



United States Department of Agriculture

One Team, One Purpose



Food Safety and Inspection Service

Protecting Public Health and Preventing Foodborne Illness



Food Safety and Inspection Service:
Mandatory Inspection of Siluriformes Fish and Fish Products

August 24, 2017
Memphis, TN
Educational Meeting



Food Safety and Inspection Service: Overview of Public Meeting



- **Welcome Remarks**
- **FSIS Agency Overview**
- **Final Rule Overview**
- **Domestic Inspection**
- **In Commerce Enforcement**

Welcome Remarks

Roberta Wagner
Assistant Administrator
Office of Policy and Program Development
FSIS, USDA

***Siluriformes Fish* Educational Meeting**
August 24, 2017
Memphis, TN

Food Safety and Inspection Service: Mission in Action



We are 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

Food Safety and Inspection Service:
Final Rule Overview

Final Rule Overview

Dr. Denise Amann

Office of Policy and Program Development

Food Safety and Inspection Service: Office of Policy and Program Development

Policy and Program Development:

- Develops regulations as well as instructions for inspectors to implement these regulations
- Modernize the agency's approach to counter emerging risks to meat, poultry, and processed egg products



This work yields constant improvements as our inspection evolves through time.

Food Safety and Inspection Service: Mandatory Inspection of Fish – Farm Bill



- Approximately every five years, Farm Bills are developed and proposed by the U.S. Congress
- Signed into **law** by the President
- Sets forth guidance and policy for the Department of Agriculture

Food Safety and Inspection Service: Mandatory Inspection of Fish – 2008 Farm Bill



The 2008 Farm Bill

Amended the Federal Meat Inspection Act (FMIA) to put **“Catfish”** under FSIS’s jurisdiction

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”
- It proposed a new **Subchapter** of FSIS regulations
- FSIS asked for comment on the definition of “Catfish” and other issues



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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

Food Safety and Inspection Service: Mandatory Inspection of Fish – 2014 Farm Bill



The 2014 Farm Bill

Re-amended the Federal Meat Inspection Act such that:

The term “amenable species” includes all fish of the order Siluriformes

Food Safety and Inspection Service: Mandatory Inspection of 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 establishes an inspection program for Siluriformes fish and fish products
- Domestic and imported Siluriformes fish and fish products will now be inspected by FSIS



FEDERAL REGISTER

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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

Food Safety and Inspection Service:

Fish species now under FSIS's jurisdiction

ORDER	FAMILY	ACCEPTABLE COMMON OR USUAL NAMES	GENUS AND 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>
		Broadhead Clarias Fish	<i>Clarias macrocephalus</i>
		Walking Clarias Fish	<i>Clarias batrachus</i>
	Pangasiidae	Swai or Sutchi or Striped Pangasius or Tra	<i>Pangasianodon (or Pangasius) 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>

Food Safety and Inspection Service: Code of Federal Regulations

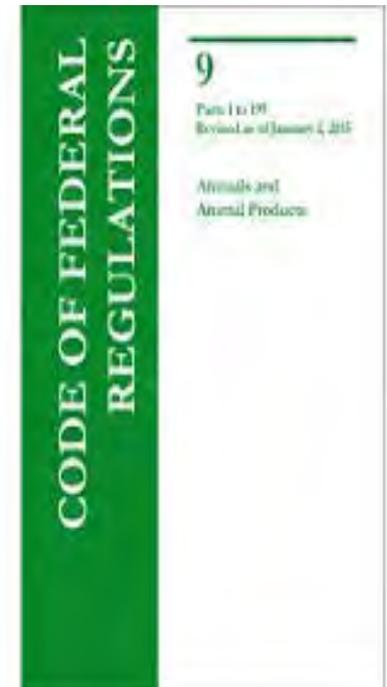
Where are FSIS Regulations Found?

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)**



Food Safety and Inspection Service: Regulatory Timeline

**December 2,
2015**

**Final Rule
published**

90 days

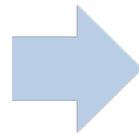
**March 1,
2016**

Effective Date

18-month
Transitional
Period

**September 1,
2017**

**Full
enforcement**



Food Safety and Inspection Service: Mandatory Inspection of Fish – Domestic

On March 1, 2016:

FSIS inspection at domestic
slaughter/processing
establishments

FSIS inspection **at least
quarterly** at processing-only
establishments



Food Safety and Inspection Service: Reinspection of Imported Siluriformes Fish Products

During the 18-month transitional period:

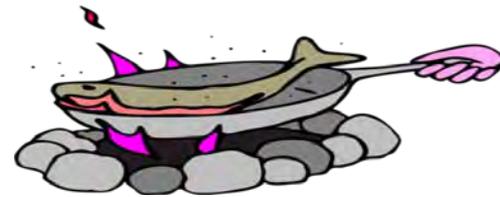
- Reinspect imported product on at least a quarterly basis
- Selected shipments presented for reinspection at Official Import Inspection Establishments

*FSIS began reinspecting all imported product
August 2, 2017*



Food Safety and Inspection Service: Exemptions for Siluriformes Fish Operations

9 CFR 532.3:



Household consumers

At least 75% of sales

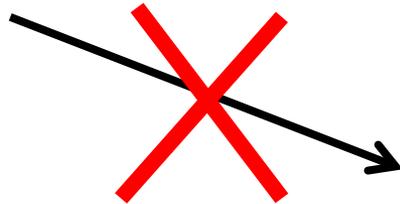


Retail-exempt operation

No more than 25%
raw product only

Other than household consumers,
i.e., in hotels, restaurants, or other
similar institutions (HRI)

Fish must be wholesome.



Distributor

grocery store

processor

Food Safety and Inspection Service:
Domestic Inspection

Domestic Inspection

Dr. Quita Bowman Blackwell

Dr. Philip Bronstein

Office of Field Operations

Food Safety and Inspection Service: Office of Field Operations

Through the work of Field Operations, FSIS has a footprint in every community and touches dinner tables from coast to coast.



Field Employees:

- Coordinate inspection and enforcement activities
- Verify regulatory requirements
- Ensure that the products that FSIS regulates are safe, wholesome, and properly labeled
- Perform in-depth evaluations and assessments

Food Safety and Inspection Service: Full Implementation – September 1, 2017

On September 1, 2017:

- All establishments requiring inspection must have a Grant of Inspection to continue operations
- All establishments with a Conditional Grant will have Sanitation Standard Operating Procedures (SSOPs), Hazard Analysis and Critical Control Point (HACCP), and Recall Plans completed and Meet SPS Requirements
- Establishment will be FSIS Inspected Daily
- All regulations will be fully enforced
- All noncompliance will be documented on NRs

Food Safety and Inspection Service: Office of Field Operations - Grant of Inspection New Establishments

New Establishments:

Establishments apply for Grant of Inspection by completing **FSIS Form 5200-2, Application for Federal Inspection**

- Establishments submit application for GOI to the appropriate District Office for review
- District Management will review the application
- District Management will assign an Frontline Supervisor (FLS) as contact
- FLS or other District Management will perform on-site review once the establishment is ready

<https://www.fsis.usda.gov/wps/portal/fsis/topics/inspection/apply-for-a-federal-grant-of-inspection>

Food Safety and Inspection Service: Office of Field Operations - Grant of Inspection New Establishments

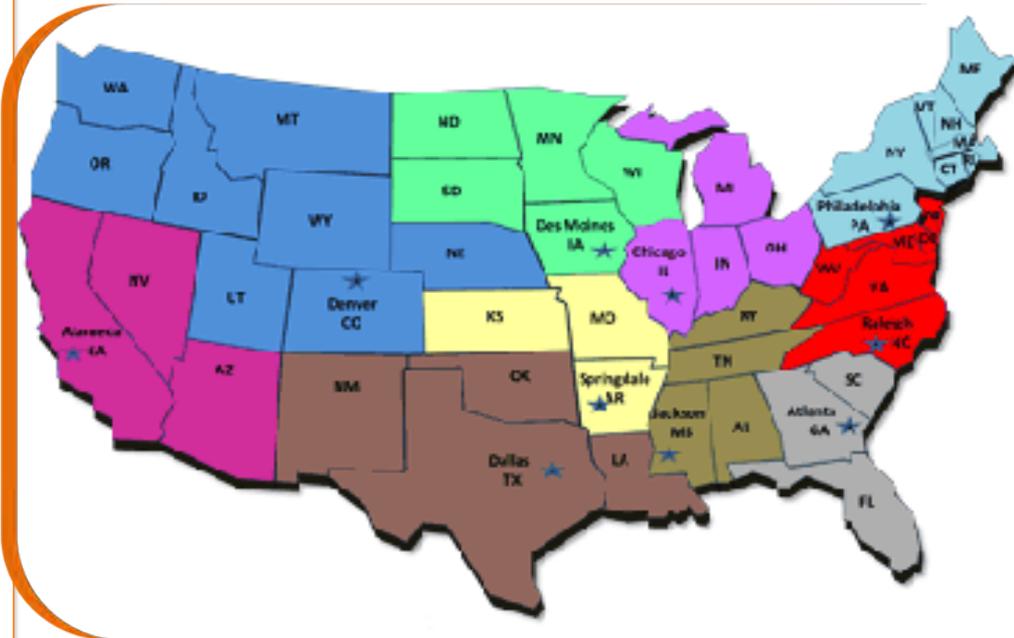
New Establishments:

- **A Conditional Grant will be provided to an establishment once all requirements are met.**
 - **All requirements must be met by September 1, 2017**
 - **Requirements include:**
 - **HACCP (validation beginning September 1, 2017)**
 - **SSOP (prevent, eliminate direct product contamination)**
 - **Sanitation Performance Standards**
 - **Written Recall Program**
 - **Labeling - including applying the inspection legend**
 - **Other Consumer Protections (retained water, batter and breading percentages, net weights, etc.)**

Food Safety and Inspection Service: Office of Field Operations - District Offices

FSIS Office of Field Operations (OFO) has 10 District Offices:

Alameda	(510) 337-5000
Atlanta	(404) 562-5900
Chicago	(630) 620-7474
Dallas	(214) 767-9116
Denver	(303) 236-9800
Des Moines	(515) 727-8960
Jackson	(601) 965-4312
Philadelphia	(215) 597-4219
Raleigh	(919) 844-8400
Springdale	(479) 751-8412



Food Safety and Inspection Service: Office of Field Operations - Grant of Inspection Exemptions

Exemptions

Retail Exemptions include operations typically conducted at retail stores and restaurants, where sales are made directly to the immediate consumer in normal retail quantities.

- **75/25 Rule (9 CFR 303.1(d)(iii)(b))**
 - To qualify for the retail exemption, at least 75 percent, in terms of dollar value, of its total sales of Siluriformes fish product must represent direct sales to household consumers
 - Sales from retail-exempt operations to other than household consumers (i.e., hotels, restaurants and other institutions (HRI)) cannot exceed 25 percent of total retail sales.
 - Retail-exempt operations are never permitted to sell Siluriformes fish products wholesale (e.g., to a different grocery store or to a distributor to resell) without FSIS inspection.

Food Safety and Inspection Service: Office of Field Operations - Grant of Inspection Exemptions

9 CFR 532.3

Retail and restaurant exemption

- **Includes slaughter of live fish at retail stores or restaurants for consumers who purchase fish at those facilities, and in accordance with consumers' request**
- **Household normal retail quantity Does Not Exceed 75 lbs**
- **Non-household consumer normal retail quantity Does Not Exceed 150 lbs**
- **9 CFR 303.1(d) for operations of types traditionally and usually conducted at retail stores and restaurants applies to fish products**

Food Safety and Inspection Service: Requirements

- **FSIS will verify 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.**



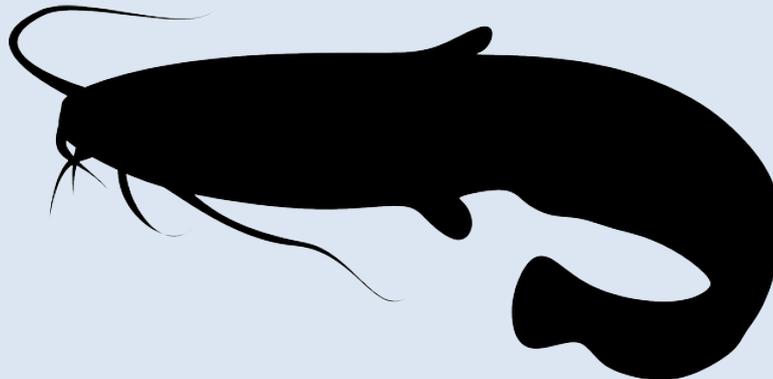
Food Safety and Inspection Service: Requirements

Verification of SPS Conditions:

- Establishment grounds & facilities
 - requires an establishment to have **potable water**
 - requires an establishment to have an acceptable **sewage system** that does not adulterate product
- Sanitary operations
 - requires an establishment **demonstrate the safety of a chemical's use in a food processing environment.**
- Establishments must provide:
 - **sufficient light** to ensure sanitary conditions are being met
 - **receptacles identified for inedible** (carcasses and parts)

Food Safety and Inspection Service: Requirements

- Inspected establishment must be **separate & distinct** from any non-inspected facilities (by time or space).
- Establishments must provide adequate office space and furnishings for FSIS inspectors.



Food Safety and Inspection Service: Requirements – Conditional Grant no later than 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.

Food Safety and Inspection Service: Requirements – Conditional Grant no later than 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 it takes 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.

Food Safety and Inspection Service:

Requirements – Conditional Grant no later than September 1, 2017

- **Establishments must comply with the Hazard Analysis & Critical Control Point (HACCP) requirements**
 - 9 CFR 417
 - Hazard Analysis must be written and available to inspection personnel
 - HACCP System must be validated



Food Safety and Inspection Service:

Requirements – Conditional Grant no later than September 1, 2017

Designing the HACCP System – 9 CFR 417

The seven principles of HACCP, which encompass a systematic approach to the identification, prevention, and control of food safety hazards include:

1. Conduct a Hazard Analysis
2. Determine Critical Control Points
3. Establish Critical Limits
4. Establish Monitoring Procedures
5. Establish Corrective Actions
6. Establish Recordkeeping and Documentation Procedures
7. Establish Verification Procedures



Food Safety and Inspection Service: Requirements – HACCP Initial Validation

90-Day Validation of HACCP System

This data will generally include 90 days of production records and any additional documents gathered to demonstrate the establishment is able to effectively execute the critical operating parameters in their HACCP system including:

- HACCP records generated during 90 days when the current HACCP system is in operation.
- Decision-making documents for the CCPs and critical operational parameters data gathering methods.
- Records associated with initial equipment set up or calibration that contain data for any critical operational parameters that did not become CCPs to support that the parameters were met during the initial validation period.
- Any establishment sampling results for the product and process of interest.



Food Safety and Inspection Service:

Resources

Resource Links:

Code of Federal Regulations (Title 9): <https://www.gpo.gov/fdsys/pkg/CFR-2017-title9-vol2/pdf/CFR-2017-title9-vol2.pdf>

Inspection Program for Siluriformes Fish:

<https://www.fsis.usda.gov/wps/portal/fsis/topics/inspection/siluriformes>

FSIS Compliance Guideline for Establishments that Slaughter or Further Process Siluriformes Fish and Fish Products March 2017: <https://www.fsis.usda.gov/wps/wcm/connect/8ec92a7f-8f9b-45ae-b80f-7c336f7d6ff5/Compliance-Guideline-Siluriformes-Fish.pdf?MOD=AJPERES>

Developing a Recall Plan: <https://www.fsis.usda.gov/wps/portal/fsis/topics/regulatory-compliance/haccp/small-and-very-small-plant-outreach>

Other FSIS Compliance Guidance: <https://www.fsis.usda.gov/wps/portal/fsis/topics/regulatory-compliance/compliance-guides-index#HACCP>

askFISH: askFISH@fsis.usda.gov

FDA's *Fish and Fishery Products - Hazards and Controls Guidance* (Fourth Edition). 2011.

Retrieved from: <http://www.fda.gov/downloads/Food/GuidanceRegulation/UCM251970.pdf>

Small Plant Help Desk: InfoSource@fsis.usda.gov or call 1- 877-374-7435

Food Safety and Inspection Service:
In-Commerce Compliance and Enforcement

In-Commerce Compliance and Enforcement

John G. O'Shaughnessy

Office of Investigation, Enforcement and Audit

Food Safety and Inspection Service: Office of Investigation, Enforcement and Audit



Investigation, Enforcement and Audit Employees:

Respond to...

- Foodborne illness outbreaks
- Natural disasters
- Intentional contamination events

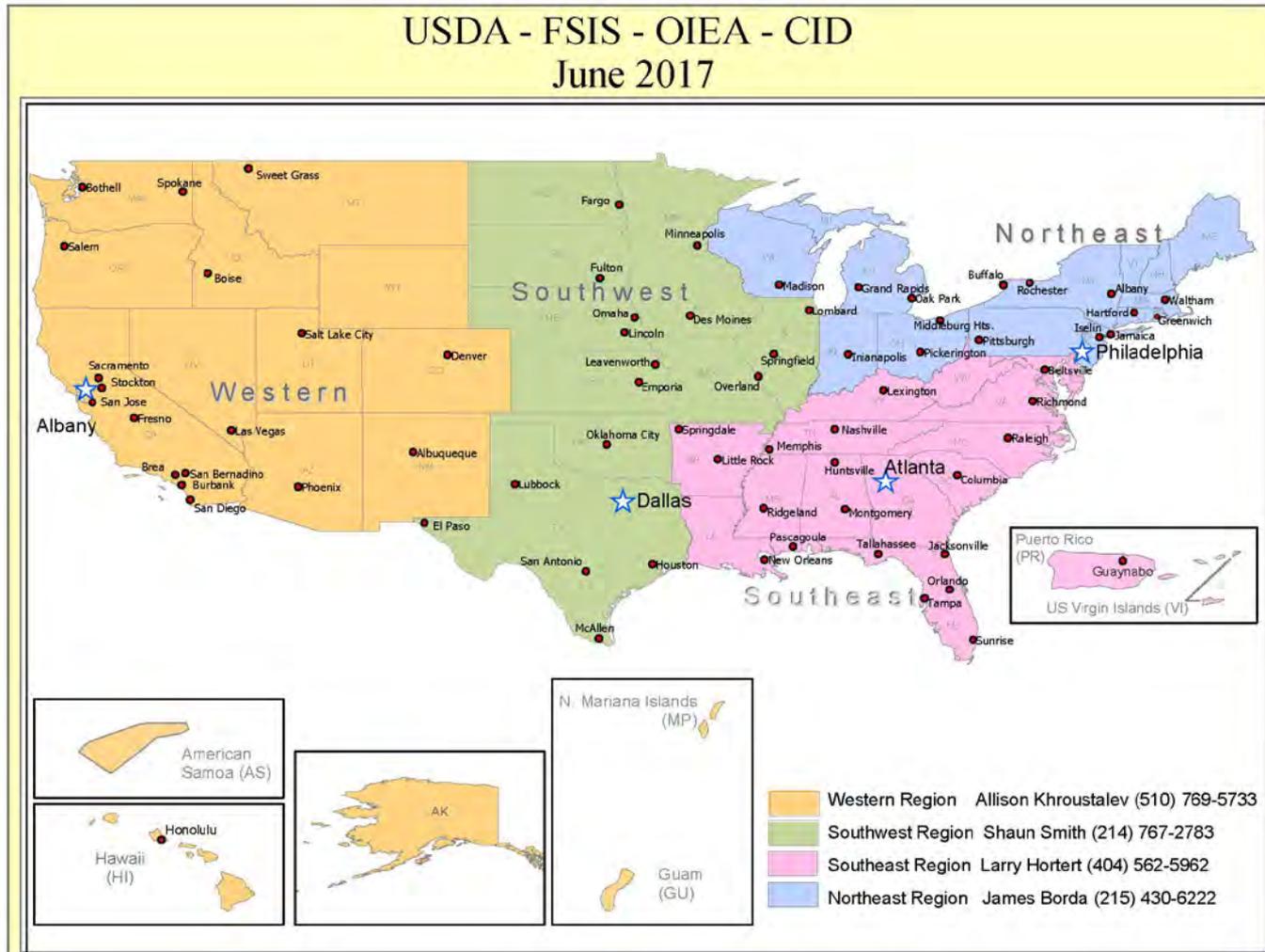
Conduct...

- Surveillances
- Investigations
- Enforcement activities

Investigation, Enforcement and Audit is the eyes and ears of the agency, enforcing policies to keep food safe for the consumer



Food Safety and Inspection Service: Office of Investigation, Enforcement and Audit



Food Safety and Inspection Service:
Office of Investigation, Enforcement and Audit

- Investigators conduct in-commerce activities at warehouses, distributors, transporters, retailers, ports of entry, and other in-commerce businesses
- Verify firms are preparing, storing, transporting, selling, offering for sale or transportation, importing, and exporting products that are in compliance with FSIS' statutory and regulatory requirements

Food Safety and Inspection Service: Office of Investigation, Enforcement and Audit

- Public health protection activities that extend to ensuring the safety of products stored, transported, and sold in interstate commerce, which includes warehouses, distributors, retail stores, and other in-commerce facilities
- Conducts surveillance, outreach, and education at in-commerce firms
- Collects samples for investigative purposes (purchases at fair market value)
- Looks at product condition, labeling, sanitation where product is stored, recordkeeping, and source of product
- Investigates and documents cases
- Is the enforcement arm of FSIS addressing administrative, civil, and criminal enforcement and sanctions

Food Safety and Inspection Service:
Office of Investigation, Enforcement and Audit

Registration of Meat and Poultry Handlers (FSIS Form 5020-1)

- Unless operate under Federal Inspection, following types of businesses are to register with FSIS: Domestic Broker, Import Broker, Renderer, Animal Food Manufacturer, Public Warehouseman, Wholesaler, Siluriformes Fish Farm/Pond, Siluriformes Fish Transporter, and 4-D Operator
 - Only those Siluriformes farms/ponds and transporters sending fish to FSIS inspected est. are to register
 - If farm/pond or your transporter does not supply to an FSIS inspected est., do not need to register those farms/ponds or transporters

Food Safety and Inspection Service:
Office of Investigation, Enforcement and Audit

Implementation on September 1, 2017:

- **All laws and regulations will be fully enforced**
- **All violations will be documented in a Report of Investigation**

Food Safety and Inspection Service:
Thank You

Visit FSIS Siluriformes Webpage at

www.fsis.usda.gov/siluriformes