USDA United States Department of Agriculture


Food Safety and Inspection Service

Protecting Public Health and Preventing Foodborne Illness


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Food Safety and Inspection Service: FSIS Labeling and Policy Update

- FSIS policy guidelines update
- Nutrition labeling update
- Claim Verification Activities
- FSIS Regulatory Initiatives

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Food Safety and Inspection Service: Animal-Raising Claims

- FSIS has evaluated animal-raising claims on meat and poultry product labels for over 25 years
- The Agency approves these claims if the animal raising information submitted with the label application supports the claim being made and the claim is truthful and not misleading
- Over the last 10 years, there has been a significant rise in the number of establishments using these claims in marketing their products

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Food Safety and Inspection Service: Label Approval

- Under the FMIA/PPIA, FSIS must approve the labels of meat and poultry products before the products can enter commerce
- Generically approved labels do not need to be submitted to the Labeling and Program Delivery Staff (LPDS) for approval before they enter commerce (9 CFR 412.2(a)(1))
- However, a label with a special statement or claim, including animal-raising claims, ***must be submitted to LPDS for prior approval*** (9 CFR 412.1(c)(3) and (e))

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Food Safety and Inspection Service: Animal-raising claims

Examples of animal-raising claims include, but are not limited to:

- Diet – "100% Grass Fed," "Vegetarian Fed"
- Animal Welfare and Environmental Stewardship – "Humanely Raised," "Sustainably Sourced," "Raised with Care"
- Breed – "Angus," "Wagyu," "Heritage Breed"
- Living/Raising/Raising Conditions – "Free Range," "Cage or Crate Free," "Pasture Grown"

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Food Safety and Inspection Service: Examples of Claims (continued)

- Negative Antibiotic Use – "Raised without antibiotics," "No antibiotics ever," "No sub-therapeutic antibiotics"
- Negative Hormone Use – "No hormones administered"
- Third-Party Certification - AMS Process Verified Program, "Animal Welfare Approved," "Best Aquaculture Practices"
- Organic – AMS National Organic Program

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Food Safety and Inspection Service:
Example of Meat Label with Multiple Animal-Raising Claims

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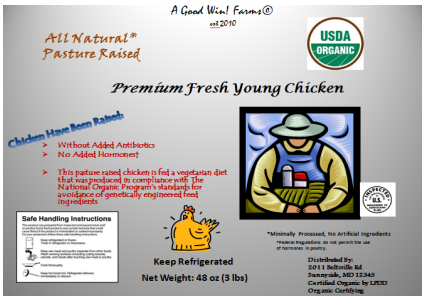
Food Safety and Inspection Service:
Example of Poultry Label with Multiple Animal Raising Claims



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Food Safety and Inspection Service:
Supporting Documentation

For most animal-raising claims, the documentation typically needed to support these claims is:

1. A detailed written description explaining the controls used for ensuring that the raising claim is valid from birth to harvest or the period of raising being referenced by the claim;

2. A signed and dated document describing how the animal are raised which may include feed formulations, to support that the specific claim made is truthful and not misleading;

3. A written description of the product tracing and segregation mechanism from time of slaughter or further processing through packaging and wholesale or retail distribution;

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Food Safety and Inspection Service:
Supporting Documentation

4. A written description for the identification, control, and segregation of non-conforming animals/product; and

5. If a third-party certifies a claim, a current copy of the certificate from the certifying organization.

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Food Safety and Inspection Service:
Labeling Guideline on Documentation Needed to Substantiate Animal Raising Claims for Label Submission

- On October 5, 2016, FSIS announced the availability of and requested comments on its ***Labeling Guideline on Documentation Needed to Substantiate Animal Raising Claims for Label Submission***
- FSIS published the guideline to assist establishments in preparing their label approval application and to facilitate LPDS's review of these labels
- We received over 4,600 comments
- Separately, we received three related petitions from animal welfare organizations
- FSIS published a Federal Register Notice and the guideline in final form on December 27, 2019
  https://www.federalregister.gov/documents/2019/12/27/2019-27845/food-safety-and-inspection-service-labeling-guideline-on-documentation-needed-to-substantiate-animal

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Food Safety and Inspection Service:
Points of Clarification on Guideline

- The guideline does not promulgate new requirements that are subject to the notice-and-comments under the Administrative Procedures Act (APA)
- FSIS does not have the authority to regulate animal raising practices; animal-raising claims are voluntary marketing claims
- Animal raising practices vary and are continuously developing; codifying claims could inappropriately restrict development
- FSIS believes its comprehensive, case-by-case label approval process is sufficient to prevent misbranded product from entering commerce

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Food Safety and Inspection Service: Points of Clarification on Guideline

- Raised Without Hormones (No Hormones Administered or No Steroids Administered): Updated information to clarify that a qualifying statement is no longer required on pork products labeled as having been raised without hormones because Federal law permits the use of certain hormones in swine, e.g., for gestation
- "100% grass-fed" claims are not permitted for animals raised on feedlots; animals can only be fed grass or forage, with the exception of milk consumed before weaning. When less than 100% percent access to grass/forage, claim must accurately reflect circumstances, e.g., "Made from cows fed 85% grass and 15% corn
- FSIS has updated the guideline to clarify why qualifying information is necessary on certain products and to emphasize that this information must be prominently- and conspicuously-displayed on the label for FSIS to approve the claim

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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")
- However, 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 reconsidered its position and now accepts the use of the terms "genetically modified organism" or "GMO" as outlined in the guideline
- 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

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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 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*"

https://www.fsis.usda.gov/wps/wcm/connect/547972e6-cd56-4f0a-a5d5-d066ac12651b/labeling-guideline-bioengineered.pdf?MOD=AJPERES

FSIS sought comments on this guidance as part of its efforts to continuously assess and improve the effectiveness of policy documents. Final guidance document published on December 30, 2019

https://www.regulations.gov/document?D=FSIS-2018-0048-0001

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Food Safety and Inspection Service: Points of Clarification on Guideline

- FSIS does not limit claims to those consistent with AMS's definition of bioengineering, in Pub. L. 114-216. Claims may reflect different standards depending on the certifying entity's standards for the claim
- The label must also bear a website address where consumers can obtain additional information regarding the claim and the third-party organization's certification process. With this approach, the labeling includes the information consumers need if unaware of the specific standards on which the negative claim is based
- Certified organic products may be labeled with negative claims without additional third-party certification or documentation when the negative claim is connected with an asterisk or other symbol to the explanatory statement "Produced in compliance with the USDA Organic Regulations"

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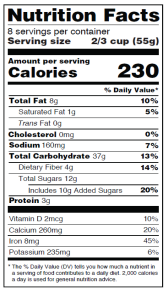
Food Safety and Inspection Service: Nutrition Labeling

- Until a final rule for FSIS is published, FSIS amenable meat and poultry product labels may continue to use the current/original nutrition regulations in 9 CFR
- In the interim, FSIS amenable meat and poultry product labels 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
- 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



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Food Safety and Inspection Service: Other FSIS Regulatory Initiatives

- Proposed Rule Stage-Prior Label Approval System: Expansion of Generic Label Approval 0583-AD78
- Final Rule Stage-Egg Products Inspection Regulations 0583-AC58
- Final Rule Stage-Elimination of Dual Weight Labeling Requirements for Certain Meat and Poultry Products 0583-AD71

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Food Safety and Inspection Service:
New Labeling Focus on Claims Verification

- December 2010 Final Rule, "Nutrition Labeling of Single-Ingredient Products and Ground or Chopped Meat and Poultry Products" (75 FR 82148) (Effective March 2012)
  - FSIS to collect samples of raw ground beef products for nutrient analysis in order to verify compliance with nutrition labeling requirements
  - **Project goal:** Surveillance sampling to identify if certain nutrient content information on labels is accurate or if further testing and enforcement by FSIS is warranted
- Criteria for sample selection:
  - Must be in consumer ready packaging with nutrition facts panel

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Food Safety and Inspection Service:
New Labeling Focus on Claims Verification

- On-going concern about the truthfulness of labeling information, e.g., evidence of significant variation from the stated value of nutrient content associated with fat in raw ground beef
- Expanded the raw ground beef surveillance sampling program to double the number of samples analyzed in the laboratory
- FSIS has observed through its label approval system an increase in the number of applications for labels bearing negative claims highlighting the absence of various substances from or products, e.g., "no soy added"

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Food Safety and Inspection Service:
New Labeling Focus on Claims Verification

- In FY2018, FSIS expanded its exploratory sampling program to include verification of labeling claims for:
  - 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
- Sampling programs continued in FY2019, will continue into FY2020
  https://www.fsis.usda.gov/wps/wcm/connect/0e1fc664-4fd3-4c10-8d10-a0472e90292d/26-19.pdf?MOD=AJPERES&CONVERT_TO=url&CACHEID=0e1fc664-4fd3-4c10-8d10-a0472e90292d
- **Purpose of the sampling:** To verify industry's compliance with the Agency's labeling regulations and policies to ensure such claims are truthful and not misleading and to protect consumers from misbranded and economically adulterated meat and poultry products

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Food Safety and Inspection Service:
Questions?

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