

# Is Your Label Gluten Free?

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*With the increased demand for “gluten-free” products in the market place, food processors and manufacturers have started to develop more and more better-tasting and nutritious food products that are also gluten-free. However, the federal food labeling regulations for gluten-free products can be very confusing for small food processors and new food product entrepreneurs.*

*The purpose of this bulletin is to assist small food processors and food entrepreneurs in their understanding of the FDA labeling requirements for putting “gluten-free” on the label of packaged food products. The authors do not claim interpretation or replacement of any other federal or state regulations about labeling requirements.*

## Why “gluten-free”?

Gluten is REALLY not much fun anymore, considering that an estimated 3 million people in the United States suffer from celiac disease and over 18 million people are sensitive to or cannot tolerate gluten.

Gluten affects individuals with celiac disease. Celiac disease is an autoimmune digestive disease that results in damage to the lining of the small intestine. Those with the disease experience distress or are unable to tolerate gluten, which triggers an adverse reaction when eating gluten-containing food products. Overtime, the reaction prevents nutrients from being absorbed by the digestive system. This may lead to gastrointestinal distress and eventually malnutrition. Adherence to a gluten-free diet is the key to treating individuals with celiac disease. Some individuals, however, could be just gluten sensitive rather than having celiac disease.



## What is gluten?

Gluten is a protein that occurs naturally in wheat, rye, barley, and crossbreeds of these grains. Foods that typically contain gluten include breads, cakes, cereals, and pastas. Gluten is the ingredient that gives breads and other grain products their shape, strength, and texture. Gluten protein in wheat flour make dough elastic and stretchy, and trap gas within baked goods, providing a light, airy structure.



## **Is gluten-free labeling required?**

The Food and Drug Administration's (FDA) final rule for gluten-free labeling compliance took effect on August 5, 2014. Any food product with a gluten-free claim on its label must meet the rule's requirements and regulations. According to the federal definition of the term "gluten-free," no food product labeled as gluten-free can be made with grains that contain gluten. And the total gluten content in a product must be less than 20 parts per million in the food item.

FDA's regulation for gluten-free food labeling provides new insight on what "gluten-free" means on a U.S. food product label. In summary, the regulation states:

- **Gluten-free is a voluntary claim that manufacturers may elect to use in the labeling of their foods.**
- **Food manufacturers that label their foods "gluten-free" are accountable for using the claim in a truthful and not misleading manner.**
- **Food manufacturers must comply with all requirements established by the regulation and enforced by FDA for gluten-free labeling.**

## **Does my product qualify for labeling?**

When a food product is manufactured with the objective to make it free of gluten, or if by nature it is free of gluten, such a food product may qualify for the gluten-free labeling claim\*.

*\*Product must meet all FDA requirements for a gluten-free food product and other food safety requirements.*

## **What foods are naturally gluten-free?**

- **Beverages (bottled spring water, fruit juices, vegetable juices, etc.)**
- **Beans, seeds, and nuts (in their natural, unprocessed form)**
- **Fresh eggs**
- **Fresh meats, fish, and poultry (not breaded, batter-coated or marinated)**
- **Fruits and vegetables**
- **Most dairy products**

However, since the gluten free claim is not required to be on a food package, a label may not appear even if the food is in fact gluten-free.

## **I own a small family owned restaurant. Do I need to worry about labeling my menu items?**

It is of the utmost importance that restaurant owners bear the same responsibility as any food manufacturer due to the health concerns of people with celiac disease. However, the rule applies to all FDA-regulated packaged foods manufactured after August 5, 2014. Also, gluten-free labeling is on a voluntary basis. If a restaurant

owner wishes to offer gluten-free products and advertise them as such, then the food products must be manufactured with no gluten-containing grains (wheat, rye, barley, or their hybrids).

### **Is there a specific location on my product label to place a gluten-free claim?**

No. The federal regulation doesn't require food manufacturers to place a food's gluten-free claim in any specific location on the food label. Food manufacturers may opt to place a gluten-free claim wherever they choose, so long as it doesn't interfere with mandatory labeling information and meets the regulatory requirements.

Some food 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.

### **What foods should consumers avoid unless it is labeled “gluten-free”?**

In general, people who are sensitive to gluten should avoid the following foods unless specifically labeled as “gluten-free:” beer, breads, cakes and pies, candies, cereals, cookies and crackers, croutons, French fries, gravies, imitation meat or seafood, matzo, pastas, processed luncheon meats, salad dressings, sauces (including soy sauce), seasoned rice mixes, and seasoned snack foods, such as potato and tortilla chips.

Certain non-gluten grains, such as oats, can be contaminated with wheat during growing and processing stages of production. For this reason, doctors and dietitians generally recommend avoiding oats unless they are specifically labeled “gluten-free,” including food additives, such as malt flavoring, modified food starch, and other food products that were manufactured using gluten as a binding agent.

### **Can a gluten-free product become cross-contaminated?**

Cross-contamination in food manufacturing facilities or in a restaurant can simply occur when gluten-free foods come into contact with foods that contain gluten. Cross-contamination can occur any time from receiving the ingredients to the shipment of the final product. Generally cross-contamination occurs during the product storage, transportation, processing, or if the same equipment is used for processing a variety of products. Some food labels may include a “may contain” statement; this type of statement is voluntary. You still need to check the actual ingredient list. If you're not sure whether a food contains gluten, don't buy it or check with the manufacturer first to ask what it contains.

Cross-contamination can also occur at home if foods are prepared on common surfaces or with utensils that weren't thoroughly cleaned after being used to prepare gluten-containing foods. Using a common toaster for gluten-free bread and regular bread is a major source of contamination, for example. If you are sensitive to gluten, consider carefully what steps you need to take to prevent cross-contamination at home, school, or work.

### **Are all FDA-regulated foods that meet the definition of “gluten-free” required to be labeled?**

No. The new FDA rule applies to the voluntary use of gluten-free claims.

### **If a food processor/manufacturer uses the gluten-free claim on some of its food, does it mean that every food they make must be free of gluten?**

No. Food processors and manufacturers may make a variety of food products that are gluten-free and that contain gluten in the same facility and in many cases, use the same equipment. Food manufacturers may choose voluntarily to use the gluten-free claim to clearly inform consumers about which of their foods meet FDA's gluten-free requirements.

Special care must be taken to ensure that processing equipment and all food contact areas/surfaces are thoroughly cleaned and sanitized before a gluten-free product can be processed. Always follow best manufacturing practices for allergens or sensitive ingredients.

### **Can foods that are naturally free of gluten be labeled “gluten-free”?**

Yes. As stated before, the claim is voluntary. However, if a manufactured food is deemed to be “free of gluten” or it is naturally free of gluten, it qualifies for a gluten-free labeling claim if it meets all FDA requirements.

### **Can grains such as rice, buckwheat, or oats be labeled “gluten-free”?**

Any grain other than the gluten-containing grains of wheat, rye, barley, or their crossbred hybrids like triticale can be labeled as gluten-free, if the presence of any unavoidable gluten due to cross-contact situations is less than 20 ppm gluten.



### **Do oats have to be certified as gluten-free to be labeled “gluten-free”?**

No. However, as with any other non-gluten-containing grain, oats that are labeled “gluten-free” must contain less than 20 ppm gluten.

### **Can a food be labeled “gluten-free” if it is made with small amounts of a gluten-containing grain or ingredients derived from such grains that were not processed to remove gluten, if the food contains less than 20 ppm gluten?**

No. A food labeled “gluten-free” cannot be intentionally made with any amount of a gluten-containing grain (wheat, rye, barley, or their crossbred hybrids like triticale) or an ingredient derived from such grain that was not processed to remove gluten. The goal of manufacturing any food labeled “gluten-free” should be for the food to not contain any gluten or to contain the lowest amount possible that is less than 20 ppm gluten.

### **Can a food processor/manufacturer include the logo of a gluten-free certification program on its food label? If so, which logo is more important for persons who are sensitive to gluten?**

Manufacturers may include the logo of a gluten-free certification program on their food labels, provided it represents the truthfulness of the manufactured product and the label is not misleading.

A food processor/manufacturer may opt to use any third party gluten-free certification programs and gluten-free certification logos under the condition that the processed food product meets FDA’s minimum criteria for a gluten-free claim. The label and logo must be consistent with any other applicable FDA labeling regulations.

## **Can a food processor/manufacturer opt to use a claim like “made with no gluten-containing ingredients” or similarly “not made with gluten-containing ingredients”?**

Yes. FDA’s general food labeling regulations does not prohibit the use of a statement like “made with no gluten-containing ingredients” or “not made with gluten-containing ingredients” on any food products, provided that the statement is truthful and not misleading.

However, unless the label of the food product making such a statement also bears the gluten-free claim, consumers should not assume that the food meets all FDA requirements for being gluten-free.

## **Are advisory statements, such as “made in a factory that also processes wheat products” permitted on labels of foods bearing a gluten-free claim?**

Yes. The FDA regulations does not prohibit the inclusion of an advisory label statement, such as “made in a facility that also processes wheat,” on foods labeled “gluten-free,” provided that the statement is truthful and not misleading.

However, any food whose label bears a gluten-free claim, regardless of whether it also has an advisory statement, must meet all the requirements of the final rule and contain less than 20 ppm gluten.

## **Why didn’t the FDA adopt zero ppm gluten instead of less than 20 ppm gluten as one of the criteria for a food labeled “gluten-free”?**

It is the view of FDA (as relevant scientific research and epidemiological evidence suggests) that most individuals with celiac disease can tolerate variable trace amounts and concentrations of gluten in foods (including levels that are less than 20 ppm gluten) without causing adverse health effects.

## **Can a food manufacturer state on the label that the foods contain less than 5 or 10 ppm gluten?**

The FDA regulation does not prohibit manufacturers from stating any truthful and non-misleading information on their food labels, including declaring the maximum amount of gluten the food may contain. However, doing so would mean that each food bearing the label statement does not contain gluten at a level that exceeds the amount declared.



## **Does FDA regulation require food processors/manufacturers to test for gluten to make a gluten-free claim on my food labels?**

No. The FDA regulation does not require food processors/manufacturers to test specifically for the presence of gluten in their starting ingredients or finished foods. However, processors/manufacturers are responsible for ensuring that foods bearing a gluten-free claim meet the FDA’s minimum requirements of the gluten-free guidelines. Manufacturers may choose to use good manufacturing practices and effective quality control methods to ensure that any foods they label “gluten-free” do not contain 20 ppm or more gluten.

Processors/manufacturers of foods may have options to:

- **Conduct an in-house gluten testing of ingredients or finished foods.**
- **Use a third-party laboratory to conduct gluten testing.**
- **Request certificates of gluten analysis from their ingredient suppliers.**
- **Offer to use a third-party gluten-free certification program.**

### **What gluten test methods should I use if I want to analyze my foods labeled “gluten-free” in order to ensure compliance with the final rule?**

Manufacturers who elect to analyze their foods for gluten can select the test methods most appropriate for them, considering the type of foods they manufacture. Manufacturers are not obligated to use any one specific method to check for gluten in their foods.

FDA recommends the use of scientifically valid methods in order for the gluten test results obtained to be reliable and consistent. Conducting gluten testing using a scientifically valid method is an effective tool that manufacturers can use to ensure that their foods labeled “gluten-free” do not contain 20 ppm or more gluten.

### **Does the FDA require any specific record keeping requirements for manufacturers who would like to claim gluten-free on their label?**

No. The FDA regulations do not require any special record keeping requirements for food processors who intend to make a gluten-free claim on their label. However, a processor must use due diligence to provide evidence (in the form of records) that the product label that bears gluten-free claim is in fact gluten-free.

### **Does the gluten-free regulation apply to food products imported from other countries?**

Yes. All foods imported into the United States must meet the same federal requirements as foods domestically produced. Therefore, if the label of an imported food that is subject to FDA regulations makes a gluten-free claim, that food must comply with the gluten-free labeling requirements.

### **What are some nutrient dense, gluten-free food ingredients that I can use for processing in my facility?**

**Fibrous foods:** Vegetables, fruits, beans, amaranth (Amaranthaceae), quinoa (Chenopodium), millet, buckwheat, sorghum, and flax.

**Vitamin B-containing foods:** Eggs, milk, meat, fish, orange juice, beans, nuts, seeds, and gluten-free whole grains.

**Iron-containing foods:** Meat, fish, chicken, beans, nuts, seeds, eggs, amaranth, and quinoa.

**Calcium-containing foods:** Milk, yogurt, cheese, sardines and salmon with bone, broccoli, collard greens, almonds, calcium-fortified juice, amaranth, and quinoa.

## Suggested Resources

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