## Frequently Asked Questions about Food Allergies

## What are the most common food allergy signs and symptoms?

Symptoms of food allergies typically appear from within a few minutes to two hours after a person has eaten the food to which he or she is allergic.

Allergic reactions can include:

- Hives
- Flushed skin or rash
- Tingling or itchy sensation in the mouth
- Face, tongue, or lip swelling
- Vomiting and/or diarrhea
- Abdominal cramps
- Coughing or wheezing
- Dizziness and/or lightheadedness
- Swelling of the throat and vocal cords
- Difficulty breathing
- Loss of consciousness

People with food allergies can also experience a severe, life-threatening allergic reaction called anaphylaxis after eating a food allergen(s).

Anaphylaxis can lead to:

- Constricted airways in the lungs
- Severe lowering of blood pressure and shock ("anaphylactic shock")
- Suffocation by swelling of the throat

Each year in the U.S., it is estimated that anaphylaxis to food results in:

- 30,000 emergency room visits
- 2,000 hospitalizations
- 150 deaths

Prompt administration of epinephrine by auto-injector during early symptoms of anaphylaxis may help prevent these serious consequences.

## What to do if symptoms occur?

Severe food allergies can be life-threatening. If you or someone you care for has symptoms of food allergies, avoid these foods and consult your health care provider for appropriate testing and evaluation.

- Read food labels and avoid the foods or ingredients that have caused symptoms.
- Recognize the early symptoms of an allergic reaction, especially in the event of accidental ingestion, and be properly educated on - and armed with - appropriate treatment measures, such as an auto-injector.
- Initiate treatment immediately if you have a known food allergy and experience symptoms while or after eating a food. Go to a nearby emergency room if symptoms progress.

For adverse events related to food products, consumers can call FDA's emergency number at 1-866-300-4374 or 301-796-8240 or report directly to Medwatch
(https://www.accessdata.fda.gov/scripts/medwatch/medwatch-online.htm). You may also contact the FDA consumer complaint coordinator (/consumer-complaint-coordinators) in your geographic area or see Your Guide To Reporting Problems to FDA (/consumers/consumer-updates/how-report-product-problems-and-complaints-fda).

## What are major food allergens?

To help Americans avoid the health risks posed by food allergens, Congress passed the Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA) (/food/allergens/food-allergen-labeling-and-consumer-protection-act-2004-falcpa). The law applies to all foods whose labeling is regulated by FDA, both domestic and imported. (FDA regulates the labeling of all foods, except for poultry, most meats, certain egg products, and most alcoholic beverages.)

Although more than 160 foods can cause allergic reactions in people with food allergies, the law identifies the eight most common allergenic foods. These foods account for 90 percent of food allergic reactions, and are the food sources from which many other ingredients are derived (such as whey from milk).

The eight foods identified by the law are:

1. Milk
2. Eggs
3. Fish (e.g., bass, flounder, cod)
4. Crustacean shellfish (e.g. crab, lobster, shrimp)
5. Tree nuts (e.g., almonds, walnuts, pecans)

## 6. Peanuts

7. Wheat

## 8. Soybeans

## What has the FDA done to educate Americans about food allergen risks?

Since Congress passed FALCPA, the law requires that labels must clearly identify the food source names of all ingredients that are - or contain any protein derived from - the eight most common food allergens, which FALCPA defines as "major food allergens." The presence of unlabeled allergens presents a significant health hazard for food-allergic consumers. Allergic consumers rely on food labels to be complete, clear and accurate so that they can avoid exposure to foods or ingredients that can provoke potentially life-threatening reactions.

FDA is working on three fronts to reduce potential food allergen risks; by researching the causes of labeling errors; working with industry on best practices; and developing new ways to test for the presence of allergens. The Food Safety Modernization Act (FSMA), specifically the Hazard Analysis and Risk Based Preventive Controls (HARPC) portion of the Preventive Controls Rule requires allergen controls, and revised good manufacturing practices (GMPs).

FDA conducts food establishment inspections and has authority to request companies to recall products with undeclared food allergens. FDA also established and manages the Reportable Food Registry (RFR or the Registry) - an electronic portal for Industry to report when there is reasonable probability that an article of food will cause serious adverse health consequences. The Registry helps the FDA better protect public health by tracking patterns and targeting inspections.

## How are major food allergens listed?

If you're allergic to a food ingredient, you probably look for it on the food product's label. The law requires that food labels identify the food source names of all major food allergens used to make the food. This requirement is met if the common or usual name of an ingredient (e.g., buttermilk) that is a major food allergen already identifies that allergen's food source name (i.e., milk). Otherwise, the allergen's food source name must be declared at least once on the food label in one of two ways.

Major food allergen names must appear:

## 1. In parentheses following the name of the ingredient.

Examples: "lecithin (soy)," "flour (wheat)," and "whey (milk)"

## 2. Immediately after or next to the list of ingredients in a "contains" statement.

 Example: "Contains Wheat, Milk, and Soy."
## What is cross-contact?

In the context of food allergens, "cross-contact" occurs when a residue or trace amount of an allergenic food becomes incorporated into another food not intended to contain it. Because of cross-contact, manufacturers may voluntarily place an advisory or precautionary allergen labeling, statement on food products to notify consumers about the possible presence of food allergen(s). FDA guidance for the food industry states that food allergen advisory statements, e.g., "may contain [allergen]", "produced in a facility that also uses [allergen]", etc. should not be used as a substitute for adhering to current good manufacturing practices and must be truthful and not misleading. FDA is considering ways to best manage the use of these types of statements by manufacturers to better inform consumers.

## What about gluten?

Gluten is the protein that occurs naturally in wheat, rye, barley, and crossbreeds of these grains. Foods that typically contain gluten include breads, cakes, cereals, pastas, and many other foods. Although gluten can cause allergic reactions in wheat allergic individuals, for the estimated 3 million Americans suffering from celiac disease, an auto-immune digestive disorder, consuming gluten can have other serious health consequences.

On August 5, 2013, FDA issued a final rule defining the term "gluten-free" for voluntary use in the labeling of foods. Food products bearing a gluten-free claim labeled on or after August 5, 2014, must meet the rule's requirements. The law requires that food labels list the product's ingredients. When lupin or gluten is present in a food, $i t$ is therefore required to be listed on the label.

