

THE FOOD ALLERGEN LABELING AND CONSUMER
PROTECTION ACT: THE REQUIREMENTS ENACTED,
CHALLENGES PRESENTED, AND STRATEGIES FATHOMED

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What is food to one man may be fierce poison to others.

LUCRETIVS, DE RERUM NATURA

(ON THE NATURE OF THINGS, 50 B.C.)¹

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¹ JOHN BARTLETT, FAMILIAR QUOTATIONS, 10th ed. (1919) *available at* <http://www.bartleby.com/100/703.2.html> (last visited Sept. 30, 2005).

INTRODUCTION²

The Food Allergen Labeling and Consumer Protection Act (“Food Allergen Act”) was signed into law on August 3, 2004.³ Allergic consumers, parents of allergic children, and consumer groups laud the new law for making it easier to identify potentially deadly allergens in foods and for unveiling allergens previously hidden in foods.⁴

Effective January 1, 2006, the new law requires the labeling of major food allergens in clear, plain language.⁵ The labeling of food allergens is a serious concern for those with food allergies. A food allergy can manifest itself in a variety of symptoms, including urticaria (hives), anaphylaxis, atopic dermatitis, and less commonly acute gastrointestinal responses such as nausea, pain, vomiting, or diarrhea.⁶ Anaphylaxis is a systemic allergic reaction that can lead to anaphylactic shock, a violent and sometimes fatal reaction characterized by hives, respiratory symptoms, and fainting.⁷

An estimated two percent of adults and five percent of infants and young children in the United States suffer from food allergy.⁸ Each year in the United States, roughly 30,000 people require emergency room treatment and 150 individuals die due to allergic reactions to food.⁹ The amount of food needed to trigger an allergic reaction can be very small.¹⁰

² A small part of this paper is adapted from the article, Neal D. Fortin, *Allergen Labeling on the Horizon*, FOOD PRODUCT DESIGN 168 (June 2005).

³ Food Allergen Labeling and Consumer Protection Act of 2004, Pub. L. No. 108-282, 118 Stat. 891 (2004) (to be codified at 21 U.S.C. § 343) (hereinafter “Food Allergen Act”).

⁴ See, e.g., Michael T. Roberts & Margie Alsbrook, *United States Food Law Update*, 1 Journal of Food Law & Policy 187, 192-193 (2005); and Press Release, Food Allergy Initiative, *Food Allergy Initiative Celebrates the Food Allergen Labeling & Consumer Protection Act Becoming Law: Millions of Americans Will Be Able to Easily Identify Safe and Unsafe Foods* (Aug. 5, 2005).

⁵ Food Allergen Act § 203(a) & (d).

⁶ Scott H. Sicherer & Suzanne Teuber, *Current Approach to the Diagnosis and Management of Adverse Reactions to Foods*, 114 J. ALLERGY CLIN. IMMUNOL. 1147 (Nov. 2004).

⁷ See, e.g., MedlinePlus Medical Dictionary at <http://www.nlm.nih.gov/medlineplus/plusdictionary.html> (last visited Oct. 8, 2005); and DORLAND’S ILLUSTRATED MEDICAL DICTIONARY 80, 1409 (25th ed. 1974).

⁸ See Food Allergen Act § 202(1); and Raymond Formack, Jr., *When Food Becomes the Enemy*, FDA CONSUMER (Aug. 31, 2001) at http://www.fda.gov/fdac/features/2001/401_food.html (last visited Apr. 12, 2005).

⁹ *Id.*; and Anne Munoz-Furlong, *Living with Food Allergies: Not as Easy as You Might Think*, FDA CONSUMER (Aug. 31, 2001) available at http://www.fda.gov/fdac/departs/2001/401_word.html (last visited Apr. 12, 2005).

¹⁰ See, e.g., S.L. Taylor, et al., *Factors affecting the determination of threshold doses for allergenic foods: how much is too much?*; 109 J ALLERGY CLIN IMMUNOL. 24-30 (Jan. 2002); Theresa Tamkins, *More Cases of Food Allergy Being Diagnosed*, REUTERS NEWS SERV., Sept. 19, 1997 (children’s’ deaths from exposure to peanuts in foods made with utensils that had touched

The labeling of food allergens is also a serious concern for those with food intolerances.¹¹ “Allergy” is the term for an adverse immune response.¹² “Food intolerance” is the term for various types of adverse reactions to food that do not involve the body’s immune system.¹³ Intolerances include metabolic reactions to food for a variety of unexplained reasons.¹⁴ For example, lactose intolerance is a metabolic intolerance in people who lack the intestinal enzyme lactase needed to digest milk sugar, lactose.¹⁵ The most severe unexplained food intolerance is sulfite sensitivity and sulfite-induced asthma, which triggers a hypersensitivity reaction that can be fatal, but does not involve the body’s immune system.¹⁶

The Food Allergen Act resulted from collaborative efforts. Consumer and patient advocacy groups, medical professionals, and the food industry provided input to Congress on how to provide clear, consistent, and reliable ingredient labeling information on food allergens.¹⁷ The result is a relatively simple and straightforward statute. Even a simple and straightforward law, however, can have some surprising twists.

This section introduces the problem of food allergens. The next section describes the history of food allergen labeling and the reasons leading up to the enactment of the Food Allergen Act. Section III explains the provisions of the Food Allergen Act.

Section IV examines the challenges presented by the requirements of the Act. While this seemingly straightforward statute had widespread support from the

peanut butter, but were considered “clean”); Lorraine Shank, *The Truth About Food Allergies; Sufferers Always Face Danger of Hidden, Related Ingredients*, THE PLAIN DEALER, OCT. 16, 1996, at 1E (a child’s allergic reaction to walnut allergens, resulting from a mother’s touch on the face with her “clean” hands that had earlier touched walnuts).

¹¹ The terms allergy and hypersensitivity are often used interchangeably in product liability case law to indicate adverse reaction to a food. In the medical context and as used in the Food Allergen Act, the terms have meanings that are more precise. See Thomas T. Rogers, *Product Liability: The Allergic Plaintiff—Formulating a Cause of Action in Oklahoma*, 30 OKLA. L. REV. 439-440 & n.3 (1977).

¹² Scott H. Sicherer & Suzanne Teuber, *Current Approach to the Diagnosis and Management of Adverse Reactions to Foods*, 114 J. ALLERGY CLIN. IMMUNOL. 1146 (Nov. 2004).

¹³ INTERNATIONAL FOOD INFORMATION COUNCIL FOUNDATION, UNDERSTANDING FOOD ALLERGY 4 and 6 (2001); citing S.L. Taylor *et al.*, *Food Allergies and Sensitivities*, in FOOD TOXICOLOGY 1-36 (Helferich W. Winter ed., 2000).

¹⁴ *Id.*

¹⁵ *Id.*

¹⁶ *Id.*

¹⁷ See, e.g., Press Release, Food Allergy Initiative, *Food Allergy Initiative Celebrates the Food Allergen Labeling & Consumer Protection Act Becoming Law: Millions of Americans Will Be Able to Easily Identify Safe and Unsafe Foods* (Aug. 5, 2005); and Press Release, Food Allergy and Anaphylaxis Network, *President Bush Signs Food Allergen Labeling and Consumer Protection Act, Historic Day for the Eleven Million Americans with Food Allergies* (Aug. 3, 2004), available at http://www.foodallergy.org/press_releases/falcpasign.html (last visited Apr. 12, 2005).

industry, it nonetheless, still presents potential problems to the food industry.¹⁸ Most of these concerns center on the lack of allergen threshold levels as triggers for labeling. Related labeling concerns arise due to the potential of excessive warnings creating confusion and counterproductive consumer behavior. Finally, Section V discusses some strategies for dealing with the challenges of the Food Allergen Act.

I. BACKGROUND

A. Some History of Allergen Labeling Requirements

The law places a heavy burden on food manufacturers to give consumers adequate warnings of any dangers associated with the consumption of their products.¹⁹ This duty includes notifying consumers of the potential allergic characteristics of their food.²⁰ In general, this duty to notify consumers applies when an ingredient's allergenicity is not generally known, or the food is one in which the consumer would not expect to find a particular allergen.²¹

¹⁸ See, e.g., Tom Trautman, *Labeling Food Allergens*, 59 FOOD TECH. 92 (Feb. 2005) (“Nevertheless, a good law that has support from all parties, including the regulated industry, can still present potential problems in terms of implementation.”); *and Id.*

¹⁹ Products Liability Cases, 12 AM. JUR. TRIALS 1 § 35; *see also* RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 6 (1998); *and* RESTATEMENT (SECOND) OF TORTS § 402A (1965).

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

²¹ Under the Restatement (Second) of Torts, “One who sells any product in a defective condition unreasonably dangerous to the user or consumer . . . is subject to liability for physical harm thereby caused to the ultimate user or consumer . . .” RESTATEMENT (SECOND) OF TORTS § 402A (1965). Comment j explains that notifications or warnings on the label of the product may be required in order to prevent the product from being unreasonably dangerous; however, the seller may reasonably assume that he need not warn against common allergies, of which allergic consumer are generally already aware. “Where, however, the product contains an ingredient to which a substantial number of the population are allergic, and the ingredient is one whose danger is not generally known, or if known is one which the consumer would reasonably not expect to find in the product, the seller is required to give warning against it, if he has knowledge, or by the application of reasonable, developed human skill and foresight should have knowledge, of the presence of the ingredient and the danger.” *Id.* at cmt. j.

The Restatement Third of Torts states a similar rule that a product is defective when it is accompanied with “inadequate instructions or warnings” and “the foreseeable risks of harm posed by the product could have been reduced or avoided” by the inclusion of “reasonable instructions or warnings.” RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 2 (1998). Section 7 specifies as to foods, “[A] harm-causing ingredient of [a] food product constitutes a defect if a reasonable consumer would not expect the food product to contain that ingredient.” *Id.* at § 7. Comment k adds, “a warning is required when the harm-causing ingredient is one to which a substantial number of persons are allergic.” *Id.* § 7 at cmt. k. The

Congress recognized the need to notify consumers of potential allergens nearly 70 years ago with passage of the Federal Food, Drug, and Cosmetic Act (FD&C Act) in 1938.²² The FD&C Act mandated ingredient labeling²³ because Congress recognized that allergic consumers need to know which foods were safe for them to eat.²⁴ The landmark nature of this 1938 labeling requirement is evident in the fact it remained essentially unchanged for decades.²⁵

B. Reasons for an Increased Interest in Food Allergens

In recent years, however, awareness grew that the 1938 requirement was no longer adequate. Although the 1938 law was advanced for its time, in today's food marketplace even the most diligent label readers may inadvertently be exposed to allergens.²⁶ In particular, to allow food manufacturers to maintain a level of secrecy in their recipes, the law allows generic listing of colors, flavorings, and spices.²⁷

1. *Peeking under the Wizard's Curtain to See What is Really in Food*

These collective listings of colors, flavorings, and spices may hide major food allergens. For example, an ingredient labeled as "natural flavoring" might include milk or soy protein. Surprising ingredients can hide under the word "flavoring," such as beef extracts in chicken nuggets or chicken patties.²⁸ This exemption from ingredient

Restatement further notes, "the degree of substantiality is not precisely quantifiable," but the burden is on the plaintiff to "show that the allergic predisposition is not unique" to her, but "[t]he more severe the harm, the more justified is a conclusion that the number of persons at risk need not be large to be considered "substantial" so as to require a warning." *Id.*

²² Pub. L. No. 75-717, 52 Stat. 1040 (1938), as amended, 21 U.S.C. §§ 301-397 (2000) (hereinafter "FD&C Act").

²³ FD&C Act § 403(i).

²⁴ S. Rep. No. 493 (Mar. 15, 1934).

²⁵ The most substantial change made was by the Nutrition Labeling and Education Act (NLEA) of 1990, which mandated changes in ingredient declarations for collective terms, sulfites, colors, spices, non-dairy, and certain specific allergenic substances. Codified at 21 U.S.C. §§ 343(Q)-(R) [FD&C Act §§ 403(Q)-(R)]. By comparison, European Union law provided a 25% compound ingredient exemption, under which ingredients making up a compound ingredient in a food were not required to be listed if the compound ingredient made up less than 25% of the finished product. Under a new EU directive, the 25% exemption is eliminated effective November 25, 2005. See EU Directive 2003/89/EC; and *Better European Food Labelling Laws to Help People with Food Intolerances*, 1 Maternal and Child Nutrition 223-224 (2005).

²⁶ Raymond Formack, Jr., *When Food Becomes the Enemy*, FDA CONSUMER (August 31, 2001) at: http://www.fda.gov/fdac/features/2001/401_food.html (last visited Apr. 12, 2005).

²⁷ FD&C Act § 403(i).

²⁸ Eric Schlosser, *Why McDonald's Fries Taste So Good*, THE ATLANTIC MONTHLY 50-56 (Jan. 2001) available at: <http://www.theatlantic.com/issues/2001/01/schlosser.htm>.

labeling has been involved in a number of reported food allergen reactions in recent years.²⁹

In addition, “incidental additives”³⁰ are exempt from ingredient labeling because they are present at what FDA has deemed to be insignificant levels in the finished food.³¹ For example, lecithin is used as a release agent on some processing equipment to help the food separate from the equipment; but this process may impart a small amount of soy protein to the food. This exemption from ingredient labeling has also been involved in a number of reported food allergen reactions in recent years.³²

Moreover, previous law did not prevent manufacturers from using a variety of names for the same type of ingredient.³³ For example, wheat may be labeled as “semolina,” and egg protein may be labeled as “albumin.”³⁴ The names of some ingredients may be particularly confusing to consumers.³⁵ For instance, many do not understand that “caseinate” is derived from milk.³⁶ This confusion is magnified when some foods labeled as “non-dairy” also contain caseinate.³⁷

²⁹ Formack, *supra* note 26.

³⁰ These incidental additives are also called “processing aids.”

³¹ 21 CFR 101.100(a)(3).

³² Formack, *supra* note 26. *Compare* Letter from Fred R. Shank, Director, Center for Food Safety and Applied Nutrition, FDA, Notice To Manufacturers: Label Declaration of Allergenic Substances in Foods (June 10, 1996) *available at*: <http://www.cfsan.fda.gov/~lrd/allerg7.html> (last visited Oct. 18, 2005) (The FDA attributes these allergic events to a misinterpretation of the exemption, which requires both that the incidental additive be present in the food at an insignificant level, and that it must not have any functional effect in the finished food. “Clearly, an amount of a substance that may cause an adverse reaction is not insignificant.”)

³³ *See, e.g., President Bush Signs Bill That Will Benefits Millions with Food Allergies*, OBESITY, FITNESS & WELLNESS WK., Sept. 4, 2004, at 39.

³⁴ 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 (last visited Apr. 12, 2005).

³⁵ *See, e.g., id.* (noting that one study showed less than seven percent of parents with milk allergies could correctly identify products that contained milk); *and* Food Allergen Act § 202(4)-(5).

³⁶ *Id.*

³⁷ Munoz-Furlong, *supra* note 34 (“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.”)

2. *The Growing Concern over Food Allergens*

Another impetus for change in the law is that food allergy is on the rise.³⁸ The prevalence of food allergy is increasing and is expected to continue to increase.³⁹ Perhaps this is the reason behind another trend—rising consumer interest in and attention to food allergens. Kellogg's, for example, reported that the number of consumers contacting their company concerning food allergens has risen from 6,000 in 2001 to more than 13,000 in 2004.⁴⁰

At the same time, the scrutiny by government regulatory agencies has increased. The number of product recalls from undeclared food allergens increased to 121 in 2000 from about 35 a decade earlier.⁴¹ FDA also increased its focus on allergens during inspections and in communication with food manufacturers.⁴² International attention to food allergens grew during this time.⁴³ All the while, increasing scientific knowledge of immunologic mechanisms and allergen chemistry added to the interest.⁴⁴

³⁸ Formack, *supra* note 26 (“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”; see also Hugh A. Sampson, *Update on Food Allergy*, 113 J. ALLERGY CLIN. IMMUNOL. 805, 806 (2004); S. H. Sicherer et al., *Prevalence of Peanut and Tree Nut Allergy in the United States Determined by a Random Digit Dial Telephone Survey: A Five Year Follow-Up Study*, 103(4) J. ALLERGY CLIN. IMMUNOL. (Apr. 1999) 559-62 (“Self-reported peanut allergy has doubled among children from 1997 to 2002.”); and Scott H. Sicherer & Suzanne Teuber, *Current Approach to the Diagnosis and Management of Adverse Reactions to Foods*, 114 J. ALLERGY CLIN. IMMUNOL. 1146 (Nov. 2004).

³⁹ *Id.*

⁴⁰ *Labeling Food Allergens Can be a Struggle*, MANAGED CARE L. WKLY. 119 (Atlanta: Aug 14, 2005) available at: <http://ezproxy.cl.msu.edu:2047/login?url=http://proquest.umi.com/pqdweb?did=877478021&sid=11&Fmt=3&clientId=3552&RQT=309&VName=PQD> (last visited Oct. 4, 2005).

⁴¹ Food Allergen Act § 202(3).

⁴² See Letter from Fred R. Shank, Director, Center for Food Safety and Applied Nutrition, FDA, Notice To Manufacturers: Label Declaration of Allergenic Substances in Foods (June 10, 1996) available at: <http://www.cfsan.fda.gov/~lrd/allerg7.html> (last visited Oct. 18, 2005); FDA, COMPLIANCE POLICY GUIDE § 555.250 STATEMENT OF POLICY FOR LABELING AND PREVENTING CROSS-CONTACT OF COMMON FOOD ALLERGENS (Apr. 19, 2001) available at: http://www.fda.gov/ora/compliance_ref/cpg/cpgfod/cpg555-250.htm (last visited Oct. 18, 2005); and FDA, GUIDANCE ON INSPECTIONS OF FIRMS PRODUCING FOOD PRODUCTS SUSCEPTIBLE TO CONTAMINATION WITH ALLERGENIC INGREDIENTS (Aug. 2001) available at: http://www.fda.gov/ora/inspect_ref/igs/Allergy_Inspection_Guide.htm (last visited Oct. 18, 2005).

⁴³ See, e.g., EU Directive 2003/89/EC; and *Better European Food Labelling Laws to Help People with Food Intolerances*, 1 Maternal and Child Nutrition 223–224 (2005).

⁴⁴ S.L. Taylor & S.L. Hefle, *Food Science Perspective on Food Allergy*, 53 (45 SUPPL.) ALLERGY. 5-7 (1998).

The fear of litigation may have also spurred attention, notably by schools and airlines,⁴⁵ but perhaps surprisingly, the filing of lawsuits has not been frequent.⁴⁶ Nonetheless, the potential for a rise in litigation existed—for example, in an FDA review of randomly selected baked goods, ice cream, and candy in Minnesota and Wisconsin in 1999, 25 percent of the foods failed to list peanuts or eggs as ingredients on the food labels.⁴⁷

Finally, medical science cannot cure food allergies;⁴⁸ therefore, the best means to treat a food allergy is to avoid of the offending substance.⁴⁹ Yet, the threshold dose for allergic reaction can be extremely low.⁵⁰ The potential consequences of an allergen mistake are severe and can even be fatal. Each year, an estimated 150 to 200 Americans die from allergic reactions to food.⁵¹ At the same time, approximately 30,000 Americans require emergency room treatment.⁵² Estimates are that nearly seven million Americans suffer from a food allergy.⁵³

⁴⁵ Jonathan Bridges, *Suing for Peanuts*, 75 NOTRE DAME L. REV. 1269 (2000) (noting the peanut bans at schools and airlines, citing James Bovard, *Designer Disabilities*, Wash. Times, Nov. 12, 1998, at A14; *Budget Deal Halts Mandate for No-Peanut Zones Aloft*, Milwaukee J. Sentinel, Oct. 25, 1998, at 5; Constance L. Hays, *A New Fear of Flying: Peanuts*, N.Y. Times, May 10, 1998, § 4, at 5; Carrie Hedges, *Peanut Ban Spreads to Cafeteria: Schools Worry About Allergies—Or Lawsuits*, USA Today, Dec. 3, 1998, at 17A.

⁴⁶ *Id.* (noting that research turned up few cases involving allergic reaction to nuts).

⁴⁷ Jonathan Bridges, *Suing for Peanuts*, 75 NOTRE DAME L. REV. 1269 (2000); see also Kevin T Higgins, *Eye Know You*, FOOD ENGINEERING 37, 39 (Dec 2004) (“An FDA spot check of 118 food items in 2001 found unlabeled peanuts, tree nuts, milk, eggs, soy, wheat, fish and shellfish in 23 samples.”)

⁴⁸ Scott H. Sicherer and Suzanne Teuber, *Current Approach to the Diagnosis and Management of Adverse Reactions to Foods*, 114 J. ALLERGY CLIN. IMMUNOL. 1146, 1149 (Nov. 2004); see also *Food Allergy*, E. R. PEARL, 1 LIPPINCOTT'S PRIMARY CARE PRACTICE 154 (1997); and Food Allergen Act § 202(2)(B).

⁴⁹ *Id.*

⁵⁰ See, e.g., See, e.g., Theresa Tamkins, *More Cases of Food Allergy Being Diagnosed*, REUTERS NEWS SERV., Sept. 19, 1997 (children's deaths from peanut allergens in foods made with “clean” utensils that had previously only touched peanut butter); Lorraine Shank, *The Truth About Food Allergies; Sufferers Always Face Danger of Hidden, Related Ingredients*, THE PLAIN DEALER, Oct. 16, 1996, at 1E (a child's near fatal allergic reaction to walnuts, resulting from a mother's touch on the face with her “clean” hands that had earlier touched walnuts); and Jim Atkinson, *Food Fright*, TEXAS MONTHLY, Aug. 1997, at 64 (child's near fatal allergic reaction to peanut from a kiss good-night from her brother who had earlier eaten peanut butter).

⁵¹ Munoz-Furlong, *supra* note 34.

⁵² Food Allergen Act § 202(1).

⁵³ Munoz-Furlong, *supra* note 34.

II. THE NEW FOOD ALLERGEN ACT

The Food Allergen Act will be administered largely by the Food and Drug Administration (FDA).⁵⁴ Significantly, the Food Allergen Act does not amend the Federal Meat Inspection Act,⁵⁵ Poultry Products Inspection Act,⁵⁶ or the Egg Products Inspection Act;⁵⁷ therefore, does not directly effect United States Department of Agriculture (USDA) regulated food products. However, the USDA is expected to adopt similar requirements by regulation and policy.⁵⁸

Under the Food Allergen Act, food manufacturers must declare the common name for allergenic substances for food labeled on or after January 1, 2006.⁵⁹ The major allergens requiring labeling are: milk, eggs, fish, Crustacea (shellfish), tree nuts, wheat, peanuts, and soybeans.⁶⁰ These eight allergens are estimated to account for 90 percent of food allergies in the United States.⁶¹

⁵⁴ Food Allergen Labeling and Consumer Protection Act § 203.

⁵⁵ 21 U.S.C. §§ 601-695 (2004).

⁵⁶ 21 U.S.C. §§ 451-470 (2004).

⁵⁷ 21 U.S.C. §§ 1031-1056 (2004).

⁵⁸ Robert C. Post, Ph.D., Director, Labeling and Consumer Protection, Food Safety Inspection Service (FSIS), USDA Remarks at the conference: "Food Allergens: The FDA and FSIS Perspectives on Allergen Labeling" (July 7, 2005) (*in* audiotape available from the Food, Drug, Law Institute <http://www.fdpi.org/pubs/audio/ac020039/>).

⁵⁹ Food Allergen Act § 203(a) & (d).

⁶⁰ Food Allergen Act § 203(c) (to be codified as FD&C Act § 201(qq)).

⁶¹ Food Allergen Act § 202(2)(A); and 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).

The Major Eight Food Allergens

Allergen	Common Name of Allergen Source	Some Foods that May Contain Protein Derived from a Major Food Allergen ⁶²
Milk	Milk	Caramel flavoring, caramel coloring, casein, caseinate, curds, ⁶³ lactalbumin, natural flavoring, nougat, rennet casein, whey
Eggs	Eggs	Albumin, eggnog, meringue
Fish	Common specific name; e.g., bass, flounder, or cod	Gelatin, isinglass, ⁶⁴ 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), marzipan, ⁶⁵ nougat, pecans, pine nuts, pistachios, macadamia, walnuts
Wheat	Wheat	Bran, bulgur, couscous, durum, farina, gluten, kamut, matzoh, semolina
Peanuts	Peanuts	Beer nuts, goobers, goober peas, peanut flour, nutmeal
Soybeans	Soybeans	Hydrolyzed soy protein, miso, soya, tempeh, TVP, textured soy protein, tofu

⁶² See Michael M. Cramer, *The Time Has Come for Clear Food Allergen Labeling*, FOOD SAFETY MAGAZINE 18, 22 (Feb.-Mar. 2005).

⁶³ These names are not necessarily the legally correct name for a food ingredient statement, but, nevertheless, consumers may encounter them.

⁶⁴ Isinglass is a semitransparent whitish very pure gelatin prepared from the air bladders of fishes (as sturgeons) and used especially as a clarifying agent and in jellies and glue. MERRIAM-WEBSTER ONLINE DICTIONARY *available at*: <http://www.m-w.com/cgi-bin/dictionary?book=Dictionary&va=isinglass&x=6&y=11> (last visited Oct. 19, 2005).

⁶⁵ Marzipan is a confection of crushed almonds or almond paste, sugar, and egg whites that is often shaped into various forms. MERRIAM-WEBSTER ONLINE DICTIONARY *available at*: <http://www.m-w.com/cgi-bin/dictionary?book=Dictionary&va=marzipan> (last visited Oct. 19, 2005).

A. What is Required?

Under the Food Allergen Act, food labeling must identify the major allergens by their common name (column two above).⁶⁶ 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).”⁶⁷

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.⁶⁸ 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.⁶⁹

Raw agricultural commodities are exempt from the new allergen-labeling requirements, but no exemption exists for flavorings, colorings, and incidental additives when they contain a major allergen.⁷⁰ This bears highlighting because the Food Allergen Act’s new requirements apply notwithstanding prior labeling exemptions for flavorings, colorings, and incidental additives in the FD&C Act or other laws.⁷¹

“Highly refined oil,” and ingredients derived from highly refined oils, are specifically exempt from the definition of “major food allergen”; therefore, will not trigger allergen source labeling.⁷² Research indicates that the quantity of protein in highly refined oil does not trigger an allergic response.⁷³

B. Exemptions, Petition, and Notification

Although there are only two exemptions specified in the statute—highly refined oil is and derivative food are exempt from the definition of major food allergen;⁷⁴ and raw agricultural commodities are specifically exempt from the Food Allergen Act

⁶⁶ Food Allergen Act §§ 203 a) (FD&C Act § 403(w)(1) as amended).

⁶⁷ *Id.*

⁶⁸ Food Allergen Act § 203(a) (FD&C Act § 403(w)(1)(B)(ii) as amended).

⁶⁹ *Id.*

⁷⁰ Food Allergen Act § 203(a) (FD&C Act § 403(w)(1), as amended).

⁷¹ Food Allergen Act § 203(a) (FD&C Act § 403(w)(4), as amended).

⁷² Food Allergen Act § 203(c) (FD&C Act § 201(qq), as amended).

⁷³ See, 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) (citing 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)).

⁷⁴ Food Allergen Act § 203(c) (FD&C Act § 201(qq), as amended).

allergen-labeling requirements⁷⁵—the Food Allergen Act provides for petitions and notifications for additional exemptions.⁷⁶

Food manufacturers may petition to exempt a food from the Act's allergen labeling requirements.⁷⁷ The burden is on the petitioner to provide the 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.”⁷⁸ 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.⁷⁹

Alternatively, 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.⁸⁰ 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.⁸¹ 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.⁸²

C. Effective Date

The effective date of the new labeling requirements is January 1, 2006.⁸³ All food labeled on or after this date must comply with the new requirements.⁸⁴ Note that a food labeled before that date need not be relabeled or pulled from grocery shelves.⁸⁵

D. More to Come

In Food Allergen Act, Congress also directs the United States Department of Health and Human Services (DHHS) to conduct a number of activities to improve our nation's approach to food allergens.⁸⁶ First, the DHHS is directed to prepare a report to Congress on food allergens.⁸⁷ This report must analyze how food is

⁷⁵ Food Allergen Act § 203(a) (FD&C Act § 403(w)(1), as amended).

⁷⁶ Food Allergen Act § 203(a) (FD&C Act §§ 403(w)(6)-(7), as amended).

⁷⁷ Food Allergen Act § 203(a) (FD&C Act § 403(w)(6), as amended).

⁷⁸ *Id.*

⁷⁹ Food Allergen Act § 203(a) (FD&C Act § 403(w)(6)(B), as amended).

⁸⁰ Food Allergen Act § 203(a) (FD&C Act § 403(w)(7), as amended).

⁸¹ Food Allergen Act § 203(a) (FD&C Act § 403(w)(7)(A), as amended).

⁸² *Id.*

⁸³ Food Allergen Act § 203(d).

⁸⁴ *Id.*

⁸⁵ *Id.*

⁸⁶ Food Allergen Act §§ 204-210.

⁸⁷ Food Allergen Act § 204.

unintentionally contaminated with major food allergens, estimate how common such practices are in the food industry, and advise whether good manufacturing practices or other measures could eliminate this cross contact of food.⁸⁸ The report is also to describe the types of allergen advisory labeling used (such as “may contain”); the food manufacturing conditions associated with the various types of advisory labeling; and describe how consumers would prefer that information about the risk of cross contact be communicated on food labels.⁸⁹ Finally, FDA is to report on the number of food inspections and describe the rate of compliance and noncompliance with respect to handling and labeling major food allergens.⁹⁰

In addition, FDA is directed to define by rule the term “gluten free”⁹¹ in order to help consumers with celiac disease.⁹² The DHHS through the FDA and the Centers for Disease Control and Prevention (CDC) are to improve the collection and publication of data on the prevalence, prevention, and treatment of allergic disease.⁹³ The DHHS through the National Institutes of Health (NIH) is to review basic and clinical research and then make recommendation on enhancing and coordinating research activities concerning food allergies.⁹⁴

FDA is to pursue revision of the Food Code to provide guidelines for preparing allergen-free foods in food establishments.⁹⁵ Finally, DHHS is to provide technical assistance relating to trauma care and emergency medical services for treatment for and prevention of allergic responses to foods.⁹⁶

III. CHALLENGES PRESENTED BY THE FOOD ALLERGEN ACT

The Food Allergen Act is seemingly simple and straightforward. The Act was written with wide support and input from the food industry, but nonetheless, still presents potential problems to the food industry.⁹⁷ The major issue is how to handle

⁸⁸ *Id.*

⁸⁹ *Id.*

⁹⁰ *Id.*

⁹¹ Food Allergen Act § 206.

⁹² Celiac disease, also called celiac sprue and gluten enteropathy, is an immune-mediated disease that renders the body incapable of tolerating the gluten found in wheat, barley, rye, and oats, and causes damage to the gastrointestinal tract, central nervous system, and other organs. Food Allergen Act § 201(6); *and* DORLAND’S ILLUSTRATED MEDICAL DICTIONARY 1146 (25th ed. 1974).

⁹³ Food Allergen Act § 207.

⁹⁴ Food Allergen Act § 208.

⁹⁵ Food Allergen Act § 209.

⁹⁶ Food Allergen Act § 210.

⁹⁷ *See, e.g.,* Tom Trautman, *Labeling Food Allergens*, 59 FOOD TECH. 92 (Feb. 2005) (“Nevertheless, a good law that has support from all parties, including the regulated industry, can still present potential problems in terms of implementation.”); *and* *Labeling Food Allergens Can be a Struggle*, *supra* note 40 (“The law is a little ahead of the science,” said Kenneth J. Falci,

the countless foods that may contain a trace of a food defined as a major food allergen, but which are not typically believed to pose a health risk.

The major concern centers on the lack of threshold levels of allergens to trigger labeling.⁹⁸ A derivative concern arises from the potential for excessive use of allergen warnings, which may foster confusion and counterproductive behavior. Finally, related concerns are the lack of definition for the terms, “highly refined oils” and “tree nuts.”

A. How Much is Too Much?—the Dilemma with Threshold Levels

As discussed above, some incidental additives are exempt from ingredient labeling because they are present at what FDA has deemed to be insignificant levels in the finished food.⁹⁹ For example, lecithin is commonly used as an anti-sticking agent on food processing equipment (like consumers use cooking sprays at home) to help the food separate from the equipment.¹⁰⁰ Lecithin made from soybeans contains some soy protein, so lecithin’s use as an anti-sticking agent may impart a minuscule amount of soy protein to the food. Although previously exempt from labeling as an incidental additive, the Food Allergen Act requires labeling for soy if there is any amount of soy protein (a major food allergen) imparted to the finished food.¹⁰¹

The dilemma with this zero detectable approach is that it may be overly cautious and create other risks. Lecithin provides a good example because nearly all baked-goods manufacturers use lecithin.¹⁰² While some allergen-free foods are likely to be manufactured, the practicalities of food processing and the sensitivity of analytical technology make zero-detectable levels unachievable on a wide scale.¹⁰³ A zero-

U.S. Food and Drug Administration, about the Food Allergen Labeling and Consumer Protection Act.”)

⁹⁸ See, e.g., Martha Filipic, *Food Law Confusing the Allergic*, CINCINNATI POST C1 (Nov. 10, 2004) available at: 2004 WLNR 7345175; and generally “Food Allergens: The FDA and FSIS Perspectives on Allergen Labeling” (July 7, 2005) (in audiotape available from the Food, Drug, Law Institute <http://www.fdpi.org/pubs/audio/ac020039/>).

⁹⁹ 21 CFR 101.100(a)(3).

¹⁰⁰ Martha Filipic, *Food Law Confusing the Allergic*, CINCINNATI POST C1 (Nov. 10, 2004) available at: 2004 WLNR 7345175.

¹⁰¹ “A food ingredient that contains protein derived from” a major food allergen triggers the Food Allergen Act labeling requirement. Food Allergen Act § 203(c)(2). The act provides no exemption which covers incidental or threshold amounts of such a protein except for highly refined oils; however, FDA may promulgate such exemptions. Food Allergen Act §§ 203(c)(2)(A) & 203(a)(w)(6)-(7).

¹⁰² Filipic, *supra* note 100.

¹⁰³ See, e.g., S.L. Taylor, et al., *Factors Affecting the Determination of Threshold Doses for Allergenic Foods: How Much is Too Much?*; 109 J ALLERGY CLIN IMMUNOL. 24-30 (Jan. 2002); and *Food Firms Against Using Analytical Methods for Allergen Thresholds*, FDA WK. (Pg. Unavail. Online) (July 15, 2005) 2005 WLNR 11110314 (“Food industry trade groups are asking FDA to not use analytical tests to establish tolerance thresholds for food allergens because as tests

detectable standard for major food allergens will likely result in widespread use of precautionary allergen labeling, such as “may contain” labeling, and far fewer foods available for allergic consumers.¹⁰⁴

Decreased choices for allergic consumers might not be a dilemma if these products truly were a risk, but trivial amounts of allergens probably pose no risk for most allergy sufferers.¹⁰⁵ The lack of health risk is precisely why FDA allows incidental additives to be left off the ingredient statement of foods—they have no functional effect in the finished, including not eliciting food allergies.¹⁰⁶

Soy lecithin was used as an example because of its widespread use, but the dilemma is not confined to lecithin or even to other incidental additives. Other food ingredients derived from soybeans include tocopherol (vitamin E), isoflavone, phytosterol, soy fiber, monoglycerides, and diglycerides.¹⁰⁷ Other common food ingredients and food contact substances that create similar dilemmas from trace amounts of major food allergens are lactose, fish gelatin, wheat starch, and many ingredients derived from fermentation, such as enzymes, flavors, or antimicrobials, when the fermentations used media containing egg, soy, or wheat.¹⁰⁸

Cross contact on food surfaces creates another enormous practical problem with the zero-detectable allergen approach. The food industry for practical economic reasons often manufactures many different food products with the same equipment or within the same building.¹⁰⁹ At some plants, hundreds of different products may be manufactured within the same building.¹¹⁰ Trace amounts of ingredients can be transferred in these situations.

Many of current food processing plants were designed and built before today’s concern over food allergens.¹¹¹ Even today, there is little or no information on the release or retention of allergenic proteins by various processing surfaces, of which

become more sensitive they detect smaller amounts of allergens, which would require companies to frequently change their labels . . . such tests could lead to labeling allergens that are present in small amounts and do not cause allergic reactions.”)

¹⁰⁴ Presentation of Stephen L. Taylor, “Food Allergens: From Chaos, Confusion and Concern to Commitment and Control,” Ohio State University (Oct. 28, 2004).

¹⁰⁵ *Id.*

¹⁰⁶ Incidental additives must be present in the food at an insignificant level, and that must not have any functional effect in the finished food. 21 CFR 101.100(a)(3); *and* Letter from Fred R. Shank, Director, Center for Food Safety and Applied Nutrition, FDA, Notice to Manufacturers: Label Declaration of Allergenic Substances in Foods (June 10, 1996) *available at*: <http://www.cfsan.fda.gov/~lrd/allerg7.html> (last visited Oct. 18, 2005).

¹⁰⁷ Presentation of Stephen L. Taylor, *supra* note 104.

¹⁰⁸ Tom Trautman, *Labeling Food Allergens*, 59 FOOD TECH. 92 (Feb. 2005).

¹⁰⁹ *See, e.g.*, S.L. Taylor, et al., *Factors affecting the determination of threshold doses for allergenic foods: how much is too much?* 109 J ALLERGY CLIN IMMUNOL. 24 (Jan. 2002).

¹¹⁰ *Id.*

¹¹¹ Presentation of Stephen L. Taylor, *supra* note 104.

there are thousands.¹¹² The predicament for the food industry is not knowing how clean is allergen clean.¹¹³

Compounding this predicament is the nature of the food supply and distribution system. Cross contact between ingredients exists from the farm to the processing plant.¹¹⁴ For example, corn and soybeans may be harvested on the same equipment, transported in the same trucks, and stored in the same storage facilities.¹¹⁵ Thus, corn may have trace residues of soybean, which triggers labeling.¹¹⁶

It is no exaggeration to say that hundreds of foods will become unavailable to diligent allergic consumers if every food with even a minuscule trace of a food allergen triggers labeling.¹¹⁷ This has been described as a potential nightmare for food allergy sufferers and could create its own health risks.¹¹⁸

B. The Predicament of the Little Boy Who Cried Wolf

In addition to limiting food choices, over labeling is likely to result in consumer confusion.¹¹⁹ Allergic consumers will wonder why a food they have eaten for years suddenly is labeled with an ingredient to which they know they are allergic.¹²⁰

Some consumers may incorrectly believe they have recovered from their allergies, while others may get in the habit of ignoring the excessive and unhelpful warnings.¹²¹ Both situations result in health risk to consumers from missing information that is truly helpful.¹²² In the face of overly cautious warnings, other consumers may simply

¹¹² *Id.*

¹¹³ Taylor, *supra* note 109.

¹¹⁴ *Id.*

¹¹⁵ *Id.*

¹¹⁶ *Id.*

¹¹⁷ See, e.g., Filipic, *supra* note 100.

¹¹⁸ *Id.* (“But unless provisions are made, the act could become a nightmare for food-allergy sufferers,” paraphrasing Steve Taylor, professor and chair of Food Science and Technology at the University of Nebraska).

¹¹⁹ See, e.g., Tom Trautman, *supra* note 108; and Presentation of Stephen L. Taylor, *supra* note 104.

¹²⁰ Filipic, *supra* note 100 (quoting Steve Taylor, professor and chair of Food Science and Technology at the University of Nebraska “Consumers will say, ‘I’ve been eating this for 20 years and never had a problem, and now it has this allergen on the label.’”)

¹²¹ See UNITED KINGDOM FOOD STANDARDS AGENCY, NUT ALLERGY LABELLING: REPORT OF RESEARCH INTO THE CONSUMER RESPONSE (2002) *available at*: <http://www.foodstandards.gov.uk/multimedia/pdfs/nutallergyresearch.pdf> (indicating that too many allergen warnings run the risk of devaluing the label); and Institute of Food Science and Technology, Information Statement, Food Allergy 12 (Oct. 2005) *available at*: <http://www.ifst.org/allergy.pdf>.

¹²² Institute of Food Science and Technology, Information Statement, Food Allergy 12 (Oct. 2005) *available at*: <http://www.ifst.org/allergy.pdf>.

engage in risk taking behavior.¹²³ In addition, too much information crowded onto food labels conflicts with the need to make this information clear and simple to read.¹²⁴

Unfortunately, little scientific information exists regarding the specific threshold levels that will elicit allergic reactions.¹²⁵ It is known that very small amounts of some allergens can provoke reactions in some individuals, but it is not known how small the amounts must be, why different allergic people react differently, or why the same person may react differently on different occasions.¹²⁶ This all makes it difficult to assess how to achieve the desired level of safety with respect to allergens by risk analysis.¹²⁷

Two undefined terms in the Food Allergen Act create a dilemma similar to that of the lack of regulatory threshold levels: “highly refined oils” and “tree nuts.”

C. What is a Highly Refined Oil

“Highly refined oil,” and ingredients derived from highly refined oils, are specifically exempt from the definition of “major food allergen”; therefore, will not trigger allergen source labeling.¹²⁸ Unfortunately, the Food Allergen Act does not define “highly refined oils.” Therefore, food manufacturers will bear the burden of being certain that any oil touted as “highly refined” actually is free of major food allergen proteins or is below the threshold that will trigger an allergic reaction.

The Senate Report on the Food Allergen Act notes that “highly refined oils” are refined, bleached, deodorized oils.¹²⁹ In addition, the food industry use of the term “highly refined oil” has similarly been that the oil is refined, bleached, deodorized.¹³⁰ This usage alone does not provide much guidance, but it does indicate what minimum requirement FDA will be looking for with these oils.¹³¹

¹²³ *Id.*

¹²⁴ *Id.*

¹²⁵ S.L. Taylor & S.L. Hefle, *Food Science Perspective on Food Allergy*, 53 (45 SUPPL.) ALLERGY. 5, 7 (1998); and S. L. Taylor *et al.*, *A Consensus Protocol for the Determination of the Threshold Doses for Allergenic Foods: How Much is Too Much?* 34 CLIN. EXP. ALLERGY 689–695 (May 2004).

¹²⁶ Presentation of Stephen L. Taylor, *supra* note 104.

¹²⁷ *Id.*

¹²⁸ Food Allergen Act § 203(c) (FD&C Act § 201(qq), as amended).

¹²⁹ S. Rep. No. 108-226 (Feb. 12, 2004).

¹³⁰ Felicia B. Satchell, Director, Division of Standards and Labeling Regulations, CFSAN, FDA, Remarks at the conference: “Food Allergens: The FDA and FSIS Perspectives on Allergen Labeling” (July 7, 2005) (*in* audiotape available from the Food, Drug, Law Institute <http://www.fdli.org/pubs/audio/ac020039/>).

¹³¹ *Id.*

D. What is a Tree Nut?

Another term lacking definition is “tree nut.” Some tree nuts have never been identified as causing allergic reactions,¹³² but as the law now stands, they all must follow the allergen labeling requirements.¹³³ Coconut, kola nut, shea nut, and annatto coloring, all are derived from a tree nut, and trigger allergen labeling.¹³⁴

IV. CONCLUSIONS

The Food Allergen Act can be both praised and criticize for being ahead of existing science.¹³⁵ On the positive side, the law will help consumers identify products that contain major food allergens. On the negative side, unless provisions are made for allergen thresholds, the Act could result in unnecessary allergen labeling of hundreds of food products with the result being consumer confusion and related health risks from ineffective allergen labeling.

Nearly everyone agrees that threshold levels should not be a substitute for poor manufacturing practices, such as sloppy cleaning or mishandling of major food allergens.¹³⁶ Nonetheless, some concern arises that threshold levels will be used as a way to avoid cleaning.¹³⁷ FDA wisely is seeking input from industry, academia, health care providers, and consumers on this issue.

Nearly all agree on 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 many of years to come. The law should spur growth in scientific and technical knowledge on food allergens. Once the details of thresholds are understood, this new law should reduce the incidence of allergic reactions and create an expanded food choices for allergic consumers.

¹³² Tom Trautman, *supra* note 108.

¹³³ Food Allergen Act § 203(c) (all tree nuts are classified as major food allergens).

¹³⁴ Tom Trautman, *supra* note 108.

¹³⁵ *Labeling Food Allergens Can be a Struggle*, *supra* note 40.

¹³⁶ See, e.g., Institute of Food Science and Technology, Information Statement, Food Allergy 12 (Oct. 2005) available at: <http://www.ifst.org/allergy.pdf>.

¹³⁷ *Food Firms Against Using Analytical Methods for Allergen Thresholds*, FDA WK. (Pg. Unavail. Online) (July 15, 2005) 2005 WLNR 11110314.