Food Allergen Thresholds and Their Potential Applications
Comment to FDA from the Celiac Disease Foundation
Docket Number: FDA-2026-N-1304

The Celiac Disease Foundation, in collaboration with its Scientific Advisory Committee, the Society for the Study of Celiac Disease, submits these comments to inform the Food and Drug Administration's (FDA) approach to food allergen thresholds. The Foundation is the leading global patient advocacy organization for celiac disease, a serious autoimmune disease affecting 3 million Americans whose only treatment is a strict gluten-free diet. The Foundation strongly supports the FDA's movement toward a risk-based threshold framework and urges the Agency to explicitly include gluten and celiac disease. To that end we submit these comments with the following recommendations:

1. **Include gluten and celiac disease in the risk-based threshold framework.**

2. **If considering requiring precautionary allergen labeling, standardize language and adopt the FAO/WHO reference dose for gluten**, which was advanced to Step 8 at the 49th Session of the Codex Committee on Food Labelling (CCFL49).

3. **Pair thresholds with clear guidance, communication, and ongoing research.**

Doing so will ensure the millions of Americans with celiac disease who rely on a gluten-free diet have access to clear, consistent, and scientifically grounded labeling, which will reduce inadvertent exposure, improve quality of life, and align the United States with the international scientific consensus already in place. We expand on each recommendation below.

Include gluten and celiac disease in the risk-based threshold framework

While the FDA acknowledges that the threshold concepts developed as part of this current effort could apply to other food allergies and intolerances that are addressed in the future, there are many benefits to incorporating gluten now. The Codex Alimentarius Commission, Food and Agriculture Organization (FAO), World Health Organization (WHO), and European Food Safety Authority (EFSA) have all moved toward risk-based allergen management frameworks that incorporate gluten and celiac disease. The FDA's threshold initiative offers an opportunity to align U.S. policy with these international approaches, which would reduce regulatory divergence for manufacturers operating in global markets, improve food safety for U.S. consumers, and ensure the U.S. is following international scientific consensus.

Currently, the FDA gluten-free labeling rule defines "gluten-free" based on the measurable gluten content of the finished food (<20 ppm), rather than the presence or absence of specific grain-derived ingredients in the production process. This label is voluntary for manufacturers to include. Since absolute zero gluten exposure is difficult to achieve in

modern food systems, risk-based thresholds are necessary to balance patient safety, feasibility in food manufacturing, regulatory consistency, nutritional adequacy, and quality of life for patients with celiac disease.

A key reason for considering gluten and celiac disease in a risk-based threshold framework now is that it is mechanistically distinct and requires its own threshold approach compared to IgE-mediated food allergies. For these food allergies, the threshold concept is designed to prevent an acute immune reaction. For celiac disease, the harm mechanism is autoimmune: repeated exposure to gluten, even at low levels, causes cumulative villous atrophy and intestinal damage that can lead to serious long-term complications including nutrient deficiencies, osteoporosis, infertility, and cancer. Considering celiac disease in a risk-based threshold framework means considering cumulative exposure over time, asymptomatic presentation, and variation in sensitivity. If the framework is developed now only considering IgE-mediated food allergies, it may not be applicable to celiac disease down the line.

In our comment to FDA's January 2026 Request for Information on gluten labeling (Docket No. FDA-2023-P-3942, Comment Tracking Number moa-leaz-e8fk), we urged FDA to require that the labeling requirements currently applicable to major food allergens apply to the gluten-containing grains rye and barley. Deferring celiac disease to a later phase in developing this threshold framework risks another multi-year gap in regulatory protection.

If considering requiring precautionary allergen labeling, standardize language and adopt the FAO/WHO reference dose for gluten

The voluntary and unregulated use of precautionary allergen labeling (PAL) creates serious confusion for consumers with celiac disease who rely on labeling to determine whether a product is safe for them to eat. Statements such as "May contain," "processed in a facility that also handles wheat," and "made on shared equipment," unnecessarily restrict food choices for patients, which is a critical issue for celiac disease patients already severely limited in their options. Contains statements are more straightforward to consumers and clearly signal whether the product exceeds the 20ppm threshold of gluten.

If precautionary labeling advances, we urge FDA to adopt the reference dose of 4 mg gluten established by the November 2025 FAO/WHO expert consultation and formally advanced at the 49th Session of the Codex Committee on Food Labelling (CCFL49) in Ottawa in May 2026.[1] The FAO/WHO modeling in developing the reference dose incorporated the fact that repeated low-level exposure causes cumulative villous atrophy for people with celiac disease, demonstrating that thresholds need to be protective enough to prevent intestinal

[1]Codex Alimentarius Commission. *Annex to the General Standard for the Labelling of Pre-packaged Foods (CXS 1-1985): Guidelines on the Use of Precautionary Allergen Labelling (PAL)*. CX/FL 26/49/5. 49th Session of the Codex Committee on Food Labelling (CCFL49), Ottawa, Canada, May 11–15, 2026. Available at: https://www.fao.org/fao-who-codexalimentarius/meetings/detail/en/?meeting=CCFL&session=49

damage over time, not just acute reactions.[2] Products below this threshold should not carry precautionary statements.

Further, we recommend that if PAL is adopted, the FDA replace current unregulated voluntary advisory statements with a single, standardized precautionary statement triggered by evidence-based thresholds, so that the statement is meaningful to consumers and clearly conveys product-specific risk.

As is stated in the Codex guidelines and recommended by the FAO/WHO expert consultation, any precautionary allergen labeling framework adopted by the FDA should remain fully consistent with the existing gluten-free labeling rule and should not permit or require precautionary statements about gluten-containing grains to appear alongside a gluten-free claim on the same product. Allowing a food that meets FDA's regulatory definition of gluten-free to also bear a statement such as "may contain wheat" creates contradictory and potentially misleading safety signals, undermining the clarity of the gluten-free label and confusing consumers who rely on that claim as the primary indication that a product meets FDA's less-than-20-ppm gluten standard.

Pair thresholds with clear guidance, communication, and ongoing research

If adopting a risk-based threshold framework that incorporates gluten, this must be paired with transparent communication, strong compliance systems, and ongoing research to ensure the thresholds truly protect individuals living with celiac disease while supporting a practical and sustainable food system.

We recommend providing clear guidance to manufacturers related to cross-contact targets and accurate labeling, laying out the differences between the 4 mg reference dose and the <20ppm gluten-free threshold. This guidance should address specific high-risk product categories (e.g. baked goods, oats, spices) where gluten cross-contact is particularly prevalent.

We also recommend educating consumers on any labeling changes. Critically, communication must make clear that thresholds represent risk minimization, not risk elimination, and that they are calibrated to protect the vast majority of people with celiac disease. The Celiac Disease Foundation is committed to working with FDA to educate the celiac disease community and ensure consumer confidence in labeling.

Lastly, we recommend both encouraging ongoing research and incorporating research into these policies to ensure thresholds remain protective as evidence evolves. This includes continued dose-response research, improvement of analytical testing standards, and long-term outcome surveillance tracking rates of inadvertent exposure and celiac disease complications over time.

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[2] World Health Organization, Food and Agriculture Organization of the United Nations. *Ad hoc Joint FAO/WHO Expert Consultation on Risk Assessment of Food Allergens: Reference Dose(s) for Cereals Containing Gluten or Gluten.* Geneva, Switzerland: World Health Organization; 2025.

Conclusion

The science is clear, the need is urgent, and there is international consensus for incorporating gluten and celiac disease in a risk-based allergen management framework. Celiac disease carries serious long-term consequences and the millions of Americans managing it deserve a regulatory framework that reflects the best available evidence. Incorporating gluten into the framework now, paired with standardized labeling and clear guidance, is a meaningful and achievable step toward that goal. The Celiac Disease Foundation stands ready to support the FDA in this work, and we are grateful for the opportunity to contribute to this important conversation.

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About The Celiac Disease Foundation: The Celiac Disease Foundation, established in 1990, is the leading global patient advocacy organization committed to accelerating diagnosis, treatments, and a cure for celiac disease, a serious genetic autoimmune disease. In partnership with the Society for the Study of Celiac Disease, the Foundation's scientific advisory and professional leadership body, we unite the strength of the clinical, research, and patient communities to drive progress. Our mission is to improve the health and well-being of the millions affected by celiac disease through strategic investments in research, advocacy, and education.