

**§ 533.4 Other facilities and conditions to be provided.**

When required by the District Manager or the frontline supervisor, each official establishment must provide 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:

(a) Sufficient light to be adequate for the proper conduct of inspection;

(b) 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;

(c) Receptacles for holding and handling diseased carcasses and parts, so constructed as to be readily cleaned and 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 frontline supervisor, to be equipped in a way that allows the receptacles to be locked or sealed;

(d) Adequate arrangements, including liquid soap and cleansers, for cleansing and disinfecting hands, for sterilizing all implements used in handling diseased carcasses, for cleaning and sanitizing floors, and such other articles and places as may be contaminated by diseased carcasses or otherwise;

(e) Adequate facilities, including denaturing materials, for the proper disposal of condemned articles in accordance with the regulations in this subchapter;

(f) Docks and receiving rooms, to be designated by the operator of the official establishment, with the frontline supervisor, for the receipt and inspection of fish, fish products, or other products.

(g) Suitable lockers in which brands bearing the official inspection legend and other official devices (excluding labels) can be stored. Official certificates shall be kept when not in use in suitable file cabinets. All such lockers and file cabinets 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.

**§ 533.5 Schedule of operations.**

The requirements governing the schedule of operations for fish processing establishments are as required by 9 CFR 307.4 for meat establishments.

**§ 533.6 Overtime and holiday inspection service.**

The requirements governing overtime and holiday inspection service in 9 CFR 307.5 apply to fish processing establishments.

**§ 533.7 Basis of billing for overtime and holiday services.**

The requirements for billing and overtime and holiday inspection services are as required by 9 CFR 307.6.

**PART 534—PRE-HARVEST STANDARDS AND TRANSPORTATION TO PROCESSING ESTABLISHMENT**

Sec.

534.1 General.

534.2 Water quality for food fish.

534.3 Standards for use of drugs in the raising of fish.

534.4 Transportation to processing plant.

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.

**§ 534.1 General.**

Fish that are harvested for use as human food must have grown and lived under conditions that will not render the fish or their products unsound, unwholesome, unhealthful, or otherwise unfit for human food.

**§ 534.2 Water quality for food fish.**

Farmers of fish should monitor the water in which the fish are raised for the presence of suspended solids, organic matter, nutrients, heavy metals, pesticides, fertilizers, and industrial chemicals that may contaminate fish. FSIS will collect samples of feed, fish, and water from producers, at intervals to be determined by the Administrator, for the purpose of verifying that fish are being raised under conditions that will yield safe, wholesome products.

**§ 534.3**

**9 CFR Ch. III (1–1–23 Edition)**

**§ 534.3 Standards for use of drugs in the raising of fish.**

New animal drugs that are the subject of an approved new animal drug application (NADA) or abbreviated new animal drug application (ANADA) under section 512 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 360b), or a conditional approval under section 571 of the Act (21 U.S.C. 360ccc), or an investigational exemption under section 512(j) of the Act (21 U.S.C. 360b(j)) may be used in the raising of fish. New animal drugs approved under section 512 of the Act may be used in an extra-label manner if such use complies with section 512(a)(4) of the Act and FDA regulations found at 21 CFR part 530.

**§ 534.4 Transportation to processing plant.**

A vehicle used to transport fish from a producer's premises to a processing establishment must be equipped with vats or other containers for holding the fish. The vats or other containers must be maintained in a sanitary condition. Sufficient water and sufficient oxygen must be provided to the vats that hold the fish to ensure that fish delivered to the processing establishment will not be adulterated. Any fish that are dead, dying, diseased, or contaminated with substances that may adulterate fish products are subject to condemnation at the official fish processing establishments.

**PART 537—SANITATION REQUIREMENTS AND HAZARD ANALYSIS AND CRITICAL CONTROL POINTS SYSTEMS; NOTIFICATION REGARDING ADULTERATED OR MISBRANDED PRODUCTS**

- Sec.
- 537.1 Basic requirements.
- 537.2 Hazard analysis and HACCP plan.
- 537.3 Notification.

AUTHORITY: 21 U.S.C. 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.

**§ 537.1 Basic requirements.**

(a)(1) Any official establishment that prepares or processes fish or fish prod-

ucts for human food must comply with the requirements contained in 9 CFR parts 416, Sanitation and 417, Hazard Analysis and Critical Control Point (HACCP) Systems, except as otherwise provided in this subchapter.

(2) For the purposes of 9 CFR part 416, Sanitation; 9 CFR part 417, Hazard Analysis and Critical Control Point (HACCP) Systems; and 9 CFR part 500, Rules of Practice, an “official establishment” or “establishment” includes a plant that prepares or processes fish or fish products.

**§ 537.2 Hazard analysis and HACCP plan.**

(a) A fish establishment's hazard analysis shall take into account the food safety hazards that can occur before, during, and after harvest.

(b) The failure of an establishment to develop and implement a hazard analysis and a HACCP plan that comply with this part or to operate in accordance with the requirements of 9 CFR Chapter III, Subchapter E, will render the products produced under these conditions adulterated.

**§ 537.3 Notification.**

Each official establishment must promptly notify the local FSIS District Office within 24 hours of learning or determining that an adulterated or misbranded fish product received by or originating from the official establishment has entered commerce, in accordance with the requirements of 9 CFR part 418.

**PART 539—MANDATORY DISPOSITIONS; PERFORMANCE STANDARDS RESPECTING PHYSICAL, CHEMICAL, OR BIOLOGICAL CONTAMINANTS**

- Sec.
- 539.1 Disposal of diseased or otherwise adulterated fish carcasses and parts or fish products.
- 539.2 Physical, chemical, or biological contaminants.

AUTHORITY: 21 U.S.C. 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.