under this subpart.

(b) Records of canning as required by subpart X of this part 381, subchapter C, 9 CFR chapter III, shall be retained as required in §381.307; except that records required by §381.302 (b) and (c) shall be retained as required by those sections.

[37 FR 9706, May 16, 1972, as amended at 51 FR 45633, Dec. 19, 1986]

§381.178 Access to and inspection of records, facilities and inventory; copying and sampling.

Every person within any of the classes specified in §381.175(a) shall, upon the presentation of official credentials by any authorized representative of the Secretary, during ordinary business hours, permit such representative to enter his or its place of business and examine the records required to be kept by §381.175(b) and the facilities and inventory pertaining to the business of such person subject to the Act, and to copy all such records, and to take reasonable samples of the inventory upon payment of the fair market value therefor. Any necessary facilities (other than reproduction equipment) for such examination and copying of records and for such examination and sampling of inventory shall be afforded to such authorized representative of the Secretary.

§381.179 Registration.

(a) Except as provided in paragraph (c) of this section, every person that engages in business, in or for commerce, as a poultry products broker, renderer, or animal food manufacturer, or engages in business in commerce as a wholesaler of any carcasses, or parts or products of the carcasses, of any poultry, whether intended for human food or other purposes, or engages in the business as a public warehouseman storing any such articles in or for commerce, or engages in the business of buying, selling, or transporting in commerce, or importing, any dead, dying, disabled, or diseased poultry, or parts of the carcasses of any poultry that died otherwise than by slaughter, shall

register with the Administrator, giving such information as is required, including his name, and the address of each place of business at which, and all trade names under which he conducts such business. Such persons shall register under this section by filing with the Administrator, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250, a form containing such information, within 90 days after the effective date hereof or after such later date as he begins to engage in such business if not engaged therein upon said effective date. All information submitted shall be current and correct. The registration form shall be obtained from the Compliance Program, Regulatory Programs, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250.

(b) Whenever any change is made in the name of, or address of any place of business at which, or any trade name under which a registrant conducts his business, he shall report such change in writing to the Administrator within 15 days after making the change.

(c) The registration requirements prescribed in this section shall not apply to persons conducting any of the businesses specified in this section only at an official establishment.

[37 FR 9706, May 16, 1972, as amended at 39 FR 4569, Feb. 5, 1974; 57 FR 53982, Nov. 16, 1992]

§ 381.180 Information and reports required from official establishment operators.

(a) The operator of each official establishment shall furnish to Program employees accurate information as to all matters needed by them for making their daily reports of the amount of products prepared or handled in the departments of the establishment to which they are assigned and such reports concerning sanitation, mandatory microbiological testing, and other aspects of the operations of the establishment and the conduct of inspection thereat, as may be required by the Administrator in special cases.

(b) The operator of each official establishment shall also make such other reports as the Administrator may from time to time require under the Act.

[37 FR 9706, May 16, 1972, as amended at 61 FR 38868, July 25, 1996]

§ 381.181 Reports by consignees of allegedly adulterated or misbranded products; sale or transportation as violations.

Whenever the consignee of any poultry product which bears an official inspection legend refuses to accept delivery of such product on the grounds that it is adulterated or misbranded, the consignee shall notify the appropriate program supervisor, Meat and Poultry Inspection Program, Food Safety and Inspection Service, U.S. Department of Agriculture, of the kind, quantity, source and present location of the product and the respects in which it is alleged to be adulterated or misbranded, and it will be a violation of the Act for any person to sell or transport, or offer for sale or transportation or receive for transportation, in commerce, any such product which is capable of use as human food and is in fact adulterated or misbranded at the time of such sale, transportation, offer, or receipt: *Provided*, That any such allegedly adulterated or misbranded product may be transported to any official establishment for reinspection.

§ 381.182 Reports of inspection work.

Reports of the inspection work carried on within official establishments shall be forwarded to the Administrator by the inspector in charge in such a manner as may be specified by the Administrator.

Subpart R—Cooperation With States and Territories; Certification of State and Territorial Programs as at Least Equal to Federal Program

§ 381.185 Assistance to State and Territorial programs.

(a) The Administrator is authorized, under paragraph (a) of section 5 of the Act, when he determines it would effectuate the purposes of the Act, to cooperate with any State (including Puerto Rico) or any organized territory in developing and administering the

poultry product inspection program of such jurisdiction, with a view to assuring that it imposes and enforces requirements at least equal to those under sections 2 through 4, 6 through 10, and 12 through 22 of the Act, with respect to establishments at which poultry are slaughtered or poultry products are processed for use as human food, solely for distribution within such jurisdiction, and with respect to the poultry products of such establishments. Such cooperation is authorized if the jurisdiction has enacted a mandatory law imposing ante mortem and post mortem inspection, reinspection, and sanitation requirements (at least equal to those under the Federal Act), with respect to all or certain classes of persons engaged in slaughtering poultry or otherwise processing poultry products for use as human food solely for distribution within such jurisdiction.

(b) The Administrator is also authorized under paragraph (a) of section 5 of the Act, to cooperate with any State (including Puerto Rico) or any organized territory in developing and administering programs under the laws of such jurisdiction containing authorities at least equal to those provided in section 11 of the Act (relating to records; registration of specified classes of operators; dead, dying, disabled, or diseased poultry; and products not intended for human food) when he determines that such cooperation would effectuate the purposes of the Act.

(c) Such cooperation may include advisory assistance, technical and laboratory assistance and training, and financial aid. The Federal contribution to any State (or territory) for any year shall not exceed 50 percent of the estimated total cost of the cooperative State (or territorial) program. A cooperative program under this section is called a State-Federal program.

§ 381.186 Cooperation of States and other jurisdictions in Federal programs.

Under the ''Talmadge-Aiken Act'' of September 28, 1962 (7 U.S.C. 450), the Administrator is authorized under stated conditions to utilize employees and facilities of any State in carrying out Federal functions under the Poultry Products Inspection Act. A cooperative program for this purpose is called a Federal-State program. Under paragraph (a) of section 5 of the Poultry Products Inspection Act, the Administrator is also authorized to conduct examinations, investigations, and inspections under the Act through any officer or employee of any State or territory or the District of Columbia commissioned by him for such purpose.

Subpart S—Transportation; Exportation; or Sale of Poultry or Poultry Products

§ 381.189 Provisions inapplicable to specimens for laboratory examination, etc., or to naturally inedible articles.

The provisions of this subpart do not apply:

(a) To dead, dying, disabled or diseased poultry and specimens of undenatured, uninspected or adulterated carcasses, parts, or products of poultry sent to or by the Department of Agriculture or divisions thereof in Washington, DC, or elsewhere, for laboratory examination, exhibition purposes, or other official use;

(b) To dead, dying, disabled or diseased poultry and specimens of undenatured, uninspected or adulterated carcasses, parts, or products of poultry thereof for educational, research, or other nonfood purposes shipped under permit issued by the inspector in charge upon his determination that collection and movement thereof will not interfere with inspection or sanitary conditions at the establishment, and the specimens are for nonfood purposes. The person desiring such specimens shall make a written application to the inspector in charge for such permit on Form MP–112 and shall obtain permission from the operator of the official establishment to obtain the specimens. Permits shall be issued for a period not longer than one year. The permit may be revoked by the inspector in charge if he determines after notice and opportunity to present views is afforded to the permittee that any such specimens were not used as stated in the application, or if the collection or handling of the specimens interferes with inspection or

the maintenance of sanitary conditions in the establishment. The specimens referred to in this paragraph shall be collected and handled only at such time and place and in such manner as not to interfere with the inspection or to cause any objectionable condition and shall be identified as inedible when they leave the establishment.

(c) To parts of poultry carcasses that are naturally inedible by humans, such as entrails and feathers in their natural state.

[40 FR 55310, Nov. 28, 1975]

§ 381.190 Transactions in slaughtered poultry and other poultry products restricted; vehicle sanitation requirements.

(a) No person shall sell, transport, offer for sale or transportation, or receive for transportation, in commerce or from any official establishment, any slaughtered poultry from which the blood, feathers, feet, head, or viscera have not been removed in accordance with the regulations.

(b)(1) No person shall sell, transport, offer for sale or transportation, or receive for transportation, in commerce, any slaughtered poultry or other poultry product which is capable of use as human food and is adulterated or fails to bear an official inspection legend or is otherwise misbranded at the time of such sale, transportation, offer or receipt, except as otherwise provided in this paragraph (b) and subpart C or T.

(2)(i) Poultry heads and feet that are collected and handled at an official establishment in an acceptable manner may be shipped from the official establishment directly for export as human food, if they have been examined and found to be suitable for such purpose, by an inspector and are labeled as prescribed in this paragraph.

(ii) The containers of all such products shall bear a label showing: (A) The name of the products; (B) the name and address of the packer or distributor, and, when the name of the distributor is shown, it shall be qualified by such terms as ''packed for,'' ''distributed by,'' or ''distributors''; and (C) the official establishment number of the establishment where packed.

(iii) Such products shall not bear the official inspection legend.

(3)(i) Poultry heads and feet that are collected and handled at an official establishment in an acceptable manner may be shipped from the official establishment and in commerce directly to another official establishment for processing before export, provided the receiving establishment maintains records that:

(A) Identify the source of the incoming undenatured poultry product;

(B) Identify the location of the product at all times during processing and preparation for export; and

(C) Contain a written certification from an official of the receiving establishment that the undenatured poultry product intended for export has not been, and will not be, commingled with any product intended for consumption in the United States.

(ii) The receiving establishment may only ship the undenatured poultry product intended for export in accordance with the inspection and labeling requirements of paragraph (b)(2) of this section.

(c) No person, engaged in the business of buying, selling, freezing, storing, or transporting, in or for commerce, poultry products capable of use as human food, or importing such articles, shall transport, offer for transportation, or receive for transportation, in commerce or in any State designated under § 381.221, any poultry product which is capable of use as human food and is not wrapped, packaged, or otherwise enclosed to prevent adulteration by airborne contaminants, unless the railroad car, truck, or other means of conveyance in which the product is contained or transported is completely enclosed with tight fitting doors or other covers for all openings. In all cases, the means of conveyance shall be reasonably free of foreign matter (such as dust, dirt, rust, or other articles or residues), and free of chemical residues, so that product placed therein will not become adulterated. Any cleaning compound, lye, soda solution, or other chemical used in cleaning the means of conveyance must be thoroughly removed from the means of conveyance prior to its use. Such means of conveyance onto which product is loaded, being loaded, or intended to be loaded, shall be subject to inspection

by an inspector at any official establishment. The decision whether or not to inspect a means of conveyance in a specific case, and the type and extent of such inspection shall be at the Inspection Service's discretion and shall be adequate to determine if poultry product in such conveyance is, or when moved could become, adulterated.

Circumstances of transport that can be reasonably anticipated shall be considered in making said determination. These include, but are not limited to, weather conditions, duration and distance of trip, nature of product covering, and effect of restowage at stops en route. Any means of conveyance found upon such inspection to be in such condition that poultry product placed therein could become adulterated shall not be used until such condition which could cause adulteration is corrected. Poultry product placed in any means of conveyance that is found by the inspector to be in such condition that the poultry product may have become adulterated shall be removed from the means of conveyance and handled in accordance with § 381.145(b).

[37 FR 9706, May 16, 1972, as amended at 39 FR 4569, Feb. 5, 1974; 40 FR 42338, Sept. 12, 1975; 41 FR 23700, June 11, 1976; 60 FR 43358, Aug. 21, 1995]

§ 381.191 Distribution of inspected products to small lot buyers.

For the purpose of facilitating the distribution in commerce of inspected poultry products to small lot buyers (such as small restaurants), distributors or jobbers may remove inspected and passed non-consumer-packaged poultry carcasses or consumer-packaged poultry products from shipping containers or immediate containers, other than consumer packages, and place them into other containers which do not bear an official inspection mark: *Provided,* That the individual non-consumer-packaged carcasses bear the official inspection legend and the official establishment number of the establishment that processed the articles; and the consumer-packaged articles are fully labeled in accordance with subpart N: *And provided further,* That the other container is marked with the name and address of the distributor or jobber and bears the statement ''The poultry product contained herein was inspected by the U.S.D.A.'' in the case of poultry products processed in the United States, or the statement ''The poultry products contained herein have been approved for importation under P.P.I.A.'' in the case of imported poultry products.

§ 381.192 Penalties inapplicable to carriers.

No carrier shall be subject to the penalties of the Act, other than the penalties for violation of section 11, by reason of his receipt, carriage, holding, or delivery, in the usual course of business, as a carrier, of poultry or poultry products, owned by another person, unless the carrier has knowledge, or is in possession of facts which would cause a reasonable person to believe that such poultry or poultry products were not inspected or marked in accordance with the provisions of the Act or where otherwise not eligible for transportation under the Act, or unless the carrier refuses to furnish on request of a representative of the Secretary, the name and address of the person from whom he received such poultry or poultry products, and copies of all documents, if any there be, pertaining to the delivery of the poultry or poultry products to such carrier.

§ 381.193 Poultry carcasses, etc., not intended for human food.

(a) Except as provided in paragraph (b) of this section, poultry carcasses, and parts and products thereof, that are not intended for use as human food may, after they have been denatured as prescribed in § 381.95, be bought, sold, transported, offered for sale or transportation, or received for transportation, in commerce, or imported, even though they do not comply with all the provisions of the regulations, provided they are marked ''Not fit for human food.'' These requirements do not apply to parts of poultry carcasses that are naturally inedible by humans, such as entrails.

(b)(1) Except as provided in paragraphs (b) (2), (3), and (4) of this section, no animal food processed, in whole or in part, from materials derived from the carcasses of poultry in an official establishment or elsewhere,

shall be bought, sold, transported, offered for sale or transportation, or received for transportation in commerce, or imported, unless:

(i) It is properly identified as animal food;

(ii) It is not represented as being a human food; and

(iii) It has been denatured as prescribed in § 381.95 so as to be readily distinguishable from an article of human food.

(2) Notwithstanding the provisions of paragraph (b)(1) of this section, an animal food that consists of less than 5 percent of parts or products of the carcasses of poultry and that is not represented by labeling or appearance or otherwise as being a human food or as a product of the poultry industry need not be denatured in accordance with § 381.95.

(3) Notwithstanding the provisions of paragraph (b)(1) of this section, animal food packed in hermetically sealed, retort processed, conventional retail-size containers, and retail-size packages of semi-moist animal food need not be denatured in accordance with § 381.95 if the name of the article clearly conveys the article's intended use for animal food and appears on the label in a conspicuous manner.

(i) Except as provided in paragraph (ii) of paragraph (b)(3) of this section, the name of the article must be stated on the label as ''Animal Food,'' ''Pet Food,'' or ''(name of species) Food'' (e.g., ''Dog Food'' or ''Cat Food''). To be considered conspicuous, the name of the article, wherever it appears on the label, must be stated in letters at least twice as high, wide, and thick as the letters indicating the presence in the article of any ingredients derived from carcasses of poultry.

(ii) Notwithstanding the provisions of paragraph (i) of paragraph (b)(3) of this section, the article's name may be stated on the label to show that it is or contains poultry carcass-source material and that the article is for animals; e.g., ''Chicken for Pets'' or ''Turkey Dinner for Cats'': *Provided,* That the entire name of the article is stated, wherever it appears on the label, as an individual, contiguous unit, whether stated on a single line or more than one line, and the letters denoting the article's intended use for animal food are at least as high, wide, and thick as the letters indicating the presence of material derived from any poultry carcass. However, when the label bears on its principal display panel a vignette which pictures, in clearly recognizable form and size, one or more animals of the species for which the article's name indicates the article is intended, the letters used to state the article's intended use shall be at least one-half as high, wide, and thick as the letters used in the article's name or other letters indicating the presence of material derived from any poultry carcass, but shall not be less than ⅛ inch high. The letters used to state the article's intended use may be separated from the article's name by the vignette.

(iii) Letters used to denote the intended use of the article must contrast as markedly with their background as the letters indicating the presence in the article of poultry carcass-source material contrast with their background.

(4) The requirements of this part do not apply to livestock or poultry feed manufactured from processed poultry byproducts (such as poultry byproduct meal, hydrolyzed poultry feathers, and hydrolyzed poultry byproducts aggregate), or to processed dry animal food.

[49 FR 47479, Dec. 5, 1984]

§ 381.194 Transportation and other transactions concerning dead, dying, disabled, or diseased poultry, and parts of carcasses of poultry that died otherwise than by slaughter.

No person engaged in the business of buying, selling, or transporting in commerce, or importing any dead, dying, disabled, or diseased poultry or parts of the carcasses of any poultry that died otherwise than by slaughter shall:

(a) Sell, transport, offer for sale or transportation or receive for transportation, in commerce, any dead, dying, disabled, or diseased poultry, or parts of the carcasses of any poultry that died otherwise than by slaughter, unless such poultry and parts are consigned and delivered, without avoidable delay, to establishments of animal food manufacturers, renderers, or collection stations that are registered as required

by §381.179, or to official establishments that operate under Federal inspection, or to establishments that operate under a State or Territorial inspection system approved by the Secretary as one that imposes requirements at least equal to the Federal requirements for purposes of section 5(c) of the Act.

(b) Buy in commerce or import any dead, dying, disabled, or diseased poultry or parts of the carcasses of any poultry that died otherwise than by slaughter, unless he is an animal food manufacturer or renderer and is registered as required by §381.179, or is the operator of an establishment inspected as required by paragraph (a) of this section and such poultry or parts of carcasses are to be delivered to establishments eligible to receive them under paragraph (a) of this section.

(c) Unload en route to any establishment eligible to receive them under paragraph (a) of this section, any dead, dying, disabled, or diseased poultry or parts of the carcasses of any poultry that died otherwise than by slaughter, which are transported in commerce or imported by any such person: *Provided*, That any such dead, dying, disabled, or diseased poultry, or parts of carcasses may be unloaded from a means of conveyance en route where necessary in case of a wreck or otherwise extraordinary emergency, and may be reloaded into another means of conveyance; but in all such cases, the carrier shall immediately report the facts by telegraph or telephone to the Director, Compliance Staff, Meat and Poultry Inspection Program, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250.

[40 FR 55310, Nov. 28, 1975]

Subpart T—Imported Poultry Products

§381.195 Definitions; requirements for importation into the United States.

(a) When used in this part, the following terms shall be construed to mean:

(1) *Import (Imported).* To bring within the territorial limits of the United States whether that arrival is accomplished by land, air, or water.

(2) For product from eligible countries other than Canada:

(i) *Offer(ed) for entry.* The point at which the importer presents the imported product to the Program for reinspection.

(ii) *Entry (entered).* The point at which imported product offered for entry receives reinspection and is marked with the official mark of inspection in accordance with §327.26 of this part.

(3) For product from Canada:

(i) *Offer(ed) for entry* from establishments participating in the ''streamlined'' inspection procedures. The point at which an official of the Canadian inspection system contacts the Import Field Office for an inspection assignment.

(ii) *Offer(ed) for entry* from nonparticipating establishments. The point at which the importer presents the imported product to the Program for reinspection.

(iii) *Entry (entered)* for product not subject to reinspection. When the containers or the products themselves if not in containers are marked with the Canadian export stamp and upon the filing of Customs Form 7533 at the port of entry or at the nearest customshouse in accordance with 19 CFR part 123.

(iv) *Entry (entered)* for product subject to reinspection. When the containers or the products themselves if not in containers are marked with the Canadian export stamp and the foreign inspection certificate accompanying the product is stamped as ''Inspected and Passed'' by the import inspector.

(b) No slaughtered poultry, or parts or products thereof, shall be imported into the United States unless they are healthful, wholesome, fit for human food, not adulterated, and contain no dye, chemical, preservative, or ingredient which renders them unhealthful, unwholesome, adulterated, or unfit for human food and they also comply with the regulations prescribed in this subpart to assure that they comply with the standards provided for in the Act: *Provided*, That the provisions of this subpart apply to such articles only if they are capable of use as human food.

(c) Except as provided in §381.207, slaughtered poultry and other poultry

products may be imported only if they were processed solely in countries listed in § 381.196(b). Slaughtered poultry may be imported only if it qualifies as ready-to-cook poultry.

[37 FR 9706, May 16, 1972, as amended at 40 FR 42338, Sept. 12, 1975; 54 FR 41049, Oct. 5, 1989]

§ 381.196 Eligibility of foreign countries for importation of poultry products into the United States.

(a)(1) Whenever it shall be determined by the Administrator that the system of poultry inspection maintained by any foreign country, with respect to establishments preparing products in such country for export to the United States, insures compliance of such establishments and their poultry products, with requirements equivalent to all the provisions of the Act and the regulations in this part which are applied to official establishments in the United States, and their poultry products, and that reliance can be placed upon certificates required under this subpart from authorities of such foreign country, notice of that fact will be given by including the name of such foreign country in paragraph (b) of this section. Thereafter, poultry products processed in such establishments which are certified and approved in accordance with paragraph (a)(3) of this section shall be eligible, so far as the regulations in this part are concerned, for importation into the United States from such foreign country after applicable requirements of this part have been met.

(2) The determination of acceptability of a foreign poultry inspection system for purposes of this section shall be based on an evaluation of the foreign program in accordance with the following requirements and procedures:

(i) The system shall have a program organized and administered by the national government of the foreign country. The system as implemented must provide standards equivalent to those of the Federal system of poultry inspection in the United States with respect to:

(A) Organizational structure and staffing, so as to insure uniform enforcement of the requisite laws and regulations in all establishments throughout the system at which poultry products are processed for export to the United States;

(B) Ultimate control and supervision by the national government over the official activities of all employees or licensees of the system;

(C) The assignment of competent, qualified inspectors;

(D) Authority and responsibility of national inspection officials to enforce the requisite laws and regulations governing poultry inspection and to certify or refuse to certify poultry products intended for export;

(E) Adequate administrative and technical support;

(F) The inspection, sanitation, quality, species verification, and residue standards applied to products produced in the United States.

(G) Other requirements of adequate inspection service as required by the regulations.

(ii) The legal authority for the system and the regulations thereunder shall impose requirements equivalent to those governing the system of poultry inspection organized and maintained in the United States with respect to:

(A) Ante mortem inspection of poultry for slaughter, which shall be performed by veterinarians or by other employees or licensees of the system under the direct supervision of veterinarians;

(B) Post mortem inspection of carcasses and parts thereof at time of slaughter, performed by veterinarians or other employees or licensees of the system under the direct supervision of veterinarians;

(C) Official controls by the national government over establishment construction, facilities, and equipment;

(D) Direct and continuous official supervision of slaughtering of poultry and processing of poultry products, by the assignment of inspectors to establishments certified under paragraph (a)(3) of this section to assure that adulterated or misbranded poultry products are not processed for export to the United States;

(E) Complete separation of establishments certified under subparagraph (3) of this paragraph from establishments not certified, and the maintenance of a

single standard of inspection and sanitation throughout all certified establishments;

(F) Requirements for sanitation at certified establishments and for sanitary handling of poultry products;

(G) Official controls over condemned material until destroyed or removed and thereafter excluded from the establishment;

(H) A Hazard Analysis and Critical Control Point (HACCP) system, as set forth in part 417 of this chapter.

(I) Other matters for which requirements are contained in the Act or the regulations in this part.

(iii) Countries desiring to establish eligibility for importation of poultry products into the United States may request a determination of eligibility by presenting copies of the laws and regulations on which the foreign poultry inspection system is based and such other information as the Administrator may require with respect to matters enumerated in paragraphs (a)(2) (i) and (ii). Determination of eligibility is based on a study of the documents and other information presented and an initial review of the system in operation by a representative of the Department using the criteria listed in paragraphs (a)(2) (i) and (ii) of this section. Maintenance of eligibility of a country for importation of poultry products into the United States depends on the results of periodic reviews of the foreign poultry inspection system in operation by a representative of the Department, and the timely submission of such documents and other information related to the conduct of the foreign inspection system as the Administrator may find pertinent to and necessary for the determinations required by this section.

(iv) The foreign inspection system must maintain a program to assure that the requirements referred to in this section, equivalent to those applicable to the Federal system in the United States, are being met. The program as implemented must provide for the following:

(A) Periodic supervisory visits by a representative of the foreign inspection system not less frequently than one such visit per month to each establishment certified in accordance with paragraph (a)(3) of this section to assure that requirements referred to in paragraphs (a)(2)(ii)(A) through (a)(2)(ii)(H) of this section are being met: *Provided,* that such visits are not required with respect to any establishment during a period when the establishment is not operating or is not engaged in producing products for exportation to the United States;

(B) Written reports prepared by the representative of the foreign inspection system who has conducted a supervisory visit, documenting his or her findings with respect to the requirements referred to in paragraphs (a)(2)(ii)(A) through (a)(2)(ii)(H) of this section, copies of which shall be made available to the representative of the Department at the time of the representative's review upon request by that representative to a responsible foreign inspection official: *Provided,* that such reports are not required during a period when the establishment is not operating or not engaged in producing products for exportation to the United States.

(C) Random sampling and testing at the point of slaughter of carcasses, including internal organs and fat, for residues identified by the exporting country's inspection authorities or by this Agency as potential contaminants, in accordance with sampling and analytical techniques approved by the Administrator: *Provided,* that such testing is required only on samples taken of carcasses from which poultry or poultry products intended for importation into the United States are produced.

(3) Only those establishments that are determined and certified to the Department by a responsible official of the foreign poultry inspection system as fully meeting the requirements of paragraphs (a)(2) (i) and (ii) of this section are eligible to have their products imported into the United States. Eligibility of certified establishments is subject to review by the Department (including observations of the establishments by Program representatives at times prearranged with the officials of the foreign inspection system). Certifications of establishments must be renewed annually. Notwithstanding certification by a foreign official, the Administrator may, at his discretion,

terminate the eligibility of any foreign establishment for importation of its poultry products into the United States if he has information that such establishment does not comply with the requirements listed in paragraphs (a)(2) (i) and (ii) of this section or if he cannot obtain current information concerning such establishment. The Administrator will provide reasonable notice to the foreign government of the proposed termination of eligibility of any foreign establishment for importation of its poultry products into the United States unless, in his judgment, delay in terminating its eligibility could result in the importation of any adulterated or misbranded poultry products. Certifications of official establishments by the responsible official of the foreign poultry inspection system shall be in the following form:

FOREIGN OFFICIAL POULTRY ESTABLISHMENT CERTIFICATE

I hereby certify that the establishment(s) listed below fully complies (comply) with requirements of (specify foreign country) equivalent to all the provisions of the Poultry Products Inspection Act and regulations issued thereunder, which apply to official establishments in the United States, and their poultry products, as provided in § 381.196(a)(2)(i) and (ii) of the poultry products inspection regulations of the United States.

Control numbers Name
Address

_____

_____

_____

Date_____.

_____
(Signature)

_____
(Official title)

(4) Poultry products from foreign countries not listed in paragraph (b) of this section are not eligible for importation into the United States, except as provided by §§ 381.207 and 381.209. The listing of any foreign country under this section may be withdrawn whenever it shall be determined by the Administrator that the system of poultry inspection maintained by such foreign country does not assure compliance with requirements equivalent to all the requirements of the Act and the regulations as applied to official establishments in the United States; or that reliance cannot be placed upon certificates required under this subpart from authorities of such foreign country; or that, for lack of current information concerning the system of poultry inspection being maintained by such foreign country, such foreign country should be required to reestablish its eligibility for listing.

(b) It has been determined that poultry products from the following countries, covered by foreign poultry inspection certificates of the country of origin as required by § 381.197, are eligible under the regulations in this subpart for entry into the United States, after inspection and marking as required by the applicable provisions of this subpart:[1]

Australia (ratites only).
Canada.
France.
Great Britain.
Hong Kong.
Israel.
Mexico.[2]
New Zealand (ratites only).

[37 FR 9706, May 16, 1972, as amended at 43 FR 8117, Feb. 28, 1978; 52 FR 23021, June 17, 1987; 54 FR 41049, Oct. 5, 1989; 54 FR 43951, Oct. 30, 1989; 60 FR 38668, July 28, 1995; 61 FR 38868, July 25, 1996; 64 FR 49645, Sept. 14, 1999; 68 FR 37071, June 23, 2003]

§ 381.197 Imported products; foreign inspection certificates required.

(a) Except as provided in §§ 381.207 and 381.209, each consignment containing any slaughtered poultry or other poultry product consigned to the United States from a foreign country shall be accompanied with a foreign inspection certificate substantially in the form illustrated in paragraph (b) of this section.

(b) The form of foreign poultry product inspection certificate shall be as follows:

[1] Listing of any country in this section does not relieve the poultry products of such country from applicable requirements under other Federal laws.

[2] May export to the United States only processed poultry products slaughtered under Federal inspection in the United States or in a country eligible to export slaughtered poultry products to the United States.

FOREIGN POULTRY PRODUCT INSPECTION CERTIFICATE

Place _____
(City)

_____
(Country)

Date _____

I hereby certify that the poultry products herein described were derived from poultry which received ante mortem and post mortem inspections at the time of slaughter; and that such poultry products are sound, healthful, wholesome, clean and otherwise fit for human food, and are not adulterated and have not been treated with and do not contain any dye, chemical, preservative, or ingredient not permitted by the regulations governing the inspection of poultry and poultry products of the U.S. Department of Agriculture, filed with me, and that said poultry products have been handled only in a sanitary manner in this country; and are otherwise in compliance with requirements at least equal to those in the Poultry Products Inspection Act and said regulations.

KIND OF PRODUCT

_____
_____
_____

Number of pieces or packages Weight

_____
_____
_____

Identification marks on containers _____
Consignor _____
Address _____
Consignee _____
Destination _____
Shipping marks _____
(Signature) _____
(Name of official of national foreign government authorized to issue inspection certificates for poultry products exported to the United States)

(Official title) _____

[37 FR 9706, May 16, 1972, as amended at 40 FR 42338, Sept. 12, 1975]

§381.198 Importer to make application for inspection of poultry products offered for entry.

(a) Each person who wishes to offer for entry any slaughtered poultry or other poultry product shall make application for inspection to the import supervisor of the import field office at the port where the poultry product is to be offered for entry, or to the Administrator, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250, as long as possible in advance of the anticipated arrival of each consignment of such product, except in the case of poultry product exempted from inspection by §§381.207 or 381.209. Each application shall state the approximate date on which the consignment is due to arrive in the United States, the name of the ship or other carrier transporting it, the name of the country where the product was processed, the name of the country from which the product was shipped, the place of destination, the quantity and kind of product, whether fresh, frozen, cured, or canned, and the point of first arrival in the United States.

(b) For participating Canadian establishments, an official of the Canadian meat inspection system shall contact the Import Field Office for an inspection assignment (see §301.2(yyy)).

(1) If the Automated Import Information System (AIIS) does not designate the consignment for reinspection, the consignment may be transported to its consignee for further distribution.

(2) If the AIIS designates the consignment for reinspection, the official shall:

(i) Select samples in accordance with USDA sampling tables.

(ii) Identify and place samples in the vehicle for easy removal and reinspection by a Program import inspector.

(3) In the event that any one of the requirements provided in paragraph (d)(2) of this section is not met, inspection of the consignment shall be conduced by a Program import inspector in accordance with established procedures provided for in the regulations for other imported products.

[37 FR 9706, May 16, 1972, as amended at 39 FR 4569, Feb. 5, 1974; 51 FR 37710, Oct. 24, 1986; 54 FR 275, Jan. 5, 1989; 54 FR 41050, Oct. 5, 1989]

§381.199 Inspection of poultry products offered for entry.

(a)(1) Except as provided in §§381.198(b)(1) and 381.209 of this part, and paragraph (c) of this section, all slaughtered poultry and poultry products offered for entry from any foreign country shall be reinspected by a Program import inspector before they shall be allowed entry into the United States.

(2) Every lot of product shall routinely be given visual inspection for appearance and condition, and checked for certification and label compliance, except as provided in § 381.198(b)(1).

(3) The computerized Automated Import Information System (AIIS) shall be consulted for reinspection instructions. The AIIS will assign inspection levels and procedures based on established sampling plans or established product and plant history and established sampling plans.

(b) Inspectors may take, without cost to the United States, from each consignment of poultry products offered for entry, such samples of the products as are deemed necessary to determine the eligibility of the products for entry into the commerce of the United States.

(c) Poultry products imported under § 381.207 shall not be sampled and inspected under this section unless there is reason for suspecting the presence therein of a substance in violation of that section, and in such case they shall be sampled and inspected in accordance with paragraph (a) of this section.

(d) In addition to the provisions specified in paragraphs (a), (b), and (c) of this section, the following requirements apply to imported canned product.

(1) Imported canned products are required to be sound, healthful, properly labeled, wholesome, and otherwise not adulterated at the time the products are offered for importation into the United States. Provided other requirements of this part are met, the determination of the acceptability of the product and the condition of the containers shall be based on the results of an examination of a statistical sample drawn from the consignment as provided in paragraph (a) of this section. If the inspector determines, on the basis of the sample examination, that the product does not meet the requirements of the Act and regulations thereunder, the consignment shall be refused entry. However, a consignment rejected for container defects but otherwise acceptable may be reoffered for inspection under the following conditions:

(i) If the defective containers are not indicative of an unsafe or unstable product as determined by the Administrator;

(ii) If the number and kinds of container defects found in the original sample do not exceed the limits specified for this purpose in FSIS guidelines; and

(iii) If the defective containers in the consignment have been sorted out and exported or destroyed under the supervision of an inspector.

(2) Representative samples of canned product designated by the Administrator in instructions to inspectors shall be incubated under the supervision of such inspectors in accordance with § 381.309 (d)(1)(ii), (d)(1)(iii), (d)(1)(iv)(*c*), (d)(1)(v), (d)(1)(vii), and (d)(1)(viii) of this subchapter. The importer or his/her agent shall provide the necessary incubation facilities in accordance with § 381.309(d)(1)(i) of this subchapter.

(3) Sampling plans and acceptance levels as prescribed in paragraphs (d)(1) and (d)(2) of this section may be obtained, upon request, from International Programs, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250.

[37 FR 9706, May 16, 1972, as amended at 49 FR 36819, Sept. 20, 1984; 51 FR 45633, Dec. 19, 1986; 54 FR 275, Jan. 5, 1989; 54 FR 41050, Oct. 5, 1989]

§ 381.200 Poultry products offered for entry, retention in customs custody; delivery under bond; movement prior to inspection; handling; facilities and assistance.

(a) No slaughtered poultry or other poultry product required by this subpart to be inspected shall be released from customs custody prior to inspection, but such product may be delivered to the consignee, or his agent, prior to inspection, if the consignee shall furnish a bond, in form prescribed by the Secretary of the Treasury, conditioned that the product shall be returned, if demanded, to the collector of the port where the same is offered for clearance through the customs.

(b) Except as provided in paragraph (a) of this section, no product required by this subpart to be inspected shall be moved, prior to inspection, from the

port of arrival where first unloaded, and if arriving by water, from the wharf where first unloaded at such port, to any place other than the place designated in accordance with this subpart as the place where the same shall be inspected; and no product shall be conveyed in any manner other than in compliance with this subpart.

(c) The consignee, or his agent, shall furnish such facilities and shall provide such assistance for handling and marking poultry products offered for entry as the inspector may require.

[37 FR 9706, May 16, 1972, as amended at 51 FR 37710, Oct. 24, 1986; 54 FR 41050, Oct. 5, 1989; 56 FR 65180, Dec. 16, 1991]

§ 381.201 Means of conveyance and equipment used in handling poultry products offered for entry to be maintained in sanitary condition.

Compartments of steamships, railroad cars, and other means of conveyance transporting any poultry product to the United States, and all chutes, platforms, racks, tables, tools, utensils, and all other devices used in moving and handling any poultry product offered for entry into the United States, shall be maintained in a sanitary condition.

§ 381.202 Poultry products offered for entry; reporting of findings to customs; handling of articles refused entry; appeals, how made; denaturing procedures.

(a)(1) Program inspectors shall report their findings as to any product which has been inspected in accordance with this part, to the Director of Customs at the original port of entry.

(2) When product has been identified as ''U.S. refused entry,'' the inspector shall request the Director of Customs to refuse admission to such product and to direct that it be exported by the owner or consignee within the time specified in this section, unless the owner or consignee, within the specified time, causes it to be destroyed by disposing of it under the supervision of a Program employee so that the product can no longer be used as human food, or by converting it to animal food uses, if permitted by the Food and Drug Administration. The owner or consignee of the refused entry product shall not transfer legal title to such product, except to a foreign consignee for direct and immediate exportation, or an end user, e.g., an animal food manufacturer or a renderer, for destruction for human food purposes. ''Refused entry'' product must be delivered to and used by the manufacturer or renderer within the 45-day time limit. Even if such title is illegally transferred, the subsequent purchaser will still be required to export the product or have it destroyed as specified in the notice under paragraph (a)(4) of this section.

(3) No lot of product which has been refused entry may be subdivided during disposition pursuant to paragraph (a)(2) of this section, except that removal and destruction of any damaged or otherwise unsound product from a lot destined for reexportation is permitted under supervision of USDA prior to exportation. Additionally, such refused entry lot may not be shipped for export from any port other than that through which the product came into the United States without the expressed consent of the Administrator, based on full information concerning the product's disposition, including the name of the vessel and the date of export. For the purposes of this paragraph, the term ''lot'' shall refer to that product identified on MP Form 410 in the original request for inspection for importation pursuant to § 381.198.

(4) The owner or consignee shall have 45 days after notice is given by FSIS to the Director of Customs at the original port of entry to take the action required in paragraph (a)(2) of this section for ''refused entry'' product. Extension beyond the 45-day period may be granted by the Administrator when extreme circumstances warrant it; e.g., a dock workers' strike or an unforeseeable vessel delay.

(5) If the owner or consignee fails to take the required action within the time specified under paragraph (a)(4) of this section, the Department will take such actions as may be necessary to effectuate its order to have the product destroyed for human food purposes. The Department shall seek court costs and fees, storage, and proper expenses in the appropriate forum.

(6) No product which has been refused entry and exported to another country pursuant to paragraph (a)(2) of this section may be returned to the United States under any circumstance. Any such product so returned to the United States shall be subject to administrative detention in accordance with section 19 of the Act, and seizure and condemnation in accordance with section 20 of the Act.

(b) Upon the request of the Director of Customs at the port where a product is offered for clearance through the customs, the consignee of the product shall, at the consignee's own expense, immediately return to the Director any product which has been delivered to consignee under this subpart and subsequently designated ''U.S. Refused Entry'' or found in any request not to comply with the requirements in this subpart.

(c) Except as provided in § 381.200(a) or (b), no person shall remove or cause to be removed from any place designated as the place of inspection, any poultry product which the regulations in this subpart require to be marked in any way, unless the same has been clearly and legibly marked in compliance with this subpart.

(d) Any person receiving inspection service may, if dissatisfied with any decision of an inspector relating to any inspection, file an appeal from such decision: *Provided,* That such appeal is filed within 48 hours from the time the decision was made. Any such appeal from a decision of an inspector shall be made to his/her immediate supervisor having jurisdiction over the subject matter of the appeal, and such supervisor shall determine whether the inspector's decision was correct. Review of such appeal determination, when requested, shall be made by the immediate supervisor of the employee of the Department making the appeal determination. The cost of any such appeal shall be borne by the appellant if the Administrator determines that the appeal is frivolous. The charges for such frivolous appeal shall be at the rate of $9.28 per hour for the time required to make the appeal inspection. The poultry or poultry products involved in any appeal shall be identified by U.S. retained tags and segregated in a manner approved by the inspector pending completion of an appeal inspection.

(e) All condemned carcasses, or condemned parts of carcasses, or other condemned poultry products, except those condemned for biological residues, shall be disposed of by one of the following methods, under the supervision of an inspector of the Inspection Service. (Facilities and materials for carrying out the requirements in this section shall be furnished by the official establishments.)

(1) Steam treatment (which shall be accomplished by processing the condemned product in a pressure tank under at least 40 pounds of steam pressure) or thorough cooking in a kettle or vat, a sufficient time to effectively destroy the product for human food purposes and preclude dissemination of disease through consumption by animals. (Tanks and equipment used for this purpose or for rendering or preparing inedible products shall be in rooms or compartments separate from those used for the preparation of edible products. There shall be no direct connection by means of pipes, or otherwise, between tanks containing inedible products and those containing edible products.)

(2) Incineration or complete destruction by burning.

(3) Chemical denaturing, which shall be accomplished by the liberal application to all carcasses and parts thereof, of:

(i) Crude carbolic acid,

(ii) Kerosene, fuel oil, or used crankcase oil, or

(iii) Any phenolic disinfectant conforming to commercial standards CS 70–41 or CS 71–41 which shall be used in at least 2 percent emulsion or solution.

(4) Any other substances or method that the Administrator approves in specific cases, which will denature the poultry product to the extent necessary to accomplish the purposes of this section.

(5) Carcasses and parts of carcasses condemned for biological residue shall

be disposed of in accordance with paragraph (e)(2) of this section or by burying under the supervision of an inspector.

[37 FR 9706, May 16, 1972, as amended at 48 FR 15890, Apr. 13, 1983; 50 FR 19908, May 13, 1985; 51 FR 37709, Oct. 24, 1986; 53 FR 17015, May 13, 1988; 54 FR 50735, Dec. 11, 1989; 60 FR 67458, Dec. 29, 1995]

§ 381.203 Products offered for entry; charges for storage, cartage, and labor with respect to products which are refused entry.

All charges for storage, cartage, and labor with respect to any product offered for entry which is refused entry pursuant to the regulations shall be paid by the owner or consignee and, in default of such payment, shall constitute a lien against any other products offered for entry thereafter by or for such owner or consignee.

[54 FR 41050, Oct. 5, 1989]

§ 381.204 Marking of poultry products offered for entry; official import inspection marks and devices.

(a) Except for products offered for entry from Canada, poultry products which upon reinspection are found to be acceptable for entry into the United States shall be marked with the official inspection legend shown in paragraph (b) of this section. Such inspection legend shall be placed upon such products only after completion of official import inspection and product acceptance.

(b) The official mark for marking poultry products offered for entry as ''U.S. inspected and passed'' shall be in the following form, and any device approved by the Administrator for applying such mark shall be an official device.[2]

FIGURE 1

(c) When products are refused entry into the United States, the official mark to be applied to the products refused entry shall be in the following form:

UNITED STATES
REFUSED ENTRY

FIGURE 2

(d) The import warning notice prescribed in § 381.200(c) is an official mark.

(e) The ordering and manufacture of brands shall be in accordance with the provisions contained in § 317.3(c) of the Federal meat inspection regulations.

(f) The inspection legend may be placed on containers of product before completion of official import inspection if the containers are being inspected by an import inspector who reports to an Import Field Office Supervisor, the product is not required to be held at the establishment pending the receipt of laboratory test results; and a written procedure for controlled

[2] The number ''I–42'' is given as an example only. The establishment number of the official establishment or official import inspection establishment where the product was inspected shall be shown on each stamp impression.

stamping, submitted by the import establishment and approved by the Director, Import Inspection Division, is on file at the import inspection facility where the inspection is to be performed.

(1) The written procedure for controlled pre-stamping should be in the form of a letter and shall include the following:

(i) That stamping under this subpart will be limited to those lots of product which can be inspected on the day that certificates for the product are examined;

(ii) That all products which have been pre-stamped will be stored in the facility where the import inspection will occur;

(iii) That inspection marks applied under this part will be removed from any lot of product subsequently refused entry on the day the product is rejected; and

(iv) That the establishment will maintain a daily stamping log containing the following information for each lot of product: the date of inspection, the country of origin, the foreign establishment number, the product name, the number of units, the shipping container marks, and the MP–410 number covering the product to be inspected. The daily stamping log must be retained by the establishment in accordance with the requirements of § 381.177.

(2) An establishment's controlled pre-stamping privilege may be cancelled orally or in writing by the inspector who is supervising its enforcement whenever the inspector finds that the establishment has failed to comply with the provisions of this subpart or any conditions imposed pursuant thereto. If the cancellation is oral, the decision and the reasons therefor shall be confirmed in writing, as promptly as circumstances allow. Any person whose controlled pre-stamping privilege has been cancelled may appeal the decision to the Administrator, in writing, within ten (10) days after receiving written notification of the cancellation. The appeal shall state all of the facts and reasons upon which the person relies to show that the controlled pre-stamping was wrongfully cancelled. The Administrator shall grant or deny the appeal, in writing, stating the reasons for such decision, as promptly as circumstances allow. If there is a conflict as to any material fact, a hearing shall be held to resolve such conflict. Rules of practice concerning such a hearing will be adopted by the Administrator. The cancellation of the controlled pre-stamping privilege will be in effect until there is a final determination in the proceeding.

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

[51 FR 37710, Oct. 24, 1986, as amended at 53 FR 17015, May 13, 1988; 54 FR 41050, Oct. 5, 1989]

§ 381.205 Labeling of immediate containers of poultry products offered for entry.

(a) Immediate containers of poultry products imported into the United States shall bear a label printed in English showing in accordance with subpart N of this part all information required by that section (except that the inspection mark and establishment number assigned by the foreign poultry inspection system and certified to the Inspection Service shall be shown instead of the official dressed poultry identification mark or other official inspection legend, and official establishment number); and in addition the label shall show the name of the country of origin preceded by the words ''Product of,'' which statement shall appear immediately under the name of the product.

(b) The labels shall not be false or misleading in any respect.

(c) All marks and other labeling for use on or with immediate containers shall be approved for use by the Food Safety and Inspection Service in accordance with §§ 381.132 and 381.133 before products bearing such marks and other labeling will be permitted for entry into the United States.

[37 FR 9706, May 16, 1972, as amended at 39 FR 4569, Feb. 5, 1974; 54 FR 41050, Oct. 5, 1989; 60 FR 67458, Dec. 29, 1995]

§ 381.206 Labeling of shipping containers of poultry products offered for entry.

Shipping containers of imported poultry products are required to bear in a prominent and legible manner the

name of the product, the name of the country of origin, the foreign inspection system establishment number of the establishment in which the product was processed, and the inspection mark of the country of origin. Labeling on shipping containers shall be examined at the time of inspection in the United States and if found to be false or misleading, the product shall be refused entry. All labeling used with a shipping container of imported poultry products must be approved in accordance with subpart N of this part.

[37 FR 9706, May 16, 1972, as amended at 54 FR 41050, Oct. 5, 1989; 60 FR 67458, Dec. 29, 1995]

§ 381.207 Small importations for consignee's personal use, display, or laboratory analysis.

Any poultry product (other than one which is forbidden entry by other Federal law or regulation) from any country in quantities of less than 50 pounds net weight, exclusively for the personal use of the consignee, or for display or laboratory analysis by the consignee, and not for sale or distribution; which is sound, healthful, wholesome, and fit for human food, and which is not adulterated and contains no substance not permitted by the Act or regulations, may be imported into the United States without a foreign inspection certificate, and such product is not required to be inspected upon arrival in the United States and may be shipped to the consignee without further restriction under this part, except as provided in § 381.199(c): *And provided,* That the Department may with respect to any specific importation, require that the consignee certify that such product is exclusively for the personal use of said consignee, or for display or laboratory analysis by said consignee, and not for sale or distribution.

[37 FR 9706, May 16, 1972, as amended at 54 FR 41050, Oct. 5, 1989]

§ 381.208 Poultry products offered for entry and entered to be handled and transported as domestic; entry into official establishments; transportation.

(a) All poultry products, after entry into the United States in compliance with this subpart, shall be deemed and treated and, except as provided in § 381.207, shall be handled and transported as domestic products, and shall be subject to the applicable provisions of this part and to the provisions of the Poultry Products Inspection Act and the Federal Food, Drug, and Cosmetic Act.

(b) Poultry products entered in accordance with this subpart may, subject to the provisions of the regulations, be taken into official establishments and be mixed with or added to poultry products that are inspected and passed or exempted from inspection in such establishments.

(c) Imported poultry products which have been inspected, passed, and marked under this subpart may be transported in commerce, only upon compliance with the applicable regulations.

[37 FR 9706, May 16, 1972, as amended at 54 FR 41050, Oct. 5, 1989]

§ 381.209 Returned United States inspected and marked poultry products; exemption.

Poultry products which have been inspected and passed by the U.S. Department of Agriculture and are so marked, and are returned from foreign countries, may be imported if they are not adulterated or misbranded at the time of such return. Such products are exempted from further requirements under this part. Such returned shipments shall be reported to the Administrator by letter prior to arrival at the United States port of entry.

Subpart U—Detention; Seizure and Condemnation; Criminal Offenses

§ 381.210 Poultry and other articles subject to administrative detention.

Any poultry carcass, or part thereof; or any product made wholly or in part from any poultry carcass or part thereof; or any dead, dying, disabled, or diseased poultry is subject to detention for a period not to exceed 20 days when found by any authorized representative of the Secretary upon any premises where it is held for purposes of, or during or after distribution in commerce or otherwise subject to the Act, and there is reason to believe that any such poultry or other article is adulterated

or misbranded and is capable of use as human food or has not been inspected, in violation of the provisions of the Act, any other Federal law, or the laws of any State or territory, or the District of Columbia; or that it has been or is intended to be distributed in violation of the provisions of the Act, any other Federal law, or the laws of any State or territory, or the District of Columbia.

§ 381.211 Method of detention; form of detention tag.

An authorized representative of the Secretary shall detain any poultry or other article to be detained under this subpart, by affixing an official ''U.S. Detained'' tag (FSIS Form 8400–2) to such article.

[55 FR 47843, Nov. 16, 1990]

§ 381.212 Notification of detention to the owner of the poultry or other article, or the owner's agent, and person having custody.

(a) When any poultry or other article is detained under this subpart, an authorized representative of the Secretary shall:

(1) Orally notify the immediate custodian of the poultry or other article detained, and

(2) Promptly furnish a copy of a completed ''Notice of Detention'' (FSIS Form 8080–1) to the immediate custodian of the detained poultry or other article.

(b) If the owner of the detained poultry or other article, or the owner's agent, is not the immediate custodian at the time of detention and if the owner, or owner's agent, can be ascertained and notified, an authorized representative of the Secretary shall furnish a copy of the completed ''Notice of Detention'' to the owner, or the owner's agent. Such copy shall be served, as soon as possible, by delivering the notification to the owner, or the owner's agent, or by certifying and mailing the notification to the owner, or the owner's agent, at his or her last known residence or principal office or place of business.

[55 FR 47843, Nov. 16, 1990]

§ 381.213 Notification of governmental authorities having jurisdiction over article detained; form of written notification.

Within 48 hours after the detention of any poultry or other article pursuant to § 381.211, an authorized representative of the Secretary shall give oral or written notification of such detention to any Federal authorities not connected with the Inspection Service, and any State or other governmental authorities, having jurisdiction over such article. In the event notification is given orally, it shall be confirmed in writing, as promptly as circumstances permit.

§ 381.214 Movement of poultry or other article detained; removal of official marks.

(a) No poultry or other article detained in accordance with the provisions in this subpart shall be moved by any person from the place at which it is located when so detained, until released by an authorized representative of the Secretary: *Provided,* That any such article may be moved from the place at which it is located when so detained, for refrigeration or freezing, or storage purposes if such movement has been approved by an authorized representative of the Secretary and the article so moved will be further detained by an authorized representative of the Secretary after such movement.

(b) Upon terminating the detention of such article, an authorized representative of the Secretary shall:

(1) Orally notify the immediate custodian of the released article, and

(2) Furnish copies of a completed ''Notice of Termination of Detention'' (FSIS Form 8400–1) to the persons notified when the article was detained. The notice shall be served by either delivering the notice to such persons or by certifying and mailing the notice to such persons at their last known residences or principal offices or places of business.

(c) All official marks may be required by such representative to be removed from such article before it is released unless it appears to the satisfaction of

the representative that the article is eligible to retain such marks.

[37 FR 9706, May 16, 1972, as amended at 55 FR 47843, Nov. 16, 1990]

§ 381.215 Poultry or other articles subject to judicial seizure and condemnation.

Any poultry carcass, or part thereof, or any product made wholly or in part from any poultry carcass or part thereof; except those exempted from the definition of a poultry product in § 381.15, or any dead, dying, disabled, or diseased poultry, that is being transported in commerce or is otherwise subject to the Act, or is held for sale in the United States after such transportation, is subject to seizure and condemnation, in a judicial proceeding pursuant to section 20 of the Act if such poultry or other article:

(a) Is or has been processed, sold, transported, or otherwise distributed or offered or received for distribution in violation of the Act; or

(b) Is capable of use as human food and is adulterated or misbranded; or

(c) In any other way is in violation of the Act.

§ 381.216 Procedure for judicial seizure, condemnation, and disposition.

Any poultry or other article subject to seizure and condemnation under this subpart is liable to be proceeded against and seized and condemned, and disposed of, at any time, on an appropriate pleading in any U.S. district court, or other proper court specified in section 21 of the Act, within the jurisdiction of which the article is found.

§ 381.217 Authority for condemnation or seizure under other provisions of law.

The provisions of this subpart relating to detention, seizure, condemnation and disposition of poultry or other articles do not derogate from authority for retention, condemnation, or seizure conferred by other provisions of the Act, or other laws.

§ 381.218 Criminal offenses.

The Act contains criminal provisions with respect to numerous offenses specified in the Act, including but not limited to forcible assaults on, or other interference with, any person while engaged in, or on account of the performance of, his official duties under the Act. Criminal provisions with respect to gifts or offers of bribes to such persons and related offenses are contained in the general criminal code (18 U.S.C. 201).

Subpart V—Special Provisions for Designated States and Territories; Criteria and Procedure for Designating Establishments With Operations Which Would Clearly Endanger the Public Health; Disposition of Poultry Products Therein

§ 381.220 Definition of "State".

For purposes of this subpart, the term ''State'' means any State (including the Commonwealth of Puerto Rico) or organized territory.

§ 381.221 Designation of States under paragraph 5(c) of the Act.

Each of the following States has been designated, under paragraph 5(c) of the Act, as a State in which the provisions of sections 1 through 4, 6 through 10, and 12 through 22 of the Act shall apply to operations and transactions wholly within the State. The Federal provisions apply, effective on the dates shown below:

States	Effective date of application of Federal provisions
Alaska	July 31, 1999.
Arkansas	Jan. 2, 1971.
California	Apr. 1, 1976.
Colorado	Jan. 2, 1971.
Connecticut	Oct. 1, 1975.
Florida	Dec. 2, 1997.
Georgia	Jan. 2, 1971.
Guam	Jan. 21, 1972.
Hawaii	Nov. 1, 1995.
Idaho	Jan. 2, 1971.
Kentucky	July 28, 1971.
Maryland	Mar. 31, 1991.
Massachusetts	Jan. 12, 1976.
Michigan	Jan. 2, 1971.
Nebraska	July 28, 1971.
Nevada	July 1, 1973.
New Hampshire	Aug. 6, 1978
New Jersey	Do.
New York	Apr. 10, 1977.
North Dakota	Jan. 2, 1971.
Northern Mariana Islands	Oct. 29, 1979.
Oregon	Jan. 2, 1971.
Pennsylvania	Oct. 31, 1971.

States	Effective date of application of Federal provisions
Puerto Rico	Jan. 17, 1972.
Rhode Island	Oct. 1, 1981.
South Dakota	Jan. 2, 1971.
Tennessee	Oct. 1, 1975.
Virgin Islands	Nov. 27, 1971.
Washington	June 1, 1973.

[42 FR 2949, Jan. 14, 1977, as amended at 42 FR 13270, Mar. 10, 1977; 43 FR 29269, July 7, 1978; 44 FR 55809, Sept. 28, 1979; 46 FR 43829, Sept. 1, 1981; 53 FR 20101, June 2, 1988; 55 FR 36609, Sept. 6, 1990; 56 FR 8909, Mar. 4, 1991; 60 FR 49495, Sept. 26, 1995; 60 FR 54414, Oct. 24, 1995; 62 FR 61010, Nov. 14, 1997; 64 FR 37667, July 13, 1999; 65 FR 6887, Feb. 11, 2000; 66 FR 2207, Jan. 11, 2001; 67 FR 61768, Oct. 2, 2002]

§ 381.222 States designated under paragraph 5(c) of the Act; application of regulations.

The provisions of the regulations in this part apply to operations and transactions wholly within each State designated in § 381.221 under paragraph 5(c) of the Act, except as otherwise provided in this section. (The provisions of the regulations apply in all respects to operations and transactions in or for commerce.)

(a) Each establishment located in such a designated State, shall be granted inspection required under § 381.6(b) only if it is found, upon a combined evaluation of its premises, facilities, and operating procedures, to be capable of producing products that are not adulterated or misbranded.

(b) Section 381.26 will apply to establishments required to have inspection under § 381.6(b), except that existing interconnections between official and unofficial establishments or between official establishments will be permitted if it is determined in specific cases that the interconnections are such that transfer of inedible poultry product into the official establishment would be difficult or unusual, and any such transfers are strictly prohibited, except as permitted under other provisions of the regulations. It is essential that separation of facilities be maintained to the extent necessary to assure that inedible poultry product does not enter the official establishment contrary to the regulations.

(c) Sections 381.49 and 381.51 shall apply to such establishments, except that separate facilities for men and women workers will not be required when the majority of the workers in the establishment are related by blood or marriage, provided that this will not conflict with municipal or State requirements; and except that separation of toilet soil lines from house drainage lines to a point outside the buildings will not be required in existing construction when positive acting backflow devices are installed.

(d) Subpart N of this part shall apply to such establishments except as provided in this paragraph (d).

(1) The operator of each such establishment shall, prior to the inauguration of inspection, identify all labeling and marking devices in use, or proposed for use (upon the date of inauguration of inspection) to the Circuit Supervisor in which the establishment is located. Temporary approval, pending formal approval under § 381.132, will be granted by the Circuit Supervisor for labeling and marking devices that he determines are neither false nor misleading, provided the official inspection legend bearing the official establishment number is applied to the principal display panel of each label, either by a mechanical printing device or a self-destructive pressure sensitive sticker, and provided the label shows the true product name, an accurate ingredient statement, the name and address of the manufacturer, packer, or distributor, and any other features required by paragraph 4(h) of the Act.

(2) The Circuit Supervisor will forward one copy of each item of labeling and a description of each marking device for which he has granted temporary approval to the Washington, DC; office of the Labels and Packaging Staff and will retain one copy in a temporary approval file for the establishment.

(3) The operator of the official establishment shall promptly forward a copy of each item of labeling and a description of each marking device for which temporary approval has been granted by the Circuit Supervisor (showing any modifications required by the Circuit Supervisor) to the Labels and Packaging Staff, Meat and Poultry Inspection Food Safety and Inspection Service, U.S. Department of Agriculture,

Washington, DC 20250, accompanied by the formula and details of preparation and packaging for each product. Within 90 days after inauguration of inspection, all labeling material and marking devices temporarily approved by the Circuit Supervisor must receive approval as required by § 381.132 or their use must be discontinued.

(4) The Circuit Supervisor will also review all shipping containers to insure that they do not have any false or misleading labeling and are otherwise not misbranded. Modifications of unacceptable information on labeling material by the use of pressure sensitive tape of a type that cannot be removed without visible evidence of such removal, or by blocking out with an ink stamp will be authorized on a temporary basis to permit the maximum allowable use of all labeling materials on hand. All unacceptable labeling material which is not modified to comply with the requirements of the regulations must be destroyed or removed from the official establishment.

(e) Sections 381.175 through 381.179 apply to operations and transactions not in or for commerce in a State designated under paragraph 5(c) only if the State is also designated under section 11 of the Act and if such provisions are applicable as shown in § 381.224.

(f) Section 381.185(a) will not apply to States designated under paragraph 5(c) of the Act.

(g) Provisions of this part relating to exports and imports do not apply to operations and transactions solely in or for intrastate commerce.

[37 FR 9706, May 16, 1972, as amended at 39 FR 4569, Feb. 5, 1974; 62 FR 45027, Aug. 25, 1997]

§ 381.223 Control and disposition of nonfederally inspected poultry products in States designated under paragraph 5(c) of the Act.

Upon the effective date of designation of a State under paragraph 5(c) of the Act, no poultry products can be processed within the State unless they are prepared under inspection pursuant to the regulations or are exempted from the requirement of inspection under § 381.10, and no unexempted poultry products which were processed without any inspection can lawfully be distributed within the State. For a period of 90 days from the effective date of such designation, poultry products which were processed in any State listed in § 381.187 and inspected and passed under the supervision of a responsible State or local inspection agency or exempted from State inspection can be distributed solely within the State, provided they are not adulterated or misbranded, except that the official inspection legend shall not be used. Such products may not enter official establishments. After said 90-day period, only federally inspected and passed products may be distributed within the designated State, except as provided in § 381.10.

§ 381.224 Designation of States under section 11 of the Act; application of sections of the Act and the regulations.

Each of the following States has been designated, effective on the date shown below, under section 11 of the Act, as a State in which the provisions of the sections of the Act and regulations specified below shall apply to operators engaged, other than in or for commerce, in the kinds of business indicated below:

Paragraphs of act and regulations	Classes of operators	State	Effective date
Act, 11(b): §§ 381.175–381.178.	Persons engaged (not in or for commerce) in (1) the business of slaughtering any poultry or processing, freezing, packaging, or labeling any poultry carcasses, or parts or products thereof, for use as human food or animal food; (2) the business of buying or selling (as a poultry products broker, wholesaler, or otherwise), transporting or storing any poultry carcasses, or parts or products thereof; or (3) business as a renderer or in the business of buying, selling, or transporting any dead, dying, disabled, or diseased poultry or parts of carcasses of any poultry that died otherwise than by slaughter.	Alaska	July 31, 1999.
		Arkansas	Apr. 1, 1976.
		California	July 1, 1975.
		Colorado	Oct. 1, 1975.
		Connecticut	Nov. 12, 1976.
		Georgia	Nov. 19, 1976.
		Guam	Nov. 12, 1976.
		Idaho	Apr. 18, 1973.
		Kentucky	Nov. 12, 1976.
		Maryland	Jan. 12, 1976.
		Massachusetts	Nov. 12, 1976.
		Michigan	Jan. 31, 1975.
		Nebraska	Jan. 31, 1975.
		Nevada	Oct. 29, 1979.
		New Hampshire	July 1, 1975.
		New Jersey	July 16, 1975.
		New York	July 23, 1973.
		North Dakota	Oct. 29, 1979.
		Northern Mariana Islands.	Jan. 31, 1975.
		Oregon	May 2, 1974.
		Pennsylvania	Nov. 19, 1976.
		Puerto Rico	Mar. 29, 1982.
		Rhode Island	Nov. 12, 1976.
		South Dakota	Oct. 1, 1975.
		Tennessee	Nov. 19, 1976.
		Virgin Islands	Jan. 31, 1975.
		Washington	Nov. 12, 1976.
Act, 11(c); § 381.179	Persons engaged (not in or for commerce) in business as a poultry products broker; renderer; animal food manufacturer; wholesaler or public warehouseman of poultry carcasses, or parts or products thereof; or buying, selling, or transporting dead, dying, disabled, or diseased poultry or parts of carcasses of any poultry that died otherwise than by slaughter.	Alaska	July 31, 1999.
		Arkansas	Apr. 1, 1976.
		California	July 1, 1975.
		Colorado	Oct. 1, 1975.
		Connecticut	Nov. 12, 1976.
		Georgia	Nov. 19, 1976.
		Guam	Nov. 12, 1976.
		Idaho	Apr. 18, 1973.
		Kentucky	Nov. 12, 1976.
		Maryland	Jan. 12, 1976.
		Massachusetts	Nov. 12, 1976.
		Michigan	Jan. 31, 1975.
		Nebraska	Jan. 31, 1975.
		Nevada	Oct. 29, 1979.
		New Hampshire	July 1, 1975.
		New Jersey	July 16, 1975.
		New York	July 23, 1973.
		North Dakota	Oct. 29, 1979.
		Northern Mariana Islands.	Jan. 31, 1975.
		Oregon	May 2, 1974.
		Pennsylvania	Nov. 19, 1976.
		Puerto Rico	Mar. 29, 1982.
		Rhode Island	Nov. 12, 1976.
		South Dakota	Oct. 1, 1975.
		Tennessee	Nov. 19, 1976.
		Virgin Islands	Jan. 31, 1975.
		Washington	Nov. 12, 1976.

Paragraphs of act and regulations	Classes of operators	State	Effective date
Act, 11(d); 381.194	Persons engaged (not in or for commerce) in the business of buying, selling or transporting any dead, dying, disabled or diseased poultry, or parts or carcasses of any poultry that died otherwise than by slaughter.	Alaska	July 31, 1999.
		Arkansas	Nov. 12, 1976.
		Georgia	Nov. 19, 1976.
		Guam	Nov. 12, 1976.
		Idaho	Nov. 12, 1976.
		Maryland	Nov. 12, 1976.
		Michigan	Oct. 29, 1979.
		New Hampshire ..	Oct. 29, 1979.
		Northern Mariana Islands.	Nov. 19, 1976.
		Puerto Rico	Mar. 29, 1982.
		Rhode Island	Nov. 12, 1976.
		South Dakota	Nov. 19, 1976.
		Virgin Islands	Nov. 12, 1976.

[37 FR 9706, May 16, 1972; 65 FR 6888, Feb. 11, 2000]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting §381.224, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and on GPO Access.

§ 381.225 Criteria and procedure for designating establishments with operations which would clearly endanger the public health; disposition of poultry products therein.

(a) An establishment in any State not listed in §381.221 that is preparing poultry products solely for distribution within such State shall be designated as one producing adulterated products which would clearly endanger the public health, if:

(1) Any poultry product processed at the establishment is adulterated in any of the following respects:

(i) It bears or contains a pesticide chemical, food additive, or color additive, that is ''unsafe'' within the meaning of section 408, 409, or 706 of the Federal Food, Drug, and Cosmetic Act or was intentionally subjected to radiation in a manner not permitted under section 409 of said Act; or if it bears or contains any other added poisonous or added deleterious substance which may render it injurious to health or make it unfit for human food; or

(ii) It consists in whole or in part of any filthy, putrid or decomposed substance or is for any other reason unsound, unhealthful, unwholesome, or otherwise unfit for human food (for example, it was prepared from a poultry carcass or other ingredients exhibiting spoilage characteristics); or it is, or was prepared from, a poultry carcass which would be required to be condemned under subpart K at official establishments; or

(iii) It has been prepared, packed or held under insanitary conditions whereby it may have become contaminated with filth or may have been rendered injurious to health (for example, if insects or vermin are not effectively controlled at the establishment, or insanitary water is used in preparing poultry products for human food); or

(iv) It is, in whole or in part, the product of poultry that died otherwise than by slaughter; or

(v) Its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health; and

(2) Such adulterated articles are intended to be or are distributed from the establishment while capable of use as human food.

(b) When any such establishment is identified by an inspector as one producing adulterated poultry products which would clearly endanger public health under the criteria in paragraph (a) of this section, the following procedure will be followed:

(1) The inspector will informally advise the operator of the establishment concerning the deficiencies found by him and report his findings to the appropriate Regional Director for the Inspection Service. When it is determined by the Regional Director that

any establishment preparing poultry products solely for distribution within any State is producing adulterated poultry products for distribution within such State which would clearly endanger the public health, written notification thereof will be issued to the appropriate State officials, including the Governor of the State and the appropriate Advisory Committee, for effective action under State or local law to prevent such endangering of the public health. Such written notification shall clearly specify the deficiencies deemed to result in the production of adulterated poultry products and shall specify a reasonable time for such action under State or local law.

(2) If effective action is not taken under State or local law within the specified time, written notification shall be issued by the Regional Director to the operator of the establishment, specifying the deficiencies involved and allowing him 10 days to present his views or make the necessary corrections, and notifying him that failure to correct such deficiencies may result in designation of the establishment and operator thereof as subject to the provisions of sections 1 through 4, 6 through 10, and 12 through 22 of the Act as though engaged in commerce.

(3) Thereafter the inspector shall survey the establishment and designate it if he determines, in consultation with the Regional Director, that it is producing adulterated poultry products, which would clearly endanger the public health, and formal notice of such designation will be issued to the operator of the establishment by the Regional Director.

(c) Poultry products on hand at the time of designation of an establishment under this section are subject to retention or detention, and seizure and condemnation in accordance with § 381.145 or subpart U of this part: *Provided,* That poultry products that have been federally inspected and so identified and that have not been further prepared at any nonfederally inspected establishment may be released for distribution if the products appear to be not adulterated or misbranded at the time of such release.

(d) No establishment designated under this section can lawfully prepare any poultry products unless it first obtains inspection or qualifies for exemption under § 381.10 of this subpart. All other provisions of the regulations shall apply to establishments designated under this section to the same extent and in the same manner as if they were engaged in commerce, except that the exceptions provided for in § 381.222 shall apply to such establishments.

Subpart X—Canning and Canned Products

SOURCE: 51 FR 45634, Dec. 19, 1986, unless otherwise noted.

§ 381.300 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 poultry food product with a water activity above 0.85 which receives a thermal process either before or after being packed in a hermetically sealed container. Unless otherwise specified, the term ''product'' as used in this 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.

(h) *Critical factor.* Any characteristic, condition or aspect of a product, container, or procedure that affects the adequacy of the process schedule. Critical factors are established by processing authorities.

(i) *Headspace.* That portion of a container not occupied by the product.

(1) *Gross headspace.* The vertical distance between the level of the product (generally the liquid surface) in an upright rigid container and the top edge of the container (i.e., the flange of an unsealed can, the top of the double seam on a sealed can, or the top edge of an unsealed jar).

(2) *Net headspace.* The vertical distance between the level of the product (generally the liquid surface) in an upright rigid container and the inside surface of the lid.

(j) *Hermetically sealed containers.* Airtight containers which are designed and intended to protect the contents against the entry of microorganisms during and after thermal processing.

(1) *Rigid container.* A container, the shape or contour of which, when filled and sealed, is neither affected by the enclosed product nor deformed by external mechanical pressure of up to 10 pounds per square inch gauge (0.7 kg/cm^2) (i.e., normal firm finger pressure).

(2) *Semirigid container.* A container, the shape or contour of which, when filled and sealed, is not significantly affected by the enclosed product under normal atmospheric temperature and pressure, but can be deformed by external mechanical pressure of less than 10 pounds per square inch gauge (0.7 kg/cm^2) (i.e., normal firm finger pressure).

(3) *Flexible container.* A container, the shape or contour of which, when filled and sealed, is significantly affected by the enclosed product.

(k) *Incubation tests.* Tests in which the thermally processed product is kept at a specific temperature for a specified period of time in order to determine if outgrowth of microorganisms occurs.

(l) *Initial temperature.* The temperature, determined at the initiation of a thermal process cycle, of the contents of the coldest container to be processed.

(m) *Low acid product.* A canned product in which any component has a pH value above 4.6.

(n) *Process schedule.* The thermal process and any specified critical factors for a given canned product required to achieve shelf stability.

(o) *Process temperature.* The minimum temperature(s) of the heating medium to be maintained as specified in the process schedule.

(p) *Process time.* The intended time(s) a container is to be exposed to the heating medium while the heating medium is at or above the process temperature(s).

(q) *Processing authority.* The person(s) or organization(s) having expert knowledge of thermal processing requirements for foods in hermetically sealed containers, having access to facilities for making such determinations, and designated by the establishment to perform certain functions as indicated in this subpart.

(r) *Program employee.* Any inspector or other individual employed by the Department or any cooperating agency who is authorized by the Secretary to do any work or perform any duty in connection with the Program (see § 301.2(f)).

(s) *Retort.* A pressure vessel designed for thermal processing of product packed in hermetically sealed containers.

(t) *Seals.* Those parts of a semirigid container and lid or of a flexible container that are fused together in order to hermetically close the container.

(u) *Shelf stability.* The condition achieved by application of heat, sufficient, alone or in combination with other ingredients and/or treatments, to render the product free of microorganisms capable of growing in the product at nonrefrigerated conditions (over 50 °F or 10 °C) at which the product is intended to be held during distribution and storage. Shelf stability and shelf stable are synonymous with commercial sterility and commercially sterile, respectively.

(v) *Thermal process.* The heat treatment necessary to achieve shelf stability as determined by the establishment's processing authority. It is quantified in terms of:

(1) Time(s) and temperature(s); or

(2) Minimum product temperature.

(w) *Venting.* The removal of air from a retort before the start of process timing.

(x) *Water activity.* The ratio of the water vapor pressure of the product to the vapor pressure of pure water at the same temperature.

§ 381.301 Containers and closures.

(a) *Examination and cleaning of empty containers.* (1) Empty containers, closures, and flexible pouch roll stock shall be evaluated by the establishment to ensure that they are clean and free of structural defects and damage that may affect product or container integrity. Such an examination should be based upon a statistical sampling plan.

(2) All empty containers, closures, and flexible pouch roll stock shall be stored, handled, and conveyed in such a manner that will prevent soiling and damage that could affect the hermetic condition of the sealed container.

(3) Just before filling, rigid containers shall be cleaned to prevent incorporation of foreign matter into the finished product. Closures, semirigid containers, preformed flexible pouches, and flexible pouch roll stock contained in original wrappings do not need to be cleaned before use.

(b) *Closure examinations for rigid containers (cans).* (1) Visual examinations. A closure technician shall visually examine the double seams formed by each closing machine head. When seam defects (e.g., cutovers, sharpness, knocked down flanges, false seams, droops) are observed, necessary corrective actions, such as adjusting or repairing the closing machine, shall be taken. In addition to the double seams, the entire container shall be examined for product leakage or obvious defects. A visual examination shall be performed on at least one container from each closing machine head, and the observations, along with any corrective actions, shall be recorded. Visual examinations shall be recorded. Visual examinations shall be conducted with sufficient frequency to ensure proper closure and should be conducted at least every 30 minutes of continuous closing machine operation. Additional visual examinations shall be made by the closure technician at the beginning of production, immediately following every jam in the closing machine and after closing machine adjustment (including adjustment for changes in container size).

(2) *Teardown examinations.* Teardown examinations of double seams formed by each closing machine head shall be performed by a closure technician at a frequency sufficient to ensure proper closure. These examinations should be made at intervals of not more than 4 hours of continuous closing machine operation. At least one container from each closing head shall be examined on the packer's end during each regular examination period. Examination results along with any necessary corrective actions, such as adjusting or repairing the closing machine, shall be promptly recorded by the closure technician. The establishment shall have container specification guidelines for double seam integrity on file and available for review by Program employees. A teardown examination of the can maker's end shall be performed on at least one container selected from each closing machine during each examination period except when teardown examinations are made on incoming empty containers or when, in the case of self-manufactured containers, the containers are made in the vicinity of the establishment and the container plant records are made available to Program employees. Additional teardown examinations on the packer's end should be made at the beginning of production, immediately following every jam in a closing machine and after closing machine adjustment (including adjustment for a change in container size). The following procedures shall be used in teardown examinations of double seams:

(i) One of the following two methods shall be employed for dimensional measurements of the double seam.

(*a*) *Micrometer measurement.* For cylindrical containers, measure the following dimensions (Figure 1) at three

points approximately 120 degrees apart on the double seam excluding and at least one-half inch from the side seam juncture:

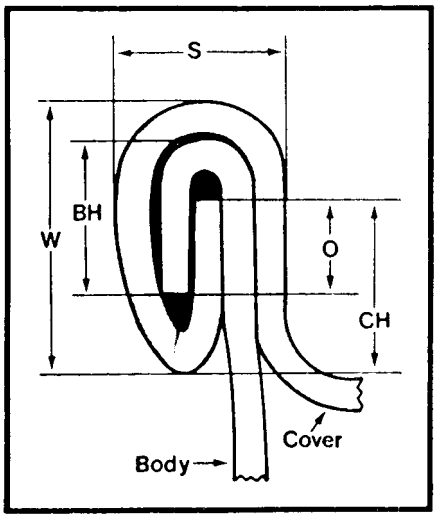
(*1*) Double seam length—W;

(*2*) Double seam thickness—S;

(*3*) Body hook length—BH; and

(*4*) Cover hook length—CH.

Maximum and minimum values for each dimensional measurement shall be recorded by the closure technician.



(*b*) *Seamscope or seam projector.* Required measurements of the seam include thickness, body hook, and overlap. Seam thickness shall be obtained by micrometer. For cylindrical containers, at least two locations, excluding the side seam juncture, shall be used to obtain the required measurements.

(ii) *Seam tightness.* Regardless of the dimensional measurement method used to measure seam dimensions, at a minimum, the seam(s) examined shall be stripped to assess the degree of wrinkling.

(iii) *Side seam juncture rating.* Regardless of the dimensional measurement method used to measure seam dimensions, the cover hook shall be stripped to examine the cover hook droop at the juncture for containers having side seams.

(iv) *Examination of noncylindrical containers.* Examination of noncylindrical containers (e.g., square, rectangular, ''D''-shaped, and irregularly-shaped) shall be conducted as described in paragraphs (b)(2) (i), (ii), and (iii) of this section except that the required dimensional measurements shall be made on the double seam at the points listed in the establishment's container specification guidelines.

(c) *Closure examinations for glass containers.* (1) *Visual examinations.* A closure technician shall visually assess the adequacy of the closures formed by each closing machine. When closure defects, such as loose or cocked caps, fractured or cracked containers and low vacuum jars, are observed, necessary corrective actions, such as adjusting or repairing the closing machine, shall be taken and recorded. In addition to the closures, the entire container shall be examined for defects. Visual examinations shall be made with sufficient frequency to ensure proper closure and should be conducted at least every 30 minutes of continuous closing machine operation. Additional visual examinations shall be made by the closure technician and the observations recorded at the beginning of production, immediately following every jam in the closing machine, and after closing machine adjustment (including adjustment for a change in container size).

(2) *Closure examinations and tests.* Depending upon the container and closure, tests shall be performed by a closure technician at a frequency sufficient to ensure proper closure. These examinations should be made either before or after thermal processing and at intervals of not more than 4 hours of continuous closing machine operation. At least one container from each closing machine shall be examined during each regular examination period. Examination results along with any necessary corrective actions, such as adjusting or repairing the closing machine, shall be promptly recorded by the closure technician. The establishment shall have specification guidelines for closure integrity on file and available for review by Program employees. Additional closure examinations should be made at the beginning of production, immediately following every jam in the closing machine and

after closing machine adjustment (including adjustment for a change in container size).

(d) *Closure examinations for semirigid and flexible containers*—(1) *Heat seals*—(i) *Visual examinations.* A closure technician shall visually examine the seals formed by each sealing machine. When sealing defects are observed, necessary corrective actions, such as adjusting or repairing the sealing machine, shall be taken and recorded. In addition to examining the heat seals, the entire container shall be examined for product leakage or obvious defects. Visual examinations shall be performed before and after the thermal processing operation with sufficient frequency to ensure proper closure. These examinations should be conducted at least in accordance with a statistical sampling plan. All defects noted and corrective actions taken shall be promptly recorded.

(ii) *Physical tests.* Tests determined by the establishment as necessary to assess container integrity shall be conducted by the closure technician at a frequency sufficient to ensure proper closure. These tests shall be performed after the thermal processing operation and should be made at least every 2 hours of continuous production. The establishment's acceptance guidelines for each test procedure shall be on file and available for review by Program employees. Test results along with any necessary corrective actions, such as adjusting or repairing the sealing machine, shall be recorded.

(2) Double seams on semirigid or flexible containers shall be examined and the results recorded as provided in paragraph (b) of this section. Any additional measurements specified by the container manufacturer shall also be made and recorded.

(e) *Container coding.* Each container shall be marked with a permanent, legible, identifying code mark. The mark shall, at a minimum, identify in code the product (unless the product name is lithographed or printed elsewhere on the container) and the day and year the product was packed.

(f) *Handling of containers after closure.* (1) Containers and closures shall be protected from damage which may cause defects that are likely to affect the hermetic condition of the containers. The accumulation of stationary containers on moving conveyors should be minimized to avoid damage to the containers.

(2) The maximum time lapse between closing and initiation of thermal processing shall be 2 hours. However, the Administrator may specify a shorter period of time when considered necessary to ensure product safety and stability. A longer period of time between closing and the initiation of thermal processing may be permitted by the Administrator.

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

§ 381.302 Thermal processing.

(a) *Process schedules.* Prior to the processing of canned product for distribution in commerce, an establishment shall have a process schedule (as defined in § 381.300(n) of this subpart) for each canned poultry product to be packed by the establishment.

(b) *Source of process schedules.* (1) Process schedules used by an establishment shall be developed or determined by a processing authority.

(2) Any change in product formulation, ingredients, or treatments that are not already incorporated in a process schedule and that may adversely affect either the product heat penetration profile or sterilization value requirements shall be evaluated by the establishment's processing authority. If it is determined that any such change adversely affects the adequacy of the process schedule, the processing authority shall amend the process schedule accordingly.

(3) Complete records concerning all aspects of the development or determination of a process schedule, including any associated incubation tests, shall be made available by the establishment to the Program employee upon request.

(c) *Submittal of process information.* (1) Prior to the processing of canned product for distribution in commerce, the establishment shall provide the inspector at the establishment with a list of the process schedules (including alternate schedules) along with any additional applicable information, such as

the retort come-up operating procedures and critical factors.

(2) Letters or other written communications from a processing authority recommending all process schedules shall be maintained on file by the establishment. Upon request by Program employees, the establishment shall make available such letters or written communications (or copies thereof). If critical factors are identified in the process schedule, the establishment shall provide the inspector with a copy of the procedures for measuring, controlling, and recording these factors, along with the frequency of such measurements, to ensure that the critical factors remain within the limits used to establish the process schedule. Once submitted, the process schedules and associated critical factors and the procedures for measuring (including the frequency), controlling, and recording of critical factors shall not be changed without the prior written submittal of the revised procedures (including supporting documentation) to the inspector at the establishment.

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

§ 381.303 Critical factors and the application of the process schedule.

Critical factors specified in the process schedule shall be measured, controlled and recorded by the establishment to ensure that these factors remain within the limits used to establish the process schedule. Examples of factors that are often critical to process schedule adequacy may include:

(a) *General.* (1) Maximum fill-in weight or drained weight;

(2) Arrangement of pieces in the container;

(3) Container orientation during thermal processing;

(4) Product formulation;

(5) Particle size;

(6) Maximum thickness for flexible, and to some extent semirigid containers during thermal processing;

(7) Maximum pH;

(8) Percent salt;

(9) Ingoing (or formulated) nitrite level (ppm);

(10) Maximum water activity; and

(11) Product consistency or viscosity.

(b) *Continuous rotary and batch agitating retorts.* (1) Minimum headspace; and

(2) Retort reel speed.

(c) *Hydrostatic retorts.* (1) Chain or conveyor speed.

(d) *Steam/air retorts.* (1) Steam/air ratio; and

(2) Heating medium flow rate.

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§ 381.304 Operations in the thermal processing area.

(a) *Posting of processes.* Process schedules (or operating process schedules) for daily production, including minimum initial temperatures and operating procedures for thermal processing equipment, shall be posted in a conspicuous place near the thermal processing equipment. Alternatively, such information shall be available to the thermal processing system operator and the inspector.

(b) *Process indicators and retort traffic control.* A system for product traffic control shall be established to prevent product from bypassing the thermal processing operation. Each basket, crate or similar vehicle containing unprocessed product, or at least one visible container in each vehicle, shall be plainly and conspicuously marked with a heat sensitive indicator that will visually indicate whether such unit has been thermally processed. Exposed heat sensitive indicators attached to container vehicles shall be removed before such vehicles are refilled with unprocessed product. Container loading systems for crateless retorts shall be designed to prevent unprocessed product from bypassing the thermal processing operation.

(c) *Initial temperature.* The initial temperature of the contents of the coldest container to be processed shall be determined and recorded by the establishment at the time the processing cycle begins to assure that the temperature of the contents of every container to be processed is not lower than the minimum initial temperature specified in the process schedule. Thermal processing systems which subject the filled and sealed containers to water at any time before process timing begins shall be operated to assure that such

water will not lower the temperature of the product below the minimum initial temperature specified in the process schedule.

(d) *Timing devices.* Devices used to time applicable thermal processing operation functions or events, such as process schedule time, come-up time and retort venting, shall be accurate to assure that all such functions or events are achieved. Pocket watches and wrist watches are not considered acceptable timing devices. Analog and digital clocks are considered acceptable. If such clocks do not display seconds, all required timed functions or events shall have at least a 1-minute safety factor over the specified thermal processing operation times. Temperature/time recording devices shall correspond within 15 minutes to the time of the day recorded on written records required by § 381.306.

(e) *Measurement of pH.* Unless other methods are approved by the Administrator, potentiometric methods using electronic instruments (pH meters) shall be used for making pH determinations when a maximum pH value is specified as a critical factor in a process schedule.

§ 381.305 Equipment and procedures for heat processing systems.

(a) *Instruments and controls common to different thermal processing systems*—(1) *Indicating temperature devices.* Each retort shall be equipped with at least one indicating temperature device that measures the actual temperature within the retort. The indicating temperature device, not the temperature/time recording device, shall be used as the reference instrument for indicating the process temperature.

(i) *Mercury-in-glass thermometers.* A mercury-in-glass thermometer shall have divisions that are readable to 1 °F (or 0.5 °C) and whose scale contains not more than 17 °F/inch (or 4.0 °C/cm) of graduated scale. Each mercury-in-glass thermometer shall be tested for accuracy against a known accurate standard upon installation and at least once a year to ensure its accuracy. Records that specify the date, standard used, test method, and the person or testing authority performing the test shall be maintained on file by the establishment and made available to Program employees. A mercury-in-glass thermometer that has a divided mercury column or that cannot be adjusted to the standard shall be repaired and tested for accuracy before further use, or replaced.

(ii) *Other devices.* Temperature-indicating devices used in lieu of mercury-in-glass thermometers, such as resistance temperature detectors, shall meet known, accurate standards for such devices when tested for accuracy. The records of such testing shall be available to FSIS program employees.

(2) *Temperature/time recording devices.* Each thermal processing system shall be equipped with at least one temperature/time recording device to provide a permanent record of temperatures within the thermal processing system. This recording device may be combined with the steam controller and may be a recording/controlling instrument. When compared to the known accurate indicating temperature device, the recording accuracy shall be equal to or better than 1 °F (or 0.5 °C) at the process temperature. The temperature recording chart should be adjusted to agree with, but shall never be higher than, the known accurate indicating temperature device. A means of preventing unauthorized changes in the adjustment shall be provided. For example, a lock or a notice from management posted at or near the recording device warning that only authorized persons are permitted to make adjustments, are satisfactory means for preventing unauthorized changes. Air-operated temperature controllers shall have adequate filter systems to ensure a supply of clean, dry air. The recorder timing mechanism shall be accurate.

(i) *Chart-type devices.* Devices using charts shall be used only with the correct chart. Each chart shall have a working scale of not more than 55 °F/inch (or 12 °C/cm) within a range of 20 °F (or 11 °C) of the process temperature. Chart graduations shall not exceed 2 °F (or 1 °C) within a range of 10 °F (or 5 °C) of the process temperature. Multipoint plotting chart-type devices shall print temperature readings at intervals that will assure that the parameters of the process time and process temperature have been met. The

frequency of recording should not exceed 1-minute intervals.

(ii) *Other devices.* Temperature/time recording devices or procedures used in lieu of chart-type devices must meet known accurate standards for such devices or procedures when tested for accuracy. Such a device must be accurate enough for ensuring that process time and temperature parameters have been met.

(3) *Steam controllers.* Each retort shall be equipped with an automatic steam controller to maintain the retort temperature. This may be a recording/controlling instrument when combined with a temperature/time recording device.

(4) *Air valves.* All air lines connected to the retorts designed for pressure processing in steam shall be equipped with a globe valve or other equivalent-type valve or piping arrangement that will prevent leakage of air into the retort during the process cycle.

(5) *Water valves.* All retort water lines that are intended to be closed during a process cycle shall be equipped with a globe valve or other equivalent-type valve or piping arrangement that will prevent leakage of water into the retort during the process cycle.

(b) *Pressure processing in steam*—(1) *Batch still retorts.* (i) The basic requirements and recommendations for indicating temperature devices and temperature/time recording devices are described in paragraphs (a) (1) and (2) of this section. Additionally, bulb sheaths or probes of indicating temperature devices and probes of temperature/time recording devices shall be installed either within the retort shell or in external wells attached to the retort. External wells shall be connected to the retort through at least a ¾ inch (1.9 cm) diameter opening and equipped with a 1⁄16 inch (1.6 mm) or larger bleeder opening so located as to provide a constant flow of steam past the length of the bulb or probe. The bleeder for external wells shall emit steam continuously during the entire thermal processing period.

(ii) Steam controllers are required as described in paragraph (a)(3) of this section.

(iii) *Steam inlet.* The steam inlet to each retort shall be large enough to provide steam for proper operation of the retort, and shall enter at a point to facilitate air removal during venting.

(iv) *Crate supports.* Vertical still retorts with bottom steam entry shall employ bottom retort crate supports. Baffle plates shall not be used in the bottom of retorts.

(v) *Steam spreader.* Perforated steam spreaders, if used, shall be maintained to ensure they are not blocked or otherwise inoperative. Horizontal still retorts shall be equipped with perforated steam spreaders that extend the full length of the retort unless the adequacy of another arrangement is documented by heat distribution data or other documentation from a processing authority. Such information shall be maintained on file by the establishment and made available to Program employees for review.

(vi) *Bleeders and condensate removal.* Bleeders, except those for external wells of temperature devices, shall have 1⁄8 inch (or 3 mm) or larger openings and shall be wide open during the entire process including the come-up time. For horizontal still retorts, bleeders shall be located within approximately 1 foot (or 30 cm) of the outermost locations of containers at each end along the top of the retort. Additional bleeders shall be located not more than 8 feet (2.4 m) apart along the top. Bleeders may be installed at positions other than those specified above, as long as the establishment has heat distribution data or other documentation from the manufacturer or from a processing authority demonstrating that the bleeders accomplish removal of air and circulate the steam within the retort. This information shall be maintained on file by the establishment and made available to Program employees for review. All bleeders shall be arranged in a way that enables the retort operator to observe that they are functioning properly. Vertical retorts shall have at least one bleeder opening located in the portion of the retort opposite the steam inlet. All bleeders shall be arranged so that the retort operator can observe that they are functioning properly. In retorts having a steam inlet above the level of the lowest container,

a bleeder shall be installed in the bottom of the retort to remove condensate. The condensate bleeder shall be so arranged that the retort operator can observe that it is functioning properly. The condensate bleeder shall be checked with sufficient frequency to ensure adequate removal of condensate. Visual checks should be performed at intervals of not more than 15 minutes and the results recorded. Intermittent condensate removal systems shall be equipped with an automatic alarm system that will serve as a continuous monitor of condensate bleeder functioning. The automatic alarm system shall be tested at the beginning of each shift for proper functioning and the results recorded. If the alarm system is not functioning properly, it must be repaired before the retort is used.

(vii) *Stacking equipment.* (*a*) Equipment for holding or stacking containers in retorts. Crates, trays, gondolas, carts, and other vehicles for holding or stacking product containers in the retort shall be so constructed to ensure steam circulation during the venting, come-up, and process times. The bottom of each vehicle shall have perforations at least 1 inch (2.5 cm) in diameter on 2 inch (or 5 cm) centers or the equivalent unless the adequacy of another arrangement is documented by heat distribution data or other documentation from a processing authority and such information is maintained on file by the establishment and made available to Program employees for review.

(*b*) *Divider plates.* Whenever one or more divider plates are used between any two layers of containers or placed on the bottom of a retort vehicle, the establishment shall have on file documentation that the venting procedure allows the air to be removed from the retort before timing of the thermal process is started. Such documentation shall be in the form of heat distribution data or documentation from a processing authority. This information shall be made available to Program employees for review.

(viii) *Bleeder and vent mufflers.* If mufflers are used on bleeders or vent systems, the establishment shall have on file documentation that the mufflers do not impede the removal of air from the retort. Such documentation shall consist of either heat distribution data or documentation from the muffler manufacturer or from a processing authority. This information shall be made available to Program employees for review.

(ix) *Vents.* (*a*) Vents shall be located in that portion of the retort opposite the steam inlet and shall be designed, installed, and operated in such a way that air is removed from the retort before timing of the thermal process is started. Vents shall be controlled by a gate, plug cock, or other full-flow valve which shall be fully opened to permit rapid removal of air from retorts during the venting period.

(*b*) Vents shall not be connected to a closed drain system without an atmospheric break in the line. Where a retort manifold connects several pipes from a single retort, the manifold shall be controlled by a gate, plug cock, or other full-flow valve and the manifold shall be of a size such that the cross-sectional area of the manifold is larger than the total cross-sectional area of all connecting vents. The discharge shall not be connected to a closed drain without an atmospheric break in the line. A manifold header connecting vents or manifolds from several still retorts shall lead to the atmosphere. The manifold header shall not be controlled by a valve and shall be of a size such that the cross-sectional area is at least equal to the total cross-sectional area of all connecting retort manifold pipes from the maximum number of retorts to be vented simultaneously.

(*c*) Some typical installations and operating procedures are described below. Other retort installations, vent piping arrangements, operating procedures or auxiliary equipment such as divider plates may be used provided there is documentation that the air is removed from the retort before the process is started. Such documentation shall be in the form of heat distribution data or other documentation from the equipment manufacturer or processing authority. This information shall be maintained on file by the establishment and made available to Program employees for review.

(*d*) For crateless retort installations, the establishment shall have heat distribution data or other documentation from the equipment manufacturer or from a processing authority that demonstrates that the venting procedure used accomplishes the removal of air and condensate. This information shall be maintained on file by the establishment and made available to Program employees for review.

(*e*) Examples of typical installations and operating procedures that comply with the requirements of this section are as follows:

(*1*) Venting horizontal retorts.

(*i*) Venting through multiple 1 inch (2.5 cm) vents discharging directly to the atmosphere.

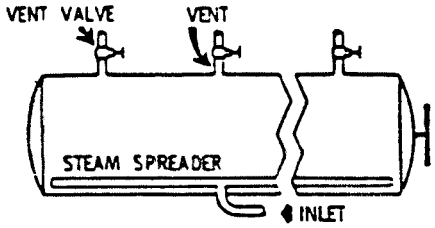

Figure 1.

Specifications (Figure 1): One, 1-inch (2.5 cm) vent for every 5 feet (1.5 m) of retort length, equipped with a gate, plug cock, or other full-flow valve and discharging to atmosphere. The end vents shall not be more than 2½ feet (or 75 cm) from ends of retort.

Venting method (Figure 1): Vent valves shall be wide open for at least 5 minutes and to at least 225 °F (or 107 °C), or at least 7 minutes and to at least 220 °F (or 104.5 °C).

(*ii*) Venting through multiple 1 inch (2.5 cm) vents discharging through a manifold to the atmosphere.

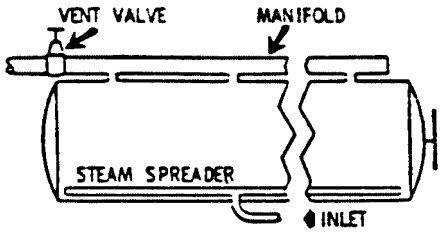

Figure 2.

Specifications (Figure 2): One, 1-inch (2.5 cm) vent for every 5 feet (1.5 m) of retort length; vents not over 2½ feet (or 75 cm) from ends of retort; size of manifold for retorts less than 15 feet (4.6 m) in length, 2½ inches (6.4 cm), and for retorts 15 feet (4.6 m) and over in length, 3 inches (7.6 cm).

Venting method (Figure 2): The manifold vent gate, plug cock, or other full-flow valve shall be wide open for at least 6 minutes and to at least 225 °F (or 107 °C) or for at least 8 minutes and to at least 220 °F (or 104.5 °C).

(*iii*) Venting through water spreaders.

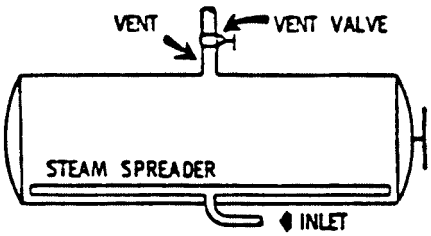

Figure 4.

Specifications (Figure 3): Size of vent and vent valve. For retorts less than 15 feet (4.6 m) in length, 2 inches (or 5 cm); for retorts 15 feet (4.6 m) and over in length, 2½ inches (6.4 cm).

Size of water spreader (Figure 3): For retorts less than 15 feet (4.6 m) in length, 1½ inches (3.8 cm); for retorts 15 feet (4.6 m) and over in length 2 inches (or 5 cm). The number of holes shall be such that their total cross-sectional area is equal to the cross-sectional area of the vent pipe inlet.

Venting method (Figure 3): The gate, plug cock, or other full-flow valve on the water spreader vent shall be wide open for at least 5 minutes and to at least 225 °F (or 107 °C), or for at least 7 minutes and to at least 220 °F (or 104.5 °C).

(*iv*) Venting through a single 2½ inch (6.4 cm) top vent for retorts not exceeding 15 feet (4.6 m) in length.

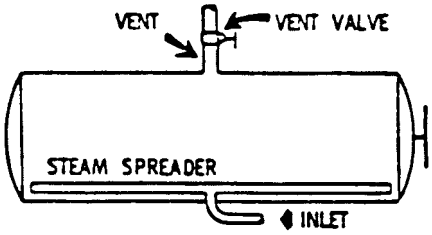

Figure 4.

Specifications (Figure 4): A 2½ inch (6.4 cm) vent equipped with a 2½ inch (6.4 cm) gate, plug cock, or other full-flow valve and located within 2 feet (61 cm) of the center of the retort.

Venting method (Figure 4): The vent valve shall be wide open for at least 4 minutes and to at least 220 °F (or 104.5 °C).

(*2*) Venting vertical retorts.

(*i*) Venting through a 1½ inch (3.8 cm) overflow.

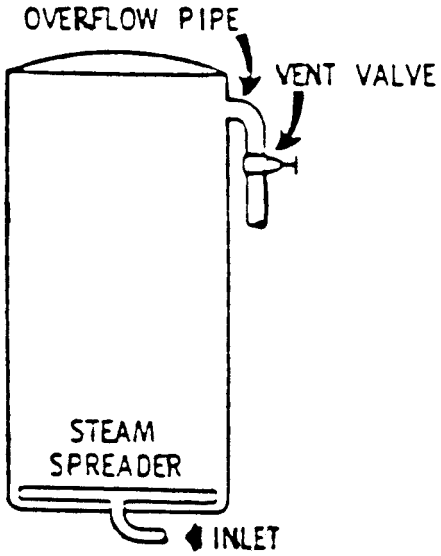

Figure 5.

Specifications (Figure 5): A 1½ inch (3.8 cm) overflow pipe equipped with a 1½ inch (3.8 cm) gate, plug cock, or other full-flow valve and with not more than 6 feet (1.8 m) of 1½ inch (3.8 cm) pipe beyond the valve before a break to the atmosphere or to a manifold header.

Venting method (Figure 5): The vent valve shall be wide open for at least 4 minutes and to at least 218 °F (or 103.5 °C), or for at least 5 minutes and to at least 215 °F (or 101.5 °C).

(*ii*) Venting through a single 1 inch (2.5 cm) side or top vent.

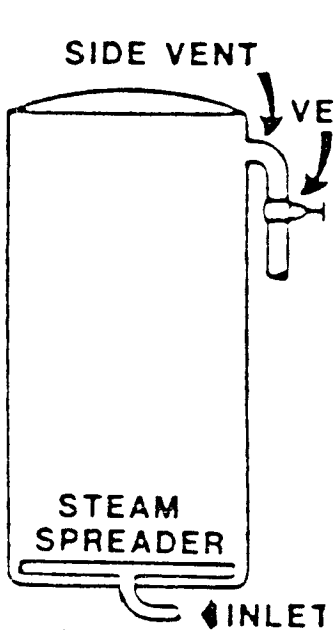

Figure 6.

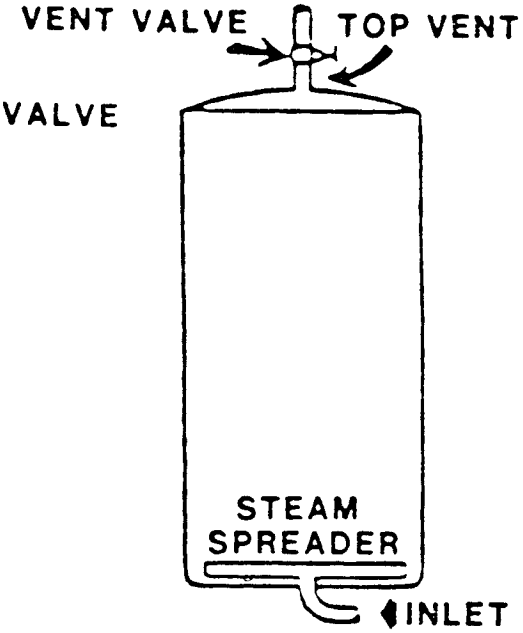

Figure 7.

Specifications (Figure 6 or 7): A 1 inch (2.5 cm) vent in lid or top side, equipped with a gate, plug cock, or other full-flow valve and discharging directly into the atmosphere or to a manifold header.

Venting method (Figure 6 or 7): The vent valve shall be wide open for at least 5 minutes and to at least 230 °F (110 °C), or for at least 7 minutes and to at least 220 °F (or 104.5 °C).

(2) *Batch agitating retorts.* (i) The basic requirements for indicating temperature devices and temperature/time recording devices are described in paragraphs (a) (1) and (2) of this section. Additionally, bulb sheaths or probes of indicating temperature devices and probes of temperature/time recording devices shall be installed either within the retort shell or in external wells attached to the retort. External wells shall be connected to the retort through at least a ¾ inch (1.9 cm) diameter opening and equipped with a 1/16 (1.6 mm) or larger bleeder opening so located as to provide a constant flow of steam past the length of the bulbs or probes. The bleeder for external wells shall emit steam continuously during the entire thermal processing period.

(ii) Steam controllers are required as described in paragraph (a)(3) of this section.

(iii) *Steam inlet.* The steam inlet to each retort shall be large enough to provide steam for proper operation of the retort and shall enter at a point(s) to facilitate air removal during venting.

(iv) *Bleeders.* Bleeders, except those for external wells of temperature devices, shall be ⅛ inch (or 3 mm) or larger and shall be wide open during the entire process including the come-up time. Bleeders shall be located within approximately 1 foot (or 30 cm) of the outermost location of containers, at each end along the top of the retort. Additional bleeders shall be located not more than 8 feet (2.4 m) apart along the top. Bleeders may be installed at positions other than those specified above, as long as the establishment has heat distribution data or other documentation from the manufacturer or from a processing authority that the

bleeders accomplish removal of air and circulate the steam within the retort. This information shall be maintained on file by the establishment and made available to Program employees for review. All bleeders shall be arranged in a way that enables the retort operator to observe that they are functioning properly.

(v) *Venting and condensate removal.* The air in the retort shall be removed before processing is started. Heat distribution data or other documentation from the manufacturer or from the processing authority who developed the venting procedure shall be kept on file by the establishment and made available to Program employees for review. At the time the steam is turned on, the drain shall be opened to remove steam condensate from the retort. A bleeder shall be installed in the bottom of the retort to remove condensate during retort operation. The condensate bleeder shall be so arranged that the retort operator can observe that it is functioning properly. The condensate bleeder shall be checked with sufficient frequency to ensure adequate removal of condensate. Visual checks should be performed at intervals of not more than 15 minutes and the results recorded. Intermittent condensate removal systems shall be equipped with an automatic alarm system that will serve as a continuous monitor of condensate bleeder functioning. The automatic alarm system shall be tested at the beginning of each shift for proper functioning and the results recorded. If the alarm system is not functioning properly, it must be repaired before the retort is used.

(vi) *Retort or reel speed timing.* The retort or reel speed shall be checked before process timing begins and, if needed, adjusted as specified in the process schedule. In addition, the rotational speed shall be determined and recorded at least once during process timing of each retort load processed. Alternatively, a recording tachometer can be used to provide a continuous record of the speed. The accuracy of the recording tachometer shall be determined and recorded at least once per shift by checking the retort or reel speed using an accurate stopwatch. A means of preventing unauthorized speed changes on retorts shall be provided. For example, a lock or a notice from management posted at or near the speed adjustment device warning that only authorized persons are permitted to make adjustments are satisfactory means of preventing unauthorized changes.

(vii) *Bleeder and vent mufflers.* If mufflers are used on bleeders or vent systems, the establishment shall have documentation that the mufflers do not impede the removal of air from the retort. Such documentation shall consist of either heat distribution data or documentation from the muffler manufacturer or from a processing authority. This information shall be maintained on file by the establishment and made available to Program employees for review.

(3) *Continuous rotary retorts.* (i) The basic requirements for indicating temperature devices and temperature/time recording devices are described in paragraphs (a) (1) and (2) of this section. Additionally, bulb sheaths or probes of indicating temperature devices and probes of temperature/time recording devices shall be installed either within the retort shell or in external wells attached to the retort. External wells shall be connected to the retort through at least a ¾ inch (1.9 cm) diameter opening and equipped with a 1/16 inch (1.6 mm) or larger bleeder opening so located as to provide a constant flow of steam past the length of the bulbs or probes. The bleeder for external wells shall emit steam continuously during the entire thermal processing period.

(ii) Steam controllers are required as described in paragraph (a)(3) of this section.

(iii) *Steam inlet.* The steam inlet to each retort shall be large enough to provide steam for proper operation of the retort, and shall enter at a point(s) to facilitate air removal during venting.

(iv) *Bleeders.* Bleeders, except those for external wells of temperature devices, shall be ⅛ inch (3.2 mm) or larger and shall be wide open during the entire process, including the come-up time. Bleeders shall be located within approximately 1 foot (or 30 cm) of the outermost location of containers at each end along the top of the retort.

Additional bleeders shall be located not more than 8 feet (2.4 m) apart along the top of the retort. Bleeders may be installed at positions other than those specified above, as long as the establishment has heat distribution data or other documentation from the manufacturer or a processing authority that the bleeders accomplish removal of air and circulate the steam within the retort. This information shall be maintained on file by the establishment and made available to Program employees for review. All bleeders shall be arranged so that the retort operator can observe that they are functioning properly.

(v) *Venting and condensate removal.* The air in the retort shall be removed before processing is started. Heat distribution data or other documentation from the manufacturer or from the processing authority who developed the venting procedure shall be kept on file by the establishment and made available to Program employees for review. At the time the steam is turned on, the drain shall be opened to remove steam condensate from the retort. A bleeder shall be installed in the bottom of the shell to remove condensate during the retort operation. The condensate bleeder shall be so arranged that the retort operator can observe that it is functioning properly. The condensate bleeder shall be checked with sufficient frequency to ensure adequate removal of condensate. Visual checks should be performed at intervals of not more than 15 minutes and the results recorded. Intermittent condensate removal systems shall be equipped with an automatic alarm system that will serve as a continuous monitor of condensate bleeder functioning. The automatic alarm system shall be tested at the beginning of each shift for proper functioning and the results recorded. If the alarm system is not functioning properly, it must be repaired before the retort is used.

(vi) *Retort speed timing.* The rotational speed of the retort shall be specified in the process schedule. The speed shall be adjusted as specified, and recorded by the establishment when the retort is started, and checked and recorded at intervals not to exceed 4 hours to ensure that the correct retort speed is maintained. Alternatively, a recording tachometer may be used to provide a continuous record of the speed. If a recording tachometer is used, the speed shall be manually checked against an accurate stopwatch at least once per shift and the results recorded. A means of preventing unauthorized speed changes on retorts shall be provided. For example, a lock or a notice from management posted at or near the speed adjustment device warning that only authorized persons are permitted to make adjustments are satisfactory means of preventing unauthorized changes.

(vii) *Bleeders and vent mufflers.* If mufflers are used on bleeders or vent systems, the establishment shall have documentation that the mufflers do not impede the removal of air from the retort. Such documentation shall consist of either heat distribution data or other documentation from the muffler manufacturer or from a processing authority. This information shall be maintained on file by the establishment and made available to Program employees for review.

(4) *Hydrostatic retorts.* (i) The basic requirements for indicating temperature devices and temperature/time recording devices are described in paragraphs (a) (1) and (2) of this section. Additionally, indicating temperature devices shall be located in the steam dome near the steam/water interface. Where the process schedule specifies maintenance of particular water temperatures in the hydrostatic water legs, at least one indicating temperature device shall be located in each hydrostatic water leg so that it can accurately measure water temperature and be easily read. The temperature/time recorder probe shall be installed either within the steam dome or in a well attached to the dome. Each probe shall have a 1/16 inch (1.6 mm) or larger bleeder opening which emits steam continuously during the processing period. Additional temperature/time recorder probes shall be installed in the hydrostatic water legs if the process schedule specifies maintenance of particular temperatures in these water legs.

(ii) Steam controllers are required as described in paragraph (a)(3) of this section.

(iii) *Steam inlet.* The steam inlets shall be large enough to provide steam for proper operation of the retort.

(iv) *Bleeders.* Bleeder openings ¼ inch (or 6 mm) or larger shall be located in the steam chamber(s) opposite the point of steam entry. Bleeders shall be wide open and shall emit steam continuously during the entire process, including the come-up time. All bleeders shall be arranged in such a way that the operator can observe that they are functioning properly.

(v) *Venting.* Before the start of processing operations, the retort steam chamber(s) shall be vented to ensure removal of air. Heat distribution data or other documentation from the manufacturer or from a processing authority demonstrating that the air is removed from the retort prior to processing shall be kept on file at the establishment and made available to Program employees for review.

(vi) *Conveyor speed.* The conveyor speed shall be calculated to obtain the required process time and recorded by the establishment when the retort is started. The speed shall be checked and recorded at intervals not to exceed 4 hours to ensure that the correct conveyor speed is maintained. A recording device may be used to provide a continuous record of the conveyor speed. When a recording device is used, the speed shall be manually checked against an accurate stopwatch at least once per shift by the establishment. A means of preventing unauthorized speed changes of the conveyor shall be provided. For example, a lock or a notice from management posted at or near the speed adjustment device warning that only authorized persons are permitted to make adjustments are satisfactory means of preventing unauthorized changes.

(vii) *Bleeders and vent mufflers.* If mufflers are used on bleeders or vent systems, the establishment shall have documentation that the mufflers do not impede the removal of air from the retort. Such documentation shall consist of either heat distribution data or other documentation from the muffler manufacturer or from a processing authority. This information shall be maintained on file by the establishment and made available to Program employees for review.

(c) *Pressure processing in water*—(1) *Batch still retorts.* (i) The basic requirements for indicating temperature devices and temperature/time recording devices are described in paragraphs (a)(1) and (2) of this section. Additionally, bulbs or probes of indicating temperature devices shall be located in such a position that they are beneath the surface of the water throughout the process. On horizontal retorts, the indicating temperature device bulb or probe shall be inserted directly into the retort shell. In both vertical and horizontal retorts, the indicating temperature device bulb or probe shall extend directly into the water a minimum of 2 inches (or 5 cm) without a separable well or sleeve. In vertical retorts equipped with a recorder/controller, the controller probe shall be located at the bottom of the retort below the lowest crate rest in such a position that the steam does not strike it directly. In horizontal retorts so equipped, the controller probe shall be located between the water surface and the horizontal plane passing through the center of the retort so that there is no opportunity for direct steam impingement on the controller probe. Air-operated temperature controllers shall have filter systems to ensure a supply of clean, dry air.

(ii) *Pressure recording device.* Each retort shall be equipped with a pressure recording device which may be combined with a pressure controller.

(iii) Steam controllers are required as described in paragraph (a)(3) of this section.

(iv) *Heat distribution.* Heat distribution data or other documentation from the equipment manufacturer or a processing authority demonstrating uniform heat distribution within the retort shall be kept on file at the establishment and made available to Program employees for review.

(v) *Crate supports.* A bottom crate support shall be used in vertical retorts. Baffle plates shall not be used in the bottom of the retort.

(vi) *Stacking equipment.* For filled flexible containers and, where applicable, semirigid containers, stacking equipment shall be designed to ensure

that the thickness of the filled containers does not exceed that specified in the process schedule and that the containers do not become displaced and overlap or rest on one another during the thermal process.

(vii) *Drain valve.* A nonclogging, water-tight drain valve shall be used. Screens shall be installed over all drain openings.

(viii) *Water level.* There shall be a means of determining the water level in the retort during operation (i.e., by using a gauge, electronic sensor, or sight glass indicator). For retorts requiring complete immersion of containers, water shall cover the top layer of containers during the entire come-up time and thermal processing periods and should cover the top layer of containers during cooling. For retorts using cascading water or water sprays, the water level shall be maintained within the range specified by the retort manufacturer or processing authority during the entire come-up, thermal processing, and cooling periods. A means to ensure that water circulation continues as specified throughout the come-up, thermal processing, and cooling periods shall be provided. The retort operator shall check and record the water level at intervals to ensure it meets the specified processing parameters.

(ix) *Air supply and controls.* In both horizontal and vertical still retorts, a means shall be provided for introducing compressed air or steam at the pressure required to maintain container integrity. Compressed air and steam entry shall be controlled by an automatic pressure control unit. A nonreturn valve shall be provided in the air supply line to prevent water from entering the system. Overriding air or steam pressure shall be maintained continuously during the come-up, thermal processing, and cooling periods. If air is used to promote circulation, it shall be introduced into the steam line at a point between the retort and the steam control valve at the bottom of the retort. The adequacy of the air circulation for maintaining uniform heat distribution within the retort shall be documented by heat distribution data or other documentation from a processing authority, and such data shall be maintained on file by the establishment and made available to Program employees for review.

(x) *Water recirculation.* When a water recirculation system is used for heat distribution, the water shall be drawn from the bottom of the retort through a suction manifold and discharged through a spreader that extends the length or circumference of the top of the retort. The holes in the water spreader shall be uniformly distributed. The suction outlets shall be protected with screens to keep debris from entering the recirculation system. The pump shall be equipped with a pilot light or a similar device to warn the operator when it is not running, and with a bleeder to remove air when starting operations. Alternatively, a flow-meter alarm system can be used to ensure proper water circulation. The adequacy of water circulation for maintaining uniform heat distribution within the retort shall be documented by heat distribution data or other documentation from a processing authority and such data shall be maintained on file by the establishment and made available to Program employees for review. Alternative methods for recirculation of water in the retort may be used, provided there is documentation in the form of heat distribution data or other documentation from a processing authority maintained on file by the establishment and made available to Program employees for review.

(xi) *Cooling water entry.* In retorts for processing product packed in glass jars, the incoming cooling water should not directly strike the jars, in order to minimize glass breakage by thermal shock.

(2) *Batch agitating retorts.* (i) The basic requirements and recommendations for indicating temperature devices and temperture/time recording devices are described in paragraphs (a)(1) and (2) of this section. Additionally, the indicating temperature device bulb or probe shall extend directly into the water without a separable well or sleeve. The recorder/controller probe shall be located between the water surface and the horizontal plane passing through the center of the retort so that

there is no opportunity for steam to directly strike the controller bulb or probe.

(ii) *Pressure recording device.* Each retort shall be equipped with a pressure recording device which may be combined with a pressure controller.

(iii) *Steam controllers* are required as described in paragraph (a)(3) of this section.

(iv) *Heat distribution.* Heat distribution data or other documentation from the equipment manufacturer or a processing authority shall be kept on file by the establishment and made available to Program employees for review.

(v) *Stacking equipment.* All devices used for holding product containers (e.g., crates, trays, divider plates) shall be so constructed to allow the water to circulate around the containers during the come-up and thermal process periods.

(vi) *Drain valve.* A nonclogging, water-tight drain valve shall be used. Screens shall be installed over all drain openings.

(vii) *Water level.* There shall be a means of determining the water level in the retort during operation (i.e., by using a gauge, electronic sensor, or sight glass indicator). Water shall completely cover all containers during the entire come-up, thermal processing, and cooling periods. A means to ensure that water circulation continues as specified throughout the come-up, thermal processing, and cooling periods shall be provided. The retort operator shall check and record the adequacy of the water level with sufficient frequency to ensure it meets the specified processing parameters.

(viii) *Air supply and controls.* Retorts shall be provided with a means for introducing compressed air or steam at the pressure required to maintain container integrity. Compressed air and steam entry shall be controlled by an automatic pressure control unit. A nonreturn valve shall be provided in the air supply line to prevent water from entering the system. Overriding air or steam pressure shall be maintained continuously during the come-up, thermal processing, and cooling periods. If air is used to promote circulation, it shall be introduced into the steam line at a point between the retort and the steam control valve at the bottom of the retort. The adequacy of the air circulation for maintaining uniform heat distribution within the retort shall be documented by heat distribution data or other documentation from a processing authority, and such data shall be maintained on file by the establishment and made available to Program employees for review.

(ix) *Retort or reel speed timing.* The retort or reel speed timing shall be checked before process timing begins and, if needed, adjusted as specified in the process schedule. In addition, the rotational speed shall be determined and recorded at least once during process timing of each retort load processed. Alternatively, a recording tachometer can be used to provide a continuous record of the speed. The accuracy of the recording tachometer shall be determined and recorded at least once per shift by the establishment by checking the retort or reel speed using an accurate stopwatch. A means of preventing unauthorized speed changes on retorts shall be provided. For example, a lock or a notice from management posted at or near the speed adjustment device warning that only authorized persons are permitted to make adjustments are satisfactory means of preventing unauthorized changes.

(x) *Water recirculation.* If a water recirculation system is used for heat distribution, it shall be installed in such a manner that water will be drawn from the bottom of the retort through a suction manifold and discharged through a spreader which extends the length of the top of the retort. The holes in the water spreader shall be uniformly distributed. The suction outlets shall be protected with screens to keep debris from entering the recirculation system. The pump shall be equipped with a pilot light or a similar device to warn the operator when it is not running and with a bleeder to remove air when starting operations. Alternatively, a flow-meter alarm system can be used to ensure proper water circulation. The adequacy of water circulation for maintaining uniform heat distribution within the retort shall be documented by heat distribution data or other documentation from a processing authority and such data shall be maintained

on file by the establishment and made available to Program employees for review. Alternative methods for recirculation of water in the retort may be used provided there is documentation in the form of heat distribution data or other documentation from a processing authority maintained on file by the establishment and made available to Program employees for review.

(xi) *Cooling water entry.* In retorts for processing product packed in glass jars, the incoming cooling water should not directly strike the jars, in order to minimize glass breakage by thermal shock.

(d) *Pressure processing with steam/air mixtures in batch retorts.* (1) The basic requirements for indicating temperature devices and temperature/time recording devices are described in paragraphs (a) (1) and (2) of this section. Additionally, bulb sheaths or probes for indicating temperature devices and temperature/time recording devices or controller probes shall be inserted directly into the retort shell in such a position that steam does not strike them directly.

(2) Steam controllers are required as described in paragraph (a)(3) of this section.

(3) *Recording pressure controller.* A recording pressure controller shall be used to control the air inlet and the steam/air mixture outlet.

(4) *Circulation of steam/air mixture.* A means shall be provided for the circulation of the steam/air mixture to prevent formation of low-temperature pockets. The efficiency of the circulation system shall be documented by heat distribution data or other documentation from a processing authority, and such data shall be maintained on file by the establishment and made available to Program employees for review. The circulation system shall be checked to ensure its proper functioning and shall be equipped with a pilot light or a similar device to warn the operator when it is not functioning. Because of the variety of existing designs, reference shall be made to the equipment manufacturer for details of installation, operation and control.

(e) *Atmospheric cookers*—(1) *Temperature/time recording device.* Each atmospheric cooker (e.g., hot water bath) shall be equipped with at least one temperature/time recording device in accordance with the basic requirements described in paragraph (a)(2) of this section.

(2) *Heat distribution.* Each atmospheric cooker shall be equipped and operated to ensure uniform heat distribution throughout the processing system during the thermal process. Heat distribution data or other documentation from the manufacturer or a processing authority demonstrating uniform heat distribution within the cooker shall be kept on file by the establishment and made available to Program employees for review.

(f) *Other systems.* All other systems not specifically delineated in this section and used for the thermal processing of canned product shall be adequate to produce shelf-stable products consistently and uniformly.

(g) *Equipment maintenance.* (1) Upon installation, all instrumentation and controls shall be checked by the establishment for proper functioning and accuracy and, thereafter, at any time their functioning or accuracy is suspect.

(2) At least once a year each thermal processing system shall be examined by an individual not directly involved in daily operations to ensure the proper functioning of the system as well as all auxiliary equipment and instrumentation. In addition, each thermal processing system should be examined before the resumption of operation following an extended shutdown.

(3) Air and water valves that are intended to be closed during thermal processing shall be checked by the establishment for leaks. Defective valves shall be repaired or replaced as needed.

(4) Vent and bleeder mufflers shall be checked and maintained or replaced by the establishment to prevent any reduction in vent or bleeder efficiency.

(5) When water spreaders are used for venting, a maintenance schedule shall be developed and implemented to assure that the holes are maintained at their original size.

(6) Records shall be kept on all maintenance items that could affect the adequacy of the thermal process. Records shall include the date and type

of maintenance performed and the person conducting the maintenance.

(h) *Container cooling and cooling water.* (1) Potable water shall be used for cooling except as provided for in paragraphs (h) (2) and (3) of this section.

(2) Cooling canal water shall be chlorinated or treated with a chemical approved by the Administrator as having a bactericidal effect equivalent to chlorination. There shall be a measurable residual of the sanitizer in the water at the discharge point of the canal. Cooling canals shall be cleaned and replenished with potable water to prevent the buildup of organic matter and other materials.

(3) Container cooling waters that are recycled or reused shall be handled in systems that are so designed, operated, and maintained so there is no buildup of microorganisms, organic matter, and other materials in the systems and in the waters. System equipment, such as pipelines, holding tanks and cooling towers, shall be constructed and installed so that they can be cleaned and inspected. In addition, the establishment shall maintain, and make available to Program employees for review, information on at least the following:

(i) System design and construction;

(ii) System operation including the rates of renewal with fresh, potable water and the means for treating the water so that there is a measurable residual of an acceptable sanitizer, per paragraph (h)(2) of this section, in the water at the point where the water exits the container cooling vessel;

(iii) System maintenance including procedures for the periodic cleaning and sanitizing of the entire system; and

(iv) Water quality standards, such as microbiological, chemical and physical, monitoring procedures including the frequency and site(s) of sampling, and the corrective actions taken when water quality standards are not met.

(i) *Post-process handling of containers.* Containers shall be handled in a manner that will prevent damage to the hermetic seal area. All worn and frayed belting, can retarders, cushions, and the like shall be replaced with nonporous materials. To minimize container abrasions, particularly in the seal area, containers should not remain stationary on moving conveyors. All post-process container handling equipment should be kept clean so there is no buildup of microorganisms on surfaces in contact with the containers.

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[51 FR 45634, Dec. 19, 1986, as amended at 65 FR 34390, May 30, 2000]

§ 381.306 Processing and production records.

At least the following processing and production information shall be recorded by the establishment: Date of production; product name and style; container code; container size and type; and the process schedule, including the minimum initial temperature. Measurements made to satisfy the requirements of § 381.303 regarding the control of critical factors shall be recorded. In addition, where applicable, the following information and data shall also be recorded:

(a) *Processing in steam*—(1) *Batch still retorts.* For each retort batch, record the retort number or other designation, the approximate number of containers or the number of retort crates per retort load, product initial temperature, time steam on, the time and temperature vent closed, the start of process timing, time steam off, and the actual processing time. The indicating temperature device and the temperature recorder shall be read at the same time at least once during process timing and the observed temperatures recorded.

(2) *Batch agitating retorts.* In addition to recording the information required for batch, still steam retorts in paragraph (a)(1) of this section, record the functioning of the condensate bleeder(s) and the retort or reel speed.

(3) *Continuous rotary retorts.* Record the retort system number, the approximate total number of containers retorted, product initial temperature, time steam on, the time and temperature vent closed, time process temperature reached, the time the first can enters and the time the last can exits the retort. The retort or reel speed shall be determined and recorded at intervals not to exceed 4 hours. Readings of the indicating temperature device(s) and

temperature recorder(s) shall be made and recorded at the time the first container enters the retort and thereafter with sufficient frequency to ensure compliance with the process schedule. These observations should be made and recorded at intervals not exceeding 30 minutes of continuous retort operation. Functioning of the condensate bleeder(s) shall be observed and recorded at the time the first container enters the retort and thereafter as specified in § 381.305(b)(3)(v).

(4) *Hydrostatic retorts.* Record the retort system number, the approximate total number of containers retorted, product initial temperature, time steam on, the time and temperature vent(s) closed, time process temperature reached, time first containers enter the retort, time last containers exit the retort, and, if specified in the process schedule, measurements of temperatures in the hydrostatic water legs. Readings of the temperature indicating device, which is located in the steam/water interface, and the temperature recording device shall be observed and the temperatures recorded at the time the first containers enter the steam dome. Thereafter, these instruments shall be read and the temperatures recorded with sufficient frequency to ensure compliance with the temperature specified in the process schedule and should be made at least every hour of continuous retort operation. Container conveyor speed, and for agitating hydrostatic retorts, the rotative chain speed, shall be determined and recorded at intervals of sufficient frequency to ensure compliance with the process schedule and should be performed at least every 4 hours.

(b) *Processing in water*—(1) *Batch still retorts.* For each retort batch, record the retort number or other designation, the approximate number of containers or number of retort crates per retort load, product initial temperature, time steam on, the start of process timing, water level, water recirculation rate (if critical), overriding pressure maintained, time steam off, and actual processing time. The indicating temperature device and the temperature recorder shall be read at the same time at least once during process timing and the observed temperatures recorded.

(2) *Batch agitating retorts.* In addition to recording the information required in paragraph (b)(1) of this section, record the retort or reel speed.

(c) *Processing in steam/air mixtures.* For each retort batch, record the retort number or other designation, the approximate number of containers or number of retort crates per retort load, product initial temperature, time steam on, venting procedure, if applicable, the start of process timing, maintenance of circulation of the steam/air mixture, air flow rate or forced recirculation flow rate (if critical), overriding pressure maintained, time steam off, and actual processing time. The indicating temperature device and the temperature recorder shall be read at the same time at least once during process timing and the observed temperatures recorded.

(d) *Atmospheric cookers*—(1) *Batch-type systems.* For each cooker batch, record the cooker number or other designation and the approximate number of containers. In addition, record all critical factors of the process schedule such as cooker temperature, initial temperature, the time the thermal process cycle begins and ends, hold time, and the final internal product temperature.

(2) *Continuous-type systems.* Record the cooker number or other designation, the time the first containers enter and the last containers exit a cooker, and the approximate total number of containers processed. In addition, record all critical factors of the process schedule such as the initial temperature, cooker speed, and final internal product temperature.

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§ 381.307 Record review and maintenance.

(a) *Process records.* Charts from temperature/time recording devices shall be identified by production date, container code, processing vessel number or other designation and other data as necessary to enable correlation with the records required in § 381.306. Each entry on a record shall be made at the time the specific event occurs, and the

recording individual shall sign or initial each record form. No later than 1 working day after the actual process, the establishment shall review all processing and production records to ensure completeness and to determine if all product received the process schedule. All records, including the temperature/time recorder charts and critical factor control records, shall be signed or initialed and dated by the person conducting the review. All processing and production records required in this subpart shall be made available to Program employees for review.

(b) *Automated process monitoring and recordkeeping.* Automated process monitoring and recordkeeping systems shall be designed and operated in a manner which will ensure compliance with the applicable requirements of § 381.306.

(c) *Container closure records.* Written records of all container closure examinations shall specify the container code, the date and time of container closure examination, the measurement(s) obtained, and any corrective actions taken. Records shall be signed or initialed by the container closure technician and shall be reviewed and signed by the establishment within 1 working day after the actual production to ensure that the records are complete and that the closing operations have been properly controlled. All container closure examination records required in this subpart shall be made available to Program employees for review.

(d) *Distribution of product.* Records shall be maintained by the establishment identifying initial distribution of the finished product to facilitate, if necessary, the segregation of specific production lots that may have been contaminated or are otherwise unsound for their intended use.

(e) *Retention of records.* Copies of all processing and production records required in § 381.306 shall be retained for no less than 1 year at the establishment, and for an additional 2 years at the establishment or other location from which the records can be made available to Program employees within 3 working days.

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[51 FR 45634, Dec. 19, 1986, as amended at 65 FR 34390, May 30, 2000]

§ 381.308 Deviations in processing.

(a) Whenever the actual process is less than the process schedule or when any critical factor does not comply with the requirements for that factor as specified in the process schedule, it shall be considered a deviation in processing.

(b) Deviations in processing (or process deviations) must be handled according to:

(1)(i) A HACCP plan for canned product that addresses hazards associated with microbial contamination, or,

(ii) Alternative documented procedures that will ensure that only safe and stable product is shipped in commerce; or

(iii) Paragraph (d) of this section.

(2) Paragraph (d) of this section.

(c) [Reserved]

(d) Procedures for handling process deviations where the HACCP plan for thermally processed/commercially sterile product does not address food safety hazards associated with microbial contamination, where there is no approved total quality control system, or where the establishment has no alternative documented procedures for handling process deviations.

(1) *Deviations identified in-process.* If a deviation is noted at any time before the completion of the intended process schedule, the establishment shall:

(i) Immediately reprocess the product using the full process schedule; or,

(ii) Use an appropriate alternate process schedule provided such a process schedule has been established in accordance with § 381.302 (a) and (b) and is filed with the inspector in accordance with § 381.302(c); or,

(iii) Hold the product involved and have the deviation evaluated by a processing authority to assess the safety and stability of the product. Upon completion of the evaluation, the establishment shall provide the inspector the following:

(*a*) A complete description of the deviation along with all necessary supporting documentation;

(*b*) A copy of the evaluation report; and,

(*c*) A description of any product disposition actions, either taken or proposed.

(iv) Product handled in accordance with paragraph (d)(1)(iii) of this section shall not be shipped from the establishment until the Program has reviewed all of the information submitted and approved the product disposition actions.

(v) If an alternate process schedule is used that is not on file with the inspector or if an alternate process schedule is immediately calculated and used, the product shall be set aside for further evaluation in accordance with paragraphs (d)(1) (iii) and (iv) of this section.

(vi) When a deviation occurs in a continuous rotary retort, the product shall be handled in accordance with paragraphs (d)(1) (iii) and (iv) of this section or in accordance with the following procedures:

(*a*) Emergency stops.

(*1*) When retort jams or breakdowns occur during the processing operations, all containers shall be given an emergency still process (developed per § 381.302(b)) before the retort is cooled or the retort shall be cooled promptly and all containers removed and either reprocessed, repacked and reprocessed, or destroyed. Regardless of the procedure used, containers in the retort intake valve and in transfer valves between retort shells at the time of a jam or breakdown shall be removed and either reprocessed, repacked and reprocessed, or destroyed. Product to be destroyed shall be handled as ''U.S. Inspected and Condemned'', as defined in § 301.2(ee) of this chapter, and disposed of in accordance with part 314 of this chapter.

(*2*) The time the retort reel stopped and the time the retort is used for an emergency still retort process shall be noted on the temperature/time recording device and entered on the other production records required in § 381.306.

(*b*) Temperature drops. When the retort temperature drops below the temperature specified in the process schedule, the reel shall be stopped and the following actions shall be taken:

(*1*) For temperature drops of less than 10 °F (or 5.5 °C) either (*i*) all containers in the retort shall be given an emergency still process (developed per § 381.302(b)) before the reel is restarted; (*ii*) container entry to the retort shall be prevented and an emergency agitating process (developed per § 381.302(b)) shall be used before container entry to the retort is restarted; or (*iii*) container entry to the retort shall be prevented and the reel restarted to empty the retort. The discharged containers shall be reprocessed, repacked and reprocessed, or destroyed. Product to be destroyed shall be handled as ''U.S. Inspected and Condemned'', as defined in § 301.2(ee) of this chapter, and disposed of in accordance with part 314 of this chapter.

(*2*) For temperature drops of 10 °F (or 5.5 °C) or more, all containers in the retort shall be given an emergency still process (developed per § 381.302(b)). The time the reel was stopped and the time the retort was used for a still retort process shall be marked on the temperature/time recording device by the establishment and entered on the other production records required in § 381.306. Alternatively, container entry to the retort shall be prevented and the reel restarted to empty the retort. The discharged containers shall be either reprocessed, repacked and reprocessed, or destroyed. Product to be destroyed shall be handled as ''U.S. Inspected and Condemned'' as defined in § 301.2(ee) of this chapter, and disposed of in accordance with part 314 of this chapter.

(2) *Deviations identified through record review.* Whenever a deviation is noted during review of the processing and production records required by § 381.307 (a) and (b), the establishment shall hold the product involved and the deviation shall be handled in accordance with paragraphs (d)(1) (iii) and (iv) of this section.

(e) *Process deviation file.* The establishment shall maintain full records regarding the handling of each deviation. Such records shall include, at a minimum, the appropriate processing and production records, a full description of the corrective actions taken, the evaluation procedures and results, and the

disposition of the affected product. Such records shall be maintained in a separate file or in a log that contains the appropriate information. The file or log shall be retained in accordance with § 381.307(e) and shall be made available to Program employees upon request.

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§ 381.309 Finished product inspection.

(a) Finished product inspections must be handled according to:

(1) A HACCP plan for canned product that addresses hazards associated with microbiological contamination; or

(2) An FSIS-approved total quality control system; or

(3) Alternative documented procedures that will ensure that only product that is safe and stable is shipped in commerce; or

(4) Paragraph (d) of this section.

(b)–(c) [Reserved]

(d) Procedures for finished product inspections where the HACCP plan for thermally processed/commercially sterile product does not address food safety hazards associated with microbial contamination, where there is no approved total quality control system, or where the establishment has no alternative documented procedures for handling process deviations.

(1) *Incubation of shelf stable canned product*—(i) *Incubator.* The establishment shall provide incubation facilities which include an accurate temperature/time recording device, an indicating temperature device, a means for the circulation of the air inside the incubator to prevent temperature variations, and a means to prevent unauthorized entry into the facility. The Program is responsible for the security of the incubator.

(ii) *Incubation temperature.* The incubation temperature shall be maintained at 95±5 °F (35±2.8 °C). If the incubation temperature falls below 90 °F (or 32 °C) or exceeds 100 °F (or 38 °C) but does not reach 103 °F (or 39.5 °C), the incubation temperature shall be adjusted within the required range and the incubation time extended for the time the sample containers were held at the deviant temperature. If the incubation temperature is at or above 103 °F (or 39.5 °C) for more than 2 hours, the incubation test(s) shall be terminated, the temperature lowered to within the required range, and new sample containers incubated for the required time.

(iii) *Product requiring incubation.* Shelf stable product requiring incubation includes:

(*a*) Low acid products as defined in § 381.300(m); and

(*b*) Acidified low acid products as defined in § 381.300(b).

(iv) *Incubation samples.* (*a*) From each load of product processed in a batch-type thermal processing system (still or agitation), the establishment shall select at least one container for incubation.

(*b*) For continuous rotary retorts, hydrostatic retorts, or other continuous-type thermal processing systems, the establishment shall select at least one container per 1,000 for incubation.

(*c*) Only normal-appearing containers shall be selected for incubation.

(v) *Incubation time.* Canned product requiring incubation shall be incubated for not less than 10 days (240 hours) under the conditions specified in paragraph (d)(1)(ii) of this section.

(vi) *Incubation checks and record maintenance.* Designated establishment employees shall visually check all containers under incubation each working day and the inspector shall be notified when abnormal containers are detected. All abnormal containers should be allowed to cool before a final decision on their condition is made. For each incubation test the establishment shall record at least the product name, container size, container code, number of containers incubated, in and out dates, and incubation results. The establishment shall retain such records, along with copies of the temperature/time recording charts, in accordance with § 381.307(e).

(vii) *Abnormal containers.* The finding of abnormal containers (as defined in § 381.300(a)) among incubation samples is cause to officially retain at least the code lot involved.

(viii) *Shipping.* No product shall be shipped from the establishment before

the end of the required incubation period except as provided in this paragraph or paragraph (b) or (c) of this section. An establishment wishing to ship product prior to the completion of the required incubation period shall submit a written proposal to the area supervisor. Such a proposal shall include provisions that will assure that shipped product will not reach the retail level of distribution before sample incubation is completed and that product can be returned promptly to the establishment should such action be deemed necessary by the incubation test results. Upon receipt of written approval from the area supervisor, product may be routinely shipped provided the establishment continues to comply with all requirements of this subpart.

(2) *Container condition.* (i) *Normal containers.* Only normal-appearing containers shall be shipped from an establishment as determined by an appropriate sampling plan or other means acceptable to Program employees.

(ii) *Abnormal containers.* When abnormal containers are detected by any means other than incubation, the establishment shall inform the inspector and the affected code lot(s) shall not be shipped until the Program has determined that the product is safe and stable. Such a determination will take into account the cause and level of abnormals in the affected lot(s) as well as any product disposition actions either taken or proposed by the establishment.

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

[51 FR 45634, Dec. 19, 1986, as amended at 57 FR 37872, Aug. 21, 1992; 57 FR 55443, Nov. 25, 1992; 62 FR 45027, Aug. 25, 1997; 65 FR 34391, May 30, 2000; 65 FR 53533, Sept. 5, 2000]

§ 381.310 Personnel and training.

All operators of thermal processing systems specified in § 381.305 and container closure technicians shall be under the direct supervision of a person who has successfully completed a school of instruction that is generally recognized as adequate for properly training supervisors of canning operations.

[51 FR 45634, Dec. 19, 1986]

§ 381.311 Recall procedure.

Establishments shall prepare and maintain a current procedure for the recall of all canned product covered by this subpart. Upon request, the recall procedure shall be made available to Program employees for review.

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

Subpart Y—Nutrition Labeling

SOURCE: 58 FR 675, Jan. 6, 1993, unless otherwise noted.

§ 381.400 Nutrition labeling of poultry products.

(a) Nutrition labeling shall be provided for all poultry products intended for human consumption and offered for sale, except single-ingredient, raw products, in accordance with the requirements of § 381.409, except as exempted under § 381.500 of this subpart.

(b) Nutrition labeling may be provided for single-ingredient, raw poultry products in accordance with the requirements of §§ 381.409 and 381.445. Significant participation in voluntary nutrition labeling shall be measured by the Agency in accordance with §§ 381.443 and 381.444 of this subpart.

[58 FR 675, Jan. 6, 1993, as amended at 60 FR 197, Jan. 3, 1995]

§ 381.401 [Reserved]

§ 381.402 Location of nutrition information.

(a) Nutrition information on a label of a packaged poultry product shall appear on the label's principal display panel or on the information panel, except as provided in paragraphs (b) and (c) of this section.

(b) Nutrition information for gift packs may be shown at a location other than on the product label, provided that the labels for these products bear no nutrition claim. In lieu of on the product label, nutrition information may be provided by alternate means such as product label inserts.

(c) Poultry products in packages that have a total surface area available to bear labeling greater than 40 square inches but whose principal display panel and information panel do not

provide sufficient space to accommodate all required information may use any alternate panel that can be readily seen by consumers for the nutrition information. In determining the sufficiency of available space for the nutrition information, the space needed for vignettes, designs, and other nonmandatory label information on the principal display panel may be considered.

[58 FR 675, Jan. 6, 1993, as amended at 59 FR 40215, Aug. 8, 1994]

§§ 381.403–381.407 [Reserved]

§ 381.408 Labeling of poultry products with number of servings.

The label of any package of a poultry product that bears a representation as to the number of servings contained in such package shall meet the requirements of § 381.121(c)(7).

§ 381.409 Nutrition label content.

(a) All nutrient and food component quantities shall be declared in relation to a serving as defined in this section.

(b)(1) The term ''serving'' or ''serving size'' means an amount of food customarily consumed per eating occasion by persons 4 years of age or older, which is expressed in a common household measure that is appropriate to the product. When the product is specially formulated or processed for use by infants or by toddlers, a serving or serving size means an amount of food customarily consumed per eating occasion by infants up to 12 months of age or by children 1 through 3 years of age, respectively.

(2) Except as provided in paragraphs (b)(8), (b)(12), and (b)(14) of this section and for products that are intended for weight control and are available only through a weight-control or weight-maintenance program, the serving size declared on a product label shall be determined from the ''Reference Amounts Customarily Consumed Per Eating Occasion—General Food Supply'' (Reference Amount(s)) that appear in § 381.412(b) using the procedures described in this paragraph (b). For products that are both intended for weight control and available only through a weight-control program, a manufacturer may determine the serving size that is consistent with the meal plan of the program. Such products must bear a statement, ''for sale only through the _____ program'' (fill in the blank with the name of the appropriate weight-control program, e.g., Smith's Weight Control), on the principal display panel. However, the Reference Amounts in § 381.412(b) shall be used for purposes of evaluating whether weight-control products that are available only through a weight-control program qualify for nutrition claims.

(3) The declaration of nutrient and food component content shall be on the basis of the product ''as packaged'' for all products, except that single-ingredient, raw products may be declared on the basis of the product ''as consumed'' as set forth in § 381.445(a)(1). In addition to the required declaration on the basis of ''as packaged'' for products other than single ingredient, raw products, the declaration may also be made on the basis of ''as consumed,'' provided that preparation and cooking instructions are clearly stated.

(4) For products in discrete units (e.g., chicken wings, and individually packaged products within a multi-serving package), and for products which consist of two or more foods packaged and presented to be consumed together where the ingredient represented as the main ingredient is in discrete units (e.g., chicken wings and barbecue sauce), the serving size shall be declared as follows:

(i) If a unit weighs 50 percent or less of the Reference Amount, the serving size shall be the number of whole units that most closely approximates the Reference Amount for the product category.

(ii) If a unit weighs more than 50 percent but less than 67 percent of the Reference Amount, the manufacturer may declare one unit or two units as the serving size.

(iii) If a unit weighs 67 percent or more but less than 200 percent of the Reference Amount, the serving size shall be one unit.

(iv) If a unit weighs 200 percent or more of the Reference Amount, the manufacturer may declare one unit as the serving size if the whole unit can

reasonably be consumed at a single eating occasion.

(v) For products that have Reference Amounts of 100 grams (or milliliter) or larger and are individual units within a multi-serving package, if a unit contains more than 150 percent but less than 200 percent of the Reference Amount, the manufacturer may decide whether to declare the individual unit as 1 or 2 servings.

(vi) For products which consist of two or more foods packaged and presented to be consumed together where the ingredient represented as the main ingredient is in discrete units (e.g., chicken wings and barbecue sauce), the serving size may be the number of discrete units represented as the main ingredient plus proportioned minor ingredients used to make the Reference Amount for the combined product as determined in § 381.412(c).

(vii) For packages containing several individual single-serving containers, each of which is labeled with all required information including nutrition labeling as specified in this section (i.e., are labeled appropriately for individual sale as single-serving containers), the serving size shall be 1 unit.

(5) For products in large discrete units that are usually divided for consumption (e.g., pizza, pan of poultry lasagna), for unprepared products where the entire contents of the package is used to prepare large discrete units that are usually divided for consumption (e.g., pizza kit), and for products which consist of two or more foods packaged and presented to be consumed together where the ingredient represented as the main ingredient is a large discrete unit usually divided for consumption, the serving size shall be the fractional slice of the ready-to-eat product (e.g., ⅛ quiche, ¼ pizza) that most closely approximates the Reference Amount for the product category. The serving size may be the fraction of the package used to make the Reference Amount for the unprepared product determined in § 381.412(d) or the fraction of the large discrete unit represented as the main ingredient plus proportioned minor ingredients used to make the Reference Amount of the combined product determined in § 381.412(c). In expressing the fractional slice, manufacturers shall use ½, ⅓, ¼, ⅕, ⅙, or smaller fractions that can be generated by further division by 2 or 3.

(6) For nondiscrete bulk products (e.g., whole turkey, turkey breast, ground poultry), and for products which consist of two or more foods packaged and presented to be consumed together where the ingredient represented as the main ingredient is a bulk product (e.g., turkey breast and gravy), the serving size shall be the amount in household measure that most closely approximates the Reference Amount for the product category and may be the amount of the bulk product represented as the main ingredient plus proportioned minor ingredients used to make the Reference Amount for the combined product determined in § 381.412(c).

(7) For labeling purposes, the term ''common household measure'' or ''common household unit'' means cup, tablespoon, teaspoon, piece, slice, fraction (e.g., ¼ pizza), ounce (oz), or other common household equipment used to package food products (e.g., jar or tray). In expressing serving size in household measures, except as specified in paragraphs (b)(7)(iv), (v), and (vi) of this section, the following rules shall be used:

(i) Cups, tablespoons, or teaspoons shall be used wherever possible and appropriate. Cups shall be expressed in ¼- or ⅓-cup increments, tablespoons in whole number of tablespoons for quantities less than ¼ cup but greater than or equal to 2 tablespoons (tbsp), 1, 1⅓, 1½, or 1⅔ tbsp for quantities less than 2 tbsp but greater than or equal to 1 tbsp, and teaspoons in whole number of teaspoons for quantities less than 1 tbsp but greater than or equal to 1 teaspoon (tsp), and in ¼-tsp increments for quantities less than 1 tsp.

(ii) If cups, tablespoons or teaspoons are not applicable, units such as piece, slice, tray, jar, and fraction shall be used.

(iii) If cups, tablespoons and teaspoons, or units such as piece, slice, tray, jar, or fraction are not applicable, ounces may be used. Ounce measurements shall be expressed in 0.5-ounce

increments most closely approximating the Reference Amount with rounding indicated by the use of the term ''about'' (e.g., about 2.5 ounces).

(iv) A description of the individual container or package shall be used for single-serving containers and meal-type products and for individually packaged products within multi-serving containers (e.g., can, box, package, meal, or dinner). A description of the individual unit shall be used for other products in discrete units (e.g., wing, slice, link, or patty).

(v) For unprepared products where the entire contents of the package is used to prepare large discrete units that are usually divided for consumption (e.g., pizza kit), the fraction or portion of the package may be used.

(vi) For products that consist of two or more distinct ingredients or components packaged and presented to be consumed together (e.g., chicken wings with a glaze packet), the nutrition information may be declared for each component or as a composite. The serving size may be provided in accordance with the provisions of paragraphs (b)(4), (b)(5), and (b)(6) of this section.

(vii) For nutrition labeling purposes, a teaspoon means 5 milliliters (mL), a tablespoon means 15 mL, a cup means 240 mL, and 1 oz in weight means 28 grams (g).

(viii) When a serving size, determined from the Reference Amount in § 381.412(b) and the procedures described in this section, falls exactly half way between two serving sizes (e.g., 2.5 tbsp), manufacturers shall round the serving size up to the next incremental size.

(8) A product that is packaged and sold individually and that contains less than 200 percent of the applicable Reference Amount shall be considered to be a single-serving container, and the entire content of the product shall be labeled as one serving, except for products that have Reference Amounts of 100 g (or mL) or larger, manufacturers may decide whether a package that contains more than 150 percent but less than 200 percent of the Reference Amount is 1 or 2 servings. Packages sold individually that contain 200 percent or more of the applicable Reference Amount may be labeled as a single-serving if the entire content of the package can reasonably be consumed at a single-eating occasion.

(9) A label statement regarding a serving shall be the serving size expressed in common household measures as set forth in paragraphs (b)(2) through (b)(8) of this section and shall be followed by the equivalent metric quantity in parenthesis (fluids in milliliters and all other foods in grams), except for single-serving containers.

(i) For a single-serving container, the parenthetical metric quantity, which will be presented as part of the net weight statement on the principal display panel, is not required except where nutrition information is required on a drained weight basis according to paragraph (b)(11) of this section. However, if a manufacturer voluntarily provides the metric quantity on products that can be sold as single servings, then the numerical value provided as part of the serving size declaration must be identical to the metric quantity declaration provided as part of the net quantity of contents statement.

(ii) The gram or milliliter quantity equivalent to the household measure should be rounded to the nearest whole number except for quantities that are less than 5 g (mL). The gram (mL) quantity between 2 and 5 g (mL) should be rounded to the nearest 0.5 g (mL) and the g (mL) quantity less than 2 g (mL) should be expressed in 0.1-g (mL) increments.

(iii) In addition, serving size may be declared in ounce, in parenthesis, following the metric measure separated by a slash where other common household measures are used as the primary unit for serving size, e.g., 1 slice (28 g/1 oz) for sliced chicken roll. The ounce quantity equivalent to the metric quantity should be expressed in 0.1-oz increments.

(iv) If a manufacturer elects to use abbreviations for units, the following abbreviations shall be used: tbsp for tablespoon, tsp for teaspoon, g for gram, mL for milliliter, and oz for ounce.

(10) Determination of the number of servings per container shall be based on the serving size of the product determined by following the procedures described in this section.

(i) The number of servings shall be rounded to the nearest whole number except for the number of servings between 2 and 5 servings and random weight products. The number of servings between 2 and 5 servings shall be rounded to the nearest 0.5 serving. Rounding should be indicated by the use of the term ''about'' (e.g., about 2 servings; about 3.5 servings).

(ii) When the serving size is required to be expressed on a drained solids basis and the number of servings varies because of a natural variation in unit size, the manufacturer may state the typical number of servings per container (e.g., usually 5 servings).

(iii) For random weight products, a manufacturer may declare ''varied'' for the number of servings per container provided the nutrition information is based on the Reference Amount expressed in ounces. The manufacturer may provide the typical number of servings in parenthesis following the ''varied'' statement (e.g., varied (approximately 8 servings per pound)).

(iv) For packages containing several individual single-serving containers, each of which is labeled with all required information including nutrition labeling as specified in this section (i.e., are labeled appropriately for individual sale as single-serving containers), the number of servings shall be the number of individual packages within the total package.

(v) For packages containing several individually packaged multi-serving units, the number of servings shall be determined by multiplying the number of individual multi-serving units in the total package by the number of servings in each individual unit.

(11) The declaration of nutrient and food component content shall be on the basis of product as packaged or purchased with the exception of products that are packed or canned in water, brine, or oil but whose liquid packing medium is not customarily consumed. Declaration of the nutrient and food component content of products that are packed in liquid which is not customarily consumed shall be based on the drained solids.

(12) Serving size for meal-type products as defined in § 381.413(l) shall be the entire content (edible portion only) of the package.

(13) Another column of figures may be used to declare the nutrient and food component information in the same format as required by § 381.409(e),

(i) Per 100 grams, 100 milliliters, or 1 ounce of the product as packaged or purchased.

(ii) Per one unit if the serving size of a product in discrete units in a multi-serving container is more than one unit.

(14) If a product consists of assortments of poultry products (e.g., variety packs) in the same package, nutrient content shall be expressed on the entire package contents or on each individual product.

(15) If a product is commonly combined with other ingredients or is cooked or otherwise prepared before eating, and directions for such combination or preparations are provided, another column of figures may be used to declare the nutrient contents on the basis of the product as consumed for the product alone (e.g., a cream soup mix may be labeled with one set of Daily Values for the dry mix (per serving), and another set for the serving of the final soup when prepared (e.g., per serving of cream soup mix and 1 cup of vitamin D fortified whole milk)): *Provided,* that the type and quantity of the other ingredients to be added to the product by the user and the specific method of cooking and other preparation shall be specified prominently on the label.

(c) The declaration of nutrition information on the label or in labeling of a poultry product shall contain information about the level of the following nutrients, except for those nutrients whose inclusion, and the declaration of amounts, is voluntary as set forth in this paragraph. No nutrients or food components other than those listed in this paragraph as either mandatory or voluntary may be included within the nutrition label. Except as provided for in paragraph (f) or (g) of this section, nutrient information shall be presented using the nutrient names specified and in the following order in the formats specified in paragraph (d) or (e) of this section.

(1) ''Calories, total,'' ''Total calories,'' or ''Calories'': A statement of the caloric content per serving, expressed to the nearest 5-calorie increment up to and including 50 calories, and 10-calorie increment above 50 calories, except that amounts less than 5 calories may be expressed as zero. Energy content per serving may also be expressed in kilojoule units, added in parenthesis immediately following the statement of the caloric content.

(i) Caloric content may be calculated by the following methods. Where either specific or general food factors are used, the factors shall be applied to the actual amount (i.e., before rounding) of food components (e.g., fat, carbohydrate, protein, or ingredients with specific food factors) present per serving.

(A) Using specific Atwater factors (i.e., the Atwater method) given in Table 13, page 25, ''Energy Value of Foods—Basis and Derivation,'' by A. L. Merrill and B. K. Watt, United States Department of Agriculture (USDA), Agriculture Handbook No. 74 (Slightly revised February 1973), which is incorporated by reference. Table 13 of the ''Energy Value of Foods—Basis and Derivation,'' Agriculture Handbook No. 74 is incorporated as it exists on the date of approval. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. It is available for inspection at the Office of the Federal Register, suite 700, 800 North Capitol Street, NW., Washington, DC, or at the office of the FSIS Docket Clerk, Room 3171, South Building, 14th and Independence Avenue, SW., Washington, DC. Copies of the incorporation by reference are available from the Product Assessment Division, Regulatory Programs, Food Safety and Inspection Service, U.S. Department of Agriculture, Room 329, West End Court Building, Washington, DC 20250–3700;

(B) Using the general factors of 4, 4, and 9 calories per gram for protein, total carbohydrate, and total fat, respectively, as described in USDA's Agriculture Handbook No. 74 (Slightly revised February 1973), pages 9–11, which is incorporated by reference. Pages 9–11, Agriculture Handbook No. 74 is incorporated as it exists on the date of approval. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. (The availability of this incorporation by reference is given in paragraph (c)(1)(i)(A) of this section.);

(C) Using the general factors of 4, 4, and 9 calories per gram for protein, total carbohydrate less the amount of insoluble dietary fiber, and total fat, respectively, as described in USDA's Agriculture Handbook No. 74 (Slightly revised February 1973), pages 9–11, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. (The availability of this incorporation by reference is given in paragraph (c)(1)(i)(A) of this section.); or

(D) Using data for specific food factors for particular foods or ingredients approved by the Food and Drug Administration (FDA) and provided in parts 172 or 184 of 21 CFR, or by other means, as appropriate.

(ii) ''Calories from fat'': A statement of the caloric content derived from total fat as defined in paragraph (c)(2) of this section per serving, expressed to the nearest 5-calorie increment, up to and including 50 calories, and the nearest 10-calorie increment above 50 calories, except that label declaration of ''calories from fat'' is not required on products that contain less than 0.5 gram of fat per serving and amounts less than 5 calories may be expressed as zero. This statement shall be declared as provided in paragraph (d)(5) of this section.

(iii) ''Calories from saturated fat'' or ''Calories from saturated'' (VOLUNTARY): A statement of the caloric content derived from saturated fat as defined in paragraph (c)(2)(i) of this section per serving may be declared voluntarily, expressed to the nearest 5-calorie increment, up to and including 50 calories, and the nearest 10-calorie increment above 50 calories, except that amounts less than 5 calories may be expressed as zero. This statement shall be indented under the statement of calories from fat as provided in paragraph (d)(5) of this section.

(2) ''Fat, total'' or ''Total fat'': A statement of the number of grams of total fat per serving defined as total

lipid fatty acids and expressed as triglycerides. Amounts shall be expressed to the nearest 0.5 (½)-gram increment below 5 grams and to the nearest gram increment above 5 grams. If the serving contains less than 0.5 gram, the content shall be expressed as zero.

(i) ''Saturated fat'' or ''Saturated'': A statement of the number of grams of saturated fat per serving defined as the sum of all fatty acids containing no double bonds, except that label declaration of saturated fat content information is not required for products that contain less than 0.5 gram of total fat per serving if no claims are made about fat or cholesterol content, and if ''calories from saturated fat'' is not declared. Saturated fat content shall be indented and expressed as grams per serving to the nearest 0.5 (½)-gram increment below 5 grams and to the nearest gram increment above 5 grams. If the serving contains less than 0.5 gram, the content shall be expressed as zero.

(A) ''Stearic Acid'' (VOLUNTARY): A statement of the number of grams of stearic acid per serving may be declared voluntarily, except that when a claim is made about stearic acid, label declaration shall be required. Stearic acid content shall be indented under saturated fat and expressed to the nearest 0.5 (½)-gram increment below 5 grams and the nearest gram increment above 5 grams. If the serving contains less than 0.5 gram, the content shall be expressed as zero.

(B) [Reserved]

(ii) ''Polyunsaturated fat'' or ''Polyunsaturated'' (VOLUNTARY): A statement of the number of grams of polyunsaturated fat per serving defined as *cis,cis*-methylene-interrupted polyunsaturated fatty acids may be declared voluntarily, except that when monounsaturated fat is declared, or when a claim about fatty acids or cholesterol is made on the label or in labeling of a product other than one that meets the criteria in § 381.462(b)(1) for a claim for ''fat free,'' label declaration of polyunsaturated fat is required. Polyunsaturated fat content shall be indented and expressed as grams per serving to the nearest 0.5 (½)-gram increment below 5 grams and to the nearest gram increment above 5 grams. If the serving contains less than 0.5 gram, the content shall be expressed as zero.

(iii) ''Monounsaturated fat'' or ''Monounsaturated'' (VOLUNTARY): A statement of the number of grams of monounsaturated fat per serving defined as *cis*-monounsaturated fatty acids may be declared voluntarily, except that when polyunsaturated fat is declared, or when a claim about fatty acids or cholesterol is made on the label or in labeling of a product other than one that meets the criteria in § 381.462(b)(1) for a claim for ''fat free,'' label declaration of monounsaturated fat is required. Monounsaturated fat content shall be indented and expressed as grams per serving to the nearest 0.5 (½)-gram increment below 5 grams and to the nearest gram increment above 5 grams. If the serving contains less than 0.5 gram, the content shall be expressed as zero.

(3) ''Cholesterol'': A statement of the cholesterol content per serving expressed in milligrams to the nearest 5-milligram increment, except that label declaration of cholesterol information is not required for products that contain less than 2 milligrams of cholesterol per serving and make no claim about fat, fatty acids, or cholesterol content, or such products may state the cholesterol content as zero. If the product contains 2 to 5 milligrams of cholesterol per serving, the content may be stated as ''less than 5 milligrams.''

(4) ''Sodium'': A statement of the number of milligrams of sodium per serving expressed as zero when the serving contains less than 5 milligrams of sodium, to the nearest 5-milligram increment when the serving contains 5 to 140 milligrams of sodium, and to the nearest 10-milligram increment when the serving contains greater than 140 milligrams.

(5) ''Potassium'' (VOLUNTARY): A statement of the number of milligrams of potassium per serving may be declared voluntarily, except that when a claim is made about potassium content, label declaration shall be required. Potassium content shall be expressed as zero when the serving contains less than 5 milligrams of potassium, to the nearest 5-milligram increment when the serving contains 5 to

140 milligrams of potassium, and to the nearest 10-milligram increment when the serving contains greater than 140 milligrams.

(6) ''Carbohydrate, total'' or ''Total carbohydrate'': A statement of the number of grams of total carbohydrate per serving expressed to the nearest gram, except that if a serving contains less than 1 gram, the statement ''Contains less than 1 gram'' or ''less than 1 gram'' may be used as an alternative, or, if the serving contains less than 0.5 gram, the content may be expressed as zero. Total carbohydrate content shall be calculated by subtraction of the sum of the crude protein, total fat, moisture, and ash from the total weight of the product. This calculation method is described in USDA's Agriculture Handbook No. 74 (Slightly revised February 1973), pages 2 and 3, which is incorporated by reference. Pages 2 and 3, Agriculture Handbook No. 74 is incorporated as it exists on the date of approval. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. (The availability of this incorporation by reference is given in paragraph (c)(1)(i)(A) of this section.).

(i) ''Dietary fiber'': A statement of the number of grams of total dietary fiber per serving, indented and expressed to the nearest gram, except that if a serving contains less than 1 gram, declaration of dietary fiber is not required, or, alternatively, the statement ''Contains less than 1 gram'' or ''less than 1 gram'' may be used, and if the serving contains less than 0.5 gram, the content may be expressed as zero.

(A) ''Soluble fiber'' (VOLUNTARY): A statement of the number of grams of soluble dietary fiber per serving may be declared voluntarily except when a claim is made on the label or in labeling about soluble fiber, label declaration shall be required. Soluble fiber content shall be indented under dietary fiber and expressed to the nearest gram, except that if a serving contains less than 1 gram, the statement ''Contains less than 1 gram'' or ''less than 1 gram'' may be used as an alternative, and if the serving contains less than 0.5 gram, the content may be expressed as zero.

(B) ''Insoluble fiber'' (VOLUNTARY): A statement of the number of grams of insoluble dietary fiber per serving may be declared voluntarily except when a claim is made on the label or in labeling about insoluble fiber, label declaration shall be required. Insoluble fiber content shall be indented under dietary fiber and expressed to the nearest gram, except that if a serving contains less than 1 gram, the statement ''Contains less than 1 gram'' or ''less than 1 gram'' may be used as an alternative, and if the serving contains less than 0.5 gram, the content may be expressed as zero.

(ii) ''Sugars'': A statement of the number of grams of sugars per serving, except that label declaration of sugars content is not required for products that contain less than 1 gram of sugars per serving if no claims are made about sweeteners, sugars, or sugar alcohol content. Sugars shall be defined as the sum of all free mono- and disaccharides (such as glucose, fructose, lactose, and sucrose). Sugars content shall be indented and expressed to the nearest gram, except that if a serving contains less than 1 gram, the statement ''Contains less than 1 gram'' or ''less than 1 gram'' may be used as an alternative, and if the serving contains less than 0.5 gram, the content may be expressed as zero.

(iii) ''Sugar alcohol'' (VOLUNTARY): A statement of the number of grams of sugar alcohols per serving may be declared voluntarily on the label, except that when a claim is made on the label or in labeling about sugar alcohol or sugars when sugar alcohols are present in the product, sugar alcohol content shall be declared. For nutrition labeling purposes, sugar alcohols are defined as the sum of saccharide derivatives in which a hydroxyl group replaces a ketone or aldehyde group and whose use in the food is listed by FDA (e.g., mannitol or xylitol) or is generally recognized as safe (e.g., sorbitol). In lieu of the term ''sugar alcohol,'' the name of the specific sugar alcohol (e.g., ''xylitol'') present in the product may be used in the nutrition label, provided that only one sugar alcohol is present in the product. Sugar alcohol content

shall be indented and expressed to the nearest gram, except that if a serving contains less than 1 gram, the statement ''Contains less than 1 gram'' or ''less than 1 gram'' may be used as an alternative, and if the serving contains less than 0.5 gram, the content may be expressed as zero.

(iv) ''Other carbohydrate'' (VOLUNTARY): A statement of the number of grams of other carbohydrate per serving may be declared voluntarily. Other carbohydrate shall be defined as the difference between total carbohydrate and the sum of dietary fiber, sugars, and sugar alcohol, except that if sugar alcohol is not declared (even if present), it shall be defined as the difference between total carbohydrate and the sum of dietary fiber and sugars. Other carbohydrate content shall be indented and expressed to the nearest gram, except that if a serving contains less than 1 gram, the statement ''Contains less than 1 gram'' or ''less than 1 gram'' may be used as an alternative, and if the serving contains less than 0.5 gram, the content may be expressed as zero.

(7) ''Protein'': A statement of the number of grams of protein per serving expressed to the nearest gram, except that if a serving contains less than 1 gram, the statement ''Contains less than 1 gram'' or ''less than 1 gram'' may be used as an alternative, and if the serving contains less than 0.5 gram, the content may be expressed as zero. When the protein in products represented or purported to be for adults and children 4 or more years of age has a protein quality value that is a protein digestibility-corrected amino acid score of less than 20 expressed as a percent, or when the protein in a product represented or purported to be for children greater than 1 but less than 4 years of age has a protein quality value that is a protein digestibility-corrected amino acid score of less than 40 expressed as a percent, either of the following shall be placed adjacent to the declaration of protein content by weight: The statement ''not a significant source of protein,'' or a listing aligned under the column headed ''Percent Daily Value'' of the corrected amount of protein per serving, as determined in paragraph (c)(7)(ii) of this section, calculated as a percentage of the Daily Reference Value (DRV) or Reference Daily Intake (RDI), as appropriate, for protein and expressed as percent of Daily Value. When the protein quality in a product as measured by the Protein Efficiency Ratio (PER) is less than 40 percent of the reference standard (casein) for a product represented or purported to be for infants, the statement ''not a significant source of protein'' shall be placed adjacent to the declaration of protein content. Protein content may be calculated on the basis of the factor of 6.25 times the nitrogen content of the food as determined by appropriate methods of analysis in accordance with § 381.409(h), except when the procedure for a specific food requires another factor.

(i) A statement of the corrected amount of protein per serving, as determined in paragraph (c)(7)(ii) of this section, calculated as a percentage of the RDI or DRV for protein, as appropriate, and expressed as percent of Daily Value, may be placed on the label, except that such a statement shall be given if a protein claim is made for the product, or if the product is represented or purported to be for infants or children under 4 years of age. When such a declaration is provided, it shall be placed on the label adjacent to the statement of grams of protein and aligned under the column headed ''Percent Daily Value,'' and expressed to the nearest whole percent. However, the percentage of the RDI for protein shall not be declared if the product is represented or purported to be for infants and the protein quality value is less than 40 percent of the reference standard.

(ii) The corrected amount of protein (grams) per serving for products represented or purported to be for adults and children 1 or more years of age is equal to the actual amount of protein (grams) per serving multiplied by the amino acid score corrected for protein digestibility. If the corrected score is above 1.00, then it shall be set at 1.00. The protein digestibility-corrected amino acid score shall be determined by methods given in sections 5.4.1, 7.2.1, and 8 in ''Protein Quality Evaluation, Report of the Joint FAO/WHO Expert

Consultation on Protein Quality Evaluation,'' Rome, 1990, which is incorporated by reference. Sections 5.4.1, 7.2.1, and 8 of the ''Report of the Joint FAO/WHO Expert Consultation on Protein Quality Evaluation,'' as published by the Food and Agriculture Organization of the United Nations/World Health Organization, is incorporated as it exists on the date of approval. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. It is available for inspection at the Office of the Federal Register, suite 700, 800 North Capitol Street, NW., Washington, DC, or at the office of the FSIS Docket Clerk, Room 3171, South Building, 14th and Independence Avenue, SW., Washington, DC. Copies of the incorporation by reference are available from the Product Assessment Division, Regulatory Programs, Food Safety and Inspection Service, U.S. Department of Agriculture, Room 329, West End Court Building, Washington, DC 20250–3700. For products represented or purported to be for infants, the corrected amount of protein (grams) per serving is equal to the actual amount of protein (grams) per serving multiplied by the relative protein quality value. The relative protein quality value shall be determined by dividing the subject product's protein PER value by the PER value for casein. If the relative protein value is above 1.00, it shall be set at 1.00.

(iii) For the purpose of labeling with a percent of the DRV or RDI, a value of 50 grams of protein shall be the DRV for adults and children 4 or more years of age, and the RDI for protein for children less than 4 years of age, infants, pregnant women, and lactating women shall be 16 grams, 14 grams, 60 grams, and 65 grams, respectively.

(8) Vitamins and minerals: A statement of the amount per serving of the vitamins and minerals as described in this paragraph, calculated as a percent of the RDI and expressed as percent of Daily Value.

(i) For purposes of declaration of percent of Daily Value as provided for in paragraphs (d) through (g) of this section, products represented or purported to be for use by infants, children less than 4 years of age, pregnant women, or lactating women shall use the RDI's that are specified for the intended group. For products represented or purported to be for use by both infants and children under 4 years of age, the percent of Daily Value shall be presented by separate declarations according to paragraph (e) of this section based on the RDI values for infants from birth to 12 months of age and for children under 4 years of age. Similarly, the percent of Daily Value based on both the RDI values for pregnant women and for lactating women shall be declared separately on products represented or purported to be for use by both pregnant and lactating women. When such dual declaration is used on any label, it shall be included in all labeling, and equal prominence shall be given to both values in all such labeling. All other products shall use the RDI for adults and children 4 or more years of age.

(ii) The declaration of vitamins and minerals as a percent of the RDI shall include vitamin A, vitamin C, calcium, and iron, in that order, and shall include any of the other vitamins and minerals listed in paragraph (c)(8)(iv) of this section when they are added, or when a claim is made about them. Other vitamins and minerals need not be declared if neither the nutrient nor the component is otherwise referred to on the label or in labeling or advertising and the vitamins and minerals are:

(A) Required or permitted in a standardized food (e.g., thiamin, riboflavin, and niacin in enriched flour) and that standardized food is included as an ingredient (i.e., component) in another product; or

(B) Included in a product solely for technological purposes and declared only in the ingredients statement. The declaration may also include any of the other vitamins and minerals listed in paragraph (c)(8)(iv) of this section when they are naturally occurring in the food. The additional vitamins and minerals shall be listed in the order established in paragraph (c)(8)(iv) of this section.

(iii) The percentages for vitamins and minerals shall be expressed to the nearest 2-percent increment up to and

including the 10-percent level, the nearest 5-percent increment above 10 percent and up to and including the 50-percent level, and the nearest 10-percent increment above the 50-percent level. Amounts of vitamins and minerals present at less than 2 percent of the RDI are not required to be declared in nutrition labeling but may be declared by a zero or by the use of an asterisk (or other symbol) that refers to another asterisk (or symbol) that is placed at the bottom of the table and that is followed by the statement ''Contains less than 2 percent of the Daily Value of this (these) nutrient (nutrients).'' Alternatively, if vitamin A, vitamin C, calcium, or iron is present in amounts less than 2 percent of the RDI, label declaration of the nutrient(s) is not required if the statement ''Not a significant source of _____ (listing the vitamins or minerals omitted)'' is placed at the bottom of the table of nutrient values.

(iv) The following RDI's and nomenclature are established for the following vitamins and minerals which are essential in human nutrition:

Vitamin A, 5,000 International Units
Vitamin C, 60 milligrams
Calcium, 1.0 gram
Iron, 18 milligrams
Vitamin D, 400 International Units
Vitamin E, 30 International Units
Thiamin, 1.5 milligrams
Riboflavin, 1.7 milligrams
Niacin, 20 milligrams
Vitamin B_6, 2.0 milligrams
Folate, 0.4 milligram
Vitamin B_{12}, 6 micrograms
Biotin, 0.3 milligram
Pantothenic acid, 10 milligrams
Phosphorus, 1.0 gram
Iodine, 150 micrograms
Magnesium, 400 milligrams
Zinc, 15 milligrams
Copper, 2.0 milligrams

(v) The following synonyms may be added in parenthesis immediately following the name of the nutrient or dietary component:

Vitamin C—Ascorbic acid
Thiamin—Vitamin B_1
Riboflavin—Vitamin B_2
Folate—Folacin
Calories—Energy

(vi) A statement of the percent of vitamin A that is present as *beta*-carotene may be declared voluntarily. When the vitamins and minerals are listed in a single column, the statement shall be indented under the information on vitamin A. When vitamins and minerals are arrayed horizontally, the statement of percent shall be presented in parenthesis following the declaration of vitamin A and the percent of Daily Value of vitamin A in the product (e.g., ''Percent Daily Value: Vitamin A 50 (90 percent as *beta*-carotene)''). When declared, the percentages shall be expressed in the same increments as are provided for vitamins and minerals in paragraph (c)(8)(iii) of this section.

(9) For the purpose of labeling with a percent of the DRV, the following DRV's are established for the following food components based on the reference caloric intake of 2,000 calories:

Food component	Unit of measurement	DRV
Fat	grams (g)	65
Saturated fatty acids	.....do	20
Cholesterol	milligrams (mg)	300
Total carbohydrate	grams (g)	300
Fiber	.....do	25
Sodium	milligrams (mg)	2400
Potassium	.....do	3500
Protein	grams (g)	50

(d)(1) Nutrient information specified in paragraph (c) of this section shall be presented on products in the following format, except on products on which dual columns of nutrition information are declared as provided for in paragraph (e) of this section, on those products on which the simplified format is permitted to be used as provided for in paragraph (f) of this section, on products for infants and children less than 4 years of age as provided for in § 381.500(c), and on products in packages that have a total surface area available to bear labeling of 40 or less square inches as provided for in paragraph (g) of this section.

(i) The nutrition information shall be set off in a box by use of hairlines and shall be all black or one color type, printed on a white or other neutral contrasting background whenever practical.

(ii) All information within the nutrition label shall utilize:

(A) A single easy-to-read type style,

(B) Upper and lower case letters,

(C) At least one point leading (i.e., space between two lines of text) except that at least four points leading shall be utilized for the information required by paragraphs (d)(7) and (d)(8) of this section, and

(D) Letters should never touch.

(iii) Information required in paragraphs (d)(3), (d)(5), (d)(7), and (d)(8) of this section shall be in type size no smaller than 8 point. Except for the heading ''Nutrition Facts,'' the information required in paragraphs (d)(4), (d)(6), and (d)(9) of this section and all other information contained within the nutrition label shall be in type size no smaller than 6 point. When provided, the information described in paragraph (d)(10) of this section shall also be in type no smaller than 6 point.

(iv) The headings required by paragraphs (d)(2), (d)(4), and (d)(6) of this section (i.e., ''Nutrition Facts,'' ''Amount Per Serving,'' and ''% Daily Value*''), the names of all nutrients that are not indented according to requirements of paragraph (c) of this section (i.e., Calories, Total fat, Cholesterol, Sodium, Potassium, Total carbohydrate, and Protein), and the percentage amounts required by paragraph (d)(7)(ii) of this section shall be highlighted by bold or extra bold type or other highlighting (reverse printing is not permitted as a form of highlighting) that prominently distinguishes it from other information. No other information shall be highlighted.

(v) A hairline rule that is centered between the lines of text shall separate ''Amount Per Serving'' from the calorie statements required in paragraph (d)(5) of this section and shall separate each nutrient and its corresponding percent of Daily Value required in paragraphs (d)(7)(i) and (d)(7)(ii) of this section from the nutrient and percent of Daily Value above and below it.

(2) The information shall be presented under the identifying heading of ''Nutrition Facts'' which shall be set in a type size larger than all other print size in the nutrition label and, except for labels presented according to the format provided for in paragraph (d)(11) of this section, unless impractical, shall be set the full width of the information provided under paragraph (d)(7) of this section.

(3) Information on serving size shall immediately follow the heading. Such information shall include:

(i) ''Serving Size'': A statement of the serving size as specified in paragraph (b)(9) of this section.

(ii) ''Servings Per Container'': The number of servings per container, except that this statement is not required on single-serving containers as defined in paragraph (b)(8) of this section.

(4) A subheading ''Amount Per Serving'' shall be separated from serving size information by a bar.

(5) Information on calories shall immediately follow the heading ''Amount Per Serving'' and shall be declared in one line, leaving sufficient space between the declaration of ''Calories'' and ''Calories from fat'' to allow clear differentiation, or, if ''Calories from saturated fat'' is declared, in a column with total ''Calories'' at the top, followed by ''Calories from fat'' (indented), and ''Calories from saturated fat'' (indented).

(6) The column heading ''% Daily Value,'' followed by an asterisk (e.g., ''% Daily Value*''), shall be separated from information on calories by a bar. The position of this column heading shall allow for a list of nutrient names and amounts as described in paragraph (d)(7) of this section to be to the left of, and below, this column heading. The column heading ''Percent Daily Value,'' ''Percent DV,'' or ''% DV'' may be substituted for ''% Daily Value.''

(7) Except as provided for in paragraph (g) of this section, and except as permitted by § 381.500(d)(2), nutrient information for both mandatory and any voluntary nutrients listed in paragraph (c) of this section that are to be declared in the nutrition label, except vitamins and minerals, shall be declared as follows:

(i) The name of each nutrient, as specified in paragraph (c) of this section, shall be given in a column and followed immediately by the quantitative amount by weight for that nutrient appended with a ''g'' for grams or ''mg'' for milligrams.

(ii) A listing of the percent of the DRV as established in paragraphs

(c)(7)(iii) and (c)(9) of this section shall be given in a column aligned under the heading ''% Daily Value'' established in paragraph (d)(6) of this section with the percent expressed to the nearest whole percent for each nutrient declared in the column described in paragraph (d)(7)(i) of this section for which a DRV has been established, except that the percent for protein may be omitted as provided in paragraph (c)(7) of this section. The percent shall be calculated by dividing either the amount declared on the label for each nutrient or the actual amount of each nutrient (i.e., before rounding) by the DRV for the nutrient, except that the percent for protein shall be calculated as specified in paragraph (c)(7)(ii) of this section. The numerical value shall be followed by the symbol for percent (i.e., %).

(8) Nutrient information for vitamins and minerals shall be separated from information on other nutrients by a bar and shall be arrayed horizontally (e.g., Vitamin A 4%, Vitamin C 2%, Calcium 15%, Iron 4%) or may be listed in two columns, except that when more than four vitamins and minerals are declared, they may be declared vertically with percentages listed under the column headed ''% Daily Value.''

(9) A footnote, preceded by an asterisk, shall be placed beneath the list of vitamins and minerals and shall be separated from that list by a hairline.

(i) The footnote shall state: Percent Daily Values are based on a 2,000 calorie diet. Your daily values may be higher or lower depending on your calorie needs.

	Calories	2,000	2,500
Total fat	Less than	65 g	80 g
Saturated fat ...	Less than	20 g	25 g
Cholesterol	Less than	300 mg	300 mg
Sodium	Less than	2400 mg	2400 mg
Total carbohydrate.	.....	300 g	375 g
Dietary fiber	.....	25 g	30 g

(ii) If the percent of Daily Value is given for protein in the Percent of Daily Value column as provided in paragraph (d)(7)(ii) of this section, protein shall be listed under dietary fiber, and a value of 50 g shall be inserted on the same line in the column headed ''2,000'' and value of 65 g in the column headed ''2,500.''

(iii) If potassium is declared in the column described in paragraph (d)(7)(i) of this section, potassium shall be listed under sodium and the DRV established in paragraph (c)(9) of this section shall be inserted on the same line in the numeric columns.

(iv) The abbreviations established in paragraph (g)(2) of this section may be used within the footnote.

(10) Caloric conversion information on a per-gram basis for fat, carbohydrate, and protein may be presented beneath the information required in paragraph (d)(9), separated from that information by a hairline. This information may be presented horizontally (i.e., ''Calories per gram: Fat 9, Carbohydrate 4, Protein 4'') or vertically in columns.

(11)(i) If the space beneath the information on vitamins and minerals is not adequate to accommodate the information required in paragraph (d)(9) of this section, the information required in paragraph (d)(9) may be moved to the right of the column required in paragraph (d)(7)(ii) of this section and set off by a line that distinguishes it and sets it apart from the percent of Daily Value information. The caloric conversion information provided for in paragraph (d)(10) of this section may be presented beneath either side or along the full length of the nutrition label.

(ii) If the space beneath the mandatory declaration of iron is not adequate to accommodate any remaining vitamins and minerals to be declared or the information required in paragraph (d)(9) of this section, the remaining information may be moved to the right and set off by a line that distinguishes it and sets it apart from the percent of Daily Value information given to the left. The caloric conversion information provided for in paragraph (d)(10) of this section may be presented beneath either side or along the full length of the nutrition label.

(iii) If there is not sufficient continuous vertical space (i.e., approximately 3 inches) to accommodate the required components of the nutrition label up to and including the mandatory declaration of iron, the nutrition label may be presented in a tabular display in which

the footnote required by paragraph (d)(9) of the section is given to the far right of the label, and additional vitamins and minerals beyond the four that are required (i.e., vitamin A, vitamin C, calcium, and iron) are arrayed horizontally following declarations of the required vitamins and minerals.

(12) The following sample label illustrates the provisions of paragraph (d) of this section:

Nutrition Facts

Serving Size 1 cup (228g)
Servings Per Container 2

Amount Per Serving	
Calories 260 Calories from Fat 120	
	% Daily Value*
Total Fat 13g	**20%**
Saturated Fat 5g	**25%**
Cholesterol 30mg	**10%**
Sodium 660mg	**28%**
Total Carbohydrate 31g	**10%**
Dietary Fiber 0g	**0%**
Sugars 5g	
Protein 5g	

Vitamin A 4%	•	Vitamin C 2%
Calcium 15%	•	Iron 4%

* Percent Daily Values are based on a 2,000 calorie diet. Your daily values may be higher or lower depending on your calorie needs:

	Calories:	2,000	2,500
Total Fat	Less than	65g	80g
Sat Fat	Less than	20g	25g
Cholesterol	Less than	300mg	300mg
Sodium	Less than	2,400mg	2,400mg
Total Carbohydrate		300g	375g
Dietary Fiber		25g	30g

Calories per gram:
Fat 9 • Carbohydrate 4 • Protein 4

(13)(i) Nutrition labeling on the outer label of packages of poultry products that contain two or more products in the same packages (e.g., variety packs) or of packages that are used interchangeably for the same type of food (e.g., poultry salad containers) may use an aggregate display.

(ii) Aggregate displays shall comply with format requirements of paragraph

(d) of this section to the maximum extent possible, except that the identity of each food shall be specified to the right of the ''Nutrition Facts'' title, and both the quantitative amount by weight (i.e., g/mg amounts) and the percent Daily Value for each nutrient shall be listed in separate columns under the name of each food.

(14) When nutrition labeling appears in a second language, the nutrition information may be presented in a separate nutrition label for each language or in one nutrition label with the information in the second language following that in English. Numeric characters that are identical in both languages need not be repeated (e.g., ''Protein/Proteinas 2 g''). All required information must be included in both languages.

(e) Nutrition information may be presented for two or more forms of the same product (e.g., both ''raw'' and ''cooked'') or for common combinations of foods as provided for in paragraph (b) of this section, or for different units (e.g., per 100 grams) as provided for in paragraph (b) of this section, or for two or more groups for which RDI's are established (e.g., both infants and children less than 4 years of age) as provided for in paragraph (c)(8)(i) of this section. When such dual labeling is provided, equal prominence shall be given to both sets of values. Information shall be presented in a format consistent with paragraph (d) of this section, except that:

(1) Following the subheading of ''Amount Per Serving,'' there shall be two or more column headings accurately describing the forms of the same product (e.g., ''raw'' and ''roasted''), the combinations of foods, the units, or the RDI groups that are being declared. The column representing the product as packaged and according to the label serving size based on the Reference Amount in § 381.412(b) shall be to the left of the numeric columns.

(2) When the dual labeling is presented for two or more forms of the same product, for combinations of foods, or for different units, total calories and calories from fat (and calories from saturated fat, when declared) shall be listed in a column and indented as specified in paragraph (d)(5) of this section with quantitative amounts declared in columns aligned under the column headings set forth in paragraph (e)(1) of this section.

(3) Quantitative information by weight required in paragraph (d)(7)(i) of this section shall be specified for the form of the product as packaged and according to the label serving size based on the Reference Amount in § 381.412(b).

(i) Quantitative information by weight may be included for other forms of the product represented by the additional column(s) either immediately adjacent to the required quantitative information by weight for the product as packaged and according to the label serving size based on the Reference Amount in § 381.412(b) or as a footnote.

(A) If such additional quantitative information is given immediately adjacent to the required quantitative information, it shall be declared for all nutrients listed and placed immediately following and differentiated from the required quantitative information (e.g., separated by a comma). Such information shall not be put in a separate column.

(B) If such additional quantitative information is given in a footnote, it shall be declared in the same order as the nutrients are listed in the nutrition label. The additional quantitative information may state the total nutrient content of the product identified in the second column or the nutrient amounts added to the product as packaged for only those nutrients that are present in different amounts than the amounts declared in the required quantitative information. The footnote shall clearly identify which amounts are declared. Any subcomponents declared shall be listed parenthetically after principal components (e.g., ½ cup skim milk contributes an additional 40 calories, 65 mg sodium, 6 g total carbohydrate (6 g sugars), and 4 g protein).

(ii) Total fat and its quantitative amount by weight shall be followed by an asterisk (or other symbol) (e.g., ''Total fat (2 g)*'') referring to another asterisk (or symbol) at the bottom of the nutrition label identifying the form(s) of the product for which quantitative information is presented.

(4) Information required in paragraphs (d)(7)(ii) and (d)(8) of this section shall be presented under the subheading ''% DAILY VALUE'' and in columns directly under the column headings set forth in paragraph (e)(1) of this section.

(5) The following sample label illustrates the provisions of paragraph (e) of this section:

Nutrition Facts

Serving Size 1/12 package
(44g, about 1/4 cup dry mix)
Servings Per Container 12

Amount Per Serving	Mix	Baked
Calories	190	280
Calories from Fat	45	140
	% Daily Value**	
Total Fat 5g*	**8%**	**24%**
Saturated Fat 2g	**10%**	**13%**
Cholesterol 0mg	**0%**	**23%**
Sodium 300mg	**13%**	**13%**
Total Carbohydrate 34g	**11%**	**11%**
Dietary Fiber 0g	**0%**	**0%**
Sugars 18g		
Protein 2g		
Vitamin A	0%	0%
Vitamin C	0%	0%
Calcium	6%	8%
Iron	2%	4%

*Amount in Mix

**Percent Daily Values are based on a 2,000 calorie diet. Your daily values may be higher or lower depending on your calorie needs:

	Calories:	2,000	2,500
Total Fat	Less than	65g	80g
Sat Fat	Less than	20g	25g
Cholesterol	Less than	300mg	300mg
Sodium	Less than	2,400mg	2,400mg
Total Carbohydrate		300g	375g
Dietary Fiber		25g	30g

Calories per gram:
Fat 9 • Carbohydrate 4 • Protein 4

(f)(1) Nutrition information may be presented in a simplified format as set forth herein when any required nutrients, other than the core nutrients (i.e., calories, total fat, sodium, total carbohydrate, and protein), are present in insignificant amounts. An insignificant amount shall be defined as that

amount that may be rounded to zero in nutrition labeling, except that for total carbohydrate, dietary fiber, sugars and protein, it shall be an amount less than 1 gram.

(2) The simplified format shall include information on the following nutrients:

(i) Total calories, total fat, total carbohydrate, sodium, and protein;

(ii) Any of the following that are present in more than insignificant amounts: Calories from fat, saturated fat, cholesterol, dietary fiber, sugars, vitamin A, vitamin C, calcium, and iron; and

(iii) Any vitamins and minerals listed in paragraph (c)(8)(iv) of this section when they are added in fortified or fabricated foods.

(3) Other nutrients that are naturally present in the product in more than insignificant amounts may be voluntarily declared as part of the simplified format.

(4) Any required nutrient, other than a core nutrient, that is present in an insignificant amount may be omitted from the tabular listing, provided that the following statement is included at the bottom of the nutrition label, ''Not a significant source of _____.'' The blank shall be filled in with the appropriate nutrient or food component. Alternatively, amounts of vitamins and minerals present in insignificant amounts may be declared by the use of an asterisk (or symbol) that is placed at the bottom of the table of nutrient values and that is followed by the statement ''Contains less than 2 percent of the Daily Value of this (these) nutrient (nutrients).''

(5) Except as provided for in paragraph (g) of this section and in § 381.500(c) and (d), nutrient information declared in the simplified format shall be presented in the same manner as specified in paragraphs (d) or (e) of this section, except that the footnote required in paragraph (d)(9) of this section is not required. When the footnote is omitted, an asterisk shall be placed at the bottom of the label followed by the statement ''Percent Daily Values are based on a 2,000 calorie diet'' and, if the term ''Daily Value'' is not spelled out in the heading, a statement that ''DV'' represents ''Daily Value.''

(g) Foods in packages that have a total surface area available to bear labeling of 40 or less square inches may modify the requirements of paragraphs (c) through (f) of this section and § 381.402(a) by one or more of the following means:

(1)(i) Presenting the required nutrition information in a tabular or linear (i.e., string) fashion, rather than in vertical columns if the product has a total surface area available to bear labeling of less than 12 square inches, or if the product has a total surface area available to bear labeling of 40 or less square inches and the package shape or size cannot accommodate a standard vertical column or tabular display on any label panel. Nutrition information may be given in a linear fashion only if the package shape or size will not accommodate a tabular display.

(ii) When nutrition information is given in a linear display, the nutrition information shall be set off in a box by the use of a hairline. The percent Daily Value is separated from the quantitative amount declaration by the use of parenthesis, and all nutrients, both principal components and subcomponents, are treated similarly. Bolding is required only on the title ''Nutrition Facts'' and is allowed for nutrient names for ''Calories,'' ''Total fat,'' ''Cholesterol,'' ''Sodium,'' ''Total carbohydrate,'' and ''Protein.''

(2) Using any of the following abbreviations:

Serving size—Serv size
Servings per container—Servings
Calories from fat—Fat cal
Calories from saturated fat—Sat fat cal
Saturated fat—Sat fat
Monounsaturated fat—Monounsat fat
Polyunsaturated fat—Polyunsat fat
Cholesterol—Cholest
Total carbohydrate—Total carb
Dietary fiber—Fiber
Soluble fiber—Sol fiber
Insoluble fiber—Insol fiber
Sugar alcohol—Sugar alc
Other carbohydrate—Other carb

(3) Omitting the footnote required in paragraph (d)(9) of this section and placing another asterisk at the bottom of the label followed by the statement ''Percent Daily Values are based on a 2,000 calorie diet'' and, if the term ''Daily Value'' is not spelled out in the

heading, a statement that ''DV'' represents ''Daily Value.''

(4) Presenting the required information on any other label panel.

(h) Compliance with this section shall be determined as follows:

(1) A production lot is a set of food production consumer units that are from one production shift. Alternatively, a collection of consumer units of the same size, type, and style produced under conditions as nearly uniform as possible, designated by a common container code or marking, constitutes a production lot.

(2) The sample for nutrient analysis shall consist of a composite of a minimum of six consumer units, each from a production lot. Alternatively, the sample for nutrient analysis shall consist of a composite of a minimum of six consumer units, each randomly chosen to be representative of a production lot. In each case, the units may be individually analyzed and the results of the analyses averaged, or the units would be composited and the composite analyzed. In both cases, the results, whether an average or a single result from a composite, will be considered by the Agency to be the nutrient content of a composite. All analyses shall be performed by appropriate methods and procedures used by the Department for each nutrient in accordance with the ''Chemistry Laboratory Guidebook,'' or, if no USDA method is available and appropriate for the nutrient, by appropriate methods for the nutrient in accordance with the 1990 edition of the ''Official Methods of Analysis'' of the AOAC International, formerly Association of Official Analytical Chemists, 15th ed., which is incorporated by reference, unless a particular method of analysis is specified in § 381.409(c), or, if no USDA, AOAC, or specified method is available and appropriate, by other reliable and appropriate analytical procedures as so determined by the Agency. The ''Official Methods of Analysis'' is incorporated as it exists on the date of approval. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be purchased from the AOAC International, 2200 Wilson Blvd., Suite 400, Arlington, VA 22201. It is also available for inspection at the Office of the Federal Register Information Center, suite 700, 800 North Capitol Street, NW., Washington, DC.

(3) Two classes of nutrients are defined for purposes of compliance:

(i) Class I. Added nutrients in fortified or fabricated foods; and

(ii) Class II. Naturally occurring (indigenous) nutrients. If any ingredient which contains a naturally occurring (indigenous) nutrient is added to a food, the total amount of such nutrient in the final food product is subject to Class II requirements unless the same nutrient is also added, which would make the total amount of such nutrient subject to Class I requirements.

(4) A product with a label declaration of a vitamin, mineral, protein, total carbohydrate, dietary fiber, other carbohydrate, polyunsaturated or monounsaturated fat, or potassium shall be deemed to be misbranded under section 4(h) of the Poultry Products Inspection Act (21 U.S.C. 453(h)(4)) unless it meets the following requirements:

(i) Class I vitamin, mineral, protein, dietary fiber, or potassium. The nutrient content of the composite is at least equal to the value for that nutrient declared on the label.

(ii) Class II vitamin, mineral, protein, total carbohydrate, dietary fiber, other carbohydrate, polyunsaturated or monounsaturated fat, or potassium. The nutrient content of the composite is at least equal to 80 percent of the value for that nutrient declared on the label; *Provided*, That no regulatory action will be based on a determination of a nutrient value which falls below this level by an amount less than the variability generally recognized for the analytical method used in that product at the level involved, and inherent nutrient variation in a product.

(5) A product with a label declaration of calories, sugars, total fat, saturated fat, cholesterol, or sodium shall be deemed to be misbranded under section 4(h) of the Poultry Products Inspection Act (21 U.S.C. 453(h)(4)) if the nutrient content of the composite is greater than 20 percent in excess of the value for that nutrient declared on the label; *Provided*, That no regulatory action will be based on a determination of a

nutrient value which falls above this level by an amount less than the variability generally recognized for the analytical method used in that product at the level involved, and inherent nutrient variation in a product.

(6) The amount of a vitamin, mineral, protein, total carbohydrate, dietary fiber, other carbohydrate, polyunsaturated or monounsaturated fat, or potassium may vary over labeled amounts within good manufacturing practice. The amount of calories, sugars, total fat, saturated fat, cholesterol, or sodium may vary under labeled amounts within good manufacturing practice.

(7) Compliance will be based on the metric measure specified in the label statement of serving size.

(8) The management of the establishment must maintain records to support the validity of nutrient declarations contained on product labels. Such records shall be made available to the inspector or any duly authorized representative of the Agency upon request.

(9) The compliance provisions set forth in paragraph (h)(1) through (8) of this section shall not apply to single-ingredient, raw poultry products, including those that have been previously frozen, when nutrition labeling is based on the most current representative data base values contained in USDA's National Nutrient Data Bank or its published form, the Agriculture Handbook No. 8 series.

(Paperwork requirements were approved by the Office of Management and Budget under control number 0583–0088.)

[58 FR 675, Jan. 6, 1993; 58 FR 43788, Aug. 18, 1993, as amended at 58 FR 47628, Sept. 10, 1993; 59 FR 45196, Sept. 1, 1994; 60 FR 197, Jan. 3, 1995; 60 FR 10304, Feb. 24, 1995]

§§ 381.410–381.411 [Reserved]

§ 381.412 Reference amounts customarily consumed per eating occasion.

(a) The general principles followed in arriving at the reference amounts customarily consumed per eating occasion (Reference Amount(s)), as set forth in paragraph (b) of this section, are:

(1) The Reference Amounts are calculated for persons 4 years of age or older to reflect the amount of food customarily consumed per eating occasion by persons in this population group. These Reference Amounts are based on data set forth in appropriate national food consumption surveys.

(2) The Reference Amounts are calculated for an infant or child under 4 years of age to reflect the amount of food customarily consumed per eating occasion by infants up to 12 months of age or by children 1 through 3 years of age, respectively. These Reference Amounts are based on data set forth in appropriate national food consumption surveys. Such Reference Amounts are to be used only when the product is specially formulated or processed for use by an infant or by a child under 4 years of age.

(3) An appropriate national food consumption survey includes a large sample size representative of the demographic and socioeconomic characteristics of the relevant population group and must be based on consumption data under actual conditions of use.

(4) To determine the amount of food customarily consumed per eating occasion, the mean, median, and mode of the consumed amount per eating occasion were considered.

(5) When survey data were insufficient, FSIS took various other sources of information on serving sizes of food into consideration. These other sources of information included:

(i) Serving sizes used in dietary guidance recommendations or recommended by other authoritative systems or organizations;

(ii) Serving sizes recommended in comments;

(iii) Serving sizes used by manufacturers and grocers; and

(iv) Serving sizes used by other countries.

(6) Because they reflect the amount customarily consumed, the Reference Amount and, in turn, the serving size declared on the product label are based on only the edible portion of food, and not bone, seed, shell, or other inedible components.

(7) The Reference Amount is based on the major intended use of the product (e.g., a mixed dish measurable with a cup as a main dish and not as a side dish).

(8) The Reference Amounts for products that are consumed as an ingredient of other products, but that may also be consumed in the form in which they are purchased (e.g., ground poultry), are based on use in the form purchased.

(9) FSIS sought to ensure that foods that have similar dietary usage, product characteristics, and customarily consumed amounts have a uniform Reference Amount.

(b) The following Product Categories and Reference Amounts shall be used as the basis for determining serving sizes for specific products:

TABLE 1—REFERENCE AMOUNTS CUSTOMARILY CONSUMED PER EATING OCCASION—INFANT AND TODDLER FOODS [1,2,3]

Product category	Reference amount
Infant & Toddler Foods:	
Dinner Dry Mix	15 g
Dinner, ready-to-serve, strained type	60 g
Dinner, soups, ready-to-serve junior type	110 g
Dinner, stew or soup ready-to-serve toddlers	170 g
Plain poultry and poultry sticks, ready-to-serve	55 g

[1] These values represent the amount of food customarily consumed per eating occasion and were primarily derived from the 1977–1978 and the 1987–1988 Nationwide Food Consumption Surveys conducted by the U.S. Department of Agriculture.

[2] Unless otherwise noted in the Reference Amount column, the Reference Amounts are for the ready-to-serve or almost ready-to-serve form of the product (i.e., heat and serve). If not listed separately, the Reference Amount for the unprepared form (e.g., dehydrated cereal) is the amount required to make one Reference Amount of the prepared form.

[3] Manufacturers are required to convert the Reference Amount to the label serving size in a household measure most appropriate to their specific product using the procedures established by the regulation.

TABLE 2—REFERENCE AMOUNTS CUSTOMARILY CONSUMED PER EATING OCCASION—GENERAL FOOD SUPPLY [1,2,3,4,5]

Product category	Reference Amount	Reference Amount
	Ready-to-serve	Ready-to-cook
Egg mixtures, (western style omelet, souffle, egg foo young with poultry).	110 g	n/a
Salad and potato toppers; e.g., poultry bacon bits	7 g	n/a
Bacon; e.g., poultry breakfast strips.	15 g	26 g = bacon. 18 g = breakfast strips
Dried; e.g., poultry jerky, dried poultry, poultry sausage products with a moisture/protein ratio of less than 2:1.	30 g	n/a
Snacks; e.g., poultry snack food sticks	30 g	n/a
Luncheon products, poultry bologna, poultry Canadian style bacon, poultry crumbles, poultry luncheon loaf, potted poultry products, poultry taco filings.	55 g	n/a
Linked poultry sausage products, poultry franks, poultry Polish sausage, smoked or pickled poultry meat, poultry smoked sausage.	55 g	n/a 69 g = uncooked sausage.
Entrees without sauce, poultry cuts, ready to cook poultry cuts, including marinated, tenderized, injected cuts of poultry, poultry corn dogs, poultry croquettes, poultry fritters, cured poultry ham products, adult pureed poultry.	85 g	114g
Canned poultry, canned chicken, canned [4] turkey	55 g	n/a
Entrees with sauce, turkey and gravy	140 g	n/a
Mixed dishes NOT measurable with a cup; [5] e.g., poultry burrito, poultry enchiladas, poultry pizza, poultry quiche, all types of poultry sandwiches, cracker and poultry lunch-type packages, poultry gyro, poultry stromboli, poultry frank on a bun, poultry burger on a bun, poultry taco, chicken cordon bleu, poultry calzone, stuffed vegetables with poultry, poultry kabobs.	140 g (plus 55 g for products toppings)	n/a
Mixed dishes, measurables with a cup; e.g., poultry casserole, macaroni and cheese with poultry, poultry pot pie, poultry spaghetti with sauce, poultry chili, poultry chili with beans, poultry hash, creamed dried poultry, poultry ravioli in sauce, poultry a la king, poultry stew, poultry goulash, poultry lasagna, poultry-filled pasta.	1 cup	n/a
Salads—pasta or potato, potato salad with poultry, macaroni and poultry salad.	140 g	n/a
Salads—all other, poultry salads, chicken salad, turkey salad	100 g	n/a
Soups—all varieties	245 g	n/a
Major main entree type sauce; e.g., spaghetti sauce with poultry	125 g	n/a
Minor main entree sauce; e.g., pizza sauce with poultry, gravy	¼ cup	n/a
Seasoning mixes dry, freeze dry, dehydrated, concentrated soup mixes, bases, extracts, dried broths and stock/juice, freeze dry trail mix products with poultry.		

TABLE 2—REFERENCE AMOUNTS CUSTOMARILY CONSUMED PER EATING OCCASION—GENERAL FOOD SUPPLY [1,2,3,4,5]—Continued

Product category	Reference Amount	Reference Amount
	Ready-to-serve	Ready-to-cook
As reconstituted: Amount to make one Reference Amount of the final dish; e.g.—		
Gravy	¼ cup	n/a
Major main entree type sauce	125 g	n/a
Soup	245 g	n/a
Entree measurable with a cup	1 cup	n/a

[1] These values represent the amount of food customarily consumed per eating occasion and were primarily derived from the 1977–78 and the 1987–88 Nationwide Food Consumption Surveys conducted by the U.S. Department of Agriculture.
[2] Manufacturers are required to convert the Reference Amounts to the label serving size in a household measure most appropriate to their specific product using the procedures established by regulation.
[3] Examples listed under Product Category are not all inclusive or exclusive. Examples are provided to assist manufacturers in identifying appropriate product Reference Amount.
[4] If packed or canned in liquid, the Reference Amount is for the drained solids, except for products in which both the solids and liquids are customarily consumed.
[5] Pizza sauce is part of the pizza and is not considered to be a sauce topping.

(c) For products that have no Reference Amount listed in paragraph (b) of this section for the unprepared or the prepared form of the product and that consist of two or more foods packaged and presented to be consumed together (e.g., poultry lunch meat with cheese and crackers), the Reference Amount for the combined product shall be determined using the following rules:

(1) For bulk products, the Reference Amount for the combined product shall be the Reference Amount, as established in paragraph (b) of this section, for the ingredient that is represented as the main ingredient plus proportioned amounts of all minor ingredients.

(2) For products where the ingredient represented as the main ingredient is one or more discrete units, the Reference Amount for the combined product shall be either the number of small discrete units or the fraction of the large discrete unit that is represented as the main ingredient that is closest to the Reference Amount for that ingredient as established in paragraph (b) of this section plus proportioned amounts of all minor ingredients.

(3) If the Reference Amounts are in compatible units, they shall be summed (e.g., ingredients in equal volumes such as tablespoons). If the Reference Amounts are in incompatible units, the weights of the appropriate volumes should be used (e.g., grams of one ingredient plus gram weight of tablespoons of a second ingredient).

(d) If a product requires further preparation, e.g., cooking or the addition of water or other ingredients, and if paragraph (b) of this section provides a Reference Amount for the product in the prepared form, then the Reference Amount for the unprepared product shall be determined using the following rules:

(1) Except as provided for in paragraph (d)(2) of this section, the Reference Amount for the unprepared product shall be the amount of the unprepared product required to make the Reference Amount for the prepared product as established in paragraph (b) of this section.

(2) For products where the entire contents of the package is used to prepare one large discrete unit usually divided for consumption, the Reference Amount for the unprepared product shall be the amount of the unprepared product required to make the fraction of the large discrete unit closest to the Reference Amount for the prepared product as established in paragraph (b) of this section.

(e) The Reference Amount for an imitation or substitute product or altered product as defined in § 381.413(d), such as a ''low calorie'' version, shall be the same as for the product for which it is offered as a substitute.

(f) The Reference Amounts set forth in paragraphs (b) through (e) of this section shall be used in determining whether a product meets the criteria for nutritional claims. If the serving

size declared on the product label differs from the Reference Amount, and the product meets the criteria for the claim only on the basis of the Reference Amount, the claim shall be followed by a statement that sets forth the basis on which the claim is made. That statement shall include the Reference Amount as it appears in paragraph (b) of this section followed, in parenthesis, by the amount in common household measure if the Reference Amount is expressed in measures other than common household measures.

(g) The Administrator, on his or her own initiative or on behalf of any interested person who has submitted a labeling application, may issue a proposal to establish or amend a Product Category or Reference Amount identified in paragraph (b) of this section.

(1) Labeling applications and supporting documentation to be filed under this section shall be submitted in quadruplicate, except that the supporting documentation may be submitted on a computer disc copy. If any part of the material submitted is in a foreign language, it shall be accompanied by an accurate and complete English translation. The labeling application shall state the applicant's post office address.

(2) Pertinent information will be considered as part of an application on the basis of specific reference to such information submitted to and retained in the files of the Food Safety and Inspection Service. However, any reference to unpublished information furnished by a person other than the applicant will not be considered unless use of such information is authorized (with the understanding that such information may in whole or part be subject to release to the public) in a written statement signed by the person who submitted it. Any reference to published information should be accompanied by reprints or photostatic copies of such references.

(3) The availability for public disclosure of labeling applications, along with supporting documentation, submitted to the Agency under this section will be governed by the rules specified in subchapter D, title 9.

(4) Data accompanying the labeling application, such as food consumption data, shall be submitted on separate sheets, suitably identified. If such data has already been submitted with an earlier labeling application from the applicant, the present labeling application must provide the data.

(5) The labeling application must be signed by the applicant or by his or her attorney or agent, or (if a corporation) by an authorized official.

(6) The labeling application shall include a statement signed by the person responsible for the labeling application, that to the best of his or her knowledge, it is a representative and balanced submission that includes unfavorable information, as well as favorable information, known to him or her pertinent to the evaluation of the labeling application.

(7) Labeling applications for a new Reference Amount and/or Product Category shall be accompanied by the following data which shall be submitted in the following form to the Director, Food Labeling Division, Regulatory Programs, Food Safety and Inspection Service, Washington, DC 20250:

(Date)

The undersigned, _____ submits this labeling application pursuant to 9 CFR 381.412 with respect to Reference Amount and/or Product Category.

Attached hereto, in quadruplicate, or on a computer disc copy, and constituting a part of this labeling application, are the following:

(i) A statement of the objective of the labeling application;

(ii) A description of the product;

(iii) A complete sample product label including nutrition label, using the format established by regulation;

(iv) A description of the form in which the product will be marketed;

(v) The intended dietary uses of the product with the major use identified (e.g., turkey as a luncheon meat);

(vi) If the intended use is primarily as an ingredient in other foods, list of foods or food categories in which the product will be used as an ingredient with information on the prioritization of the use;

(vii) The population group for which the product will be offered for use (e.g., infants, children under 4 years of age);

(viii) The names of the most closely-related products (or in the case of foods for special dietary use and imitation or substitute foods, the names of the products for which they are offered as substitutes);

(ix) The suggested Reference Amount (the amount of edible portion of food as consumed, excluding bone, skin or other inedible components) for the population group for which the product is intended with full description of the methodology and procedures that were used to determine the suggested Reference Amount. In determining the Reference Amount, general principles and factors in paragraph (a) of this section should be followed.

(x) The suggested Reference Amount shall be expressed in metric units. Reference Amounts for foods shall be expressed in grams except when common household units such as cups, tablespoons, and teaspoons are more appropriate or are more likely to promote uniformity in serving sizes declared on product labels. For example, common household measures would be more appropriate if products within the same category differ substantially in density such as mixed dishes measurable with a cup.

(A) In expressing the Reference Amount in grams, the following general rules shall be followed:

(*1*) For quantities greater than 10 grams, the quantity shall be expressed in nearest 5 grams increment.

(*2*) For quantities less than 10 grams, exact gram weights shall be used.

(B) [Reserved]

(xi) A labeling application for a new subcategory of food with its own Reference Amount shall include the following additional information:

(A) Data that demonstrate that the new subcategory of food will be consumed in amounts that differ enough from the Reference Amount for the parent category to warrant a separate Reference Amount. Data must include sample size, and the mean, standard deviation, median, and modal consumed amount per eating occasion for the product identified in the labeling application and for other products in the category. All data must be derived from the same survey data.

(B) Documentation supporting the difference in dietary usage and product characteristics that affect the consumption size that distinguishes the product identified in the labeling application from the rest of the products in the category.

(xii) In conducting research to collect or process food consumption data in support of the labeling application, the following general guidelines should be followed.

(A) Sampled population selected should be representative of the demographic and socioeconomic characteristics of the target population group for which the food is intended.

(B) Sample size (i.e., number of eaters) should be large enough to give reliable estimates for customarily consumed amounts.

(C) The study protocol should identify potential biases and describe how potential biases are controlled for or, if not possible to control, how they affect interpretation of results.

(D) The methodology used to collect or process data including study design, sampling procedures, materials used (e.g., questionnaire, interviewer's manual), procedures used to collect or process data, methods or procedures used to control for unbiased estimates, and procedures used to correct for nonresponse, should be fully documented.

(xiii) A statement concerning the feasibility of convening associations, corporations, consumers, and other interested parties to engage in negotiated rulemaking to develop a proposed rule.

Yours very truly,

Applicant _____

By _____

(Indicate authority)

(8) Upon receipt of the labeling application and supporting documentation, the applicant shall be notified, in writing, of the date on which the labeling application was received. Such notice shall inform the applicant that the labeling application is undergoing Agency review and that the applicant shall subsequently be notified of the Agency's decision to consider for further review or deny the labeling application.

(9) Upon review of the labeling application and supporting documentation, the Agency shall notify the applicant, in writing, that the labeling application is either being considered for further review or that it has been summarily denied by the Administrator.

(10) If the labeling application is summarily denied by the Administrator, the written notification shall state the reasons therefor, including why the Agency has determined that the proposed Reference Amount and/or Product Category is false or misleading. The notification letter shall inform the applicant that the applicant may submit a written statement by way of answer to the notification, and that the applicant shall have the right to request a hearing with respect to the merits or validity of the Administrator's decision to deny the use of the proposed Reference Amount and/or Product Category.

(i) If the applicant fails to accept the determination of the Administrator and files an answer and requests a hearing, and the Administrator, after review of the answer, determines the

initial determination to be correct, the Administrator shall file with the Hearing Clerk of the Department the notification, answer, and the request for a hearing, which shall constitute the complaint and answer in the proceeding, which shall thereafter be conducted in accordance with the Department's Uniform Rules of Practice.

(ii) The hearing shall be conducted before an administrative law judge with the opportunity for appeal to the Department's Judicial Officer, who shall make the final determination for the Secretary. Any such determination by the Secretary shall be conclusive unless, within 30 days after receipt of notice of such final determination, the applicant appeals to the United States Court of Appeals for the circuit in which the applicant has its principal place of business or to the United States Court of Appeals for the District of Columbia Circuit.

(11) If the labeling application is not summarily denied by the Administrator, the Administrator shall publish in the FEDERAL REGISTER a proposed rule to amend the regulations to authorize the use of the Reference Amount and/or Product Category. The proposal shall also summarize the labeling application, including where the supporting documentation can be reviewed. The Administrator's proposed rule shall seek comment from consumers, the industry, consumer and industry groups, and other interested persons on the labeling application and the use of the proposed Reference Amount and/or Product Category. After public comment has been received and reviewed by the Agency, the Administrator shall make a determination on whether the proposed Reference Amount and/or Product Category shall be approved for use on the labeling of poultry products.

(i) If the Reference Amount and/or Product Category is denied by the Administrator, the Agency shall notify the applicant, in writing, of the basis for the denial, including the reason why the Reference Amount and/or Product Category on the labeling was determined by the Agency to be false or misleading. The notification letter shall also inform the applicant that the applicant may submit a written statement by way of answer to the notification, and that the applicant shall have the right to request a hearing with respect to the merits or validity of the Administrator's decision to deny the use of the proposed Reference Amount and/or Product Category.

(A) If the applicant fails to accept the determination of the Administrator and files an answer and requests a hearing, and the Administrator, after review of the answer, determines the initial determination to be correct, the Administrator shall file with the Hearing Clerk of the Department the notification, answer, and the request for a hearing, which shall constitute the complaint and answer in the proceeding, which shall thereafter be conducted in accordance with the Department's Uniform Rules of Practice.

(B) The hearing shall be conducted before an administrative law judge with the opportunity for appeal to the Department's Judicial Officer, who shall make the final determination for the Secretary. Any such determination by the Secretary shall be conclusive unless, within 30 days after receipt of notice of such final determination, the applicant appeals to the United States Court of Appeals for the circuit in which the applicant has its principal place of business or to the United States Court of Appeals for the District of Columbia.

(ii) If the Reference Amount and/or Product Category is approved, the Agency shall notify the applicant, in writing, and shall also publish in the FEDERAL REGISTER a final rule amending the regulations to authorize the use of the Reference Amount and/or Product Category.

(Paperwork requirements were approved by the Office of Management and Budget under control number 0583–0088.)

[58 FR 675, Jan. 6, 1993; 58 FR 43789, Aug. 18, 1993, as amended at 58 FR 47628, Sept. 10, 1993; 59 FR 45198, Sept. 1, 1994; 60 FR 207, Jan. 3, 1995]

§ 381.413 Nutrient content claims; general principles.

(a) This section applies to poultry products that are intended for human consumption and that are offered for sale.

(b) A claim which, expressly or by implication, characterizes the level of a nutrient (nutrient content claim) of the type required in nutrition labeling pursuant to § 381.409, may not be made on a label or in labeling of that product unless the claim is made in accordance with the applicable provisions in this subpart.

(1) An expressed nutrient content claim is any direct statement about the level (or range) of a nutrient in the product, e.g., ''low sodium'' or ''contains 100 calories.''

(2) An implied nutrient content claim is any claim that:

(i) Describes the product or an ingredient therein in a manner that suggests that a nutrient is absent or present in a certain amount (e.g., ''high in oat bran''); or

(ii) Suggests that the product, because of its nutrient content, may be useful in maintaining healthy dietary practices and is made in association with an explicit claim or statement about a nutrient (e.g., ''healthy, contains 3 grams (g) of fat'').

(3) Except for claims regarding vitamins and minerals described in paragraph (q)(3) of this section, no nutrient content claims may be made on products intended specifically for use by infants and children less than 2 years of age unless the claim is specifically provided for in subpart Y of this part.

(4) Reasonable variations in the spelling of the terms defined in applicable provisions in this subpart and their synonyms are permitted provided these variations are not misleading (e.g., ''hi'' or ''lo'').

(c) Information that is required or permitted by § 381.409 to be declared in nutrition labeling, and that appears as part of the nutrition label, is not a nutrient content claim and is not subject to the requirements of this section. If such information is declared elsewhere on the label or in labeling, it is a nutrient content claim and is subject to the requirements for nutrient content claims.

(d) A ''substitute'' product is one that may be used interchangeably with another product that it resembles, i.e., that it is organoleptically, physically, and functionally (including shelf life) similar to, and that it is not nutritionally inferior to unless it is labeled as an ''imitation.''

(1) If there is a difference in performance characteristics that materially limits the use of the product, the product may still be considered a substitute if the label includes a disclaimer adjacent to the most prominent claim as defined in paragraph (j)(2)(iii) of this section, informing the consumer of such difference (e.g., ''not recommended for frying'').

(2) This disclaimer shall be in easily legible print or type and in a size no less than that required by § 381.121(c) for the net quantity of contents statement, except where the size of the claim is less than two times the required size of the net quantity of contents statement, in which case the disclaimer statement shall be no less than one-half the size of the claim but no smaller than 1/16-inch minimum height, except as permitted by § 381.500(d)(2).

(e)(1) Because the use of a ''free'' or ''low'' claim before the name of a product implies that the product differs from other products of the same type by virtue of its having a lower amount of the nutrient, only products that have been specially processed, altered, formulated, or reformulated so as to lower the amount of the nutrient in the product, remove the nutrient from the product, or not include the nutrient in the product, may bear such a claim (e.g., ''low sodium chicken noodle soup'').

(2) Any claim for the absence of a nutrient in a product, or that a product is low in a nutrient when the product has not been specially processed, altered, formulated, or reformulated to qualify for that claim shall indicate that the product inherently meets the criteria and shall clearly refer to all products of that type and not merely to the particular brand to which the labeling attaches (e.g., ''chicken breast meat, a low sodium food'').

(f) A nutrient content claim shall be in type size and style no larger than two times that of the statement of identity and shall not be unduly prominent in type style compared to the statement of identity.

(g) Labeling information required in §§ 381.413, 381.454, 381.456, 381.460, 381.461, 381.462, and 381.480, whose type size is

not otherwise specified, is required to be in letters and/or numbers no less than 1/16 inch in height, except as permitted by § 381.500(d)(2).

(h) [Reserved]

(i) Except as provided in § 381.409 or in paragraph (q)(3) of this section, the label or labeling of a product may contain a statement about the amount or percentage of a nutrient if:

(1) The use of the statement on the product implicitly characterizes the level of the nutrient in the product and is consistent with a definition for a claim, as provided in subpart Y of this part, for the nutrient that the label addresses. Such a claim might be, ''less than 10 g of fat per serving;''

(2) The use of the statement on the product implicitly characterizes the level of the nutrient in the product and is not consistent with such a definition, but the label carries a disclaimer adjacent to the statement that the product is not ''low'' in or a ''good source'' of the nutrient, such as ''only 200 milligrams (mg) sodium per serving, not a low sodium product.'' The disclaimer must be in easily legible print or type and in a size no less than required by § 381.121(c) for the net quantity of contents, except where the size of the claim is less than two times the required size of the net quantity of contents statement, in which case the disclaimer statement shall be no less than one-half the size of the claim but no smaller than 1/16-inch minimum height, except as permitted by § 381.500(d)(2);

(3) The statement does not in any way implicitly characterize the level of the nutrient in the product and it is not false or misleading in any respect (e.g., ''100 calories'' or ''5 grams of fat''), in which case no disclaimer is required.

(4) ''Percent fat free'' claims are not authorized by this paragraph. Such claims shall comply with § 381.462(b)(6).

(j) A product may bear a statement that compares the level of a nutrient in the product with the level of a nutrient in a reference product. These statements shall be known as ''relative claims'' and include ''light,'' ''reduced,'' ''less'' (or ''fewer''), and ''more'' claims.

(1) To bear a relative claim about the level of a nutrient, the amount of that nutrient in the product must be compared to an amount of nutrient in an appropriate reference product as specified in this paragraph (j).

(i)(A) For ''less'' (or ''fewer'') and ''more'' claims, the reference product may be a dissimilar product within a product category that can generally be substituted for one another in the diet or a similar product.

(B) For ''light,'' ''reduced,'' and ''added'' claims, the reference product shall be a similar product, and

(ii)(A) For ''light'' claims, the reference product shall be representative of the type of product that includes the product that bears the claim. The nutrient value for the reference product shall be representative of a broad base of products of that type; e.g., a value in a representative, valid data base; an average value determined from the top three national (or regional) brands, a market basket norm; or, where its nutrient value is representative of the product type, a market leader. Firms using such a reference nutrient value as a basis for a claim, are required to provide specific information upon which the nutrient value was derived, on request, to consumers and appropriate regulatory officials.

(B) For relative claims other than ''light,'' including ''less'' and ''more'' claims, the reference product may be the same as that provided for ''light'' in paragraph (j)(1)(ii)(A) of this section or it may be the manufacturer's regular product, or that of another manufacturer, that has been offered for sale to the public on a regular basis for a substantial period of time in the same geographic area by the same business entity or by one entitled to use its trade name, provided the name of the competitor is not used on the labeling of the product. The nutrient values used to determine the claim when comparing a single manufacturer's product to the labeled product shall be either

the values declared in nutrition labeling or the actual nutrient values, provided that the resulting labeling is internally consistent (i.e., that the values stated in the nutrition information, the nutrient values in the accompanying information, and the declaration of the percentage of nutrient by which the product has been modified are consistent and will not cause consumer confusion when compared), and that the actual modification is at least equal to the percentage specified in the definition of the claim.

(2) For products bearing relative claims:

(i) The label or labeling must state the identity of the reference product and the percent (or fraction) of the amount of the nutrient in the reference product by which the nutrient has been modified, (e.g., ''50 percent less fat than 'reference product'' or ''⅓fewer calories than 'reference product'''); and

(ii) This information shall be immediately adjacent to the most prominent claim in easily legible boldface print or type, in distinct contrast to other printed or graphic matter, that is no less than that required by § 381.121(c) for net quantity of contents, except where the size of the claim is less than two times the required size of the net quantity of contents statement, in which case the referral statement shall be no less than one-half the size of the claim, but no smaller than 1/16-inch minimum height, except as permitted by § 381.500(d)(2).

(iii) The determination of which use of the claim is in the most prominent location on the label or labeling will be made based on the following factors, considered in order:

(A) A claim on the principal display panel adjacent to the statement of identity;

(B) A claim elsewhere on the principal display panel;

(C) A claim on the information panel; or

(D) A claim elsewhere on the label or labeling.

(iv) The label or labeling must also bear:

(A) Clear and concise quantitative information comparing the amount of the subject nutrient in the product per labeled serving size with that in the reference product; and

(B) This statement shall appear adjacent to the most prominent claim or to the nutrition information.

(3) A relative claim for decreased levels of a nutrient may not be made on the label or in labeling of a product if the nutrient content of the reference product meets the requirement for a ''low'' claim for that nutrient.

(k) The term ''modified'' may be used in the statement of identity of a product that bears a relative claim that complies with the requirements of this part, followed immediately by the name of the nutrient whose content has been altered (e.g., ''modified fat 'product'''). This statement of identity must be immediately followed by the comparative statement such as ''contains 35 percent less fat than 'reference product'.'' The label or labeling must also bear the information required by paragraph (j)(2) of this section in the manner prescribed.

(l) For purposes of making a claim, a ''meal-type product'' shall be defined as a product that:

(1) Makes a significant contribution to the diet by weighing at least 6 ounces, but no more than 12 ounces per serving (container), and

(2) Contains ingredients from two or more of the following four food groups:

(i) Bread, cereal, rice and pasta group,

(ii) Fruits and vegetables group,

(iii) Milk, yogurt, and cheese group, and

(iv) Meat, poultry, fish, dry beans, eggs, and nuts group, and

(3) Is represented as, or is in a form commonly understood to be a breakfast, lunch, dinner, meal, main dish, entree, or pizza. Such representations may be made either by statements, photographs, or vignettes.

(m) [Reserved]

(n) Nutrition labeling in accordance with § 381.409 shall be provided for any food for which a nutrient content claim is made.

(o) Compliance with requirements for nutrient content claims shall be in accordance with § 381.409(h).

(p)(1) Unless otherwise specified, the reference amount customarily consumed set forth in § 381.412(b) through

(e) shall be used in determining whether a product meets the criteria for a nutrient content claim. If the serving size declared on the product label differs from the reference amount customarily consumed, and the amount of the nutrient contained in the labeled serving does not meet the maximum or minimum amount criterion in the definition for the descriptor for that nutrient, the claim shall be followed by the criteria for the claim as required by §381.412(f) (e.g., ''very low sodium, 35 mg or less per 55 grams'').

(2) The criteria for the claim shall be immediately adjacent to the most prominent claim in easily legible print or type and in a size that is no less than that required by §381.121(c) for net quantity of contents, except where the size of the claim is less than two times the required size of the net quantity of contents statement, in which case the criteria statement shall be no less than one-half the size of the claim but no smaller than 1/16-inch minimum height, except as permitted by §381.500(d)(2).

(q) The following exemptions apply:

(1) Nutrient content claims that have not been defined by regulation and that appear as part of a brand name that was in use prior to November 27, 1991, may continue to be used as part of that brand name, provided they are not false or misleading under section 4(h) of the Act (21 U.S.C. 453(h)(4)).

(2) [Reserved]

(3) A statement that describes the percentage of a vitamin or mineral in the food, including foods intended specifically for use by infants and children less than 2 years of age, in relation to a Reference Daily Intake (RDI) as defined in §381.409 may be made on the label or in the labeling of a food without a regulation authorizing such a claim for a specific vitamin or mineral.

(4) The requirements of this section do not apply to infant formulas and medical foods, as described in 21 CFR 101.13(q)(4).

(5) [Reserved]

(6) Nutrient content claims that were part of the name of a product that was subject to a standard of identity as of November 27, 1991, are not subject to the requirements of paragraph (b) of this section whether or not they meet the definition of the descriptive term.

(7) Implied nutrient content claims may be used as part of a brand name, provided that the use of the claim has been authorized by FSIS. Labeling applications requesting approval of such a claim may be submitted pursuant to §381.469.

[58 FR 675, Jan. 6, 1993; 58 FR 43789, Aug. 18, 1993, as amended at 58 FR 47628, Sept. 10, 1993; 59 FR 40215, Aug. 8, 1994; 59 FR 45198, Sept. 1, 1994; 60 FR 208, Jan. 3, 1995]

§§ 381.414–381.442 [Reserved]

§ 381.443 Significant participation for voluntary nutrition labeling.

(a) In evaluating significant participation for voluntary nutrition labeling, FSIS will consider only the major cuts of single-ingredient, raw poultry products, as identified in §381.444, including those that have been previously frozen.

(b) FSIS will judge a food retailer to be participating at a significant level if the retailer provides nutrition labeling information for at least 90 percent of the major cuts of single-ingredient, raw poultry products, listed in §381.444, that it sells, and if the nutrition label is consistent in content and format with the mandatory program, or nutrition information is displayed at point-of-purchase in an appropriate manner.

(c) To determine whether there is significant participation by retailers under the voluntary nutrition labeling guidelines, FSIS will select a representative sample of companies allocated by type and size.

(d) FSIS will find that significant participation by food retailers exists if at least 60 percent of all companies that are evaluated are participating in accordance with the guidelines.

(e) FSIS will evaluate significant participation of the voluntary program every 2 years beginning in May 1995.

(1) If significant participation is found, the voluntary nutrition labeling guidelines shall remain in effect.

(2) If significant participation is not found, FSIS shall initiate rulemaking to require nutrition labeling on those products under the voluntary program.

§ 381.444 Identification of major cuts of poultry products.

The major cuts of single-ingredient, raw poultry products are: Whole chicken (without neck and giblets), chicken breast, chicken wing, chicken drumstick, chicken thigh, whole turkey (without necks and giblets; separate nutrient panels for white and dark meat permitted as an option), turkey breast, turkey wing, turkey drumstick, and turkey thigh.

§ 381.445 Guidelines for voluntary nutrition labeling of single-ingredient, raw products.

(a) Nutrition information on the cuts of single-ingredient, raw poultry products, including those that have been previously frozen, shall be provided in the following manner:

(1) If a retailer or manufacturer chooses to provide nutrition information on the label of these products, these products shall be subject to all requirements of the mandatory nutrition labeling program, except that nutrition labeling may be declared on the basis of either ''as consumed'' or ''as packaged.'' In addition, the declaration of the number of servings per container need not be included in nutrition labeling of single-ingredient, raw poultry products, including those that have been previously frozen.

(2) A retailer may choose to provide nutrition information at the point-of-purchase, such as by posting a sign, or by making the information readily available in brochures, notebooks, or leaflet form in close proximity to the food. The nutrition labeling information may also be supplemented by a video, live demonstration, or other media. If a nutrition claim is made on point-of-purchase materials all of the requirements of the mandatory nutrition labeling program apply. However, if only nutrition information—and not a nutrition claim—is supplied on point-of-purchase materials:

(i) The requirements of the mandatory nutrition labeling program apply, but the nutrition information may be supplied on an ''as packaged'' or ''as consumed,'' basis;

(ii) The listing of percent of Daily Value for the nutrients (except vitamins and minerals specified in § 381.409(c)(8)) and footnote required by § 381.409(d)(9) may be omitted; and

(iii) The point-of-purchase materials are not subject to any of the format requirements.

(b) [Reserved]

(c) The declaration of nutrition information may be presented in a simplified format as specified in § 381.409(f) for the mandatory nutrition labeling program.

(d) The nutrition label data should be based on either raw or cooked edible portions of poultry cuts with skin. If data are based on cooked portions, the methods used to cook the products must be specified and should be those which do not add nutrients from other ingredients such as flour, breading, and salt. Additional nutritional data may be presented on an optional basis for the raw or cooked edible portions of the skinless poultry meat.

(e) Nutrient data that are the most current representative data base values contained in USDA's National Nutrient Data Bank or its published form, the Agriculture Handbook No. 8 series, may be used for nutrition labeling of single-ingredient, raw poultry products, including those that have been previously frozen. These data may be composite data that reflect different classes of turkey or other variables affecting nutrient content. Alternatively, data that reflect specific classes or other variables may be used, except that if data are used on labels attached to a product which is labeled as to class of poultry or other variables, the data must represent the product in the package when such data are contained in the representative data base. When data are used on labels attached to a product, the data must represent the edible poultry tissues present in the package.

(f) If the nutrition information is in accordance with paragraph (e) of this section, a nutrition label or labeling will not be subject to the Agency compliance review under § 381.409(h), unless a nutrition claim is made on the basis of the representative data base values.

(g) Retailers may use data bases that they believe reflect the nutrient content of single-ingredient, raw poultry products, including those that have been previously frozen; however, such

labeling shall be subject to the compliance procedures of paragraph (e) of this section and the requirements specified in this subpart for the mandatory nutrition labeling program.

[58 FR 675, Jan. 6, 1993, as amended at 58 FR 47628, Sept. 10, 1993; 60 FR 209, Jan. 3, 1995]

§§ 381.446–381.453 [Reserved]

§ 381.454 Nutrient content claims for "good source," "high," and "more."

(a) *General requirements.* Except as provided in paragraph (e) of this section, a claim about the level of a nutrient in a product in relation to the Reference Daily Intake (RDI) or Daily Reference Value (DRV), established for that nutrient (excluding total carbohydrate) in § 381.409(c), may only be made on the label or in labeling of the product if:

(1) The claim uses one of the terms defined in this section in accordance with the definition for that term;

(2) The claim is made in accordance with the general requirements for nutrient content claims in § 381.413; and

(3) The product for which the claim is made is labeled in accordance with § 381.409.

(b) *''High'' claims.* (1) The terms ''high,'' ''rich in,'' or ''excellent source of'' may be used on the label or in labeling of products, except meal-type products as defined in § 381.413(l), provided that the product contains 20 percent or more of the RDI or the DRV per reference amount customarily consumed.

(2) The terms defined in paragraph (b)(1) of this section may be used on the label or in labeling of a meal-type product as defined in § 381.413(l), provided that:

(i) The product contains a food that meets the definition of ''high'' in paragraph (b)(1) of this section; and

(ii) The label or labeling clearly identifies the food that is the subject of the claim (e.g., ''the serving of broccoli in this meal is high in vitamin C'').

(c) *''Good Source'' claims.* (1) The terms ''good source,'' ''contains,'' or ''provides'' may be used on the label or in labeling of products, except meal-type products as described in § 381.413(l), provided that the product contains 10 to 19 percent of the RDI or the DRV per reference amount customarily consumed.

(2) The terms defined in paragraph (c)(1) of this section may be used on the label or in labeling of a meal-type product as defined in § 381.413(l), provided that:

(i) The product contains a food that meets the definition of ''good source'' in paragraph (c)(1) of this section; and

(ii) The label or labeling clearly identifies the food that is the subject of the claim (e.g., ''the serving of sweet potatoes in this meal is a good source of fiber'').

(d) *Fiber claims.* (1) If a nutrient content claim is made with respect to the level of dietary fiber, i.e., that the product is high in fiber, a good source of fiber, or that the product contains ''more'' fiber, and the product is not ''low'' in total fat as defined in § 381.462(b)(2) or, in the case of a meal-type product, is not ''low'' in total fat as defined in § 381.462(b)(3), then the labeling shall disclose the level of total fat per labeled serving size (e.g., ''contains 12 grams (g) of fat per serving''); and

(2) The disclosure shall appear in immediate proximity to such claim and be in a type size no less than one-half the size of the claim.

(e) *''More'' claims.* (1) A relative claim using the terms ''more'' and ''added'' may be used on the label or in labeling to describe the level of protein, vitamins, minerals, dietary fiber, or potassium in a product, except meal-type products as defined in § 381.413(l), provided that:

(i) The product contains at least 10 percent more of the RDI or the DRV for protein, vitamins, minerals, dietary fiber, or potassium (expressed as a percent of the Daily Value) per reference amount customarily consumed than an appropriate reference product as described in § 381.413(j)(1); and

(ii) As required in § 381.413(j)(2) for relative claims:

(A) The identity of the reference product and the percent (or fraction) that the nutrient is greater relative to the RDI or DRV are declared in immediate proximity to the most prominent such claim (e.g., ''contains 10 percent more of the Daily Value for fiber than 'reference product' ''); and

(B) Quantitative information comparing the level of the nutrient in the product per labeled serving size with that of the reference product that it replaces is declared adjacent to the most prominent claim or to the nutrition information (e.g., ''fiber content of 'reference product' is 1 g per serving; 'this product' contains 4 g per serving'').

(2) A relative claim using the terms ''more'' and ''added'' may be used on the label or in labeling to describe the level of protein, vitamins, minerals, dietary fiber, or potassium in meal-type products as defined in § 381.413(l), provided that:

(i) The product contains at least 10 percent more of the RDI or the DRV for protein, vitamins, minerals, dietary fiber, or potassium (expressed as a percent of the Daily Value) per 100 g of product than an appropriate reference product as described in § 381.413(j)(1); and

(ii) As required in § 381.413(j)(2) for relative claims:

(A) The identity of the reference product and the percent (or fraction) that the nutrient is greater relative to the RDI or DRV are declared in immediate proximity to the most prominent such claim (e.g., ''contains 10 percent more of the Daily Value for fiber per 3 ounces (oz) than does 'reference product' ''), and

(B) Quantitative information comparing the level of the nutrient in the meal-type product per specified weight with that of the reference product that it replaces is declared adjacent to the most prominent claim or to the nutrition information (e.g., ''fiber content of 'reference product' is 2 g per 3 oz; 'this product' contains 5 g per 3 oz'').

[60 FR 210, Jan. 3, 1995]

§ 381.455 [Reserved]

§ 381.456 Nutrient content claims for "light" or "lite."

(a) *General requirements.* A claim using the terms ''light'' or ''lite'' to describe a product may only be made on the label or in labeling of the product if:

(1) The claim uses one of the terms defined in this section in accordance with the definition for that term;

(2) The claim is made in accordance with the general requirements for nutrient content claims in § 381.413; and

(3) The product for which the claim is made is labeled in accordance with § 381.409.

(b) *''Light'' claims.* The terms ''light'' or ''lite'' may be used on the label or in labeling of products, except meal-type products as defined in § 381.413(l), without further qualification, provided that:

(1) If the product derives 50 percent or more of its calories from fat, its fat content is reduced by 50 percent or more per reference amount customarily consumed compared to an appropriate reference product as described in § 381.413(j)(1); or

(2) If the product derives less than 50 percent of its calories from fat:

(i) The number of calories is reduced by at least one-third (33⅓ percent) per reference amount customarily consumed compared to an appropriate reference product as described in § 381.413(j)(1); or

(ii) Its fat content is reduced by 50 percent or more per reference amount customarily consumed compared to the appropriate reference product as described in § 381.413(j)(1); and

(3) As required in § 381.413(j)(2) for relative claims:

(i) The identity of the reference product and the percent (or fraction) that the calories and the fat were reduced are declared in immediate proximity to the most prominent such claim (e.g., ''⅓fewer calories and 50 percent less fat than the market leader''); and

(ii) Quantitative information comparing the level of calories and fat content in the product per labeled serving size with that of the reference product that it replaces is declared adjacent to the most prominent claim or to the nutrition information (e.g., ''lite 'this product'—200 calories, 4 grams (g) fat; regular 'reference product'—300 calories, 8 g fat per serving''); and

(iii) If the labeled product contains less than 40 calories or less than 3 g fat per reference amount customarily consumed, the percentage reduction for that nutrient need not be declared.

(4) A ''light'' claim may not be made on a product for which the reference

product meets the definition of ''low fat'' and ''low calorie.''

(c)(1)(i) A product for which the reference product contains 40 calories or less and 3 g fat or less per reference amount customarily consumed may use the terms ''light'' or ''lite'' without further qualification if it is reduced by 50 percent or more in sodium content compared to the reference product; and

(ii) As required in §381.413(j)(2) for relative claims:

(A) The identity of the reference product and the percent (or fraction) that the sodium was reduced are declared in immediate proximity to the most prominent such claim (e.g., ''50 percent less sodium than the market leader''); and

(B) Quantitative information comparing the level of sodium per labeled serving size with that of the reference product it replaces is declared adjacent to the most prominent claim or to the nutrition information (e.g., ''lite 'this product'—500 milligrams (mg) sodium per serving; regular 'reference product'—1,000 mg sodium per serving'').

(2)(i) A product for which the reference product contains more than 40 calories or more than 3 g fat per reference amount customarily consumed may use the terms ''light in sodium'' or ''lite in sodium'' if it is reduced by 50 percent or more in sodium content compared to the reference product, provided that ''light'' or ''lite'' is presented in immediate proximity with ''in sodium'' and the entire term is presented in uniform type size, style, color, and prominence; and

(ii) As required in §381.413(j)(2) for relative claims:

(A) The identity of the reference product and the percent (or fraction) that the sodium was reduced are declared in immediate proximity to the most prominent such claim (e.g., ''50 percent less sodium than the market leader''); and

(B) Quantitative information comparing the level of sodium per labeled serving size with that of the reference product it replaces is declared adjacent to the most prominent claim or to the nutrition information (e.g., or ''lite 'this product'—170 mg sodium per serving; regular 'reference product'—350 mg per serving'').

(3) Except for meal-type products as defined in §381.413(l), a ''light in sodium'' claim may not be made on a product for which the reference product meets the definition of ''low in sodium.''

(d)(1) The terms ''light'' or ''lite'' may be used on the label or in labeling of a meal-type product as defined in §381.413(l), provided that:

(i) The product meets the definition of:

(A) ''Low in calories'' as defined in §381.460(b)(3); or

(B) ''Low in fat'' as defined in §381.462(b)(3); and

(ii)(A) A statement appears on the principal display panel that explains whether ''light'' is used to mean ''low fat,'' ''low calories,'' or both (e.g., ''Light Delight, a low fat meal''); and

(B) The accompanying statement is no less than one-half the type size of the ''light'' or ''lite'' claim.

(2)(i) The terms ''light in sodium'' or ''lite in sodium'' may be used on the label or in labeling of a meal-type product as defined in §381.413(l), provided that the product meets the definition of ''low in sodium'' as defined in §381.461(b)(5)(i); and

(ii) ''Light'' or ''lite'' and ''in sodium'' are presented in uniform type size, style, color, and prominence.

(3) The terms ''light'' or ''lite'' may be used in the brand name of a product to describe the sodium content, provided that:

(i) The product is reduced by 50 percent or more in sodium content compared to the reference product;

(ii) A statement specifically stating that the product is ''light in sodium'' or ''lite in sodium'' appears:

(A) Contiguous to the brand name; and

(B) In uniform type size, style, color, and prominence as the product name; and

(iii) As required in §381.413(j)(2) for relative claims:

(A) The identity of the reference product and the percent (or fraction) that the sodium was reduced are declared in immediate proximity to the most prominent such claim; and

(B) Quantitative information comparing the level of sodium per labeled serving size with that of the reference

product it replaces is declared adjacent to the most prominent claim or to the nutrition information.

(e) Except as provided in paragraphs (b) through (d) of this section, the terms ''light'' or ''lite'' may not be used to refer to a product that is not reduced in fat by 50 percent, or, if applicable, in calories by ⅓ or, when properly qualified, in sodium by 50 percent unless:

(1) It describes some physical or organoleptic attribute of the product such as texture or color and the information (e.g., ''light in color'' or ''light in texture'') so stated, clearly conveys the nature of the product; and

(2) The attribute (e.g., ''color'' or ''texture'') is in the same style, color, and at least one-half the type size as the word ''light'' and in immediate proximity thereto.

(f) If a manufacturer can demonstrate that the word ''light'' has been associated, through common use, with a particular product to reflect a physical or organoleptic attribute to the point where it has become part of the statement of identity, such use of the term ''light'' shall not be considered a nutrient content claim subject to the requirements in this part.

(g) The term ''lightly salted'' may be used on a product to which has been added 50 percent less sodium than is normally added to the reference product as described in § 381.413(j)(1)(i)(B) and (j)(1)(ii)(B), provided that if the product is not ''low in sodium'' as defined in § 381.461(b)(4), the statement ''not a low sodium food,'' shall appear adjacent to the nutrition information and the information required to accompany a relative claim shall appear on the label or labeling as specified in § 381.413(j)(2).

[60 FR 210, Jan. 3, 1995]

§§ 381.457–381.459 [Reserved]

§ 381.460 Nutrient content claims for calorie content.

(a) *General requirements.* A claim about the calorie or sugar content of a product may only be made on the label or in labeling of the product if:

(1) The claim uses one of the terms defined in this section in accordance with the definition for that term;

(2) The claim is made in accordance with the general requirements for nutrient content claims in § 381.413; and

(3) The product for which the claim is made is labeled in accordance with § 381.409.

(b) *Calorie content claims.* (1) The terms ''calorie free,'' ''free of calories,'' ''no calories,'' ''zero calories,'' ''without calories,'' ''trivial source of calories,'' ''negligible source of calories,'' or ''dietarily insignificant source of calories'' may be used on the label or in labeling of products, provided that:

(i) The product contains less than 5 calories per reference amount customarily consumed and per labeled serving size; and

(ii) If the product meets this condition without the benefit of special processing, alteration, formulation, or reformulation to lower the caloric content, it is labeled to clearly refer to all products of its type and not merely to the particular brand to which the label attaches.

(2) The terms ''low calorie,'' ''few calories,'' ''contains a small amount of calories,'' ''low source of calories,'' or ''low in calories'' may be used on the label or in labeling of products, except meal-type products as defined in § 381.413(l), provided that:

(i)(A) The product has a reference amount customarily consumed greater than 30 grams (g) or greater than 2 tablespoons (tbsp) and does not provide more than 40 calories per reference amount customarily consumed; or

(B) The product has a reference amount customarily consumed of 30 g or less or 2 tbsp or less and does not provide more than 40 calories per reference amount customarily consumed and per 50 g (for dehydrated products that must be reconstituted before typical consumption with water or a diluent containing an insignificant amount, as defined in § 381.409(f)(1), of all nutrients per reference amount customarily consumed, the per-50-g criterion refers to the ''as prepared'' form).

(ii) If the product meets these conditions without the benefit of special processing, alteration, formulation, or reformulation to lower the caloric content, it is labeled to clearly refer to all products of its type and not merely to

the particular brand to which the label attaches.

(3) The terms defined in paragraph (b)(2) of this section may be used on the label or in labeling of a meal-type product as defined in § 381.413(l), provided that:

(i) The product contains 120 calories or less per 100 g of product; and

(ii) If the product meets this condition without the benefit of special processing, alteration, formulation, or reformulation to lower the calorie content, it is labeled to clearly refer to all products of its type and not merely to the particular brand to which it attaches.

(4) The terms ''reduced calorie,'' ''reduced in calories,'' ''calorie reduced,'' ''fewer calories,'' ''lower calorie,'' or ''lower in calories'' may be used on the label or in labeling of products, except meal-type products as defined in § 381.413(l), provided that:

(i) The product contains at least 25 percent fewer calories per reference amount customarily consumed than an appropriate reference product as described in § 381.413(j)(1); and

(ii) As required in § 381.413(j)(2) for relative claims:

(A) The identity of the reference product and the percent (or fraction) that the calories differ between the two products are declared in immediate proximity to the most prominent such claim (e.g., lower calorie 'product'—''33 ⅓ percent fewer calories than our regular 'product' ''); and

(B) Quantitative information comparing the level of calories in the product per labeled serving size with that of the reference product that it replaces is declared adjacent to the most prominent claim or to the nutrition information (e.g., ''calorie content has been reduced from 150 to 100 calories per serving'').

(iii) Claims described in paragraph (b)(4) of this section may not be made on the label or in labeling of products if the reference product meets the definition for ''low calorie.''

(5) The terms defined in paragraph (b)(4) of this section may be used on the label or in labeling of a meal-type product as defined in § 381.413(l), provided that:

(i) The product contains at least 25 percent fewer calories per 100 g of product than an appropriate reference product as described in § 381.413(j)(1); and

(ii) As required in § 381.413(j)(2) for relative claims:

(A) The identity of the reference product and the percent (or fraction) that the calories differ between the two products are declared in immediate proximity to the most prominent such claim (e.g., ''calorie reduced 'product', 25% less calories per ounce (oz) (or 3 oz) than our regular 'product' ''); and

(B) Quantitative information comparing the level of calories in the product per specified weight with that of the reference product that it replaces is declared adjacent to the most prominent claim or to the nutrition information (e.g., ''calorie content has been reduced from 110 calories per 3 oz to 80 calories per 3 oz'').

(iii) Claims described in paragraph (b)(5) of this section may not be made on the label or in labeling of products if the reference product meets the definition for ''low calorie.''

(c) *Sugar content claims.* (1) Terms such as ''sugar free,'' ''free of sugar,'' ''no sugar,'' ''zero sugar,'' ''without sugar,'' ''sugarless,'' ''trivial source of sugar,'' ''negligible source of sugar,'' or ''dietarily insignificant source of sugar'' may reasonably be expected to be regarded by consumers as terms that represent that the product contains no sugars or sweeteners, e.g., ''sugar free,'' or ''no sugar,'' as indicating a product which is low in calories or significantly reduced in calories. Consequently, except as provided in paragraph (c)(2) of this section, a product may not be labeled with such terms unless:

(i) The product contains less than 0.5 g of sugars, as defined in § 381.409(c)(6)(ii), per reference amount customarily consumed and per labeled serving size or, in the case of a meal-type product, less than 0.5 g of sugars per labeled serving size;

(ii) The product contains no ingredient that is a sugar or that is generally understood by consumers to contain sugars unless the listing of the ingredient in the ingredients statement is followed by an asterisk that refers to

the statement below the list of ingredients, which states: ''Adds a trivial amount of sugar,'' ''adds a negligible amount of sugar,'' or ''adds a dietarily insignificant amount of sugar;'' and

(iii)(A) It is labeled ''low calorie'' or ''reduced calorie'' or bears a relative claim of special dietary usefulness labeled in compliance with paragraphs (b)(2), (b)(3), (b)(4), or (b)(5) of this section; or

(B) Such term is immediately accompanied, each time it is used, by either the statement ''not a reduced calorie product,'' ''not a low calorie product,'' or ''not for weight control.''

(2) The terms ''no added sugar,'' ''without added sugar,'' or ''no sugar added'' may be used only if:

(i) No amount of sugars, as defined in § 381.409(c)(6)(ii), or any other ingredient that contains sugars that functionally substitute for added sugars is added during processing or packaging;

(ii) The product does not contain an ingredient containing added sugars such as jam, jelly, or concentrated fruit juice;

(iii) The sugars content has not been increased above the amount present in the ingredients by some means such as the use of enzymes, except where the intended functional effect of the process is not to increase the sugars content of a product, and a functionally insignificant increase in sugars results;

(iv) The product that it resembles and for which it substitutes normally contains added sugars; and

(v) The product bears a statement that the product is not ''low calorie'' or ''calorie reduced'' (unless the product meets the requirements for a ''low'' or ''reduced calorie'' product) and that directs consumers' attention to the nutrition panel for further information on sugar and calorie content.

(3) Paragraph (c)(1) of this section shall not apply to a factual statement that a product, including products intended specifically for infants and children less than 2 years of age, is unsweetened or contains no added sweeteners in the case of a product that contains apparent substantial inherent sugar content, e.g., juices.

(4) The terms ''reduced sugar,'' ''reduced in sugar,'' ''sugar reduced,'' ''less sugar,'' ''lower sugar,'' or ''lower in sugar'' may be used on the label or in labeling of products, except meal-type products as defined in § 381.413(l), provided that:

(i) The product contains at least 25 percent less sugars per reference amount customarily consumed than an appropriate reference product as described in § 381.413(j)(1); and

(ii) As required in § 381.413(j)(2) for relative claims:

(A) The identity of the reference product and the percent (or fraction) that the sugars differ between the two products are declared in immediate proximity to the most prominent such claim (e.g., ''this product contains 25 percent less sugar than our regular product''); and

(B) Quantitative information comparing the level of the sugar in the product per labeled serving size with that of the reference product that it replaces is declared adjacent to the most prominent claim or to the nutrition information (e.g., ''sugar content has been lowered from 8 g to 6 g per serving'').

(5) The terms defined in paragraph (c)(4) of this section may be used on the label or in labeling of a meal-type product as defined in § 381.413(l), provided that:

(i) The product contains at least 25 percent less sugars per 100 g of product than an appropriate reference product as described in § 381.413(j)(1); and

(ii) As required in § 381.413(j)(2) for relative claims:

(A) The identity of the reference product and the percent (or fraction) that the sugars differ between the two products are declared in immediate proximity to the most prominent such claim (e.g., ''reduced sugar 'product'—25% less sugar than our regular 'product' ''); and

(B) Quantitative information comparing the level of the nutrient in the product per specified weight with that of the reference product that it replaces is declared adjacent to the most prominent claim or to the nutrition information (e.g., ''sugar content has been reduced from 17 g per 3 oz to 13 g per 3 oz'').

[60 FR 211, Jan. 3, 1995]

§ 381.461 Nutrient content claims for the sodium content.

(a) *General requirements.* A claim about the level of sodium in a product may only be made on the label or in labeling of the product if:

(1) The claim uses one of the terms defined in this section in accordance with the definition for that term;

(2) The claim is made in accordance with the general requirements for nutrient content claims in § 381.413; and

(3) The product for which the claim is made is labeled in accordance with § 381.409.

(b) *Sodium content claims.* (1) The terms ''sodium free,'' ''free of sodium,'' ''no sodium,'' ''zero sodium,'' ''without sodium,'' ''trivial source of sodium,'' ''negligible source of sodium,'' or ''dietarily insignificant source of sodium'' may be used on the label or in labeling of products, provided that:

(i) The product contains less than 5 milligrams (mg) of sodium per reference amount customarily consumed and per labeled serving size or, in the case of a meal-type product, less than 5 mg of sodium per labeled serving size;

(ii) The product contains no ingredient that is sodium chloride or is generally understood by consumers to contain sodium unless the listing of the ingredient in the ingredients statement is followed by an asterisk that refers to the statement below the list of ingredients, which states: ''Adds a trivial amount of sodium,'' ''adds a negligible amount of sodium'' or ''adds a dietarily insignificant amount of sodium;'' and

(iii) If the product meets these conditions without the benefit of special processing, alteration, formulation, or reformulation to lower the sodium content, it is labeled to clearly refer to all products of its type and not merely to the particular brand to which the label attaches.

(2) The terms ''very low sodium'' or ''very low in sodium'' may be used on the label or in labeling of products, except meal-type products as defined in § 381.413(l), provided that:

(i)(A) The product has a reference amount customarily consumed greater than 30 grams (g) or greater than 2 tablespoons (tbsp) and contains 35 mg or less sodium per reference amount customarily consumed; or

(B) The product has a reference amount customarily consumed of 30 g or less or 2 tbsp or less and contains 35 mg or less sodium per reference amount customarily consumed and per 50 g (for dehydrated products that must be reconstituted before typical consumption with water or a diluent containing an insignificant amount, as defined in § 381.409(f)(1), of all nutrients per reference amount customarily consumed, the per-50-g criterion refers to the ''as prepared'' form); and

(ii) If the product meets these conditions without the benefit of special processing, alteration, formulation, or reformulation to lower the sodium content, it is labeled to clearly refer to all products of its type and not merely to the particular brand to which the label attaches.

(3) The terms defined in paragraph (b)(2) of this section may be used on the label or in labeling of a meal-type product as defined in §381.413(l), provided that:

(i) The product contains 35 mg or less of sodium per 100 g of product; and

(ii) If the product meets this condition without the benefit of special processing, alteration, formulation, or reformulation to lower the sodium content, it is labeled to clearly refer to all products of its type and not merely to the particular brand to which the label attaches.

(4) The terms ''low sodium,'' ''low in sodium,'' ''little sodium,'' ''contains a small amount of sodium,'' or ''low source of sodium'' may be used on the label and in labeling of products, except meal-type products as defined in §381.413(l), provided that:

(i)(A) The product has a reference amount customarily consumed greater than 30 g or greater than 2 tbsp and contains 140 mg or less sodium per reference amount customarily consumed; or

(B) The product has a reference amount customarily consumed of 30 g or less or 2 tbsp or less and contains 140 mg or less sodium per reference amount customarily consumed and per 50 g (for dehydrated products that must be reconstituted before typical consumption with water or a diluent containing an insignificant amount, as defined in §381.409(f)(1), of all nutrients

per reference amount customarily consumed, the per-50-g criterion refers to the ''as prepared'' form); and

(ii) If the product meets these conditions without the benefit of special processing, alteration, formulation, or reformulation to lower the sodium content, it is labeled to clearly refer to all products of its type and not merely to the particular brand to which the label attaches.

(5) The terms defined in paragraph (b)(4) of this section may be used on the label or in labeling of a meal-type product as defined in § 381.413(l), provided that:

(i) The product contains 140 mg or less sodium per 100 g of product; and

(ii) If the product meets these conditions without the benefit of special processing, alteration, formulation, or reformulation to lower the sodium content, it is labeled to clearly refer to all products of its type and not merely to the particular brand to which the label attaches.

(6) The terms ''reduced sodium,'' ''reduced in sodium,'' ''sodium reduced,'' ''less sodium,'' ''lower sodium,'' or ''lower in sodium'' may be used on the label or in labeling of products, except meal-type products as defined in § 381.413(l), provided that:

(i) The product contains at least 25 percent less sodium per reference amount customarily consumed than an appropriate reference product as described in § 381.413(j)(l); and

(ii) As required in § 381.413(j)(2) for relative claims:

(A) The identity of the reference product and the percent (or fraction) that the sodium differs between the two products are declared in immediate proximity to the most prominent such claim (e.g., ''reduced sodium 'product', 50 percent less sodium than regular 'product' ''); and

(B) Quantitative information comparing the level of sodium in the product per labeled serving size with that of the reference product that it replaces is declared adjacent to the most prominent claim or to the nutrition information (e.g., ''sodium content has been lowered from 300 to 150 mg per serving'').

(iii) Claims described in paragraph (b)(6) of this section may not be made on the label or in labeling of a product if the nutrient content of the reference product meets the definition for ''low sodium.''

(7) The terms defined in paragraph (b)(6) of this section may be used on the label or in labeling of a meal-type product as defined in § 381.413(l), provided that:

(i) The product contains at least 25 percent less sodium per 100 g of product than an appropriate reference product as described in § 381.413(j)(l); and

(ii) As required in § 381.413(j)(2) for relative claims:

(A) The identity of the reference product and the percent (or fraction) that the sodium differs between the two products are declared in immediate proximity to the most prominent such claim (e.g., ''reduced sodium 'product'—30% less sodium per 3 oz than our 'regular product' ''); and

(B) Quantitative information comparing the level of sodium in the product per specified weight with that of the reference product that it replaces is declared adjacent to the most prominent claim or to the nutrition information (e.g., ''sodium content has been reduced from 220 mg per 3 oz to 150 mg per 3 oz'').

(iii) Claims described in paragraph (b)(7) of this section may not be made on the label or in labeling of products if the nutrient content of the reference product meets the definition for ''low sodium.''

(c) The term ''salt'' is not synonymous with ''sodium.'' Salt refers to sodium chloride. However, references to salt content such as ''unsalted,'' ''no salt,'' ''no salt added'' are potentially misleading.

(1) The term ''salt free'' may be used on the label or in labeling of products only if the product is ''sodium free'' as defined in paragraph (b)(1) of this section.

(2) The terms ''unsalted,'' ''without added salt,'' and ''no salt added'' may be used on the label or in labeling of products only if:

(i) No salt is added during processing;

(ii) The product that it resembles and for which it substitutes is normally processed with salt; and

(iii) If the product is not sodium free, the statement ''not a sodium free product'' or ''not for control of sodium in the diet'' appears adjacent to the nutrition information of the product bearing the claim.

(3) Paragraph (c)(2) of this section shall not apply to a factual statement that a product intended specifically for infants and children less than 2 years of age is unsalted, provided such statement refers to the taste of the product and is not false or otherwise misleading.

[60 FR 213, Jan. 3, 1995; 60 FR 5762, Jan. 30, 1995]

§ 381.462 Nutrient content claims for fat, fatty acids, and cholesterol content.

(a) *General requirements.* A claim about the level of fat, fatty acid, and cholesterol in a product may only be made on the label or in labeling of products if:

(1) The claim uses one of the terms defined in this section in accordance with the definition for that term;

(2) The claim is made in accordance with the general requirements for nutrient content claims in § 381.413; and

(3) The product for which the claim is made is labeled in accordance with § 381.409.

(b) *Fat content claims.* (1) The terms ''fat free,'' ''free of fat,'' ''no fat,'' ''zero fat,'' ''without fat,'' ''nonfat,'' ''trivial source of fat,'' ''negligible source of fat,'' or ''dietarily insignificant source of fat'' may be used on the label or in labeling of products, provided that:

(i) The product contains less than 0.5 gram (g) of fat per reference amount customarily consumed and per labeled serving size or, in the case of a meal-type product, less than 0.5 g of fat per labeled serving size;

(ii) The product contains no added ingredient that is a fat or is generally understood by consumers to contain fat unless the listing of the ingredient in the ingredients statement is followed by an asterisk that refers to the statement below the list of ingredients, which states: ''Adds a trivial amount of fat,'' ''adds a negligible amount of fat,'' or ''adds a dietarily insignificant amount of fat''; and

(iii) If the product meets these conditions without the benefit of special processing, alteration, formulation, or reformulation to lower the fat content, it is labeled to clearly refer to all products of its type and not merely to the particular brand to which the label attaches.

(2) The terms ''low fat,'' ''low in fat,'' ''contains a small amount of fat,'' ''low source of fat,'' or ''little fat'' may be used on the label and in labeling of products, except meal-type products as defined in § 381.413(l), provided that:

(i)(A) The product has a reference amount customarily consumed greater than 30 g or greater than 2 tablespoons (tbsp) and contains 3 g or less of fat per reference amount customarily consumed; or

(B) The product has a reference amount customarily consumed of 30 g or less or 2 tbsp or less and contains 3 g or less of fat per reference amount customarily consumed and per 50 g (for dehydrated products that must be reconstituted before typical consumption with water or a diluent containing an insignificant amount, as defined in § 381.409(f)(1), of all nutrients per reference amount customarily consumed, the per-50-g criterion refers to the ''as prepared'' form).

(ii) If the product meets these conditions without the benefit of special processing, alteration, formulation, or reformulation to lower the fat content, it is labeled to clearly refer to all products of its type and not merely to the particular brand to which the label attaches.

(3) The terms defined in paragraph (b)(2) of this section may be used on the label or in labeling of a meal-type product as defined in § 381.413(l), provided that:

(i) The product contains 3 g or less of total fat per 100 g of product and not more than 30 percent of calories from fat; and

(ii) If the product meets these conditions without the benefit of special processing, alteration, formulation, or reformulation to lower the fat content, it is labeled to clearly refer to all products of its type and not merely to the particular brand to which the label attaches.

(4) The terms ''reduced fat,'' ''reduced in fat,'' ''fat reduced,'' ''less fat,'' ''lower fat,'' or ''lower in fat'' may be used on the label or in labeling of products, except meal-type products as defined in § 381.413(l), provided that:

(i) The product contains at least 25 percent less fat per reference amount customarily consumed than an appropriate reference product as described in § 381.413(j)(1); and

(ii) As required in § 381.413(j)(2) for relative claims:

(A) The identity of the reference product and the percent (or fraction) that the fat differs between the two products are declared in immediate proximity to the most prominent such claim (e.g., ''reduced fat—50 percent less fat than our regular 'product' ''); and

(B) Quantitative information comparing the level of fat in the product per labeled serving size with that of the reference product that it replaces is declared adjacent to the most prominent claim or to the nutrition information (e.g., ''fat content has been reduced from 8 g to 4 g per serving'').

(iii) Claims described in paragraph (b)(4) of this section may not be made on the label or in labeling of a product if the nutrient content of the reference product meets the definition for ''low fat.''

(5) The terms defined in paragraph (b)(4) of this section may be used on the label or in labeling of a meal-type product as defined in § 381.413(l), provided that:

(i) The product contains at least 25 percent less fat per 100 g of product than an appropriate reference product as described in § 381.413(j)(1); and

(ii) As required in § 381.413(j)(2) for relative claims:

(A) The identity of the reference product and the percent (or fraction) that the fat differs between the two products are declared in immediate proximity to the most prominent such claim (e.g., ''reduced fat 'product', 33 percent less fat per 3 oz than our regular 'product' ''); and

(B) Quantitative information comparing the level of fat in the product per specified weight with that of the reference product that it replaces is declared adjacent to the most prominent such claim or to the nutrition information (e.g., ''fat content has been reduced from 8 g per 3 oz to 5 g per 3 oz'').

(iii) Claims described in paragraph (b)(5) of this section may not be made on the label or in labeling of a product if the nutrient content of the reference product meets the definition for ''low fat.''

(6) The term ''_____percent fat free'' may be used on the label or in labeling of products, provided that:

(i) The product meets the criteria for ''low fat'' in paragraph (b)(2) or (b)(3) of this section;

(ii) The percent declared and the words ''fat free'' are in uniform type size; and

(iii) A ''100 percent fat free'' claim may be made only on products that meet the criteria for ''fat free'' in paragraph (b)(1) of this section, that contain less than 0.5 g of fat per 100 g, and that contain no added fat.

(iv) A synonym for ''_____percent fat free'' is ''_____percent lean.''

(c) *Fatty acid content claims.* (1) The terms ''saturated fat free,'' ''free of saturated fat,'' ''no saturated fat,'' ''zero saturated fat,'' ''without saturated fat,'' ''trivial source of saturated fat,'' ''negligible source of saturated fat,'' or ''dietarily insignificant source of saturated fat'' may be used on the label or in labeling of products, provided that:

(i) The product contains less than 0.5 g of saturated fat and less than 0.5 g *trans* fatty acids per reference amount customarily consumed and per labeled serving size or, in the case of a meal-type product, less than 0.5 g of saturated fat and less than 0.5 g *trans* fatty acids per labeled serving size;

(ii) The product contains no ingredient that is generally understood by consumers to contain saturated fat unless the listing of the ingredient in the ingredients statement is followed by an asterisk that refers to the statement below the list of ingredients, which states: ''Adds a trivial amount of saturated fat,'' ''adds a negligible amount of saturated fat,'' or ''adds a dietarily insignificant amount of saturated fat;'' and

(iii) If the product meets these conditions without the benefit of special processing, alteration, formulation, or

reformulation to lower saturated fat content, it is labeled to clearly refer to all products of its type and not merely to the particular brand to which the label attaches.

(2) The terms ''low in saturated fat,'' ''low saturated fat,'' ''contains a small amount of saturated fat,'' ''low source of saturated fat,'' or ''a little saturated fat'' may be used on the label or in labeling of products, except meal-type products as defined in § 381.413(l), provided that:

(i) The product contains 1 g or less of saturated fat per reference amount customarily consumed and not more than 15 percent of calories from saturated fat; and

(ii) If the product meets these conditions without benefit of special processing, alteration, formulation, or reformulation to lower saturated fat content, it is labeled to clearly refer to all products of its type and not merely to the particular brand to which the label attaches.

(3) The terms defined in paragraph (c)(2) of this section may be used on the label or in labeling of a meal-type product as defined in § 381.413(l), provided that:

(i) The product contains 1 g or less of saturated fat per 100 g and less than 10 percent calories from saturated fat; and

(ii) If the product meets these conditions without the benefit of special processing, alteration, formulation, or reformulation to lower saturated fat content, it is labeled to clearly refer to all products of its type and not merely to the particular brand to which the label attaches.

(4) The terms ''reduced saturated fat,'' ''reduced in saturated fat,'' ''saturated fat reduced,'' ''less saturated fat,'' ''lower saturated fat,'' or ''lower in saturated fat'' may be used on the label or in labeling of products, except meal-type products as defined in § 381.413(l), provided that:

(i) The product contains at least 25 percent less saturated fat per reference amount customarily consumed than an appropriate reference product as described in § 381.413(j)(1); and

(ii) As required in § 381.413(j)(2) for relative claims:

(A) The identity of the reference product and the percent (or fraction) that the saturated fat differs between the two products are declared in immediate proximity to the most prominent such claim (e.g., ''reduced saturated fat 'product', contains 50 percent less saturated fat than the national average for 'product' ''); and

(B) Quantitative information comparing the level of saturated fat in the product per labeled serving size with that of the reference product that it replaces is declared adjacent to the most prominent claim or to the nutrition information (e.g., ''saturated fat reduced from 3 g to 1.5 g per serving'').

(iii) Claims described in paragraph (c)(4) of this section may not be made on the label or in labeling of a product if the nutrient content of the reference product meets the definition for ''low saturated fat.''

(5) The terms defined in paragraph (c)(4) of this section may be used on the label or in labeling of a meal-type product as defined in § 381.413(l), provided that:

(i) The product contains at least 25 percent less saturated fat per 100 g of product than an appropriate reference product as described in § 381.413(j)(1); and

(ii) As required in § 381.413(j)(2) for relative claims:

(A) The identity of the reference product and the percent (or fraction) that the saturated fat differs between the two products are declared in immediate proximity to the most prominent such claim (e.g., ''reduced saturated fat 'product', 50 percent less saturated fat than our regular 'product' ''); and

(B) Quantitative information comparing the level of saturated fat in the product per specified weight with that of the reference product that it replaces is declared adjacent to the most prominent claim or to the nutrition information (e.g., ''saturated fat content has been reduced from 2.5 g per 3 oz to 1.5 g per 3 oz'').

(iii) Claims described in paragraph (c)(5) of this section may not be made on the label or in labeling of a product if the nutrient content of the reference product meets the definition for ''low saturated fat.''

(d) *Cholesterol content claims.* (1) The terms ''cholesterol free,'' ''free of cholesterol,'' ''zero cholesterol,'' ''without cholesterol,'' ''no cholesterol,'' ''trivial source of cholesterol,'' ''negligible source of cholesterol,'' or ''dietarily insignificant source of cholesterol'' may be used on the label or in labeling of products, provided that:

(i) The product contains less than 2 milligrams (mg) of cholesterol per reference amount customarily consumed and per labeled serving size or, in the case of a meal-type product as defined in § 381.413(l), less than 2 mg of cholesterol per labeled serving size;

(ii) The product contains no ingredient that is generally understood by consumers to contain cholesterol, unless the listing of the ingredient in the ingredients statement is followed by an asterisk that refers to the statement below the list of ingredients, which states: ''Adds a trivial amount of cholesterol,'' ''adds a negligible amount of cholesterol,'' or ''adds a dietarily insignificant amount of cholesterol'';

(iii) The product contains 2 g or less of saturated fat per reference amount customarily consumed or, in the case of a meal-type product as defined in § 381.413(l), 2 g or less of saturated fat per labeled serving size; and

(iv) If the product meets these conditions without the benefit of special processing, alteration, formulation, or reformulation to lower cholesterol content, it is labeled to clearly refer to all products of its type and not merely to the particular brand to which it attaches; or

(v) If the product meets these conditions only as a result of special processing, alteration, formulation, or reformulation, the amount of cholesterol is reduced by 25 percent or more from the reference product it replaces as described in § 381.413(j)(1) and for which it substitutes as described in § 381.413(d) that has a significant (e.g., 5 percent or more of a national or regional market) market share. As required in § 381.413(j)(2) for relative claims:

(A) The identity of the reference product and the percent (or fraction) that the cholesterol was reduced are declared in immediate proximity to the most prominent such claim (e.g., ''cholesterol free 'product', contains 100 percent less cholesterol than 'reference product' ''); and

(B) Quantitative information comparing the level of cholesterol in the product per labeled serving size with that of the reference product that it replaces is declared adjacent to the most prominent claim or to the nutrition information (e.g., ''contains no cholesterol compared with 30 mg in one serving of 'reference product' '').

(2) The terms ''low in cholesterol,'' ''low cholesterol,'' ''contains a small amount of cholesterol,'' ''low source of cholesterol,'' or ''little cholesterol'' may be used on the label or in labeling of products, except meal-type products as defined in § 381.413(l), provided that:

(i)(A) If the product has a reference amount customarily consumed greater than 30 g or greater than 2 tbsp:

(*1*) The product contains 20 mg or less of cholesterol per reference amount customarily consumed; and

(*2*) The product contains 2 g or less of saturated fat per reference amount customarily consumed; or

(B) If the product has a reference amount customarily consumed of 30 g or less or 2 tbsp or less:

(*1*) The product contains 20 mg or less of cholesterol per reference amount customarily consumed and per 50 g (for dehydrated products that must be reconstituted before typical consumption with water or a diluent containing an insignificant amount, as defined in § 381.409(f)(1), of all nutrients per reference amount customarily consumed, the per-50-g criterion refers to the ''as prepared'' form); and

(*2*) The product contains 2 g or less of saturated fat per reference amount customarily consumed.

(ii) If the product meets these conditions without the benefit of special processing, alteration, formulation, or reformulation to lower cholesterol content, it is labeled to clearly refer to all products of its type and not merely to the particular brand to which the label attaches; or

(iii) If the product contains 20 mg or less of cholesterol only as a result of special processing, alteration, formulation, or reformulation, the amount of cholesterol is reduced by 25 percent or more from the reference product it replaces as described in § 381.413(j)(1) and

for which it substitutes as described in § 381.413(d) that has a significant (e.g., 5 percent or more of a national or regional market) market share. As required in § 381.413(j)(2) for relative claims:

(A) The identity of the reference product and the percent (or fraction) that the cholesterol has been reduced are declared in immediate proximity to the most prominent such claim (e.g., ''low cholesterol 'product', contains 85 percent less cholesterol than our regular 'product'''); and

(B) Quantitative information comparing the level of cholesterol in the product per labeled serving size with that of the reference product that it replaces is declared adjacent to the most prominent claim or to the nutrition information (e.g., ''cholesterol lowered from 30 mg to 5 mg per serving'').

(3) The terms defined in paragraph (d)(2) of this section may be used on the label or in labeling of a meal-type product as defined in § 381.413(l), provided that:

(i) The product contains 20 mg or less of cholesterol per 100 g of product;

(ii) The product contains 2 g or less of saturated fat per 100 g of product; and

(iii) If the product meets these conditions without the benefit of special processing, alteration, formulation, or reformulation to lower cholesterol content, it is labeled to clearly refer to all products of its type and not merely to the particular brand to which the label attaches.

(4) The terms ''reduced cholesterol,'' ''reduced in cholesterol,'' ''cholesterol reduced,'' ''less cholesterol,'' ''lower cholesterol,'' or ''lower in cholesterol'' may be used on the label or in labeling of products or products that substitute for those products as specified in § 381.413(d), excluding meal-type products as defined in § 381.413(l), provided that:

(i) The product has been specifically formulated, altered, or processed to reduce its cholesterol by 25 percent or more from the reference product it replaces as described in § 381.413(j)(1) and for which it substitutes as described in § 381.413(d) that has a significant (e.g., 5 percent or more of a national or regional market) market share;

(ii) The product contains 2 g or less of saturated fat per reference amount customarily consumed; and

(iii) As required in § 381.413(j)(2) for relative claims:

(A) The identity of the reference product and the percent (or fraction) that the cholesterol has been reduced are declared in immediate proximity to the most prominent such claim (e.g., ''25 percent less cholesterol than 'reference product'''); and

(B) Quantitative information comparing the level of cholesterol in the product per labeled serving size with that of the reference product that it replaces is declared adjacent to the most prominent claim or to the nutrition information (e.g., ''cholesterol lowered from 55 mg to 30 mg per serving'').

(iv) Claims described in paragraph (d)(4) of this section may not be made on the label or in labeling of a product if the nutrient content of the reference product meets the definition for ''low cholesterol.''

(5) The terms defined in paragraph (d)(4) of this section may be used on the label or in labeling of a meal-type product as defined in § 381.413(l), provided that:

(i) The product has been specifically formulated, altered, or processed to reduce its cholesterol by 25 percent or more from the reference product it replaces as described in § 381.413(j)(1) and for which it substitutes as described in § 381.413(d) that has a significant (e.g., 5 percent or more of a national or regional market) market share;

(ii) The product contains 2 g or less of saturated fat per 100 g of product; and

(iii) As required in § 381.413(j)(2) for relative claims:

(A) The identity of the reference product and the percent (or fraction) that the cholesterol has been reduced are declared in immediate proximity to the most prominent such claim (e.g., ''25% less cholesterol than 'reference product'''); and

(B) Quantitative information comparing the level of cholesterol in the product per specified weight with that of the reference product that it replaces is declared adjacent to the most prominent claim or to the nutrition information (e.g., ''cholesterol content

has been reduced from 35 mg per 3 oz to 25 mg per 3 oz).

(iv) Claims described in paragraph (d)(5) of this section may not be made on the label or in labeling of a product if the nutrient content of the reference product meets the definition for ''low cholesterol.''

(e) *''Lean'' and ''Extra Lean'' claims.* (1) The term ''lean'' may be used on the label or in labeling of a product, provided that the product contains less than 10 g of fat, 4.5 g or less of saturated fat, and less than 95 mg of cholesterol per 100 g of product and per reference amount customarily consumed for individual foods, and per 100 g of product and per labeled serving size for meal-type products as defined in §381.413(l).

(2) The term ''extra lean'' may be used on the label or in labeling of a product, provided that the product contains less than 5 g of fat, less than 2 g of saturated fat, and less than 95 mg of cholesterol per 100 g of product and per reference amount customarily consumed for individual foods, and per 100 g of product and per labeled serving size for meal-type products as defined in §381.413(l).

[60 FR 214, Jan. 3, 1995]

§381.463 Nutrient content claims for "healthy."

(a) The term ''healthy,'' or any other derivative of the term ''health,'' may be used on the labeling of any poultry product, provided that the product is labeled in accordance with §381.409 and §381.413.

(b)(1) The product shall meet the requirements for ''low fat'' and ''low saturated fat,'' as defined in §381.462, except that single-ingredient, raw products may meet the total fat and saturated fat criteria for ''extra lean'' in §381.462.

(2) The product shall not contain more than 60 milligrams (mg) of cholesterol per reference amount customarily consumed, per labeled serving size, and, only for foods with reference amounts customarily consumed of 30 grams (g) or less or 2 tablespoons (tbsp) or less, per 50 g, and, for dehydrated products that must be reconstituted with water or a diluent containing an insignificant amount, as defined in §381.409(f)(1), of all nutrients, the per-50-g criterion refers to the prepared form, except that:

(i) A meal-type product, as defined in §381.413(l), and including meal-type products that weigh more than 12 ounces (oz) per serving (container), shall not contain more than 90 mg of cholesterol per labeled serving size; and

(ii) Single-ingredient, raw products may meet the cholesterol criterion for ''extra lean'' in §381.462.

(3) The product shall not contain more than 360 mg of sodium, except that it shall not contain more than 480 mg of sodium effective through January 1, 2006, per reference amount customarily consumed, per labeled serving size, and, only for foods with reference amounts customarily consumed of 30 g or less or 2 tbsp or less, per 50 g, and, for dehydrated products that must be reconstituted with water or a diluent containing an insignificant amount, as defined in §381.409(f)(1), of all nutrients, the per-50-g criterion refers to the prepared form, except that:

(i) A meal-type product, as defined in §381.413(l), and including meal-type products that weigh more than 12 oz per serving (container), shall not contain more than 480 mg of sodium, except that it shall not contain more than 600 mg of sodium effective through January 1, 2006, per labeled serving size; and

(ii) The requirements of this paragraph (b)(3) do not apply to single-ingredient, raw products.

(4) The product shall contain 10 percent or more of the Reference Daily Intake or Daily Reference Value as defined in §381.409 for vitamin A, vitamin C, iron, calcium, protein, or fiber per reference amount customarily consumed prior to any nutrient addition, except that:

(i) A meal-type product, as defined in §381.413(l), and including meal-type products that weigh at least 6 oz but less than 10 oz per serving (container), shall meet the level for two of the nutrients per labeled serving size; and

(ii) A meal-type product, as defined in §381.413(l), and including meal-type products that weigh 10 oz or more per serving (container), shall meet the

level for three of the nutrients per labeled serving size.

[59 FR 24228, May 10, 1994, as amended at 60 FR 217, Jan. 3, 1995; 63 FR 7281, Feb. 13, 1998; 64 FR 72492, Dec. 28, 1999; 68 FR 463, Jan. 6, 2003]

§§ 381.464–381.468 [Reserved]

§ 381.469 Labeling applications for nutrient content claims.

(a) This section pertains to labeling applications for claims, express or implied, that characterize the level of any nutrient required to be on the label or in labeling of product by this subpart.

(b) Labeling applications included in this section are:

(1) Labeling applications for a new (heretofore unauthorized) nutrient content claim,

(2) Labeling applications for a synonymous term (i.e., one that is consistent with a term defined by regulation) for characterizing the level of a nutrient, and

(3) Labeling applications for the use of an implied claim in a brand name.

(c) Labeling applications and supporting documentation to be filed under this section shall be submitted in quadruplicate, except that the supporting documentation may be submitted on a computer disc copy. If any part of the material submitted is in a foreign language, it shall be accompanied by an accurate and complete English translation. The labeling application shall state the applicant's post office address.

(d) Pertinent information will be considered as part of an application on the basis of specific reference to such information submitted to and retained in the files of the Food Safety and Inspection Service. However, any reference to unpublished information furnished by a person other than the applicant will not be considered unless use of such information is authorized (with the understanding that such information may in whole or part be subject to release to the public) in a written statement signed by the person who submitted it. Any reference to published information should be accompanied by reprints or photostatic copies of such references.

(e) If nonclinical laboratory studies accompany a labeling application, the applicant shall include, with respect to each nonclinical study included with the application, either a statement that the study has been, or will be, conducted in compliance with the good laboratory practice regulations as set forth in part 58 of chapter 1, title 21, or, if any such study was not conducted in compliance with such regulations, a brief statement of the reason for the noncompliance.

(f) If clinical investigations accompany a labeling application, the applicant shall include, with respect to each clinical investigation included with the application, either a statement that the investigation was conducted in compliance with the requirements for institutional review set forth in part 56 of chapter 1, title 21, or was not subject to such requirements in accordance with § 56.194 or § 56.105, and that it was conducted in compliance with the requirements for informed consents set forth in part 50 of chapter 1, title 21.

(g) The availability for public disclosure of labeling applications, along with supporting documentation, submitted to the Agency under this section will be governed by the rules specified in subchapter D, title 9.

(h) The data specified under this section to accompany a labeling application shall be submitted on separate sheets, suitably identified. If such data has already been submitted with an earlier labeling application from the applicant, the present labeling application must provide the data.

(i) The labeling application must be signed by the applicant or by his or her attorney or agent, or (if a corporation) by an authorized official.

(j) The labeling application shall include a statement signed by the person responsible for the labeling application, that to the best of his or her knowledge, it is a representative and balanced submission that includes unfavorable information, as well as favorable information, known to him or her pertinent to the evaluation of the labeling application.

(k)(1) Labeling applications for a new nutrient content claim shall be accompanied by the following data which shall be submitted in the following

form to the Director, Food Labeling Division, Regulatory Programs, Food Safety and Inspection Service, Washington, DC 20250:

_____
(Date)

The undersigned, _____ submits this labeling application pursuant to 9 CFR 381.469 with respect to (statement of the claim and its proposed use).

Attached hereto, in quadruplicate, or on a computer disc copy, and constituting a part of this labeling application, are the following:

(i) A statement identifying the nutrient content claim and the nutrient that the term is intended to characterize with respect to the level of such nutrient. The statement shall address why the use of the term as proposed will not be misleading. The statement shall provide examples of the nutrient content claim as it will be used on labels or labeling, as well as the types of products on which the claim will be used. The statement shall also specify the level at which the nutrient must be present or what other conditions concerning the product must be met for the appropriate use of the term in labels or labeling, as well as any factors that would make the use of the term inappropriate.

(ii) A detailed explanation supported by any necessary data of why use of the food component characterized by the claim is of importance in human nutrition by virtue of its presence or absence at the levels that such claim would describe. This explanation shall also state what nutritional benefit to the public will derive from use of the claim as proposed and why such benefit is not available through the use of existing terms defined by regulation. If the claim is intended for a specific group within the population, the analysis shall specifically address nutritional needs of such group, and scientific data sufficient for such purpose, and data and information to the extent necessary to demonstrate that consumers can be expected to understand the meaning of the term under the proposed conditions of use.

(iii) Analytical data that demonstrates the amount of the nutrient that is present in the products for which the claim is intended. The assays should be performed on representative samples in accordance with 381.409(h). If no USDA or AOAC methods are available, the applicant shall submit the assay method used, and data establishing the validity of the method for assaying the nutrient in the particular food. The validation data shall include a statistical analysis of the analytical and product variability.

(iv) A detailed analysis of the potential effect of the use of the proposed claim on food consumption, and any corresponding changes in nutrient intake. The analysis shall specifically address the intake of nutrients that have beneficial and negative consequences in the total diet. If the claim is intended for a specific group within the population, the above analysis shall specifically address the dietary practices of such group, and shall include data sufficient to demonstrate that the dietary analysis is representative of such group.

Yours very truly,

Applicant _____

By _____
(Indicate authority)

(2) Upon receipt of the labeling application and supporting documentation, the applicant shall be notified, in writing, of the date on which the labeling application was received. Such notice shall inform the applicant that the labeling application is undergoing Agency review and that the applicant shall subsequently be notified of the Agency's decision to consider for further review or deny the labeling application.

(3) Upon review of the labeling application and supporting documentation, the Agency shall notify the applicant, in writing, that the labeling application is either being considered for further review or that it has been summarily denied by the Administrator.

(4) If the labeling application is summarily denied by the Administrator, the written notification shall state the reasons therefor, including why the Agency has determined that the proposed nutrient content claim is false or misleading. The notification letter shall inform the applicant that the applicant may submit a written statement by way of answer to the notification, and that the applicant shall have the right to request a hearing with respect to the merits or validity of the Administrator's decision to deny the use of the proposed nutrient content claim.

(i) If the applicant fails to accept the determination of the Administrator and files an answer and requests a hearing, and the Administrator, after review of the answer, determines the initial determination to be correct, the Administrator shall file with the Hearing Clerk of the Department the notification, answer, and the request for a hearing, which shall constitute the

complaint and answer in the proceeding, which shall thereafter be conducted in accordance with the Department's Uniform Rules of Practice.

(ii) The hearing shall be conducted before an administrative law judge with the opportunity for appeal to the Department's Judicial Officer, who shall make the final determination for the Secretary. Any such determination by the Secretary shall be conclusive unless, within 30 days after receipt of notice of such final determination, the applicant appeals to the United States Court of Appeals for the circuit in which the applicant has its principal place of business or to the United States Court of Appeals for the District of Columbia Circuit.

(5) If the labeling application is not summarily denied by the Administrator, the Administrator shall publish in the FEDERAL REGISTER a proposed rule to amend the regulations to authorize the use of the nutrient content claim. The proposal shall also summarize the labeling application, including where the supporting documentation can be reviewed. The Administrator's proposed rule shall seek comment from consumers, the industry, consumer and industry groups, and other interested persons on the labeling application and the use of the proposed nutrient content claim. After public comment has been received and reviewed by the Agency, the Administrator shall make a determination on whether the proposed nutrient content claim shall be approved for use on the labeling of poultry products.

(i) If the claim is denied by the Administrator, the Agency shall notify the applicant, in writing, of the basis for the denial, including the reason why the claim on the labeling was determined by the Agency to be false or misleading. The notification letter shall also inform the applicant that the applicant may submit a written statement by way of answer to the notification, and that the applicant shall have the right to request a hearing with respect to the merits or validity of the Administrator's decision to deny the use of the proposed nutrient content claim.

(A) If the applicant fails to accept the determination of the Administrator and files an answer and requests a hearing, and the Administrator, after review of the answer, determines the initial determination to be correct, the Administrator shall file with the Hearing Clerk of the Department the notification, answer, and the request for a hearing, which shall constitute the complaint and answer in the proceeding, which shall thereafter be conducted in accordance with the Department's Uniform Rules of Practice.

(B) The hearing shall be conducted before an administrative law judge with the opportunity for appeal to the Department's Judicial Officer, who shall make the final determination for the Secretary. Any such determination by the Secretary shall be conclusive unless, within 30 days after receipt of the notice of such final determination, the applicant appeals to the United States Court of Appeals for the circuit in which the applicant has its principal place of business or to the United States Court of Appeals for the District of Columbia Circuit.

(ii) If the claim is approved, the Agency shall notify the applicant, in writing, and shall also publish in the FEDERAL REGISTER a final rule amending the regulations to authorize the use of the claim.

(l)(1) Labeling applications for a synonymous term shall be accompanied by the following data which shall be submitted in the following form to the Director, Food Labeling Division, Regulatory Programs, Food Safety and Inspection Service, Washington, DC 20250:

(Date)

The undersigned, _____ submits this labeling application pursuant to 9 CFR 381.469 with respect to (statement of the synonymous term and its proposed use in a nutrient content claim that is consistent with an existing term that has been defined under subpart Y of part 381).

Attached hereto, in quadruplicate, or on a computer disc copy, and constituting a part of this labeling application, are the following:

(i) A statement identifying the synonymous term, the existing term defined by a regulation with which the synonymous term is claimed to be consistent, and the nutrient that the term is intended to characterize the level of. The statement shall address why the use of the synonymous term as proposed will

not be misleading. The statement shall provide examples of the nutrient content claim as it will be used on labels or labeling, as well as the types of products on which the claim will be used. The statement shall also specify whether any limitations not applicable to the use of the defined term are intended to apply to the use of the synonymous term.

(ii) A detailed explanation supported by any necessary data of why use of the proposed term is requested, including whether the existing defined term is inadequate for the purpose of effectively characterizing the level of a nutrient. This explanation shall also state what nutritional benefit to the public will derive from use of the claim as proposed, and why such benefit is not available through use of existing terms defined by regulation. If the claim is intended for a specific group within the population, the analysis shall specifically address nutritional needs of such group, scientific data sufficient for such purpose, and data and information to the extent necessary to demonstrate that consumers can be expected to understand the meaning of the term under the proposed conditions of use.

Yours very truly,

Applicant _____

By _____

(Indicate authority)

(2) Upon receipt of the labeling application and supporting documentation, the applicant shall be notified, in writing, of the date on which the labeling application was received. Such notice shall inform the applicant that the labeling application is undergoing Agency review and that the applicant shall subsequently be notified of the Agency's decision to consider for further review or deny the labeling application.

(3) Upon review of the labeling application and supporting documentation, the Agency shall notify the applicant, in writing, that the labeling application is either being considered for further review or that it has been summarily denied by the Administrator.

(4) If the labeling application is summarily denied by the Administrator, the written notification shall state the reasons therefor, including why the Agency has determined that the proposed synonymous term is false or misleading. The notification letter shall inform the applicant that the applicant may submit a written statement by way of answer to the notification, and that the applicant shall have the right to request a hearing with respect to the merits or validity of the Administrator's decision to deny the use of the proposed synonymous term.

(i) If the applicant fails to accept the determination of the Administrator and files an answer and requests a hearing, and the Administrator, after review of the answer, determines the initial determination to be correct, the Administrator shall file with the Hearing Clerk of the Department the notification, answer, and the request for a hearing, which shall constitute the complaint and answer in the proceeding, which shall thereafter be conducted in accordance with the Department's Uniform Rules of Practice.

(ii) The hearing shall be conducted before an administrative law judge with the opportunity for appeal to the Department's Judicial Officer, who shall make the final determination for the Secretary. Any such determination by the Secretary shall be conclusive unless, within 30 days after receipt of notice of such final determination, the applicant appeals to the United States Court of Appeals for the circuit in which the applicant has its principal place of business or to the United States Court of Appeals for the District of Columbia Circuit.

(5) If the claim is approved, the Agency shall notify the applicant, in writing, and shall publish in the FEDERAL REGISTER a notice informing the public that the synonymous term has been approved for use.

(m)(1) Labeling applications for the use of an implied nutrient content claim in a brand name shall be accompanied by the following data which shall be submitted in the following form to the Director, Food Labeling Division, Regulatory Programs, Food Safety and Inspection Service, Washington, DC 20250:

_____

(Date)

The undersigned, _____ submits this labeling application pursuant to 9 CFR 381.469 with respect to (statement of the implied nutrient content claim and its proposed use in a brand name).

Attached hereto, in quadruplicate, or on a computer disc copy, and constituting a part of this labeling application, are the following:

(i) A statement identifying the implied nutrient content claim, the nutrient the claim

is intended to characterize, the corresponding term for characterizing the level of such nutrient as defined by a regulation, and the brand name of which the implied claim is intended to be a part. The statement shall address why the use of the brand-name as proposed will not be misleading. The statement shall provide examples of the types of products on which the brand name will appear. It shall also include data showing that the actual level of the nutrient in the food would qualify the label of the product to bear the corresponding term defined by regulation. Assay methods used to determine the level of a nutrient shall meet the requirements stated under labeling application format in paragraph (k)(1)(iii) of this section.

(ii) A detailed explanation supported by any necessary data of why use of the proposed brand name is requested. This explanation shall also state what nutritional benefit to the public will derive from use of the brand name as proposed. If the branded product is intended for a specific group within the population, the analysis shall specifically address nutritional needs of such group and scientific data sufficient for such purpose.

Yours very truly,

Applicant _____

By _____

(2) Upon receipt of the labeling application and supporting documentation, the applicant shall be notified, in writing, of the date on which the labeling application was received. Such notice shall inform the applicant that the labeling application is undergoing Agency review and that the applicant shall subsequently be notified of the Agency's decision to consider for further review or deny the labeling application.

(3) Upon review of the labeling application and supporting documentation, the Agency shall notify the applicant, in writing, that the labeling application is either being considered for further review or that it has been summarily denied by the Administrator.

(4) If the labeling application is summarily denied by the Administrator, the written notification shall state the reasons therefor, including why the Agency has determined that the proposed implied nutrient content claim is false or misleading. The notification letter shall inform the applicant that the applicant may submit a written statement by way of answer to the notification, and that the applicant shall have the right to request a hearing with respect to the merits or validity of the Administrator's decision to deny the use of the proposed implied nutrient content claim.

(i) If the applicant fails to accept the determination of the Administrator and files an answer and requests a hearing, and the Administrator, after review of the answer, determines the initial determination to be correct, the Administrator shall file with the Hearing Clerk of the Department the notification, answer, and the request for a hearing, which shall constitute the complaint and answer in the proceeding, which shall thereafter be conducted in accordance with the Department's Uniform Rules of Practice.

(ii) The hearing shall be conducted before an administrative law judge with the opportunity for appeal to the Department's Judicial Officer, who shall make the final determination for the Secretary. Any such determination by the Secretary shall be conclusive unless, within 30 days after receipt of notice of such final determination, the applicant appeals to the United States Court of Appeals for the circuit in which the applicant has its principal place of business or to the United States Court of Appeals for the District of Columbia Circuit.

(5) If the labeling application is not summarily denied by the Administrator, the Administrator shall publish a notice of the labeling application in the FEDERAL REGISTER seeking a comment on the use of the implied nutrient content claim. The notice shall also summarize the labeling application, including where the supporting documentation can be reviewed. The Administrator's notice shall seek comment from consumers, the industry, consumer and industry groups, and other interested persons on the labeling application and the use of the implied nutrient content claim. After public comment has been received and reviewed by the Agency, the Administrator shall make a determination on whether the implied nutrient content claim shall be approved for use on the labeling of poultry products.

(i) If the claim is denied by the Administrator, the Agency shall notify the applicant, in writing, of the basis for the denial, including the reason

why the claim on the labeling was determined by the Agency to be false or misleading. The notification letter shall also inform the applicant that the applicant may submit a written statement by way of answer to the notification, and that the applicant shall have the right to request a hearing with respect to the merits or validity of the Administrator's decision to deny the use of the proposed implied nutrient content claim.

(A) If the applicant fails to accept the determination of the Administrator and files an answer and requests a hearing, and the Administrator, after review of the answer, determines the initial determination to be correct, the Administrator shall file with the Hearing Clerk of the Department the notification, answer, and the request for a hearing, which shall constitute the complaint and answer in the proceeding, which shall thereafter be conducted in accordance with the Department's Uniform Rules of Practice.

(B) The hearing shall be conducted before an administrative law judge with the opportunity for appeal to the Department's Judicial Officer, who shall make the final determination for the Secretary. Any such determination by the Secretary shall be conclusive unless, within 30 days after receipt of the notice of such final determination, the applicant appeals to the United States Court of Appeals for the circuit in which the applicant has its principal place of business or to the United States Court of Appeals for the District of Columbia Circuit.

(ii) If the claim is approved, the Agency shall notify the applicant, in writing, and shall also publish in the FEDERAL REGISTER a notice informing the public that the implied nutrient content claim has been approved for use.

(Paperwork requirements were approved by the Office of Management and Budget under control number 0583–0088.)

[58 FR 675, Jan. 6, 1993, as amended at 59 FR 45198, Sept. 1, 1994; 60 FR 217, Jan. 3, 1995]

§§ 381.470–381.479 [Reserved]

§ 381.480 Label statements relating to usefulness in reducing or maintaining body weight.

(a) *General requirements.* Any product that purports to be or is represented for special dietary use because of usefulness in reducing body weight shall bear:

(1) Nutrition labeling in conformity with § 381.409 of this subpart, unless exempt under that section, and

(2) A conspicuous statement of the basis upon which the product claims to be of special dietary usefulness.

(b) *Nonnutritive ingredients.* (1) Any product subject to paragraph (a) of this section that achieves its special dietary usefulness by use of a nonnutritive ingredient (i.e., one not utilized in normal metabolism) shall bear on its label a statement that it contains a nonnutritive ingredient and the percentage by weight of the nonnutritive ingredient.

(2) A special dietary product may contain a nonnutritive sweetener or other ingredient only if the ingredient is safe for use in the product under the applicable law and regulations of this chapter. Any product that achieves its special dietary usefulness in reducing or maintaining body weight through the use of a nonnutritive sweetener shall bear on its label the statement required by paragraph (b)(1) of this section, but need not state the percentage by weight of the nonnutritive sweetener. If a nutritive sweetener(s) as well as nonnutritive sweetener(s) is added, the statement shall indicate the presence of both types of sweetener; e.g., ''Sweetened with nutritive sweetener(s) and nonnutritive sweetener(s).''

(c) *''Low calorie'' foods.* A product purporting to be ''low calorie'' must comply with the criteria set forth for such foods in § 381.460.

(d) *''Reduced calorie'' foods and other comparative claims.* A product purporting to be ''reduced calorie'' or otherwise containing fewer calories than a reference food must comply with the criteria set forth for such foods in § 387.460(b) (4) and (5).

(e) *''Label terms suggesting usefulness as low calorie or reduced calorie foods''.* (1) Except as provided in paragraphs (e)(2) and (e)(3) of this section, a product may be labeled with terms such as ''diet,'' ''dietetic,'' ''artificially sweetened,'' or ''sweetened with nonnutritive sweetener'' only if the claim is not false or misleading, and the product is labeled ''low calorie'' or ''reduced calorie'' or bears another comparative calorie claim in compliance with the applicable provisions in this subpart.

(2) Paragraph (e)(1) of this section shall not apply to any use of such terms that is specifically authorized by regulation governing a particular food, or, unless otherwise restricted by regulation, to any use of the term ''diet'' that clearly shows that the product is offered solely for a dietary use other than regulating body weight, e.g., ''for low sodium diets.''

(3) Paragraph (e)(1) of this section shall not apply to any use of such terms on a formulated meal replacement or other product that is represented to be of special dietary use as a whole meal, pending the issuance of a regulation governing the use of such terms on foods.

(f) ''Sugar free'' and ''no added sugar''. Criteria for the use of the terms ''sugar free'' and ''no added sugar'' are provided for in § 381.460(c).

[58 FR 675, Jan. 6, 1993; 58 FR 43789, Aug. 18, 1993, as amended at 58 FR 47628, Sept. 10, 1993; 60 FR 217, Jan. 3, 1995]

§§ 381.481–381.499 [Reserved]

§ 381.500 Exemption from nutrition labeling.

(a) The following poultry products are exempt from nutrition labeling:

(1) Food products produced by small businesses, provided that the labels for these products bear no nutrition claims or nutrition information,

(i) A food product, for purposes of the small business exemption, is defined as a formulation, not including distinct flavors which do not significantly alter the nutritional profile, sold in any size package in commerce.

(ii) For purposes of this paragraph, a small business is any single-plant facility or multi-plant company/firm that employs 500 or fewer people and produces no more than the following amounts of pounds of the product qualifying the firm for exemption from this subpart:

(A) During the first year of implementation of nutrition labeling, from July 1994 to July 1995, 250,000 pounds or less,

(B) During the second year of implementation of nutrition labeling, from July 1995 to July 1996, 175,000 pounds or less, and

(C) During the third year of implementation and subsequent years thereafter, 100,000 pounds or less.

(iii) For purposes of this paragraph, calculation of the amount of pounds shall be based on the most recent 2-year average of business activity. Where firms have been in business less than 2 years or where products have been produced for less than 2 years, reasonable estimates must indicate that the annual pounds produced will not exceed the amounts specified.

(2) Products intended for further processing, provided that the labels for these products bear no nutrition claims or nutrition information,

(3) Products that are not for sale to consumers, provided that the labels for these products bear no nutrition claims or nutrition information,

(4) Products in small packages that are individually wrapped packages of less than ½ ounce net weight, provided that the labels for these products bear no nutrition claims or nutrition information,

(5) Products custom slaughtered or prepared,

(6) Products intended for export, and

(7) The following products prepared and served or sold at retail provided that the labels or the labeling of these products bear no nutrition claims or nutrition information:

(i) Ready-to-eat products that are packaged or portioned at a retail store or similar retail-type establishment; and

(ii) Multi-ingredient products (e.g. sausage) processed at a retail store or similar retail-type establishment.

(b) Restaurant menus generally do not constitute labeling or fall within the scope of these regulations.

(c)(1) Foods represented to be specifically for infants and children less than

2 years of age shall bear nutrition labeling as provided in paragraph (c)(2) of this section, except such labeling shall not include calories from fat, calories from saturated fat, saturated fat, stearic acid, polyunsaturated fat, monounsaturated fat, and cholesterol.

(2) Foods represented or purported to be specifically for infants and children less than 4 years of age shall bear nutrition labeling except that:

(i) Such labeling shall not include declarations of percent of Daily Value for total fat, saturated fat, cholesterol, sodium, potassium, total carbohydrate, and dietary fiber;

(ii) Nutrient names and quantitative amounts by weight shall be presented in two separate columns;

(iii) The heading ''Percent Daily Value'' required in § 381.409(d)(6) shall be placed immediately below the quantitative information by weight for protein;

(iv) The percent of the Daily Value for protein, vitamins, and minerals shall be listed immediately below the heading ''Percent Daily Value''; and

(v) Such labeling shall not include the footnote specified in § 381.409(d)(9).

(d)(1) Products in packages that have a total surface area available to bear labeling of less than 12 square inches are exempt from nutrition labeling, provided that the labeling for these products bear no nutrition claims or other nutrition information. The manufacturer, packer, or distributor shall provide, on the label of packages that qualify for and use this exemption, an address or telephone number that a consumer can use to obtain the required nutrition information (e.g., ''For nutrition information call 1–800–123–4567'').

(2) When such products bear nutrition labeling, either voluntarily or because nutrition claims or other nutrition information is provided, all required information shall be in a type size no smaller than 6 point or all upper case type of $^{1}/_{16}$-inch minimum height, except that individual serving-size packages of poultry products that have a total area available to bear labeling of 3 square inches or less may provide all required information in a type size no smaller than $^{1}/_{32}$-inch minimum height.

[58 FR 675, Jan. 6, 1993, as amended at 58 FR 47628, Sept. 10, 1993; 59 FR 45198, Sept. 1, 1994; 60 FR 217, Jan. 3, 1995]

SUBCHAPTERS B–C [RESERVED]

SUBCHAPTER D—FOOD SAFETY AND INSPECTION SERVICE ADMINISTRATIVE PROVISIONS

PART 390—FREEDOM OF INFORMATION AND PUBLIC INFORMATION

Sec.
390.1 Scope and purpose.
390.2 Published materials.
390.3 Indexes, reference guide, and handbook.
390.4 Facilities for inspection and copying.
390.5 Requests for records.
390.6 Fee schedule.
390.7 Appeals.
390.8 Agency response to requests.
390.9 Communications with State and other Federal government agencies.

AUTHORITY: 5 U.S.C. 301, 552; 7 CFR 1.3, 2.7.

SOURCE: 64 FR 43903, Aug. 12, 1999, unless otherwise noted.

§ 390.1 Scope and purpose.

This part is issued pursuant to the Freedom of Information Act (FOIA) as amended (5 U.S.C. 552), and in accordance with the directives of the Department of Agriculture regulations in part 1, subpart A, of Title 7. The availability of records, including electronic records created on or after November 1, 1996, of the Food Safety and Inspection Service (FSIS), and the procedures by which the public may request such information, will be governed by the FOIA and by the Department regulations as implemented and supplemented by the regulations in this part.

§ 390.2 Published materials.

FSIS rules and regulations relating to its regulatory responsibilities and administrative procedures are published and made available to the public in the FEDERAL REGISTER and codified in chapter III, title 9, of the Code of Federal Regulations. FSIS also issues numerous publications relating to Agency programs, which implement the laws listed in the Delegation of Authority, 7 CFR 2.15(a). Most of these publications are available free from the USDA Publications Division, Office of Governmental and Public Affairs, or at established rates from the Superintendent of Documents, U.S. Government Printing Office, Washington, 20402–9328.

§ 390.3 Indexes, reference guide, and handbook.

(a) Pursuant to the regulations in 7 CFR 1.4(c), FSIS will maintain and make available for public inspection and copying an index providing identifying information regarding the materials required to be published or made available under the Freedom of Information Act (5 U.S.C. 552(a)(2)). The Agency will make the index available by computer telecommunications by December 31, 1999. Quarterly publication of the index is unnecessary and impractical, since the material is voluminous and does not change often enough to justify the expense of quarterly publication. The Agency will provide copies of any index, upon request, at a cost not to exceed direct cost of duplication.

(b) FSIS is responsible for preparing reference material or a guide for requesting records or information from the Agency. This guide also will include an index of all major information systems and a description of major information and record locator systems.

(c) FSIS will prepare a handbook for obtaining information from the Agency. The handbook will be available on paper and through electronic means, and will discuss how the public can use it to access Agency FOIA annual reports. Similarly, the annual reports will refer to the handbook and how to obtain it.

§ 390.4 Facilities for inspection and copying.

Facilities for public inspection and copying of the material described in §§ 390.2 and 390.3 of this part will be provided by FSIS pursuant to 7 CFR 1.5(a) in a reading area, on business days between the hours of 8:30 a.m. and 4:30 p.m., upon request to the Freedom of Information Coordinator or designee at the following address:

Freedom of Information Act Coordinator (FOIA), Food Safety and Inspection Service, Department of Agriculture, Washington, DC 20250–3700

§390.5 Request for records.

(a) The FOIA Coordinator of FSIS is authorized to receive requests and to exercise authority under 7 CFR 1.3(a) to—

(1) Make determinations to grant or deny such requests,

(2) Extend the 20-day deadline,

(3) Make discretionary releases of exempt records, except where disclosure is specifically prohibited by Executive Order, statute, and applicable regulations,

(4) Consider expedited processing when appropriate,

(5) Make determinations regarding the charging of fees pursuant to the established schedule, and

(6) Determine the applicability of 7 CFR 1.5 to requests for records.

(b) Requests for FSIS records or information will be made in writing in accordance with 7 CFR 1.5 and submitted to the FSIS Freedom of Information Act Coordinator at the following address:

Freedom of Information Act Coordinator (FOIA Request), Food Safety and Inspection Service, Department of Agriculture, Washington, DC 20250–3700

The submitter will identify each record with reasonable specificity as prescribed in 7 CFR 1.3. All requests to inspect or obtain copies of any record or to obtain a fee waiver must be submitted in writing.

(c) In exercising authority under 7 CFR 1.3(a)(3) to grant and deny requests, the Coordinator or designee will comply with subsection (b) of the Freedom of Information Act (5 U.S.C. 552(b)), as amended, which requires that any reasonably segregated portion of a document will be provided to a person requesting the document after deletion of any portions within the scope of the request for which an exemption is being claimed under the Act. Therefore, unless the disclosable and nondisclosable portions are so inextricably linked that it is not reasonably possible to separate them, the document will be released with the nondisclosable portions deleted. The Coordinator or designee may exercise discretion as limited by 7 CFR l.15 to release the entire document or make only a minimum number of deletions. If portions of a document in electronic format have been redacted, the Agency must indicate, on the released portion of the document, the amount of information that has been deleted from a record, unless that indication would harm an interest protected by an applicable exemption.

§390.6 Fee schedule.

Department regulations provide for a schedule of reasonable standard charges for document search and duplication. See 7 CFR 1.17. Fees to be charged are in 7 CFR part 1, subpart A, appendix A.

§390.7 Appeals.

(a) If the request for information or for a waiver of search or duplication is denied, in whole or in part, the FOIA Coordinator or designee will explain in the letter of response the grounds for any denial of access and offer the requester an opportunity to file an administrative appeal, pursuant to 7 CFR 1.3(a)(4). The appeal should be filed in writing within 45 days of the date of denial (departmental regulations, 7 CFR 1.14) and addressed as follows:

Administrator, Food Safety and Inspection Service (FOIA Appeals), Department of Agriculture, Washington, DC 20250–3700

(b) The FSIS Administrator is authorized under 7 CFR 1.3(a)(4) to extend the 20-day deadline, make discretionary releases, and make determinations regarding the charging of fees.

§390.8 Agency response to requests.

(a) The response to Freedom of Information requests and appeals by officials named in §§390.5 and 390.7 of this part shall be governed by and made in accordance with 7 CFR 1.7 and the regulations in this part.

(b) If requests for records and information are received by field offices, the field office will immediately notify the FOIA Coordinator or designee by telephone and transmit the request to the FOIA office. In rare instances, the FOIA Coordinator or designee will authorize a release of the requested

records to the field office receiving the request. The request will be considered as having been received on the date of arrival in the office of the Coordinator or designee. Any person whose request for records has been granted may inspect and copy the records (or copies) at the office listed in § 390.4 of this part in accordance with the provisions of that section and with § 390.6. Copies also may be obtained by mail.

§ 390.9 Communications with State and other Federal government agencies.

(a) The Administrator of the Food Safety and Inspection Service (FSIS), or designee, may authorize the disclosure of distribution lists (records that show where and when product was shipped) obtained from a firm recalling products, or incorporated into agency-prepared records, to State and other Federal government agencies to verify the removal of the recalled product, provided that:

(1) The State agency has provided both a written statement establishing its authority to protect confidential distribution lists from public disclosure and a written commitment not to disclose any information provided by FSIS, without the written permission of the submitter of the information or written confirmation by FSIS that the information no longer has confidential status. Federal government agencies must provide a written commitment not to disclose the information and to refer any request for distribution lists to FSIS for response; and

(2) The Administrator of FSIS or designee determines that disclosure would be in the interest of public health.

(b) This provision does not authorize the disclosure to State or other Federal government agencies of trade secret information, unless otherwise provided by law or pursuant to an express written authorization provided by the submitter of the information.

(c) Information disclosed under this section is not a disclosure of information to the public. Disclosures made under this section do not waive any FOIA exemption protection.

[67 FR 20013, Apr. 24, 2002]

PART 391—FEES AND CHARGES FOR INSPECTION SERVICES AND LABORATORY ACCREDITATION

Sec.

391.1 Scope and purpose.
391.2 Base time rate.
391.3 Overtime and holiday rate.
391.4 Laboratory service rate.
391.5 Laboratory accreditation fees.

AUTHORITY: 7 U.S.C. 138f; 7 U.S.C. 394, 1622, 1624; 21 U.S.C. 451 *et seq.;* 21 U.S.C. 601–695; 7 CFR 2.17 (g) and (i), 2.55.

§ 391.1 Scope and purpose.

Fees shall be charged by the Agency for certain specified inspection services provided on a holiday, on an overtime basis, and/or which are voluntary inspection services.

[54 FR 6390, Feb. 10, 1989]

§ 391.2 Base time rate.

The base time rate for inspection services provided pursuant to §§ 350.7, 351.8, 351.9, 352.5, 354.101, 355.12, and 362.5 is $43.64 per hour per program employee.

[68 FR 37956, June 26, 2003]

§ 391.3 Overtime and holiday rate.

The overtime and holiday rate for inspection services provided pursuant to §§ 307.5, 350.7, 351.8, 351.9, 352.5, 354.101, 355.12, 362.5 and 381.38 is $50.04 per hour per program employee.

[68 FR 37956, June 26, 2003]

§391.4 Laboratory services rate.

The rate for laboratory services provided pursuant to §§350.7, 351.9, 352.5, 354.101, 355.12, and 362.5 is $61.80 per hour per program employee.

[68 FR 37956, June 26, 2003]

§391.5 Laboratory accreditation fees.

(a) The annual fee for the initial accreditation and maintenance of accreditation provided pursuant to §§318.21 and 381.153 shall be $1,500 per accreditation.

(b) Laboratories that request special onsite inspections shall pay FSIS the actual cost of reasonable travel and other expenses necessary to perform the unscheduled or non-routine onsite inspections.

[58 FR 65269, Dec. 13, 1993 as amended at 59 FR 66449, Dec 27, 1994; 64 FR 19868, Apr. 23, 1999]

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

PART 416—SANITATION

Sec.
416.1 General rules.
416.2 Establishment grounds and facilities.
416.3 Equipment and utensils.
416.4 Sanitary operations.
416.5 Employee hygiene.
416.6 Tagging insanitary equipment, utensils, rooms or compartments.
416.11 General rules.
416.12 Development of sanitation SOP's.
416.13 Implementation of SOP's.
416.14 Maintenance of Sanitation SOP's.
416.15 Corrective Actions.
416.16 Recordkeeping requirements.
416.17 Agency verification.

AUTHORITY: 21 U.S.C. 451–470, 601–695; 7 U.S.C. 450, 1901–1906; 7 CFR 2.18, 2.53.

SOURCE: 61 FR 38868, July 25, 1996, unless otherwise noted.

§ 416.1 General rules.

Each official establishment must be operated and maintained in a manner sufficient to prevent the creation of insanitary conditions and to ensure that product is not adulterated.

[64 FR 56417, Oct. 20, 1999]

§ 416.2 Establishment grounds and facilities.

(a) *Grounds and pest control.* The grounds about an establishment must be maintained to prevent conditions that could lead to insanitary conditions, adulteration of product, or interfere with inspection by FSIS program employees. Establishments must have in place a pest management program to prevent the harborage and breeding of pests on the grounds and within establishment facilities. Pest control substances used must be safe and effective under the conditions of use and not be applied or stored in a manner that will result in the adulteration of product or the creation of insanitary conditions.

(b) *Construction.* (1) Establishment buildings, including their structures, rooms, and compartments must be of sound construction, be kept in good repair, and be of sufficient size to allow for processing, handling, and storage of product in a manner that does not result in product adulteration or the creation of insanitary conditions.

(2) Walls, floors, and ceilings within establishments must be built of durable materials impervious to moisture and be cleaned and sanitized as necessary to prevent adulteration of product or the creation of insanitary conditions.

(3) Walls, floors, ceilings, doors, windows, and other outside openings must be constructed and maintained to prevent the entrance of vermin, such as flies, rats, and mice.

(4) Rooms or compartments in which edible product is processed, handled, or stored must be separate and distinct from rooms or compartments in which inedible product is processed, handled, or stored, to the extent necessary to prevent product adulteration and the creation of insanitary conditions.

(c) *Light.* Lighting of good quality and sufficient intensity to ensure that sanitary conditions are maintained and that product is not adulterated must be provided in areas where food is processed, handled, stored, or examined; where equipment and utensils are cleaned; and in hand-washing areas, dressing and locker rooms, and toilets.

(d) *Ventilation.* Ventilation adequate to control odors, vapors, and condensation to the extent necessary to prevent adulteration of product and the creation of insanitary conditions must be provided.

(e) *Plumbing.* Plumbing systems must be installed and maintained to:

(1) Carry sufficient quantities of water to required locations throughout the establishment;

(2) Properly convey sewage and liquid disposable waste from the establishment;

(3) Prevent adulteration of product, water supplies, equipment, and utensils and prevent the creation of insanitary conditions throughout the establishment;

(4) Provide adequate floor drainage in all areas where floors are subject to

flooding-type cleaning or where normal operations release or discharge water or other liquid waste on the floor;

(5) Prevent back-flow conditions in and cross-connection between piping systems that discharge waste water or sewage and piping systems that carry water for product manufacturing; and

(6) Prevent the backup of sewer gases.

(f) *Sewage disposal.* Sewage must be disposed into a sewage system separate from all other drainage lines or disposed of through other means sufficient to prevent backup of sewage into areas where product is processed, handled, or stored. When the sewage disposal system is a private system requiring approval by a State or local health authority, the establishment must furnish FSIS with the letter of approval from that authority upon request.

(g) *Water supply and water, ice, and solution reuse.* (1) A supply of running water that complies with the National Primary Drinking Water regulations (40 CFR part 141), at a suitable temperature and under pressure as needed, must be provided in all areas where required (for processing product, for cleaning rooms and equipment, utensils, and packaging materials, for employee sanitary facilities, etc.). If an establishment uses a municipal water supply, it must make available to FSIS, upon request, a water report, issued under the authority of the State or local health agency, certifying or attesting to the potability of the water supply. If an establishment uses a private well for its water supply, it must make available to FSIS, upon request, documentation certifying the potability of the water supply that has been renewed at least semi-annually.

(2) Water, ice, and solutions (such as brine, liquid smoke, or propylene glycol) used to chill or cook ready-to-eat product may be reused for the same purpose, provided that they are maintained free of pathogenic organisms and fecal coliform organisms and that other physical, chemical, and microbiological contamination have been reduced to prevent adulteration of product.

(3) Water, ice, and solutions used to chill or wash raw product may be reused for the same purpose provided that measures are taken to reduce physical, chemical, and microbiological contamination so as to prevent contamination or adulteration of product. Reuse that which has come into contact with raw product may not be used on ready-to-eat product.

(4) Reconditioned water that has never contained human waste and that has been treated by an onsite advanced wastewater treatment facility may be used on raw product, except in product formulation, and throughout the facility in edible and inedible production areas, provided that measures are taken to ensure that this water meets the criteria prescribed in paragraph (g)(1) of this section. Product, facilities, equipment, and utensils coming in contact with this water must undergo a separate final rinse with non-reconditioned water that meets the criteria prescribed in paragraph (g)(1) of this section.

(5) Any water that has never contained human waste and that is free of pathogenic organisms may be used in edible and inedible product areas, provided it does not contact edible product. For example, such reuse water may be used to move heavy solids, to flush the bottom of open evisceration troughs, or to wash antemortem areas, livestock pens, trucks, poultry cages, picker aprons, picking room floors, and similar areas within the establishment.

(6) Water that does not meet the use conditions of paragraphs (g)(1) through (g)(5) of this section may not be used in areas where edible product is handled or prepared or in any manner that would allow it to adulterate edible product or create insanitary conditions.

(h) *Dressing rooms, lavatories, and toilets.* (1) Dressing rooms, toilet rooms, and urinals must be sufficient in number, ample in size, conveniently located, and maintained in a sanitary condition and in good repair at all times to ensure cleanliness of all persons handling any product. They must be separate from the rooms and compartments in which products are processed, stored, or handled.

(2) Lavatories with running hot and cold water, soap, and towels, must be placed in or near toilet and urinal

rooms and at such other places in the establishment as necessary to ensure cleanliness of all persons handling any product.

(3) Refuse receptacles must be constructed and maintained in a manner that protects against the creation of insanitary conditions and the adulteration of product.

[64 FR 56417, Oct. 20, 1999]

§ 416.3 Equipment and utensils.

(a) Equipment and utensils used for processing or otherwise handling edible product or ingredients must be of such material and construction to facilitate thorough cleaning and to ensure that their use will not cause the adulteration of product during processing, handling, or storage. Equipment and utensils must be maintained in sanitary condition so as not to adulterate product.

(b) Equipment and utensils must not be constructed, located, or operated in a manner that prevents FSIS inspection program employees from inspecting the equipment or utensils to determine whether they are in sanitary condition.

(c) Receptacles used for storing inedible material must be of such material and construction that their use will not result in the adulteration of any edible product or in the creation of insanitary conditions. Such receptacles must not be used for storing any edible product and must bear conspicuous and distinctive marking to identify permitted uses.

[64 FR 56417, Oct. 20, 1999]

§ 416.4 Sanitary operations.

(a) All food-contact surfaces, including food-contact surfaces of utensils and equipment, must be cleaned and sanitized as frequently as necessary to prevent the creation of insanitary conditions and the adulteration of product.

(b) Non-food-contact surfaces of facilities, equipment, and utensils used in the operation of the establishment must be cleaned and sanitized as frequently as necessary to prevent the creation of insanitary conditions and the adulteration of product.

(c) Cleaning compounds, sanitizing agents, processing aids, and other chemicals used by an establishment must be safe and effective under the conditions of use. Such chemicals must be used, handled, and stored in a manner that will not adulterate product or create insanitary conditions. Documentation substantiating the safety of a chemical's use in a food processing environment must be available to FSIS inspection program employees for review.

(d) Product must be protected from adulteration during processing, handling, storage, loading, and unloading at and during transportation from official establishments.

[64 FR 56417, Oct. 20, 1999]

§ 416.5 Employee hygiene.

(a) *Cleanliness.* All persons working in contact with product, food-contact surfaces, and product-packaging materials must adhere to hygienic practices while on duty to prevent adulteration of product and the creation of insanitary conditions.

(b) *Clothing.* Aprons, frocks, and other outer clothing worn by persons who handle product must be of material that is disposable or readily cleaned. Clean garments must be worn at the start of each working day and garments must be changed during the day as often as necessary to prevent adulteration of product and the creation of insanitary conditions.

(c) *Disease control.* Any person who has or appears to have an infectious disease, open lesion, including boils, sores, or infected wounds, or any other abnormal source of microbial contamination, must be excluded from any operations which could result in product adulteration and the creation of insanitary conditions until the condition is corrected.

[64 FR 56417, Oct. 20, 1999]

§ 416.6 Tagging insanitary equipment, utensils, rooms or compartments.

When an FSIS program employee finds that any equipment, utensil, room, or compartment at an official establishment is insanitary or that its use could cause the adulteration of product, he will attach to it a ''U.S.

Rejected'' tag. Equipment, utensils, rooms, or compartments so tagged cannot be used until made acceptable. Only an FSIS program employee may remove a ''U.S. Rejected'' tag.

[64 FR 56417, Oct. 20, 1999]

§416.11 General rules.

Each official establishment shall develop, implement, and maintain written standard operating procedures for sanitation (Sanitation SOP's) in accordance with the requirements of this part.

§416.12 Development of Sanitation SOP's.

(a) The Sanitation SOP's shall describe all procedures an official establishment will conduct daily, before and during operations, sufficient to prevent direct contamination or adulteration of product(s).

(b) The Sanitation SOP's shall be signed and dated by the individual with overall authority on-site or a higher level official of the establishment. This signature shall signify that the establishment will implement the Sanitation SOP's as specified and will maintain the Sanitation SOP's in accordance with the requirements of this part. The Sanitation SOP's shall be signed and dated upon initially implementing the Sanitation SOP's and upon any modification to the Sanitation SOP's.

(c) Procedures in the Sanitation SOP's that are to be conducted prior to operations shall be identified as such, and shall address, at a minimum, the cleaning of food contact surfaces of facilities, equipment, and utensils.

(d) The Sanitation SOP's shall specify the frequency with which each procedure in the Sanitation SOP's is to be conducted and identify the establishment employee(s) responsible for the implementation and maintenance of such procedure(s).

§416.13 Implementation of SOP's.

(a) Each official establishment shall conduct the pre-operational procedures in the Sanitation SOP's before the start of operations.

(b) Each official establishment shall conduct all other procedures in the Sanitation SOP's at the frequencies specified.

(c) Each official establishment shall monitor daily the implementation of the procedures in the Sanitation SOP's.

§416.14 Maintenance of Sanitation SOP's.

Each official establishment shall routinely evaluate the effectiveness of the Sanitation SOP's and the procedures therein in preventing direct contamination or adulteration of product(s) and shall revise both as necessary to keep them effective and current with respect to changes in facilities, equipment, utensils, operations, or personnel.

§416.15 Corrective Actions.

(a) Each official establishment shall take appropriate corrective action(s) when either the establishment or FSIS determines that the establishment's Sanitation SOP's or the procedures specified therein, or the implementation or maintenance of the Sanitation SOP's, may have failed to prevent direct contamination or adulteration of product(s).

(b) Corrective actions include procedures to ensure appropriate disposition of product(s) that may be contaminated, restore sanitary conditions, and prevent the recurrence of direct contamination or adulteration of product(s), including appropriate reevaluation and modification of the Sanitation SOP's and the procedures specified therein or appropriate improvements in the execution of the Sanitation SOP's or the procedures specified therein.

[61 FR 38868, July 25, 1996, as amended at 62 FR 26219, May 13, 1997]

§416.16 Recordkeeping requirements.

(a) Each official establishment shall maintain daily records sufficient to document the implementation and monitoring of the Sanitation SOP's and any corrective actions taken. The establishment employee(s) specified in the Sanitation SOP's as being responsible for the implementation and monitoring of the procedure(s) specified in

the Sanitation SOP's shall authenticate these records with his or her initials and the date.

(b) Records required by this part may be maintained on computers provided the establishment implements appropriate controls to ensure the integrity of the electronic data.

(c) Records required by this part shall be maintained for at least 6 months and made accesable available to FSIS. All such records shall be maintained at the official establishment for 48 hours following completion, after which they may be maintained off-site provided such records can be made available to FSIS within 24 hours of request.

§ 416.17 Agency verification.

FSIS shall verify the adequacy and effectiveness of the Sanitation SOP's and the procedures specified therein by determining that they meet the requirements of this part. Such verification may include:

(a) Reviewing the Sanitation SOP's;

(b) Reviewing the daily records documenting the implementation of the Sanitation SOP's and the procedures specified therein and any corrective actions taken or required to be taken;

(c) Direct observation of the implementation of the Sanitation SOP's and the procedures specified therein and any corrective actions taken or required to be taken; and

(d) Direct observation or testing to assess the sanitary conditions in the establishment.

PART 417—HAZARD ANALYSIS AND CRITICAL CONTROL POINT (HACCP) SYSTEMS

Sec.

417.1 Definitions.
417.2 Hazard Analysis and HACCP plan.
417.3 Corrective actions.
417.4 Validation, Verification, Reassessment.
417.5 Records.
417.6 Inadequate HACCP Systems.
417.7 Training.
417.8 Agency verification.

AUTHORITY: 7 U.S.C. 450; 21 U.S.C. 451–470, 601–695; 7 U.S.C. 1901–1906; 7 CFR 2.18, 2.53.

SOURCE: 61 FR 38868, July 25, 1996, unless otherwise noted.

§ 417.1 Definitions.

For purposes of this part, the following definitions shall apply:

Corrective action. Procedures to be followed when a deviation occurs.

Critical control point. A point, step, or procedure in a food process at which control can be applied and, as a result, a food safety hazard can be prevented, eliminated, or reduced to acceptable levels.

Critical limit. The maximum or minimum value to which a physical, biological, or chemical hazard must be controlled at a critical control point to prevent, eliminate, or reduce to an acceptable level the occurrence of the identified food safety hazard.

Food safety hazard. Any biological, chemical, or physical property that may cause a food to be unsafe for human consumption.

HACCP System. The HACCP plan in operation, including the HACCP plan itself.

Hazard. SEE *Food Safety Hazard.*

Preventive measure. Physical, chemical, or other means that can be used to control an identified food safety hazard.

Process-monitoring instrument. An instrument or device used to indicate conditions during processing at a critical control point.

Responsible establishment official. The individual with overall authority onsite or a higher level official of the establishment.

§ 417.2 Hazard Analysis and HACCP Plan.

(a) *Hazard analysis.* (1) Every official establishment shall conduct, or have conducted for it, a hazard analysis to determine the food safety hazards reasonably likely to occur in the production process and identify the preventive measures the establishment can apply to control those hazards. The hazard analysis shall include food safety hazards that can occur before, during, and after entry into the establishment. A food safety hazard that is reasonably likely to occur is one for which a prudent establishment would establish controls because it historically has occurred, or because there is a reasonable possibility that it will occur in the

particular type of product being processed, in the absence of those controls.

(2) A flow chart describing the steps of each process and product flow in the establishment shall be prepared, and the intended use or consumers of the finished product shall be identified.

(3) Food safety hazards might be expected to arise from the following:

(i) Natural toxins;

(ii) Microbiological contamination;

(iii) Chemical contamination;

(iv) Pesticides;

(v) Drug residues;

(vi) Zoonotic diseases;

(vii) Decomposition;

(viii) Parasites;

(ix) Unapproved use of direct or indirect food or color additives; and

(x) Physical hazards.

(b) *The HACCP plan.* (1) Every establishment shall develop and implement a written HACCP plan covering each product produced by that establishment whenever a hazard analysis reveals one or more food safety hazards that are reasonably likely to occur, based on the hazard analysis conducted in accordance with paragraph (a) of this section, including products in the following processing categories:

(i) Slaughter—all species.

(ii) Raw product—ground.

(iii) Raw product—not ground.

(iv) Thermally processed—commercially sterile.

(v) Not heat treated—shelf stable.

(vi) Heat treated—shelf stable.

(vii) Fully cooked—not shelf stable.

(viii) Heat treated but not fully cooked—not shelf stable.

(ix) Product with secondary inhibitors—not shelf stable.

(2) A single HACCP plan may encompass multiple products within a single processing category identified in this paragraph, if the food safety hazards, critical control points, critical limits, and procedures required to be identified and performed in paragraph (c) of this section are essentially the same, provided that any required features of the plan that are unique to a specific product are clearly delineated in the plan and are observed in practice.

(3) HACCP plans for thermally processed/commercially sterile products do not have to address the food safety hazards associated with microbiological contamination if the product is produced in accordance with the requirements of part 318, subpart G, or part 381, subpart X, of this chapter.

(c) *The contents of the HACCP plan.* The HACCP plan shall, at a minimum:

(1) List the food safety hazards identified in accordance with paragraph (a) of this section, which must be controlled for each process.

(2) List the critical control points for each of the identified food safety hazards, including, as appropriate:

(i) Critical control points designed to control food safety hazards that could be introduced in the establishment, and

(ii) Critical control points designed to control food safety hazards introduced outside the establishment, including food safety hazards that occur before, during, and after entry into the establishment;

(3) List the critical limits that must be met at each of the critical control points. Critical limits shall, at a minimum, be designed to ensure that applicable targets or performance standards established by FSIS, and any other requirement set forth in this chapter pertaining to the specific process or product, are met;

(4) List the procedures, and the frequency with which those procedures will be performed, that will be used to monitor each of the critical control points to ensure compliance with the critical limits;

(5) Include all corrective actions that have been developed in accordance with § 417.3(a) of this part, to be followed in response to any deviation from a critical limit at a critical control point; and

(6) Provide for a recordkeeping system that documents the monitoring of the critical control points. The records shall contain the actual values and observations obtained during monitoring.

(7) List the verification procedures, and the frequency with which those procedures will be performed, that the establishment will use in accordance with § 417.4 of this part.

(d) *Signing and dating the HACCP plan.* (1) The HACCP plan shall be signed and dated by the responsible establishment individual. This signature

shall signify that the establishment accepts and will implement the HACCP plan.

(2) The HACCP plan shall be dated and signed:

(i) Upon initial acceptance;

(ii) Upon any modification; and

(iii) At least annually, upon reassessment, as required under § 417.4(a)(3) of this part.

(e) Pursuant to 21 U.S.C. 456, 463, 608, and 621, the failure of an establishment to develop and implement a HACCP plan that complies with this section, or to operate in accordance with the requirements of this part, may render the products produced under those conditions adulterated.

[61 FR 38868, July 25, 1996, as amended at 62 FR 61009, Nov. 14, 1997]

§ 417.3 Corrective actions.

(a) The written HACCP plan shall identify the corrective action to be followed in response to a deviation from a critical limit. The HACCP plan shall describe the corrective action to be taken, and assign responsibility for taking corrective action, to ensure:

(1) The cause of the deviation is identified and eliminated;

(2) The CCP will be under control after the corrective action is taken;

(3) Measures to prevent recurrence are established; and

(4) No product that is injurious to health or otherwise adulterated as a result of the deviation enters commerce.

(b) If a deviation not covered by a specified corrective action occurs, or if another unforeseen hazard arises, the establishment shall:

(1) Segregate and hold the affected product, at least until the requirements of paragraphs (b)(2) and (b)(3) of this section are met;

(2) Perform a review to determine the acceptability of the affected product for distribution;

(3) Take action, when necessary, with respect to the affected product to ensure that no product that is injurious to health or otherwise adulterated, as a result of the deviation, enters commerce;

(4) Perform or obtain reassessment by an individual trained in accordance with § 417.7 of this part, to determine whether the newly identified deviation or other unforeseen hazard should be incorporated into the HACCP plan.

(c) All corrective actions taken in accordance with this section shall be documented in records that are subject to verification in accordance with § 417.4(a)(2)(iii) and the recordkeeping requirements of § 417.5 of this part.

§ 417.4 Validation, Verification, Reassessment.

(a) Every establishment shall validate the HACCP plan's adequacy in controlling the food safety hazards identified during the hazard analysis, and shall verify that the plan is being effectively implemented.

(1) *Initial validation.* Upon completion of the hazard analysis and development of the HACCP plan, the establishment shall conduct activities designed to determine that the HACCP plan is functioning as intended. During this HACCP plan validation period, the establishment shall repeatedly test the adequacy of the CCP's, critical limits, monitoring and recordkeeping procedures, and corrective actions set forth in the HACCP plan. Validation also encompasses reviews of the records themselves, routinely generated by the HACCP system, in the context of other validation activities.

(2) *Ongoing verification activities.* Ongoing verification activities include, but are not limited to:

(i) The calibration of process-monitoring instruments;

(ii) Direct observations of monitoring activities and corrective actions; and

(iii) The review of records generated and maintained in accordance with § 417.5(a)(3) of this part.

(3) *Reassessment of the HACCP plan.* Every establishment shall reassess the adequacy of the HACCP plan at least annually and whenever any changes occur that could affect the hazard analysis or alter the HACCP plan. Such changes may include, but are not limited to, changes in: raw materials or source of raw materials; product formulation; slaughter or processing methods or systems; production volume; personnel; packaging; finished product distribution systems; or, the intended use or consumers of the finished product. The reassessment shall be performed by an individual trained

in accordance with §417.7 of this part. The HACCP plan shall be modified immediately whenever a reassessment reveals that the plan no longer meets the requirements of §417.2(c) of this part.

(b) *Reassessment of the hazard analysis.* Any establishment that does not have a HACCP plan because a hazard analysis has revealed no food safety hazards that are reasonably likely to occur shall reassess the adequacy of the hazard analysis whenever a change occurs that could reasonably affect whether a food safety hazard exists. Such changes may include, but are not limited to, changes in: raw materials or source of raw materials; product formulation; slaughter or processing methods or systems; production volume; packaging; finished product distribution systems; or, the intended use or consumers of the finished product.

§417.5 Records.

(a) The establishment shall maintain the following records documenting the establishment's HACCP plan:

(1) The written hazard analysis prescribed in §417.2(a) of this part, including all supporting documentation;

(2) The written HACCP plan, including decisionmaking documents associated with the selection and development of CCP's and critical limits, and documents supporting both the monitoring and verification procedures selected and the frequency of those procedures.

(3) Records documenting the monitoring of CCP's and their critical limits, including the recording of actual times, temperatures, or other quantifiable values, as prescribed in the establishment's HACCP plan; the calibration of process-monitoring instruments; corrective actions, including all actions taken in response to a deviation; verification procedures and results; product code(s), product name or identity, or slaughter production lot. Each of these records shall include the date the record was made.

(b) Each entry on a record maintained under the HACCP plan shall be made at the time the specific event occurs and include the date and time recorded, and shall be signed or initialed by the establishment employee making the entry.

(c) Prior to shipping product, the establishment shall review the records associated with the production of that product, documented in accordance with this section, to ensure completeness, including the determination that all critical limits were met and, if appropriate, corrective actions were taken, including the proper disposition of product. Where practicable, this review shall be conducted, dated, and signed by an individual who did not produce the record(s), preferably by someone trained in accordance with §417.7 of this part, or the responsible establishment official.

(d) *Records maintained on computers.* The use of records maintained on computers is acceptable, provided that appropriate controls are implemented to ensure the integrity of the electronic data and signatures.

(e) *Record retention.* (1) Establishments shall retain all records required by paragraph (a)(3) of this section as follows: for slaughter activities for at least one year; for refrigerated product, for at least one year; for frozen, preserved, or shelf-stable products, for at least two years.

(2) Off-site storage of records required by paragraph (a)(3) of this section is permitted after six months, if such records can be retrieved and provided, on-site, within 24 hours of an FSIS employee's request.

(f) *Official review.* All records required by this part and all plans and procedures required by this part shall be available for official review and copying.

§417.6 Inadequate HACCP Systems.

A HACCP system may be found to be inadequate if:

(a) The HACCP plan in operation does not meet the requirements set forth in this part;

(b) Establishment personnel are not performing tasks specified in the HACCP plan;

(c) The establishment fails to take corrective actions, as required by §417.3 of this part;

(d) HACCP records are not being maintained as required in §417.5 of this part; or

(e) Adulterated product is produced or shipped.

§ 417.7 Training.

(a) Only an individual who has met the requirements of paragraph (b) of this section, but who need not be an employee of the establishment, shall be permitted to perform the following functions:

(1) Development of the HACCP plan, in accordance with § 417.2(b) of this part, which could include adapting a generic model that is appropriate for the specific product; and

(2) Reassessment and modification of the HACCP plan, in accordance with § 417.3 of this part.

(b) The individual performing the functions listed in paragraph (a) of this section shall have successfully completed a course of instruction in the application of the seven HACCP principles to meat or poultry product processing, including a segment on the development of a HACCP plan for a specific product and on record review.

§ 417.8 Agency verification.

FSIS will verify the adequacy of the HACCP plan(s) by determining that each HACCP plan meets the requirements of this part and all other applicable regulations. Such verification may include:

(a) Reviewing the HACCP plan;

(b) Reviewing the CCP records;

(c) Reviewing and determining the adequacy of corrective actions taken when a deviation occurs;

(d) Reviewing the critical limits;

(e) Reviewing other records pertaining to the HACCP plan or system;

(f) Direct observation or measurement at a CCP;

(g) Sample collection and analysis to determine the product meets all safety standards; and

(h) On-site observations and record review.

PART 424—PREPARATION AND PROCESSING OPERATIONS

Subpart A—General

Sec.

424.1 Purpose and scope.

Subpart C—Food Ingredients and Sources of Radiation

424.21 Use of food ingredients and sources of radiation.
424.22 Certain other permitted uses.
424.23 Prohibited uses.

AUTHORITY: 7 U.S.C. 450, 1901–1906; 21 U.S.C. 451–470, 601–695; 7 CFR 2.18, 2.53.

SOURCE: 64 FR 72175, Dec. 23, 1999, unless otherwise noted.

Subpart A—General

§ 424.1 Purpose and scope.

This part of the regulations prescribes rules for the preparation of meat and the processing of poultry products. The rules in this part further the purposes of the Federal Meat Inspection Act (FMIA) and the Poultry Products Inspection Act (PPIA) by, among other things, preventing the adulteration or misbranding of meat and poultry products at official establishments. 9 CFR Chapter III, Subchapter A, Parts 318 and 319, Subpart C of this part, and 21 CFR Chapter I, Subchapter A or Subchapter B, specify rules for the use of certain food ingredients (e.g., food additives and color additives) and sources of radiation that may render meat or poultry products adulterated or misbranded.

Subpart C—Food Ingredients and Sources of Radiation

§ 424.21 Use of food ingredients and sources of radiation.

(a)(1) *General.* No meat or poultry product shall bear or contain any food ingredient that would render it adulterated or misbranded, or which is not approved in this part, part 318 or part 319 of this chapter, or by the Administrator in specific cases.

(2)(i) Poultry products and poultry broth used in the processing of poultry products shall have been processed in the United States only in an official establishment or imported from a foreign country listed in § 381.196(b), and have been inspected and passed in accordance with the regulations. Detached ova and offal shall not be used in the processing of any poultry products, except that poultry feet may be processed

for use as human food in a manner approved by the Administrator in specific cases and detached ova may be used in the processing of poultry products if the processor demonstrates that such ova comply with the requirements of the Federal Food, Drug, and Cosmetic Act.

(ii) Liquid, frozen, and dried egg products used in the processing of any poultry product shall have been prepared under inspection and be so marked in accordance with the Egg Products Inspection Act.

(3)(i) Carcasses, parts thereof, and products of cattle, sheep, swine, goats, or equines may be used in the processing of poultry products only if they were prepared in the United States in an official meat packing establishment or imported from a foreign country listed in § 327.2(b), were inspected and passed in accordance with the Federal Meat Inspection Act and the regulations under such Act (subchapter A of this chapter), and are so marked.

(ii) Pork from carcasses or carcass parts used as an ingredient in poultry products that has been found free of trichinae, as described under § 318.10 (a)(2), (e) and (f) of the Federal meat inspection regulations (9 CFR 318.10 (a)(2), (e) and (f)), is not required to be treated for the destruction of trichinae.

(iii) Poultry products containing pork muscle tissue which the Administrator determines at the time the labeling for the product is submitted for approval in accordance with part 381 of the regulations in subchapter A 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, shall be effectively heated, refrigerated, or cured to destroy any possible live trichinae, as prescribed in § 318.10(c) of this chapter, at the official establishment where such products are prepared. In lieu of such treatment of poultry products containing pork, the pork ingredient may be so treated.

(b)(1) *Food ingredients and sources of radiation.* Food ingredients and sources of radiation listed or approved for use in the production of meat or poultry products in 21 CFR chapter I, subchapter A or subchapter B, shall be listed for such use under this chapter, subject to declaration requirements in parts 316 and 317, or subparts M and N, of part 381 of this chapter, unless precluded from such use or further restricted in parts 318 or 319, or subparts O and P, of part 381 of this chapter, or unless such use otherwise results in the adulteration or misbranding of meat or poultry products. Food ingredients and sources of radiation listed or approved for use in the production of meat or poultry products in 21 CFR Chapter I, subchapter A or subchapter B, may be listed or approved for such use under this chapter by the Administrator in § 424.21, subject to declaration requirements in parts 316 and 317, or subparts M and N, of part 381 of this chapter.

(2) No food ingredients or sources of radiation may be used in the preparation of any meat or poultry product, for any purpose, unless the use is listed or approved in 21 CFR chapter I as a direct food additive (21 CFR part 172), a secondary direct food additive (21 CFR part 173), indirect food additive (21 CFR parts 174–178), radiation source (21 CFR part 179), an interim-listed direct food additive (21 CFR part 180), a prior-sanctioned substance (21 CFR part 181), a Generally Recognized As Safe (GRAS) substance (21 CFR parts 182 or 184), or by a regulation in this chapter. Part 319 of this chapter also specifies other food ingredients that are acceptable in preparing specified products.

(3) No food ingredient, the intended use of which is to impart color in any meat or poultry product, shall be used unless such use is approved in 21 CFR Chapter I as a color additive (21 CFR Parts 73, 74, 81, and 82) or in a regulation in this chapter.

(4) Petitions to amend 21 CFR chapter I to provide for uses of food additives, or other substances or sources of radiation necessary in the preparation of meat or poultry products, or food ingredients used to impart color to product, should be sent to the Food and Drug Administration, in accordance with the provisions of 21 CFR parts 71 or 171, as appropriate.

(5) Inquiries concerning the regulatory status under the Federal Food, Drug, and Cosmetic Act of any articles

intended for use as components of, or in contact with, meat or poultry products, may be addressed to the Food and Drug Administration, Center for Food Safety and Applied Nutrition, 200 C Street, SW, Washington, DC 20204, or the Department of Agriculture, Food Safety and Inspection Service, Office of Policy, Program Development and Evaluation, Washington, DC 20250–3700.

(6) Inquiries concerning the use in specific meat or poultry products of substances that are not affirmed by the Food and Drug Administration as Generally Recognized as Safe (GRAS) or otherwise listed in 21 CFR Part 182 or Part 184, or of food or color additives listed in 21 CFR regulations for general use in foods or for use in meat, or poultry products, generally, including mixtures of such substances or additives, should be addressed to the Department of Agriculture, Food Safety and Inspection Service, Office of Policy, Program Development and Evaluation, Washington, DC 20250–3700.

(c) The food ingredients specified in the following chart are approved for use in the preparation of meat products, provided they are used for the purposes indicated, within the limit of the amounts stated, and under other conditions specified in this part and Part 317 of this chapter. Part 319 of this chapter specifies other food ingredients that are acceptable in preparing specified meat products. This chart also contains food ingredients that are acceptable for use in poultry products, provided they are used for the purpose indicated, within the limits of the amounts stated and under other conditions specified in this part. No meat or poultry product shall bear or contain any food ingredient that would render it adulterated or misbranded, or which is not approved in this part, or by the Administrator in specific cases.

Class of substance	Substance	Purpose	Products	Amount
Acidifiers	Acetic acid	To adjust acidity	Various meat and poultry products[2].	Sufficient for purpose.[3]
	Citric acid	do	do	Do.
	Glucono delta-lactone.	do	do	Do.
	Lactic acid	do	do	Do.
	Phosphoric acid	do	do	Do.
	Tartaric acid	do	do	Do.
Anti-coagulants	Citric acid	To prevent clotting	Fresh blood of livestock	0.2 percent with or without water. When water is used to make a solution of citric acid added to the blood of livestock, not more than 2 parts of water to 1 part of citric acid shall be used.
	Sodium citrate	do	do	Not to exceed 0.5 percent based on the ingoing weight of the product. When water is used to make a solution of sodium citrate added to livestock blood, not more than 2 parts of water to 1 part of sodium citrate shall be used.
Antifoaming agent	Methyl polysilicone	To retard foaming	Soups (meat and poultry)	10 ppm.
		do	Rendered fats (meat and poultry).	Do.
		do	Curing pickle (meat and poultry).	50 ppm.
Antimicrobial Agents	Potassium lactate	To inhibit microbial growth.	Various meat and poultry products, except infant formulas and infant food.	4.8% by weight of total formulation.
	Sodium diacetate	do	do	0.25% by weight of total formulation.
	Sodium lactate	do	do	4.8% by weight of total formulation.

Class of substance	Substance	Purpose	Products	Amount
	Trisodium phosphate.	To reduce microbial levels.	Raw, chilled poultry carcasses.	8 to 12 percent; solution to be maintained at 45 °F. to 55 °F. and applied by spraying or dipping carcasses for up to 15 seconds when used in accordance with 21 CFR 182.1778.
Antioxidants and oxygen interceptors.	Ascorbyl palmitate ..	To retard rancidity ..	Margarine or oleomargarine	0.02 percent (by wt. of finished product) individually or in combination with other antioxidants approved for use in margarine.
	Ascorbyl stearate.			
	BHA (butylated hydroxyanisole).			
.....	.....do	Dry sausage	0.003 based on total weight	0.006 percent in combination with other anti-oxidants for use in meat.
	.....do	Rendered animal fat or a combination of such fat and vegetable fat.	0.01 percent	0.02 percent in combination with other anti-oxidants for use in meat.
	.....do	Fresh pork, sausage, brown and serve sausages, fresh Italian sausage products, pregrilled beef patties, fresh sausage made from beef or beef and pork, cooked or raw pizza topping and cooked or raw meatballs.	0.01 percent based on fat content.	0.02 percent in combination with other anti-oxidants for use in meat, based on fat content.
	.....do	Dried meats	0.01 percent based on total weight.	0.01 percent in combination with other anti-oxidants for use in meat.
	.....do	Margarine or oleomargarine.	0.02 percent (by wt. of the finished product) individually or in combination with other antioxidants approved for use in margarine..	
	.....do	Various poultry products.	0.01 percent based on fat content (0.02 percent in combination with any other antioxidant for use in poultry) based on fat content..	
	BHT (butylated hydroxytoluene).	.....do	Dry sausage	0.003 percent based on total weight 0.006 percent in combination with other anti-oxidants for use in meat.
	.....do	Rendered animal fat or a combination of such fat and vegetable fat.	0.01 percent	0.02 percent in combination with other anti-oxidants for use in meat.

Class of substance	Substance	Purpose	Products	Amount
	.....do	Fresh pork, sausage, brown and serve sausages, fresh Italian sausage products, pregrilled beef patties, fresh sausage made from beef or beef and pork, cooked or raw pizza topping and cooked or raw meatballs.	0.01 percent based on fat content.	0.02 percent in combination with other anti-oxidants for use in meat, based on fat content.
	.....do	Dried meats	0.01 percent based on total weight.	0.01 percent in combination with other anti-oxidants for use in meat.
	.....do	Margarine or oleomargarine.	0.02 percent (by wt. of the finished product) individually or in combination with other antioxidants approved for use in margarine..	
	.....do	Various poultry products.	0.01 percent based on fat content (0.02 percent in combination with any other antioxidant for use in poultry) based on fat content..	
	Dodecyl gallate	.....do	Margarine or oleomargarine	0.02 percent (by wt. of the finished product) individually or in combination with other antioxidants approved for use in margarine.
	Glycine	.....do	Rendered animal fat or a combination of such fat and vegetable fat.	0.01 percent 0.02 percent in combination with other anti-oxidants for use in meat.
	Octyl gallate	.....do	Margarine or oleomargarine	0.02 percent (by wt. of the finished product) individually or in combination with other antioxidants approved for use in margarine.
	Propyl gallate	.....do	Dry sausage	0.003 percent based on total weight 0.006 percent in combination with other anti-oxidants for use in meat.
	.....do	Rendered animal fat or a combination of such fat and vegetable fat.	0.01 percent	0.02 percent in combination with other anti-oxidants for use in meat.
	.....do	Fresh pork, sausage, brown and serve sausages, fresh Italian sausage products, pregrilled beef patties, fresh sausage made from beef or beef and pork, cooked or raw pizza topping and cooked or raw meatballs.	0.01 percent based on fat content.	0.02 percent in combination with other anti-oxidants for use in meat, based on fat content.
	.....do	Dried meats	0.01 percent based on total weight.	0.01 percent in combination with other anti-oxidants for use in meat.

Class of substance	Substance	Purpose	Products	Amount
	.....do	Margarine or oleo-margarine.	0.02 percent (by wt. of the finished product) individually or in combination with other antioxidants approved for use in margarine..	
	.....do	Various poultry products.	0.01 percent based on fat content (0.02 percent in combination with any other antioxidant for use in poultry, except TBHQ, based on fat content)..	
	Resin guaiac	.....do	Rendered animal fat or a combination of such fat and vegetable fat 0.01 percent.	0.02 percent in combination with other antioxidants for use in meat.
	TBHQ (tertiary butylhydroquinone).	.....do	Dry sausage 0.003 percent based on weight.	0.006 percent in combination only with BHA and/or BHT.
	.....do	Rendered animal fat or a combination of such fat and vegetable fat.	0.01 percent	0.02 percent in combination only with BHA or BHT.
	.....do	Fresh pork, sausage, brown and serve sausages, fresh Italian sausage products, pregrilled beef patties, fresh sausage made from beef or beef and pork, cooked or raw pizza topping and cooked or raw meatballs.	0.01 percent based on fat content.	0.02 percent in combination only with BHA and/or BHT, based on fat content.
	.....do	Dried meats	0.01 percent based on total weight.	0.01 percent in combination only with BHA and/or BHT.
		.....do	Margarine or oleo-margarine.	0.02 percent alone or in combination only with BHA and/or BHT, based on oil or fat content.
		.....do	Various poultry products	0.01 percent based on fat content (0.02 percent in combination only with BHA and/or BHT, based on fat content).
	Tocopherols	.....do	Rendered animal fat or a combination of such fat and vegetable fat.	0.03 percent. A 30 percent concentration of tocopherols in vegetable oils shall be used when added as an antioxidant to products designated as ''lard'' or ''rendered pork fat.''
		.....do	Dry sausage, semidry sausage, dried meats, uncooked or cooked fresh sausage made with beef and/or pork, uncooked or cooked Italian sausage products, uncooked or cooked meatballs, uncooked or cooked meat pizza toppings, brown and serve sausages, pregrilled beef patties, and restructured meats.	Not to exceed 0.03 percent based on fat content. Not used in combination with other antioxidants.

Class of substance	Substance	Purpose	Products	Amount
		.....do	Various poultry products	0.03 percent based on fat content (0.02 percent in combination with any other antioxidant for use in poultry, except TBHQ, based on fat content).
Artificial Sweeteners	Saccharin	To sweeten product	Bacon	0.01 percent.
Binders and Extenders.	Agar-agar	To stabilize and thicken.	Thermally processed canned and jellied meat food products.	0.25 percent of finished product.
	Algin	To extend and stabilize product.	Breading mix; sauces (meat only) and various poultry products.	Sufficient for purpose in accordance with 21 CFR 172.5.
	A mixture of sodium alginate, calcium carbonate and calcium lactate/lactic acid (or glucono delta lactone).	To bind meat pieces	Restructured meat food products.	Sodium alginate not to exceed 1.0 percent; calcium carbonate not to exceed 0.2 percent; and lactic acid/calcium lactate (or glucono delta-lactone) not to exceed 0.3 percent of product formulation. Added mixture may not exceed 1.5 percent of product at formulation. Mixture ingredients must be added dry.
	A mixture of sodium alginate, calcium carbonate, lactic acid, and calcium lactate.	To bind poultry pieces.	Ground and formed raw or cooked poultry pieces.	Sodium alginate not more than 0.8 percent, calcium carbonate not more than 0.15 percent; lactic acid and calcium lactate, in combination, not more than 0.6 percent of product formulation. Added mixture may not exceed 1.55 percent of product at formulation. The mixture must be added in dry form.
	Bread	To bind and extend product.	Bockwurst	3.5 percent individually or collectively with other binders for use in meat.
		.....do	Chili con carne, chili con carne with beans.	8 percent individually or collectively with other binders for use in meat.
		.....do	Spaghetti with meat balls and sauce, spaghetti with meat and sauce and similar products.	12 percent individually or collectively with other binders for use in meat.
	Carboxymethyl cellulose (cellulose gum).	To extend and stabilize product.	Baked pies (meat only) and various poultry products.	Sufficient for purpose in accordance with 21 CFR 172.5.
	Carrageenan	To extend and stabilize product.	Breading mix; sauces (meat only) and various poultry products.	Sufficient for purpose in accordance with 21 CFR 172.5.
		To prevent purging of brine solution.	Cured pork products as provided in 9 CFR 319.104(d).	Not to exceed 1.5 percent of product formulation; permitted in combination only with soy protein concentrate, combination not to exceed 1.5 percent of product formulation; in accordance with 21 CFR 172.620, 172.623, and 172.626.

Class of substance	Substance	Purpose	Products	Amount
	Carrageenan, Locust bean gum, and Xanthan gum blend.	.....do	.....do	In combination, not to exceed 0.5 percent of formulation; not permitted in combination with other binders approved for use in cured pork products; in accordance with 21 CFR 172.620, 172.623, 172.626, 184.1343, and 172.695.
	Cereal	To bind and extend product.	Sausages as provided in 9 CFR Part 319, bockwurst.	3.5 percent individually or collectively with other binders for use in meat.
		.....do	Chili con carne, chili con carne with beans.	8 percent individually or collectively with other binders for use in meat.
	Dried milk	.....do	Sausages as provided for in 9 CFR Part 319.	3.5 percent individually or collectively with other binders for use in meat
	Dried skim milk, calcium reduced.	.....do	Sausages as provided in 9 CFR 9 CFR Part 319.	Do.
		.....do	Chili con carne, chili con carne with beans.	8 percent individually or collectively with other binders for use in meat.
	Enzyme (rennet) treated with calcium reduced dried skim milk and calcium lactate.	.....do	Sausages as provided for in 9 CFR Part 319.	3.5 percent total finished product (calcium lactate required at rate of 10 percent of binder.)
		.....do	Imitation sausages; nonspecific loaves; soups, stews (meat only) and various poultry products.	Sufficient for purpose in accordance with 21 CFR 172.5 (calcium lactate required at a rate of 10 percent of binder).
	Enzyme (rennet) treated with sodium caseinate and calcium lactate.	.....do	Imitation sausages; nonspecific loaves; soups, stews (meat only) and various poultry products.	Sufficient for purpose in accordance with 21 CFR 172.5 (calcium lactate required at a rate of 25 percent of binder).
	Food starch modified.	To prevent purging of brine solution.	Cured pork products as provided for in 9 CFR 319.104(d).	Not to exceed 2 percent of product formulation in ''Ham Water Added'' and ''Ham with Natural Juices'' products; not to exceed 3.5 percent of product formulation in ''Ham and Water Product—X percent of Weight is Added Ingredients'' products; permitted in combination only with soy protein concentrate, with combination of modified food starch at 3 percent of product formulation and soy protein concentrate at 0.5 percent of product formulation; in accordance with 21 CFR 172.892.
	Gelatin	To bind and extend product.	Various poultry products	Sufficient for purpose in accordance with 21 CFR 172.5.
	Gums, vegetable	.....do	Egg roll (meat only) and various poultry products.	Sufficient for purpose in accordance with 21 CFR 172.5.
	Isolated soy protein	.....do	Sausage as provided for in 9 CFR Part 319, bockwurst.	2 percent.

Class of substance	Substance	Purpose	Products	Amount
		.....do	Imitation sausages; nonspecific loaves; soups; stews (meat only) and various poultry products.	Sufficient for purpose in accordance with 21 CFR 172.5.
		.....do	Chili con carne, chili con carne with beans.	8 percent individually or collectively with other binders for use in meat.
		.....do	Spaghetti with meatballs and sauce, spaghetti with meat and sauce and similar products.	12 percent individually or collectively with other binders and extenders for use in meat.
		To prevent purging of brine solution.	Cured pork products as provided for in 9 CFR 319.104(d).	Not to exceed 2 percent of product formulation, not permitted in combination with other binders approved for use in cured pork products.
	Methyl cellulose	To extend and stabilize product (also carrier).	Meat and vegetable patties; various poultry products.	0.15 percent.
	Sodium caseinate ...	To bind and extend product.	Imitation sausages, nonspecific loaves, soups, stews (meat only).	Sufficient for purpose in accordance with 21 CFR 182.1748 and 21 CFR 172.5.
		.....do	Sausages as provided for in 9 CFR Part 319.	2 percent in accordance with 21 CFR 182.1748.
		.....do	Chili con carne, chili con carne with beans.	8 percent individually or collectively with other binders and extenders for use in meat in accordance with 21 CFR 182.1748.
		.....do	Spaghetti with meatballs and sauce, spaghetti with meat and sauce and similar products.	12 percent individually or collectively with other binders and extenders for use in meat in accordance with 21 CFR 182.1748.
		To prevent purging of brine solution.	Cured pork products as provided for in 9 CFR 319.104(d).	Not to exceed 2 percent of product formulation; not permitted in combination with other binders approved for use in cured pork products, in accordance with 21 CFR 182.1748.
		To bind and extend product.	Various poultry products	3 percent in cooked product, 2 percent in raw product, in accordance with 21 CFR 172.5 and 182.1748.
	Soy flour	.....do	Sausages as provided for in 9 CFR Part 319, bockwurst.	3.5 percent individually or collectively with other binders and extenders for use in meat.
		.....do	Chili con carne, chili con carne with beans.	8 percent individually or collectively with other binders and extenders for use in meat.
		.....do	Spaghetti with meatballs and sauce, spaghetti with meat and sauce and similar products.	12 percent individually or collectively with other binders and extenders for use in meat.
	Soy protein concentrate.	.....do	Sausage as provided for in 9 CFR Part 319, bockwurst.	3.5 percent individually or collectively with other binders and extenders for use in meat.
		.....do	Chili con carne, chili con carne with beans.	8 percent individually or collectively with other binders and extenders for use in meat.
		.....do	Spaghetti with meatballs and sauce, spaghetti with meat and sauce and similar products.	12 percent individually or collectively with other binders and extenders for use in meat.

Class of substance	Substance	Purpose	Products	Amount
		To prevent purging of brine solution.	Cured pork products as provided for in 9 CFR 319.104(d).	Not to exceed 3.5 percent of product formulation; permitted in combination only with modified food starch, with combination of modified food starch at 3 percent of product formulation and soy protein concentrate at 0.5 percent of product formulation; in combination only with carrageenan, combination not to exceed 1.5 percent of product formulation.
	Starchy vegetable flour.	To bind and extend product.	Sausage as provided for in 9 CFR Part 319, bockwurst.	3.5 percent individually or collectively with other binders and extenders for use in meat.
		.....do	Chili con carne, chili con carne with beans.	8 percent individually or collectively with other binders and extenders for use in meat.
	Tapioca dextrin	.....do	Sausage as provided for in 9 CFR Part 319, bockwurst.	3.5 percent individually or collectively with other binders and extenders for use in meat, in accordance with 21 CFR 184.1277.
		.....do	Chili con carne, chili con carne with beans.	8 percent individually or collectively with other binders and extenders for use in meat, in accordance with 21 CFR 184.1277.
		.....do	Spaghetti with meatballs and sauce, spaghetti with meat and sauce and similar products.	12 individually or collectively with other binders and extenders for use in meat, in accordance with 21 CFR 184.1277.
		.....do	Various poultry products	Sufficient for purpose in accordance with 21 CFR 184.1277.
	Vegetable starch	.....do	Sausage as provided for in 9 CFR Part 319, bockwurst.	3.5 percent individually or collectively with other binders and extenders for use in meat.
		.....do	Chili con carne, chili con carne with beans.	8 percent individually or collectively with other binders and extenders for use in meat.
	Wheat gluten	To bind and extend product.	Sausage as provided for in 9 CFR Part 319, bockwurst.	3.5 percent individually or collectively with other binders and extenders for use in meat, in accordance with 21 CFR 184.1322.
		.....do	Chili con carne, chili con carne with beans.	8 percent individually or collectively with other binders for use in meat, in accordance with 21 CFR 184.1322.
		.....do	Spaghetti with meatballs and sauce, spaghetti with meat and sauce and similar products.	12 percent individually or collectively with other binders and extenders for use in meat, in accordance with 21 CFR 184.1322.
		.....do	Various poultry products	Sufficient for purpose in accordance with 21 CFR 184.1322.

Class of substance	Substance	Purpose	Products	Amount
	Whey, Dry or dried	To bind or thicken ..	Sausage as provided for in 9 CFR Part 319, bockwurst.	3.5 percent individually or collectively with other binders and extenders for use in meat.
		.....do	Imitation sausages, nonspecific loaves, soups, stews (meat only).	8 percent individually or collectively with other binders and extenders for use in meat.
		.....do	Chili con carne, chili con carne with beans, pork or beef with barbecue sauce.	8 percent individually or collectively with other binders and extenders for use in meat.
		.....do	Various poultry products	Sufficient for purpose in accordance with 21 CFR 184.1322.
	Whey, Reduced lactose.	To bind or thicken ..	Sausage as provided for in 9 CFR Part 319, bockwurst.	3.5 percent individually or collectively with other binders and extenders for use in meat.
		.....do	Imitation sausages, nonspecific loaves, soups, stews (meat only).	Sufficient for purpose in accordance with 21 CFR 172.5.
		.....do	Chili con carne, chili con carne with beans, pork or beef with barbecue sauce.	8 percent individually or collectively with other binders and extenders for use in meat.
	Whey, Reduced minerals.	.....do	Sausage as provided for in 9 CFR Part 319, bockwurst.	3.5 percent individually or collectively with other binders and extenders for use in meat.
		.....do	Imitation sausages, nonspecific loaves, soups, stews (meat only).	Sufficient for purpose in accordance with 21 CFR 172.5.
		.....do	Chili con carne, chili con carne with beans, pork or beef with barbecue sauce.	8 percent individually or collectively with other binders and extenders for use in meat.
	Whey protein concentrate.	.....do	Sausage as provided in 9 CFR Part 319, bockwurst.	3.5 percent individually or collectively with other binders and extenders for use in meat, in accordance with 21 CFR 184.1979c.
		.....do	Imitation sausages, nonspecific loaves, soups, stews.	Sufficient for purpose in accordance with 21 CFR 184.1979c.
		.....do	Chili con carne, chili con carne with beans, pork or beef with barbecue sauce.	8 percent individually or collectively with other binders and extenders for use in meat, in accordance with 21 CFR 184.1979c
		To bind meat pieces	Restructured meat food products, whole muscle meat cuts.	3.5 percent individually or collectively with other binders and extenders for use in meat, in accordance with 21 CFR 184.1979c.
	Xanthan gum	To maintain: uniform viscosity; suspension of particulate matter, emulsion stability; freeze-thaw stability.	Meat sauces, gravies or sauces and meats, canned or frozen and/or refrigerated meat salads, canned or frozen meat stews, canned chili or chili with beans, pizza topping mixes and batter or breading mixes.	Sufficient for purpose in accordance with 21 CFR 172.5.
		.....do	Various poultry products, except uncooked products or sausages or other products with a moisture limitation established by Subpart P of Part 381.	Sufficient for purpose

Class of substance	Substance	Purpose	Products	Amount
Bleaching Agent	Hydrogen peroxide	To remove color	Tripe (substance must be removed from product by rinsing with clear water).	Sufficient for purpose.
Catalysts (substances must be eliminated during process).	Nickel	To accelerate chemical reaction.	Rendered animal fats or a combination of such fats and vegetable fats.	Do.
	Sodium amide	Rearrangement of fatty acid radicals.	.....do	Do.
	Sodium methoxide ..	.....do	.....do	
Chilling Media	Salt (NaCl)	To aid in chilling	Raw poultry products	700 lbs. to 10,000 gallons of water.
Coloring Agents (artificial).	Coal tar dyes (FD&C certified).	To color products ...	Various poultry products	Sufficient for purpose.
	Color additives listed in 21 CFR Part 74, Subpart A of Part 82, Subpart B (operator must furnish evidence to inspector in charge that color additive has been certified for use in connection with foods by the Food and Drug Administration).	To color casings or rendered fats; marking and branding product.	Sausage casings, oleomargarine, shortening, marking or branding ink on product (meat only).	Sufficient for purpose (may be mixed with approved natural coloring matters or harmless inert material such as common salt and sugar).
	Titanium oxide	To whiten	Canned ham salad spread and creamed-type canned meat products. Poultry salads and poultry spreads.	0.5 percent.
Coloring Agents (natural).	Alkanet, annatto, carotene, cochineal, green chlorophyll, saffron and tumeric.	To color casings or rendered fats; marking and branding product.	Sausage casings, oleomargarine, shortening, marking or branding ink on product (meat only).	Sufficient for purpose (may be mixed with approved artificial dyes or harmless inert material such as common salt and sugar).
	Annatto, carotene ...	To color products ...	Various poultry products	Sufficient for purpose.
Curing accelerators (must be used only in combination with curing agents).	Ascorbic acid	To accelerate color fixing or preserve color during storage.	Cured pork and beef cuts, cured poultry, cured comminuted poultry and meat food products.	75 oz to 100 gal pickle at 10 percent pump level; ¾ oz to 100 lb meat, meat byproduct or poultry product; 10 percent solution to surfaces of cured meat cuts or poultry products prior to packaging. (The use of such solution shall not result in the addition of a significant amount of moisture to the product).
	Citric acid or sodium citrate.	To accelerate color fixing or preserve color during storage.	Cured pork and beef cuts, cured comminuted meat food product, cured comminuted poultry or poultry products.	May be used in cured meat products or in 10 percent solution used to spray surfaces of cured meat cuts prior to packaging to replace up to 50 percent of the ascorbic acid, erythorbic acid, sodium ascorbate, or sodium erythorbate that is used. May be used in cured poultry products to replace 50 percent of the ascorbic acid or sodium ascorbate that is used.

Class of substance	Substance	Purpose	Products	Amount
	Erythorbic acid	To accelerate color fixing or preserve color during storage.	Cured pork and beef cuts, cured poultry, cured comminuted poultry and meat food products.	75 oz to 100 gal pickle at 10 percent pump level; 3/4 oz to 100 lb meat, meat byproduct or poultry product; 10 percent solution to surfaces of cured meat cuts or poultry products prior to packaging. (The use of such solution shall not result in the addition of a significant amount of moisture to the product).
	Fumaric acid	.....do	Cured, comminuted meat, poultry or meat and poultry products.	0.065 percent (or 1 oz to 100 lb) of the weight of the meat, poultry or the meat or poultry byproducts before processing.
	Glucono delta lactone.	.....do	Cured, comminuted meat or meat food product.	8 oz to each 100 lb of meat or meat byproduct.
		.....do	Genoa salami	16 oz to 100 lb of meat (1.0 percent).
	Sodium acid pyrophosphate.	.....do	Frankfurters, wieners, vienna, bologna, garlic bologna, knockwurst and similar products.	Not to exceed alone or in combination with other curing accelerators for use in meat the following: 8 oz in 100 lb of meat, or meat and meat byproducts, content of the formula; nor 0.5 percent in the finished product.
	Sodium ascorbate ..	To accelerate color fixing or preserve color during storage.	Cured pork and beef cuts, cured comminuted meat food product, cured comminuted poultry or poultry products.	87.5 oz to 100 gal pickle at 10 percent pump level; 7/8 oz to 100 lb meat, meat byproduct or poultry product; 10 percent solution to surfaces of cured meat cuts or poultry products prior to packaging. (The use of such solution shall not result in the addition of a significant amount of moisture to the product).
	Sodium erythorbate	To accelerate color fixing or preserve color during storage.	Cured pork and beef cuts, cured comminuted meat food products, cured comminuted poultry or poultry products.	87.5 oz to 100 gal pickle at 10 percent pump level; 7/8 oz to 100 lb meat, meat byproduct or poultry product; 10 percent solution to surfaces of cured meat cuts or poultry products prior to packaging. (The use of such solution shall not result in the addition of a significant amount of moisture to the product.)
Curing Agents	Sodium or potassium nitrate.	Source of nitrite	Cured meat products other than bacon. Nitrates may not be used in baby, junior, and toddler foods. Cured, comminuted poultry or poultry products.	7 lb to 100 gal pickle; 3½ oz to 100 lb meat or poultry product (dry cure); 2¾ oz to 100 lb chopped meat or poultry.

Class of substance	Substance	Purpose	Products	Amount
	Sodium or potassium nitrite (supplies of sodium nitrite and potassium nitrite and mixtures containing them must be kept under the care of a responsible employee of the establishment. The specific nitrite content of such supplies must be known and clearly marked accordingly).	To fix color	Cured meat and poultry products. Nitrites may not be used in baby, junior, or toddler foods.	2 lb to 100 gal pickle at 10 percent pump level; 1 oz to 100 lb meat or poultry product (dry cure); ¼ oz to 100 lb chopped meat, meat byproduct or poultry product. The use of nitrites, nitrates or combination shall not result in more than 200 ppm of nitrite, calculated as sodium nitrite in finished product, except that nitrites may be used in bacon only in accordance with paragraph (b) of this section.
Denuding Agents (may be used in combination. Must be removed from tripe by rinsing with potable water.).	Lime (calcium oxide, calcium hydroxide).	To denude mucous membranes.	Tripe	Sufficient for purpose.
	Sodium carbonate	.....do	.....do	Do.
	Sodium citrate	.....do	.....do	Do.
	Sodium gluconate	.....do	.....do	Do.
	Sodium hydroxide	.....do	.....do	Do.
	Sodium persulfate	.....do	.....do	Do.
	Sodium silicates (ortho, meta, and sesqui).	.....do	.....do	Do.
	Trisodium phosphate.	.....do	.....do	Do.
Emulsifying Agents	Actylated monoglycerides.	To emulsify product	Shortening and various poultry products.	Sufficient for purpose.
	Diacetyl tartaric acid esters of mono- and diglycerides.	.....do	.....do	Do.
	Glycerol-lacto stearate, oleate, or palmitate.	.....do	.....do	Do.
	Lecithin	To emulsify product (also as an antioxidant).	Oleomargarine, shortening, various meat and poultry products.	0.5 percent in oleomargarine, use in other products—sufficient amount for emulsification.
	Mono and diglycerides (glycerol palmitate, etc.).	To emulsify product	Rendered animal fat or a combination of such fat with vegetable fat; oleomargarine.	Sufficient for purpose in lard and shortening; 0.5 percent in oleomargarine.
		.....do	Various poultry products	Sufficient for purpose.
	Mono and diglycerides of fatty acids esterified with any of the following acids: acetic, acetyltartaric, citric, lactic, tartaric, and their sodium and calcium salts; the sodium sulfoacetate derivatives of these mono and diglycerides.	.....do	Margarine or oleomargarine	0.5 percent.

Class of substance	Substance	Purpose	Products	Amount
	Polyglycerol esters of fatty acids (polyglycerol esters of fatty acids are restricted to those up to and including the decaglycerol esters and otherwise meeting the requirements of § 172.854(a) of the Food Additive Regulations).	.....do	Rendered animal fat or a combination of such fat with vegetable fat when use is not precluded by standards of identity of composition; oleomargarine.	Sufficient for purpose for rendered animal fat or combination with vegetable fat; 0.5 percent for oleomargarine.
	Polysorbate 60 (polyoxyethylene (20) sorbitan monostearate).	.....do	Shortening for use in nonstandardized baked goods, baking mixes, icings, fillings, and toppings and in the frying of foods (meat only). Rendered poultry fat or a combination of such fat with vegetable fat.	1 percent when used alone. If used with polysorbate 80 the combined total shall not exceed 1 percent.
	Polysorbate 80 (polyoxyethylene (20) sorbitan monooleate).	.....do	Shortening for use in nonstandardized baked goods, baking mixes, icings, fillings, and toppings and in the frying of foods (meat only). Various poultry products.	1 percent when used alone. If used with polysorbate 60 the combined total shall not exceed 1 percent.
	1,2-propylene glycol esters of fatty acids.	.....do	Margarine or oleomargarine	2.0 percent.
	Propylene glycol mono and diesters of fats and fatty acids.	.....do	Rendered animal or poultry fat or a combination of such fat with vegetable fat.	Sufficient for purpose.
	Stearyl-2-lactylic acid.	.....do	Shortening to be used for cake icings and fillings (meat only).	3.0 percent.
	Stearyl monoglyceridyl citrate.	.....do	Shortening	Sufficient for purpose
Film Forming Agents	A mixture consisting of water, sodium alginate, calcium chloride, sodium carboxymethylcellulose, and corn syrup solids.	To reduce cooler shrinkage and help protect surface.	Freshly dressed meat carcasses. Such carcasses must bear a statement ''Protected with a film of water, corn syrup solids, sodium alginate, calcium chloride and sodium carboxymethyl-cellulose.''.	Formulation may not exceed 1.5 percent of hot carcass weight when applied. Chilled weight may not exceed hot weight.
Flavoring Agents; Protectors and Developers.	Artificial smoke flavoring.	To flavor product	Various (meat and poultry) [2]	Sufficient for purpose.
	Autolyzed yeast extract.	.....do	.....do	Do.
	Benzoic acid (sodium, potassium and calcium salts).	To retard flavor reversion.	Margarine or oleomargarine	0.1 percent individually, or if used in combination with other flavoring agents for use in meat or with sorbic acid and its salts, 0.2 percent (expressed as the acids in the wt. of the finished foods).
	Calcium lactate	To protect flavor	Cooked semi-dry and dry products including sausage, imitation sausage, and nonspecific meat food sticks.	0.6 percent in product formulation.
	Citric acid	.....do	Various poultry products	Sufficient for purpose.
		Flavoring	Chili con carne	Do.

Class of substance	Substance	Purpose	Products	Amount
	Corn syrup solids; corn syrup; glucose syrup.	To flavor product	Various poultry products, sausage, hamburger, meat loaf, luncheon meat, chopped or pressed ham.	Do.
	Dextrose	do	Sausage, ham and cured products.	Do.
	Diacetyl	do	Oleomargarine	Do.
	Disodium guanylate	do	Various meat and poultry products.[2]	
	Disodium inosinate	do	do	Do.
	Harmless bacteria starters of the acidophilus type, lactic acid starter or culture of *Pediococcus cerevisiae*.	To develop flavor	Dry sausage, pork roll, thuringer, lebanon bologna, cervelat, and salami.	0.5 percent.
	Harmless lactic acid producing bacteria.	To prevent the growth of *Clostridium botulinum*.	Bacon	Sufficient for purpose.
	Hydrolyzed plant protein.	To flavor product	Various meat and poultry products.[2]	Do.
	Isopropyl citrate	To protect flavor	Oleomargarine	0.02 percent.
	Malt syrup	To flavor product	Cured meat products	2.5 percent.
		do	Various poultry products	Sufficient for purpose.
	Milk protein hydrolysate.	do	Various meat and poultry products.[2]	Do.
	Monoammonium glutamate.	do	do	Do.
	Monosodium glutamate.	do	do	Do.
	Potassium lactate	do	Various meat and meat food products, poultry and poultry food products, except infant formula and infant food.[2]	Not to exceed 2 percent of formulation; in accordance with 21 CFR 184.1639.
	Smoke flavoring	To flavor product	Various meat and poultry products.	Sufficient for purpose.
	Sodium acetate	To flavor products	Various meat and poultry products.	Not to exceed 0.25% of formulate in accordance with 21 CFR 184.1721.
	Sodium diacetate	do	do	Not to exceed 0.25% of formulate in accordance with 21 CFR 184.1754.
	Sodium lactate	do	Various meat and meat food products, poultry and poultry food products, except infant formula and infant food.[2]	Not to exceed 2 percent of formulation in accordance with 21 CFR 184.1768.
	Sodium sulfoacetate derivative of mono and diglycerids.	do	Various meat and poultry products.[2]	0.5 percent.
	Sodium tripolyphosphate.	To help protect flavor.	''Fresh Beef,''[2] ''Beef for further cooking, ''Cooked Beef,'' Beef Patties, Meat Loaves, Meat Toppings, and similar products derived from pork, lamb, veal, mutton, and goat meat which are cooked or frozen after processing.	0.5 percent of total product.
	Sodium tripolyphosphate and sodium mixtures, metaphosphate, insoluble; and sodium polyphosphates, glassy.	do	do	Do.

Class of substance	Substance	Purpose	Products	Amount
	Sorbitol	To flavor, to facilitate the removal of casings from product, and to reduce caramelization and charring.	Cooked sausage labeled frankfurter, frank, furter, wiener, and knockwurst; cured pork and pork products, as provided for in 9 CFR Part 319.	Not to exceed 2 percent of the weight of the formula excluding the formula weight of water or ice, when used in accordance with 21 CFR 184.1835.
	Starter distillate	To help protect flavor.	Oleomargarine	Sufficient for purpose.
	Stearyl citrate	.....do	.....do	0.15 percent.
	Sugars (sucrose and dextrose).	To flavor product	Various meat and poultry products.	Sufficient for purpose.
Gases	Carbon dioxide liquid.	Contact freezing	Various poultry products	Do.
	Carbon dioxide solid (dry ice).	To cool product	Chopping of meat, packing of product.	Sufficient for purpose.
		To cool product or facilitate chopping or packaging.	Various poultry products	Do.
	Nitrogen	To exclude oxygen from sealed containers.	Various meat and poultry products.	Do.
	Nitrogen, liquid	Contact freezant	.....do	Do.
Hog Scald Agents (must be removed by subsequent cleaning operations).	Caustic soda	To remove hair	Hog carcasses	Sufficient for purpose.
	Dicotyl sodium sulfosuccinate.	.....do	.....do	Do.
	Dimethylpolysiloxane.	.....do	.....do	Do.
	Disodium-calcium ethylenediaminetetra-acetate.	.....do	.....do	Do.
	Disodium phosphate	.....do	.....do	Do.
	Ethylenediaminetetra-acetic acid (sodium salts).	.....do	.....do	Do.
	Lime (calcium oxide, calcium hydroxide).	.....do	.....do	Do.
	Potassium hydroxide.			Do.
	Propylene glycol	.....do	.....do	Do.
	Soap (prepared by the reaction of calcium, potassium, or sodium with rosin or fatty acids of natural fats and oils).	.....do	.....do	Do.
	Sodium acid pyrophosphate.	.....do	.....do	Do.
	Sodium carbonate	.....do	.....do	Do.
	Sodium dodecylbenzene sulfonate.	.....do	.....do	Do.
	Sodium gluconate	.....do	.....do	Do.
	Sodium hexametaphosphate.	.....do	.....do	Do.
	Sodium lauryl sulfate.	.....do	.....do	Do.
	Sodium mono and dimethylnaphthalene sulfonate (molecular weight 245–260).	.....do	.....do	Do.

Class of substance	Substance	Purpose	Products	Amount
	Sodium n-alkylbenzene sulfonate (alkyl group predominantly C12 and C13 and not less than 95 percent C10 and C16).	.....do	.....do	Do.
	Sodium pyrophosphate.	.....do	.....do	Do.
	Sodium silicates (ortho, meta, and sesqui).	.....do	.....do	Do.
	Sodium sulfate	.....do	.....do	Do.
	Sodium tripolyphosphate.	.....do	.....do	Do.
	Sucrose	.....do	.....do	Do.
	Triethanolamine dodecylbenzene sulfonate.	.....do	.....do	Do.
	Trisodium phosphate.	.....do	.....do	Do.
Miscellaneous	Adipic acid	To acidify	Margarine or oleomargarine	Sufficient for purpose.
	Ascorbic acid, erythorbic acid, citric acid, sodium ascorbate and sodium citrate, singly or in combination.	To delay discoloration.	Fresh beef cuts, fresh lamb cuts, and fresh pork cuts.	Not to exceed, singly or in combination, 500 ppm or 1.8 mg/sq inch of product surface of ascorbic acid (in accordance with 21 CFR 182.3013), erythorbic acid (in accordance with 21 CFR 182.3041), or sodium ascorbate (in accordance with 21 CFR 182.3731); and/or not to exceed, singly or in combination, 250 ppm or 0.9 mg/sq inch of product surface of citric acid (in accordance with 21 CFR 182.6033), or sodium citrate (in accordance with 21 CFR 182.6751).
	Calcium disodium, EDTA (calcium disodium ethylenediaminetetraacetate.	To preserve product and to protect flavor.	Margarine or oleomargarine	75 ppm by weight of the finished oleomargarine or margarine.
	Calcium propionate	To retard mold growth.	Pizza crust	0.32 percent alone or in combination based on weight of the flour brace used.
		.....do	Fresh pie dough (poultry only).	0.3 percent of calcium propionate or sodium propionate alone, or in combination, based on weight of flour used.
	Citric acid	To preserve cured color during storage.	Cured pork cuts	Not to exceed 30 percent in water solution used to spray surfaces of cured cuts, prior to packaging, in accordance with 21 CFR 184.1033. (The use of such solution shall not result in the addition of a significant amount of moisture to the product and shall be applied only once to product).
	Citric acid (sodium and potassium salts).	To acidify	Margarine and oleomargarine.	Sufficient for purpose.
	d- and dl-alpha-tocopherol.	To inhibit nitrosamine formation.	Pump-cured bacon	500 ppm; by injection or surface application.

Class of substance	Substance	Purpose	Products	Amount
	Dipotassium phosphate.	To decrease the amount of cooked out juices.	Meat food products except where otherwise prohibited by the meat inspection regulations and poultry food products except where otherwise prohibited by the poultry products inspection regulations..	For meat food products, 5 percent of phosphate in pickle at 10 percent pump level; 0.5 percent of phosphate in meat food product (only clear solution may be injected into meat food product). For poultry food products, 0.5 percent of total product.
	Disodium phosphate	.....do	.....do	Do.
	Glycerine	Humectant	Shelf stable meat snacks ...	Not to exceed 2 percent of the formulation weight of the product in accordance with 21 CFR 182.1320.
	Hydrochloric acid	To acidify	Margarine or oleomargarine	Sufficient for purpose.
	Lactic acid (sodium and potassium salts).	.....do	.....do	Do.
	L-Tartaric acid (sodium and sodium potassium salts).	.....do	.....do	Do.
	Monopotassium phosphate.	To decrease the amount of cooked out juices.	Meat food products except where otherwise prohibited by the meat inspection regulations and poultry food products except where otherwise prohibited by the poultry products inspection regulations..	For meat food products, 5 percent of phosphate in pickle at 10 percent pump level; 0.5 percent of phosphate in meat food product (only clear solution may be injected into meat food product). For poultry products, 0.5 percent of total product.
	Monosodium phosphate.	.....do	.....do	Do.
	Phosphoric acid	To acidify	Margarine or oleomargarine	Sufficient for purpose.
	Potassium bicarbonate.	To alkalize	Margarine or oleomargarine	Sufficient for purpose.
	Potassium carbonate.	.....do	.....do	Do.
	Potassium pyrophosphate.	To decrease the amount of cooked out juices.	Meat food products except where otherwise prohibited by the meat inspection regulations and poultry food products except where otherwise prohibited by the poultry products inspection regulations..	5 percent of phosphate in pickle at 10 percent pump level; 0.5 percent of phosphate in meat food product (only clear solution may be injected into meat food product). For poultry food products, 0.5 percent of total product.
	Potassium sorbate ..	To retard mold growth.	Dry sausage	10 percent in water solution may be applied to casings after stuffing or casings may be dipped in solution prior to stuffing.
	Potassium tripolyphosphate.	To decrease the amount of cooked out juices.	Meat food products except where otherwise prohibited by the meat inspection regulations and poultry food products except where otherwise prohibited by the poultry products inspection regulations.	5 percent of phosphate in pickle at 10 percent pump level; 0.5 percent of phosphate in meat food product (only clear solution may be injected into meat food product). For poultry food products, 0.5 percent of total product.
	Propyl paraben (propyl p-hydroxybenzoate).	To retard mold growth.	Dry sausage	3.5 percent in water solution may be applied to casings after stuffing or casings may be dipped in solution prior to stuffing.
	Silicon dioxide	Processing aid/dispersant.	Tocopherol containing bacon curing mixes.	At level not to exceed 4.0 percent in the dry mix.

Class of substance	Substance	Purpose	Products	Amount
	Sodium acid pyrophosphate.	To decrease the amount of cooked out juices.	Meat food products except where other prohibited by the meat inspection regulations and poultry food products except where otherwise prohibited by the poultry products inspection regulations..	For meat food products, 5 percent of phosphate in pickle at 10 percent pump level; 0.5 percent of phosphate in meat food product (only clear solution may be injected into meat food product). For poultry products, 0.5 percent of total product.
	Sodium bicarbonate	To neutralize excess acidity, cleaning vegetables.	Rendered fats, soups, curing pickle (meat and poultry).	Sufficient for purpose.
		To alkalize	Margarine or oleomargarine	Do.
	Sodium carbonate ..	.....do	.....do	Do.
	Sodium citrate buffered with citric acid to a pH of 5.6.	To inhibit the growth of micro-organisms and retain product flavor during storage.	Cured and uncured, processed whole muscle meat and poultry food products, e.g., ham, chicken breasts.	Not to exceed 1.3 percent of the formulation weight of the product in accordance with 21 CFR 184.1751.
	Sodium hydroxide ...	To alkalize	Margarine or oleomargarine	Sufficient for purpose.
		To decrease the amount of cooked out juices.	Poultry food products containing phosphates.	May be used only in combination with phosphate in a ratio not to exceed one part sodium hydroxide to four parts phosphate.
		.....do	Meat food products containing phosphates.	May be used only in combination with phosphates in a ratio not to exceed one part sodium hydroxide to four parts phosphate; the combination shall not exceed 5 percent in pickle at 10 percent pump level; 0.5 percent in product.
	Sodium metaphosphate, insoluble.	.....do	Meat food products except where other prohibited by the meat inspection regulations, and poultry food products except where otherwise prohibited by the poultry products inspection regulations.	For meat food products, 5 percent of phosphate in pickle at 10 percent pump level; 0.5 percent of phosphate in meat food product (only clear solution may be injected into meat food product). For poultry products, 0.5 percent of total product.
	Sodium polyphosphate, glassy.	.....do	.....do	Do.
	Sodium proprionate	To retard mold growth.	Pizza crust	0.32 percent alone or in combination based on weight of the flour brace used.
		.....do	Fresh pie dough (poultry only).	0.3 percent of calcium proprionate or sodium proprionate alone, or in combination, based on weight of flour used.
	Sodium pryophosphate.	To decrease the amount of cooked out juices.	Meat food products except where otherwise prohibited by the meat inspection regulations and poultry food products except where otherwise prohibited by the poultry products inspection regulations.	For meat food products, 5 percent of phosphate in pickle at 10 percent pump level; 0.5 percent of phosphate in meat food product (only clear solution may be injected into meat food product). For poultry products, 0.5 percent of total product.
	Sodium tripolyphosphate.	.....do	.....do	Do.

Class of substance	Substance	Purpose	Products	Amount
	Sorbic acid (sodium, potassium, and calcium salts).	To preserve product and to retard mold growth.	Margarine or oleomargarine	0.1 percent individually, or if used in combination or with benzoic acid or its salts, 0.2 percent (expressed as the acids in the wt. of the finished foods).
	Tricalcium phosphate.	To preserve product color during dehydration process.	Mechanically deboned chicken to be dehydrated.	Not to exceed 2 percent of the weight of the mechanically deboned chicken prior to dehydration, in accordance with 21 CFR 182.1217.
Poultry scald agents (must be removed by subsequent cleaning operations).	Alpha-hydro-omega-hydroxy-poly (oxyethylene) poly (oxypropylene) (minimum 15 moles) poly (oxyethylene) block copolymer (poloxamer).	To remove feathers	Poultry carcasses	Not to exceed 0.05 percent by weight in scald water.
	Dimethylpolysiloxane.	do	do	Sufficient for purpose.
	Dioctyl sodium sulfosuccinate.	do	do	Do.
	Dipotassium phosphate.	do	do	Do.
	Ethylenediaminetetra-acetic acid (sodium salts).	do	do	Do.
	Lime (calcium oxide, calcium hydroxide).	do	do	Do.
	Polyoxyethylene (20) sorbitan monooleate.	do	do	Not to exceed 0.0175 percent in scald water.
	Potassium hydroxide.	do	do	Sufficient for purpose.
	Propylene glycol	do	do	Do.
	Sodium acid phosphate.	do	do	Do.
	Sodium acid pyrophosphate.	do	do	Do.
	Sodium bicarbonate	do	do	Do.
	Sodium carbonate	do	do	Do.
	Sodium dodecylbenzene-sulfonate.	do	do	Do.
	Sodium-2-ethylhexyl sulfate.	do	do	Do.
	Sodium hexametaphosphate.	do	do	Do.
	Sodium hydroxide	do	do	Do.
	Sodium lauryl sulfate.	do	do	Do.
	Sodium phosphate (mono-, di-, tribasic).	do	do	Do.
	Sodium pyrophosphate.	do	do	Do.
	Sodium sesquicarbonate.	do	do	Do.
	Sodium sulfate	do	do	Do.
	Sodium tripolyphosphate.	do	do	Do.
	Tetrasodium pyrophosphate.	do	do	Do.

Class of substance	Substance	Purpose	Products	Amount
Proteolytic Enzymes	Aspergillus flavus oryzae group.	To soften tissue	Raw poultry muscle tissue of hen, cock, mature turkey, mature duck, mature goose, and mature guinea, and raw meat cuts.	Solutions consisting of water and approved proteolytic enzyme applied or injected into raw meat or poultry tissue shall not result in a gain of more than 3 percent above the weight of the untreated product.
	Aspergillus oryzae ..	.....do	.....do	Do.
	Bromelin	.....do	.....do	Do.
	Ficin	.....do	.....do	Do.
	Papain	.....do	.....do	Do.
Refining Agents (must be eliminated during process of manufacturing).	Acetic acid	To separate fatty acids and glycerol.	Rendered fats (meat only) ..	Sufficient for purpose.
	Bicarbonate of soda	.....do	.....do	Do.
	Carbon (purified charcoal).	To aid in refining of animal fats.	.....do	Do.
	Caustic soda (sodium hydroxide).	To refine fats	.....do	Do.
	Diatomaceous earth; Fuller's earth.	.....do	.....do	Do.
	Sodium carbonate ..	.....do	.....do	Do.
	Tannic acid	.....do	.....do	Do.
Rendering agents	Tricalcium phosphate.	To aid rendering	Animal fats	Do.
	Trisodium phosphate.	.....do	.....do	Do.
Synergists (used in combination with antioxidants).	Citric acid	To increase effectiveness of antioxidants.	Any meat product permitted to contain antioxidants as provided for in this part.	Not to exceed 0.01 percent based on fat content.
		.....do	Poultry fats	0.01 percent alone or in combination with antioxidants in poultry fats.
	Malic acid	.....do	Lard and shortening	0.01 percent based on total weight in combination with antioxidants for use in meat products only.
		.....do	Poultry fats	0.01 percent alone or in combination with antioxidants in poultry fats.
	Monoglyceride citrate.	.....do	Lard, shortening, fresh pork sausage, dried meats and poultry fats.	0.02 percent.
	Monoisopropyl citrate.	.....do	Lard, shortening, oleomargarine, fresh pork sausage, dried meats.	Do.
		.....do	Poultry fats	0.01 percent poultry fats.
	Phosphoric acid	.....do	Lard, shortening, and poultry fats.	0.01 percent.
Tenderizing agents ..	Aspergillus flavus oryzae group.	To soften tissue	Raw poultry muscle tissue of hen, cock, mature turkey, mature duck, mature goose, and mature guinea, and raw meat cuts.	Solutions consisting of water and approved proteolytic enzyme applied or injected into raw meat or poultry tissue shall not result in a gain of more than 3 percent above the weight of the untreated product.
	Aspergillus oryzae ..	.....do	.....do	Not more than 3 percent of a of a 0.8 molar solution.
	Bromelin	.....do	.....do	Do.
	Calcium chloride	.....do	.....do	Do.
	Magnesium chloride	.....do	.....do	Do.

Class of substance	Substance	Purpose	Products	Amount
	Papain	To soften tissue	Raw poultry muscle tissue of hen, cock, mature turkey, mature duck, mature goose, and mature guinea, and raw meat cuts.	Solutions consisting of water and approved proteolytic enzyme applied or injected into raw meat or poultry tissue shall not result in a gain of more than 3 percent above the weight of the untreated product.
	Potassium chloride	do	do	Not more than 3 percent of a 2.0 molar solution.
	Potassium, magnesium or calcium chloride.	do	do	A solution of approved inorganic chlorides injected into or applied to raw meats or poultry cuts shall not result in a gain of more than 3 percent above the weight of the untreated product.

[1] [Reserved]
[2] Information as to the specific products for which use of this additive is approved may be obtained upon inquiry addressed to the Labeling and Additives Policy Division, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250.
[3] Provided, that its use is functional and suitable for the product and it is permitted for use at the lowest level necessary to accomplish the desired technical effect as determined in specific cases prior to label approval under §§ 317.4 or 381.32.
[4] Special labeling requirements are prescribed in 381.120 for raw poultry chilled in a medium with more than 70 lbs. of salt to 10,000 gals. of water.

[64 FR 72175, Dec. 23, 1999, as amended at 65 FR 3123, Jan. 20, 2000; 65 FR 34391, May 30, 2000]

§ 424.22 Certain other permitted uses.

(a) Under appropriate declaration as required in parts 316 and 317 of this chapter, the following substances may be added to meat:

(1) *General.* Common salt, approved sugars (sucrose, cane or beet sugar), maple sugar, dextrose, invert sugar, honey, corn syrup solids (corn syrup, glucose syrup and fructose), wood smoke, vinegar, flavorings, spices, sodium nitrate, sodium nitrite, potassium nitrate, potassium nitrite, and other food and color additives specified in the chart in paragraph (c) of this section may be added to meat under conditions, if any, specified in this part or in part 317 of this chapter.

(2) *Artifical flavorings.* Other harmless artificial flavorings may be added to meat, with the approval of the Administrator in specific cases.

(3) *Coloring matter and dyes.* Coloring matter and dyes, other than those specified in a regulation permitting that use in this chapter or in 21 CFR Chapter I, Subchapter A and Subchapter B, may be applied to meat mixed with rendered fat, applied to natural and artificial casings, and applied to such casings enclosing products, if approved by the Administrator in specific cases. When any coloring matter or dye is applied to casings, there shall be no penetration of coloring into the product.

(b) *Use of nitrite and sodium ascorbate or sodium erythorbate (isoascorbate) in bacon.*

(1) *Pumped bacon.* With respect to bacon injected with curing ingredients and massaged bacon, sodium nitrite shall be used at 120 parts per million (ppm) ingoing or an equivalent amount of potassium nitrite shall be used (148 ppm ingoing); and 550 ppm of sodium ascorbate or sodium erythorbate (isoascorbate) shall be used. Sodium ascorbate or sodium erythorbate have a molecular weight of approximately 198. Hydrated forms of these substances shall be adjusted to attain the equivalent of 550 ppm of sodium ascorbate or sodium erythorbate.

(i) The Department shall collect samples of pumped bacon from producing plants and analyze them for the level of nitrosamines by the Thermal Energy Analyzer (TEA). In the event that a TEA analysis indicates that a confirmable level of nitrosamines might be present, additional samples shall be collected and analyzed by gas chromatography. Presumptive positive results

must be confirmed by mass spectrometry before being considered positive. If during the interval required for the Department to analyze the confirmatory samples by gas chromatography and mass spectrometry, changes are made in processing procedures which are expected to result in no confirmable levels of nitrosamines in pumped bacon produced by these new procedures, an establishment may submit samples to USDA for analysis upon prior notification and arrangements with USDA. If, however, an establishment furnishes USDA with laboratory results from testing five consecutive lots of pumped bacon produced under the new procedures and the testing is performed by the USDA methodology and procedures, those results will be utilized in making the determination concerning the product produced under the new procedures. Should the results of these tests reveal that confirmable levels of nitrosamines are not indicated in any of the five consecutive lots, the confirmation analysis by USDA shall be terminated and the establishment shall revert to normal monitoring status. In the event the test results continue to indicate nitrosamines, however, USDA shall proceed in its confirmation analysis on the original samples taken for confirmation. If any one of the original samples collected by USDA for confirmation is found to contain confirmable levels of nitrosamines, all pumped bacon in the producing establishment and all future production will be retained. The Department shall sample and analyze such retained pumped bacon for nitrosamines on a lot by lot basis. A production lot shall be that pumped bacon produced by the establishment in any single shift. Samples from any lot of pumped bacon under retention found to contain nitrosamines at a confirmable level shall cause the lot of pumped bacon to be disposed of in a manner to ensure it will not form nitrosamines when cooked. Such disposal may include incorporation of the uncooked pumped bacon as an ingredient of another meat provided it is processed for eating without further preparation in a manner to preclude the formation of nitrosamines. Bacon subsequently produced shall not be retained because of nitrosamines if the operator of the establishment makes adjustments in the processing of the product and laboratory results obtained by TEA analysis of samples from five consecutive normal sized lots of pumped bacon indicates that the product being produced contains no confirmable levels of nitrosamines. These tests from five consecutive normal sized lots of pumped bacon shall be conducted by the Department. However, if the establishment furnishes the Department with the results of tests conducted under the methodology and procedures used by the Department, such test results will be utilized in making the determination concerning the nitrosamine content of the product. All tests of pumped bacon for nitrosamines under this paragraph (b)(1)(i) shall be made on pumped bacon cooked at 340 degrees F. for 3 minutes on each side. In order to determine that no confirmable levels of nitrosamines are present in a sample tested, the testing must be performed by methodology and procedures that would detect the presence of any nitrosamines at 10 ppb.

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

(A) 100 ppm ingoing (potassium nitrite at 123 ppm ingoing); and 550 ppm sodium ascorbate or sodium erythorbate (isoascorbate) shall be used; or

(B) A predetermined level between 40 and 80 ppm (potassium nitrite at a level between 49 and 99 ppm); 550 ppm sodium ascorbate or sodium erythorbate (isoascorbate); and additional sucrose or other similar fermentable carbohydrate at a minimum of 0.7 percent and an inoculum of lactic acid producing bacteria such as *Pediococcus acetolactii* or other bacteria demonstrated to be equally effective in preventing the production of botulinum toxin at a level sufficient for the purpose of preventing the production of botulinum toxin.

(C) The Department shall collect samples of bacon from establishments producing under paragraph (b)(1)(ii) of this section and analyze them for the level of nitrosamines. Samples shall be randomly selected throughout the production of a lot. The actual sampling

plans and methods of analysis that are used will result in approximately the same likelihood as under paragraph (b)(1)(i) of this section of having a presumptive positive result when the true mean level of nitrosamines in a production lot is 10 ppb. In the event of a presumptive positive result, the establishment shall become subject to the provisions of paragraph (b)(1)(i) of this section.

(2) *Immersion cured bacon.* Immersion cured bacon may be placed in a brine solution containing salt, nitrite and flavoring material or in a container with salt, nitrite and flavoring material. Sodium nitrite shall not exceed 120 ppm ingoing or an equivalent amount of potassium nitrite (148 ppm ingoing) based on the actual or estimated skin-free green weight of the bacon bellies.

(3) *Bacon made with dry curing materials.* With respect to bacon made with dry curing materials, the product shall be cured by applying a premeasured amount of cure mixture to the bacon belly surfaces, completely covering the surfaces. Sodium nitrite shall not exceed 200 ppm ingoing or an equivalent amount of potassium nitrite (246 ppm ingoing) in dry cured bacon based on the actual or estimated skin-free green weight of the bacon belly.

(c) Irradiation of meat food and poultry products.

(1) *General requirements.* Meat food and poultry products may be treated to reduce foodborne pathogens and to extend product shelf-life by the use of sources of ionizing radiation as identified in 21 CFR 179.26(a). Official establishments must irradiate meat food and poultry products in accordance with 21 CFR 179.26(b), the Hazard Analysis and Critical Control Point (HACCP) system requirements in part 417 of this chapter, and the provisions of this section.

(2) *Dosimetry.* Official establishments that irradiate meat food and poultry products must have the following procedures in place:

(i) Laboratory operation procedures for determining the absorbed dose value from the dosimeter.

(ii) Calibration criteria for verifying the accuracy and consistency of any means of measurement (*e.g.*, time clocks and weight scales).

(iii) Calibration and accountability criteria for verifying the traceability and accuracy of dosimeters for the intended purpose, and the verification of calibration at least every 12 months. To confirm traceability, establishments must relate, through documentation, the end point measurement of a dosimeter to recognized standards.

(iv) Procedures for ensuring that the product unit is dose mapped to identify the regions of minimum and maximum absorbed dose and such regions are consistent from one product unit to another of like product.

(v) Procedures for accounting for the total absorbed dose received by the product unit (e.g., partial applications of the absorbed dose within one production lot).

(vi) Procedures for verifying routine dosimetry, i.e., assuring each production lot receives the total absorbed dose. Establishments may either position one dosimeter at the regions of minimum and maximum absorbed dose (or at one region verified to represent such) on at least the first, middle, and last product unit in each production lot or use statistically based validation and dose mapping to determine the number and placement of dosimeters in each production lot.

(vii) Procedures for verifying the relationship of absorbed dose as measured by the dosimeter to time exposure of the product unit to the radiation source.

(viii) Procedures for verifying the integrity of the radiation source and processing procedure. Aside from expected and verified radiation source activity decay for radionuclide sources, the radiation source or processing procedure must not be altered, modified, replenished, or adjusted without repeating dose mapping of product units to redefine the regions of minimum and maximum absorbed dose.

(3) *Documentation.* Official establishments that irradiate meat food or poultry products must have the following documentation on premises, available to FSIS:

(i) Documentation that the irradiation facility is licensed or possesses gamma radiation sources registered

with the Nuclear Regulatory Commission (NRC) or the appropriate State government acting under authority granted by the NRC.

(ii) Documentation that the machine radiation source irradiation facility is registered with the appropriate State government, if applicable.

(iii) Documentation that a worker safety program addressing OSHA regulations (29 CFR chapter XVII) is in place.

(iv) Citations or other documents that relate to incidences in which the establishment was found not to comply with Federal or State agency requirements for irradiation facilities.

(v) A certification by the operator that the irradiation facility personnel will only operate under supervision of a person who has successfully completed a course of instruction for operators of food irradiation facilities.

(vi) A certification by the operator that the key irradiation personnel, who monitor or control daily operations, have been trained in food technology, irradiation processing, and radiation health and safety.

(vii) Guarantees from the suppliers of all food-contact packaging materials that may be subject to irradiation that those materials comply with the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 *et seq.*).

(4) *Labeling.* (i) The labels on packages of meat food and poultry products irradiated in their entirety, in conformance with this section and with 21 CFR 179.26(a) and (b), must bear the logo shown at the end of this paragraph (c)(4)(i). Unless the word ''Irradiated'' is part of the product name, labels also must bear a statement such as ''Treated with radiation'' or ''Treated by irradiation.'' The logo must be placed in conjunction with the required statement, if the statement is used. The statement is not required to be more prominent than the declaration of ingredients required under § 317.2(c)(2). Any label bearing the logo or any wording of explanation with respect to this logo must be approved as required by Section 317.4. of this chapter or subparts M and N of part 381.

(ii) For meat food or poultry products that have been irradiated in their entirety, but that are not sold in packages, the required logo must be displayed to the purchaser with either the labeling of the bulk container plainly in view or a counter sign, card, or other appropriate device bearing the information that the product has been treated with radiation. In either case, the information must be prominently and conspicuously displayed to purchasers. Unless the word ''Irradiated'' is part of the product name, the labeling counter sign, card, or other device also must bear a statement such as ''Treated with radiation'' or ''Treated by irradiation.'' The logo must be placed in conjunction with the required statement, if the statement is used.

(iii) The inclusion of an irradiated meat food or poultry product ingredient in any multi-ingredient meat food or poultry product must be reflected in the ingredient statement on the finished product labeling.

(iv) Optional labeling statements about the purpose for radiation processing may be included on the product label in addition to the stated requirements elsewhere in this section, provided that such statements are not false or misleading. Statements that there has been a specific reduction inmicrobial pathogens must be substantiated by processing documentation.

[64 FR 72175, Dec. 23, 1999, as amended at 64 FR 72165, Dec. 23, 1999; 65 FR 34391, May 30, 2000]

§ 424.23 Prohibited uses.

(a) *Substances that conceal damage or inferiority or make products appear better or of greater value.* No substance may be used in or on any meat if it conceals damage or inferiority or makes the

product appear to be better or of greater value than it is. Therefore:

(1) Paprika or oleoresin paprika may not be used in or on fresh meat, such as steaks, or comminuted fresh meat, such as chopped and formed steaks or patties; or in any other meat consisting of fresh meat (with or without seasoning).

(2) Paprika or oleoresin paprika may be used in or on chorizo sausage and other meat in which paprika or oleoresin paprika is permitted as an ingredient in a standard of identity or composition in part 319 of this subchapter.

(3) Sorbic acid, calcium sorbate, sodium sorbate, and other salts of sorbic acid shall not be used in cooked sausages or any other meat; sulfurous acid and salts of sulfurous acid shall not be used in or on any meat; and niacin or nicotinamide shall not be used in or on fresh meat product; except that potassium sorbate, propylparaben (propyl p-hydroxybenzoate), calcium propionate, sodium propionate, benzoic acid, and sodium benzoate may be used in or on any product, only as provided in 9 CFR Chapter III.

(b) *Nitrates.* Nitrates shall not be used in curing bacon.

PART 430—REQUIREMENTS FOR SPECIFIC CLASSES OF PRODUCT

Sec.
430.1 Definitions.
430.4 Control of Listeria monocytogenes in post-lethality exposed ready-to-eat products.

AUTHORITY: 7 U.S.C. 450; 7 U.S.C. 1901–1906; 21 U.S.C. 451–470, 601–695; 7 CFR 2.18, 2.53.

SOURCE: 68 FR 34224, June 6, 2003, unless otherwise noted.

§ 430.1 Definitions.

Antimicrobial agent. A substance in or added to an RTE product that has the effect of reducing or eliminating a microorganism, including a pathogen such as *L. monocytogenes,* or that has the effect of suppressing or limiting growth of *L. monocytogenes* in the product throughout the shelf life of the product. Examples of antimicrobial agents added to RTE products are potassium lactate and sodium diacetate.

Antimicrobial process. An operation, such as freezing, applied to an RTE product that has the effect of suppressing or limiting the growth of a microorganism, such as *L. monocytogenes,* in the product throughout the shelf life of the product.

Deli product. A ready-to-eat meat or poultry product that typically is sliced, either in an official establishment or after distribution from an official establishment, and typically is assembled in a sandwich for consumption.

Hotdog product. A ready-to-eat meat or poultry frank, frankfurter, or wiener, such as a product defined in 9 CFR 319.180 and 319.181.

Lethality treatment. A process, including the application of an antimicrobial agent, that eliminates or reduces the number of pathogenic microorganisms on or in a product to make the product safe for human consumption. Examples of lethality treatments are cooking or the application of an antimicrobial agent or process that eliminates or reduces pathogenic microorganisms.

Post-lethality exposed product. Ready-to-eat product that comes into direct contact with a food contact surface after the lethality treatment in a post-lethality processing environment.

Post-lethality processing environment. The area of an establishment into which product is routed after having been subjected to an initial lethality treatment. The product may be exposed to the environment in this area as a result of slicing, peeling, re-bagging, cooling semi-permeable encased product with a brine solution, or other procedures.

Post-lethality treatment. A lethality treatment that is applied or is effective after post-lethality exposure. It is applied to the final product or sealed package of product in order to reduce or eliminate the level of pathogens resulting from contamination from post-lethality exposure.

Prerequisite program. A procedure or set of procedures that is designed to provide basic environmental or operating conditions necessary for the production of safe, wholesome food. It is called ''prerequisite'' because it is considered by scientific experts to be prerequisite to a HACCP plan.

Ready-to-eat (RTE) product. A meat or poultry product that is in a form that

is edible without additional preparation to achieve food safety and may receive additional preparation for palatability or aesthetic, epicurean, gastronomic, or culinary purposes. RTE product is not required to bear a safe-handling instruction (as required for non-RTE products by 9 CFR 317.2(l) and 381.125(b)) or other labeling that directs that the product must be cooked or otherwise treated for safety, and can include frozen meat and poultry products.

§430.4 Control of Listeria monocytogenes in post-lethality exposed ready-to-eat products.

(a) *Listeria monocytogenes* can contaminate RTE products that are exposed to the environment after they have undergone a lethality treatment. *L. monocytogenes* is a hazard that an establishment producing post-lethality exposed RTE products must control through its HACCP plan or prevent in the processing environment through a Sanitation SOP or other prerequisite program. RTE product is adulterated if it contains *L. monocytogenes* or if it comes into direct contact with a food contact surface which is contaminated with *L. monocytogenes.*

(b) In order to maintain the sanitary conditions necessary to meet this requirement, an establishment producing post-lethality exposed RTE product must comply with the requirements included in one of the three following alternatives:

(1) *Alternative 1.* Use of a post-lethality treatment (which may be an antimicrobial agent) that reduces or eliminates microorganisms on the product *and* an antimicrobial agent or process that suppresses or limits the growth of *L. monocytogenes.* If an establishment chooses this alternative:

(i) The post-lethality treatment must be included in the establishment's HACCP plan. The antimicrobial agent or process used to suppress or limit the growth of the pathogen must be included in either the establishment's HACCP plan or its Sanitation SOP or other prerequisite program.

(ii) The establishment must validate the effectiveness of the post-lethality treatment incorporated in its HACCP plan in accordance with §417.4. The establishment must document, either in its HACCP plan or in its Sanitation SOP or other prerequisite program, that the antimicrobial agent or process, as used, is effective in suppressing or limiting growth of *L. monocytogenes.*

(2) *Alternative 2.* Use of either a post-lethality treatment (which may be an antimicrobial agent) that reduces or eliminates microorganisms on the product *or* an antimicrobial agent or process that suppresses or limits growth of *L. monocytogenes.* If an establishment chooses this alternative:

(i) The post-lethality treatment must be included in the establishment's HACCP plan. The antimicrobial agent or process used to suppress or limit growth of the pathogen must be included in either the establishment's HACCP plan or its Sanitation SOP or other prerequisite program.

(ii) The establishment must validate the effectiveness of a post-lethality treatment incorporated in its HACCP plan in accordance with §417.4. The establishment must document in its HACCP plan or in its Sanitation SOP or other prerequisite program that the antimicrobial agent or process, as used, is effective in suppressing or limiting growth of *L. monocytogenes.*

(iii) If an establishment chooses this alternative and chooses to use only an antimicrobial agent or process that suppresses or limits the growth of *L. monocytogenes,* its sanitation program must:

(A) Provide for testing of food contact surfaces in the post-lethality processing environment to ensure that the surfaces are sanitary and free of *L. monocytogenes* or of an indicator organism;

(B) Identify the conditions under which the establishment will implement hold-and-test procedures following a positive test of a food-contact surface for *L. monocytogenes* or an indicator organism;

(C) State the frequency with which testing will be done;

(D) Identify the size and location of the sites that will be sampled; and

(E) Include an explanation of why the testing frequency is sufficient to ensure that effective control of *L. monocytogenes* or of indicator organisms is maintained.

(iv) An establishment that chooses this alternative and uses a post-lethality treatment of product will likely be subject to more frequent verification testing by FSIS than if it had chosen Alternative 1. An establishment that chooses this alternative and uses an antimicrobial agent or process that suppresses or limits the growth of *L. monocytogenes* will likely be subject to more frequent FSIS verification testing than if it uses a post-lethality treatment.

(3) *Alternative 3.* Use of sanitation measures only.

(i) If an establishment chooses this alternative, its sanitation program must:

(A) Provide for testing of food contact surfaces in the post-lethality processing environment to ensure that the surfaces are sanitary and free of *L. monocytogenes* or of an indicator organism;

(B) Identify the conditions under which the establishment will implement hold-and-test procedures following a positive test of a food-contact surface for *L. monocytogenes* or an indicator organism;

(C) State the frequency with which testing will be done;

(D) Identify the size and location of the sites that will be sampled; and

(E) Include an explanation of why the testing frequency is sufficient to ensure that effective control of *L. monocytogenes* or of indicator organisms is maintained.

(ii) An establishment producing a deli product or a hotdog product, in addition to meeting the requirements of paragraph (b)(3)(i) of this section, must meet the following requirements:

(A) The establishment must verify that the corrective actions that it takes with respect to sanitation after an initial positive test for *L. monocytogenes* or an indicator organism on a food contact surface in the post-lethality processing environment are effective by conducting follow-up testing that includes a targeted test of the specific site on the food contact surface area that is the most likely source of contamination by the organism and such additional tests in the surrounding food contact surface area as are necessary to ensure the effectiveness of the corrective actions.

(B) During this follow-up testing, if the establishment obtains a second positive test for *L. monocytogenes* or an indicator organism, the establishment must hold lots of product that may have become contaminated by contact with the food contact surface until the establishment corrects the problem indicated by the test result.

(C) Further, in order to be able to release into commerce the lots of product that may have become contaminated with *L. monocytogenes,* the establishment must sample and test the lots for *L. monocytogenes* or an indicator organism using a sampling method and frequency that will provide a level of statistical confidence that ensures that each lot is not adulterated with *L. monocytogenes.* The establishment must document the results of this testing. Alternatively, the establishment may rework the held product using a process that is destructive of *L. monocytogenes* or the indicator organism.

(iii) An establishment that chooses Alternative 3 is likely to be subject to more frequent verification testing by FSIS than an establishment that has chosen Alternative 1 or 2. An establishment that chooses Alternative 3 and that produces deli meat or hotdog products is likely to be subject to more frequent verification testing than one that does not produce such products.

(c) For all three alternatives in paragraph (b):

(1) Establishments may use verification testing that includes tests for *L. monocytogenes* or an indicator organism, such as *Listeria* species, to verify the effectiveness of their sanitation procedures in the post-lethality processing environment.

(2) Sanitation measures for controlling *L. monocytogenes* and procedures for antimicrobial agents or processes that suppress or limit the growth of the pathogen may be incorporated either in the establishment's HACCP plan or in its Sanitation SOP or other prerequisite program. When these control procedures are incorporated into the Sanitation SOP or prerequisite program, and not as a CCP in the HACCP

plan, the establishment must have documentation that supports the decision in its hazard analysis that *L. monocytogenes* is not a hazard that is reasonably likely to occur.

(3) The establishment must maintain sanitation in the post-lethality processing environment in accordance with part 416.

(4) If *L. monocytogenes* control measures are included in the HACCP plan, the establishment must validate and verify the effectiveness of measures for controlling *L. monocytogenes* included in its HACCP plan in accordance with §417.4.

(5) If *L. monocytogenes* control measures are included in the Sanitation SOP, the effectiveness of the measures must be evaluated in accordance with §416.14.

(6) If the measures for addressing *L. monocytogenes* are addressed in a prerequisite program other than the Sanitation SOP, the establishment must include the program and the results produced by the program in the documentation that the establishment is required to maintain under 9 CFR 417.5.

(7) The establishment must make the verification results that demonstrate the effectiveness of the measures it employs, whether under its HACCP plan or its Sanitation SOP or other prerequisite program, available upon request to FSIS inspection personnel.

(d) An establishment that produces post-lethality exposed RTE product shall provide FSIS, at least annually, or more often, as determined by the Administrator, with estimates of annual production volume and related information for the types of meat and poultry products processed under each of the alternatives in paragraph (b) of this section.

(e) An establishment that controls *L. monocytogenes* by using a post-lethality treatment or an antimicrobial agent or process that eliminates or reduces, or suppresses or limits the growth of the organism may declare this fact on the product label provided that the establishment has validated the claim.

PART 441—CONSUMER PROTECTION STANDARDS: RAW PRODUCTS

AUTHORITY: 21 U.S.C. 451–470, 601–695; 7 U.S.C. 450, 1901–1906; 7 CFR 2.18, 2.53.

SOURCE: 66 FR 1771, Jan. 9, 2001, unless otherwise noted.

§441.10 Retained water.

(a) Raw livestock and poultry carcasses and parts will not be permitted to retain water resulting from post-evisceration processing unless the establishment preparing those carcasses and parts demonstrates to FSIS, with data collected in accordance with a written protocol, that any water retained in the carcasses or parts is an unavoidable consequence of the process used to meet applicable food safety requirements.

(b) Raw livestock and poultry carcasses and parts that retain water from post-evisceration processing and that are sold, transported, offered for sale or transportation, or received for transportation, in commerce, must bear a statement on the label in prominent letters and contiguous to the product name or elsewhere on the principal display panel of the label stating the maximum percentage of water that may be retained (*e.g.*, ''up to X% retained water,'' ''less than X% retained water,'' ''up to X% water added from processing''). The percent water statement need not accompany the product name on other parts of the label. Raw livestock and poultry carcasses and parts that retain no water may bear a statement that no water is retained.

(c)(1) An establishment subject to paragraph (a) of this section must maintain on file and available to FSIS its written data-collection protocol. The protocol must explain how data will be collected and used to demonstrate the amount of retained water in the product covered by the protocol that is an unavoidable consequence of the process used to meet specified food safety requirements.

(2) The establishment must notify FSIS as soon as it has a new or revised protocol available for review by the

Agency. Within 30 days after receipt of this notification, FSIS may object to or require the establishment to make changes in the protocol.

(d) Expected elements of a protocol for gathering water retention data:

(1) *Purpose statement.* The primary purpose of the protocol should be to determine the amount or percentage of water absorption and retention that is unavoidable using a particular chilling system while achieving the regulatory pathogen reduction performance standard for *Salmonella* as set forth in the PR/HACCP regulations (9 CFR 310.25(b), 381.94(b)) and the time/temperature requirements set forth in 9 CFR 381.66. Additional purposes that could be included are determining chilling system efficiency and evaluating product quality.

(2) *Type of washing and chilling system used by the establishment.* Any post-evisceration washing or chilling processes that affect water retention levels in and microbial loads on raw products should be described. For poultry establishments, the main chiller types, identified by the mechanism used to transport the birds through the chiller or to agitate the water in the chiller, are the drag-through, the screw type, and the rocker-arm type.

(3) *Configuration and any modifications of the chiller system components.* A description of chiller-system configurations and modifications should be provided. The description should include the number and type of chillers in a series and arrangements of chilling system components, and the number of evisceration lines feeding into a chiller system. If there is a pre-chilling step in the process, its purpose and the type of equipment used should be accurately described. Any mechanical or design changes made to the chilling equipment should be described.

(4) *Special features in the chilling process.* Any special features in the chilling process, such as antimicrobial treatments, should be described. Also, the length and velocity of the dripping line should be described, as well as the total time allowed for dripping. Any special apparatus, such as a mechanism for squeezing excessive water from chilled birds, should be explained.

(5) *Description of variable factors in the chilling system.* The protocol should describe variable factors that affect water absorption and retention. In poultry processing, such factors are typically considered to be the time in chiller water, the water temperature, and agitation. The protocol should consider air agitation, where applicable. Additional factors that may affect water absorption and retention are scalding temperature and the pressure or amount of buffeting applied to birds by feather removal machinery, and the resultant loosening of the skin. Another factor that should be considered is the method used to open the bird for evisceration.

(6) *Standards to be met by the chilling system.* For example, the chilling system may be designed simply to achieve a reduction in temperature of ready-to-cook poultry to less than 40 °F within the time limit specified by the regulations, or in less time. As to the standard for pathogen minimization, the *Salmonella* pathogen reduction standards, as set forth in the PR/HACCP final rule, have been suggested. Although there is not yet an applicable *Salmonella* standard for turkeys, establishments are free to adopt practicable criteria for use in gathering data on turkeys under the protocols here suggested. Additional microbiological targets, such as *E. coli* or *Campylobacter* levels, or reductions in numbers of other microorganisms, may also be used.

(7) *Testing methods to be employed.* The protocol should detail the testing methods to be used both for measuring water absorption and retention and for sampling and testing product for pathogen reductions. The protocol should call for water retention and pathogen reduction tests at various chilling equipment settings and chilling time-and-temperature combinations. The method to be used in calculating water absorption and retention should be reproducible and statistically verifiable. With respect to the pathogen-reduction aspect of the testing, FSIS recommends the methods used for *E. coli* and *Salmonella* testing under the PR/HACCP regulations. The number of samples, the type of samples, the sampling time period, and the

type of testing or measurement should be included in the protocol.

(8) *Reporting of data and evaluation of results.* The protocol should explain how data obtained are to be reported and summarized. The criteria for evaluating the results and the basis for conclusions to be drawn should be explained.

(9) *Conclusions.* The protocol should provide for a statement of what the data obtained demonstrate and what conclusions were reached.

PART 500—RULES OF PRACTICE

Sec.
500.1 Definitions.
500.2 Regulatory control action.
500.3 Withholding or suspension of inspection without prior notification.
500.4 Withholding action or suspension of inspection with prior notification.
500.5 Notification, appeals, and actions held in abeyance.
500.6 Withdrawal of inspection.
500.7 Refusal to grant inspection.
500.8 Procedures for rescinding or refusing approval of marks, labels, sizes, and containers.

AUTHORITY: 21 U.S.C. 451–470, 601–695; 7 U.S.C. 450, 1901–1906; 7 CFR 2.18, 2.53.

SOURCE: 64 FR 66546, Nov. 29, 1999, unless otherwise noted.

§500.1 Definitions.

(a) A ''regulatory control action'' is the retention of product, rejection of equipment or facilities, slowing or stopping of lines, or refusal to allow the processing of specifically identified product.

(b) A ''withholding action'' is the refusal to allow the marks of inspection to be applied to products. A withholding action may affect all product in the establishment or product produced by a particular process.

(c) A ''suspension'' is an interruption in the assignment of program employees to all or part of an establishment.

§500.2 Regulatory control action.

(a) FSIS may take a regulatory control action because of:

(1) Insanitary conditions or practices;

(2) Product adulteration or misbranding;

(3) Conditions that preclude FSIS from determining that product is not adulterated or misbranded; or

(4) Inhumane handling or slaughtering of livestock.

(b) If a regulatory control action is taken, the program employee will immediately notify the establishment orally or in writing of the action and the basis for the action.

(c) An establishment may appeal a regulatory control action, as provided in §§306.5 and 381.35 of this chapter.

§500.3 Withholding action or suspension without prior notification.

(a) FSIS may take a withholding action or impose a suspension without providing the establishment prior notification because:

(1) The establishment produced and shipped adulterated or misbranded product as defined in 21 U.S.C. 453 or 21 U.S.C. 602;

(2) The establishment does not have a HACCP plan as specified in §417.2 of this chapter;

(3) The establishment does not have Sanitation Standard Operating Procedures as specified in §§416.11–416.12 of this chapter;

(4) Sanitary conditions are such that products in the establishment are or would be rendered adulterated;

(5) The establishment violated the terms of a regulatory control action;

(6) An establishment operator, officer, employee, or agent assaulted, threatened to assault, intimidated, or interfered with an FSIS employee; or

(7) The establishment did not destroy a condemned meat or poultry carcass, or part or product thereof, in accordance with part 314 or part 381, subpart L, of this chapter within three days of notification.

(b) FSIS also may impose a suspension without providing the establishment prior notification because the establishment is handling or slaughtering animals inhumanely.

§500.4 Withholding action or suspension with prior notification.

FSIS may take a withholding action or impose a suspension after an establishment is provided prior notification and the opportunity to demonstrate or achieve compliance because:

(a) The HACCP system is inadequate, as specified in § 417.6 of this chapter, due to multiple or recurring noncompliances;

(b) The Sanitation Standard Operating Procedures have not been properly implemented or maintained as specified in §§ 416.13 through 416.16 of this chapter;

(c) The establishment has not maintained sanitary conditions as prescribed in §§ 416.2–416.8 of this chapter due to multiple or recurring noncompliances;

(d) The establishment did not collect and analyze samples for *Escherichia coli* Biotype I and record results in accordance with § 310.25(a) or § 381.94(a) of this chapter;

(e) The establishment did not meet the *Salmonella* performance standard requirements prescribed in § 310.25(b) or § 381.94(b) of this chapter.

§ 500.5 Notification, appeals, and actions held in abeyance.

(a) If FSIS takes a withholding action or imposes a suspension, the establishment will be notified orally and, as promptly as circumstances permit, in writing. The written notification will:

(1) State the effective date of the action(s),

(2) Describe the reasons for the action(s),

(3) Identify the products or processes affected by the action(s),

(4) Provide the establishment an opportunity to present immediate and corrective action and further planned preventive action; and

(5) Advise the establishment that it may appeal the action as provided in §§ 306.5 and 381.35 of this chapter.

(b) The prior notification provided for in § 500.4 of this part will:

(1) State the type of action that FSIS may take;

(2) Describe the reason for the proposed action;

(3) Identify the products or processes affected by the proposed action;

(4) Advise the establishment of its right to contact FSIS to contest the basis for the proposed action or to explain how compliance has been or will be achieved; and

(5) Advise the establishment that it will have three business days from receipt of the written notification to respond to FSIS unless the time period is extended by FSIS.

(c) An establishment may appeal the withholding action or suspension, as provided in §§ 306.5 and 381.35 of this chapter.

(d) If FSIS suspends inspection and does not hold the suspension action in abeyance as provided in paragraph (e) of this section, the establishment may request a hearing pursuant to the Uniform Rules of Practice, 7 CFR Subtitle A, part 1, subpart H. Upon such request, the Administrator will file a complaint that will include a request for an expedited hearing.

(e) FSIS may hold a suspension in abeyance and allow the establishment to operate under the conditions agreed to by FSIS and the establishment.

§ 500.6 Withdrawal of inspection.

The FSIS Administrator may file a complaint to withdraw a grant of Federal inspection in accordance with the Uniform Rules of Practice, 7 CFR Subtitle A, part 1, subpart H because:

(a) An establishment produced and shipped adulterated product;

(b) An establishment did not have or maintain a HACCP plan in accordance with part 417 of this chapter;

(c) An establishment did not have or maintain Sanitation Standard Operating Procedures in accordance with part 416 of this chapter;

(d) An establishment did not maintain sanitary conditions;

(e) An establishment did not collect and analyze samples for *Escherichia coli* Biotype I and record results as prescribed in § 310.25(a) or § 381.94(a) of this chapter;

(f) An establishment did not comply with the Salmonella performance standard requirements as prescribed in §§ 310.25(b) and 381.94(b) of this chapter;

(g) An establishment did not slaughter or handle livestock humanely;

(h) An establishment operator, officer, employee, or agent assaulted, threatened to assault, intimidated, or interfered with an FSIS program employee; or

(i) A recipient of inspection or anyone responsibly connected to the recipient is unfit to engage in any business requiring inspection as specified in section 401 of the FMIA or section 18(a) of the PPIA.

§500.7 Refusal to grant inspection.

(a) The FSIS Administrator may refuse to grant Federal inspection because an applicant:

(1) Does not have a HACCP plan as required by part 417 of this chapter;

(2) Does not have Sanitation Standard Operating Procedures as required by part 416 of this chapter;

(3) Has not demonstrated that adequate sanitary conditions exist in the establishment as required by part 308 or part 381, subpart H, and part 416 of this chapter;

(4) Has not demonstrated that livestock will be handled and slaughtered humanely; or

(5) Is unfit to engage in any business requiring inspection as specified in section 401 of the FMIA or section 18(a) of the PPIA.

(b) If the Administrator refuses to grant inspection, the applicant will be provided the opportunity for a hearing in accordance with the Uniform Rules of Practice, 7 CFR Subtitle A, part 1, subpart H.

§500.8 Procedures for rescinding or refusing approval of marks, labels, and containers.

(a) FSIS may rescind or refuse approval of false or misleading marks, labels, or sizes or forms of any container for use with any meat or poultry product under section 7 of the FMIA or under section 8 of the PPIA.

(b) FSIS will provide written notification that:

(1) Explains the reason for rescinding or refusing the approval;

(2) Provides an opportunity for the establishment to modify the marking, labeling, or container so that it will no longer be false or misleading; and

(3) Advises the establishment of its opportunity to submit a written statement to respond to the notification and to request a hearing.

(c) If FSIS rescinds or refuses approval of false or misleading marks, labels, or sizes or forms of any container for use with any meat or poultry product, an opportunity for a hearing will be provided in accordance with the Uniform Rules of Practice, 7 CFR Subtitle A, part 1, subpart H.

SUBCHAPTER I—EGG PRODUCTS INSPECTION

PART 590—INSPECTION OF EGGS AND EGG PRODUCTS (EGG PRODUCTS INSPECTION ACT)

DEFINITIONS

Sec.
590.1 Meaning of words.
590.5 Terms defined.

ADMINISTRATION

590.10 Authority.
590.13 Federal and State cooperation.
590.17 Nondiscrimination.
590.18 OMB control numbers assigned pursuant to the Paperwork Reduction Act.

SCOPE OF INSPECTION

590.20 Inspection in accordance with methods prescribed or approved.
590.22 Basis of service.
590.24 Egg products plants requiring continuous inspection.
590.26 Egg products entering or prepared in official plants.
590.28 Other inspections.

RELATION TO OTHER AUTHORITIES

590.30 At official plants.
590.35 Eggs and egg products outside official plants.

EGGS AND EGG PRODUCTS NOT INTENDED FOR HUMAN FOOD

590.40 Continuous inspection not provided.
590.45 Prohibition on eggs and egg products not intended for use as human food.

REFRIGERATION OF SHELL EGGS

590.50 Temperature and labeling requirements.

EXEMPTIONS

590.100 Specific exemptions.
590.105 Suspension or termination of exemptions.

PERFORMANCE OF SERVICE

590.110 Licensed inspectors.
590.112 Suspension of license or authority; revocation.
590.114 Surrender of license.
590.116 Activities of inspectors.
590.118 Identification.
590.119 Political activity.
590.120 Financial interest of inspectors.
590.122 Time of inspection.
590.124 Schedule of operation of official plants.
590.126 Overtime inspection service.
590.128 Holiday inspection service.
590.130 Basis of billing plants.
590.132 Access to plants.
590.134 Accessibility of product and cooler rooms.
590.136 Facilities and equipment to be furnished by official plants for use of inspectors in performing service.

APPLICATION FOR SERVICE

590.140 How application shall be made.
590.142 Filing of application.
590.144 Authority of applicant.
590.146 Application for continuous inspection in official plants; approval.
590.148 Order of service.

INAUGURATION OF SERVICE

590.150 Official plant numbers.
590.155 Inauguration of service.

DENIAL OF SERVICE

590.160 Refusal, suspension, or withdrawal of service.
590.161 Termination of plant approval.

RECORDS AND RELATED REQUIREMENTS FOR EGGS AND EGG PRODUCTS HANDLERS AND RELATED INDUSTRIES

590.200 Records and related requirements.
590.220 Information and assistance to be furnished to inspectors.

ADMINISTRATIVE DETENTION

590.240 Detaining product.

APPEAL OF AN INSPECTION OR DECISION

590.300 Who may request an appeal inspection or review of an inspector's decision.
590.310 Where to file an appeal.
590.320 How to file an appeal.
590.330 When an application for an appeal inspection may be refused.
590.340 Who shall perform the appeal.
590.350 Procedures for selecting appeal samples.
590.360 Appeal inspection certificates.
590.370 Cost of appeals.

CERTIFICATES

590.400 Form of certificates.
590.402 Egg products inspection certificates.
590.404 Erasures or alterations made on official certificates.
590.406 Disposition of official certificates.

IDENTIFYING AND MARKING PRODUCT

590.410 Shell eggs and egg products required to be labeled.
590.411 Requirement of formulas and approval of labels for use in official egg products plants.

590.412 Form of official identification symbol and inspection mark.
590.414 Products bearing the official inspection mark.
590.415 Use of other official identification.
590.417 Unauthorized use or disposition of approved labels.
590.418 Supervision of marking and packaging.
590.419 Reuse of containers bearing official identification prohibited.

INSPECTION, REINSPECTION, CONDEMNATION, AND RETENTION

590.420 Inspection.
590.422 Condemnation.
590.424 Reinspection.
590.426 Retention.

ENTRY OF MATERIALS INTO OFFICIAL EGG PRODUCTS PLANTS

590.430 Limitation on entry of material.
590.435 Wholesomeness and approval of materials.
590.440 Processing ova.

SANITARY, PROCESSING, AND FACILITY REQUIREMENTS

590.500 Plant requirements.
590.502 Equipment and utensils; PCB–containing equipment.
590.504 General operating procedures.
590.506 Candling and transfer-room facilities and equipment.
590.508 Candling and transfer-room operations.
590.510 Classifications of shell eggs used in the processing of egg products.
590.515 Egg cleaning operations.
590.516 Sanitizing and drying of shell eggs prior to breaking.
590.520 Breaking room facilities.
590.522 Breaking room operations.
590.530 Liquid egg cooling.
590.532 Liquid egg holding.
590.534 Freezing facilities.
590.536 Freezing operations.
590.538 Defrosting facilities.
590.539 Defrosting operations.
590.540 Spray process drying facilities.
590.542 Spray process drying operations.
590.544 Spray process powder; definitions and requirements.
590.546 Albumen flake process drying facilities.
590.547 Albumen flake process drying operations.
590.548 Drying, blending, packaging, and heat treatment rooms and facilities.
590.549 Dried egg storage.
590.550 Washing and sanitizing room or area facilities.
590.552 Cleaning and sanitizing requirements.
590.560 Health and hygiene of personnel.
590.570 Pasteurization of liquid eggs.
590.575 Heat treatment of dried whites.

LABORATORY

590.580 Laboratory tests and analyses.

EXEMPTED EGG PRODUCTS PLANTS

590.600 Application for exemption.
590.610 Criteria for exemption.
590.620 Authority of applicant.
590.630 Filing of application.
590.640 Application for exemption; approval.
590.650 Exempted plant registration number.
590.660 Inspection of exempted plants.
590.670 Termination of exemption.
590.680 Approval of labeling for egg products processed in exempted egg products processing plants.

IDENTIFICATION OF RESTRICTED EGGS OR EGG PRODUCTS NOT INTENDED FOR HUMAN CONSUMPTION

590.800 Identification of restricted eggs.
590.840 Identification of inedible, unwholesome, or adulterated egg products.
590.860 Identification wording.

IMPORTS

590.900 Requirements for importation of egg products or restricted eggs into the United States.
590.905 Importation of restricted eggs or eggs containing more restricted eggs than permitted in the official standards for U.S. Consumer Grade B.
590.910 Eligibility of foreign countries for importation of egg products into the United States.
590.915 Foreign inspection certification required.
590.920 Importer to make application for inspection of imported eggs and egg products.
590.925 Inspection of imported egg products.
590.930 Imported egg products; retention in customs custody; delivery under bond; movement prior to inspection; sealing; handling; facilities, and assistance.
590.935 Means of conveyance and equipment used in handling egg products to be maintained in sanitary condition.
590.940 Marking of egg products offered for importation.
590.945 Foreign egg products offered for importation; reporting of findings to customs; handling of products refused entry.
590.950 Labeling of containers of eggs or egg products for importation.
590.955 Labeling of shipping containers of eggs or egg products for importation.
590.956 Relabeling of imported egg products.
590.960 Small importations for consignee's personal use, display, or laboratory analysis.
590.965 Returned U.S. inspected and marked products; not importations.

590.970 Charges for storage, cartage, and labor with respect to products imported contrary to the Act.

AUTHORITY: 21 U.S.C. 1031–1056.

SOURCE: 36 FR 9814, May 28, 1971, unless otherwise noted. Redesignated at 42 FR 32514, June 27, 1977 and 46 FR 63203, Dec. 31, 1981. Further redesignated at 63 FR 72353, Dec. 31, 1998.

DEFINITIONS

§ 590.1 Meaning of words.

Under these regulations, words in the singular shall be deemed to mean the plural and vice versa, as the case may demand.

§ 590.5 Terms defined.

For the purpose of these regulations, unless the context otherwise requires, the following terms shall be construed, respectively, as follows:

Acceptable means suitable for the purpose intended and acceptable to the Administrator.

Act means the applicable provisions of the Egg Products Inspection Act (Pub. L. 91–597, 84 Stat. 1620 *et seq.*).

Administrator means the Administrator of the Agricultural Marketing Service of the Department or any other officer or employee of the Department to whom there has heretofore been delegated, or to whom there may hereafter be delegated the authority to act in his stead.

Adulterated means any egg or egg product under one or more of the following circumstances:

(a) If it bears or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance, such article shall not be considered adulterated under this clause if the quantity of such substance in or on such article does not ordinarily render it injurious to health;

(b)(1) If it bears or contains any added poisonous or added deleterious substance (other than one which is (i) a pesticide chemical in or on a raw agricultural commodity; (ii) a food additive; or (iii) a color additive) which may in the judgment of the Secretary, make such article unfit for human food;

(2) If it is, in whole or in part, a raw agricultural commodity and such commodity bears or contains a pesticide chemical which is unsafe within the meaning of section 408 of the Federal Food, Drug, and Cosmetic Act;

(3) If it bears or contains any food additive which is unsafe within the meaning of section 409 of the Federal Food, Drug, and Cosmetic Act;

(4) If it bears or contains any color additive which is unsafe within the meaning of section 706 of the Federal Food, Drug, and Cosmetic Act: Provided, that an article which is not otherwise deemed adulterated under paragraph (b)(2), (3), or (4) of this definition shall nevertheless be deemed adulterated if use of the pesticide chemical, food additive, or color additive, in or on such article, is prohibited by regulations of the Secretary in official plants;

(c) If it consists in whole or in part of any filthy, putrid, or decomposed substance, or if it is otherwise unfit for human food;

(d) If it has been prepared, packaged, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health;

(e) If it is an egg which has been subjected to incubation or the product of any egg which has been subjected to incubation;

(f) If its container is composed, in whole or in part of any poisonous or deleterious substance which may render the contents injurious to health;

(g) If it has been intentionally subjected to radiation, unless the use of the radiation was in conformity with a regulation or exemption in effect pursuant to section 409 of the Federal Food, Drug, and Cosmetic Act; or

(h) If any valuable constituent has been, in whole or in part, omitted or abstracted therefrom; or if any substance has been substituted, wholly or in part therefor; or if damage or inferiority has been concealed in any manner; or if any substance has been added thereto or mixed or packed therewith so as to increase its bulk or weight, or reduce its quality or strength, or make it appear better or of greater value than it is.

Ambient temperature means the air temperature maintained in an egg storage facility or transport vehicle.

Applicant means any person who requests any inspection service as authorized under the Act or the regulations of this part.

Capable of use as human food means any egg or egg product, unless it is denatured, or otherwise identified, as required by these regulations to deter its use as human food.

Chief of the Grading Branch means Chief of the Poultry Grading Branch, Poultry Division, Agricultural Marketing Service.

Class means any subdivision of a product based on essential physical characteristics that differentiate between major groups of the same kind, type, or method of processing.

Commerce means interstate, foreign, or intrastate commerce.

Condition means any condition (including, but not being limited to, the state of preservation, cleanliness, soundness, wholesomeness, or fitness for human food) of any product which affects its merchantability; or any condition, including but not being limited to, the processing, handling, or packaging which affects such product.

Container or *Package* includes for egg products, any box, can, tin, plastic, or other receptacle, wrapper, or cover and for shell eggs, any carton, basket, case, cart, pallet, or other receptacle.

(a) *Immediate container* means any package or other container in which egg products or shell eggs are packed for household or other ultimate consumers.

(b) *Shipping container* means any container used in packing an immediate container.

Department means the U.S. Department of Agriculture.

Dirty egg or *Dirties* means an egg(s) that has an unbroken shell with adhering dirt or foreign material.

Egg means the shell egg of the domesticated chicken, turkey, duck, goose, or guinea. Some of the terms applicable to shell eggs are as follows:

(a) *Check* means an egg that has a broken shell or crack in the shell but has its shell membranes intact and contents not leaking.

(b) *Clean and sound shell egg* means any egg whose shell is free of adhering dirt or foreign material and is not cracked or broken.

(c) *Dirty egg* or *Dirties* means an egg(s) that has a shell that is unbroken and has adhering dirt, foreign material, or prominent stains.

(d) *Incubator reject* means an egg that has been subjected to incubation and has been removed from incubation during the hatching operations as infertile or otherwise unhatchable.

(e) *Inedible* means eggs of the following descriptions: Black rots, yellow rots, white rots, mixed rots, sour eggs, eggs with green whites, eggs with stuck yolks, moldy eggs, musty eggs, eggs showing blood rings, and eggs containing embryo chicks (at or beyond the blood ring stage).

(f) *Leaker* means an egg that has a crack or break in the shell and shell membranes to the extent that the egg contents are exposed or are exuding or free to exude through the shell.

(g) *Loss* means an egg that is unfit for human food because it is smashed or broken so that its contents are leaking; or overheated, frozen, or contaminated; or an incubator reject; or because it contains a bloody white, large meat spots, a large quantity of blood, or other foreign material.

(h) *Restricted egg* means any check, dirty egg, incubator reject, inedible, leaker, or loss.

Egg handler means any person, excluding the ultimate consumer, who engages in any business in commerce that involves buying or selling any eggs (as a poultry producer or otherwise), or processing any egg products, or otherwise using any eggs in the preparation of human food.

Egg product means any dried, frozen, or liquid eggs, with or without added ingredients, excepting products which contain eggs only in a relatively small proportion or historically have not been, in the judgment of the Secretary, considered by consumers as products of the egg food industry, and which may be exempted by the Secretary under such conditions as he may prescribe to assure that the egg ingredients are not adulterated and such products are not represented as egg products. For the purposes of this part, the following

products, among others, are exempted as not being egg products: Freeze-dried products, imitation egg products, egg substitutes, dietary foods, dried no-bake custard mixes, egg nog mixes, acidic dressings, noodles, milk and egg dip, cake mixes, French toast, and sandwiches containing eggs or egg products, provided, such products are prepared from inspected egg products or eggs containing no more restricted eggs than are allowed in the official standards for U.S. Consumer Grade B shell eggs. Balut and other similar ethnic delicacies are also exempted from inspection under this part.

Eggs of current production means shell eggs which have moved through the usual marketing channels since the time they were laid and are not in excess of 60 days old.

Fair Packaging and Labeling Act means the Act so entitled, approved November 3, 1966 (80 Stat. 1296), and Acts amendatory thereof or supplementary thereto.

Federal Food, Drug, and Cosmetic Act means the Act so entitled, approved June 25, 1938 (52 Stat. 1040), and Acts amendatory thereof or supplementary thereto.

Inspection means the application of such inspection methods and techniques as are deemed necessary by the responsible Secretary to carry out the provisions of the Egg Products Inspection Act and the regulations under this part.

Inspection service means the official service within the Department having the responsibility for carrying out the provisions of the Egg Products Inspection Act. Inspection service also means the activities performed, including official reporting by such official service.

Inspector/Grader means:

(a) Any employee or official of the United States Government authorized to inspect eggs or egg products under the authority of this part; or

(b) Any employee or official of the government of any State or local jurisdiction authorized by the Secretary to inspect eggs or egg products under the authority of this part, under an agreement entered into between the Secretary and the appropriate State or other agency.

Interested party means any person financially interested in a transaction involving any inspection or appeal inspection of any product, or the decision of an inspector.

Label means a display of any printed, graphic, or other method of identification upon the shipping container, if any, or upon the immediate container, including but not limited to, an individual consumer package of eggs and egg products, or accompanying such product.

Misbranded means any egg products which are not labeled and packaged in accordance with the requirements prescribed by regulations of the Administrator under this part.

National Supervisor means:

(a) The officer in charge of the inspection service; and

(b) Such other employee of the Service as may be designated by him.

Nest-run eggs means eggs which are packed as they come from the production facilities without having been washed, sized and/or candled for quality, with the exception that some checks, dirties, or other obvious undergrades may have been removed.

Official certificate means any certificate prescribed by regulations of the Administrator for issuance by an inspector or other person performing official functions under this part.

Official device means any device prescribed or authorized by the Secretary for use in applying any official mark.

Official identification means the official inspection mark or any other symbol prescribed by regulations of this part to identify the status of any article.

Official inspection mark means any symbol prescribed by the regulations of the Administrator showing that egg products were inspected in accordance with this part.

Official standard means the standards of quality, grades, and weight classes for eggs.

Office of inspection means the office of any inspector.

Pasteurize means the subjecting of each particle of egg products to heat or other treatments to destroy harmful viable microorganisms by such processes as may be prescribed by these regulations.

Person means any individual, partnership, corporation, association, or other business unit.

Pesticide chemical, Food additive, Color additive, and *Raw agricultural commodity* shall have the same meaning for purposes of this part as under the Federal Food, Drug, and Cosmetic Act.

Plant means any place of business where egg products are processed:

(a) *Exempted plant* means any plant where the Administrator has determined the facilities and operating procedures meet such standards as may be prescribed by this part, and where the eggs received or used in the manufacture of egg products contain no more restricted eggs than are allowed by the official standards of U.S. Consumer Grade B for shell eggs, and where an exemption has been granted.

(b) *Official plant* means any plant in which the plant facilities, methods of operation and sanitary procedures have been found suitable and adequate by the Administrator for the continuous inspection of egg products in accordance with this part and in which inspection service is carried on.

Potable water means water that has been approved by a State health authority or other agency or laboratory acceptable to the Administrator as safe for drinking and suitable for food processing.

Processing means manufacturing of egg products, including breaking eggs or filtering, mixing, blending, pasteurizing, stabilizing, cooling, freezing or drying, or packaging egg products at official plants.

Producer-packer means any producer who sorts eggs only from his own production and packs them into their various qualities.

Quality means the inherent properties of any product which determine its relative degree of excellence.

Regional Director means any employee of the Department in charge of inspection service in a designated geographical region.

Regulations means the provisions in this part.

Regulatory inspector means any employee of the U.S. Government, or State or local jurisdiction, who is authorized by the Secretary to make such inspections as required in § 590.28 of these regulations.

Sampling means the act of taking samples of any product for inspection or analyses.

Sanitize means the application of a bactericidal treatment which is approved as being effective in destroying microorganisms, including pathogens.

Secretary means the Secretary of Agriculture or his delegate.

Service means the Agricultural Marketing Service (AMS) of the Department.

Shell egg packer (grading station) means any person engaged in the sorting of eggs from sources other than or in addition to his own production into their various qualities, either mechanically or by other means.

Stabilization means the subjection of any egg product to a desugaring process.

State means any State of the United States, the Commonwealth of Puerto Rico, the Virgin Islands of the United States, and the District of Columbia.

Ultimate consumer means any household consumer, restaurant, institution, or any other party who has purchased or received shell eggs or egg products for consumption.

United States means the States.

Washed ungraded eggs means eggs which have been washed but not sized or segregated for quality.

White or albumen means, for the purpose of this part, the product obtained from the egg as broken from the shell and separated from the yolk.

[36 FR 9814, May 28, 1971, as amended at 37 FR 6657, Apr. 4, 1972; 40 FR 20057, May 8, 1975. Redesignated at 42 FR 32514, June 27, 1977, as amended at 43 FR 60138, Dec. 26, 1978. Redesignated at 46 FR 63203, Dec. 31, 1981, as amended at 47 FR 46070, Oct. 15, 1982; 47 FR 54421, Dec. 3, 1982; 54 FR 37289, Sept. 8, 1989; 60 FR 49168, Sept. 21, 1995; 60 FR 58199, Nov. 27, 1995; 63 FR 45674, Aug. 27, 1998; 63 FR 69971, Dec. 17, 1998]

ADMINISTRATION

§ 590.10 Authority.

The Administrator shall perform, for and under the supervision of the Secretary, such duties as the Secretary may require in the enforcement or administration of the provisions of the Act, and this part. The Administrator

may waive for a limited period any particular provisions of the regulations to permit experimentation so that new procedures, equipment, and processing techniques may be tested to facilitate definite improvements and at the same time to maintain full compliance with the spirit and intent of the regulations. The Agricultural Marketing Service and its officers and employees shall not be liable in damages through acts of commission or omission in the administration of this part.

[42 FR 2971, Jan. 14, 1977. Redesignated at 42 FR 32514, June 27, 1977, and further redesignated at 46 FR 63203, Dec. 31, 1981]

§ 590.13 Federal and State cooperation.

The Secretary shall, whenever he determines that it would effectuate the purposes of the Act, authorize the Administrator to cooperate with appropriate State and other governmental agencies in carrying out any provisions of the Egg Products Inspection Act and these regulations. In carrying out the provisions of the Act and the regulations, the Secretary may conduct such examinations, investigations, and inspections as he determines practicable through any officer or employee of any such agency commissioned by him for such purpose. The Secretary shall reimburse the States and other agencies for the services rendered by them in such cooperative programs as agreed to in the cooperative agreements as signed by the Administrator and the duly authorized agent of the State or other agency.

§ 590.17 Nondiscrimination.

The conduct of all services and the licensing of graders and inspectors under these regulations shall be accomplished without discrimination as to race, color, religion, sex, national origin, age, or disability.

[40 FR 20057, May 8, 1975. Redesignated at 42 FR 32514, June 27, 1977. Further redesignated at 46 FR 63203, Dec. 31, 1981, and amended at 60 FR 49169, Sept. 21, 1995]

§ 590.18 OMB control numbers assigned pursuant to the Paperwork Reduction Act.

(a) *Purpose.* This section collects and displays the control numbers assigned to information collection requirements by the Office of Management and Budget contained in 7 CFR 590 pursuant to the Paperwork Reduction Act of 1980, Pub. L. 96–511.

(b) *Display.*

7 CFR section where identified and described	Current OMB control number
§ 590.10	0581–0113
§ 590.13	0581–0113
§ 590.22	0581–0113
§ 590.28(a)(1)	0581–0113
§ 590.40	0581–0113
§ 590.45(c)(1)	0581–0113
§ 590.45(c)(3)	0581–0113
§ 590.45(d)	0581–0113
§ 590.110(a)	0581–0113
§ 590.112	0581–0113
§ 590.122	0581–0113
§ 590.124	0581–0113
§ 590.126	0581–0113
§ 590.128(a)	0581–0113
§ 590.140	0581–0113
§ 590.144	0581–0113
§ 590.146(b)	0581–0113
§ 590.146(d)	0581–0113
§ 590.155	0581–0113
§ 590.160(c)	0581–0113
§ 590.160(d)	0581–0113
§ 590.160(f)(3)	0581–0113
§ 590.160(f)(4)	0581–0113
§ 590.200(a)	0581–0113
§ 590.200(b)	0581–0113
§ 590.220	0581–0113
§ 590.240	0581–0113
§ 590.320	0581–0113
§ 590.402(a)	0581–0113
§ 590.411(a)	0581–0113
§ 590.411(b)	0581–0113
§ 590.411(e)	0581–0113
§ 590.411(f)	0581–0113
§ 590.418(c)	0581–0113
§ 590.430(b)	0581–0113
§ 590.435(b)	0581–0113
§ 590.435(c)	0581–0113
§ 590.440(c)	0581–0113
§ 590.500(h)	0581–0113
§ 590.504(c)	0581–0113
§ 590.504(d)	0581–0113
§ 590.504(h)	0581–0113
§ 590.504(k)	0581–0113
§ 590.504(o)(1)	0581–0113
§ 590.504(o)(2)	0581–0113
§ 590.504(o)(3)(i)	0581–0113
§ 590.504(o)(3)(iii)	0581–0113
§ 590.504(o)(3)(iv)	0581–0113
§ 590.504(o)(3)(v)	0581–0113
§ 590.515(a)(8)	0581–0113
§ 590.520(h)	0581–0113
§ 590.522(f)	0581–0113
§ 590.522(x)	0581–0113
§ 590.522(aa)(2)	0581–0113
§ 590.530(d)	0581–0113
§ 590.534(a)	0581–0113
§ 590.544(b)	0581–0113
§ 590.544(c)	0581–0113
§ 590.544(d)	0581–0113
§ 590.552(a)(3)	0581–0113
§ 590.552(b)(1)(i)	0581–0113
§ 590.552(b)(2)	0581–0113
§ 590.570(c)	0581–0113
§ 590.575(b)(3)	0581–0113
§ 590.575(d)	0581–0113

7 CFR section where identified and described	Current OMB control number
§590.580(c)	0581–0113
§590.600	0581–0113
§590.610(a)	0581–0113
§590.620	0581–0113
§590.640(b)(1)	0581–0113
§590.680(a)	0581–0113
§590.800	0581–0113
§590.840	0581–0113
§590.905(a)	0581–0113
§590.915(a)	0581–0113
§590.915(b)	0581–0113
§590.920	0581–0113
§590.930(f)	0581–0113
§590.950(a)	0581–0113
§590.960	0581–0113
§590.965	0581–0113

[48 FR 34238, July 28, 1983, as amended at 50 FR 23270, June 3, 1985; 54 FR 37290, Sept. 8, 1989]

SCOPE OF INSPECTION

§590.20 Inspection in accordance with methods prescribed or approved.

Inspection of eggs and egg products shall be rendered pursuant to these regulations and under such conditions and in accordance with such methods as may be prescribed or approved by the Administrator.

§590.22 Basis of service.

These regulations provide for inspection services pursuant to the Egg Products Inspection Act. Eggs and egg products shall be inspected in accordance with such standards, methods, and instructions as may be issued or approved by the Administrator. Inspection services shall be subject to supervision at all times by the applicable Federal-State supervisor, egg products supervisor, Regional Director, and National Supervisor.

§590.24 Egg products plants requiring continuous inspection.

No plant in which egg products processing operations are conducted shall process egg products without continuous inspection under these regulations, except as expressly exempted in §590.100.

§590.26 Egg products entering or prepared in official plants.

Eggs and egg products processed in an official plant shall be inspected, processed, marked, and labeled as required by these regulations. Egg products entering an official plant shall have been inspected, processed, marked, and labeled as required by these regulations.

§590.28 Other inspections.

(a) Periodic inspections shall be made of:

(1) The records of all persons engaged in the business of transporting, shipping, or receiving any eggs or egg products.

(2) Exempted plants to determine that such plants are operating pursuant to these regulations.

(b) Inspections shall be made of imported eggs and egg products as required in this part.

[36 FR 9814, May 28, 1971, as amended at 40 FR 20057, May 8, 1975. Redesignated at 42 FR 32514, June 27, 1977, and further redesignated at 46 FR 63203, Dec. 31, 1981, as and amended at 60 FR 49169, Sept. 21, 1995; 63 FR 45675, Aug. 27, 1998; 63 FR 69971, Dec. 17, 1998]

RELATION TO OTHER AUTHORITIES

§590.30 At official plants.

(a) Requirements within the scope of the Act with respect to premises, facilities, and operations of any official plant which are in addition to or different than those made under this part may not be imposed by any State or local jurisdiction except that any such jurisdiction may impose recordkeeping and other requirements within the scope of §590.200, if consistent therewith, with respect to any such plant.

(b) Labeling, packaging, or ingredient requirements in addition to or different than those made under this part, the Federal Food, Drug, and Cosmetic Act and the Fair Packaging and Labeling Act may not be imposed by any State or local jurisdiction with respect to egg products processed at any official plant in accordance with the requirements under this part and such Acts.

§590.35 Eggs and egg products outside official plants.

Any State or local jurisdiction may exercise jurisdiction with respect to eggs and egg products for the purpose of preventing the distribution for human food purposes of any such articles which are outside of the official

plant and are in violation of this part or any of said Federal Acts or any State or local law consistent therewith.

[36 FR 9814, May 28, 1971. Redesignated at 42 FR 32514, June 27, 1977, and further redesignated at 46 FR 63203, Dec. 31, 1981, as amended at 63 FR 69971, Dec. 17, 1998]

EGGS AND EGG PRODUCTS NOT INTENDED FOR HUMAN FOOD

§ 590.40 Continuous inspection not provided.

Continuous inspection shall not be provided under this part at any plant for the processing of any egg products which are not intended for use as human food, but such articles prior to their offer for sale or transportation in commerce shall be denatured or decharacterized unless shipped under seal as authorized in §§ 590.504(c), and identified as prescribed by the regulations in this part to prevent their use for human food. Periodic inspections shall be made of such operations and records to assure compliance with the Act and the regulations in this part.

[37 FR 6657, Apr. 1, 1972. Redesignated at 42 FR 32514, June 27, 1977, and further redesignated at 46 FR 63203, Dec. 31, 1981, as amended at 63 FR 69971, Dec. 17, 1998]

§ 590.45 Prohibition on eggs and egg products not intended for use as human food.

(a) No person shall buy, sell, or transport or offer to buy or sell, or offer or receive for transportation in commerce, any eggs or egg products which are not intended for use as human food, unless they are denatured or decharacterized, unless shipped under seal as authorized in paragraphs (c) and (d) of this section or in §§ 590.504(c) and 590.720(a) and identified as required by the regulations in this part.

(b) No person shall import or export shell eggs classified as loss, inedible, or incubator rejects or any egg products which are unwholesome, adulterated, or are otherwise unfit for human food purposes, except as provided in paragraphs (c) and (d) of this section, unless they are denatured or decharacterized and identified as required by the regulations in this part.

(c) Egg products which are unwholesome, adulterated, or are otherwise unfit for human food purposes that are not denatured or decharacterized may be exported to foreign countries for industrial use or animal food under the following provisions:

(1) Authorized government official of the foreign country shall approve the importation of such products into that country.

(2) The egg products shall be shipped under U.S. Government seal and identified as required in § 590.840.

(3) Provisions for the control of such inedible product in the foreign country to preclude its use as human food must be established and approved by the Administrator. Such control may consist of, but not be limited to, receipt and inspection by an appropriate U.S. Government official, an official of an approved meat, poultry, or egg products inspection system of the foreign government, or, when acceptable to the Administrator, a foreign government official including other foreign health authorities.

(d) Foreign governments may petition the Administrator for approval to import into this country egg products which are unwholesome, adulterated, or otherwise unfit for human food purposes that are not denatured or decharacterized for industrial use or animal food requirements. Such products shall be subject to the provisions of this part and other applicable laws and regulations for importation into the United States.

[48 FR 34238, July 28, 1983]

REFRIGERATION OF SHELL EGGS

§ 590.50 Temperature and labeling requirements.

(a) No shell egg handler shall possess any shell eggs that are packed into containers destined for the ultimate consumer unless they are stored and transported under refrigeration at an ambient temperature of no greater than 45°F (7.2°C).

(b) No shell egg handler shall possess any shell eggs that are packed into containers destined for the ultimate consumer unless they are labeled to indicate that refrigeration is required.

(c) Any producer-packer with an annual egg production from a flock of 3,000 or fewer hens is exempt from the temperature and labeling requirements of this section.

[63 FR 45675, Aug. 27, 1998]

EXEMPTIONS

§590.100 Specific exemptions.

The following are exempt to the extent prescribed as to the provision for continuous inspection of processing operations in section 5(a) of the Act: *Provided*, That the conditions for exemption and provisions of these regulations are met:

(a) [Reserved]

(b) Subject to the approval of the Administrator as provided in §§590.600 through 590.670, the processing of egg products without continuous inspection at any plant where the facilities, sanitation, and operating procedures are the same as are required in this part for official plants and where the eggs received or used in the manufacture of egg products contain no more restricted eggs than are allowed by the official standards for U.S. Consumer Grade B shell eggs, and the egg products processed at such plant;

(c)–(d) [Reserved]

(e) The processing and sale of egg products by any poultry producer from eggs of his own flock's production when sold directly to a household consumer exclusively for use by such consumer and members of his household and his nonpaying guests and employees;

(f) [Reserved]

(g) The processing in nonofficial plants, including but not limited to bakeries, restaurants, and other food processors, without continuous inspection, of certain categories of food products which contain eggs or egg products as an ingredient, and the sale and possession of such products: *Provided*, That such products are manufactured from inspected egg products processed in accordance with this part or from eggs containing no more restricted eggs than are allowed in the official standards for U.S. Consumer Grade B shell eggs;

[36 FR 9814, May 28, 1971, as amended at 40 FR 20057, May 8, 1975. Redesignated at 42 FR 32514, June 27, 1977, and further redesignated at 46 FR 63203, Dec. 31, 1981, as amended at 63 FR 69971, Dec. 17, 1998]

§590.105 Suspension or termination of exemptions.

(a) The Administrator may immediately suspend or terminate any exemption under §590.100(b) at any time with respect to any person, if the conditions of exemption prescribed by this section are not being met. The Administrator may modify or revoke any regulation of this part, granting exemptions whenever he determines such action appropriate to effectuate the purposes of the Act.

(b) Failure to comply with the condition of the exemptions contained in §590.100 shall subject such person to the penalties provided for in the Act and in this part.

[36 FR 9814, May 28, 1971, as amended at 40 FR 20057, May 8, 1975. Redesignated at 42 FR 32514, June 27, 1977, and further redesignated at 46 FR 63203, Dec. 31, 1981]

PERFORMANCE OF SERVICE

§590.110 Licensed inspectors.

(a) Any person who is a Federal or State employee, or the employee of a local jurisdiction possessing proper qualifications as determined by an examination for competency and who is to perform services pursuant to this part, may be licensed by the Secretary as an inspector.

(b) Licenses issued by the Secretary are to be countersigned by the Administrator or by any other designated official of the Service.

(c) No person may be licensed to inspect any product in which he is financially interested.

[36 FR 9814, May 28, 1971; 36 FR 10841, June 4, 1971. Redesignated at 42 FR 32514, June 27, 1977, and further redesignated at 46 FR 63203, Dec. 31, 1981]

§ 590.112 Suspension of license or authority; revocation.

Pending final action by the Secretary, any person authorized to countersign a license to perform inspection services may, whenever he deems such action necessary to assure that any inspection service is properly performed, suspend any license to perform inspection services issued pursuant to this part by giving notice of such suspension to the respective licensee, accompanied by a statement of the reasons therefor. Within 7 days after the receipt of the aforesaid notice and statement of reasons by the licensee, he may file an appeal in writing, with the Secretary, supported by any argument or evidence that he may wish to offer as to why his license should not be suspended or revoked. After the expiration of the aforesaid 7-day period and consideration of such argument and evidence, the Secretary will take such action as he deems appropriate with respect to such suspension or revocation. When no appeal is filed within the prescribed 7 days, the license is revoked or suspended.

§ 590.114 Surrender of license.

Upon termination of his services as an inspector or whenever his license has been suspended or revoked, the licensee shall surrender his license and other items of identification furnished by the Department immediately to the inspection service.

§ 590.116 Activities of inspectors.

Inspectors at official plants shall confine their activities to those duties necessary in the rendering of inspection service and such closely related activities as may be approved by the Administrator.

§ 590.118 Identification.

Inspectors shall have in their possession at all times while on duty, and present upon request, the means of identification furnished by the Department to such persons.

[36 FR 9814, May 28, 1971; 36 FR 10841, June 4, 1971. Redesignated at 42 FR 32514, June 27, 1977, and further redesignated at 46 FR 63203, Dec. 31, 1981]

§ 590.119 Political activity.

Inspectors are forbidden during the period of their respective appointments, or licenses, to take an active part in political management or in political campaigns. Political activity in city, county, State, or national elections, whether primary or regular, or in behalf of any party or candidate, except as authorized by law or regulation of the Department, is prohibited. This applies to all appointees, including but not being limited to temporary and cooperative employees and employees on leave of absence with or without pay. Willful violation of this section or § 590.120 will constitute grounds for dismissal in the case of appointees and revocation of licenses in the case of licensees.

[36 FR 9814, May 28, 1971, as amended at 42 FR 2971, Jan. 14, 1977. Redesignated at 42 FR 32514, June 27, 1977, and further redesignated at 46 FR 63203, Dec. 31, 1981]

§ 590.120 Financial interest of inspectors.

No inspector shall inspect any product in which he is financially interested.

§ 590.122 Time of inspection.

The inspector who is to perform the inspection in an official plant shall be given reasonable advance notice by plant management of the hours when such inspection will be required.

[60 FR 49169, Sept. 21, 1995]

§ 590.124 Schedule of operation of official plants.

Operating schedules for an official plant shall be subject to approval of the Administrator. The normal operating schedule shall consist of a continuous 8-hour period per day (excluding not to exceed 1 hour for lunch), 5 consecutive days per week, within the administrative workweek, Sunday through Saturday, for each full shift required. Clock hours of daily operations need not be specified in a schedule, although as a condition of continuance of approval of a schedule, the hours of operation must be reasonably uniform from day to day.

[48 FR 20683, May 9, 1983]

§ 590.126 Overtime inspection service.

When operations in an official plant require the services of inspection personnel beyond their regularly assigned tour of duty on any day or on a day outside the established schedule, such services are considered as overtime work. The official plant must give reasonable advance notice to the inspector of any overtime service necessary and must pay the Agency for such overtime at an hourly rate of $50.04.

[68 FR 37957, June 26, 2003]

§ 590.128 Holiday inspection service.

(a) When an official plant requires inspection service on a holiday or a day designated in lieu of a holiday, such service is considered holiday work. The official plant must, in advance of such holiday work, request the inspector in charge to furnish inspection service during such period and must pay the Agency for such holiday work at an hourly rate of $50.04.

(b) The term ''holiday'' shall mean the legal public holidays specified by the Congress in paragraph (a) of section 6103, title 5 of the United States Code. Information on legal holidays may be obtained from the supervisor.

[37 FR 6657, Apr. 1, 1972. Redesignated at 42 FR 32514, June 27, 1977, as amended at 46 FR 9, Jan. 2, 1981. Redesignated at 46 FR 63203, Dec. 31, 1981, as amended at 47 FR 46071, Oct. 15, 1982; 59 FR 52637, Oct. 18, 1994; 65 FR 60095, Oct. 10, 2000; 67 FR 3430, Jan. 24, 2002; 68 FR 37957, June 26, 2003]

§ 590.130 Basis of billing plants.

Overtime and/or holiday services shall be billed to the official plant on the basis of each 15 minutes of overtime and/or holiday service performed by each inspector providing such service to the plant, except that when an official plant requires the services of an inspector after he has completed his day's assignment and left the plant or when he is called back to duty on a day outside the established normal operating schedule or on a holiday, the official plant shall pay for a minimum of 2 hours service at the applicable established rate. Extra travel expense incurred while rendering overtime or holiday service shall be billed to the official plant. Bills are payable upon receipt and become delinquent 30 days from date of billing. Overtime or holiday inspection service will not be performed at any plant that is delinquent, and processing operations shall be confined to the regular operating schedule of the plant. In addition, fees will be charged and collected for certifications requested by and provided for the official plant that are not within the scope of these regulations.

[36 FR 9814, May 28, 1971. Redesignated at 42 FR 32514, June 27, 1977, and further redesignated at 46 FR 63203, Dec. 31, 1981, as amended at 60 FR 49169, Sept. 21, 1995; 65 FR 44950, July 20, 2000]

§ 590.132 Access to plants.

Access shall not be refused to any representative of the Secretary to any plant, place of business, or transport vehicle subject to inspection under the provisions of this part upon presentation of proper credentials.

[63 FR 45675, Aug. 27, 1998]

§ 590.134 Accessibility of product and cooler rooms.

(a) Each product for which inspection service is required shall be so placed as to disclose fully its class, quality, quantity, and condition as the circumstances may warrant.

(b) The perimeter of each cooler room used to store shell eggs packed in containers destined for the ultimate consumer shall be made accessible in order for the Secretary's representatives to determine the ambient temperature under which shell eggs are stored.

[36 FR 9814, May 28, 1971. Redesignated at 42 FR 32514, June 27, 1977, and further redesignated at 46 FR 63203, Dec. 31, 1981, as amended at 63 FR 45675, Aug. 27, 1998]

§ 590.136 Facilities and equipment to be furnished by official plants for use of inspectors in performing service.

(a) Such facilities and equipment shall include but not be limited to a room or area suitable for sampling product, and acceptable candling light, flashlight, heavy duty, high speed drill with an eleven sixteenths-inch or larger bit of sufficient length to reach the bottom of containers used for frozen eggs, metal stem thermometer(s), test

thermometer(s), stop watch, test weighing scale(s) and test weight(s), test kit for determining the bactericidal strength of sanitizing solutions, and stationary or adequately secured storage box or cage (capable of being locked only by the inspector) for holding official samples.

(b) Furnished office space and equipment, including but not being limited to a desk (equipped with a satisfactory locking device), lockers or cabinets suitable for the protection and storage of supplies, and facilities suitable for inspectors to change clothing.

[36 FR 9814, May 28, 1971. Redesignated at 42 FR 32514, June 27, 1977, and further redesignated at 46 FR 63203, Dec. 31, 1981, as amended at 60 FR 49169, Sept. 21, 1995]

APPLICATION FOR SERVICE

§ 590.140 How application shall be made.

The proprietor or operator of each plant processing egg products, unless exempted by § 590.100, shall make application to the Administrator for inspection service. The application shall be made in writing on forms furnished by the inspection service. In cases of change of name or ownership or change of location, a new application shall be made.

§ 590.142 Filing of application.

An application for inspection service shall be regarded as filed only when it has been filled in completely and signed by the applicant and has been received in the office of the Chief of the Grading Branch.

[36 FR 9814, May 28, 1971. Redesignated at 42 FR 32514, June 27, 1977, as amended at 43 FR 60138, Dec. 26, 1978. Redesignated at 46 FR 63203, Dec. 31, 1981]

§ 590.144 Authority of applicant.

Proof of authority of any person applying for inspection service may be required at the discretion of the Administrator.

§ 590.146 Application for continuous inspection in official plants; approval.

Any person desiring to process egg products under continuous inspection service must receive approval of such plant and facilities as an official plant prior to the installation of such service. An application for continuous inspection service to be installed in an official plant shall be approved according to the following procedure:

(a) Initial survey: When an application for continuous inspection in a plant has been filed, a supervisory egg products inspector will make a survey and inspection of the premises and plant to determine if the facilities and methods of operation therein are suitable and adequate for service in accordance with:

(1) These regulations, and

(2) Such other administrative instructions as may be issued from time to time by the Service and which are in effect at the time of the aforesaid survey and inspection.

(b) Drawings and specifications to be furnished:

(1) Applicants may obtain information or assistance as to the requirements before submitting prints of drawings, specifications, and supplemental information from the inspection service.

(2) Three copies of each print drawing as specified in this section of the complete floor plan, plot plan, supplemental information, and specifications shall be submitted. Sheet size of the print shall not exceed 34 by 44 inches, the wording shall be legible, all lines sharp and clear, and properly drawn to scale. Each print shall show the scale used, north point of the compass, and the firm name, street, city, state, and zip code or an accurate description of the location.

(3) Plot plan of entire premises shall include location of all buildings, railroads, roadways, alleys, wells, reservoirs, drains, catch basins, nearby buildings adjoining property, drainage and slope of terrain, character and surfacing of roadways, driveways, and vehicular loading areas. The plot plan may be drawn to a scale of one-thirty-second inch per foot.

(4) Floor plan prints shall include all space on each floor of the official plant, accurately illustrating and describing the facilities. Detailed drawings of processing area shall be drawn to a scale of one-fourth inch per foot. Prints showing only nonprocessing

areas may be drawn to a scale of one-eighth inch per foot.

(5) Floor plans shall show the location of such features as walls, partitions, posts, doorways, windows, floor drains and channel drains, air systems, ventilation fans, principal pieces of equipment, storage tanks, hose connections for cleaning purposes, hand-washing facilities, lockers, and toilets. The prints shall show slope of floors to drains.

(6) The official plant shall include all processing rooms and other rooms used in the official plant, including but not being limited to the breaking room, equipment washing and sanitizing rooms, shell egg washing rooms, packaging rooms, shell egg and egg products storage rooms (including coolers, freezers, hot rooms), drying rooms, toilet and dressing rooms, storerooms for supplies, and all other rooms, compartments, or passageways where products or any ingredients to be used in the preparation of products under this service will be handled or kept and may include other rooms located in the building comprising the official plant. Except in public warehouses, all rooms, compartments, etc., of the building not to be considered as part of the official plant shall not have direct access into any part of the official plant.

(7) Supplemental information may be shown as notations on the drawings or on supplemental sheets. Supplemental information shall include clarifying information such as sequence of processing edible products, handling of inedible product, shell disposal, handling of packaging material, liquid pumping systems, cleaned-in-place systems, description of pasteurizer, description of drier, type and efficiency of air filtration, hot water facilities, sewage disposal, and such other notations as may be required.

(8) Specification sheets shall include height of ceilings and type construction, type of floors, and wall construction, wall and partition material, and number of employees who will use each toilet room and facilities.

(c) Upon approval of the prints of drawing, supplemental information, and specifications, the application for service may be approved.

(d) Changes and revisions of official plant: When changes are planned in official plant construction, facilities, and equipment covered by previously approved prints, revised prints shall be submitted for review and approval prior to making the changes by: A completely revised sheet(s) showing proposed alterations and additions or an overlay print drawn to same scale as print to be modified or revised. A final survey of the completed alterations and additions shall be made by the supervisory egg products inspector to determine if the changes are in accordance with approved drawings and the regulations.

(e) Final survey and plant approval: Prior to the inauguration of continuous inspection service, a final survey of the plant and premises shall be made by the supervisory egg products inspector to determine if the plant is constructed and facilities are installed in accordance with the approved drawings and these regulations. The plant may be approved only when these requirements have been met.

[36 FR 9814, May 28, 1971; 36 FR 10841, June 4, 1971. Redesignated at 42 FR 32514, June 27, 1977, and further redesignated at 46 FR 63203, Dec. 31, 1981]

§ 590.148 Order of service.

Inspection service shall be performed, insofar as practicable, in the order in which applications therefor are made.

[36 FR 9814, May 28, 1971, as amended at 42 FR 2971, Jan. 14, 1977. Redesignated at 42 FR 32514, June 27, 1977, and further redesignated at 46 FR 63203, Dec. 31, 1981]

INAUGURATION OF SERVICE

§ 590.150 Official plant numbers.

An official plant number shall be assigned to each plant granted inspection service. Such plant number shall be used to identify all containers of inspected products prepared in the plant which are capable of use as human food. A plant shall not have more than one plant number.

§ 590.155 Inauguration of service.

Prior to the inauguration of service, the proprietor or operator of the plant

shall be knowledgeable of the requirements of these regulations.

[36 FR 9814, May 28, 1971. Redesignated at 42 FR 32514, June 27, 1977, and further redesignated at 46 FR 63203, Dec. 31, 1981, as amended at 60 FR 49169, Sept. 21, 1995]

DENIAL OF SERVICE

§ 590.160 Refusal, suspension, or withdrawal of service.

(a) The Administrator (for such period, or indefinitely, as he deems necessary to effectuate the purposes of the Act) may refuse to provide or may withdraw inspection service under this part with respect to any plant if he determines after opportunity for a hearing (following the procedures of 7 CFR, part 1, subpart H) is accorded to the applicant for, or recipient of, such service, that such applicant or recipient is unfit to engage in any business requiring inspection under the Act or this part, because the applicant or recipient or anyone responsibly connected with such person has been convicted in any Federal or State court, within the previous 10 years, of (1) any felony or more than one misdemeanor under any law based upon the acquiring, handling, or distributing of adulterated, mislabeled, or deceptively packaged food or fraud in connection with transactions in food or (2) any felony, involving, fraud, bribery, extortion, or any other act or circumstances indicating a lack of the integrity needed for the conduct of operations affecting the public health.

(b) For the purpose of this section, a person shall be deemed to be responsibly connected with the business if he is a partner, officer, director, holder, or owner of 10 percentum or more of its voting stock, or employee in a managerial or executive capacity.

(c) The determination and order of the Administrator with respect thereto under this section shall be final and conclusive unless the affected applicant for, or recipient of, inspection service files application for judicial review within 30 days after the effective date of such order in the U.S. Court of Appeals for the circuit in which such applicant or recipient has its principal place of business or in the U.S. Court of Appeals for the District of Columbia Circuit. Judicial review of any such order shall be upon the record upon which the determination and order are based. The provisions of section 204 of the Packers and Stockyards Act, 1921, as amended (7 U.S.C. 194) shall be applicable to appeals taken under this section. This section shall not affect in any way other provisions of the Act or these regulations for refusal of inspection services.

(d) Any applicant for inspection at a plant where the operations thereof may result in any discharge into the navigable waters in the United States is required by subsection 401(a)(1) (33 U.S.C. 1341) of the Clean Water Act as amended (86 Stat. 816, 91 Stat. 1566; 33 U.S.C. 1251 *et seq.*), to provide the Administrator with a certification, as prescribed in said subsection, that any such discharge will comply with the applicable provisions of sections 301, 302, 303, 306, and 307 of the Act (33 U.S.C. 1311, 1312, 1313, 1316, and 1317). No grant of inspection can be issued unless such certification has been obtained, or is waived, because of failure or refusal of the State, interstate agency, or the Administrator of the Environmental Protection Agency to act on a request for certification within a reasonable period (which shall not exceed 1 year after receipt of such request). Further, upon receipt of an application for inspection and a certification as required by subsection 401(a)(1) of the Clean Water Act, the Administrator (as defined in § 590.5) is required by subparagraph (2) of said subsection to notify the Administrator of the Environmental Protection Agency for proceedings in accordance with that subsection. No grant of inspection can be made until the requirements of 401(a) (1) and (2) have been met.

(e) Inspection may be suspended or revoked and plant approval terminated as provided in subsection 401(a) (4) and (5) of the Clean Water Act, as amended (33 U.S.C. 1341(a) (4) and (5)).

(f) Suspension of plant approval and withdrawal of service:

(1) Any plant approval given pursuant to these regulations may be suspended by the Administrator for (i) failure to maintain premises, facilities, and equipment in a satisfactory state of repair; (ii) the use of operating procedures or practices which are not in

accordance with the regulations; (iii) the alterations of buildings, facilities, or equipment which have not been approved in accordance with the regulations; or (iv) assaulting, intimidating, impeding, obstructing, or interfering with any person engaged in or on account of the performance of his official duties.

(2) During such period of suspension, no processing of egg products for commerce shall be carried on in the official plant. If the plant facilities or methods of operation are not brought into compliance within a reasonable period of time, to be specified by the Administrator, inspection service shall be withdrawn from the official plant. Upon withdrawal of inspection service in an official plant, the plant approval for processing egg products shall also become terminated.

(3) The operator shall be notified of the withdrawal action and the reasons therefor and afforded an opportunity to present his views informally prior to the effective date of such withdrawal, and upon written request, he shall be afforded an opportunity for a hearing in accordance with the applicable rules of practice (7 CFR, part 1, subpart H), with respect to the merits or validity of the withdrawal, but such a suspension or other withdrawal shall continue in effect pending the outcome of any such hearing unless otherwise ordered by the Administrator.

(4) In any case where inspection service is suspended under this paragraph (f) of this section, such service, after appropriate corrective action is taken, will be restored immediately, or as soon thereafter as an inspector can be made available. In any case where inspection service is withdrawn for a specified period under this paragraph (f) of this section, the person concerned may, after said specified period has expired, apply for inspection service as provided in §§ 590.140 through 590.146.

[36 FR 9814, May 28, 1971, as amended at 37 FR 6657, Apr. 1, 1972. Redesignated at 42 FR 32514, June 27, 1977, as amended at 43 FR 60138, Dec. 26, 1978; 45 FR 23640, Apr. 8, 1980. Redesignated at 46 FR 63203, Dec. 31, 1981]

§ 590.161 Termination of plant approval.

When inspection service is not performed at any plant for a period of at least 90 days, plant approval shall terminate upon notice by the Administrator without further proceedings; provided, however, that this section shall not apply to any plant where the Administrator determines that such a plant operates on a seasonal basis and the inspection service has not been used as a result of such seasonal operation, or where operations have ceased due to extraordinary circumstances determined by the Administrator as not warranting termination of plant approval.

[45 FR 23641, Apr. 8, 1980. Redesignated at 46 FR 63203, Dec. 31, 1981]

RECORDS AND RELATED REQUIREMENTS FOR EGGS AND EGG PRODUCTS HANDLERS AND RELATED INDUSTRIES

§ 590.200 Records and related requirements.

(a) Persons engaged in the business of transporting, shipping, or receiving any eggs or egg products in commerce, or holding such articles so received, and all egg handlers, including hatcheries, shall maintain records showing, for a period of 2 years, to the extent that they are concerned therewith, the receipt, delivery, sale, movement, and disposition of all eggs and egg products handled by them, and shall, upon the request of an authorized representative of the Secretary, permit him, at reasonable times, to have access to and to copy all such records.

(b) Production records by categories of eggs such as graded eggs, nest-run eggs, dirties, checks, leakers, loss, inedible, etc., bills of sale, inventories, receipts, shipments, shippers, receivers, dates of shipment and receipt, carrier names, etc., as determined by the Administrator, shall be maintained by all egg processing operations, except that, official egg products plants which use all shell eggs received and do not reship any shell eggs need only to maintain records indicating the amount of eggs received, date received,

and the name and address of the shipper.

[37 FR 6657, Apr. 1, 1972. Redesignated at 42 FR 32514, June 27, 1977, and further redesignated at 46 FR 63203, Dec. 31, 1981, as amended at 47 FR 745, Jan. 7, 1982; 63 FR 69971, Dec. 17, 1998]

§ 590.220 Information and assistance to be furnished to inspectors.

When inspection service is performed at any plant, the plant operator shall furnish the inspector such information and assistance as may be required for the performance of inspection functions, preparing certificates, reports, and for other official duties.

ADMINISTRATIVE DETENTION

§ 590.240 Detaining product.

Whenever any eggs or egg products subject to the Act are found by any authorized representative of the Secretary upon any premises, and there is reason to believe that they are or have been processed, bought, sold, possessed, used, transported, or offered or received for sale or transportation in violation of the Act or the regulations in this part, or that they are in any other way in violation of the Act, such articles may be detained by such representative for a period not to exceed 20 days, as more fully provided in section 19 of the Act. A detention tag or other similar device shall be used to identify detained product, and the custodian or owner shall be given a written notice of such detention. Only authorized representatives of the Secretary shall affix or remove detention identification. The provisions of this section shall in no way derogate from authority for condemnation or seizure conferred by other provisions of the Act, the regulations in this part, or other laws.

[37 FR 6658, Apr. 1, 1972. Redesignated at 42 FR 32514, June 27, 1977, and further redesignated at 46 FR 63203, Dec. 31, 1981, as amended at 63 FR 69972, Dec. 17, 1998]

APPEAL OF AN INSPECTION OR DECISION

§ 590.300 Who may request an appeal inspection or review of an inspector's decision.

Any appeal inspection may be requested by any interested party who is dissatisfied with the determination by an inspector of the class, quantity, or condition of any product, and a review may be requested by the operator of an official plant with respect to an inspector's decision or on any other matter related to inspection in the official plant.

[36 FR 9814, May 28, 1971. Redesignated at 42 FR 32514, June 27, 1977, and further redesignated at 46 FR 63203, Dec. 31, 1981, as amended at 60 FR 49169, Sept. 21, 1995]

§ 590.310 Where to file an appeal.

(a) *Appeal of resident inspector's inspection or decision in an official plant.* Any interested party who is not satisfied with the determination of the class, quantity, or condition of product which was inspected by an inspector in an official plant and has not left such plant, and the operator of any official plant who is not satisfied with a decision by an inspector on any other matter relating to inspection in such plant may request an appeal inspection or review of the decision by the inspector by filing such request with the inspector's immediate supervisor.

(b) *All other appeal requests.* Any interested party who is not satisfied with the determination of the class, quantity, or condition of product which has left the official plant where it was inspected may request an appeal inspection by filing such request with the Regional Director in the region where the product is located or with the Chief of the Grading Branch.

[36 FR 9814, May 28, 1971. Redesignated at 42 FR 32514, June 27, 1977, as amended at 43 FR 60138, Dec. 26, 1978. Redesignated at 46 FR 63203, Dec. 31, 1981, as amended at 60 FR 49169, Sept. 21, 1995; 63 FR 69972, Dec. 17, 1998]

§ 590.320 How to file an appeal.

The request for an appeal inspection or review of an inspector's decision may be made orally or in writing. If made orally, written confirmation may be required. The applicant shall clearly state the identity of the product, the decision which is questioned, and the reason(s) for requesting the appeal service. If such appeal request is based on the results stated on an official certificate, the original and all copies of the certificate available at the appeal inspection site shall be provided to the

inspector assigned to make the appeal inspection.

[60 FR 49169, Sept. 21, 1995]

§590.330 When an application for an appeal inspection may be refused.

When it appears to the official with whom an appeal request is filed that the reasons given in the request are frivolous or not substantial, or that the condition of the product has undergone a material change since the original inspection, or that the original lot has changed in some manner, or the Act or the regulations in this part have not been complied with, the applicant's request for the appeal inspection may be refused. In such case, the applicant shall be promptly notified of the reason(s) for such refusal.

[60 FR 49169, Sept. 21, 1995, as amended at 63 FR 69972, Dec. 17, 1998]

§590.340 Who shall perform the appeal.

(a) An appeal inspection or review of a decision requested under §590.310(a) shall be made by the inspector's immediate supervisor or by a licensed inspector assigned by the immediate supervisor other than the inspector whose inspection or decision is being appealed.

(b) The assignment of the inspector(s) who will make the appeal inspection under §590.310(b) shall be made by the Regional Director or the Chief of the Grading Branch, Poultry Division, Agricultural Marketing Service.

§590.350 Procedures for selecting appeal samples.

(a) *Prohibition on movement of product.* Products shall not have been moved from the place where the inspection being appealed was performed and must have been maintained under adequate refrigeration when applicable.

(b) *Laboratory analyses.* The appeal sample shall consist of product taken from the original sample containers plus an equal number of containers selected at random. When the original sample containers cannot be located, the appeal sample shall consist of product taken at random from double the number of original sample containers.

(c) *Condition inspection.* The appeal sample shall consist of product taken from the original sample containers plus an equal number of containers selected at random. A condition appeal cannot be made unless all originally sampled containers are available.

[36 FR 9814, May 28, 1971. Redesignated at 42 FR 32514, June 27, 1977, and further redesignated at 46 FR 63203, Dec. 31, 1981, as amended at 60 FR 49169, Sept. 21, 1995]

§590.360 Appeal inspection certificates.

Immediately after an appeal inspection is completed, an appeal certificate shall be issued to show that the original inspection was sustained or was not sustained. Such certificate shall supersede any previously issued certificate for the product involved and shall clearly identify the number and date of the superseded certificate. The issuance of the appeal certificate may be withheld until any previously issued certificate and all copies have been returned when such action is deemed necessary to protect the interest of the Government. When the appeal inspector assigns a different class to the lot or determines that a net weight shortage exists, the lot shall be retained pending correction of the labeling or approval of the product disposition by the National Supervisor.

[36 FR 9814, May 28, 1971. Redesignated at 42 FR 32514, June 27, 1977, and further redesignated at 46 FR 63203, Dec. 31, 1981, as amended at 60 FR 49169, Sept. 21, 1995]

§590.370 Cost of appeals.

(a) There shall be no cost to the appellant when the appeal inspection discloses a material error was made in the original determination.

(b) The costs of an appeal shall be borne by the appellant at an hourly rate of $27.36, including travel time and expenses if the appeal was frivolous, including but not being limited to the following: The appeal inspection discloses that no material error was made in the original inspection, the condition of the product has undergone a material change since the original inspection, the original lot has changed in some manner, or the Act or these

regulations have not been complied with.

[36 FR 9814, May 28, 1971. Redesignated at 42 FR 32514, June 27, 1977, as amended at 46 FR 49571, Oct. 7, 1981. Redesignated at 46 FR 63203, Dec. 31, 1981, as amended at 58 FR 57539, Oct. 26, 1993; 59 FR 52636, Oct. 18, 1994]

CERTIFICATES

§ 590.400 Form of certificates.

All certificates shall be issued on forms approved by the Administrator.

§ 590.402 Egg products inspection certificates.

(a) Upon request of the applicant or the Service, any inspector is authorized to issue an egg products inspection certificate with respect to any lot of egg products inspected by him. In addition, an inspector is authorized to issue an inspection certificate covering product inspected in whole or in part by another inspector when the inspector has knowledge that the product is eligible for certification based on personal examination of the product or official inspection records.

(b) Each egg products inspection certificate shall show the name and address of the processor, the class and quantity of the egg products covered by such certificate, such shipping marks as are necessary to identify such products, all pertinent information concerning the wholesomeness thereof, and such other information as the Administrator may prescribe or approve.

§ 590.404 Erasures or alterations made on official certificates.

Erasures or alterations shall be initialed by the issuing inspector on the original certificate and any copy thereof. All certificates made useless through clerical error or otherwise and all certificates canceled for whatever cause shall be voided and initialed and the original and all other copies shall be forwarded as prescribed by the Administrator.

§ 590.406 Disposition of official certificates.

The original and up to two copies of each official certificate shall be issued to the applicant or person designated by him. Other copies shall be filed and retained in accordance with the disposition schedule for inspection program records.

IDENTIFYING AND MARKING PRODUCT

§ 590.410 Shell eggs and egg products required to be labeled.

(a) All shell eggs packed into containers destined for the ultimate consumer shall be labeled to indicate that refrigeration is required, e.g., ''Keep Refrigerated,'' or words of similar meaning.

(b) Containers and portable tanks of edible egg products, prior to leaving the official plant, shall be labeled in accordance with §§ 590.411 through 590.415 and shall bear the official identification shown in Figure 2 of § 590.412 or Figure 3 or 4 of § 590.415. Bulk transport shipments of liquid pasteurized egg products to nonofficial outlets need not be sealed. Bulk shipments of liquid egg products transported from one official plant to another shall be sealed and accompanied by an official certificate.

[40 FR 20058, May 8, 1975. Redesignated at 42 FR 32514, June 27, 1977, and further redesignated at 46 FR 63203, Dec. 31, 1981, as amended at 63 FR 45675, Aug. 27, 1998]

§ 590.411 Requirement of formulas and approval of labels for use in official egg products plants.

(a) No label, container, or packaging material which bears official identification may bear any statement that is false or misleading. Any label, container, or packaging material which bears any official identification shall be used only in such manner as the Administrator may prescribe. No label, container, or packaging material bearing official identification may be used unless it is approved by the Administrator in accordance with paragraph (b) of this section. The use of finished labels must be approved as prescribed by the Administrator. If the label is printed on or otherwise applied directly to the container or packaging material, the principal display panel thereof shall be considered as the label.

(b) No label, container, or packaging material bearing official identification may be printed or prepared for use until the printers' or other final proof

has been approved by the Administrator in accordance with the regulations in this part, the Egg Products Inspection Act, the Federal Food, Drug, and Cosmetic Act, the Fair Packaging and Labeling Act, and the regulations promulgated under these acts. Copies of each label submitted for approval shall be accompanied by:

(1) A statement showing by their common or usual names the kinds and percentages of the ingredients comprising the egg product. A range may be given in cases where the percentages may vary from time to time. Formulas are to be expressed in terms of a liquid product except for products which are dry blended. Also, for products to be dried, the label may show the ingredients in the order of descending proportions by weight in the dried form. However, the formula submitted must include the percentage of ingredients in both liquid and dried form.

(2) When required, scientific data demonstrating that the substance or mixture is safe and effective for its intended use and does not promote deception or cause the product to be otherwise adulterated or misbranded.

(c) Containers of product bearing official identification shall display the following information:

(1) The common or usual name, if any, and if the product is comprised of two or more ingredients, such ingredients shall be listed in the order of descending proportions by weight in the form in which the product is to be marketed (sold), except that ingredients in dried products (other than dry blended) may be listed in either liquid or dried form. When water (excluding that used to reconstitute dehydrated ingredients back to their normal composition) is added to a liquid or frozen egg product or to an ingredient of such products (in excess of the normal water content of that ingredient), the total amount of water added, including the water content of any cellulose or vegetable gums used, shall be expressed as a percentage of the total product weight in the ingredient statement on the label.

(2) The name, address, and ZIP code of the packer or distributor. When the distributor is shown, it shall be qualified by such terms as ''packed for,'' ''distributed by,'' or ''distributors'';

(3) The lot number or approved alternative code number indicating date of production;

(4) The net contents;

(5) Official identification and plant number;

(6) Egg products which are produced in an official plant from edible shell eggs of other than current production or from other egg products produced from shell eggs of other than current production, shall be clearly and distinctly labeled in close proximity to the common or usual name of the product, e.g., ''Manufactured from eggs of other than current production'';

(7) Egg products produced from edible shell eggs or the egg product produced from such shell eggs of the turkey, duck, goose, or guinea shall be clearly and distinctly labeled as to the common or usual name of the product indicating the type of eggs or egg products used in the product, e.g., ''Frozen whole turkey eggs,'' ''Frozen whole chicken and turkey eggs.'' Egg products labeled without qualifying words as to the type of shell egg used in the product shall be produced only from the edible shell egg of the domesticated chicken or the egg product produced from such shell eggs.

(d) Liquid or frozen egg products identified as whole eggs and prepared other than in natural proportions, as broken from the shell, shall have a total egg solids content of 24.20 percent or greater.

(e) Nutrition information may be included on labels used to identify egg products, providing such labeling complies with the provisions of 21 CFR part 101, promulgated under the Federal Food, Drug, and Cosmetic Act and the Fair Packaging and Labeling Act. Since these regulations have different requirements for consumer packaged products than for bulk packaged egg products not for sale or distribution to household consumers, label submission shall be accompanied with information indicating whether the label covers consumer packaged or bulk packaged product. Nutrition labeling is required when nutrients, such as proteins, vitamins, and minerals are added to the product, or when a nutritional claim or information is presented on the labeling, except for the following which are

exempt from nutrition labeling requirements:

(1) Egg products shipped in bulk form for use solely in the manufacture of other food and not for distribution to household consumers in such bulk form or containers.

(2) Products containing an added vitamin, mineral, or protein, or for which a nutritional claim is made on the label, or in advertising, which is supplied for institutional food use only: *Provided*, That the manufacturer or distributor provides the required nutrition information directly to those institutions.

(3) Any nutrient(s) included in product solely for technological purpose may be declared solely in the ingredients statement, without complying with nutrition labeling, if the nutrient(s) is otherwise not referred to in labeling or in advertising. All labels showing nutrition information or claims are subject to review by the Food and Drug Administration prior to approval by the Department.

(f) If the Administrator has reason to believe that the statement on formulation shows the product to be adulterated or misbranded or that any labeling, or the size or form of any container in use or proposed for use in respect to egg products at any official plant is false or misleading in any way, he may direct that such use be withheld unless the labeling or container is modified in such a manner as he may prescribe so that it will not be false or misleading, and/or the formulation of the product is altered in such a manner that he may prescribe so that it is not adulterated, or would not cause misbranding. Any person so denied the approval of any label shall be notified promptly of the reasons for the denial on a form approved by the Administrator. If the person using or proposing to use the label does not accept the determination of the Administrator, he may request a hearing by filing with the Administrator within 10 days after receiving the notice of denial, a written application for a hearing setting forth specifically, the errors alleged to have been made by the Administrator in denying approval of the label. The use of the label shall be withheld pending hearing and final determination by the Administrator if the Administrator so directs. Hearings held pursuant to this subsection shall be presided at by the Administrator. The applicant shall be given the opportunity to present evidence both oral and written in support of his allegation that the Administrator erred in denying approval of the label. The notice of denial together with all other available data and information used as a basis for such denial shall be considered part of the record. The Administrator may take official notice of such matters as are judicially noticed by the Courts of the United States and of any other matter of technical, scientific, or commercial fact of established character. The Administrator shall make his final determination with respect to the matter upon the basis of evidence before him. Such determination shall be conclusive unless, within 30 days after the receipt of notice of such final determination, the person adversely affected thereby appeals to the U.S. Court of Appeals for the circuit in which he has his principal place of business, or to the U.S. Court of Appeals for the District of Columbia Circuit. The provisions of section 204 of the Packers and Stockyards Act of 1921, as amended, shall be applicable to appeals taken under this section.

[37 FR 6658, Apr. 1, 1972, as amended at 40 FR 20058, May 8, 1975. Redesignated at 42 FR 32514, June 27, 1977, as amended at 45 FR 23641, Apr. 8, 1980. Redesignated at 46 FR 63203, Dec. 31, 1981, as amended at 53 FR 23751, June 24, 1988; 60 FR 49169, Sept. 21, 1995]

§ 590.412 Form of official identification symbol and inspection mark.

(a) The shield set forth in Figure 1 containing the letters ''USDA'' shall be the official identification symbol for purposes of this part and, when used, imitated, or simulated in any manner in connection with a product, shall be deemed to constitute a representation that the product has been officially inspected.

(b) The inspection mark which is to be used on containers of edible egg products shall be contained within the outline of a shield and with the wording and design set forth in Figure 2 of this section, except the plant number may be preceded by the letter ''P'' in

lieu of the word ''plant''. Alternatively, it may be omitted from the official shield if applied on the container's principal display panel or other prominent location and preceded by the letter ''P'' or the word ''Plant''.

FIGURE 1.

FIGURE 2.

[36 FR 9814, May 28, 1971, as amended at 40 FR 20058, May 8, 1975. Redesignated at 42 FR 32514, June 27, 1977, and further redesignated at 46 FR 63203, Dec. 31, 1981, as amended at 60 FR 49170, Sept. 21, 1995]

§590.414 Products bearing the official inspection mark.

Egg products which are permitted to bear the inspection mark shall be processed in an official plant from edible shell eggs or other edible egg products and may contain other edible ingredients. The official mark shall be printed or lithographed and applied as a part of the principal display panel of the container but shall not be applied to a detachable cover.

§590.415 Use of other official identification.

Other official identification as shown in this section shall be printed or lithographed and applied as a part of the principal display panel, but shall not be applied to a detachable cover. The plant number may be omitted from the identification if applied elsewhere on the container's principal display panel or other prominent location and preceded by the letter ''P'' or the word ''plant''. Such products shall meet all requirements for egg products which are permitted to bear the official inspection mark shown in §590.412, except for pasteurization, heat treatment, or other such methods of treatment approved by the Administrator. Such products shall not be released into consuming channels until they have been subjected to pasteurization, heat treatment, or other approved methods of treatment.

(a) All nonpasteurized egg products, except as provided in paragraph (b) of this section, shipped from an official plant in packaged form shall be marked with the identification set forth in Figure 3 of this section. After pasteurization or treatment, the product may bear the official inspection mark as shown in §590.412.

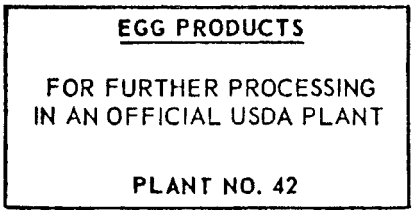

FIGURE 3.

(b) All nonpasteurized egg products, containing 10 percent or more added salt, shipped from an official plant in packaged form to an acidic dressing manufacturer shall be marked with the identification set forth in Figure 4 of this section.

UNPASTEURIZED
SALTED EGG PRODUCTS

FOR USE IN
ACIDIC DRESSINGS ONLY

PLANT NO. 42

FIGURE 4.

[36 FR 9814, May 28, 1971; 36 FR 10841, June 4, 1971. Redesignated at 42 FR 32514, June 27, 1977, and further redesignated at 46 FR 63203, Dec. 31, 1981, as amended at 60 FR 49170, Sept. 21, 1995]

§ 590.417 Unauthorized use or disposition of approved labels.

(a) Containers or labels which bear official identification approved for use pursuant to § 590.411 shall be used only for the purpose for which approved. Any unauthorized use or disposition of approved containers or labels which bear any official identification may result in cancellation of the approval and denial of the use of containers or labels bearing official identification and may subject such violator to the penalties and denial of the benefits of the Act;

(b) The use of simulations or imitations of any official identification by any person is prohibited;

(c) Upon termination of inspection service in an official plant pursuant to these regulations, all labels or packaging materials indicating product packed by the plant which bear official identification shall either be destroyed under the supervision of the Service or, if used in another location, modified in a manner acceptable to the Service before use.

[36 FR 9814, May 28, 1971, as amended at 40 FR 20059, May 8, 1975; 42 FR 2971, Jan. 14, 1977. Redesignated at 42 FR 32514, June 27, 1977, and further redesignated at 46 FR 63203, Dec. 31, 1981, as amended at 60 FR 49170, Sept. 21, 1995]

§ 590.418 Supervision of marking and packaging.

(a) *Evidence of label approval.* No inspector shall authorize the use of official identification on any inspected product unless he has on file evidence that such official identification or packaging material bearing such official identification has been approved in accordance with the provisions of § 590.411.

(b) *Affixing of official identification.* No official identification shall be, or caused to be affixed to or placed on any product or container except by an inspector or under the supervision of an inspector or other person authorized by the Administrator. All such products shall have been inspected in accordance with these regulations. The inspector shall have supervision over the use and handling of all material bearing any official identification.

(c) *Labels for products sold under Government contract.* The inspector in the official plant may approve use of labels for containers of product sold under a contract specification to governmental agencies when such product is not offered for resale to the general public: *Provided,* That the contract specifications have been approved by the Administrator and include complete specific requirements with respect to labeling and are made available to the inspector.

§ 590.419 Reuse of containers bearing official identification prohibited.

The reuse, by any person, of containers bearing official identification is prohibited unless such identification is applicable in all respects to product being packed therein. In such instances, the container and label may be used provided the packaging is accomplished under the supervision of an inspector and the container is in compliance with § 590.504(k).

INSPECTION, REINSPECTION, CONDEMNATION, AND RETENTION

§ 590.420 Inspection.

(a) Continuous inspection shall be made, pursuant to these regulations, of the processing of egg products in each official plant processing egg products for commerce unless exempted under § 590.100. Inspections, certifications, or specification-type gradings, and other inspections which may be requested by the official plant and are in addition to the normal inspection requirements and functions for the processing, production, or certification of a wholesome egg product under this part, shall

be made pursuant to the voluntary egg products inspection service (part 55 of this chapter).

(b) Any food manufacturing establishment or institution which uses any eggs that do not meet the requirements of §590.100(a) in the preparation of any articles for human food shall be deemed to be a plant processing egg products requiring continuous inspection under this part.

(c) Any product which is prepared under inspection in an official plant shall be inspected in such plant as often as the inspector deems necessary in order to ascertain if the product is unadulterated, wholesome, properly labeled, and fit for human food at the time it leaves the plant. Upon any such inspection, if any product or portion thereof is found to be adulterated, unwholesome, or otherwise unfit for human food, such product or portion thereof shall be condemned and shall receive such treatment as provided in §590.422.

§590.422 Condemnation.

Eggs and egg products found to be adulterated at official plants shall be condemned and, if no appeal be taken from such determination of condemnation, such articles shall be destroyed for human food purposes under the supervision of an inspector: *Provided,* That articles which may by reprocessing be made not adulterated need not be condemned and destroyed if so reprocessed under the supervision of an inspector and thereafter found to be not adulterated. If an appeal is requested, the eggs or egg products shall be appropriately marked and segregated pending completion of an appeal inspection. The appeal shall be at the cost of the appellant if the Administrator determines that the appeal is frivolous, as defined in §590.370.

§590.424 Reinspection.

(a) No egg product may be brought into an official plant except as provided in §590.430(b) unless it has been prepared and handled in accordance with these regulations, and the container of such product is marked so as to identify the article as so inspected in accordance with this part.

(b) All egg products shall be reinspected by an inspector at the time they are brought into the official plant. Upon reinspection, if any such product or portion thereof is found to be unsound, unwholesome, adulterated, or otherwise unfit for human food, such product or portion thereof, shall be condemned and shall receive such treatment as provided in §590.422, and shall, in the case of other products be disposed of according to applicable law.

§590.426 Retention.

Retention tags or other devices and methods as may be approved by the Administrator shall be used for the identification and control of products which are not in compliance with the regulations or are held for further examination, and any equipment, utensils, rooms or compartments which are found to be unclean or otherwise in violation of the regulations. No product, equipment, utensil, room, or compartment shall be released for use until it has been made acceptable. Such identification shall not be removed by anyone other than an inspector.

ENTRY OF MATERIAL INTO OFFICIAL EGG PRODUCTS PLANTS

§590.430 Limitation on entry of material.

(a) The Administrator shall limit the entry of eggs and egg products and other materials into official plants under such conditions as he may prescribe to assure that allowing the entry of such articles will be consistent with the purposes of the Act and these regulations.

(b) Inedible egg products may be brought into an official plant for storage and reshipment: *Provided,* they are handled in such a manner that adequate segregation and inventory controls are maintained at all times. Inedible egg products may be processed in official plants: *Provided,* That prior approval is obtained from the Administrator and under such conditions and time limitations as the Administrator may specify. The processing of inedible egg products shall be done under conditions which will not affect the processing of edible products, such as processing in separate areas, or at times

when no edible product is being processed. All equipment and processing areas must be thoroughly cleaned and sanitized prior to processing any edible product.

[36 FR 9814, May 28, 1971, as amended at 40 FR 20059, May 8, 1975. Redesignated at 42 FR 32514, June 27, 1977, and further redesignated at 46 FR 63203, Dec. 31, 1981]

§ 590.435 Wholesomeness and approval of materials.

(a) Substances and ingredients used in the manufacture or preparation of any egg product capable of use as human food shall be clean, wholesome, and unadulterated.

(b) The use of chemical additives in egg products shall be permitted only when they are approved by the Administrator. The Administrator may require, in addition to listing the ingredients, a declaration of the additive, and the purpose of its use.

(c) Chemical additives to be used in the preparation of egg products will be approved only if they comply with the following criteria:

(1) The additive shall be safe under the conditions of its intended use.

(2) The additive shall not promote deception or cause the product to be otherwise adulterated or unwholesome. Scientific data acceptable to the Administrator showing that the additive meets the criteria specified in this paragraph (c) shall be submitted by the person interested in having the additive approved.

(d) Containers and packing or packaging materials in which shell eggs are received into the official plant shall be free from odors and materials which could contaminate or adulterate the eggs or egg products.

§ 590.440 Processing ova.

(a) Ova from slaughtered poultry may be brought into the official plant for processing: *Provided,* That the ova is from wholesome poultry inspected in a plant operating under the Poultry Products Inspection Act (21 U.S.C. 451 *et seq.*) and such product is harvested in a sanitary manner, properly handled, cooled, packaged and labeled: *And provided further,* That such product is wholesome and the containers of such product bear official identification which assures the provisions of this paragraph have been met.

(b) The ova and products containing ova shall be processed, cooled, and pasteurized in the official plant in the same manner as liquid, frozen, or dried yolk products.

(c) The labeling for all products containing ova shall be approved by the Administrator prior to use.

SANITARY, PROCESSING, AND FACILITY REQUIREMENTS

§ 590.500 Plant requirements.

(a) The plant shall be free from objectionable odors, dust, and smokeladen air.

(b) The premises shall be free from refuse, rubbish, waste, and other materials and conditions which constitute a source of odors or a harbor for insects, rodents, and other vermin.

(c) The buildings shall be of sound construction and kept in good repair to prevent the entrance or harboring of vermin.

(d) Rooms shall be kept free from refuse, rubbish, waste materials, odors, insects, rodents, and from any conditions which may constitute a source of odors or engender insects and rodents. Materials and equipment not currently needed shall be handled or stored in a manner so as not to constitute a sanitary hazard.

(e) Doors and windows that open to the outside shall be protected against the entrance of flies and other insects. Doors and windows serving rooms where edible product is exposed shall be so designed and installed to prevent the entrance of dust and dirt. Doors leading into rooms where edible product is processed shall be of solid construction and such doors, other than freezer and cooler doors, shall be fitted with self-closing devices.

(f) Doors and other openings which are accessible to rodents shall be of rodent-proof construction.

(g) There shall be an efficient drainage and plumbing system for the plant and premises. Drains and gutters shall be properly installed with approved traps and vents. The sewage system shall have adequate slope and capacity to readily remove waste from the various processing operations. Floor

drains shall be equipped with traps, and constructed so as to minimize clogging. In new or remodeled construction the drainage systems from toilets and laboratories shall not be connected with other drainage systems within the plant.

(h) The water supply (both hot and cold) shall be ample, clean, and potable, with adequate pressure and facilities for its distribution throughout the plant or portion thereof utilized for egg processing and handling operations and protected against contamination and pollution. A water report, issued under the authority of a State or municipal health agency, certifying to the potability of the water supply shall be obtained by the applicant and furnished to the Administrator whenever such report is required by the Administrator.

(i) The floors, walls, ceiling, partitions, posts, doors, and other parts of all structures shall be of such materials, construction, and finish to permit their ready and thorough cleaning. The floors and curbing shall be watertight.

(j) Each room and each compartment in which any shell eggs or egg products are handled or processed shall be so designed, constructed, and maintained to insure processing and operating conditions of a clean and orderly character, free from objectionable odors and vapors, and maintained in a clean and sanitary condition.

(k) Every precaution shall be taken to exclude dogs, cats, and vermin (including, but not being limited to, rodents and insects) from the plant, or portion thereof utilized in which shell eggs or egg products are handled or stored.

(l)(1) There shall be a sufficient number of adequately lighted dressing rooms and toilet rooms, ample in size, conveniently located and separated from the rooms and compartments in which shell eggs or egg products are handled, processed, or stored. The dressing rooms and toilet rooms shall be separately ventilated, and shall meet all requirements as to sanitary construction and equipment.

(2) The following formula shall serve as a basis for determining the toilet facilities required:

Persons of same sex	Toilet bowls required
1 to 15, inclusive	1
16 to 35, inclusive	2
36 to 55, inclusive	[1] 3
56 to 80, inclusive	[1] 4
For each additional 30 persons in excess of 80	[1] 1

[1] Urinals may be substituted for toilet bowls but only to the extent of one-third of the total number of bowls stated.

(m) Lavatory accommodations (including, but not being limited to, hot and cold running water, single service towels, and soap which does not impart an odor which interferes with accurate evaluation of the product) shall be placed at such locations in the plant to assure cleanliness of each person handling any shell eggs or egg products. The hand washing facilities in the processing areas shall be operated by other than hand operated controls and the drains shall be trapped and connected to the plumbing system.

(n) Suitable facilities for cleaning and sanitizing utensils and equipment shall be provided at convenient locations throughout the plant.

(o) Refuse rooms shall be provided for the accumulation and storage of shells, trash, and other refuse. They shall be separate rooms completely enclosed without doorways opening into breaking rooms or rooms where egg products or packaging materials are handled or stored and have concrete floors with approved drains, facilities for cleaning, and an approved exhaust system vented to the outside. Alternative systems of handling shells, trash, and other refuse may be approved by the Administrator when such systems adequately contain all refuse and provide equivalent sanitary methods for the handling and removal of refuse.

[36 FR 9814, May 28, 1971; 36 FR 10841, June 4, 1971, as amended at 40 FR 20059, May 8, 1975. Redesignated at 42 FR 32514, June 27, 1977, as amended at 45 FR 23641, Apr. 8, 1980. Redesignated at 46 FR 63203, Dec. 31, 1981]

§ 590.502 Equipment and utensils; PCB-containing equipment.

(a) Equipment and utensils used in processing shell eggs and egg products shall be of such design, material, and construction as will:

(1) Enable the examination, segregation, and processing of such products in

an efficient, clean, and satisfactory manner;

(2) Permit easy access to all parts to insure thorough cleaning and sanitizing. So far as is practicable, all such equipment shall be made of metal or other impervious material which will not affect the product by chemical action or physical contact.

(b) Except as authorized by the Administrator, in new or remodeled equipment and equipment installations, the equipment and installation shall comply with the applicable 3–A or E–3–A Sanitary Standards and accepted practices currently in effect for such equipment.

(c) New or replacement equipment or machinery (including any replacement parts) brought onto the premises of any official plant shall not contain liquid polychlorinated biphenyls (PCBs) in concentrations above 50 parts per million by weight of the liquid medium. This provision applies to both food processing and nonfood processing equipment and machinery, and any replacement parts for such equipment and machinery. Totally enclosed capacitors containing less than 3 pounds of PCBs are exempted from this prohibition.

[36 FR 9814, May 28, 1971. Redesignated at 42 FR 32514, June 27, 1977, as amended at 45 FR 68919, Oct. 17, 1980. Redesignated at 46 FR 63203, Dec. 31, 1981, as amended at 60 FR 49170, Sept. 21, 1995]

§ 590.504 General operating procedures.

(a) Operations involving processing, storing, and handling of shell eggs, ingredients, and egg products shall be strictly in accord with clean and sanitary methods and shall be conducted as rapidly as practicable. Pasteurization, heat treatment, stabilization, and other processes shall be in accord with this part and as approved by the Administrator. Processing methods and temperatures in all operations shall be such as will prevent a deterioration of the egg products.

(b) Shell eggs and egg products processed in official plants shall be subjected to constant and continuous inspection throughout each and every processing operation. Any shell egg or egg product which was not processed in accordance with these regulations or is not fit for human food shall be removed and segregated.

(c) All loss and inedible eggs or egg products shall be placed in a container clearly labeled ''inedible'' and containing a sufficient amount of approved denaturant or decharacterant, such as FD&C brown, blue, black, or green colors, meat and fish by-products, grain and milling by-products, or any other substance, as approved by the Administrator, that will accomplish the purposes of this section. Shell eggs shall be crushed and the substance shall be dispersed through the product in amounts sufficient to give the product a distinctive appearance or odor. Notwithstanding the foregoing, and upon permission of the Inspector, the applicant may hold inedible product in containers clearly labeled inedible which do not contain a denaturant if such inedible product is denatured or decharacterized prior to shipment from the official plant: *Provided,* That such product is properly packaged, labeled, segregated, and inventory controls are maintained. In addition, product shipped from the official plant for industrial use or animal food need not be denatured or decharacterized, provided, that such product is properly packaged, labeled, segregated, and inventory controls are maintained, and that such product is shipped under Government seal and certificate and received at the destination location by an inspector or grader as defined in this part.

(d) The inspector may, prior to receipt of laboratory results for salmonella, or for other reasons such as labeling as to solids content, permit egg products to be shipped from the official plant when he has no reason to suspect noncompliance with any of the provisions of this part. However, such shipments shall be made under circumstances which will assure the return of the product to the plant for reprocessing, relabeling, or under such other conditions as the Administrator may determine to assure compliance with this part.

(e) Pasteurizing, stabilizing, or drying operations shall start as soon as practicable after breaking to prevent deterioration of product, preferably

within 72 hours from time of breaking for egg products other than whites which are to be desugared.

(f) Each person who is to handle any exposed or unpacked egg products or any utensils or container which may come into contact with egg product, shall wash his hands and maintain them in a clean condition.

(g) No product or material which creates an objectionable condition shall be processed, stored, or handled in any room, compartment, or place where any shell eggs or egg products are processed, stored or handled.

(h) Only germicides, insecticides, rodenticides, detergents, or wetting agents or other similar compounds which will not deleteriously affect the eggs or egg products when used in an approved manner and which have been approved by the Administrator, may be used in an official plant. The identification, storage, and use of such compounds shall be in a manner approved by the Administrator.

(i) Utensils and equipment which are contaminated during the course of processing any shell eggs or egg products shall be removed from use immediately and shall not be used again until cleaned and sanitized.

(j) Any substance or ingredient added in the processing of any egg products shall be clean and fit for human food.

(k) Packages or containers for egg products shall be of sanitary design and clean when being filled with any egg products; and all reasonable precautions shall be taken to avoid soiling or contaminating the surface of any package or container liner which is, or will be, in direct contact with such egg products. Only new containers or used containers that are clean, in sound condition and lined with suitable inner liners shall be used for packaging edible egg products. Fiber containers used without liners require the approval of the Administrator.

(l) Egg products shall be inspected to determine the wholesomeness of the finished product.

(m) Egg products shall be processed in such a manner as to insure the immediate removal of blood and meat spots, shell particles, and foreign materials.

(n) Utensils and equipment, except drying units, powder conveyors, sifters, blenders, and mechanical powder coolers shall be clean and sanitized at the start of processing operations. Equipment and utensils shall be kept clean and sanitary during all processing operations.

(o) Egg products prior to being released into consuming channels shall be pasteurized in accordance with § 590.570 except that dried whites prepared from nonpasteurized liquid shall be heat treated in accordance with § 590.575.

(1) To assure adequate pasteurization, egg products shall be sampled and tested for the presence of salmonella. Sampling for the presence of salmonella shall be in accordance with § 590.580 and product found to be salmonella positive shall be reprocessed, pasteurized, and analyzed for the presence of salmonella, or denatured.

(2) Nonpasteurized or salmonella positive egg product may be shipped from an official plant only when it is to be pasteurized, repasteurized, or heat treated in another official plant. Shipments of products from one official plant to another for pasteurization, repasteurization, or heat treatment shall be in sealed cars or trucks with an accompanying certificate stating that the product is not pasteurized or is salmonella positive. If nonpasteurized or salmonella positive products are to be stored in other than the official plant facilities, the inspector at the consignee's and consignor's plants shall be given full knowledge of the disposition of the product, including warehouse inventory receipts, until such time as product is pasteurized, repasteurized, or heat treated. The containers of such nonpasteurized or salmonella positive product shall be marked with the identification mark shown in Figure 3 of § 590.415.

(3) Notwithstanding the provision of paragraph (o)(2) of this section, nonpasteurized salted egg products containing 10 percent or more salt added may be shipped from an official plant directly to a manufacturer of acidic dressings only under the following provisions:

(i) Before such shipment is made, the manufacturer of the acidic dressing

shall apply in writing and receive permission from the Administrator to receive and use unpasteurized egg products. The applicant shall sign a written statement containing the specification for the treatment of the nonpasteurized egg product in a manner that will insure that viable salmonella microorganisms are destroyed, and such processing treatment shall be approved by the Administrator prior to use.

(ii) Product shall be shipped under seal from the official plant, accompanied by an official USDA certificate stating that the product is nonpasteurized and for use in acidic dressings only.

(iii) The applicant shall acknowledge receipt of each shipment by indicating on the reverse side of the USDA certificate. ''The quantity of nonpasteurized egg product stated on this certificate was received at _____,'' the blank being filled in with the name and address of the receiving company and the date and signature of the person completing the form. The certificate shall be returned to the USDA inspector at the origin plant.

(iv) The acidic dressing manufacturer shall maintain processing records indicating the use of each shipment of unpasteurized salted product and the code lots of acidic dressing into which it was processed. Records of the pH and the acidity expressed as percent acetic acid of each code lot shall be maintained. The records shall also demonstrate that the acidic dressing was held 72 hours prior to shipment. These records shall be maintained for 2 years and shall be available for inspection by a representative of the Department.

(v) Each container of salted egg product shipped from the official plant shall be labeled as required in § 590.411, and shall bear the words ''Caution—this egg product has not been pasteurized or otherwise treated to destroy viable salmonella microorganisms,'' and shall bear the official identification shown in figure 4 of § 590.415.

(p) Air which is to come in contact with product or with product contact surfaces shall come from approved filtered outside air sources.

(q) All liquid and solid waste material in the official plant shall be disposed of in a manner approved by the Administrator to prevent product contamination and in accordance with acceptable environmental protection practices.

[36 FR 9814, May 28, 1971, as amended at 37 FR 6658, Apr. 1, 1972; 40 FR 20059, May 8, 1975. Redesignated at 42 FR 32514, June 27, 1977, and further redesignated at 46 FR 63203, Dec. 31, 1981, as amended at 47 FR 745, Jan. 7, 1982; 60 FR 49170, Sept. 21, 1995]

§ 590.506 Candling and transfer-room facilities and equipment.

(a) The room shall be so constructed that it can be adequately darkened to assure accuracy in removal of inedible or loss eggs by candling. Equipment shall be arranged so as to facilitate cleaning and the removal of refuse and excess packing material.

(b) The construction of the floor shall allow thorough cleaning. The floors shall be of water-resistant composition and provided with proper drainage.

(c) An approved exhaust system shall be provided for the continuous removal directly to the outside of any steam, vapors, odors, or dust in the room. The room shall be maintained at reasonable working temperatures during operations.

(d) Candling devices of an approved type shall be provided to enable candlers to detect loss, inedible, dirty eggs, and eggs other than chicken eggs.

(e) Leaker trays shall be made of a material and of such design that is conducive to easy cleaning and sanitizing.

(f) Containers made of a material and of such design that are conducive to easy cleaning shall be provided for inedible eggs. All such containers shall be conspicuously marked.

(g) Containers made of a material and of such design that are conducive to easy cleaning shall be provided for trash unless clean, disposable containers are furnished daily.

(h) Shell egg conveyors shall be constructed so that they can be thoroughly cleaned.

[36 FR 9814, May 28, 1971, as amended at 37 FR 6659, Apr. 1, 1972. Redesignated at 42 FR 32514, June 27, 1977, and further redesignated at 46 FR 63203, Dec. 31, 1981, as amended at 60 FR 49170, Sept. 21, 1995]

§590.508 Candling and transfer-room operations.

(a) Candling and transfer rooms and equipment shall be kept clean, free from cobwebs, dust, objectionable odors, and excess packing materials.

(b) Containers for trash and inedible eggs shall be removed from the candling rooms as often as necessary but at least once daily; and shall be cleaned and treated in such a manner as will prevent off odors or objectionable conditions in the plant.

(c) Shell eggs shall be handled in a manner to minimize sweating prior to breaking.

(d) Shell eggs with extensively damaged shells, unless prohibited under §590.510(d), shall be placed into leaker trays and shall be broken promptly.

§590.510 Classifications of shell eggs used in the processing of egg products.

(a) The shell eggs shall be sorted and classified into the following categories in a manner approved by the National Supervisor:

(1) Eggs listed in paragraph (d) of this section.

(2) Dirty.

(3) Leakers as described in paragraph (c)(2) of this section.

(4) Eggs from other than chicken; duck, turkey, guinea, and goose eggs.

(5) Other eggs—satisfactory for use as breaking stock.

(b) Shell eggs having strong odors or eggs received in cases having strong odors shall be candled and broken separately to determine their acceptability.

(c) Shell eggs, when presented for breaking, shall be of edible interior quality and the shell shall be sound and free of adhering dirt and foreign material, except that:

(1) Checks and eggs with a portion of the shell missing may be used when the shell is free of adhering dirt and foreign material and the shell membranes are not ruptured.

(2) Eggs with clean shells which are damaged in candling and/or transfer and have a portion of the shell and shell membranes missing may be used only when the yolk is unbroken and the contents of the egg are not exuding over the outside shell. Such eggs shall be placed in leaker trays and be broken promptly.

(3) Eggs with meat or blood spots may be used if the spots are removed in an acceptable manner.

(d) All loss or inedible eggs shall be placed in a designated container and be handled as required in §590.504(c). Inedible and loss eggs for the purpose of this section and §590.522 are defined to include black rots, white rots, mixed rots, green whites, eggs with diffused blood in the albumen or on the yolk, crusted yolks, stuck yolks, developed embryos at or beyond the blood ring state, moldy eggs, sour eggs, any eggs that are adulterated as such term is defined pursuant to this part, and any other filthy and decomposed eggs including the following:

(1) Any egg with visible foreign matter other than removable blood and meat spots in the egg meat.

(2) Any egg with a portion of the shell and shell membranes missing and with egg meat adhering to or in contact with the outside of the shell.

(3) Any egg with dirt or foreign material adhering to the shell and with cracks in the shell and shell membranes.

(4) Liquid egg recovered from shell egg containers and leaker trays.

(5) Open leakers made in the washing operation.

(6) Any egg which shows evidence that the contents are or have been exuding prior to transfer from the case.

(e) Incubator reject eggs shall not be brought into the official plant.

[36 FR 9814, May 28, 1971, as amended at 40 FR 20059, May 8, 1975. Redesignated at 42 FR 32514, June 27, 1977, and further redesignated at 46 FR 63203, Dec. 31, 1981]

§590.515 Egg cleaning operations.

(a) The following requirements shall be met when washing shell eggs to be presented for breaking:

(1) Shell egg cleaning equipment shall be kept in good repair and shall be cleaned after each day's use or more frequently if necessary.

(2) The temperature of the wash water shall be maintained at 90 °F or higher, and shall be at least 20 °F warmer than the temperature of the eggs to be washed. These temperatures

shall be maintained throughout the cleaning cycle.

(3) An approved cleaning compound shall be used in the wash water. (The use of metered equipment for dispensing the compound into solution is recommended.)

(4) Wash water shall be changed approximately every 4 hours or more often if needed to maintain sanitary conditions and at the end of each shift. Remedial measures shall be taken to prevent excess foaming during the egg washing operation.

(5) Replacement water shall be added continuously to the wash water of washers to maintain a continuous overflow. Rinse water and chlorine sanitizing rinse may be used as part of the replacement water. Iodine sanitizing rinse may not be used as part of the replacement water.

(6) Waste water from the egg washing operation shall be piped directly to drains.

(7) The washing operation shall be continuous and shall be completed as rapidly as possible. Eggs shall not be allowed to stand or soak in water. Immersion-type washers shall not be used.

(8) Prewetting shell eggs prior to washing may be accomplished by spraying a continuous flow of water over the eggs in a manner which permits the water to drain away, or by other methods which may be approved by the Administrator.

(b) Shell eggs shall not be washed in the breaking room or any room where edible products are processed.

[36 FR 9814, May 28, 1971, as amended at 40 FR 20059, May 8, 1975. Redesignated at 42 FR 32514, June 27, 1977, and further redesignated at 46 FR 63203, Dec. 31, 1981, as amended at 60 FR 49170, Sept. 21, 1995]

§ 590.516 Sanitizing and drying of shell eggs prior to breaking.

(a) Immediately prior to breaking, all shell eggs shall be spray rinsed with potable water containing an approved sanitizer of not less than 100 ppm nor more than 200 ppm of available chlorine or its equivalent. Alternative procedures may be approved by the Administrator in lieu of sanitizing shell eggs washed in the plant.

(b) Shell eggs shall be sufficiently dry at time of breaking to prevent contamination or adulteration of the liquid egg product from free moisture on the shell.

[60 FR 49170, Sept. 21, 1995]

§ 590.520 Breaking room facilities.

(a) The breaking room shall have at least 30 foot-candles of light on all working surfaces except that light intensity shall be at least 50 foot-candles at breaking and inspection stations. Lights shall be protected with adequate safety devices.

(b) The surface of the ceiling and walls shall be smooth and made of a water-resistant material.

(c) The floor shall be of water-proof composition, reasonably free from cracks or rough surfaces, sloped for adequate drainage, and the intersections with walls and curbing shall be impervious to water.

(d) Ventilation shall provide for:

(1) A positive flow of outside filtered air through the room;

(2) Air of suitable working temperature during operations.

(e) There shall be provided adequate hand washing facilities which are easily accessible to all breaking personnel, an adequate supply of warm water, clean towels or other facilities for drying hands, odorless soap, and containers for used towels. Hand washing facilities shall be operated by other than hand operated controls.

(f) Containers for packaging egg products are not acceptable as liquid egg buckets.

(g) A suitable container conspicuously identified shall be provided for the disposal of rejected liquid.

(h) Strainers, filters, or centrifugal clarifiers of approved construction shall be provided for the effective removal of shell particles and foreign material, unless specific approval is obtained from the National Supervisor for other mechanical devices.

(i) A separate drawoff room with a filtered positive air ventilation system shall be provided for packaging liquid egg product, except product packaged

by automatic, closed packaging systems.

[36 FR 9814, May 28, 1971, as amended at 37 FR 6659, Apr. 1, 1972. Redesignated at 42 FR 32514, June 27, 1977, and further redesignated at 46 FR 63203, Dec. 31, 1981]

§ 590.522 Breaking room operations.

(a) The breaking room shall be kept in a dust-free clean condition and free from flies, insects, and rodents. The floor shall be kept clean and reasonably dry during breaking operations and free of egg meat and shells.

(b) All breaking room personnel shall wash their hands thoroughly with odorless soap and water each time they enter the breaking room and prior to receiving clean equipment after breaking an inedible egg.

(c) Paper towels or tissues shall be used at breaking tables, and shall not be reused. Cloth towels are not permitted.

(d) Breakers shall use a complete set of clean equipment when starting work and after lunch periods. All table equipment shall be rotated with clean equipment every 2½ hours.

(e) Cups shall not be filled to overflowing.

(f) Each shell egg shall be broken in a satisfactory and sanitary manner and inspected for wholesomeness by smelling the shell or the egg meat and by visual examination at the time of breaking. All egg meat shall be reexamined by a person qualified to perform such functions before being emptied into the tank or churn, except as otherwise approved by the National Supervisor.

(g) Shell particles, meat and blood spots, and other foreign material accidentally falling into the cups or trays shall be removed with a spoon or other approved instrument.

(h) Whenever an inedible egg is broken, the affected breaking equipment shall be cleaned and sanitized.

(i) Inedible and loss eggs as defined in § 590.510 apply to this section.

(j) The contents of any cup or other liquid egg receptacle containing one or more inedible or loss eggs shall be rejected.

(k) Contents of drip trays shall be emptied into a cup and smelled carefully before pouring into liquid egg bucket. Drip trays shall be emptied at least once for each 15 dozen eggs or every 15 minutes.

(l) Edible leakers as defined in § 590.510(c)(2) and checks which are liable to be smashed in the breaking operation shall be broken at a separate station by specially trained personnel.

(m) Ingredients and additives used in, or for, processing egg products, shall be handled in a clean and sanitary manner.

(n) Liquid egg containers shall not pass through the candling room.

(o) Test kits shall be provided and used to determine the strength of the sanitizing solution. (See §§ 590.515(a)(9) and 590.552.)

(p) Leaker trays shall be washed and sanitized whenever they become soiled and at the end of each shift.

(q) Shell egg containers whenever dirty shall be cleaned and drained; and shall be cleaned, sanitized, and drained at the end of each shift.

(r) Belt-type shell egg conveyors shall be cleaned and sanitized approximately every 4 hours in addition to continuous cleaning during operation. When not in use, belts shall be raised to permit air drying.

(s) Cups, knives, racks, separators, trays, spoons, liquid egg pails, and other breaking equipment, except for mechanical egg breaking equipment, shall be cleaned and sanitized at least every 2½ hours. This equipment shall be cleaned at the end of each shift and shall be clean and sanitized immediately prior to use.

(t) Utensils and dismantled equipment shall be drained and air dried on approved self-draining metal racks and shall not be nested.

(u) Dump tanks, drawoff tanks, and churns shall be cleaned approximately every 4 hours. All such equipment and all other liquid handling equipment, unless cleaned by acceptable cleaned in-place methods, shall be dismantled and cleaned after each shift. Pasteurization equipment shall be cleaned at the end of each day's use or more often if necessary. All such equipment shall be clean and shall be sanitized prior to placing in use.

(v) Strainers, clarifiers, filtering and other devices used for removal of shell particles and other foreign material

shall be cleaned and sanitized each time it is necessary to change such equipment, but at least once each 4 hours of operation.

(w) Breaking room processing equipment shall not be stored on the floor.

(x) Metal containers and lids for other than dried products shall be thoroughly washed, rinsed, sanitized, and drained immediately prior to filling. The foregoing sequence shall not be required if equally effective measures approved by the National Supervisor in writing are followed to assure clean and sanitary containers at the time of filling.

(y) Liquid egg holding vats and containers (including tank trucks) used for transporting liquid eggs shall be cleaned after each use. Such equipment shall be clean and sanitized immediately prior to placing in use.

(z) Tables, shell conveyors, and containers for inedible egg product shall be cleaned at the end of each shift.

(aa) Mechanical egg breaking machines shall be operated at a rate to maintain complete control and accurately inspect and segregate each egg to insure the removal of all loss and inedible eggs. The machine shall be operated in a sanitary manner.

(1) When an inedible egg is encountered on mechanical egg breaking equipment, the inedible egg and contaminated liquid shall be removed. The machine shall be cleaned and sanitized, or contaminated parts replaced with clean ones in the manner prescribed by the Administrator for the type of inedible egg encountered and the kind of egg breaking machine.

(2) Systems for pumping egg liquid directly from egg breaking machines shall be of approved sanitary design and construction, and designed to minimize the entrance of shells into the system and be disconnected when inedible eggs are encountered. The pipelines of the pumping system shall be cleaned or flushed as often as needed to maintain them in a sanitary condition, and they shall be cleaned and sanitized at the end of each shift. Other pumping system equipment shall be cleaned and sanitized approximately every 4 hours or as often as needed to maintain it in a sanitary condition. All liquid egg pumped directly from egg breaking machines shall be reexamined, except as otherwise prescribed and approved by the Administrator.

(3) Mechanical egg breaking equipment shall be clean and sanitized prior to use, and during operations the machines shall be cleaned and sanitized approximately every 4 hours or more often if needed to maintain them in a sanitary condition. This equipment shall be cleaned at the end of each shift.

[36 FR 9814, May 28, 1971, as amended at 37 FR 6659, Apr. 1, 1972; 40 FR 20059, May 8, 1975; 40 FR 20941, May 14, 1975. Redesignated at 42 FR 32514, June 27, 1977, and further redesignated at 46 FR 63203, Dec. 31, 1981]

§ 590.530 Liquid egg cooling.

(a) Liquid egg storage rooms, including surface coolers and holding tank rooms, shall be kept clean and free from objectionable odors and condensation. Surface coolers and liquid holding vats containing product shall be kept covered while in use. Liquid cooling units shall be of approved construction and have sufficient capacity to cool all liquid eggs to the temperature requirements specified in this section.

(b) Compliance with temperature requirements applying to liquid eggs shall be considered as satisfactory only if the entire mass of the liquid meets the requirements.

(c) The cooling and temperature requirements for liquid egg products shall be as specified in Table I of this section.

TABLE I—MINIMUM COOLING AND TEMPERATURE REQUIREMENTS FOR LIQUID EGG PRODUCTS

[Unpasterurized product temperature within 2 hours from time of breaking]

Product	Liquid (other than salt product) to be held 8 hours or less	Liquid (other than salt product) to be held in excess of 8 hours	Liquid salt product	Temperature within 2 hours after pasteurization	Temperature within 3 hours after stabilization
Whites (not to be stabilized)	55 °F. or lower	45 °F. or lower	.....	45 °F. or lower	
Whites (to be stabilized)	70 °F. or lower	55 °F. or lower	.....	55 °F. or lower	(1)

TABLE I—MINIMUM COOLING AND TEMPERATURE REQUIREMENTS FOR LIQUID EGG PRODUCTS—Continued

[Unpasterurized product temperature within 2 hours from time of breaking]

Product	Liquid (other than salt product) to be held 8 hours or less	Liquid (other than salt product) to be held in excess of 8 hours	Liquid salt product	Temperature within 2 hours after pasteurization	Temperature within 3 hours after stabilization
All other product (except product with 10 percent or more salt added).	45 °F. or lower	40 °F. or lower	.....	If to be held 8 hours or less 45 °F. or lower. If to be held in excess of 8 hours, 40 °F. or lower.	If to be held 8 hours or less, 45 °F. or lower. If to be held in excess of 8 hours, 40 °F. or lower.
Liquid egg product with 10 percent or more salt added.	.....	.....	If to be held 30 hours or less, 65 °F. or lower. If to be held in excess of 30 hours, 45 °F. or lower.	65 °F. or lower[2].	

[1] Stabilized liquid whites shall be dried as soon as possible after removal of glucose. The storage of stabilized liquid whites shall be limited to that necessary to provide a continuous operation.

[2] The cooling process shall be continued to assure that any salt product to be held in excess of 24 hours is cooled and maintained at 45 °F. or lower.

(d) Upon written request and under such conditions as may be prescribed by the National Supervisor, liquid cooling and holding temperatures not otherwise provided for in this section may be approved.

(e) Agitators shall be operated in such a manner as will minimize foaming.

(f) When ice is used as an emergency refrigerant by being placed directly into the egg meat, the source of the ice must be certified by the local or State board of health. Such liquid shall be dried. All ice shall be handled in a sanitary manner.

(g) Previously frozen egg or egg product cannot be added to liquid product for the purpose of complying with liquid cooling requirements.

[36 FR 9814, May 28, 1971. Redesignated at 42 FR 32514, June 27, 1977 and further redesignated at 46 FR 63203, Dec. 31, 1981, as amended at 47 FR 745, Jan. 7, 1982; 60 FR 49170, Sept. 21, 1995]

§ 590.532 Liquid egg holding.

(a) Tanks and vats used for holding liquid eggs shall be of approved construction, fitted with covers, and located in rooms maintained in a sanitary condition. Notwithstanding the foregoing, tanks designed for installation partially outside of a room or building are acceptable, providing all openings into the tanks terminate in the processing room.

(b) Liquid egg holding tanks or vats shall be equipped with suitable thermometers and agitators.

(c) Inlets to holding tanks or vats shall be such as to prevent excessive foaming.

(d) Gaskets, if used, shall be of a sanitary type.

[36 FR 9814, May 28, 1971. Redesignated at 42 FR 32514, June 27, 1977, as amended at 45 FR 23641, Apr. 8, 1980. Redesignated at 46 FR 63203, Dec. 31, 1981]

§ 590.534 Freezing facilities.

(a) Freezing rooms, either on or off the premises, shall be capable of freezing all liquid egg products in accordance with the freezing requirements as set forth in § 590.536. Use of off-premise freezing facilities is permitted only when prior approval in writing from the National Supervisor is on file.

(b) Adequate air circulation shall be provided in all freezing rooms.

§ 590.536 Freezing operations.

(a) Freezing rooms shall be kept clean and free from objectionable odors.

(b) Requirements. (1) Nonpasteurized egg products which are to be frozen shall be solidly frozen or reduced to a temperature of 10 °F or lower within 60 hours from time of breaking.

(2) Pasteurized egg products which are to be frozen shall be solidly frozen or reduced to a temperature of 10 °F or lower within 60 hours from time of pasteurization.

(3) The temperature of the products not solidly frozen shall be taken at the center of the container to determine compliance with this section.

(c) Containers shall be stacked so as to permit circulation of air around the containers.

(d) The outside of liquid egg containers shall be clean and free from evidence of liquid egg.

(e) Frozen egg products shall be examined by organoleptic examination after freezing to determine their fitness for human food. Any such products which are found to be unfit for human food shall be denatured and any official identification mark which appears on any container thereof shall be removed or completely obliterated and the containers identified as required in §§ 590.840 and 590.860.

§ 590.538 Defrosting facilities.

(a) Approved metal defrosting tanks or vats constructed so as to permit ready and thorough cleaning shall be provided.

(b) Frozen egg crushers, when used, shall be of approved metal construction. The crushers shall permit ready and thorough cleaning and the bearings and housing shall be fabricated in such a manner as to prevent contamination of the egg products.

(c) Service tables shall be of approved metal construction without open seams and the surfaces shall be smooth to allow thorough cleaning.

§ 590.539 Defrosting operations.

(a) Frozen egg products which are to be defrosted shall be defrosted in a sanitary manner.

(b) Each container of frozen eggs shall be checked for condition and odor just prior to being emptied into the crusher or receiving tank. Frozen eggs which have objectionable odors and are unfit for human food (e.g., sour, musty, fermented, or decomposed odors) shall be denatured.

(c) Frozen whites to be used in the production of dried albumen may be defrosted at room temperature. All other whites shall be defrosted in accordance with paragraph (d) of this section.

(d) Frozen whole eggs, whites and yolks, and yolks may be tempered or partially defrosted for not to exceed 48 hours at a room temperature no higher than 40 °F. or not to exceed 24 hours at a room temperature above 40 °F.: *Provided,* That no portion of the defrosted liquid shall exceed 50 °F. while in or out of the container.

(1) Frozen eggs packed in metal or plastic containers may be placed in running tap water (70 F° or lower) without submersion to speed defrosting.

(2) The defrosted liquid shall be held at 40 °F. or less, except for product to be pasteurized or stabilized by glucose removal as provided in § 590.530. Defrosted liquid shall not be held more than 16 hours prior to processing or drying.

(e) Sanitary methods shall be used in handling containers and removing egg product.

(f) Crushers and other equipment used in defrosting operations shall be dismantled at the end of each shift and shall be washed, rinsed, and sanitized.

(1) Where crushers are used intermittently, they shall be flushed after each use and again before being placed in use.

(2) Floors and work tables shall be kept clean.

[36 FR 9814, May 28, 1971. Redesignated at 42 FR 32514, June 27, 1977, as amended at 43 FR 60138, Dec. 26, 1978. Redesignated at 46 FR 63203, Dec. 31, 1981, as amended at 60 FR 49170, Sept. 21, 1995]

§ 590.540 Spray process drying facilities.

(a) Driers shall be of a continuous discharge type and so constructed and equipped to prevent an excess accumulation of powder in the drier, bags, and powder conveyors.

(b) Driers shall be of approved construction and materials, with welded seams, and the surfaces shall be smooth to allow for thorough cleaning.

(c) Driers shall be equipped with approved air intake filters.

(d) Air shall be drawn into the drier from sources free from foul odors, dust, and dirt.

(e) Indirect heat or the use of an approved premixing device or other approved devices for securing complete combustion in direct-fired units is required. A premix-type burner, if used, shall be equipped with approved air filters at blower intake.

(f) High-pressure pump heads and lines shall be of stainless steel construction or equivalent which will allow for thorough cleaning.

(g) Preheating units, if used, shall be of stainless steel construction, or equivalent which will allow thorough cleaning.

(h) Powder conveying equipment shall be so constructed as will facilitate thorough cleaning.

(i) Sifters shall be constructed of an approved metal or metal lined interior. The sifting screens and frames shall be of an approved metal construction. Sifters shall be so constructed that accumulations of large particles or lumps of dried eggs can be removed continuously while the sifters are in operation.

[36 FR 9814, May 28, 1971; 36 FR 10841, June 4, 1971. Redesignated at 42 FR 32514, June 27, 1977, and further redesignated at 46 FR 63203, Dec. 31, 1981]

§ 590.542 Spray process drying operations.

(a) The drying room shall be kept in a clean condition and free of flies, insects, and rodents.

(b) Low-pressure lines, high-pressure lines, high- and low-pressure pumps, homogenizers, and pasteurizers shall be cleaned by acceptable inplace cleaning methods or dismantled and cleaned after use or as necessary when operations have been interrupted.

(1) Spray nozzles, orifices, cores, or whizzers shall be cleaned immediately after cessation of drying operations.

(2) Equipment shall be sanitized within 2 hours prior to resuming operations.

(c) Drying units, conveyors, sifters, and packaging systems shall be cleaned whenever wet powder is encountered or when other conditions occur which would adversely affect the product. The complete drying unit, including sifters, conveyors, and powder coolers shall be either wet washed or dry cleaned. A combination of wet washing and dry cleaning of the complete drying unit shall not be permitted unless that segment of the unit to be cleaned in a different manner is completely detached or disconnected from the balance of the drying unit.

(1) Sifters and conveyors used for other than dried albumen shall be cleared of powder when such equipment is not to be used for a period of 24 hours or longer.

(2) Collector bags shall be cleaned as often as needed to maintain them in an acceptable clean condition.

(d) Powder shall be sifted and the screen shall be replaced whenever torn or worn.

(e) Accumulations of large particles or lumps of dried eggs shall be removed from the sifter screens continuously.

(f) All openings into the drier around ports, augers, high-pressure lines, etc., shall be closed to the extent possible during the drying operation to prevent entrance of nonfiltered air.

(g) Openings into the drying unit shall be closed when the drier is not in use, except when the drying unit has been completely emptied of powder and wet washed. This includes, but is not limited to, openings, for the air intake and exhaust systems, nozzle openings, ports, augers, etc.

§ 590.544 Spray process powder; definitions and requirements.

(a) Definition of product:

(1) *Primary powder* is that powder which is continuously removed from the primary or main drying chamber while the drying unit is in operation.

(2) *Secondary powder* is that powder which is continuously and automatically removed from the secondary chamber and/or bag collector chamber while the drying unit is in operation.

(3) *Sweep-down powder* is that powder which is recovered in the brush-down process from the primary or secondary chamber and conveyors.

(4) *Brush bag powder* is that powder which is brushed from the collector bags.

(b) Secondary powder shall be continuously discharged and mixed with

the primary powder by methods approved by the Administrator.

(c) Edible dried egg products, including edible ingredients which may be added to such dried products, may be dry-blended: *Provided,* That the blending is done in a room as provided in § 590.548 or in a closed blending system and in accordance with clean, sanitary practices and such procedures as may be prescribed by the Administrator.

(d) Any edible dried egg powder may be reconstituted, repasteurized, and redried when accomplished in a clean, sanitary manner and in accordance with such procedures as may be prescribed by the Administrator.

(e) Edible dried egg powder obtained from the sweep down, screenings, brush bag (except for brush bag powder from albumen driers), and improperly dried or scorched powder shall be reconstituted, repasteurized, and redried.

(f) Approximately the first and last 175 pounds of powder from the main driers for each continuous operation shall be checked for improperly dried or scorched powder.

§ 590.546 Albumen flake process drying facilities.

(a) Drying facilities shall be constructed in such a manner as will allow thorough cleaning and be equipped with approved intake filters.

(b) The intake air source shall be free from foul odors, dust, and dirt.

(c) Premix-type burners, if used, shall be equipped with approved air filters at blower intake.

(d) Fermentation tanks, drying pans, trays or belts, scrapers, curing racks, and equipment used for pulverizing pan dried albumen shall be constructed of approved materials in such a manner as will permit thorough cleaning.

(e) Sifting screens shall be constructed of approved materials in such a manner as will permit thorough cleaning and be in accordance with the specification for the type of albumen produced.

§ 590.547 Albumen flake process drying operations.

(a) The fermentation, drying, and curing rooms shall be kept in a dust-free clean condition and free of flies, insects, and rodents.

(b) Drying units, racks, and trucks shall be kept in a clean and sanitary condition.

(c) Drying pans, trays, belts, scrapers, or curing racks, if used, shall be kept in a clean condition.

(d) Oils and waxes used in oiling drying pans or trays shall be of edible quality.

(e) Equipment used for pulverizing or sifting dried albumen shall be kept in a clean condition.

§ 590.548 Drying, blending, packaging, and heat treatment rooms and facilities.

(a) *General.* Processing rooms shall be maintained in a clean condition and free of flies, insects, and rodents. The drying, blending, and packaging rooms shall be well-lighted and have ceilings and walls of a tile surface, enamel paint, or other water-resistant material.

(1) The floors shall be free from cracks or rough surfaces where water or dirt could accumulate.

(2) The intersections of the walls and floors shall be impervious to water and the floor shall be sloped for adequate drainage.

(3) Metal storage racks or cabinets shall be provided for storing of tools and accessories.

(b) Dry blending of edible egg products, including adding edible dry ingredients, and/or packaging of spray-dried products shall be done in a room separate from other processing operations. Dry blending may also be done in other areas: *Provided,* That it is accomplished in an approved closed blending system.

(1) Blending and packaging rooms for pasteurized products shall be provided with an adequate positive flow of approved outside filtered air.

(2) Blending and packaging equipment and accessories which come into contact with the dried product shall be of an approved construction without open seams and of materials that can be kept clean and which will have no deleterious effect on the product. Service tables shall be of approved metal construction without open seams and surfaces shall be smooth to permit thorough cleaning.

(3) Package liners shall be inserted in a sanitary manner, and equipment and

supplies used in the operation shall be kept off the floor.

(4) Utensils used in packaging dried eggs shall be kept clean at all times and whenever contaminated shall be cleaned and sanitized. When not in use, scoops, brushes, tampers, and other similar equipment shall be stored in sanitary cabinets or racks provided for this purpose.

(5) Automatic container fillers shall be of a type that will accurately fill given quantities of product into the containers. Scales shall be provided to accurately check the weight of the filled containers. All equipment used in mechanically packaging dried egg products shall be vacuum cleaned daily.

(c) The heat treatment room shall be of an approved construction and be maintained in a clean condition. The room or rooms shall be of sufficient size so that product to be heat treated can be so spaced to assure adequate heat and air circulation. The room shall have an adequate heat supply and a continuous air circulation system.

§ 590.549 Dried egg storage.

Dried egg storage shall be sufficient to adequately handle the production of the plant and shall be kept clean, dry, and free from objectionable odors.

§ 590.550 Washing and sanitizing room or area facilities.

(a) This room or area shall be well lighted, and of sufficient size to permit operators to properly wash and sanitize all equipment at the rate required by the size of the operation. Adequate exhaust shall be provided to assure the prompt removal of odors and vapors and the air flow shall be away from the breaking room. If the washing and sanitizing is not done in a separate room, it shall be in an area well segregated from the breaking areas and be well ventilated with air movement directed away from the breaking operations so that odors and vapors do not permeate the breaking areas.

(b) Ceiling and walls shall have a surface of tile, enamel paint, or other water-resistant material.

(c) Floors shall be adequately sloped for proper drainage, be free from cracks or rough surfaces where water and dirt could accumulate and the intersections with walls shall be impervious to water.

§ 590.552 Cleaning and sanitizing requirements.

(a) *Cleaning.* (1) Equipment used in egg processing operations which comes in contact with liquid eggs or exposed edible products shall be cleaned to eliminate organic matter and inorganic residues. This may be accomplished by any sanitary means but it is preferable (unless high pressure cleaning is used) to flush soiled equipment with clean cool water, dismantle it when possible, wash by brushing with warm water containing a detergent and followed by rinsing with water. It is essential to have the equipment surfaces thoroughly clean if effective sanitizing is to be attained.

(2) Equipment shall be cleaned with such frequency as is specified elsewhere under the sanitary requirements for the particular kind of operation and type of equipment involved.

(3) C.I.P. (cleaned-in-place) shall be considered to be acceptable only if the methods and procedures used accomplish cleaning equivalent to that obtained by thorough manual washing and sanitizing of dismantled equipment. The Administrator shall determine the acceptability of C.I.P. cleaning procedures and may require bacteriological tests and periodic dismantling of equipment as a basis for such determination.

(b) *Sanitizing.* (1) Sanitizing shall be accomplished by such methods as approved by the Administrator.

(i) Chemicals and compounds used for sanitizing shall have approval by the Administrator prior to use.

(ii) Sanitizing by use of hypochlorites or other approved sanitizing solutions shall be accomplished by subjecting the equipment surfaces to such sanitizing solution containing a maximum strength of 200 p.p.m. of available chlorine or its equivalent. These solutions shall be changed whenever the strength drops to 100 p.p.m. or less of available chlorine or its equivalent.

(2) Shell eggs which have been sanitized and equipment which comes in contact with edible products shall be rinsed with clean water after sanitizing

if other than hypochlorites are used as sanitizing agents unless otherwise approved by the Administrator.

§ 590.560 Health and hygiene of personnel.

(a) Personnel facilities, including toilets, lavatories, lockers, and dressing rooms shall be adequate and meet State and local requirements for food processing plants.

(b) Toilets and dressing rooms shall be kept clean and adequately ventilated to eliminate odors and kept adequately supplied with soap, towels, and tissues. Toilet rooms shall be ventilated to the outside of the building.

(c) No person affected with any communicable disease in a transmissible stage or a carrier of such disease, or with boils, sores, infected wounds, or wearing cloth bandages on hands shall be permitted to come in contact with eggs in any form or with equipment used to process such eggs.

(d) Workers coming into contact with liquid or dried eggs, containers, or equipment shall wear clean outer uniforms.

(e) Plant personnel handling exposed edible product shall wash their hands before beginning work, and upon returning to work after leaving the work room.

(f) Expectorating, or other unsanitary practices, shall not be permitted.

(g) Use of tobacco in any form or the wearing of jewelry, nail polish, or perfumes shall not be permitted in any area where edible products are exposed.

(h) Hair nets or caps shall be properly worn by all persons in breaking and packaging rooms.

§ 590.570 Pasteurization of liquid eggs.

(a) Pasteurization facilities: The facilities for pasteurization of egg products shall be adequate and of approved construction so that all products will be processed as provided for in this section. Pasteurization equipment for liquid egg product shall include a holding tube, an automatic flow diversion valve, thermal controls, and recording devices to determine compliance for pasteurization as set forth in paragraph (b) of this section. The temperature of the heated liquid egg product shall be continuously and automatically recorded during the process.

(b) Pasteurizing operations: Every particle of all products must be rapidly heated to the required temperature and held at that temperature for the required minimum holding time as set forth in this section. The temperatures and holding times listed in Table I of this section are minimum. The product may be heated to higher temperatures and held for longer periods of time. Pasteurization procedures shall assure complete pasteurization, and holding, packaging, facilities and operations shall be such as to prevent contamination of the product.

TABLE I—PASTEURIZATION REQUIREMENTS [1]

Liquid egg product	Minimum temperature requirements (°F.)	Minimum holding time requirements (*Minutes*)
Albumen (without use of chemicals)	134	3.5
	132	6.2
Whole egg	140	3.5
Whole egg blends (less than 2 percent added nonegg ingredients)	142	3.5
	140	6.2
Fortified whole egg and blends (24–38 percent egg solids, 2–12 percent added nonegg ingredients)	144	3.5
	142	6.2
Salt whole egg (with 2 percent or more salt added)	146	3.5
	144	6.2
Sugar whole egg (2–12 percent sugar added)	142	3.5
	140	6.2
Plain yolk	142	3.5
	140	6.2
Sugar yolk (2 percent or more sugar added)	146	3.5
	144	6.2
Salt yolk (2–12 percent salt added)	146	3.5
	144	6.2

[1] Pasteurization of egg products not listed in this table shall be in accordance with paragraph (c) of this section.

(c) Other methods of pasteurization may be approved by the Administrator when such treatments give equivalent effects to those specified in paragraph (b) of this section for those products or other products and results in a salmonella negative product.

§ 590.575 Heat treatment of dried whites.

Heat treatment of dried whites is an approved method for pasteurization and the product shall be heated throughout for such times and at such

temperatures as will result in salmonella negative product.

(a) The product to be heat treated shall be held in the heat treatment room in closed containers and shall be spaced to assure adequate heat penetration and air circulation. Each container shall be identified as to type of product (spray or pan dried) and with the lot number or production code number.

(b) The minimum requirements for heat treatment of spray or pan dried albumen shall be as follows:

(1) Spray dried albumen shall be heated throughout to a temperature not less than 130 °F and held continuously at such temperature not less than 7 days and until it is salmonella negative.

(2) Pan dried albumen shall be heated throughout to a temperature of not less than 125 °F and held continuously at such temperature not less than 5 days and until it is salmonella negative.

(3) Methods of heat treatment of spray dried or pan dried albumen, other than listed in paragraphs (b) (1) and (2) of this section, may be approved by the Administrator upon receipt of satisfactory evidence that such methods will result in salmonella negative products.

(c) Dried whites which have been heat treated in the dried form shall be sampled and analyzed for the presence of Salmonellae as required in §590.580.

(d) Records shall be maintained for 1 year of the following:

(1) Types of product;

(2) Lot number;

(3) Heat treatment room temperatures;

(4) Product temperatures;

(5) Length of time product is held in heat treatment room;

(6) Results of all laboratory analyses made for the presence of Salmonellae.

(e) Dried whites processed and tested in accordance with all of the applicable requirements specified in this section may be labeled ''Pasteurized.''

[36 FR 9814, May 28, 1971. Redesignated at 42 FR 32514, June 27, 1977, and further redesignated at 46 FR 63203, Dec. 31, 1981, as amended at 47 FR 745, Jan. 7, 1982; 60 FR 49169, Sept. 21, 1995; 60 FR 58199, Nov. 27, 1995]

LABORATORY

§590.580 Laboratory tests and analyses.

The official plant, at their expense, shall make tests and analyses to determine compliance with the Act and the regulations.

(a) Samples shall be drawn from liquid, frozen or dried egg products and analyzed for compliance with the standards of identity (if any) and with the product label.

(b) To assure adequate pasteurization, pasteurized egg products and heat treated dried egg whites shall be sampled and analyzed for the presence of Salmonellae in accordance with such sequence, frequency, and approved laboratory methods as prescribed by the AMS Science Division Director. The samples of pasteurized egg products and heat treated dried egg whites shall be drawn from the final packaged form.

(c) Results of all analyses and tests performed under paragraphs (a) and (b) of this section shall be provided to the inspector promptly upon receipt by the plant. If samples of pasteurized products or heat treated dried egg whites, in addition to those described in paragraphs (a) and (b) of this section, are analyzed for the presence of Salmonella, the plant shall immediately advise the inspector of any such samples which are determined to be Salmonella positive.

(d) USDA will draw confirmation samples and submit them to a AMS Science Division laboratory at USDA's expense to determine the adequacy of the plant's tests and analyses.

[36 FR 9814, May 28, 1971. Redesignated at 42 FR 32514, June 27, 1977, and further redesignated at 46 FR 63203, Dec. 31, 1981, as amended at 58 FR 42413, Aug. 9, 1993; 60 FR 49170, Sept. 21, 1995; 60 FR 58199, Nov. 27, 1995]

EXEMPTED EGG PRODUCTS PLANTS

§590.600 Application for exemption.

An application for exemption from the continuous inspection requirements must be made in writing on

forms approved by the Administrator and filed with the inspection service.

[36 FR 9814, May 28, 1971. Redesignated at 42 FR 32514, June 27, 1977, and further redesignated at 46 FR 63203, Dec. 31, 1981, as amended at 47 FR 745, Jan. 7, 1982]

§ 590.610 Criteria for exemption.

Any plant processing egg products may qualify for exemption where:

(a) The facility, operating procedures and practices, and sanitation meet the standards required for official egg products plants as are contained in §§ 590.500 through 590.580, and such exempted plants shall thereafter be subject to other provisions applicable to official plants which shall include maintaining records such as pasteurization temperatures and holding times, laboratory records, egg products testing procedures, and making all such records available for review.

(b) The eggs received or used in the manufacture of egg products contain no more restricted eggs than are allowed by the official standards for U.S. Consumer Grade B shell eggs.

[36 FR 9814, May 28, 1971. Redesignated at 42 FR 32514, June 27, 1977, and further redesignated at 46 FR 63203, Dec. 31, 1981, as amended at 47 FR 745, Jan. 7, 1982]

§ 590.620 Authority of applicant.

Proof of authority of any person applying for exemption from continuous inspection may be required by the Administrator.

§ 590.630 Filing of application.

An application for exemption shall be regarded as filed only when it has been filled in completely and signed by the applicant and has been received in the office of the inspection service.

§ 590.640 Application for exemption; approval.

Any person desiring to process egg products pursuant to the exemption provision of the Act and these regulations must receive approval of such plant, facilities, and operating procedures as an exempted plant. An application for exemption shall be according to the following:

(a) *Initial survey*. When an application for exemption of a plant has been filed, a Supervisory Egg Products Inspector will make a survey and inspection of the premises and plant to determine if the facilities, methods of operation, and eggs received or used therein are suitable and adequate in accordance with:

(1) Section 590.610; and

(2) Such other administrative instructions as may be issued, from time to time, by the Service and which are in effect at the time of the aforesaid survey and inspection.

(b) *Final survey and exemption approval.* Upon notification by the applicant for exemption that all the criteria for exemption required in § 590.610 are in effect and an initial survey has been performed, the applicant shall:

(1) Submit drawings and specifications in accordance with the same requirements as official plants as specified in § 590.146(b);

(2) Submit labels for approval as specified in § 590.680;

(3) Request a final survey be made by a Supervisory Egg Products Inspector to determine if the plant is constructed and the facilities are installed in accordance with the approved drawings and these regulations.

(c) The plant will be approved for exemption only when all the requirements of this section have been met.

[36 FR 9814, May 28, 1971; 36 FR 10841, June 4, 1971. Redesignated at 42 FR 32514, June 27, 1977, and further redesignated at 46 FR 63203, Dec. 31, 1981]

§ 590.650 Exempted plant registration number.

Each plant processing egg products which receives the Administrator's approval for exemption shall be assigned an ''Exempted Registration Number'' at the time the exemption approval is provided.

§ 590.660 Inspection of exempted plants.

Duly authorized representatives of the Administrator shall make such periodic inspections of exempted plants and records thereof as the Administrator may require to ascertain if any of the provisions of the Act or these regulations applicable to exempted plants have been violated. Such representatives shall be afforded access, at any reasonable time, to any plant or

place of business subject to inspection under the provisions of the Act.

§590.670 Termination of exemption.

The Administrator may suspend or terminate any exemption if the criteria for exemption required in §590.610 are not being met. In addition, if any violation has been committed, the applicable penalties provided in this part may be enforced as provided in the Act.

§590.680 Approval of labeling for egg products processed in exempted egg products processing plants.

(a) The labels for egg products which are capable for use as human food shall be submitted to the Administrator for approval. The submission and approval shall be the same as for official plants as required in §590.411 except the labels or containers shall not bear official identification.

(b) The label or container shall legibly and conspicuously bear the statement: ''Exempted—E.P.I.A. Registration No. _____.'' The registration number shall be that assigned to the exempted plant as provided in §590.650.

IDENTIFICATION OF RESTRICTED EGGS OR EGG PRODUCTS NOT INTENDED FOR HUMAN CONSUMPTION

§590.800 Identification of restricted eggs.

The shipping container of restricted eggs shall be determined to be satisfactorily identified if such container bears the packer's name and address, the quality of the eggs in the container (e.g., dirties, checks, inedibles, or loss), or the statement ''Restricted Eggs—For Processing Only In An Official USDA Egg Products Plant,'' for checks or dirties, or ''Restricted Eggs—Not To Be Used As Human Food,'' for inedibles, loss, and incubator rejects, or ''Restricted Eggs—To Be Regraded'' for graded eggs which contain more restricted eggs than are allowed in the official standards for U.S. Consumer Grade B shell eggs. The size of the letters of the identification wording shall be as required in §590.860.

[40 FR 20060, May 8, 1975. Redesignated at 42 FR 32514, June 27, 1977, and further redesignated at 46 FR 63203, Dec. 31, 1981, as amended at 60 FR 49171, Sept. 21, 1995; 63 FR 69972, Dec. 17, 1998]

§590.840 Identification of inedible, unwholesome, or adulterated egg products.

All inedible, unwholesome, or adulterated egg products shall be identified with the name and address of the processor, the words ''Inedible Egg Products—Not To Be Used as Human Food.''

§590.860 Identification wording.

The letters of the identification wording shall be legible and conspicuous.

[37 FR 6659, Apr. 1, 1972. Redesignated at 42 FR 32514, June 27, 1977, and further redesignated at 46 FR 63203, Dec. 31, 1981]

IMPORTS

§590.900 Requirements for importation of egg products or restricted eggs into the United States.

(a) Egg products and restricted eggs may be imported into the United States from any foreign country only in accordance with these regulations. The term *United States* means any State of the United States, the Commonwealth of Puerto Rico, the Virgin Islands of the United States, and the District of Columbia. The importation of any egg or egg product in violation of the regulations of this part is prohibited.

(b) All such imported articles shall upon entry into the United States be deemed and treated as domestic articles and be subject to the other provisions of the Act, these regulations, and other Federal or State requirements.

§590.905 Importation of restricted eggs or eggs containing more restricted eggs than permitted in the official standards for U.S. Consumer Grade B.

No containers of restricted egg(s) other than checks or dirties shall be

imported into the United States. The shipping containers of such eggs shall be identified with the name, address, and country of origin of the exporter, and the date of pack and quality of the eggs (e.g., checks, or dirties) preceded by the word ''Imported'' or the statement ''Imported Restricted Eggs—For Processing Only In An Official USDA Plant,'' or ''Restricted Eggs—Not To Be Used As Human Food.'' Such identification shall be legible and conspicuous. Alternatively, for properly sealed and certified shipments of shell eggs imported for breaking at an official egg products plant, the shipping containers need not be labeled, provided that the shipment is segregated and controlled upon arrival at the destination breaking plant.

[36 FR 9814, May 28, 1971, as amended at 37 FR 6659, Apr. 1, 1972. Redesignated at 42 FR 32514, June 27, 1977, and further redesignated at 46 FR 63203, Dec. 31, 1981, as amended at 60 FR 49171, Sept. 21, 1995; 63 FR 69972, Dec. 17, 1998]

§ 590.910 Eligibility of foreign countries for importation of egg products into the United States.

(a) Whenever it is determined by the Administrator that the system of egg products inspection maintained by any foreign country is such that the egg products produced in such country are processed, labeled, and packaged in accordance with, and otherwise comply with, the standards of the Act and these regulations including, but not limited to the same sanitary, processing, facility requirements, and continuous Government inspection as required in §§ 590.500 through 590.580 applicable to inspected articles produced within the United States, notice of that fact will be given by listing the name of such foreign country in paragraph (b) of this section. Thereafter, egg products from the countries so listed shall be eligible, subject to the provisions of this part and other applicable laws and regulations, for importation into the United States. Such products to be imported into the United States from these foreign countries must meet, to the extent applicable, the same standards and requirements that apply to comparable domestic products as set forth in these regulations. Egg products from foreign countries not listed herein are not eligible for importation into the United States, except as provided by § 590.960. In determining if the inspection system of a foreign country is the equivalent of the system maintained by the United States, the Administrator shall review the inspection regulations of the foreign country and make a survey to determine the manner in which the inspection system is administered within the foreign country. The survey of the foreign inspection system may be expedited by payment by the interested Government agency in the foreign country of the travel expenses incurred in making the survey. After approval of the inspection system of a foreign country, the Administrator may, as often and to the extent deemed necessary, authorize representatives of the Department to review the system to determine that it is maintained in such a manner as to be the equivalent of the system maintained by the United States.

(b) It has been determined that each of the following foreign countries maintain an egg products inspection system that is the equivalent of the system maintained by the United States: Canada, The Netherlands.

[36 FR 9814, May 28, 1971. Redesignated at 42 FR 32514, June 27, 1977, as amended at 42 FR 48327, Sept. 23, 1977. Redesignated at 46 FR 63203, Dec. 31, 1981, as amended at 52 FR 42426, Nov. 5, 1987]

§ 590.915 Foreign inspection certification required.

(a) Except as provided in § 590.960, each consignment of egg products, as defined in this part, shall be accompanied by a foreign egg products inspection certificate, which, unless otherwise approved by the Administrator, contains the following information:

(1) Country exporting product;

(2) City and date where issued;

(3) Kind of product, number of containers, and weight;

(4) Production date(s) of product;

(5) Identification marks on containers;

(6) Name and address of exporter;

(7) Name, address, and plant number of processing plant;

(8) Name and address of importer;

(9) A certification that the egg products were produced under the approved regulations, requirements, and continuous Government inspection of the exporting country and;

(10) Name (including signature) and official title of person authorized to issue inspection certificates for egg products exported to the United States.

(b) [Reserved]

[36 FR 9814, May 28, 1971, as amended at 37 FR 6659, Apr. 1, 1972. Redesignated at 42 FR 32514, June 27, 1977, and further redesignated at 46 FR 63203, Dec. 31, 1981, as amended at 60 FR 49171, Sept. 21, 1995; 63 FR 45675, Aug. 27, 1998; 63 FR 69972, Dec. 17, 1998]

§590.920 Importer to make application for inspection of imported eggs and egg products.

Each person importing any eggs or egg products shall make application for inspection to the Chief, Poultry Grading Branch, Poultry Division, Agricultural Marketing Service, U.S. Department of Agriculture, Washington, DC 20250, or to the Poultry Division, Poultry Grading Branch office at the port where the product is to be offered for importation. Application shall be made as long as possible prior to the arrival of each consignment of product, except in the case of product exempted from inspection by §590.960. Each application shall state the approximate date of product arrival in the United States, the name of the ship or other carrier, the country from which the product was shipped, the destination, the quantity and class of product, whether fresh, frozen, or dried, and the point of first arrival in the United States.

[36 FR 9814, May 28, 1971. Redesignated at 42 FR 32514, June 27, 1977, as amended at 43 FR 60138, Dec. 26, 1978. Redesignated at 46 FR 63203, Dec. 31, 1981, as amended at 47 FR 46070, Oct. 15, 1982; 47 FR 54421, Dec. 3, 1982; 63 FR 69972, Dec. 17, 1998]

§590.925 Inspection of imported egg products.

(a) Except as provided in §590.960, egg products offered for importation from any foreign country shall be subject to inspection in accordance with established inspection procedures, including the examination of the labeling information on the containers, by an inspector before the product shall be admitted into the United States. Importers will be advised of the point where inspection will be made, and in case of small shipments (less than carload lots), the importer may be required to move the product to the location of the nearest inspector.

(b) Inspectors may take samples, without cost to the United States, of any product offered for importation which is subject to analysis or quality determination, except that samples shall not be taken of any products offered for importation under §590.960, unless there is reason for suspecting the presence therein of a substance in violation of that section.

[36 FR 9814, May 28, 1971. Redesignated at 42 FR 32514, June 27, 1977, and further redesignated at 46 FR 63203, Dec. 31, 1981, as amended at 63 FR 69972, Dec. 17, 1998]

§590.930 Imported egg products; retention in customs custody; delivery under bond; movement prior to inspection; sealing; handling; facilities, and assistance.

(a) No egg products required by this part to be inspected shall be released from customs custody prior to required inspections, but such product may be delivered to the consignee, or his agent, prior to inspection if the consignee shall furnish a bond, in the form prescribed by the Secretary of the Treasury, conditioned that the product shall be returned, if demanded, to the collector of the port where the same is offered for clearance through customs.

(b) Notwithstanding paragraph (a) of this section, no product required by this part to be inspected shall be moved prior to inspection from the port of arrival where first unloaded, and if arriving by water from the wharf where first unloaded at such port, to any place other than the place designated in accordance with this part as the place where the same shall be inspected; and no product shall be conveyed in any manner other than in compliance with this part.

(c) Means of conveyance or packages in which any product is moved in accordance with this part, prior to inspection, from the port or wharf where first unloaded in the United States, shall be sealed with special import

seals of the U.S. Department of Agriculture or otherwise identified as provided herein, unless already sealed with customs or consular seals in accordance with the customs regulations. Such special seals shall be affixed by an inspector or, if there is no inspector at such port, by a customs officer. In lieu of sealing packages, the carrier or importer may furnish and attach to each package of product a warning notice on bright yellow paper, not less than 5×8 inches in size, containing the following legend in black type of a conspicuous size:

(Name of Truck Line or Carrier)

NOTICE

This package of _____ must be delivered intact to an inspector of the Poultry Division, U.S. Department of Agriculture.

WARNING

Failure to comply with these instructions will result in penalty action being taken against the holder of the customs entry bond.

If the product is found to be acceptable upon inspection, the product may be released to the consignee, or his agent, and this warning notice defaced.

(d) No person shall affix, break, alter, deface, mutilate, remove, or destroy any special import seal of the U.S. Department of Agriculture, except customs officers or inspectors, or as provided in paragraph (f) of this section.

(e) No product shall be removed from any means of conveyance or package sealed with a special import seal of the U.S. Department of Agriculture, except under the supervision of an inspector or a customs officer, or as provided in paragraph (f) of this section.

(f) In case of a wreck or similar extraordinary emergency, the special import seal of the U.S. Department of Agriculture on a car, truck, or other means of conveyance may be broken by the carrier and, if necessary, the articles may be reloaded into another means of conveyance for transportation to destination. In all such cases, the carrier shall immediately report the facts by telegraph to the Chief of the Grading Branch.

(g) The consignee or his agent shall provide such facilities and assistance as the inspector may require for the inspection and handling and marking of products offered for importation.

[36 FR 9814, May 28, 1971, as amended at 37 FR 6660, Apr. 1, 1972; 40 FR 20060, May 8, 1975. Redesignated at 42 FR 32514, June 27, 1977, as amended at 43 FR 60138, Dec. 26, 1978. Redesignated at 46 FR 63203, Dec. 31, 1981, as amended at 47 FR 46070, Oct. 15, 1982; 47 FR 54421, Dec. 3, 1982; 63 FR 69972, Dec. 17, 1998]

§ 590.935 Means of conveyance and equipment used in handling egg products to be maintained in sanitary condition.

Compartments of boats, railroad cars, and other means of conveyance transporting any product to the United States, and all chutes, platforms, racks, tables, tools, utensils, and all other devices used in moving and handling such product offered for importation, shall be maintained in a sanitary condition.

§ 590.940 Marking of egg products offered for importation.

Egg products which, upon inspection, are found to be acceptable for importation into the United States, and are properly labeled and bear the inspection mark of the country of origin, need no further identification.

[40 FR 20060, May 8, 1975. Redesignated at 42 FR 32514, June 27, 1977, and further redesignated at 46 FR 63203, Dec. 31, 1981, as amended at 60 FR 49171, Sept. 21, 1995]

§ 590.945 Foreign egg products offered for importation; reporting of findings to customs; handling of products refused entry.

(a) Inspectors shall report their findings to the collector of customs at the port where products are offered for entry, and shall request the collector to refuse entry to egg products which are marked or designated ''U.S. Refused Entry'' or otherwise are not in compliance with the regulations in this part. Unless such products are exported by the consignee within a time specified by the collector of customs (usually 30 days), the consignee shall cause the destruction of such products for human food purposes under the supervision of an inspector. If products are destroyed for human food purposes under the supervision of an inspector, he shall give prompt notice thereof to the District Director of Customs.

(b) Consignees shall, at their own expense, return immediately to the collector of customs, in means of conveyance or packages sealed by the U.S. Department of Agriculture, any egg products received by them under this part which in any respect do not comply with this part.

(c) Except as provided in § 590.930(a), no person shall remove or cause to be removed from any place designated as the place of inspection, any egg products which the regulations require to be marked in any way, unless the same has been clearly and legibly marked in compliance with this part.

[36 FR 9814, May 28, 1971, as amended at 37 FR 6660, Apr. 1, 1972. Redesignated at 42 FR 32514, June 27, 1977, and further redesignated at 46 FR 63203, Dec. 31, 1981, as amended at 60 FR 49171, Sept. 21, 1995; 63 FR 69972, Dec. 17, 1998]

§ 590.950 Labeling of containers of eggs or egg products for importation.

(a) Immediate containers of product offered for importation shall bear a label, printed in English, showing:

(1) The name of product;

(2) the name of the country of origin of the product, and for consumer packaged products, preceded by the words ''Product of,'' which statement shall appear immediately under the name of the product;

(3) [Reserved]

(4) For shell eggs, the words, ''Keep Refrigerated,'' or words of similar meaning;

(5) for egg products, the word ''Ingredients'' followed by a list of the ingredients in order of descending proportions by weight;

(6) the name and place of business of manufacturer, packer, or distributor, qualified by a phrase which reveals the connection that such person has with the product;

(7) an accurate statement of the quantity;

(8) for egg products, the inspection mark of the country of origin; and

(9) The date of production and plant number of the plant at which the egg product was processed and/or packed.

(b) For properly sealed and certified shipments of shell eggs imported for breaking at an official egg products plant, the immediate containers need not be labeled, provided that the shipment is segregated and controlled upon arrival at the destination breaking plant.

(c) The labels shall not be false or misleading in any respect.

[36 FR 9814, May 28, 1971. Redesignated at 42 FR 32514, June 27, 1977, as amended at 45 FR 23641, Apr. 8, 1980. Redesignated at 46 FR 63203, Dec. 31, 1981, as amended at 60 FR 49171, Sept. 21, 1995; 63 FR 45675, Aug. 27, 1998; 63 FR 69972, Dec. 17, 1998]

§ 590.955 Labeling of shipping containers of eggs or egg products for importation.

(a) Shipping containers of foreign product which are shipped to the United States shall bear in a prominent and legible manner:

(1) The common or usual name of the product;

(2) The name of the country of origin;

(3) The plant number of the plant in which the egg product was processed and/or packed;

(4) The inspection mark of the country of origin;

(5) [Reserved]

(6) For shell eggs, the words ''Keep refrigerated'' or words of similar meaning.

(b) Labeling on shipping containers examined at the time of inspection in the United States, if found to be false or misleading, shall be cause for the product to be refused entry.

(c) [Reserved]

(d) In the case of products which are not in compliance solely because of misbranding, such products may be brought into compliance with the regulations only under the supervision of an authorized representative of the Administrator.

[36 FR 9814, May 28, 1971. Redesignated at 42 FR 32514, June 27, 1977, and further redesignated at 46 FR 63203, Dec. 31, 1981, as amended at 60 FR 49171, Sept. 21, 1995; 63 FR 45675, Aug. 27, 1998; 63 FR 69972, Dec. 17, 1998]

§ 590.956 Relabeling of imported egg products.

(a) Egg products eligible for importation may be relabeled with an approved label under the supervision of an inspector at an official egg products plant or other location. The new label for such product shall indicate the country of origin except for products

which are reprocessed (repasteurized, or in the case of dried products, dry blended with products produced in the United States) in an official egg products plant.

(b) The label for relabeled products must state the name, address, and zip code of the distributor, qualified by an appropriate term such as ''packed for'', ''distributed by'' or ''distributors''.

[60 FR 49171, Sept. 21, 1995]

§ 590.960 Small importations for consignee's personal use, display, or laboratory analysis.

Any egg products which are offered for importation, exclusively for the consignee's personal use, display, or laboratory analysis, and not for sale or distribution; which is sound, healthful, wholesome, and fit for human food; and which is not adulterated and does not contain any substance not permitted by the Act or regulations, may be admitted into the United States without a foreign inspection certificate. Such product is not required to be inspected upon arrival in the United States and may be shipped to the consignee without further restriction under this part: *Provided*, That the Department may, with respect to any specific importation, require that the consignee certify that such product is exclusively for the consignee's personal use, display, or laboratory analysis and not for sale or distribution. The amount of such product imported shall not exceed 30 pounds of liquid or frozen eggs, or 50 pounds of dried egg products, unless otherwise authorized by the Administrator.

[37 FR 6660, Apr. 1, 1972. Redesignated at 42 FR 32514, June 27, 1977, and further redesignated at 46 FR 63203, Dec. 31, 1981, as amended at 63 FR 69972, Dec. 17, 1998]

§ 590.965 Returned U.S. inspected and marked products; not importations.

Products which have been inspected by the United States Department of Agriculture and so marked, and which are returned from foreign countries are not importations within the meaning of this part. Such returned shipments shall be reported to the Administrator by letter.

§ 590.970 Charges for storage, cartage, and labor with respect to products imported contrary to the Act.

All charges for storage, cartage, and labor with respect to any product which is imported contrary to this part shall be paid by the owner or consignee, and in default of such payment shall constitute a lien against such product and any other product thereafter imported under the Act by or for such owner or consignee.

[36 FR 9814, May 28, 1971. Redesignated at 42 FR 32514, June 27, 1977, and further redesignated at 46 FR 63203, Dec. 31, 1981, as amended at 47 FR 46071, Oct. 15, 1982; 47 FR 54421, Dec. 3, 1982]

PART 592—VOLUNTARY INSPECTION OF EGG PRODUCTS

Sec.
592.1 Scope and purpose.
592.2 Base time rate.
593.3 Overtime rate.
593.4 Holiday rate.

AUTHORITY: 7 U.S.C. 1621–1627.

SOURCE: 67 FR 3430, Jan. 24, 2002, unless otherwise noted.

§ 592.1 Scope and purpose.

The fees that shall be charged for, and collected by the Food Safety and Inspection Service for the voluntary base time, overtime, and holiday time inspection services of egg products as provided by FSIS on other than a continuous resident basis shall be at the applicable rates, and on the basis set forth in §§ 592.2 through 592.4 below, in lieu of that for such services set forth in 7 CFR part 55. The fees and charges for such services shall be paid by check, draft, or money order to the Food Safety and Inspection Service.

§ 592.2 Base time rate.

The base time rate for voluntary inspection services of egg products is $43.64 per hour per program employee.

[68 FR 37957, June 26, 2003]

§ 592.3 Overtime rate.

When operations in an official plant require the services of inspection personnel beyond their regularly assigned tour of duty on any day or on a day outside the established schedule, such

services are considered as overtime work. The official plant must give reasonable advance notice to the inspector of any overtime service necessary and must pay the Agency for such overtime at an hourly rate of $50.04.

[68 FR 37957, June 26, 2003]

§592.4 Holiday rate.

When an official plant requires voluntary inspection service on a holiday or a day designated in lieu of a holiday, such service is considered holiday work. The official plant must, in advance of such holiday work, request the inspector in charge to furnish inspection service during such period and must pay the Agency for such holiday work at an hourly rate of $50.04.

[68 FR 37957, June 26, 2003]