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SUBCHAPTER A—MANDATORY MEAT INSPECTION

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 2.17, 2.55.

§ 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:

(a) *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.*).

(b) *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.

(c) *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.

(d) *Anesthesia.* Loss of sensation or feeling.

(e) *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).

(f) *Animal food manufacturer.* Any person engaged in the business of manufacturing or processing animal food.

(g) *Area.* One or more circuits under the supervision of an area supervisor.

(h) *Area Supervisor.* The official in charge of an area.

(i) *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.

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

(k) *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.

(l) *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.

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

(n) *Carbon dioxide.* A gaseous form of the chemical formula CO_2.

(o) *Carbon dioxide concentration.* Ratio of carbon dioxide gas and atmospheric air.

(p) *Carcass.* All parts, including viscera, of any slaughtered livestock.

(q) *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.

(r) *Circuit.* One or more official establishments included under the supervision of a circuit supervisor.

(s) *Circuit supervisor.* The supervisor of a circuit.

(t) *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.

(u) *Consciousness.* Responsiveness of the brain to the impressions made by the senses.

(v) *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.

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

(x) *The Department.* The United States Department of Agriculture.

(y) *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.

(z) *Edible.* Intended for use as human food.

(aa) *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.

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

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

(dd) *Firm.* Any partnership, association, or other unincorporated business organization.

(ee) *Food Safety and Inspection Service.* The Food Safety and Inspection Service of the Department.

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

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

(hh) *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.

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

(jj) *Inedible.* Adulterated, uninspected, or not intended for use as human food.

(kk) *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.

(ll) *''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.

(mm) *Inspector.* An inspector of the Program.

(nn) *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.

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

(pp) *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.

(qq) *Livestock.* Cattle, sheep, swine, goat, horse, mule, or other equine.

(rr) *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.

(ss) *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.

(tt) *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.

(uu) *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.

(vv) *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.

(ww) *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.

(xx) *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.

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

(zz) *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.

(aaa) *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.

(bbb) *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.

(ccc) *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.

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

(eee) *Person.* Any individual, firm, or corporation.

(fff) *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.

(ggg) *Prepared.* Slaughtered, canned, salted, rendered, boned, cut up, or otherwise manufactured or processed.

(hhh) *Product.* Any carcass, meat, meat byproduct, or meat food product, capable of use as human food.

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

(jjj) *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.

(kkk) *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.

(lll) *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.

(mmm) *Secretary.* The Secretary of Agriculture of the United States or his/her delegate.

(nnn) *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.

(ooo) *State.* Any State of the United States or the Commonwealth of Puerto Rico.

(ppp) *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.

(qqq) *Surgical anesthesia.* A state of unconsciousness measured in conformity with accepted surgical practices.

(rrr) *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.

(sss) *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.

(ttt) *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.

[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.

(uuu) *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.

(vvv) *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.

(www) *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.

(xxx) *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.

(yyy) *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 in the Finding Aids section of this volume.

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) The establishment in which the custom operations are conducted is maintained and operated in accordance with the provisions of §§ 308.4 through 308.11, 308.13, 308.14, and 308.3 (except § 308.3(d) (2) and (3), of this subchapter: *Provided,* That the provisions of said sections relating to inspection or supervision of specified activities or other action by a Program employee shall not apply to the preparation and handling of such exempted products: *Provided, further,* That the requirement of § 308.4 for separate facilities for men and women workers shall not apply to such establishments when the majority of the workers in the establishment are related by blood or marriage and this arrangement will not conflict with municipal or State requirements, and the requirement of § 308.4 for separation of toilet soil lines from house drainage lines to a point outside the buildings will not apply to such establishments when positive acting backflow devices are installed: *And provided, further,* That the requirements of § 308.13 for paved driveways, approaches, yards, pens, and alleys shall not apply to such establishments. However, if custom operations are conducted in an official establishment, all of the provisions of part 308 shall apply to such establishment.

(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 308 of this subchapter, except §§308.1, 308.2, and 308.15. 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*) 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

[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.

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]

§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 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]

[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.

PART 304—APPLICATION FOR INSPECTION; GRANT OR REFUSAL 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 308 of this subchapter 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 of this subchapter. When inspection is refused for any reason, the applicant shall be informed of the action and the reasons therefor and afforded an opportunity to present his views.

(c) Inspection may also be refused in accordance with section 401 of the Act and the applicable rules of practice.

(d)(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.

(e) Inspection may be refused in accordance with humane slaughter and handling provisions of the Act (21 U.S.C. 603(b)) and the applicable rules of practice.

[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]

§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.
305.5 Withdrawal of inspection; statement of policy.
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.

§ 305.5 Withdrawal of inspection; statement of policy.

(a) The Administrator is authorized to withdraw inspection from an official establishment where the sanitary conditions are such that its products are rendered adulterated, or for failure of the operator to destroy condemned products as required by the Act and the regulations in this subchapter. Inspection may be withdrawn in accordance with section 401 of the Act and the applicable rules of practice.

(b) The assignment of inspectors may be temporarily suspended, in whole or in part, by the Administrator to the extent it is determined necessary to

avoid impairment of the effective conduct of the program when the operator of any official establishment or any subsidiary therein, or any officer, employee, or agent of any such operator or any subsidiary therein, acting within the scope of his office, employment, or agency, threatens to forcibly assault or forcibly assaults, intimidates, or interferes with any program employee in or on account of the performance of his official duties under the act, unless promptly upon the incident being brought by an authorized supervisor of the program employee to the attention of the operator of the establishment the operator (1) satisfactorily justifies the incident, (2) takes effective steps to prevent a recurrence, or (3) provides acceptable assurance that there will not be any recurrences. Such suspension shall remain in effect until one of such actions is taken by the operator: *Provided,* That upon request of the operator he shall be afforded an opportunity for an expedited hearing to show cause why the suspension should be terminated.

(c) Inspection service may be temporarily suspended, in whole or in part, at an official establishment, by the Administrator, to the extent that it is determined necessary to prevent in-humane slaughtering or handling in connection with slaughter of livestock as defined in §301.2(kk) (9 CFR 301.2(kk)). The Administrator shall notify the operator of an establishment orally or in writing, as promptly as circumstances permit, of such suspension and the reasons therefor. Such suspension shall remain in effect until the operator of the establishment takes effective steps to prevent a recurrence, or provides other satisfactory assurances that there will not be any recurrences. Upon request, the operator shall be afforded an opportunity for a hearing to show cause why the suspension should be terminated.

[38 FR 9794, Apr. 20, 1973, as amended at 44 FR 68813, Nov. 30, 1979; 53 FR 49848, Dec. 12, 1988]

§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 establishment.
307.3 Inspectors to furnish implements and maintain hands and implements in 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 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 § 308.4 of this subchapter.

(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]

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

Inspectors shall furnish their own work clothing and implements, such as flashlights and triers, for conducting inspection and shall cleanse their hands and implements as prescribed by § 308.8 of this subchapter.

§ 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 rub-bar, a conveyor with energized surfaces traveling with the carcass, or any other method found to be acceptable by the Administrator. The Administrator will evaluate EST equipment to determine its acceptability for its proposed use before it is installed in an official establishment as set forth in § 308.5 of this subchapter.

(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]

PART 308—SANITATION

Sec.

308.1 Examination and specifications for equipment and sanitation prior to granting inspection.
308.2 [Reserved]
308.3 Establishments; sanitary condition; requirements.
308.4 Sanitary facilities and accommodations; specific requirements.
308.5 Equipment and utensils to be easily cleaned; those for inedible products to be so marked; PCB-containing equipment.
308.6 Scabbards for knives.
308.7 Rooms, compartments, etc., to be clean and sanitary.
308.8 Operations, procedures, rooms, clothing, utensils, etc., to be clean and sanitary.
308.9 Protective handling of products.
308.10 Slack barrels and similar containers and means of conveyance used for product; paper in contact with product.
308.11 Burlap wrapping for meat.
308.12 Second-hand tubs, barrels, and other containers.
308.13 Inedible operating and storage rooms; outer premises, docks, driveways, approaches, pens, alleys, etc.; flybreeding material; other conditions.
308.14 Employment of diseased persons.
308.15 Tagging insanitary equipment, utensils, rooms or compartments.
308.16 Sanitation requirements for electrical stimulating (EST) equipment.

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

SOURCE: 35 FR 15561, Oct. 3, 1970, unless otherwise noted.

§308.1 Examination and specifications for equipment and sanitation prior to granting inspection.

Prior to the inauguration of inspection, an examination of the establishment and premises shall be made by a Program employee and the requirements for sanitation and the necessary facilities for inspection shall be specified by him in accordance with the regulations in this part and part 307 of this subchapter.

§308.2 [Reserved]

§308.3 Establishments; sanitary condition; requirements.

(a) Official establishments shall be maintained in sanitary condition, and to this end the requirements of this section shall be complied with. The provisions of part 416 of this chapter apply to all establishments, *except* establishments that are exempt in accordance with §303.1 of this chapter.

(b) There shall be abundant light, of good quality and well distributed, and sufficient ventilation for all rooms and compartments to insure sanitary condition.

(c) There shall be an efficient drainage and plumbing system for the establishment and premises, and all drains and gutters shall be properly installed with traps and vents approved by the circuit supervisor.

(d)(1) 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. Every establishment shall make known and, whenever required by the circuit supervisor, shall afford opportunity for inspection of the source of its water supply, the storage facilities, and the distribution system. Equipment using potable water shall be so installed as to prevent back-siphonage into the potable water system. Nonpotable water is permitted only in those parts of official establishments where no edible product is handled or prepared, and then only for limited purposes such as on ammonia condensers not connected with the potable water supply, in vapor lines serving inedible product rendering tanks, in connection with equipment used for hashing and washing inedible products preparatory to tanking, and in sewer lines for moving heavy solids in the sewage. Nonpotable water is not permitted for washing floors,

[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.

areas, or equipment involved in trucking materials to and from edible product departments nor is it permitted in hog scalding vats, dehairing machines, or vapor lines serving edible product rendering equipment, or for cleanup of shackling pens, bleeding areas, or runways within the slaughtering department. In all cases, nonpotable waterlines shall be clearly identified and shall not be cross-connected with the potable water supply unless this is necessary for fire protection and such connection is of a type with an adequate break to assure against accidental contamination, and is approved by local authorities and by the circuit supervisor.

(2) The circuit supervisor may permit the reuse of water in vapor lines leading from deodorizers used in the preparation of lard and similar edible product and in equipment where such water is used to thermally process canned product packed in hermetically sealed containers, provided:

(i) The reuse is for the identical original purpose.

(ii) All pipelines, reservoirs, tanks, cooling towers, and like equipment employed in handling the reused water are so constructed and installed so they can be cleaned and drained, and are kept clean.

(3) Approval for the reuse of water other than as specified in paragraph (d)(2) of this section or in § 318.305(h) shall be obtained from the Administrator in specific cases.

(4) An ample supply of water at not less than 180 °F. shall be furnished and used for the cleaning of inspection equipment and other equipment, floors, and walls which are subject to contamination by the dressing or handling of diseased carcasses, their viscera, and other parts. Whenever necessary to determine compliance with this requirement, conveniently located thermometers shall be installed by the operator of the official establishment to show the temperature of the water at the point of use.

(5) Hot water for cleaning rooms and equipment other than those mentioned in paragraph (d)(4) of this section shall be delivered under pressure to sufficient convenient outlets and shall be of such temperature as to accomplish a thorough cleanup.

(e) The floors, walls, ceilings, partitions, posts, doors, and other parts of all structures shall be of such materials, construction, and finish as will make them susceptible of being readily and thoroughly cleaned. The floors shall be kept watertight. The rooms and compartments used for edible product shall be separate and distinct from those used for inedible product.

(f) Rails should be located and passageway space provided so that exposed product does not come in contact with posts, walls, and other fixed parts of the building, or with barrels, boxes, and other containers trafficked through holding and operating areas. Exposed product shall not be placed or stored beneath carcasses in coolers or holding areas.

(g) The rooms and compartments in which any product is prepared or handled shall be free from dust and from odors from dressing and toilet rooms, catch basins, hide cellars, casing rooms, inedible tank and fertilizer rooms, and livestock pens.

(h) Every practicable precaution shall be taken to exclude flies, rats, mice, and other vermin from official establishments. The use of poisons for any purpose in rooms or compartments where any unpacked product is stored or handled is forbidden, except under such restrictions and precautions as are prescribed by the regulations in this part or by the circuit supervisor in specific cases. The use of insecticides, rodenticides, and similar pest control substances in hide cellars, inedible product departments, outbuildings, or similar places, or in storerooms containing canned or tierced products is not forbidden but only those approved by the Administrator may be used.[1] So-called rat viruses shall not be used in any part of an establishment or the premises thereof.

(i) Dogs and cats shall be excluded from the interior of official establishments; however, dogs may be permitted

[1] A list of approved pest control substances 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.

on the outer premises for guard purposes.

[35 FR 15561, Oct. 3, 1970, as amended at 51 FR 45619, Dec. 19, 1986; 61 FR 38864, July 25, 1996; 62 FR 26217, May 13, 1997]

§ 308.4 Sanitary facilities and accommodations; specific requirements.

Adequate sanitary facilities and accommodations shall be furnished by every official establishment. 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. The rooms shall be provided with facilities to provide abundant light of good quality and well distributed. They shall be properly ventilated, and meet all requirements of the regulations in this part as to sanitary construction and equipment. They shall be separate from the rooms and compartments in which products are prepared, stored, or handled. Where both sexes are employed, separate facilities shall be provided.

(b) Acceptable lavatories, including running hot and cold water, soap, and towels, shall be placed in or near toilet and urinal rooms and also at such other places in the establishment as may be essential to assure cleanliness of all persons handling any product.

(c) Toilet soil lines shall be separate from house drainage lines to a point outside the building and drainage from toilet bowls and urinals shall not be discharged into a grease catch basin.

(d) Properly located facilities shall be provided for cleansing and disinfecting utensils and hands of all persons handling any product.

§ 308.5 Equipment and utensils to be easily cleaned; those for inedible products to be so marked; PCB-containing equipment.

(a) Equipment and utensils used for preparing or otherwise handling any edible product or ingredient thereof in any official establishment shall be of such material and construction as will facilitate their thorough cleaning and insure cleanliness in the preparation and handling of all edible products and otherwise avoid adulteration and misbranding of such products. In addition to these requirements, equipment and utensils shall not in any way interfere with or impede inspection procedures. Receptacles used for handling inedible material shall be of such material and construction that their use will not result in adulteration of any edible product or in insanitary conditions at the establishment, and they shall bear conspicuous and distinctive marking to identify them as only for such use and shall not be used for handling any edible product.

(b) New or replacement equipment or machinery (including any replacement parts) brought onto the premises of any official establishment 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.

[40 FR 25439, June 16, 1975, as amended at 40 FR 60053, Dec. 31, 1975; 45 FR 68918, Oct. 17, 1980; 62 FR 45024, Aug. 25, 1997]

§ 308.6 Scabbards for knives.

Scabbards and similar devices for the temporary retention of knives, steels, triers, etc., by workers and others at official establishments shall be constructed of rust-resisting metal or other impervious material, shall be of a type that may be readily cleaned, and shall be kept clean.

§ 308.7 Rooms, compartments, etc., to be clean and sanitary.

Rooms, compartments, places, equipment, and utensils used for preparing, storing, or otherwise handling any product, and all other parts of the establishment, shall be kept clean and in sanitary condition. There shall be no handling or storing of materials which create an objectionable condition in rooms, compartments, or places where any product is prepared, stored, or otherwise handled.

§ 308.8 Operations, procedures, rooms, clothing, utensils, etc., to be clean and sanitary.

(a) Operations and procedures involving the preparation, storing, or handling of any product shall be strictly in accord with clean and sanitary methods.

(b) Rooms and compartments in which inspections are made and those in which livestock are slaughtered or any product is prepared shall be kept sufficiently free of steam and vapors to enable Program employees to make inspections and to insure clean operations. The walls, ceilings, and overhead structure of rooms and compartments in which product is prepared, handled, or stored shall be kept reasonably free from moisture to prevent dripping and contamination of product.

(c) Butchers and others who dress or handle diseased carcasses or parts shall, before handling or dressing other carcasses or parts, cleanse their hands with liquid soap and hot water, and rinse them in clean water. Implements used in dressing diseased carcasses shall be thoroughly cleansed with hot water having a minimum temperature of 180 °F. or in a disinfectant[2] approved by the Administrator, followed by rinsing in clean water. The employees of the establishment who handle any product shall keep their hands clean, and in all cases after visiting the toilet rooms or urinals shall wash their hands before handling any product or implements used in the preparation of product.

(d) Aprons, frocks, and other outer clothing worn by persons who handle any product shall be of material that is readily cleansed. Clean garments shall be worn at the start of each working day and the garments shall be changed during the day when required by the inspector in charge.

(e) Such practices as spitting on whetstones; spitting on the floor; placing skewers, tags, or knives in the mouth; inflating lungs or casings with air from the mouth; or testing with air from the mouth such receptacles as tierces, kegs, or casks, containing or intended as containers of any product, are prohibited. Only mechanical means may be used for such testing. Care shall be taken to prevent the contamination of product with perspiration, hair, cosmetics, medications, and similar substances.

(f) Equipment or substances which generate gases or odors shall not be used in official establishments except as permitted by the regulations in this part or by the circuit supervisor in specific cases in which he determines that such use will not result in adulteration of any product.

§ 308.9 Protective handling of products.

Products shall be protected from contamination from any source such as dust, dirt, or insects during storage, loading, or unloading at and transportation from official establishments.

§ 308.10 Slack barrels and similar containers and means of conveyance used for product; paper in contact with product.

(a) When necessary to avoid contamination of product with wood splinters or similar contaminants, slack barrels and similar containers and the cargo space of trucks, railroad cars, or other means of conveyance shall be lined with suitable material of good quality before packing.

(b) Slack barrels and similar containers and trucks, railroad cars, and other means of conveyance in which any product is transported shall be kept in a clean and sanitary condition.

(c) Paper used for covering or lining slack barrels and similar containers and the cargo space of trucks, railroad cars, or other means of conveyance shall be of a kind which does not tear during use but remains intact when moistened by the product and does not disintegrate.

§ 308.11 Burlap wrapping for meat.

Since burlap used without any other material as a wrapping for meat deposits lint on the meat and does not sufficiently protect it from outside contamination, the use of burlap as a

[2] A list of approved disinfectants 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.

wrapping for meat will not be permitted 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 matter.

§308.12 Second-hand tubs, barrels, and other containers.

Second-hand tubs, barrels, and boxes intended for use as containers of any product shall be inspected when received at the official establishment and before they are cleaned. Those showing evidence of misuse rendering them unfit to serve as containers for food products shall be rejected. The use of those showing no evidence of previous misuse may be allowed after they have been thoroughly and properly cleaned. Steaming, after thorough scrubbing and rinsing, is essential to cleaning tubs and barrels.

[35 FR 15561, Oct. 3, 1970, as amended at 38 FR 29214, Oct. 23, 1973; 41 FR 23700, June 11, 1976]

§308.13 Inedible operating and storage rooms; outer premises, docks, driveways, approaches, pens, alleys, etc.; flybreeding material; other conditions.

All operating and storage rooms and departments of official establishments used for inedible materials shall be maintained in acceptably clean condition. The outer premises of every official establishment, including docks and areas where cars and vehicles are loaded, and the driveways, approaches, yards, pens, and alleys, shall be properly paved and drained and kept in clean and orderly condition. All catch basins 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. Catch basins shall not be located in departments where any product is prepared, handled, or stored. The accumulation on the premises of official establishments of any material in which flies may breed, such as hog hair, bones, paunch contents, or manure, is forbidden. No other conditions that may result in adulteration of product or interfere with inspection shall be allowed in any official establishment or on its premises.

§308.14 Employment of diseased persons.

No operator of an official establishment or other person preparing product in an official establishment shall employ, in any department where any product is handled or prepared, any person showing evidence of a communicable disease in a transmissible stage, or known to be a carrier of such a disease, or while affected with boils, sores, infected wounds, or other abnormal sources of microbiological contaminants.

§308.15 Tagging insanitary equipment, utensils, rooms or compartments.

When, in the opinion of a Program employee, any equipment, utensil, room, or compartment at an official establishment is unclean or its use would be in violation of any of the regulations in this subchapter, he will attach a ''U.S. Rejected'' tag thereto. No equipment, utensil, room, or compartment so tagged shall again be used until made acceptable. Such tag so attached shall not be removed by anyone other than a Program employee.

§308.16 Sanitation requirements for electrical stimulating (EST) equipment.

(a) *Hide-on stimulation.* Automatic and manually operated equipment may be used to apply electrical stimualtion to the hide-on surface of slaughtered carcasses provided no opening cuts other than the stick wound or foot removal have been made in the carcass. If the hide is penetrated by electrodes, the penetrated tissue shall be trimmed. Disinfection of electrodes between each hide-on carcass stimulation is not necessary.

(b) *Hide-off stimulation.* (1) Automatic or manually operated equipment may be used to apply electrical stimulation to carcasses after complete hide removal. Partially skinned carcasses shall not be stimulated.

(2) If stimulation is applied before the carcass has been inspected, the carcass contact surfaces of the equipment shall be disinfected with a disinfectant

approved by the Administrator[1] before stimulation of the next carcass. In the event that carcass contact surfaces of the equipment cannot be cleaned and disinfected between carcass stimulations, those surfaces shall be immediately removed from contact with the exposed carcass and cleaned and disinfected before carcass contact is resumed.

(3) If stimulation is applied after the carcass has been inspected, carcass contact surfaces of the equipment need not be disinfected with a disinfectant approved by the Administrator before stimulation of the next carcass. Carcass contact surfaces shall be maintained in a clean and sanitary condition.

(c) *Preventing product contamination.* Carcass contamination of edible tissue by stomach contents, feces and/or urine is unacceptable. To prevent such occurrences, any of the following optional procedures may be used before stimulation to prevent this contamination:

(1) Leave the sphincter muscles intact;

(2) Cut the rectum and the urethra free from surrounding tissue and securely tie each off;

(3) Partially open the mid-line and/or saw the brisket to reduce pressure on the visceral organs; or

(4) Any other pressure-relieving or discharge-restricting alternative acceptable to the Administrator. Alternatives should be presented in writing, through the inspector-in-charge, to the Program for approval.

(d) *Cleaning.* All equipment must be thoroughly cleaned at least daily.

[53 FR 46433, Nov. 17, 1988]

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.
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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

[1] A list of approved disinfectants 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.

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

(b) If any equine is suspected on ante-mortem inspection of being infected with glanders or dourine, the nearest Veterinary Services unit of the Animal and Plant Health Inspection Service shall be so informed by a Program employee. Tests shall be performed by said unit to determine whether the animal is, in fact, infected with such disease. If it is found on such tests to be infected, the animal shall be disposed of in accordance with paragraph (a) of this section. Otherwise, the animal shall be identified as a U.S. Suspect and disposed of as provided in §311.10 of this subchapter.

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

§309.5 Swine; disposal because of hog cholera.

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

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

[40 FR 27225, June 27, 1975]

§309.6 Epithelioma of the eye.

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

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

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

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

(c) Apparently healthy livestock (other than hogs) from a lot in which

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

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

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

§ 309.8 Cattle affected with anasarca and generalized edema.

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

§ 309.9 Swine erysipelas.

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

§ 309.10 Onset of parturition.

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

§ 309.11 Vaccine livestock.

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

§ 309.12 Emergency slaughter; inspection prior to.

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

§ 309.13 Disposition of condemned livestock.

(a) Except as otherwise provided in this part, livestock identified as U.S. Condemned shall be killed by the official establishment, if not already dead. Such animals shall not be taken into the official establishment to be slaughtered or dressed; nor shall they be conveyed into any department of the establishment used for edible products; but they shall be disposed of in the manner provided for condemned carcasses in part 314 of this subchapter. The official U.S. Condemned tag shall not be removed from, but shall remain on the carcass until it goes into the tank, or is otherwise disposed of as prescribed in part 314 of this subchapter,

at which time such tag may be removed by a Program employee only. The number of such tag shall be reported to the veterinary medical officer by the inspector who affixed it, and also by the inspector who supervised the tanking of the carcass.

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

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

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

§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; pathogen reduction performance standards for Salmonella.

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

STEERS AND HEIFERS—Continued

Maximum slaughter rates (head per hour)	Number of inspectors by stations		
	Head	Viscera	Carcass
87 to 143	2	2	1

COWS AND BULLS

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

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

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

ONE-INSPECTOR CATTLE KILL—VISCERA TRUCK

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

1 Number of feet between points	2 Head rack and high rail		3 Viscera and low rail		4 Low rail and head rack		5 Head rack and carcass [2]		6 Carcass [2] and washbasin		7 Tags—brands and low rail		8 Viscera and washbasin		9 Viscera and high rail		10 Low rail and high rail		11 Head rack and closest washbasin		12 Washbasin and high rail [1]		13 Head rack and 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]	
	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	
Number of feet between points	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

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
66 to 70	90	95	87	92
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 specified in § 318.7(c)(4) of this subchapter may be used in lieu of defibrination.

[39 FR 1973, Jan. 16, 1974]

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Testing level	Sampling Rate (percent of estimated day's slaughter)	
	Certified	Noncertified
A	100	100
B	50	50
C	20	30
(Start) D	5	10
E	2	5

[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
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; pathogen reduction performance standards for Salmonella.

(a) Criteria for verifying process control; *E. coli* testing.

(1) Each official establishment that slaughters cattle and/or swine shall 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 shall collect samples from all chilled swine or cattle carcasses, *except* those boned before chilling (hot-boned), which must be sampled after the final wash. Samples shall be collected by either sponging or excising tissue from three sites on the selected carcass. On cattle carcasses, establishments shall sponge or excise tissue from the flank, brisket and rump, *except* for hide-on calves, in which case establishments shall take samples by sponging from inside the flank, inside the brisket, and inside the rump; on swine carcasses, establishments shall sponge or excise tissue from the ham, belly and jowl areas.[1]

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

Cattle: 1 test per 300 carcasses, but at a minimum one sample each week of operation.

Swine: 1 test per 1000 carcasses, but at a minimum one sample each week of operation.

(iii) *Sampling frequency.* Samples shall be taken at a frequency proportional to a slaughter establishment's volume of production, at the following rates:

Bovines: 1 test per 300 carcasses
Swine: 1 test per 1,000 carcasses

(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, 20,000 swine, or a combination of cattle and swine not exceeding 6,000 cattle and 20,000 total of both types. 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

[1] A copy of FSIS's ''Guidelines for *E. coli* Testing for Process Control verification in Cattle and Swine Slaughter Establishments'' is available for inspection in the FSIS Docket Room.

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	30	53	18

[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.)

(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; 62 FR 6100, Nov. 14, 1997]

EFFECTIVE DATE NOTE: At 62 FR 61008, Nov. 14, 1997, § 310.25 was amended by revising the table in paragraph (b)(1), effective Jan. 13, 1998. For the convenience of the user, the superseded text is set forth as follows:

§ 310.25 Contamination with microorganisms; pathogen reduction performance standards for Salmonella.

* * * * *

[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.

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.

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

Sec.

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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

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

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.

(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 folliculorum, 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 bladderworms.

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

passed for human food. If the infestation is excessive, the carcass shall be condemned. If the infestation is moderate, the carcass may be passed for cooking, but in case such carcass is not cooked as required by part 315 of this subchapter, it shall be condemned.

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

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

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

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

§ 311.26 Emaciation.

Carcasses of livestock too emaciated to produce wholesome meat, and carcasses which show a serous infiltration of muscle tissues, or a serous or mucoid degeneration of the fatty tissue, shall be condemned. A gelatinous change of the fat of the heart and kidneys of well-nourished carcasses and mere leanness shall not be classed as emaciation.

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

§ 311.27 Injured animals slaughtered at unusual hours.

When it is necessary for humane reasons to slaughter an injured animal at night or on Sunday or a holiday when the inspector cannot be obtained, the carcass and all parts 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 nonaffected parts of the carcass may be passed for human food after the removal and condemnation of the affected portion. If a part of the carcass shows numerous lesions, or if the character of the lesion is such that complete extirpation is difficult and uncertainly accomplished, or if the lesion renders the part in any way unfit for human food, the part shall be condemned.

(c) If the lesions are slight or of such character as to be insignificant from a standpoint of wholesomeness, the carcass or parts may be passed for use in the manufacture of comminuted cooked product, after removal and condemnation of the visibly affected portions.

§311.36 Coccidioidal granuloma.

(a) Carcasses which are affected with generalized coccidioidal granuloma or which show systemic changes because of such disease shall be condemned.

(b) Carcasses affected with localized lesions of this disease may be passed for human food after the affected parts are removed and condemned.

§311.37 Odors, foreign and urine.

(a) Carcasses which give off a pronounced odor of medicinal, chemical, or other foreign substance shall be condemned.

(b) Carcasses which give off a pronounced urine odor shall be condemned.

(c) Carcasses, organs, or parts affected by odor to a lesser degree than as described in paragraphs (a) and (b) of this section and in which the odor can be removed by trimming or chilling may be passed for human food, after removal of affected parts or dissipation of the condition.

§ 311.38 Meat and meat byproducts from livestock which have been exposed to radiation.

Meat and meat byproducts from livestock which have been administered radioactive material shall be condemned unless the use of the radiation was in conformity with a regulation or exemption in effect pursuant to section 409 of the Federal Food, Drug, and Cosmetic Act.

§ 311.39 Biological residues.

Carcasses, organs, or other parts of carcasses of livestock shall be condemned if it is determined that they are adulterated because of the presence of any biological residues.

PART 312—OFFICIAL MARKS, DEVICES AND CERTIFICATES

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.

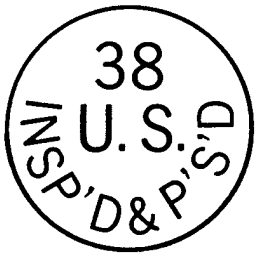
§ 312.1 General.

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.

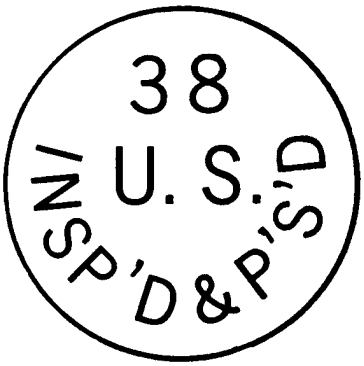
(a) The official inspection legend required by part 316 of this subchapter to be applied to inspected and passed carcasses and parts of carcasses of cattle, sheep, swine and goats, meat food products in animal casings, and other products as approved by the Administrator, shall be in the appropriate form 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.

[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 beef and hog carcasses primal parts and cuts therefrom, beef livers, beef tongues, beef hearts, and smoked meats not in casings.

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.

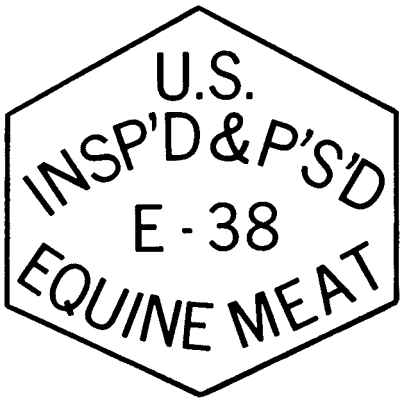
(3) The official inspection legend described in paragraph (b)(1) of this section may also be used for purposes of part 316 of this subchapter on shipping containers, band labels, artificial casings, and other articles with the approval of the Administrator.

(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.

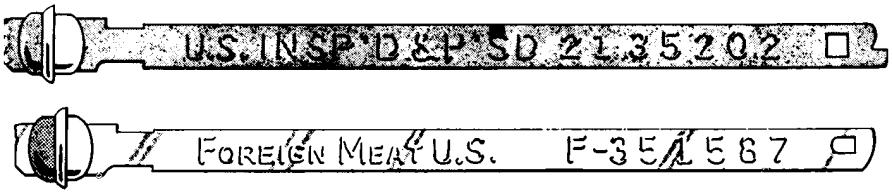
§ 312.5 Official seals for transportation of products.

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]

[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.

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]

§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 308 and 310 of this subchapter 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 308 of this subchapter 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]

§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]

§ 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]

[1] The number ''529893'' is given as an example only. The number of the offical export certificate will be shown in lieu thereof.

§ 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 shall be in rooms or compartments separate from those used for preparing or storing edible products. There shall be no connection between rooms or compartments containing inedible products and those containing edible products, except that there may be one connecting doorway between the slaughtering or viscera separating department and the tank charging room of the inedible products rendering department. Pipes and chutes installed in accordance with such arrangements as are permitted by part 308 of this subchapter, or as may be approved by the Administrator in specific cases, may be used to convey inedible and condemned material from edible product departments to inedible product departments.

§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 shall be properly equipped with condensers and other appliances which will acceptably suppress odors incident to such preparation.

§ 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

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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, or other equine not heat processed in a manner that conforms to the time and temperature combinations in the Table for Time/Temperature Combination For Cooked Beef, Roast Beef, and Cooked Corned Beef in § 318.17, or that have not undergone other further 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 Sections Affected in the Finding Aids section of this volume.

§ 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]

(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

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[1] ''Sec. 407(a) Colored oleomargarine or colored margarine which is sold in the same State or Territory in which it is produced shall be subject in the same manner and to the same extent to the provisions of this Act as if it had been introduced in interstate commerce.

(b) No person shall sell, or offer for sale, colored oleomargarine or colored margarine unless—

(1) Such oleomargarine or margarine is packaged,

(2) The net weight of the contents of any package sold in a retail establishment is one pound or less,

(3) There appears on the label of the package (A) The word 'oleomargarine' or 'margarine' in type or lettering at least as large as any other type or lettering on such label, and (B) A full and accurate statement of all the ingredients contained in such oleomargarine, or margarine, and

(4) Each part of the contents of the package is contained in a wrapper which bears the word 'oleomargarine' or 'margarine' in type or lettering not smaller than 20-point type.

The requirements of this subsection shall be in addition to and not in lieu of any of the other requirements of this Act.

(c) No person shall possess in a form ready for serving colored oleomargarine or colored margarine at a public eating place unless a notice that oleomargarine or margarine is served is displayed prominently and conspicuously in such place and in such manner as to render it likely to be read and understood by the ordinary individual being served in such eating place or is printed or is otherwise set forth on the menu in type or lettering not smaller than that normally used to designate the serving of other food items. No person shall serve colored oleomargarine or colored margarine at a public eating place, whether or not any charge is made therefor, unless (1) each separate serving bears or is accompanied by labeling identifying it as oleomargarine or margarine, or (2) each separate serving thereof is triangular in shape.

(d) Colored oleomargarine or colored margarine when served with meals at a public eating place shall at the time of such service be exempt from the labeling requirements of section 343 of this Act (except subsection (a) and (f) of section 343 of this title) if it complies with the requirements of subsection (b) of this section.

(e) For the purpose of this section colored oleomargarine or colored margarine is oleomargarine or margarine having a tint or shade containing more than one and six tenths degrees of yellow or of yellow and red collectively, but with an excess of yellow over red, measured in terms of Lovibond tintometer scale or its equivalent'' (21 U.S.C. 347).

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.

(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) [Reserved]

[35 FR 15580, Oct. 3, 1970]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 317.8, see the List of CFR Sections Affected in the Finding Aids section of this volume.

§ 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,'' 1994 Edition, October 1993, 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]

§ 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 a net weight program under a Total Quality Control System or Partial Quality Control Program in accordance with § 318.4 of this subchapter.

[55 FR 49834, Nov. 30, 1990, as amended at 62 FR 45024, Aug. 25, 1997]

§ 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)

[58 FR 664, Jan. 6, 1993; 58 FR 43788, Aug. 18, 1993; 58 FR 47627, Sept. 10, 1993; 59 FR 45194, Sept. 1, 1994; 60 FR 176, Jan. 3, 1995]

§§ 317.310–317.311 [Reserved]

§ 317.312 Reference amounts customarily consumed per eating occasion.

(a) The general principles followed in arriving at the reference amounts customarily consumed per eating occasion (Reference Amount(s)), as set forth in paragraph (b) of this section, are:

(1) The Reference Amounts are calculated for persons 4 years of age or older to reflect the amount of food customarily consumed per eating occasion by persons in this population group. These Reference Amounts are based on data set forth in appropriate national food consumption surveys.

(2) The Reference Amounts are calculated for an infant or child under 4 years of age to reflect the amount of food customarily consumed per eating occasion by infants up to 12 months of age or by children 1 through 3 years of age, respectively. These Reference Amounts are based on data set forth in appropriate national food consumption surveys. Such Reference Amounts are to be used only when the product is specially formulated or processed for use by an infant or by a child under 4 years of age.

(3) An appropriate national food consumption survey includes a large sample size representative of the demographic and socioeconomic characteristics of the relevant population group and must be based on consumption data under actual conditions of use.

(4) To determine the amount of food customarily consumed per eating occasion, the mean, median, and mode of the consumed amount per eating occasion were considered.

(5) When survey data were insufficient, FSIS took various other sources of information on serving sizes of food into consideration. These other sources of information included:

(i) Serving sizes used in dietary guidance recommendations or recommended by other authoritative systems or organizations;

(ii) Serving sizes recommended in comments;

(iii) Serving sizes used by manufacturers and grocers; and

(iv) Serving sizes used by other countries.

(6) Because they reflect the amount customarily consumed, the Reference Amount and, in turn, the serving size declared on the product label are based on only the edible portion of food, and not bone, seed, shell, or other inedible components.

(7) The Reference Amount is based on the major intended use of the product (e.g., a mixed dish measurable with a cup as a main dish and not as a side dish).

(8) The Reference Amounts for products that are consumed as an ingredient of other products, but that may also be consumed in the form in which they are purchased (e.g., ground beef), are based on use in the form purchased.

(9) FSIS sought to ensure that foods that have similar dietary usage, product characteristics, and customarily consumed amounts have a uniform Reference Amount.

(b) The following Product Categories and Reference Amounts shall be used as the basis for determining serving sizes for specific products:

TABLE 1.—REFERENCE AMOUNTS CUSTOMARILY CONSUMED PER EATING OCCASION—INFANT AND TODDLER FOODS [1,2,3]

Product category	Reference amount
Infant & Toddler Foods:	
Dinner Dry Mix	15 g
Dinner, ready-to-serve, strained type	60 g
Dinner, soups, ready-to-serve junior type	110 g
Dinner, stew or soup ready-to-serve toddlers	170 g
Plain meats and meat sticks, ready-to-serve	55 g

[1] These values represent the amount of food customarily consumed per eating occasion and were primarily derived from the 1977–1978 and the 1987–1988 Nationwide Food Consumption Surveys conducted by the U.S. Department of Agriculture.

[2] Unless otherwise noted in the Reference Amount column, the Reference Amounts are for the ready-to-serve or almost ready-to-serve form of the product (i.e., heat and serve). If not listed separately, the Reference Amount for the unprepared form (e.g., dehydrated cereal) is the amount required to make one Reference Amount of the prepared form.

[3] Manufacturers are required to convert the Reference Amount to the label serving size in a household measure most appropriate to their specific product using the procedures established by regulation.

TABLE 2.—REFERENCE AMOUNTS CUSTOMARILY CONSUMED PER EATING OCCASION—GENERAL FOOD SUPPLY [1,2,3,4,5]

Product category	Reference amount	Reference amount
	Ready-to-serve	Ready-to-cook
Egg mixtures, (western style omelet, souffle, egg foo young	110 g	n/a.
Lard, margarine, shortening	1 tbsp	n/a.
Salad and potato toppers; e.g., bacon bits	7 g	n/a.
Bacon (bacon, beef breakfast strips, pork breakfast strips, pork rinds)	15 g	54 g=bacon. 30 g = breakfast strips.
Dried; e.g., jerky, dried beef, Parma ham sausage products with a moisture/protein ratio of less than 2:1; e.g., pepperoni.	30 g	n/a.
Snacks; e.g., meat snack food sticks	30 g	n/a.
Luncheon meat, bologna, Canadian style bacon, pork pattie crumbles, beef pattie crumbles, blood pudding, luncheon loaf, old fashioned loaf, berlinger, bangers, minced luncheon roll, thuringer, liver sausage, mortadella, uncured sausage (franks), ham and cheese loaf, P&P loaf, scrapple souse, head cheese, pizza loaf, olive loaf, pate, deviled ham, sandwich spread, teawurst, cervelet, Lebanon bologna, potted meat food product, taco fillings, meat pie fillings.	55 g	n/a.
Linked meat sausage products, Vienna sausage, frankfurters, pork sausage, imitation frankfurters, bratwurst, kielbasa, Polish sausage, summer sausage, mettwurst, smoked country sausage, smoked sausage, smoked or pickled meat, pickled pigs feet.	55 g	n/a. 75 g=uncooked sausage.
Entrees without sauce, cuts of meat including marinated, tenderized, injected cuts of meat, beef patty, corn dog, croquettes, fritters, cured ham, dry cured ham, dry cured cappicola, corned beef, pastrami, country ham, pork shoulder picnic, meatballs, pureed adult foods.	85 g	114 g.
Canned meats, canned beef, canned pork. [4]	55 g	n/a.
Entrees with sauce, barbecued meats in sauce	140 g	n/a.
Mixed dishes NOT measurable with a cup; [5] e.g., burrito, egg roll, enchilada, pizza, pizza roll, quiche, all types of sandwiches, cracker and meat lunch type packages, gyro, stromboli, burger on a bun, frank on a bun, calzone, taco, pockets stuffed with meat, foldovers, stuffed vegetables with meat, shish kabobs, empanada.	140 g (plus 55 g for products with sauce toppings)	n/a.
Mixed dishes measurable with a cup; e.g., meat casserole, macaroni and cheese with meat, pot pie, spaghetti with sauce, meat chili, chili with beans, meat hash, creamed chipped beef, beef ravioli in sauce, beef stroganoff, Brunswick stew, goulash, meat stew, ragout, meat lasagna, meat filled pasta.	1 cup	n/a.
Salads—pasta or potato, potato salad with bacon, macaroni and meat salad	140 g	n/a.
Salads—all other meat, salads, ham salad	100 g	n/a.
Soups—all varieties	245 g	n/a.
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..		

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 sauce topping.

(c) For products that have no Reference Amount listed in paragraph (b) of this section for the unprepared or the prepared form of the product and that consist of two or more foods packaged and presented to be consumed together (e.g., lunch meat with cheese and crackers), the Reference Amount for the combined product shall be determined using the following rules:

(1) For bulk products, the Reference Amount for the combined product shall be the Reference Amount, as established in paragraph (b) of this section, for the ingredient that is represented as the main ingredient plus proportioned amounts of all minor ingredients.

(2) For products where the ingredient represented as the main ingredient is one or more discrete units, the Reference Amount for the combined product shall be either the number of small discrete units or the fraction of the large discrete unit that is represented as the main ingredient that is closest to the Reference Amount for that ingredient as established in paragraph (b) of this section plus proportioned amounts of all minor ingredients.

(3) If the Reference Amounts are in compatible units, they shall be summed (e.g., ingredients in equal volumes such as tablespoons). If the Reference Amounts are in incompatible units, the weights of the appropriate volumes should be used (e.g., grams of one ingredient plus gram weight of tablespoons of a second ingredient).

(d) If a product requires further preparation, e.g., cooking or the addition of water or other ingredients, and if paragraph (b) of this section provides a Reference Amount for the product in the prepared form, then the Reference Amount for the unprepared product shall be determined using the following rules:

(1) Except as provided for in paragraph (d)(2) of this section, the Reference Amount for the unprepared product shall be the amount of the unprepared product required to make the Reference Amount for the prepared product as established in paragraph (b) of this section.

(2) For products where the entire contents of the package is used to prepare one large discrete unit usually divided for consumption, the Reference Amount for the unprepared product shall be the amount of the unprepared product required to make the fraction of the large discrete unit closest to the Reference Amount for the prepared product as established in paragraph (b) of this section.

(e) The Reference Amount for an imitation or substitute product or altered product as defined in § 317.313(d), such as a ''low calorie'' version, shall be the same as for the product for which it is offered as a substitute.

(f) The Reference Amounts set forth in paragraphs (b) through (e) of this section shall be used in determining whether a product meets the criteria for nutritional claims. If the serving

size declared on the product label differs from the Reference Amount, and the product meets the criteria for the claim only on the basis of the Reference Amount, the claim shall be followed by a statement that sets forth the basis on which the claim is made. That statement shall include the Reference Amount as it appears in paragraph (b) of this section followed, in parentheses, by the amount in common household measure if the Reference Amount is expressed in measures other than common household measures.

(g) The Administrator, on his or her own initiative or on behalf of any interested person who has submitted a labeling application, may issue a proposal to establish or amend a Product Category or Reference Amount identified in paragraph (b) of this section.

(1) Labeling applications and supporting documentation to be filed under this section shall be submitted in quadruplicate, except that the supporting documentation may be submitted on a computer disc copy. If any part of the material submitted is in a foreign language, it shall be accompanied by an accurate and complete English translation. The labeling application shall state the applicant's post office address.

(2) Pertinent information will be considered as part of an application on the basis of specific reference to such information submitted to and retained in the files of the Food Safety and Inspection Service. However, any reference to unpublished information furnished by a person other than the applicant will not be considered unless use of such information is authorized (with the understanding that such information may in whole or part be subject to release to the public) in a written statement signed by the person who submitted it. Any reference to published information should be accompanied by reprints or photostatic copies of such references.

(3) The availability for public disclosure of labeling applications, along with supporting documentation, submitted to the Agency under this section will be governed by the rules specified in subchapter D, title 9.

(4) Data accompanying the labeling application, such as food consumption data, shall be submitted on separate sheets, suitably identified. If such data has already been submitted with an earlier labeling application from the applicant, the present labeling application must provide the data.

(5) The labeling application must be signed by the applicant or by his or her attorney or agent, or (if a corporation) by an authorized official.

(6) The labeling application shall include a statement signed by the person responsible for the labeling application, that to the best of his or her knowledge, it is a representative and balanced submission that includes unfavorable information, as well as favorable information, known to him or her pertinent to the evaluation of the labeling application.

(7) Labeling applications for a new Reference Amount and/or Product Category shall be accompanied by the following data which shall be submitted in the following form to the Director, Food Labeling Division, Regulatory Programs, Food Safety and Inspection Service, Washington, DC 20250:

(Date)

The undersigned, _____ submits this labeling application pursuant to 9 CFR 317.312 with respect to Reference Amount and/or Product Category.

Attached hereto, in quadruplicate, or on a computer disc copy, and constituting a part of this labeling application, are the following:

(i) A statement of the objective of the labeling application;

(ii) A description of the product;

(iii) A complete sample product label including nutrition label, using the format established by regulation;

(iv) A description of the form in which the product will be marketed;

(v) The intended dietary uses of the product with the major use identified (e.g., ham as a luncheon meat);

(vi) If the intended use is primarily as an ingredient in other foods, list of foods or food categories in which the product will be used as an ingredient with information on the prioritization of the use;

(vii) The population group for which the product will be offered for use (e.g., infants, children under 4 years of age);

(viii) The names of the most closely-related products (or in the case of foods for special dietary use and imitation or substitute foods, the names of the products for which they are offered as substitutes);

(ix) The suggested Reference Amount (the amount of edible portion of food as consumed, excluding bone, skin or other inedible components) for the population group for which the product is intended with full description of the methodology and procedures that were used to determine the suggested Reference Amount. In determining the Reference Amount, general principles and factors in paragraph (a) of this section should be followed.

(x) The suggested Reference Amount shall be expressed in metric units. Reference Amounts for foods shall be expressed in grams except when common household units such as cups, tablespoons, and teaspoons are more appropriate or are more likely to promote uniformity in serving sizes declared on product labels. For example, common household measures would be more appropriate if products within the same category differ substantially in density such as mixed dishes measurable with a cup.

(A) In expressing the Reference Amount in grams, the following general rules shall be followed:

(*1*) For quantities greater than 10 grams, the quantity shall be expressed in nearest 5 grams increment.

(*2*) For quantities less than 10 grams, exact gram weights shall be used.

(B) [Reserved]

(xi) A labeling application for a new subcategory of food with its own Reference Amount shall include the following additional information:

(A) Data that demonstrate that the new subcategory of food will be consumed in amounts that differ enough from the Reference Amount for the parent category to warrant a separate Reference Amount. Data must include sample size, and the mean, standard deviation, median, and modal consumed amount per eating occasion for the product identified in the labeling application and for other products in the category. All data must be derived from the same survey data.

(B) Documentation supporting the difference in dietary usage and product characteristics that affect the consumption size that distinguishes the product identified in the labeling application from the rest of the products in the category.

(xii) In conducting research to collect or process food consumption data in support of the labeling application, the following general guidelines should be followed.

(A) Sampled population selected should be representative of the demographic and socioeconomic characteristics of the target population group for which the food is intended.

(B) Sample size (i.e., number of eaters) should be large enough to give reliable estimates for customarily consumed amounts.

(C) The study protocol should identify potential biases and describe how potential biases are controlled for or, if not possible to control, how they affect interpretation of results.

(D) The methodology used to collect or process data including study design, sampling procedures, materials used (e.g., questionnaire, interviewer's manual), procedures used to collect or process data, methods or procedures used to control for unbiased estimates, and procedures used to correct for nonresponse, should be fully documented.

(xiii) A statement concerning the feasibility of convening associations, corporations, consumers, and other interested parties to engage in negotiated rulemaking to develop a proposed rule.

Yours very truly,

Applicant _____

By _____

(Indicate authority)

(8) Upon receipt of the labeling application and supporting documentation, the applicant shall be notified, in writing, of the date on which the labeling application was received. Such notice shall inform the applicant that the labeling application is undergoing Agency review and that the applicant shall subsequently be notified of the Agency's decision to consider for further review or deny the labeling application.

(9) Upon review of the labeling application and supporting documentation, the Agency shall notify the applicant, in writing, that the labeling application is either being considered for further review or that it has been summarily denied by the Administrator.

(10) If the labeling application is summarily denied by the Administrator, the written notification shall state the reasons therefor, including why the Agency has determined that the proposed Reference Amount and/or Product Category is false or misleading. The notification letter shall inform the applicant that the applicant may submit a written statement by way of answer to the notification, and that the applicant shall have the right to request a hearing with respect to the merits or validity of the Administrator's decision to deny the use of the proposed Reference Amount and/or Product Category.

(i) If the applicant fails to accept the determination of the Administrator and files an answer and requests a hearing, and the Administrator, after review of the answer, determines the

initial determination to be correct, the Administrator shall file with the Hearing Clerk of the Department the notification, answer, and the request for a hearing, which shall constitute the complaint and answer in the proceeding, which shall thereafter be conducted in accordance with the Department's Uniform Rules of Practice.

(ii) The hearing shall be conducted before an administrative law judge with the opportunity for appeal to the Department's Judicial Officer, who shall make the final determination for the Secretary. Any such determination by the Secretary shall be conclusive unless, within 30 days after receipt of notice of such final determination, the applicant appeals to the United States Court of Appeals for the circuit in which the applicant has its principal place of business or to the United States Court of Appeals for the District of Columbia Circuit.

(11) If the labeling application is not summarily denied by the Administrator, the Administrator shall publish in the FEDERAL REGISTER a proposed rule to amend the regulations to authorize the use of the Reference Amount and/or Product Category. The proposal shall also summarize the labeling application, including where the supporting documentation can be reviewed. The Administrator's proposed rule shall seek comment from consumers, the industry, consumer and industry groups, and other interested persons on the labeling application and the use of the proposed Reference Amount and/or Product Category. After public comment has been received and reviewed by the Agency, the Administrator shall make a determination on whether the proposed Reference Amount and/or Product Category shall be approved for use on the labeling of meat food products.

(i) If the Reference Amount and/or Product Category is denied by the Administrator, the Agency shall notify the applicant, in writing, of the basis for the denial, including the reason why the Reference Amount and/or Product Category on the labeling was determined by the Agency to be false or misleading. The notification letter shall also inform the applicant that the applicant may submit a written statement by way of answer to the notification, and that the applicant shall have the right to request a hearing with respect to the merits or validity of the Administrator's decision to deny the use of the proposed Reference Amount and/or Product Category.

(A) If the applicant fails to accept the determination of the Administrator and files an answer and requests a hearing, and the Administrator, after review of an answer, determines the initial determination to be correct, the Administrator shall file with the Hearing Clerk of the Department the notification, answer, and the request for a hearing, which shall constitute the complaint and answer in the proceeding, which shall thereafter be conducted in accordance with the Department's Uniform Rules of Practice.

(B) The hearing shall be conducted before an administrative law judge with the opportunity for appeal to the Department's Judicial Officer, who shall make the final determination for the Secretary. Any such determination by the Secretary shall be conclusive unless, within 30 days after receipt of the notice of such final determination, the applicant appeals to the United States Court of Appeals for the circuit in which the applicant has its principal place of business or to the United States Court of Appeals for the District of Columbia Circuit.

(ii) If the Reference Amount and/or Product Category is approved, the Agency shall notify the applicant, in writing, and shall also publish in the FEDERAL REGISTER a final rule amending the regulations to authorize the use of the Reference Amount and/or Product Category.

(Paperwork requirements were approved by the Office of Management and Budget under control number 0583–0088)

[58 FR 664, Jan. 6, 1993; 58 FR 43788, Aug. 18, 1993 as amended at 58 FR 47627, Sept. 10, 1993; 59 FR 45196, Sept. 1, 1994; 60 FR 186, Jan. 3, 1995]

§ 317.313 Nutrient content claims; general principles.

(a) This section applies to meat or meat food products that are intended for human consumption and that are offered for sale.

(b) A claim which, expressly or by implication, characterizes the level of a nutrient (nutrient content claim) of the type required in nutrition labeling pursuant to § 317.309, may not be made on a label or in labeling of that product unless the claim is made in accordance with the applicable provisions in this subpart.

(1) An expressed nutrient content claim is any direct statement about the level (or range) of a nutrient in the product, e.g., ''low sodium'' or ''contains 100 calories.''

(2) An implied nutrient content claim is any claim that:

(i) Describes the product or an ingredient therein in a manner that suggests that a nutrient is absent or present in a certain amount (e.g., ''high in oat bran''); or

(ii) Suggests that the product, because of its nutrient content, may be useful in maintaining healthy dietary practices and is made in association with an explicit claim or statement about a nutrient (e.g., ''healthy, contains 3 grams (g) of fat'').

(3) Except for claims regarding vitamins and minerals described in paragraph (q)(3) of this section, no nutrient content claims may be made on products intended specifically for use by infants and children less than 2 years of age unless the claim is specifically provided for in subpart B of this part.

(4) Reasonable variations in the spelling of the terms defined in applicable provisions in this subpart and their synonyms are permitted provided these variations are not misleading (e.g., ''hi'' or ''lo'').

(c) Information that is required or permitted by § 317.309 to be declared in nutrition labeling, and that appears as part of the nutrition label, is not a nutrient content claim and is not subject to the requirements of this section. If such information is declared elsewhere on the label or in labeling, it is a nutrient content claim and is subject to the requirements for nutrient content claims.

(d) A ''substitute'' product is one that may be used interchangeably with another product that it resembles, i.e., that it is organoleptically, physically, and functionally (including shelf life) similar to, and that it is not nutritionally inferior to unless it is labeled as an ''imitation.''

(1) If there is a difference in performance characteristics that materially limits the use of the product, the product may still be considered a substitute if the label includes a disclaimer adjacent to the most prominent claim as defined in paragraph (j)(2)(iii) of this section, informing the consumer of such difference (e.g., ''not recommended for frying'').

(2) This disclaimer shall be in easily legible print or type and in a size no less than that required by § 317.2(h) for the net quantity of contents statement, except where the size of the claim is less than two times the required size of the net quantity of contents statement, in which case the disclaimer statement shall be no less than one-half the size of the claim but no smaller than 1/16-inch minimum height, except as permitted by § 317.400(d)(2).

(e)(1) Because the use of a ''free'' or ''low'' claim before the name of a product implies that the product differs from other products of the same type by virtue of its having a lower amount of the nutrient, only products that have been specially processed, altered, formulated, or reformulated so as to lower the amount of the nutrient in the product, remove the nutrient from the product, or not include the nutrient in the product, may bear such a claim (e.g., ''low sodium beef noodle soup'').

(2) Any claim for the absence of a nutrient in a product, or that a product is low in a nutrient when the product has not been specially processed, altered, formulated, or reformulated to qualify for that claim shall indicate that the product inherently meets the criteria and shall clearly refer to all products of that type and not merely to the particular brand to which the labeling attaches (e.g., ''lard, a sodium free food'').

(f) A nutrient content claim shall be in type size and style no larger than two times that of the statement of identity and shall not be unduly prominent in type style compared to the statement of identity.

(g) Labeling information required in §§ 317.313, 317.354, 317.356, 317.360, 317.361, 317.362, and 317.380, whose type size is

not otherwise specified, is required to be in letters and/or numbers no less than 1/16 inch in height, except as permitted by § 317.400(d)(2).

(h) [Reserved]

(i) Except as provided in § 317.309 or in paragraph (q)(3) of this section, the label or labeling of a product may contain a statement about the amount or percentage of a nutrient if:

(1) The use of the statement on the product implicitly characterizes the level of the nutrient in the product and is consistent with a definition for a claim, as provided in subpart B of this part, for the nutrient that the label addresses. Such a claim might be, ''less than 10 g of fat per serving;''

(2) The use of the statement on the product implicitly characterizes the level of the nutrient in the product and is not consistent with such a definition, but the label carries a disclaimer adjacent to the statement that the product is not ''low'' in or a ''good source'' of the nutrient, such as ''only 200 milligrams (mg) sodium per serving, not a low sodium product.'' The disclaimer must be in easily legible print or type and in a size no less than required by § 317.2(h) for the net quantity of contents, except where the size of the claim is less than two times the required size of the net quantity of contents statement, in which case the disclaimer statement shall be no less than one-half the size of the claim but no smaller than 1/16-inch minimum height, except as permitted by § 317.400(d)(2);

(3) The statement does not in any way implicitly characterize the level of the nutrient in the product and it is not false or misleading in any respect (e.g., ''100 calories'' or ''5 grams of fat''), in which case no disclaimer is required.

(4) ''Percent fat free'' claims are not authorized by this paragraph. Such claims shall comply with § 317.362(b)(6).

(j) A product may bear a statement that compares the level of a nutrient in the product with the level of a nutrient in a reference product. These statements shall be known as ''relative claims'' and include ''light,'' ''reduced,'' ''less'' (or ''fewer''), and ''more'' claims.

(1) To bear a relative claim about the level of a nutrient, the amount of that nutrient in the product must be compared to an amount of nutrient in an appropriate reference product as specified in this paragraph (j).

(i)(A) For ''less'' (or ''fewer'') and ''more'' claims, the reference product may be a dissimilar product within a product category that can generally be substituted for one another in the diet or a similar product.

(B) For ''light,'' ''reduced,'' and ''added'' claims, the reference product shall be a similar product, and

(ii)(A) For ''light'' claims, the reference product shall be representative of the type of product that includes the product that bears the claim. The nutrient value for the reference product shall be representative of a broad base of products of that type; e.g., a value in a representative, valid data base; an average value determined from the top three national (or regional) brands, a market basket norm; or, where its nutrient value is representative of the product type, a market leader. Firms using such a reference nutrient value as a basis for a claim, are required to provide specific information upon which the nutrient value was derived, on request, to consumers and appropriate regulatory officials.

(B) For relative claims other than ''light,'' including ''less'' and ''more'' claims, the reference product may be the same as that provided for ''light'' in paragraph (j)(1)(ii)(A) of this section or it may be the manufacturer's regular product, or that of another manufacturer, that has been offered for sale to the public on a regular basis for a substantial period of time in the same geographic area by the same business entity or by one entitled to use its trade name, provided the name of the competitor is not used on the labeling of the product. The nutrient values used to determine the claim when comparing a single manufacturer's product to the labeled product shall be either

the values declared in nutrition labeling or the actual nutrient values, provided that the resulting labeling is internally consistent (i.e., that the values stated in the nutrition information, the nutrient values in the accompanying information, and the declaration of the percentage of nutrient by which the product has been modified are consistent and will not cause consumer confusion when compared), and that the actual modification is at least equal to the percentage specified in the definition of the claim.

(2) For products bearing relative claims:

(i) The label or labeling must state the identity of the reference product and the percent (or fraction) of the amount of the nutrient in the reference product by which the nutrient has been modified, (e.g., ''50 percent less fat than 'reference product'' or ''⅓ fewer calories than 'reference product'''); and

(ii) This information shall be immediately adjacent to the most prominent claim in easily legible boldface print or type, in distinct contrast to other printed or graphic matter, that is no less than that required by § 317.2(h) for net quantity of contents, except where the size of the claim is less than two times the required size of the net quantity of contents statement, in which case the referral statement shall be no less than one-half the size of the claim, but no smaller than 1/16-inch minimum height, except as permitted by § 317.400(d)(2).

(iii) The determination of which use of the claim is in the most prominent location on the label or labeling will be made based on the following factors, considered in order:

(A) A claim on the principal display panel adjacent to the statement of identity;

(B) A claim elsewhere on the principal display panel;

(C) A claim on the information panel; or

(D) A claim elsewhere on the label or labeling.

(iv) The label or labeling must also bear:

(A) Clear and concise quantitative information comparing the amount of the subject nutrient in the product per labeled serving size with that in the reference product; and

(B) This statement shall appear adjacent to the most prominent claim or to the nutrition information.

(3) A relative claim for decreased levels of a nutrient may not be made on the label or in labeling of a product if the nutrient content of the reference product meets the requirement for a ''low'' claim for that nutrient.

(k) The term ''modified'' may be used in the statement of identity of a product that bears a relative claim that complies with the requirements of this part, followed immediately by the name of the nutrient whose content has been altered (e.g., ''modified fat 'product''''). This statement of identity must be immediately followed by the comparative statement such as ''contains 35 percent less fat than 'reference product'.'' The label or labeling must also bear the information required by paragraph (j)(2) of this section in the manner prescribed.

(l) For purposes of making a claim, a ''meal-type product'' 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.,

''⅓ fewer calories and 50 percent less fat than the market leader''); and

(ii) Quantitative information comparing the level of calories and fat content in the product per labeled serving size with that of the reference product that it replaces is declared adjacent to the most prominent claim or to the nutrition information (e.g., ''lite 'this product'—200 calories, 4 grams (g) fat; regular 'reference product'—300 calories, 8 g fat per serving''); and

(iii) If the labeled product contains less than 40 calories or less than 3 g fat per reference amount customarily consumed, the percentage reduction for that nutrient need not be declared.

(4) A ''light'' claim may not be made on a product for which the reference product meets the definition of ''low fat'' and ''low calorie.''

(c)(1)(i) A product for which the reference product contains 40 calories or less and 3 g fat or less per reference amount customarily consumed may use the terms ''light'' or ''lite'' without further qualification if it is reduced by 50 percent or more in sodium content compared to the reference product; and

(ii) As required in § 317.313(j)(2) for relative claims:

(A) The identity of the reference product and the percent (or fraction) that the sodium was reduced are declared in immediate proximity to the most prominent such claim (e.g., ''50 percent less sodium than the market leader''); and

(B) Quantitative information comparing the level of sodium per labeled serving size with that of the reference product it replaces is declared adjacent to the most prominent claim or to the nutrition information (e.g., ''lite 'this product'—500 milligrams (mg) sodium per serving; regular 'reference product'—1,000 mg sodium per serving'').

(2)(i) A product for which the reference product contains more than 40 calories or more than 3 g fat per reference amount customarily consumed may use the terms ''light in sodium'' or ''lite in sodium'' if it is reduced by 50 percent or more in sodium content compared to the reference product, provided that ''light'' or ''lite'' is presented in immediate proximity with ''in sodium'' and the entire term is presented in uniform type size, style, color, and prominence; and

(ii) As required in § 317.313(j)(2) for relative claims:

(A) The identity of the reference product and the percent (or fraction) that the sodium was reduced are declared in immediate proximity to the most prominent such claim (e.g., ''50 percent less sodium than the market leader''); and

(B) Quantitative information comparing the level of sodium per labeled serving size with that of the reference product it replaces is declared adjacent to the most prominent claim or to the nutrition information (e.g., or ''lite 'this product'—170 mg sodium per serving; regular 'reference product'—350 mg per serving'').

(3) Except for meal-type products as defined in § 317.313(l), 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 during the first 24 months of implementation, 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 during the first 24 months of implementation, 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]

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

Subpart A—General

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

§ 318.1 Products and other articles entering official establishments.

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

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

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

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

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

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

(f) [Reserved]

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

§ 318.5 Requirements concerning procedures.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(11) [Reserved]

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

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

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

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

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

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

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

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

(iii) The Administrator has determined that:

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

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

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

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

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

(1) *Pumped bacon.* With respect to bacon injected with curing ingredients and massaged bacon: sodium nitrite shall be used at 120 parts per million (PPM) ingoing or an equivalent amount of potassium nitrite shall be used (148 PPM ingoing); and 550 PPM of sodium ascorbate or sodium erythorbate (isoascorbate) shall be used. Sodium ascorbate or sodium erythorbate have a molecular weight of approximately 198. Hydrated forms of these substances shall be adjusted to attain the equivalent of 550 PPM of sodium ascorbate or sodium erythorbate.

(2) The Department shall collect samples of pumped bacon from producing plants and analyze them for the level of nitrosamines by the Thermal Energy Analyzer (TEA). In the event that a TEA analysis indicates that a confirmable level of nitrosamines might be present, additional samples shall be collected and analyzed by gas chromatography. Presumptive positive results must be confirmed by mass spectrometry before being considered positive. If, during the interval required for the Department to analyze the confirmatory samples by gas chromotography and mass spectrometry, changes are made in processing procedures which are expected to result in no confirmable levels of nitrosamines in pumped bacon produced by these new procedures, an establishment may submit samples to USDA for analysis upon prior notification and arrangements with USDA. If, however, an establishment furnishes USDA with laboratory results from testing five consecutive lots of pumped bacon produced under the new procedures and the testing is performed by the USDA methodology and procedures, those results will be utilized in making the determination concerning the product produced under the new procedures. Should the results of these tests reveal that confirmable levels of nitorosamines are not indicated in any of the five consecutive lots, the confirmation analysis by USDA shall be terminated and the establishment shall revert to normal monitoring status. In the event the test results continue to indicate nitrosamines, however, USDA shall proceed in its confirmation analysis on the original samples taken for confirmation. If any one of the original samples collected by USDA for confirmation if found to contain confirmable levels of nitrosamines, all pumped bacon in the producing establishment and all future production will be retained. The Department shall sample and analyze such retained pumped bacon for nitrosamines on a lot by lot basis. A production lot shall be that pumped bacon produced by the establishment in any single shift. Samples from any lot of pumped bacon under retention found to contain nitrosamines at a confirmable level shall cause the lot of pumped bacon to be disposed of in a manner to assure it will not form nitrosamines when cooked. Such disposal may include incorporation of the uncooked pumped bacon as an ingredient of another meat food product provided it is processed for eating without further preparation in a manner to preclude the formation of nitrosamines. Bacon subsequently produced shall not be retained because of nitrosamines if

the operator of the establishment makesadjustments in the processing of the product and laboratory results obtained by TEA analysis of samples from five consecutive normal sized lots of pumped bacon indicates that the product being produced contains no confirmable levels of nitrosamines. These tests from five consecutive normal sized lots of pumped bacon shall be conducted by the Department: *Provided, however,* That if the establishment furnishes the Department with the results of tests conducted under the methodology and procedures used by the Department, such test results will be utilized in making the determination concerning the nitrosamine content of the product. All tests of pumped bacon for nitrosamines under this subparagraph shall be made on pumped bacon cooked 340 °F. for 3 minutes on each side. In order to determine that no confirmable levels of nitrosamines are present in a sample tested, the testing must be performed by methodology and procedures that would detect the presence of any nitrosamines at 10 PPB.

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

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

(ii) A predetermined level between 40 and 80 ppm (potassium nitrite at a level between 49 and 99 ppm); 550 ppm sodium ascorbate or sodium erythorbate (isoascorbate); and additional sucrose or other similar fermentable carbohydrate at a minimum of 0.7 percent and an inoculum of lactic acid producing bacteria such as *Pediococcus acetolactii* or other bacteria demonstrated to be equally effective in preventing the growth of botulinum toxin at a level sufficient for the purpose of preventing the growth of botulinum toxin; provided that the establishment has a partial quality control program as provided in § 318.4(d) that results in compliance with this provision.

(4) The Department shall collect samples of bacon from plants producing under paragraph (b)(3) of this section and analyze them for the level of nitrosamines. Samples shall be randomly selected throughout the production of a lot. The actual sampling plans and methods of analysis that are used will result in approximately the same likelihood as under paragraph (b)(2) of this section of having a presumptive positive result when the true mean level of nitrosamines in a production lot is 10 ppb. In the event of a presumptive positive result, the plant shall become subject to the provisions of paragraph (b)(2) of this section.

(5) *Immersion cured bacon.* Immersion cured bacon may be placed in a brine solution containing salt, nitrite and flavoring material or in a container with salt, nitrite and flavoring material. Sodium nitrite shall not exceed 120 ppm ingoing or an equivalent amount of potassium nitrite (148 ppm ingoing) based on the actual or estimated skin-free green weight of the bacon bellies.

(6) *Bacon made with dry curing materials.* With respect to bacon made with dry curing materials, the product shall be cured by applying a premeasured amount of cure mixture to the bacon belly surfaces, completely covering the surfaces. Sodium nitrite shall not exceed 200 ppm ingoing or an equivalent amount of potassium nitrite (246 ppm ingoing) in dry cured bacon based on the actual or estimated skin-free green weight of the bacon belly.

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

(1) Common salt, approved sugars (sucrose, cane or beet sugar), maple sugar, dextrose, invert sugar, honey, corn syrup solids, (corn syrup, glucose syrup and fructose), wood smoke, vinegar, flavorings, spices, sodium nitrate, sodium nitrite, potassium nitrate, potassium nitrite, and other substances specified in the chart in paragraph (c)(4) of this section may be added to products under conditions, if any, specified in this part or in part 317 of this subchapter.

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

with the approval of the Administrator in specific cases.

(3) Coloring matter and dyes other than those specified in the chart in paragraph (c)(4) of this section may be applied to products, mixed with rendered fat, applied to natural and artificial casings, and applied to such casings enclosing products, if approved by the Administrator in specific cases. When any coloring matter or dye is applied to casings, there shall be no penetration of coloring into the product.

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

Class of substance	Substance	Purpose	Products	Amount	
Acidifiers	Acetic acid	To adjust acidity	Various[2]	Sufficient for purpose.[3]	
	Citric acid	do	do	Do.	
	Glucono delta-lactone	do	do	Do.	
	Lactic acid	do	do	Do.	
	Phosphoric acid	do	do	Do.	
	Tartaric acid	do	do	Do.	
Anti-coagulants	Citric acid	To prevent clotting	Fresh blood of livestock.	0.2 percent with or without water. When Water is used to make a solution of citric acid added to blood of livestock, not more than 2 parts of water to 1 part of citric acid shall be used.	
	Sodium citrate	do	do	Not to exceed 0.5 percent based on the ingoing weight of the product. When water is used to make a solution of sodium citrate added to blood of livestock, not more than 2 parts of water to 1 part of sodium citrate shall be used.	
Antifoaming agent	Methyl polysilicone	To retard foaming	Soups	10 parts per million.	
			Rendered fats	Do.	
			Curing pickle	50 parts per million.	
Antioxidants and oxygen interceptors.	BHA (butylated hydroxyanisole).	To retard rancidity	Dry sausage	0.003 percent based on total weight.	.006 percent in combination.
	BHT (butylated hydroxytoluene).	do	do	do	
	Propyl gallate	do	do	do	
	TBHQ (tertiary butylhydroquinone).	do	do	do	0.006 percent in combination only with BHA and/or BHT.
	BHA (butylated hydroxyanisole).	do	Rendered animal fat or a combination of such fat and vegetable fat.	0.01 percent	0.02 percent in combination.
	BHT (butylated hydroxytoluene).	do	do	do	
	Glycine	do	do	do	
	Propyl gallate	do	do	do	
	Resin guaiac	do	do	do	
	TBHQ (tertiary butylhydroquinone).	do	do	do	0.02 percent in combination only with BHA and/or BHT.

	Tocopherols	.....do	.....do	0.03 percent. A 30 percent concentration of tocopherols in vegetable oils shall be used when added as an antioxidant to products designated as ''lard'' or ''rendered pork fat.''	
		.....do	Dry sausage, semidry sausage, dried meats, uncooked or cooked fresh sausage made with beef and/or pork, uncooked or cooked Italian sausage products, uncooked or cooked meatballs, uncooked or cooked meat pizza toppings, brown and serve sausage, pregrilled beef patties, and restructured meats.	Not to exceed 0.03 percent based on fat content. Not used in combination with other antioxidants.	
	BHA (butylated hydroxyanisole).	.....do	Fresh pork, sausage, brown and serve sausages, fresh Italian sausage products, pregrilled beef patties, fresh sausage made from beef or beef and pork, cooked or raw pizza topping and cooked or raw meatballs.	0.01 percent based on fat content.	0.02 percent in combination based on fat content.
	BHT (butylated hydroxytoluene).	.....do	.....do	.....do	
	Propyl gallate	.....do	.....do	.....do	
	TBHQ (tertiary butylhydroquinone).	.....do	.....do	.....do	0.02 percent in combination only with BHA and/or BHT based on fat content.
	BHA (butylated hydroxyanisole).	.....do	Dried meats	0.01 percent based on total weight.	0.01 percent in combination.
	BHT (butylated hydroxytoluene).	.....do	.....do	.....do	
	Propyl gallate	.....do	.....do	.....do	
	TBHQ (tertiary butylhydroquinone).	.....do	.....do	.....do	0.01 percent in combination only with BHA and/or BHT.
	BHA (butylated hydroxyanisole).	.....do	Margarine or oleomargarine.	0.02 percent (by wt. of the finished product) individually or in combination with other antioxidants approved for use in margarine.	
	BHT (butylated hydroxytol-)uene).	.....do	.....do	Do.	
	Octyl gallate	.....do	.....do	Do.	
	Propyl gallate	.....do	.....do	Do.	
	Dodecyl gallate	.....do	.....do	Do.	
	Ascorbyl palmitate	.....do	.....do	Do.	

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

Class of substance	Substance	Purpose	Products	Amount
Binders and extenders.	Agar-agar	To stabilize and thicken.	Thermally processed canned jellied meat food products	0.25 percent of finished product.
	Algin	To extend and stabilize product	Breading mix; sauces	Sufficient for purpose in accordance with 21 CFR 172.5.
	A mixture of sodium alginate, calcium carbonate and calcium lactate/lactic acid (or glucono delta-lactone)	To bind meat pieces	Restructured meat food products.	Sodium alginate not to exceed 1.0 percent; calcium carbonate not to exceed 0.2 percent; and lactic acid/calcium lactate (or glucono delta-lactone) not to exceed 0.3 percent of product formulation. Added mixture may not exceed 1.5 percent of product at formulation. Ingredients of mixture must be added dry.
	Bread	To bind and extend product.	Bockwurst	3.5 percent individually or collectively with other binders.
	Calcium reduced dried skim milk.	.....do	Sausages as provided in part 319.	Do.
	.....do	.....do	Chili con carne, chili con carne with beans.	8 percent individually or collectively with other binders.
	.....do	.....do	Spaghetti with meatballs and sauce, spaghetti with meat and sauce and similar products	12 percent individually or collectively with other binders.
	Carrageenan	To extend and stabilize product	Breading mix; sauces	Sufficient for purpose in accordance with 21 CFR 172.5.
	Carboxymethyl cellulose (cellulose gum)	.....do	Baked pies	Do.
	Cereal	To bind and extend product.	Sausages as provided in part 319, bockwurst	3.5 percent individually or collectively with other binders.
	.....do	.....do	Chili con carne, chili con carne with beans	8 percent individually or collectively with other binders.
	Dried milk	.....do	Sausage as provided in part 319.	3.5 percent individually or collectively with other binders.
	.....do	.....do	Chili con carne, chili con carne with beans	8 percent individually or collectively with other binders.
	Enzyme (rennet) treated calcium reduced dried skim milk and calcium lactate	To bind and extend product.	Sausages as provided in part 319.	3.5 percent total finished product. (Calcium lactate required at rate of 10 percent of binder).
	.....do	.....do	Imitation sausages, nonspecific loaves, soups, stews	Sufficient for purpose in accordance with 21 CFR 172.5 (Calcium lactate required at rate of 10 percent of binder).
	Enzyme (rennet) treated sodium caseinate and calcium lactate	.....do	Imitation sausages, nonspecific loaves, soups, stews	Sufficient for purpose in accordance with 21 CFR 172.5. (Calcium lactate required at rate of 25 percent of binder).
	Gums, vegetable	.....do	Egg roll	Sufficient for purpose in accordance with 21 CFR 172.5.

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

Class of substance	Substance	Purpose	Products	Amount
	Soy protein concentrate	.....do	.....do	Do.
	Starchy vegetable flour	.....do	.....do	Do.
	Vegetable starch	.....do	.....do	Do.
	Wheat gluten	.....do	.....do	Do. In accordance with 21 CFR 184.1322.
	Tapioca dextrin	.....do	.....do	Do. In accordance with 21 CFR 184.1277.
	Soy flour	.....do	Spaghetti with meatballs and sauce, spaghetti with meat and sauce and similar products	12 percent individually or collectively with other binders and extenders.
	Soy protein concentrate	.....do	.....do	Do.
	Wheat gluten	.....do	.....do	Do. In accordance with 21 CFR 184.1322.
	Tapioca dextrin	.....do	.....do	Do. In accordance with 21 CFR 184.1277.
	Xanthan gum	To maintain uniform viscosity; suspension of particulate matter, emulsion stability; freeze-thaw stability.	Meat sauces, gravies or sauces and meats, canned or frozen and/or refrigerated meat salads, canned or frozen meat stews, canned chili or chili with beans, pizza topping mixes and batter or breading mixes.	Sufficient for purpose in accordance with 21 CFR 172.5.
	Carrageenan	To prevent purging of brine solution.	Cured pork products as provided in 9 CFR 319.104.	Not to exceed 1.5 percent of product formulation; not permitted in combination with other binders approved for use in cured pork products; in accordance with 21 CFR 172.620, 172.623, and 172.626.
	Food starch modified	.....do	.....do	Not to exceed 2 percent of product formulation; not permitted in combination with other binders approved for use in cured pork products; in accordance with 21 CFR 172.892.
	Sodium caseinate	.....do	.....do	Not to exceed 2 percent of product formulation; not permitted in combination with other binders approved for use in cured pork products; in accordance with 21 CFR 182.1748.
	Isolated soy protein	.....do	.....do	Not to exceed 2 percent of product formulation; not permitted in combination with other binders approved for use in cured pork products.
	Carrageenan, Locust bean gum, and Xanthan gum blend..	To prevent purging of solution..	Cured pork products as provided in 9 CFR 319.104(d)..	In combination, not to exceed 0.5 percent of product formulation; not permitted in combination with other binders approved for use in cured pork products; in accordance with 21 CFR 172.620, 172.623, 172.626, 184.1343, and 172.695.
Bleaching agent	Hydrogen peroxide	To remove color	Tripe (substance must be removed from product by rinsing with clear water).	

Class of substance	Substance	Purpose	Products	Amount
Catalysts (substances must be eliminated during process).	Nickel	To accelerate chemical reaction.	Rendered animal fats or a combination of such fats and vegetable fats.	Do.
	Sodium amide	Rearrangement of fatty acid radicals.	.....do	Do.
	Sodium methoxide	.....do	.....do	Do.
Coloring agents (natural).	Alkanet, annatto, carotene cochineal, green chlorophyl, saffron and tumeric.	To color casings or rendered fats; marking and branding product.	Sausage casings, oleomargarine, shortening, marking or branding ink on product.	Sufficient for purpose (may be mixed with approved artificial dyes or harmless inert material such as common salt and sugar).
Coloring agents (artificial).	Color additives listed in 21 CFR Part 74, Subpart A of Part 82, Subpart B (operator must furnish evidence to inspector in charge that color additive has been certified for use in connection with foods by the Food and Drug Administration).	.....do	.....do	Sufficient for purpose (may be mixed with approved natural coloring matters or harmless inert material such as common salt or sugar).
	Titanium dioxide	.....do	Canned ham salad spread and creamed type canned products.	0.5 percent.
Curing accelerators' must be used only in combination with curing agents.	Ascorbic acid	To accelerate color fixing or preserve color during storage.	Cured pork and beef cuts, cured comminuted meat food product.	75 oz to 100 gal pickle at 10 percent pump level; ¾ oz to 100 lb meat or meat byproduct; 10 percent solution to surfaces of cured cuts prior to packaging. (The use of such solution shall not result in the addition of a significant amount of moisture to the product.)
	Erythorbic acid	.....do	.....do	Do.
	Fumaric acid	To accelerate color fixing.	Cured, comminuted meat or meat food products.	0.065 percent (or 1 oz to 100 lb) of the weight of the meat or meat byproducts, before processing.
	Glucone delta lactone	To accelerate color fixing.	Cured, comminuted meat or meat food product.	8 oz to each 100 lb of meat or meat byproduct.
			Genoa salami	16 oz to 100 lb of meat (1.0 percent).
	Sodium acid pyrophosphate.	.....do	Frankfurters, wieners, vienna, bologna, garlic bologna, knockwurst, and similar products.	Not to exceed, alone or in combination with other curing accelerators, the following: 8 oz in 100 lb of the meat, or meat and meat byproducts, content of the formula; nor 0.5 percent in the finished product.
	Sodium ascorbate	To accelerate color fixing or preserve color during storage.	Cured pork and beef cuts, cured comminuted meat food product.	87.5 oz to 100 gal pickle at 10 percent pump level; ⅞ oz to 100 lb meat or meat byproduct; 10 percent solution to surfaces of cured cuts prior to packaging. (The use of such solution shall not result in the addition of a significant amount of moisture to the product.)
	Sodium erythorbate	.....do	.....do	Do.

Class of substance	Substance	Purpose	Products	Amount
	Citric acid or sodium citrate.	.....do	.....do	May be used in cured products or in 10 percent solution used to spray surfaces of cured cuts prior to packaging to replace up to 50 percent of the ascorbic acid, erythorbic acid, sodium ascorbate, or sodium erythorbate that is used.
Curing agents	Sodium or potassium nitrate.	Source of nitrite	Cured products other than bacon. Nitrates may not be used in baby, junior, and toddler foods.	7 lb to 100 gal pickle; 3½ oz to 100 lb meat (dry cure); 2¾ oz to 100 lb chopped meat.
	Sodium or potassium nitrite. (Supplies of sodium nitrite and potassium nitrite and mixtures containing them must be kept securely under the care of a responsible employee of the establishment. The specific nitrite content of such supplies must be known and clearly marked accordingly).	To fix color	Cured products. Nitrites may not be used in baby, junior, or toddler foods.	2 lb to 100 gal pickle at 10 percent pump level; 1 oz to 100 lb meat (dry cure); ¼ oz to 100 lb chopped meat and/or meat byproduct. The use of nitrites, nitrates, or combination shall not result in more than 200 parts per million of nitrite, calculated as sodium nitrite, in finished product. Except that nitrites may be used in bacon only in accordance with paragraph (b) of this section.
Denuding agents; may be used in combination. Must be removed from tripe by rinsing with potable water..	Lime (calcium oxide, calcium hydroxide)	To denude mucous membranes.	Tripe	Sufficient for purpose.
	Sodium carbonate.	.....do	.....do.	Do.
	Sodium Citrate	.....do	.....do	Do.
	Sodium gluconate	.....do	.....do	Do.
	Sodium hydroxide	.....do	.....do	Do.
	Sodium persulfate	.....do	.....do	Do.
	Sodium silicates (ortho, meta, and sesqui).	.....do	.....do	Do.
	Trisodium phosphate	.....do.	.....do.	Do.
Emulsifying agents	Acetylated monoglycerides.	To emulsify product ...	Shortening	Do.
	Diacetyl tartaric acid esters of mono- and diglycerides.	.....do	Rendered animal fat or a combination of such fat with vegetable fat.	Do.
	Glycerol-lacto stearate, oleate, or palmitate.	.....do	.....do	Do.
	Lecithin	To emulsify product (also as an Antioxidant).	Oleomargarine, shortening, various meat food products.	0.5 percent in oleomargarine; use in other products—sufficient amount for emulsification.
	Mono and diglycerides (glycerol palmitate, etc.).	To emulsify product ...	Rendered animal fat or a combination of such fat with vegetable fat; oleomargarine.	Sufficient for purpose in lard and shortening; 0.5 percent in oleomargarine.
	Mono and diglycerides of fatty acids esterified with any of the following acids: acetic, acetyltartaric, citric, lactic, tartaric, and their sodium and calcium salts; the sodium sulfoacetate derivatives of these mono and diglycerides.	.....do	Margarine or oleomargarine.	0.5 percent.

Class of substance	Substance	Purpose	Products	Amount
	Polygylcerol esters of fatty acids (polygylcerol esters of fatty acids are restricted to those up to and including the decaglycerol esters and otherwise meeting the requirements of § 172.854(a) of the Food Additive Regulations).	.....do	Rendered animal fat or a combination of such fat with vegetable fat when use is not precluded by standards of identity or composition; oleomargaine.	Sufficient for purpose for rendered animal fat or combination with vegetable fat; 0.5 percent for oleomargarine.
	1,2-propylene glycol esters of fatty acids.	.....do	Margarine or oleomargarine.	2.0 percent.
	Polysorbate 80 (polyoxyethylene (20) sorbitan monooleate).	.....do	Shortening for use in nonstandardized baked goods, baking mixes, icings, fillings, and toppings and in the frying of foods.	1 percent when used alone. If used with polysorbate 60 the combined total shall not exceed 1 percent.
	Propylene glycol mono and diesters of fats and fatty acids.	.....do	Rendered animal fat or a combination of such fat with vegetable fat.	Sufficient for purpose.
	Polysorbate 60 (polyoxyethylene (20) sorbitan monostearate).	.....do	Shortening for use in nonstandardized baked goods, baking mixes, icings, fillings, and toppings and in the frying of foods.	1 percent when used alone. If used with polysorbate 80 the combined total shall not exceed 1 percent.
	Stearyl-2-lactylic acid	.....do	Shortening to be used for cake icings and fillings.	3.0 percent.
	Stearyl monoglyceridyl citrate.	.....do	Shortening	Sufficient for purpose.
Film forming agents	A mixture consisting of water, sodium alginate, calcium chloride, sodium carboxymethyl-cellulose, and corn syrup solids.	To reduce cooler shrinkage and help protect surface.	Freshly dressed meat carcasses. Such carcasses must bear a statement ''Protected with a film of water, corn syrup solids, sodium alginate, calcium chloride and sodium carboxymethyl-cellulose.	Formulation may not exceed 1.5% of hot carcass weight when applied. Chilled weight may not exceed hot weight.
Flavoring agents; protectors and developers.	Artificial smoke flavoring	To flavor product	Various [2]	Do.
	Smoke flavoring	.....do	.....do	Do.
	Autolyzed yeast extract	.....do	.....do	Do.
	Harmless bacteria starters of the acidophilus type, lactic acid starter or culture of *Pediococcus cerevisiae.*	To develop flavor	Dry sausage, pork roll, thuringer, lebanon bologna, cervelat, and salami.	0.5 percent.
	Harmless lactic acid producing bacteria.	To prevent growth of *Clostridium botulinum.*	Bacon	Sufficient for purpose.
	Benzoic acid (sodium, potassium and calcium salts).	To retard flavor reversion.	Margarine or oleomargarine.	0.1 percent individually, or if used in combination or with sorbic acid and its salts, 0.2 percent (expressed as the acids in the wt. of the finished foods).

Class of substance	Substance	Purpose	Products	Amount
	Calcium lactate	To protect flavor	Cooked semi-dry and dry products including sausage, imitation sausage, and non-specific meat food sticks.	0.6 percent in product formulation.
	Citric acid	Flavoring	Chili con carne	Sufficient for purpose.
	Corn syrup solids, corn syrup, glucose syrup.	To flavor	Sausage, hamburger, meat loaf, luncheon meat, chopped or pressed ham.	Sufficient for purpose.
	Dextrose	To flavor product	Sausage, ham and cured products.	Sufficient for purpose.
	Diacetyl	....do	Oleomargarine	Do.
	Disodium guanylate	....do	Various [2]	Do.
	Disodium inosinate	....do	....do	Do.
	Hydrolyzed plant protein	....do	....do	Do.
	Isopropyl citrate	To protect flavor	Oleomargarine	0.02 percent.
	Malt syrup	To flavor product	Cured products	2.5 percent.
	Milk protein hydrolysate	....do	Various [2]	Sufficient for purpose.
	Monosodium glutamate	....do	....do	Do.
	Monoammonium glutamate.	....do	....do	Do.
	Sodium sulfoacetate derivative of mono and diglycerides.	....do	....do	0.5 percent.
	Sodium tripoly-phosphate.	To help protect flavor	''Fresh Beef,'' [2] ''Beef for Further Cooking,'' ''Cooked Beef,'' Beef Patties, Meat Loaves, Meat Toppings, and similar products derived from pork, lamb, veal, mutton, and goat meat which are cooked or frozen after processing.	0.5 percent of total product.
	Mixtures of sodium tripolyphosphate and sodium metaphosphate, insoluble; and sodium polyphosphates, glassy.	....do	....do	Do.
	Sorbitol	To flavor, to facilitate the removal of casings from product, and to reduce carmelization and charring.	Cooked sausage labeled frankfurter, frank, furter, wiener, and knockwurst; cured pork and pork products, as provided in part 319 of this subchapter.	Not to exceed 2 percent of the weight of the formula, excluding the formula weight of water or ice, when used in accordance with 21 CFR 184.1835.
	Starter distillate	To help protect flavor	Oleomargarine	Sufficient for purpose.
	Stearyl citrate	To protect flavor	....do	0.15 percent.
	Sugars (sucrose and dextrose).	To flavor product	Various [2]	Sufficient for purpose.
	Potassium lactate	To flavor product	Various meat and meat food products, except infant formula and infant food.[2]	Not to exceed 2 percent of formulation; in accordance with 21 CFR 184.1639.
	Sodium lactate	....do	....do	Not to exceed 2 percent of formulation; in accordance with 21 CFR 184.1768.
	Sodium acetate	To flavor products	Various	Not to exceed 0.12 percent of formulate in accordance
	Sodium diacetate	....do	....do	Not to exceed 0.1 percent of formulate in accordance with 21 CFR 184.1754
Gases	Carbon dioxide solid (dry ice).	To cool product	Chopping of meat, packaging of product.	Do.

Class of substance	Substance	Purpose	Products	Amount
	Liquid nitrogen	Contact freeze	Various	Sufficient for purpose
	Nitrogen	To exclude oxygen	Sealed container	Do.
Hog scald agents; must be removed by subsequent cleaning operations.	Caustic soda	To remove hair	Hog carcasses	Do.
	Dimethylpolysiloxane	....do	....do	Do.
	Dioctyl sodium sulfosuccinate.	....do	....do	Do.
	Disodium-calcium ethylenediamine-tetraacetate.	....do.	....do.	Do.
	Disodium phosphate	....do	....do	Do.
	Ethylenediamine-tetraacetic acid (sodium salts).	....do	....do	Do.
	Lime (calcium oxide, calcium hydroxide).	....do	....do	Do.
	Potassium hydroxide	....do	....do	Do.
	Propylene glycol	....do	....do	Do.
	Soap (prepared by the reaction of calcium, potassium, or sodium with rosin or fatty acids of natural fats and oils).	....do	....do	Do.
	Sodium acid pyrophosphate.	....do	....do	Do.
	Sodium carbonate	....do	....do	Do.
	Sodium dodecylbenzene sulfonate.	....do	....do	Do.
	Sodium gluconate	....do	....do	Do.
	Sodium hexametaphosphate.	....do	....do	Do.
	Sodium lauryl sulfate	....do	....do	Do.
	Sodium mono and dimethylnaphthalene sulfonate (molecular weight 245–260).	....do	....do	Do.
	Sodium n-alkylbenzene sulfonate (alkyl group predominantly C_{12} and C_{13} and not less than 95 percent C_{10} and C_{16}.	....do	....do	Do.
	Sodium pyrophosphate	....do	....do	Do.
	Sodium silicates (ortho, meta, and sesqui).	....do	....do	Do.
	Sodium sulfate	....do	....do	Do.
	Sodium tripolyphosphate.	....do	....do	Do.
	Sucrose	....do	....do	Do.
	Triethanolamine dodecylbenzene sulfonate.	....do	....do	Do.
	Trisodium phosphate	....do	....do	Do.
Miscellaneous	Ascorbic acid, erythorbic acid, citric acid, sodium ascorbate and sodium citrate, singly or in combination under quality control.	To delay discoloration	Fresh beef cuts, fresh lamb cuts, and fresh pork cuts.	Not to exceed, singly or in combination, 500 ppm or 1.8 mg/sq inch of product surface of ascorbic acid (in accordance with 21 CFR 182.3013), erythorbic acid (in accordance with 21 CFR 182.3041), or sodium ascorbate (in accordance with 21 CFR 182.3731); and/or not to exceed, singly or in combination, 250 ppm or 0.9 mg/sq inch of product surface of citric acid (in accordance with 21 CFR 182.6033), or sodium citrate (in accordance with 21 CFR 182.6751).
	d- and dl-alphatocopherol.	To inhibit nitrosamine formation.	Pump-cured bacon	500 ppm; by injection or surface application.

Class of substance	Substance	Purpose	Products	Amount
	Potassium sorbate	To retard mold growth	Dry sausage	10 percent in water solution may be applied to casings after stuffing or casings may be dipped in a 10 percent water solution prior to stuffing.
	Silicon dioxide	Processing aid/dispersant.	Tocopherol-containing bacon curing premixes.	At level not to exceed 4.0 percent in the dry mix.
	Sorbic acid (sodium, potassium, and calcium salts).	To preserve product and to retard mold growth.	Margarine or oleomargarine.	0.1 percent individually, or if used in combination or with benzoic acid or its salts, 0.2 percent (expressed as the acids in the wt. of the finished foods).
	Calcium disodium, EDTA (calcium disodium ethylenediaminetetraacetate).	To preserve product and to protect flavor.	do	75 parts per million by weight of the finished oleomargarine or margarine.
	Propyl paraben (propyl p-hydroxybenzoate).	To retard mold growth	Dry sausage	3.5 percent in water solution may be applied to casings after stuffing, or casings may be dipped in solution prior to stuffing.
	Sodium bicarbonate	To neutralize excess acidity, cleaning vegetables.	Rendered fats, soups, curing pickle.	Sufficient for purpose.
	Calcium propionate	To retard mold growth	Pizza crust	0.32 percent alone or in combination based on weight of the flour brace used.
	Sodium propionate	do	do	Do.
	Sodium hydroxide	To decrease the amount of cooked out juices.	Meat food products containing phosphates.	May be used only in combination with phosphates in a ratio not to exceed one part sodium hydroxide to four parts phosphate; the combination shall not exceed 5 percent in pickle at 10 percent pump level; 0.5 percent in product.
	Disodium phosphate	do	Meat food products except where otherwise prohibited by the Federal meat inspection regulations.	5 percent of phosphate in pickle at 10 percent pump level; 0.5 percent of phosphate in product (only clear solution may be injected into product).
	Monosodium phosphate	do	do	Do.
	Sodium metaphosphate, insoluble.	do	do	Do.
	Sodium polyphosphate, glassy.	do	do	Do.
	Sodium tripolyphosphate.	do	do	Do.
	Sodium pyrophosphate	do	do	Do.
	Sodium acid pyrophosphate.	do	do	Do.
	Dipotassium phosphate	do	do	Do.
	Monopotassium phosphate.	do	do	Do.
	Potassium tripolyphosphate.	do	do	Do.
	Potassium pyrophosphate.	do	do	Do.
	Citric acid (sodium and potassium salts).	To acidify	Margarine or oleomargarine.	Sufficient for purpose.
	Lactic acid (sodium and potassium salts).	do	do	Do.
	L–Tartaric acid (sodium and sodium potassium salts).	do	do	Do.
	Adipic acid	do	do	Do.
	Phosphoric acid	do	do	Do.
	Hydrochloric acid	do	do	Do.
	Sodium bicarbonate	To alkalize	do	Do.

Class of substance	Substance	Purpose	Products	Amount
	Sodium carbonate	.....do	.....do	Do.
	Sodium hydroxide	.....do	.....do	Do.
	Potassium carbonate	.....do	.....do	Do.
	Potassium bicarbonate	.....do	.....do	Do.
	Citric acid	To preserve cured color during storage.	Cured pork cuts	Not to exceed 30 percent in water solution used to spray surfaces of cured cuts, prior to packaging, in accordance with 21 CFR 182.1033. (The use of such solution shall not result in the addition of a significant amount of moisture to the product and shall be applied only once to the product.)
	Sodium citrate buffered with citric acid to a pH of 5.6.	To inhibit the growth of micro-organisms and retain product flavor during storage.	Cured and uncured, processed whole-muscle meat food products, e.g., ham.	Not to exceed 1.3 percent of the formulation weight of the product in accordance with 21 CFR 184.1751.
	Glycerine	Humecant	Shelf stable (Can Be stored at room temperature) meat snacks..	Not to exceed 2 percent of the formulation weight of the product in accordance with 21 CFR 182.1320
Proteolytic enzymes	Aspergillus oryzae	To soften tissues	Raw meat cuts	Solutions consisting of water and approved proteolytic enzymes applied or injected into raw meat cuts shall not result in a gain of more than 3 percent above the weight of the untreated product.
	Aspergillus flavusoryzae group.	.....do	.....do	Do.
	Bromelin	.....do	.....do	Do.
	Ficin	.....do	.....do	Do.
	Papain	.....do	.....do	Do.
Refining agents (must be eliminated during process of manufacturing).	Acetic acid	To separate fatty acids and glycerol.	Rendered fats	Sufficient for purpose.
	Bicarbonate of soda	.....do	.....do	Do.
	Carbon (purified charcoal).	To aid in refining of animal fats.	.....do	Do.
	Caustic soda (sodium hydroxide).	To refine fats	.....do	Do.
	Diatomaceous earth; Fuller's earth.	.....do	.....do	Do.
	Sodium carbonate	.....do	.....do	Do.
	Tannic acid	.....do	.....do	Do.
Rendering agents	Tricalcium phosphate	To aid rendering	Animal fats	Do.
	Trisodium phosphate	.....do	.....do	Do.
Sources of radiation	Ionizing radiation limited to gamma rays from cobalt-60 or cesium-137.	To control *Trichinella spiralis*.	Pork carcasses, or fresh or previously frozen cuts of pork carcasses that have not been cured or heat-processed.	Minimum absorbed dose of 0.3 kiloGray (30 kilorads) to a maximum absorbed dose of 1 kiloGray (100 kilorads).
Artificial sweetners	Saccharin	To sweeten product	Bacon	0.01 percent.
Synergists (used in combination with antioxidants).	Citric acid	To increase effectiveness of antioxidants.	Any product permitted to contain antioxidants as provided in this part.	Not to exceed 0.01 percent based on fat content.
	Malic acid	.....do	Lard and shortening	0.01 percent based on total weight in combination with antioxidants.
	Monoisopropyl citrate	.....do	Lard, shortening, oleomargarine, fresh pork sausage, dried meats.	0.02 percent.
	Phosphoric acid	.....do	Lard and shortening	0.01 percent.

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

[1] [Reserved]

[2] Information as to the specific products for which use of this substance is approved may be obtained upon inquiry addressed to the Standards and Labeling Division, Meat and Poultry Inspection Technical Services, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250.

[3] Provided, that its use is functional and suitable for the product and it is permitted for use at the lowest level necessary to accomplish the desired technical effect as determined in specific cases prior to label approval under § 317.4.

(d) No substance may be used in or on any product if it conceals damage or inferiority or makes the product appear to be better or of greater value than it is. Therefore:

(1) Paprika or oleoresin paprika may not be used in or on fresh meat, such as steaks, or comminuted fresh meat food products, such as chopped and formed steaks or patties; or in any other meat food products consisting of fresh meat (with or without seasoning), except chorizo sausage, and except other meat food products in which paprika or oleoresin paprika is permitted as an ingredient in a standard of identity or composition in part 319 of this subchapter.

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

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

[35 FR 15586, Oct. 3, 1970]

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

TABLE 1—REQUIRED PERIOD OF FREEZING AT TEMPERATURE INDICATED

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

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

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

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

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

TABLE 2—ALTERNATE PERIODS OF FREEZING AT TEMPERATURES INDICATED

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

[2] Either room temperature or internal product temperature shall be used for sausages that will be subsequently dried to a moisture-protein ratio of 2.3:1 or less. Internal product temperature shall be used for all other sausages.

[3] Trichinae will be destroyed during fermentation or smoking at the temperature and length of time indicated. Therefore, no drying room period is required for products so treated.

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

TRICHINA TREATMENT OF SAUSAGE BY METHOD NO. 6;

TABLE 4—REDUCED SALT CONTENT—DRYING ROOM TIMES

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Method No. 2. [Reserved]

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Drying Times and Temperatures for Trichina Inactivation in Hams and Shoulders

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

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

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

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

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

Method No. 4.

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

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

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

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

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

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

Method No. 5

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Method No. 6

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

any other treatment designed to remove salt.

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

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

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

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

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

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

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

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

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

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

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

§ 318.11 [Reserved]

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

§318.16 Pesticide chemicals and other residues in products.

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

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

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

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

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

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

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

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

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

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

Minimum internal temperature		Minimum processing time in minutes after minimum temperature is reached
Degrees Fahrenheit	Degrees Centigrade	
145	62.8	Instantly

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

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

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

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

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

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

and maintaining the required relative humidity.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(j) To prevent indirect contamination of cooked product:

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

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

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

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

approved, upon written request, by the Circuit Supervisor.

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

[48 FR 24316, June 1, 1983]

§ 318.18 Handling of certain material for mechanical processing.

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

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

§ 318.19 Compliance procedure for cured pork products.

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

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

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

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

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

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

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

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

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

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

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

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

[2] Rules for Rounding:

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

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

Continued

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

§ 318.20 Use of animal drugs.

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

[50 FR 32165, Aug. 9, 1985]

§ 318.21 Accreditation of chemistry laboratories.

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

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

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

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

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

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

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

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

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

process is ''in control''. Each CUSUM value is constructed by accumulating incremental values obtained from observed results of the process, and then determined to either exceed or fall within acceptable limits for that process. The initial CUSUM values for each laboratory whose application for accreditation is accepted are set at zero. The four CUSUM procedures are:

(1) Positive systemic laboratory difference CUSUM (CUSUM–P)—monitors how consistently an accredited laboratory gets numerically greater results than the comparison mean;

(2) Negative systematic laboratory difference CUSUM (CUSUM–N)—monitors how consistently an accredited laboratory gets numerically smaller results than the comparison mean;

(3) Variability CUSUM (CUSUM–V)—monitors the average ''total discrepancy'' (i.e., the combination of the random fluctuations and systematic differences) between an accredited laboratory's results and the comparison mean;

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

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

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

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

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

Minimum proficiency level—The minimum concentration of a residue at which an analytical result will be used to assess a laboratory's quantification capability. This concentration is an estimate of the smallest concentration for which the average coefficient of variation (CV) for reproducibility (i.e., combined within and between laboratory variability) does not exceed 20 percent. (See Table 2)

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

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

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

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

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

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

Responsibly connected—Any individual who or entity which is a partner, officer, director, manager, or owner of 10 per centum or more of the voting stock of the applicant or recipient of accreditation or an employee in a managerial or executive capacity or any employee who conducts or supervises the chemical analysis of FSIS official samples.

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

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

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

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

Standardized Difference—The quotient of the difference between a laboratory's result on a sample and the comparison mean of the sample divided by the standardizing constant.

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

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

Systematic laboratory difference—A comparison of one laboratory's results with the comparison means on samples that shows, on average, a consistent relationship. A laboratory that is reporting, on average, numerically greater results than the comparison mean has a positive systematic laboratory difference and, conversely, numerically smaller results indicate a negative systematic laboratory difference.

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

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

TABLE 1.—STANDARDIZING VALUES FOR FOOD CHEMISTRY

[By product class and analyte]

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

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

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

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

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

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

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

Class of residues	Minimum proficiency level	Percent expected recovery (QC and QA)	Standardizing value [3]
Volatile Nitrosamine [2]	5 ppm	70–110	0.25

[1] Laboratory statistics are computed over all results (excluding PCB results), and for specific chemical residues.
[2] Laboratory statistics are only computed for specific chemical residues.
[3] The standardizing value of all initial accreditation and probationary check samples computations is 0.15.

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

(1) *Applying for accreditation*. Application for accreditation shall be made on designated forms provided by FSIS, or otherwise in writing, by the owner or manager of a non-Federal analytical laboratory and sent to the Accredited Laboratory Program, room 516–A, Annex Building, Food Safety and Inspection Service, U.S. Department of Agriculture, 300 12th Street SW., Washington, DC 20250–3700, and shall specify the kinds of accreditation that are wanted by the owner or manager of the laboratory. A laboratory whose accreditation has been refused or revoked may reapply for accreditation after 60 days from the effective date of that action, and must provide written documentation specifying what corrections were made.

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

(ii) Simultaneously with the initial application for accreditation, the management of a laboratory shall forward a check, bank draft, or money order in the amount specified in 9 CFR 391.5 made payable to the U.S. Department of Agriculture along with the completed application for the accreditation(s) sought by the laboratory. Accreditation will not be granted or continued, without further procedure, for failure to pay the accreditation fee(s). The fee(s) paid shall be nonrefundable and shall be credited to the account from which the expenses of the laboratory accreditation program are paid.

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

(iv) Bills are payable upon receipt by check, bank draft, or money order, made payable to the U.S. Department of Agriculture, and become delinquent 30 days from the date of the bill. Accreditation will be terminated without further procedure for having a delinquent account. The fee(s) paid shall be nonrefundable and shall be credited to the account from which the expenses of the Accredited Laboratory Program are paid.

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

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

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

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

(ii) Demonstrate acceptable levels of systematic laboratory difference, variability, and individual large deviations in the analyses of moisture, protein, fat, and salt content using AOC methods. An applying laboratory will successfully demonstrate these capabilities if its moisture, protein, fat, and salt results from a 36 check sample accreditation study each satisfy the criteria presented below.[2] If the laboratory's analysis of an analyte (or analytes) from the first set of 36 check samples does not meet the criteria for obtaining accreditation, a second set of 36 check samples will be provided within 30 days following the date of receipt by FSIS of a request from the applying laboratory. The second set of samples shall be analyzed for only the analyte(s) for which unacceptable initial results had been obtained by the laboratory. If the results of the second set of samples do not meet the accreditation criteria, the laboratory may reapply after a 60-day waiting period, commencing from the date of refusal of accreditation by FSIS. At that time, a new application, all fees, and all documentation of corrective action required for accreditation must be submitted.

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

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

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

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

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

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

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

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

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

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

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

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

[3] A result will have a large deviation measure equal to zero when the absolute value of the result's standardized difference, (d), is less than 2.5, and otherwise a measure equal to $1-(2.5/d)^4$.

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

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

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

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

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

(A) *Systematic laboratory difference:*

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

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

2.0, if the standardized difference is greater than 1.6,
−2.0, if the standardized difference is less than −1.6,
or
the standardized difference minus 0.4, if the standardized difference lies between −1.6 and 2.4, inclusive.

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

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

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

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

2.0, if the standardized difference is greater than 1.6,
−2.0, if the standardized difference is less than −2.4,
or
the standardized difference plus 0.4, if the standardized difference lies between −2.4 and 1.6, inclusive.

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

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

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

the CUSUM increment to the last previously computed CUSUM–N value. If this computation yields a value smaller than 0, the new CUSUM–N value is set equal to 0. [CUSUM–N values are initialized at zero; that is, the CUSUM–N value associated with the first sample is set equal to the CUSUM increment for that sample.]

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

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

(*1*) Determine the CUSUM increment for the sample. The CUSUM increment is set equal to the larger of −0.4 and the absolute value of the standardized difference minus 0.9. If this computation yields a value larger than 1.6, the increment is set equal to 1.6.

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

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

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

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

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

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

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

(A) Send all official samples that have not been analyzed as of the date of written notification of probation to a specified FSIS laboratory by certified mail or private carrier or, as an alternative, to an accredited laboratory approved for food chemistry. Mailing expenses will be paid by FSIS.

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

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

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

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

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

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

[6] *See* footnote 3.

Agriculture, 300 12th Street, SW., Washington, DC 20250–3700, and shall specify the kinds of accreditation that are wanted by the owner or manager of the laboratory. A laboratory whose accreditation has been refused or revoked may reapply for accreditation after 60 days from the effective date of that action, and must provide written documentation specifying what corrections were made.

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

(ii) Simultaneously with the initial application for accreditation, the management of a laboratory shall forward a check, bank draft, or money order in the amount specified in 9 CFR 391.5 made payable to the U.S. Department of Agriculture along with the completed application for the accreditation(s) sought for the laboratory. Accreditation will not be granted or continued, without further procedure, for failure to pay the accreditation fee(s). The fee(s) paid shall be nonrefundable and shall be credited to the account from which the expenses of the laboratory accreditation program are paid.

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

(iv) Bills are payable upon receipt by check, bank draft, or money order, made payable to the U.S. Department of Agriculture, and become delinquent 30 days from the date of the bill. Accreditation will be terminated without further procedure for having a delinquent account. The fee(s) paid shall be nonrefundable and shall be credited to the account from which the expenses of the Accredited Laboratory Program are paid.

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

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

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

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

(c)(2)(ii).[7] In addition, if the laboratory is requesting accreditation for the analysis of chlorinated hydrocarbons, all analytical results for the residue class must collectively satisfy the criteria. [Conformance to criteria (c)(2)(ii)(A), (B), (C), (D), (E), and (F) will only be determined when six or more analytical results with associated comparison means at or above the logarithm of the minimum proficiency level are available.] If the results of the first set of check samples do not meet these criteria for obtaining accreditation, a second set of at least 14 samples will be provided within 30 days following the date of receipt by FSIS of a request from the applying laboratory. If the results of the second set of samples do not meet accreditation criteria, the laboratory may reapply after a 60-day waiting period, commencing from the date of refusal of accreditation by FSIS. At that time, a new application, all fees, and all documentation of corrective action required for accreditation must be submitted.

(A) *Systematic laboratory difference:* The absolute value of the average standardized difference must not exceed 1.67 (2.00 if there are less than 12 analytical results) minus the product of 0.29 and the standard deviation of the standardized differences.

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

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

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

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

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

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

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

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

(i) [Reserved]

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

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

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

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

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

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

[8] A result will have a large deviation measure equal to zero when the absolute value of the result's standardized difference, (d), is less than 2.5 and otherwise a measure equal $1–(2.5/d)^4$.

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

(vii) Permit any duly authorized representative of the Secretary to perform both announced and unannounced 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 in this paragraph (c)(3)(ix).[9,10] In addition, if the laboratory is accredited for the analysis of chlorinated hydrocarbons, all analytical results for the residue class must collectively satisfy the criteria.

(A) *Systematic laboratory difference:*

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

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

2.0, if the standardized difference is greater than 2.5,
−2.0, if the standardized difference is less than −1.5,
or
the standardized difference minus 0.5, if the standardized difference lies between −1.5 and 2.5, inclusive.

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

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

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

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

2.0, if the standardized difference is greater than 1.5,
−2.0, if the standardized difference is less than −2.5,
or
the standardized difference plus 0.5, if the standardized difference lies between −2.5 and 1.5, inclusive.

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

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

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

[11] When determining compliance with this criterion for all chlorinated hydrocarbon results in a sample collectively, the following statistical procedure must be followed to account for the correlation of analytical results within a sample: the average of the standardized differences of the analytical results within the sample, divided by a constant, is used in place of a single standardized difference to determine the CUSUM–P (or CUSUM–N) value for the sample. The constant is a function of the number of analytical results used to compute the average standardized difference.

[12] *See* footnote 11.

the CUSUM increment to the last previously computed CUSUM–N value. If this computation yields a value smaller than 0, the new CUSUM–N value is set equal to 0. [CUSUM–N values are initialized at zero; that is, the CUSUM–N value associated with the first sample is set equal to the CUSUM increment for that sample.]

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

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

(*1*) Determine the CUSUM increment for the sample. The CUSUM increment is set equal to the larger of −0.4 and the absolute value of the standardized difference minus 0.9. If this computation yields a value larger than 1.6, the increment is set equal to 1.6.

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

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

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

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

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

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

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

(A) Send all official samples that have not been analyzed as of the date of written notification of probation to a specified FSIS laboratory by certified mail or private carrier or, as an alternative, to an accredited laboratory accredited for this specific chemical residue. Mailing expense will be paid by FSIS.

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

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

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

[13] When determining compliance with this criterion for all chlorinated hydrocarbon results in a sample collectively, the following statistical procedure must be followed to account for the correlation of analytical results within a sample: the square root of the sum of the within sample variance and the average standardized difference of the sample, divided by a constant, is used in place of the absolute value of the standardized difference to determine the CUSUM–V value for the sample. The constant is a function of the number of analytical results used to compute the average standardized difference.

[14] A result will have a large deviation measure equal to zero when the absolute value of the result's standardized difference, (d), is less than 2.5, and otherwise a measure equal to $1-(2.5/d)^4$.

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

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

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

(A) *Systematic laboratory difference—* (*1*) *Positive systematic laboratory difference:* The standardized difference between the accredited laboratory's result and the comparison mean for each interlaboratory accreditation maintenance check sample is used to determine a CUSUM value, designated as CUSUM–P.[15] This value is computed and evaluated as follows:

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

2.0, if the standardized difference is greater than 2.5,
−2.0, if the standardized difference is less than −1.5,
or
the standardized difference minus 0.5, if the standardized difference lies between −1.5 and 2.5, inclusive.

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

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

(*2*) *Negative systematic laboratory difference:* The standardized difference between the accredited laboratory's result and the comparison mean for each interlaboratory accreditation maintenance check sample is used to determine a CUSUM value, designated as CUSUM–N.[16] This value is computed and evaluated as follows:

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

2.0, if the standardized difference is greater than 1.5,
−2.0, if the standardized difference is less than −2.5,
or
the standardized difference plus 0.5, if the standardized difference lies between −2.5 and 1.5, inclusive.

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

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

(B) *Variability:* The absolute value of the standardized difference between the accredited laboratory's result and the comparison mean for each interlaboratory accreditation maintenance check sample is used to determine a CUSUM value, designated as CUSUM–V.[17] This value is computed and evaluated as follows:

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

[15] *See* footnote 11.

[16] *See* footnote 11.

[17] *See* footnote 13.

absolute value of the standardized difference minus 0.9. If this computation yields a value larger than 1.6, the increment is set equal to 1.6.

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

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

(C) *Large deviations:* The large deviation measure of the accredited laboratory's result for each interlaboratory accreditation maintenance check sample is used to determine a CUSUM value, designated as CUSUM–D.[18] This value is computed and evaluated as follows:

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

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

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

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

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

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

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

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

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

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

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

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

(i) Any felony.

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

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

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

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

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

[18] A result will have a large deviation measure equal to zero when the absolute value of the result's standardized difference, (d), is less than 2.5, and otherwise a measure equal to $1-(2.5/d)^4$.

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

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

(1) Any felony.

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

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

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

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

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

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

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

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

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

(4) An accredited laboratory shall have its accreditation revoked if the laboratory or any individual or entity responsibly connected with the laboratory is convicted in a Federal or State court of any of the following violations of law:

(i) Any felony.

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

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

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

(h) *Notification and hearings.* Accreditation of any laboratory shall be refused, suspended, or revoked under the conditions previously described herein. The owner or operator of the laboratory shall be sent written notice of the refusal, suspension, or revocation of accreditation by the Administrator. In such cases, the laboratory owner or operator will be provided an opportunity to present, within 30 days of the date of the notification, a statement challenging the merits or validity of such action and to request an oral hearing with respect to the denial, suspension,

or revocation decision. An oral hearing shall be granted if there is any dispute of material fact joined in such responsive statement. The proceeding shall thereafter be conducted in accordance with the applicable rules of practice which shall be adopted for the proceeding. Any such refusal, suspension, or revocation shall be effective upon the receipt by the laboratory of the notification and shall continue in effect until final determination of the matter by the Administrator.

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

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

§318.22 Determination of added water in cooked sausages.

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

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

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

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

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

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

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

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

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

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

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

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

[55 FR 7299, Mar. 1, 1990]

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

[58 FR 41151, Aug. 2, 1993]

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

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

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

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

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

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

[59 FR 62561, Dec. 6, 1994]

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

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

Subparts B—F [Reserved]

Subpart G—Canning and Canned Products

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

§ 318.300 Definitions.

(a) *Abnormal container.* A container with any sign of swelling or product leakage or any evidence that the contents of the unopened container may be spoiled.

(b) *Acidified low acid product.* A canned product which has been formulated or treated so that every component of the finished product has a pH of 4.6 or lower within 24 hours after the completion of the thermal process unless data are available from the establishment's processing authority demonstrating that a longer time period is safe.

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

(d) *Canned product.* A meat food product with a water activity above 0.85 which receives a thermal process either before or after being packed in a hermetically sealed container. Unless otherwise specified, the term ''product'' as used in this subpart G shall mean ''canned product.''

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

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

(g) *Come-up time.* The elapsed time, including venting time (if applicable), between the introduction of the heating medium into a closed retort and the start of process timing.

(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:

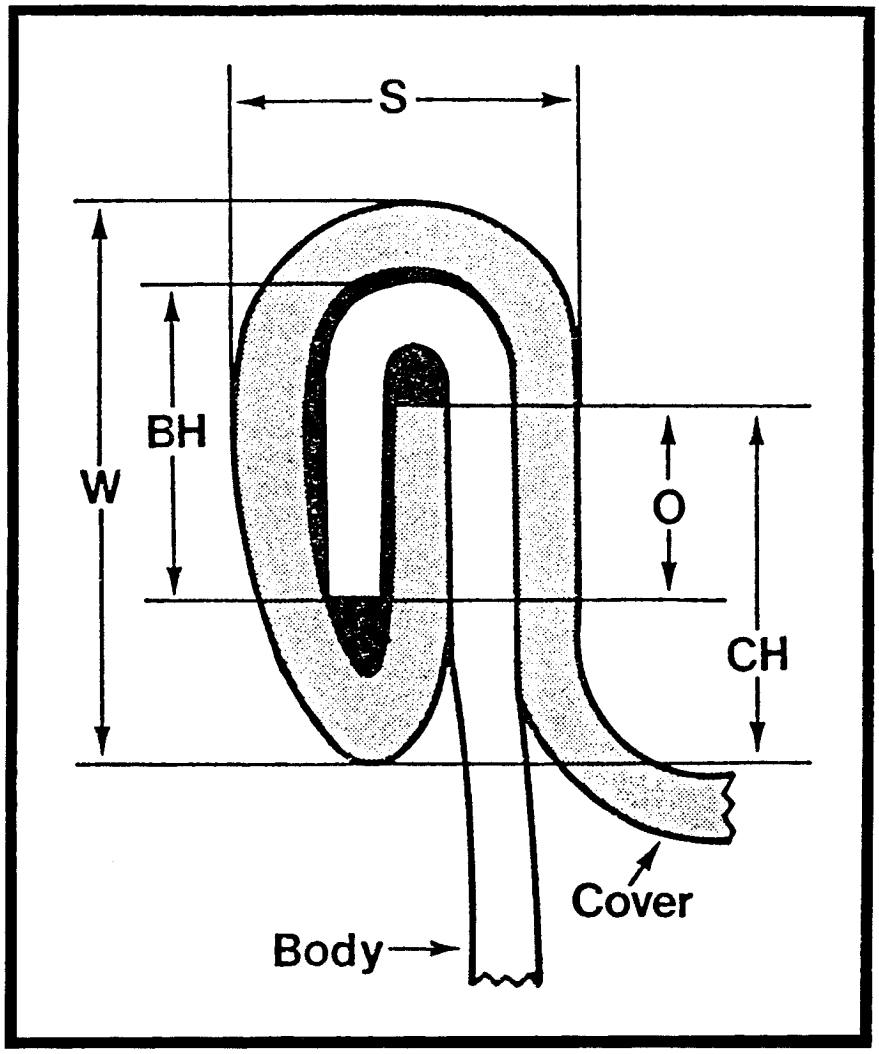
(*1*) Double seam length—W;

(*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.* In lieu of mercury-in-glass thermometers, the Administrator, upon request, will consider other indicating temperature devices, such as resistance temperature detectors. Any such device that is approved shall, upon installation and at least once a year thereafter, be tested for accuracy against a known accurate standard. 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. Any such device which cannot be adjusted to the standard shall be replaced, or repaired and tested for accuracy before further use.

(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.* In lieu of chart-type devices, the Administrator will consider for approval other recording devices upon request.

(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.

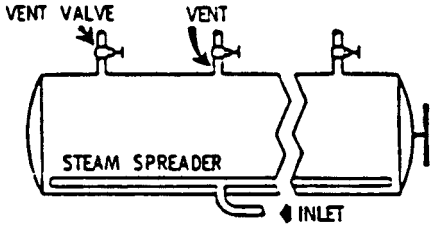


Figure 1.

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.

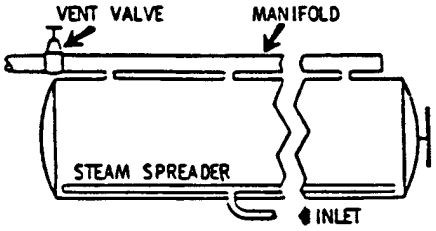


Figure 2.

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.

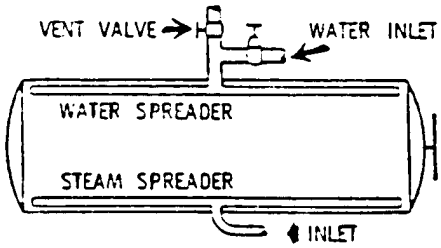


Figure 3.

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.

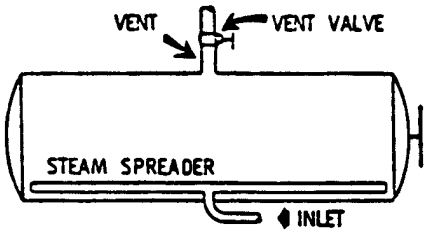


Figure 4.

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.

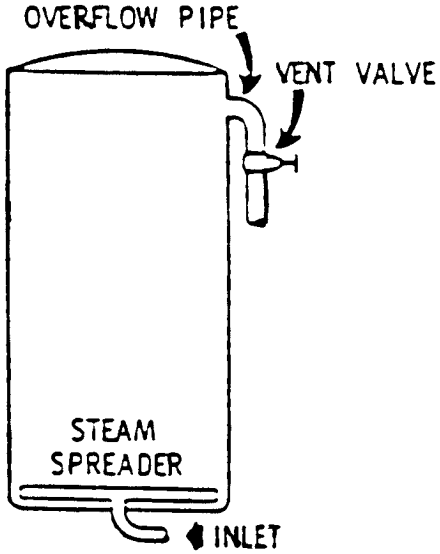


Figure 5.

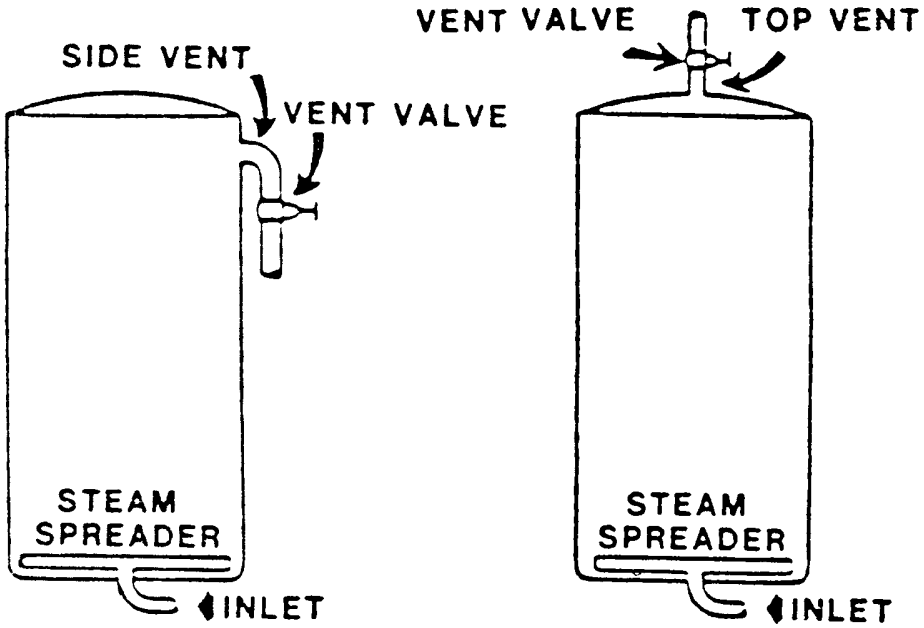
Figure 5.

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.

(5) The Administrator shall be notified immediately by the official establishment of any such system in use or placed into use on or after the effective date of this rule.

(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 will be evaluated on a case-by-case basis by the Adminstrator. Systems will be approved if they are found to conform to the applicable requirements of this section and 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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§ 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.* When requested by an establishment, the Administrator will consider the approval of automated process monitoring and recordkeeping systems. An approved system, alone or in combination with written records, shall be designed and operated in a manner which 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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§ 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) shall be handled under quality control as provided in paragraph (c) of this section or shall be handled in accordance with paragraph (d) of this section.

(c) Any partial quality control program or any portion of a total quality control system for handling process deviations shall be prepared in accordance with § 318.4.

(d) Handling process deviations without an approved quality control program. (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.

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

[51 FR 45619, Dec. 19, 1986, as amended at 53 FR 49848, Dec. 12, 1988; 62 FR 45025, Aug. 25, 1997]

§ 318.309 Finished product inspection.

(a) Finished product inspections shall be handled under quality control as provided in paragraph (b) or paragraph (c) of this section or shall be handled in accordance with paragraph (d) of this section.

(b) Any partial quality control program for finished product inspection shall be prepared in accordance with § 318.4 of this part.

(c) That portion of a total quality control system for finished product inspection shall be prepared in accordance with § 318.4 of this part.

(d) Handling finished product inspections without an approved quality control program.

(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.

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

[51 FR 45619, Dec. 19, 1986, as amended at 57 FR 37872, Aug. 21, 1992; 57 FR 55443, Nov. 25, 1992; 62 FR 45025, Aug. 25, 1997]

§ 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.

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

PART 319—DEFINITIONS AND STANDARDS OF IDENTITY OR COMPOSITION

Subpart A—General

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319.600 Pizza.

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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.

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.

§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) A prerequisite for label approval for products consisting of or containing ''Mechanically Separated (Species)'' is that such ''Mechanically Separated (Species)'' shall have been produced by an establishment under an establishment quality control system. Such a plant quality control system shall provide the controls and information necessary to assure that the product will meet the requirements described in §319.5(a) and to enable establishment personnel and program employees to monitor the system for effectiveness. The system shall include a written description of the methods used by the establishment to maintain uniformity of the raw ingredients used in manufacturing product, to control the handling and processing of the raw ingredients and the finished product, and shall contain provisions for chemical analyses of the product and other procedures to determine and assure compliance with standards for the product. For purposes of this paragraph, a lot shall consist of the ''Mechanically Separated (Species)'' 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. All units of any lot must be available for inspection by program employees. Analysis of a sample of at

least 1 pound from each lot to verify contents of fat, protein, and calcium in ''Mechanically Separated (Species)'' shall be performed by the operator of the establishment or his or her agent to assure that finished product will meet the requirements in § 319.5(a), except that such analyses with respect to fat, protein, and calcium content shall be required to be performed with respect to only one randomly selected lot of every five lots if the preceding ten analyses and all such analyses performed by the Department during the preceding ten analyses period establish compliance with the requirements of § 319.5(a), and that no analyses with respect to fat or protein content shall be required where the finished product is represented as product for processing. An analysis of a sample of at least 1 pound to verify essential amino acid content and/or protein efficiency ratio in ''Mechanically Separated (Species)'' shall be performed by the operator of the establishment or his or her agent at the rate of at least one per month during production to assure that finished product will meet the requirements of § 319.5(a), except that such analyses with respect to essential amino acid content and/or protein efficiency ratio shall be required to be performed only once every 6 months if the preceding three analyses and all such analyses performed by the Department during the preceding three analyses period establish compliance with the requirements of § 319.5(a). Finished product samples shall be analyzed in accordance with ''Official Methods of Analysis of the Association of Official Analytical Chemists,'' (AOAC), 15th edition, 1990, §§ 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 accordance with the ''Chemistry Laboratory Guidebook,'' U.S. Department of Agriculture, Washington, DC, March 1986 edition, sections 6.011–6.013, Revised June 1987 (pages 6–35 through 6–65). 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. Alternative methods of analysis may be submitted to the Administrator to determine their acceptability based upon their accuracy, repeatability, reproducibility, and lowest level of reliable measurement, as demonstrated by at least 3 laboratories. Copies of AOAC's ''Official Methods'' may be obtained from: AOAC, 2200 Wilson Boulevard, Suite 400, Arlington, VA 22201. Copies of USDA's Chemistry Laboratory Guidebook may be obtained from: Superintendent of Documents, Government Printing Office, Washington, DC 20402. This incorporation by reference was approved by the Director of the FEDERAL REGISTER on December 30, 1981 and March 15, 1982. These materials are incorporated as they exist on the date of the approval. A notice of any change in the sections of the AOAC methods or the Chemistry Laboratory Guidebook cited herein will be published in the FEDERAL REGISTER.) The plant quality control system shall be subject to periodic review, and the approval of such system may be terminated in accordance with § 318.4(g)(2) of this subchapter.

[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]

§ 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, binders or extenders. 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]

§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. 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]

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 § 318.7(c) (1) and (4) of this subchapter. 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]

§ 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. A prerequisite for label approval of these products is a quality control program.

(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 in § 318.7(c)(4) of this subchapter for use in cured pork products may be used singly in those cured pork products labeled as ''Ham water added'' and ''Ham and water product—X% of weight is added ingredients.'' These binders are not permitted to be used in combination with one or more such binders approved for use in cured pork products. 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.

[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]

§ 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.

Type of cured pork product	Minimum meat PFF percentage [1]	Product name and qualifying statements
''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. A prerequisite for label approval of these products is a quality control program.

(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]

§ 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 §318.7(c)(4) of this subchapter.

[42 FR 3299, Jan. 18, 1977]

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 §318.7(c)(4) of this subchapter. Sausage may not contain phosphates except that phosphates listed in §318.7(c)(4) of this subchapter 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]

§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 § 318.7(c)(4) of this subchapter.

[55 FR 34683, Aug. 24, 1990]

§ 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 the chart following § 318.7(c)(4), 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 in §318.7(c)(4) of this subchapter.

(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]

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 §318.7(c) of this chapter. 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 § 318.7(c) of this chapter. 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) One or more of the binders and extenders as provided in § 318.7(c)(4) of this subchapter may be used in cooked sausage otherwise complying with paragraph (a) or (b) of this section. 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.

(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]

§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 § 318.7 (c)(4) of this subchapter.

(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]

§ 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 Pizza.

(a) ''Pizza with Meat'' is a bread base meat food product with tomato sauce, cheese, and meat topping. It shall contain cooked meat made from not less than 15 percent raw meat. Mechanically Separated (Species) may be used in accordance with § 319.6.

(b) ''Pizza with Sausage'' is a bread base meat food product with tomato sauce, cheese, and not less than 12 percent cooked sausage or 10 percent dry sausage; e.g., pepperoni. 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 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

[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.

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 § 318.7(c)(4) of this chapter, 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 § 318.7(c)(4) of this chapter, within these maximum amounts in percent by weight of the finished food: Sorbic acid, benzoic acid and their sodium, potassium, and calcium salts, individually, 0.1 percent, or in combination, 0.2 percent, expressed as the acids; calcium disodium EDTA, 0.0075 percent; stearyl citrate, 0.15 percent; isopropyl citrate mixture, 0.02 percent.

(6) Antioxidants identified in § 318.7(c)(4) of this chapter, 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 § 318.7(c)(4) of this chapter, 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 § 318.7(c)(4) of this chapter, 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 § 318.7(c)(4) of this chapter, 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]

§ 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

[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.

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) 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) Records of processing procedures for cooked beef and roast beef as required in §318.17(d).

(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]

§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 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.

§ 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

[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.

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 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.
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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,

[1] For convenience in filing, it is requested that these certificates be made on paper 5½ x 8 inches in size.

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 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

[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.

for 1 minute in a solution of 0.022 percent FD&C yellow No. 5 coloring;

(4) Meat may be denatured by dipping it in a solution of 0.0625 percent tannic acid, followed by immersion in a water bath, then dipping it in a solution of 0.0625 percent ferric acid; and

(5) When meat, meat byproducts, or meat food products are in ground form, 4 percent by weight of coarsely ground hard bone, which shall be in pieces no smaller than the opening size specified for No. 5 mesh in the standards issued by the U.S. Bureau of Standards or 6 percent by weight of coarsely ground hard bone, which shall be in pieces no smaller than the opening size specified for No. 8 mesh in said Standards, uniformly incorporated with the product may be used in lieu of the agents prescribed in paragraph (a)(2) of this section.

(6) Before the denaturing agents are applied to articles in pieces more than 4 inches in diameter, the pieces shall be freely slashed or sectioned. (If the articles are in pieces not more than 4 inches in diameter, slashing or sectioning will not be necessary.) The application of any of the denaturing agents listed in paragraph (a)(1) or (2) of this section to the outer surface of molds or blocks of boneless meat, meat byproducts, or meat food products shall not be adequate. The denaturing agent must be mixed intimately with all of the material to be denatured, and must be applied in such quantity and manner that it cannot easily and readily be removed by washing or soaking. A sufficient amount of the appropriate agent shall be used to give the material a distinctive color, odor, or taste so that such material cannot be confused with an article of human food.

(7) Carcasses (other than viscera), parts thereof, cuts of meat, and unground pieces of meat darkened by charcoal or other black dyes shall be deemed to be denatured pursuant to this section only if they contain at least that degree of darkness depicted by diagram 1 of the Meat Denaturing Guide (MP Form 91).[1]

(b) Inedible rendered animal fats shall be denatured by thoroughly mixing therein denaturing oil, No. 2 fuel oil, brucine dissolved in a mixture of alcohol and pine oil or oil of rosemary, finely powdered charcoal, or any proprietary denaturing agent approved for the purpose by the Administrator in specific cases. The charcoal shall be used in no less quantity than 100 parts per million and shall be of such character that it will remain suspended indefinitely in the liquid fat. Sufficient of the chosen identifying agents shall be used to give the rendered fat so distinctive a color, odor, or taste that it cannot be confused with an article of human food.

[35 FR 15605, Oct. 3, 1970, as amended at 41 FR 22930, June 8, 1976; 44 FR 67626, Nov. 27, 1979]

§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

[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.

course of importation or otherwise in commerce any product unless the waybill, transfer bill, running slip, conductor's card, or other papers accompanying the same includes the signed statement in the following form:

(Name of transportation company)
U.S. inspected and passed, as evidenced by shipper's certificate on file with initial carrier.
(signed) _____
Agent

(b) Signatures of agents to statements required under this section shall be written in full.

[47 FR 17276, Apr. 22, 1982]

§ 325.16 Official seals; forms, use, and breaking.

(a) The official seals required by this part shall be those prescribed in § 312.5(a) of this subchapter.

(b) Except as provided in § 325.18(b), official seal affixed under this part shall be affixed or broken only by Program employees, and no person other than a Program employee shall affix, detach, break, change, or tamper with any such seal in any way whatever. Commission of any such acts contrary to this regulation is a criminal offense.

§ 325.17 Loading or unloading products in sealed railroad cars, trucks, etc., en route prohibited; exception.

Unloading any product from an officially sealed railroad car, truck, or other means of conveyance containing any unmarked product or loading any product or any other commodity in the means of conveyance while en route from one official establishment to another official establishment is not permitted, except that product transported under § 325.5 from one official establishment to another for further processing may be unloaded and stored in transit at any approved warehouse which is operated under the identification service provided under the regulations in part 350 of subchapter B of this chapter and which has railroad facilities or a receiving dock for unloading the product directly into such warehouse: *Provided,* That the product is stored in rooms which are of such size and type as will not result in adulteration or misbranding of the product: *And provided further,* That the product is transported to and from such warehouse, and under official seal as provided in § 325.5 and stored in such rooms at such warehouse.

§ 325.18 Diverting of shipments, breaking of seals, and reloading by carrier in emergency; reporting to Regional Director.

(a) Shipments of inspected and passed product that bear the inspection legend may be diverted from the original destination without a reinspection of the articles, provided the waybills, transfer bills, running slips, conductor's card, or other papers accompanying the shipments are marked, stamped, or have attached thereto signed statements in accordance with § 325.15.

(b) In case of wreck or similar extraordinary emergency, the Department seals on a railroad car or other means of conveyance containing any inspected and passed product may be broken by the carrier, and if necessary, the articles may be reloaded into another means of conveyance, or the shipment may be diverted from the original destination, without another shipper's certificate; but in all such cases the carrier shall immediately report the facts by telephone or telegraph to the Regional Director in the area in which the emergency occurs. Such report shall include the following information:

(1) Nature of the emergency.

(2) Place where seals were broken.

(3) Original points of shipment and destination.

(4) Number and initial of the original car or truck.

(5) Number and initials of the car or truck into which the articles are reloaded.

(6) New destination of the shipment.

(7) Kind and amount of articles.

[35 FR 15605, Oct. 3, 1970, as amended at 42 FR 39087, Aug. 2, 1977]

§ 325.19 Provisions inapplicable to specimens for laboratory examination, etc., or to naturally inedible articles.

The provisions of this part do not apply:

(a) To specimens of product sent to or by the Department of Agriculture or

divisions thereof in Washington, DC, or elsewhere, for laboratory examination, exhibition purposes, or other official use;

(b) To material released for educational, research and other nonfood purposes, as prescribed in § 314.9 of this subchapter;

(c) To glands and organs for use in preparing pharmaceutical, organotherapeutic, or technical products and not used for human food, as described in § 318.1(g) of this subchapter;

(d) To material or specimens of product for laboratory examination, research, or other nonhuman food purposes, when authorized by the Administrator, and under conditions prescribed by him in specific cases; and

(e) To articles that are naturally inedible by humans, such as hoofs, horns, and hides in their natural state.

§ 325.20 Transportation and other transactions concerning dead, dying, disabled, or diseased livestock, and parts of carcasses of livestock that died otherwise than by slaughter.

No person engaged in the business of buying, selling, or transporting in commerce, or importing any dead, dying, disabled or diseased animals or parts of the carcasses of any animals that died otherwise than by slaughter shall:

(a) Buy, sell, transport, or offer for sale or transportation, in commerce, or import any dead livestock if its hide or skin has been removed;

(b) Sell, transport, offer for sale or transportation, or receive for transportation, in commerce, any dead, dying, disabled, or diseased livestock, or parts of the carcasses of any livestock that died otherwise than by slaughter, unless such livestock and parts are consigned and delivered, without avoidable delay, to establishments of animal food manufacturers, renderers, or collection stations that are registered as required by part 320 of this subchapter, or to official establishments that operate under Federal inspection, or to establishments that operate under a State or Territorial inspection system approved by the Secretary as one that imposes requirements at least equal to the Federal requirements for purposes of paragraph 301(c) of the Act;[4]

(c) Buy in commerce or import any dead, dying, disabled, or diseased livestock or parts of the carcasses of any livestock that died otherwise than by slaughter, unless he is an animal food manufacturer or renderer and is registered as required by part 320 of this subchapter, or is the operator of an establishment inspected as required by paragraph (b) of this section and such livestock or parts of carcasses are to be delivered to establishments eligible to 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.

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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!!rs⊖

_____

_____

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 in the Finding Aids section of this volume.

§ 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 308.3, 308.4, 308.5, 308.6, 308.7, 308.8, 308.9, 308.11, 308.13, 308.14, and 308.15 of this subchapter 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. If it is determined that the establishment does not meet such requirements, approval of the establishment as an official import inspection establishment may be refused in accordance with the applicable rules of practice. A written notice, specifying the premises to which the approval applies, shall be given to each applicant granted approval. When approval is refused for any such reason, the applicant shall be informed of the action and the reason therefor. Approval may also be refused in accordance with section 401 of the act and applicable rules of practice.

(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

[1] [Reserved]

[2] For example: Canned product, boneless meat, carcasses and cuts.

of the sample examination, that the product does not meet the requirements of the Act and regulations thereunder, the consignment shall be refused entry. However, a consignment rejected for container defects but otherwise acceptable may be reoffered for inspection under the following conditions:

(1) If the defective containers are not indicative of an unsafe and unstable product as determined by the Administrator;

(2) If the number and kinds of container defects found in the original sample do not exceed the limits specified for this purpose in FSIS guidelines; and

(3) If the defective containers in the consignment have been sorted out and exported or destroyed under the supervision of an inspector.

(k) Program inspectors or Customs officers at border or seaboard ports shall report the sealing of cars, trucks, or other means of conveyance, and the sealing or identification of containers of foreign product 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]

§ 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

[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.

for No. 5 mesh in the standards issued by the U.S. Bureau of Standards or 6 percent by weight of coarsely ground hard bone, which shall be in pieces no smaller than the opening size specified for No. 8 mesh in said Standards, uniformly incorporated with the product, may be used in lieu of the agents prescribed in paragraph (a)(2) of this section.

(5) Before the denaturing agents are applied to articles in pieces more than 4 inches in diameter, the pieces shall be freely slashed or sectioned. (If the articles are in pieces not more than 4 inches in diameter, slashing or sectioning will not be necessary.) The application of any of the denaturing agents listed in paragraph (a) (1) or (2) of this section to the outer surface of molds or blocks or boneless meat, meat by-products, or meat food products shall not be adequate. The denaturing agent must be mixed intimately with 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.

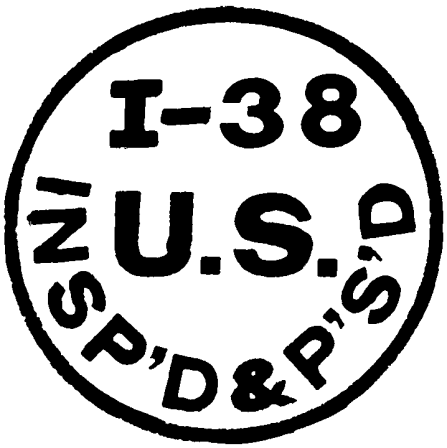
(b) Inedible rendered animal fats shall be denatured by thoroughly mixing therein denaturing oil, No. 2 fuel oil, brucine dissolved in a mixture of alcohol and pine oil or oil of rosemary, finely powdered charcoal, or any proprietary denaturing agent approved for the purpose by the Administrator in specific 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.

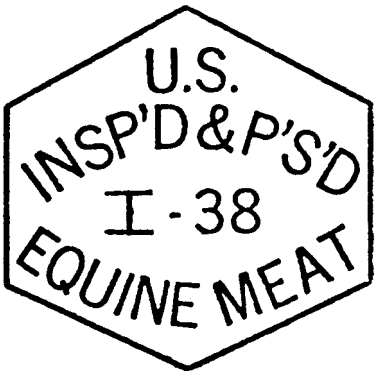


For application to outside containers of meat and meat food products prepared from cattle, sheep, swine, and goats.

[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
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.
Maine	May 12, 1980.
Maryland	March 31, 1991
Massachusetts	Jan. 12, 1976.
Michigan	Oct. 3, 1981.
Minnesota	May 16, 1972.
Missouri	Aug. 18, 1972.
Nebraska	Oct. 1, 1971.
Nevada	July 1, 1973.
New Hampshire	Aug. 6, 1978.
New Jersey	July 1, 1975.
New York	July 16, 1975.
North Dakota	June 22, 1970.
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 in the Finding Aids section of this volume.

§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) Section 308.4 of this subchapter 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 back-flow devices are installed.

(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]

§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.	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.
		Maine	Feb. 9, 1981.
		Maryland	Mar. 31, 1991.
		Massachusetts	Jan. 12, 1976.
		Michigan	Mar. 29, 1982.
		Minnesota	Jan. 31, 1975.
		Missouri	Jan. 31, 1975.
		Nebraska	Jan. 31, 1975.
		Nevada	Jan. 31, 1975.
		New Hampshire	Oct. 29, 1979.
		New Jersey	July 1, 1975.
		New York	July 16, 1975.
		North Dakota	July 23, 1973.
		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.	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.
		Maine	Feb. 9, 1981.
		Maryland	Mar. 31, 1991.
		Massachusetts	Jan. 12, 1975.
		Michigan	Mar. 29, 1982.
		Minnesota	Jan. 31, 1975.
		Missouri	Jan. 31, 1975.
		Nebraska	Jan. 31, 1975.
		Nevada	Jan. 31, 1975.
		New Hampshire	Oct. 29, 1979.
		New Jersey	July 1, 1975.
		New York	July 16, 1973.
		North Dakota	July 23, 1975.
		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.	Arkansas	Mar. 29, 1982.
		Connecticut	Oct. 1, 1975.
		Guam	Nov. 19, 1976.
		Idaho	Mar. 29, 1982.
		Kentucky	Apr. 18, 1973.
		Maine	Feb. 9, 1981.
		Maryland	Mar. 31, 1991.
		Massachusetts	Jan. 12, 1976.
		Michigan	Mar. 29, 1982.
		Minnesota	Jan. 31, 1975.
		Nevada	Jan. 31, 1975.
		New Hampshire	Oct. 29, 1979.
		New Jersey	July 1, 1975.
		New York	July 16, 1975.
		North Dakota	July 23, 1973.
		Northern Mariana Islands.	Oct. 29, 1979.

Sections of act and regulations	Classes of operators	State	Effective date of designation
		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 in the Finding Aids section of this volume.

PART 335—RULES OF PRACTICE GOVERNING PROCEEDINGS UNDER THE FEDERAL MEAT INSPECTION ACT

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Subpart E—Criminal Violations

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—General

§335.1 Scope and applicability of rules of practice.

(a) The Uniform Rules of Practice for the Department of Agriculture promulgated in subpart H of part 1, subtitle A, title 7, Code of Federal Regulations, are the Rules of Practice applicable to adjudicatory, administrative proceedings under sections 4, 6, 7(e), 8, and 401 of the Federal Meat Inspection Act (21 U.S.C. 604, 606, 607(e), 608 and 671). In addition, the Supplemental Rules of Practice set forth in subpart B of this part shall be applicable to such proceedings.

(b) The rules of practice set forth in subpart C of this part shall be applicable to the suspension of assignment of inspectors for threats to forcibly assault or forcible assault, intimidation or interference with any inspection service employee pursuant to §305.5(b) of the regulations (9 CFR 305.5(b)) under the Federal Meat Inspection Act. In addition, the definitions applicable to proceedings under the Uniform Rules of Practice (7 CFR 1.132) shall apply with equal force and effect to proceedings under subpart C.

(c) The rules of practice set forth in subpart D of this part shall be applicable to the suspension of assignment of

inspectors under section 3(b) of the Act (21 U.S.C. 603(b)). In addition, the definitions applicable to proceedings under the Uniform Rules of Practice (7 CFR 1.132) shall apply with equal force and effect to proceedings under part 313.

[42 FR 10960, Feb. 25, 1977, as amended at 44 FR 68817, Nov. 30, 1979]

Subpart B—Supplemental Rules of Practice

§335.10 Refusal or withdrawal of inspection service under section 401 of the Act.

If the Administrator has reason to believe that the applicant for or recipient of service under Title I of the Act is unfit to engage in any business requiring such inspection because of any of the reasons specified in section 401 of the Act, he may institute a proceeding by filing a complaint with the Hearing Clerk, who shall promptly serve a true copy thereof upon each respondent, as provided in §1.147(b) of the Uniform Rules of Practice (9 CFR 1.147(b)).

§335.11 Withdrawal of inspection service for failure of an establishment to destroy any condemned carcass or part thereof or any condemned meat or meat food product.

(a) In any situation in which the Administrator has reason to believe that an establishment which receives inspection service under Title I of the Federal Meat Inspection Act has failed to destroy any condemned carcass or part thereof or any condemned meat or meat food product, as required under sections 4 and 6 of the Federal Meat Inspection Act (21 U.S.C. 604 and 606) and the regulations in this subchapter, he may notify the operator of the establishment, orally or in writing, of the Administrator's intent to withdraw (for such period or indefinitely as the Administrator deems necessary to effectuate the purposes of the Act) inspection service from the establishment, pursuant to sections 4, 6, and 401 of the Act (21 U.S.C. 604, 606, and 671) and §305.5(a) of the regulations (9 CFR 305.5(a)), if the establishment fails to destroy the condemned articles involved, as specified in the notification, within three days of the receipt of the notification by the operator of the establishment. In the event of oral notification, a written confirmation shall be given, as promptly as circumstances permit, to the operator of the establishment of the intent to withdraw inspection. The written notification or confirmation shall be served upon the operator of the establishment in the manner prescribed in §1.147(b) of the Uniform Rules of Practice (7 CFR 1.147(b)).

(b) If any establishment so notified fails to destroy any condemned carcass or part thereof or any condemned meat or meat food product as specified in the notice, the Administrator may issue and file a complaint in accordance with the Uniform Rules of Practice. Effective upon service of the complaint, inspection service under the Act shall be withdrawn from such establishment as provided in sections 4, 6, and 401 of the Federal Meat Inspection Act (21 U.S.C. 604, 606 and 671), pending final determination in the proceeding.

§335.12 Withholding use of marking, labeling, or containers from use under section 7 of the Federal Meat Inspection Act.

(a) In any situation in which the Administrator determines that any marking or labeling or size or form of any container in use or proposed for use with respect to any article subject to Title I of the Federal Meat Inspection Act is false or misleading in any particular, he shall notify, in writing, the person, firm, or corporation using or proposing to use such marking, labeling, or container that such use shall be withheld unless the marking, labeling, or container is modified in such a manner as the Administrator may prescribe so that it would not be false or misleading.

(b) The written notification shall briefly set forth the reason for withholding the use of the marking, labeling, or container, and shall offer the respondent an opportunity to submit a written statement by way of answer to the notification and a right to request a hearing with respect to the merits or validity of the withholding action. The written notification shall be served in the manner prescribed in §1.147(b) of the Uniform Rules of Practice (7 CFR 1.147(b)).

(c) Effective upon service of the notification, the use of the marking, labeling, or container shall be withheld, if the Administrator so directs.

(d) If any person, firm, or corporation so notified 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, he shall file with the Hearing Clerk the notification, answer and request for hearing, which shall constitute the complaint and answer in the proceeding, which shall thereafter be governed by the Uniform Rules of Practice.

§ 335.13 Refusal or withdrawal of inspection service under the Federal Meat Inspection Act for failure to maintain sanitary conditions.

(a) In any situation in which the Administrator determines that the sanitary conditions of an establishment which is applying for inspection or receiving inspection under Title I of the Federal Meat Inspection Act are such that any meat or meat food product prepared therein are or would be rendered adulterated, he shall refuse to allow said meat or meat food products to be labeled, marked, stamped, or tagged as ''inspected and passed,'' pursuant to section 8 of the Act (21 U.S.C. 608). The Administrator shall notify the applicant or operator of the establishment, orally or in writing, as promptly as circumstances permit, of such refusal to inspect and pass the meat or meat food products and the reasons therefor, and the action which the Administrator deems necessary to eliminate the insanitary conditions. In the event of oral notification, written confirmation shall be given, as promptly as circumstances permit, to the applicant or operator of the establishment in the manner prescribed in § 1.147(b) of the Uniform Rules of Practice (7 CFR 1.147(b)).

(b) If any applicant or operator of an establishment so notified fails to take the necessary action to eliminate the insanitary conditions within the period specified in the notice, the Administrator may issue a complaint in accordance with the Uniform Rules of Practice. Effective upon service of the complaint, inspection service shall be refused or withdrawn from such establishment as provided in sections 8 and 401 of the Act pending final determination in the proceeding.

Subpart C—Rules Applicable to Suspension of Assignment of Inspectors for Threats to Forcibly Assault or Forcible Assault, Intimidation or Interference With Any Inspection Service Employee

§ 335.20 Notification to operator of establishment of incident.

In any situation in which a supervisor of an inspection service employee determines that the operator of any official establishment or any subsidiary therein, or any officer, employee, or agent of any such operator or any subsidiary therein, acting within the scope of his office, employment, or agency, has threatened to forcibly assault or has forcibly assaulted, intimidated or interfered with any inspection service employee, under his supervision, in or on account of the performance of the employee's official duties under the Act, he shall notify the operator of the establishment, orally or in writing, of the incident in accordance with § 305.5(b) of the regulations in this subchapter (9 CFR 305.5(b)).

§ 335.21 Procedure upon failure of operator of establishment to take action required by § 305.5(b) of the regulations.

(a) If any operator of an establishment notified pursuant to § 335.20 fails to promply take any of the actions specified in § 305.5(b) of the regulations (9 CFR 305.5(b)), the Administrator may suspend the assignment of inspectors at that establishment, in whole or in part, as the Administrator determines necessary to avoid impairment of the effective conduct of inspection service, by notifying the operator of the establishment, orally or in writing, of such suspension. In the event of oral notification, a written confirmation shall be given, as promptly as circumstances permit, to the operator of the establishment. The written notification or confirmation shall be served upon the operator of the establishment

in the manner prescribed in §1.147(b) of the Uniform Rules of Practice (7 CFR 1.147(b)).

(b) The written notification or confirmation, specified in paragraph (a) of this section, which shall constitute the complaint in the proceeding, shall briefly set forth the reason for the suspension of the assignment of inspectors, including allegations of fact which constitute a basis for the action. The complaint shall offer the respondent opportunity to submit a specific written statement by way of answer and the right to request a hearing with respect to the merits or validity of the suspension action, and shall state the time within which answer by the respondent must be made, which shall not be less than 10 days after service of the complaint. At any time prior to the close of the hearing, the complaint may be amended; but, in case of an amendment adding new provisions, the hearing shall, on the request of the respondent, be adjourned for a period not exceeding 15 days, if the judge determines that such and adjournment is necessary to avoid prejudice to the respondent.

(c) A copy of the complaint served upon the respondent shall be filed with the Hearing Clerk who shall assign the matter a docket number.

(d) After the complaint is served upon the respondent, as provided in paragraphs (a) and (b) of this section, the proceeding shall thereafter be conducted in accordance with rules of practice which shall be adopted for the proceeding.

Subpart D—Rules Applicable to Suspension of Assignment of Inspectors Under Section 3(b) of the Federal Meat Inspection Act

AUTHORITY: Sec. 21, 34 Stat. 1260, as amended, 21 U.S.C. 621; 92 Stat. 1069, 42 FR 35625, 35626, 35631.

SOURCE: 44 FR 68817, Nov. 30, 1979, unless otherwise noted.

§335.30 Suspension of the assignment of inspectors under section 3(b) of the Act.

In any situation in which the Administrator has determined that livestock have been inhumanely slaughtered or handled in connection with slaughter at an official establishment, the Administrator may suspend the assignment of inspectors at that establishment, in whole or in part, as the Administrator determines necessary to prevent inhumane treatment of livestock. The Administrator shall notify the operator of an establishment orally or in writing, of such suspension as soon as possible. In the event of oral notification, a written confirmation shall be given as promptly as circumstances permit to the operator of the establishment. The written notification or confirmation shall be served upon the operator of the establishment in a manner prescribed in §1.147(b) of the Uniform Rules of Practice (7 CFR 1.147(b)).

§335.31 Written notification to operator of establishment of incident.

The written notification or confirmation, specified in §335.30, shall constitute the complaint in the proceeding and shall briefly set forth the reason for the suspension of the assignment of inspectors, including allegations of fact which constitute a basis for the action. The complaint shall offer the establishment the opportunity to request a hearing with respect to the merits or validity of the suspension action and shall give the establishment the opportunity to furnish written assurances satisfactory to the Secretary that all inhumane slaughtering and handling in connection with slaughter have stopped and will not recur. The complaint shall state the time within which the respondent's answer must be made, which shall not be less than 10 days after service of the complaint.

§335.32 Procedure upon receipt of the establishment answer.

If any establishment notified in accordance with §335.31:

(a) Returns an answer and requests a hearing, the complaint, answer, and request for hearing shall be filed with the Hearing Clerk, who shall assign the matter a docket number. The proceeding shall thereafter be conducted in accordance with the rules of practice which shall be adopted for the proceeding; or

(b) Returns written assurances which the Secretary determines to be unsatisfactory, the establishment shall promptly be informed of this determination in a written notification. Said notification shall briefly set forth the reason the assurances were deemed unacceptable and shall offer the establishment the right to file an answer to the original complaint and to request a hearing with respect to the merits or validity of the suspension action. If any establishment so notified files an answer to the original complaint and requests a hearing, a copy of the complaint, answer, and request for hearing shall be filed with the Hearing Clerk, who shall assign the matter a docket number. The proceeding shall thereafter be conducted in accordance with the rules of practice which shall be adopted for the proceeding.

(c) Returns written assurances which the Secretary determines to be satisfactory, the suspension shall be terminated and the establishment informed of this action as soon as possible.

Subpart E—Criminal Violations

AUTHORITY: Sec. 406, Pub. L. 99–641, 100 Stat. 3571; 21 U.S.C. 606 note.

§ 335.40 Opportunity for presentation of views before report of criminal violations.

(a) Except as provided in paragraphs (a)(1) through (5) of this section, before any violation of the Federal Meat Inspection Act is reported to the Department of Justice by the Secretary for criminal prosecution the Secretary must give reasonable notice to the suspected violator that the Secretary intends to report the violation for prosecution and give the suspected violator an opportunity to present the violator's views to the Secretary with respect to such proceeding.

(1) Notice and opportunity need not be provided if the Secretary has any reason to believe that providing such notice and opportunity could result in the alteration or destruction of evidence, or where disclosure could result in injury to persons or property.

(2) Notice and opportunity need not be provided if the Secretary has any reason to believe that providing such notice and opportunity could result in flight of a suspected violator to avoid prosecution.

(3) Notice and opportunity need not be provided if the Secretary has any reason to believe that providing such notice and opportunity could result in compromising special investigative techniques, such as undercover or other covert operations.

(4) Notice and opportunity need not be provided when the impending criminal referral involves suspicion of bribery and related offenses, or clandestine slaughtering and/or processing operations.

(5) Notice and opportunity need not be provided when the impending referral is part of an investigation involving non-Act violations, and the Act and non-Act violations are jointly referred for prosecution.

(b) A notice of opportunity to present views will be sent by registered or certified mail, summarize the violations that constitute the basis of the contemplated prosecution, and describe the procedures for presentation of views. Any information given by a respondent, orally or in writing, shall become part of the Department's official record concerning the matter. The Department is under no obligation to disclose evidence to the suspected violator.

[52 FR 13828, Apr. 27, 1987]