

Temporary FDA Food Labeling Policy during COVID-19: Implications for Those Following a Gluten-Free Diet

Food manufacturers are facing unforeseen ingredient shortages and supply chain disruptions due to the COVID-19 pandemic. Manufacturers are concerned that having to change the labels to reflect necessary MINOR ingredient substitutions could result in less product availability. In response to the dilemma, the [FDA issued this policy guidance](#) allowing certain temporary and minor formulation changes due to supply chain challenges during this time without making conforming label changes. The FDA strongly encourages manufacturers to continue to comply with labeling as best they can, whenever possible, and to notify consumers of ingredient changes by using stickers or updating product websites to reflect any changes that are made.

How does this affect the gluten-free consumer?

Tricia Thompson, MS, RDN, of Gluten Free Watchdog posted an excellent summary on her website about this temporary FDA issue with several practical recommendations for the gluten-free community. Click [here](#) to read her [post](#).

The policy is relatively explicit about avoiding ingredient substitutions with the top 8 allergens. This is comforting because wheat is one of the top 8 allergens and manufacturers are well informed about allergen labeling for these major allergens.

However, barley and rye are **not** considered allergens. If a food is NOT labeled gluten-free, under this policy, a manufacturer could *potentially* use a barley-based ingredient, such as malt or malt extract without changing the label.

The policy change also allows for different varieties of the same ingredient to be substituted without a label change. A less experienced manufacturer may not be aware of the gluten cross contact issues associated with regular oats or regular flours and, for example, could *potentially* substitute gluten-free labeled rice flour with rice flour that is not labeled gluten-free.

Per the FDA, any permitted minor formulation changes “should be consistent with” these general factors:

- **SAFETY:** the ingredient being substituted for the labeled ingredient **does not cause any adverse health effect** (including food allergens, **gluten**, sulfates, or other ingredients known to cause sensitivities in some people, for example, glutamates).
- **QUANTITY:** generally present at **2% or less** by weight of the finished food
- **PROMINENCE:** the ingredient being omitted or substituted for the labeled ingredient is **not a major (prominent) ingredient** (for example, replacing rice flour for wheat flour in a muffin) or an ingredient that is the subject of a label statement.
- **CHARACTERIZING OR INGREDIENT IN NAME:** the ingredient being omitted or substituted for the labeled ingredient is **not a characterizing ingredient** (such as omitting raisins in a raisin bread) where the presence of the ingredient has a material bearing on consumer purchasing.
- **CLAIMS:** an omission or substitution of the ingredient **does not affect any voluntary nutrient content or health claims on the label**
- **NUTRITION/FUNCTION:** an omission or substitution of the labeled ingredient will not significantly impact the finished product.

The Celiac Center’s Recommendation:

We agree with Tricia Thompson of Gluten Free Watchdog’s recommendation to purchase a reasonable supply of the labeled gluten-free products that you have come to trust, including trusted brands of gluten-free oats (if you eat gluten-free oats), gluten-free grains, flours, legumes, and products labeled gluten-free that contain these ingredients. It also makes sense to supply yourself with your favorite brands of trusted

foods that are not labeled gluten-free but appear to be free of gluten containing ingredients. Some examples of these products that have a low risk of cross contact with gluten are yogurt and frozen vegetables, etc. Remember, you can always call the manufacturer directly to ask if ingredient changes are being made without label changes.

Urgent Call to Action from Gluten Free Watchdog:

Working together, seven celiac patient/consumer advocacy and professional groups submitted a letter to FDA noting their concerns about the effect of this policy on the gluten-free community. The letter is available here: https://www.glutenfreewatchdog.org/news/wp-content/uploads/2020/06/GFWD_Letter_FDA-Temporary-Guidance_FINALVERSION.pdf

To submit your own comment to the docket, click here: <https://www.regulations.gov/document?D=FDA-2020-D-1139-0009>

If the link above doesn't work, try: <https://beta.regulations.gov/comment/FDA-2020-D-1139-0009>.

Gluten Free Watchdog suggests using any portions of (or the entire) group letter in your comment. You can also write in support of the letter and upload it to the docket.

Thank you,

Melinda Dennis, MS, RDN, LD and the Clinicians of the Celiac Center