One Team, One Purpose

Food Safety and Inspection Service
Protecting Public Health and Preventing Foodborne Illness
Food Safety and Inspection Service: Labeling - FDA vs. FSIS

- Does not require prior label approval
- No mark of inspection
- Approves the safety of food ingredients used in food products
- 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
• Labels have up to nine (9) required features (9 CFR 541.7, cross-referencing 9 CFR 317.2; 9 CFR 557.14 cross-referencing 9 CFR 327.14)

• Regulations specify where the required features must be located on the immediate container:
  - Principal Display Panel (PDP)
    (9 CFR 541.7, cross-referencing 317.2(c) and (d))
  - Information Panel (IP)
    (9 CFR 541.7, cross-referencing 317.2 (m))
Food Safety and Inspection Service: Principal Display Panel (PDP) and Information Panel (IP)

- PDP is the part of the label most likely to be displayed, presented...when offered for sale under customary conditions
- IP is any portion of a label not on the PDP that displays certain mandatory features
Food Safety and Inspection Service:
Required Features: Principal Display Panel on Domestic Labels

**FDA requirements:**

1. Name of Product
2. Net Quantity of Contents

**FSIS requirements:**

1. Name of Product
2. Net Quantity of Contents
3. “Product of (country of origin)” on Imported product only
4. Official Inspection Legend
5. Handling Statement (perishable product)

*Feature unique to FSIS
“Catfish” may only be used on products from fish in the Ictaluridae family

Non-Ictaluridae fish must be labeled according to their common or usual name (e.g., Basa, Swai, Giant Pangasius)
Labels on raw Siluriformes fish products containing added solutions must include a descriptive designation (e.g., “Contains 10% added solution of water, salt, phosphates....”)

- Product name and descriptive designation must be in one easy-to-read type style, in one color, on a single color contrasting background (also 1/3 height requirement, ¼ until 1/1/18)
- Statement must list all ingredients by common or usual name in descending order of predominance
- Multi-ingredient components (e.g. purchased soy sauce, seasoning blend) not required to sublist all ingredients in descriptive designation; ingredients statement must list all individual ingredients
- 9 CFR 317.2(e)(2), 541.7(a)
Inspection legend may be any size but must be legible
(9 CFR 541.2, 312.2(b)(1))

Siluriformes Inspection Legend = Meat Inspection Legend
For perishable products that need special handling to maintain their wholesomeness
(9 CFR 541.7, 317.2 (k))

- Keep Refrigerated
- Keep Frozen
- Keep Refrigerated or Frozen
- Previously Handled Frozen For Your Protection - Refreeze or Keep Refrigerated
Food Safety and Inspection Service:
Required Features: Information Panel on Domestic Labels

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

**FDA requirements:**

1. Name and place of business of manufacturer/packer/distributor
2. Ingredients statement
3. Nutrition labeling

**FSIS requirements:**

4. Name and place of business of manufacturer/packer/distributor
5. Ingredients statement
6. Nutrition labeling
7. Ingredients statement
8. Nutrition labeling
9. Safe Handling Instructions if the product is not ready-to-eat (may be located on any panel)

*Feature unique to FSIS*
Food Safety and Inspection Service:
Safe Handling Instructions

- Must be on any product that is NOT ready-to-eat
- Required if destined for retail, hotels, restaurants and institutions
- Not required on products shipped for further processing at an official establishment (USDA-inspected)
- “Meat and/or poultry” replaced with “fish” on labels for Siluriformes fish and fish products to minimize customer confusion

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.
## Food Safety and Inspection Service: Domestic Labeling Requirements - Summary

<table>
<thead>
<tr>
<th>Feature</th>
<th>Reference</th>
<th>Location</th>
<th>Applies to</th>
</tr>
</thead>
<tbody>
<tr>
<td>Product Name</td>
<td>9 CFR 541.7(a), 317.2(c)(1)</td>
<td>Principal display panel</td>
<td>All products</td>
</tr>
<tr>
<td>Inspection Legend</td>
<td>9 CFR 541.2, 541.7(a), 317.2(c)(5)</td>
<td>Principal display panel</td>
<td>All products</td>
</tr>
<tr>
<td>Handling Statement (e.g. “Keep Frozen”)</td>
<td>9 CFR 541.7(a), 317.2(k)</td>
<td>Principal display panel</td>
<td>Products requiring special handling to maintain wholesomeness</td>
</tr>
<tr>
<td>Net Weight Statement</td>
<td>9 CFR 541.7(a), 317.2(h)</td>
<td>Principal display panel</td>
<td>Products sold at retail, unless the net weight is applied at retail</td>
</tr>
<tr>
<td>Ingredients Statement</td>
<td>9 CFR 541.7(a), 317.2(f)</td>
<td>Information panel or Principal display panel</td>
<td>Products with two or more ingredients</td>
</tr>
<tr>
<td>Address Line</td>
<td>9 CFR 541.7(a), 317.2(g)</td>
<td>Information panel or principal display panel</td>
<td>All products</td>
</tr>
<tr>
<td>Nutrition Facts Panel</td>
<td>9 CFR 541.7(f), 317.300</td>
<td>Information panel or Principal display panel</td>
<td>Products not exempted by 9 CFR 317.400</td>
</tr>
<tr>
<td>Safe Handling Instructions</td>
<td>9 CFR 541.7(c), 317.2(l)</td>
<td>Any panel</td>
<td>Products with a not-ready-to-eat meat (fish) component</td>
</tr>
</tbody>
</table>
• Establishments must obtain FSIS prior approval for labels of Siluriformes fish products before products may be marketed.

• Label approval is granted one of two ways:
  – Sketch approval by the Labeling and Program Delivery Staff (LPDS)
  – Generic approval by being in compliance with applicable regulations
Only certain types of labeling require submission for evaluation by the 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 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 LPDS for approval

Many fish labels can be generically approved and do not need to be submitted to LPDS

Establishments may submit labels to LPDS during the 18-month transitional period.

On September 1, 2017 all labels requiring LPDS approval must have a label approval on file.
Food Safety and Inspection Service:
How to Submit Labels

• 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.
  – LPDS 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](http://www.eauth.egov.usda.gov)
- Helpdesk: [www.eauthhelpdesk@ftc.usda.gov](http://www.eauthhelpdesk@ftc.usda.gov)
- Helpdesk telephone: 800-457-3642
Web-based software application

- Requires Level 2 eAuthentication
- Integrates and implements a secure electronic label application process for establishments to submit label applications and appeals
- Application processing via LSAS is faster than paper
- Enrollment and use instructions at:

Use FSIS Form 7234-1, available at:

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<tr>
<th>50. NAME AND ADDRESS OF FIRM (Enter and between dots):</th>
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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 at:

Food Safety and Inspection Service:  
**Label Submission: Paper**

- All labels submitted via paper application will be scanned into LSAS by the labeling staff
- Since they must be scanned into LSAS, paper applications will take longer to review than those submitted electronically
- Establishments strongly encouraged to submit label applications electronically
- Address and additional information at:  
Food Safety and Inspection Service:  
**Pressure Sensitive Stickers**

- Alternative to reprinting labels which require changes or added information
- May cover inaccurate and/or misleading labeling information with corrected text
- May be used to add information such as the USDA legend and Establishment number or a handling statement
- Must destroy the underlying label or package if removed, or be self-destructive
- Temporary label approval is not required when the entire label including the pressure sensitive sticker is truthful, not misleading, and the product is not misbranded
- Labeling bearing pressure sensitive stickers falls under the provisions of the generically approved labeling regulations 9 CFR 412.2
Establishments are required to keep records of all labeling (9 CFR 550.1, 320.1(b)(11) and 9 CFR 541.7(g), 412.1)

Labeling record must include:

- Final label applied to product
- Product formulation and processing procedures
- Supporting documentation for statements and/or claims on the label, including prior sketch approval from LPDS (if applicable). For example:
  - Support for the use of state-approved agricultural logos such as “Go Texan” or “Kentucky Proud”
  - Support for the statement “Certified Gluten Free”
  - Documentation supporting the claim “Fish never administered antibiotics”

Labeling record kept in-house, must be presented to FSIS personnel on request
During the transitional period, FSIS will find noncompliance if one or more of the following scenarios occur:

• There is no label on the product
• An undeclared “Big 8” allergen is present in the product
  The “Big 8” allergens are milk, eggs, fish, crustacean shellfish, tree nuts, peanuts, soy and wheat
• The product is labeled as “Catfish” but does not contain fish from the family Ictaluridae
• The net weight is over-declared

For all other labeling deficiencies, FSIS will work with establishments to bring their labels into compliance with FSIS requirements by the end of the transitional period (September 1, 2017)
Food Safety and Inspection Service: Questions