U.S. Department of Agriculture

FOOD AND DRUG LAW INSTITUTE: INTRODUCTION TO FOOD LAW

BRIAN P. SYLVESTER | MARCH 19, 2024

Agenda

- USDA - Food Safety and Inspection Service (FSIS) Jurisdiction
- FSIS Labeling Oversight
- Special Statements and Claims
- Joint FSIS and FDA Ingredient Approval
- Food Tech: Cell Cultured Meat
- USDA National Bioengineered Food Disclosure Standard
- USDA’s Supplemental Nutrition Assistance Program (SNAP)

Overview: US Federal Food Regulation

- Federal Food, Drug, and Cosmetic Act
- Public Health Services Act

- Federal Meat Inspection Act
- Poultry Products Inspection Act
- Egg Products Inspection Act

- Federal Trade Commission Act
- Fair Packaging and Labeling Act

FSIS Jurisdiction

FDA v. USDA

- USDA covers all products containing meat or poultry, except products containing:
  - 3 percent or less raw meat or poultry, or
  - 2 percent or less cooked meat or poultry

USDA Federal Statutes

- **Federal Meat Inspection Act**
- **Poultry Products Inspection Act**
- **Egg Products Inspection Act**

FSIS Inspection and Compliance

- 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 re-inspected; HACCP is mandatory
- Compliance and Investigations Division
  - Investigates violations of the food safety, food defense, and other consumer protection statutory requirements
  - Protects against unsafe or violative products through detentions, civil seizures, and voluntary recalls according to USDA laws, regulations and directives

Import Inspection Division

- 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 inspectors carry out reinspection in approximately 125 official import establishments. *See FSIS Directive 9900.2, Rev. 2 ("Import Reinspection of Meat, Poultry and Egg Products")*

USDA Inspection Exemptions

Livestock slaughtered for personal use

Livestock custom slaughtered or prepared

Retail stores

Restaurants

Restaurant central kitchens

Caterers

FSIS Labeling Oversight

Food Labeling Compliance

- Unlawful to introduce uninspected, misbranded, adulterated meat/poultry products into commerce
- Official establishments must maintain records to document compliance
- Inspectors perform label verification activities

USDA Penalties for Misbranding

- Withholding or rescinding use of labeling
- Product retention
- Product detention
- Request for product recall, press releases, and/or fines;
- Criminal prosecution
- Inspection suspension or withdrawal

Mandatory Labeling Requirements

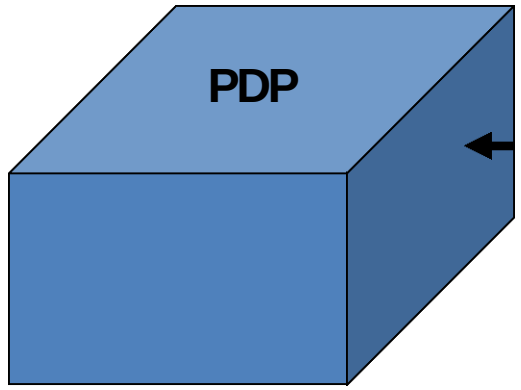
- Label: A display of written, printed, or graphic matter upon the immediate container of any article
(FD&C Act 201(k), FMIA 601(o), PMIA 453(s))
- Labeling: All labels and other written, printed or graphic matter upon any article or any of its containers or wrappers or accompanying such article (FD&C Act 201(m), FMIA 601(p), PMIA 453(s)))
- Point of Sale Materials: Labeling regulations extend to point-of-purchase materials, including promotional brochures and shelf-talkers, but USDA does not require pre-approval of such materials.
- Advertising: materials that do not accompany the article are advertising not labeling

USDA Required Labeling - 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 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)	Information panel or Principal display panel	Products with a not-ready-to-eat meat or poultry component

Principal Display Panel (PDP) and Information Panel (IP)

- PDP is the part of the label most likely to be
  - displayed, presented...when offered for sale
  - under customary conditions
- IP is any portion of a label not on the PDP that is
  - displaying certain mandatory features



- Information Panel

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PDP | Required Labeling Elements

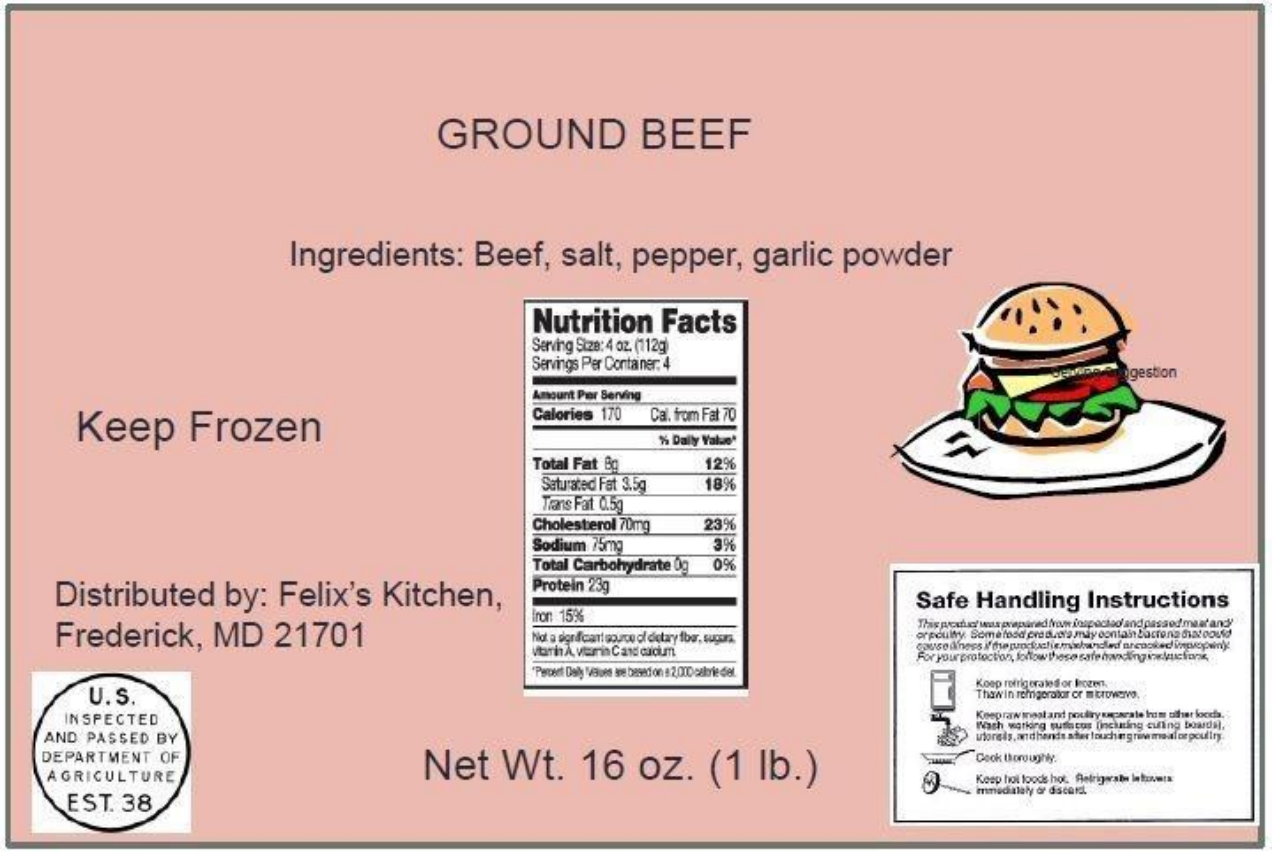
- Four features are required on the principal display panel (PDP):
  - **Product name**
    - 9 CFR 317.2(e)/381.117(a)
  - **Handling Statement**, if product is perishable
    - 9 CFR 317.2(k)/381.125(a)
  - **Inspection Legend/Est, number**
    - 9 CFR 312.2(b)/381.96 &381.123(b)(2)
  - **Net weight for product sold at retail (except variable net weight products)**
    - 9 CFR 317.2(h)/381.121

Required Labeling Features

- The remaining four features may be located on the PDP or on the information panel:
  - **Name and place of business** of the manufacturer, packer or distributor
    - 9 CFR 317.2(g)(2)/381.122
  - **Ingredients statement** displaying all ingredients in descending order of predominance
    - 9 CFR 317.2(c)(2)/381.118
  - **Nutrition labeling** (unless an exemption applies)
    - 9 CFR 317.300-400/381.400-500
  - **Safe Handling Instructions** if the product is not ready-to-eat (may be located on any panel)
    - 9 CFR 317.2(l)/381.125(b)

Mandatory Labeling Elements (CONT'D)

- All label information must be conspicuous and prominent



Source: FSIS

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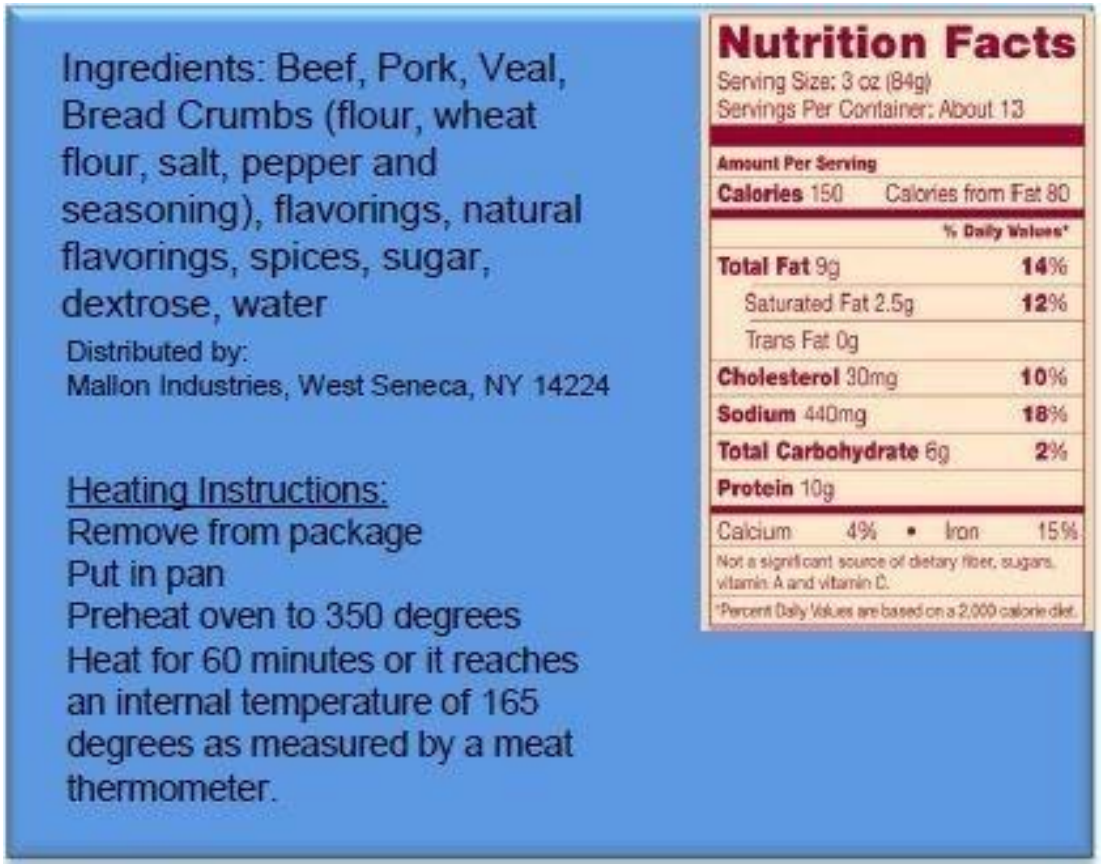
Sample Label

PDP

IP



Source: FSIS

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Product Identity Statement - PDP

- Standard of Identity (SOI)
  - Requires use of specified ingredients, sometimes quantities; optional ingredients may be permitted
  - If product meets SOI, must bear that name; if product does not meet SOI, may not use that name
  - If product is similar to standardized food, may use “substitute” but if similar product is nutritionally inferior must use “imitation”

Product Identity Statement - PDP

- Common or Usual Name/Appropriately Descriptive Term
  - Name must accurately identify or describe basic nature of the food, including characterizing ingredient or flavor
  - FDA and USDA may establish common or usual names by regulation
  - May be different names (e.g., lima (butter) beans); Use more widely known name, may add regional name in parentheses
  - If food is marketed in various forms (e.g., sliced), form must be part of name unless depicted in vignette or seen through container
  - USDA – processing methods must be included (e.g., salted, smoked, dried) unless nature of processing is clear from product name or manner of packaging

Inspection Legend & Est. Number

- Inspection legend and establishment or plant number required on PDP
- Proves product inspected and passed
- Specific dimensions and placement for the inspection legend
  - 9 CFR 312.2 for meat
  - 9 CFR 381.96 for poultry

Handling Statement

- If special handling needed to maintain wholesome condition must use handling statement-
  - “Keep Refrigerated”
  - “Keep Frozen” or
  - “Perishable-Keep Refrigerated or Frozen”
- 9 CFR 317.2(k) and 381.125(a)

Safe Handling Instructions

- Required if the meat or poultry component is raw or partially cooked (not RTE) and the product is for household consumers or institutional use
- Should not be used on RTE products

Nutrition Facts Requirements

- On January 19, 2017, FSIS published a proposed rule to revise its nutrition labeling requirements for meat and poultry products to reflect current scientific research and dietary recommendations. 82 FR 6732.
- The changes seek to parallel the FDA's recently revised nutrition labeling requirements.
- 60 day public comment period – comments were due by March 20, 2017.
- FSIS is actively working on finalizing the rule.

FSIS Label Approval

- FMIA and PPIA require food manufacturers to obtain **prior approval** for labels of meat and poultry products before products may be marketed.
- **Prior approval** is granted in 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

Sketch Approval

- Meat and poultry plants submit labels for **sketch approval** to FSIS' Labeling and Program Delivery Staff (LPDS).
- LPDS only evaluates certain categories of **sketch labels** (9 CFR 412.1 (c)):
  - Labels for religious exempt products - 9 CFR 412.1 (c)(1);
  - Labels for temporary approval - 9 CFR 412.1 (c)(4); and
  - Labels with **special statements and claims** - 9 CFR 412.1 (c)(3).

Special Statements and Claims

Key USDA Resource

FSIS Guideline for Label Approval

March 2024

FSIS-GD-2024-0001

This guideline is designed to help establishments determine whether their labels must be submitted to FSIS' Labeling and Program Delivery Staff (LPDS) for approval.

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Examples of Special Statements and Claims

- 3rd party raising claims or programs (i.e. Global Animal partnership, AMS Process verified or certified programs, American Heart Association (AHA) claims)
- Claims regarding meat and poultry production practices (i.e. claims regarding the raising of animals such as “no antibiotics administered” or “vegetarian fed”)
- Implied Nutrition Claims (i.e., Heart Smart, Baked Not Fried, Made without Butter)

Examples of Special Statements and Claims

- “Whole Grain”, “Made with Whole Grains”, “Made with whole wheat” claims

- Claims that are undefined in FSIS regulations or the Food Standards and Labeling Policy Book (**Note**: Although **natural** is defined in the FSIS Policy Book, the Agency requires natural claims to be submitted for approval).

Generic Label Approval

- Labels will be generically approved if they meet the criteria listed in 9 CFR 412.2(b)
- Generic approval forgoes the need to obtain sketch approval
- Generic labeling approval requires that all mandatory labeling features are in conformance with applicable FSIS regulations
- Proposed Rule published on September 14, 2020 to expand generic eligibility and cease FSIS review of generically approved labels; Final Rule published on January 18, 2023.

Generic Approval Permitted

- All, 100%, pure
- Allergen or “Contains (name of ingredient)” statements (e.g., contains soy)
- AMS Grading (Prime, choice, grade A)
- Child Nutrition Boxes
- Flavor Profiles (e.g. made with fennel, teriyaki flavored, made with real cheese, only white meat)
- Foreign Language on domestic products

Generic Approval Permitted

- Geographic claims (refer to 9 CFR 317.8(b)(1))
- Green Claims/Environmental Claims
- Halal, Kosher (not certified)
- Hand pulled style/hand pinched style
- Handcrafted, handmade, hand slaughtered, hand crafted style

Statements and Claims: Generic Example

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Additional Notes

- Labels that do not fit into one or more of the four categories of labels requiring “sketch approval” are generically approved by their compliance with applicable regulations
- FSIS no longer reviews generically approved labels.

Timeline for FSIS Label Review

- The timeline for the label evaluation process is dependent on a variety of factors:
  - The complexity of the label (e.g., claims and special features) and the data accompanying it to support claims;
  - The accuracy and completeness of label submissions;
  - The number of labels in the queue and staff availability; and prevailing project priorities.

Recordkeeping

- FSIS in-plant personnel verify that establishments comply with labeling regulations
- Labeling record must include:
  - Final label applied to product
  - Product formulation
  - Processing procedures
  - Supporting documentation, including prior sketch approval from FSIS (if applicable)

Label Approval Q & A #1

- **Q**: If a label is approved with a negative claim such as "**gluten free**" can I modify the formula by removing an ingredient or changing the order of predominance of the ingredients?
- **A**: **Yes**, in this case, the removal of an ingredient or change in its order of predominance will not affect the claim. Further, under a 2023 FSIS final rule expanding generic approval to include negative claims, "gluten free" is generically approved under 9 CFR 412.2, and so any changes thereto are likewise generically approved.

Label Approval Q & A #2

- **Q**: If a label is approved with an **animal raising claim** (e.g., raised without antibiotics) for a chicken breast label, can the cut of chicken be changed to a thigh or back generically?
- **A**: **Yes**. The change is generically approved provided the source of the chicken is the same as documented in the previously approved label. In this case, changing the name of the cut of poultry will not affect the special statement or claim.

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 it will no longer add new material to it.
- The Agency will convey new labeling policy by other means, such as compliance policy guides.

Food Standards and Labeling Policy Book

- Available online
- 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
- Claims found in the Policy Book may be approved generically **except**: **natural claims**

Animal Raising Claims

- FSIS Labeling Guideline on Documentation Needed to Substantiate Animal Raising Claims for Label Submissions (December 2019).
- Examples of animal raising claims include: “Raised Without Antibiotics,” “Grass- Fed,” “Free-Range”, and “Humanely Raised”.

Substantiating Animal Raising Claims

- Documentation typically needed to support animal raising claims include:
  - Detailed written description explaining the controls used to ensure that the claim is valid from birth to harvest or the period of raising being referenced by the claim;
  - Signed and dated document describing how the animals are raised (e.g., vegetarian-fed, grass- fed, etc.), to support that the specific claim made is truthful and not misleading;
  - Written description of the product-tracing and segregation mechanism from time of slaughter or further processing through packaging and wholesale or retail distribution;
  - Written description for the identification, control, and segregation of non-conforming animals or products; and
  - If a third party certifies a claim, a current copy of the certificate.

Animal Welfare Claims

- Examples:
  - “Raised with Care”
  - “Humanely Raised”
  - “Sustainably Raised”
- FSIS has **not** defined any animal raising claims in regulations or policy guidelines.
- FSIS must approve **all** animal welfares claims affixed to USDA regulated food labels.
- An approvable claim must show ownership and include an explanation of the meaning of the claim for consumers
  - e.g., “XYZ Ranch Defines Raised with Care as [explain the meaning of the claim on the label]" or “XYZ Ranch Defines Sustainably Raised as [explain meaning of the claim on the label].”

Animal Welfare Claims - Substantiation

- A detailed written description explaining the meaning of the **animal welfare** claim and 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;
- A signed and dated document describing how the animals are raised to support that the claims are not false or misleading;
- A written description of the product tracing and segregation mechanism from time of slaughter or further processing through packaging and wholesale or retail distribution; and
- A written description for the identification, control, and segregation of non-conforming animals/product (e.g., how animals not raised in accordance with the specific animal welfare guidelines are segregated from animals eligible to bear the claim).

“Natural” Claims

- Challenges to “natural” claims on food products have proliferated in recent years.
- USDA does not define “natural” by regulation, but includes guidance on “natural” claims in the FSIS Labeling Policy Book.

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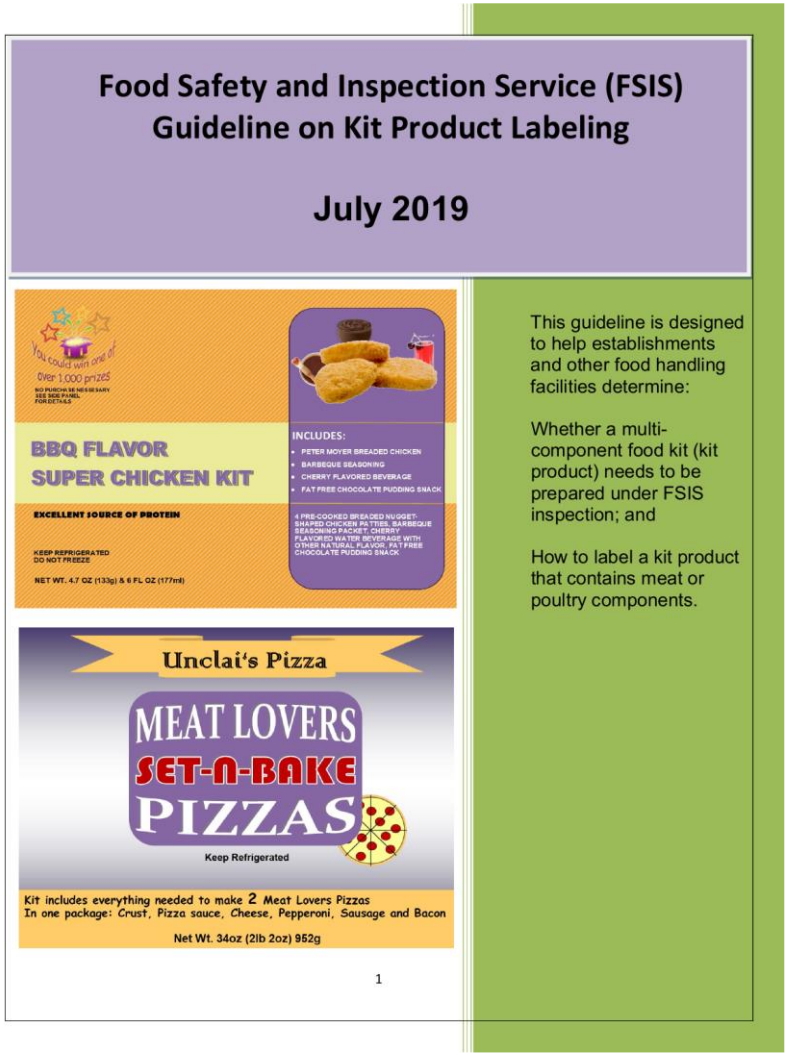
USDA Policy on “Natural” Claims

- Under current USDA Policy, the term “natural” may be used on labeling for meat products and poultry products, provided the applicant for such labeling demonstrates that:
  - (1) the product does not contain any artificial flavor or flavoring, coloring ingredient, or chemical preservative (as defined in 21 CFR 101.22), or any other artificial or synthetic ingredient; and
  - (2) the product and its ingredients are not more than minimally processed. Minimal processing may include:
    - (a) those traditional processes used to make food edible or to preserve it or to make it safe for human consumption, e.g., smoking, roasting, freezing, drying, and fermenting, or
    - (b) those physical processes which do not fundamentally alter the raw product and/or which only separate a whole, intact food into component parts, e.g., grinding meat, separating eggs into albumen and yolk, and pressing fruits to produce juices.

Multi-Component Food Kit Labeling



Food Safety and Inspection Service (FSIS)
Guideline on Kit Product Labeling

July 2019

1

This guideline is designed to help establishments and other food handling facilities determine:

Whether a multi-component food kit (kit product) needs to be prepared under FSIS inspection; and

How to label a kit product that contains meat or poultry components.

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Kit Labeling

- The Guideline only applies to “Multi-Component Food Kits”
- FSIS inspection is no longer required if the following conditions are met:
  - The meat or poultry component is prepared and separately packaged under FSIS inspection and labeled with all required features
  - The outer kit label identifies all of the individual components in the kit
  - The outer kit label clearly identifies the product as a single unit or “kit” (e.g., “Spaghetti Dinner Kit”)
- Multi-component food kit labels do not require FSIS approval.

Ingredient Approvals

USDA Ingredient Approval Requirements

- 9 CFR 424.21 (c) contains a list of approved food ingredients, permitted use levels, types of products
- For meat and poultry, FDA authorizes safety and FSIS determines suitability/efficacy of use
- FDA-USDA MOU
- All ingredients approved since 2000 are listed in FSIS Directive 7120.1

Suitability

- Substance must be approved, “listed,” or otherwise “no objection” by FDA
- Proposed use must have a specific, technical purpose in the product/product category
- Must be properly declared on the label unless determined to be a processing aid or incidental additive (21 CFR 101.100 (a)(3))

Substance Classification

- Generally Recognized As Safe (GRAS)
  - 21 CFR Part 170.30 - Criteria for eligibility, e.g., safety recognized by scientific community, scientific procedures, or history of common use in food prior to 1958 (i.e., Prior Sanction GRAS)
- Direct, Secondary Direct, and Indirect Food Additives
  - Direct- 21 CFR Part 172, e.g., Sucralose and Disodium Inosinate
  - Secondary Direct- 21 CFR Part 173, e.g., Peroxyacids, Cetylpyridinium chloride
  - Indirect- 21 CFR Part 174, e.g., Paraffin
- Food Contact Substances, e.g., FCN 1011 for use of chlorine dioxide in poultry processing water

Food Additive Petitions Under MOU

- Petitioner must demonstrate to FDA that additive is safe for its intended use
- FDA consults with FSIS as appropriate
- FDA publishes petition for comments
- FDA publishes final rule amending its regulations to approve substance as food additive

GRAS Notification and Listings

- 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
- Examples
  - 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. 240)
  - Lauramide arginine ethyl ester (LAE) at up to 200 ppm on ready to eat meat and poultry products (GRAS Notice No. 164)

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
    - 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

Reasons for 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 that prevents use (e.g., 9 CFR 424.23) 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.
- See e.g., Final Rule (78 FR 14636) amending FSIS regulations to remove sodium benzoate, sodium propionate, and benzoic acid from the list of substances that the regulations prohibited for use in meat or poultry products

Key Takeaways

- FSIS inspection
- Joint FSIS and FDA ingredient approval process
- USDA requires “prior approval” of labeling claims
- Final rule (2023) updated FSIS approach to generic label approval
- USDA has specific substantiation requirements in place for “animal raising” claims
- USDA is actively working to revise Nutrition Facts Requirements to align with FDA

Alternative Protein: Cell Cultured Meat

Status Update – FDA & USDA (As of Summer 2023)

FDA

- Launched CCC inventory regarding cultivated meat products
- Two companies have completed CCC process
- FDA issued “no questions” letters to those two companies – cultivated poultry “as safe as comparable foods produced by other methods”

FDA U.S. FOOD & DRUG ADMINISTRATION

Human Food Made with Cultured Animal Cells Inventory

USDA

- USDA approved the labeling of two company’s “cell-cultured chicken” products
- USDA issued grants of inspection to two companies

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

Cultivated Meat: Recent Scrutiny

THE WALL STREET JOURNAL.

Issues Identified:

- Expense
- Scaling Production Batches
- Contamination Concerns
- Time- and Labor-Intensive Production Processes

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Cultivated Meat: Labeling | USDA's RFI

USDA's labeling questions align with FDA's Request for Information (RFI) on labeling cultured seafood.

Key USDA Questions for Stakeholders:

- Should USDA require that product name of cell cultured products inform consumers that the product was made using animal cell culture technology? If so, what terms should be used to convey this information (e.g. "cultured" or "cell cultured")?
- How should USDA regulate the labeling of products comprised of both cell cultured meat and non-cultured meat?
- Should USDA establish regulatory standards of identity for cell cultured products? If so, should terms for slaughtered meat and poultry products established by common usage (e.g., "Pork Loin"), statute, or regulation be included in these standards of identity?
- Should USDA amend its regulatory definitions of the terms "meat," "meat byproduct," "meat food product," "poultry product," or "poultry food product" to specifically include or exclude cell cultured products?
- Are cell cultured products likely to use label claims for which USDA should develop new regulations or guidance?

USDA received 1,100+ comments from stakeholders.

Food Tech Thought Leadership

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USDA Issues New Directives as Cell-Cultured Meat Moves to Market

07.12.2023 | UPDATES

The U.S. Department of Agriculture's Food Safety and Inspection Service (USDA-FSIS) issued Directive 7800.1 on June 21, 2023, providing further insight into the agency's inspection and verification activities for the harvesting and processing of cell-cultured meat and poultry food products. With this new directive, USDA-FSIS also clarified instructions on interagency communications, label reviews, and import/export regulations for these products. FSIS also updated Directive 5730.1, specifying certain requirements for information sharing and liaison responsibilities regarding establishments regulated by USDA-FSIS and the U.S. Food and Drug Administration (FDA). In addition, FSIS issued new Notice 31-23 regarding sampling and testing for cell-cultured meat products.

USDA-FSIS's actions come on the heels of the agency's approval of labeling and issuances of federal grants of inspection to two U.S. cell-cultured chicken manufacturers in June 2023—which also both recently received FDA "no-questions" letters finding that the companies' products "are as safe as comparable foods produced by other methods." According to FDA Commissioner Robert Califf and the FDA's director of the Center for Food Safety and Applied Nutrition, federal agencies are "committed to supporting innovation in the food supply" and working collaboratively with USDA-FSIS in a joint regulatory framework.

This Update summarizes these new USDA-FSIS directives and discusses implications for cell-cultured meat more generally.

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USDA updates for cell-cultured meat and poultry

By Guest Contributor on July 24, 2023

— OPINION —

In June 2023, the U.S. Department of Agriculture Food Safety and Inspection Service (USDA-FSIS) issued new Directives and a Notice regarding the regulation of cell cultured food products derived from cell lines of USDA-amenable species. These newly-released USDA-FSIS documents — Directive 7800.1, Directive 5730.1, and Notice 31-23 — address the inspection, sampling, and responsibilities of establishments producing cell-cultured meat and poultry products also commonly referred to as cultivated meat.

With the publication of these Directives and Notice, we now have much more clarity on how USDA-FSIS plans to execute its regulatory obligations in this space, fresh off the heels of the agency's June 2023 issuance of federal grants of inspection to two U.S. cell-cultured chicken manufacturers and approval of their cell-cultured chicken labeling. USDA's actions also both follow FDA's relatively recent issuances of "no-questions" letters to both companies finding that the companies' products "are as safe as comparable foods produced by other methods." According to FDA Commissioner Robert Califf and the FDA's director of the Center for Food Safety and Applied Nutrition, federal agencies are "committed to supporting innovation in the food

FOOD DIVE

The sticky regulatory landscape of cultivated meat and what to expect next

Attorneys Brian Sylvester and Tommy Tobin outline where regulation is heading and what it means for the major players in the space.

Published Aug. 31, 2023

The slow road to retail: How consumers are dictating cultivated meat's strategy

Consumer acceptance is a major challenge facing the space, and a big reason why Upside Foods and Eat Just are only available at exclusive restaurants.

Published Oct. 16, 2023

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National Bioengineered Food

USDA's BE Labeling Rule

July 2016
Congress passes the National Bioengineered Food Disclosure Standard

- Directs USDA to establish, by two years after enactment, a national mandatory bioengineered (BE) food disclosure standard
- Requires USDA to issue regulations, but doesn't set a date for final rules

December 2018
USDA's Agricultural Marketing Service (AMS) issues a final BE disclosure rule.

December 2019
USDA AMS proposes instructions for validating a refining process to ensure no detectable BE material.

February 2020
USDA AMS proposes instructions on testing methods

July 2020
USDA AMS publishes:

- Final guidance documents and FAQs on process validation and testing methods; and
- Proposed updates to list of BE Foods (would add insect-resistant sugarcane and limit squash listing to virus-resistant summer squash).

January 1, 2022
Compliance deadline.

BE Labeling Rule: FAQs

- **Which foods are subject to the Standard?**
  - Foods subject to FDA labeling requirements.
  - Foods subject to FMIA, PPIA, or EPIA labeling requirements **if** predominant ingredient would be subject to FDCA labeling requirements or predominant ingredient is broth, stock, water or similar solution and second most predominant ingredient would be subject to l FDCA labeling requirements
- **How must BE disclosures be made?**
  - On-package text
  - USDA approved symbol for BE food
  - Electronic or digital link (e.g., QR code)
  - Text message disclosure

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USDA BE List

- The List of Bioengineered Foods appears at 7 CFR § 66.6
- Foods included on the List are presumed BE.
- AMS must consider updates to the List annually.
- On November 29, 2023, USDA-AMS published a final rule making the following changes to the List:
  - Adding “sugarcane (Bt insect-resistant varieties)”
  - Modifying existing entry for squash to read “squash (summer, coat protein-mediated virus-resistant varieties).”

Organic

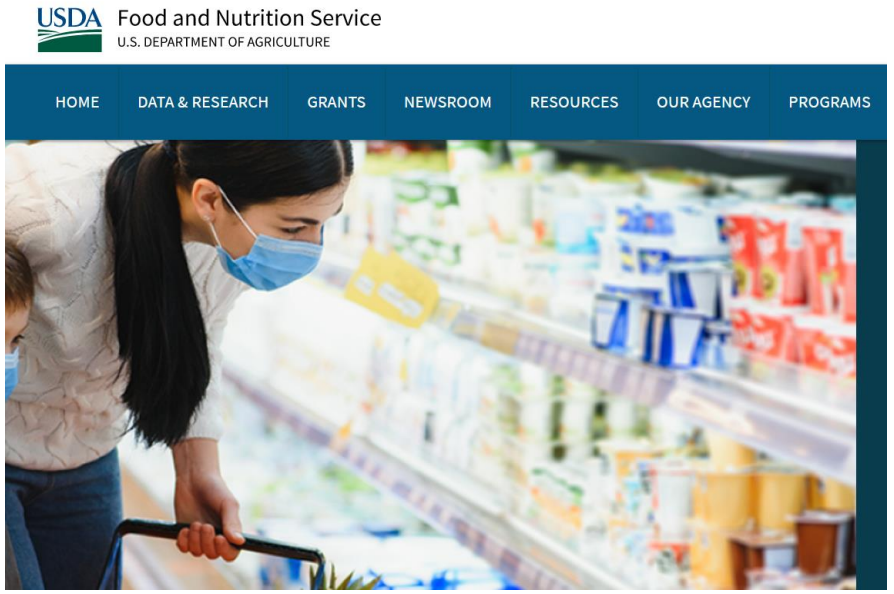
USDA National Organic Program Updates

- Strengthening Organic Enforcement Final Rule
- Makes changes to NOP regulations at 21 CFR Part 205
- Implementation Date: **TODAY**, March 19, 2024
- Key impacts (non-exhaustive). SOE final rule requires:
  - Certification of more businesses.
  - NOP Import Certificates for all organic imports.
  - Certified operations to implement new or more robust traceability, recordkeeping, and fraud prevention procedures

SNAP

What is SNAP?

- Administered by the Food and Nutrition Service (FNS)
- Provides food benefits to low-income families to supplement their grocery budget so they can afford the nutritious food essential to health and well-being.
  - To get SNAP benefits, you must apply in the state in which you currently live and meet certain requirements
  - If your state agency determines that you are eligible to receive SNAP benefits, you will receive benefits back to the date you submitted your application.



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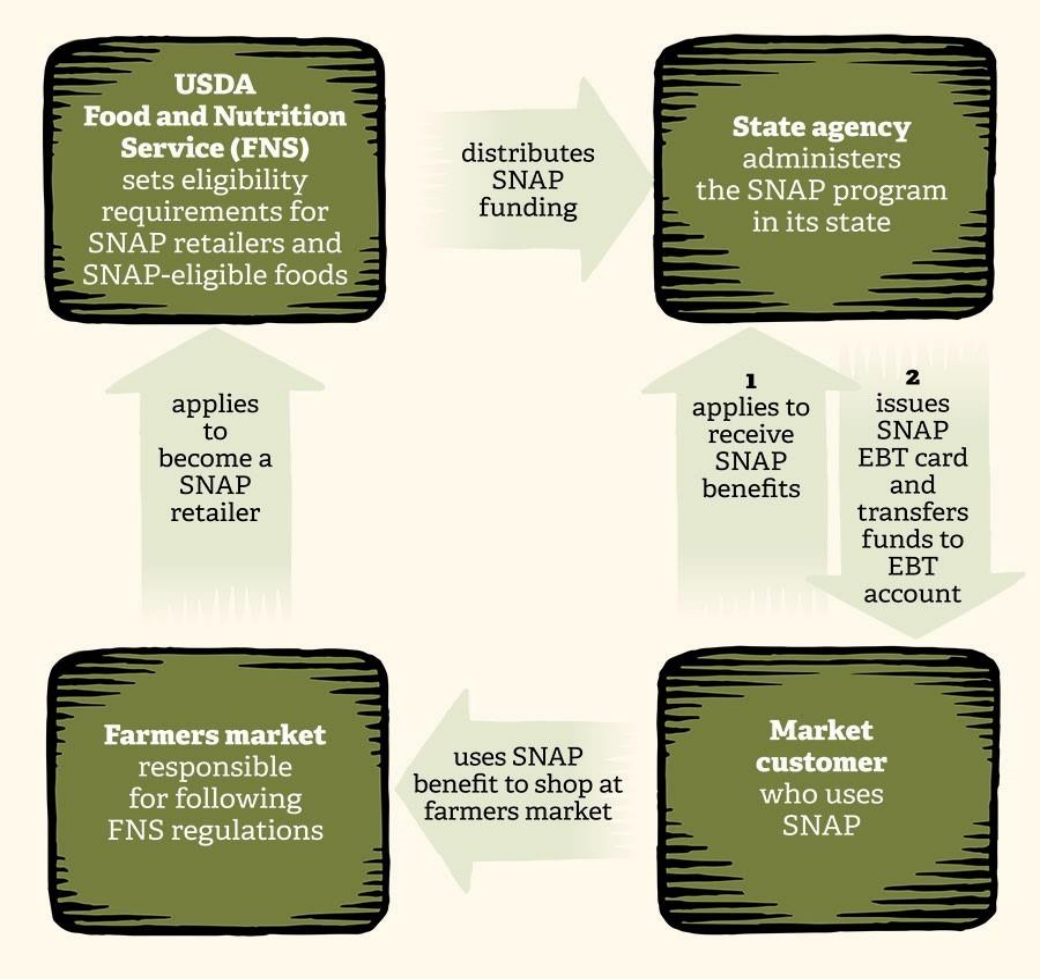
USDA SNAP

Retailer Eligibility Requirements

SNAP retailers play a crucial role in ensuring that eligible households
have access to nutritious food options.

To become a SNAP retailer, a store must meet one of the following requirements:
•Criterion A - staple food inventory; or
•Criterion B - staple food sales



Source: Center for Agriculture & Food Systems, Vermont Law & Graduate School

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SNAP Online Retailer Pilot Program

- **2014 Farm Bill**: mandated pilot to test feasibility and implications of allowing retailers to accept SNAP benefits through online transactions.
- **2016**: USDA issues request for retailer volunteers to participate in two-year SNAP Online Purchasing Pilot.
- **2017**: USDA began selecting retailers to participate in SNAP Online Purchasing Pilot.
- **2019-Present**: Online Purchasing Pilot in progress.

Thank You!

QUESTIONS?

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