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Title 21 - FOOD AND DRUGS

CHAPTER 12 - MEAT INSPECTION

SUBCHAPTER I - INSPECTION REQUIREMENTS; ADULTERATION AND MISBRANDING

Sec. 601 - Definitions

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### §601. Definitions

As used in this chapter, except as otherwise specified, the following terms shall have the meanings stated below:

- (a) The term "Secretary" means the Secretary of Agriculture of the United States or his delegate.
- (b) The term "firm" means any partnership, association, or other unincorporated business organization.
- (c) The term "meat broker" means any person, firm, or corporation engaged in the business of buying or selling carcasses, parts of carcasses, meat, or meat food products of cattle, sheep, swine, goats, horses, mules, or other equines on commission, or otherwise negotiating purchases or sales of such articles other than for his own account or as an employee of another person, firm, or corporation.
- (d) The term "renderer" means any person, firm, or corporation engaged in the business of rendering carcasses or parts or products of the carcasses, of cattle, sheep, swine, goats, horses, mules, or other equines, except rendering conducted under inspection or exemption under this subchapter.
- (e) The term "animal food manufacturer" means any person, firm, or corporation engaged in the business of manufacturing or processing animal food derived wholly or in part from carcasses, or parts or products of the carcasses, of cattle, sheep, swine, goats, horses, mules, or other equines.
- (f) The term "State" means any State of the United States and the Commonwealth of Puerto Rico.
- (g) The term "Territory" means Guam, the Virgin Islands of the United States, American Samoa, and any other territory or possession of the United States, excluding the Canal Zone.
- (h) The term "commerce" means commerce between any State, any Territory, or the District of Columbia, and any place outside thereof; or within any Territory not organized with a legislative body, or the District of Columbia.
- (i) The term "United States" means the States, the District of Columbia, and the Territories of the United States.
- (j) The term "meat food product" means any product 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, excepting products which 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 which are exempted from definition as a meat food product by the Secretary under such conditions as he may prescribe to assure that the meat or other portions of such carcasses contained in such product are not adulterated and that such products 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.
- (k) The term "capable of use as human food" shall apply to any carcass, or part or product of a carcass, of any animal, unless it is denatured or otherwise identified as required by regulations prescribed by the Secretary to deter its use as human food, or it is naturally inedible by humans.
- (l) The term "prepared" means slaughtered, canned, salted, rendered, boned, cut up, or otherwise manufactured or processed.

(m) The term "adulterated" shall apply 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 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)(A) 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 (i) a pesticide chemical in or on a raw agricultural commodity; (ii) a food additive; or (iii) a color additive) which may, in the judgment of the Secretary, make such article unfit for human food;

(B) 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 346a of this title,

(C) if it bears or contains any food additive which is unsafe within the meaning of section 348 of this title,

(D) if it bears or contains any color additive which is unsafe within the meaning of section 379e of this title: *Provided*, That an article which is not adulterated under clause (B), (C), or (D) shall nevertheless be deemed adulterated if use of the pesticide chemical, food additive, or color additive in or on such article is prohibited by regulations of the Secretary in establishments at which inspection is maintained under this subchapter;

(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 insanitary 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 348 of this title;

(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.

(n) The term "misbranded" shall apply 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 (A) the name and place of business of the manufacturer, packer, or distributor; and (B) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count: *Provided*, That under clause (B) of this subparagraph (5), reasonable variations may be permitted, and exemptions as to small packages may be established, by regulations prescribed by the Secretary;

(6) if any word, statement, or other information required by or under authority of this chapter 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 regulations of the Secretary under section 607 of this title unless (A) it conforms to such definition and standard, and (B) its label bears the name of the food specified in the definition and standard and, insofar as may be required by such regulations, the

common names of optional ingredients (other than spices, flavoring, and coloring) present in such food;

(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 regulations of the Secretary under section 607 of this title, 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 subparagraph (7), unless its label bears (A) the common or usual name of the food, if any there be, and (B) in case it is fabricated from two or more ingredients, the common or usual name of each such ingredient; except that spices, flavorings, and colorings may, when authorized by the Secretary, be designated as spices, flavorings, and colorings without naming each: *Provided*, That to the extent that compliance with the requirements of clause (B) of this subparagraph (9) is impracticable, or results in deception or unfair competition, exemptions shall be established by regulations promulgated by the Secretary;

(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 the Secretary, after consultation with the Secretary of Health and Human Services, determines to be, and by regulations prescribes as, necessary in order fully to inform purchasers as to its value for such uses;

(11) if it bears or contains any artificial flavoring, artificial coloring, or chemical preservative, unless it bears labeling stating that fact: *Provided*, That, to the extent that compliance with the requirements of this subparagraph (11) is impracticable, exemptions shall be established by regulations promulgated by the Secretary; or

(12) if it fails to bear, directly thereon or on its container, as the Secretary may by regulations prescribe, the inspection legend and, unrestricted by any of the foregoing, such other information as the Secretary 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.

(o) The term "label" means a display of written, printed, or graphic matter upon the immediate container (not including package liners) of any article.

(p) The term "labeling" means 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.

(q) The term "Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.]" means the Act so entitled, approved June 25, 1938 (52 Stat. 1040), and Acts amendatory thereof or supplementary thereto.

(r) The terms "pesticide chemical," "food additive," "color additive," and "raw agricultural commodity" shall have the same meanings for purposes of this chapter as under the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.].

(s) The term "official mark" means the official inspection legend or any other symbol prescribed by regulations of the Secretary to identify the status of any article or animal under this chapter.

(t) The term "official inspection legend" means any symbol prescribed by regulations of the Secretary showing that an article was inspected and passed in accordance with this chapter.

(u) The term "official certificate" means any certificate prescribed by regulations of the Secretary for issuance by an inspector or other person performing official functions under this chapter.

(v) The term "official device" means any device prescribed or authorized by the Secretary for use in applying any official mark.

(w) The term "amenable species" means—

- (1) those species subject to the provisions of this chapter on the day before November 10, 2005;
- (2) all fish of the order Siluriformes; and
- (3) any additional species of livestock that the Secretary considers appropriate.

(Mar. 4, 1907, ch. 2907, title I, §1, as added Pub. L. 90–201, §2, Dec. 15, 1967, 81 Stat. 584; amended Pub. L. 96–88, title V, §509(b), Oct. 17, 1979, 93 Stat. 695; Pub. L. 102–571, title I, §107(14), Oct. 29, 1992, 106 Stat. 4499; Pub. L. 109–97, title VII, §798[(a)](2), Nov. 10, 2005, 119

Stat. 2166; Pub. L. 110–234, title XI, §11016(b)(1)(A), May 22, 2008, 122 Stat. 1369; Pub. L. 110–246, §4(a), title XI, §11016(b)(1)(A), June 18, 2008, 122 Stat. 1664, 2130; Pub. L. 113–79, title XII, §12106(a)(1), Feb. 7, 2014, 128 Stat. 980.)

#### REFERENCES IN TEXT

The Federal Food, Drug, and Cosmetic Act, referred to in pars. (q) and (r), is act June 25, 1938, ch. 675, 52 Stat. 1040, as amended, which is classified generally to chapter 9 (§301 et seq.) of this title. For complete classification of this Act to the Code, see section 301 of this title and Tables.

#### CODIFICATION

Pub. L. 110–234 and Pub. L. 110–246 made identical amendments to this section. The amendments by Pub. L. 110–234 were repealed by section 4(a) of Pub. L. 110–246.

#### AMENDMENTS

**2014**—Subsec. (w)(2). Pub. L. 113–79 added par. (2) and struck out former par. (2) which read as follows: "catfish, as defined by the Secretary; and".

**2008**—Subsec. (w)(2), (3). Pub. L. 110–246, §11016(b)(1)(A), added par. (2) and redesignated former par. (2) as (3).

**2005**—Par. (w). Pub. L. 109–97 added par. (w).

**1992**—Par. (m)(2)(D). Pub. L. 102–571 substituted "379e" for "376".

#### CHANGE OF NAME

"Secretary of Health and Human Services" substituted for "Secretary of Health, Education, and Welfare" in par. (n)(10) pursuant to section 509(b) of Pub. L. 96–88, which is classified to section 3508(b) of Title 20, Education.

#### EFFECTIVE DATE OF 2014 AMENDMENT

Pub. L. 113–79, title XII, §12106(c), Feb. 7, 2014, 128 Stat. 982, provided that: "This section [amending this section, sections 606 and 625 of this title, and section 1622 of Title 7, Agriculture, and enacting and repealing provisions set out as notes under this section] and the amendments made by this section shall take effect as if enacted as part of section 11016(b) of the Food, Conservation, and Energy Act of 2008 (Public Law 110–246; 122 Stat. 2130) [amending this section, enacting sections 606 and 625 of this title, repealing former section 606 of this title, and enacting provisions set out as notes below]."

#### EFFECTIVE DATE OF 2008 AMENDMENT

Amendment of this section and repeal of Pub. L. 110–234 by Pub. L. 110–246 effective May 22, 2008, the date of enactment of Pub. L. 110–234, except as otherwise provided, see section 4 of Pub. L. 110–246, set out as an Effective Date note under section 8701 of Title 7, Agriculture.

Pub. L. 110–234, title XI, §11016(b)(2)(A), May 22, 2008, 122 Stat. 1369, and Pub. L. 110–246, §4(a), title XI, §11016(b)(2)(A), June 18, 2008, 122 Stat. 1664, 2131, provided that the amendments made by section 11016(b)(1) of Pub. L. 110–234 and section 11016(b)(1) of Pub. L. 110–246 (enacting sections 606 and 625 of this title, amending this section, and repealing former section 606 of this title) would not apply until the date on which the Secretary of Agriculture issued final regulations to carry out such amendments, prior to repeal by Pub. L. 113–79, title XII, §12106(b)(4), Feb. 7, 2014, 128 Stat. 981, effective as if enacted as part of section 11016(b) of the Food, Conservation, and Energy Act of 2008 (Public Law 110–246; 122 Stat. 2130), see Effective Date of 2014 Amendment note above.

[Pub. L. 110–234 and Pub. L. 110–246 enacted identical provisions. Pub. L. 110–234 was repealed by section 4(a) of Pub. L. 110–246, set out as a note under section 8701 of Title 7, Agriculture.]

#### EFFECTIVE DATE OF 2005 AMENDMENT

Pub. L. 109–97, title VII, §798(b), Nov. 10, 2005, 119 Stat. 2166, provided that: "The amendments made by subsection (a) [amending this section and sections 603 to 605, 608, 609, 615, and 617 to 621 of this title] shall take effect on the day after the effective date of section 794 of the Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Act, 2006 [section 794 of Pub. L. 109–97, 119 Stat. 2164, effective 120 days after Nov. 10, 2005]."

#### EFFECTIVE DATE

Pub. L. 90–201, §20, Dec. 15, 1967, 81 Stat. 601, provided that: "This Act [see Short Title note below] shall become effective upon enactment [Dec. 15, 1967] except as provided in paragraphs (a) through (d):

"(a) The provisions of paragraph (b)(1) and (c) of section 10 and the provisions of section 20 of the Federal Meat Inspection Act, as amended by sections 7 and 10 of this Act [sections 610 and 620 of this title], and the provisions of section 18 of this Act repealing paragraph (b) of section 306 of the Tariff Act of 1930 [section 1306(b) of Title 19, Customs Duties], shall become effective upon the expiration of sixty days after enactment [Dec. 15, 1967], hereof.

"(b) The provisions of title I of the Federal Meat Inspection Act, as amended by this Act [this subchapter], shall become effective with respect to equines (other than horses) and their carcasses and parts thereof, meat, and meat food products thereof upon the expiration of sixty days after enactment [Dec. 15, 1967] hereof.

"(c) Section 11 of this Act, amending section 23, of the Federal Meat Inspection Act [section 623 of this title], shall become effective upon the expiration of sixty days after enactment hereof [Dec. 15, 1967].

"(d) Section 204 of the Federal Meat Inspection Act, as added by section 14 of this Act [section 644 of this title], shall become effective upon the expiration of sixty days after enactment hereof [Dec. 15, 1967]."

#### SHORT TITLE OF 1986 AMENDMENT

Pub. L. 99–641, title IV, §401, Nov. 10, 1986, 100 Stat. 3567, provided that: "This title [amending sections 606, 609, 621, 671, and 676 of this title and enacting provisions set out as notes under sections 606, 609, 621, 671, and 676 of this title] may be cited as the 'Processed Products Inspection Improvement Act of 1986'."

#### SHORT TITLE OF 1978 AMENDMENT

Pub. L. 95–445, §1, Oct. 10, 1978, 92 Stat. 1069, provided: "That this Act [amending sections 603, 610, and 620 of this title and sections 1902 and 1904 of Title 7, Agriculture, repealing sections 1903 and 1905 of Title 7, and enacting provisions set out as notes under this section and section 603 of this title] may be cited as the 'Humane Methods of Slaughter Act of 1978'."

#### SHORT TITLE

Pub. L. 90–201, §1, Dec. 15, 1967, 81 Stat. 584, provided in part: "That this Act [enacting this section and sections 602, 624, 641 to 645, 661, 671 to 680, and 691 of this title, amending sections 603 to 623 of this title, repealing section 96 of this title and section 1306(b) of Title 19, Customs Duties, and enacting provisions set out as notes under this section] may be cited as the 'Wholesome Meat Act'."

Pub. L. 90–201, §1, Dec. 15, 1967, 81 Stat. 584, provided in part that the provisions of act Mar. 4, 1907, as amended, classified to subchapters I to IV–A of this chapter, are designated as the "Federal Meat Inspection Act".

#### REGULATIONS

Pub. L. 113–79, title XII, §12106(b)(1)–(3), Feb. 7, 2014, 128 Stat. 981, provided that:

"(1) IN GENERAL.—The Secretary shall—

"(A) not later than 60 days after the date of enactment of this Act [Feb. 7, 2014], issue final regulations to carry out the amendments made by section 11016(b)(1) of the Food, Conservation, and Energy Act of 2008 (Public Law 110–246; 122 Stat. 2130) [amending this section, enacting sections 606 and 625 of this title, and repealing former section 606 of this title], as further clarified by the amendments made by this section [amending this section, sections 606 and 625 of this title, and section 1622 of Title 7, Agriculture, and enacting and repealing provisions set out as notes under this section]; and

"(B) not later than 1 year after the date of enactment of this Act, implement the amendments described in subparagraph (A).

"(2) NOTIFICATION.—Beginning 30 days after the date of enactment of this Act and every 30 days thereafter until the date of full implementation of the amendments described in paragraph (1)(A), the Secretary shall submit a report describing the status of implementation to—

"(A) the Committee on Agriculture of the House of Representatives;

"(B) the Committee on Agriculture, Nutrition and Forestry of the Senate;

"(C) the Subcommittee on Agriculture, Rural Development, Food and Drug Administration, and Related Agencies of the Committee on Appropriations of the House of Representatives; and

"(D) the Subcommittee on Agriculture, Rural Development, and Related Agencies of the Committee on Appropriations of the Senate.

"(3) PROCEDURE.—Section 1601(c)(2) [7 U.S.C. 9091(c)(2)] applies to the promulgation of the regulations and administration of this section and the amendments made by this section."

Pub. L. 110–246, title XI, §11016(b)(2), as added by Pub. L. 113–79, title XII, §12106(b)(4), Feb. 7,

2014, 128 Stat. 981, provided that:

"(A) REGULATIONS.—Not later than 60 days after the date of enactment of the Agricultural Act of 2014 [Feb. 7, 2014], the Secretary [of Agriculture], in consultation with the Commissioner of Food and Drugs, shall issue final regulations to carry out the amendments made by paragraph (1) [amending this section, enacting sections 606 and 625 of this title, and repealing former section 606 of this title] and section 12106 of that Act [amending this section, sections 606 and 625 of this title, and section 1622 of Title 7, Agriculture, and enacting and repealing provisions set out as notes under this section] in a manner that ensures that there is no duplication in inspection activities.

"(B) INTERAGENCY COORDINATION.—Not later than 60 days after the date of enactment of the Agricultural Act of 2014, the Secretary shall execute a memorandum of understanding with the Commissioner of Food and Drugs for the following purposes:

"(i) To improve interagency cooperation on food safety and fraud prevention, building upon any other prior agreements, including provisions, performance metrics, and timelines as appropriate.

"(ii) To maximize the effectiveness of limited personnel and resources by ensuring that—

"(I) inspections conducted by the Department satisfy requirements under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.);

"(II) inspections of shipments and processing facilities for fish of the order Siluriformes by the Department and the Food and Drug Administration are not duplicative; and

"(III) any information resulting from examination, testing, and inspections conducted is considered in making risk-based determinations, including the establishment of inspection priorities."

Pub. L. 110–234, title XI, §11016(b)(2)(B), May 22, 2008, 122 Stat. 1370, and Pub. L. 110–246, §4(a), title XI, §11016(b)(2)(B), June 18, 2008, 122 Stat. 1664, 2131, required the Secretary of Agriculture, in consultation with the Commissioner of Food and Drugs, to issue final regulations to carry out the amendments made by section 11016(b)(1) of Pub. L. 110–234 and section 11016(b)(1) of Pub. L. 110–246 (enacting sections 606 and 625 of this title, amending this section, and repealing former section 606 of this title) not later than 18 months after June 18, 2008, prior to repeal by Pub. L. 113–79, title XII, §12106(b) (4), Feb. 7, 2014, 128 Stat. 981, effective as if enacted as part of section 11016(b) of the Food, Conservation, and Energy Act of 2008 (Public Law 110–246; 122 Stat. 2130), see Effective Date of 2014 Amendment note above.

[Pub. L. 110–234 and Pub. L. 110–246 enacted identical provisions. Pub. L. 110–234 was repealed by section 4(a) of Pub. L. 110–246, set out as a note under section 8701 of Title 7, Agriculture.]

#### SEPARABILITY

Pub. L. 90–201, §19, Dec. 15, 1967, 81 Stat. 601, provided that: "If any provision of this Act or of the amendments made hereby [see Short Title note above] or the application thereof to any person or circumstances is held invalid, the validity of the remainder of the Act and the remaining amendments [see Short Title note above] and of the application of such provision to other persons and circumstances shall not be affected thereby."