



**Policy Objective: Reduce Diet-Related Disease
by Labeling Gluten as a Major Food Allergen**

EXECUTIVE SUMMARY

CELIAC JOURNEY'S FDA CITIZEN PETITION FOR THE LABELING OF GLUTEN AS A MAJOR FOOD ALLERGEN

September 13, 2023

Background

Labeling Gluten (Wheat, Barley, Rye and Oats) as a Major Food Allergen on all packaged foods in the U.S., like Gluten is labeled in more than 85 other countries around the world, will better protect 3.3 million Americans with Celiac Disease. Labeling Gluten is in alignment with the conclusions of international food safety authorities and expert committees comprised of scientists, regulators, physicians, clinicians, individuals and risk managers from academia, government and the food industry including:

- 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, "[b]ased 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)."¹ (emphasis added)
- 1,576 Comments submitted to the FDA on Labeling Gluten in Summer 2022 including from Dr. Virginia Stallings, a board-certified nutrition pediatrician, Professor of Pediatrics and Director of the Nutrition Center at the Children's Hospital of Philadelphia, Beyond Celiac, National Celiac Association, Gluten Free Watchdog, University of Chicago Center for Celiac Disease, etc. (Docket: FDA-2021-N-0553)²

Requested Action

Today, Wheat is required to be labeled in the U.S., but Gluten is not. Gluten is found in Wheat, Barley, Rye and most Oats. This Citizen Petition is requesting a long-overdue reckoning 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, just like labeling Gluten is required in more than 85 other countries. Under its existing authority in the Food Allergen Labeling and Consumer Protection Act in statute at 21 U.S.C. § 343(x), we request that the FDA issue a rule to: 1) require that all ingredients with Gluten be listed by name in the ingredient lists of all foods and; 2) add Gluten to the FDA's list of allergens in Sec. 555.250 of its Compliance

¹ <http://www.fao.org/3/cb4653en/cb4653en.pdf>

² <https://www.regulations.gov/docket/FDA-2021-N-0553/comments?filter=celiac>

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.

Advancing Equity Must Be a Central Component of FDA Decision-Making to Evaluate this Citizen Petition and Protect Celiacs, An Underserved Community With a Chronic Disability

The labeling of Gluten as a Major Food Allergen sits at the Intersection of President Biden’s Executive Orders on Advancing Equity for Underserved Communities, the White House Conference and National Strategy on Hunger, Health, and Nutrition and human rights.

We are respectfully requesting that the evaluation of this Citizen Petition be conducted now through the lens of President Biden’s Executive Order 13985 on “Advancing Racial Equity and Support for Underserved Communities Through the Federal Government” (January 20, 2021) and President Biden’s Executive Order 14091 on “Further Advancing Racial Equity and Support for Underserved Communities Through the Federal Government.” (February 16, 2023):

“Because advancing equity requires a systematic approach to embedding fairness in decision-making processes, executive departments and agencies (agencies) must recognize and work to redress inequities in their policies and programs that serve as barriers to equal opportunity.”³

According to the U.S. Department of Health of Human Services (“HHS”) HHS Equity Action Plan, “advancing equity must be a central component of the decision-making framework that all agency functions are routed through.”⁴

The Celiac community represents an underserved community which shares a particular characteristic including a chronic disability as per the Fourth Circuit Court of Appeals⁵ and a potentially life-threatening and life-debilitating food allergy to eating Gluten with numerous adverse health consequences.

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.

This Citizen Petition includes a detailed analysis of how Celiacs belong to an underserved community of persons with disabilities who have systematically been denied a full opportunity to participate in aspects of economic, social, and civic life.

³ <https://www.federalregister.gov/documents/2021/01/25/2021-01753/advancing-racial-equity-and-support-for-underserved-communities-through-the-federal-government>

⁴ <https://www.hhs.gov/sites/default/files/hhs-equity-action-plan.pdf>

⁵ United States Court of Appeals for the Fourth Circuit, No. 18-1725, Argued: January 29, 2019; Decided: May 31, 2019, See www.celiacjourney.com/williamsburg and <https://www.ca4.uscourts.gov/opinions/181725.P.pdf>

Celiac Disease Overview

- Celiac Disease is a potentially life-threatening food allergy, auto-immune disease and digestive disease that impacts at least 3.3 million Americans, greater than 1.0% of the general population.
- Researchers are finding that Celiac Disease prevalence is doubling approximately every 15 years, making it a public health epidemic. Gluten ingestion for people with Celiac can cause anemia, cancer, heart disease, immunological scarring, intestinal damage, malnutrition, etc.
- The only available treatment is strict adherence to a lifelong, Gluten Free diet. There is no rescue medication in the event of accidental ingestion and one cannot outgrow Celiac.
- 44% of people with Celiac Disease who follow a strict Gluten Free diet still get glutened once a month, and “many with celiac disease pay over 40% more in annual healthcare costs.”⁶

For More Information:

Celiac Journey

www.celiacjourney.com/citizenpetition

⁶ <https://twitter.com/abast/status/1551780196243603457> and <https://www.beyondceliac.org/>