USDA

United States Department of Agriculture

One Team, One Purpose

Food Safety and Inspection Service

Protecting Public Health and Preventing Foodborne Illness

Review of FSIS Import Labeling Requirements

Food Safety and Inspection Service:
Labeling - FDA vs. FSIS

FDA

- Does not require prior label approval
- No mark of inspection
- Approves the safety of food ingredients used in food products

USDA Food Safety and Inspection Service

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- Requires prior approval for all labels before the products may be marketed
- Requires inspection legend and establishment number on all inspected and passed products
- Permits only FDA-sanctioned food ingredients in products under its jurisdiction

Food Safety and Inspection Service:

Immediate Containers

The immediate container includes any covering that is ordinarily sold to or purchased by a consumer or any other container in which products are directly enclosed

Food Safety and Inspection Service:

Immediate Containers

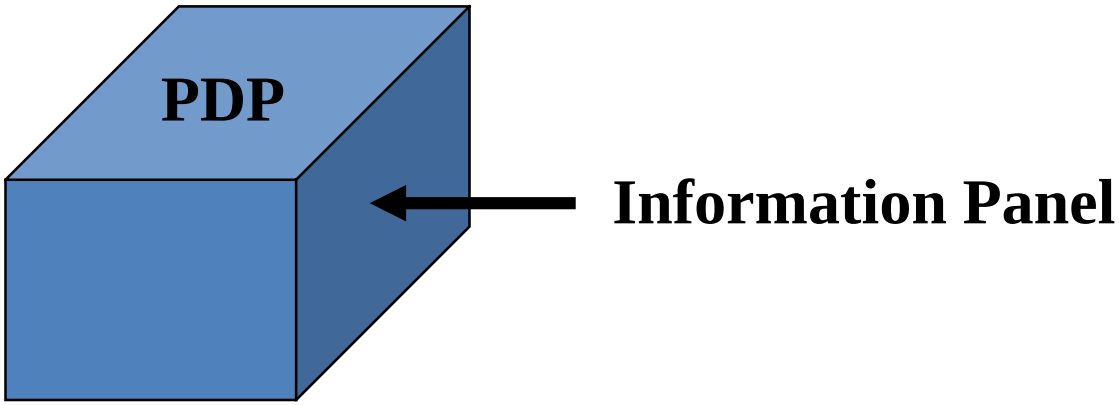
Labels for immediate containers destined for export to the U.S. must have up to nine (9) required features (9 CFR 327.14). All required features must be in English

- **FSIS regulations specify where some of these required features must be located on the immediate container:**
  - ✓ **On the Principal Display Panel (PDP) (9 CFR 317.2(c) and (d))**
  - ✓ **On the Information Panel (IP) (9 CFR 317.2(m))**

Food Safety and Inspection Service:
Principal Display Panel (PDP) and Information Panel (IP)

The PDP is the part of the label most likely to be displayed or presented to the purchaser when the product is offered for sale (e.g., sitting in a cooler at a retail store)

The IP is any portion of a label (typically to the right of the PDP) that displays certain mandatory features



Food Safety and Inspection Service:

Required Features for Principle Display Panel - Imports

FDA requirements:

(1) Name of Product

(2) Net Quantity Statement

FSIS requirements:

(1) Name of Product

(2) Net Quantity Statement

*(3) The name of the country of origin preceded by the words "product of," ***immediately under the product name***

*(4) Handling Statement (for perishable product)

****Feature unique to FSIS***

Food Safety and Inspection Service:
Product Name

Name of Product:

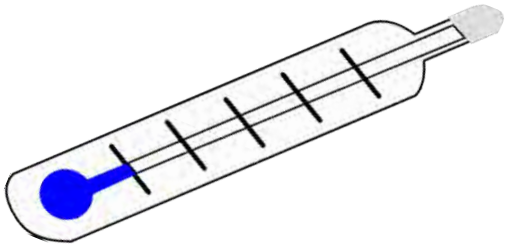
- **"Catfish" may only be used to label products that contain fish in the family Ictaluridae**
- **Non-Ictaluridae fish products must be labeled with their common or usual name (e.g., "Basa," "Swai," "Giant Pangasius") *for that product in the United States***

Food Safety and Inspection Service:
Added Solutions

Labeling for raw Siluriformes fish products containing added solutions must include a descriptive designation **(e.g., "Contains 10% added solution of water, salt, sodium phosphates….")**

- **Product name and descriptive designation must be in one easy-to-read type style, in one color, on a single color contrasting background**
- **May appear in upper and lower case letters, with lower case letters not smaller than one-third (1/3) size of the largest letter**
- **Statement must list all ingredients by common or usual name in descending order of predominance**
- **9 CFR 317.2(e)(2), 541.7(a)**

For perishable products that need special handling to maintain their wholesomeness



- Keep Refrigerated
- Keep Frozen
- Keep Refrigerated or Frozen
- Previously Handled Frozen For Your Protection - Refreeze or Keep Refrigerated

Food Safety and Inspection Service:

Information Panel

The remaining features may be located on the PDP or IP or other panel:

FDA requirements:

(3) Name and address of manufacturer/packer/distributor

(4) Ingredients List

(5) Nutrition Labeling

FSIS requirements:

(5) Name and address of manufacturer/packer/distributor (PDP or IP)

(6) Ingredients List (PDP or IP)

(7) Nutrition Labeling (PDP or IP)

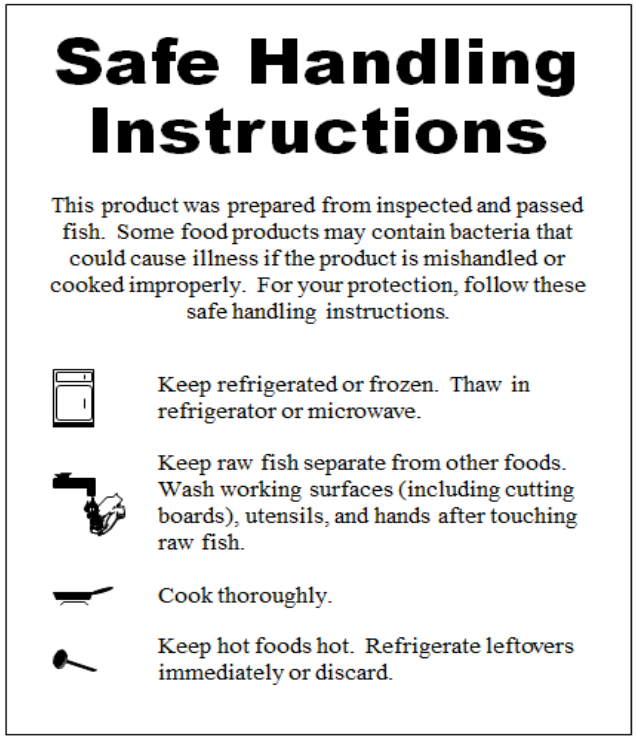
***(8) Safe Handling Instructions if the product is not ready-to-eat (any panel)**

***(9) Foreign establishment number (any panel)**

Food Safety and Inspection Service:

Safe Handling Instructions

- **Must be on any product that is NOT ready-to-eat AND destined for consumers, hotels, restaurants and institutions**
- **"Fish" on labels for Siluriformes fish and fish products (*exactly as it appears in regulations*).**
- **May appear on any panel**



Safe Handling Instructions

This product was prepared from inspected and passed fish. Some food products may contain bacteria that could cause illness if the product is mishandled or cooked improperly. For your protection, follow these safe handling instructions.

Keep refrigerated or frozen. Thaw in refrigerator or microwave.

Keep raw fish separate from other foods. Wash working surfaces (including cutting boards), utensils, and hands after touching raw fish.

Cook thoroughly.

Keep hot foods hot. Refrigerate leftovers immediately or discard.

Foreign establishment number of *the firm where the product was last processed* and the inspection mark (or symbol) of the foreign inspection program used to identify status (e.g., "approved" or "inspected & passed") of the product.

- May appear on any panel
- May be any size but must be legible

Food Safety and Inspection Service:
Labeling Requirements for Immediate Container - Imports

Feature	Reference	Location	Applies to
Product Name, "Product of"	9 CFR 557.14, 317.2(c)(1), 327.14(b)(1)	Principal display panel	All products
Foreign Establishment Number	9 CFR 557.14, 327.14(b)(1)	Any panel	All products
Handling Statement (e.g. "Keep Frozen")	9 CFR 557.14, 317.2(k), 327.14(b)(1)	Principal display panel	Products requiring special handling to maintain wholesomeness
Net Weight Statement	9 CFR 557.14, 317.2(h), 327.14(b)(1)	Principal display panel	Products sold at retail, unless the net weight is applied at retail
Ingredients Statement	9 CFR 557.14, 317.2(f), 327.14(b)(1)	Information panel or Principal display panel	Products with multiple ingredients
Address Line	9 CFR 557.14, 317.2(g), 327.14(b)(1)	Information panel or principal display panel	All products
Nutrition Facts Panel	9 CFR 557.14, 317.300, 327.14(b)(1)	Information panel or Principal display panel	Products not exempted by 9 CFR 317.400
Safe Handling Instructions	9 CFR 557.14, 317.2(l), 327.14(b)(1)	Any panel	Products with a not-ready-to-eat meat (fish) component

Food Safety and Inspection Service:
Shipping Containers - Imports

- **Strictly speaking, a shipping container *would always contain fully-labeled product inside;* thus, there is not a requirement for a shipping container to be labeled with all features**
- **Shipping containers need to have sufficient space for application of the USDA mark of import inspection**
- **In some cases, however, the immediate container is the outermost container because the product inside is not labeled. In this scenario, the outermost container needs to bear all the required features of an immediate container and of a shipping container**

Food Safety and Inspection Service:
Labeling Requirements for Shipping Containers– Imports (9 CFR 327.15)

In English,

1. **Name of the country of origin**
2. **Foreign establishment number *of the establishment that packed the shipping container***
3. **Name of the product**
4. **Shipping or identification mark (a unique symbol or number used to link the product/lot *to the foreign inspection certificate*)**
5. **Handling statement (e.g., Keep refrigerated)(for products that are perishable and require special handling to maintain their wholesomeness)**

Food Safety and Inspection Service:
Label Approval by FSIS

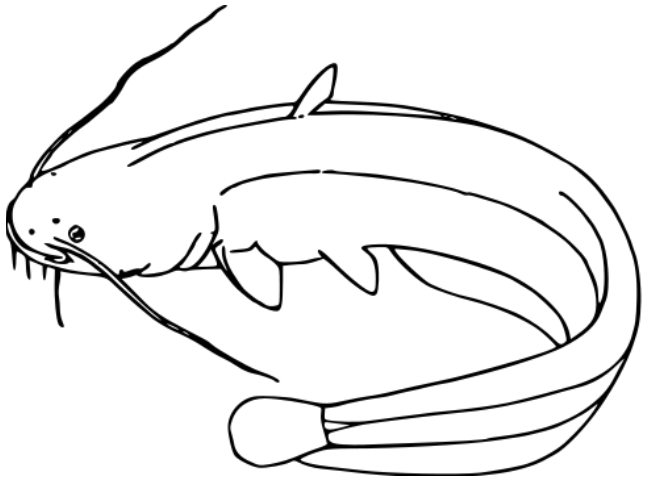
- **Prior approval by FSIS is needed for labels of Siluriformes fish products before they are marketed in the U.S.**
- **Applies to products produced in a foreign country for export to the U.S.**
- **Prior label approval is granted in one of two ways:**
  - **Sketch approval by the FSIS Labeling and Program Delivery Staff (LPDS)**
  - **Generic approval by being in compliance with applicable labeling regulations**

Food Safety and Inspection Service:
Label Approval by FSIS

- **Only certain types of Siluriformes fish product labeling must be submitted for evaluation by the FSIS Labeling and Program Delivery Staff (9 CFR 541.7(g), 412.1):**
  - labels for temporary approval (e.g., change in product formula ingredients listed are no longer in descending order of predominance)
  - labels for products for export from the U.S. with labeling deviations (e.g., nutrition facts panel in a format not permitted on domestic labels)
  - **labels with special statements and claims (e.g., "all natural" or "no antibiotics administered")**
- ***ALL OTHER labels do not require submission to FSIS for prior approval***

Food Safety and Inspection Service:
Label Approval by FSIS

- Foreign establishments or their representatives must submit labels requiring sketch approval to the FSIS labeling staff
- Applicants are *strongly encouraged to submit label applications electronically*



- Web-based: Label Submission and Approval System (LSAS)
- Paper: express mail, mail, courier, or consultant
  - Fax applications are typically illegible and will not be accepted.
  - FSIS cannot accept labels via e-mail

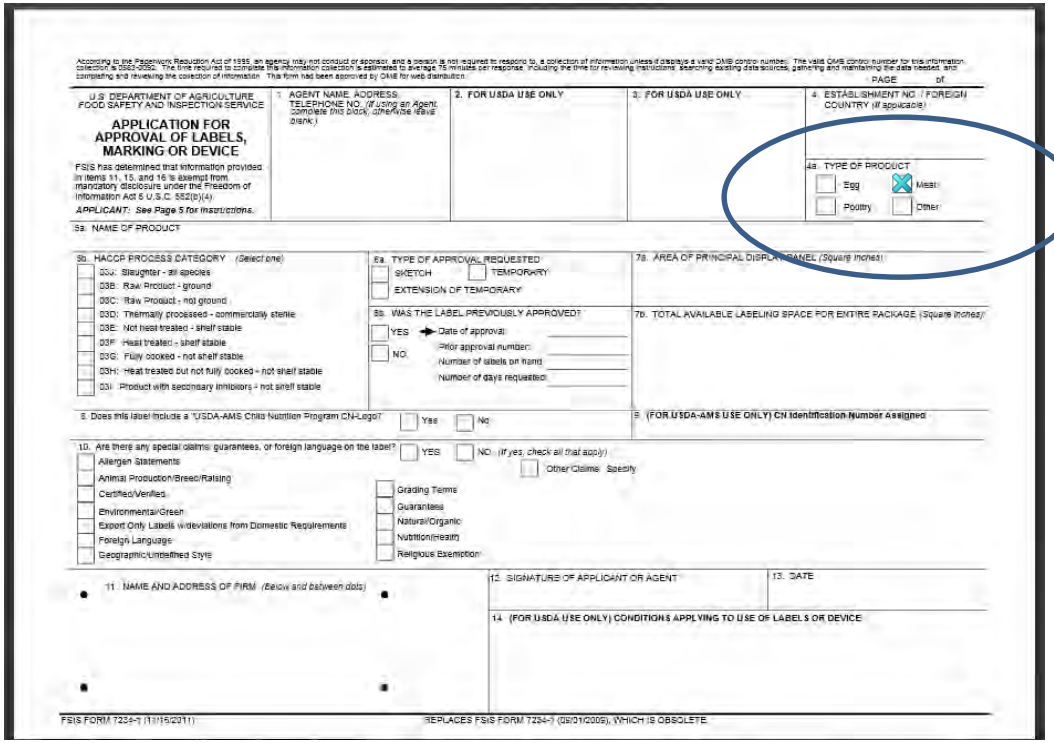
E-Authentication (Level 2) is required to use Label Submission and Approval System (LSAS)

- Persons conducting business with government
- Managed by the Department of Agriculture
- Website: www.eauth.egov.usda.gov.
- Helpdesk: www.eauthhelpdesk@ftc.usda.gov.
- Helpdesk telephone: 800-457-3642

Food Safety and Inspection Service:
Label Submission – Paper

Use FSIS Form 7234-1, available at:

http://www.fsis.usda.gov/Regulations_&_Policies/Label_Application_Guidance/index.asp



U.S. DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE

APPLICATION FOR APPROVAL OF LABELS, MARKING OR DEVICE

FSIS has determined that information provided in items 11, 15, and 16 is exempt from mandatory disclosure under the Freedom of Information Act 5 U.S.C. 552(b)(4).

APPLICANT: See Page 5 for instructions.

1. AGENT NAME, ADDRESS, TELEPHONE NO. *(If using an Agent, complete this block; otherwise leave blank.)*
2. FOR USDA USE ONLY
3. FOR USDA USE ONLY
4. ESTABLISHMENT NO. / FOREIGN COUNTRY *(If applicable)*

4a. TYPE OF PRODUCT
☐ Egg ☒ Meat
☐ Poultry ☐ Other

5a. NAME OF PRODUCT

5b. HACCP PROCESS CATEGORY *(Select one)*
☐ 03A: Slaughter - all species
☐ 03B: Raw Product - ground
☐ 03C: Raw Product - not ground
☐ 03D: Thermally processed - commercially sterile
☐ 03E: Not heat treated - shelf stable
☐ 03F: Heat treated - shelf stable
☐ 03G: Fully cooked - not shelf stable
☐ 03H: Heat treated but not fully cooked - not shelf stable
☐ 03I: Product with secondary inhibitors - not shelf stable

6a. TYPE OF APPROVAL REQUESTED
☐ SKETCH ☐ TEMPORARY
☐ EXTENSION OF TEMPORARY

7a. AREA OF PRINCIPAL DISPLAY PANEL *(Square inches)*

8a. WAS THE LABEL PREVIOUSLY APPROVED?
☐ YES → Date of approval:
Prior approval number:
☐ NO
Number of labels on hand:
Number of days requested:

7b. TOTAL AVAILABLE LABELING SPACE FOR ENTIRE PACKAGE *(Square inches)*

8. Does this label include a "USDA-AMS Child Nutrition Program CN-Logo? ☐ Yes ☐ No

9. (FOR USDA-AMS USE ONLY) CN Identification Number Assigned

10. Are there any special claims, guarantees, or foreign language on the label? ☐ YES ☐ NO *(If yes, check all that apply)*
☐ Allergen Statements
☐ Animal Production/Breed/Raising
☐ Certified/Verified
☐ Environmental/Green
☐ Export Only Labels w/deviations from Domestic Requirements
☐ Foreign Language
☐ Geographic/Undefined Style
☐ Other Claims Specify
☐ Grading Terms
☐ Guarantees
☐ Natural/Organic
☐ Nutrition/Health
☐ Religious Exemption

11. NAME AND ADDRESS OF FIRM *(Below and between dots)*

12. SIGNATURE OF APPLICANT OR AGENT

13. DATE

14. (FOR USDA USE ONLY) CONDITIONS APPLYING TO USE OF LABELS OR DEVICE

FSIS FORM 7234-1 (11/15/2011) REPLACES FSIS FORM 7234-1 (09/01/2005), (WHICH IS OBSOLETE

Check "Meat" for Siluriformes fish and fish products

Food Safety and Inspection Service:
Label Submission – Paper

- Submit two copies of the application and two copies of the label
- Application is three pages (includes product formula page and processing procedures page)
- Address and additional information is available at:

http://www.fsis.usda.gov/wps/portal/fsis/topics/regulatory-compliance/labeling/labeling-procedures/label-application-guidance

Food Safety and Inspection Service:
Label Submission – Paper

- All labels submitted via paper application will be scanned into LSAS by the FSIS labeling staff
- Since they must be scanned into LSAS, paper applications will take longer to review than those submitted electronically
- Again, applicants are *strongly encouraged to submit label applications electronically*

Food Safety and Inspection Service:
Labeling Records on File in Establishments

- Labeling record must include:
  - Final label applied to product
  - Product formulation and processing procedures
  - Supporting documentation for statements or claims on the label, *including prior sketch approval from FSIS* (if applicable). For example:
    - Support for a "certified" claim such as "Certified Gluten Free"
    - Support for the statement "farm-raised" on a label
- Labeling records must be presented to FSIS personnel *on request*.

Food Safety and Inspection Service:
Pressure Sensitive Stickers

- *Alternative to reprinting labels which require changes or added information*
- May cover inaccurate or misleading labeling information with corrected text
- May be used to add information such as a handling statement
- Must destroy the underlying label or package if removed, or be self-destructive

Food Safety and Inspection Service:
Questions