

Food Allergen Labeling and Consumer Protection Act of 2004 in Effect

On January 1, 2006, the Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA) (1) took effect, making it easier for consumers to identify the eight most common food allergens. The FALCPA amended section 403 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343), which is enforced by the Food and Drug Administration (FDA). The FALCPA requires that the labels of all FDA-regulated food products, labeled on or after January 1, 2006, clearly state whether a food or an ingredient found in a food is or contains a “major food allergen.” The FALCPA defines “major food allergen” as one of the following eight foods/food groups or an ingredient that contains protein derived from one of them: milk; eggs; fish (eg, bass, flounder, cod); crustacean shellfish (eg, crab, lobster, shrimp); tree nuts (eg, almonds, pecans, walnuts); wheat; peanuts; and soybeans. Congressional findings in the FALCPA state that these allergens are responsible for 90% of food allergies.

MAJOR POINTS OF THE FALCPA

Labeling Changes of Food Products Impacted by FALCPA Requirements

Manufacturers have two alternatives for identifying ingredients that are major food allergens on food labels (1). One alternative is to state the

food source names of any major food allergens within the list of ingredients. For example, the food source name (eg, milk) may be stated parenthetically immediately after an ingredient that is a major food allergen (eg, casein or whey) when its name does not identify its food source and when that same food source name is not already declared elsewhere in the ingredient list. Thus, food that contains casein might include in the ingredient list: casein (milk). Another option is to include a “contains” statement immediately following or next to the list of ingredients (eg, contains milk). However, if the food source name of a major food allergen is already included in the list of ingredients (eg, nonfat dry milk, lactose, albumin [egg]), no additional identification of that same major food allergen is required within the ingredient list (1). If a manufacturer chooses to use a “contains” statement, all major food allergens used as ingredients must be identified in that statement (eg, contains milk and egg) (2).

Food Products and Ingredients Included under FALCPA Requirements. The labels of all domestic and imported food products, including conventional foods, dietary supplements, infant formula, and medical foods, regulated by the FDA are subject to FALCPA requirements (3,4). This includes the labels of prepackaged foods sold by grocery stores and restaurants, such as those available in self-service display cases (3). Most food ingredients, except those specifically discussed below, are subject to FALCPA requirements, including colorings, flavorings, and incidental additives (1). By definition, an incidental additive, such as a processing aid, is a food ingredient used at an insignificant level that does not have a technical or functional effect in the finished food product. For example, as allowed in FDA regulations (see 21 CFR 101.100 (a) [3]), a release agent sprayed on

cooking pans to make it easier for baked foods to be removed is an incidental additive that serves as a processing aid.

Food Products and Ingredients Not Included under FALCPA Requirements. FALCPA requirements do not apply to food products not regulated by the FDA, such as meat products, poultry products, and egg products regulated by the US Department of Agriculture (2). FALCPA requirements also do not apply to raw agricultural commodities sold in their natural state, such as fruits and vegetables (1). Furthermore, highly refined oils, ingredients derived from them, and ingredients specifically exempt under a petition or notification process provided for in the FALCPA are not required to comply with the FALCPA’s allergen labeling requirements.

Food manufacturers may request an exemption from FALCPA labeling through either a petition or notification (1). In the case of an FALCPA petition, the submitter, such as a food manufacturer, must provide scientific evidence (including the analytical method used to produce the evidence) demonstrating that the ingredient, as derived by the method specified in the petition, “does not cause an allergic response that poses a risk to human health” (1). In the case of an FALCPA notification, the submitter must provide scientific evidence (including the analytical method used) demonstrating either that (a) the ingredient, as derived by the method specified in the notification, either “does not contain allergenic protein”; or (b) that under a premarket food additive review process, the FDA has determined that the ingredient “does not cause an allergic response that poses a risk to human health” (1). The law establishes time periods for the FDA’s response to FALCPA petitions and notifications.

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Children aren't concerned about osteoporosis.

But their parents should be.



As a dietitian, you know that if kids eat three daily servings of dairy, it can help reduce their risk of osteoporosis years from now. But some parents don't know; so you can help by informing them that dairy foods supply key nutrients necessary for better bone health.

The U.S. Surgeon General's report on Bone Health and Osteoporosis recognizes the role that nutrients in dairy foods – including calcium, magnesium, phosphorus, potassium, protein, and vitamin D – play in helping to build and protect bones.

In fact, a report from the American Academy of Pediatrics states that eating calcium-rich foods such as milk, cheese and yogurt during childhood and adolescence will help build strong bones, which may reduce the risk of fractures and osteoporosis later in life.

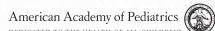
Helping patients can be easy. Just remind them to get three servings of low-fat or fat-free milk, cheese or yogurt every day, as recommended by the U.S. Dietary Guidelines for Americans. Or, direct them to MyPyramid.gov to learn more.

And remind parents that it's never too late for them to take care of their own bone health too. By getting three daily servings of dairy and participating in weight-bearing exercise, adults can help protect their bones while setting a good example for their children. To learn more, visit nationaldairyCouncil.org.

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FUTURE MANDATES OF THE FALCPA

The FALCPA includes several other mandates, two of which are discussed below (1).

A Report on Food Allergens

The FDA was directed to submit a report to Congress that addresses several issues related to the cross-contact of foods with major food allergens. These issues include: how foods are unintentionally contaminated with major food allergens during processing resulting in the foods containing those allergens, whether adherence to standards of good manufacturing practice reduces cross-contact, manufacturer use of advisory

language (eg, may contain) on food labels, and consumer preferences regarding the use of advisory language on food labels.

Gluten-free Labeling

The FDA was directed to issue a proposed rule in 2006 and a final rule in 2008 to define and permit use of the term “gluten-free” on food labels. The final rule will specify a date for the food industry to comply with the new labeling requirements. On or after that date, food manufacturers who elect to make a gluten-free claim on the label of their products must conform to the FDA regulatory standard for a gluten-free food.

RECOMMENDATIONS FOR DIETITIANS

While the FALCPA makes it easier for consumers with food allergies to identify certain allergens on the food label, consumers must continue to be diligent label readers. There is a large educational component to label reading and registered dietitians will still need to spend considerable time instructing their patients and clients about food allergies. Also, because food labels packaged before January 1, 2006 will remain on store shelves for some period of time, patients should continue to be advised to look for hidden sources of allergens, at least in the near future.

Resources on Food Allergies

www.cfsan.fda.gov

Center for Food Safety and Applied Nutrition (CFSAN). This Web site provides links to numerous food and nutrition topics.

www.cfsan.fda.gov/~dms/wh-argy.html

This specific CFSAN Web site on information about food allergens provides links to the FALCPA and related guidance documents.

www3.niaid.nih.gov

National Institute of Allergy and Infectious Disease (NIAID).

www.niaid.nih.gov/publications/pdf/foodallergy.pdf

Web site of the NIAID for accessing the publication *Food Allergy: An Overview*.

<http://digestive.niddk.nih.gov/ddiseases/pubs/celiac/>

National Digestive Diseases Information Clearinghouse. This Web site provides information about celiac disease.

www.foodallergy.org

Food Allergy and Anaphylaxis Network.

www.foodallergyinitiative.org

Food Allergy Initiative.

References

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