

January 5, 2024

Dockets Management, FDA-2023-P-3942
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Comments on FDA Citizen Petition to Label Gluten as a Major Food Allergen
FDA Docket Number: [FDA-2023-P-3942](#) (“Citizen Petition”)

Thank you for the opportunity to provide comments in support of Celiac Journey’s FDA Citizen Petition to require the labeling of Gluten on all food packages in the United States, as it is required to be declared on food labels in 87 other countries worldwide.¹

This petition has important consumer protection implications for those who have Celiac Disease and their parents and caregivers, and they have a right to know whether food they purchase contains Gluten.

Requested Action

Currently, Wheat is required to be labeled in the U.S., but Gluten is not, even though Gluten is found in Wheat, Barley, Rye and most Oats. This Citizen Petition is requesting a long-overdue action by the FDA to better protect more than 3.3 million Americans with Celiac by labeling Gluten (Wheat, Barley, Rye and Oats) as a Major Food Allergen on all packaged foods.

Under its existing authority in the Food Allergen Labeling and Consumer Protection Act in statute at 21 U.S.C. § 343(x), Consumer Reports requests that the FDA grant the petition and issue a rule to:

- 1) require that all ingredients with Gluten be listed by name in the ingredient lists of all foods.
- 2) add gluten to the FDA’s list of allergens in Sec. 555.250 of its Compliance Policy Guides Manual, “Statement of Policy for Labeling and Preventing Cross-contact of Common Food Allergens” to address both labeling and cross contact issues related to food manufacturing practices.

FALCPA makes clear that the FDA is not precluded from adding to the list of major allergens requiring identification under the FALCPA's labeling scheme. The FALCPA's labeling requirements “do not prevent the Secretary from requiring labels of labeling changes for other food allergens that are not major food allergens.”

In addition, the Senate report for FALCPA made clear that the FDA could expand the list of major food allergens² in a "manner consistent with" the FALCPA.

¹ <https://www.regulations.gov/document/FDA-2023-P-3942-0001>

² See footnote 423 in Derr LE. 2006. When food is poison: the history, consequences, and limitations of the FALCPA. *Food Drug Law J* 61(1):65-165.

Celiacs Face Potentially Life-Threatening and Life-Debilitating Adverse Health Effects from Ingesting Gluten

The FDA has correctly indicated that people with Celiac Disease “face potentially life-threatening illnesses if they eat gluten, typically found in breads, cakes, cereals, pastas, and many other foods... There is no cure for celiac disease and the only way to manage the disease is to avoid eating gluten.”³

However, research has shown that 44 percent of people with Celiac Disease who follow a strict Gluten Free diet still get glutened once a month,⁴ and “many with celiac disease pay over 40% more in annual healthcare costs.”⁵

Importantly, unlike food allergies with IgE-Mediated mechanisms, there is no rescue medicine (i.e., adrenaline or antihistamine) to treat accidental ingestion of Gluten and the start of the auto-immune cascade in food allergy with Non-IgE-Mediated mechanisms such as Celiac Disease. Additionally, those with a Non-IgE-Mediated food allergy to Gluten cannot outgrow their food allergy – Celiac is lifelong (until such time as a cure may be developed).

In addition to vomiting and diarrhea, Gluten ingestion for people with Celiac can cause anemia, cancer, heart disease, immunological scarring, intestinal damage, malnutrition, etc.

According to the NIH’s “Notice of Special Interest (NOSI): Accelerating Progress in Celiac Disease Research” that was published on November 23, 2021, there are more than 3 million Americans who have Celiac Disease.

“Celiac disease is an autoimmune disease that occurs in genetically susceptible individuals who develop an immune response to ingested gluten. This disease affects greater than 1% of the US population, and incidence appears to have been increasing over the last several decades. The only known treatment is life-long strict avoidance of all forms of wheat, rye, and barley. Although a gluten-free diet is an effective treatment in many individuals, recent research has revealed that up to 50% of individuals following a gluten-free diet are inadvertently exposed to gluten, and a substantial minority develop persistent or recurrent symptoms.

Clinical manifestations are multifaceted and include gastrointestinal (ranging from severe malabsorption to subclinical damage of the gastrointestinal tract) as well as extraintestinal (e.g., skin) expressions of disease. Additional manifestations may vary from subclinical damage of the gastrointestinal tract to refractory celiac disease that is non-responsive to a gluten-free diet. Although rare, celiac disease is associated with increased risk of gastrointestinal tract cancers and lymphomas.”⁶

³ <https://www.fda.gov/consumers/consumer-updates/gluten-free-means-what-it-says>

⁴ <https://twitter.com/abast/status/1551780196243603457>

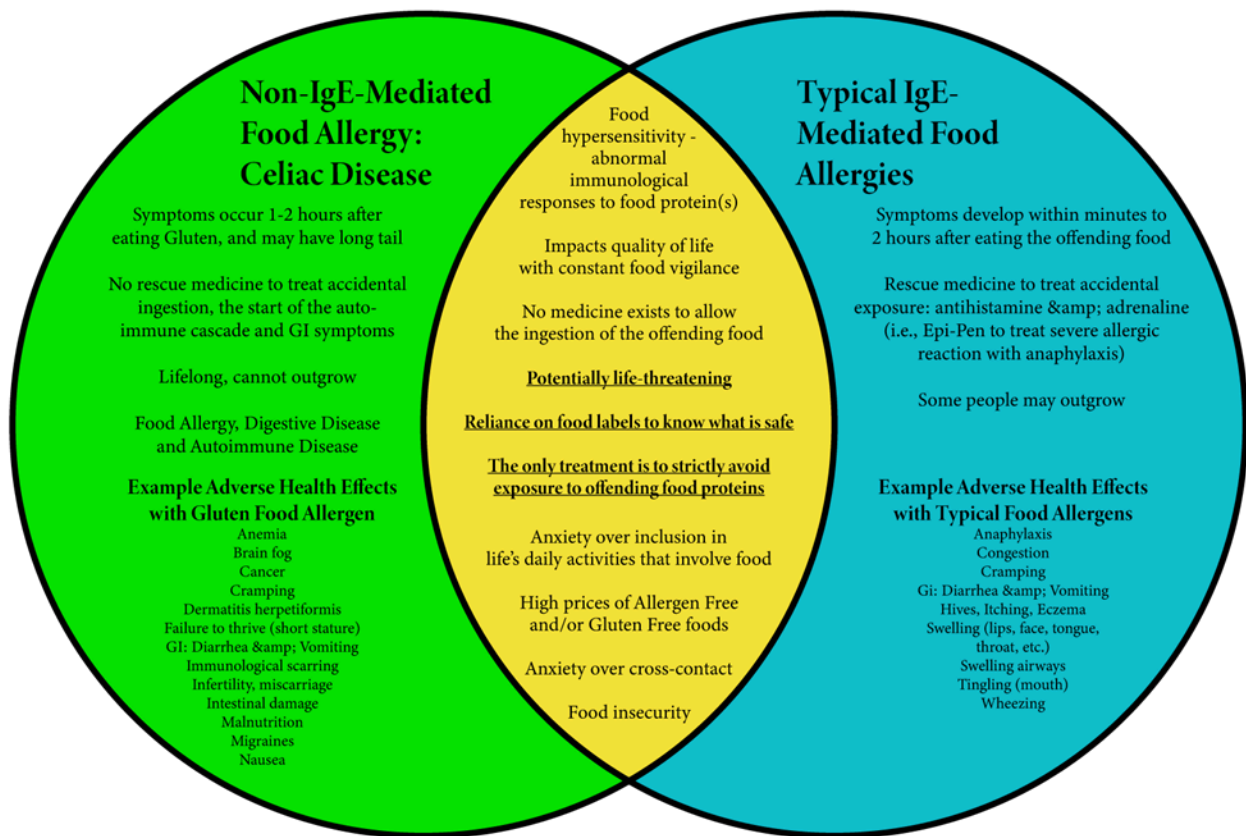
⁵ <https://www.beyondceliac.org/>

⁶ <https://grants.nih.gov/grants/guide/notice-files/NOT-AI-22-004.html>

For someone with Celiac Disease, eating, sleeping, thinking, learning and working are major life activities that can be impacted on a daily basis through the ingestion of Gluten, and there are various bodily systems which can be impacted including: gastrointestinal (digestive), nervous (anxiety, ataxia and neuropathy), skeletal, reproductive (infertility) and integumentary. Celiacs are also at a greater risk of being diagnosed with additional auto-immune disorders.

The Venn diagram below illustrates the key near-peer similarities between food allergies that are Non-IgE-Mediated Mechanisms with Celiac Disease (Gluten) and typical IgE-Mediated Mechanisms: potentially life-threatening, the only treatment is to strictly avoid the food allergen(s), and consumers' reliance on food labels to know what is safe to eat.

The Similarities and Differences Between Non-IgE-Mediated Mechanisms with Celiac Disease & Typical IgE-Mediated Mechanisms



Labeling Gluten as a Major Food Allergen is congruent with the conclusions of international food safety authorities and expert committees comprised of scientists, regulators, physicians, clinicians and risk managers from academia, government and the food industry including:

- 1999 Joint Food and Agriculture Organization of the United Nations/World Health Organization Expert Committee on Food Additives “Evaluation of Certain Food Additives and Contaminants: Fifty-third Report of the Joint FAO/WHO Expert Committee on Food Additives. 2000. WHO Technical Report Series 896. World Health

Organization, Geneva (“1999 FAO-WHO Expert Consultation”; also referred to as the “1999 Codex criteria”).⁷

- 2021 Food and Agriculture Organization of the United Nations/World Health Organization Expert Consultation on Risk Assessment of Food Allergens, which included the FDA’s Dr. Lauren Jackson, Chair, and the FDA’s Dr. Stefano Luccioli (“2021 FAO/WHO Expert Consultation”). The 2021 FAO/WHO Expert Consultation found, “based on systematic and thorough assessments which used all three criteria (prevalence, severity and potency), the Committee recommended that the following should be listed as priority allergens: Cereals containing gluten (i.e., wheat and other Triticum species, rye and other Secale species, barley and other Hordeum species and their hybridized strains), crustacea, eggs, fish, milk, peanuts, sesame, specific tree nuts (almond, cashew, hazelnut, pecan, pistachio and walnut).”⁸

According to research cited in the [FAO and WHO 2022 Risk Assessment of Food Allergens](#), Part 1 - Review and validation of Codex Alimentarius Priority Allergen List Through Risk Assessment. Meeting Report, Food Safety and Quality Series No. 14, Rome,

“It might be considered that oats should be on a regional priority allergen list because oats are generally contaminated, and often at significant levels, with gluten containing cereals. In Canada, taking into consideration lot-to-lot variability, approximately 88 percent of commercial oats samples (n = 133) were reported to be contaminated above the Codex-recommended gluten-free level (20 ppm), gluten concentration ranging from 21 to 3800 mg/kg of oats (Koerner et al., 2011). If oats are not on a priority allergen list, the possible presence of (contaminated) oats as an ingredient remains, and several products may cause reactions in consumers with coeliac disease. For this reason, oats are included in Canadian legislation.”⁹

The global implementation of the 1999 Codex Criteria and the 2021 FAO-WHO Expert Consultation can be seen in how 87 countries worldwide require that Gluten be labeled on all packaged foods, according to the map and chart produced by the Food Allergy Research and Resource Program at the University of Nebraska-Lincoln.¹⁰

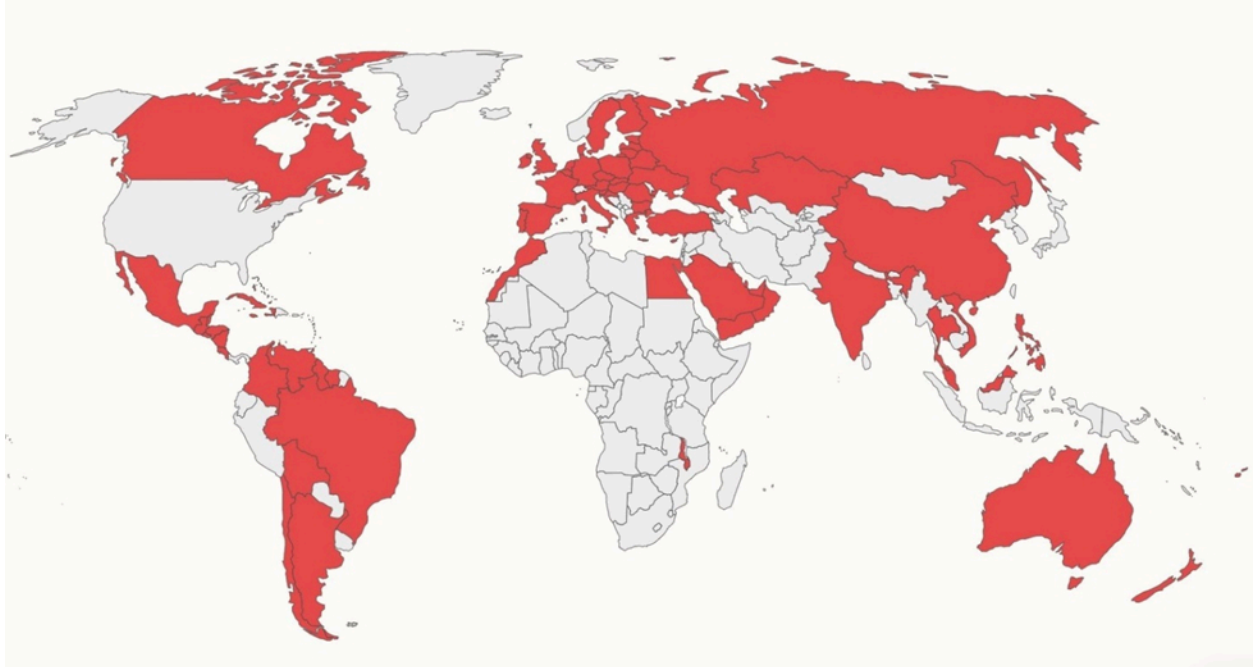
⁷ https://apps.who.int/iris/bitstream/handle/10665/42378/WHO_TRS_896.pdf

⁸ <http://www.fao.org/3/cb4653en/cb4653en.pdf>

⁹ <https://www.fao.org/3/cb9070en/cb9070en.pdf> and

<https://www.tandfonline.com/doi/pdf/10.1080/19440049.2011.579626?>

¹⁰ <https://farrp.unl.edu/IRChart>



Consumer Choice

This petition also has important implications on consumer choice.

For example, research strongly suggests that mandatory Gluten labeling would significantly expand the number of Gluten-free products available to those who have Celiac Disease because food products that do not contain Gluten would be labeled as such. According to The [New York Times](#), “because use of the gluten-free claim is voluntary, many foods that are in fact gluten-free might not be labeled as such.”

The voluntary labeling scheme has made Celiacs beholden to a premium marketplace of food items in which the price of Gluten Free foods is often two to six times more expensive on a per ounce basis than their Gluten containing counterparts. (Please see Section XI of the petition – “The Economics of Celiac Disease -- The Consumer Financial Burden of the Medically Required Gluten Free Diet.”)

While U.S. consumers’ reactions to a top 9 Major Food Allergens and Gluten vary, their consumer habits are the same -- they avoid purchasing foods that contain the allergen(s) that cause a potentially life-threatening immunological adverse reaction.

However, the key difference from a consumer protection standpoint is that under the Food Allergen Labeling and Consumer Protection Act of 2004 (“FALCPA”), the labeling scheme for the top 9 Major Food Allergens in the U.S. is mandatory, but the labeling of Gluten is permissive.

It’s important to note that because something is Wheat free, it does not mean it is Gluten Free. In other words, whereas sufferers of the current top 9 Major Food Allergens in the U.S. rely on

what ingredients are expressly included in required labeling disclosures of packaged foods, the Celiac community cannot rely on manufacturers to declare Gluten on food labels.

The requested action under this Citizen Petition is for the FDA to require all ingredients with Gluten to be listed by name in the ingredients list of all foods and to add gluten to the FDA's list of allergens in Sec. 555.250 of its Compliance Policy Guides Manual, "Statement of Policy for Labeling and Preventing Cross-contact of Common Food Allergens" to address both labeling and cross contact issues related to food manufacturing practices..

Sincerely,

Brian Ronholm
Director, Food Policy
Consumer Reports

Michael Hansen, PhD
Senior Scientist
Consumer Reports