

FSIS Compliance Guideline for Establishments that Slaughter or Further Process Siluriformes Fish and Fish Products March 2017



This guideline is designed to help establishments that slaughter or further process Siluriformes fish and fish products meet FSIS regulatory requirements and policies. In particular, this guideline covers how to:

- Apply for a Grant of Inspection (GOI)
- Submit Labels for Approval – Understand Labeling Requirements
- Comply with Sanitation Performance Standards (SPS) and Sanitation Standard Operating Procedure (Sanitation SOP) Requirements
- Comply with Hazard Analysis and Critical Control Point (HACCP) Requirements
- Understand Product Sampling Requirements
- Understand Export and Import Requirements for Siluriformes fish and fish products
- Develop Written Recall and Food Defense Plans

Preface

What is the purpose of this compliance guideline?

FSIS developed this compliance guideline to assist establishments that slaughter or further process Siluriformes fish and fish products in understanding and implementing their regulatory responsibilities. This guidance represents **best practice** recommendations by FSIS, based on the best scientific and practical considerations, and an establishment must meet or exceed FSIS food safety requirements with the written plans, policies, programs, and procedures as implemented during the production of food for human consumption. FSIS will enforce all requirements starting September 1, 2017. Until then, FSIS will focus on ensuring that adulterated product does not enter commerce. Also, FSIS will take action when product labeled as “catfish” is not catfish and when it finds that the net weight is over declared on the label.

This compliance guideline contains information, in part, on how establishments can apply for a Grant of Inspection (GOI); submit labels for approval; develop written recall plans; comply with Sanitation Performance Standards (SPS) and Sanitation SOP requirements; and comply with HACCP requirements. This compliance guideline also contains information to help establishments understand sampling requirements and requirements for exporting and importing Siluriformes fish and fish products.

FSIS developed this guideline for the domestic industry. However, foreign countries that are interested in obtaining an equivalence determination from FSIS can also use it to inform the design of their inspection program.

FSIS will likely update this guidance after the transitional period.

How can I comment on this guideline?

FSIS requests that all interested persons submit comments on any aspect of this document, including but not limited to: content, readability, applicability, and accessibility. The comment period will be 60 days from March 24, 2017. 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 or attach a file for lengthier comments. Go to <http://www.regulations.gov> and follow the online instructions for submitting comments.

Mail, including CD-ROMs, and hand- or courier-delivered submittals: Send to Docket Clerk, U.S. Department of Agriculture (USDA), FSIS, OPPD, RIMS, Patriots Plaza 3, 1400 Independence Avenue SW, Mailstop 3782, 8-163A, Washington, DC 20250-3700.

All items submitted by mail or electronic mail must include the Agency name and docket number FSIS-2017-0017. 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>.

What if I still have questions after I read this guideline?

If the desired information cannot be found within the Compliance Guideline, FSIS recommends that users search the publicly posted Questions & Answers (Q&As) in the [askFSIS](#) database or submit questions through [askFSIS](#). Documenting these questions helps FSIS improve and refine present and future versions of the Compliance Guideline and associated issuances.

When submitting a question, use the Submit a Question tab, and enter the following information in the fields provided:

Subject Field:	Enter FSIS Compliance Guideline for Establishments that Slaughter or Further Process Siluriformes Fish and Fish Products .
Question Field:	Enter question with as much detail as possible.
Product Field:	Select General Inspection Policy from the drop-down menu.
Category Field:	Select Sampling - General from the drop-down menu.
Policy Arena:	Select Domestic (U.S.) Only from the drop-down menu.

When all fields are complete, press **Continue**.

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FSIS Compliance Guideline for Establishments that Slaughter or Further Process Siluriformes Fish and Fish Products

Purpose

This guideline is designed to help establishments that produce Siluriformes fish and fish products meet FSIS regulatory requirements. In particular, this guideline covers how to:

- Apply for a Grant of Inspection (GOI)
- Submit Labels for Approval
- Comply with Sanitation Performance Standards (SPS) and Sanitation Standard Operating Procedure (Sanitation SOP) Requirements
- Comply with Hazard Analysis and Critical Control Point (HACCP) Requirements
- Understand Pre-Harvest Standards and Transportation to Processing Establishment Requirements
- Understand FSIS Product Sampling Requirements
- Understand Retained Water Requirements for Siluriformes Fish and Fish Products
- Understand Exporting and Importing Requirements of Siluriformes Fish and Fish Products
- Develop Written Recall and Food Defense Plans

Background

FSIS administers a regulatory program under the Federal Meat Inspection Act (FMIA) (21 U.S.C. 601 *et seq.*), the Poultry Products Inspection Act (PPIA) (21 U.S.C. 451 *et seq.*), and the Egg Products Inspection Act (EPIA) (21 U.S.C. 1031 *et seq.*) to protect the health and welfare of consumers. The Agency is responsible for ensuring that the nation's commercial supply of meat, poultry, and egg products is safe, wholesome, not adulterated, and correctly labeled and packaged.

The 2008 and 2014 Farm Bills

The Food, Conservation, and Energy Act of 2008 (Pub. L. 110-246, Section 10016(b)), known as the 2008 Farm Bill, amended the FMIA to provide that “catfish, as defined by the Secretary,” is an amenable species subject to FSIS jurisdiction and inspection (21 U.S.C. 601 (w)(2)). The 2008 Farm Bill also 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 and 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. In addition, the 2008 Farm Bill revised 21 U.S.C. 606, requiring that the conditions under which catfish are raised and transported to processing establishments be taken into consideration when meat food products derived from catfish are examined and inspected (21 U.S.C. 606(a) and (b)).

On February 24, 2011, FSIS published the proposed rule, “Mandatory Inspection of Catfish and Catfish Products” (76 FR 10434), implementing provisions of the 2008 Farm Bill. The proposed regulations were adapted from FSIS’ meat inspection regulations.

On February 7, 2014, the Agricultural Act of 2014 (Pub. L. 113-79, Sec. 12106), known as the 2014 Farm Bill, amended Section 1(w) of the FMIA to remove the phrase “catfish, as defined by the Secretary,” and replace it with “all fish of the order Siluriformes,” thus including these fish among the amenable species for meat under FSIS jurisdiction and inspection (21 U.S.C. 601(w)(2)).

On December 2, 2015, FSIS published the final rule, “Mandatory Inspection of Fish of the order Siluriformes and Products Derived from Such Fish” (80 FR 75589). The final rule implements the provisions of the 2008 and 2014 Farm Bills that mandate FSIS inspection of Siluriformes fish and fish products. As a result, effective March 1, 2016, jurisdiction and regulatory oversight over Siluriformes fish and fish products changed from the U.S. Food and Drug Administration (FDA) to FSIS.

FSIS Regulations

All establishments under FSIS jurisdiction must operate according to FSIS regulations found in Title 9 of the *Code of Federal Regulations* (CFR), Chapter III, Parts 300 – 592. Within Parts 300 – 592, there are regulations that apply to all establishments and products and others that are more specific and apply only to certain types of products or operations within establishments. The latest copy of 9 CFR 300-592 may be accessed on-line at: <http://www.ecfr.gov/cgi-bin/text-idx?SID=1be3e532c5856d2b7f938789c0a62564&mc=true&tpl=/ecfrbrowse/Title09/9chapterIII.tpl>.

There is an 18-month transitional period to ensure that domestic slaughter and further processing establishments of Siluriformes fish and fish products understand all FSIS’ food safety requirements. Therefore, at this time, FSIS will not take enforcement action if establishments do not meet all of the regulatory requirements discussed in this guideline.

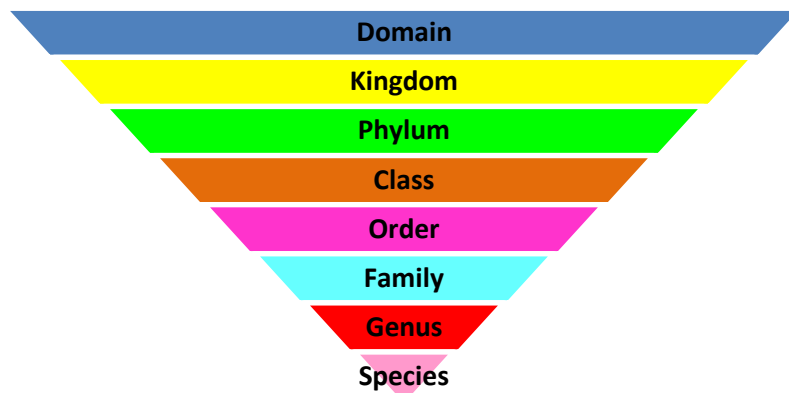
FSIS is working closely with establishments to provide guidance on meeting FSIS regulations and training personnel to bring their operations into full compliance with the regulations. FSIS personnel will also use broad discretion in enforcing the regulatory requirements, except when the establishment has produced adulterated or misbranded

fish product, or when there is intimidation of or interference with FSIS personnel. See the timeline of regulatory action below:



Siluriformes Fish

Organisms are classified according to the following hierarchy: Domain, Kingdom, Phylum, Class, Order, Family, Genus, and Species. Domain is the least specific or broadest group, and species is the most specific or narrowest.



Siluriformes is an order of bony fish that includes all catfish. The name catfish refers to the long barbels, or feelers, which are present about the mouth of the fish and resemble cat whiskers. All catfish have at least one pair of barbels on the upper jaw, with many possessing spines in front of the dorsal and pectoral fins. Catfish comprise nearly 2,900 species placed in about 35 families. Most species inhabit fresh water, but a few species are marine (salt-water). Catfish are generally bottom dwellers, and are more active at night than in the day.

The order Siluriformes includes the family Ictaluridae, the North American catfish, which includes 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 (*Ameiurus catus*), and the black, brown, and yellow bullhead (*A. melas*, *A. nebulosus*, and *A. natalis*). Also among the Siluriformes are the air-breathing catfishes

of the Clariidae family, which includes *Clarias fuscus*, a Chinese species raised on a small scale in Hawaii (ITIS).

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

Grant of Inspection (GOI)

Domestic establishments and import inspection establishments that want to be inspected by FSIS must first apply for a Federal GOI. Establishments that receive a Federal GOI are known as official establishments, are assigned an establishment number, and products of official establishments receive the USDA mark of inspection.

A comprehensive guide to obtaining an FSIS Federal GOI is available on the FSIS Web site at: <http://www.fsis.usda.gov/wps/portal/fsis/topics/inspection/apply-for-a-federal-grant-of-inspection>. Establishments should also contact their District Office (DO) to obtain a GOI Packet: <http://www.fsis.usda.gov/districtoffices>.

For a simple explanation, there are eight basic steps to receiving FSIS inspection:

1. File an application for Federal inspection services.
2. Ensure facilities meet regulatory sanitation performance standards.
3. Obtain approval for each label requiring sketch approval by the Office of Policy and Program Development (OPPD) Labeling and Program Delivery Staff (LPDS).
4. Obtain a water report attesting to the potability of the water supply.
5. Obtain approval from the State or local health authority if sewage disposal system is a private system.
6. Provide written Sanitation SOPs.
7. Provide a written hazard analysis, a flow chart, and intended use.
8. Provide a written recall plan.

Registration

Any person, firm, or corporation that engages in commerce as a Siluriformes fish or fish products broker, renderer, animal food manufacturer, wholesaler, or public warehouseman must register their business as required by the regulations in 9 CFR 320.5 (see 21 U.S.C. 643; 9 CFR 550.5). **This list includes farmers and transporters that supply Siluriformes fish to official establishments.** FSIS Form 5020-1, *Registration of Meat and Poultry Handlers* (see 9 CFR 550.5) must be completed and

submitted to FSIS. The form can be downloaded from the FSIS Web site at:
<http://www.fsis.usda.gov/wps/wcm/connect/245282ee-4cd5-4247-8fe0-04f8b7e94db5/Form-5020-1.pdf?MOD=AJPERES>.

Official establishments are not required to complete Form 5020-1.

Note: FSIS is not enforcing registration requirements until September 1, 2017.

Official Inspection Legend

Products receive the USDA official inspection legend after they are inspected by FSIS and found to be wholesome, unadulterated, and accurately labeled. The official inspection legend must be shown on all labels for inspected and passed Siluriformes fish and fish products. The inspection legend requirements for Siluriformes fish and fish products are found in 9 CFR 541.1–541.5. Official inspection legend requirements can also be found at: <http://www.fsis.usda.gov/siluriformes>.

Because all Siluriformes fish are amenable species under the FMIA, FSIS requires the same inspection legend for those products as it does meat products (see 9 CFR 541.2, referencing 9 CFR 312.2). The inspection legend must contain the establishment number and the words “U.S. Inspected and Passed” or an abbreviation of those words approved by the Administrator. The inspection legend must be of a sufficient size and color to be conspicuously displayed, and readily legible, and in the same proportions of letter size and boldness as the one seen to the right.



This legend must be applied by mechanical means and must not be applied by a hand stamp. 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 Siluriformes fish and fish 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. The legend may also be used for the purposes of marking shipping containers, band labels, and other articles with the approval of the Administrator.

FSIS recognizes that it may be impractical to physically apply the inspection legend to whole, eviscerated, Siluriformes fish carcasses. Therefore, whole, eviscerated, Siluriformes fish carcasses that have been inspected and passed at an official establishment, and that are intended for sale as whole, gutted fish may be stamped with the inspection legend or properly packaged in an immediate container and then labeled with the official inspection legend, as well as with all other required labeling features (see 9 CFR 541.7, referencing 9 CFR 317.2). The inspection legend used for this purpose must be in the form illustrated to the right or in another form determined by the Administrator.



FSIS Inspection at Domestic Official Establishments and Official Import Inspection Establishments

Inspections in domestic official establishments and official import inspection establishments are conducted by the Office of Field Operations (OFO) inspection program personnel. OFO has District Offices (DOs), each headed by a District Manager (DM), who is responsible for the delivery of major aspects of the Agency's food safety and public health regulatory mission. More information on the DOs, including the States covered by each office and contact information for the DMs, is available at <http://www.fsis.usda.gov/districtoffices>.

During the transitional period until September 1, 2017, FSIS will conduct inspection during all hours of operation for all Siluriformes fish slaughter establishments and will conduct at least quarterly inspection at processing establishments.

In addition, FSIS will select certain imported shipments for reinspection at official import establishments.

FSIS provides up to eight consecutive hours per shift of inspection to all official establishments free of charge, during the official hours of operation designated on the FSIS GOI (9 CFR 307.4(c)). However, during the transitional period, FSIS is providing inspection of fish processing establishments on a quarterly basis. Similarly, FSIS is selecting imported shipments on a quarterly basis.

FSIS inspection personnel assigned to an establishment have a tour of duty that coincides with the hours of operation. Any activities performed by FSIS inspection personnel outside of the official hours of operation, including Federal holidays, are performed outside this tour of duty; therefore, the time spent will be charged to the establishment as overtime. In other words, the establishment is charged for overtime and holiday work performed by FSIS inspection personnel. The regulations covering the schedule of operations, overtime and holiday inspection service, and the basis of billing for overtime and holiday services may be found in 9 CFR 533.5 –533.7.

Domestic official establishments and official import establishments must allow FSIS inspection program personnel access to every part of the establishment where product is produced, day or night, even if the establishment is not in operation, for the purpose of conducting an inspection or performing any other inspection program duty. FSIS inspection program personnel must also be allowed access to all other facilities or areas associated with the production and transportation of product regulations. For Siluriformes fish, this also includes facilities or areas associated with the raising of fish. FSIS inspection program personnel must also be granted access to all records pertaining to all aspects of production, including but not limited to: slaughter, processing, sanitation, sampling, and transportation. In the case of Siluriformes fish, this includes records associated with how the fish were raised, including feed. The official establishment has the right to request that FSIS inspection program personnel show identification (i.e., a numbered official badge) before granting them access.

According to 9 CFR 532.1 (a), “No establishment may process or prepare fish, fish parts, or fish products capable of use as human food, or sell, transport, or offer for sale or transportation in commerce any of these articles without inspection under these regulations, except as expressly exempted in §532.3.” In addition, 9 CFR 532.1 (b) (4)

states, “All fish and fish products prepared in an official establishment must be inspected, handled, processed, marked, and labeled as required by the regulations.” 9 CFR 532.5 provides the exemptions for human food products that have not traditionally been considered fish products or that contain relatively small amounts of fish and are therefore not subject to FSIS regulations.

Submitting Labels for Approval – Labeling Requirements

FSIS must approve all labels used on products produced by official establishments. FSIS approves labels either through the sketch approval process or through generic label approval. More detailed information is available at <http://www.fsis.usda.gov/wps/wcm/connect/bf170761-33e3-4a2d-8f86-940c2698e2c5/Label-Approval-Guide.pdf?MOD=AJPERES>.

Generic label approval is labeling that is not required to be evaluated by the Labeling and Program Delivery Staff (LPDS) prior to use. Generic labels are approved without evaluation if they comply with all regulatory requirements.

Labels for temporary approval, labels of products that are for export only with labeling deviations, labels for poultry products that are under a religious exemption, and labels that bear special statements and claims must be submitted to LPDS for sketch approval. FSIS defines a “sketch” label as the concept of a label. It may be a printer’s proof or equivalent that is sufficiently legible to clearly show all labeling features, size, and location. FSIS will accept sketches that are hand drawn or computer generated, or other reasonable facsimiles that clearly reflect and project the final version of the label.

For a list, periodically updated, of statements or claims that require sketch approval by LPDS, please see: <http://www.fsis.usda.gov/wps/wcm/connect/bf170761-33e3-4a2d-8f86-940c2698e2c5/Comp-Guide-Labeling-Evaluation-Approval.pdf?MOD=AJPERES>. The list is extensive; however, because of the wide variety of possible claims that may be submitted, the absence of a claim from this list does not necessarily indicate that a claim does not require sketch approval. If establishments need clarification on whether or not a claim requires sketch approval by LPDS, a claim inquiry can be submitted via the online question and answer forum [askFSIS](#).

Note: During the transitional period until September 1, 2017, FSIS will not take action against misbranded product unless FSIS finds that product is labeled as “catfish” and is not from the family Ictaluridae, the net weight is over declared, the product contains an undeclared allergen, or if the product bears no label.

FSIS’ regulations permit certain labels, including those that are not likely to present significant policy issues that have health or economic significance, to be “generically approved” without having to be submitted to the Agency’s headquarters-based labeling staff, as long as the labels comply with the regulations. Although not submitted to FSIS, generically approved labels are approved by FSIS by being in compliance with applicable regulations (see 9 CFR 541.7, referencing 9 CFR 412).

Submissions through any means other than the electronic Label Submission and Approval System (LSAS) requires two copies each of a completed FSIS Form 7234-1, *Application for Approval of Labels, Marking or Device*, the label, and supporting

documentation, if applicable. To avoid delays, however, applicants are encouraged to register for a Level 2 eAuthentication account and submit label requests electronically through LSAS. USDA eAuthentication is the system used by USDA agencies to enable customers to obtain accounts allowing them to access USDA Web applications and services. Information on signing up for an eAuthentication account and electronically submitting labels is available at:

<https://www.fsis.usda.gov/wps/portal/fsis/topics/regulatory-compliance/labeling/label-submission-and-approval-system>.

The labeling regulations (9 CFR 541.7, referencing 9 CFR 412) permit the use of the term “catfish” only on labels of fish classified within the family Ictaluridae, consistent with provisions of the Federal Food, Drug, and Cosmetic (FD&C) Act (at 21 U.S.C. 321d (a) and 343(t)). The Agency is also requiring in 9 CFR 541.7 that fish and fish products in all other families in the order Siluriformes be labeled with appropriate common or usual names. Domestic and foreign fish establishments should consult FDA's "Guidance for Industry: The Seafood List--FDA's Guide to Acceptable Market Names for Seafood Sold in Interstate Commerce," for appropriate common or usual names

<http://www.fda.gov/food/guidanceregulation/guidancedocumentsregulatoryinformation/seafood/ucm113260.htm>.

All labels must bear these mandatory features:

- Product name;
- Inspection legend and establishment number;
- Handling statement (if required);
- Net weight statement (if required);
- Ingredients statement (if composed of two or more ingredients);
- Name and address of the manufacturer, packer or distributor;
- Nutrition facts (unless exemption applies); and
- Safe handling instructions (if required).

Generally, any required label information must be prominent, conspicuous (as compared to other words, statements, and designs on the label), 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.”

The principal display panel, or “PDP,” is the part of the label most likely to be displayed, presented, shown, or examined by the consumer. The PDP must include the name of the product, net quantity of contents, the official inspection legend, number of the official establishment, and, if necessary, a handling statement. The PDP must be large enough to accommodate the mandatory labeling information.

The information panel typically is that part of the label adjoining and to the right of the PDP; however, it can in certain circumstances be the back panel or any panel adjoining the PDP. All information required to appear on the label of a package must appear either on the PDP or the information panel unless otherwise specified by regulation. The information panel must be prominent and conspicuous.

Certain other label information that may be placed on the information panel (unless on the PDP) includes: an ingredients statement, name and address of the manufacturer or distributor, and nutrition labeling, if required. The safe handling instructions may be placed anywhere on the label.

Sanitation Performance Standards (SPS) and Sanitation Standard Operating Procedure (Sanitation SOP) Requirements

Sanitation

The Secretary has prescribed the rules and regulations of sanitation under which establishments shall be maintained. These rules have been issued in 9 CFR 416, and 417 as the Sanitation Performance Standards (SPS), Sanitation Standard Operating Procedures (Sanitation SOP), and HACCP requirements.

Note: During the transitional period, FSIS personnel will use broad discretion in enforcing the regulatory requirements and will not document noncompliance, except when the establishment has produced adulterated or misbranded Siluriformes fish product as per instructions to inspection program personnel (https://www.fsis.usda.gov/wps/wcm/connect/9dc3dddb-d0d7-42af-bd48-dc9af16e003f/23-16.pdf?MOD=AJPERES&CONVERT_TO=url&CACHEID=9dc3dddb-d0d7-42af-bd48-dc9af16e003f).

Siluriformes fish and fish products produced, packed, or held under insanitary conditions where they may have become contaminated with filth or may have been rendered injurious to health are deemed adulterated (see 21 U.S.C. 601(m)(4)).

Adulterated is defined in 9 CFR 531.1 Adulterated (4), which states that fish or fish food product is adulterated “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”. Insanitary conditions include situations such as a state, condition, or occurrence in which any edible meat or poultry products may become contaminated or adulterated through exposure, slaughter, processing, handling, and packaging or by any other means. As stated in [FSIS Directive 5000.1](#), “insanitary conditions may be isolated (e.g., damaged box, product residue in containers from previous day’s production) and only affect a limited area of an establishment and not affect the sanitary condition of other product or equipment... In other instances, the insanitary conditions may be such that the product produced in the establishment has become contaminated with filth or otherwise rendered injurious to health.”

Insanitary facilities and equipment (especially food contact surfaces), poor food handling, improper personal hygiene, improper sanitary dressing, and similar insanitary practices create an environment conducive to contamination of products. Examples of potential adulteration include:

- The establishment’s structures, rooms, and compartments cause insanitary conditions or product adulteration because they are not of sound construction, not maintained in good repair, or are too small to allow for processing, handling, or storage of product in a sanitary manner.

- Flaking rust or flaking paint in edible areas on ceilings or walls.
- The establishment does not clean and sanitize the walls, floors, and ceilings as necessary to prevent insanitary conditions.
- The establishment does not maintain walls, floors, ceilings, and any outside openings in a manner that prevents entry of vermin such as flies, rats, and mice.
- Food contact surfaces, including utensils and equipment, are not properly cleaned or sanitized resulting in direct product contamination. (9 CFR 537.1, 416.3, and 531.1)
- Establishment personnel do not adhere to hygienic practices and by not doing so directly adulterate product. (9 CFR 537.1, 416.5(a) or (c) and 531.1)
- Existing ventilation system is inadequate to control odors or condensation resulting in direct product adulteration. (9 CFR 537.1, 416.2(d) and 531.1)

To prevent insanitary conditions, domestic official establishments and official import inspection establishments must meet the requirements for Sanitation SOPs and SPS (see 9 CFR 537 and 9 CFR 557.6, referencing 9 CFR 416).

Sanitation Performance Standards

The SPS requirements identify the results to be achieved, but they do not prescribe the step-by-step procedures to produce safe Siluriformes fish and fish products. The SPS requirements allow establishments the flexibility to develop and employ innovative and unique sanitation procedures to achieve the desired results. Most of the SPS requirements address conditions within and around the establishment (e.g., ventilation, lighting, facility and equipment construction, and maintenance of the grounds). A few requirements address establishment operations and may be met through the Sanitation SOP (e.g., cleaning and sanitizing food contact surfaces) or HACCP plan (e.g., water reuse).

There are SPS requirements for:

- Grounds and pest control (9 CFR 416.2(a))
- Construction (9 CFR 416.2(b))
- Light (9 CFR 416.2(c))
- Ventilation (9 CFR 416.2(d))
- Plumbing (9 CFR 416.2(e))
- Sewage disposal (9 CFR 416.2(f))
- Water supply (including ice) (9 CFR 416.2(g))
- Dressing rooms, lavatories and toilets (9 CFR 416.2(h))
- Equipment and utensils (9 CFR 416.3)
- Sanitary operations (9 CFR 416.4)
- Employee hygiene (9 CFR 416.5)
 - Cleanliness
 - Clothing

- Disease Control

If FSIS determines that any equipment, utensil, room, or compartment at an establishment is insanitary, or that its use could cause the adulteration of product, an FSIS program employee will attach to it a “U.S. Rejected” tag. Equipment, utensils, rooms, or compartments so tagged cannot be used until made acceptable by the establishment. Only FSIS program employees may remove a “U.S. Rejected” tag.

Sanitation SOPs

Each establishment must develop, implement, and maintain written Sanitation SOPs for the procedures it conducts daily, before and during operations, to prevent product from direct contamination and adulteration. Sanitation SOPs must be signed and dated by someone that has overall onsite authority at the establishment, or a higher level establishment official. The signature means the establishment agrees to implement and maintain the Sanitation SOPs as specified. The Sanitation SOPs must be signed and dated on initial implementation and whenever changes are made.

Implementation of the Sanitation SOPs involves conducting all of the pre-operational procedures before operations begin, as well as conducting all other procedures at the frequencies specified. Implementation must be monitored daily.

Maintenance of the Sanitation SOPs involves routine evaluations of the effectiveness of the Sanitation SOPs in preventing direct contamination or adulteration of product. It also involves revising the Sanitation SOPs to keep the procedures effective, or if there is any change to facilities, equipment, utensils, operations, or personnel.

Farmers and transporters that provide fish to official establishments must meet the sanitary requirements for pre-harvest and transportation of fish to processing facilities (see 9 CFR 534).

Corrective Actions

If FSIS or the establishment determines that the Sanitation SOPs are not effective in preventing direct contamination or adulteration of product, then the establishment must take appropriate corrective actions.

Corrective actions include:

- Ensuring appropriate disposition of contaminated or adulterated product;
- Restoring sanitary conditions;
- Preventing recurrence of direct contamination or adulteration of products;
- Reevaluation and modification of Sanitation SOPs, if necessary; and
- Improvements in execution of Sanitation SOPs, if necessary.

The establishment must maintain daily records that document the implementation and monitoring of Sanitation SOPs and any corrective actions that were taken. These

records must be initialed and dated by the establishment employee(s) identified in the written Sanitation SOPs as being responsible for implementation and monitoring of each procedure.

Establishments are allowed to store records on computers as long as they can show that controls are in place to ensure the data and signatures aren't corrupted or falsified.

Sanitation SOP records must be maintained for at least six months, and made available to FSIS upon request. All Sanitation SOP records must be maintained at the establishment for 48 hours following completion, after which they may be maintained off-site. If stored off-site, Sanitation SOP records must be made available to FSIS within 24 hours of request.

FSIS verifies the adequacy and effectiveness of Sanitation SOPs. To do this, FSIS personnel may review the Sanitation SOPs; review the daily records documenting the implementation of the Sanitation SOPs, including any corrective actions taken; directly observe the implementation of the Sanitation SOPs and any corrective actions taken; and directly observe or test to assess the sanitary conditions.

Hazard Analysis and Critical Control Point (HACCP) Requirements

HACCP Plan

Domestic official establishments must comply with the HACCP regulations in 9 CFR 537, referencing 9 CFR 417. Domestic official establishments must conduct a hazard analysis, and document the results. After conducting the hazard analysis, establishments must develop and implement a written HACCP plan covering each product for which the hazard analysis revealed a food safety hazard that was reasonably likely to occur (RLTO). A hazard may be determined to be not reasonably likely to occur (NRLTO) if the nature of the process, or product, prevents the hazard from occurring or prerequisite programs are in place to prevent the hazard from occurring. If a hazard is determined to be NRLTO because a prerequisite program prevents the hazard, the establishment must have documentation to support the decisions in their hazard analysis.

The person who develops the HACCP plan and does any reassessment or modification of the plan must successfully complete a class or classes in the seven HACCP principles. The class(es) must also include the development of a HACCP plan for a specific product and instructions on how to conduct a records review. (Attachment 3 provides a generic Hazard Analysis/HACCP Plan to assist in developing the HACCP plan).

In accordance with 9 CFR 417.2(a), the written hazard analysis must:

- Identify food safety hazards that are reasonably likely to occur before, during, and after entering the establishment. Food safety hazards may arise from:
 - Natural toxins
 - Microbiological contamination

- Chemical contamination
 - Pesticides
 - Drug residues
 - Zoonotic diseases
 - Decomposition
 - Parasites
 - Unapproved use of direct or indirect food or color additives
 - Physical hazards
- A food safety hazard is any **Biological**, **Chemical**, or **Physical** property that may cause a food to be unsafe for human consumption. The following provides examples of the potential hazards associated with the slaughter and processing of fish:
 - **Biological** – Raw product pathogens and parasites
 - **Chemical** – Chemicals for cleaning, pesticide residues, antibiotics, other drugs, dyes, heavy metals, unapproved lubricants, etc.
 - **Physical** – Metal from broken blades and equipment
 - Identify preventative measures that can be used to control those hazards.
 - Contain a flow chart that describes the steps for each process, product flow in the establishment, and intended use or consumers of the finished product. Examples of generic flow charts for ice pack product, IQF product, and breaded IQF product are provided in: Attachment 1A – Ice Pack Product Flow Chart; Attachment 1B – IQF Product Flow Chart; and Attachment 1C – Breaded IQF Product Flow Chart. An example of generic processing steps for a catfish producer operation is provided in Attachment 2 - Generic Catfish Producer Operation Processing Steps.

Under 9 CFR 417.2(c), the HACCP plan must contain, at a minimum:

- A list of food safety hazards identified by the hazard analysis that must be controlled for each process.
- A list of critical control points (CCPs) for each of the identified food safety hazards, including:
 - CCPs designed to control food safety hazards introduced in the establishment; and
 - CCPs designed to control food safety hazards introduced outside the establishment.
- A list of critical limits (CLs) that must be met at each of the CCPs. CLs must at a minimum, be designed to meet targets and performance standards set by FSIS.

- A list of monitoring procedures used to monitor each CCP to ensure CLs are met. This includes the frequency of the monitoring procedure for each CCP.
- A list of corrective actions that will be taken when any deviation from any CL is found at any CCP.
- A record keeping system for documenting the monitoring of CCPs.
- A list of verification procedures used to verify that monitoring procedures for each CCP are performed correctly and the information and data obtained are accurate. This includes the frequency of the verification procedure for each CCP.

The HACCP plan must be signed and dated by a responsible person at the establishment. The signature on the plan means that the establishment accepts the plan and agrees to implement it. The HACCP plan must also be signed and dated whenever a change is made, and when it is reassessed (9 CFR 417.2(d)). Reassessment of the plan must take place at least once a year, or whenever there is a change that could affect the hazard analysis (9 CFR 417.4(a)(3)). An example of a generic model HACCP plan for catfish is provided in Attachment 3 - *Raw Model Hazard Analysis – Raw Product – Catfish*.

After developing and implementing a HACCP system, the establishment must validate it. The establishment does this by gathering scientific support and in-plant validation data for the HACCP system. Scientific or technical support for the design of those prerequisite programs used to support decisions in the hazard analysis may include published processing guidelines, journal articles, challenge studies, or other documents. In-plant validation may include observations, measurements, microbiological test results, or other information demonstrating that control measures, as written into the HACCP system, can be executed within a particular establishment to achieve the process' intended results (61 FR 38806, 38826 (July 25, 1996)).

For more information, see the *HACCP Systems Validation Guideline* (http://www.fsis.usda.gov/wps/wcm/connect/a70bb780-e1ff-4a35-9a9a-3fb40c8fe584/HACCP_Systems_Validation.pdf?MOD=AJPERES). After validation has been performed, the establishment must verify that the plan is being effectively implemented on an ongoing basis.

According to 9 CFR 417.5, the establishment must maintain HACCP records. All records, plans, and procedures must be available for FSIS to review and copy. This includes:

- The written hazard analysis and all supporting documents.
- The written HACCP plan. This includes:
 - The plan itself;
 - Decision-making documents associated with choosing the CCPs;
 - Decision-making documents associated with choosing the CLs;

- Documents supporting the monitoring procedures and frequency with which they are performed; and
- Documents supporting the verification procedures and frequency with which they are performed.
- Records documenting the monitoring of the CCPs and the CLs. These records must include the date the record was made. These include:
 - Recording of actual times, temperatures, or other measurable values as stated in the HACCP plan;
 - Calibration of process-monitoring instruments;
 - Corrective actions and all actions taken in response to a deviation;
 - Verification procedures and results; and
 - Product code(s), product name or identity, or slaughter production lot.
- Records showing a pre-shipment review should demonstrate the following:
 - Review of all records associated with a specific production of the product (i.e., production lot) for completeness and to ensure CLs were met and corrective actions were taken if necessary.
 - Review was conducted, signed, and dated by a person that did not produce the records reviewed, where practical.
- Record retention requirements include:
 - Records for slaughter activities and refrigerated product must be maintained for at least one year, and for at least two years for frozen, preserved, or shelf-stable products.
 - Records may be stored off-site after six months, but must be available within 24 hours onsite if an FSIS employee requests to review them.

Every entry made on a record under the HACCP plan must be made at the time the specific event occurred, include the date and time recorded, and should be signed or initialed by the person making the entry.

Establishments are allowed to store records on computers as long as they can show that controls are in place to ensure the data and signatures are not corrupted or falsified.

FSIS verifies the adequacy of the HACCP plan at each establishment by determining that each HACCP plan meets the requirements of 9 CFR 417 and all other applicable regulations.

If an establishment does not have a HACCP plan in place and is required to have one based on its hazard analysis or is not implementing the plan in accordance with FSIS regulations, any product produced at that establishment may be considered adulterated.

Pre-Harvest Standards and Transportation to Processing Establishments

Siluriformes fish that are harvested for use as human food must be raised under conditions that will not render the fish or their products unsound, unwholesome, unhealthful, or otherwise unfit for human food.

Site Selection Criteria

- The location, design, and construction of ponds and raceways used for fish farms should adhere to the principles of good aquaculture practices for Siluriformes fish.
- Siluriformes fish farms should be set in areas where there is minimal risk of contamination by microbiological, chemical (e.g., pesticides, herbicides, and fertilizers), or physical hazards and where any sources of pollution can be controlled. These contaminants may accumulate in fish at levels that can cause human health problems.
- Soil that is used to construct earthen ponds or raceways should not contain such concentrations of chemicals and other substances that may lead to the occurrence of unacceptable levels of contamination in fish.
- Ponds should have separated inlets and discharge canals to prevent the mixing of water supplies and effluent.
- Fertilizers, liming materials or other chemicals and biological materials should be used in accordance with good aquaculture practices.
- All sites should be operated so as not to cause adverse impacts on human health from the consumption of the farmed fish.

Water Quality Criteria for Siluriformes Food Fish Ponds and Raceways

Siluriformes fish farmers 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 may collect samples of feed or water from producers on a “for cause” basis. Feed and water will only be assessed as part of a traceback activity when FSIS finds hazardous levels of heavy metals, pesticides, or other chemical residues in fish samples. Water and/or feed will be tested for the specific compound(s) of interest.

Water Quality Criteria for Siluriformes Pond Production

- **Dissolved Oxygen in Pond Water** (Silva, 2016)
 - Fish need to breathe in oxygen for their metabolism. Dissolved oxygen is required in aquatic environments to oxidize potentially toxic metabolic wastes into less toxic forms, such as ammonia (NH_3) to nitrite (NO_2^-) and then to nitrate (NO_3^-). The recommended range for dissolved oxygen in pond water is from 4 mg/l to saturation.
 - If the range for dissolved oxygen in pond water falls to 0 – 1.5 mg/l, this can be lethal for fish, especially if exposed for prolonged periods. If the range falls to 1.5 – 5 mg/l, fish will survive, but will result in reduced feed intake, slow growth rate, and increased susceptibility to diseases.
 - When the water is supersaturated (i.e., more oxygen in the water than it would normally hold) to levels of 300% and above, this will interfere with the fish's ability to process excess oxygen taken up by the gills. Excess oxygen will concentrate in the blood causing "gas bubble disease" in fish, which may be lethal in severe cases.
- **Temperature** (Silva, 2016)
 - Fish are cold-blooded animals, and their metabolic rate is directly influenced by water temperature. The recommended range for water temperature is 79 – 90°F (26 – 32°C).
 - If the temperature falls below 59°F (15°C), the growth rate stops and death occurs at extreme temperatures. When the temperature is between 59 – 79°F (15 – 26°C), one will see reduced feed intake and growth rates.
 - At lower temperatures, fish are more stressed (less active) and are more susceptible to disease.
 - There is lower solubility of oxygen in pond water at temperatures above 90°F, resulting in stress in fish and death at extreme temperatures.
- **pH** (Silva, 2016)
 - The pH of water affects the solubility (i.e., ability to dissolve in water) and some chemical forms of various compounds, including aquaculture chemicals, can be toxic to fish.
 - The recommended pH range in water is 6.5 – 9. Fish will die if the pH falls below 4 (acidic death point). Fish will survive if the pH is between 4 – 6, but will be stressed and see slow growth and reduced feed intake.
 - Higher pH levels between 9 – 11 are stressful to fish and will result in a slow growth rate. Fish will die at pH levels above 11 (alkaline death point), and all life in the pond will die.
- **Alkalinity and Hardness** (Silva, 2016)
 - Alkalinity and hardness influence the buffering capacity of pond water. The hardness of water is primarily due to calcium and magnesium, which affects the physiological condition of the fish.
 - Alkalinity influences the amount and form of carbon dioxide in pond water.

- The recommended level for both hardness and alkalinity of pond water is greater than 20 ppm. Total alkalinity and hardness above 60 ppm is desirable in pond water.
- If the levels for both alkalinity and hardness fall below 20 ppm or total alkalinity and hardness is below 40 ppm, then this may cause extreme fluctuations in pond pH levels during the day, which are stressful to the fish.
- **Total Ammonia Nitrogen** (Silva, 2016)
 - Ammonia is the by-product of protein breakdown, and it occurs in both a toxic form (ammonia) and non-toxic form (ammonium), depending on the pH of the pond water.
 - The toxic form (ammonia) of total ammonia nitrogen should not be more than 0.3 – 2 mg/l, and is likely to rise as the pH of the pond water increases above 7.

Sampling Pond Water

Siluriformes fish growers need to sample grow-out ponds and raceways to ensure that water quality parameters (such as dissolved oxygen, temperature, pH, alkalinity and hardness, and total ammonia nitrogen) are within acceptable levels to ensure the health of the fish.

Environmental chemical contaminants (i.e., industrial chemicals and heavy metals) and pesticides that are reasonably likely to be present in grow-out ponds and raceways may accumulate in fish at levels that can cause human health problems. FSIS recommends that Siluriformes fish growers collect and analyze water samples for those environmental chemicals and pesticides that are likely to be present before the first harvest and at least once per year thereafter for each production site. The levels found should not be so high that they are reasonably likely to result in concentrations in harvested fish tissue above established tolerance or action levels set by the Environmental Protection Agency (EPA) or FDA, respectively. Established tolerances and action levels for some of the most toxic and persistent contaminants found in fish are listed in Table 9-1 of FDA's *Fish and Fishery Products - Hazards and Controls Guidance* (Fourth Edition – April, 2011), <http://www.fda.gov/downloads/Food/GuidanceRegulation/UCM251970.pdf>. The EPA has developed water quality guidance documents that also can be used in evaluating water quality in local situations (*U.S. EPA Water Quality Standards Handbook*, Appendix I).

As stated, levels of environmental chemicals and pesticides in grow-out ponds and raceways must not be so high that they are reasonably likely to result in harvested fish tissue concentrations that are above the established tolerance or action levels set by FDA and EPA, respectively. Therefore, FSIS will conduct follow-up sampling of water whenever a violative residue is found in fish tissue samples collected at processing

establishments to verify that fish are being raised under conditions that will yield safe and wholesome products.

Siluriformes fish growers should provide processors with a certificate of analysis (COA) or letter of guarantee (LOG) for each lot to ensure that the fish were not harvested from contaminated waters that could cause levels of environmental chemicals and pesticides in fish tissue that exceed established Federal tolerance and action levels.

Requirements for Transportation of Siluriformes Fish to Processing Establishments

Harvesting Siluriformes Fish

Fish should be harvested from the pond or raceway in a manner to ensure that they are in good condition for transport to the processing facility. It is important to remember that fish are sensitive to handling, and harvesting can cause stress.

There are two methods that are usually used for harvesting fish: 1) a complete harvest where all of the fish are removed from the pond or raceway; and 2) a partial harvest where only a portion of the fish are removed from the pond or raceway at a time. A complete harvest is generally done by seining and draining the pond. (A seine is a fishing net that hangs vertically in the water with floats at the top and weights at the bottom edge, and the ends are drawn together to encircle the fish.) Partial harvesting is usually done by using a seine for trapping the fish.

A common method for removing fish from a pond is lifting with a loading basket attached to a hydraulic boom, and placing into a live-haul tank or car. The harvesting areas and all equipment used for harvesting, catching, sorting, grading, and conveying fish to the transport vehicle should be designed for their rapid and efficient handling of the fish without causing mechanical damage and to minimize stress. The conveying equipment should be constructed of appropriate corrosion-resistant materials that do not transmit toxic substances and do not cause mechanical injuries to the fish (Jensen et al., 1992; Minchew et al., 2007).

Seines, dip nets, and other equipment used for harvesting fish should be scrubbed, dried, and disinfected between loads of fish to reduce the spread of diseases between groups of fish. Dip nets and other equipment used for harvesting fish may be cleaned with detergents, rinsed, dried, and disinfected with sodium or calcium hypochlorite, formalin, or iodine solutions. Any dead fish or nuisance aquatic weeds should be removed from seines to prevent the transmission of infectious diseases and parasites between groups of fish as well as from pond to pond. Diseases such as bacterial enteric septicemia of catfish (ESC) may be viable and can persist in moist mud balls that are not cleaned from seines (Jensen et al., 1992; Minchew et al., 2007).

Transporting Siluriformes Fish to Processing Establishments

Fish are generally transported from the pond or raceway to the processing establishment in trucks that are equipped with tanks, commonly referred to as “live-haul tanks” or “live-haulers.” Fish health and survival depend on limiting stress, therefore, transporting fish requires care to avoid fish losses. Fish are crowded into a relatively small amount of water when transported. Oxygen, often pure, is added to the transport water and incorporated with the use of blowers and agitators. Other options include adding compressed air, compressed oxygen, or liquid oxygen that can be used singly or in combination. The most important factor that determines whether fish live or die is the dissolved oxygen content in the transport water (Wynne et al., 2009; Wynne et al., 2011).

When adding oxygen to transport water, care must be taken to ensure not to supersaturate the water, which can result in excessive oxygen and lead to injured or dead fish. The dissolved oxygen concentrations in the transport water are determined by water temperature, salinity, and local altitude. The saturation concentration decreases as water temperature, salinity, and elevation increase. Super saturation of the water will lead to excess oxygen concentrating in the blood of fish, causing “gas bubble disease,” which may be lethal in severe cases (Wynne et al., 2009; Wynne et al., 2011).

Care should be exercised to maintain water quality factors that affect the health of fish (e.g., temperature, dissolved oxygen, carbon dioxide, total hardness, total alkalinity, and pH) when transporting fish. The transport water quality parameters for Siluriformes fish are listed below (Jensen, 1990).

- Temperature: 50 – 60°F
- Dissolved Oxygen: >5 mg/L
- Carbon Dioxide: <20 – 30 mg/L
- Total Hardness: 50 – 100 mg/L
- Total Alkalinity: 50 – 100 mg/L
- pH: 7.0 – 7.5

Transport tank compartments should be constructed of suitable corrosion-resistant materials that do not cause mechanical injury to the fish. Tank compartments should be sterilized after each load to prevent the transfer of diseases that may have been present in previous loads of fish. It is recommended that tank compartments be scrubbed with detergent, sprayed and rinsed with a sanitizer (such as iodine or chlorine solutions), rinsed again, and then air-dried after each load (Wynne et al., 2009; Wynne et al., 2011).

FSIS Product Sampling

FSIS will conduct sampling and testing of Siluriformes fish and fish products at inspected establishments, including import establishments, to test for species, drug residues, chemical residues, and pathogens under various sampling programs to

ensure product is not adulterated, or, based on species testing, the product is not misbranded. Fish products, like other meat products, that are prepared at retail stores and restaurants performing operations traditionally and usually conducted at those venues are exempt from mandatory FSIS inspection (i.e., daily inspection by FSIS) under 21 U.S.C. 661(c)(2) (9 CFR 532.3). However, retail stores are not exempt from the adulteration and misbranding provisions of the Act. Therefore, the Office of Investigation, Enforcement and Audit (OIEA) can collect fish samples at retail establishments to verify that fish products are not adulterated or misbranded.

FSIS has developed a testing program that includes the capacity to test for malachite green, nitrofurans, fluoroquinolones, gentian violet, pesticides, and other chemicals. Product will be considered adulterated when compounds in fish, including heavy metals, pesticides, and antimicrobials, are found to be above tolerances set by the FDA and EPA, or if a compound is found but no tolerance exists for the compound. If a sample tests positive for a violative residue or other adulterant, or is misbranded based on species testing results, FSIS will immediately initiate the appropriate regulatory control action.

FSIS is also analyzing samples for *Salmonella* to determine the national baseline prevalence and levels of *Salmonella* on raw Siluriformes fish and fish products during the 18-month transitional period. Raw product positive *Salmonella* sample results will not result in regulatory control actions. After the 18-month transitional period, FSIS will update the sampling program based on sampling results and findings.

During the transitional period, while FSIS is learning about Siluriformes fish production practices and about the parameters affecting biological, chemical, and physical relatedness of hazards in fish in domestic operations, FSIS will apply the mark of inspection prior to determining whether applicable FSIS test results for adulterants or species are acceptable. At this time, FSIS believes that fish are reared more similarly to poultry flocks than other livestock species in that exposure to possible contaminants, including medical treatment with drugs, is likely to impact all fish rather than individual fish. However, for imported product, because discrete units of product are presented for reinspection at the Point of Entry (POE) and such product generally is frozen, FSIS will not apply the mark of inspection until acceptable FSIS results for adulterants and species become available.

Note: For lotting purposes, lots should be defined so that if a violative result were found for one lot, the product from another lot would not be implicated. In the United States, fish are routinely grown in the same pond and later harvested as a single population for slaughter. Most residues of public health concern are absorbed or ingested by the fish directly from the water. In addition, data supports that if one fish sampled from a pond contains a violative residue, most of the fish collected at the same time from the same pond would likely contain the same violative residue. Thus establishments are to be aware that it would be nearly impossible to justify a lotting system in which fish collected at the same time from the same pond are identified as separate lots.

For product exported to the United States, FSIS will conduct sampling for chemical residues speciation, and *Salmonella*, at official import inspection establishments (OIIEs) that have a GOI for Siluriformes fish. This sampling and testing will be conducted to ensure that the product is not adulterated due to the presence of illegal chemical residues, or, based on species testing, the product is not misbranded. In addition, FSIS will begin collecting data to determine the prevalence of *Salmonella* in imported raw fish.

If a domestic product sample tests positive for violative residues or other adulterants, FSIS may “collect samples of feed, fish, and water from producers, at intervals to be determined by the Administrator, for the purpose of verifying that fish are being raised under conditions that will yield safe, wholesome products” according to 9 CFR 534.2.

9 CFR 548.3 describes that “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.” That is, the FMIA provides that meat products derived from amenable species, including Siluriformes fish, must bear an official inspection legend in order to enter commerce.

Net Weight Requirements for Siluriformes Fish and Fish Products

FSIS requires that labels of fish and fish products accurately display the net weight (see 9 CFR 541.7(a) and (e), cross-referencing 9 CFR 317, subpart A, and 9 CFR 442). FSIS periodically verifies the accuracy of net weight statements by testing products in both official establishments and in commerce. Fish and fish products may be fresh, frozen (including individually quick frozen or “IQF”), ice-glazed, or encased-in-ice. As stated in 9 CFR 442.2, FSIS adopts the net weight measuring procedures from the National Institute of Standards and Technology (NIST) Handbook 133 (<http://www.nist.gov/pml/wmd/pubs/hb133.cfm>).

For fresh or frozen fish or fish products, establishments should use the procedure described in NIST Handbook 133 Section 2.3. For ice-glazed or encased-in-ice products, establishments should use the procedure in Section 2.6. Neither procedure requires that the product be thawed in order to measure the net weight, but FSIS acknowledges that some thawing is inevitable under the procedure described in Section 2.6. For example, placing the product under a gentle spray of cold water to remove the ice glaze may partially thaw the product.

To verify accurate net weight labeling, establishments should also use the sampling plans recommended by NIST Handbook 133. For example, the Category B sampling plan located in NIST Handbook 133, Table 2.2, should be used for net weight determinations within official establishments. For all other testing, the sampling plan in Category A is recommended (see Table 2.1). This is the case whether the product is fresh, frozen, ice glazed, or encased in ice. Note that both Category A and B sampling

plans require the tester to determine the number of minus package errors that exceed the Maximum Allowable Variation (MAV). The MAV values for Category A sampling are found in Table 2.5 of NIST Handbook 133, and the values for Category B sampling are found in Table 2.9. FSIS will handle lots found out of compliance with the net weight requirements according to 9 CFR 442.5, *Handling of failed product*.

Note: During the 18-month transitional period, FSIS will document noncompliance in lots if the net weight is over-declared resulting in economic adulteration of product, in accordance with 9 CFR 541.7(e), 317.2(c)(4), 442.2(a), and 531.1.

Export and Import Requirements of Siluriformes Fish and Fish Products

Import Inspection

FSIS is responsible for ensuring that meat (including Siluriformes fish and fish products), poultry, and egg products imported into the United States are safe, wholesome, unadulterated, and properly labeled and packaged. FSIS also verifies that meat, poultry, and egg products imported into the United States are produced under standards equivalent to U.S. inspection standards, and facilitates the certification of exported goods. The FSIS regulations for imported Siluriformes fish and fish products are found in 9 CFR 557.

At the U.S. port-of-entry (POE), the U.S. Customs and Border Protection (CBP) verifies that the imported shipment meets customs and animal disease requirements. Importers or their customs brokers must apply for FSIS reinspection by submitting either a paper application for inspection (FSIS Form 9540-1) or an electronic application (FSIS Message Set). During the transitional period, FSIS will reinspect select imported shipments. At the end of the transitional period, FSIS will reinspect all imported product. The inspection application must be submitted to FSIS as early as possible, but no later than when entry is filed with CBP. In addition to the application submitted to FSIS by the importer/broker, the foreign government must also provide a foreign inspection certificate for the shipment. FSIS accepts either paper or electronic certification.

When the product is presented for reinspection, FSIS import inspectors first check the inspection application and foreign inspection certification to assure the shipment is from an eligible country and establishment

(<http://www.fsis.usda.gov/wps/portal/fsis/topics/international-affairs/importing-products/eligible-countries-products-foreign-establishments/eligible-foreign-establishments>), and is properly certified by the foreign country. Inspectors next examine each shipment for general condition and labeling and conduct the reinspection assignments as directed by FSIS' Public Health Information System (PHIS).

PHIS is a centralized computer database that generates reinspection assignments, receives and stores assignment results, and compiles performance histories for foreign

establishments. PHIS assigns FSIS inspectors the types of inspection (TOI) to be completed for a specific shipment based on programmed frequencies for the country, establishment, process category, species, and past performance.

Several TOI may be assigned by PHIS, including net weight checks of retail packages; examination of container condition; examination for product defects; incubation of canned goods; and laboratory analysis for product composition, microbiological contamination, residues, and species. Additionally, FSIS randomly samples imported products for drug and chemical residues.

Products that pass FSIS reinspection are stamped with the USDA mark of inspection and may enter U.S. commerce for distribution and use as if they were produced domestically. If imported meat or poultry products do not meet U.S. requirements, they are stamped "U.S. Refused Entry," and within 45 days must be exported, destroyed, or converted to animal food (if eligible and with the approval of the FDA). For meat products that are refused entry solely for misbranding, the importer has the opportunity to correct the label violation and bring the product into compliance within the 45 day timeframe. Relabeling of the product must be done with FSIS present, under reimbursable services, and may require coordination with the exporting country's government and the specific exporter to bring the product into compliance.

A shipment that bypasses FSIS reinspection and enters U.S. commerce (Failure to Present, or FTP) is no longer eligible for FSIS reinspection. The product must be destroyed or re-exported, and may be subject to recall. FSIS will request, through CBP, redelivery of FTP shipments, and that associated CBP penalties are applied.

Imports during Transitional Period

On the Agency's Web site at <http://www.fsis.usda.gov/siluriformes>, FSIS has published a list of foreign countries and foreign establishments that may continue to export Siluriformes fish and fish products to the United States during the transitional period. FSIS has also posted on this Web site a list of official import inspection establishments that are approved for Siluriformes fish and fish products import activities.

Brokers who have not registered with FSIS should complete and submit FSIS Form 5020-1, Registration of Meat and Poultry Handlers, which can be found at:

<https://www.fsis.usda.gov/wps/wcm/connect/245282ee-4cd5-4247-8fe0-04f8b7e94db5/Form-5020-1.pdf?MOD=AJPERES> .

Imports during Full Enforcement

FSIS has provided importers with a [checklist](#) identifying basic requirements that need to be met in order to import meat (which includes Siluriformes fish), poultry and processed egg products to the United States. The checklist includes the following:

- Products must originate from eligible countries and eligible establishments approved to export to the United States.
- USDA's Animal and Plant Health Inspection Service (APHIS) restricts some products from entering the United States because of animal disease conditions in the country of origin. For information on restrictions related to animal diseases and information about APHIS, contact the APHIS Veterinary Services, National Center for Import and Export (<http://www.aphis.usda.gov/wps/portal/aphis/ourfocus/importexport>).
- Countries and establishments become eligible following an equivalence determination process by FSIS.
- Imported products must meet the same labeling requirements as domestically produced products.
- After filing the necessary forms for CBP (<http://www.cbp.gov/trade/basic-import-export>) and meeting animal disease requirements of APHIS, all imported meat, poultry and processed egg products must be presented for reinspection by FSIS at an official import establishment.

Import Hold-and-Test Sampling Procedure

FSIS samples imported product, in part, for drug, pesticide, and other chemical residues to ensure that the products are safe, wholesome, and not adulterated. Drug, pesticide, or other chemical residues present at levels in excess of tolerances or action levels set by FDA or EPA, or dyes or other residues not approved for use in amenable species including Siluriformes fish and fish products adulterate these products. Product is also adulterated if no tolerance exists. During the transitional period, FSIS is conducting random and targeted sampling and testing of both domestic and imported Siluriformes products, in part, for violative chemical residues until full implementation of the Siluriformes fish and fish product inspection regulations which begin on September 1, 2017.

In order to make the best use of available resources for sampling and testing during the transitional period and to ensure that the transitional process is as smooth and effective as possible for all parties, while still fulfilling our mission to protect public health, FSIS is following an interim policy (outlined below) specifically for imported products. During the transitional period, if imported Siluriformes fish and fish products are determined to be violative through testing for drugs, pesticides, dyes, metals, nitrofurans, or other chemical residues that are not permitted for use or are found in excess of acceptable tolerance or action levels, FSIS will:

- Immediately notify the Central Competent Authority (CCA) – the agency or agencies responsible for food inspection – for the country in which the shipping establishment is located of the findings.

- FSIS will expect a timely response from the CCA that ensures appropriate corrective actions are implemented.
- Immediately notify the United States importer of record (IOR) responsible for the shipment, and other known importers of Siluriformes fish products from the same foreign establishment. The IOR can choose to return subsequent shipments from the same producing establishment back to the country of origin or to hold such entries intact and not release them into commerce until they have sampled and tested the product through a third-party laboratory. If the IOR chooses to sample subsequent shipments, the laboratory's scope of accreditation must include methods that detect and confirm the compounds identified by FSIS in the [Chemical Laboratory Guidebook](#), and results must be presented to the Agency through an analytical package submission that shows the product is "not adulterated."
 - The IOR will have to notify FSIS of the location of the shipments that are on hold. The location of the shipments may or may not be an official import inspection establishment ("I-house").
 - FSIS may elect to collect a sample from such shipments.
 - The IOR should obtain and submit information about each shipment that provides the rationale as to why the shipment is chemically independent of the shipment found by FSIS to be positive for a chemical residue.
- Have the IOR submit the private laboratory analytical information packages along with the rationale for why the shipment is chemically independent of the shipment found by FSIS to be violative for a chemical residue to the Agency at importinspection@fsis.usda.gov for review.
- The Agency will review the packages and analytical results to decide whether the shipment should be released into commerce or refused entry and if FSIS will collect a verification sample from this shipment. At a minimum, laboratory packages should include:
 - Description of the product including identification and size of lot;
 - Rationale from the establishment to support why fish in this shipment are chemically independent from the violative lot from the same establishment (e.g., fish were sourced from a different supplier or pond);
 - Production dates for fish in the shipment;
 - Name and accreditation number of the private laboratory;
 - Type of analysis conducted;
 - Analytical method and results;
 - Details about how the sample was collected and integrity maintained;
 - Details about sample preparation;
 - Standard data; and
 - Details about instrumentation used.

Note: The FDA's [Submission of Laboratory Packages by Accredited Laboratories](#) is the best available guidance on the quality and type of test data and information from accredited laboratories FSIS would expect to see in a laboratory package submission. IORs that follow the guidance in this document can be fairly certain that they would

meet FSIS expectations when the package also includes the few FSIS-specific items bulleted above.

FSIS may pursue a recall action for any product with violative residues that is not destroyed or returned to the exporting country intact. FSIS will also pursue a recall action for any product that enters commerce without submission of a laboratory package that contains test results and chemical independence rationale after the time in which the IOR, and all other importers, has been notified of a FSIS-positive test result from the same establishment.

Once the CCA proffers adequate corrective measures that have been effectuated and a production date is assigned to fish from the establishment that is determined to be chemically independent of the fish in the shipment found by FSIS to be violative for a chemical residue, FSIS will notify the CCA and importers that shipments of fish produced on or after the implementation date for corrective actions are no longer subject to the hold-and-test sampling protocol defined in this communication for Siluriformes fish products.

Questions about this process should be submitted to importinspection@fsis.usda.gov.

Export Inspection

Effective April 1, 2016 FSIS Form 9060-5S, Siluriformes Fish and Fish Products Export Certificate of Wholesomeness became available through the Materiel Management Service Center's (previously known as the Beltsville Service Center) Web site at <https://www.bsc.usda.gov/> or by calling toll free at 1-877-576-6329. Until FSIS inspectors have received their first order of Form 9060-5S, U.S. Department of Commerce (USDC) National Oceanic and Atmospheric Administration (NOAA) may continue to issue their own certificates at slaughter and slaughter/processing establishments. The exporter should work with the slaughter/processing establishment to determine what is needed for the export of Siluriformes fish. The export checklist also provides an overview of the steps that need to be taken when exporting meat, poultry, or processed egg products from the United States, and may be useful as an overview for Siluriformes fish.

On September 1, 2017, the products must be inspected and passed by FSIS and receive the USDA mark of inspection in order to export Siluriformes fish and fish products from the United States. FSIS is only involved with one aspect of exporting, which is certification. This includes the attestations and other information on the certificate form(s) that are signed by FSIS inspection program personnel. Exporters and the applicant establishment are responsible for making sure that product to be exported meets the receiving country's requirements as posted on the FSIS Web site.

Note: There is a difference between U.S. export regulations and foreign export requirements. FSIS regulations are based on the statutes or laws of the United States, and basically all the regulations require is that an export certificate be issued to attest to the fact that the product for export is wholesome. Foreign requirements are in addition

to domestic regulatory requirements that must be met as a condition for export to a particular country. The additional conditions to be met may include animal health or public health attestations, facility requirements, inspection procedures and labeling. Whether or not FSIS agrees with the rationale for additional foreign requirements, FSIS must ensure compliance to certify products for that country.

Export Library

FSIS provides exporters with a [checklist](#) identifying basic requirements they need to meet to be able to export meat, poultry, and processed egg products from the United States. The checklist includes the following statements:

- The FSIS Export Library lists the export requirements for specific countries (see <http://www.fsis.usda.gov/wps/portal/fsis/topics/international-affairs/exporting-products/export-library-requirements-by-country>).
 - These files contain information FSIS obtains by communicating directly with government officials in the importing country.
 - If a country is not listed in the Export Library, it should be assumed that either nothing is known about that country's import requirements or it has no additional requirements, and FSIS will issue the FSIS Form 9060-5, "MEAT AND POULTRY EXPORT CERTIFICATE OF WHOLESOMENESS," with no additional information in the "Remarks" section.
 - For a country that is not listed, exporters are advised to work closely with the importer in that country for information regarding the eligibility of the product, certification requirements, and the existence of a valid import permit for the product.
- The Export Library also lists the U.S. official establishments eligible to export to specific countries.
 - Most countries accept products from all federally authorized official establishments, but some only accept product from establishments that have been pre-certified by FSIS. FSIS pre-certifies an establishment by adding it to the list of eligible establishments and sending the updated list to the requesting country. In the case of countries accepting product from all federally authorized establishments, this is indicated in the country requirements under the section entitled "Plant Eligibility."
 - If the country requires pre-certification of the establishment, the exporter should obtain and complete FSIS Form 9080-3, "ESTABLISHMENT APPLICATION FOR EXPORT," from the FSIS inspection official assigned to the establishment or from the FSIS Web site and submit the application through the inspector to the appropriate FSIS DO.
- If the product is eligible for export to a specific country, the exporter should complete a copy of FSIS Form 9060-6, "APPLICATION FOR EXPORT CERTIFICATE." The exporter should submit the completed form to the FSIS inspector who performs export reinspection.

- The exporter should read the form carefully because it requires the exporter to certify that the products meet the import requirements of the country to which the products are being exported.
- The inspector will sign the application and provide a blank export certificate or the certificate's serial number to the exporter. The serial number on the certificate must be stamped on each shipping container with the export stamp required by 9 CFR 322.1 (a).
- The exporter should present the export certificate for signature to the appropriate FSIS signing official along with any other certificates required by the country.
 - Most certificates may be signed by the FSIS inspector, but some countries may require the signature of the FSIS Public Health Veterinarian (PHV).
 - The country requirements will indicate when the signature of the FSIS PHV is required.
 - If the country requirements do not indicate a signature requirement, the signature of an FSIS inspector will suffice.
- The original copy of the certificate will be provided to the exporter and must be provided to the importing country with the shipment.
 - FSIS Form 9060-5S will be the FSIS form for all Siluriformes fish exports, unless a country requires a different form. For example, Canada requires certification of meat and poultry products on FSIS Form 9135-3, and Russia requires certification of poultry products on FSIS Form 9450-4. In addition, a Letterhead Certificate (LC) is often needed because of the number of required attestations. The LC requires an FSIS signature and always accompanies the relevant 9060-5 or dedicated certificate.
 - Only statements found in the FSIS Export Library will be certified by FSIS.

Recall and Food Defense Plans

Recalls and the Recall Plan

A recall is a voluntary action conducted by a firm to remove adulterated or misbranded product from commerce. FSIS coordinates with the official establishment to ensure that recalled product has been properly identified and removed from commerce by verifying the effectiveness of the establishment's recall activities. FSIS also notifies the public about product recalls.

FSIS classifies recalls according to three levels:

- Class I: There is a reasonable probability that eating the product will cause serious, adverse health consequences or death.

- Class II: There is a remote probability of adverse health consequences if the product is eaten.
- Class III: Eating the product will not cause adverse health consequences.

Domestic official establishments must develop and maintain a written recall plan in the event adulterated or misbranded product enters commerce (9 CFR 532.2, referencing 9 CFR 304.3). The written recall plan must contain the procedures the establishment will use for the recall of any product produced and shipped by the establishment, including how the establishment will determine the need for a product recall and all of the procedures the establishment will use to conduct the recall.

Also, domestic official establishments must notify the appropriate FSIS DO within 24 hours of learning or determining that it has received or shipped adulterated or misbranded product into commerce (9 CFR 537.3, referencing 9 CFR 418). The official establishment must inform the DO of the type, amount, origin and destination of the adulterated or misbranded product.

All records associated with the recall plan and documentation of procedures must be available for FSIS review and copying. FSIS recommends that official establishments periodically conduct recall simulations to test the effectiveness of the recall plan.

The guidebook “How to Develop a Meat and Poultry Product Recall Plan,” as well as a sample recall plan for fish, is available on the FSIS Web site at <http://www.fsis.usda.gov/wps/wcm/connect/d87d635d-75fa-4a9b-8301-378675435a68/RecallPlanBooklet.pdf?MOD=AJPERES>.

Note: FSIS is not requiring that Siluriformes establishments maintain recall plans until after the transition period. Similarly, FSIS is not enforcing requirements that these establishments notify FSIS within 24 hours of shipping or receiving adulterated or misbranded product until after the transitional period.

Food Defense and Food Defense Plans

Food defense is the protection of food products from intentional contamination or adulteration where there is an intent to cause public health harm and/or economic disruption. Implementing food defense measures is voluntary; however, it is encouraged as a good business practice and to further protect public health.

In order to better prevent and prepare for an intentional attack on meat (which includes Siluriformes fish), poultry, and processed egg products, FSIS conducts vulnerability assessments of these food systems. Based upon its assessments, FSIS develops countermeasures or food defense practices that establishments can implement to protect the food supply. The Agency also conducts research activities and develops guidance materials and food defense training programs. These initiatives are conducted in collaboration and coordination with other Federal, State, and local partners, including academia and industry.

The Agency currently monitors FSIS-regulated facilities to determine the extent to which establishments are implementing food defense practices. This is done through food

defense tasks performed by FSIS in-plant inspection personnel. The information from these tasks assists FSIS in determining what further measures may need to be taken in the area of food defense.

A functional food defense plan can help establishments identify steps to take to minimize the risk that food products in the establishment will be intentionally tampered with or contaminated. These should take into account not only the official establishment, but also the feed supply, transportation, and farms where the fish are raised. A functional food defense plan is: 1) developed (documented and signed), 2) implemented (food defense practices are implemented), 3) tested (food defense practices are monitored and validated), and 4) reviewed and maintained (at least annually).

FSIS does not require official establishments to adopt a functional food defense plan; however, the Agency strongly encourages establishments to do so. Although the plan should be in place at all times, it may be particularly helpful during emergencies. During a crisis, when stress is high and response time is at a premium, a documented set of procedures improves an establishment's ability to respond quickly. A functional food defense plan helps establishments maintain a safe working environment for employees, provide a quality product to customers, and protect the bottom line.

FSIS developed a generic food defense plan template for fish farmers and producers, in addition to food defense guidelines for fish production and processing. To access these documents and other food defense resources, visit the FSIS web site at www.fsis.usda.gov/fooddefense. In addition, questions regarding food defense can be sent to: FoodDefense@fsis.usda.gov.

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