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Part I: How To Prevent Undeclared Allergen Recalls

By Scott Seys, Senior Health Scientist, Office of Policy and Program Development

Since 2008, recalls of products regulated by the USDA Food Safety and Inspection Service (FSIS) have been increasing due to undeclared allergens and ingredients of public health concern. In 2015 alone, a total of 65 undeclared allergen-related recalls occurred, affecting nearly 12 million pounds of meat and poultry products. All but two of these recalls were of products from small and very small establishments.

These recalls are preventable. Many have been the result of ingredient changes that were overlooked, products in the wrong package, or products with misprinted labels.

Consuming meat, poultry, and processed egg products that contain undeclared allergens or ingredients of public health concern may result in dangerous health effects for certain at-risk individuals. The signs and symptoms of food allergies vary depending on the person, allergy, and food. However, they can include such serious conditions as difficult breathing, loss of consciousness, and even anaphylaxis; a life-threatening condition that could result in shock and death.

Experts have estimated that as many as 29,000 episodes of anaphylaxis related to food occur in the United States each year. Those with food allergies rely on avoiding specific foods by reviewing labels in order to avoid harmful reactions.

What are some straightforward steps an establishment can immediately take to identify allergens?

- Review the list of all ingredients and products in use to determine whether they are, or contain, allergens;
- Using a schematic, conduct a walk-through of the establishment, noting the paths of allergenic ingredients and products through the production process and areas of concern where cross- contact may occur;
- Keep a list of ingredients used in product formulations and label records at the receiving area to compare against incoming ingredients;
- Ensure all incoming ingredients containing allergenic material are clearly labeled and identified;
- Use a color coding system for 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 (LOG) from suppliers; and
- Maintain open communication of expectations with suppliers and inquire about suppliers' allergen-control programs.

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In 2015, FSIS issued guidance to establishments that was specifically targeted at allergens and ingredients of public health concern. The final document, titled "Allergens and Ingredients of Public Health Concern: Identification, Prevention and Control, and Declaration through Labeling," is now available in the Compliance Assistance section of FSIS' website at *www.fsis.usda.gov/wps/wcm/connect/f9cbb0e9-6b4d-4132-ae27-53e0b52e840e/Allergens-Ingredientspdf?MOD=AJPERES*.

(Appendixes to the document include a number of resources in the form of diagrams, flow charts, checklists, scenarios, and references.)

The guidelines provide information on proper procedures for processing, handling, storing, and labeling a product containing allergens or ingredients of public health concern based on three basic principles:

1. Identify;
2. Prevent and Control; and
3. Declare.

In this first of a series of three *Small Plant News* articles on allergen control, we'll focus on the key components of the **Identify** principle for allergenic ingredients, which include hazard analysis, inspection of incoming ingredients, cross-referencing product components, and separation of allergenic materials. Subsequent articles will include information on **Prevent and Control** and **Declare**.

Identify: Inspection of Incoming Ingredients, Cross-Referencing Components, and Separation

At the heart of the **Identify** principle is a meticulous and comprehensive hazard analysis. The hazard identification and subsequent hazard evaluation serve as the foundation for a strong and successful Hazard Analysis and Critical Control Points (HACCP) plan.

Therefore, it's important for you to invest the necessary time and resources in the analysis. The hazard analysis includes identifying any chemical hazards, such as allergens and ingredients of public health concern, in addition to any biological and physical hazards that are reasonably likely to occur in the production process. The introduction of an allergen could occur anywhere during your production process. As a result, it's necessary to evaluate each step in the process from receiving to packaging and shipment.

Following the identification of chemical hazards during the analysis, you should have a list of allergens and other ingredients of public health concern that may be introduced at various steps in production. You should then evaluate each of these potential hazards based on the public health impact, as well as the likelihood of occurrence. This evaluation could be based upon historical data, scientific literature, or establishment records. Once the hazard evaluation is completed, you should work to develop approaches to prevent or control those hazards at each step in production cycle where they may appear.

The "Big Eight" Allergens

- Wheat
- Crustacean shellfish (e.g., shrimp, crab, lobster)
- Eggs
- Fish
- Peanuts
- Milk
- Tree nuts (e.g. almonds, pecans, walnuts)
- Soybeans

To fully address all allergens and ingredients of public health concern in the final product, you should first assess ingredients present in all your components. Seek out information about the allergens and ingredients of public health concern used by your suppliers.

In addition, you should seek information on your suppliers' production practices, such as whether they employ methods to prevent the cross-utilization of equipment or cross-contact of product.

This information may come in the form of a LOG, which should not be confused with a Certificate of Analysis (COA). A COA typically includes test results associated with a specific lot, while a LOG may be provided by the supplier to describe the ingredients used in the production of products.

Based on the component and complexity of the supplier's process, the content of the LOG can vary significantly; from a general statement, which is common, to a more detailed description of the supplier's process (e.g., details including ingredient components, processing aids, rework, processing steps, environmental conditions, or product carryover).

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In either situation, the LOG should accomplish the same function and be detailed enough to support the decisions made in your hazard analysis. You should review the LOGs regularly to ensure that the decisions made in the hazard analysis are supported and to ensure that any formulation changes made by your suppliers are detected prior to incorporating the associated ingredient into the production process. Generally, an annual LOG will not be sufficient to support decisions made in the hazard analysis.

If you don't routinely review and verify the components and ingredients your plant receives, then you might overlook the presence of an allergen. Sometimes ingredient suppliers may reformulate their products without notifying their customers. The result may be the inclusion of a component that's not declared in a product, resulting in adulteration and misbranding, which could ultimately lead to a product recall.

FSIS recommends that an establishment maintain an approved supplier list along with ingredient information from each supplier. You should use the list when receiving incoming ingredients to verify proper identification of allergens and ingredients of public health concern for each lot of ingredients.

For accuracy, you should also cross-reference the sketch label approval for the product being produced, if applicable, to the actual label being used and the formulation data. It's imperative that the label approval, the actual label, and formulation all match for proper ingredient identification. If there's a discrepancy between the label and the formulation, you should separate the product and ingredients in question and hold them in a secure place, so that they're not used until the ingredients can be properly identified for use in specific products.

In addition to the FSIS Compliance Guideline mentioned above, there are a number of resources available for more information about preventing and controlling undeclared allergens, such as the North American Meat Institute's Guidance for Allergen Control in Meat Establishments, available at: *https://www.meatinstitute.org/index.php?display=GeneralSearch&action=AddSearchTermAction&searchstring=guidance*.

FSIS-regulated establishments have a responsibility to protect public health by declaring all ingredients on product labels and preventing undeclared allergens. A number of guidance documents are available on FSIS' website to assist establishments with product labeling. For further information visit: *www.fsis.usda.gov/wps/portal/fsis/topics/regulatory-compliance/compliance-guides-index#Labeling*.

For specific questions, submit questions to askFSIS at *http://askfsis.custhelp.com* or contact the Small Plant Help Desk at 1-877-FSIS-HELP (1-877-374-7435) or email InfoSource@fsis.usda.gov. The Small Plant Help Desk is available Monday through Friday from 8:00 a.m. to 5:00 p.m. Eastern time. After hours, please leave a voice mail, and you will receive a follow-up call from an FSIS subject-matter expert within 24 hours.

Commonly Asked Questions & Answers

Q: Is there a "sensitivity level" below which potential allergens or known allergens may be permitted for use without declaration on the label regulated by the USDA?

A: No. All ingredients used to formulate a meat and poultry product must be declared by common or usual name except for substances whose use has been determined to be consistent with FDA's labeling definition of an incidental additive or processing aid (21 CFR 101.100(a)(3)). For meat, poultry, and processed egg products under the jurisdiction of FSIS, the Agency makes determinations of whether ingredients are processing aids or incidental additives on a case-by- case basis. FSIS is not aware of any threshold level below which an ingredient that contains protein does not need declaration.

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FSIS Small Plant Help Desk:
1-877-374-7435
InfoSource@FSIS.usda.gov

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