

# Finding Food Allergens Where They Shouldn't Be

If you're allergic to a food ingredient, you probably look for it on the food product's label. But some labels may not be as reliable as they should be. In fact, allergens not listed on the label, referred to as "undeclared allergens," are the leading cause of food recalls requested by the Food and Drug Administration.

FDA is working on three fronts to reduce the number of such recalls: by researching the causes of these errors; working with industry on best practices; and developing new ways to test for the presence of allergens.

Federal law requires that labels of FDA-regulated foods marketed in the U.S. identify major food allergens. In some people, these allergens—milk, eggs, fish, crustacean shellfish, tree nuts, wheat, peanuts, and soybeans—can cause potentially life-threatening reactions. A food product with a label that omits required allergen information is misbranded and can be seized by FDA. However, firms generally recall such food products from the marketplace voluntarily.

## Help Report Food-Allergic Reactions

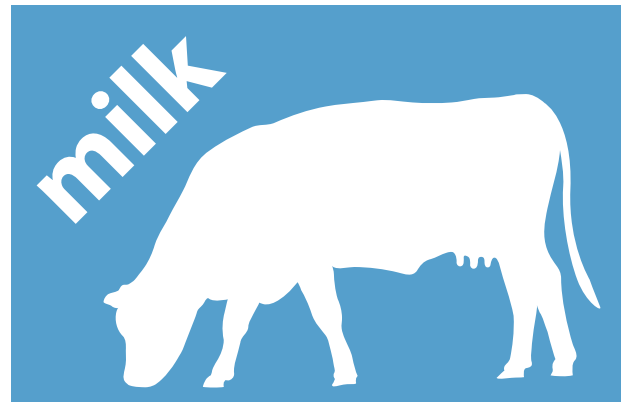
The first step is learning more about the problem. Steven Gendel, Ph.D., FDA food allergen coordinator, emphasizes that consumers can help by reporting food-allergic reactions to the FDA consumer complaint coordinator in their district ([www.fda.gov/safety/reportaproblem/consumercomplaintcoordinators/default.htm](http://www.fda.gov/safety/reportaproblem/consumercomplaintcoordinators/default.htm)). "We look at every complaint to determine the appropriate course of action," he says.

"What we're trying to learn," Gendel explains, "is what foods are most affected, what allergens are most involved, and how labeling errors might have happened. Those answers will help us to reduce the number of recalls for undeclared allergens."

## Recalled Foods and the Allergens Involved

Looking for these answers, Gendel has sifted through FDA-collected recall data and found some clear trends.

For example, from September 2009 to September 2012,



The allergens most often involved in food recalls are milk, wheat and soy. Any allergen present but not declared on a product's label poses a serious health risk.

*“If someone wants us to analyze a food for peanut allergen, with mass spectrometry we can detect and differentiate among the 11 different allergenic proteins in a peanut.”*

about one-third of foods reported to FDA as serious health risks involved undeclared allergens. The five food types most often involved in food allergen recalls were bakery products; snack foods; candy; dairy products and dressings (such as salad dressings, sauces and gravies).

The allergens most often involved in recalls were milk, wheat and soy. Consumers can find out what products have been recalled recently at FDA’s website ([www.fda.gov/safety/recalls/default.htm#additional-info](http://www.fda.gov/safety/recalls/default.htm#additional-info)) and at the Food Allergy Research and Education (FARE) website ([www.foodallergy.org/alerts-feed](http://www.foodallergy.org/alerts-feed)), as well as from the companies that make the products.

Within the candy category, there were many reports of undeclared milk in products containing dark chocolate. For example undeclared milk led to several recalls for chocolate-coated snack bars with labels that the products were “dairy-free” or “vegan.” “This represented a significant risk for milk-allergic consumers,” says Gendel.

### The Source of the Problem

Recall data show that such labeling errors occur most commonly because of the use of the wrong label. This may happen when similar products made with different ingredients, including allergens, are sold in look-alike packages.

Gendel also found mistakes associated with the use of new technologies,

such as computerization and the ability to print labels directly on packaging. This can save costs but also create new opportunities for errors.

The data suggest that food allergen recalls can be reduced through improved industry awareness and simple changes in the way packages, labels and ingredients are handled and tracked within production facilities.

To encourage improvements, FDA shares its findings with industry at conferences and cooperates with the Food Safety Preventive Controls Alliance (FSPCA) ([www.iit.edu/ifsh/alliance/](http://www.iit.edu/ifsh/alliance/)). FSPCA’s mission is to enhance safe food production by developing training and outreach programs that support preventive controls described in the FDA Food Safety Modernization Act (FSMA) ([www.fda.gov/food/guidanceregulation/fsma/default.htm](http://www.fda.gov/food/guidanceregulation/fsma/default.htm)).

### FDA Exploring New Ways to Test for Allergens

Of course, keeping unwanted allergens out of food requires good methods for detecting them.


The most common test used worldwide is the enzyme-linked immunosorbent assay (ELISA), which uses antibodies (parts of the immune system that help neutralize viruses and bacteria) and spectroscopic detection to test for allergens.

Mark Ross, Ph.D., an FDA chemist, says ELISA is the standard test because it is easy to use, relatively


low-cost, and has been improved by scientists over time. But ELISA, like similar tests used in medicine, can produce false positive results, so backup methods are needed. In addition, some allergens are so similar that scientists need another test besides ELISA to tell them apart.

Ross is working with other FDA researchers to develop methods for analyzing allergens based on mass spectrometry, a technology that more effectively determines the allergen protein content of a complex mixture of proteins, fats, sugars, and chemicals in a food.

“If someone wants us to analyze a food for peanut allergen, with mass spectrometry we can detect and differentiate among the 11 different allergenic proteins in a peanut,” he says.

FDA researchers are also developing DNA-based methods, in particular to detect fish and shellfish allergens. 

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