Food Safety and Inspection Service
U.S. DEPARTMENT OF AGRICULTURE

USDA Labeling, Inspection, and Ingredient Approval Requirements

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Deputy Director, LPDS
March 28, 2021

About FSIS:

Our Mission

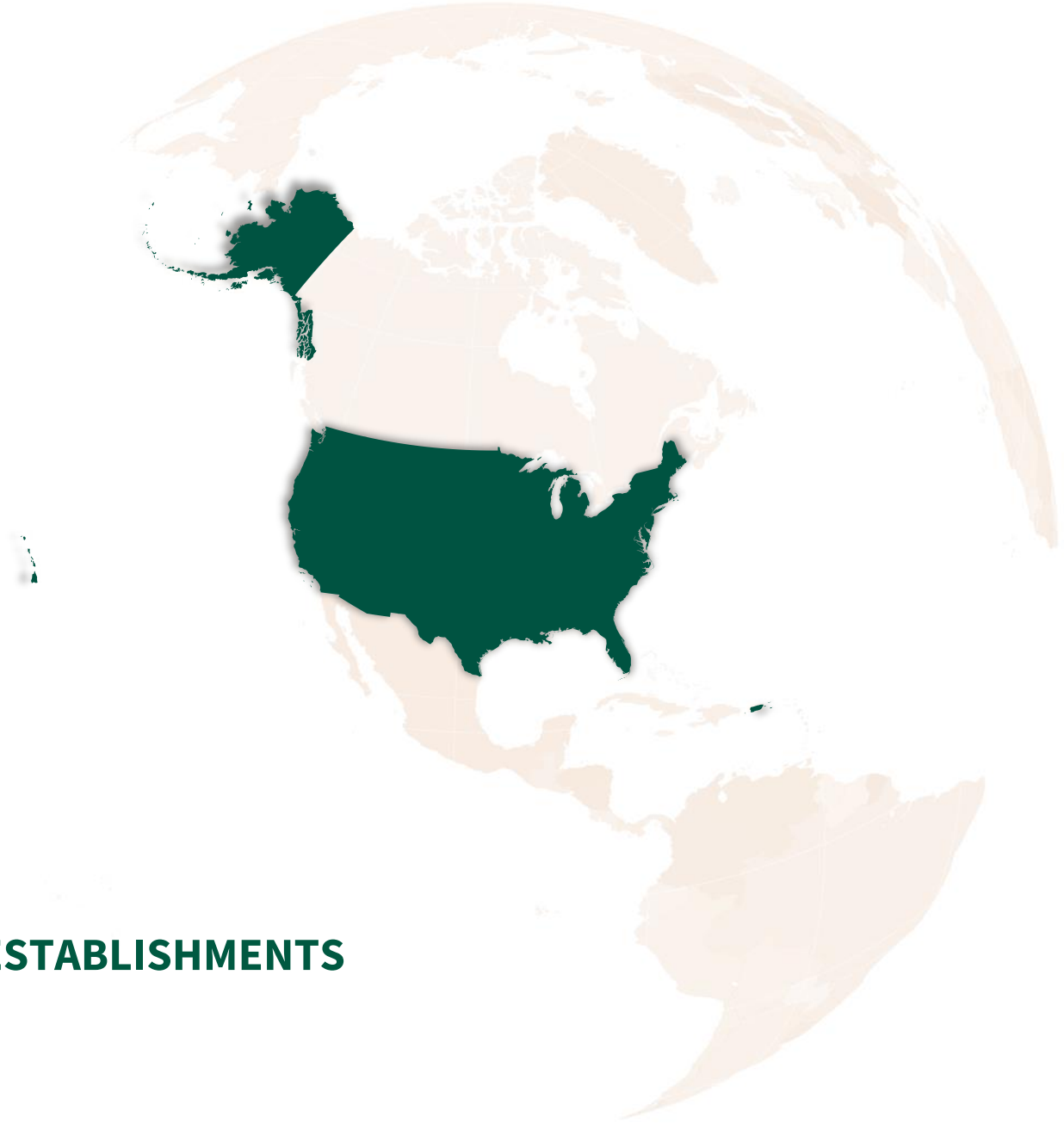
The Food Safety and Inspection Service is responsible for ensuring that meat, poultry and egg products are safe and that they are properly labeled and packaged.

Our Presence

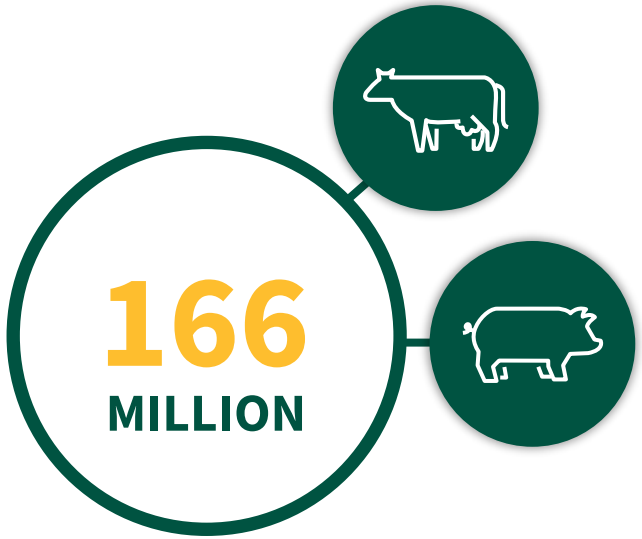
8,700
FSIS EMPLOYEES

7,800
FRONT LINE WORKFORCE

6,500
FEDERALLY REGULATED ESTABLISHMENTS

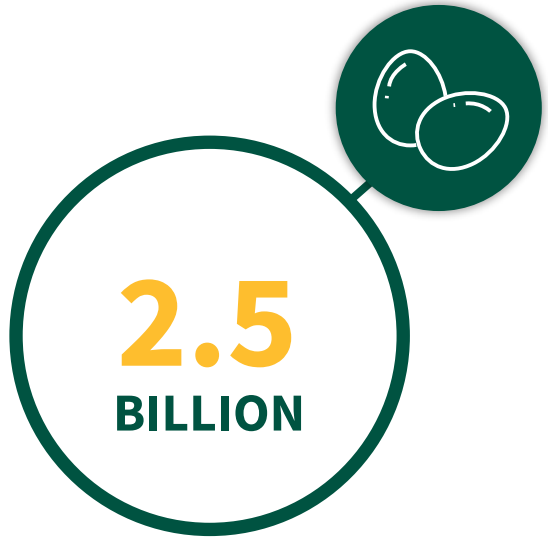


Our Inspection by the Numbers



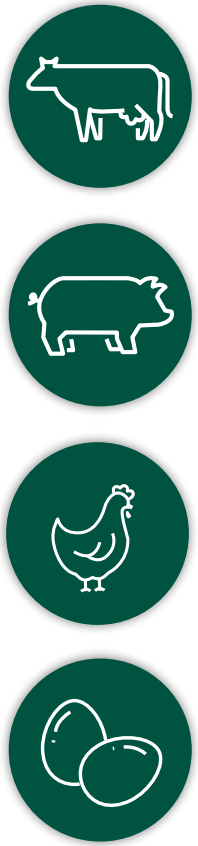
HEAD OF LIVESTOCK INSPECTED

POULTRY CARCASSES INPECTED



POUNDS OF LIQUID, FROZEN AND DRIED EGG PRODUCTS INSPECTED

Federal Acts Governing FSIS



- Federal Meat Inspection Act (FIMA), 1906
- Agricultural Marketing Act (AMA), 1946
- Poultry Products Inspection Act (PPIA), 1957
- Egg Products Inspection Act (EPIA), 1970
- Humane Methods of Livestock Slaughter Act, 1958

Outline

- Jurisdiction and FSIS inspection
- Prior label approval system
- Generic regulation update
- Special claims overview
- Joint FSIS and FDA ingredient approval process

Jurisdiction

Jurisdiction

- General “Amenability” Rule: Products subject to the Acts are formulated with at least 3% raw or 2% or more cooked meat/poultry and/or meat/poultry byproducts; more than 10% poultry fat
- Exemptions from definition of a poultry product are listed in 9 CFR 381.15, general policy found in Food Standards and Labeling Policy Book
- USDA-FSIS has jurisdiction over broad range of foods, e.g., reaction/process flavors; seasonings with meat/poultry; dinners/meals; soups; stews; sausages; cuts of meat/poultry ……

Jurisdiction

- Determinations of whether a food product is “amenable” to the FSIS jurisdiction under the FMIA, PPIA and EPIA are made by the Office of Policy and Program Development (OPPD), FSIS

- Determinations are usually made in situations involving:
  - New product development/marketing
  - Exploration by a processor/importer
  - Compliance investigations

FSIS Inspection

FSIS Inspection – Activities

- Inspection Program Personnel in official establishments
  - Continuous inspection of slaughter and process facilities
  - Animals receive ante-mortem inspection
  - Carcasses receives post-mortem inspection
  - Processed products are inspected; HACCP is mandatory

- FSIS Imports Inspection
  - FSIS plans and administers a national import reinspection program
  - After the U.S. Customs Service and USDA-APHIS requirements are met, shipments imported into the U.S. must be reinspected by FSIS at an approved import inspection facility

FSIS Inspection – In-Depth

FSIS Inspection Employees:

- Coordinate inspection and enforcement activities
- Ensure the products that FSIS regulates are safe, wholesome, and properly labeled
- Perform in-depth evaluations and analyses of establishment HACCP systems and sanitation
- Gather data to inform our understanding of the risks in the food system

FSIS Inspection – Sanitation Performance Standards

Verify Sanitation Performance Standards (SPS)

Focus on conditions that may result in adulteration of product:

- Establishment grounds & facilities
  - potable water
  - acceptable sewage system
- Sanitary operations
  - demonstrate the safety of a chemical usage
- Establishments must provide:
  - sufficient light
  - receptacles identified for inedible

FSIS Inspection – Sanitation SOPs

Written procedures must:

- Contain procedures performed daily, before and during operation.
- Identify procedures to verify sanitation of food contact surfaces, equipment, and utensils.
- Specify the procedure frequency
- Identify personnel responsible for the implementation of the procedures
- Be signed and dated

FSIS Inspection – Sanitation SOPs

Verify that establishments:

- Conduct pre-operation procedures in the Sanitation SOPs
- Conduct procedures in the frequencies specified.
- Monitor the daily implementation of the procedures
- Take appropriate corrective action when the sanitation SOPs have failed

FSIS Inspection – HACCP

Comply with Hazard Analysis & Critical Control Point (HACCP) requirements (9 CFR 417)

- Hazard Analysis, Plan, and records must be written and available to inspection personnel
- HACCP System must be validated

FSIS Inspection – HACCP

Designing the HACCP System – 9 CFR 417

The seven principles of HACCP, which encompass a systematic approach to the identification, prevention, and control of food safety hazards include:

1. Conduct a Hazard Analysis
2. Determine Critical Control Points
3. Establish Critical Limits
4. Establish Monitoring Procedures
5. Establish Corrective Actions
6. Establish Recordkeeping and Documentation Procedures
7. Establish Verification Procedures

FSIS Inspection – Investigation, Surveillance and Enforcement

Investigation, Enforcement and Audit Employees:

Conduct:
- Surveillance
- Investigations
- Enforcement activities

Respond to:
- Foodborne illness outbreaks
- Natural disasters
- Intentional contamination events

FSIS Inspection – Food labeling Under HACCP

- Plants identify and correct problems. FSIS monitors plants' documentation and verifies plants' procedures
- Official establishments must maintain records to support products and labels are in conformance with the acts and regulations (9 CFR Part 320 and 9 CFR Part 381, Subpart Q)
- Inspectors perform label verification activities to ensure that establishments apply labels that are in compliance with FSIS regulations and policies (e.g., properly declare all ingredients), and are formulated with only safe and suitable ingredients
  - FSIS Directive 7221.1- Prior Labeling Approval

Prior Label Approval

Prior Label Approval

FMIA-21 U.S.C. 607(d), PPIA 21 U.S.C 458(b), EPIA 21 U.S.C. 1036

- The Acts require food manufacturers to obtain prior approval for labels of meat and poultry products before products may be marketed

- "No article subject to this [Act] shall be sold or offered for sale …. But established trade names and other marking and labeling and containers which are not false or misleading and which are approved by the Secretary are permitted."

Prior Label Approval

Responsibility for USDA's Label Approval Process Rests with FSIS in 9 CFR 412.1, and 412.2

- USDA has established requirements for the content and design of labels [9 CFR Part 317 (meat), 9 CFR 381 Subpart N and Y (poultry), 9 CFR 590.411]
- Requirements are based on the statutory mandate to assure that labels are truthful, accurate, and not misleading, and that products are not misbranded
- Required labeling features in regulations are linked to misbranding provisions of Acts
- Policy Memos/Food Standards and Labeling Policy Book/Compliance Policy Guides = interpretations of the Acts and regulatory requirements

Prior Label Approval

- Generic labeling approval- approval of labeling or modifications to labeling prior approved by the Agency without submitting such labeling to FSIS for sketch approval. To be generically approved, all mandatory labeling features are in conformance with FSIS regulations
- Sketch approval- approval provided by LPDS when labels, other than those submitted for temporary, are submitted to LPDS for approval
- Final labels- labels applied to product prior to distribution in commerce
- Temporary approval- approval granted for up to 6 months to use labels that are not in compliance with FSIS regulations. May not misrepresent the product, create a health or safety situation, or provide an economic advantage

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

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

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: FSIS Inspectors do not generically approve labels. Establishments do not generically approve labels. FSIS approves labels through generic labeling regulations.

Prior Label Approval – Sketch

- Since 2014, only certain types of labeling require submission for evaluation by FSIS's Labeling and Program Delivery Staff (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 above four categories do not require sketch approval by LPDS

Prior Label Approval - Temporary

- 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

Prior Label Approval – Religious Exempt

- Religious-exempt product (poultry) does not receive the mark of inspection and, therefore, deviates from the general labeling requirements for meat and poultry products. 9 CFR 412.1(c)(1))

- 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)

Prior Label Approval – Export Labels with Deviations

- Exports of U.S. meat and poultry products occur under agreements between the U.S. government and foreign governments
- Includes ensuring 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

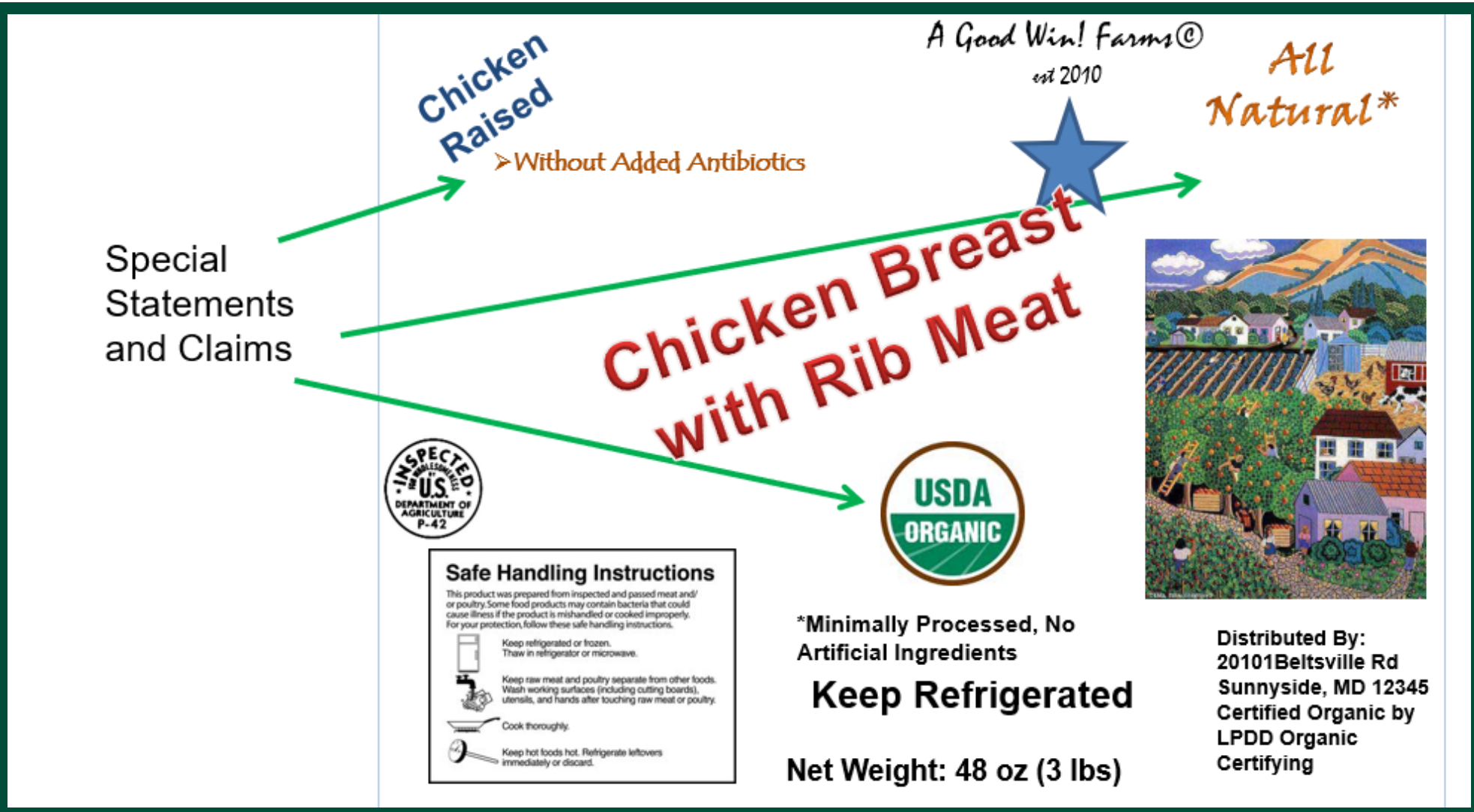
Prior Label Approval – Special Statements and Claims

- 9 CFR 412.1(e)
- A detailed list of special statements and claims requiring LPDS approval and examples of claims eligible for generic approval is available on the FSIS website
- List includes commonly used special statements and claims
- List will be periodically updated to reflect commonly asked questions regarding special statements and claims
- Last guideline update was in July 2020
- https://www.fsis.usda.gov/guidelines/2017-0011

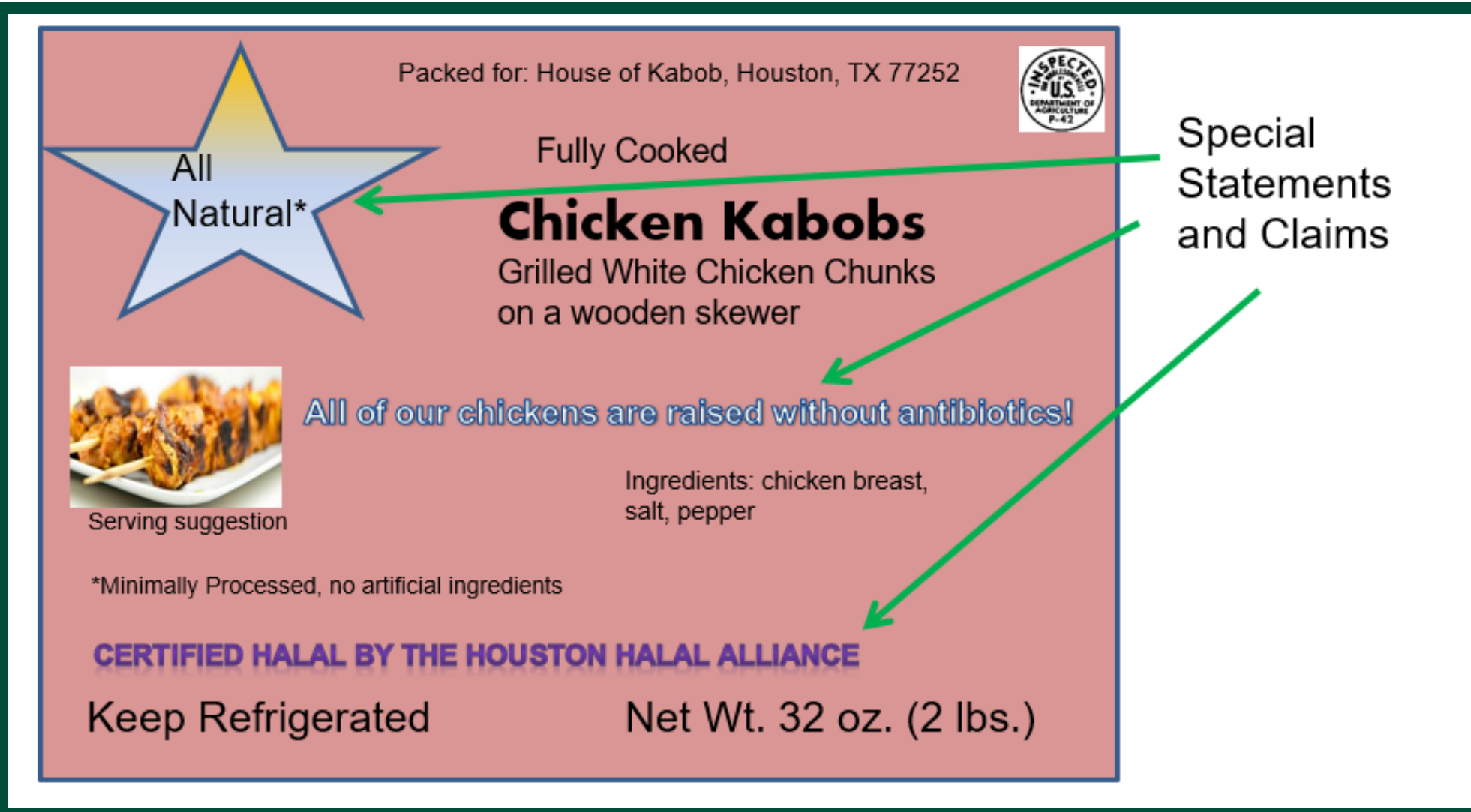
Prior Label Approval – Special Statements and Claims Examples

- 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 on-farm production/raising practices (e.g., claims regarding the raising of animals such as “no antibiotics administered,” “pasture raised,” or “vegetarian fed”)

Prior Label Approval – Special Statements and Claims Examples



Prior Label Approval – Special Statements and Claims Examples



Generic Approval

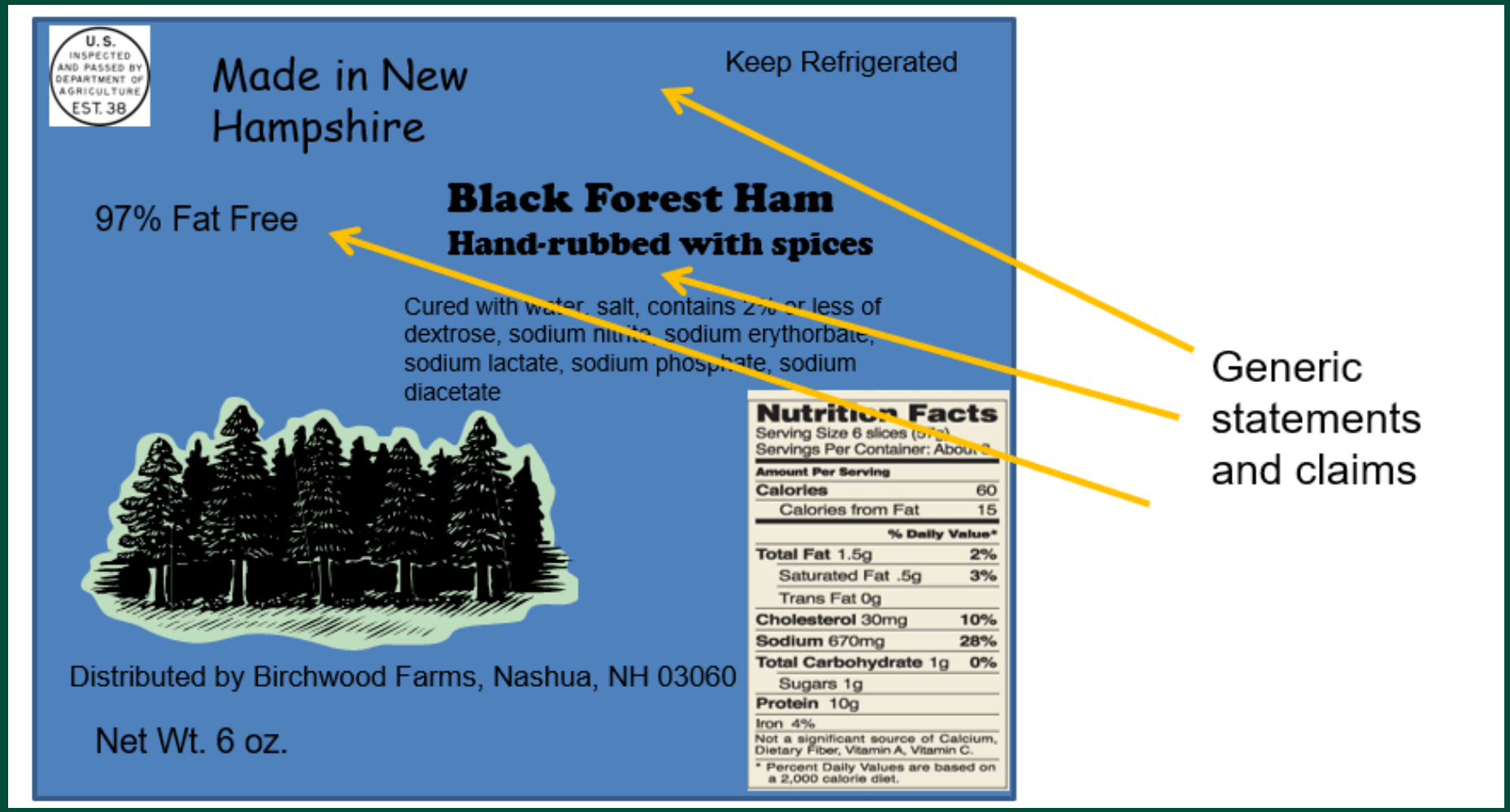
Generic Approval

- Some statements do not require submitting for approval and are approved generically under 9 CFR 412.2(b)

- Examples include:
  - Allergen or contains statements “contains: (name of ingredient)”
  - AMS Grading (USDA Prime, Choice, Select)
  - Flavor profiles (teriyaki flavored)
  - Foreign language on domestic products
  - Geographic claims (refer to 9 CFR 317.8(b)(1))

Generic Approval – Examples

Generic Approval – Examples



Generic Approval – Points of Clarification

- FSIS Inspection Program Personnel (IPP) do not generically approve labels
- IPP conduct in-plant label verification activities
  - FSIS Directive 7230.1, "Ongoing Verification of Product Formulation and Labeling Targeting the Eight Most Common ("Big 8") Food Allergens
- 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 display all applicable mandatory features in compliance with Federal regulations

Generic Approval – Labeling Records

- 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
- The final rule added the requirement establishments maintain as part of the labeling record, supporting documentation needed to show that the label is consistent with the Federal meat and poultry regulations and policies on labeling as described in 9 CFR 412.1
- Labeling record for any label generically approved must include a complete copy of the original LPDS approval (if the original required LPDS approval)

Required Labeling Features: Summary Table

Feature	Reference	Location	Applies to
Product Name	9 CFR 317.2(c)(1) or 381.117	Principal display panel	All products
Inspection Legend	9 CFR 317.2(c)(5) or 381.123	Principal display panel	All products
Handling Statement (e.g. "Keep Frozen")	9 CFR 317.2(k) or 381.125(a)	Principal display panel	Products requiring special handling to maintain wholesomeness
Net Weight Statement	9 CFR 317.2(h) or 381.121	Principal display panel	Product sold at retail, unless the net weight is applied at retail
Ingredients Statement	9 CFR 317.2(f) or 381.118	Information panel or Principal display panel	Products with multiple ingredients
Address Line	9 CFR 317.2(g) or 381.112	Information panel or Principal display panel	All products
Nutrition Facts Panel	by 9 CFR 317.300 or 381.400	Information panel or Principal display panel	Products not exempted by 9 CFR 317.400 or 381.500
Safe Handling Instructions	9 CFR 317.2(l) or 381.125(b)	Any panel	Products with a not-ready-to-eat meat or poultry component

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

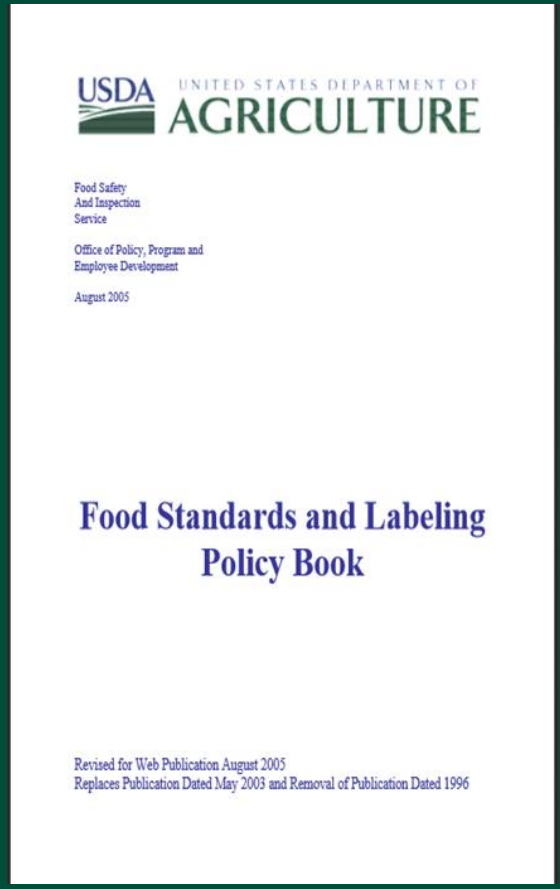
- FSIS recommends control measures in establishments HACCP system to prevent the potential of undeclared allergens based on three basic principles:
  - Identify: Cross-referencing labels and product formulations with incoming ingredients; separation of allergenic materials in designated areas
  - Prevent 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

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 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 existing items in the book, as necessary, but it will no longer add new material to it
- The Agency will convey new labeling policy by other means, such as compliance guidelines
- https://www.fsis.usda.gov/guidelines/2005-0003



Special Claims Overview

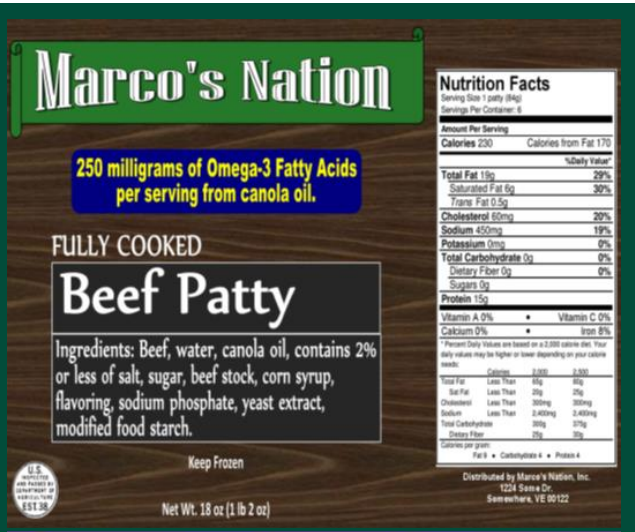
Labeling Guidance

- FSIS typically announces the availability of and requests comments on labeling guidance in the Federal Register
- FSIS consults with the Food and Drug Administration (FDA), Agriculture Marketing Service (AMS), Center for Nutrition Policy and Promotion (CNPP) and other government agencies as needed when developing guidance
- Consistency with food labeling policies across all food categories is an important consideration

Labeling Guidance – Examples

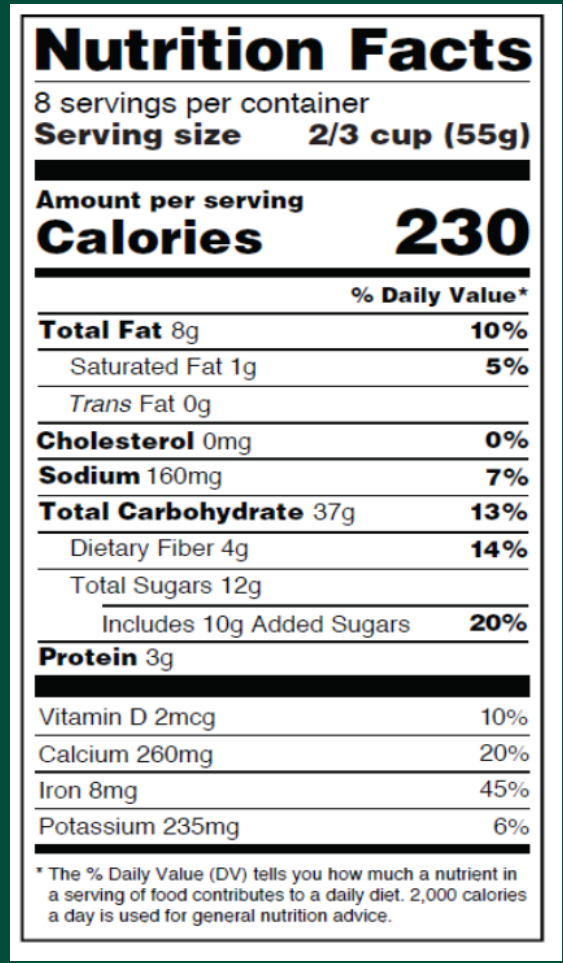
- Omega 3 Fatty Acids
  - "X mg Omega 3 Fatty Acids per serving" from meat or poultry fed special diets
  - If a particular ingredient is being added, source must be identified, e.g., "X mg Omega 3 Fatty Acids from Fish Oil in Breading"

- Draft kit guidance published in 2019



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.federalregister.gov/documents/2016/11/16/2016-27506/nutrition-facts-label-compliance



Nutrition Facts

8 servings per container

Serving size **2/3 cup (55g)**

Amount per serving

Calories **230**

	% 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	
Vitamin D 2mcg	10%
Calcium 260mg	20%
Iron 8mg	45%
Potassium 235mg	6%

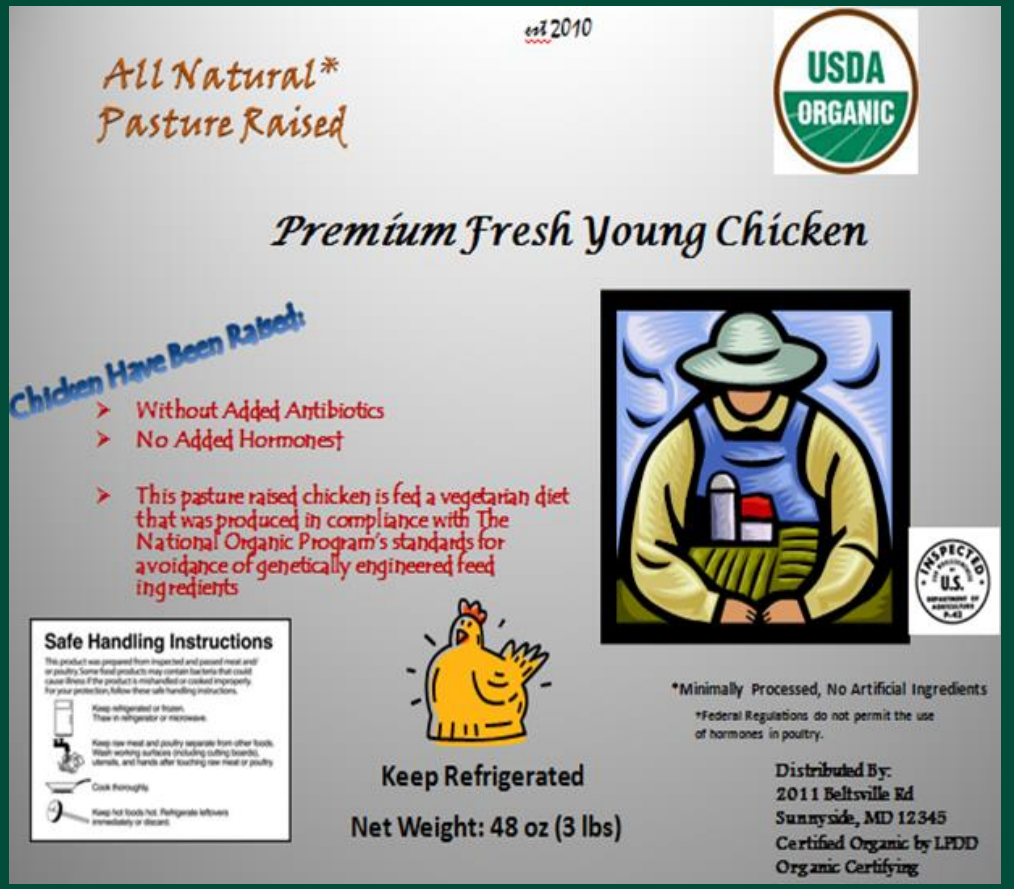
* The % Daily Value (DV) tells you how much a nutrient in a serving of food contributes to a daily diet. 2,000 calories a day is used for general nutrition advice.

Animal Raising Claims

- For over 25 years FSIS has evaluated animal raising claims by considering information on animal raising practices submitted by companies as part of their label approval requests
- The Agency will approve these claims if the animal raising information submitted with the label application supported the claim being made and the claim is truthful and not misleading, and if the claim (including any qualifying information) is prominently and conspicuously displayed on the label
- Because FSIS jurisdiction starts at the establishment, FSIS uses written supporting documentation to substantiate the claims. Supporting documentation includes but is not limited to assessing protocols and controls, affidavits, and feed formulations

Animal Raising Claims

- 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.fsis.usda.gov/guidelines/2019-0009



Examples of Raising Claims

- Breeds Beef (Angus, Piedmontese, Wagyu), Poultry (Silkie, Plymouth Rock) Pork (Berkshire, Duroc)
- Raised Without Antibiotics
- AMS Process Verified Program – 3rd Party Certification
- Living/Raising/Raising Conditions (These claims refer to environment in which the animals were raised during their lifespan

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")

- 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

- In December 2019, FSIS published an updated compliance policy guide titled, "Statements That Bioengineered or Genetically Modified (GM) Ingredients or Animal Feed Were Not Used in Meat, Poultry, or Egg Products" FSIS sought comments on this guidance as part of its efforts to continuously assess and improve the effectiveness of policy documents.

- https://www.fsis.usda.gov/guidelines/2019-0004

Non-Genetically Engineered Claims

- FSIS has approved labels that state the products meet the standards of a third-party certifier regarding the use of ingredients or animal feed that are not genetically engineered
- The National Organic Program within the Agriculture Marketing Service in USDA is one example of a third-party certifying organization
- 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

Non-Genetically Engineered Claims – Examples

Non-Genetically Engineered Claims - Examples

Joint FDA and FSIS Ingredient Approval Process

Joint FDA and FSIS Ingredient Approval Process

- Final rule published on December 23, 1999, "Food Ingredients and Sources of Radiation Listed or Approved for Use in the Production of Meat and Poultry Products"
- Consolidated 9 CFR 318.7 and 381.147 into new table of approved substances in 9 CFR 424.21 (c). Lists substance, general classification, permitted use levels, types of products
- MOU signed in 2000 that outlined the procedures for how FSIS and FDA will work together to implement the ingredient approval process
- For meat and poultry, FDA authorizes safety and FSIS determines suitability/efficacy of use
- All ingredients approved since 2000 are listed in FSIS Directive 7120.1
- Risk Management and Innovations Staff (RMIS) evaluates ingredients for FSIS, updates directive, and coordinates efforts with FDA
- https://www.fsis.usda.gov/guidelines/2013-0016

Suitability in Meat and Poultry Products

- Substance must be approved, “listed,” or otherwise “no objection” by FDA
- Proposed use must have a specific, technical purpose in the product/product category
- Use must be limited to specific amounts or ranges, lowest level for intended effect
- Use must not promote deception or mask spoilage indicators
- Must be properly declared on the label unless determined to be a processing aid or incidental additive (21 CFR 101.100 (a)(3))
- FSIS has the authority to make an independent evaluation of an additive with respect to use in meat, poultry, or egg products and restricts its use

Food Additive Petitions Under MOU

- Petitioner must demonstrate to FDA that additive is safe for intended use
- Proposed use in meat and poultry products, if desired, should be identified as part of the petition
- FDA consults with FSIS as appropriate
- FDA publishes petition for comments
- FDA publishes final rule amending its regulations to approve the substance as food additive

GRAS Notifications

- If the use includes meat/poultry products, FDA will consult with FSIS
- FDA's response (e.g., a notice on their website) will include the requirements under the FMIA or PPIA
- FDA may issue a statement addressing the GRAS status
- Examples include:
  - Cultured sugar (derived from corn, cane, or beets) at up to 4.8% of product formula in ready to eat meat and poultry products (GRAS Notice No. 000240)
  - Lauramide arginine ethyl ester (LAE) at up to 200 ppm on ready to eat meat and poultry products (GRAS Notice No. 000164)
  - Carrot Fiber at up to 3.5% of product formula in meat and poultry products where binders are permitted (GRAS Notice No. 000116)

Acceptability Determinations

- Process used by FSIS when a GRAS substance is listed or the subject of a GRAS notification but does not include a use in meat or poultry
- Requires affirmative written opinion from FDA regarding safety of use under conditions proposed by company and decision regarding suitability by FSIS
- Examples include:
  - up to 5% citric acid solution applied to beef trimmings prior to grinding
  - Anhydrous ammonia used to treat finely textured beef
  - Up to 0.5% carrageenan as a thickener in poultry franks
  - Citric and Hydrochloric acid solution as pH control agent in poultry processing water

FDA and FSIS Regulatory Distinctions

- FSIS does not accept self determinations of GRAS
- FSIS must be able to find product not adulterated before it will apply mark of inspection to enter commerce, all ingredients must be determined to be safe and suitable prior to use in Federal establishment

Reasons for FSIS Rulemaking on Ingredients

- Standard of identity limits or restricts the use
- Italian Sausage: Standard in 9 CFR 319.145 specific to the types of optional ingredients that may be used

- Use is not expected (e.g., milk in hamburger)

- A prohibition in FSIS regulations (9 CFR 424.23) that prevents use or where use would result in adulterated or misbranded product. FSIS can conduct rulemaking to permit specific use based on new scientific data to support safety and suitability

- Food Safety and Inspection Service (FSIS) amended the Federal meat and poultry products inspection regulations to remove sodium benzoate, sodium propionate, and benzoic acid from the list of substances that the regulations prohibit for use in meat or poultry

- https://www.govinfo.gov/content/pkg/FR-2013-03-07/html/2013-05341.htm

Processing Aids and Incidental Additives

- FSIS has policy guidance on processing aids and incidental additives. Follows FDA's definition in 21 CFR 101.100(a)(3) https://www.fsis.usda.gov/guidelines/2008-0003

- 21 CFR 101.100 (a)(3)(ii)) defines as:
  - (a) Substances that are added to a food during the processing of such food but are removed in some manner from the food before it is packaged in its finished form (e.g., substances used for the clarification of beverages that are later removed by filtering)

  - (b) Substances that are added to a food during processing, are converted into constituents normally present in the food, and do not significantly increase the amount of the constituents naturally found in the food (e.g., applying lactic acid to beef carcasses)

  - (c) Substances that are added to a food for their technical or functional effect in the processing but are present in the finished food at insignificant levels and do not have any technical or functional effect in that food (e.g., many antimicrobial agents such as acidified sodium chlorite, chlorine dioxide, peroxyacids that have been shown to only have a momentary effect)

Processing Aids and Incidental Additives

- Establishment's responsibility to provide data to FSIS for case-by case determination:
  - Document the amount that is in the finished meat/poultry product
  - Show that the ingredient does not have a lasting affect on the meat or poultry product (e.g., antimicrobial agent does not suppress the growth of microorganisms)
  - No "self-determinations" by industry for processing aids in FSIS regulated products

Processing Aids and Incidental Additives

- Some substances have longstanding acceptance by FSIS as incidental additives (e.g., red color used to tint cure mixes and anticaking agents in purchased seasoning mixes)
- Use of a new processing aid or incidental additive has never prohibited use of generically approved labeling
- Establishments may use askFSIS as a mechanism to confirm whether or not a substance meets the definition of a processing aid or incidental additive

USDA Food Safety and Inspection Service
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AskFSIS

- https://www.fsis.usda.gov/wps/portal/fsis/topics/regulatory-compliance/svsp/askfsis-form

*Questions are triaged, and assigned to the correct expert based on subject matter.

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