USDA United States Department of Agriculture
Food Safety and Inspection Service

Small Plant NEWS

Vol. 6, No. 1

Inside

Small Plant NEWS

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Staying on Top of Allergen Management in Your Plant

By Tracy Hewitt, Ph.D.

Most scientists agree that there are no defined threshold levels or limits for allergens or their derivatives because the amount of an allergenic material that's needed to provoke a response in people varies. Some individuals in the general population are very sensitive to extremely low levels of an allergen, while others may have a higher tolerance and require a greater level of exposure to provoke a reaction.

Likewise, symptoms of an allergic reaction may be mildly inconvenient to quite severe and life threatening. In any case, avoidance of an allergen is the only tried-and-true preventative measure. Therefore, consumers must rely on you, the plant operator, to identify accurately any allergens you use and properly label your products.

The U.S. Department of Agriculture's (USDA) Food Safety and Inspection Service (FSIS) strongly recommends that you address food allergens in your hazard analysis. Prudent plants adopt a "zero tolerance" policy for allergen cross-contamination. These plants employ a multi-intervention approach to prevent cross-contamination of products and processes and to ensure that products containing allergens are clearly and accurately labeled.

There are five areas to consider within a production or processing environment: ingredients, production, packaging and labeling, sanitation, and consumer feedback. With this in mind, your allergen management program may involve the following:

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- Insist that your suppliers provide adequate notification of changes in ingredients;
- Establish procedures to evaluate your labels and specifications of all ingredients;
- Secure and properly store all allergenic foods and ingredients;
- Audit your suppliers' allergen management programs;
- Determine the stage in your production or processing environment that allergen cross-contamination could occur;
- Verify the accuracy of your ingredient statement during label preparation, at printing, during packaging, and when there are changes in product development or formulas;
- Review the agents or materials associated with packaging materials;
- Ensure that your sanitation procedures are sufficient to prevent cross-contamination of allergens and their derivatives, keeping in mind that just because something is "visibly clean" doesn't mean that it is "allergen clean";
- Determine whether problems with allergens are the underlying cause of consumer complaints;
- Prior to distribution, ensure that all allergens have been declared on your product label.

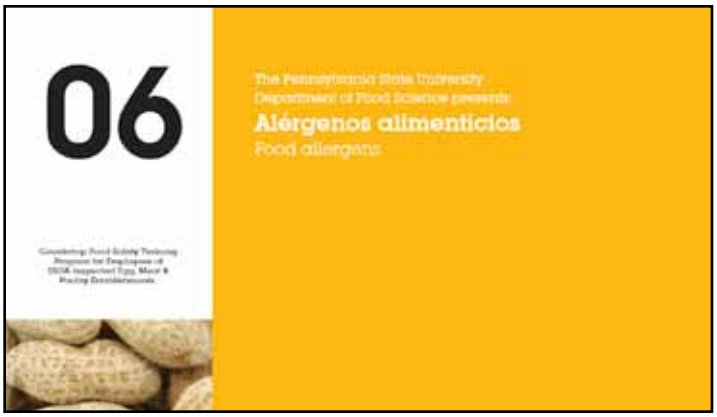
In addition, an allergen control program should include all of the measures and policies that must be followed at your food processing plant to protect sensitive consumers from food allergens. An allergen control program may include:

- Identification of all allergen-containing materials;
- Designated allergen storage area in the warehouse;
- Identification and implementation of weigh area control procedures;
- Identification of all allergen-containing formulae;
- Individual scoops or measuring devices in allergen containers;
- Identification of all allergen containers and cleaning procedures, and documentation of cleaning activities;
- Identification of critical plant areas and cleaning programs, and documentation of cleaning activities;
- Implementation of a rework control program and documentation of rework usage; and
- Ensuring that package labels for products containing allergens have any allergens correctly listed in their ingredient statement.

As previously stated, the labeling of products containing any allergen or allergen derivative is very important. There are eight major food allergens: milk, soybeans, wheat, eggs, tree nuts, peanuts, fish, and shellfish. If a food product contains a major food allergen or a protein derived from one of the eight, the allergen must be listed on the label. If a food product contains fish or shellfish, the labels must state the species (e.g., crab, flounder, or shrimp). If a food product contains tree nuts, the labels must state the type (e.g., almonds, pecans, or walnuts). Wheat includes any species in the genus *Triticum.*

There are three ways that food allergens may be listed: (1) list the names of the allergens in the ingredient list (e.g., crab, shrimp, or lobster); (2) list the names of the allergens next to the ingredient that does not disclose what is in it (e.g., flour (wheat), whey (from milk)); or (3) list the allergens after the word "contains" (e.g., "contains wheat, soy, peanuts").

For more information on labeling for food allergens, refer to 21 of the *Code of Federal Regulations*, part 101.4 (21 CFR 101.4), *Food Allergen Labeling and Consumer Protection Act,* or go to *www.fsis.usda.gov/PDF/Labeling_Requirements_Guide.pdf.* You may also submit questions through askFSIS at *http://askfsis.custhelp.com* or call (800) 233-3935. You may also call the FSIS Labeling and Program Delivery Division directly at (301) 504-0878.



The *Countertop Food Safety Training Program*, Module 6, titled *Food Allergens*, is another helpful resource that may be accessed on FSIS' Web site at *www.fsis.usda.gov/PDF/6_Food_Alergens.pdf*. The *Countertop Food Safety Training Program* is an English/Spanish bilingual training program that provides an educational tool for the processed egg, meat, poultry, and other food processing industries to train their line employees on essential concepts in short periods of time. It was prepared under an USDA-FSIS cooperative agreement by Dr. Cathy Cutter of Pennsylvania State University, in cooperation with Dr. Sergio Nieto-Montenegro of Hispanic Workforce Management, LLC, and USDA.

If you have any questions or need more information regarding the control of allergens in your plant, contact the Small Plant Help Desk at 1-877-FSISHELP (1-877-374-7435) or *InfoSource@fsis.usda.gov.*

Proposed Rule for Labeling Announced

On December 5, 2011, FSIS announced a new proposed rule that would expand the circumstances in which the Agency will generically approve the labels of meat and poultry products. FSIS also proposed combining the regulations that provide for the approval of labels for meat products and poultry products into a new *Code of Federal Regulations* (CFR) part. The proposed rule, titled "Prior Label Approval System: Generic Label Approval," may be viewed on FSIS' Web site at *www.fsis.usda.gov/Frame/FrameRedirect.asp?main=http://www.fsis.usda.gov/OPPDE/rdad/FRPubs/2005-0016.htm*.

Generic label approval refers to the prior approval of labels or modifications to labels by the agency without submitting such labels to FSIS for sketch approval. Generic label approval requires that all mandatory label features be in conformance with FSIS regulations (9 CFR 317.5(a)(1) and 381.133(a)(1)). Although such labels are not submitted to FSIS for approval, they are deemed to be approved and, therefore, may be applied to product in accordance with the agency's prior label approval system. Guidance on current generic labeling information and regulations may be accessed on FSIS' Web site at *www.fsis.usda.gov/OPPDE/larc/Procedures/generic.pdf*.

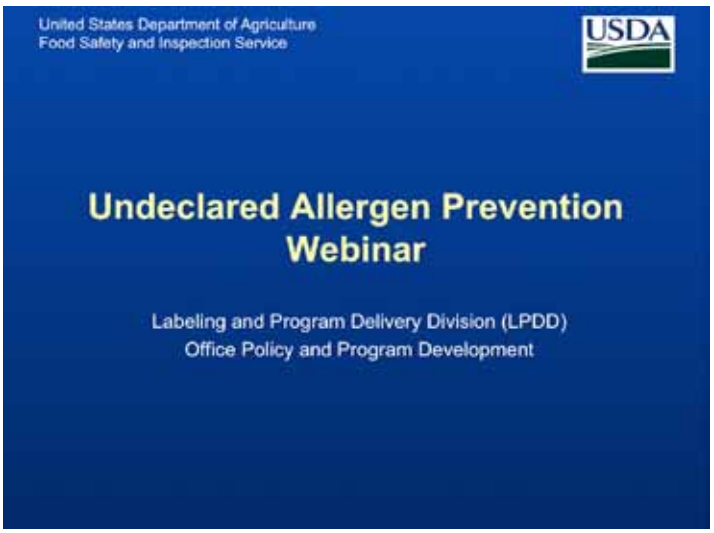
Comments on "Prior Label Approval System: Generic Label Approval" were accepted until March 3, 2012.

For more information, contact Jeff Canavan, Food Technologist, Labeling and Program Delivery Division, Office of Policy and Program Development, Food Safety and Inspection Service, U.S. Department of Agriculture, Stop Code 3784, Patriots Plaza III, 8-161A, 1400 Independence Avenue, SW, Washington, DC 20250-3700; telephone (301) 504-0879; fax (301) 504-0872.

To sign up for email updates when new FSIS Federal Register notices, proposed rules, interim rules, and final rules are published, visit FSIS' Web site at *www.fsis.usda.gov/regulations_&_policies/federal_register_publications_&_related_documents/index.asp* and click on the link provided.

Undeclared Allergens Subject of Webinar

The FSIS Office of Policy and Program Development, Labeling and Program Delivery Division, hosted a series of regulatory webinars titled "Recalls of Products with Undeclared Allergens." The webinars focused on the steps you can take to prevent production of items containing undeclared allergens. The presentation used during the webinars has been posted on FSIS' Web site and may be accessed at *www.fsis.usda.gov/PPT/Undeclared_Allergen_Prevention.ppt*.



Commonly Asked Questions & Answers

Q. *Is it acceptable for a cattle slaughter establishment to use its "zero tolerance" critical control point (CCP) to control the food safety hazard of* E. coli *O157:H7?*

A. No, a cattle slaughter establishment's "zero tolerance" CCP is designed to identify visible fecal, ingesta, and milk contamination, and is not sufficient to control the microscopic pathogen *E. coli* O157:H7. A cattle slaughter establishment's CCP for the identification of visible fecal contamination is an indication of the establishment's control of its sanitary dressing procedures during the slaughter process (62 FR 63254, Nov. 28, 1997, *Livestock Carcasses and Poultry Carcasses Contaminated With Visible Fecal Material*). In 2002, the agency published a *Federal Register* Notice [Docket No. 00-022N] titled *E. coli* O157:H7 *Contamination of Beef Products*. In that notice, FSIS stated that it may be "more effective to control the risk of *E. coli* O157:H7 contamination while the product is still intact," and that it believes that the cattle slaughter establishments needed to put one or more validated CCPs in place that are designed to eliminate or reduce *E. coli* O157:H7 and other pathogens. Section 417.2(a)(1) of the Hazard Analysis and Critical Control Point (HACCP) regulations states that a food safety hazard that is reasonably likely to occur is one for which a prudent establishment would establish control measures because the hazard historically has occurred, or because there is a reasonable possibility that it will occur in the particular type of product being processed in the absence of those controls. In addition to a CCP to address the microbiological food safety hazard, the agency believes cattle slaughter establishments must have other controls in place to limit the cross-contamination and spread of the pathogen on the live animals in the lairage (i.e., holding pen) and subsequent steps in the slaughter process. A prudent establishment considers controls of its process, for example, based on conditions of the animals' hides at ante-mortem (e.g., mud score). The agency believes that cattle slaughter establishments must control the processing environment on the slaughter floor. Effective implementation of Sanitation Standard Operating Procedures (SOPs) (9 CFR 416.12), sanitary dressing procedures (9 CFR 416.1), temperature controls, and good manufacturing procedures limit the food safety hazard of *E. coli* O157:H7 through written control (prerequisite) programs (FSIS Directive 6410.1, *Verifying Sanitary Dressing and Process Control Procedures in Slaughter Operations of Cattle of Any Age*).

Additionally, the agency recommended in the *Federal Register* Notice [Docket No. 00-022N] that cattle slaughter establishments "consider that *E. coli* O157:H7 prevalence may be higher in April through September than during other times of the year, resulting in a need to account for this increased prevalence in its HACCP systems." Cattle slaughter establishments may need to conduct more frequent or more rigorous verification activities, and they may need to employ more rigorous interventions during April through September than during other times of the year.

Q. *Are establishments required to provide access to their HACCP plan and supporting documentation to inspection program personnel so that they can record information into Public Health Information System (PHIS)?*

A. Yes. 9 CFR 417.5(f) states: "All records required by this part (Part 417) and all plans and procedures required by this part shall be available for official review." The type of information recorded into PHIS includes the HACCP product categories, general processing steps, hazards controlled or prevented, a list of CCPs and prerequisite programs, finished product categories, and product volume ranges. The agency requires the type of data that it does record in order to best focus its inspection resources, including sampling to verify compliance with its requirements, and protect public health.