

Follow-Up Fact Sheet from September 18, 2013 Webinar: “Understanding the FDA’s Gluten-Free Labeling Rule Part 1: What You Need to Know”

Featuring Panelists:

Tricia Thompson, MS, RD; The Gluten-Free Dietitian, Nutrition Consultant Celiac Disease, Founder Gluten Free Watchdog, LLC
Matthew Cox, Marketing Director for Bob's Red Mill Natural Foods

Are you ready to keep learning? Follow the “Let’s Advance” boxes for more information and further explanations.

Basic Info to Know:

- The FDA’s gluten-free labeling rule is voluntary - manufacturers are not required to call out “gluten” in food products.
- While the regulation is voluntary, what’s important to know is that any product that is labeled gluten-free *must* meet the FDA requirements - that accountability is key.
- The use of a “gluten-free” label does not replace or eliminate the need to comply with the mandatory allergen labeling that requires wheat and the other top allergens to be listed.
- In its most basic sense, a packaged food product regulated by the FDA that is labeled gluten-free must contain less than 20 parts per million (ppm) gluten – but it must also comply with additional criteria beyond this specific threshold.
- Manufacturers are not required to test for gluten. The FDA does share some suggestions with manufacturers on how they can ensure that gluten-free foods contain less than 20 ppm gluten.
- Gluten-free ≠ zero ppm. There is currently no way to guarantee “zero gluten.” Current validated testing methods cannot test to that level.
- Food products that are labeled “no gluten,” “free of gluten,” and “without gluten” must also comply with the FDA’s gluten-free ruling. The claims “made with no gluten-containing ingredients” and “not made with gluten-containing ingredients” do not have to comply with the ruling.

Let’s Advance:

Visit the [Beyond Celiac FDA](#) section to learn what other criteria foods labeled gluten-free must meet.

Let’s Advance:

Visit the [Beyond Celiac FDA](#) section for a short presentation on the assays used to test for gluten.

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- Because the use of a “gluten-free” label is optional, remember that non-labeled products may still be gluten-free. Reading the label to check ingredients remains an essential part of successfully managing the gluten-free diet.
- The regulation will allow inherently gluten-free foods, such as a bag of raw carrots or bottle water, to be labeled gluten-free. Here’s an example: While there can still be the case where one package of fresh broccoli may be labeled gluten-free while another may not be, both are still safe for people with celiac disease because broccoli in its natural state is gluten-free.
- The new regulation also applies to dietary supplements, such as vitamins and minerals. The rule does not apply to:
 - Foods regulated by the U.S. Department of Agriculture (USDA)
 - Alcoholic beverages regulated by the Alcohol and Tobacco Tax and Trade Bureau (TTB)
 - Prescription and non-prescription drugs
 - Pet food
 - Cosmetics
- The rule became effective on September 4, 2013 and the compliance date for the rule was August 5, 2014.

Let’s Advance:

Head to the [Webinar Archive](#) to listen to “It’s Not Just Food Anymore: An Update on Gluten-Free Alcoholic Beverage Labeling”

Let’s Advance:

Visit www.BeyondCeliac.org and search “Journal Article Sheds New Light on Gluten in Cosmetics”

Follow-Up Q&A

Answers provided by either Tricia Thompson, MS, RD or Beyond Celiac Staff

Question 1

Q: Under the FDA’s final gluten-free labeling rule, oats are NOT considered a gluten-containing grain. Does this mean that oats are safe to consume on a gluten-free diet?

A: By definition oats are naturally gluten-free. In their natural form oats do not contain the gluten protein. However, fields where oats are grown and mills that produce and store oats may also grow and manufacture wheat, barley or rye. These practices result in cross-contact (also known as cross-contamination). The good news is that cross-contact is preventable.

Current research strongly suggests that the majority of patients with celiac disease can tolerate oats in their pure, uncontaminated form. It is important to note that a very small percentage of individuals with celiac disease do react to pure, uncontaminated oats. Although the cause for this reaction is not completely understood, some literature suggests that a protein in oats can trigger a response similar to gluten.

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Individuals who would like to add gluten-free oats to their diet should do so under the guidance of their dietitian or physician. For persons with celiac disease, oat intake should be limited to the equivalent of ½ cup of rolled gluten-free oats per day.

Any oats and products containing oats that are eaten must be labeled gluten-free. When shopping, look for oats that are specifically labeled “gluten-free.” This applies to both single ingredient oat products and multi-ingredient products containing oats.

Let’s Advance:

Head to slides 30-34 for more information on oats and the gluten content of oats not labeled gluten-free.

Individuals who develop any new symptoms after adding gluten-free oats to their diet should bring this to the attention of their dietitian or physician.

Question 2

Q: Why is wheat starch allowed in products that are labeled gluten-free?

A: Wheat starch is considered an ingredient processed to remove gluten because the ingredient is intended to be free of gluten through special manufacturing. It is the case, however, that wheat starch may contain varying amounts of wheat protein (protein being the key word). Gluten is a pesky substance to get rid of.

Wheat starch and ingredients made from hydrolyzed wheat starch (such as “glucose syrup (wheat)”) may be included in a product labeled gluten-free as long as the final food product contains less than 20 ppm gluten.

The wheat starch that may be used in labeled gluten-free foods must contain low amounts of gluten protein in order for the final food product to contain less than 20 ppm gluten. In such situations the labeling must indicate that: “The wheat has been processed to allow this food to meet FDA requirements for gluten-free foods.”

Products containing wheat starch that are NOT labeled gluten-free should not be eaten by individuals with celiac disease.

Question 3

Q: It’s unclear to me whether I should still steer clear of products containing malt and hydrolyzed wheat protein. What does the FDA’s gluten-free labeling rule say about these ingredients? For example, can I eat soy sauce?

A: The final rule does not specifically mention whether malt or hydrolyzed wheat protein are still considered ingredients that are not processed to remove gluten and, therefore, not allowed in products labeled gluten-free.

Let’s Advance:

Head to slides 47-52 for background information on fermented and hydrolyzed foods.

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According to Tricia Thompson's presentation, there is nothing in the final rule that leads her to believe that the FDA has changed their stance on malt or hydrolyzed wheat protein. It is her recommendation that individuals with celiac disease should continue to not consume products containing barley malt or hydrolyzed wheat protein.

Regular soy sauce is one example of a product containing hydrolyzed wheat protein. Hydrolyzed wheat protein has been partially broken down to contain shorter protein fragments. It remains controversial whether current testing methods are able to accurately measure these protein fragments and translate results into intact gluten protein.

Question 4

Q: While I understand that less than 20 ppm gluten is less than a crumb and, therefore, not visible to the eye, I still have several questions about this amount. Can you...

1. Help put this into context for me?
2. Clarify whether I should be concerned with cumulated gluten intake?
3. Explain how many servings of less than 20 ppm can a person with celiac disease safely consume in one day?

A: Before addressing these questions, let's lay some groundwork.

20 ppm = 20 milligrams (mg) of gluten per 1 kilogram (kg) of food. And, 1 kg of food contains 1,000,000 mg of food.

Part 1 – If you could take a 1 oz. slice of regular bread and break it into 7,030 tiny pieces, one of these tiny pieces would contain the same amount of gluten found in an entire 1 oz. slice of gluten-free bread.

Parts 2 and 3: – Each 1 oz. slice of bread containing 20 ppm gluten contains 0.57 milligrams (mg) of gluten – which is still under the 10 mg of gluten threshold that limited research suggests that most individuals with celiac disease can tolerate each day.

Question 5

Q: What vinegar, if any, is safe to eat on a gluten-free diet?

A: Pure distilled vinegar is gluten-free, malt vinegar is not. Flavored and seasoned vinegars may contain gluten, most

Let's Advance:

Fermented and hydrolyzed foods have proved to be difficult when testing for gluten. Read about the findings of a recent collaborative study on the competitive R5 ELISA, an assay that may be used to help assess gluten content of these types of foods. Visit www.BeyondCeliac.org and search "Study Validates the R5 Competitive ELISA"

Let's Advance:

Head to slides 21-24 to listen to Tricia Thompson explain "Confusion over 20 ppm."

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typically in the form of malt, so ingredient lists should be carefully read. If wheat protein is contained in vinegar, the label will say so. The single word “vinegar” on a food label implies cider/apple vinegar and is gluten-free.

Question 6

Q: I know that you recommend purchasing naturally gluten-free grains and flours and grain and flour-based products that are labeled gluten-free. Are there other dry food products that might fall into this category? For example, what about seeds, beans and nuts?

A. Seeds and beans also fall into the category of products that may be more likely to be contaminated with wheat, barley, or rye. This is due to grain, seed, and bean standards, which allow a certain amount of other grain or foreign material.

Question 7

Q: Does this ruling mean that the products labeled gluten-free now aren't under 20 ppm?

A: According to Tricia Thompson's presentation, just because up to, but not including, 20 ppm gluten is allowed in foods labeled gluten-free, does not mean that these products contain anywhere close to this amount. Based on testing hundreds of samples of food products labeled gluten-free through Gluten-Free Watchdog using the formally validated sandwich R5 ELISA Mendez Method, the vast majority of product samples are testing well below 20 ppm.

Further, according to the FDA, most products currently labeled gluten-free will already meet the FDA's final gluten-free labeling rule. The FDA estimates that about 5% of current products on the market *do not* currently meet the standards.

Question 8

Q: If a product is now labeled gluten-free but its label says that it is “processed in a facility that also processes wheat,” is this product really gluten-free?

A. As outlined in Tricia Thompson's presentation, voluntary allergen advisory statements, like the one listed above, may be included on foods labeled gluten-free without additional clarifying language. However, you can rest assured because foods with allergen advisory statements for wheat that are also labeled gluten-free must comply with the gluten-free labeling rule. If a product has a gluten-free claim, it must contain less than 20 ppm and meet the ruling's additional criteria.

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Question 9

Q: I know that we have to start somewhere, but I don't understand the significance of the rule if it's not mandatory and manufacturers aren't required to test. How does this rule impact people on a medically necessary gluten-free diet as opposed to individuals "riding out the fad"?

A: The gluten-free labeling rule is especially important in light of the recent "fad" surrounding gluten-free diets. The rule makes it clear that gluten-free food is a serious medical need for people with celiac disease and other gluten-related disorders. It has also brought more attention to these medical needs in the press, so it's a strong statement on behalf of those consumers.

To view the webinar "Understanding the FDA's Gluten-Free Labeling Rule Part 1: What You Need to Know" and all past Beyond Celiac webinars, visit www.BeyondCeliac.org/webinars/archive.

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