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Food Labeling: Allergy Information

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CRS Report for Congress

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 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, which it did in July 2006. The Food Allergen Labeling and Consumer Protection Act of 2004 (P.L. 108-282) was enacted on August 2, 2004. FDA proposed a rule for gluten labeling in January 2007. This report provides background on food allergies and review efforts to provide improved labeling information for food allergy sufferers; it will be updated to reflect new developments.

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 suggests that a monoclonal antibody being studied may provide short-term protection

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

against most unintended ingestion of peanuts.² Other research is trying to determine whether children with peanut allergies can be desensitized and eventually cured.³

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, while relatively rare, is a 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 an 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 (e.g., reactions 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 a person’s association of a food with a traumatic event or an eating disorder. Food addiction involves the body craving a 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

In June 1996, FDA issued an Allergy Warning Letter⁴ 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

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 Nash, S.D. et al. Oral peanut immunotherapy for peanut allergic patients. Abstract 622, J. Allergy Clinical Immunology, January 2007, vol. 199 no. 1.

⁴ 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.

(FDCA) generally requires a complete listing of all ingredients in a food, two narrow exemptions appear to be connected to the recent allergic incidents. The first exemption provides for spices, flavorings, and colorings to be declared collectively, without specifying 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 2000, FDA received a petition from attorneys general in nine states requesting that the agency issue new labeling regulations for food allergens.⁵ 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 the voluntary compliance policy guide entitled Statement of Policy for Labeling and Preventing Cross-contact of Common Food Allergens.⁶ The FDA guide recommends complete listings of direct additions of allergenic ingredients (or sub-ingredients), 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.

That year FDA also announced plans to conduct inspections in thousands of plants of candy makers, bakeries, and other food manufacturers over a two-year period to assure that allergenic ingredients were not inadvertently becoming part of the food and candy through cross-contamination.⁷ Candy is a particular problem because of the frequent use of nuts and peanut oil in some products and not in others. Cross-contamination occurs due to residues left after inadequate cleaning of assembly line equipment.

⁵ Citizen Petition to the Food and Drug Administration, at [http://www.oag.state.ny.us/press/2000/may/may26a_attach_00.html].

⁶ 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].

⁷ FDA to continue allergen inspections, Food Chemical News, vol. 43, no. 18, June 18, 2001, pp. 27-28.

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 practices.⁸ 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.⁹

In July 2004, FDA announced plans to propose rules 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, but no proposed rules have been published. In 2005, FDA convened a public meeting to obtain comments on defining and permitting voluntary use on food labeling of the term “gluten-free.”¹⁰ It focused on food manufacturing, analytical methods, and consumer issues related to reduced levels of gluten in food. In January 2007, the agency published a proposed rule for a definition of gluten-free for the voluntary labeling of food products.¹¹

Voluntary Guidelines

In May 2001 the Food Allergy Issues Alliance submitted to FDA a consensus document entitled Food Allergen Labeling Guidelines.¹² The Alliance is a group of food trade associations and other interested organizations that convene to discuss allergy issues. The Guidelines were 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 sought FDA clarification through appropriate guidance that presentation of this information would not be considered mislabeling, and the document was presented as an alternative to new regulations.

The Food Allergen Labeling Guidelines identified the eight types of allergens (listed on page 1) that are estimated to cause more than 90% of all food reactions. The Guidelines specified the use of ingredient terms commonly understood by consumers so that the words eggs, fish, milk, peanuts, shrimp, soy, walnut, and 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 through the use of a specific statement, asterisk, parenthetical, naming or

⁸ 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.

⁹ 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.

¹⁰ 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.

¹¹ U.S. Food and Drug Administration, *Food Labeling; Gluten-Free Labeling of Foods*; Proposed rule; *Federal Register*, vol. 72, no. xxx, January 23, 2007, p. 2795.

¹² *Food Allergy Issues Alliance*, Food Allergen Labeling Guidelines, May 22, 2001, p. 6.

bolding. Supplemental allergen statements would be used in rare cases where the inadvertent and uncontrollable contact with a major food allergen occurs, although the Guidelines indicated 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 contained provisions that would have limited the availability of peanut snacks on airplane flights; however, none of these provisions has ever been enacted. 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 amendment offered by Representative Lowey was adopted during its consideration of the FY2002 appropriations bill for the Department of Agriculture and FDA (P.L. 107-76). It also required FDA to report to the committee by March 1, 2002, on its plans for preventing cross-contamination of foods by undeclared allergens. In 2001, FDA announced the start of a two-year inspection survey of manufacturing operations to provide data for the cross-contamination report, which it anticipated delivering by the end of 2003. This report was released in July 2006.¹³

Bills were introduced in the 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 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 required 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 was to issue a proposed rule, within two years and a final rule within four years, that defined the term gluten-free for voluntary use in food labeling. The Centers for Disease Control and Prevention was required to establish a system for tracking food-allergic-related deaths and other clinically significant and serious adverse events. The National Institutes of Health was directed to convene an expert panel to develop recommendations for research activities concerning food allergens within a year. The Secretary was 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.

¹³ HHS. Food and Drug Administration. Food Allergen Labeling and Consumer Protection Act of 2004 Public Law 108-282 Report to Congress, July 2006, 33p.

Observations on Food Allergy Labeling

For food allergy sufferers, providing ingredient information that will facilitate their selection of foods that do not contain allergens should be useful. Easy identification, by use of a well-recognized symbol and/or specific terms or phrases on packages, as frequently suggested in the past, is now mandated under the 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 the identification of incidental additives are several mechanisms that have 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 individuals in identifying ingredients they wish to avoid may be necessary to alert food allergy sufferers to 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 imposing 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 an affected child after someone has unwittingly sent a peanut butter sandwich to school. A particular individual in a school could be designated as the person prepared to administer injections of epinephrine to a child who has a reaction. However, this decision would be made within local school districts, and would require 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 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 reports required to be prepared by FDA for its use 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 reports frequently are released after the statutory delivery dates. 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.