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FOOD ALLERGEN LABELING

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Background

The law places the burden on food manufacturers to give consumers adequate warnings of any dangers associated with the consumption of their products.¹ This duty includes notifying consumers of the potential allergic characteristics of their food.²

Congress recognized this need to notify consumers back in 1938 with passage of the Federal Food, Drug, and Cosmetic Act (FDCA), which mandated ingredient labeling.³ Congress recognized that allergic consumers need to know which foods were safe for them to eat.⁴ This landmark 1938 labeling requirement remained basically unchanged for decades.

In recent years, however, awareness grew that the 1938 requirement was no longer adequate. Medical science cannot cure food allergies. Therefore, the only way to treat a food allergy is to avoid of the offending substance. The consequences of a mistake can be fatal. Each year, an estimated 150 to 200 Americans die from allergic reactions to food.⁵

Unfortunately, under the 1938 law, however, even the most diligent label readers can inadvertently be exposed to allergens. In particular, the law allows generic listing of colors, flavors, and spices. Flavors and colors may contain hidden allergens because they were derived from a major food allergen.

Consumers may also become confused by the names of ingredients. A child, for example, is not likely to understand that potassium caseinate is derived from milk. This confusion can be aggravated if the food is also labeled “non-dairy.”

According to Anne Munoz-Furlong, “Every year milk-allergic children have a reaction because their parents, babysitters, grandparents, or friend’s parents believe the ‘nondairy’ description on the front of the package actually means the product does not contain milk proteins or derivatives. Only after a reaction do these caregivers learn that even if a product contains casein, a milk protein.”⁶

Another impetus for change in the law is that food allergy appears to be on the rise. “The prevalence of food allergy is growing and probably will continue to grow along with all allergic diseases,” says Robert A. Wood, M.D., director of the pediatric allergy clinic at Johns Hopkins Medical Institutions in Baltimore.⁷

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The New Food Allergen Labeling Act

Under the Food Allergen Labeling and Consumer Protection Act (FALCPA), food manufacturers must declare the common name for allergenic substances for food labeled on or after January 1, 2006.⁸ The major allergens requiring labeling are: milk, eggs, fish, Crustacea (shellfish), tree nuts, wheat, peanuts, and soybeans.⁹ These eight allergens are estimated to account for 90 percent of food allergies in the United States.¹⁰

The Major Eight Food Allergens

Allergen	Common Name of Allergen Source	Some Foods Derived from the Allergen Source
Milk	Milk	Casein, caseinate, curds, lactalbumin, nougat, rennet casein, whey
Eggs	Eggs	Albumin, eggnog, meringue
Fish	Common specific name, e.g., bass, flounder, or cod	Surimi
Crustacea (shellfish)	Common specific name; e.g., crab, lobster, or shrimp	Crab, lobster, shrimp
Tree Nuts	Common specific name; e.g., almonds, pecans, or walnuts	Almonds, Brazil nuts, cashews, hazelnuts (filberts), pecans, pine nuts, pistachios, macadamia, walnuts
Wheat	Wheat	Bran, bulgur, couscous, durum, farina, gluten, matzoh, kamut, semolina
Peanuts	Peanuts	Beer nuts, goobers, peanut flour, nutmeal
Soybeans	Soybeans	Hydrolyzed soy protein, miso, TVP, textured soy protein

What is Required?

Under the FALCPA, food labeling must identify the major allergens by their common name (column two above). Two labeling options are available:

- 1) Label with the statement, “Contains [allergen food source]” immediately after or adjacent to the list of ingredients in a type size no smaller than the type size used in the list of ingredients (e.g., “Contains peanuts”); or
- 2) Include the allergen source name in parentheses in the list of ingredients immediately after the ingredient; e.g., “Casein (Milk).”¹¹

There is an exemption from the above labeling, if the name of the food source from which the major food allergen is derived appears elsewhere in the ingredient list. However, this exemption does not apply if the name of the food source appears as part of the name of a food ingredient that is not a major food allergen.

Note that flavorings, colorings, and incidental additives are subject to these new allergen labeling requirements when they contain a major allergens. This bears highlighting because the FALCPA requirements apply notwithstanding exemptions listed for flavorings, colorings, and incidental additives in other laws.

Exemptions, Petition, and Notification

Highly refined oils, and ingredients derived from those oils, are specifically exempt from the definition of major food allergen. This is based on research that indicates that protein is not detectable in highly refined oil.¹² Unfortunately, “highly refined oils” is not defined in the act. The Senate Report on FALCPA does note that “highly refined oils” are refined, bleached, deodorized oils, but this does not provide much guidance.¹³ Therefore, firms bear the burden of care that any oil touted as “highly refined” actually is free of major allergen proteins.

Highly refined oil is the only FALCPA exemption for a specific food. However, food manufacturers may petition for exemption from the requirements for other foods. The petitioner must provide scientific evidence that the “food ingredient, as derived by the method specified in the petition, does not cause an allergic response that poses a risk to human health.”¹⁴ The Food and Drug Administration (FDA) then has 180 days to approve or deny the petition, or the petition is deemed denied unless both parties agree to an extension.

However, a notification may be filed instead of a petition, if the manufacturer can provide scientific evidence that the food ingredient does not contain allergic protein.¹⁵ The notification must contain either the scientific evidence that demonstrates that the food ingredient does not contain allergenic protein; or a determination by the FDA that the ingredient does not cause an allergic response that poses a risk to human health. This latter provision recognizes that FDA, during evaluation of a food additive approval petition or other FDA activities, may determine that a food ingredient does not cause an allergic response. Ninety days after FDA’s receipt of the notification, a food ingredient may be introduced into interstate commerce, unless FDA determines the notification is inadequate.

Effective Date

The effective date of the new labeling requirements is January 1, 2006. All food labeling on or after this date must comply with the new requirements. However, a food labeled before that date does not have to be relabeled or pulled from grocery shelves.

Nonetheless, manufacturers would be prudent to adopt the new labeling requirements as soon as practical. Among other reasons, advance compliance may reduce liability from consumer lawsuits.¹⁶

Of course, many firms already have voluntarily labeled their products with special allergen labeling. These voluntary efforts may comply with the new FALCPA requirements. In 2001, an alliance of food industry and other interested associations published voluntary food allergy labeling guidelines.¹⁷ Two of the alliance’s recommended formats are essentially the same as the FALCPA labeling requirements.

More to Come

In FALCPA, Congress also directs FDA to conduct a number of activities to improve our nation’s approach to food allergens. FDA is directed to define the term “gluten free” in order to help consumers with celiac disease.¹⁸ FDA is also directed to report to Congress on the issues of contamination of food with food allergens and the use of “may contain” advisories on labels. FDA, in addition, is given the authority to require by regulation further labeling of food allergens.

Congress also directed the Centers for Disease Control (CDC) to improve the collection of data on the prevalence, incidence, and treatment of food allergies.

For these reasons, and the seriousness of the concern over food allergens, there is likely to be a heightened attention by regulatory officials and the food industry on food allergens for a number of years to come. Reduction in the incidence of food allergic reactions is the obvious benefit. However, the food industry can also expect reduced liability. Further, this new law is likely to create an expanded marketplace for food choices offered to allergic consumers.

This summary is for educational and informational purposes only, and is not intended as legal advice. If you have any questions, please contact Neal Fortin.

Endnotes

¹ Products Liability Cases, 12 AM. JUR. TRIALS 1 § 35.

² 47 AM. JUR. PROOF OF FACTS 2d 227 § 1.

³ FDCA § 403(i).

⁴ S. Rep. No. 493 (Mar. 15, 1934).

⁵ Anne Munoz-Furlong., *Living with Food Allergies: Not as Easy as You Might Think*, FDA CONSUMER (August 31, 2001) available at: http://www.fda.gov/fdac/departs/2001/401_word.html (April 12, 2005).

⁶ Anne Munoz-Furlong., *Living with Food Allergies: Not as Easy as You Might Think*, FDA CONSUMER (August 31, 2001) available at: http://www.fda.gov/fdac/departs/2001/401_word.html (April 12, 2005).

⁷ Raymond Formack, Jr., *When Food Becomes the Enemy*, FDA CONSUMER (August 31, 2001) available at: http://www.fda.gov/fdac/features/2001/401_food.html (April 12, 2005); *see also*, Hugh A. Sampson, *Update on Food Allergy*, 113 J. ALLERGY CLIN. IMMUNOL. 805, 806 (2004).

⁸ Pub. L. No. 108-282, 118 Stat. 891(2004).

⁹ FALCPA §203, to be codified as FDCA § 201(qq).

¹⁰ Ricardo Carvajal, *New Food Labeling Requirements on the Horizon: The Food Allergen Labeling and Consumer Protection Act of 2004*, UPDATE: FOOD AND DRUG LAW, REGULATION, AND EDUCATION 20 (January/February 2005).

¹¹ FDCA § 403(w)(1).

¹² *See, e.g.*, Jonathan O. - B. Hourihane, Simon J. Bedwani, Taraneh P. Dean & John O. Warner, *Randomized, Double-Blind, Crossover Challenge Study of Allergenicity of Peanut Oils in Subjects Allergic to Peanuts*, 314 BRIT. MED. J. 1084 (1997).

¹³ S. Rep. No. 108-226 (Feb. 12, 2004).

¹⁴ FDCA § 403(w)(6).

¹⁵ FDCA § 403(w)(7).

¹⁶ If a manufacturer fails in its duty to warn a consumer of possible allergenic ingredient, the consumer can seek to recover damages against the manufacturer under several theories of products liability, including negligence, breach of warranty, and strict liability. These different theories are not mutually exclusive. 47 AM. JUR. PROOF OF FACTS 2d 227 § 1 (2004).

¹⁷ GMA News, *Food Allergy Issues Alliance Labeling Guidelines* (May 31, 2001), available at <http://www.gmabrands.com/news/docs/Testimony.cfm?docid=768&> (last visited April 12, 2005).

¹⁸ Celiac disease is a genetic disease that renders the body incapable of tolerating the gluten found in wheat, barley, rye, and oats.