

Jurisdiction

1. What fish are now under FSIS jurisdiction?

As of March 1, 2016, FSIS has jurisdiction over all wild-caught and farm-raised Siluriformes fish that are harvested and sold for human food in the United States. This includes Siluriformes fish and fish products that are imported into the United States.

The following chart* lists some of the Siluriformes fish most commonly marketed in the United States. Please note that this list is not all-inclusive. Because common names of the fish can vary, reference the scientific name to determine whether the product is in the order Siluriformes.

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 microcephalus</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 chart is not inclusive. See also the [“Guidance for Industry: The Seafood List--FDA's Guide to Acceptable Market Names for Seafood Sold in Interstate Commerce”](#) and the [Integrated Taxonomic Information System \(ITIS\)](#) for appropriate common or usual names.

2. Are “roe” (eggs) and “maw” (air bladders) from Siluriformes fish subject to the final rule?

Yes, the requirements in the final rule apply to the production of Siluriformes fish parts other than the skeletal muscle (including “roe” and “maw”) to be sold for human food.

3. What activities require FSIS inspection?

Generally, under the Federal Meat Inspection Act (FMIA) and its implementing regulations, any establishment preparing Siluriformes fish or fish products for the wholesale market is required to

operate under FSIS inspection. Retail businesses that prepare fish and fish products for sale to the end consumer are exempt from the requirements for inspection.

4. For a product with multiple ingredients, what amount of Siluriformes fish in the product would make it a product that falls under FSIS jurisdiction?

Generally, a product with multiple ingredients falls under FSIS jurisdiction and subject to its inspection if the product contains at least 3 percent raw or at least 2 percent cooked Siluriformes fish and is not otherwise exempt from inspection (see 9 CFR § 532.5 and 532.3, respectively).

Grant of Inspection/Approved Hours/On-site Inspector Presence

1. How do I apply for federal inspection?

The instructions for applying for a Grant of Federal Inspection can be accessed on the FSIS website at the link below:

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

2. Can an official meat or poultry establishment update its Grant of Federal Inspection to include Siluriformes fish?

Yes. The establishment would need to submit an updated FSIS Form 5200-2 to their District Office.

3. Do “box-in, box-out” distribution facilities currently registered with FSIS need to amend their registration to include Siluriformes fish?

Yes, these facilities will need to submit an updated FSIS Form 5020-1 to the Office of Investigation, Enforcement and Audit. The completed form should be submitted to the address at the top of the form and also here: USDA, FSIS, OIEA, ELD, 1400 Independence Ave. SW, Stop Code 3753, PP3, Cubicle 8-235A, Washington, D.C., 20250-3700.

Labeling

A. Generic Approval and Farm Raised

1. Does the “FSIS Compliance Guideline for Label Approval” released August 2017 apply to Siluriformes fish products?

Yes, with one exception. The special statements and claims listed in the guide as requiring sketch approval by FSIS apply to meat products including Siluriformes fish; however, the claim “farm-raised” on Siluriformes fish labels *does not* require sketch approval by FSIS. As explained in the preamble of the Siluriformes fish final rule, the statements “farm-raised” and “wild-caught” may both be approved generically when added to Siluriformes fish labels, provided that they are truthful statements. <https://www.fsis.usda.gov/wps/wcm/connect/bf170761-33e3-4a2d-8f86-940c2698e2c5/Label-Approval-Guide.pdf?MOD=AJPERES>

2. Do Siluriformes fish product labels with “farm-raised” or “wild-caught” claims have to be submitted to FSIS for sketch approval?

No. As explained in the preamble to the Siluriformes fish final rule, the raising claims “farm-raised” or “wild-caught” do not require FSIS sketch approval under 9 CFR 412.1(c)(3) and 541.7(g). However, as is the case for any statement or claim on a label, whether or not FSIS sketch approval is required, the establishment must have support for the claim on file, and make it available to FSIS personnel upon request.

B. Ice Glaze

1. If Siluriformes fish products are misted with water and then frozen or ice-glazed, may the labeled net weight include the weight of the mist or glaze?

No, the net weight should reflect the weight of the product without the mist or glaze.

2. When Siluriformes fish products are misted with water and then frozen or ice-glazed, must these processes be declared on the label?

No. FSIS has found that water misting and ice glazing Siluriformes fish is a common industry practice, and recognized as such by consumers. Therefore, FSIS is not stipulating that a statement that these products have been water-misted or ice-glazed appear on the label. Note that if the glaze contains a solution that includes flavoring ingredients, e.g., spices, then the product would no longer be considered ice-glazed and would need to bear an ingredients statement that includes any ingredients.

C. Breading

1. Does 9 CFR 319.880 (which limits the amount of batter and breading used as a coating for breaded meat products) apply to breaded Siluriformes fish products?

Yes. Siluriformes fish products labeled as “Breaded” are limited to 30% or less breading. Siluriformes fish products that contain more than 30% breading may not be labeled as “Breaded.” However, FSIS would permit these products to be labeled as a “fritter,” or with a reference to the characterizing ingredients of the breading in the product name. Please refer to the FSIS Food Standards and Labeling Policy Book entry for “Fritters” for additional information:
<https://www.fsis.usda.gov/wps/wcm/connect/7c48be3e-e516-4ccf-a2d5-b95a128f04ae/Labeling-Policy-Book.pdf?MOD=AJPERES>

D. Added Solution

1. Do the requirements in 9 CFR 317.2(e)(2) apply to Siluriformes fish products containing added solution, regardless of the method of incorporating the solution (for example, marinating, basting, injection, vacuum tumbling)?

Yes. The requirements would apply to products where solution has been incorporated into raw Siluriformes fish through any method, for example, marinating, basting, injection, or vacuum tumbling. For additional questions and answers about added solutions:

<https://www.fsis.usda.gov/wps/wcm/connect/70c4707c-d4cf-4845-b97f-ad8dc23e4c46/Q-A-Added-Solutions-122415.pdf?MOD=AJPERES>

2. How is the percent solution pickup calculated? Does the establishment need to weigh the Siluriformes fish prior to being marinated or injected and then weigh it after to see how much was absorbed?

Determining the percent pick up involves weighing the raw Siluriformes fish before solution is added, weighing the raw Siluriformes fish after adding solution, and then performing a calculation to determine the percent solution pick up. From 9 CFR 317.2(e)(2)(i): "The percentage of added solution (total weight of the solution ingredients divided by the weight of the raw Siluriformes fish without solution or any other added ingredients multiplied by 100)." For example, a formulation which includes 80% fish and 20% solution of water, salt and sodium phosphate would need to bear the solution statement "Contains 25% solution of water, salt and sodium phosphate" because 20 (weight of the solution) divided by 80 (weight of the fish without added ingredients) is 25.

Imports

1. Can foreign countries continue exporting Siluriformes fish and fish products after the transitional period, September 1, 2017?

To continue exporting Siluriformes fish and fish products after September 1, 2017, foreign countries had to submit adequate documentation showing the equivalence of their Siluriformes fish inspection system with that of the U.S. Foreign countries that made such submissions by September 1, 2017, can continue exporting these products to the U.S. while FSIS evaluates equivalency. The lists of foreign countries and foreign establishments currently eligible to export Siluriformes fish and fish products to the United States are available on our website at

<https://www.fsis.usda.gov/wps/portal/fsis/topics/inspection/siluriformes/operations-inspection#plants>

A. Reinspection

1. Are imported shipments of Siluriformes fish and fish products subject to FSIS reinspection?

Yes, all imported shipments of Siluriformes fish and fish products must be presented to FSIS for reinspection at an official import inspection establishment.

2. What exactly is needed for import paperwork?

The importer of record or broker will need to apply for FSIS reinspection using FSIS Form 9540-1. In addition, an original foreign inspection certificate must accompany every shipment of Siluriformes fish and fish products imported into the United States (see 9 CFR 557.4).

3. Can imported products be shipped to a processing establishment for the import reinspection?

No. Consistent with how FSIS handles other meat, poultry and egg product reinspection of

imported product, FSIS will only reinspect shipments of imported Siluriformes fish and fish products at an official import inspection establishment.

4. What is the process to become an official import inspection establishment?

Existing facilities that wish to be an official import inspection establishment for Siluriformes must contact their District Office to update their Grant of Inspection to include Siluriformes fish. New applicants should also contact their [District Office](#).

5. Can official import inspection establishments expect to have the same inspectors for Siluriformes fish product as they do for meat and poultry products?

Yes, the same FSIS employees that conduct reinspection of meat, poultry, and processed egg products will also conduct reinspection of Siluriformes fish products.

6. What will the import inspection hours be for Siluriformes fish?

All questions regarding hours of inspection should be addressed with the official import inspection establishment. Hours of operation will be defined on the grant of inspection.

B. Lab Sampling

1. Will imported Siluriformes fish and fish products be sampled and tested as part of FSIS reinspection activities?

Yes. FSIS will periodically collect samples of raw imported Siluriformes fish and fish products during reinspection. The samples could be analyzed for chemical residues, *Salmonella*, or speciation.

2. Where does the above sampling take place?

Sampling during reinspection will occur at the official import inspection establishment.

3. What residues will FSIS test for in imported product and domestic?

When sampled, FSIS will test raw Siluriformes fish products for veterinary drug residues, including nitrofurans and some fluoroquinolones; malachite green; gentian violet; metals; and pesticides. A complete list of contaminants can be found within the appropriate residue method at: <http://www.fsis.usda.gov/wps/portal/fsis/topics/science/laboratories-and-procedures/guidebooks-and-methods/chemistry-laboratory-guidebook>.

4. Why does FSIS sample and test products?

FSIS samples and tests regulated products to verify compliance with the regulations and inform the effectiveness of Agency policy and procedures.

5. How long will it take to receive sample results (for imported and domestic product)?

For residue testing and speciation, it takes approximately seven days for a negative result and about 3 additional days to conduct more confirmatory tests if a sample screens positive. For *Salmonella* testing, negative results may be reported as soon as 2 days after sample receipt. Confirmation of a positive *Salmonella* result typically takes up to 7 days from sample receipt to report.

6. Who pays for the testing of samples collected by FSIS?

FSIS pays for the testing of samples it collects.

C. Equivalence

1. When will foreign audits begin for equivalency determinations?

On-site verification audits of a foreign country's Siluriformes fish inspection system will occur once FSIS has analyzed the foreign country's responses to the Self-Reporting Tool (SRT) questions and supporting documentation and determined, based on the document review, that the country has an equivalent system. To continue exporting Siluriformes fish and fish products to the U.S., countries had to submit SRT responses and supporting documentation by September 1, 2017. FSIS will review the submission, and if the submission provides an initial basis for believing the country to be equivalent, FSIS will schedule an in-country audit.

2. What will be the scope of foreign audits?

Consistent with FSIS audit procedures, the scope of the audit will likely include government inspection offices, slaughter and processing establishments, cold storage facilities, and laboratories and may include farms.

3. Has the Self-Reporting Tool been modified for Siluriformes fish?

Yes. It is available at <https://www.fsis.usda.gov/wps/wcm/connect/b1383586-d229-43d2-808b-e3e983718a0c/Siluriformes-SRT.pdf?MOD=AJPERES>.

D. Foreign Establishments

1. What exactly is a "foreign establishment" as it applies to FSIS' list of establishments eligible to export Siluriformes fish and fish products to the United States?

The foreign establishment is the facility that produces the final product for export to the United States. However, if the production chain involves more than one foreign establishment (e.g., the live fish are slaughtered at one establishment, further processed at a different establishment and then exported to the United States), each foreign establishment in the production chain must be listed on FSIS' website as eligible to export Siluriformes fish and fish products to the United States.

2. Will FSIS set up inspection offices in foreign countries?

FSIS does not set up "inspection offices" in foreign countries and is not present in foreign

inspection establishments except when performing equivalence audits.

E. Labeling

1. Are the labeling requirements for immediate containers different for imported products?

The required mandatory features for immediate container labels of imported product are consistent with the requirements for domestic product* and include the following:

- a. Name of product or descriptive designation of product;**
- b. Ingredients statement, if the product is fabricated from two or more ingredients;
- c. Foreign establishment number and inspection mark (canned products must comply with 9 CFR 327.14 (b) (2));
- d. Handling statement, such as "Keep Frozen" or "Keep Refrigerated," if applicable;
- e. Net quantity of contents, if applicable;
- f. Name and address of manufacturer, packer or distributor;
- g. Nutrition facts, unless an exemption applies;
- h. Name of the country of origin, preceded by the words "Product of" placed immediately under the product name; and
- i. Safe handling instructions for not-ready-to-eat (NRTE) products that have not undergone further processing that would render them ready-to-eat (RTE) and are destined for the consuming public.

*Siluriformes fish and fish products entering into the U.S. must bear labeling that meets the same FSIS labeling requirements as for domestic products, as applicable (see 9 CFR 541.7 for all labeling requirements).

** Labels for raw Siluriformes fish products containing added solution must include a descriptive designation (e.g., "contains 10% added solution of water, salt, phosphates.....")(9 CFR 317.2)(e)(2))

2. If label deficiencies are found during reinspection of shipments of imported Siluriformes fish and fish products, will the importer of record or broker be allowed to correct the deficiencies?

Yes, consistent with existing policy, the importer of record will be provided with an opportunity to correct any label deficiency, except shipping marks, by stenciling or stamping or applying pressure sensitive stickers and obliterating the incorrect markings on all non-complying labels. Import inspection personnel will verify the correction before releasing the product into commerce.

3. What types of labels (for foreign and domestic product) need to be submitted to FSIS for approval prior to use?
 - a. The types of labels requiring submission to and approval by the FSIS Labeling and Program Delivery Staff are listed in 9 CFR 412.1(c)(1)-(4):
 - i. Labels for temporary approval;
 - ii. Labels for products prepared under religious exemption (poultry only, not applicable to fish);

- iii. Labels for products for export with deviations from FSIS domestic labeling requirements; and
 - iv. Labels with special statements and claims. Guidance for what constitutes a "special statement or claim" can be found online at the following website: <http://www.fsis.usda.gov/wps/wcm/connect/bf170761-33e3-4a2d-8f86-940c2698e2c5/Comp-Guide-Labeling-Evaluation-Approval.pdf?MOD=AJPERES>.*
- b. If a label does not fall into any of the above categories, it may be approved generically and need not be submitted to FSIS for prior approval. Such labels, however, must be in compliance with all other applicable labeling regulations.

*As explained in the preamble of the Siluriformes fish final rule, the raising claims "farm-raised," or "wild-caught" would not require FSIS sketch approval under 9 CFR 412.1(c)(3) and 541.7(g). However, as is the case for any statement or claim on a label, whether or not FSIS sketch approval is required, the establishment would need to have support for the claim on file and make such support available to FSIS personnel upon request.

4. What is the average time it takes for approval by the FSIS Labeling and Program Delivery Staff?

Sketch label approval turnaround is typically 7-10 business days for labels that need to be reviewed by FSIS.

5. What is the best way to submit a label for approval?

The best way is by submitting a label application through the electronic Label Submission and Approval System (LSAS) system. Guidance on accessing LSAS is available at: <http://www.fsis.usda.gov/wps/portal/fsis/topics/regulatory-compliance/labeling/label-submission-and-approval-system>

6. Will pressure sensitive stickers be permitted on labels?

Yes, as an alternative to reprinting, for labels that are missing a required feature or contain inaccurate information, labels may be modified using pressure sensitive stickers. The pressure sensitive sticker must destroy the underlying label or package, if removed.

7. What information is required on shipping containers of imported products?

Required information on shipping containers includes product name, establishment number, handling statement (if product inside is perishable) and country of origin are required on all shipping containers containing immediate containers.

8. Will FSIS continue to accept FDA's common or usual names for Siluriformes fish?

Yes, the FDA-recognized common or usual name would be acceptable. For additional guidance on acceptable common or usual names, see [Siluriformes Fish Species List](#) and FDA's Seafood List at <https://www.accessdata.fda.gov/scripts/fdcc/?set=seafoodlist>.

F. Importers/Brokers

1. When does the importer of record need to submit the FSIS Form 9540-1, Import Inspection Application?

The importer of record or broker is required to provide the import inspection application (i.e., FSIS Form 9540-1) to FSIS at the official import inspection establishment no later than the time the entry is made with U.S. Customs.

2. How does FSIS define the terms importer or broker?

The importer, whether an entity or individual, is responsible for ensuring that legal goods are imported in accordance with U.S. law. Customs brokers are private individuals, partnerships, associations or corporations licensed, regulated and empowered by U.S. Customs and Border Protection (CBP) to assist importers and exporters in meeting Federal requirements governing imports and exports.

Sampling

1. For product that FSIS samples for residues, will FSIS withhold the mark of inspection until acceptable results become available?

At this time, FSIS is electing not to require domestic establishments to hold raw product that FSIS samples and tests for residues. If FSIS finds widespread non-compliance in domestically-produced product that is sampled, the Agency will issue instructions to inspection program personnel regarding holding domestic product as well until acceptable test results become available.

Transshipments

1. Do imported Siluriformes fish and fish products just transshipping through the United States in route to another country need to be presented for FSIS reinspection?

No, shipments of imported Siluriformes fish and fish products that do not make U.S. Customs entry and are transshipping through the United States under bond would not be subject to reinspection by FSIS.

Miscellaneous

1. Please clarify the exemption for retail stores and restaurants in the regulations.

Siluriformes fish products, like other meat products, that are prepared at retail stores and restaurants are exempt from FSIS inspection under 9 CFR 532.3. To qualify for this exemption sales of retail-exempt product must be:

- Directly to consumers only;

- Specifically, at least 75% of sales must be to household consumers, and no more than 25% of sales to other than household consumers, i.e., those being served in hotels, restaurants, or other similar institutions (HRI); and
- Sold in normal retail quantities. A normal retail quantity for a household consumer is up to 75 pounds, and for HRI is up to 150 pounds. For clarification, the poundage is that of the retail-exempt product being purchased from the retail store.

Retail stores are also regulated by State and local health authorities, and would still be subject to State and local requirements for operating a food business.