Food Safety and Inspection Service
Protecting Public Health and Preventing Foodborne Illness
Food Safety and Inspection Service:

FSIS Labeling Requirements

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Labeling and Program Delivery Staff, FSIS
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Food Safety and Inspection Service:
Presentation Outline

- Label approval
- Generic labeling regulations
- New regulations and guidance documents
- Rulemaking and policy development initiatives
- Labeling trends and regulatory considerations
- Label Submission Approval System (LSAS)
- References
Federal Meat Inspection Act (FMIA) and Poultry Products Inspection Act (PPIA) require food manufacturers to obtain prior approval for labels of meat and poultry products before products may be marketed.

Prior approval is granted one of two ways:
- Sketch approval which is approved by the Labeling and Program Delivery Staff (LPDS)
- Generic approval which is approved by being in compliance with applicable regulations
Label approval regulations for meat and poultry products now in 9 CFR 412.1; approval of generic labels now in 9 CFR 412.2

Four categories of labels REQUIRE LPDS review

ALL OTHER labels that do not fit into one of the four categories do not require sketch approval by LPDS
Food Safety and Inspection Service: Label Approval

- Only certain types of labeling require submission for evaluation by LPDS
  - labels for temporary approval (9 CFR 412.1(c)(4))
  - labels for products produced under religious exemption (9 CFR 412.1(c)(1))
  - labels for products for export with labeling deviations (9 CFR 412.1(c)(2))
  - labels with special statements and claims (9 CFR 412.1(c)(3))

- FSIS will continue to require the submission of such labels because they are more likely to present significant policy issues that have health or economic significance
A temporary label approval may be granted for labels with a deficiency that does not pose any potential health, safety or dietary problems to the consumer or provide a company an economic advantage (9 CFR 412.1(f)(1))

Temporary approvals typically do not to exceed 180 days, may be less and extensions can be granted on a case-by-case basis

Examples include:

- Incorrect legend on label (e.g. poultry legend on a meat label)
- Order of predominance of ingredients has changed
- Nutrition values not rounded in accordance with FSIS regulations
Religious-exempt product (poultry) does not receive the mark of inspection and, therefore, deviates from the general labeling requirements for meat and poultry products.

Poultry processed in accordance with:

- Buddhist religious beliefs (head and feet remain on eviscerated poultry)
- Confucian religious beliefs (poultry is not eviscerated, head and feet intact)
- Islamic (or Halal) religious beliefs (poultry is eviscerated, head-on, with or without the feet intact, in ready-to-cook form)
Exports of U.S. meat and poultry products occur under agreements between the U.S. government and foreign governments.

Includes ensuring that any changes made to labels on meat and poultry products are allowed per the importing country’s laws (9 CFR 317.7 and 381.128).

Most labels marked “for export only” bear labeling deviations that cannot be used domestically must be sketch approved by LPDS.

412.1(c)(2) allows for export only labels with only changes to the net weight in metric units and required features entirely in a foreign language to be approved generically.
Detailed list of commonly used special statements and claims requiring LPDS approval and examples of claims eligible for generic approval is available on FSIS website


Compliance Policy Guide for generic labeling is in clearance. This will expand upon the list of special statements and claims.
- Natural claims, e.g. “All Natural”, “100% Natural”
- Negative Claims, e.g., “no milk,” “no preservatives”
- Statements that identify a product as “organic”
- Front of Pack (FOP) nutrition statements, e.g., “0 grams trans fat per serving”
- Claims of the use of non-genetically engineered ingredients
- Health claims defined in 21 CFR Subpart E, e.g. dietary saturated fat and cholesterol and risk of coronary heart disease (21 CFR 101.75)
- Breed claims (Berkshire, Angus, Hereford)
- Claims regarding meat and poultry production practices (e.g., claims regarding the raising of animals such as “no antibiotics administered” or “vegetarian fed”)

Food Safety and Inspection Service: Special Statements and Claim Examples
Once a label is approved with a special statement or claim, changes can be made generically that are unrelated to the special claim, e.g., brand name, net weight, updating nutrition facts values, serving sizes (must be based on RACCs or longstanding appetizer RACC) and in some cases formulation changes.

In many cases, a change to the formula will not effect the special claim. Exceptions are claims involving a negative or natural claim or organic.

- Label is approved by LPDS with a “No MSG” claim. The establishment may change the order of predominance or remove ingredients from the product generically as the changes will not effect the claim. However, if the establishment were to add new ingredients to the formula the change would require resubmission to LPDS to approve the claim with the new ingredients and verify compliance with the negative claim.

Some special statements and claims can be the subject of a blanket request, e.g., use of front of pack format across a line of products.
Some statements are not considered special statements or claims under 9 CFR 412.1 (e).

Statements and claims of this type may be approved generically under 9 CFR 412.2(b).

Examples include:
- Allergen or contains statements (contains: soy, wheat, milk, eggs)
- AMS Grading on beef (Prime, Choice, Select) or poultry (Grade A)
- Nutrition claims defined in 9 CFR 317 or 381 (low fat, good source of fiber)
- Flavor profiles (teriyaki flavored)
- Foreign language on domestic products
- Geographic claims (refer to 9 CFR 317.8(b)(1))
Generic approval regulations do not apply to egg products
  – Expanding the generic labeling criteria for processed egg products is being considered as a separate rule

Generic approval regulations also do not apply to exotic species under voluntary inspection
  – All labels for exotic species products must be approved by LPDS, including any changes to sketch approved labels (e.g. “Buffalo Jerky”)
  – Amenable products with exotic species used as an ingredient may be generically approved if they do not fall into any of the four categories of labels requiring LPDS approval (e.g. “Buffalo Jerky, Beef Added”)
**Types of Label Approval**

**Sketch**
- Label review process by LPDS
- Printer’s proof or equivalent that is sufficiently legible to clearly show all labeling features, size, and location
- May be hand drawn, computer generated or other reasonable facsimile
- Must clearly reflect and project the final version of the label
- Specific categories of labels require sketch approval
- Sketch approved labels reviewed by LPDS are either “approved” or “approved as modified”
- A “Sketch” label is the concept of a label while “Final” label is the label that is applied to product before distribution in commerce

**Generic**
- The approval of labeling or modifications to labeling prior approved by the Agency without submitting such labeling to FSIS for sketch approval
- Requires that all mandatory labeling features are in conformance with FSIS regulations
- Although not submitted to FSIS for approval, generically approved labels are approved by being in compliance with applicable regulations

*NOTE: Establishments are responsible for ensuring final labels applied to product are in compliance with FSIS regulations, including making modifications noted by LPDS during sketch review*

*NOTE: FSIS Inspectors do not generically approve labels. Establishments do not generically approve labels. FSIS approves labels through generic labeling regulations.*
## Food Safety and Inspection Service: Required Labeling Features: Summary Table

<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 317.2(c)(1) or 381.117</td>
<td>Principal display panel</td>
<td>All products</td>
</tr>
<tr>
<td>Inspection Legend</td>
<td>9 CFR 317.2(c)(5) or 381.123</td>
<td>Principal display panel</td>
<td>All products</td>
</tr>
<tr>
<td>Handling Statement (e.g. “Keep Frozen”)</td>
<td>9 CFR 317.2(k) or 381.125(a)</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 317.2(h) or 381.121</td>
<td>Principal display panel</td>
<td>Product sold at retail, unless the net weight is applied at retail</td>
</tr>
<tr>
<td>Ingredients Statement*</td>
<td>9 CFR 317.2(f) or 381.118</td>
<td>Information panel or Principal display panel</td>
<td>Products with multiple ingredients</td>
</tr>
<tr>
<td>Address Line</td>
<td>9 CFR 317.2(g) or 381.112</td>
<td>Information panel or Principal display panel</td>
<td>All products</td>
</tr>
<tr>
<td>Nutrition Facts Panel</td>
<td>by 9 CFR 317.300 or 381.400</td>
<td>Information panel or Principal display panel</td>
<td>Products not exempted by 9 CFR 317.400 or 381.500</td>
</tr>
<tr>
<td>Safe Handling Instructions</td>
<td>9 CFR 317.2(l) or 381.125(b)</td>
<td>Information panel or Principal display panel</td>
<td>Products with a not-ready-to-eat meat or poultry component</td>
</tr>
</tbody>
</table>
Food Safety and Inspection Service:
Special Statements and Claims: Sketch Approval Required

**Beef Raised**
- Without Added Antibiotics
- Barn Roaming, Never Confined to a Lot
- Grass Fed
- Organic

**Beef Flat Iron Steak**

*Minimally Processed, No Artificial Ingredients*

Keep Refrigerated

Net Weight: 48 oz (3 lbs)

**Safe Handling Instructions**

-keep refrigerated or frozen.
- Thaw in refrigerator or microwave.
- Keep raw meat and poultry separate from other foods.
- Wash working surfaces including cutting boards, utensils, and hands after touching raw meat or poultry.
- Cook thoroughly.
- Keep hot foods hot. Refrigerate leftovers immediately or discard.

Distributed By:
20101 Beltsville Rd
Sunnyside, MD 12345
Certified Organic by LPDD Organic Certifying

**A Good Win Farms®**
est 2010

**All Natural* Pasture Raised**
Food Safety and Inspection Service: Statements and Claims: Generic Example

NEW! Chicken Kabobs
Grilled White Chicken Chunks on a wooden skewer

Fully Cooked

HALAL

Made with only White Chicken!!!

Ingredients: chicken breast, salt, pepper

Serving suggestion
Keep Refrigerated

Net Wt. 32 oz. (2 lbs.)

Packed for: House of Kabob, Houston, TX 77252
Food Safety and Inspection Service:
Special Statements and Claims: Sketch Approval Required

Packed for: House of Kabob, Houston, TX 77252

All Natural*

Fully Cooked Chicken Kabobs
Grilled White Chicken Chunks on a wooden skewer

All of our chickens are raised without antibiotics!

Serving suggestion

Ingredients: chicken breast, salt, pepper

*Minimally Processed, no artificial ingredients

CERTIFIED HALAL BY THE HOUSTON HALAL ALLIANCE

Keep Refrigerated Net Wt. 32 oz. (2 lbs.)
Food Safety and Inspection Service:
Statements and Claims: Generic Example

Made in New Hampshire

Black Forest Ham
Hand-rubbed with spices

Cured with water, salt, contains 2% or less of dextrose, sodium nitrite, sodium erythorbate, sodium lactate, sodium phosphate, sodium diacetate

97% Fat Free

Keep Refrigerated

Distributed by Birchwood Farms, Nashua, NH 03060

Net Wt. 6 oz.

Generic statements and claims
- FSIS Inspectors do not generically approve labels
- FSIS in-plant inspection personnel will continue to conduct in-plant label verification activities
- Labels are generically approved if they meet the criteria listed in 9 CFR 412.2(b)
- Establishments do not generically approve labels
- Generically approved labels are approved by FSIS and display all applicable mandatory features in compliance with federal regulations
Establishments are required to keep records of all labeling

Labeling record must include:

- Final label applied to product
- Product formulation
- Processing procedures
- Supporting documentation, including prior sketch approval from LPDS (if applicable)

Required records prescribed by 9 CFR 320.1(b)(11), 381.175(b)(6), and 412.1

Labeling record for any generically approved label must include a complete copy of the original LPDS approval (if the original required LPDS approval)
OPPD reissued FSIS Directive 7221.1 on January 6, 2014

Reissuance needed because:

- Information in directive reflected old regulations in 9 CFR 317.5 and 381.133
- Needed permanent instructions on how to conduct and document a label verification activity
- Focus is appropriately placed on “final” label that is applied to product. Consistent with public health focus and previous FSIS notices involving label verification activities (FSIS Notices 35-11, 54-11, and 29-13)
- Whether or not a label is generically approved or needs to be submitted to LPDS for sketch approval is only one step in the label verification process
- Provides relevant regulations for each of the required features and where they may be located; a question often raised in askFSIS
As described in Section VI, when labeling is non-compliant, establishments may take corrective actions by submitting for temporary approval.

As described in Section VII, a recall may be warranted only when any of the “big 8” allergens or other ingredients of public health concern are not properly declared.

Recalls are not conducted for minor label deficiencies that are eligible for temporary approval (i.e., use of labels would not result in a public health or safety issue or provide the company with an economic advantage).
1. Final Rule: Descriptive Designation for Raw Meat and Poultry Products Containing Added Solutions

2. Final Rule: Descriptive Designation for Needle- or Blade-Tenderized (Mechanically Tenderized) Beef Products

3. Compliance Guideline: STEC “Sampled and Tested” claims on boneless beef trim


5. FSIS Directive 7230.1: Ongoing Verification of Product Formulation and labeling Targeting the Eight Most Common (“Big 8”) Food Allergens
Product name must include “descriptive designation”

Descriptive designation: % added solution and all ingredients in descending order of predominance.

Separate ingredient statement is required if the descriptive designation does not sublist all multi-ingredient components.

“Enhanced” may not be in the product name.

Effective January 1, 2016.
Product name and descriptive designation must be in the same type font, the same color, and on the same single-color background.

Percent solution must be a number with the percent sign.

Effective January 1, 2018: the smallest letter in the product name and descriptive designation may be no less than \( \frac{2}{3} \) the size of the largest letter (currently the requirement is \( \frac{1}{4} \) the size).
Food Safety and Inspection Service:
Descriptive Designation for Needle- or Blade-Tenderized (Mechanically Tenderized) Beef Products

- FSIS published final rule titled, “Descriptive Designation for Needle- or Blade-Tenderized (Mechanically Tenderized) Beef Products” published in *Federal Register* on May 18, 2015 (80 FR 28153)
- Effective May 17, 2016 (delaying enforcement of beef with added solutions until May 17th instead of January 1st 2016)
- Products covered under proposal:
  - Needle- or blade-tenderized beef products
  - Beef products injected with marinade or solution
- Products not covered under proposal:
  - Products destined to be fully cooked at an official establishment
Food Safety and Inspection Service:
Mechanically Tenderized Beef Products

- Labels must bear:
  1) The descriptive designation “mechanically tenderized,” “blade tenderized,” or “needle tenderized” and an accurate description of the beef component in the product name; and
  2) All words in the descriptive designation be in the same style, color, and on a single-color contrasting background. Print may appear in upper and lower case letters (smallest letters must be at least 1/3 size largest letters used)
  3) Validated cooking instructions for subject products destined for household consumers, hotels, restaurants, or similar institutions. Instructions need to include:
     - cooking method (baking, frying, etc.)
     - that these products need to be cooked to a specified minimum internal temperature,
     - whether these products need to be held at that minimum temperature or higher for a specified time before consumption, i.e., dwell time or rest time, to ensure that potential pathogens are destroyed,
     - and that the internal temperature should be measured by a thermometer.
Food Safety and Inspection Service: Sample Label for Mechanically Tenderized Beef Flank Steak

KEEP REFRIGERATED

Mechanically Tenderized Beef Flank Steak

Cooking Instructions

Nutrition Facts Panel

Safe Handling Instructions

Meat Company, 501 Main Street, Beltsville, MD 20706

NET WEIGHT: 32 OZ (2 LB)
Food Safety and Inspection Service

Shiga toxin *Escherichia coli* (STEC) Organisms Sampled and Tested Labeling Claims for Boneless Beef Manufacturing Trimmings

- Published in 2014, announced in *Federal Register*
- *Includes FSIS approved testing methods*
- Includes examples of acceptable “sampled and tested” claims
- Includes examples of sufficient documentation to support sampled and tested labeling claims
Food Safety and Inspection Service
Allergens and Ingredients of Public Health Concern: Identification, Prevention and Control, and Declaration through Labeling

- Published in 2014, announced in Federal Register
- Includes scenarios, diagrams, checklists
- FSIS responding to comments and will announce in the Federal Register when updated version is republished
Food Safety and Inspection Service: Ingredient Labeling: Area of Special Emphasis

- “Big 8” allergens (wheat, crustacean shellfish, eggs, fish, peanuts, milk, tree nuts, and soybeans) of greatest public health concern

- Situations involving non-declaration of “Big 8” allergens can result in Class 1 or Class 2 recall. Often the result of:
  - New ingredient and/or new supplier, product reformulation
  - Misprinted label or product placed in wrong package

- FSIS recommends control measures in establishments HACCP system to prevent the potential of undeclared allergens based on three basic principles:
  - Identify: Cross-referencing labels and product formulations with incoming ingredients; separation of allergenic materials in designated areas
  - Prevent and Control: Dedicated equipment; documented cleaning procedures with checklists; maintain methods for tracking product
  - Declare: Systems and checklists for determining labeling compliance (e.g., declaration of all ingredients) on final product and procedures for handling labeling discrepancies
Sustained rate of recalls since 2008. Undeclared ingredients of public health concern previously addressed in notices but expire after 1 year (e.g., 35-11, 54-11, 29-13)


Updated and permanent label verification activities focused on highest risk products

IPP may schedule “Big 8 Formulation Verification Task” more frequently if there are indicators of increased risk of undeclared allergens or ingredients of public health concern:

- Recall within last year for undeclared allergen or ingredient of public health concern
- History of sanitation and HACCP NRs associated with undeclared allergen or ingredient of public health concern
- Ingredient labeling NRs within last year
- Product formulation changes, supplier changes
FSIS has reviewed the FDA proposals for the updating of the nutrition facts panel and the updating of the Reference Amounts Customarily Consumed (RACC) and supports the updating of both regulations.

FSIS is developing a proposed rule consistent with the changes that FDA is proposing including all the technical changes and the supporting economic assessment.

FDA worked closely with FSIS in our analysis of potential RACC changes.

Any label change published as a final rule is expected to be subject to the uniform compliance date which defers implementation by two years.
“Clean Labeling” not defined in FSIS regulations or policies; subjective terminology influenced by consumer perception and demand

“Shortage of Real Estate” on labels. Streamlined ingredients statement and choosing most impactful claims are important considerations with limited space

Trends in label claims include:
- Animal production raising claims
- Avoidance of genetically engineered ingredients
- Elimination of ingredients of public health concern (e.g., free of “Big 8” allergens such as soy)
- Elimination of ingredients of consumer concern (e.g., free of color additives, monosodium glutamate, high fructose corn syrup)
- Use of ingredients perceived to be natural or consumer friendly (e.g., vinegar or cultured sugar in lieu of chemical preservatives)
Food Safety and Inspection Service:
Regulatory Considerations

- Use of safe and suitable ingredients approved for use in meat and poultry products (refer to 9 CFR 424.21(c) and FSIS Directive 7120.1)
- Ingredient labeling regulations and policies, labeling exemptions, allergen labeling
- Determining whether a label needs to be submitted to FSIS for label approval under 9 CFR 412.1 (e.g., special claims)
- Are the claims approvable?
Food Safety and Inspection Service: Negative Claim Example
Food Safety and Inspection Service:
Negative Claim Example
In some cases, undefined claims may be approved provided they are not false or misleading under 9 CFR 317.8 and 381.129.

FSIS does not distinguish between “natural” and “artificial” preservative.

“No Artificial Preservatives” permitted under certain conditions to ensure consumers were not misled:

1. A statement “See back panel for ingredients used to preserve quality” would appear on the front panel in immediate proximity to the “No Artificial Preservatives” claim. This will provide consumers with details about the claim—namely, the fact that the product has added ingredients that will help preserve product quality.

2. Each antimicrobial ingredient would be declared with an asterisk in the ingredient line. The asterisk would lead to the following explanatory statement below the ingredient line: “Ingredient to preserve quality” or perhaps a shortened form like “to preserve quality.”
Food Safety and Inspection Service:
No Artificial Preservatives
FSIS has approved labels that state the products meet the standards of a third-party certifier regarding the use of feed containing ingredients that are not genetically engineered, e.g. “This pasture raised beef is fed a vegetarian diet that was produced in compliance with the Non GMO Project standard for avoidance of genetically engineered ingredients.”

The Agency has not developed any new policy regarding non-GE products and is not certifying that the labeled products are free of genetic engineering or genetic modifications.

The National Organic Program within the Agriculture Marketing Service in USDA is one example of a third-party certifying organization.

FSIS has determined that certain statements of this type are truthful and not misleading, and that they are claims that are verifiable.
• LSAS is the electronic submission system for label applications
• Both sketch approvals and voluntary generic approvals may be submitted through LSAS
• To get an LSAS account, you must first get a Level II E-Authentication account
• Interactive tutorials are available online
• The Generic Label Adviser (GLA) can assist you in determining if your label requires sketch approval
• Release 2 enhancements implemented in April 2015
• All label applications received on paper will be scanned and converted into electronic format. These will be evaluated in LSAS, and the records will be kept in LSAS
• Paper label applications must be legible to the scanner
  – Use the standard form and not an approximated form
  – Type all applications
• Release 3 enhancements scheduled for 2016
• FSIS inspectors will have access to labeling records for verification activities
Food Safety and Inspection Service: 
**Label Backlog**

- LPDS has maintained a 1 week or less backlog for 1\textsuperscript{st} priority labels
- Backlog for labels eligible for generic approval voluntarily submitted for approval (2\textsuperscript{nd} priority) is approximately 4 weeks
- FSIS strongly encourages industry’s use of generic labeling regulations and will continue with outreach for industry and training for FSIS personnel
Food Safety and Inspection Service:

Resources
Available online at:

Provides additional guidance regarding FSIS standards outside of the regulations

Used in conjunction with the Meat and Poultry Inspection Regulations and FSIS Directives and Notices

Composite of policy and day-to-day labeling decisions

Claims found in the Policy Book may be approved generically except: natural claims, negative claims
Food Safety and Inspection Service:  
**Food Standards and Labeling Policy Book**

- FSIS has decided to stop adding policy guidance to the Food Standards and Labeling Policy Book.
- FSIS will continue to amend or remove items in the book, as necessary, but will no longer add new material to it.

The Agency will convey new labeling policy by other means, such as compliance policy guides.
Food Safety and Inspection Service: Available Resources

FSIS Main Labeling Website:
http://www.fsis.usda.gov/wps/portal/fsis/topics/regulatory-compliance/labeling

Generic Labeling Resources:

Allergens - Voluntary Labeling Statements:

Submit questions through askFSIS http://askfsis.custhelp.com
Call LPDS at (800) 233-3935