

therefor, take reasonable samples of the inventory.

[63 FR 72354, Dec. 31, 1998, as amended at 69 FR 254, Jan. 5, 2004]

PART 301—TERMINOLOGY; ADULTERATION AND MISBRANDING STANDARDS

Sec.

301.1 General.

301.2 Definitions.

AUTHORITY: 21 U.S.C. 601–695; 7 U.S.C. 138–1381, 450, 1901–1906; 7 CFR 2.7, 2.18, 2.53.

§ 301.1 General.

For purposes of this chapter and unless otherwise specifically provided by regulation or required in the context of particular regulations:

(a) Terms have the meanings set forth in this part;

(b) The singular form also imports the plural, and the masculine form also imports the feminine and vice versa.

[69 FR 254, Jan. 5, 2004]

§ 301.2 Definitions.

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

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

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

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

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

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

(B) A food additive; or

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

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

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

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

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

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

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

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

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

(8) If any valuable constituent has been in whole or in part omitted or abstracted therefrom; or if any substance has been substituted, wholly or in part therefor; or if damage or inferiority has been concealed in any manner; or if any substance has been added thereto or mixed or packed therewith so as to

increase its bulk or weight, or reduce its quality or strength, or make it appear better or of greater value than it is; or,

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

Anesthesia. Loss of sensation or feeling.

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

(1) Processed dry animal food or

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

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

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

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

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

Capable of use as human food. This term applies to any carcass, or part or product of a carcass, of any livestock, unless it is denatured or otherwise identified as required by the applicable provisions of §§314.3, 314.10, 325.11, and

325.13 of this subchapter to deter its use as a human food, or it is naturally inedible by humans; e.g., hoofs or horns in their natural state.

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

Carbon dioxide. A gaseous form of the chemical formula CO₂.

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

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

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

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

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

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

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

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

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

- (1) Central nervous system disorder;
- (2) Abnormal temperature (high or low);
- (3) Difficult breathing;
- (4) Abnormal swellings;
- (5) Lack of muscular coordination;
- (6) Inability to walk normally or stand;
- (7) Any of the conditions for which livestock is required to be condemned

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on ante-mortem inspection in accordance with the regulations in part 309 of this subchapter.

Edible. Intended for use as human food.

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

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

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

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

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

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

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

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

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

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

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

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

(2) Accompanying such article.

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

Meat. (1) The part of the muscle of any cattle, sheep, swine, or goats which is skeletal or which is found in the tongue, diaphragm, heart, or esophagus, with or without the accompanying and overlying fat, and the portions of bone (in bone-in product such as T-bone or porterhouse steak), skin, sinew, nerve, and blood vessels which normally accompany the muscle tissue and that are not separated from it in the process of dressing. As applied to products of equines, this term has a comparable meaning.

(i) Meat does not include the muscle found in the lips, snout, or ears.

(ii) Meat may not include significant portions of bone, including hard bone and related components, such as bone marrow, or any amount of brain, trigeminal ganglia, spinal cord, or dorsal root ganglia (DRG).

(2) [Reserved]

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

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

Meat food product. Any article capable of use as human food which is made wholly or in part from any meat or other portion of the carcass of any cattle, sheep, swine, or goats, except those exempted from definition as a meat food product by the Administrator in specific cases or by the regulations in part 317 of this subchapter, upon a determination that they contain meat or other portions of such carcasses only in

a relatively small proportion or historically have not been considered by consumers as products of the meat food industry, and provided that they comply with any requirements that are imposed in such cases or regulations as conditions of such exemptions to assure that the meat or other portions of such carcasses contained in such articles are not adulterated and that such articles are not represented as meat food products. This term, as applied to food products of equines, shall have a meaning comparable to that provided in this paragraph with respect to cattle, sheep, swine, and goats.

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

- (1) If its labeling is false or misleading in any particular;
- (2) If it is offered for sale under the name of another food;
- (3) If it is an imitation of another food, unless its label bears, in type of uniform size and prominence, the word "imitation" and immediately thereafter, the name of the food imitated;
- (4) If its container is so made, formed, or filled as to be misleading;
- (5) If in a package or other container unless it bears a label showing:
 - (i) The name and place of business of the manufacturer, packer, or distributor; and
 - (ii) An accurate statement of the quantity of the contents in terms of weight, measure, or numerical count; except as otherwise provided in part 317 of this subchapter with respect to the quantity of contents;
- (6) If any word, statement, or other information required by or under authority of the Act to appear on the label or other labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use;
- (7) If it purports to be or is represented as a food for which a definition and standard of identity or composition has been prescribed by the reg-

ulations in part 319 of this subchapter unless:

- (i) It conforms to such definition and standard, and
- (ii) Its label bears the name of the food specified in the definition and standard and, insofar as may be required by such regulations, the common names of optional ingredients (other than spices, flavoring, and coloring) present in such food;
- (8) If it purports to be or is represented as a food for which a standard or standards of fill of container have been prescribed by the regulations in part 319 of this subchapter, and it falls below the standard of fill of container applicable thereto, unless its label bears, in such manner and form as such regulations specify, a statement that it falls below such standard;
- (9) If it is not subject to the provisions of paragraph (vv)(7)(ii) of this section unless its label bears:
 - (i) The common or usual name of the food, if any there be, and
 - (ii) In case it is fabricated from two or more ingredients, the common or usual name of each such ingredient, except as otherwise provided in part 317 of this subchapter;
- (10) If it purports to be or is represented for special dietary uses, unless its label bears such information concerning its vitamin, mineral, and other dietary properties as is required by the regulations in part 317 of this subchapter.
- (11) If it bears or contains any artificial flavoring, artificial coloring, or chemical preservative, unless it bears a label stating that fact; except as otherwise provided by the regulations in part 317 of this subchapter; or
- (12) If it fails to bear, directly thereon or on its containers, when required by the regulations in part 316 or 317 of this subchapter, the inspection legend and, unrestricted by any of the foregoing, such other information as the Administrator may require in such regulations to assure that it will not have false or misleading labeling and that the public will be informed of the manner of handling required to maintain the article in a wholesome condition.

Nonfood compound. Any substance proposed for use in official establishments, the intended use of which will

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not result, directly or indirectly, in the substance becoming a component or otherwise affecting the characteristics of meat food and meat products, excluding labeling and packaging materials as covered in part 317 of the subchapter.

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

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

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

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

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

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

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

Person. Any individual, firm, or corporation.

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

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

Process authority. A person or organization with expert knowledge in meat production process control and rel-

evant regulations. This definition does not apply to subpart G of part 318.

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

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

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

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

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

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

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

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

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

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

under the regulations in this subchapter.

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

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

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

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

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

[35 FR 15554, Oct. 3, 1970]

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

PART 302—APPLICATION OF INSPECTION AND OTHER REQUIREMENTS

Sec.

302.1 Establishments requiring inspection.

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

302.3 Livestock and products entering official establishments.

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

§ 302.1 Establishments requiring inspection.

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

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

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

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

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

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

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

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

§ 302.3 Livestock and products entering official establishments.

All livestock and all products entering any official establishment and all products prepared, in whole or in part, therein, shall be inspected, handled,