FSIS Siluriformes Fish Update

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Update Topics

• Establishment of FSIS Jurisdiction, Final Rule & Important Rule Implementation Dates
• Domestic Siluriformes Fish Inspection
• Imported Siluriformes Fish Inspection
• Other
  – Recalls
  – President/Congress Activities
  – Availability of Additional Information
Siluriformes Fish: Establishment of FSIS Jurisdiction over Inspection, Final Rule, Important Rule Implementation Dates
USDA Food Safety and Inspection Service

FSIS is the public health agency in the USDA and is responsible for ensuring that meat, poultry, and processed egg products are safe, wholesome, and accurately labeled.

Our Authority
Through a series of Acts, Congress empowers FSIS to inspect all meat, poultry, and processed egg products in interstate commerce.

- Federal Meat Inspection Act (FMIA), 1906
- Agricultural Marketing Act (AMA), 1946
- Poultry Products Inspection Act (PPIA), 1957
- Humane Methods of Slaughter Act (HMSA), 1958
- Egg Products Inspection Act (EPIA), 1970
Amended the Federal Meat Inspection Act (FMIA - 21 U.S.C. 601, et. seq.) to provide that:

- "Catfish" as defined by the Secretary is an amenable species
- The ante-mortem, post-mortem, humane handling inspection, and custom exemption provisions of the Act do not apply to "catfish"
- The Secretary is to take into account the conditions under which catfish are raised and transported
• On **February 24, 2011**, FSIS published the proposed rule, “Mandatory Inspection of Catfish and Catfish Products”

• The proposed regulations:
  - adapted from the appropriate meat inspection regulations that prevent the transportation, sale, offer for sale or transportation, or receipt for transportation, in commerce, of adulterated or misbranded products
  - asked for comment on the scope of the definition of “catfish”
Re-amended the Federal Meat Inspection Act to provide that:

The term “amenable species” means—

• (1) those species subject to the provisions of this chapter on the day before November 10, 2005;

• (2) all fish of the order Siluriformes;

• (3) any additional species of livestock that the Secretary considers appropriate
<table>
<thead>
<tr>
<th>ORDER</th>
<th>FAMILY</th>
<th>ACCEPTABLE COMMON OR USUAL NAMES</th>
<th>GENUS SPECIES</th>
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<tbody>
<tr>
<td>SILURIFORMES*</td>
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<tr>
<td>Ictaluridae</td>
<td></td>
<td>Blue Catfish or Catfish</td>
<td>Ictalurus furcatus</td>
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<td></td>
<td></td>
<td>Channel Catfish or Catfish</td>
<td>Ictalurus punctatus</td>
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<td></td>
<td></td>
<td>White Catfish or Catfish</td>
<td>Ameiurus catus</td>
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<td></td>
<td></td>
<td>Black Bullhead or Bullhead or Catfish</td>
<td>Ameiurus melas</td>
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<td></td>
<td></td>
<td>Yellow Bullhead or Bullhead or Catfish</td>
<td>Ameiurus natalis</td>
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<td></td>
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<td>Brown Bullhead or Bullhead or Catfish</td>
<td>Ameiurus nebulosus</td>
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<td>Flat Bullhead or Bullhead or Catfish</td>
<td>Ameiurus platycephalus</td>
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<tr>
<td>Claridae</td>
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<td>Whitespotted fish or Chinese fish</td>
<td>Clarias fuscus</td>
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<td></td>
<td></td>
<td>Sharptooth Clarias Fish</td>
<td>Clarias gariepinus</td>
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<td>Broadhead Clarias Fish</td>
<td>Clarias macrocephalus</td>
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<tr>
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<td>Walking Clarias Fish</td>
<td>Clarias batrachus</td>
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<tr>
<td>Pangasiidae</td>
<td></td>
<td>Swai or Sutchi or Striped Pangasius or Tra</td>
<td>Pangasianodon hypophthalmus</td>
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<td></td>
<td></td>
<td>Basa</td>
<td>Pangasius bocourti</td>
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<tr>
<td></td>
<td></td>
<td>Mekong Giant Pangasius</td>
<td>Pangasius gigas</td>
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<tr>
<td></td>
<td></td>
<td>Giant Pangasius</td>
<td>Pangasius sanitwongsei</td>
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</tbody>
</table>

* This list is not all-inclusive. A complete list is available in the Integrated Taxonomic Information System (ITIS) at [http://www.itis.gov](http://www.itis.gov).
On December 2, 2015, FSIS published the final rule, “Mandatory Inspection of Fish of the Order Siluriformes and Products Derived From Such Fish”

The final rule adopted the proposed regulations with changes
Where are the FSIS Siluriformes Fish Regulations Found?

CODE OF FEDERAL REGULATIONS (CFR) at www.ecfr.gov

Title 9

Chapter III – Food Safety and Inspection Service, Department of Agriculture

- Subchapter A – Agency Organization and Terminology; Mandatory Meat and Poultry Products Inspection and Voluntary Inspection and Certification
- Subchapters B and C (reserved)
- Subchapter D – Food Safety and Inspection Service Administrative Provisions
- Subchapter E – Regulatory Requirement Under the Federal Meat Inspection Act and the Poultry Products Inspection Act
- **Subchapter F – Mandatory Inspection of Fish of the Order Siluriformes and Products of Such Fish (Parts 530 -561.2)**
SANITATION SOPs

These written procedures must:

• Contain all the procedures the establishment will conduct daily, before and during operation.

• Identify the procedures to be conducted prior to operations (pre-op) and address, at a minimum, the cleaning of food contact surfaces of facilities, equipment, and utensils.

• Specify the frequency with which each procedure in the Sanitation SOP is to be conducted.

• Identify the establishment employee or position responsible for the implementation and maintenance of the procedures.

• Be signed and dated by the individual with overall authority on-site or a higher-level official of the establishment.
SANITATION SOPs

- Conduct pre-operation procedures in the Sanitation SOPs before the start of operations.
- Conduct all other procedures in the Sanitation SOPs at the frequencies specified.
- Monitor the daily implementation of the procedures in the Sanitation SOPs.

- Take appropriate corrective action when the Sanitation SOPs have failed to prevent direct contamination or adulteration of product.
- Maintain a daily record of the actions taken that are prescribed in the Sanitation SOPs and make the records available to FSIS.
- Record deviations from the Sanitation SOPs, along with corrective actions taken in conjunction with the monitoring of daily sanitation activities.
Establishments must comply with the Hazard Analysis & Critical Control Point (HACCP) requirements

– Hazard Analysis must be written and available to inspection personnel for validation.
USDA Food Safety and Inspection Service
Regulatory Timeline Outlined in Final Rule

December 2, 2015
Final Rule Published

March 1, 2016
Effective Date

**18-Month Transitional Period

September 1, 2017
Full Enforcement

90 Days
USDA Food Safety and Inspection Service
Purpose: 18-Month Transitional Period

- Provides establishments an opportunity to train personnel and to bring their operations into full compliance with the new regulations.
- FSIS will focus inspections on verifying that establishments meet Sanitation Performance Standards (SPS)
  - *Sanitation Performance Standards (SPS)* focus on specific areas or conditions in and around the establishment that may result in insanitary conditions that could lead to the adulteration of product.
Adulterated Product:
• Produced without the benefit of inspection
• Violative residue
• Undeclared Allergen
• Prepared, packed, or held under insanitary conditions

Misbranded Product:
• Product offered for sale as “Catfish,” but does not contain fish of the family Ictaluridae
• Net weight over-declared
• Missing label
• If FSIS finds other noncompliances with final FSIS regulations, FSIS will work with the establishment to bring it into compliance during the 18-month transitional period

• FSIS is developing compliance guidelines to aid establishments in complying with the new regulations
Inspection Program Personnel Notices Completed

Notices Issued March/April 2016

• **Notice 23-16**: CSIs Responsibilities At Fish (Of The Order Siluriformes) Establishments During the 18-month Transitional Period

• **Notice 24-16**: IPP Responsibilities At Official Import Inspection Establishments (With An Updated Siluriformes Grant Of Inspection) During the Transitional Period
Domestic *Siluriformes* Fish and Fish Products

*Note: Rule Applies to Farm Raised and Wild caught Catfish*
On March 1, 2016

FSIS present during all hours of operation at slaughter/processing (primary) establishments***

FSIS present at least quarterly at processing-only (secondary) establishments
On March 1, 2016

Sample Collection/Testing to Create Industry Scans at Domestic Slaughter/Processors

• Chemical Residues (Veterinary Drugs, Dyes, Pesticides, Metals, Nitrofurans)
• Speciation
• Salmonella (Non-regulatory)

FSIS Laboratories

• Western Laboratory (Albany, CA)
• Midwestern Laboratory (St. Louis, MO)
• Eastern Laboratory (Athens, GA)
Noncompliance Reports Have Been Issued Due to Product Contamination for the Following:

- **Condensation/Leaks Dripping Onto Exposed Product/Production Equipment**
  - Water from ceiling dripping on exposed product
  - Condensation drip from PVC pipe onto production belt
  - Ceiling leak dripping water onto product/production belt
- **Product from Floor Returned to Production Without Reconditioning/Adequate Reconditioning**
- **Contaminated Product/Ice**
  - Black mold like residue in 5 tubs containing product
  - Blackish grey substance dripping on fish in totes
  - Ice with unidentifiable foreign substance, dead fly, brown water
- **Insanitary Ice House Practices**
- **Insanitary Product/Ingredient Storage**
On September 1, 2017

• All regulations will be fully enforced.

• Sanitation Standard Operating Procedures (SSOPs), Hazard Analysis and Critical Control Point (HACCP), and Recall Plans must be in place

• All noncompliance will be documented on Noncompliance Reports (NRs)
Imported *Siluriformes* Fish and Fish Products

*Note: Rule Applies to Farm Raised and Wild caught Catfish*
Foreign countries that currently export Siluriformes fish/fish products to the U.S., and intend to continue during the 18-month transitional period, must submit:

• A complete list of establishments with establishment name and number

• Documentation to demonstrate the country’s authority to regulate the growing and processing of fish for human food and an attestation/documentation supporting compliance with FDA’s good manufacturing practices, Hazard Analysis and Critical Control Point (HACCP) plans, Sanitation Control Procedures, & other regulatory requirements
<table>
<thead>
<tr>
<th>Country</th>
<th>Plants</th>
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<tbody>
<tr>
<td>Bangladesh</td>
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<tr>
<td>Brazil</td>
<td>1</td>
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<tr>
<td>Canada</td>
<td>4</td>
</tr>
<tr>
<td>Guyana</td>
<td>20</td>
</tr>
<tr>
<td>Myanmar</td>
<td>23</td>
</tr>
<tr>
<td>Pakistan</td>
<td>9</td>
</tr>
<tr>
<td>People’s Republic of China</td>
<td>19</td>
</tr>
<tr>
<td>Thailand</td>
<td>7</td>
</tr>
<tr>
<td>Vietnam</td>
<td>58</td>
</tr>
<tr>
<td>Gambia</td>
<td>1</td>
</tr>
</tbody>
</table>
Import Entry Inspection Targeting Procedures

Targeting Criteria
- Ineligible Country/Establishment
- FDA Import Alerts/Compliance History
- Random (Eligible Country/Establishment)
- Goal: At least 1 Inspection per Eligible Country/Establishment Shipping Product

Inspections – Small Subset of Shipments
- Documentation Check/Condition of Shipment
- Labeling
- Sampling

Sampling – Hold Intact Pending Sample Results
- Chemical (veterinary drugs, dyes, pesticides, metals, nitrofurans)
- Speciation
- *Salmonella*
Since April 15, 2016, FSIS prevented from entering/removed from U.S. commerce 847,551 lbs. of adulterated or ineligible imported Siluriformes product. Another 29,645 lbs. has been recalled.

Inspections
- 150 Entries Selected for Inspection
- 106 Passed, 20 Pending Completion, 24 Violative/Refused
  - Violations found in product originating from Vietnam, China, Thailand and Bangladesh
  - Violations for chemical, drug and pesticide residues including: crystal violet, leucocrystal violet, malachite green, leucomalachite green, nitrofurazone, AOZ (3-amino-2-oxazolidinone)- a metabolite of furazolidone (a nitrofuran), enrofloxacin, and chlorpyrifos

Other
- 26 shipments identified of Siluriformes fish from ineligible countries/establishments; 134,390 lbs. of fish prevented from entering/removed from U.S. commerce.
- 2 shipments distributed w/o meeting FSIS hold/test requirements recalled
On September 1, 2017:

• Foreign countries that want to continue exporting Siluriformes fish to the U.S. must:
  • Have submitted, by September 1, 2017, a letter requesting an equivalence determination and a completed self reporting tool (SRT) with supporting documentation showing equivalence of their Siluriformes inspection system with that of the U.S.
  • Foreign countries that make such submissions by the deadline can continue exporting Siluriformes fish to U.S. while FSIS undertakes evaluation as to equivalency
  • FSIS will refuse entry if a foreign country has not submitted the required information

• All imported Siluriformes fish shipments will be inspected just as all imported meat and poultry products from equivalent countries are inspected
Other: Recalls, President/Congress Activity, Availability of Additional Information
Recalls

- **June 20, Expanded June 25 and July 14, 2016**: *U.S. Cado Holdings, Inc., a Santa Ana, Calif.* recalls approximately 25,760 lbs. (June 20), 2235 lbs. (June 25) and 1,650 lbs. (July 14) of imported frozen Swai fillets products (from Vietnam) distributed in U.S. commerce without meeting federal requirements (Hold and Test)

- **July 14, 2016**: *Haring Catfish, Inc., a Wisner, La.* recalls approximately 21,521 pounds of catfish products that may be adulterated with a residue of public health concern, gentian (crystal) violet

- **March 24, 2017**: *Lakes Farm Raised Catfish Inc., a Dundee, Miss.* recalls approximately 1,695 pounds of catfish products that may be adulterated with residues of public health concern, specifically malachite green and leucomalachite green

- **June 16, 2017**: *Channel Fish Processing Co., Inc., Boston, Mass.* recalls approximately 840 pounds of breaded Swai products due to misbranding and undeclared allergens
Congressional Activity to repeal *Siluriformes* regulations, transfer regulatory oversight back to FDA; use of authority under the Congressional Review Act (CRA), lawmakers can overturn controversial regulations from the Obama administration with a simple majority

May 2016 – Senate Activity
- “Senate voted to block the USDA from inspecting catfish, as lawmakers from both sides of the aisle clashed over the program”
- “The USDA announced new catfish inspection standards in December, but lawmakers rejected such inspections Wednesday in a 55-43 vote. The measure now goes to the House”

July 2016 – House Inactivity
- “House of Representatives left Washington for six weeks without voting on a proposed resolution of disapproval of the rule that FSIS promulgated to implement the farm bill provision moving catfish inspection from the FDA to FSIS”

Not Voted on Prior to Administration Change
**USDA Food Safety and Inspection Service**  
**President/Congressional Activity**

### FY2017 FSIS Budget
- Money provided to FSIS to reinspect all imported Siluriformes fish shipments, as all imported meat/poultry products from equivalent countries that export product to the US are reinspected.
- Explanatory notes in the Omnibus spending bill direct FSIS to:
  - Complete equivalence determinations for Siluriformes inspection programs in foreign countries exporting fish to the US not later than 180 days after the 18-month transition period ends.
  - Move up the schedule for the 100% reinspection of imported fish.
  - FSIS is working to address both.

### FY2018 President’s Budget
- 2018 Budget for USDA doesn't include additional funding for FSIS Siluriformes Inspection Program:
  - This results in a $2.5 million decrease from the 2017 funding level.
- Budget proposes to return function to FDA:
  - FSIS still has the authority/responsibility for Siluriformes inspection so the Agency is moving ahead with full implementation.
FSIS has set up an email box where questions can be submitted: AskFish@fsis.usda.gov.

FSIS’ Siluriformes web page has extensive information, including News and Information, Statutes and Regulations, Reports and MOU’s, and Resources: http://www.fsis.usda.gov/siluriformes.