

# USDA Food Safety and Inspection Service

## *FSIS Siluriformes Fish Update*

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AFDO Annual Meeting

### *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



## **USDA Food Safety and Inspection Service**

# ***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

# USDA Food Safety and Inspection Service

## Mandatory Inspection of Fish – 2008 Farm Bill



- 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

# USDA Food Safety and Inspection Service

## Mandatory Inspection of Fish – Proposed Rule

- 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”



## FEDERAL REGISTER

Vol. 76 Thursday,  
No. 37 February 24, 2011

Part II

Department of Agriculture

Food Safety and Inspection Service

9 CFR Parts 300, 441, 530, et al.  
Mandatory Inspection of Catfish and Catfish Products; Proposed Rule

# USDA Food Safety and Inspection Service

## Mandatory Inspection of Fish – 2014 Farm Bill



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

# USDA Food Safety and Inspection Service

## Siluriformes Fish – Order and Families

ORDER	FAMILY	ACCEPTABLE COMMON OR USUAL NAMES	GENUS SPECIES
SILURIFORMES*	Ictaluridae	Blue Catfish or Catfish	<i>Ictalurus furcatus</i>
		Channel Catfish or Catfish	<i>Ictalurus punctatus</i>
		White Catfish or Catfish	<i>Ameiurus catus</i>
		Black Bullhead or Bullhead or Catfish	<i>Ameiurus melas</i>
		Yellow Bullhead or Bullhead or Catfish	<i>Ameiurus natalis</i>
		Brown Bullhead or Bullhead or Catfish	<i>Ameiurus nebulosus</i>
		Flat Bullhead or Bullhead or Catfish	<i>Ameiurus platycephalus</i>
	Clariidae	Whitespotted fish or Chinese fish	<i>Clarias fuscus</i>
		Sharptooth Clarias Fish	<i>Clarias gariepinus</i>
		Broadhead Clarias Fish	<i>Clarias macrocephalus</i>
		Walking Clarias Fish	<i>Clarias batrachus</i>
	Pangasius	Swai or Sutchi or Striped Pangasius or Tra	<i>Pangasianodon hypophthalmus</i>
		Basa	<i>Pangasius bocourti</i>
		Mekong Giant Pangasius	<i>Pangasius gigas</i>
		Giant Pangasius	<i>Pangasius sanitwongsei</i>

\* This list is not all-inclusive. A complete list is available in the Integrated Taxonomic Information System (ITIS) at <http://www.itis.gov>.

# USDA Food Safety and Inspection Service

## Mandatory Inspection of Fish – Final Rule



### FEDERAL REGISTER

Vol. 80      Wednesday,  
No. 231      December 2, 2015

Part III

Department of Agriculture

Food Safety and Inspection Service  
9 CFR Parts 300, 441, 530, et al.  
Mandatory Inspection of Fish of the Order Siluriformes and Products  
Derived From Such Fish; Final Rule

- 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

# USDA Food Safety and Inspection Service

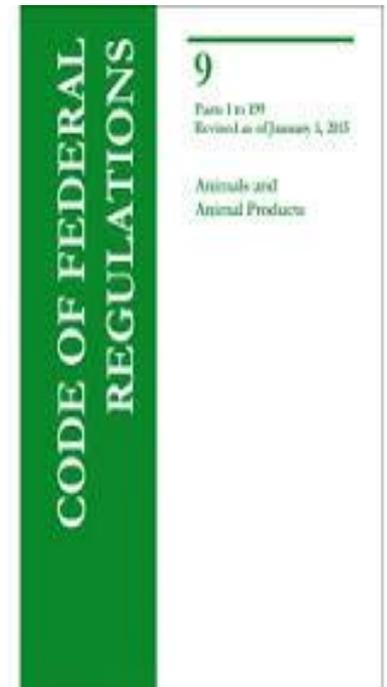
## Where are the FSIS Siluriformes Fish Regulations Found?

CODE OF FEDERAL REGULATIONS (CFR) at [www.ecfr.gov](http://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)**



# USDA Food Safety and Inspection Service

## Rule Requirements – September 1, 2017

### 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.

# USDA Food Safety and Inspection Service

## Rule Requirements – September 1, 2017

### 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.

# USDA Food Safety and Inspection Service

## Rule Requirements – Establishments Need to Meet by September 1, 2017

- 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

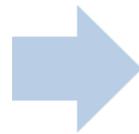
**December 2,  
2015**  
Final Rule  
Published

90 Days

**March 1, 2016**  
Effective Date

**\*\*18-Month  
Transitional  
Period**

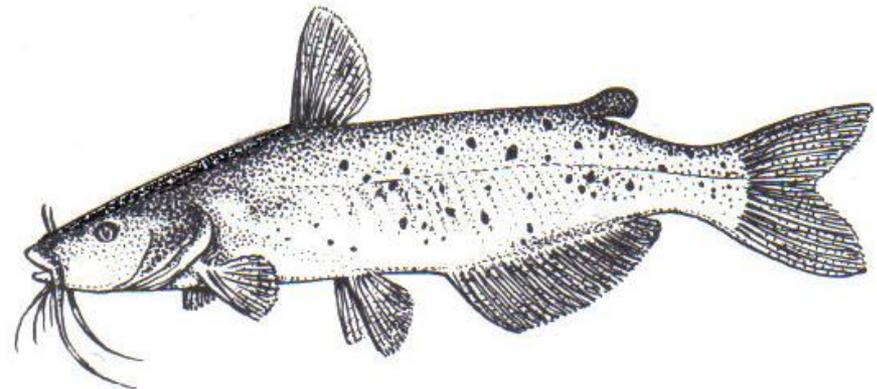
**September 1,  
2017**  
Full  
Enforcement



# 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.



# USDA Food Safety and Inspection Service

## Enforcement During the 18-Month Transitional Period



### 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

# **USDA Food Safety and Inspection Service**

## **Educational Approach During 18-Month Transitional Period**

- **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**



**USDA Food Safety and Inspection Service**  
**Instructions for Conducting Inspections**

# Inspection Program Personnel Notices Completed

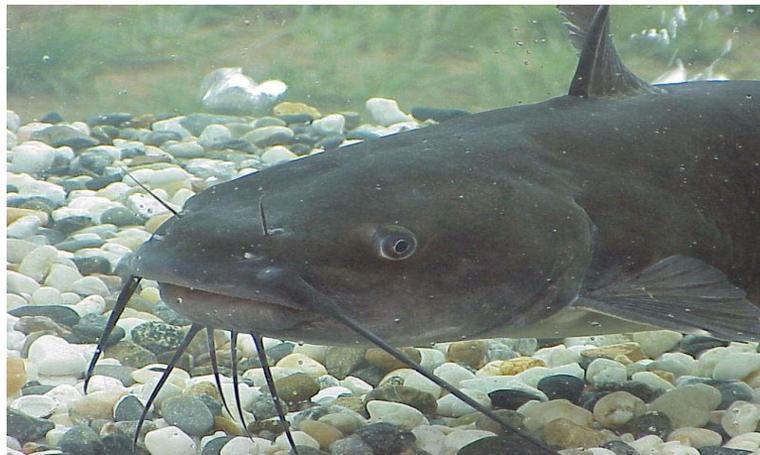
## Notices Issued March/April 2016

- **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*

**USDA Food Safety and Inspection Service**

# **Domestic *Siluriformes* Fish and Fish Products**

***Note: Rule Applies to Farm Raised and Wild caught  
Catfish***



# USDA Food Safety and Inspection Service

## Mandatory Inspection of Fish – Domestic Implementation

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



# USDA Food Safety and Inspection Service

## Transitional Period: Domestic Sampling

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)

# USDA Food Safety and Inspection Service

## Domestic Establishment Conditions Observed to Date

### 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**

# Food Safety and Inspection Service Implementation – September 1, 2017

## 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)

**USDA Food Safety and Inspection Service**

# **Imported *Siluriformes* Fish and Fish Products**

***Note: Rule Applies to Farm Raised and Wild caught Catfish***

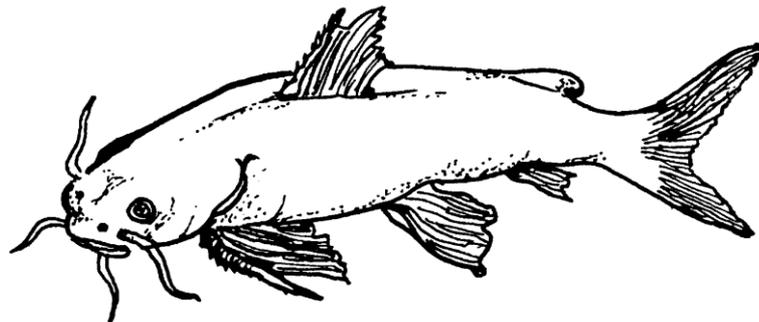


# USDA Food Safety and Inspection Service

## Mandatory Inspection of Fish – Foreign Country Requirements

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



## **USDA Food Safety and Inspection Service**

### **Countries/Establishments Eligible to Import Siluriformes**

<b>Bangladesh</b>	<b>30 plants</b>
<b>Brazil</b>	<b>1 plant</b>
<b>Canada</b>	<b>4 plants</b>
<b>Guyana</b>	<b>20 plants</b>
<b>Myanmar</b>	<b>23 plants</b>
<b>Pakistan</b>	<b>9 plants</b>
<b>People's Republic of China</b>	<b>19 plants</b>
<b>Thailand</b>	<b>7 plants</b>
<b>Vietnam</b>	<b>58 plants</b>
<b>Gambia</b>	<b>1 plant</b>

## 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*

## **USDA Food Safety and Inspection Service**

### **Imported Siluriformes Fish Inspections/Findings/Actions**

*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

## **USDA Food Safety and Inspection Service**

### **Implementation – Imported Product – After Transition Period**

#### **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**

# USDA Food Safety and Inspection Service

*Other: Recalls, President/Congress Activity,  
Availability of Additional Information*



# USDA Food Safety and Inspection Service

## *Siluriformes Fish Product Recalls*

### 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

# USDA Food Safety and Inspection Service

## Congressional Activity

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

**Food Safety and Inspection Service**  
**Contacting FSIS/Additional Information**

FSIS has set up an email box where questions can be submitted: [AskFish@fsis.usda.gov](mailto: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>.

# USDA Food Safety and Inspection Service

