National Agricultural Law Center Webinar: Overview of USDA Meat and Poultry Labeling Requirements

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Jurisdiction USDA vs. FDA



USDA Food Safety and Inspection Service

FDA

















Jurisdiction

FDA is the "default" inspection authority → statutes provide USDA with jurisdiction for specific products

- Federal Meat Inspection Act 21 U.S.C. §§ 601 et seq.
 - Amenable species: cattle, sheep, swine, goats, horses, mules, other equines, Siluriformes fish (catfish)
- Poultry Products Inspection Act 21 U.S.C. §§ 451 et seq.
 - Amenable species: domesticated chickens, turkeys, ducks, geese, ratites, squabs

Minimum content:

- 2% cooked basis
 - 3% raw basis

Egg Products also regulated under the Egg Products Inspection Act (liquid eggs, freeze dried eggs, etc)



USDA vs. FDA

- Inspection frequency
 - FDA minimum of once every:
 - 3 years high-risk facilities
 - 5 years non-high risk facilities
 - USDA
 - Slaughter carcass-by-carcass
 - Processing "continuous" at least once per shift
- Label Approval
 - Required for USDA-inspected products, not FDA foods
- Federal Preemption (including labeling)
 - Meat 21 U.S.C. § 678
 - Poultry 21 U.S.C. § 467e

States can impose labeling requirements on FDA foods (Vermont GMO, rBST; Prop 65)



FSIS Jurisdiction

- FSIS has jurisdiction over labels and labeling
 - Label: a display of written, printed, or graphic matter upon the immediate container (not including package liners) of any article
 - Meat 9 CFR 301.2; Poultry 9 CFR 381.1(b)
 - Labeling: All labels and other written, printed, or graphic matter (i) upon any article or any of its containers or wrappers, or (ii) accompanying such article.
 - Prior approval required for labels entering commerce, but not all labeling
- Federal Trade Commission has jurisdiction over advertisements
 - FTC's enforcement informed by FSIS regulations

Online store websites can be regulated as "labeling"

Labeling Basics





Labels Required

- Each shipping container and immediate container must bear a label containing the required label elements
 - Meat 9 CFR 317.1
 - Poultry 9 CFR 381.115



Prior Approval Required

- FSIS must "approve" all labels on meat and poultry entering commerce from FSIS establishments
 - Meat 21 U.S.C. § 607(d); Poultry 21 U.S.C. § 457(c)
 - Retailers not required to receive approval for their labels (e.g., deli meat)
 - Inspection legend cannot be applied without FSIS inspection
- Label Review
 - Evaluated by FSIS Labeling and Program Delivery Staff in DC HQ
 - Must receive approval prior to applying label, entering commerce
- Generic Approval
 - Establishment responsible for applying truthful, not misleading label
 - FSIS in-plant inspectors monitor labels, schedule inspection tasks



Misbranding

- Label is false or misleading in any particular
- Food is offered for sale under the name of another food
- Imitation foods are not disclosed as such
- Failure to include required elements
- Failure to conform with standard of identity
- Failure to disclose artificial colors or flavors, chemical preservatives
- Failure to include inspection legend

Meat - 21 U.S.C. § 601(n) / Poultry - 21 U.S.C. § 453(h)



Consequences of Misbranding

- Recall products
 - Most common cause of recalls is failure to disclose major allergens
- Retention (placed on hold in establishment)
- Detention (prohibit sale, movement in commerce)
- Trigger enforcement actions
 - Withhold or suspend inspection
- Criminal enforcement

Required Label Elements





Principal Display Panel vs. Information Panel

Principal Display Panel (PDP)



Information Panel





Required Elements

- Product Name (Meat 9 CFR 317.2(c)(1); Poultry 9 CFR 381.117)
 - Must appear on prominently on PDP
 - Name must be:
 - Standard of Identity (statute, regulation) if none, then:
 - Common or usual name (industry standard, FSIS policy) if none then:
 - Truthful descriptive designation (9 CFR 317.2(e)
- Ingredient Declaration (Meat 9 CFR 317.2(k); Poultry 9 CFR 381.118)
 - Can appear on PDP or information panel
 - Required for multi-ingredient products
 - List by order of predominance, except ingredients under 2% inclusion



Required Elements

- Address / Signature Line (Meat 9 CFR 317.2(g); Poultry 9 CFR 381.112)
 - Identify name and place of business of manufacturer, packer, or distributor
 - Located on PDP or information panel
- Inspection Legend (Meat 9 CFR 317.2(c)(5); Poultry 9 CFR 381.123)
 - Must be located on PDP
 - Often includes establishment number, but Est. # can be printed elsewhere
- Nutrition Facts Panel (Meat 9 CFR 317.300; Poultry 9 CFR 381.400)
 - Can appear on PDP or Information Panel
 - Required for retail multi-ingredient products, "major" cuts
 - Some exemptions apply (e.g., business size, package size)





Required Elements

- Net Weight Statement (Meat 9 CFR 317.2(h); Poultry 9 CFR 381.121)
 - Must appear on PDP of products sold at retail, unless net weight is applied at retail
- Handling Statement (Meat 9 CFR 317.2(k); Poultry 9 CFR 381.125(a))
 - Ex: "Keep Frozen" or "Keep Refrigerated"
 - Must appear on PDP of products requiring special handling
- Safe Handling Instructions (Meat 9 CFR 317.2(I); Poultry 9 CFR 381.125(b))
 - Required for not-ready-to-eat products
 - Can appear on any panel



Label Approval





Labeling and Program Delivery Staff Review

- FSIS Labeling and Program Delivery Staff evaluate label sketches, product formulations, claim substantiation
- Label applications:
 - Hard Copy FSIS Form 7234-1 and supporting documentation
 - Hand deliver to LPDS Office
 - USPS, UPS, FedEx
 - Electronic Submission –Label Submission and Approval System
- Turnaround time is typically 4 to 7 days
- LPDS response:
 - Approved
 - Approved as modified (LPDS will ID easy fixes)
 - Returned (rejected must modify and resubmit for approval)



When is LPDS Approval Required? 9 CFR 412.1(c)

- Labels for products produced under a religious exemption
- "Special statements"
 - Statements not defined in FSIS regulations or <u>Food Standards and Labeling Policy Book</u>
 - "Natural" claims
 - Animal raising claims (antibiotics, hormones, grass-fed, animal welfare, diet, breed)
 - Organic, non-GMO
 - Health claims
- Temporary label approval
 - Allows for minor errors on labels for limited time period
 - Cannot misrepresent the product or pose health/safety risk



Generic Approval 9 CFR 412.2

- Establishments may apply "generic" labels without prior LPDS approval
 - FSIS inspectors periodically review during operations
- Generic labels must:
 - Contain all mandatory label elements
 - Not contain "special statements" requiring LPDS approval
 - Allows for many statements that can be verified by in-plant inspectors



Expansion of Generic Approval

88 Fed. Reg. 2798 (Jan. 18, 2023)

- FSIS recently expanded the scope of claims eligible for generic approval:
 - Allergen statements (e.g., "Contains wheat")
 - Negative claims regarding ingredients not listed in the ingredient declaration (e.g., "No MSG")
 - Nutrient content claims that align with FSIS regulations
 - Geographic origin claims and marks
 - "Organic" claims in ingredient declaration
 - Products intended only for export that deviate from domestic labeling requirements

Animal Raising Claims





Animal Raising Claims

To support an animal raising claim, application must include:

- Written description of controls to ensure claims is valid from birth to slaughter (or claimed time period)
- Signed and dated document describing how animals are raised to meet the claim
- Description of tracing and segregation protocols to ensure claim is valid
- Address how non-conforming animals/product is handled
- Current copy of third-party certification (if applicable)



Animal Raising Claims

- Third-party certification required for:
 - Animal welfare
 - Environmental stewardship
 - Organic
 - Non-GMO
- Third-party certification not required (but permitted) for:
 - Breed (e.g., Angus)
 - Diet (e.g., grass-fed, vegetarian diet)
 - Living/raising (e.g., gestation crate, pasture-raised, cage free)
 - No Added Hormones
 - Raised without Antibiotics
 - Source, traceability



Changes Under Consideration

June 14th USDA Announcement:

- Forthcoming updated guidance (anticipated winter 2023):
 - Strengthen documentation requirements for animal-raising claims, such as "grass-fed" and "free-range"
 - Strongly encourage third-party certification
- "Raised without Antibiotics"
 - FSIS & USDA ARS sampling carcasses in "Raised without Antibiotics" programs for residue
 - Based on results, FSIS may:
 - Require establishments to submit laboratory results, OR
 - FSIS may institute a verification sampling program

Recent Developments





Cell Culture Labeling Developments

- FSIS has jurisdiction over harvest of cell biomass, further processing, and labeling
 - FDA approves ingredients, oversees bioreactors
- FSIS developing regulations for cell culture products
 - Proposed rule anticipated in December 2023
 - Address product name, how products are labeled
- FSIS has approved labels for 2 companies (foodservice)
 - Allowing products to be labeled as "cell cultivated" or "cell culture" chicken
- FSIS intends to release draft guidance prior to final rule



Voluntary Product of USA Claims

 Current policy allows US origin claims on products that are processed in the US before final packaging

March 13, 2023 Proposed Rule:

- Limit US origin claims to:
 - Products derived from animals born, raised, and slaughtered within the US
 - If multi-ingredient, all components, except spices and flavorings, must be of domestic origin
- Distinct from mandatory County-of-Origin labeling
 - Required for chicken, lamb, imported finished products

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