

Gluten and Food Labeling

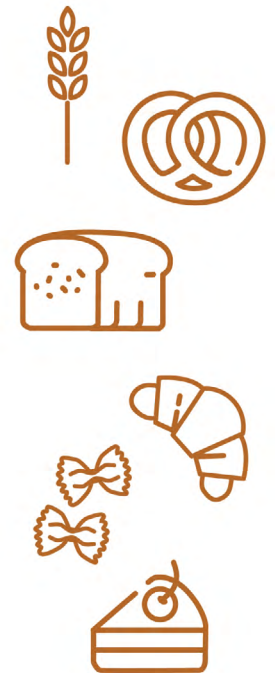


Since 2014, the U.S. Food and Drug Administration (FDA) has required that claims on food labels that a food contains no gluten meet a clear standard that assures consumers that “gluten-free” claims on food products truly will be truthful and consistent. The gluten-free labeling regulation gives consumers a standardized tool for managing their health and dietary intake — especially those with celiac disease, an auto-immune reaction to eating gluten, a protein found in wheat, barley and rye.

What is Gluten?

Gluten occurs naturally in wheat, rye, barley, and crossbreeds of these grains. Foods that typically contain gluten include breads, cakes, cereals, pastas, and many other grain-based 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, consuming gluten causes damage to the lining of the small intestine which prevents absorption of vital nutrients causing deficiencies that can lead to serious conditions, including anemia, osteoporosis, diabetes, thyroid disease, and intestinal cancers.



FDA’s Regulation of “Gluten-Free” Claims

While “gluten-free” is a voluntary claim that manufacturers may choose to use in the labeling of their foods, FDA’s gluten-free food labeling rule specifies what the claim actually means on a food label. Accordingly, manufacturers that label their foods as free of gluten are responsible for using the claim in an accurate and not misleading manner, and for complying with all requirements established by the regulation and enforced by FDA.

Inside the Regulation

The rule specifies, among other criteria, that any foods that carry the label “gluten-free,” “no gluten,” “free of gluten,” or “without gluten” must contain less than 20 parts per million (ppm) of 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 whether a food was free of gluten.

Besides the limit of gluten to 20 ppm, the rule permits labeling a food “gluten-free, if the food does *not* contain:

- An ingredient that is any type of wheat, rye, barley, or crossbreeds of these grains,
- An ingredient derived from these grains that has *not* been processed to remove gluten, or,
- An ingredient derived from these grains that *has* been processed to remove gluten, but results in the food containing more than 20 ppm of gluten

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. In 2017, FDA released the results of an analysis of 702 samples from more than 250 products labeled “gluten-free.” Only one of the products did not comply with the labeling requirements. That product was recalled and subsequent testing did not find any products that violated the regulation.



Grains: A Closer Look

Certain grains are especially likely to contain naturally occurring gluten. However, these grains can be processed to remove gluten, including:

- Wheat
- Barley
- Rye
- Crossbred hybrids like triticale

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.



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, providing that 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 regulation may look the same as they did before because the foods already met the 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**, which are regulated by the U.S. Department of Agriculture (USDA), and,
- **Most alcoholic beverages** (all distilled spirits, wines with 7 percent or more alcohol by volume, and beverages made with malted barley and hops), which are regulated by Alcohol and Tobacco Tax and Trade Bureau (TTB), U.S. Department of the Treasury.





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, given the public health significance of gluten, restaurants' use of gluten-free labeling should be consistent with the federal definition.

State and local governments play an important role in oversight of restaurants. FDA continues to work with state and local government partners with respect to gluten-free labeling in restaurants.

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>

More Information for Industry, Consumers and Other Stakeholders

FDA has established a landing page, [Gluten-Free Labeling of Foods](#), that includes links to all of the agency's information and compliance guidance on "gluten-free" labeling.