

FSIS Releases Proposed Egg Products HACCP Rule

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Food, Beverage, and Dietary Supplements

On Tuesday, January 9, 2018, USDA's Food Safety and Inspection Service (FSIS) released a [proposed rule](#) that would require egg products plants to develop and implement hazard analysis and critical control point (HACCP) plans, Sanitation Standard Operating Procedures (SOPs), and include safe-handling instructions on the labels of certain egg products.

FSIS explains that the proposed egg HACCP rule aligns its requirements for egg products with its HACCP requirements for meat and poultry products and would make products safer while conserving agency resources.

FSIS intends to phase in the egg HACCP requirements for domestic producers over a two-year period after the rule is finalized, and intends to enforce the Sanitation SOPs and sanitation requirements one year after publication of the final rule.

Key Changes in the Proposed Rule

The following are some of the key changes in the proposed rule, many of which are consistent with current requirements for meat and poultry products regulated by FSIS:

- redefines the requirement for continuous inspection in 21 U.S.C. 1034(a) (proposes that instead of requiring inspection during all processing operations, inspections would take place at least once per shift);
- 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;
- eliminates the requirements for prior approval by FSIS of egg products plant drawings, specifications, and equipment;
- incorporates egg products plants into the coverage of the "Rules of Practice" that FSIS follows when initiating administrative enforcement actions; 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.

Jurisdiction Over Freeze-Dried Egg Products and Egg Substitutes

FSIS proposes to assume jurisdiction over freeze-dried egg products and egg substitutes because it views these products as posing the same risks as egg products. FDA currently regulates certain categories of egg products that FSIS has exempted from its oversight (see Table 1). FSIS is requesting stakeholder input on the number of facilities that would be subject to dual jurisdiction (inspections from both FSIS and FDA) if these two product categories are no longer exempt from FSIS inspection and oversight shifts from FDA to FSIS.

Table 1 Current FDA and USDA FSIS Jurisdiction over Egg-based Products

FDA	USDA FSIS
Freeze-dried egg products (proposed rule would transfer to FSIS)	Dried eggs with or without added ingredients
Egg substitutes (proposed rule would transfer to FSIS)	Frozen eggs with or without added ingredients
Imitation egg products	Liquid eggs with or without added ingredients
Dietary foods	
Dried no-bake custard mixes	
Egg nog mixes	
Acidic dressings	
Noodles	
Milk and egg dip	
Cake mixes	
French toast	
Sandwiches containing eggs or egg products	
Cooked egg products (cooked egg patties, cooked omelets, freeze-dried cooked eggs)	

Impact on FSMA Food Safety Assessments

If finalized, FSIS’s egg products HACCP requirements would 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.

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There will be a 120-day period for comment once the proposed rule is published in the Federal Register. If you have any questions concerning FSIS's proposed rule or any other USDA-related question, please contact the following attorneys:

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