

### § 534.3

#### § 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-

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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.

**§ 539.1 Disposal of diseased or otherwise adulterated fish carcasses and parts or fish products.**

(a)(1) Carcasses or parts of fish affected by abscesses or lesions, zoonotic and non-zoonotic parasites such as cestodes, or such parasites as digenean trematodes, metacercaria (*Bolbophorus* spp.), yellow grubs (*Clinostomum* spp.), or white grubs (*Hysteromorpha* spp.) are subject to condemnation unless properly disposed of by the establishment to prevent their use as human food.

(2) Fish affected by Heterophyid intestinal flukes or *Dictophymatidae* nematodes are subject to condemnation unless properly disposed of by the establishment.

(b) Fish affected by diseases, including columnaris (infection by *Flavobacterium columnare*/*Flexibacter columnaris*) and enteric septicemia of fish (ESC), are subject to condemnation unless properly disposed of by the establishment to prevent their use as human food.

(c) Fish carcasses or parts or fish products that are found to be in a state of spoilage or decomposition are subject to condemnation unless properly disposed of by the establishment to prevent their use as human food.

(d) Fish with unusual gross deformities caused by disease or chemical contamination may not be used for human food.

**§ 539.2 Physical, chemical, or biological contaminants.**

(a) Fish and fish products that are contaminated with physical matter are subject to official retention and condemnation.

(b) Antibiotic or other drug residues in fish tissues must be within applicable tolerances in 21 CFR part 556 or within an applicable import tolerance established under 21 U.S.C. 360b(a)(6).

(c) Pesticide residues in fish tissues must be within applicable tolerances in 40 CFR part 180.

(d) Fish or fish products containing violative concentrations of drugs or other chemicals are subject to condemnation.

**PART 540—HANDLING AND DISPOSAL OF CONDEMNED AND OTHER INEDIBLE MATERIALS**

Sec.

540.1 Dead fish.

540.2 Specimens for educational, research, and other nonfood purposes; permits.

540.3 Handling and disposal of condemned or other inedible materials.

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.

**§ 540.1 Dead fish.**

(a) With the exception of dead fish that have died en route to an official establishment that have been received with live fish at the official establishment, and that are subject to sorting and disposal at the official establishment, no fish or part of the carcass of fish that died otherwise than by slaughter may be brought onto the premises of an official establishment without advance permission from the FSIS frontline supervisor.

(b) The official establishment shall maintain physical separation between slaughtered fish and the edible parts or products of slaughtered fish and any fish or parts of fish that have died otherwise than by slaughter. Fish or any parts of fish that have died otherwise than by slaughter shall be excluded from any room or compartment in which edible product is prepared, handled, or stored.

**§ 540.2 Specimens for educational, research, and other nonfood purposes; permits.**

The requirements of 9 CFR 314.9 apply to the handling and release of specimens of condemned or other inedible fish materials.

**§ 540.3 Handling and disposal of condemned or other inedible materials.**

Condemned or other inedible fish and fish parts shall be separated from edible fish. If not disposed of on the premises of the establishment, the condemned and inedible fish parts shall be conveyed from the official establishment for disposition at a rendering plant, an animal feed manufacturing