

Allergens are a leading cause of product recalls in the United States and prevalent health concern for millions of consumers worldwide. Our allergen testing services can help you insure the integrity of your product, protect your company from damaging liability claims and minimize the risk of costly recalls.

According to estimates, eleven million people in the U.S., both young and old, suffer from food allergies. Although they affect only a small portion of our population, the health implications can be serious. Allergic reactions lead to about 29,000 hospital visits and 150 – 200 estimated deaths each year, according to a Journal of Allergy and Clinical Immunology report.

Food companies are making allergen management programs an integral part of their quality systems.

Executive Summary: Food Allergen Labeling and Consumer Protection Act

On August 2, President Bush signed into law the 'Food Allergen Labeling and Consumer Protection Act of 2004'. Under the Senate bill (S. 741), food manufacturers are required to clearly label food products with common names to describe the presence of the eight major food allergens.

The Big Eight allergens include milk, eggs, fish (i.e. bass, flounder, or cod), crustacean shellfish (i.e. crab, lobster, or shrimp), tree nuts (i.e. almonds, pecans, or walnuts), peanuts, wheat, and soybeans. The eight major food allergens are associated with 90 percent of all reported allergic reactions to foods in the United States.

Labeling requirements

Under Section 203 of the Act, food manufacturers are required to identify all allergens in a 'plain, common language,' and to use the word 'Contains' on food labeling to identify major allergens by their 'common or usual name.' The disclosure of all allergenic ingredients will require manufacturers to clarify technical ingredient names (i.e. whey) in order to notify consumers of potential allergens using common names (i.e. milk).

If an ingredient is derived from a major food allergen, then manufacturers will be required to use the word 'Contains,' followed by the name of the food allergen adjacent to the list of ingredients. The use of 'Contains' to underscore the name of the food source is not required if "the common or usual name of the ingredient uses the name of the food source" (i.e. wheat starch) or if the name of the food source "appears elsewhere in the ingredient list." If two or more ingredients are derived from the same allergen, then only one ingredient must be identified as derived from a major allergen.

Any flavoring, coloring or incidental additive that contains a major food allergen will be subject to the new labeling law (Section 203). Food manufacturers can request labeling exemptions to this rule if scientific evidence can demonstrate the food ingredient will not pose a risk to human health.

Ingredients containing or derived from major food allergens can be exempt from the labeling requirements if scientific evidence shows the ingredient lacks allergenic protein, or the ingredient does not pose a risk to human health. Moreover, any highly refined oil or any ingredient derived from a highly refined oil is exempt. For example, a highly refined oil containing an allergenic protein would not be required to list the major food allergen on the label since the allergenic properties of the ingredient should be destroyed during processing. Currently, highly refined oils, raw agricultural commodities, and alcoholic beverages are exempt from the labeling requirements.

Under Section 206 of the Act, the Food and Drug Administration is required to issue a proposed rule to "define, and permit the use of, the term 'gluten-free' on the labeling of foods. A final rule to permit the use of 'gluten-free' on food labels is expected within four years. Currently, Canadian labeling regulations state that a 'gluten-free' food cannot contain any amount of wheat (including spelt and kamut), oats, barley, rye or triticale.

Inspections

Section 205 of the Act requires the FDA to conduct inspections of all food facilities (manufacturing, processing, packaging, and storage) to:

- (1) ensure the firm is complying with practices to reduce or eliminate the cross-contact of a food with unintentional allergenic ingredients or allergenic protein residues; and to
- (2) verify the proper labeling of major food allergens on foods.

Food Code revision

Section 209 of the Act recommends a revision of the federal Food Code “to provide guidelines for preparing allergen-free foods in food establishments, including restaurants, grocery store delicatessens and bakeries, and elementary and secondary school cafeterias.”

Report on food allergens (Section 204)

Within 18 months, the Department of Health and Human Services will be required to issue a report to Congress concerning the handling of allergens during food processing. The study will evaluate the unintentional contamination of foods with major allergens during processing, and determine if good manufacturing practices or other methods can be utilized to alleviate this problem. In addition, the report will summarize the number of food facility inspections conducted within the previous two years, and describe the violations found in facilities. Violations commonly found in food facilities include the improper labeling of foods containing food allergens and ineffective manufacturing controls that allow the cross-contact of allergen residues with non-allergenic foods during processing.

Effective Date

All packaged foods must be in compliance by January 1, 2006.