

## Gluten and Food Labeling



In August of 2013, the U.S. Food and Drug Administration (FDA) issued a regulation that defined the term “gluten-free” for food labeling. The definition provided consumers – especially those with celiac disease – the assurance that “gluten-free” claims on food products will be consistent and reliable across the food industry, and gave them a standardized tool for managing their health and dietary intake.

### FDA’s Regulation of Gluten-Free Claims

FDA’s regulation for gluten-free food labeling standardized what “gluten-free” means on the food label. “Gluten-free” is a voluntary claim that manufacturers may elect to use in the labeling of their foods. However, manufacturers that label their foods “gluten-free” are accountable for using the claim in a truthful and not misleading manner, and for complying with all requirements established by the regulation and enforced by FDA.

#### Gluten-Free Terms

Gluten-free foods may be labeled in a variety of ways:

- “Gluten-free”
- “No gluten”
- “Free of gluten”
- “Without gluten”

The FDA regulation applies to these four variations.

### Inside the Regulation

FDA established, among other criteria, a gluten limit of less than **20 parts per million (ppm)** for foods that carry the label “gluten-free,” “no gluten,” “free of gluten,” or “without gluten.” This level is the lowest that can be reliably detected in foods using scientifically validated analytical methods. Other countries and international bodies use these same criteria, as most people with celiac disease can tolerate foods with very small amounts of gluten.

Before the regulation was issued in 2013, there were no U.S. standards or definitions for the food industry to use in labeling products as “gluten-free.” This left many consumers, especially those with a health concern, unsure of a food’s gluten content.

## What is 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.



Gluten is the substance that gives breads and other grain products their shape, strength, and texture. But for the estimated 3 million Americans suffering from **celiac disease**, an auto-immune digestive disorder, consuming gluten can have serious health consequences.

## Foods That Can Be Labeled As “Gluten-Free”

Whether a food is *manufactured* to be free of gluten or *by nature* is free of gluten, it may bear a “gluten-free” labeling claim if it meets all FDA requirements for a gluten-free food. Some foods and beverages, such as bottled spring water, fruits, vegetables, and eggs, are naturally gluten-free. However, because a “gluten-free” claim isn’t *required* to be on a food package, it may not appear even if the food is, in fact, gluten-free.

## Grains: A Closer Look

Certain grains are especially likely to contain naturally occurring gluten. However, these grains can be made gluten-free, including:

- Wheat
- Barley
- Rye
- Crossbred hybrids like triticale

An ingredient that has been derived from a gluten-containing grain can be labeled as “gluten-free” if it has been **processed to remove gluten** and use of that ingredient results in the presence of less than 20 ppm of gluten in the food.



## What About Restaurants?

FDA recognizes that compliance with the gluten-free regulation in processed foods and food served in restaurants is important for the health of people with celiac disease.

FDA’s regulation established a federal definition of the term “gluten-free” for **food manufacturers** that voluntarily label FDA-regulated foods as “gluten-free.” The definition was intended to provide a reliable way for people with celiac disease to avoid gluten, and it is expected that restaurants’ use of gluten-free labeling will be consistent with the federal definition.

Given the public health significance of gluten-free labeling, FDA also encouraged the **restaurant industry** to move quickly to ensure that its use of gluten-free labeling was consistent with the federal definition.

In addition, state and local governments play an important role in oversight of restaurants. FDA works with state and local government partners with respect to gluten-free labeling in restaurants, and will consider appropriate action as needed, alone or with other agencies, to protect consumers.

## Gluten-Free Labeling: What It Looks Like

The regulation doesn't require manufacturers to place a food's "gluten-free" claim in any specific location on the food label. So, manufacturers may choose where they place a "gluten-free" claim, as long as it doesn't interfere with mandatory labeling information and meets the regulatory requirements.



- Some manufacturers may choose to include the logo of a gluten-free certification program on their food labels; however, FDA does not endorse, accredit, or recommend any particular third-party gluten-free certification program.
- Packaging of some foods that were labeled as "gluten-free" *prior* to the new regulation may look the same as they did before because the foods already met the new definition and did not need revised packaging.

## Products Covered by the Gluten-Free Regulation

FDA's regulation applies to all foods and beverages (including packaged foods, dietary supplements, fruits and vegetables, shell eggs, and fish) **except for**:

- **Meat, poultry, and certain egg products:** Regulated by U.S. Department of Agriculture (USDA)
- **Most alcoholic beverages** (all distilled spirits, wines with 7 percent or more alcohol by volume, and beverages made with malted barley and hops): Regulated by Alcohol and Tobacco Tax and Trade Bureau (TTB)

## Compliance with the Regulation

Manufacturers had until August of 2014 to bring their labels into compliance, allowing them sufficient time to make whatever changes were needed in the formulation or labeling of their foods bearing a "gluten-free" claim. Today, a food that is labeled as "gluten-free" but fails to meet the requirements of the regulation is subject to regulatory action by FDA.

## Reporting Adverse Effects and Labeling Concerns

Individuals who have experienced an injury or illness that they believe is associated with having eaten a particular food, including individuals with food allergies and those with celiac disease, should first seek appropriate medical care. Afterward, individuals should contact FDA.

Individuals can report a problem with a food or its labeling, such as potential misuse of "gluten-free" claims, to FDA in either of these ways:

1. Contact MedWatch, FDA's Safety Information and Adverse Event Reporting Program, at 800-332-1088, or file a MedWatch voluntary report at <http://www.fda.gov/MedWatch>
2. Contact the consumer complaint coordinator in their area. The list of FDA consumer complaint coordinators is available at <http://www.fda.gov/Safety/ReportaProblem/ConsumerComplaintCoordinators>

