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USDA Updates: FSIS Proposes Significant Updates to Generic Label Approval Oversight, and Finalizes Rule on Modernizing Egg Inspection

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Food, Drug, and Device

The first half of September has seen two major regulatory updates from USDA's Food Safety and Inspection Service (FSIS).

First, on September 14, 2020, FSIS published a proposed rule to expand the circumstances under which FSIS will generically approve the labels of meat, poultry, and egg products, which specifically proposes that FSIS will cease evaluating generically approved labels submitted to FSIS for review.

Second, on September 9, 2020, FSIS released a final rule modernizing the Agency's egg inspection requirements, the first such update to the Agency's egg product inspection methods since Congress passed the Egg Products Inspection Act in 1970.[1] The final rule aims to more closely align food safety, labeling, and import requirements for egg products with those for meat and poultry products, and expands generic label approval eligibility to egg products. The final rule additionally shifts jurisdiction over egg substitutes and freeze-dried egg products from FDA to FSIS.

We summarize each development, in turn, below.

Proposed Rule on Generic Label Approval

FSIS oversees the labeling of meat, poultry, and egg products. Under the FSIS paradigm (and unlike FDA), FSIS implements a "prior approval" program for labels intended to be used on federally inspected meat and poultry, and egg products (9 CFR Part 412 and 9 CFR 590.411). Prior approval is a prerequisite to selling, offering for sale, or otherwise distributing these

[1] https://www.fsis.usda.gov/wps/portal/fsis/newsroom/news-releases-statements-and-transcripts/news-release-archives-by-year/archive/2020/nr-09092020-01

products in commerce. FSIS approves labels through two pathways known in FSIS parlance as: (1) the sketch approval process, and (2) generic label approval.

Labels subject to sketch approval must be submitted to FSIS for review and approval before use. This includes, for example, labels containing special statements and claims, such as animal raising claims. For labels without claims or other elements that FSIS has determined require sketch approval, "generic label approval" applies. Labels subject to generic label approval do not require any FSIS evaluation prior to use, therefore aligning with FDA's approach to labeling compliance oversight for FDA-regulated foods. Under current law, meat and poultry labels are generically approved if they meet the criteria listed in 9 CFR 412.2(b).

Section 412.2(b) provides, in relevant part, that generically approved labels must bear all applicable mandatory labeling features and may also bear claims and statements meeting definitions enumerated in FSIS regulations or the Food Standards and Labeling Policy Book (except for natural and negative claims). FSIS also considers allergen statements (*e.g.,* "contains soy") used in line with the Food Allergen Labeling and Consumer Protection Act to be eligible for generic label approval. Other label claims eligible for generic approval include certain factual statements and claims like: Agricultural Marketing Service (AMS) grading, flavor profiles, foreign language on domestic products, geographic claims, as well as Kosher and Halal claims (excluding certified claims).[2] Under current Agency policy, FSIS allows establishments to request voluntary evaluation of generically approved labels, but such requests are placed in a second priority queue and take longer to be reviewed, with sketch approval taking priority.

FSIS has authorized generic label approval for certain categories of labels since 1983. And, over the years, FSIS has expanded the categories of labeling claims eligible for generic approval. For example, in 2013, FSIS published new regulations to expand the circumstances in which FSIS would generically approve the labels of meat and poultry products. FSIS has additionally published a proposed rule that, if finalized as drafted, would authorize generic approval for egg product labels (83 FR 6314, February 13, 2018). In the proposed rule published this month, FSIS is seeking to expand the categories of meat, poultry, and egg product labels that it will deem generically approved and thus will not require submission to FSIS for review and approval.

Key Elements of the Proposed Rule

- FSIS would stop reviewing labels that are eligible for generic approval;
- FSIS would allow generic approval of labels containing the following statements and claims:
  - "Negative" claims identifying the absence of certain ingredients or types of ingredients, such as "No MSG Added," "Preservative Free," "No Milk," "No Pork," or "Made Without Soy"
  - Geographic landmarks, such as a foreign country's flag, monument, or map

[2] FSIS Generic Labeling Overview, dated September 25, 2019, https://www.fsis.usda.gov/wps/wcm/connect/f6524867-fe2b-40bc-897c-aa8a242ec8a8/generic-labeling-webinar.pdf?MOD=AJPERES

    - Ingredient statements that specify particular ingredients as being certified "organic" under the AMS National Organic Program
- FSIS would expand generic approval eligibility to include labels on products for export that deviate from FSIS requirements
- FSIS would allow generic approval of products that receive voluntary FSIS inspection, including exotic species such as bison and rabbit

FSIS states that the proposed changes aim to reduce the number of labels submitted to FSIS for evaluation and to lessen the paperwork burden on official establishments. FSIS further indicates that the reduction in staff time spent approving generically approved labels would allow the Agency to focus resources on developing guidance materials, answering labeling policy questions, providing outreach to stakeholders, and more effectively exercising inspection oversight to verify labeling compliance.

Notable label categories that will continue to require review by FSIS include: (1) labels that bear negative claims relating to the raising of the animal from which the product is derived (e.g., "no antibiotics administered"), (2) negative claims relating to the use of genetically modified ingredients, and (3) labels certifying a total product as organic.

Comment Period

FSIS is accepting comments on the proposed rule until November 13, 2020.

Consistent with past amendments to the Agency's generic label approval rules, key issues on which FSIS will likely be eager to receive feedback include input on the effectiveness of the generic approval process, and any potential advantages or disadvantages to industry – or consumers – from not having the opportunity to submit labeling claims eligible for generic approval.

Final Rule: FSIS Modernizes Egg Inspection

On September 9, 2020, FSIS released a final rule modernizing egg inspection requirements. This final rule represents the first update to the Agency's egg products inspection program in five decades. The final rule also transfers primary oversight of certain egg products from FDA to USDA.

The final rule requires egg product plants to develop and implement hazard analysis and critical control point (HACCP) plans and Sanitation Standard Operating Procedures (SOPs), and to include safe-handling instructions on the labels of certain egg products. FSIS intends to phase in the egg HACCP requirements for domestic producers over a two-year period following publication of the final rule in the Federal Register, and intends to enforce the Sanitation SOPs and sanitation requirements one year after publication of the final rule in the Federal Register. FSIS testing for Salmonella and Listeria monocytogenes (*Lm*) in egg products will continue.

Key Changes

The following are notable key changes being implemented by the final rule, all of which were set forth in the proposed rule, and many of which are consistent with current requirements for meat and poultry products regulated by FSIS:

- requires egg products to be processed to be edible without additional preparation to achieve food safety;
- allows generic approval for certain categories of egg product labels, limiting prior approval to labels: intended for temporary approval, for products produced under religious exemption, for products for export with labeling deviations, and with special statements and claims;
- revises the labeling requirements for shell eggs held by egg handlers inspected by FSIS to be consistent with those in FDA's regulations;
- requires special handling instructions on certain egg products; and
- aligns the import requirements for egg products to be more in line with those for meat and poultry products and to help facilitate the use of imported egg products in combination with domestic egg products for purposes of further processing.

Under the new HACCP requirements, egg products plants will be able to tailor a food safety system that suits their particular facility and equipment. FSIS states that by modernizing its regulation to remove prescriptive regulations, the new flexibility afforded to egg products plants will incentivize and facilitate continued strides in enhancing food safety.

The new HACCP requirements also harmonize well with FDA's FSMA food safety requirements. For example, for FDA-registered food facilities that use egg products subject to the new HACCP requirements as ingredients in foods subject to an FDA-required food safety plan, the facilities could request, review, and rely on the HACCP plans when conducting FSMA-related hazard analyses and supply-chain program activities. Presumably, for ingredients subject to the egg HACCP requirements, the HACCP plans would be a good resource for assessing potential food safety hazards and any relevant supply-chain applied controls.

The final rule also gives FSIS jurisdiction over freeze-dried egg products and egg substitutes. FDA currently regulates certain categories of egg products that FSIS has exempted from its oversight (see Table 1). Egg substitutes and freeze-dried egg products will become subject to FSIS oversight three years following publication of this final rule in the Federal Register. Prior to the effective date of this portion of the final rule, FSIS plans to provide additional information to facilitate compliance for those plants – such as those producing egg substitutes – that are not currently under FSIS inspection.

Table 1: New FDA and FSIS Jurisdiction over Egg-Based Products under Final Rule

FDA	USDA FSIS
▪ Imitation egg products ▪ Dietary foods ▪ Dried no-bake custard mixes ▪ Egg nog mixes ▪ Acidic dressings ▪ Noodles ▪ Milk and egg dip	▪ Dried eggs with or without added ingredients ▪ Frozen eggs with or without added ingredients ▪ Liquid eggs with or without added ingredients ▪ ***Freeze-dried egg products*** ▪ ***Egg substitutes***

▪ Cake mixes ▪ French toast ▪ Sandwiches containing eggs or egg products ▪ Cooked egg products (cooked egg patties, cooked omelets, freeze-dried cooked eggs)	

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If you have any questions concerning the USDA FSIS updates discussed in this client alert, please contact the following members of our Food, Drug, and Device practice.

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