

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.

[80 FR 75616, Dec. 2, 2015]

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.

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

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.

§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

section 301 of the Act (21 U.S.C. 661) as one producing adulterated fish products which would clearly endanger the public health.

(4) *Coverage of fish and fish products processed in official establishments.* All fish and fish products prepared in an official establishment must be inspected, handled, processed, marked, and labeled as required by the regulations.

(5) *Other inspection.* Periodic inspections may be made of:

(i) The records of all persons engaged in the business of hatching, feeding, growing, or transporting fish between premises where fish are bred, hatcheries, and premises where fish are grown, and from these premises to processing establishments.

(ii) Exempted retail establishments to determine that those establishments are operating in accordance with these regulations.

§ 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.

(a) Application for inspection is as required by 9 CFR 304.1.

(b) Information to be furnished is as required by 9 CFR 304.2(a), (b), and (c)(1). Conditions for receiving inspection, including having written Sanitation SOPs, HACCP plans and written recall procedures, are as required by 9 CFR 304.3.

(c) *Official numbers; inauguration of inspection; withdrawal of inspection; reports of violation.* The requirements for assignment of official numbers, inauguration of inspection, withdrawal of inspection, and reports of violations at fish processing establishments are as required by part 305 of this chapter for meat establishments.

(d) *Assignment and authorities of program employees.* The requirements concerning the assignment and authorities of Program employees at fish processing establishments are as required by parts 306 and 307 of this chapter with respect to Program employees at meat establishments.

§ 532.3 Exemption of retail operations.

(a) The exemption in 9 CFR 303.1(d) for operations of types traditionally and usually conducted at retail stores and restaurants applies with respect to fish products as it does with respect to products of other amenable species under the FMIA.

(b) The exemption also applies to the slaughtering of fish conducted at and by the operator of a retail store or restaurant, with respect to live fish purchased by a consumer at the retail store or restaurant, in accordance with the consumer's instructions.

(c) A retail quantity of fish or fish products sold to a household consumer is a normal retail quantity if it does not exceed 75 pounds and the quantity of fish or fish product sold by a retail supplier to a non-household consumer is a normal retail quantity if it does not exceed 150 pounds in the aggregate.

§ 532.4 Inspection at official establishments; relation to other authorities.

(a) Requirements within the scope of the Act with respect to premises, facilities, and operations of any official establishment that are in addition to or different than those made under this subchapter may not be imposed by any State or local jurisdiction except that the State or local jurisdiction may impose recordkeeping and other requirements within the scope of § 550.1 of this subchapter, if consistent with those requirements, with respect to the establishment.

(b) Labeling, packaging, or ingredient requirements in addition to or different than those made under this subchapter, the Federal Food, Drug, and Cosmetic Act and Fair Packaging and Labeling Act may not be imposed by any State or local jurisdiction with respect to any fish or fish products processed at any official establishment in accordance with the requirements under this subchapter and those Acts.

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

The following articles contain fish ingredients only in a relatively small proportion or historically have not been considered by consumers to be

products of the fish food products industry. Therefore, the articles are exempted from the definition of “fish product” and the requirements of the Act and the regulations that apply to fish products, if they comply with the conditions specified in this section.

(a) Any human food product if:

(1) It contains less than 3 percent raw or 2 percent cooked fish;

(2) The fish ingredients used in the product were prepared under Federal inspection or were inspected under a foreign inspection system approved under §557.2 of this subchapter and imported in compliance with the Act and the regulations;

(3) The immediate container of the product bears a label which shows the name of the product in accordance with this section; and

(4) The product is not represented as a fish product. The percentage of cooked fish ingredients must be computed on the basis of the moist, deboned, cooked fish in the ready-to-serve product when prepared according to the serving directions on the consumer package.

(b) A product exempted under this section will be deemed to be represented as a fish product if the term “fish” or a term representing a fish species that is covered by the definition of “fish” in part 531 of this subchapter is used in the product name of the product without appropriate qualification.

(c) A product exempted under this section is subject to the requirements of the Federal Food, Drug, and Cosmetic Act.

PART 533—SEPARATION OF ESTABLISHMENT; FACILITIES FOR INSPECTION; FACILITIES FOR PROGRAM EMPLOYEES; OTHER REQUIRED FACILITIES

Sec.

533.1 Separation of establishments.

533.2 [Reserved]

533.3 Facilities for Program employees.

533.4 Other facilities and conditions to be provided.

533.5 Schedule of operations.

533.6 Overtime and holiday inspection service.

533.7 Basis of billing for overtime and holiday services.

AUTHORITY: 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.

§533.1 Separation of establishments.

Each official establishment shall be separate and distinct from any unofficial establishment and from any other official establishment, except an establishment preparing products under the FMIA, the PPIA, or the EPIA, or under State fish inspection requirements and authorities that are deemed to be at least equal to those provided under the FMIA. Further, doorways, or other openings, may be permitted between establishments at the discretion of the Administrator and under such conditions as he may prescribe. An official establishment that is not separate and distinct from another official or unofficial establishment must ensure that no sanitary hazards are created by the lack of separation.

§533.2 [Reserved]

§533.3 Facilities for Program employees.

Office space, including necessary furnishings, light, heat, and janitor service, must 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 District Manager or the frontline supervisor and must 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 facilities are deemed necessary by the frontline supervisor. At the discretion of the Administrator, small establishments 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 must be provided by each establishment.