Food Labels Identify Allergens More Clearly

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When you drink a glass of milk, are you consuming casein and lactoglobulin? How about potassium caseinate and lactalbumin?

According to food scientists, all of these substances are proteins found in milk. And until recently, food manufacturers could use technical terms such as these on food labels without further explanation, instead of listing the more common term "milk."

That changed at the beginning of 2006, when a new food labeling law, the Food Allergen Labeling and Consumer Protection Act (FALCPA), took effect.

Under FALCPA, food labels are required to state clearly whether the food contains a "major food allergen." The law identifies as a major food allergen any of eight allergenic foods: milk; eggs; fish such as bass, flounder, and cod; crustacean shellfish such as crab, lobster, and shrimp; tree nuts such as almonds, walnuts, and pecans; peanuts; wheat; and soybeans. The law also identifies as a major food allergen any ingredient that contains protein derived from any of these eight foods.

The plain language declaration requirement of FALCPA also applies to flavorings, colorings, and incidental additives that are or contain a major food allergen.

"FALCPA recognizes that eight major foods or food groups account for 90 percent of all food allergies in the United States, and some allergic reactions may be severe or life-threatening," says Robert E. Brackett, Ph.D., director of the Food and Drug Administration's Center for Food Safety and Applied Nutrition (CFSAN).

About 2 percent of adults and 5 percent of infants and young children in the United States suffer from food allergies. About 30,000 consumers require emergency room treatment, and 150 Americans die each year because of allergic reactions to food.

There is no cure for food allergies. Avoidance of the food that causes the allergy is the only way a person can prevent a reaction. The improved label will make it easier for food allergic people and their caregivers to identify and avoid foods that contain major food allergens, says Catherine Copp, policy advisor in the CFSAN. For example, if a product contains the milk-
derived protein casein, the product's label will have to use the term “milk” in addition to the term “casein" so that those with milk allergies can clearly understand the presence of the allergen they need to avoid.

“We're very excited about this change,” says Anne Muñoz-Furlong, founder and CEO of The Food Allergy & Anaphylaxis Network based in Fairfax, Va. “People with food allergies will be able to tell right away whether a food is safe for them to eat or not.”

Food allergies are on the rise in children, says Muñoz-Furlong, and the improved food labeling information will be especially helpful to children who must learn to recognize the presence of substances they need to avoid. Parents often take children with them when they shop for groceries, she says. “They want to teach children early on to start reading food labels. They have the children read the label to them and figure out if the product contains an allergy-causing food and whether it should go in the grocery cart or go back on the shelf.”

“When the child is too young to read, parents will read the label to the child,” adds Muñoz-Furlong. “It’s almost impossible to keep the attention of a 5-year-old when you say ‘ammonium caseinate,’ but when you say ‘milk,’ the child with a milk allergy will instantly say, ‘That’s not good for me.’”

Manufacturers must identify the presence of a major food allergen in one of two ways: in the list of ingredients, manufacturers must state the source of an allergenic ingredient in parentheses after the name of that ingredient; or after or next to the ingredient list, manufacturers must add “contains” followed by the name of the source of each allergenic ingredient in the food. For example:

Option 1:

**Ingredients:** Enriched flour (wheat flour, malted barley, niacin, reduced iron, thiamin mononitrate, riboflavin, folic acid), sugar, partially hydrogenated soybean oil, and/or cottonseed oil, high fructose corn syrup, whey (milk), eggs, vanilla, natural and artificial flavoring, salt, leavening (sodium acid pyrophosphate, monocalcium phosphate), lecithin (soy), mono- and diglycerides (emulsifier)

Option 2:

**Contains Wheat, Milk, Eggs and Soy**

“These statements are not required if the major food allergen’s common name already identifies its food source,” says Copp. For example, the ingredients whole wheat flour, buttermilk, and peanut butter already state that they contain wheat, milk, and peanuts, respectively, so no further explanatory terms are required.

FALCPA applies to both domestically produced and imported packaged foods that the FDA regulates. So even if you purchase a box of candy from overseas, it should be in compliance, says Copp. Raw agricultural commodities, such as fresh fruits and vegetables, are exempt from FALCPA. So are highly refined oils made from one of the eight allergenic foods identified by the law.

FALCPA establishes two separate processes that food manufacturers can use to request an exemption for their product from the FALCPA declaration requirement—the notification and petition processes. “The notification process may be used by manufacturers who can demonstrate that their ingredient does not contain an allergenic protein; the petition process may be used by a manufacturer who can demonstrate that, although the ingredient does contain protein derived from an allergenic food, the ingredient does not cause an adverse reaction that poses a risk to human health,” says Felicia Billingslea, director of the FDA’s Division of Food Labeling and Standards.

The law applies only to products labeled on or after Jan. 1, 2006, so until products labeled before that date are sold or otherwise removed from the market, consumers will continue to see some products without the plain language allergen labeling on grocery store shelves, says Copp, “particularly nonperishables such as canned goods.”

Even if consumers have purchased a product in the past that does not aggravate their allergies, they should not take it for granted that it will always be nonallergenic, says Copp. “We encourage consumers to always read the ingredient list, because manufacturers may change their product formulation.”

The FDA will enforce the new law. “We intend to document violations of the law when inspecting manufacturing plants,” says Betty Harden, an FDA consumer safety officer in the Office of Compliance. A food product that contains an undeclared allergen may be subject to recall. In addition, a food product not properly labeled may be misbranded and subject to seizure and removal from the marketplace.

FALCPA also requires the FDA to submit a report to Congress on food allergens, particularly with respect to identifying ways to reduce or eliminate cross-contact and stating the risk of cross-contact on food labels. Cross-contact occurs when a residue or other trace amount of an allergenic food is unintentionally incorporated into another food that is not intended to contain that allergenic food; cross-contact may occur during harvesting, transportation, manufacturing, processing, or storage.

In addition, the agency is required to propose a regulation by August 2006, and to issue a final regulation by August 2008, to define the term “gluten-free” for voluntary use in food labeling. Gluten is a term that describes a group of proteins that occur naturally in certain grains, including wheat, barley, and rye. When present in certain amounts, gluten can cause a serious reaction in people with celiac disease, a chronic digestive disease that damages the small intestine and interferes with absorption of nutrients from food. About 2 million people in the United States have this disease.

“Consumers susceptible to celiac disease need accurate, complete, and informative labels on food to protect themselves,” says Billingslea, "and a standardized definition of 'gluten-free' and use of the term on labels will help.”

**For More Information**

The FDA’s Food Allergens Page
www.cfsan.fda.gov/~dms/wh-alergy.html