

GLUTEN-FREE LABEL READING – FDA and USDA and Alcohol Labeling (FDA, TTB)

KEY POINTS

- If a product is labeled “gluten-free,” it has been determined that it is gluten-free by the manufacturer.
- Foods labeled gluten-free must contain less than 20 parts per million of gluten.
- You must read the labels of all packaged food products to determine if they are appropriate to include in a gluten-free diet.
- Two government agencies regulate the labeling of food - the Food and Drug Administration (FDA) and the United States Department of Agriculture (USDA).

Food and Drug Administration (FDA)

- There are two types of labeling that can help you determine whether a food is appropriate for you to eat - gluten-free labeling and allergen labeling.
 - **Gluten-free labeling:** The (FDA) has a rule that defines the use of **voluntary** gluten-free claims on food labels. Under this rule a food labeled gluten-free:
 - Will not include as an ingredient the grains wheat, barley, rye, or cross-bred varieties of these grains.
 - Will not include an ingredient derived from wheat, barley, rye, or cross-bred varieties of these grains that has **not** been processed to remove gluten (e.g., hydrolyzed wheat protein, wheat flour, vital gluten, wheat bran, wheat germ, barley malt extract or flavoring, and malt vinegar)
 - **Can** include an ingredient derived from wheat, barley, rye, or cross-bred varieties of these grains as long as it had been processed to remove gluten (e.g., modified food starch from wheat, wheat starch, dextrin from wheat,) **and** the final food product contains less than 20 parts per million (ppm) of gluten.
 - Will contain less than 20 ppm of gluten from ingredients and/or gluten that may be in a product unintentionally due to cross contact with wheat, barley, or rye.

Note: Other wheat starch hydrolysates, such as glucose syrup from wheat, caramel color from wheat, and maltodextrin from wheat, are considered gluten-free because they are so highly processed. If you see these ingredients in products NOT labeled gluten-free it is highly unlikely that they would cause a food product to contain 20 ppm or more gluten. Visit “Ingredients You Don’t Have to Worry About” on celiacnow.org.

The FDA also considers the claims “**no gluten**,” “**free of gluten**,” and “**without gluten**” to be the same as the term gluten-free when used on a food label. Products making any of these claims must comply with the FDA’s gluten-free labeling rule.

Note: Foods also may contain the claims “made with no gluten-containing ingredients” and “not made with gluten-containing ingredients.” Products making these claims do

Parts per million or [ppm](#) also means milligrams per kilogram (there are 1 million milligrams in 1 kilogram). It is simply how we measure gluten content. You can look at it this way: if you purchased a bag of 1 million blue M&Ms and when you got it home you discovered that it actually contained 999,980 blue candies and 20 RED candies, you could say that your blue M&Ms were contaminated with 20 ppm red M&Ms.

Another way to imagine 20ppm: If you could cut a regular slice of bread (1 ounce) into 7,030 tiny pieces, 1 tiny piece would contain as much gluten as a whole slice of gluten-free bread (1 ounce) that contains 20ppm gluten.

NOT need to comply with the gluten-free labeling rule. Therefore, they are likely NOT gluten-free.

Allergen labeling: In 2004 the Food Allergen Labeling and Consumer Protection Act (FALCPA) became law. Under this law, food products regulated by the FDA must clearly state when an ingredient in a food product contains protein. Therefore, if an ingredient in a food contains protein from wheat, the word "wheat" must be included on the food label either in the **ingredients list** or **Contains statement**.

- **Wheat**
- Eggs
- Fish
- Crustacean Shellfish
- Milk
- Peanuts
- Soy
- Tree nuts

Sample label

Ingredients: Enriched flour (wheat flour, malted barley, niacin, reduced iron, thiamin mononitrate, riboflavin, folic acid), sugar, partially hydrogenated soybean oil, and/or cottonseed oil, high fructose corn syrup, whey (milk), eggs, vanilla, natural and artificial flavoring) salt, leavening (sodium acid pyrophosphate, monocalcium phosphate), lecithin (soy), mono-and diglycerides (emulsifier)

OR

Contains Wheat, Milk, Egg, and Soy

FALCPA does not cover barley or rye protein.

FALCPA also does not cover wheat protein that may be in a product unintentionally due to cross contact.

- FALCPA also pertains to ingredients only. If a food labeled gluten-free includes the word wheat in either the ingredients list or the Contains statement, the gluten-free labeling rule states that additional language must be included on the food label. Specifically, an asterisk must be included after the word wheat and the following statement must be made: “The wheat has been processed to allow this food to meet the FDA requirements for gluten-free food.”
- Under FALCPA, “food” also includes medical foods, dietary supplements and infant formula. Many dietary supplements voluntarily label their products “gluten free” or “free of gluten.” Choose supplements that are labeled gluten-free. If it is not labeled gluten-free, check the label carefully for gluten-containing ingredients and contact the manufacturer to ask about cross-contamination. The term “food” does NOT include any medications, either prescription or over-the-counter drugs. The gluten-free status of medications has to be verified.

Per the FDA labeling rule if a food is labeled gluten-free the manufacturer has determined that it is gluten-free and it may be used as part of a gluten-free diet.

- Manufacturers of labeled gluten-free foods take several steps to ensure that their products are truly gluten-free. These steps may include:
 - Hazard Analysis and Critical Control Points program
 - Allergen control programs
 - Routine testing of raw ingredients and finished products

If you have any questions regarding the protocols followed by a manufacturer of labeled gluten-free foods, call and ask to speak with a quality assurance representative.

- For foods regulated by the FDA **not labeled gluten-free**, you should read the ingredients list and, in the case of wheat, the Contains statement looking for these words and terms:
 - Wheat
 - Barley
 - Rye
 - Malt
 - Oats (this grain is highly likely to be contaminated with gluten)
 - Brewer's yeast
 - Yeast extract and Autolyzed yeast extract: (Avoid unless you have contacted the manufacturer and have been told the source of the yeast is NOT spent yeast from

beer manufacturing. Spent yeast is likely contaminated with barley protein from malt.)

Foods containing these words and ingredients should not be eaten. By definition, these ingredients contain protein and nothing about their normal processing removes the protein.

- **Malt, malt flavoring, and malt extract** mean barley malt, barley malt flavoring, and barley malt extract. If a source other than barley is used it will be stated in the ingredients list, such as "corn malt."
- **Brewer's yeast**, when used as an ingredient in a food product, may be spent brewer's yeast which is a by-product of beer brewing. As a result it may be contaminated with malt and grain.
- **Yeast extract or autolyzed yeast extract**, when used as an ingredient in a food product, may be spent brewer's yeast which is a by-product of beer brewing. As a result this ingredient may be contaminated with barley protein from malt.

If you do not see any of these words on the label of an FDA-regulated food then the product is unlikely to include any gluten-containing ingredients.

Naturally gluten-free grains, flours, and products made from them may be contaminated with wheat, barley, and/or rye. Whenever possible, choose labeled gluten-free versions of these products.

A FEW INGREDIENTS TO KEEP IN MIND IF AN FDA-REGULATED PRODUCT IS NOT LABELED GLUTEN-FREE:

Brown rice syrup may be processed with some form of barley, such as barley enzymes, but it is unclear whether these enzymes sometimes contain residual barley gluten and, thus, whether it is actually an issue for those with celiac disease. Choose to avoid or include this ingredient in your diet at your own discretion.

Some **dry smoke flavoring** may use malted barley flour as a carrier for the smoke. If this ingredient is used in an FDA-regulated food, component ingredients (called subingredients of an ingredient) may or may not be included.

Wheat starch: A food labeled gluten-free may contain wheat starch if the food contains less than 20 parts per million of gluten. The FDA has mandated that if a food labeled gluten-free includes the word wheat in the ingredients list or Contains statement as required by FALCPA then the food label must include the verbiage, "The wheat has been processed to allow this food to meet the Food and Drug Administration requirements for gluten-free foods." **Food containing wheat starch that is not labeled gluten-free should not be eaten.**

A SPECIAL WORD ABOUT OATS (May 2016): Gluten-free oats should not be added to the diet until you get the okay from your dietitian or doctor. We at the BIDMC Celiac Center are concerned about the safety of the relatively new mechanically/optically sorted oats methodology and its use by certain gluten-free grain millers and several food manufacturers of gluten-free oat-based products. Although this method of mechanically separating wheat and barley from regular oats is promising, there can be a risk of cross contamination. At this time, it is not clear that the testing measures are successful in consistently and sufficiently identifying gluten contamination in all cases. In addition, different companies are using different testing methods, some more stringent than others. For this reason, each manufacturer must be assessed on an individual basis. We believe best practices methodology, more rigorous and precise testing, and transparency of gluten-free testing data are necessary to feel comfortable with the safety of gluten-free oats.

We, as clinicians, feel more comfortable with the gluten-free oats grown under the purity protocol process at this time. However, we recognize that some companies may be doing a good job at consistently providing mechanically sorted gluten-free oats. We encourage our patients to look into how the gluten-free oats they may choose to purchase are grown and processed to be gluten-free. Keep in mind that some companies are using a combination of both purity protocol oats and mechanically sorted oats. Talk to your celiac health care team to help you make an informed decision about what choices may be best for you. Oats and products containing oats should only be eaten if they are labeled gluten-free. The amount eaten should initially be limited to 50 grams of dry oats a day which is about 1/2 cup of dry rolled oats or 1/4 cup of dry steel cut oats. Drink adequate water if you are adding gluten-free oats to your diet since they are high in fiber.

Keep in mind that while most patients with celiac disease can tolerate gluten-free oats, not everyone can. Patients who are eating gluten-free oats are advised to maintain routine follow-ups with their medical team diligently. Patients with persistent symptoms and/or an elevated anti-TTG antibody level should avoid all gluten-free oats and oat products until these symptoms and/or level have substantially improved and should follow up with their medical team. Patients who develop new symptoms that seem to correlate with gluten-free oat ingestion should follow up with a physician who is expert in the monitoring of celiac disease/non celiac gluten sensitivity so as to determine whether gluten exposure or an alternative diagnosis can account for these symptoms.

The information on www.glutenfreewatchdog.com can help patients stay current on the oats situation in the United States.

United States Department of Agriculture (USDA)

The USDA has not issued a rule to define “gluten-free” on the labels of the foods it regulates.

- Allergen labeling (listing wheat, fish, milk, etc.) is voluntary for food products regulated by the USDA.
- Approximately, 80-90% of USDA regulated products are voluntarily labeling foods for allergens, including sometimes labeling the product “gluten-free” on the package. Among the 10-20% of foods that are not voluntarily labeling foods for allergens, the number of foods containing ingredients actually derived from wheat is likely small.
- Inclusion of a 'Contains' statements or allergens included in the ingredients list in parentheses indicate that a manufacturer of a USDA-regulated food is voluntarily following FALCPA-like allergen labeling.

The USDA regulates:

- "Egg products" (meaning eggs outside of their shells, which are considered, dried, frozen, or liquid whole eggs, egg yolks, and egg whites with or without added ingredients) . Note: Egg substitutes, such as products containing egg whites but no whole egg, that have added colorings to make them look like a whole egg product are not regulated by USDA. They are regulated by the FDA.
- Meat products (hot dogs, deli meats, bacon, processed sausage)
- Poultry products (seasoned chicken breast, sliced turkey breast)
 - Meat products and poultry products include processed meat and processed poultry as well as mixed food products containing, in general, >3% raw meat or 2% or more cooked meat or poultry (e.g. beef stew, Asian style rice and beef).

If an egg product is regulated by the USDA it will include a shield on product packaging.



If a meat, poultry or mixed food product containing meat or poultry is regulated by the USDA it will include a mark of inspection on product packaging.



For USDA-regulated foods **not** labeled gluten-free and **not** voluntarily complying with FALCPA, read the food label looking for these words and terms:

- Wheat
- Barley
- Rye
- Oats
- Malt
- Brewer's yeast
- Yeast extract or autolyzed yeast extract
- **Starch** (unless a gluten-free source is named)
- **Dextrin** (unless a gluten-free source is named)
- **Modified food starch** (unless a gluten-free source is named)

Foods containing these words and ingredients should not be eaten. If you do not see any of these ingredients on the label of a USDA-regulated food, however, the product is unlikely to include any gluten-containing ingredients.

You also may want to familiarize yourself with the other common or usual names for "wheat flour" that rarely may be used in the ingredients list of a USDA-regulated food product:

- Semolina
- Farina
- Durum flour
- Enriched flour
- Graham flour
- White flour
- Plain flour

A FEW INGREDIENTS TO KEEP IN MIND IF AN USDA-REGULATED PRODUCT IS NOT LABELED GLUTEN-FREE:

Brown rice syrup may be processed with some form of barley, such as barley enzymes, but it is unclear whether these enzymes sometimes contain residual barley gluten and, thus, whether it is actually an issue for those with celiac disease. It is also unlikely that brown rice syrup would appear in a USDA labeled product. Choose to avoid or include this ingredient in your diet at your own discretion.

Some **dry smoke flavoring** may use malted barley flour as a carrier for the smoke. If this ingredient is in a meat or poultry product regulated by the USDA, any barley ingredient used in the smoke flavoring will be listed in the ingredient's list by its common or usual name [e.g. malt].

Wheat starch: A food labeled gluten-free may contain wheat starch if the food contains less than 20 parts per million of gluten. Food containing wheat starch that is not labeled gluten-free should not be eaten.

ALCOHOL:

Alcoholic beverages are either fermented or distilled. If an alcohol is **fermented**, it may contain protein from the starting materials that provided the starch or sugar. Whether a fermented alcohol is considered free of gluten protein depends upon the starting material.

The following fermented alcohols are considered free of gluten protein:

- Wine
- True hard cider
- Labeled gluten-free beer (made without malted barley)

The following fermented alcohols are NOT considered free of gluten protein:

- Beer and other malt beverages
- Flavored hard cider containing malt
- Flavored hard lemonade containing malt
- Flavored wine coolers containing malt

If the alcohol is a **distilled** product, proteins from the starting materials that provided the starch or sugar are removed. Distilled alcohols include:

- Pure distilled spirits such as vodka, gin, whisky, brandy, rum, and tequila
- Flavored spirits, such as flavored vodka and flavored gin
- Liqueurs and cordials

Distilled spirits are considered to be free of gluten protein even if the starting material for the alcohol is wheat, barley, or rye.

Most alcohol is regulated by the Alcohol and Tobacco Tax and Trade Bureau (TTB).

Certain alcohols are regulated by the Food and Drug Administration including:

- Beer: that is not made with both malted barley and hops, such as labeled gluten-free beer. Gluten-free beers are made using a substitute for malted barley, such as sorghum malt.
 - The TTB regulates malt beverages. Because gluten-free beers are not malt beverages (they do not contain barley malt) they are not regulated by the TTB. Instead they are regulated by the FDA. The TTB does not consider so-called gluten-free beer to be beer.
- Wine that contains less than 7% alcohol by volume
- Hard cider that contains less than 7% alcohol by volume

Alcohol regulated by the FDA must comply with the Food Allergen Labeling and Consumer Protection Act. Alcohol regulated by the FDA can be labeled gluten-free as long as it complies with the gluten-free labeling rule.

Allergen labeling for alcohol regulated by the TTB is voluntary.

The TTB recently released an Interim Policy (February 2014) allowing gluten-free claims on product labels if the alcohol is made WITHOUT wheat, barley, rye, or crossbred varieties of these grains OR ingredients derived from these grains (examples: wine fermented from grapes and vodka distilled from corn). BUT producers must ensure that their raw ingredients and finished products (among other things) are NOT cross-contaminated with gluten.

The TTB will NOT allow gluten-free claims on product labels if the alcohol is made with wheat, barley, rye, or crossbred varieties of these grains OR any ingredients derived from these grains. This means that distilled alcohol that has wheat, barley, or rye as a starting material can NOT be labeled gluten-free. This can be confusing to consumers.

Regardless, pure distilled alcohol is considered to be free of gluten protein by consensus of celiac disease experts.

Gluten-reduced beers made with barley malt may NOT be labeled gluten-free. Gluten reduced beers should be avoided by those following a gluten-free diet.

The TTB will allow the statement on product labels and in advertising, “Processed (or treated or crafted) to remove gluten” for products made with wheat, barley, rye, or crossbred varieties of these grains OR any ingredients derived from these grains IF these grains or ingredients have been processed (or treated or crafted) to remove all or some of the gluten.

- Fermented products (e.g., beer) must also include the following statement, “Product fermented from grains containing gluten and processed to remove gluten. The gluten content of this product cannot be verified, and this product may contain gluten.”
- Distilled products made from wheat, barley, or rye must also include the following statement, “This product was distilled from grains containing gluten, which removed some or all of the gluten. The gluten content of this product cannot be verified, and this product may contain gluten.”

Visit www.celiac.org for more information on:

Simple Label Reading, FDA versus USDA Food Labeling, Allergen Advisory Statements, Food and Ingredients You Don’t Need to Worry About (pending revision May 2016), Gluten-Free Grains- Safety and Contamination, Certification of Gluten-Free Foods, Alcohol (pending revision as of Feb 2016)

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