

ALERTS

Agriculture & Food Processing Law Alert - Food Safety And Inspection Service Issues New Allergen Handling Guidelines

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On Nov. 13, the Food Safety and Inspection Service (FSIS) released new guidelines regarding management of ingredients that could trigger adverse reactions in consumers with sensitivities to certain food ingredients. The guidelines are said to represent “FSIS’s current thinking,” and producers, including FSIS-regulated establishments, state-regulated establishments, and operations where all or part of the premises meet the “food processing plant” definition of the 2013 Food Code, are encouraged to adhere to the new guidelines. The guidelines provide information on processing, handling and storing products with allergenic ingredients. The focus of the guidelines is on meat and poultry products.

The FSIS guidelines involve three main principles: (1) identify, (2) prevent and control and (3) declare.

Identify Guidelines

FSIS recommends that producers implement a meticulous, comprehensive hazard analysis to identify and control allergens. This hazard analysis should be part of a Hazard Analysis and Critical Control Point (HACCP) plan. The new guidelines indicate that regulated producers should ensure their hazard analyses include all steps of the production process, from receiving to packaging and shipment. FSIS encourages the following “practical steps” to identify allergens:

- Review lists of ingredients and products used to determine whether they are or may contain allergens
- Using a schematic, conduct a walkthrough of the facility, noting paths of allergenic ingredients and products and areas where cross-contact may occur
- Keep lists of ingredients used in product formulations and records of labels to compare against incoming ingredients
- Ensure incoming ingredients containing allergenic material are clearly labeled and identified
- Color code allergen-containing ingredients and products
- Store ingredients containing allergenic materials in separate, designated areas that are clearly identified and marked
- Become familiar with letters of guarantee from suppliers

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- Maintain open communication of expectations with suppliers and inquire about their allergen control programs

Alongside the FSIS guidelines for implementing procedures to identify allergens, the FSIS provided guidance on distinguishing between Letters of Guarantee (LOGs) and Certificates of Analysis (COAs), and further clarified that an annual LOG from a supplier will typically be insufficient to support a producer's hazard analysis decisions. FSIS encourages producers to cross-reference labels with both incoming and outgoing products and to follow FSIS's existing labeling guidelines.

Prevent and Control Guidelines

FSIS also issued guidelines for preventing cross-contact of allergenic and non-allergenic products, as well as misbranding of items containing allergenic ingredients. FSIS recommends the following "practical steps" for preventing cross-contact:

- Color code ingredient packages, supplies, uniforms, and utensils used for products containing allergens throughout processing to facilitate identification
- Document cleaning procedures with checklists including spill clean-up procedures
- Employ a method for verification and validation of cleaning
- Maintain a documented process flow along with mapping the route of allergenic product through the facility
- Employ methods for tracking lot codes through production
- Carefully evaluate rework and work-in-progress
- Dedicate equipment or separate allergenic products by time, space, etc. (if dedication of equipment is not feasible).

Cleaning and sanitization of equipment, utensils and food contact surfaces (FCS) should occur after any contact with an allergenic product. FSIS also recommends that producers make plans to handle non-allergenic products **before** handling allergenic products, to help prevent cross-contact. Further, FSIS recommends avoiding use of the same cooking medium for both allergenic and non-allergenic products.

FSIS states in the guidelines that the agency **does not recognize** a threshold for any allergenic ingredient—even a trace presence of any of the above-listed allergen imposes a mandatory labeling requirement under the current rules and guidelines. To test for allergens, FSIS encourages producers to use test kits as a supplement to existing cleaning and sanitizing programs.

Declare Guidelines

The final area of FSIS's new guidelines deals with declaring the presence of allergens in packaging, labeling and storage. Once a regulated producer identifies potential allergens, FSIS warns, the producer has a responsibility to ensure the product is properly packaged, labeled and stored. FSIS recommends the following "practical steps" to avoid

mislabeling:

- Systems and checklists for labeling of the final product
- Conduct simulations with inaccurate product labels to test systems, checklists and procedures
- Color coding of products containing allergenic ingredients
- Procedures for labeling discrepancies to ensure product disposition is evaluated
- Verify accuracy of product labels
- Methods of tracking lot codes through the production, storage and shipping process
- Storage of products containing allergenic materials in areas that are clearly identified and marked.

FSIS emphasized the importance of product separation in storage as well as the importance of following a formal HACCP system to carry out producer obligations under the regulations. FSIS also clarified that “may contain” statements are not required for the mere presence of an allergen, but that “processed in a facility that uses” labels are only to be used when good manufacturing practices cannot reasonably eliminate the unintended presence of the allergen in question. Further, FSIS encourages producers to view its document “Compliance Assistance: Allergens-Voluntary Labeling Statements” for more information on labeling statements.

In addition to the three primary focus areas of the guidelines, FSIS encouraged producers to implement allergen handling training for employees. While the guidelines are non-mandatory, FSIS reminds producers that a failure to declare presence of one of the following allergens may result in a Class I or Class II recall:

- Wheat
- Crustacean shellfish
- Eggs
- Fish
- Peanuts
- Milk
- Tree nuts
- Soybeans

Producers serving countries outside the U.S. should also adhere to reporting requirements for other allergens under local law. FSIS also notes that compliance with existing federal regulations and labeling laws remains mandatory.

The FSIS [Allergen Guidelines and appendices](#), [labeling policies](#), and

the [Voluntary Labeling Statements Guidance](#) are available for PDF download.

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