

February 27, 2024

Dockets Management Staff (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

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

RE: Docket FDA-2023-P-3942-0001 Citizen Petition from Jonathan H. Bari on behalf of Celiac Journey

On behalf of the more than 33 million Americans who suffer directly from life-threatening food allergies, and the 85 million-plus that are directly and indirectly affected by food allergies and/or intolerances to one of the top nine food allergens, [FARE \(Food Allergy Research and Education\)](#) appreciates the opportunity to submit the following comments to the Food and Drug Administration (FDA) in support of the outcome of the citizen petition to FDA regarding food labeling of gluten from Jonathan H. Bari on behalf of Celiac Journey.

FARE is the nation's leading non-profit engaged in food allergy advocacy as well as the largest private funder of food allergy research. FARE's innovative education, advocacy, and research initiatives transform the future of food allergy through the advancement of new and improved treatments and prevention strategies, effective policies and legislation, and novel approaches to managing the disease.

Many in the food allergy community are part of the more than 3.3 million Americans with celiac disease and gluten intolerance. Therefore, we support the outcome of the Celiac Journey petition to require labeling of gluten to better protect those with celiac disease similar to the requirements to label the current top nine food allergens.

In support of Celiac Journey's desired outcome, FARE elevates the following points summarized from the petition:

- Celiac disease affects more than 3.3 million Americans.
- Food allergies are immune mediated reactions to foods. Allergies do not need to be IgE mediated, because these reactions can be either IgE mediated or non-IgE mediated. Non-IgE mediated food allergies include food protein-induced enterocolitis (FPIES), eosinophilic esophagitis (EoE), and celiac disease.
- Non-IgE mediated food allergy is not capable of triggering anaphylaxis and being immediately life-threatening. However, those with celiac disease do experience severe adverse health effects from ingestion of gluten, including intestinal damage, malnutrition, anemia, cancer, heart disease, intestinal damage, malnutrition, etc. Celiac disease must be thought of as an immune-mediated food allergy as well as an auto-immune disease.
- Gluten currently is required to be labeled in 87 countries worldwide.
- To date, wheat and wheat-derived ingredients are required to be labeled as "wheat" under the Food Allergen Labeling and Consumer Protection Act (FALCPA), but not as "gluten" and other gluten-containing grains are not required to note "gluten." The absence of wheat does not mean that a food product is free of gluten (see definition of "Cereal containing grains" that contain gluten below).

- Whether having IgE-mediated food allergy or celiac disease, consumer behavior to prevent reactions is the same—they avoid purchasing foods with food allergens or gluten. Both rely heavily on food labels to know what is safe to eat, every time they purchase a food, and every time they eat a food.
- FARE is a strong supporter of the current work of the Codex Committee on Food Labeling and its work to revise the Global Standard for the Labeling of Packaged Foods (GSLPF) related to food allergen labeling. This work includes cereals containing gluten in addition to priority food allergens requiring labeling. This work is supported by the work of the Ad hoc Joint Food and Agriculture Organization (FAO) and World Health Organization (WHO) Expert Consultation on Risk Assessment of Food Allergens.
- In the Part 1 report from the FAO/WHO expert consultation, based on its systematic review, it recommended that “Cereals containing gluten (i.e., wheat and other *Triticum* species, rye and other *Secale* species, barley and other *Hordeum* species and their hybridized strains)” be listed as priority allergens in addition to other food allergens.
- Regarding FDA assessment to move forward with mandatory labeling of gluten, FARE reiterates the similarities relative to negative health outcomes to those with IgE-mediated food allergy and those with celiac disease when foods containing gluten are consumed and are not labeled. Thus, FARE supports FDA using its draft framework, *Evaluating the Public Health Importance of Food Allergens Other Than the Major Food Allergens listed in the Federal Food, Drug, and Cosmetic Act*, to evaluate the need for gluten to be required in food labeling because of its public health importance to protect consumers with celiac disease. Simply stated, FARE believes gluten should be labeled.

FARE supports all labeling requirements and initiatives that assist our community and those in the celiac community. Labeling will reduce the burden of the disease and it is time that the FDA join the regulatory bodies in 87 other countries, and label gluten. If you have any questions about the content of this submission, please contact Robert Earl, Vice President, Regulatory Affairs, at rearl@foodallergy.org or 571-771-8582.

Respectfully submitted,



Sung Poblete, PhD, RN
CEO, FARE