

## SUBCHAPTER F—MANDATORY INSPECTION OF FISH OF THE ORDER SILURIFORMES AND PRODUCTS OF SUCH FISH

### PART 530—GENERAL REQUIREMENTS; DEFINITIONS

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AUTHORITY: 7 U.S.C. 138f; 7 U.S.C. 450; 21 U.S.C. 601–602, 606–622, 624–695; 7 CFR 2.7, 2.18, 2.53.

SOURCE: 80 FR 75616, Dec. 2, 2015, unless otherwise noted.

#### § 530.1 General.

(a) The regulations in this subchapter provide for the inspection of Siluriformes fish and fish products. The inspection and regulations are intended to prevent the sale, transportation, offer for sale or transportation, or receipt for transportation, in commerce of any fish or fish product that is capable of use as human food and is adulterated or misbranded at the time of the sale, transportation, offer for sale or transportation, or receipt for transportation.

(b) Fish as defined in this subchapter are amenable to the Act, including, as the Administrator may determine, to provisions of the Act in which other amenable species are named, except where the Act specifically excludes the provisions from applicability to fish.

#### § 530.2 FSIS organization for inspection of fish and fish products.

The Food Safety and Inspection Service, U.S. Department of Agriculture, administers an inspection program for fish and fish products. The organization of FSIS and the principal offices of FSIS and their functions are described, and organizational terms defined, in 9 CFR part 300, subchapter A of this chapter. Section 300.3 lists the FSIS district offices and the geographic areas of the districts.

#### § 530.3 Access to establishments.

The provisions of 9 CFR 300.6 apply to fish processing establishments and related industries as they do to other establishments subject to the FMIA.

### PART 531—DEFINITIONS

AUTHORITY: 7 U.S.C. 138f; 7 U.S.C. 450; 21 U.S.C. 601–602, 606–622, 624–695; 7 CFR 2.7, 2.18, 2.53.

#### § 531.1 Definitions.

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

*Act.* The Federal Meat Inspection Act, as amended, (34 Stat. 1260, as amended, 81 Stat. 584, 84 Stat. 438, 92 Stat. 1069, 106 Stat. 4499, 119 Stat. 2166, 122 Stat. 1369, 122 Stat. 2130, 21 U.S.C., sec. 601 *et seq.*)

*Adulterated.* This term applies to any carcass, part thereof, fish or fish 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 (2)(ii), (iii), or (iv) of this definition shall nevertheless be deemed adulterated if use of the pesticide chemical food additive, or color additive in or on such article is prohibited by 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 that 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 therefore; 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.

*Amenable species.* A species that is, and whose products are, subject to the Act and regulations promulgated under the Act, except as the Act may provide.

*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 amenable species, except that the term animal food as used herein does not include:

(1) Processed dry animal food or

(2) Feeds for amenable species manufactured from processed by products of amenable species.

*Applicant.* Any person who requests inspection service, exemption, or other authorization under the regulations.

*Biological residue.* Any substance, including metabolites, remaining in fish at time of slaughter or in any of their tissues after slaughter as the result of treatment or exposure of the fish to a pesticide, organic or inorganic compound, hormone, hormone like substance, anthelmintic, 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 fish unless it is denatured or otherwise identified as required by § 540.3 of this subchapter to deter its use as a human food, or it is naturally inedible by humans; e.g., barbels or fins in their natural state.

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

*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.

*Consumer package.* Any container in which a fish product is enclosed for the purpose of display and sale to household consumers.

*Container.* Any box, can, tin, cloth, plastic, or any other receptacle, wrapper, or cover.

*Dead fish.* The body of a fish that has died otherwise than by slaughter.

*Dying or diseased fish.* Fish affected by any of the conditions for which the fish are required to be condemned under part 539 or other regulations in this subchapter.

*Edible.* Intended for use as human food.

*Farm-raised.* Grown under controlled conditions, within an enclosed space, as on a farm.

*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.

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*Fish.* (1) For the purposes of this subchapter, any fish of the order Siluriformes, whether live or dead.

(2) The skeletal muscle tissue of fish. As applied to products of fish of the order Siluriformes, this term has a meaning comparable to that of "meat" in the meat inspection regulations (9 CFR 301.2).

*Fish byproduct.* Any fish part capable of use as human food, other than the skeletal muscle tissue, that has been derived from one or more fish.

*Fish food product.* Any article capable of use as human food that is made wholly or in part from any fish or part thereof; or any product that is made wholly or in part from any fish or part thereof, excepting those exempted from definition as a fish product by the Administrator in specific cases or by a regulation 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;

*Fish product.* Any fish or fish part; or any product that is made wholly or in part from any fish or fish part, except for those exempted from definition as a fish product by the Administrator in a regulation in this subchapter. Except where the context requires otherwise (e.g., in part 540 of this subchapter), this term is limited to articles capable of use as human food.

*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.

*"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.

*Misbranded.* This term applies to any carcass, part thereof, fish or fish 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 (7)(ii) of this definition 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 man-

ner of handling required to maintain the article in a wholesome condition.

*Nonfood compound.* Any substance proposed for use in official establishments, the intended use of which will not result, directly or indirectly, in the substance becoming a component or otherwise affecting the characteristics of fish food and fish products excluding labeling and packaging materials as covered in part 541 of this 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, fish product 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 this section, where inspections are authorized to be conducted as prescribed in part 557 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, fish, or fish product under the Act.

*Packaging material.* Any cloth, paper, plastic, metal, or other material used to form a container, wrapper, label, or cover for fish 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, 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 fish production process control and relevant regulations. This definition does not apply to §548.6 of this subchapter or to subpart G of part 318 of this chapter.

*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 §548.6 of this subchapter or to subpart G of part 318 of this chapter.

*Producer.* Any person engaged in the business of growing farm-raised fish.

*Product.* Any carcass, fish, fish product, or fish food product, capable of use as human food.

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

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

*Slaughter.* With respect to fish, intentional killing under controlled conditions.

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

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

*U.S. Condemned.* This term means that the fish, part, or product of fish so identified was inspected and found to be adulterated and is condemned.

*U.S. Detained.* This term applies to fish, fish products, and other articles which are held in official custody in accordance with section 402 of the Act (21 U.S.C. 672), pending disposal as provided in the same section 402.

*U.S. Retained.* This term means that the fish, part, or product of fish so identified is held for further examination by an inspector at an official establishment to determine its disposal.

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

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## PART 532—REQUIREMENTS FOR INSPECTION

Sec.

532.1 Establishments requiring inspection.

532.2 Application for inspection; information to be furnished; grant or refusal of inspection; conditions for receiving inspection; official numbers and inspection; assignment and authorities of Program employees.

532.3 Exemption of retail operations.

532.4 Inspection at official establishments; relation to other authorities.

532.5 Exemption from definition of fish product of certain human food products containing fish.

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### §532.1 Establishments requiring inspection; other inspection.

(a) No establishment may process or prepare fish, fish parts, or fish products capable of use as human food, or sell, transport, or offer for sale or transportation in commerce any of these articles without inspection under these regulations, except as expressly exempted in §532.3.

(b) Inspection under the regulations is required at:

(1) Every establishment, except as provided in the regulation on exemption of retail operations (§532.3), in which any fish or fish products are wholly or in part, processed for transportation or sale in commerce, as articles intended for use as human food.

(2) Every establishment, except as provided in the regulation on exemption of retail operations (§532.3), within any State or organized territory which is designated pursuant to section 301 of the Act (21 U.S.C. 661), at which any fish or fish products are processed for use as human food solely for distribution within that State or territory.

(3) Except as provided in the regulation on exemption of retail operations (§532.3), every establishment designated by the administrator under