



U.S. Department of Agriculture

One Team. One Purpose.



Food Safety and Inspection Service

Ensuring nutritious and wholesome food for you



Food Safety and Inspection Service:

Overview and Update on Current FSIS Labeling Activities

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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:

Presentation Outline

- Label Approval including the Label Submission and Approval System (LSAS)
- Allergens and related claims
- Label assessments and label claim verification
- Special statements and claims, e.g., animal raising and Non-GMO
- Nutrition Labeling



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 continues to require the submission of such labels because they are more likely to present significant policy issues that have health or economic significance
- 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: Special Statements and Claims (9 CFR 412.1(e))

- Detailed list of special statements and claims requiring LPDS approval and examples of claims eligible for generic approval is available on FSIS website
<http://www.fsis.usda.gov/wps/wcm/connect/bf170761-33e3-4a2d-8f86-940c2698e2c5/Comp-Guide-Labeling-Evaluation-Approval.pdf?MOD=AJPERES>
- List includes commonly used special statements and claims
- List will be periodically updated to reflect commonly asked questions regarding special statements and claims

Food Safety and Inspection Service: Special Statements and Claim Examples

- 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
- 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 Claims: Sketch Approval Required

Special
Statements
and Claims

Beef Raised

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



Safe Handling Instructions

This product was prepared from inspected and passed meat and/or poultry. 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.

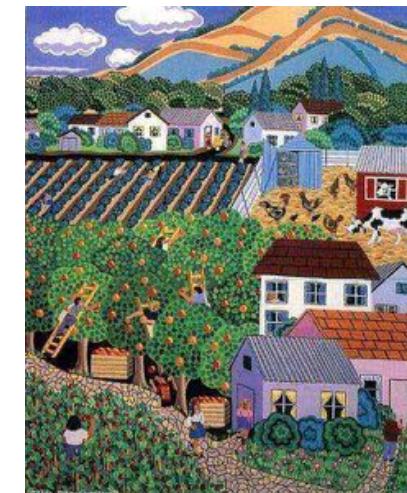
- Keep refrigerated or frozen. Store in refrigerator or microwave.
- Keep raw meat and poultry separate from other foods. Wash working surfaces (including cutting boards), utensils, and hands after touching raw meat or poultry.
- Cook thoroughly.
- Keep hot foods hot. Refrigerate leftovers immediately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

Beef Flat Iron
Steak

A Good Win! Farms[©]
est 2010



All Natural*
Pasture
Raised



*Minimally Processed, No
Artificial Ingredients

Keep Refrigerated

Net Weight: 48 oz (3 lbs)

Distributed By:
2010 Beltsville Rd
Sunnyside, MD 12345
Certified Organic by
LPDD Organic
Certifying

Food Safety and Inspection Service: Label Submission and Approval System (LSAS) Update

- LSAS is the electronic submission system for label applications
- To get an LSAS account, you must first get a Level 2 e-Authentication account
- 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
- Interactive tutorials will be available online soon
- The Generic Label Advisor (GLA) can assist you in determining if your label requires sketch approval
- Enrollment and use instructions at:
<http://www.fsis.usda.gov/wps/portal/fsis/topics/regulatory-compliance/labeling/labeling-procedures/label-submission-and-approval-system/lsas>
- FSIS has contract in place for making enhancements

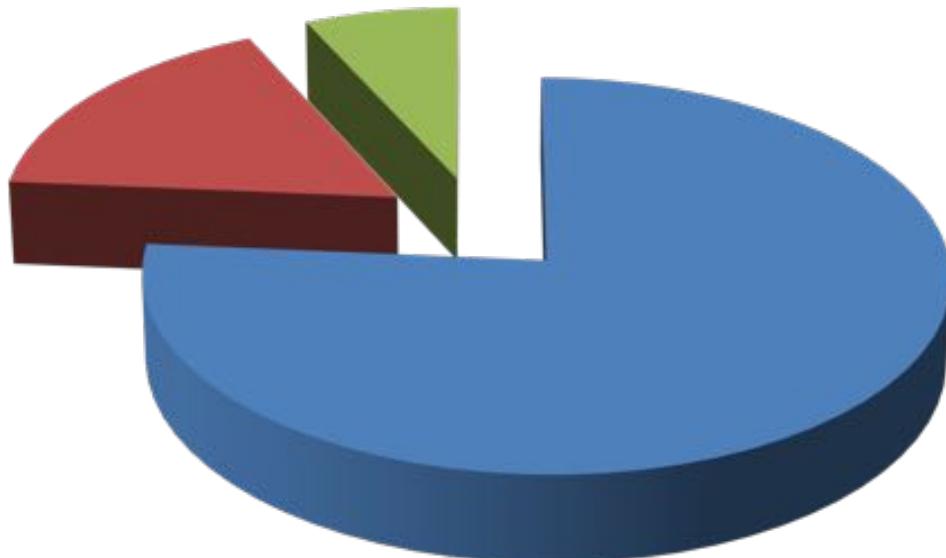
Food Safety and Inspection Service:

Allergen Labeling: Area of Continued 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

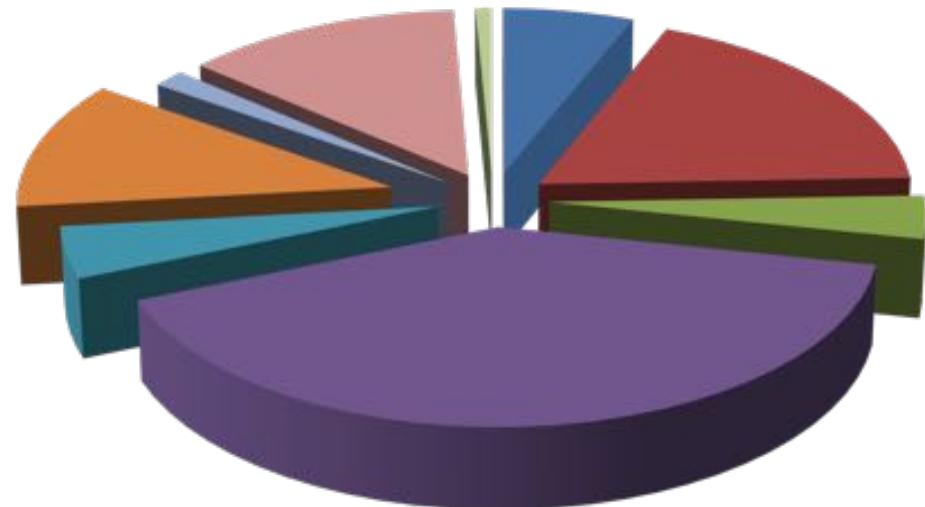
Food Safety and Inspection Service: 2017 Recall Summary by Classification and Reasons for Recall

**Calendar Year 2017 - Recall
Classification (N = 131 Recalls)**



■ Class I (100) ■ Class II (22) ■ Class III (9)

**Calendar Year 2017 - Reasons for
Recall (N = 131 recalls)**



■ STECs (8) ■ Extraneous /Foreign Material (24)
■ Processing Deviation (5) ■ Undeclared Allergen (53)
■ Undeclared Substance (6) ■ Listeria monocytogenes (15)
■ Residue (2) ■ Other (17)
■ Salmonella (1)

Food Safety and Inspection Service

FSIS Directive 7230.1: Ongoing Formulation Verification Task

IPP verify that all ingredients

- being used in the production of the product are present on the product formulation record

IPP verify that all ingredients

- from the product formulation are declared in the ingredients statement on the product label by common and usual name

IPP verify the label approval is on file

- and the applied labels are consistent with the establishment's label approval on file

Food Safety and Inspection Service

FSIS Directive 7230.1: Ongoing Formulation Verification Task Observations

- Less establishments reporting no allergens
- Soy, wheat, milk most common allergens
 - Fish, tree nuts, shellfish, peanuts uncommon
- Increasing number of establishments incorporate multi-ingredient component
- Increasing number of establishments had an allergen control plan/program (typically prerequisite program)

Food Safety and Inspection Service: Negative Claims

- Provided for by Food Standards and Labeling Policy Book entry. Refers to absence of an ingredient or source of an ingredient (e.g., “No MSG,” “No Soy”)
- May also be used to highlight the absence of a class of ingredients (e.g., “No Preservatives,” “Preservative Free Crust”)
- FSIS has observed through the prior label approval system a continued increase in the use of claims of this type, particularly gluten free as well as free of big 8 allergens

Food Safety and Inspection Service:

Generic Label Assessment

- FSIS will select samples of generically approved labeling to determine compliance under 9 CFR 412.2(a)(2); OPPD conducted initial pilot sampling in 2016
- Assessment protocol
(<http://www.fsis.usda.gov/wps/portal/fsis/topics/regulatory-compliance/labeling/labeling-policies/assessment-generically-approved-label>)
 - 2 Weeks prior to the first assessment an FSIS constituent update will be published announcing the onset of the pilot project
 - A meeting will be held with affected District Offices to discuss the selected establishments, required resources (if any) and dates of the assessments
 - Two labeling subject matter experts (SMEs) and one policy analysis SME will attend each assessment. The SMEs will travel to the establishment on the first day of the assessment
 - SMEs will review each label record to determine if it is a generically approved label record and will document any deficiencies
- If SMEs determine deficiency has public health significance they will contact the IIC or FLS to alert them to the deficiency
- If SME's determine deficiency does not have public health significance the SMEs will inform the establishment of the deficiency

Food Safety and Inspection Service: Sampling Associated with Certain Labeling Claims

- FSIS has observed through its label approval system an increase in the number of applications for labels bearing claims highlighting the absence of various substances from or products, e.g., “no soy added.”
- FSIS issued a PHIS questionnaire to IPP (Notice 21-17) in April 2017 to identify those establishments producing products with the aforementioned claims via FSIS Notice 42-17. Results will be used to build the sampling program
- In FY18 FSIS intends to begin three exploratory sampling programs targeting labeling claims
 - raw, ground beef products with negative/no hormone claims
 - raw chicken parts with negative/no antibiotics claims
 - ready-to-eat products with negative/no soy claims

Food Safety and Inspection Service: Sampling Associated with Certain Labeling Claims

- Purpose of sampling to verify industry's compliance with Agency's labeling regulations and policies to ensure such claims are truthful, not misleading and that labels display a complete listing of ingredients; to protect consumers from misbranded and economically adulterated meat and poultry products
- FSIS began sampling raw ground beef products and conducting nutrient analysis on September 29, 2014. We intend to continue the nutrient content sampling program at Federal establishments – FSIS Notice 77-16: FSIS Sampling of Raw Ground Beef Products for Nutrient Content and expand sampling
- Notice in clearance titled **FSIS SAMPLING FOR LABELING CLAIMS VERIFICATION**
 - Includes contents of FSIS Notice 77-16 and expands sampling to include verification of certain labeling claims
 - Products in consumer-ready packaging that bear certain labeling claims or raw ground beef in consumer-ready packaging that bears a nutrition label that have been assigned a directed Label Verification Sample Task in PHIS – IPP to collect these product samples for verification testing
 - Sampling anticipated to begin this fiscal year

Food Safety and Inspection Service: Non-Genetically Engineered Claims

- Historically, FSIS has allowed the use of the terms “genetically modified organism” or “GMO” on product labels or labeling only if the name of the third-party certifying organization contains these terms (e.g. “Non-GMO Project”)
- Recent legislation was enacted (Pub. L. 114-216) requiring the Secretary of Agriculture to develop and implement a mandatory national bioengineered food disclosure standard within 2 years
- FSIS has reconsidered its position and will allow the use of the terms “genetically modified organism” or “GMO” in negative claims provided that the label or labeling is otherwise truthful and not misleading
- Examples include:
 - “Chicken raised on a diet containing no genetically engineered ingredients,” or “Derived from beef fed no GMO feed.”
 - “No GMO ingredients,” “No genetically modified ingredients,” “Ingredients used are not bioengineered,” or “No genetically engineered ingredients through the use of modern biotechnology

Food Safety and Inspection Service: Non-Genetically Engineered Claims

- 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 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
- FSIS published a compliance policy guide titled, *"Statements That Bioengineered or Genetically Modified (GM) Ingredients or Animal Feed Were Not Used in Meat, Poultry, or Egg Products"*
<http://www.fsis.usda.gov/wps/portal/fsis/topics/regulatory-compliance/labeling/claims-guidance/procedures-nongenetically-engineered-statement>

Food Safety and Inspection Service: Non-Genetically Engineered Claims

- For meat, poultry or egg products with previously approved GE negative claims, establishments are allowed to change the terms “non-genetically engineered” or “non-GE” to “non-GMO” or “no genetically modified organisms” without approval from FSIS; such changes are generically approved under 9 CFR 412.2
- If FSIS has approved an organic claim on the product label, establishments may add an applicable negative claim of the kind discussed in guidance document

Food Safety and Inspection Service:
Non-Genetically Engineered Claim Example

PROGRESSIVE MEATS

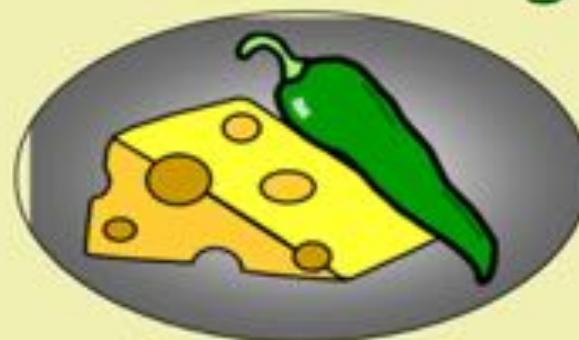
EST. 1998

**Jalapeno Peppers and Cheese
Chicken Sausage**

**NO GE
INGREDIENTS***



*Certified No Genetically Engineered ingredients by True 2 Earth.
true2earth.net/non-ge



KEEP REFRIGERATED

**NET WT.
48 OZ (3 LB)**



Ingredients: Chicken,
Cheese (pasteurized milk,
cheese cultures, salt,
enzymes and annatto color),
water, red peppers, seasoning
(sugar, salt, spices), Jalapeno
peppers (jalapeno peppers,
water, citric acid).

Distributed by PROGRESSIVE
MEATS Co.
1234 Unique Rd.
Calambia, VA 00123

Food Safety and Inspection Service: Non-Genetically Engineered Claim Example

A Good Wind Farms® est 2010

All Natural**
Raised without
Added Antibiotics
No Added Hormones†

Fed a vegetarian diet
with No GMO
feed ingredients*

Organic Premium Fresh Young Chicken



Safe Handling Instructions
This product was prepared from inspected and passed meat and/or poultry. 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.
These in refrigerator or microwave.
- Keep raw meat and poultry separate from other foods.
Wash washing 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 A Good Wind Farms®
1224 Unique Dr.
Orlando, FL 32812
Certified Organic by ABC Green.

KEEP REFRIGERATED

**NET WT.
48 OZ (3 LB)**

**INSPECTED
U.S.
DAIRY INSPECTION
BUREAU**

**USDA
ORGANIC**

"This pasture raised chicken is fed an organic vegetarian diet with no GMO feed ingredients in compliance with the National Organic Program regulation."

**** Minimally Processed, No Artificial Ingredients**

† Federal Regulations do not permit the use of hormones in poultry.

Food Safety and Inspection Service: Voluntary Statements about Use of Genetically Engineered Ingredients

- FSIS will evaluate voluntary statements on the presence of GE ingredients on a case by case basis
- Voluntary statements may be:
 - specific to a particular ingredient (e.g., “this product contains cornmeal from corn that was produced using modern biotechnology”) or
 - more general in cases where a meat or poultry product contains one or more genetically engineered ingredient (e.g., “made with genetically engineered ingredients”) or
 - Describe the purpose of use (e.g., “made with genetically engineered ingredients to reduce the impact of pesticide use on the environment”)
- The Agency will consider statements of this type special statements or claims that require review and approval by FSIS for compliance under 9 CFR 412.1(e)
- Establishments will need to submit documentation with their request for label approval to support that the statements are truthful and not misleading

Food Safety and Inspection Service: Animal Production Raising Claims

Examples of claims include, but are not limited to:

Grass Fed

Organic – certified Organic by a NOP certifying entity

No Added Antibiotics

No Added Hormones –Note: Hormones are only approved for use in beef cattle and sheep production. Therefore, the claim on other species of meat cannot be approved unless it is further qualified, e.g., linked to the statement on the same panel as the claim “Federal regulations prohibit the use of hormones in poultry (or pork, veal, or exotic, non-amenable meat products)”

Food Safety and Inspection Service: Animal Production Raising Claims

- For most animal production claims, the documentation needed to support these claims are:
 - 1. A detailed written protocol explaining controls for assuring the production claim from birth to harvest. If purchased, include protocol information from the supplier
 - 2. A signed affidavit declaring the specifics of the animal production claim(s) and that the claims are not false or misleading
 - 3. Product tracing and segregation mechanism from time of slaughter and/or further processing through packaging
 - 4. A protocol for the identification, control, and segregation of non-conforming animals/product
 - 5. A complete, current feed formulation using common and usual language or copies of the feed tags
 - 6. If a third-party certifies/verifies a claim, a current copy of the certification/verification should be provided

Food Safety and Inspection Service: Animal Production Raising Claims Guideline

- FSIS published new guideline in September 2016 titled,
“Documentation Needed to Substantiate Animal Raising Claims for Label Submissions”
- Provided clarification on the types of documentation needed to support specific raising claims (e.g., diet and breed)
- Comment period closed on December 15, 2016. Over 4000 comments received
- FSIS is in the process of evaluating all comments

Food Safety and Inspection Service: Nutrition Labeling

- FSIS is currently in the rule making process to update the nutrition regulations
- Proposed rule published in the FR January 19, 2017 (Docket No. FSIS_FRDOC_0001-0515). Proposal very similar to FDA final, followed same process for RACC analysis
- In the Fall Regulatory Agenda, the rule was listed as “Long Term Action”
<https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=201710&RIN=0583-AD56>
- Long-Term Actions are items under development but for which the agency does not expect to have a regulatory action within the 12 months after publication of this edition of the Unified Agenda

Food Safety and Inspection Service: Nutrition Labeling

- Until a final rule for FSIS is published, FSIS amenable product labels may continue to use the current/original nutrition regulations in 9 CFR
- In the interim, FSIS labeling may Voluntarily use the new FDA format
- Companies should obtain one LPDS sketch for each specific format then same panel may be added to other labeling with generic approval per 9 CFR 412.2
- Once FSIS nutrition rule is final, amenable meat and poultry product labels will need to comply with the FSIS requirements within the applicable effective date
- FSIS Federal Register Notice (11/16/2016): Nutrition Facts Label Compliance <https://www.fsis.usda.gov/wps/wcm/connect/815c1ec3-0779-42e5-b5ec-b85494392efb/2016-0030.html?MOD=AJPERES>

Food Safety and Inspection Service: Nutrition Labeling

- FDA Final (5/27/2016): Food Labeling: Revision of the Nutrition and Supplement Facts Labels
- <https://www.federalregister.gov/documents/2016/05/27/2016-11867/food-labeling-revision-of-the-nutrition-and-supplement-facts-labels#h-188>
- FDA Final (5/27/2016): Food Labeling: Serving Sizes of Foods That Can Reasonably Be Consumed At One Eating Occasion; Dual-Column Labeling; Updating, Modifying, and Establishing Certain Reference Amounts Customarily Consumed; Serving Size for Breath Mints; and Technical Amendments
- <https://www.federalregister.gov/documents/2016/05/27/2016-11865/food-labeling-serving-sizes-of-foods-that-can-reasonably-be-consumed-at-one-eating-occasion>
- FSIS Proposed (1/19/2017): Revision of the Nutrition Facts Labels for Meat and Poultry Products and Updating Certain Reference Amounts Customarily Consumed
- https://www.regulations.gov/document?D=FSIS_FRDOC_0001-0515

Nutrition Facts	
8 servings per container	
Serving size 2/3 cup (55g)	
<hr/>	
Amount per serving	
Calories	230
<hr/>	
	% Daily Value*
Total Fat 8g	10%
Saturated Fat 1g	5%
Trans Fat 0g	
Cholesterol 0mg	0%
Sodium 160mg	7%
Total Carbohydrate 37g	13%
Dietary Fiber 4g	14%
Total Sugars 12g	
Includes 10g Added Sugars	20%
Protein 3g	
<hr/>	
Vitamin D 2mcg	10%
Calcium 260mg	20%
Iron 8mg	45%
Potassium 235mg	6%
<hr/>	
* The % Daily Value (DV) tells you how much a nutrient in a serving of food contributes to a daily diet. 2,000 calories a day is used for general nutrition advice.	

Food Safety and Inspection Service: Questions? Contact LPDS

