

**DEPARTMENT OF AGRICULTURE****Food Safety and Inspection Service**

**9 CFR Parts 300, 441, 530–534, 537, 539–554, 544, 548, 550, 552, 555, 557, and 559–561**

[Docket No. FSIS–2008–0031]

RIN 0583–AD36

**Mandatory Inspection of Catfish and Catfish Products**

**AGENCY:** Food Safety and Inspection Service, USDA.

**ACTION:** Proposed rule.

**SUMMARY:** The Food Safety and Inspection Service (FSIS) is proposing regulations requiring continuous inspection of catfish and catfish products. FSIS is proposing these regulations to implement provisions of the Food, Conservation, and Energy Act (Farm Bill) of 2008. The proposed regulations are intended to ensure that catfish products distributed in commerce are wholesome, not adulterated, and properly marked, labeled, and packaged.

**DATES:** Comments must be received on or before June 24, 2011.

**ADDRESSES:** FSIS invites interested persons to submit comments on this proposed rule. Comments may be submitted by either of the following methods:

- *Federal eRulemaking Portal:* This Web site provides the ability to type short comments directly into the comment field on this Web page or attach a file for lengthier comments. Go to <http://www.regulations.gov>. Follow the online instructions at that Web site for submitting comments.

- *Mail, including floppy disks or CD-ROMs, and hand- or courier-delivered items:* Send to Docket Clerk, U.S. Department of Agriculture (USDA), FSIS, Room 2–2127 George Washington Carver Center, 5601 Sunnyside Avenue, Beltsville, MD 20705.

*Instructions:* All items submitted by mail or electronic mail must include the Agency name and docket number FSIS–2008–0031. Comments received in response to this docket will be made available for public inspection and posted without change, including any personal information, to <http://www.regulations.gov>.

*Docket:* For access to background documents or comments received, go to the FSIS Docket Room at the address listed above between 8:30 a.m. and 4:30 p.m., Monday through Friday.

**FOR FURTHER INFORMATION CONTACT:** Dr. Daniel Engeljohn, Assistant

Administrator, Office of Policy and Program Development, Food Safety and Inspection Service, U.S. Department of Agriculture, Room 350–E Whitten Building, 1400 Independence Avenue, SW., Washington, DC 20250–3700; (202) 205–0495.

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**Background****I. Farm Bill Mandate for Catfish Inspection**

The Food, Conservation, and Energy Act of 2008 (Pub. L. 110–246, § 10016(b)), known as the 2008 Farm Bill, amended the Federal Meat Inspection Act (FMIA) to provide that “catfish, as defined by the Secretary,” is an amenable species (21 U.S.C. 601 (w)(2)). Catfish and catfish products are therefore subject to continuous inspection under the FMIA, which FSIS administers. The definition of “catfish” determines the scope of the FSIS inspection program. FSIS considered two possible definitions: Fish belonging to the family Ictaluridae and, a broader definition, all fish of the order Siluriformes. If catfish are defined as all fish of the order Siluriformes, FSIS will inspect domestically produced and imported Siluriformes, including basa, swai, and others. If the term “catfish” is defined as fish of the family Ictaluridae, FSIS will inspect all domestically and foreign produced Ictaluridae, which would account for virtually all of domestically produced Siluriformes and approximately 20–25% of foreign

produced Siluriformes. Such a rule would cover approximately 70% of Siluriformes consumed in the United States in recent years. This proposed rule is silent on the scope of the term “catfish”. USDA is asking for public comments on the scope of the definition and will fully define and describe the term in the final rule. For purposes of convenience, this proposed rule uses the term “catfish” to refer to all fish classified within the order of Siluriformes. The use of this term is not with prejudice to what fish FSIS will ultimately determine to be “catfish” for purposes of the final rule.

**II. 2002 Farm Bill**

Before 2002, various species of fish in the order Siluriformes were commonly labeled and sold as “catfish” in the United States. However, the Farm Security and Rural Investment Act of 2002, known as the 2002 Farm Bill, amended the Federal Food, Drug, and Cosmetic Act (FD&C Act) by adding a section declaring, for the purposes of the FD&C Act and notwithstanding any other provision of law, that the term “catfish” is the common or usual name (or part thereof) only of fish classified in the family Ictaluridae and permitting the labeling or advertising only for fish classified in that family to include the term “catfish” (21 U.S.C. 321d(a), 343(t); Pub. L. 107–171, Title X, § 10806, 116 Stat. 526).<sup>1</sup> Accordingly, non-Ictaluridae Siluriformes, such as fish belonging to the family of Pangasiidae that are produced in Asia (e.g., basa, tra, and swai), could no longer be marketed as “catfish” in the United States. FDA advised importers to use alternative common or usual names for these non-Ictaluridae species that did not include the term “catfish,” and suggested ways of devising those names.<sup>2</sup>

<sup>1</sup> The FD&C Act, as amended, (21 U.S.C. 321 *et seq.*) prohibits the adulteration or misbranding of any food, drug, device, or cosmetic in interstate commerce (21 U.S.C. 331(b)). A food is considered misbranded if, among other circumstances of misbranding, its labeling is false or misleading (21 U.S.C. 343(a)(1)); it is offered for sale under the name of another food (21 U.S.C. 343(b)); if its label does not bear the common or usual name of the food, if there is any, or, if the food is made of two or more ingredients, the common or usual name of the ingredients (21 U.S.C. 343(i)); or if it purports to be or is represented as catfish, unless it is fish classified within the family Ictaluridae (21 U.S.C. 343(t)). The provision in 21 U.S.C. 321d, “Market names for catfish and ginseng,” on catfish labeling, states, “(a)(1) Notwithstanding any other provision of law, for the purposes of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 *et seq.*)—(A) the term “catfish” may only be considered to be a common or usual name (or part thereof) for fish classified within the family Ictaluridae; and (B) only labeling or advertising for fish classified within that family may include the term “catfish.”

<sup>2</sup> U.S. Department of Health and Human Services. Food and Drug Administration. February 28, 2003.

In the 2008 Farm Bill (the Food, Conservation, and Energy Act (Farm Bill) of 2008 (Pub. L. 110–246, § 11016(b)), Congress gave the Secretary of Agriculture and, by delegation, FSIS, the authority to determine to which fish the term “catfish” would apply.

**III. 2008 Farm Bill**

In amending the FMIA to make “catfish” an amenable species (21 U.S.C. 601(w)(2)), Congress recognized that there are differences in how catfish and the other species that are subject to the FMIA are slaughtered and processed. The Farm Bill added 21 U.S.C. 625, which provides that the sections of the FMIA dealing with ante-mortem and post-mortem inspection and humane slaughter (21 U.S.C. 603, 604), inspection of carcasses and parts before their entry into establishments or further-processing departments (21 U.S.C. 605), and exemptions from inspection for custom and farm slaughter and processing and other

exemptions (21 U.S.C. 623), do not apply to catfish.

The 2008 Farm Bill also revised 21 U.S.C. 606, which requires the appointment of inspectors to examine and inspect all meat food products prepared for commerce, by designating the existing section as 21 U.S.C. 606(a) and adding a paragraph, 21 U.S.C. 606(b). This new paragraph provides that the examination and inspection of meat food products derived from catfish are to take into account the conditions under which catfish are raised and transported to processing establishments.

The 2008 Farm Bill provides that the amendments are not to apply until the date on which the Agency issues final regulations to carry out the amendments. The Bill instructs the Agency to consult with the FDA in issuing these final regulations.

**IV. Defining “Catfish”**

The definition of “catfish” is a threshold issue in this rulemaking as it

determines the scope of the FSIS catfish inspection program. Before discussing the options for how to define “catfish”, it is first helpful to review the scientific classification, or taxonomy, of the catfishes.

*Taxonomy of the Catfishes*

Taxonomy is the science of classification. Seven major hierarchical groupings are used to classify all living organisms. These are kingdom, phylum, class, order, family, genus, and species. The kingdom is the broadest grouping. The kingdom Animalia, for example, includes all known animals. The kingdom is comprised of individual phyla, phyla of classes, classes of orders, orders of families, families of genera, and genera of species. In the taxonomy of the fishes, fish of the order Siluriformes are commonly and collectively known as “catfishes” (Table 1).

TABLE 1<sup>3</sup>—TAXONOMY OF THE CATFISHES. THE ORDER SILURIFORMES, OR “CATFISHES,” INCLUDES THIRTY-SIX FAMILIES, COMMON NAMES OF WHICH ARE IN PARENTHESES

Order	Siluriformes (catfishes [English], silures [French])
Family .....	Akysidae (stream catfishes)
Family .....	Amblycipitidae (torrent catfishes)
Family .....	Amphiliidae (loach catfishes)
Family .....	Ariidae (bagres marinos, fork-tailed catfishes, poissons-chats marins, sea catfishes)
Family .....	Aspredinidae (banjo catfishes)
Family .....	Astroblepidae (climbing catfishes, naked sucker-mouth catfishes)
Family .....	Auchenipteridae (driftwood catfishes)
Family .....	Bagridae (bagrid catfishes, naked catfishes)
Family .....	Callichthyidae (armored catfishes, callichthyid armored catfishes, coridoras, mailed catfishes, plated catfishes, poissons-chats cuirasses)
Family .....	Cetopsidae (whale catfishes, whalelike catfishes)
Family .....	Chacidae (angler catfishes, frogmouth catfishes, squarehead catfishes)
Family .....	Clariidae (airbreathing catfishes, bagres laberintos, labyrinth catfishes, poissons-chats à labyrinths)
Family .....	Cranoglanididae (armorhead catfishes, armored catfishes)
Family .....	Diplomystidae (diplomystid catfishes, velvet catfishes)
Family .....	Doradidae (bagres sierra, poissons-chats épineux, thorny catfishes)
Family .....	Erethistidae
Family .....	Heptapteridae (heptapterids)
Family .....	Heteropneustidae (airsac catfishes)
Family .....	Hypophthalmidae (loweye catfishes)
Family .....	Ictaluridae (bagres de agua dulce, barbottes, barbottes et barbues, barbues, bullhead catfishes, North American catfishes, North American freshwater catfishes)
Family .....	Lacantuniidae
Family .....	Loricariidae (armored catfishes, loricariidés, plecoóstomas, suckermouth armored catfishes, suckermouth catfishes)
Family .....	Malapteruridae (electric catfishes)
Family .....	Mochokidae (naked catfishes, squeakers, upside-down catfishes)
Family .....	Nematogenyidae (mountain catfishes)
Family .....	Olyridae
Family .....	Pangasiidae (giant catfishes)
Family .....	Parakysidae
Family .....	Pimelodidae (flat-hosed catfishes, juiles, long-whiskered catfishes, longwhiskered catfishes, poissons-chats à longues moustaches)

Memorandum “To All Interested Parties” on “market names for fish that are outside the family

Ictaluridae and that were previously marketed with the term ‘catfish’ in their names.”

TABLE 1<sup>3</sup>—TAXONOMY OF THE CATFISHES. THE ORDER SILURIFORMES, OR “CATFISHES,” INCLUDES THIRTY-SIX FAMILIES, COMMON NAMES OF WHICH ARE IN PARENTHESES—Continued

Order	Siluriformes (catfishes [English], silures [French])
Family .....	Plotosidae (coral catfishes, eel catfishes, stinging catfishes)
Family .....	Pseudopimelodidae (bumblebee catfishes, dwarf marbled catfishes)
Family .....	Schilbeidae (glass catfishes, schilbid catfishes)
Family .....	Scoloplacidae (spiny dwarf catfishes)
Family .....	Siluridae (freshwater catfishes, sheatfishes)
Family .....	Sisoridae (sisorid catfishes, sucker catfishes)
Family .....	Trichomycteridae (parasitic catfishes, pencil catfishes)

The order Siluriformes includes the family Ictaluridae, the North American catfish, to which belong the fork-tailed channel catfish (*Ictalurus punctatus*) and blue catfish (*I. furcatus*), the principal U.S. farm-raised species, and the flathead catfish (*Pylodictis olivaris*). Other species in the United States that are in the Ictaluridae family are the white catfish (*I. catus*), and the black, brown, and yellow bullhead (*I. melas*, *I. nebulosus*, and *I. natalis*). Also among the Siluriformes are the air-breathing catfishes of the Clariidae family, to which belongs *Clarias fuscus*, a Chinese species raised on a small scale in Hawaii.

Another family of Siluriformes, the Pangasiidae, the so-called “giant catfishes,”<sup>4</sup> includes the aquaculture species basa (*Pangasius bocourti*), and tra or swai (*Pangasius hypophthalmus*; synonym, *Pangasius sutchi*), raised principally in Southeast Asia for domestic consumption and export. Other catfish types commercially raised in Asia include the hybrid *Clarias macrocephalus* and North American channel catfish (*I. punctatus*).

*Options for Defining “Catfish”*

The Agency settled on two options for defining “catfish” after reviewing the legislative and regulatory history and scientific classification system. One option, was a definition adopted by Congress in the 2002 Farm Bill that defined “catfish” to be only fish of the Ictaluridae family for marketing and labeling purposes under the FD&C Act. This is the current definition used by FDA in its seafood program. The other option was an order definition including all fish of the order Siluriformes. This definition was used by FDA prior to the 2002 Farm Bill, and would follow established scientific practice that defines “catfish” as all fish of the order Siluriformes.

<sup>3</sup> Adapted from Integrated Taxonomic Information System (ITIS) report on “Siluriformes.” At <http://www.itis.gov> (accessed October 4, 2009).

<sup>4</sup> ITIS report on “Siluriformes.” At <http://www.itis.gov> (accessed Jan. 26, 2009).

The 2008 Farm Bill grants the Secretary of Agriculture the authority to define “catfish” anew for purposes of the 2008 amendments of the FMIA. The FMIA, like the FD&C Act, prohibits the adulteration and misbranding of foods that are subject to it. Accordingly, FSIS examined the available data in deciding how it could carry out the FMIA to the best effect.

Specifically, the Agency looked at data describing the presence of chemical residues in, and the presence of microorganisms on or in, catfish or catfish products, and the amount and types of catfish and catfish products consumed in the United States. Sparse information on the distribution of microbial contamination and chemical residues on catfish limit our ability to make strong statements about the baseline risk. Furthermore, the lack of experience in implementing continuous inspection programs in the context of aquaculture makes estimating the impact of such a program on risk difficult. However, the Agency has been able to conduct an illustrative assessment of potential human health risks associated with catfish consumption, using *Salmonella* as the example.<sup>5</sup> The Agency considered information about the extent of misbranding, and it evaluated outputs from its benefit-cost analysis for catfish inspection.

USDA is requesting public comments on the scope of the definition of the term “catfish.”

**V. Catfish Farming and Processing**

*Domestic Catfish Farming and Processing*

The catfish growing process in the United States begins after eggs from breeding ponds are transferred to hatcheries. Hatchlings are reared in the hatcheries for several days before being placed in nursery or fry ponds, where they are raised until, as 3-inch to 8-inch

fingerlings, they are transferred to grow-out ponds. There, the fish are fed a ration of pelletized floating feed made with soybean meal, fishmeal, corn, wheat, or other grains until they reach marketable size.

In some instances, medicated feeds containing antimicrobials may be fed to catfish for therapeutic treatment of bacterial infections. Also, pond water may be treated with chemicals to control algal growth and prevent off-flavor in the fish.

Catfish-raising ponds are generally of two types: Levee or delta ponds and watershed ponds. Levee ponds are built on flat land and filled with groundwater or surface water. In hilly areas, dams built across valleys and between hillsides capture runoff from rainfall to fill “watershed” ponds. Though water to fill and maintain watershed ponds usually comes from watershed runoff, wells are often necessary to supplement the watershed supply. Watershed ponds tend to be deeper than levee ponds and can efficiently nourish more fish per acre than levee ponds.

Water quality—proper temperature, pH, ammonia, nitrite, alkalinity, hardness, carbon dioxide, chloride, and oxygen—must be maintained to ensure fish health and maximize feed efficiency. Aerators are used to prevent oxygen depletion in the ponds. The oxygen levels are monitored regularly to ensure fish health and to help in limiting algal blooms.

When catfish reach marketable length and weight—optimally 9 to 12 inches and 0.75 to 1.5 pounds—they are collected with seines and put in aerated tanks mounted on trucks that then transport fish to the processing plant. A truck may carry from 4 to 10 of these vats, each loaded with about 3,000 pounds of water and catfish.

The following generally describes catfish processing in the United States. Individual operations may vary. At the processing plant, fish are unloaded into a holding vat and carried by conveyor to an electrical stunner. The fish are then sorted and sized. Fish of incorrect species, such as shad (used in the ponds

<sup>5</sup> U.S. Department of Agriculture. Food Safety and Inspection Service. Office of Public Health Science. December 2010. Draft Risk Assessment of the Potential Human Health Effect of Applying Continuous Inspection to Catfish. Washington, DC.

to reduce algae), or incorrect size are sorted out. Fish of the correct size are sent to the next operation where they are headed and gutted. Next, the fish are trimmed and mounted on conveyors and sent tail-first through filleting machinery. After further trimming, including removal of the belly flap, or “nugget,” fillets are skinned and sent through a chiller. Fillets are then prepared for packaging or freezing. Nuggets may be used in lower-grade edible product.

Most catfish fillets are shipped frozen. Preservatives, including sodium tripolyphosphate, may be used as humectants or to minimize oxidation and freezer burn. Some fillets are sold fresh; some marinated; and some breaded. Little if any U.S. farm-raised catfish undergoes complex processing. There are few multi-ingredient commercial catfish products. Fish too big for further processing with automated equipment are sent through a separate processing line to be hand-processed and sold as whole gutted fish (head on), mainly to restaurants and institutions.

Waste materials and byproducts from heading, gutting, and trimming are taken from the food processing area of the establishment to be separately processed or packaged and shipped. Muscle tissue separated from bones, called mince, may be processed into surimi (a white-fish food product). Other byproducts may be rendered to produce fish oils, or they may be used in animal feed manufacture, or processed into fishmeal or fertilizer. Fish heads may be sold as bait for commercial fishermen.

#### *Foreign Catfish Farming and Processing*

Foreign catfish farming and processing is done in a similar manner to that of the United States, but it may differ in specific methods. In general, it is more labor-intensive than U.S. farming and processing. It may involve the use of hatcheries and inland ponds. In some countries, however, catfish may be grown in net enclosures in rivers, in floating cages, sometimes alongside or under houseboats, or in “raceway” inlets fed by river waters.

Fish may be fed homemade or pelleted feed. Homemade feed is composed of fishmeal, mixed with rice bran. (In the United States, only a very low percentage of catfish feed—zero to 3 percent—is fishmeal.) In some instances, pelleted feed can be a source of contamination with unapproved antimicrobials or chemical residues.

Some reports suggest that antimicrobials prohibited for extra-label use in food-producing animals in the

United States (e.g., fluoroquinolones) have been used in the raising of catfish in foreign countries.<sup>6</sup> Also, the quality of the river water is more difficult to control or less subject to control by fish farmers than is pond water.

#### **VI. Current Inspection of Domestic and Imported Catfish**

U.S. catfish processors, exporters, and importers are subject to the U.S. Food and Drug Administration’s seafood Hazard Analysis Critical Control Point (HACCP) regulations (21 CFR 123) and to other requirements under the Food, Drug, and Cosmetic (FD&C) Act. FDA’s regulations on current good manufacturing practices (cGMPs, at 21 CFR part 110) and on recordkeeping and registration requirements (21 CFR part 1, subpart H), issued under the Bioterrorism Act of 2002 (Pub. L. 107–188, Jun. 12, 2002) also apply to these establishments.

For imported products, FDA requires that the importer either (1) obtain fish or fish products from a country that has an active memorandum of understanding with FDA that covers the product and documents the equivalence or compliance of the foreign inspection system with that of the United States, or (2) have and implement written verification procedures for ensuring fish and fish products offered for import into the United States were processed in accordance with FDA regulations in 21 CFR part 123 (21 CFR 123.12).

The arrangement for imported fish products does not presuppose a regulatory finding by FDA that the foreign inspection system is equivalent to that of the United States, nor does FDA conduct continuous re-inspection of imported fish products as a condition of their entry into the United States.

In addition to FDA regulations, some U.S. catfish processing establishments have contracted for voluntary, fee-for-service inspection and certification programs administered by the Department of Commerce’s National Marine Fisheries Service (NMFS) under the Agricultural Marketing Act (7 U.S.C. 1622, 1624) and implementing regulations (50 CFR 260). NMFS administers three levels of seafood inspection programs under authority of the Agricultural Marketing Act (7 U.S.C. 1622, 1624) and regulations implementing that act (50 CFR 260).

<sup>6</sup> U.S. Department of Health and Human Services. Food and Drug Administration. July 2007. Congressional Testimony: Safety of Chinese Imports. Washington, DC; U.S. Department of Health and Human Services. Food and Drug Administration. November 2008. Enhanced Aquaculture and Seafood Inspection—Report to Congress. Washington, DC.

These are: (1) A resident inspection program, which provides continuous inspection to qualifying establishments; (2) an integrated quality assurance program, under which an establishment operates an NMFS-approved quality assurance system and assists NMFS personnel in carrying out U.S. grading or specification regulations; and (3) a HACCP-Quality Management Program (QMP), under which the establishment’s quality program is enhanced to meet the ISO 9001 quality management standards.

An establishment that participates in the continuous inspection program must agree to prepare products using only wholesome raw materials and to correctly label inspected items. The establishment must also agree to prior label approval by NMFS and to furnish the Agency with reports that the Agency may request on processing, packaging, grading, laboratory analysis, and production of inspected products. The establishment must provide facilities to NMFS inspectors and agree to conditions under which inspection may be suspended or terminated (50 CFR 260.97). The premises of the establishment must be free from conditions that may result in food contamination (50 CFR 260.98). Buildings and structures must be equipped with adequate lighting, ventilation, drains and gutters, and hot and cold water. Processing facilities must be of sound construction and capable of being efficiently and thoroughly cleaned. Animals and pests must be excluded. The use of chemical compounds, such as cleaning agents, insecticides, rodenticides, and bactericides must be limited to circumstances and conditions approved by NMFS (50 CFR 260.99).

An establishment participating in any of the NMFS inspection programs is expected to have organized food-safety management systems that are implemented through a combination of operational prerequisite programs that document how food safety hazards are to be controlled, and HACCP plans for each product processed by the establishment. The establishment must maintain documented Sanitation Standard Operating Procedures (Sanitation SOPs) and prerequisite programs. The programs must ensure the safety of processing water, ensure employee hygiene, prevent contamination of food-contact surfaces, and prevent cross-contamination generally in the establishment. The establishment is expected to document how it will control nonconforming products, handle recalls, and withdraw defective products from the market. All

HACCP-related records must be available to NMFS inspectors.

## VII. Public Health Protection: Chemical and Microbiological Contaminants

FDA and the Centers for Disease Control and Prevention (CDC) consider commercially raised catfish to be a low-risk food. Even so, because catfish of domestic or foreign origin may be exposed to chemical and microbiological contaminants, it is incumbent on FSIS to consider the food safety hazards that might be presented by catfish in planning the Agency's regulatory approach.

### Chemical Residues in Catfish

Most of the chemical residues identified in some domestic and foreign catfish fall into three main classes—heavy metals, pesticides, and antimicrobials.

### Heavy Metals

At sufficient levels, these heavy metals are associated with ischemic heart disease, developmental abnormalities, decreased intelligent quotient (IQ) values, and other harmful effects in humans.<sup>7</sup>

FSIS tested 737 samples collected under a sampling plan representing catfish consumption in the United States during the course of one year, April 2008 through March 2009. Samples of seafood labeled as “catfish” were taken from the retail market system in the United States and were tested for the presence of arsenic, cadmium, lead, and mercury. Seventeen samples from among domestic and imported products had detectable heavy metal residues. Six domestic samples contained lead and cadmium. Four samples contained lead at a mean concentration of 43.48 parts per billion (ppb), with a range of 29.49 ppb to 76.92 ppb, while 2 samples contained cadmium at a mean concentration of 11.6 ppb, with a range of 10.9 ppb to 13.11 ppb. Twelve imported samples contained lead and arsenic. Ten samples contained lead at a mean concentration of 46.08 ppb, with a range of 27.96 ppb to 103.24 ppb, while 2 samples contained arsenic at a mean concentration of 1.34, with a range of 1.03 ppm to 1.64 ppm. We are unaware of regulatory action levels for arsenic,

<sup>7</sup> U.S. Centers for Disease Control and Prevention. Agency for Toxic Substances and Disease Registry. (1999). Toxicological Profile for Mercury.

U.S. Centers for Disease Control and Prevention. Agency for Toxic Substances and Disease Registry. (2007a). Toxicological Profile for Arsenic.

U.S. Centers for Disease Control and Prevention. Agency for Toxic Substances and Disease Registry. (2007b). Toxicological Profile for Lead.

cadmium, and lead; the action level for mercury is 1,00 ppb.<sup>8</sup>

In a 2001 study of 257 domestic catfish (*i.e.*, Ictaluridae) samples conducted by Santerre *et al.*, lead residues were detected in 11 percent, arsenic residues in 5 percent, and mercury residues in 83 percent.<sup>9</sup> Average metal residues detected in the study were lower than recommended safety limits, although it should be noted that the Environmental Protection Agency has not established a reference dose (maximum acceptable oral dose) for lead.

### Pesticides

In 2008, the USDA Agricultural Marketing Service<sup>10</sup> tested 552 catfish samples collected under a sampling plan representing catfish consumption in the U.S. (including 435 samples of domestic and 108 samples of foreign catfish, as well as 9 samples of catfish of unknown origin) for pesticide residues.<sup>11</sup> Of note, chlorpyrifos<sup>12</sup> residues were detected in less than 1 percent of the domestic samples and in 32 percent of the import samples. DDE (p,p'-Dichlorodiphenyldichloroethylene), a metabolite of dichlorodiphenyltrichloroethane (DDT)<sup>13</sup> was detected in 97 percent of the domestic samples and 34 percent of imported samples at levels below regulatory concern; endosulfan<sup>14</sup> and its metabolites were detected in less than 1 percent of the domestic samples and in 27 percent of the import samples; and Toxaphene<sup>15</sup> was detected in 1

<sup>8</sup> U.S. Department of Agriculture. Food Safety and Inspection Service. 2010. Analysis of Heavy Metals and Veterinary Drugs found in 737 Catfish Samples from Retail Markets in the United States. Washington, DC.

<sup>9</sup> Santerre, C.R., P.B. Bush, D.H. Xu, G.W. Lewis, J.T. Davis, R.M. Grodner, R. Ingram, C.I. Wei, J.M. Hinshaw. 2001. Metal Residues in Farm-Raised Channel Catfish, Rainbow Trout, and Red Swamp Crayfish from the Southern U.S. *Journal of Food Science*. 66:270–273.

<sup>10</sup> U.S. Department of Agriculture. Agriculture Marketing Service. December 2009. Pesticide Data Program Annual Report 2008. Washington, DC.

<sup>11</sup> U.S. Department of Agriculture. Agriculture Marketing Service. December 2009. Pesticide Data Program annual Report 2008. Washington, DC.

<sup>12</sup> An organophosphate insecticide linked to neurological and birth defects.

<sup>13</sup> A synthetic organochlorine pesticide often used for mosquito control, DDT is a suspected carcinogen. Use of DDT was banned in the U.S. in 1972. Today it is banned in most developed countries. Because of its long half-life (ca. 25 years), DDT is classified as a persistent organic pollutant. This perhaps explains its presence in domestic and imported catfish samples.

<sup>14</sup> An organochlorine insecticide with acute toxicity and high bioaccumulation potential, endosulfan is an endocrine disruptor.

<sup>15</sup> Toxaphene is a mixture of approximately 200 organic compounds. Used as an insecticide in

percent of the domestic samples and none of the import samples.

### Unapproved Antimicrobials

If antimicrobials that are not approved by the FDA, such as malachite green and fluoroquinolones, are used in catfish production, they can result in the presence of chemical residues in edible tissue. Some research suggests that antimicrobial residues in food may hasten the development of antimicrobial-resistant infections in humans.<sup>16</sup> Exposure to high levels of malachite green and similar antimicrobials has been shown to be carcinogenic and mutagenic in rats. In 2006, the FDA found 15 imported catfish samples positive for malachite green and 2 for fluoroquinolones. In 2007, 868,000 lines of seafood fish and fishery products were submitted for import to the U.S.; FDA obtained samples from approximately 10,400 of those lines; and FDA tested 686 of those samples for antimicrobial residues. Meanwhile, about one percent of the 10.5 billion pounds of imported fish and fisheries products in 2007 were Siluriformes. In their 2008 report “Enhanced Aquaculture and Seafood Inspection—Report to Congress,” available at: <http://www.fda.gov/Food/FoodSafety/Product-SpecificInformation/Seafood/SeafoodRegulatoryProgram/ucm150954.htm>. FDA reported that in 2007 it found 12 imported catfish samples positive for malachite green and 6 for fluoroquinolones. Since June 2008, FDA rejected 31 shipments of catfish imports for presence of unsafe animal drug residues.

In conjunction with the April 2008—March 2009 heavy metals survey, FSIS tested 733 catfish samples for the presence of chloramphenicol, gentian

cotton and soybean growing areas of the United States, it was banned for use in 1986. Toxaphene is a carcinogen.

<sup>16</sup> Heuer, O.E. Kruse, H., Grave K., Karunasagar, I., & Angulo, F.J. (2009). Human Health Consequences of Use of Antimicrobial Agents in Aquaculture. *Clinical Infectious Diseases*. 49:1248–1253.

Muller, L., Kasper, P. Kersten, B. & Zhang, J. (1998). Photochemical genotoxicity and photochemical carcinogenesis. Two Sides of a Coin? *Toxicology Letters*. 102–103: 383–387.

Culp, S.J., Mellick, P.W., Trotter, R.W., Greenlees, K.J., Kodell, R.L., Beland, F.A. (2006). Carcinogenicity of Malachite Green Chloride and Leucomalachite Green in B6C3F1 Mice and F344 Rats. *Food and Chemical Toxicology*. 44:1204–1212.

There are three approved classes of antimicrobials for use in catfish: florfenicol, Romet 30 and TC, and several terramycin formulations. See <http://www.fda.gov/downloads/AnimalVeterinary/ResourcesforYou/AnimalHealthLiteracy/UCM109808.pdf> (Accessed Feb. 15, 2011).

violet, malachite green, and nitrofurans. (The number of samples tested for some chemicals differs slightly due to insufficient amount of material in some samples to do all of the tests.) A total of 10 samples were confirmed positive for nitrofurans (AOZ and AMOZ), gentian violet, and malachite green. Five domestic samples had confirmed positive results, 4 for gentian violet and 1 for malachite green. Five imported samples had confirmed positive results, each for AOZ and AMOZ, 2 for gentian violet, and 1 for malachite green. Detects were at levels below regulatory concern.

The foregoing shows that, while catfish may not frequently harbor residues of illegal drugs or other chemicals, the potential exists for such contamination. Because some shipments of imported catfish have been found with residues of drugs that FDA has banned and that are unsafe, FSIS proposes to conduct regular verification to ensure the safety of catfish and catfish products.

#### Microbial Pathogens in Catfish

The hazard identification component of the FSIS catfish risk assessment<sup>17</sup> identified certain microorganisms as higher-priority. The prioritization was based on association with catfish-related outbreaks and on the severity of

resultant illness. The microorganisms identified included *Salmonella*, *Listeria monocytogenes*, and Enterotoxigenic *E. coli*.

#### Salmonella

In a study by McCaskey and colleagues<sup>18</sup> reviewed by FSIS, *Salmonella* were found on 2 percent of 220 domestic catfish fillets. Among 136 imported catfish violations listed by FDA for 1998–2004, 42 percent were for *Salmonella*.<sup>19</sup> It is difficult to compare prevalence values described here because the domestic fillets were sampled randomly, whereas the imported fillets were likely not sampled randomly.<sup>20</sup>

#### Listeria

Though no catfish-borne listeriosis outbreaks have been identified, Chou *et al.* (2006) identified *L. monocytogenes* in 25–47% of raw catfish fillets at three U.S. processing plants.<sup>21</sup> Some isolates were persistently found in processed fillets, suggesting either that the sanitation was inadequate, or that these isolates originated from the natural habitats of the catfish. McCaskey *et al.* (1998) found a prevalence of 5.9% for *L. monocytogenes* on catfish fillets. Significant risk may exist if cross-contamination occurs between raw products and ready-to-eat (RTE)

products (Fernandes *et al.* 1998). Chou *et al.* (2006) found that *L. monocytogenes* was most commonly isolated from catfish in the winter with a prevalence rate of 51 percent, compared to 41 percent in the spring, 36.7 percent in the fall, and 19 percent in the summer. This finding may be attributable to the ability of *L. monocytogenes* to out-compete other bacterial species at lower temperatures.

#### Escherichia coli

A 2003 outbreak linked catfish or coleslaw consumption to 41 cases of Enterotoxigenic *E. coli* (ETEC) O169:H41-related illness (Beatty, 2004).<sup>22</sup> However, FSIS is aware of no data to describe the occurrence of ETEC on catfish.

#### Illness Outbreaks From Catfish

Cases of human illness have been linked to catfish consumption. Since 1990, the Centers for Disease Control and Prevention (CDC) have identified seven illness outbreaks where such catfish were consumed. In only one of these outbreaks was catfish specifically identified as possible vehicles of infection. These outbreaks, which are described below, have included 66 illnesses and 8 hospitalizations (Table 2).

TABLE 2—CDC DATA ON OUTBREAKS OF FOODBORNE ILLNESS IN WHICH CATFISH WAS A CONFIRMED OR SUSPECTED VEHICLE, 1991–2007, UNITED STATES.<sup>23</sup>

Year	State	Setting	Etiology	Illnesses	Hospitalizations	Deaths
1991	NJ	Restaurant	<i>Salmonella</i>	10	6	0
1999	FL	Private Home	Unknown	2	0	0
1999	FL	Restaurant/Deli	Unknown	5	0	0
2000	OH	Restaurant/Deli	Chemical	2	0	0
2003	TN	Workplace	<i>E. coli</i> O169	41	2	0
2003	CO	Restaurant/Deli	Unknown	4	0	0
2007	FL	Private Home	Unknown	2	0	0

In 1991, an illness outbreak occurred in New Jersey that affected ten case-patients. Nine stool specimens tested positive for *Salmonella* Hadar. Catfish was identified as a possible vehicle for illnesses.

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In 1999, two illness outbreaks occurred in Florida with undetermined etiology or causal agent. The first affected five case-patients, all reporting

catfish consumption. Statistical evidence suggested catfish might be the vehicle, although the restaurant where case-patients dined had poor sanitation and inadequate refrigeration. The second affected two case-patients who experienced illnesses after preparing and consuming catfish and yellow rice

<sup>17</sup> U.S. Department of Agriculture. Food Safety and Inspection Service. Office of Public Health Science. December 2010. Draft Risk Assessment of the Potential Human Health Effect of Applying Continuous Inspection to Catfish. Washington, DC.

<sup>18</sup> McCaskey T, TC Hannah, T Lovell, *et al.* 1998. *Safe and Delicious* study shows catfish is low risk for foodborne illness. Highlights of Agricultural Research. Vol. 45, No. 4. Available at <http://www.ag.auburn.edu/aaes/communications/highlights/winter98/catfish.html>.

<sup>19</sup> U.S. Department of Agriculture. Economic Research Service. 2009. Economic Research Service Staff Analysis of FDA Import Refusals for Catfish, 1998–2004. Washington, DC.

<sup>20</sup> Because of this, the FSIS catfish draft risk assessment assumed that the prevalence of *Salmonella* on imported catfish was the same as that on domestic fish, *i.e.* 2%.

<sup>21</sup> Chou, C.H., Silva, J.L., & Wang, C. (2006). Prevalence and Typing of *Listeria monocytogenes* in Raw Catfish Fillets. *Journal of Food Protection*, 69, 815–819.

<sup>22</sup> Beatty, M.E., Bopp, C.A., Wells, J.G., Greene, K.D., Puh, N.D., & Mintz, E.D. (2004). Enterotoxin-producing *Escherichia coli* O169:H41, United States. *Emerging Infectious Diseases*. Retrieved from <http://www.cdc.gov/ncidod/EID/vol10no3/03-0268.htm> Oct. 16, 2009.

<sup>23</sup> Data from the Centers for Disease Control and Prevention's (CDC) electronic Foodborne Disease Outbreak Reporting System (eFORS). Provided to FSIS by CDC, Sept. 15, 2008.

at home. Both foods were identified as implicated items.

In 2000, an Ohio illness outbreak was reported that affected two case-patients experiencing signs and symptoms suggestive of chemical contamination. Samples of raw and fried, farm-raised catfish were tested, and results indicated contamination with an unidentified chemical.

In 2003, two reported illness outbreaks identified catfish as an implicated food item. One outbreak occurred in Tennessee and included 41 illnesses and 12 confirmed cases of *E. coli* O169:H41. An epidemiologic study was conducted and identified multiple food items, including catfish. A food worker was suspected as the source of contamination. The second outbreak occurred in Colorado, and investigators reported that four out of five people became ill after eating catfish at a restaurant. The fifth, well person did not report eating catfish.

The most recent reported illness outbreak occurred in Florida in 2007. Two case-patients were identified after consuming in a private home catfish prepared at a grocery store. Improper cold storage and reheating practices at the food service facility (grocery store) were noted.

Table 2 shows that there has been one catfish-associated outbreak from *Salmonella* in the past twenty years. Because only a small proportion of all foodborne illnesses reported are identified as associated with outbreaks (<http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5931a1.htm>), it is possible that there may be a low level of sporadic cases of salmonellosis associated with catfish that are not detected with current levels of surveillance. FSIS notes, however, that this case occurred before FDA's implementation of regulations (21 CFR part 123) that require processors of fish and fishery products to develop and implement HACCP systems for their operations. Since implementation, no cases of salmonellosis linked to catfish have been reported.

#### *The FSIS Catfish Draft Risk Assessment*

FSIS conducted an illustrative assessment of the potential risk to human health of catfish consumption, using the example of *Salmonella* contamination. We are particularly interested in *Salmonella* because the general burden of illness from this pathogen in the United States remains a concern and there is evidence that at least one outbreak of human salmonellosis may have been related to

catfish consumption.<sup>24</sup> *Salmonella* is a useful model because its presence provides an indication of the sanitary conditions under which food is produced, and because an approach that produces a reduction in *Salmonella* through improved process control is effective in controlling for the presence of other microbial pathogens.<sup>25</sup>

With regard to the risk assessment for catfish, FSIS continues to evaluate the hazards, particularly *Salmonella*, associated with this fish. FSIS invites all interested stakeholders to submit additional data and scientific evidence specific to catfish food safety. FSIS will consider this information and other data in the development of a final risk assessment in this proceeding.

Further, USDA is seeking public comments on the evidence regarding the public health benefits and cost-effectiveness to be achieved with the proposed program.

### **VIII. Proposed Regulations Implementing Continuous Inspection of Catfish and Catfish Products**

As stated above, this proposal implements provisions of the FMIA added by the 2008 Farm Bill respecting the amenable species "catfish, as defined by the Secretary" (21 U.S.C. 601(w)(2)). It is intended to prevent and eliminate any burdens on commerce imposed by adulterated or misbranded catfish or catfish products and to protect the health and welfare of consumers from such adulterated or misbranded catfish or catfish products (21 U.S.C. 602).

#### *A. Coverage of the FMIA: Provisions Applicable to Catfish and Catfish Products*

The FMIA (21 U.S.C. 601–695) requires FSIS to carry out a continuous inspection program for the species that are subject to this statute, which now includes catfish. FSIS inspects food products derived from those species, verifies that the products are prepared for commerce under sanitary conditions, and inspects products that are exported from or imported into the United States. The inspection may include testing for pathogens or for drug or other chemical

residues. The FMIA also gives FSIS the authority to take action with respect to meat products in commerce that may be adulterated or misbranded. FSIS intends to apply to catfish and catfish products provisions of the FMIA that now apply to meat and meat food products, except for the provisions that the 2008 Farm Bill excludes from applicability to catfish.

#### *B. Catfish and Catfish Product Inspection Regulations Under the FMIA*

FSIS is proposing to establish regulatory requirements for the continuous inspection of catfish and catfish products. FSIS is adapting for use in the regulation and inspection of catfish and catfish products those meat inspection regulations that are appropriate in preventing the transportation, sale, offer for sale or transportation, or receipt for transportation, in commerce, of adulterated or misbranded products (21 U.S.C. 602, 610, 621). Because there are differences between fish and mammalian livestock species, some of the regulations for catfish will be separate within the Code of Federal Regulations from those for the inspection of meat and meat food products. Other regulations apply as written to catfish and will simply be cross-referenced.

#### *Organization of Catfish Inspection*

In general, the catfish regulations parallel the sequence of operations from the harvesting and delivery of the fish to the processing plant, through the in-plant operations, to transportation in commerce, specifying export and import requirements where appropriate.

After outlining the district-level supervision of catfish inspection in proposed 9 CFR 530.2, FSIS makes clear in proposed § 530.3 that, as provided in 9 CFR 300.6, persons that are subject to the FMIA, and specifically the catfish inspection provisions, are to grant authorized Agency or Department personnel access to establishments that process catfish and to other establishments in industries related to the catfish processing industry (21 U.S.C. 606, 642(a)).

#### *Definitions*

FSIS is proposing largely to use the same definitions for the catfish inspection regulations (proposed 9 CFR 531.1) as for the meat inspection regulations (9 CFR 301.2), which are incorporated into proposed 9 CFR 531.1 by reference. However, recognizing the differences between the commercial production and processing of catfish products, as opposed to other products

<sup>24</sup> U.S. Department of Agriculture. Food Safety and Inspection Service. Office of Public Health Science. December 2010. Draft Risk Assessment of the Potential Human Health Effect of Applying Continuous Inspection to Catfish. Washington, DC.

<sup>25</sup> Food Safety and Inspection Service. 2006. Review of the Pathogen Reduction; Hazard Analysis and Critical Control Point (HACCP) Systems Final Rule pursuant to Section 610 of the Regulatory Flexibility Act, as Amended. Available at: [http://www.fsis.usda.gov/OPPDE/rdad/FRPubs/2007-0022P/610\\_Report\\_PR\\_HACCP.pdf](http://www.fsis.usda.gov/OPPDE/rdad/FRPubs/2007-0022P/610_Report_PR_HACCP.pdf) (Accessed Oct. 14, 2009).

that are subject to the FMIA, the Agency is proposing to add definitions for “catfish,” “farm-raised,” “catfish food product,” “farm-raised,” and some other terms. The Agency also is adapting certain terms used in the meat inspection regulations, such as “applicant” and “consumer package,” to apply in the context of catfish production and processing.

FSIS is proposing that the term “catfish”—aside from what animal species the term is to denote—mean the skeletal muscle tissue of catfish, the edible portion of the fish that is prepared for the consumer.

FSIS is proposing to define “catfish food product” to parallel the definition of “meat food product,” and “catfish product” to mean any catfish or catfish part, as well as any product made wholly or in part from any catfish or catfish part, except for products exempted from definition as a catfish product in the regulations. In the context of the proposed regulations, the term “catfish product” generally denotes an edible product.

The Agency is proposing to define “farm-raised,” as “grown under controlled conditions, within an enclosed space, as on a farm.” As indicated in earlier discussion, FSIS understands “farm-raised catfish” to be those that are typically raised in confinement from incubated eggs to harvest and fed commercial feed throughout the stages of production until harvested. Production schemes include culturing catfish in ponds and high-density culture systems that utilize tanks, raceways, and cages. The Agency recognizes that variations of these arrangements may be in use in the United States and in foreign countries. FSIS also recognizes that there are situations in which wild-caught catfish are processed for commercial distribution and requests comment on how the Agency should address these situations.

FSIS expects that, in general, catfish that will be subject to the proposed regulations will be grown as food for human consumption in a controlled environment by a commercial operator. Many of the remaining proposed definitions are adaptations from the definitions in the meat inspection regulations. For example, a “product” is any carcass, catfish, catfish product, or catfish food product that is capable of use as human food; an “official mark,” is a symbol to identify the status of any article, catfish, or catfish product under the FMIA; and such terms as “U.S. Condemned,” “U.S. Detained,” and “U.S. Retained,” are redefined to apply in situations involving catfish products.

Inasmuch as the ante-mortem inspection, post-mortem inspection, and humane slaughter provisions of the amended FMIA do not apply to catfish, there is little need for a definition or other requirements addressing slaughtering methods. However, the FMIA defines as adulterated a food product that is, in whole or in part, the product of an animal that has died otherwise than by slaughter (21 U.S.C. 601(m)(5)). In the view of FSIS, catfish that died under circumstances other than the controlled circumstances of commercial fish harvesting and processing would be adulterated under this provision of the FMIA and unacceptable for food. (For example, a fish that fell onto the pavement in the delivery area of a processing plant and lay there until it died would not be acceptable for human food.) Also, it may be necessary for the Agency to apply the detention, seizure, and condemnation provisions of the Act (21 U.S.C. 672, 673) in cases where the Agency finds dead, dying, or diseased catfish. It would then be necessary to distinguish catfish slaughtered for the purpose of being processed into human food from catfish that died from a disease, from accidental asphyxiation, from poisoning by environmental contaminants, or by any other cause that would render the catfish unacceptable for human food.

Moreover, the Agency has become aware of methods used in transporting catfish to, or in holding catfish at, processing establishments that involve holding the fish at so low a temperature that the catfish are intentionally killed before being delivered for processing for human food. To the extent that the methods are applied under controlled conditions in a manner that does not create a human food-safety hazard, FSIS would likely view these methods as constituting slaughter.

The question therefore arises whether the Agency should propose a definition of “slaughter” that would encompass various methods of killing catfish for food and that would ensure that catfish that died otherwise than by slaughter would not be used for food. FSIS’s tentative view is that it should. Thus, it has proposed to define “slaughter,” with respect to catfish, as intentional killing under controlled conditions. FSIS requests comment on this proposed definition, and on whether there is a need for it.

#### *Establishments Requiring Inspection; Grant and Approval of Inspection*

In proposed 9 CFR part 532, FSIS identifies the classes of establishments that handle catfish that require inspection. Under this proposal,

establishments that process catfish or catfish products for transportation or sale in commerce for use as human food will need to be under FSIS inspection. Also, the records not only of official catfish establishments but those of related businesses, including retail establishments that are exempt from continuous inspection, will be subject to periodic inspection.

FSIS is proposing requirements for catfish processing establishments to qualify for a grant of inspection that are similar to those that apply to meat processing establishments. These requirements cover facilities, potable water and water sanitation performance standards, Sanitation SOPs, and validated HACCP plans. FSIS intends to assign inspection personnel to catfish processing establishments.

Proposed 9 CFR 532.2 sets out the application procedures, cross-referencing the application procedures for, and grant and approval of, meat inspection in 9 CFR part 304 because the procedures for catfish establishments will be similar to those for meat establishments.

Establishments will have to complete an Application for Federal Inspection (currently, FSIS Form 5200–2, available from the appropriate District Office). In addition to completing the application, establishments will need to attach a description of the limits of the premises of the establishment that are to be under Federal inspection (Item No. 106 on the current application form). This description could be written, or it could be a drawing.

Under this proposal, a catfish establishment intending to conduct operations under an FSIS Grant of Inspection will be subject, consistent with 9 CFR 304.3, to the sanitation performance standard requirements (distinct from Sanitation SOPs) in 9 CFR part 416. After the establishment files its application with the appropriate District Office, FSIS will reserve an official plant number, in accordance with 9 CFR 305.1, that will identify all inspected and passed products prepared in an establishment and that must be printed on the label of any packaged product. All packaged catfish products also will have to bear the U.S. Inspection legend. All labeling material will have to be Federally approved and on-hand before inspection could be granted per 9 CFR 317.4.

Under the proposed regulations (requirements for sanitary operation under 21 U.S.C. 608 and 621), the establishment will have to have documentation supporting the potability of the water it uses for catfish (per 9 CFR and 416.2(g)).



FSIS also cross-references 9 CFR 305, on the assignment of establishment numbers and the inauguration of inspection, and 9 CFR 306, on the assignment and authorities of FSIS personnel, because they are essentially the same for meat and catfish inspection (proposed 9 CFR 532.2(c) and (d)). Before the inauguration of inspection, FSIS inspection personnel will examine the establishment and premises. If this examination shows that the facilities are satisfactory, FSIS will assign inspection personnel. No establishment operations may be conducted except under the supervision of an inspection program employee. FSIS provides inspection service to official establishments without charge, up to eight (8) consecutive hours per shift on consecutive days during the basic workweek. The regulations further provide that each official establishment is to submit a work schedule to the District Manager for approval (proposed 9 CFR 533.5; 9 CFR 307.4(d)(1)).

Any work conducted over the 8-hour shift, or any time past the initial 5-consecutive-day period, will be charged to the plant at the prevailing hourly overtime rate. If the operator of the establishment requests inspection during odd hours, a minimum of 2 hours will be charged to the plant at the above rate. This rate also is charged if the plant works on any Federal holiday.

Although there is no exemption from inspection in the amended FMIA for custom catfish slaughter and processing facilities, FSIS is providing an exemption for retail stores and restaurants in proposed 9 CFR 532.3 (under 21 U.S.C. 661(c)) and paralleling 9 CFR 303.1(d) and (e). FSIS is tentatively using the poultry exemption regulations set out in 9 CFR 381.10 as a model in proposing a limit of 75 pounds for individual household (single-sale) purchases of catfish to be deemed retail purchases; the quantity for non-household consumers would be 150 pounds. FSIS solicits comments on what the limits on retail sales to household or non-household consumers ought to be.

In proposed 9 CFR 532.4, the Agency asserts Federal pre-emption of State or local authority with respect to premises, facilities, and operations at an official establishment, and with respect to labeling, packaging, and ingredient requirements (pursuant to 21 U.S.C. 678).

Finally, in proposed 9 CFR 532.5, FSIS exempts from inspection articles that do not contain a minimum amount of catfish (3 percent raw or 2 percent cooked catfish) or historically are not regarded by consumers as products of

the catfish food products industry per 9 CFR 301.2. The catfish ingredients of the exempt products will have to be FSIS-inspected or inspected under an equivalent foreign system (under 21 U.S.C. 601(j)). Also, the labels of these exempt products cannot represent the products as catfish products. Products exempt from the definition of "catfish product" will be subject to regulation under the FD&C Act.

#### *Facility Requirements for Catfish Inspection*

In proposed part 533, FSIS sets out facility requirements for catfish processing establishments (under 21 U.S.C. 608, 621). To ensure that sanitary operating conditions are maintained, official catfish processing establishments will have to be separate and distinct from any unofficial establishment and separate from any other official establishment, except an establishment preparing products under the FMIA, the Poultry Products Inspection Act (PPIA), or the Egg Products Inspection Act (EPIA) (proposed 9 CFR 533.1). Common areas for inspected and uninspected products may be used if the inspected product is acceptably maintained and protected to prevent product adulteration.

FSIS is proposing to require that official catfish establishments provide office space and furnishings for the exclusive use of the inspector and other Program employees assigned to the establishment (proposed 9 CFR 533.3). This is essentially the same requirement as that applying to establishments that prepare other products under the FMIA. The space set aside for this purpose will have to meet with the approval of Agency supervisors. As the Agency does in the meat inspection program, FSIS will exercise its discretion to determine whether small establishments requiring the services of less than one full-time inspector will not have to furnish Government office space if adequate facilities exist in a nearby location. Each establishment, however, will have to provide laundry service for inspectors' outer work clothing.

Other facilities to be provided by an official establishment include sufficient lighting for the proper conduct of inspection, facilities for performing inspection, receptacles for diseased carcasses and parts, and materials for cleansing and disinfecting hands, for sterilizing instruments used in handling diseased carcasses, and for cleaning and sanitizing floors and other articles or places contaminated by diseased carcasses (proposed 9 CFR 533.4). Establishments will have to provide adequate facilities, including denaturing

materials for the proper disposal of condemned articles, and docks and receiving rooms for receipt and inspection of catfish and catfish products (proposed 9 CFR 533.4).

FSIS approves operating schedules for official meat establishments and is proposing to require such approval for catfish processing establishments (proposed 9 CFR 533.5, referencing 9 CFR 307.4). This is necessary to ensure that the Agency can maintain an inspector presence during establishment operations. The proposed regulations thus define a shift and the basic workweek for Program employees and require each official establishment to submit a work schedule to the District Manager<sup>26</sup> for approval. Under the proposed regulations, each official establishment will be required to maintain a consistent work schedule and, except for minor deviations, will not be allowed to change it without submitting the proposed change to the District Manager at least two weeks in advance. The Agency also is proposing to require that official establishments request inspection service outside the regular workday as far as possible in advance of receiving the service.

FSIS offers overtime and holiday inspection service for a fee. The FSIS regulations list the Federal holidays (9 CFR 307.5, referred to by proposed 9 CFR 533.6) and the terms of overtime and holiday inspection (9 CFR 307.6, referred to by proposed 9 CFR 533.7, and 9 CFR 391.3).

#### *Pre-Harvest and Transport to Processing Establishment*

In proposed 9 CFR part 534 (under 21 U.S.C. 606(b)), FSIS outlines the pre-harvest standards to be applied to catfish to ensure that the environmental conditions and source waters in which the fish are grown will not render the fish unfit for food. The Agency is proposing to require that catfish harvested for human food must not have lived under conditions that would render them unsound, unwholesome, unhealthful, or otherwise unfit for human food (proposed 9 CFR 534.1)—that is, whether the fish would be "adulterated" as the term is defined in 21 U.S.C. 601(m)(3) in the FMIA. The Agency advises catfish producers to monitor the water in which the fish are raised for suspended solids, organic matter, nutrients, heavy metals, antimicrobials, pesticides, fertilizers, and industrial chemicals that may contaminate the fish. FSIS may take

<sup>26</sup> The District Manager, in the current Agency organization, has absorbed functions of the former Area Supervisor, mentioned in 9 CFR 307.4.

samples of fish and water (proposed 9 CFR 534.2) to assess whether the fish are being raised under conditions that will produce safe and wholesome product.

The Agency reminds producers in proposed 9 CFR 534.3 that only certain new animal drugs are legally available for use in raising catfish for human food. Approved drugs and tolerances are listed in the FDA regulations (21 CFR parts 516, subpart E; 520; 524; 526; 529; 556; and 558).

FSIS is proposing general standards for the transportation of catfish to the processing plant (proposed 9 CFR 534.4, under 21 U.S.C. 606(b)). A vehicle used to transport catfish to a processing establishment will need to contain sufficient water and oxygen to ensure that the catfish that arrive at the establishment are not adulterated per 9 CFR 301.2(5) in that they have perished by means other than slaughter. Any catfish that are dead or dying (otherwise than by slaughter), diseased, or contaminated with substances that would adulterate catfish food products are subject to condemnation at the establishment. (See also proposed 9 CFR 555.11 and .12.)

#### *Sanitation and HACCP Requirements for Processing Facilities*

FSIS is proposing (under 21 U.S.C. 608, 621) that catfish processing establishments will have to meet certain basic requirements that parallel those that meat establishments must meet and those that seafood processing establishments are already required to meet under FDA regulations. FSIS is proposing (proposed 9 CFR 537.1) to require that any official establishment that prepares or processes catfish or catfish products for human food comply with the sanitation requirements in 9 CFR 416. These requirements include the sanitation performance standards and the requirement that every official meat (or poultry) establishment have written Sanitation SOPs.

The sanitation performance standards (9 CFR 416.1–416.6) resemble in some ways FDA's current good manufacturing practice regulations for buildings and facilities (21 CFR part 110, subpart B) but provide for continuous FSIS inspection. The sanitation performance standards set forth requirements in terms of an objective to be achieved but do not prescribe the means to achieve the objective. To meet the performance standards, establishments must develop and employ sanitation or processing procedures customized to the nature and volume of their production.

Compliance with FSIS's Sanitation SOP requirement is a condition for

receiving a grant of inspection. FSIS verifies the adequacy and effectiveness of the Sanitation SOPs as part of its inspection (9 CFR 416.17).

Under the proposed rule, catfish establishments will be required to detail, in writing, the procedures that they will carry out to prevent direct contamination or adulteration of product before and during operations (9 CFR 416.12(a)). Each catfish establishment will be responsible for evaluating the effectiveness of its Sanitation SOPs and for revising them as necessary to keep them effective and current with respect to changes in facilities, equipment, utensils, operations, or personnel (9 CFR 416.14).

Under the proposed regulations, catfish establishments will have to conduct the pre-operation procedures in the Sanitation SOPs before the start of operations, conduct all other procedures in the Sanitation SOPs at the frequencies specified, and monitor the daily implementation of the procedures in the Sanitation SOPs (9 CFR 416.13). Establishments will be responsible for taking and required to take appropriate corrective action when the Sanitation SOPs have failed to prevent direct contamination or adulteration of product as detailed in 9 CFR 416.15(a). Corrective actions include procedures to ensure the appropriate disposition of product that may be contaminated, to restore sanitary conditions, and to prevent the recurrence of direct contamination or adulteration of product. Corrective actions may also need to include reevaluating and modifying the Sanitation SOPs or improving their execution (9 CFR 416.15(b)).

If this proposed rule is adopted, each catfish establishment will be required to maintain a daily record of the actions it takes that are prescribed in the Sanitation SOPs and to make such records available to Program employees for inspection and verification (9 CFR 416.16(a) and (c)). The establishment will be required, at a minimum, to record deviations from the Sanitation SOPs, along with corrective actions taken—including procedures to prevent the direct contamination or adulteration of products—in conjunction with the monitoring of daily sanitation activities.

The establishments will also be responsible for complying and will have to comply with the HACCP requirements (proposed 9 CFR 537.1(a)(1) cross-referencing to 9 CFR part 417; issued under 21 U.S.C. 601(m)(1), 601(m)(3), 601(m)(4), 602, 608, and 621). These requirements are similar to the FDA requirements for processors of fish or fishery products

(21 CFR 123.6–123.10). The FSIS regulations include requirements that implement the principles of HACCP—hazard analysis, supporting documentation, decision-making documents, critical control points, critical limits, monitoring, corrective actions, verification, and recordkeeping (9 CFR 417.1 to 417.5)—and require a HACCP-trained individual to perform certain key functions (9 CFR 417.7). The FSIS regulations also define an inadequate HACCP system (9 CFR 417.6); they require a review, preferably by a HACCP-trained individual, of records associated with the production of a product before the product is shipped (“pre-shipment review”) (9 CFR 417.5(c)); and, of course, they provide for Agency verification of HACCP plan adequacy (9 CFR 417.8).

The Agency's verification includes a review of the HACCP plan to determine that it meets regulatory requirements; a review of Critical Control Point CCP records; a review and determination of the adequacy of corrective actions taken when there is a deviation from a critical limit; a review of the critical limits; review of other records pertaining to the HACCP plan or system; direct observation or measurement at a CCP; sample collection and analysis to determine whether the product meets all regulatory requirements respecting biological, chemical, or physical hazards; and on-site observations and records review (9 CFR 417.8). The frequency of FSIS verification activities will vary, depending on a number of factors, such as the establishment's past performance, risk inherent in the processes or products, quantity of product, and likely uses.

FSIS is proposing, under 21 U.S.C. 606(b), to require that a catfish establishment's hazard analysis take into account the hazards that can occur before, during, and after the harvest of catfish (proposed 9 CFR 537.2). Moreover, FSIS provides that catfish products not produced under a hazard analysis and HACCP plan that fully complies with the regulations will be adulterated under the FMIA because they will have been prepared and packed under insanitary conditions that may render them injurious to health (9 CFR 537.2(b)).

#### *Mandatory Dispositions; Performance Standards Respecting Physical, Chemical, or Biological Contaminants*

In proposed 9 CFR part 539, FSIS lists the diseases or other conditions that would lead to condemnation of catfish carcasses or parts affected upon inspection (under 21 U.S.C. 606). Both zoonotic and non-zoonotic diseases are

included because FSIS is required to ensure that the food products it regulates are not adulterated either for food safety reasons, or because they are unwholesome or otherwise unfit for human food. Catfish and catfish products affected by these diseases or conditions would be adulterated under 21 U.S.C. 601(m)(3) in that they are unsound, unwholesome, or otherwise unfit for human food.

The Agency intends to condemn, as unwholesome or unfit for human food, carcasses or parts of catfish whose tissues are affected by abscesses or lesions, and catfish tissues affected by non-zoonotic parasites such as cestodes, or by such parasites as digenean trematodes, metacercaria (*Bolbophorus* spp.), yellow grubs (*Clinostomum* spp.), or white grubs (*Hysterbomorpha* spp.). FSIS also intends to condemn catfish affected by Heterophyid intestinal flukes or *Dictyophmatidae* nematodes, columnaris (infection by *Flexibacter columnaris*), or enteric septicemia of catfish (ESC) (proposed 9 CFR 539.1). The Agency will condemn catfish carcasses, parts, or catfish products found to be in a state of spoilage or decomposition or that are otherwise unwholesome. FSIS requests comments on what extent of columnaris or other infection should result in condemnation and on whether there are other conditions found in catfish that require such disposition.

Under proposed 9 CFR 539.2, catfish and catfish products that are contaminated with physical matter will be subject to retention by Program employees. Also, any antibiotic or other drug residues or pesticide residues in catfish tissues will have to be within applicable tolerances in the FDA or Environmental Protection Agency regulations (21 CFR part 556; 40 CFR part 180).<sup>27</sup> The FSIS National Residue Program determines whether there are violative concentrations of drug or other chemical residues in the products the Agency regulates.<sup>28</sup> Catfish or catfish products containing violative residues will not be eligible to bear the mark of inspection because FSIS could not find them to be not adulterated under 21 U.S.C. 601(m)(2)(A). The products will be subject to condemnation. The residue

standards will apply to imported as well as domestic catfish and catfish products.

With respect to microbiological contamination, FSIS plans to implement a pathogen reduction program for catfish that would be similar to that for other classes of raw product subject to the FMIA. After completing a study to determine the national baseline prevalence and levels of *Salmonella* on raw catfish, FSIS will conduct regular testing in processing establishments for the purpose of measuring industry performance against the baseline.

#### *Handling and Disposal of Condemned and Inedible Materials*

FSIS is proposing to require that a processor prevent catfish that have died otherwise than by slaughter from entering the official establishment (under 21 U.S.C. 601(m)(3), 601(m)(4), 608, 621, 644) (proposed 9 CFR 540.1(a)). The establishment will have to maintain physical separation between slaughtered catfish and those that have died otherwise than by slaughter (proposed 9 CFR 540.1(b)) to prevent commingling of edible and inedible product. All condemned or otherwise inedible catfish parts will have to be conveyed from the official premises for further disposition at a rendering plant or other facility that handles inedible products (proposed 9 CFR 540.3).

#### *Marks, Marking, and Labeling of Products and Containers*

##### Official Marks and Devices

FSIS is proposing (under 21 U.S.C. 601(n)(12), 601(s)–(v), 606, 611) to use certain official marks, devices, and certificates for the purpose of identifying inspected and passed catfish and catfish products and their status. FSIS is proposing to provide that an official inspection legend containing the number of the official establishment be shown on all labels of inspected and passed product (9 CFR 541.2(a)). The form of the official legend will be that for meat products (9 CFR 312.2(b)(1)), reproduced in proposed 9 CFR 541.2), or another form that the Agency would prescribe. Comments and suggestions on what an alternative form might be are welcome.

FSIS is proposing to require that whole, gutted catfish carcasses that have been inspected and passed at an official establishment, and that are intended for sale as whole, gutted catfish, be marked or labeled with an official inspection legend containing the number of the establishment at the time of inspection (proposed 9 CFR 541.2(d)). The form of the inspection legend will be that in 9 CFR 312.2(a) and as illustrated in

proposed 9 CFR 541.2(d) or as otherwise determined by the FSIS Administrator. The marking must ensure that the catfish will be identified as having been inspected and will not become misbranded while in commerce. Comments are welcome on whether marking is necessary, the form of the mark that would be satisfactory, and how the mark should be applied.

In proposed 9 CFR 541.3, FSIS is providing that the official mark used in sealing railroad cars, cargo containers, or other transport conveyances, as prescribed in proposed 9 CFR part 555, be in the form of the inscription and serial number shown in 9 CFR 312.5 or in another form approved by FSIS. The Agency-approved seal will be an official device under the FMIA. The seal will have to be attached to the means of conveyance by an Agency employee.

FSIS is also proposing (proposed 9 CFR 541.4) that the official export inspection mark for catfish (*see* proposed 9 CFR part 552) be that specified in 9 CFR 312.8(a), and that the export certificate for catfish and catfish products be the same as that prescribed in 9 CFR 312.8(b) for meat and meat food products.

FSIS also is proposing (proposed 9 CFR 541.5) that the official mark for shipments of articles and catfish that are officially detained be the designation “U.S. Detained.” The device for applying the mark would be the same “U.S. Detained” tag that FSIS uses for detained meat articles.

#### *Labeling Requirements; Prior Approval of Labeling*

FSIS is proposing (proposed 9 CFR 541.7) to apply to catfish and catfish products many of the same labeling and label approval requirements as those for meat and meat food products in 9 CFR 317, Subpart A, except where those regulations apply specifically, or could only apply, to meat or meat food products (under 21 U.S.C. 607). The requirements that FSIS is proposing to apply to catfish address labels and labeling, the abbreviations of official marks, label approval, generically approved labeling, the use of approved labels, the labeling of products for foreign commerce, prohibited practices, the reuse of official inspection marks, filling of containers, relabeling of products, the storage and distribution of labels, and the requirements for packaging materials.

Under this proposal, the basic requirements for a label (most, in 9 CFR 317.2) will be similar in a number of respects to those that FDA requires for the label of food products under its jurisdiction. Unlike FDA, however, FSIS

<sup>27</sup> FSIS notes, in addition, that the FDA Compliance Policy Guide, Section 575.100, Pesticide Chemicals in Food—Enforcement Criteria, lists action levels for banned but persistent chlorinated pesticides. Most pesticides detected in catfish are listed in this guidance.

<sup>28</sup> The program is explained at: <http://www.fsis.usda.gov/Science/Chemistry/index.asp> (Accessed 10/29/2008.)

requires that the label bear the official inspection legend. Also, unlike FDA, FSIS forbids any final labeling from being used on any product unless the sketch of the final labeling has been approved by the Agency.

Another requirement that differs from the FDA requirements is the requirement for safe-handling labeling (9 CFR 317.2(l)) on products that are not ready-to-eat, that is, products that are raw or that undergo minimal treatment, such as heating, before being consumed. FSIS is proposing to require that safe-handling instructions appear on the label of every not-ready-to-eat catfish product that is destined for household consumers, hotels, restaurants, or similar institutions.

#### *Generically Approved Labeling*

Under this proposed rule, processors of catfish and catfish products will be able to use generically approved labeling if the labeling meets the conditions for such labeling in 9 CFR 317.5. Generically approved labeling usually involves minor modifications of labeling that has been approved by FSIS.

#### *Prevention of False or Misleading Labeling Practices*

Under the FSIS regulations, no product or any of its wrappers, packaging, or other containers may bear any false or misleading marking, label, or other labeling, and no statement, word, picture, design, or device that conveys any false impression or gives any false indication of origin or quality or that is otherwise false or misleading may appear in any marking or other labeling. No product may be enclosed wholly or partly in any wrapper, packaging, or other container that is made, formed, or filled in a manner that would make it misleading. (9 CFR 317.8.)

To prevent the misuse of labeling, FSIS enforces regulations controlling the conditions under which product may be relabeled at a location other than an official establishment (9 CFR 317.12). The Agency also regulates the conditions under which labels, wrappers, or containers bearing official marks may be transported from one official establishment to another official establishment (9 CFR 317.13). All these requirements, which apply to meat and meat food products, will apply to catfish and catfish products under this proposed rule.

A major challenge to the identification of processed fish products is the inability to visually identify the species of fish after processing. Because of the interest of the catfish products

industry and consumers in ensuring that product labeling correctly represents the actual species of fish in the product, FSIS is considering the use of various technological means to verify catfish species. There is available chemical taxonomic information consisting of species-characteristic biochemical patterns that may be compared quantitatively to patterns obtained by an appropriate laboratory analysis of the fish in question. These patterns include data from isoelectric focusing (IEF), a type of electrophoresis, and restriction fragment length polymorphism (RFLP) studies. RFLP is a technique in which organisms may be differentiated by analysis of patterns derived from cleavage of their DNA. If two organisms differ in the distance between sites of cleavage of a particular restriction endonuclease, the length of the fragments produced will differ when the DNA is digested with a restriction enzyme. The similarity of the patterns generated can be used to differentiate species (and even strains) from one another.

In recent years, interest in another technique, known as “DNA bar coding,” has been growing. It involves the DNA sequencing of mitochondrial gene cytochrome c oxidase I (COI) in seafood tissue samples to obtain unique, species-specific identifications, or “barcodes.” The method is considered robust and sensitive to small phylogenetic differences. FDA has been considering it as a replacement for IEF as that agency’s standard for species identification and FSIS is considering this approach as well. FSIS welcomes comment and suggestions on species verification methods that the Agency might use.

#### *Net Weight and Retained Water*

FSIS labeling regulations on net weight of meat products incorporate by reference Handbook 133 of the National Institute of Standards and Technology (NIST). These regulations include provisions for determining compliance with net weight requirements and prescribe the reasonable variations from the declared net weight on the labels of immediate containers of products (9 CFR 317.18–317.22). To ensure that there is compliance, the regulations prescribe requirements for scales to determine accurate weights and for the testing of scales (9 CFR 317.20–317.21).

FSIS has learned from FDA and industry sources that catfish presents a specific challenge regarding net weight because of the frequent and varying use of glazing. (A glaze is a thin coating of ice on a catfish or catfish product that is intended to preserve the freshness of

the product.) To regulate net weight for raw catfish products, FSIS is proposing to apply to raw catfish the requirements for control of retained water from processing in raw meat and poultry products through 9 CFR part 441 (referenced in proposed 9 CFR 541.7(b)), slightly amended to include raw catfish and catfish products. Retained water—water remaining in raw product after it undergoes immersion chilling or a similar process—will not be permitted unless the official establishment is able to show, with data collected under a written protocol, that the retained water is an unavoidable consequence of the process used to meet applicable food-safety requirements (9 CFR 441.10(a)). The establishment will have to label its products to state, besides net weight, the maximum percentage of water retained in the product from such processing as chilling (e.g., up to X% retained water, less than X% water retained from chilling). The protocol, to be maintained in the establishment’s files, will have to explain how data will be collected and used to demonstrate that the amount of retained water in the product covered by the protocol is an unavoidable consequence of the process used to meet specified food-safety requirements. The establishment will have to notify FSIS as soon as it has a new or revised protocol (9 CFR 441.10(c)). Expected elements of the protocol are given in the regulations (9 CFR 441.10(d)).

FSIS also is proposing to apply to catfish and catfish products the requirements in part 442, subchapter E, governing quantity of contents labeling, the testing of scales, and the handling of product that is found to be out of compliance with net weight requirements (referenced in proposed 9 CFR 541.7(b)).

FSIS is proposing, in particular, that packages of fresh or fresh-frozen catfish carcasses or parts be labeled to reflect 100-percent net weight (gross weight less the weight of glaze) after thawing. The de-glazed net weight must average 100 percent of the stated net weight of the frozen product when sampled and weighed according to the method prescribed in NIST Handbook 133 Chapter 2, Section 2.6.<sup>29</sup> Interested persons may want to consult NIST Handbook 133 for maximum allowable variations.

#### *Nutrition Labeling Requirements*

Under the FMIA (21 U.S.C. 601(n)(1), 621), FSIS is proposing to apply the nutrition labeling requirements to

<sup>29</sup> U.S. Department of Commerce. NIST Handbook 133: Checking the Net Contents of Packaged Goods, Fourth Edition, January 2005. Washington, DC.

catfish and catfish products that are not raw, single-ingredient products (proposed 9 CFR 541.7(d)). The FSIS requirements for meat and meat food products (9 CFR 317.300–317.500) are similar to FDA's (21 CFR 101.9 *et seq.*) in that a nutrition facts panel has to appear on the label. The FSIS nutrition facts panel includes information on serving size, servings per container, amount of calories per serving, and calories from fat. Also the panel includes amount and percent daily value of total fat and saturated fat, cholesterol, sodium, total carbohydrates, dietary fiber, sugar, and protein, as well as information on percent daily intake of vitamins and minerals. Processors may provide additional nutritional labeling that is not false or misleading.

#### *Food Ingredients Permitted*

FSIS is proposing to apply to catfish products requirements in 9 CFR part 424 prohibiting a product from bearing or containing any food ingredient that would render it adulterated or misbranded under 21 U.S.C. 601(m)(2)(C) (proposed 9 CFR part 544). This prohibition is consistent with the current regulation of catfish products under the FD&C Act.

Few further-processed catfish products are produced domestically; however, FSIS is aware of the use in some fresh-frozen catfish of sodium tripolyphosphate and other sodium phosphates as humectants. Also, marinade solutions and breading ingredients are used in the preparation of some catfish products. FDA has approved these various ingredients for uses that include catfish products or has determined them to be Generally Recognized As Safe (GRAS) for these uses.

Under the FMIA, establishments will only be able to prepare a further-processed catfish product when the establishment is under inspection by an FSIS inspection program employee. Under 21 U.S.C. 601, 606, and 608, preparation of edible product will have to be carried out in compliance with the sanitary and other requirements in the regulations (proposed 9 CFR 548.1(a)).

Under this proposed rule, FSIS will make determinations on the safety and suitability of uses of food ingredients in catfish products in consultation and coordination with FDA, as it does for all food ingredients. FSIS will compile safe and suitable uses, including limits and conditions of use, of food ingredients in these products and make the information available in an instruction to its inspection force, FSIS Directive 7120.1. This directive is regularly updated and published on the Agency's

Web site at: [http://www.fsis.usda.gov/Regulations\\_Policies/7000\\_Series-Processed\\_Products/index.asp](http://www.fsis.usda.gov/Regulations_Policies/7000_Series-Processed_Products/index.asp) (accessed Feb. 15, 2011).

#### *Ready-to-Eat and Canned Catfish Products: Control of Listeria Monocytogenes*

Only a few ready-to-eat (RTE) catfish products, such as smoked catfish, are distributed in commerce. Under this proposed rule, these products will have to comply with appropriate performance standards, as must all RTE meat and poultry products if they are not to be considered adulterated under either the FMIA (21 U.S.C. 601(m)) or the PPIA (21 U.S.C. 453(g)). Any pathogen on an RTE product adulterates the product because RTE products are likely not to be cooked before consumption. Currently, there are requirements for the control of *Listeria monocytogenes* in RTE products that are exposed to the processing environment after undergoing a process that is lethal to *L. monocytogenes*. FSIS is proposing to make post-lethality-exposed catfish products subject to these requirements (proposed 9 CFR 548.6, referencing 9 CFR part 430).

An RTE product is adulterated if it contains *L. monocytogenes*, or if it comes into direct contact with a food-contact surface that is contaminated with *L. monocytogenes* because it is likely to be consumed without further processing such as cooking. An RTE catfish product, as well as an RTE meat or poultry product, would be adulterated in either of these situations.

#### *Canned Products*

FSIS is not aware of any canned catfish products that are processed in the United States for human consumption, but canned catfish soups are imported into this country. Under this proposed rule, any domestic canned catfish products that an official establishment manufactures will be subject to requirements similar to those for canning and canned meat products (proposed 9 CFR 548.6, cross-referencing to 9 CFR part 318, subpart G (§§ 318.300–318.311)). Domestic canned fish products currently are subject to FDA requirements for low-acid canned foods (21 CFR 113) and imported canned products are subject to equivalency requirements for process filing (21 CFR 108.35). Under the proposed rule, imported canned catfish products will have to be produced under requirements that are equivalent to those that would apply to domestic products.

#### *Accredited Laboratories*

Under this proposed rule, FSIS will allow catfish processing establishments to use third-party accredited laboratories instead of an FSIS laboratory to analyze official regulatory samples for residues (proposed 9 CFR 548.9). This practice has been allowed so as to provide an option for establishments of receiving, at their own expense, sample results more quickly than would be the case with the limited laboratory capacity of FSIS. An establishment that holds sampled product until the receipt of test results might be especially interested in the availability of accredited laboratory services. Use of an accredited laboratory would always be at the establishment's discretion, and the establishment would have to pay for the service. The requirements for laboratory accreditation are in 9 CFR part 439, subchapter E.

FSIS is proposing to bring catfish within the coverage of the accredited laboratory program for species identification—which would be a new program service—as well as for residue detection. The Agency would amend the accredited laboratory regulations as necessary to include species identification methods in the program.

#### *Standards of Identity and Composition*

FSIS may promulgate standards of composition for catfish products composed of more than one ingredient. A standard of composition prescribes the minimum amount of catfish for a product to be called by a name that asserts that it was made with catfish. The Agency also may prescribe standards of identity for catfish products. A standard of identity prescribes the specific ingredients or components, and relative amounts, in a product that are necessary to meet consumer expectations for the product. However, there is at present only a relatively small number of commercially distributed catfish products, and FSIS is not aware of any product identity issues requiring a regulatory intervention.

Comments are welcome on whether the Agency should promulgate any standards of identity or composition in this rulemaking. This issue is separate from the basic product identity issue of what species of fish or catfish is actually in a product.

#### *Exports*

FSIS is proposing (proposed 9 CFR 552, cross-referencing provisions of 9 CFR 322) to adopt requirements for exported catfish and catfish products that are similar to those that apply to

meat articles under 9 CFR 322 (issued under 21 U.S.C. 615–616). Some of the meat regulations, e.g., those addressing the transport of lard or tallow, are not applicable to catfish. The Agency is proposing to require that the outside container of any inspected and passed catfish product for export, with certain exceptions, bear an official export stamp, as depicted in the regulations (9 CFR 312.8), that includes the number of the export certificate. Under this proposal, the FSIS inspector in charge at the official catfish establishment will be authorized to issue official export certificates for shipments of inspected and passed product to any foreign country. FSIS will expect that the certificates will be issued at the time the products leave the official establishment. The certificates could be issued at a later time only after identification and reinspection of the products. Under the proposal, the certification will have to show the names of the exporter and consignee, the destination, the number and types of packages, the shipping marks, the kinds of products, and the weight of the products.

#### *Transportation in Commerce*

The FMIA gives FSIS the authority to regulate amenable products in commerce (21 U.S.C. 602). Since, under the FMIA and this proposal, catfish and catfish products are amenable to inspection, no person may sell, transport, offer for sale or transportation, or receive for transportation, in commerce, any catfish or catfish product that is capable of use as human food if it is adulterated, misbranded, or does not bear an official inspection legend at the time of such sale, transportation, offer, or receipt (21 U.S.C. 610(c)).

Under the authority in 21 U.S.C. 610 and 621, FSIS is proposing (proposed 9 CFR 555.1) to require that any catfish product capable of use as human food that is to be transported in commerce be properly handled and maintained to ensure that it is not adulterated and is properly marked and labeled. A transport conveyance intended to carry catfish products will be subject to FSIS inspection to determine its sanitary condition. A transport conveyance that is insanitary may cause contamination of catfish products and thus may not be used until the insanitary conditions are corrected. Under these proposed regulations, products on an insanitary vehicle must be removed and either handled in accordance with the regulations on mandatory dispositions or on the handling of condemned and

inedible materials (proposed 9 CFR 539 or 540).

FSIS has tentatively determined that other regulations on the transportation of meat and meat food products (in 9 CFR part 325) are appropriate for the transportation of catfish products (proposed 9 CFR 555.3–555.8). These proposed regulations address: The transportation of unmarked, inspected product under FSIS affixed-seal; product that may have become adulterated in transit or storage; inedible products; the filing of original certificates for unmarked inspected products; and the unloading of any catfish product from an officially sealed conveyance or loading after the conveyance has left the official establishment. These regulations would serve to prevent the diversion of adulterated catfish and catfish products into food channels (proposed 9 CFR 555.9).

#### *Imported Products*

The FMIA prohibits the importation of carcasses, parts, meat, or meat food products of amenable species if these articles are adulterated or misbranded, and unless they comply with all the inspection, building, construction standards, and other provisions of the FMIA and regulations applicable to the products (21 U.S.C. 620). FSIS enforces this provision through random inspection for species verification and for residues, and through the random sampling and testing of the tissues of amenable species by the exporting country.

Each foreign country from which products of amenable species are offered for importation into the United States must obtain a certification from FSIS stating that the country maintains a program using reliable analytical methods to ensure compliance with U.S. standards for residues in those products. FSIS periodically reviews the certifications and revokes any certification if the Agency determines that the country involved is not maintaining a program that uses reliable analytical methods to ensure compliance with U.S. standards for residues in the products it exports. In considering any application for certification, FSIS takes into account inspection at individual establishments in order to ensure that the foreign country's inspection program is meeting the United States standards (21 U.S.C. 620(f)).

As mentioned previously, under the FMIA, as amended by the 2008 Farm Bill, the provisions governing imports apply to catfish and catfish products. FSIS is proposing to apply the

requirements for the inspection of imported meat products (21 U.S.C. 620) to the inspection of imported catfish products (9 CFR part 557, referencing 9 CFR part 327). FSIS must find that a foreign inspection system ensures compliance of processing establishments and catfish products with requirements that are equivalent to the inspection and other requirements of the FMIA and the regulations that implement it that apply to official catfish establishments in the United States. When the Agency determines that a foreign country's inspection system for catfish and catfish products is equivalent to that operated by FSIS, the Agency will give notice of that fact (in the **Federal Register**) and will list the name of the country in the regulations (in proposed 9 CFR 557.2(b)).

#### *Demonstrating Equivalence of Foreign Systems*

FSIS is proposing that countries demonstrate the equivalence of their inspection system to the U.S. system, in the following respects:

(1) *Program administration.* Under proposed 9 CFR 557.2 (under 21 U.S.C. 620(a)), as must foreign programs for other species under the FMIA, the foreign program for catfish will have to be staffed in a way that will ensure uniform enforcement of the laws and regulations. Ultimate control and supervision must rest with the national government or employees of the system (9 CFR 327.2(a)(2)(i)(B)). Qualified, competent inspectors must be assigned (9 CFR 327.2(a)(2)(i)(C)). National inspection officials must have the authority to enforce requisite laws and regulations and certify or refuse to certify products intended for export (9 CFR 327.2(a)(2)(i)(D)). There must be adequate administrative and technical support and inspection, sanitation, quality, and species verification, residue standards, and other regulatory requirements that are equivalent to those of the United States (9 CFR 327.2(a)(2)(i)(E)–(G)).

(2) *Legal authority and requirements governing catfish and catfish products inspection.* To be considered eligible to export catfish products to the United States, foreign countries will have to enforce laws and regulations that address the conditions under which catfish are raised and transported to the processing establishment (9 CFR 327.2(a)(2)(ii)(I); 21 U.S.C. 606(b), 620(a); proposed 9 CFR 557.3). FSIS recognizes that in some countries, in addition to having fish ponds like those in the United States, catfish producers use floating cages on rivers and

“raceway ponds” that are filled and emptied by the continuous flow of water from nearby rivers. Under this proposed rule, the water quality, residue, and other standards applying in these catfish-raising situations will have to be equivalent to those applying to catfish raised in the United States.

Also, eligible foreign countries will have to establish standards for, and maintain continuous official supervision of, preparation and processing of product to ensure that adulterated or misbranded product is not prepared for export to the United States (9 CFR 327.2(a)(ii)(D)). A single standard of inspection and sanitation will need to be maintained throughout all certified establishments (9 CFR 327.2(a)(ii)(E)). The country’s requirements will need to address sanitary handling of product and provide for official controls over condemned material; a HACCP system equivalent to that set forth in 9 CFR part 417; and other applicable controls under the FMIA or implementing regulations (9 CFR 327.2(a)(2)(ii)(F)–(I)).

(3) *Document evaluation and system review.* Foreign countries seeking eligibility to export catfish and catfish products into the United States (proposed 9 CFR 557.2(a)), under 21 U.S.C. 620) will also have to present to FSIS copies of laws, regulations, and other information pertaining to their systems of catfish products inspection, just as countries now do when they seek eligibility to export products of other species amenable to the FMIA. FSIS will make a determination of eligibility on the basis of a study of these documents and an on-site visit to the country of the system in operation by FSIS. FSIS will also conduct periodic reviews of foreign catfish products inspection systems to determine their continued eligibility (9 CFR 327.2(a)(3)).

(4) *Maintenance of standards.* In addition, countries seeking eligibility to export catfish and catfish products into the United States will have to provide for periodic supervisory visits to certified establishments to ensure that U.S. requirements are being met and for written reports on the supervisory visits (proposed 9 CFR 557.2, under 21 U.S.C. 620). The reports will have to be available to FSIS. The foreign program will have to conduct random sampling of catfish tissues and the testing of the tissues for residues identified by FSIS or by the foreign inspection authority as potential contaminants, in accordance with FSIS-approved sampling and analytical methods (9 CFR 327.2(a)(2)(iv)(C)). The residue testing will have to be conducted on samples

from catfish intended for export to the United States.

Under this proposal, only certified foreign catfish establishments will be eligible to export their catfish products to the United States. However, if a foreign establishment is not in compliance with U.S. requirements for imported products, FSIS will terminate the eligibility of the establishment. FSIS will provide reasonable notice to the foreign government of the proposed termination of eligibility, unless delay in notification could result in the importation of adulterated or misbranded product. (9 CFR 327.2(a)(3).)

#### *Marking and Labeling of Imported Products*

The proposed regulations (proposed 9 CFR 557.14 and 557.15, under 21 U.S.C. 620) will apply to catfish and catfish products the requirements in 9 CFR 327.14 and 327.15 for the marking of catfish and catfish products and the labeling of immediate and outside containers of product that is imported. An imported catfish product will have to be marked “product of [country of origin]” under multiple authorities (7 CFR part 60, under 7 U.S.C. 1638a(a)(3)), proposed 9 CFR 541.7, and 9 CFR 317.9(b)(9)(xxv), 317.8(b)(40), under 21 U.S.C. 607, 620, 621).

#### *2. Proposed Regulations Under Other FMIA Subchapters*

##### *Rules of Practice; Reference To Rules of Practice*

FSIS is proposing to apply its rules of practice (9 CFR part 500, under 21 U.S.C. 601, 606, 608, 610, 621, and 671)) in enforcing the proposed catfish inspection regulations (proposed 9 CFR 561.1). Also, FSIS is proposing to provide establishments with an opportunity for presentation of views (proposed 9 CFR 561.2, referencing 9 CFR part 335) before reporting violations to the Department of Justice for criminal prosecution. The procedure to be followed in a case relating to catfish and catfish products inspection would be the same as that followed in a case relating to meat and meat food products inspection. FSIS uses its rules of practice for enforcement processes that may lead to such actions as withholding (refusing to allow the mark of inspection to be applied to product) or suspension (withdrawing inspection program employees from a facility) of inspection. The USDA uniform rules of practice (7 CFR 1.130–1.151) apply in actions commenced pursuant to section 401 of the FMIA (21 U.S.C. 671). Establishment management has a right

to appeal enforcement decisions made by inspection program personnel (9 CFR 306.5).

#### *Detention, Seizure, Condemnation*

##### *Detention*

Under this proposal, FSIS will exercise its detention authority under the FMIA upon finding that catfish or catfish products in commerce are adulterated, misbranded, or otherwise in violation of the Act or regulatory requirements (21 U.S.C. 672, proposed 9 CFR 559.1, 9 CFR 329.1–329.6). The FMIA authorizes detentions if the Secretary has reason to believe that the article is adulterated or misbranded and is capable of use as human food, or that it has not been inspected in violation of the FMIA or of any other Federal or State law.

Detained product may not be further distributed or sold to consumers. Detained product is either appropriately disposed of by the product owner, agent, or custodian (*e.g.*, through voluntary destruction, by personal use, donation, or other FSIS-acceptable option), or FSIS initiates an action to seize the product.

##### *Seizure and Condemnation*

When detained product is not destroyed or properly disposed of, it is subject to seizure and condemnation by a U.S. District Court under Section 403 of the FMIA (21 U.S.C. 673). FSIS is proposing to apply the provisions for seizure and condemnation in the meat regulations (9 CFR 329.7–329.9) to catfish (proposed 9 CFR 559.2). The regulations also address criminal offenses addressed in Sections 22 and 405 of the FMIA (21 U.S.C. 622, 675), such as bribery of Program employees, receipt of gifts by Program employees, and assaults on, or other interference with, Program employees while engaged in, or on account of, the performance of their official duties under the Act.

##### *Records Required To Be Kept*

FSIS is proposing (under 21 U.S.C. 642(b)) to require persons involved in processing, buying and selling, or rendering catfish or catfish products to keep records on their activities respecting catfish sold, transported, offered for sale or transport, in commerce. Under this proposal, the classes of records they will be required to keep include sales records or invoices, shippers’ certificates and required permits, records of seal numbers used in the sealed transport of inedible products, guaranties provided by suppliers of packaging materials, canning records as required by 9 CFR

part 318, subpart G, nutrition labeling records, and records of all labeling, along with the formulation and processing procedures (proposed 9 CFR 550.1).

Under this proposal, persons subject to these requirements will have to keep the records and maintain them at the place where the business generating the records is conducted. In the case where one person or firm conducts catfish operations at several establishments or locations, the records could be kept at a headquarters office (proposed 9 CFR 550.2). The Agency is proposing to require the records be retained for a period of 2 years after December 31 of the year in which the transaction to which the record relates occurred (proposed 9 CFR 550.3).

Canning records will have to be maintained in accordance with current requirements for records of the canning of meat food products. Processing and production records would have to be retained for at least 1 year at the canning establishment and for an additional 2 years at the establishment or other location from which the records could be made available to authorized FSIS employees (proposed 9 CFR 550.3, 9 CFR 318.307(e)). Records of scheduled processes will have to be maintained on file at the processing establishment and available to Program employees (proposed 9 CFR 550.3, 9 CFR 318.302).

Authorized representatives of the Secretary will have to be afforded access to the businesses that would be subject to the recordkeeping requirements (under 21 U.S.C. 642(a)). They will have to be afforded any necessary facilities, except reproduction equipment, for the examination and copying of records and

for the examination and sampling of inventory (proposed 9 CFR 550.4).

Persons and firms covered by the recordkeeping requirements will have to register with the FSIS Administrator using a form obtained from the Agency (proposed 9 CFR 550.5). FSIS is asking for comment on a proposed time frame for completion of this registration under "Proposed Phasing of Implementation". This registration requirement will apply to farms and transporters that supply catfish to official processing establishments and will enable FSIS to conduct sampling and other activities as necessary to account for the conditions under which catfish are raised and transported to the processing establishment (under 21 U.S.C. 606(b)). The registration would have to be updated whenever a change is made in the name, address, or trade name under which the registrant operates. These registration requirements would not apply, however, to any person conducting business only at an official establishment (proposed 9 CFR 550.5(c)). This registration requirement is similar to that with which food establishments must already comply under FDA regulations.

FSIS will require each official establishment to provide accurate information to FSIS employees so that they can report on the amount of products prepared or handled in the establishment, and on sanitation, microbiological testing, and other aspects of the establishment's operations. FSIS is proposing that the operator of each establishment report quarterly on the number of pounds of catfish processed. The report would have to be filed within 15 days after the

end of each quarter. The establishment operator also will have to file other reports as FSIS might require from time to time under the FMIA (proposed 9 CFR 550.6.) FSIS notes that production data from individual establishments is protected from disclosure under the Freedom of Information Act. The Agency releases only aggregate data for reporting purposes.

Finally, FSIS is proposing to require that a consignee who refuses delivery of a product bearing the mark of inspection because the product is adulterated or misbranded notify the Inspector-in-Charge of the kind, quantity, source, and present location of the product. The consignee also will have to report on the respects in which the product is adulterated or misbranded. Movement of the product, except back to the official establishment from where it came, is prohibited (proposed 9 CFR 550.7), and if the product moves back to the originating establishment, the use of seals, documentation, or other conditions applies.

*Summary of Proposed Regulations*

In general, FSIS has attempted to apply to catfish and catfish inspection, with some modifications, the regulations governing the inspection of other species under the FMIA. In many cases the proposed regulations merely cross-reference the existing regulations for meat and meat food products. The accompanying table shows how the catfish regulations in proposed Subchapter F correspond to the meat inspection regulations in Subchapter A (9 CFR parts 300–335) or Subchapter E (9 CFR parts 416, 417, 424, 439, 441, 442).

TABLE 5—RELATIONSHIP BETWEEN CATFISH AND CATFISH PRODUCT INSPECTION REGULATIONS IN SUBCHAPTER F AND MEAT INSPECTION REGULATIONS IN SUBCHAPTER A OR SUBCHAPTER E

Subject	Subchapter F designation	Corresponding Subchapter A or E part or section reference
GENERAL REQUIREMENTS; DEFINITIONS	PART 530	Part 300.
General	§ 530.1	§ 300.1, § 300.2.
FSIS organization for inspection of catfish and catfish products	§ 530.2	§ 300.3.
Access to establishments	§ 530.3	§ 300.6.
DEFINITIONS	PART 531	Part 301.
Definitions	§ 531.1	§ 303.1.
REQUIREMENTS FOR INSPECTION	PART 532	Part 302, Part 304, Part 305.
Establishments requiring inspection; other inspection	§ 532.1	§ 302.1.
Application for inspection, etc.	§ 532.2	§ 304.1, § 304.2, § 304.3.
Exemption of retail operations	§ 532.3	§ 303.1.
Inspection at official establishments; relation to other authorities	§ 532.4	§ 302.2.
Exemption from definition of catfish product of certain human food products containing catfish.	§ 532.5.	
SEPARATION OF ESTABLISHMENT; FACILITIES FOR INSPECTION	PART 533	Part 305, Part 306, Part 307.
Separation of establishments	§ 533.1	§ 305.2.
Facilities for Program employees	§ 533.3	§ 307.1.
Other facilities and conditions to be provided	§ 533.4	§ 307.2.
Schedule of operations	§ 533.5	§ 307.4.
Overtime and holiday inspection service	§ 533.6	§ 307.5.
Basis of billing for overtime and holiday services	§ 533.7	§ 307.6.



TABLE 5—RELATIONSHIP BETWEEN CATFISH AND CATFISH PRODUCT INSPECTION REGULATIONS IN SUBCHAPTER F AND MEAT INSPECTION REGULATIONS IN SUBCHAPTER A OR SUBCHAPTER E—Continued

Subject	Subchapter F designation	Corresponding Subchapter A or E part or section reference
PRE-HARVEST STANDARDS AND TRANSPORTATION TO PROCESSING ESTABLISHMENT.	PART 534.	
General	§ 534.1.	
Water quality for food fish	§ 534.2.	
Standards for use of drugs and other chemicals in feed and in catfish growing ponds.	§ 534.3.	
Transportation to processing plant	§ 534.4.	
SANITATION REQUIREMENTS AND HAZARD ANALYSIS AND CRITICAL CONTROL POINTS SYSTEMS.	PART 537	Part 416, Part 417.
Basic requirements	§ 537.1	Part 416, Part 417.
Hazard Analysis and HACCP plan	§ 537.2	Part 417, § 417.2.
MANDATORY DISPOSITIONS; PERFORMANCE STANDARDS	PART 539	Part 311.
HANDLING AND DISPOSAL OF CONDEMNED AND OTHER INEDIBLE MATERIALS.	PART 540	Part 314.
Dead catfish	§ 540.1	§ 314.8.
Specimens for educational, research, and other nonfood purposes; permits	§ 540.2	§ 314.9.
Handling and disposal of condemned or other inedible materials	§ 540.3	Part 314.
MARKS, MARKING AND LABELING OF PRODUCTS AND CONTAINERS	PART 541	Part 312, Part 316.
General	§ 541.1.	
Official marks and devices to identify inspected and passed catfish and catfish products.	§ 542.2	§ 312.2.
Official seals for transportation of products	§ 541.3	§ 312.5.
Official export inspection marks, devices, and certificates	§ 541.4	§ 312.8.
Official detention marks and devices	§ 541.5	§ 329.2.
Labels required; supervision of a Program employee	§ 541.7	Part 317, Part 441, Part 442.
FOOD INGREDIENTS PERMITTED	PART 544	Part 424.
Use of food ingredients	§ 544.1	Part 424.
PREPARATION OF PRODUCTS	PART 548	Part 318.
Preparation of catfish products	§ 548.1.	
Requirements concerning ingredients and other articles used in the preparation of catfish products.	§ 548.2	§ 318.6.
Samples of products, water, dyes, chemicals to be taken for examination	§ 548.3	§ 318.9.
Mixtures containing product but not amenable to the Act	§ 548.4	§ 318.13.
Ready-to-eat catfish products	§ 548.5	Part 430.
Canning and canned products	§ 548.6	Part 318, Subpart G (§§ 318.300–318.311).
Use of animal drugs	§ 548.7.	
Polluted water contamination at establishment	§ 548.8	§ 318.4.
Accreditation of non-Federal chemistry laboratories	§ 548.9	Part 439.
STANDARDS OF IDENTITY AND COMPOSITION	PART 549 (RESERVED).	Part 319.
RECORDS REQUIRED TO BE KEPT	PART 550	Part 320.
Records required to be kept	§ 550.1	§ 320.1.
Place of maintenance of records	§ 550.2	§ 320.2.
Record retention period	§ 550.3	§ 320.3.
Access to and inspection of records, facilities, and inventory; copying and sampling.	§ 550.4	§ 320.4.
Registration	§ 550.5	§ 320.5.
Information and reports required from official establishment operators	§ 550.6	§ 320.6.
Reports by consignees of allegedly adulterated or misbranded products; sale or transportation as violations.	§ 550.7	§ 320.7.
EXPORTS	PART 552	Part 320.
Affixing stamps and marking products for export; issuance of export certificates; clearance of vessels and transportation.	§ 552.1	§ 322.1, § 322.2, § 322.4.
TRANSPORTATION OF CATFISH PRODUCTS IN COMMERCE	PART 555	Part 325.
Transportation of catfish products	§ 555.1	§ 325.1.
Catfish product transported within the United States as part of export movement	§ 555.2	§ 325.3.
Unmarked, inspected catfish product transported under official seal between official establishments for further processing.	§ 555.3	§ 325.5.
Handling of catfish products that may have become adulterated	§ 555.4	§ 325.10.
Transportation of inedible catfish product in commerce	§ 555.5	§ 325.11.
Certificates	§ 555.6	§ 325.14.
Official seals; forms, use, and breaking	§ 555.7	§ 325.16.
Loading or unloading of catfish products in sealed transport conveyances	§ 555.8	§ 325.18.
Diverting of shipments	§ 555.9	§ 325.18.
Provisions inapplicable to specimens for laboratory examination or to naturally inedible articles.	§ 555.10	§ 325.19.
Transportation and other transactions concerning dead, dying, or diseased catfish, and catfish or parts of catfish that died otherwise than by slaughter.	§ 555.11	§ 325.20.

TABLE 5—RELATIONSHIP BETWEEN CATFISH AND CATFISH PRODUCT INSPECTION REGULATIONS IN SUBCHAPTER F AND MEAT INSPECTION REGULATIONS IN SUBCHAPTER A OR SUBCHAPTER E—Continued

Subject	Subchapter F designation	Corresponding Subchapter A or E part or section reference
Means of conveyance in which dead, dying, or diseased catfish or parts of catfish must be transported.	§ 555.12 .....	§ 325.21.
IMPORTATION .....	PART 557 .....	Part 327.
Definitions; application of provisions .....	§ 557.1 .....	§ 327.1.
Eligibility of foreign countries for importation of catfish products into the United States.	§ 557.2 .....	§ 327.2.
No catfish product to be imported without compliance with applicable regulations	§ 557.3 .....	§ 327.3.
Imported catfish products; foreign certificates required .....	§ 557.4 .....	§ 327.4.
Importer to make application for inspection of catfish products for entry .....	§ 557.5 .....	§ 327.5.
Catfish products for importation; program inspection, time and place; application for approval of facilities as official import inspection establishment.	§ 557.6 .....	§ 327.6.
Import catfish products; equipment and means of conveyance used in handling to be maintained in sanitary condition.	§ 557.8 .....	§ 327.8.
[Reserved] .....	§ 557.9 .....	§ 327.9.
Samples; inspection of consignments; refusal of entry; marking .....	§ 557.10 .....	§ 327.10.
Receipts to importers for import catfish product samples .....	§ 557.11 .....	§ 327.11.
Foreign canned or packaged catfish products bearing trade labels; sampling and inspection.	§ 557.12 .....	§ 327.12.
Foreign catfish products offered for importation; reporting of findings to Customs	§ 557.13 .....	§ 327.13.
Marking of catfish products and labeling of immediate containers thereof for importation.	§ 557.14 .....	§ 327.14.
Outside containers of foreign catfish products; marking and labeling; application of official inspection legend.	§ 557.15 .....	§ 327.15.
Small importations for importer's own consumption; requirements .....	§ 557.16 .....	§ 327.16.
Returned U.S. inspected and marked catfish products .....	§ 557.17 .....	§ 327.17.
Catfish products offered for entry and entered .....	§ 557.18 .....	§ 327.18.
Specimens for laboratory examination and similar purposes .....	§ 557.19 .....	§ 327.19.
[Reserved] .....	§ 557.20 [Reserved].	
[Reserved] .....	§ 557.21 [Reserved].	
[Reserved] .....	§ 557.22 [Reserved].	
[Reserved] .....	§ 557.23 [Reserved].	
Appeals; how made .....	§ 557.24 .....	§ 327.24.
Disposition procedures for catfish product condemned or ordered destroyed under import inspection.	§ 557.25 .....	§ 327.25.
Official import inspection marks and devices .....	§ 557.26 .....	§ 327.26.
DETENTION, SEIZURE, CONDEMNATION .....	PART 559 .....	Part 329.
Catfish and other articles subject to administrative detention .....	§ 559.1 .....	§§ 329.1, 329.2, 329.3, 329.4, 329.5.
Articles or catfish subject to judicial seizure and condemnation .....	§ 559.2 .....	§§ 329.6, 329.7, 329.8.
Criminal offenses .....	§ 559.3 .....	§ 329.9.
STATE—FEDERAL, FEDERAL—STATE COOPERATIVE AGREEMENTS; STATE DESIGNATIONS.	PART 560 .....	Part 321, Part 331.
Cooperation with States and Territories .....	§ 560.1 .....	§ 321.1.
Cooperation of States in Federal programs .....	§ 560.2 .....	§ 321.2.
Designation of States under the FMIA .....	§ 560.3 .....	Part 331, § 331.3, § 331.5, § 331.6.
RULES OF PRACTICE .....	PART 561 .....	Part 335.
Rules of practice governing inspection actions .....	§ 561.1 .....	Part 500.
Rules of practice governing proceedings under the FMIA for criminal violations ...	§ 561.2 .....	Part 335.

## IX. FSIS Implementation

Farm-raised catfish establishments have been operating under the FDA Seafood HACCP Regulations (21 CFR part 123). The Seafood HACCP Regulations describe procedures for the safe and sanitary processing of fish and fish products. The FDA regulations require all processors of fish and fishery products to develop HACCP programs when necessary and to meet the requirements of 21 CFR part 110 as they relate to the eight key sanitation areas defined in the regulations (21 CFR

123.11). FDA has recommended that each processor develop and implement written Sanitation SOPs for each facility where fish and fishery products are produced. The provisions on sanitation control procedures are in 21 CFR 123.11.

FSIS anticipates that moving the catfish industry from FDA's regulatory regime to the FSIS inspection system will have some impact on the industry. If this proposed rule is adopted, all catfish processing establishments will be required to follow the regulations in

9 CFR part 416 for sanitation. The establishments will have to meet the FSIS sanitation performance standards. To meet the standards, establishments may develop and employ sanitation or processing procedures customized to the nature and volume of their production.

A catfish processing establishment will have the flexibility to innovate in facility design, construction, and operations. The establishment, however, will have to continue to operate under sanitary conditions in a manner that

ensures that the product is not adulterated and that does not interfere with FSIS inspection and its enforcement of such standards.

In its catfish products inspection, FSIS intends to focus on verification of Sanitation SOPs and HACCP plans. Under the proposed Sanitation SOPs, FSIS inspection program personnel will verify that plant management is conducting its operations in a sanitary environment and manner.

Catfish processing establishments will be able to include elements of their Sanitation SOPs in their HACCP plans. Sanitation activities that directly affect the control of a processing hazard will be evaluated in the hazard analysis. Where appropriate, the activities could be identified as CCPs in the HACCP plan. Sanitation activities not identified as a CCP in the HACCP plan could remain in the Sanitation SOPs or in another prerequisite program for which the hazard analysis accounts. Any sanitation activity incorporated into a HACCP plan as a CCP could be removed from the facility's Sanitation SOPs or other prerequisite program. FSIS will verify the activity's effectiveness, whether as an element of the Sanitation SOPs or as a CCP in a HACCP plan.

FSIS will also verify (under 9 CFR 417.8) that HACCP plans comply with the requirements of part 417 and have been validated by the establishment in accordance with 9 CFR 417.4. Potential verification activities by FSIS include, but would not be limited to, sampling activities (targeted and non-targeted, marketplace, rapid screening tests for chemical residues); hands-on verification (organoleptic inspection, use of temperature or other monitoring devices); and review of establishment monitoring records.

In addition to verifying Sanitation SOPs and HACCP systems, FSIS intends to verify establishment compliance with the other regulatory requirements that become part of the final rule. As previously noted, the frequency of FSIS verification activities will vary, depending on such factors as the establishment's past performance, the risk inherent in processes or products, quantity of product, and likely uses of the product. FSIS also will verify the conditions under which catfish are raised and transported to the establishment, both as a check on the effectiveness of the establishment's HACCP plan and to provide additional assurance that only safe, wholesome raw materials are processed for human food.

#### *Proposed Phasing of Implementation*

To provide for an orderly transition from FDA's regulatory program to FSIS's continuous inspection program, FSIS is proposing a four-phase approach to implementation of the final rule that establishes the new catfish inspection program. The Agency requests comment on the implementation time frame. During the transition period to full implementation, FSIS plans to provide establishments and foreign countries that will be subject to the final rule with the opportunity to train their personnel and to bring their operations into compliance with the new regulations. FSIS is aware that Ictaluridae, Pangasius and species of other families are imported into the United States. Although a determination as to the definition of "catfish" has not yet been made, any foreign producers or processors handling catfish, as defined by a final rule, will be subject to FSIS processes and procedures.

FSIS is proposing a phased implementation of the final catfish inspection rule to provide a reasonable timeframe for countries to develop and implement equivalent catfish inspection programs. FSIS intends to work with exporting countries to ensure that the catfish products exported to the United States during the phase-in period achieve an equivalent level of sanitary protection as catfish products produced in domestic establishments.

The following is FSIS's proposed timeline for implementing the final rule requiring continuous inspection of catfish and catfish products. The Agency is proposing to allow exporting establishments to operate under FSIS's transitional requirements until the final rule is fully implemented. It is also proposing to permit exporting establishments in foreign countries to continue to export their products during the phased implementation if they comply with the transitional requirements.

The proposed phase-in will not, however, preclude establishments that are prepared to bring their operations into full compliance with the final rule before the final implementation date from operating under the new inspection program. Such establishments will need to work with their District Office to obtain the necessary inspection services.

The proposed phasing of implementation will begin on the effective date of the final rule, 90 days after publication in the **Federal Register**. FSIS is requesting comment on what the duration of each of the following phases should be, and on the

compliance dates that affected establishments will be required to meet for each of the following phases until the final rule is fully implemented:

#### *Phase One*

- FSIS will deploy inspection personnel to domestic catfish processing establishments.
- Domestic establishments will be required to continue to comply with the requirements of 21 CFR part 123 until FSIS sanitation procedures (under proposed 9 CFR part 537) are in place. The regulations in 21 CFR part 123 require processors to monitor conditions and practices to ensure conformity with FDA's current Good Manufacturing Practices in 21 CFR part 110.
- Foreign countries that are exporting catfish to the United States at the time the final rule is published and that intend to continue to do so will need to submit documentation to demonstrate that they have a law or other appropriate legal measure in place that provides authority to regulate the growing and processing of catfish for human food. At this phase of implementation, FSIS will accept written documentation that countries have provided to importers pursuant to FDA's regulations in 21 CFR 123.12(a)(2)(ii)(B) as evidence of a country's authority to regulate the production of catfish products and to assure compliance with the requirements of 21 CFR part 123. FSIS will post a list on its Web site of countries that have met this initial, minimum requirement. FSIS will recognize current arrangements under 21 CFR part 123, including certification of foreign facilities by competent third parties, until complete implementation of the final rule or FSIS determines whether foreign inspection systems are equivalent to that of the United States.
- FSIS will begin a series of on-site audits of foreign countries that export catfish products to the United States to verify that establishments that produce catfish products for export to the United States are complying with the required transitional measures.
- Domestic producers will be required to begin to submit the labels of catfish products to FSIS for prior approval. Labels will have to meet the requirements in proposed 9 CFR 541.7.
- Labels of catfish products produced in foreign establishments will be required, at a minimum, to bear the basic labeling features prescribed in proposed 9 CFR 541.7. These features include the product name, handling statement, net weight statement, ingredients statement, address line, and nutrition facts panel. The labels will

also need to include safe handling instructions as well as the inspection legend and establishment number by the final implementation date.

#### Phase Two

- Persons and firms covered by the recordkeeping requirements in proposed 9 CFR 550.5 will have to register with FSIS.

#### Phase Three

- Domestic and foreign establishments will be required to comply with the sanitation requirements in 9 CFR part 416 (proposed 9 CFR part 537).

#### Phase Four

- The transitional measures will expire. FSIS will require that all establishments that produce catfish and catfish products comply with all provisions of the final catfish inspection regulations.

- Foreign countries that export catfish products to the United States will be required to have implemented a catfish inspection program that is equivalent to the U.S. inspection program. To be eligible for the importation of their products into the United States, the countries will have to be listed in proposed 9 CFR part 557.

### X. Executive Order 12866 and Regulatory Flexibility Act

This proposed rule has been reviewed under Executive Order 12866, "Regulatory Planning and Review." FSIS would amend Title 9, Code of Federal Regulations, Chapter III by adding regulations on the mandatory inspection of catfish and catfish products. The regulations, if adopted, will continue to ensure that catfish and catfish products produced and sold in commerce for use as human food are safe, wholesome, and not adulterated. The regulations will also ensure that they are properly marked, labeled, and packaged. FSIS will verify that catfish are raised and transported to processing establishments under conditions that ensure that catfish products used for human food are not adulterated.

The proposed regulations require establishments that process and prepare catfish to apply for FSIS inspection and meet the conditions for receiving inspection. Establishments will be required to meet sanitation performance standards, have written Sanitation SOPs, and operate validated HACCP systems. FSIS will verify the Sanitation SOPs and HACCP systems and will conduct other verification activities to ensure that the establishments are in compliance with the FMIA and

regulatory requirements under the Act that apply to catfish and catfish products. The establishments will be subject to sampling as part of microbiological, chemical, and other testing by FSIS of catfish and catfish products. The labeling of inspected products will bear a distinctive mark or legend to reflect that the product has been inspected and passed by FSIS.

The proposed regulations also require the listing in the regulations of foreign countries after their food safety systems for catfish have been found by FSIS to be equivalent to that of the United States. The equivalency determination and the listing in the regulations are necessary in order for the catfish products of these countries to be imported into the United States. The proposed regulations also require the inspection (actually, re-inspection) of catfish products offered for entry into this country.

FSIS is proposing these regulations to carry out the requirements of the Food, Conservation, and Energy Act of 2008 (Pub. L. 110–246, Sec. 11016), known as the 2008 Farm Bill, that amended the FMIA to make catfish, as defined by the Secretary of Agriculture, an amenable species under the FMIA and subject to many of the requirements of the FMIA.

#### Regulatory Approaches Considered

Regardless of the definition of catfish that is adopted an alternative to current FDA practices would be proposed.

FSIS has considered two basic regulatory approaches to catfish inspection—a more command-and-control, traditional approach or an approach that focuses on the verification of an establishment's food safety system. Strictly in terms of implementing the FMIA with respect to catfish and catfish products, FSIS could take a prescriptive, command-and-control approach to inspection, as it has in the past with meat and poultry and currently does with egg products. Command-and-control requirements specify, often in great detail, how an establishment is to achieve a particular food-safety objective. They may involve the use of specific techniques or processing parameters; the review and approval of equipment, establishment drawings and specifications; and the review and approval of particular process control programs. FSIS, however, rejected this command-and-control approach in 1996 with the adoption of the Pathogen Reduction/Hazard Analysis and Critical Control Points Systems final rule (61 FR 38806; July 25, 1996).

Thus, the Agency is proposing to adopt, as it has for meat and poultry, an

approach to inspection that focuses on the verification of an establishment's food safety system, which consists of an establishment's HACCP plan, Sanitation SOPs, and prerequisite programs. As mentioned elsewhere in this document, the FSIS HACCP requirements for meat and poultry establishments are in some ways similar to the FDA HACCP requirements for seafood processors (in 21 CFR 123), yet supported by much more intensive inspection by FSIS.

USDA is requesting public comments on the approach.

#### Costs and Benefits

##### Costs

##### Siluriformes

If catfish are defined as members of the order Siluriformes, the mean total first-year and one-time cost to the catfish and catfish food products domestic supply chain industries of the proposed measures is projected to be about \$306,000. The first year cost is projected to be about \$543,000. For the catfish and catfish food product domestic industry, the mean annual cost is projected at \$187,000. The projected mean estimated annualized cost is \$240,000 (See Table 18 of the RIA Appendix). The projected lower bound (10th percentile) is \$237,000, and the projected upper bound (90th percentile) is \$243,000.<sup>30</sup> The present value of the mean cost, using a 7-percent discount rate over 10 years is projected at \$1.7 million. The projected additional mean total annualized cost to the catfish and catfish food products supply chain industries of the provisions of the proposal analyzed is about \$0.0008 per pound (\$240,000/285 million pounds, in 2007) of aggregate processed catfish and catfish food products.

For the domestic industry and the Government, the additional mean total first-year one-time cost to the catfish and catfish products supply chain industries and additional cost to the government of the proposed measures is projected at \$1.3 million. The additional mean total first-year cost is projected at \$15.4 million. Additional mean annual cost is projected at \$14.0 million. The projected mean annualized cost is \$14.2 million (See Table 18 of the RIA Appendix). The projected lower bound (10th percentile) is \$14.1 million. The projected upper bound (90th percentile) is \$14.3 million. The present value of

<sup>30</sup> A stochastic simulation model was used to determine the distribution of values. Uncertainty analyses are conducted to estimate cost distributions for each of the alternatives for the proposed rule. The stochastic model uses @RISK (Version 4.5, Palisades Corp.) to examine the effects of uncertainty.

the mean total cost, using a 7-percent discount rate over 10 years is projected at \$100.0 million.

#### Ictaluridae

For catfish defined as Ictaluridae, the mean total first-year and one-time cost to the catfish and catfish food products domestic supply chain industries of the proposed measures is projected to be about \$286,000. The first year cost is projected at about \$516,000. For the catfish and catfish food product domestic industry, the mean annual cost is projected at \$181,000. The projected mean estimated annualized cost is \$230,000. The projected lower bound (10th percentile) is \$227,000, and the projected upper bound (90th percentile) is \$233,000.<sup>31</sup> The present value of the mean cost, using a 7 percent discount rate over 10 years is projected at \$1.6 million.

The projected mean total annualized cost to the catfish and catfish food products supply chain industries of the provisions of the proposal analyzed is about \$0.0011 per pound (\$230,000/204 million pounds, in 2007) of aggregate processed catfish and catfish food products.

The cost of the provisions to the catfish and catfish food products industry compares to a 2006–2008 average price of \$0.83 per pound for frozen whole catfish,<sup>32</sup> \$1.14 per pound for frozen catfish fillets,<sup>33</sup> and \$0.402 per pound for frozen catfish nuggets.<sup>34</sup> These costs compare to an estimated cost of about 1 cent per pound of meat and poultry associated with the Pathogen Reduction/Hazard Analysis and Critical Control Points (PR/HACCP) rule of 1996.<sup>35</sup> For the domestic industry and the Government, the mean total first-year one-time cost to the catfish and catfish products supply chain industries and cost to the Government of the proposed measures is projected at \$1.2 million. The mean total first-year cost is projected at \$11.8 million. The mean annual cost is

projected at \$10.5 million. The projected mean annualized cost is \$10.6 million. The projected lower bound (10th percentile) is \$10.3 million. The projected upper bound (90th percentile) is \$10.9 million. The present value of the mean total cost, using a 7-percent discount rate over 10 years is projected at \$74.8 million.

#### Break-Even Analysis

FSIS anticipates that all catfish and catfish products establishments will be in compliance with the requirements for Sanitation SOPs and HACCP according to the yet-to-be-determined implementation schedule. From discussions with industry experts, FSIS believes that a significant share of the catfish and catfish products industry is compliant with many of the individual proposed measures; although, because of differences between FDA and FSIS regulations, FSIS believes the industry will need time to make adjustments. Even though compliance rates for some HACCP related activities may be relatively high, the performance of HACCP systems depends on how well all the elements—hazard analysis, monitoring of CCPs and critical limits, recordkeeping, verification—are being performed. FSIS conducted an illustrative assessment of the potential risk to human health of catfish consumption, using the example of *Salmonella* contamination. Thus, we use *Salmonella* to illustrate potential benefits in this break-even analysis.

Epidemiological evidence suggests that salmonellosis leads to both acute and chronic illnesses. The acute illness that accompanies salmonellosis generally causes gastrointestinal symptoms that can lead to lost productivity and medical expenses. In rare instances, salmonellosis may result in acute or chronic arthritis. Arthritis is characterized by limited mobility, pain and suffering, productivity losses, and medical expenditures. Finally, salmonellosis can result in death. The risk of death appears to be higher in the elderly, children, and people with compromised immune systems. FSIS has estimated the costs for each of these severity levels.

Applying the same methodology as FDA in projecting a monetary value for each QALD, using the value of a statistical life (VSL); and the value of a statistical life year (VSLY), FSIS projects a mean annualized cost of about \$18,000 per new average case of salmonellosis (FDA, 2009). Thus, under the proposed rule for catfish defined as Siluriformes, using the projected annualized cost of \$14.2 million and the estimated mean annualized cost of an average case of

*Salmonella* spp. of approximately \$18,000 (at a 7 percent discount rate), if roughly 790 illnesses were averted, the benefits of the proposed rule would equal the additional costs.

Under the proposed rule applied to the catfish family Ictaluridae, using the projected annualized cost of \$10.6 million and the estimated mean annualized cost of an average case of *Salmonella* spp. of \$18,000, roughly 590 illnesses would have to be averted for the benefits of the proposed rule to equal the additional costs.

#### Effects on Small Entities

The Administrator has determined that, for the purposes of the Regulatory Flexibility Act (5 U.S.C. 601–602), this proposed rule will not have a significant economic impact on a substantial number of small entities in the United States. Catfish farms (about 1,300) and slaughtering and primary processing establishments (about 23), and as many as 116 further processing establishments, live-fish haulers, importers, and feed mills would be affected by the rule. Most of these plants meet the Small Business Administration (SBA) size criteria for small businesses in the food manufacturing classification or other categories, in that they have 500 or fewer employees. The action would affect a substantial number of these small entities because the requirements would apply to all processing establishments in the catfish processing industry that ship their products in interstate commerce and would to some extent pertain to fish-farming practices. However, this action may have a significant effect on a substantial number of businesses that import catfish because imported catfish will be required to be inspected under a foreign system that is equivalent to that of the United States and from establishments that the foreign inspection authority has certified as complying with United States requirements.

The proposed rule would directly and indirectly affect multiple sectors of the U.S. economy, including numerous small firms, jobs (*i.e.*, employment) and on the government (*e.g.*, local, State, and Federal). Sectors likely to be affected (directly and indirectly), in addition to the types of entities already mentioned, include transportation firms, importing and exporting firms, food service and restaurant firms, domestic and international trade, consumers, and government agencies. The economic analysis of the effects of this proposed rule accompanying this document is available at: [http://www.fsis.usda.gov/Regulations\\_Policies/Proposed\\_Rules/index.asp](http://www.fsis.usda.gov/Regulations_Policies/Proposed_Rules/index.asp).

<sup>31</sup> A stochastic simulation model was used to determine the distribution of values. Uncertainty analyses are conducted to estimate cost distributions for each of the alternatives for the proposed rule. The stochastic model uses @RISK (Version 4.5, Palisades Corp.) to examine the effects of uncertainty.

<sup>32</sup> Wholesale price. Source: Catfish Market Statistics, NASS, USDA.

<sup>33</sup> Wholesale price. Source: Catfish Monthly Summary, NASS, USDA.

<sup>34</sup> Wholesale price. Source: Catfish Market Statistics Annual, NASS, USDA.

<sup>35</sup> M. Ollinger, V. Mueller. 2003. Managing for Safer Food: The Economics of Sanitation and Process Controls in Meat and Poultry Establishments. Agricultural Economics Report 817. Economics Research Service, U.S. Department of Agriculture. Washington, DC.

## XI. Paperwork Reduction Act

*Title:* Mandatory Inspection of Catfish and Catfish Products.

*Type of Collection:* Sanitation SOPs; HACCP Plans; Applications for Grants of Inspection; Applications for labeling approval; various records required to be kept.

*Abstract:* FSIS has reviewed the paperwork and recordkeeping requirements in this proposed rule in accordance with the Paperwork Reduction Act. Under this proposed rule, FSIS is requiring an information collection associated with the inspection of catfish.

FSIS would require an official catfish processing establishment to maintain HACCP plans and records, Sanitation SOPs, and other prerequisite program records, and conduct and keep records for microbiological testing. Currently, catfish establishments must have a HACCP plan and records and this information collection burden is reported by FDA. Once this information collection is approved by OMB, the FDA seafood information collection burden will be reduced appropriately. Catfish establishments will have to develop, submit, and maintain records of labels for their catfish products. In addition, they will have to develop nutrition labels for their catfish products. There is also a requirement for a consignee of any inspected catfish product who refuses to accept delivery of the product because it is adulterated or misbranded to notify the FSIS Inspector in Charge of the establishment that prepared the product.

In addition, transporters of live catfish would have to register with the Agency.

This estimate does not include collections of information that are a usual and customary part of business' normal activities.

*Estimate of Burden:* An average of 0.25 hours per response.

*Respondents:* Official establishments that process catfish, catfish importers, and transporters of live catfish.

*Estimated Number of Respondents:* For catfish defined as Siluriformes, 230: There are 23 catfish slaughter and primary processing establishments, 10 further processing establishments, and 11 transporters of catfish to processing plants, plus approximately 80 import-export brokers.

For catfish defined as Ictaluridae, 51, including 23 catfish slaughter and processing establishments, at least 10 further processing establishments, and 11 transporters of catfish to processing plants, plus approximately 7 import-export brokers.

*Estimated Number of Responses per Respondent:* 1,512.

*Estimated Total Annual Burden on Respondents:* For catfish defined as Siluriformes: 47,350 hours.

For catfish defined as Ictaluridae: 32,002.5 hours.

Copies of this information collection assessment can be obtained from John O'Connell, Paperwork Reduction Act Coordinator, Food Safety and Inspection Service, USDA, Room 3532 South Agriculture Building, 1400 Independence Avenue, SW., Washington, DC 20250.

*Comments are invited on:* (a) Whether the proposed collection of information is necessary for the proper performance of FSIS's functions, including whether the information will have practical utility; (b) the accuracy of FSIS's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; and (c) ways to enhance the quality, utility, and clarity of the information to be collected; ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques, or other forms of information technology. Comments may be sent to both John O'Connell, Paperwork Reduction Act Coordinator, at the address provided above, and the Desk Officer for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20253.

All responses to this notice will be summarized and included in the request for OMB approval. All comments will also become a matter of public record.

## XII. E-Government Act

FSIS and USDA are committed to achieving the purposes of the E-Government Act (44 U.S.C. 3601 *et seq.*) by, among other things, promoting the use of the Internet and other information technologies and providing increased opportunities for citizen access to Government information and services, and for other purposes.

## XIII. Executive Order 12988, Civil Justice Reform

This proposed rule has been reviewed under Executive Order 12988, Civil Justice Reform. States and local jurisdictions are preempted by the FMIA from imposing any marking, labeling, packaging, or ingredient requirements on Federally inspected catfish products that are in addition to, or different than, those imposed under the FMIA. States and local jurisdictions may, however, exercise concurrent jurisdiction over catfish products that

are outside official establishments for the purpose of preventing the distribution of catfish products that are misbranded or adulterated under the FMIA or, in the case of imported articles that are not at such an establishment, after their entry into the United States. This proposed rule is not intended to have retroactive effect.

Administrative proceedings would not be required before parties may file suit in court challenging this proposed rule. However, the administrative procedures specified in 9 CFR 306.5 would have to be exhausted before any judicial challenge of the application of the provisions of this final rule, if the challenge involved any decision of an FSIS employee relating to inspection services provided under the FMIA.

## XIV. Expected Environmental Impact

FSIS has tentatively determined that this proposed rule would not have a significant individual or cumulative effect on the human environment. Therefore, this proposed action would be appropriately subject to the categorical exclusion from the preparation of an environmental assessment or environmental impact statement provided under 7 CFR 1b.4(6) of the U.S. Department of Agriculture regulations.

## XV. Executive Order 13175, USDA Nondiscrimination Statement, and Additional Public Notification

### *Executive Order 13175*

The policies contained in this proposed rule do not have Tribal Implications that preempt Tribal Law.

### *USDA Nondiscrimination Statement*

The U.S. Department of Agriculture (USDA) prohibits discrimination in all its programs and activities on the basis of race, color, national origin, gender, religion, age, disability, political beliefs, sexual orientation, and marital or family status. (Not all prohibited bases apply to all programs.) Persons with disabilities who require alternative means for communication of program information (Braille, large print, or audiotape) should contact USDA's Target Center at 202-720-2600 (voice and TTY).

To file a written complaint of discrimination, write USDA, Office of the Assistant Secretary for Civil Rights, 1400 Independence Avenue, SW., Washington, DC 20250-9410 or call 202-720-5964 (voice and TTY). USDA is an equal opportunity provider and employer.

### *Additional Public Notification*

Public awareness of all segments of rulemaking and policy development is

important. Consequently, in an effort to ensure that the public and in particular minorities, women, and persons with disabilities, are aware of this proposed rule, FSIS will announce it on-line through the FSIS Web page located at [http://www.fsis.usda.gov/regulations\\_&\\_policies/Proposed\\_Rules/index.asp](http://www.fsis.usda.gov/regulations_&_policies/Proposed_Rules/index.asp).

The Regulations.gov Web site is the central on-line rulemaking portal of the United States Government. It is offered as a public service to increase participation in the Federal Government's regulatory activities. FSIS participates in Regulations.gov and will accept comments about documents published on the site. The site allows visitors to search by keyword or Department or Agency for rulemakings that provide for public comment. Each entry provides a quick link to a comment form so that visitors can type in their comments and submit them to FSIS. The Web site is located at <http://www.regulations.gov/>.

FSIS also will make copies of this **Federal Register** publication available through the FSIS Constituent Update, which is used to provide information regarding FSIS policies, procedures, regulations, **Federal Register** notices, public meetings, recalls, and other types of information that could affect, or would be of interest to, our constituents and stakeholders. The update is communicated via Listserv, a free e-mail subscription service consisting of industry, trade, and farm groups, consumer interest groups, allied health professionals, scientific professionals, and other individuals who have requested to be included. The update also is available on the FSIS Web page at [http://www.fsis.usda.gov/News\\_&\\_Events/Constituent\\_Update/index.asp](http://www.fsis.usda.gov/News_&_Events/Constituent_Update/index.asp). Through Listserv and the Web page, FSIS is able to provide information to a much broader, more diverse audience.

In addition, FSIS offers an e-mail subscription service which provides an automatic and customized notification when popular pages are updated, including **Federal Register** publications and related documents. This service is available at [http://origin-www.fsis.usda.gov/News\\_&\\_Events/EmailSubscription/index.asp](http://origin-www.fsis.usda.gov/News_&_Events/EmailSubscription/index.asp) and allows FSIS customers to sign up for subscription options in eight categories. The subscription options categories include recalls, export information, regulations, directives, and notices. Customers can add or delete subscriptions themselves and have the option to password protect their accounts.

## **XVI. Proposed Regulations**

### **List of Subjects**

#### *9 CFR Part 300*

Meat inspection.

#### *9 CFR Part 441*

Consumer protection standards, Meat and meat products, Poultry products, Catfish and catfish products.

#### *9 CFR Part 530*

Catfish and catfish products, Catfish inspection.

#### *9 CFR Part 531*

Catfish and catfish products, Catfish inspection.

#### *9 CFR Part 532*

Catfish and catfish products, Catfish inspection, Reporting and recordkeeping requirements.

#### *9 CFR Part 533*

Catfish and catfish products, Catfish inspection, Government employees.

#### *9 CFR Part 534*

Aquaculture, Catfish and catfish products, Catfish inspection.

#### *9 CFR Part 537*

Catfish and catfish products, Catfish inspection, Hazard Analysis and Critical Control Point (HACCP) Systems, Sanitation.

#### *9 CFR Part 539*

Animal diseases, Catfish and catfish products, Catfish inspection.

#### *9 CFR Part 540*

Catfish and catfish products, Catfish inspection.

#### *9 CFR Part 541*

Catfish and catfish products, Catfish inspection, Food labeling, Food packaging, Nutrition, Reporting and recordkeeping requirements, Signs and symbols.

#### *9 CFR Part 544*

Catfish and catfish products, Catfish inspection, Food additives, Food packaging, Laboratories, Reporting and recordkeeping requirements.

#### *9 CFR Part 548*

Catfish and catfish products, Catfish inspection, Food additives, Food packaging, Laboratories, Reporting and recordkeeping requirements, Signs and symbols.

#### *9 CFR Part 550*

Catfish and catfish products, Catfish inspection, Reporting and recordkeeping requirements.

#### *9 CFR Part 552*

Catfish and catfish products, Catfish inspection, Exports.

#### *9 CFR Part 555*

Catfish and catfish products, Catfish inspection, Reporting and recordkeeping requirements, Transportation.

#### *9 CFR Part 557*

Catfish and catfish products, Catfish inspection, Food labeling, Food packaging, Imports.

#### *9 CFR Part 559*

Catfish and catfish products, Catfish inspection, Crime, Seizures and forfeitures.

#### *9 CFR Part 560*

Catfish and catfish products, Catfish inspection, Intergovernmental relations.

#### *9 CFR Part 561*

Administrative practice and procedure, Catfish and catfish products, Catfish inspection, Crime, Government employees.

For the reasons set forth in the preamble, 9 CFR chapter III is proposed to be amended as follows:

### **Subchapter A—Agency Organization and Terminology; Mandatory Meat and Poultry Products Inspection and Voluntary Inspection and Certification**

#### **PART 300—AGENCY MISSION AND ORGANIZATION**

1. The authority citation for 9 CFR part 300 continues to read as follows:

**Authority:** 21 U.S.C. 450–471, 601–695, 1031–1056; 7 U.S.C. 138–138i, 450, 1621–1627, 1901–1906; 7 CFR 2.7, 2.18, 2.53.

2. Section 300.3 is amended by revising paragraphs (a), (b) introductory text, and (b)(1) to read as follows:

#### **§ 300.3 FSIS organization.**

(a) *General.* The organization of FSIS reflects the Agency's primary regulatory responsibilities: implementation of the FMIA, including catfish, the PPIA, and the EPIA. FSIS implements the inspection provisions of the FMIA, the PPIA, and the EPIA through its field structure.

(b) *Headquarters.* FSIS has ten principal components or offices, each of which is under the direction of an Assistant Administrator. The Assistant Administrators, along with their staffs, and the Administrator, along with the Office of the Administrator and ten staff offices that report to the Administrator, are located at U.S. Department of Agriculture headquarters in Washington, DC.

(1) *Program Offices.* FSIS's headquarters offices are the Office of Public Health Science; the Office of Management; the Office of Policy and Program Development; the Office of Field Operations; the Office of Data Integration and Food Protection; the Office of Program Evaluation, Enforcement, and Review; the Office of Public Affairs and Consumer Education; the Office of Outreach, Employee Education, and Training; the Office of International Affairs; and the Office of Catfish Inspection Programs.

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#### Subchapter E—Regulatory Requirements under the Federal Meat Inspection Act and the Poultry Products Inspection Act

### PART 441—CONSUMER PROTECTION STANDARDS: RAW PRODUCTS

3. The authority citation for 9 CFR part 441 continues to read as follows:

**Authority:** 21 U.S.C. 451–470, 601–695; 7 U.S.C. 450, 1901–1906; 7 CFR 2.18, 2.53

#### § 441.10 [Amended]

4. In § 441.10, remove the term “Raw livestock and poultry” and add in its place the term “Raw livestock, poultry, and catfish” at the beginning of the first sentence of paragraph (a) and at the beginning of the first sentence of paragraph (b).

5. A new Subchapter F, consisting of Parts 530 to 561, is added to Chapter III to read as follows:

#### Subchapter F—Mandatory Inspection of Catfish and Catfish Products

### PART 530—GENERAL REQUIREMENTS; DEFINITIONS

Sec.

530.1 General.

530.2 FSIS organization for inspection of catfish and catfish products.

530.3 Access to establishments.

**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, 7 CFR 2.18, 2.53.

#### § 530.1 General.

(a) The regulations in this subchapter provide for the inspection of catfish and catfish 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 catfish or catfish 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) Catfish 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 catfish.

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

The Food Safety and Inspection Service, U.S. Department of Agriculture, administers a continuous inspection program for catfish and catfish 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. 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 catfish processing establishments and related industries as they do to other establishments subject to the FMIA.

### PART 531—DEFINITIONS

Sec.

531.1 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, 7 CFR 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, catfish or catfish 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 section 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 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.

*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 catfish at time of slaughter or in any of their tissues after slaughter as the result of treatment or exposure of the catfish to a pesticide, organic or inorganic compound, hormone, hormone like substance, antihelminthic, 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 catfish unless it is denatured or otherwise identified as required by section 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.

*Catfish.* The skeletal muscle tissue of catfish. As applied to products of catfish species, this term has a meaning comparable to that of "meat" in the meat inspection regulations (9 CFR 301.2).

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

*Catfish food product.* Any article capable of use as human food that is made wholly or in part from any catfish or part thereof; or any product that is made wholly or in part from any catfish or part thereof, excepting those exempted from definition as a catfish product by the Administrator in specific cases or by a regulation in this subchapter; upon a determination that they contain catfish ingredients only in a relatively small proportion or historically have not been considered by consumers as products of the catfish food industry, and provided that they comply with any requirements that are imposed in such cases or regulations as conditions of such exemptions to ensure that the catfish meat or other portions of such carcasses contained in such articles are not adulterated, and that such articles are not represented as catfish food products.

*Catfish product.* Any catfish or catfish part; or any product that is made wholly or in part from any catfish or catfish part, except for those exempted from definition as a catfish 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.

*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 catfish 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 catfish.* The body of catfish that has died otherwise than by slaughter.

*Dying or diseased catfish.* Catfish affected by any of the conditions for which the catfish 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.

*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, 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:

(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 section 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 manner 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 meat food and meat 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, catfish 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, catfish, or catfish product under the Act.

**Packaging material.** Any cloth, paper, plastic, metal, or other material used to

form a container, wrapper, label, or cover for meat 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 catfish 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 catfish.

**Product.** Any carcass, catfish, catfish product, or catfish 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 catfish, 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 catfish, part, or product of catfish so identified was inspected and found to be adulterated and is condemned.

**U.S. Detained.** This term applies to catfish, catfish 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 catfish, part, or product of catfish 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.

## PART 532—REQUIREMENTS FOR INSPECTION

Sec.

532.1 Establishments requiring inspection; other inspection.

532.2 Application for inspection.

532.3 Exemption of retail operations.

532.4 Inspection at official establishments; relation to other authorities.

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

*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, 7 CFR 2.18, 2.53.

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

(a) No establishment may process or prepare catfish, catfish parts, or catfish products capable of use as human food, or sell, transport, or offer for sale or transportation in commerce any of these articles without continuous 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 catfish or catfish 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 catfish or catfish 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 catfish products which would clearly endanger the public health.

(4) *Coverage of catfish and catfish products processed in official establishments.* All catfish and catfish 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 catfish between premises where catfish are bred, hatcheries, and premises where catfish 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.

(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 and HACCP plans, 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 catfish processing establishments are as required by 9 CFR part 305 for meat establishments.

(d) *Assignment and authorities of program employees.* The requirements concerning the assignment and authorities of Program employees at catfish processing establishments are as required by 9 CFR parts 306 and 307 with respect to Program employees at meat establishments.

#### § 532.3 Exemption of retail operations.

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 catfish products as it does with respect to products of other amenable species under the FMIA. However, a retail quantity of catfish or catfish products sold to a household consumer is a normal retail quantity if it does not exceed 75 pounds and the quantity of catfish or catfish 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 chapter, 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 catfish or catfish products processed at any official establishment in accordance with the requirements under this subchapter and those Acts.

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

The following articles contain catfish ingredients only in a relatively small proportion or historically have not been considered by consumers as products of the catfish food products industry. Therefore, the articles are exempted from the definition of “catfish product” and the requirements of the Act and the regulations that apply to catfish 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 catfish;

(2) The catfish ingredients used in the product were prepared under Federal inspection or were inspected under a foreign inspection system approved under § 557.2 of this chapter 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 catfish product. The percentage of cooked catfish ingredients must be computed on the basis of the moist, deboned, cooked catfish 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 catfish product if the term “catfish” or a term representing a fish species that is covered by the definition of “catfish” 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, 7 CFR 2.18, 2.53.

#### § 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 catfish 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.

**§ 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 catfish, catfish 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 catfish 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 catfish 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 catfish.

534.4 Transportation to processing plant.

*Authority:* 21 U.S.C. 601–602, 606–622, 624–695; 7 CFR 2.7, 7 CFR 2.18, 2.53.

**§ 534.1 General.**

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

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

Producers of catfish 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 pond water from producers, at intervals to be determined by the Administrator, for the purpose of verifying that catfish are being raised under conditions that will yield safe, wholesome products.

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

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 USC 360b], or a conditional approval under section 571 of the Act [21 USC 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 catfish. 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 catfish from a producer's premises to a processing establishment must be equipped with vats or other containers

for holding the catfish. 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 catfish to ensure that catfish delivered to the processing establishment will not be adulterated. Any catfish that are dead, dying, diseased, or contaminated with substances that may adulterate catfish products are subject to condemnation at the official catfish processing establishments.

**PART 537—SANITATION REQUIREMENTS AND HAZARD ANALYSIS AND CRITICAL CONTROL POINTS SYSTEMS**

Sec.

537.1 Basic requirements.

537.2 Hazard analysis and HACCP plan.

*Authority:* 21 U.S.C. 601–602, 606–622, 624–695; 7 CFR 2.7, 7 CFR 2.18, 2.53.

**§ 537.1 Basic requirements.**

(a) Any official establishment that prepares or processes catfish or catfish products for human food must comply with the requirements contained in 9 CFR parts 416 and 417, except as otherwise provided in this subchapter.

(b) For the purposes of 9 CFR parts 416, 417, and 500, an "official establishment" or "establishment" includes a plant that prepares or processes catfish or catfish products.

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

(a) A catfish 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.

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

Sec.

539.1 Disposal of diseased or otherwise adulterated catfish carcasses and parts or catfish products.

539.2 Physical, chemical, or biological contaminants.

*Authority:* 21 U.S.C. 601–602, 606–622, 624–695; 7 CFR 2.7, 7 CFR 2.18, 2.53.

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

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

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

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

(c) Catfish carcasses or parts or catfish 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) Grossly deformed fish may not be used for human food.

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

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

(b) Antibiotic or other drug residues in catfish tissues must be within applicable tolerances in 21 CFR part 556.

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

(d) Catfish or catfish 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 catfish.

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. 601–602, 606–622, 624–695; 7 CFR 2.7, 7 CFR 2.18, 2.53.

**§ 540.1 Dead catfish.**

(a) With the exception of dead catfish that have died en route to an official establishment that have been received with live catfish at the official

establishment, and that are subject to sorting and disposal at the official establishment, no catfish or part of the carcass of catfish 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 catfish and the edible parts or products of slaughtered catfish and any catfish or parts of catfish that have died otherwise than by slaughter. Catfish or any parts of catfish 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 catfish materials.

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

Condemned or other inedible catfish and catfish parts shall be separated from edible catfish. If not disposed of on the premises of the establishment, the condemned and inedible catfish parts shall be conveyed from the official establishment for disposition at a rendering plant, an animal feed manufacturing establishment, or at another establishment for other non-food use. If not decharacterized by use of approved denaturants or colorings, the inedible materials shall be enclosed in containers that are conspicuously marked to indicate that the contents are condemned or otherwise inedible. The materials may be shipped under company or official seal to a rendering facility or for other inedible processing.

**PART 541—MARKS, MARKING AND LABELING OF PRODUCTS AND CONTAINERS**

Sec.

541.1 General.

541.2 Official marks and devices to identify inspected and passed catfish and catfish products.

541.3 Official seals for transportation of products.

541.4 Official export inspection marks, devices, and certificates.

541.5 Official detention marks and devices.

541.7 Labels required; supervision of a Program employee.

**Authority:** 21 U.S.C. 601–602, 606–622, 624–695; 7 CFR 2.7, 7 CFR 2.18, 2.53.

**§ 541.1 General.**

The marks, devices, and certificates prescribed or referenced in this part are official marks, devices, and certificates for the purposes of the Act respecting catfish and catfish products. The marks, devices, and certificates shall be used only in accordance with the regulations in this part.

**§ 541.2 Official marks and devices to identify inspected and passed catfish and catfish products.**

(a)(1) The official inspection legend required by this part must be shown on all labels for inspected and passed catfish and catfish products and must be in the following form prescribed in 9 CFR 312.2(b)(1) for inspected and passed products of cattle, sheep, swine, and goats, or in another form to be prescribed by the Administrator, except that it need not be of the size illustrated, if it is of a sufficient size and color to be conspicuously displayed, and readily legible, and in the same proportions of letter size and boldness are maintained as illustrated:



(2) The official inspection legend shall contain the words "U.S. Inspected and Passed" or an abbreviation of those words approved by the Administrator.

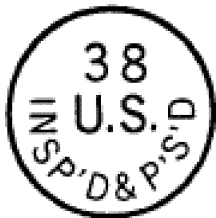
(b) This official mark must be applied by mechanical means and must not be applied by a hand stamp.

(c)(1) The official inspection legend, or the approved abbreviation of the legend, must be printed on consumer packages and other immediate containers of inspected and passed catfish products or on labels to be securely affixed to the containers of the products and may be printed or stenciled on the containers but must not be applied by rubber stamping.

(2) The official inspection legend may also be used for the purposes of marking shipping containers, band labels, and other articles with the approval of the Administrator.

(d) Whole gutted catfish carcasses that have been inspected and passed in an official establishment and are intended for sale as whole gutted catfish must be marked or labeled in a manner that will ensure that the catfish carcasses are identified as "Inspected and Passed" and will not become misbranded while in

commerce. The official inspection legend used for this purpose must be in the form illustrated below or in another form determined by the Administrator:



**§ 541.3 Official seals for transportation of products.**

The official mark for use in sealing railroad cars, cargo containers, or other means of conveyance as prescribed in part 555 of this subchapter must be the inscription and serial number shown in 9 CFR 312.5 or another official mark approved by the Administrator. Any seal approved by the Administrator for applying the official mark is an official device for the purposes of the Act. The seal must be attached to the means of conveyance only by a Program employee, who shall also affix a "Warning Tag" (Form MP-408-3 or similar official form).

**§ 541.4 Official export inspection marks, devices, and certificates.**

(a) The official export inspection mark for catfish required by part 552 of this subchapter must be in the same form as that specified in 9 CFR 312.8(a) or otherwise as prescribed by the Administrator.

(b) The official export certificate for catfish and catfish products required by part 552 of this subchapter must be in the same form as that prescribed for meat and meat food products in 9 CFR 312.8(b) or otherwise as prescribed by the Administrator.

**§ 541.5 Official detention marks and devices.**

The official mark for shipments of articles and catfish detained under this subchapter is the designation "U.S. Detained," and the official device for applying the mark is the official "U.S. Detained" tag (FSIS Form 8400-2) as prescribed in 9 CFR 329.2 or otherwise by the Administrator.

**§ 541.7 Labels required; supervision of a Program employee.**

(a) *General labeling requirements.* The requirements in part 317, subpart A, of this chapter, governing labels and labeling, safe-handling labeling, abbreviations of official marks, labeling approval, generically approved labeling, the use of approved labels, the labeling of products for foreign commerce, prohibited practices, the reuse of official

inspection marks, filling of containers, relabeling of products, the storage and distribution of labels, and the requirements for packaging materials, apply to catfish and catfish products.

(b) The requirements in part 441, subchapter E, governing water retained from processing in raw meat and poultry, apply to retained water in catfish. The requirements in part 442, subchapter E, governing quantity of contents labeling, the testing of scales, and the handling of product that is found to be out of compliance with net weight requirements, apply to catfish and catfish products.

(1) Packages of frozen or fresh-frozen catfish carcasses or parts must be labeled to reflect 100-percent net weight after thawing. The de-glazed net weight must average 100 percent of the stated net weight of the frozen product when sampled and weighed according to the method prescribed in National Institute of Standards and Technology (NIST) Handbook 133 Chapter 2, Section 2.6.<sup>36</sup>

(2) [Reserved]

(c) *Nutrition labeling.* The requirements for nutrition labeling of meat and meat food products in part 317, subpart B, of this chapter, also apply to the labeling of catfish and catfish food products.

**PART 544—FOOD INGREDIENTS PERMITTED**

Sec.

544.1 Use of food ingredients.

**Authority:** 21 U.S.C. 601-602, 606-622, 624-695; 7 CFR 2.7, 7 CFR 2.18, 2.53.

**§ 544.1 Use of food ingredients.**

(a) No catfish product may bear or contain any food ingredient that would render it adulterated or misbranded or that is not approved in part 424 of subchapter E, or in this part or elsewhere in this subchapter, or by the Administrator in specific cases.

(b) [Reserved]

**PART 548—PREPARATION OF PRODUCTS**

Sec.

548.1 Preparation of catfish products.

548.2 Requirements concerning ingredients and other articles used in the preparation of catfish products.

548.3 Samples of products, water, dyes, chemicals, etc. to be taken for examination.

548.4 Mixtures containing product but not amenable to the Act.

548.5 Ready-to-eat catfish products.

548.6 Canning and canned products.

548.7 Use of animal drugs.

548.8 Polluted water contamination at establishment.

548.9 Accreditation of non-Federal chemistry laboratories.

**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, 7 CFR 2.18, 2.53.

**§ 548.1 Preparation of catfish products.**

(a) All processes used in preparing any catfish product in official establishments shall be subject to inspection by Program employees unless such preparation is conducted as or consists of operations that are exempted from inspection under 9 CFR 303.1. No fixtures or appliances, such as tables, trucks, trays, tanks, vats, machines, implements, cans, or containers of any kind, shall be used unless they are of such materials and construction as will not contaminate or otherwise adulterate the product and are clean and sanitary. All steps in the preparation of edible products shall be conducted carefully and with strict cleanliness in rooms or compartments separate from those used for inedible products.

(b) It shall be the responsibility of the operator of every official establishment to comply with the Act and the regulations in this subchapter. To carry out this responsibility effectively, the operator of the establishment shall institute appropriate measures to ensure the maintenance of the establishment and the preparation, marking, labeling, packaging and other handling of its products strictly in accordance with the sanitary and other requirements of this subchapter.

**§ 548.2 Requirements concerning ingredients and other articles used in the preparation of catfish products.**

All ingredients and other articles used in the preparation of any catfish product must be clean, sound, healthful, wholesome, and otherwise such as will not result in the product's being adulterated.

**§ 548.3 Samples of products, water, dyes, chemicals, etc. to be taken for examination.**

Samples of products, water, dyes, chemicals, preservatives, spices, or other articles in any official establishment shall be taken, without cost to the Program, for examination, as often as may be deemed necessary for the efficient conduct of the inspection.

**§ 548.4 [Reserved]**

**§ 548.5 Ready-to-eat catfish products.**

Ready-to-eat catfish products are subject to the requirements in part 430, subchapter E, of this chapter.

<sup>36</sup>U.S. Department of Commerce. NIST Handbook 133: Checking the Net Contents of Packaged Goods, Fourth Edition, January 2005. Washington, DC.

**§ 548.6 Canning and canned products.**

The requirements for canning and canned products in 9 CFR part 318, subpart G (§§ 318.300–318.311) apply to catfish products that are canned.

**§ 548.7 Use of animal drugs.**

Edible tissues of catfish with residues exceeding tolerance levels specified in 21 CFR part 556 are adulterated within the meaning of section 402(a)(2)(C)(ii) of the Federal Food, Drug, and Cosmetic Act because they bear or contain a new animal drug that is unsafe within the meaning of section 512 of the Federal Food, Drug, and Cosmetic Act.

**§ 548.8 Polluted water contamination at establishment.**

In the event that there is polluted water (including but not limited to flood water) in an official establishment, all products and ingredients for use in the preparation of the products that have been rendered adulterated by the water must be condemned. After the polluted water has receded from the establishment, the establishment must follow the cleaning and sanitizing procedures in § 318.4 of subchapter A of this chapter.

**§ 548.9 Accreditation of non-Federal chemistry laboratories.**

A non-Federal analytical laboratory that has met the requirements for accreditation specified in 9 CFR 439 and hence, at an establishment's discretion, may be used in lieu of an FSIS laboratory for analyzing official regulatory samples. Payment for the analysis of regulatory samples is to be made by the establishment using the accredited laboratory.

**PART 549—[RESERVED]****PART 550—RECORDS REQUIRED TO BE KEPT**

Sec.

- 550.1 Records required to be kept.
- 550.2 Place of maintenance of records.
- 550.3 Record retention period.
- 550.4 Access to and inspection of records, facilities and inventory; copying and sampling.
- 550.5 Registration.
- 550.6 Information and reports required from official establishment operators.
- 550.7 Reports by consignees of allegedly adulterated or misbranded products; sale or transportation as violations.

**Authority:** 21 U.S.C. 601–602, 606–622, 624–695; 7 CFR 2.7, 7 CFR 2.18, 2.53.

**§ 550.1 Records required to be kept.**

The requirements in 9 CFR 320.1 for records to be kept apply to persons that engage in businesses relating to catfish and catfish products as they do to

persons that engage in businesses relating to the carcasses, parts, or products of other species amenable to the FMIA.

**§ 550.2 Place of maintenance of records.**

The requirements in 9 CFR 320.2 for the place where records are to be maintained apply in the keeping of records under this part.

**§ 550.3 Record retention period.**

The record retention requirements in 9 CFR 320.3 apply to records required to be kept under this part.

**§ 550.4 Access to and inspection of records, facilities and inventory; copying and sampling.**

The provisions of 9 CFR 320.4 apply to businesses dealing in catfish and catfish products.

**§ 550.5 Registration.**

The registration requirements in 9 CFR 320.5 apply to persons engaging in businesses, in or for commerce, relating to catfish and catfish products as they do to persons engaging in businesses relating to the carcasses, parts, and products, or any livestock, of other animal species that are amenable to the FMIA.

**§ 550.6 Information and reports required from official establishment operators.**

The information and reporting requirements in 9 CFR 320.6 for operators of official establishments apply with respect to catfish and catfish products as they do with respect to other species amenable to the FMIA.

**§ 550.7 Reports by consignees of allegedly adulterated or misbranded products; sale or transportation as violations.**

The requirements in 9 CFR 320.7 for reports by consignees of allegedly adulterated or misbranded products apply with respect to catfish and catfish products as they do with respect to products of other species amenable to the Act.

**PART 552—EXPORTS**

Sec.

- 552.1 Affixing stamps and marking products for export; issuance of export certificates; clearance of vessels and transportation.

**Authority:** 21 U.S.C. 601–602, 606–622, 624–695; 7 CFR 2.7, 7 CFR 2.18, 2.53.

**§ 552.1 Affixing stamps and marking products for export; issuance of export certificates; clearance of vessels and transportation.**

(a) The manner of affixing stamps and marking products for export is that prescribed in § 322.1(a) of this chapter.

(b) The requirements for the issuance of export certificates are as prescribed in § 322.2 of this chapter.

(c) The requirements for clearing vessels and other transportation vehicles are set out in § 322.4 of this chapter.

**PART 555—TRANSPORTATION OF CATFISH PRODUCTS IN COMMERCE**

Sec.

- 555.1 Transportation of catfish products.
- 555.2 Catfish product transported within the United States as part of export movement.
- 555.3 Unmarked, inspected catfish product transported under official seal between official establishments for further processing; certificate.
- 555.4 Handling of catfish products that may have become adulterated.
- 555.5 Transportation of inedible catfish product in commerce.
- 555.6 Certificates.
- 555.7 Official seals; forms, use, and breaking.
- 555.8 Loading or unloading of catfish products in sealed transport conveyances.
- 555.9 Diverting of shipments.
- 555.10 Provisions inapplicable to specimens for laboratory examination, *etc.*, or to naturally inedible articles.
- 555.11 Transportation and other transactions concerning dead, dying, or diseased catfish, and catfish or parts of catfish that died otherwise than by slaughter.
- 555.12 Means of conveyance in which dead, dying, or diseased catfish or parts of catfish must be transported.

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

**§ 555.1 Transportation of catfish products.**

(a) No person may sell, transport, offer for sale or transportation, or receive for transportation, in commerce, any catfish or catfish product that is capable of being used as human food and is adulterated or fails to bear an official inspection legend or is otherwise misbranded at the time of such sale, transportation, offer or receipt, except otherwise provided in this paragraph or in part 557 of this chapter.

(b) No person, engaged in the business of buying, selling, freezing, storing, or transporting, in or for commerce, catfish products capable of use as human food, or importing such articles, shall transport, offer for transportation, or receive for transportation, in commerce or in any State designated under § 560.3 of this subchapter, any catfish product which is capable of use as human food and is not wrapped, packaged, or otherwise enclosed to prevent adulteration by airborne contaminants, unless the railroad car, truck, or other

means of conveyance in which the product is contained or transported is completely enclosed with tight fitting doors or other covers for all openings. In all cases, the means of conveyance shall be reasonably free of foreign matter (such as dust, dirt, rust, or other articles or residues), and free of chemical residues, so that product placed therein will not become adulterated.

(c) Any cleaning compound, lye, soda solution, or other chemical used in cleaning the means of conveyance must be thoroughly removed from the means of conveyance prior to its use. Such means of conveyance onto which product is loaded, being loaded, or intended to be loaded, shall be subject to inspection by an inspector at any official establishment.

(d) The decision whether or not to inspect a means of conveyance in a specific case, and the type and extent of such inspection shall be at the Agency's discretion and shall be adequate to determine if catfish product in such conveyance is, or when moved could become, adulterated.

(e) Circumstances of transport that can be reasonably anticipated shall be considered in making said determination. These include, but are not limited to, weather conditions, duration and distance of trip, nature of product covering, and effect of restowage at stops en route. Any means of conveyance found upon such inspection to be in such condition that catfish product placed therein could become adulterated shall not be used until such condition which could cause adulteration is corrected.

(f) Catfish product placed in any means of conveyance that is found by the inspector to be in such condition that the catfish product may have become adulterated shall be removed from the means of conveyance and handled in accordance with part 539 or § 540.3 of this subchapter.

**§ 555.2 Catfish product transported within the United States as part of export movement.**

When any shipment of any catfish product is offered to any carrier for transportation within the United States as a part of an export movement, the same certificate shall be required as if the shipment were destined to a point within the United States.

**§ 555.3 Unmarked, inspected catfish product transported under official seal between official establishments for further processing; certificate.**

The requirements governing transportation of catfish product that has been inspected and passed, but not so marked, from one official

establishment to another official establishment are the same as those in § 325.5 of this chapter that apply to unmarked inspected meat products.

**§ 555.4 Handling of catfish products that may have become adulterated.**

The provisions of § 325.10 regarding the handling of products that may have become adulterated or misbranded apply to catfish and catfish products.

**§ 555.5 Transportation of inedible catfish product in commerce.**

The provisions in § 325.11(e) of this chapter regarding the transportation of inedible livestock products apply to the transportation of inedible catfish parts or products.

**§ 555.6 Certificates.**

The provisions in § 325.14 of this chapter regarding the filing of original certificates of unmarked inspected meat products delivered to carriers applies with respect to catfish and catfish products.

**§ 555.7 Official seals; forms, use, and breaking.**

The official seals required by this part are those prescribed in § 541.3 and § 312.5 of this chapter.

**§ 555.8 Loading or unloading of catfish products in sealed transport conveyances.**

The requirements in 9 CFR 325.18 governing the unloading of any meat or meat food product from an officially sealed railroad car, truck, or other means of conveyance containing any unmarked product or loading any means of conveyance after the product leaves an official establishment are applicable to catfish and catfish products.

**§ 555.9 Diverting of shipments.**

(a) Shipments of inspected and passed catfish products that bear the inspection legend may be diverted from the original destination without a reinspection of the articles if the waybills, transfer bills, running slips, conductor's card, or other papers accompanying the shipments are marked, stamped, or have attached thereto signed statements in accordance with § 325.15.

(b) In case of a wreck or similar extraordinary emergency, the Department seals on a railroad car or other means of conveyance containing any inspected and passed product may be broken by the carrier, and if necessary, the articles may be reloaded into another means of conveyance, or the shipment may be diverted from the original destination, without another shipper's certificate; but in all such cases the carrier must immediately

report the facts by telephone or telegraph to the District Manager in the area in which the emergency occurs. The report must include the following information:

- (1) Nature of the emergency.
- (2) Place where seals were broken.
- (3) Original points of shipment and destination.
- (4) Number and initial of the original car or truck.
- (5) Number and initials of the car or truck into which the articles are reloaded.
- (6) New destination of the shipment.
- (7) Kind and amount of articles.

**§ 555.10 Provisions inapplicable to specimens for laboratory examination, etc., or to naturally inedible articles.**

The provisions of this part do not apply:

(a) To specimens of product sent to or by the Department of Agriculture or divisions thereof in Washington, DC, or elsewhere, for laboratory examination, exhibition purposes, or other official use;

(b) To material released for educational, research, and other nonfood purposes, as prescribed in § 540.2 of this subchapter;

(c) To tissues for use in preparing pharmaceutical, organotherapeutic, or technical products and not used for human food, as described in § 540.2 of this subchapter;

(d) To material or specimens of product for laboratory examination, research, or other nonhuman food purposes, when authorized by the Administrator, and under conditions prescribed by him in specific cases; and

(e) To articles that are naturally inedible by humans.

**§ 555.11 Transportation and other transactions concerning dead, dying, or diseased catfish, and catfish or parts of catfish that died otherwise than by slaughter.**

No person engaged in the business of buying, selling, or transporting in commerce, or importing any dead, dying, or diseased catfish or parts of catfish that died otherwise than by slaughter shall:

(a) Sell, transport, offer for sale or transportation, or receive for transportation, in commerce, any dead, dying, or diseased catfish or parts of catfish that died otherwise than by slaughter, unless the catfish and parts are consigned and delivered, without avoidable delay, to establishments of animal food manufacturers, renderers, or collection stations that are registered as required by part 550 of this subchapter, or to official establishments that operate under Federal inspection,



or to establishments that operate under a State or Territorial inspection system approved by FSIS as one that imposes requirements at least equal to the Federal requirements for purposes of paragraph 301(c) of the Act;

(b) Buy in commerce or import any dead, dying, or diseased catfish or parts of catfish that died otherwise than by slaughter, unless he is an animal food manufacturer or renderer and is registered as required by part 550 of this subchapter, or is the operator of an establishment inspected as required by paragraph (a) of this section and such catfish or parts of catfish are to be delivered to establishments eligible to receive them under paragraph (a) of this section;

(c) Unload en route to any establishment eligible to receive them under paragraph (a) of this section, any dead, dying, or diseased catfish or parts of catfish that died otherwise than by slaughter, which are transported in commerce or imported by any such person: *Provided*, That any such dead, dying, or diseased catfish, or parts of catfish may be unloaded from a means of conveyance en route where necessary in case of a wreck or otherwise extraordinary emergency, and may be reloaded into another means of conveyance; but in all such cases, the carrier must immediately report the facts by telephone or other electrical or electronic means to the Office of Program Evaluation, Enforcement, and Review, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250.

(d) Load into any means of conveyance containing any dead, dying, or diseased catfish, or parts of catfish that died otherwise than by slaughter, while in the course of importation or other transportation in commerce any catfish or parts of catfish not within the foregoing description or any other products or other commodities.

**§ 555.12 Means of conveyance in which dead, dying, or diseased catfish or parts of catfish must be transported.**

All vehicles and other means of conveyance used by persons subject to § 555.11 for transporting in commerce or importing, any dead, dying, or diseased catfish or parts of catfish that died otherwise by slaughter must be leak proof and so constructed and equipped as to permit thorough cleaning and sanitizing. The means of conveyance used in conveying the catfish or parts of catfish must be cleaned and disinfected before being used in the transportation of any product intended for use as human food. The cleaning procedure must include the complete removal

from the means of conveyance of any fluid, parts, or product of dead, dying, or diseased catfish and the thorough application of a disinfectant approved by the Administrator to the interior surfaces of the cargo space.

**PART 557—IMPORTATION**

Sec.

- 557.1 Definitions; application of provisions.
- 557.2 Eligibility of foreign countries for importation of catfish products into the United States.
- 557.3 No catfish product to be imported without compliance with applicable regulations.
- 557.4 Imported catfish products; foreign certificates required.
- 557.5 Importer to make application for inspection of catfish products for entry.
- 557.6 Catfish products for importation; program inspection, time and place; application for approval of facilities as official import inspection establishment; refusal or withdrawal of approval; official numbers.
- 557.7 Products for importation; movement prior to inspection; handling; bond; assistance.
- 557.8 Import catfish products; equipment and means of conveyance used in handling to be maintained in sanitary condition.
- 557.9 [Reserved]
- 557.10 Samples; inspection of consignments; refusal of entry; marking.
- 557.11 Receipts to importers for import catfish products samples.
- 557.12 Foreign canned or packaged catfish products bearing trade labels; sampling and inspection.
- 557.13 Foreign catfish products offered for importation; reporting of findings to Customs.
- 557.14 Marking of catfish products and labeling of immediate containers thereof for importation.
- 557.15 Outside containers of foreign products; marking and labeling; application of official inspection legend.
- 557.16 Small importations for importer's own consumption; requirements.
- 557.17 Returned U.S. inspected and marked catfish products.
- 557.18 Catfish products offered for entry and entered to be handled and transported as domestic; exception.
- 557.19 Specimens for laboratory examination and similar purposes.
- 557.20–557.23 [Reserved]
- 557.24 Appeals; how made.
- 557.25 Disposition procedures for catfish product condemned or ordered destroyed under import inspection.
- 557.26 Official import inspection marks and devices.

**Authority:** 21 U.S.C. 601–602, 606–622, 624–695; 7 CFR 2.7, 7 CFR 2.18, 2.53.

**§ 557.1 Definitions; application of provisions.**

(a) When used in this part, the following terms shall be construed to mean:

(1) *Import*. To bring within the territorial limits of the United States whether that arrival is accomplished by land, air, or water.

(2) *Offer for entry*. Presentation of the imported product by the importer to the Program for reinspection.

(3) *Entry*. The point at which imported product offered for entry receives reinspection and is marked with the official mark of inspection in accordance with § 557.26 of this subchapter.

(b) The provisions of this part shall apply to catfish and catfish products that are capable of use as human food. Compliance with the conditions for importation of products under this part does not excuse the need for compliance with applicable requirements under other laws, including the provisions in part 94 of chapter I of this title.

**§ 557.2 Eligibility of foreign countries for importation of catfish products into the United States.**

(a) The requirements in 9 CFR 327.2(a)(1), 327.2(a)(2)(i), 327.2(a)(2)(ii)(C)–(I), 327.2(a)(2)(iii)–(iv), and 327.2(a)(3), for determining the acceptability of foreign meat inspection systems for the importation of meat and meat food products into the United States, apply in determining the acceptability of foreign catfish inspection systems for the importation of catfish and catfish products into the United States. In determining the acceptability of these systems, the Agency will evaluate the manner in which they take into account the conditions under which catfish are raised and transported to a processing establishment.

(b)(1) It has been determined that catfish and catfish products from the following countries covered by foreign inspection certificates of the country of origin as required by 9 CFR 557.4, are eligible under the regulations in this subchapter for entry into the United States after inspection and marking as required by the applicable provisions of this part: (None listed as of [PUBLICATION DATE OF FINAL RULE]).

(2) Persons interested in having the most recent list of eligible countries and establishments may contact the Office of International Affairs, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250.

**§ 557.3 No catfish product to be imported without compliance with applicable regulations.**

No catfish or catfish product offered for importation from any foreign country shall be admitted into the

United States if it is adulterated or misbranded or does not comply with all the requirements of this subchapter that would apply to it if it were a domestic product.

**§ 557.4 Imported catfish products; foreign certificates required.**

Except as provided in § 557.16, each consignment containing any catfish or catfish products consigned to the United States from a foreign country must be accompanied by a foreign inspection certificate for catfish and catfish products. The certificate, in paper or electronic format, must contain those data elements that the Administrator may prescribe to carry out the intent of this section.

**§ 557.5 Importer to make application for inspection of catfish products for entry.**

(a) Each importer must apply for inspection of any catfish product offered for entry (*See* Sec. 301.2(yyy)).

(b) The application should be made as long as possible in advance of the anticipated arrival of each consignment into the United States, except in case of consignments of products expressly exempted from inspection by §§ 557.16 and 557.17.

(c) Each application must state the approximate date on which the consignment is due to arrive at such port in the United States, the name of the ship or other carrier transporting it, the name of the country from which the product was, or is to be, shipped, the place where inspection is desired in accordance with § 557.6, the quantity and kind of product, and whether it is fresh, cured, canned or otherwise prepared. In case of consignments arriving in the United States by water, the application must state the port of first arrival in the United States.

**§ 557.6 Catfish products for importation; program inspection, time and place; application for approval of facilities as official import inspection establishment; refusal or withdrawal of approval; official numbers.**

(a)(1) Except as provided in §§ 557.16 and 557.17, all catfish products offered for entry from any foreign country shall be reinspected by a Program inspector before they shall be allowed entry into the United States.

(2) Every lot of product shall routinely be given visual inspection by a Program import inspector for appearance and condition, and checked for certification and label compliance.

(3) FSIS operates an electronic system to provide reinspection instructions. The electronic system assigns reinspection levels and procedures that are based on established sampling plans

or established sampling plans and established product, country, and plant history.

(4) When the inspector deems it necessary, the inspector may sample and inspect lots not designated by the electronic system.

(b) Catfish and catfish products required by this part to be inspected must be inspected only at an official establishment or at an official import inspection establishment approved by the Administrator as provided in this section.

(c) Owners or operators of establishments, other than official establishments, who want to have import inspections made at their establishments, shall apply to the Administrator for approval of their establishments for such purpose. Application must be made on a form furnished by the Program, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC, 20250, and must include all information called for by that form.

(d) Approval for Federal import inspection must be in accordance with §§ 304.1 and 304.2 of this chapter. Also, before approval is granted, the establishment must have developed written Sanitation Standard Operating Procedures in accordance with part 416 of this chapter.

(e) Owners or operators of establishments at which import inspections of product are to be made shall furnish adequate sanitary facilities and equipment for examination of such product. The requirements of §§ 307.1, 307.2 (b), (d), (f), (h), (k), and (l) and 416.1 through 416.6 of this chapter shall apply as conditions for approval of establishments as official import inspection establishments to the same extent and in the same manner as they apply with respect to official establishments.

(f) The Administrator is authorized to approve any establishment as an official import inspection establishment provided that an application has been filed in accordance with the requirements of paragraphs (c) and (d) of this section and he determines that such establishment meets the requirements under paragraph (e) of this section. Any application for inspection under this section may be denied or refused in accordance with the rules of practice in part 500 of this chapter.

(g) Approval of an official import inspection establishment may be withdrawn in accordance with applicable rules of practice if it is determined that the sanitary conditions are such that the product is rendered adulterated, that such action is

authorized by section 21(b) of the Federal Water Pollution Control Act, as amended (84 Stat. 91), or that the requirements of paragraph (e) of this section were not complied with. Approval may be withdrawn in accordance with section 401 of the Act and applicable rules of practice.

(h) A special official number shall be assigned to each official import inspection establishment. Such number shall be used to identify all products inspected and passed for entry at the establishment.

(i) A product examination must be made, as provided in paragraph (a) of this section, of a foreign catfish or catfish product, including defrosting if necessary to determine its condition. Inspection standards for foreign chilled fresh or frozen fresh catfish shall be the same as those used for domestic catfish or catfish products. Samples may be collected at no cost to FSIS and submitted to an FSIS laboratory for analysis (*See* § 557.18).

(j) Imported canned products are required to be sound, healthful, properly labeled, wholesome, and otherwise not adulterated at the time the products are offered for importation into the United States. Provided other requirements of this part are met, the determination of the acceptability of the product and the condition of the containers shall be based on the results of an examination of a statistical sample drawn from the consignment as provided in paragraph (a) of this section. If the inspector determines, on the basis of the sample examination, that the product does not meet the requirements of the Act and regulations thereunder, the consignment shall be refused entry. However, a consignment rejected for container defects but otherwise acceptable may be reoffered for inspection under the following conditions:

(1) If the defective containers are not indicative of an unsafe and unstable product as determined by the Administrator;

(2) If the number and kinds of container defects found in the original sample do not exceed the limits specified for this purpose in FSIS guidelines; and

(3) If the defective containers in the consignment have been sorted out and exported or destroyed under the supervision of an inspector.

(k) Program inspectors or Customs officers at border or seaboard ports shall report the sealing of cars, trucks, or other means of conveyance, and the sealing or identification of containers of foreign product to Program personnel at

points where such product is to be inspected.

(l) Representative samples of canned product designated by the Administrator in instructions to inspectors shall be incubated under supervision of such inspectors in accordance with § 318.309(d)(1)(ii), (d)(1)(iii), (d)(1)(iv)(c), (d)(1)(v), (d)(1)(vii) and (d)(1)(viii) of this subchapter. The importer or his/her agent shall provide the necessary incubation facilities in accordance with § 318.309(d)(1)(i) of this subchapter.

(m) Sampling plans and acceptance levels as prescribed in paragraphs (j) and (l) of this section may be obtained, upon request, from the Office of International Affairs, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250.

**§ 557.7 Products for importation; movement prior to inspection; handling; bond; assistance.**

The requirements in 9 CFR 327.7 respecting the movement or conveyance from any port, or delivery to the consignee, of any product required to be inspected under part 327, apply to catfish and catfish products.

**§ 557.8 Import catfish products; equipment and means of conveyance used in handling to be maintained in sanitary condition.**

Compartments of ocean vessels, railroad cars, and other means of conveyance transporting any catfish or catfish product to the United States, and all trucks, chutes, platforms, racks, tables, tools, utensils, and all other devices used in moving and handling any catfish or catfish product offered for importation into the United States, shall be maintained in a sanitary condition.

**§ 557.9 [Reserved]**

**§ 557.10 Samples; inspection of consignments; refusal of entry; marking.**

The provisions in 9 CFR 327.10 governing the taking of samples, the inspection of consignments, the refusal of entry, and the controlled pre-stamping of shipments of meat and meat food products apply with respect to catfish and catfish products.

**§ 557.11 Receipts to importers for import catfish product samples.**

FSIS will issue to importers official receipts for samples of foreign products collected for laboratory analysis, as provided in § 327.11 of this chapter.

**§ 557.12 Foreign canned or packaged catfish products bearing trade labels; sampling and inspection.**

Foreign canned or packaged catfish products bearing on their immediate

containers trade labels that have or have not been approved in accordance with the regulations in § 541.7 of this subchapter are to be sampled and inspected in the same manner as provided by § 327.12 of this chapter for foreign canned meat food products.

**§ 557.13 Foreign catfish products offered for importation; reporting of findings to Customs.**

Program inspectors are to report their findings as to any catfish product that has been inspected in accordance with this part in the same manner as that provided by § 327.13 of this chapter for meat products. Catfish products that are refused entry are to be handled in the same manner as provided by § 327.13 for meat products that are refused entry. Import personnel will identify to the Port Director of U.S. Customs and Border Protection and the Importer of record any products refused entry into the United States.

**§ 557.14 Marking of catfish products and labeling of immediate containers thereof for importation.**

The regulations in 9 CFR 327.14 governing the marking of meat and meat food products and the labeling of immediate containers of those products for importation apply with respect to catfish and catfish products.

**§ 557.15 Outside containers of foreign products; marking and labeling; application of official inspection legend.**

The requirements in 9 CFR 327.15 governing the marking and labeling of outside containers of meat and meat food products apply also with respect to catfish and catfish products.

**§ 557.16 Small importations for importer's own consumption; requirements.**

The exemption in 9 CFR 327.16 for small importations of meat or meat food products for the importer's own consumption applies with respect to catfish or catfish products.

**§ 557.17 Returned U.S. inspected and marked catfish products.**

U.S. inspected and passed and so marked catfish products exported to and returned from foreign countries will be admitted into the United States without compliance with this part upon notification of and approval by the Assistant Administrator, Office of International Affairs, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250, in specific cases.

**§ 557.18 Catfish products offered for entry and entered to be handled and transported as domestic; exception.**

The regulations in 9 CFR 327.18 governing the offer for entry into the United States of meat and meat food products apply with respect to catfish and catfish products. Products that fail to meet these regulatory requirements are subject to penalties as administered by the U.S. Port Director of Customs and Border Protection. Likewise, the products may be subject to detention and to being proceeded against as determined by the Administrator.

**§ 557.19 Specimens for laboratory examination and similar purposes.**

Importation of catfish or catfish product samples for trade show exhibition, laboratory examination, research, evaluative testing, trade show exhibition, or other scientific purposes are subject to the same conditions as imported meat or meat product specimens under § 327.19.

**§ 557.20–557.23 [Reserved]**

**§ 557.24 Appeals; how made.**

An appeal from a decision of any Program employee is to be made as provided by 9 CFR 327.24.

**§ 557.25 Disposition procedures for catfish product condemned or ordered destroyed under import inspection.**

Disposition procedures for condemned catfish or catfish products ordered destroyed under import inspection are as those for carcasses, parts, meat, and meat food products under 9 CFR 327.25.

**§ 557.26 Official import inspection marks and devices.**

The official inspection legend and other marks to be applied to imported catfish and catfish products are as required by 9 CFR 327.26 for meat food products prepared from cattle, sheep, swine, and goats.

**PART 559—DETENTION, SEIZURE, CONDEMNATION**

Sec.

559.1 Catfish and other articles subject to administrative detention.

559.2 Articles or catfish subject to judicial seizure and condemnation.

559.3 Criminal offenses.

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

**§ 559.1 Catfish and other articles subject to administrative detention.**

The provisions of 9 CFR 329.1 through 329.5 governing the administrative detention of carcasses, parts, meat, and meat food products of

livestock apply also with respect to the carcasses, parts, and products of catfish.

**§ 559.2 Articles or catfish subject to judicial seizure and condemnation.**

The provisions of 9 CFR 329.6 through 329.8 governing the judicial seizure and condemnation of carcasses, parts, meat, and meat food products of livestock apply also with respect to the carcasses, parts, and products of catfish.

**§ 559.3 Criminal offenses.**

The criminal provisions of the Act apply with respect to the inspection of catfish and catfish products as they do with respect to the inspection of other food products subject to the Act.

**PART 560—STATE–FEDERAL, FEDERAL–STATE COOPERATIVE AGREEMENTS; STATE DESIGNATIONS**

Sec.

560.1 Cooperation with States and Territories.

560.2 Cooperation of States in Federal programs.

560.3 Designation of States under the Federal Meat Inspection Act.

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

**§ 560.1 Cooperation with States and Territories.**

The provisions in § 321.1 of this chapter authorizing the Administrator to

cooperate with any State (including Puerto Rico) or any organized Territory in developing and administering a meat inspection program for the State or Territory apply with respect to catfish products inspection.

**§ 560.2 Cooperation of States in Federal programs.**

Under the “Talmadge-Aiken Act” of September 28, 1962 (7 U.S.C. 450), the Administrator is authorized to utilize employees and facilities of any State in carrying out Federal functions under the FMIA, including functions relating to the inspection of catfish and catfish products. A cooperative program for this purpose is called a Federal-State program.

**§ 560.3 Designation of States under the Federal Meat Inspection Act**

The requirements in part 331 of this chapter apply with respect to catfish and catfish products inspection, including:

(a) The requirements in 9 CFR 331.3 governing the designation of States for Federal inspection under section 301(c) of the Act (21 U.S.C. 661(c));

(b) The requirements in 9 CFR 331.5 governing the designation under section 301(c) of the Act of establishments whose operations would clearly endanger the public health; and

(c) The requirements in 9 CFR 331.6 governing the designation of States under paragraph 205 of the Act.

**PART 561—RULES OF PRACTICE**

Sec.

561.1 Rules of practice governing inspection actions.

561.2 Rules of practice governing proceedings under the Federal Meat Inspection Act.

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

**§ 561.1 Rules of practice governing inspection actions.**

The rules of practice in part 500 of this chapter, governing inspection actions taken by FSIS with respect to establishments and products, apply to actions taken with respect to catfish processing establishments, catfish, and catfish products regulated under this subchapter.

**§ 561.2 Rules of practice governing proceedings under the Federal Meat Inspection Act.**

The procedures that the Agency must follow before reporting a violation of the Federal Meat Inspection Act for prosecution by the Department of Justice are given in part 335, subchapter A of this chapter.

Done, at Washington, DC.

**Alfred V. Almanza,**  
*Administrator.*

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