

CRS Report for Congress

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Food Labeling: Allergy Information

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Summary

Media attention to food allergies is the result of the recent tracking of food allergy sufferers and a clear rise in the number of affected individuals. Several efforts are underway to improve the ability of individuals who have a food allergy to avoid products that cause symptoms that can range from mild to serious. The Food and Drug Administration (FDA) and the Food Allergy Issues Alliance each have released guidelines to address the issues of labeling and cross-contamination. Nine state attorneys general have petitioned FDA for stricter rules, which are also supported by some consumer groups. The FY2002 agriculture appropriations bill directed FDA to address and report on cross-contamination; however, this report had not yet been submitted. Most recently, the Food Allergen Labeling and Consumer Protection Act of 2004 (P.L. 108-282) was enacted on August 2, 2004. This report will provide background on food allergies and review efforts to provide improved labeling information for food allergy sufferers; it will be updated to reflect legislative or other activity.

Background

The media attention to the reported incidence of food allergies and a number of fatal reactions seems to be the result of recent government tracking of the incidence of this health problem as well as a recognized increase in the number of cases.¹ The most common food allergies are caused by milk, tree nuts, fish, shellfish, soy, eggs, peanuts and wheat. These foods account for about 90% of all food allergies. Food allergies are estimated to affect about 4 million individuals in the United States. Sensitive individuals can develop a range of symptoms that can be mild or life-threatening allergic reactions, if exposed to a causative allergen. There is no known cure for food allergies and they can only be managed by avoiding foods containing the known allergens. Recent research

¹ S. Dominus, *The Allergy Prison* New York Times Magazine, Section 6, June 10, 2001, p. 62.

suggests that a monoclonal antibody being studied may provide short-term protection against most unintended ingestion of peanuts.²

A number of different conditions tend to fall under the heading of food allergies in the common vernacular. In most cases, the term “allergy” is used to describe the reaction to a food ingredient that causes a sensitivity response in the person who consumed it. A classic allergy occurs when the body’s immune system mistakes a harmless food protein (amino acid sequence) for a virus or bacterium. Antibodies attach themselves to the food molecule which then signal other immune cells to attack by releasing histamines or other destructive chemicals. The body’s attempt to rid itself of this “foreign substance” can produce various symptoms, including skin rash, nausea, vomiting, diarrhea, intestinal cramps and spasm, headache or migraine, and swelling in various parts of the body.

A small percentage of food-allergic individuals experience severe reactions, called anaphylaxis. Anaphylactic shock is a relatively rare, but severe and potentially life-threatening, allergic reaction resulting in swelling of the throat and air passage constrictions. Symptoms usually appear within minutes of exposure to the allergen and immediate medical attention is necessary. This reaction requires the intravenous administration of epinephrine (adrenaline) to open the airways, and close medical followup. An estimated 150 Americans die each year from severe allergic reactions to food, such as the reaction to peanuts.

There are several adverse reactions to foods that involve the body’s metabolism, but not the immune system, and therefore, the sensitivity is not a true allergy. Food intolerance occurs when the body is unable to metabolize certain foods because of food poisoning or the inability to digest certain food components, such as lactose (milk sugar), usually due to a lack of a particular enzyme. Food aversion is a dislike and avoidance of a food or foods for purely psychological reasons, usually due to an association of that food with a traumatic event or an eating disorder. Food addiction involves the body craving one particular food and suffering withdrawal symptoms when it is removed from the diet. For general sensitivity, the cause is usually unknown, but chemical additives or pesticide residues may be a factor.

FDA Activities

FDA issued an Allergy Warning Letter in June 1996,³ which sought to alert food manufacturers to the agency’s concerns about the labeling of foods that contain allergenic substances. The letter followed numerous reports to FDA concerning consumers who had experienced adverse reactions after exposure to an allergenic substance in a food that did not declare the allergen in the food labeling. While the Food, Drug and Cosmetic Act (FDCA) requires, in virtually all cases, a complete listing of all ingredients of a food, two narrow exemptions appear to provide the reason for recent allergic incidents. The first exemption provides for spices, flavorings and colorings to be declared collectively,

² D. Leung, et al., Effect of Anti-IgE Therapy in Patients with Peanut Allergy, *New England Journal of Medicine*, vol. 348, no. 11, Mar. 13, 2003, pp. 986-993.

³ U.S. Food and Drug Administration, Center for Food Safety and Applied Nutrition, FDA Allergy Warning Letter: Label Declaration of Allergenic Substances in Foods, from Fred Shank, June 10, 1996, p. 3.

without naming each one present. The second exemption from ingredient declarations concerns incidental additives, such as processing aids, that are present in insignificant amounts and do not provide a technical or functional effect in the finished food. For the allergic individual, knowledge that a specific allergenic spice, flavoring or color or incidental additive, even in insignificant amounts, is present, may be very important in avoiding these foods.

In the spring of 2000, FDA received a petition from attorneys general in nine states requesting that the agency issue new labeling regulations for food allergens.⁴ The petition requested that a symbol (such as the letter A in a circle) be created and prominently displayed on the upper right corner of food packages, a toll-free hotline be set up for reliable food ingredient information, food labels be required to specify when allergen ingredients were known to be used, and food industry guidelines be established to prevent cross-contamination. Allergenic ingredients can be inadvertently introduced into a food through “cross-contamination,” which is the migration of such substances from equipment and utensils resulting in an allergenic food. FDA has yet to respond to this petition in the form of regulations.

In April 2001, FDA released its most recent voluntary guidance on this issue, which is the compliance policy guide entitled Statement of Policy for Labeling and Preventing Cross-contact of Common Food Allergens.⁵ The FDA guide recommends complete listing of direct addition of an allergenic ingredient (or sub-ingredient), no ingredient labeling exemptions for incidental additives known to be allergens, and sanitary practices to prevent potential allergen cross-contact. The compliance policy guidance also contains regulatory action criteria for determining when product seizure and legal action are necessary, because of mislabeling or adulteration of the product containing a known food allergen.

FDA announced plans to conduct inspections of plants to assure that allergenic ingredients are not becoming part of the food and candy inadvertently through cross-contamination.⁶ The agency stated in 2001 that it would inspect thousands of candy makers, bakeries and other food manufacturers over the next two years. Candy is a particular problem because of the frequent use of nuts and peanut oil in some products and not in others, but cross-contamination occurs due to residues left after inadequate cleaning of assembly line equipment.

The agency convened a public meeting on August 13, 2001 to discuss the labeling of foods containing allergens and the inadvertent addition of allergens due to processing

⁴ Citizen Petition to the Food and Drug Administration, at [http://www.oag.state.ny.us/press/2000/may/may26a_attach_00.html].

⁵ Food and Drug Administration, Compliance Policy Guide, Compliance Policy Guidance for FDA Staff, Notice to Manufacturers on Policy for Labeling and Preventing Cross-Contact of Common Allergens, at [http://www.fda.gov/ora/compliance_ref/cpg/cpgfod/cpg555-250.htm].

⁶ FDA to continue allergen inspections, Food Chemical News, vol. 43, no. 18, June 18, 2001, pp. 27-28.

practices.⁷ The session focused on whether the source of the ingredient or plain English labeling should be used, the need for supplemental labeling (such as “may contain”), and labeling of ingredients exempted from declaration, such as common or usual names of flavorings, colors and spices. A subsequent workshop on food labeling and allergen declaration was convened in January 2002 in Kansas City at the request of the State of Missouri to address these issues and the particular impact on small business and startups.⁸

In July 2004 FDA announced plans to propose rules by the end of 2004 to require companies to clearly label the color additives carmine and cochineal extract when used in food products, because they can illicit the same symptoms as the other known food allergens. On August 19, 2005, FDA convened a public meeting to obtain comments on defining and permitting voluntary use on food labeling of the term ‘gluten-free’.⁹ The meeting focused on food manufacturing, analytical methods and consumer issues related to reduced levels of gluten in food. No further regulatory action has been taken on either issue.

Voluntary Guidelines

In May 2001 the Food Allergy Issues Alliance submitted to FDA a consensus document entitled Food Allergen Labeling Guidelines.¹⁰ The Alliance is a group of food trade associations and other interested organizations that convene to discuss allergy issues. The Guidelines are intended to assist food manufacturers to inform food allergic consumers about the presence of the eight major food allergens in their products in consumer-friendly terms. These terms would be listed on the information panel of food products separate from the ingredient declaration. The Alliance seeks FDA clarification through appropriate guidance that presentation of this information would not be considered mislabeling. The Guidelines are presented as an option that would not require new regulations.

The Food Allergen Labeling Guidelines contain four parts. They identify the eight types of allergens that are estimated to cause more than 90% of all food reactions (see listing on page 1). The Guidelines specify the use of ingredient terms commonly understood by consumers so that the words eggs, fish, milk, peanuts, shrimp, soy, walnut or wheat would be disclosed following the label declaration. Product labels complying with these Guidelines would contain a label declaration of a major food allergen, by highlighting its presence in one of several ways (specific statement, asterisk, parenthetical, naming or bolding). Supplemental allergen statements would be used in rare cases where the inadvertent and uncontrollable contact with a major food allergen

⁷ U.S. Food and Drug Administration, Food Safety and Food Labeling: Presence and Labeling of Allergens in Foods, Announcement of Public Meeting, *Federal Register*, vol. 66, no. 143, July 25, 2001, p. 38572.

⁸ U.S. Food and Drug Administration, *FDA Food Labeling and Allergen Declaration*; Notice of Public Workshop, *Federal Register*, vol. 66, no. 246, Dec. 21, 2001, p. 65976.

⁹ U.S. Food and Drug Administration, *Food Labeling; Gluten-Free Labeling of Foods*; Public Meeting; Request for Comments, *Federal Register*, vol. 70, no. 137, July 19, 2005, p. 41356.

¹⁰ *Food Allergy Issues Alliance*, Food Allergen Labeling Guidelines, May 22, 2001, p. 6.

occurs, although the Guidelines indicate that these statements are not a substitute for good manufacturing practices.

Legislation

In recent Congresses, constituent mail has generated concern about the food allergy labeling issue. Several transportation funding bills have contained provisions that would limit the availability of peanut snacks on airplane flights. However, none of these provisions have ever passed in the final appropriations bills. Several resolutions have been introduced in past years that would direct the Department of Transportation to rescind an earlier DOT directive to establish peanut-free zones on airplane flights when the problem of allergic reactions to air travel peanut snacks first began to occur.

On June 13, 2001, the House Committee on Appropriations adopted an amendment encouraging FDA to promulgate regulations to prevent cross-contamination of foods by undeclared allergens. The Committee adopted the amendment offered by Representative Lowey during its consideration of the FY2002 appropriations bill for the Department of Agriculture and FDA (P.L. 107-76). The amendment also required FDA to report to the Committee by March 1, 2002 on its plans for preventing cross-contamination of foods by undeclared allergens. However, FDA's two-year inspection survey of manufacturing operations, which started in 2001, was to provide the data for this report, which the agency anticipated delivering by the end of 2003. Thus far, this report has not been submitted.

Bills were introduced in the last three Congresses to require the labeling of food products to provide specific information on known allergens. Most recently, the Food Allergen Labeling and Consumer Protection Act of 2004 was introduced as companion bills, S. 741 and H.R. 3684, by Senator Sessions and Representative Lowey and enacted as P.L.108-282 on August 2, 2004. The new law requires that food labeling list in common language any of the eight known food allergens and their food source contained in a product. The labeling requirements apply to raw agricultural commodities, spices, flavorings, colorings, and incidental additives, if food allergens are present. The law also specifies two format options for allergen information to appear on products, and provides for civil penalties for noncompliance after the effective date of January 1, 2006. The legislation requires the Secretary to issue a report to Congress within 18 months of enactment about food allergen cross-contact, advisory labeling and food allergen inspections conducted under this authority. The Secretary is to issue a proposed rule, within two years and a final rule within four years, that defines the term gluten-free for voluntary use in food labeling. The Centers for Disease Control and Prevention will be required to establish a system for tracking food-allergic-related deaths and other clinically significant and serious adverse events. The National Institutes of Health is directed to convene an expert panel to develop recommendations for research activities concerning food allergens within a year. The Secretary is directed to pursue revision of the Food Code to provide guidelines for preparing allergen-free foods in food establishments and provide technical assistance relating to emergency treatment of allergic responses to foods.

Observations on Food Allergy Labeling

For food allergy sufferers, providing ingredient information that will facilitate their selection of foods that do not contain allergens will be useful. Easy identification, by use of a well-recognized symbol and/or specific terms or phrases on packages, frequently suggested in the past, is now mandated under the new law. The requirements for full listing of all known allergenic ingredients, without exceptions for spices, flavoring and colors, the adoption of good manufacturing practices that eliminate the cross-contamination of food products, and identification of incidental additives are several mechanisms that had been sought by various proponents of food allergy labeling. Also suggested have been the elimination of peanut snacks on airlines and peanut butter in school/child care settings. The recent tracking of the incidence and severity of food allergies in some individuals led to increased support for additional labeling information on food packages, since the number of affected individuals seems to have increased.

However, alternative options and additional issues may be raised. Consumer education on the terms, technical or not, and symbols that assist in identifying ingredients that individuals wish to avoid may be necessary to alert food allergy sufferers of the presence of potential allergens. The separate listing of potential allergens, while easily identifiable, may create space and printing size problems on small food packages. Many food allergy reactions occur in situations outside of individuals' homes where label information is not available. The law has addressed this situation by requiring revision of the food code for restaurants, schools, day care, summer camps, grocery store delicatessens and bakeries. In the early 1990s, when sulfites in salad bars were a problem, restaurants used posted signs to alert consumers. Some child care centers and schools have considered an outright ban on peanut butter in their facilities. While this solution appears easy on the surface, it assumes 100% compliance and could create a more hazardous situation, if no one is prepared and trained to assist a child when someone unwittingly sends a peanut butter sandwich to school. Someone could be designated as the individual in a particular school to be prepared to administer injections of epinephrine to a child who has a reaction. However, this decision would be made within local school districts, along with consideration of training and liability.

A recent concern related to food allergy has been development of genetically modified foods and the potential for certain genes to cause food allergies when inserted into other plants and animals. There has been no evidence to date that this technology has resulted in any allergenic problems. Use of these foods will continue to be closely monitored by the federal agencies and outside groups with interest in food allergy problems. FDA's policy continues to be that the presence of any known allergen needs to be labeled. On the other hand, genetically modified foods may hold the potential to eliminate food allergies by removing the allergenic gene from plants or animal products that otherwise need to be avoided by individuals who are allergic to a particular food.

Congressional interest in this issue is likely to continue, with the reports required to be prepared for its use by FDA on regulating the labeling of food allergens, CDC data collection on the food-related allergic response and NIH on research needs. Completion of the reports may become the issue, as the FDA cross-contamination report requested in the FY2002 agriculture appropriation by March 1, 2002 has not yet been transmitted. Future attention will likely be through oversight of the new law's impact on addressing the problems of consumers with allergic reactions to certain food constituents.