

PRESIDENTIAL ACTIONS - EXECUTIVE ORDER

SUGGESTED DRAFT, Revised 8/13/26

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Note: yellow highlights represent the critical parts of this draft Executive Order and footnotes have been added to provide citations for the Trump Administration's due diligence and evaluation.

Making America Healthy Again for Millions of Americans with Celiac Disease & Gluten-Related Food Allergies by Requiring the Labeling of Gluten Grains as Major Food Allergens

By the authority vested in me as President by the Constitution and the laws of the United States of America, it is hereby ordered:

Section 1. Purpose. Millions of Americans with Celiac Disease and their loved ones struggle daily with eating. Celiac Disease affects greater than 1% of the US population, and the incidence has been increasing over the last several decades.¹

Celiac Disease is a potentially life-threatening and life-debilitating food allergy,² autoimmune disease,³ and digestive disease.⁴ Celiac is triggered by eating gluten, a protein found in wheat, barley, rye and most oats. The only known treatment for Celiac Disease is a strict gluten-free diet for life.

Since the Food Allergen Labeling and Consumer Protection Act (FALCPA) became law on January 1, 2006, only wheat has been required to be labeled in the United States, but barley, rye, and oats have not. In contrast, 87 other countries around the world (including in Canada, in the United Kingdom, and across the European Union) require the declaration of all gluten-containing grains as a major/priority food allergen on all packaged food items.⁵

According to the FDA, Celiacs face “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.”⁶ There is no rescue medication (i.e., adrenaline) in the event of accidental gluten ingestion, and unlike other food allergies, one cannot outgrow Celiac. 44% of people with Celiac Disease who follow a

¹ <https://grants.nih.gov/grants/guide/notice-files/NOT-AI-22-004.html>

² <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4241964/pdf/nihms247178.pdf> (pages 5, 11-12); and <https://www.fda.gov/media/157637/download> (page 10)

³ <https://grants.nih.gov/grants/guide/notice-files/not-ai-22-004.html#>

⁴ <https://www.niddk.nih.gov/health-information/digestive-diseases>

⁵ <https://farrp.unl.edu/IRChart/> - According to the University of Nebraska-Lincoln, the following countries require that Gluten be labeled on packaged foods: Anguilla, Antigua and Barbuda, Argentina, Australia, Austria, Bahamas, Barbados, Belarus, Belgium, Belize, Bermuda, Bolivia, Brazil, British Virgin Islands, Bulgaria, Canada, Cayman Island, Chile, China, Colombia, Costa Rica, Croatia, Cuba, Cyprus, Czech Republic, Denmark, Dominica, Egypt, El Salvador, Estonia, Fiji, Finland, France, Germany, Greece, Grenada, Guatemala, Guyana, Haiti, Honduras, Hong Kong, Hungary, India, Ireland, Italy, Jamaica, Kazakhstan, Kuwait, Latvia, Lithuania, Luxembourg, Malawi, Malaysia, Malta, Mexico, Montserrat, Morocco, Netherlands, New Zealand, Nicaragua, Oman, Philippines, Poland, Portugal, Qatar, Romania, Russia, Saint Lucia, Saudi Arabia, Singapore, Slovakia, Slovenia, Spain, St. Kitts and Nevis, St. Vin. and Grenada, Suriname, Sweden, Thailand, Trinidad and Tobago, Turkey, Turks and Caicos Island, Ukraine, United Arab Emirates, United Kingdom, Venezuela, Vietnam, and Yemen.

⁶ <https://www.fda.gov/consumers/consumer-updates/gluten-free-means-what-it-says>

strict gluten-free diet still accidentally ingest gluten once a month.⁷ There are more than 200 debilitating symptoms and adverse health effects that gluten ingestion causes for people with Celiac Disease including anemia, cancer, immunological scarring, intestinal damage, and malnutrition.

On February 13, 2025, I signed an Executive Order establishing the Make America Healthy Again Commission (MAHA Commission), and its initial mission has been focusing on the childhood chronic disease crisis. For example, 30 million U.S. children (40.7%) have at least one health condition, such as allergies, asthma, or an autoimmune disease. In the U.S., out of 3.3+ million Americans with Celiac Disease, there are approximately 729,000 U.S. children with Celiac Disease.

60% of Americans have at least one chronic disease, and 40% of Americans have two or more chronic diseases. The estimated prevalence of Celiac Disease in patients with Type 1 Diabetes is approximately 6%.⁸ Upwards of 15% of Celiac patients will develop other autoimmune diseases.⁹

The United States has the highest age-standardized cancer incidence rate among 204 countries, nearly double that of the next highest rate, with an 88% increase from 1990-2021. Research published in December 2024 showed that there is a high risk of digestive cancers in patients with Celiac Disease.¹⁰

78.8 years is the average life expectancy in the United States, which is below that of other comparable countries where the life expectancy averages 82.6 years. This equates to 1.25 billion fewer life years for the United States population. A study published in the Journal of the American Medical Association in 2020 found a small but significant increased risk of mortality in people with Celiac Disease.¹¹ 77% of young adults do not qualify for military service in the United States. According to the U.S. Department of Defense, DoD Instruction 6130.03, Celiac Disease is a disqualifying condition from service in the military (Medical Standards for Appointment, Enlistment, or Induction into the Military Services, Section 5.12.c.(3), May 6, 2018).¹²

On May 22, 2025, the MAHA Commission released THE MAHA REPORT, MAKING OUR CHILDREN HEALTHY AGAIN (Assessment), and found that “allergies are widespread, and autoimmune disorders are rising.” THE MAHA REPORT continued:

- “Today, over 1 in 4 American children suffers from allergies, including seasonal allergies, eczema, and food allergies.
- Eczema (atopic dermatitis) and skin allergies increased from 7.4% of children under 18 from 1997-1999 to 12.7% from 2016-2018.
- Between 1997 and 2018, childhood food-allergy prevalence rose 88%.
- Celiac disease rates have increased 5-fold in American children since the 1980s.”¹³

On September 9, 2025, the MAHA Commission released the Make Our Children Healthy Again Strategy Report (MAHA Strategy Report) which provides a policy roadmap for addressing

⁷ <https://www.beyondceliac.org/>

⁸ <https://www.uchicagomedicine.org/forefront/pediatrics-articles/are-pediatric-celiac-disease-and-type-1-diabetes-related>

⁹ <https://pmc.ncbi.nlm.nih.gov/articles/PMC3741914/>

¹⁰ [https://www.cghjournal.org/article/S1542-3565\(24\)01081-4/fulltext](https://www.cghjournal.org/article/S1542-3565(24)01081-4/fulltext)

¹¹ <https://jamanetwork.com/journals/jama/fullarticle/2764182>

¹² <https://www.esd.whs.mil/DD/>

¹³ <https://www.whitehouse.gov/wp-content/uploads/2025/05/WH-The-MAHA-Report-Assessment.pdf>

the childhood chronic disease crisis. The MAHA Strategy Report detailed 128 bold initiatives including policy reforms that will make a meaningful difference in the lives of 3.3 million Americans with Celiac Disease by requiring the labeling of gluten as a food allergen: **“Food Allergies: FDA will develop guidance on diagnostics and treatments for food allergies. FDA will also make recommendations about requiring transparency in disclosures of ingredients that impact certain health conditions, such as gluten for those with Celiac disease, and other established food allergens.”**¹⁴

On January 21, 2026, the FDA issued a Request for Information on Labeling Gluten (RFI) in response to a Citizen Petition filed by Celiac Journey.¹⁵ The RFI advanced the MAHA Strategy’s directive by demanding radical transparency in packaged food ingredients that affect health conditions and diet-related allergies. Public input calling for honest labeling will protect consumers, prevent harm, and Make America Healthy Again.¹⁶ There were more than 6,100 comments submitted to the RFI, and many people shared that barley, rye and oats are often hidden in seasonings, natural flavors, and spices, and not disclosed. Gluten is also often hidden in plain sight when these are not declared by common name.¹⁷ ¹⁸ Gluten can also be buried in long ingredient lists with small print and not called out as allergens.

Americans deserve clear, reliable information about what is in their food and how their food is made. With 40% of the American population having the genetic biomarker necessary to develop Celiac Disease, millions more remain at risk of developing this chronic disability that impacts major life activities on a daily basis including eating, learning, working, sleeping, socializing, travelling, etc.

While the availability of gluten-free food options has increased over the past decade, too many American Celiacs and their loved ones must still contend with the daily challenge of managing their diet, including with the voluntary labeling of gluten grains, the constant risk of cross-contamination with gluten, especially when eating outside of their home, the dangers of long-term adverse health complications, the high price of gluten-free food and the frustration of being diagnosed with a disease that has yet to be cured. Food insecurity happens daily for Celiacs regardless of a person’s age or social status.

In 1985, the FDA Final Rule stated: “The Agency finds that labeling packaged foods as ‘gluten free’ would not be as desirable as actually identifying on the food label the source of the gluten that is used in the food. Under 21 CFR 101.4(a),¹⁹ wheat gluten and other gluten sources must be identified by name when they are used in food.”²⁰ ²¹

There is significant scientific agreement that the best way to protect Celiacs is to require the labeling of gluten grains which are the dietary drivers of this disease.

¹⁴ <https://www.whitehouse.gov/wp-content/uploads/2025/09/The-MAHA-Strategy-WH.pdf>

¹⁵ <https://www.federalregister.gov/documents/2026/01/22/2026-01121/labeling-and-preventing-cross-contact-of-gluten-for-packaged-foods-request-for-information>

¹⁶ <https://www.fda.gov/news-events/press-announcements/fda-takes-steps-improve-gluten-ingredient-disclosure-foods>

¹⁷ For example, it can appear as “malt flavor” instead of “barley malt flavor”.

¹⁸ <https://www.regulations.gov/document/FDA-2023-P-3942-1120>

¹⁹ <https://www.ecfr.gov/current/title-21/chapter-I/subchapter-B/part-101/subpart-A/section-101.4>

²⁰ FDA Final Rule, Supplementary Information, March 6, 1985, https://archives.federalregister.gov/issue_slice/1985/3/6/8991-8997.pdf

²¹ <https://www.celiacjourney.com/rule>

The 1999 Codex Criteria from the UN's Food & Agriculture Organization (FAO) and World Health Organization (WHO) stated, "The revised list of those foods and ingredients known to cause food allergies and intolerance and whose presence should always be declared was identified as the following: Cereals containing gluten (i.e., wheat, rye, barley, oats, spelt or their hybridized strains) and their products."²²

Requiring the labeling of gluten on all packaged foods in the U.S. is in alignment with the conclusions of the 2021 Food and Agriculture Organization of the United Nations ("FAO")/World Health Organization ("WHO") Expert Consultation, which was chaired by the FDA's Dr. Lauren Jackson²³ ("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)."²⁴ The 2021 FAO/WHO Expert Consultation "determined that only foods or ingredients that cause immune-mediated hypersensitivities such as IgE-mediated food allergies and coeliac²⁵ [Celiac] disease should be included on the list of foods and ingredients included in section 4.2.1.4 of the GSLPF [General Standard for the Labelling of Prepacked Foods],"²⁶ and that the GSLPF list includes gluten.

Oats and wheat belong to the same botanical family (Poaceae) and oats also contain prolamin storage proteins called avenins, which can trigger Celiac in a small proportion of people.²⁷ Oats are naturally gluten-free. However, oats cultivated in North America and Europe are commonly contaminated by gluten containing grains, including wheat, barley, rye and triticale. Cross contamination of commercial oats with gluten is inevitable. The reason for this is the manner in which oats are grown, harvested, transported, stored, and milled.²⁸

Section 2. Policy. HHS Actions. Within 180 days of the date of this order, I am directing the Secretary of Health and Human Services to issue rulemaking to require the labeling of gluten-containing grains as "Major Food Allergens." This will prioritize a public health problem long overdue for robust action. To Make America Healthy Again, it is time for the FDA to address this critical consumer protection and food safety issue with the urgency it requires based on this Executive Order and the Secretary of HHS's existing statutory authority including under the Federal Food, Drug & Cosmetic Act the Food Allergy Safety, Treatment, Education, and Research Act of 2021 and FALCPA.²⁹ FALCPA "makes clear that it does not preclude FDA from

²² https://iris.who.int/bitstream/handle/10665/42378/WHO_TRS_896.pdf

²³ <http://www.fao.org/3/cb4653en/cb4653en.pdf>

²⁴ "Due to the lack of data on prevalence, severity and/or potency, or due to regional consumption of some foods, the Committee recommended that some of the allergens,... oats, ... should not be listed as global priority allergens but [Oats] may be considered for inclusion on priority allergen lists in individual countries."
<http://www.fao.org/3/cb4653en/cb4653en.pdf>

²⁵ "Coeliac" is the Greek spelling of Celiac which is used in some parts of the world.

²⁶ <http://www.fao.org/3/cb4653en/cb4653en.pdf>

²⁷ <https://www.fdf.org.uk/globalassets/resources/publications/guidance/fdf-gluten-labelling-guidance.pdf>

²⁸ <https://www.celiacjourney.com/oats>

²⁹ See Derr LE. "When food is poison: the history, consequences, and limitations of the Food Allergen Labeling and Consumer Protection Act of 2004." Food Drug Law Journal, 2006;61(1):65-165. PMID: 16838459. When Food is Poison was written by Laura Derr when she was a student at Harvard Law School, under the supervision of Lecturer on Law Peter Barton Hutt, Partner at Covington & Burling in Washington, D.C., for Harvard Law School's Winter 2005 Food and Drug Law course. Mr. Hutt was also former Chief Counsel to the FDA from 1971-1975. When Food is Poison won First Place in the 2005 H. Thomas Austern Memorial Writing Competition (long papers) sponsored by the Food and Drug Law Institute.

expanding via regulation the list of major allergens requiring identification under the FALCPA's labeling scheme."³⁰ Section 203(b) states that the labeling requirements established under new section 403(w) "do not prevent the Secretary from requiring labels or labeling changes for other food allergens that are not [yet] major food allergens."³¹ The new rulemaking shall apply to any food that is introduced or delivered for introduction into interstate commerce 12 months after the Secretary of Health and Human Services issues the rulemaking.

The FDA's definitional designation of Major Food Allergens is not merely informational. The term Major Food Allergens informs various federal and state programs and laws. The term Major Food Allergen determines regulatory treatment and drives compliance across federal and state regulatory schemes, including USDA FSIS requirements, Current Good Manufacturing Practices, SNAP and WIC programs, military food service standards, VA food service standards, and state laws such as California's Allergen Disclosure for Dining Experiences Act. Therefore, FDA's decisions establish the governing definitional baseline for allergen protection nationwide, and properly classifying gluten-containing grains is essential to ensure coherent and consistent implementation as well as to provide Celiac patients with protections equivalent and consistent with those afforded to individuals allergic to the existing Top 9 Major Food Allergens.

Additionally, withing 180 days of this order, the Secretary of Health and Human Services will add gluten-containing grains 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.

³⁰ When Food is Poison, Page 141, including footnotes 423-424 (<https://www.jstor.org/stable/26660870>): "See FALCPA 203(b), 21 U.S.C.A. 343(note); FALCPA 203(a), 21 U.S.C.A. 343(x). The Senate Committee Report states that it intends for any regulations issued by FDA requiring the identification of additional allergens to prescribe disclosure in 'a manner consistent with' the FALCPA. S. Rep. No. 108-226, at 10." (Source: <https://www.congress.gov/108/crpt/srpt226/CRPT-108srpt226.pdf>) "The legislation also adds a second misbranding provision to account for other food allergens. In particular, section 403(x) provides that FDA has the authority to require by regulation appropriate labeling of any spice, flavoring, coloring, or incidental additive ingredient that is, or includes as a constituent, a food allergen that is not a major food allergen. The committee does not intend the listing of all spices or flavorings in a product but intends that the Secretary will require the food allergen to be identified on the label in a manner consistent with this legislation."

<https://www.congress.gov/108/crpt/srpt226/CRPT-108srpt226.pdf>

³¹ H.R. Rep. No. 108-608, at 18. (2004), <https://www.congress.gov/108/crpt/hrpt608/CRPT-108hrpt608.pdf>

Additionally, within 180 days of this order, the Secretary of Health and Human Services will issue a report on Celiac Disease and prioritize funding Celiac Disease research to: 1) develop new treatment options and therapeutics to prevent, manage and cure Celiac Disease; 2) collect data on the prevalence of Celiac Disease and severity of allergic reactions, including the identification of any gaps in such activities; 3) develop effective Celiac Disease diagnostics; 4) identify the causes for the Celiac Disease epidemic, and 5) prevent Celiac Disease from activating in more at-risk Americans.

Section 3. Definitions. For purposes of this order:

A. The term “Gluten-containing grains” means any one of the following grains (or any crossbred hybrid thereof):

- a. Wheat, including any species belonging to the genus *Triticum*.
- b. Rye, including any species belonging to the genus *Secale*.
- c. Barley, including any species belonging to the genus *Hordeum*.
- d. Oats, including any species belonging to the genus *Avena sativa*.

B. The term “Gluten” means the proteins that:

- a. naturally occur in a Gluten-containing grains;
- b. Oats which are generally contaminated, and often at significant levels, with wheat, barley and rye due to being grown, harvested, transported, stored, and processed together.
- c. cause adverse health effects in persons with Non-IgE-Mediated food allergies including Celiac Disease, IgE-Mediated food allergies, food hypersensitivities and/or food intolerances related thereto.

Section 4. General Provisions. (a) Nothing in this order shall be construed to impair or otherwise affect:

- (i) the authority granted by law to an executive department or agency, or the head thereof; or
- (ii) the functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.

(b) This order shall be implemented consistent with applicable law and subject to the availability of appropriations.

(c) This order is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

(d) The Department of Health and Human Services shall provide funding for this order’s publication in the *Federal Register*.

DONALD J. TRUMP

THE WHITE HOUSE,

[Month Date], 2026.

Notes:

Food & Drug Law Journal

Congress established the list of Major Food Allergens, and Congress also created mechanisms including through the Food Allergen Labeling and Consumer Protection Act (FALCPA) for the FDA to act and to expand the list of Major Food Allergens by granting statutory authority to the Secretary of Health and Human Services to do so.

In 2006, *Food and Drug Law Journal* published an authoritative article by Laura Derr and Peter Barton Hutt, FDA's former Chief Counsel, Harvard Law Professor and Partner at Covington & Burling, on FALCPA which stated in relevant part that FALCPA "makes clear that it does not preclude FDA from expanding via regulation the list of major allergens requiring identification under the FALCPA's labeling scheme."³²

Senate Health, Education, Labor, and Pensions (HELP) Committee Report, February 12, 2004

In 2004, the Senate Health, Education, Labor, and Pensions (HELP) Committee, chaired by Senator Judd Gregg (R, NH), issued a report on FALCPA with an "Explanation of Bill and Committee Views" which stated in relevant part, "**The legislation [FALCPA] gives FDA the authority to modify or eliminate those requirements [including for Major Food Allergens] by regulation...** FDA must demonstrate in the regulations that modifications or eliminations of an allergen labeling requirement is necessary to protect public health. The committee considers this standard to impose a high burden on the Secretary to justify changing these requirements of the legislation... **The committee does not intend the listing of all spices or flavorings in a product but intends that the Secretary will require the food allergen to be identified on the label in a manner consistent with this legislation.**" See, S. Rep. No. 108-226, at 9.³³

House Committee on Energy and Commerce, July 15, 2004

In 2004, the House Committee on Energy and Commerce was chaired by Rep. Joe Barton (R, TX). According to the House Committee on Energy and Commerce Report, H.R. Rep. No. 108-608 (2004), Section 203(b) states that the labeling requirements established under new section 403(w) "do not prevent the Secretary from requiring labels or labeling changes for other food allergens that are not major food allergens."³⁴

FASTER Act of 2021

The Food Allergy Safety, Treatment, Education, and Research Act of 2021 (FASTER Act) explicitly directed the Secretary of Health and Human Services to submit, within eighteen months, a report to Congress that not only evaluates existing federal efforts but also includes "recommendations for the development and implementation of a regulatory process and scientific framework" to enable "timely, transparent, and evidence-based modification of the definition of 'major food allergen.'"³⁵

FDA Only Used its Existing Statutory Authority Once in 21 Years (FALCPA's 403(w) and 403(x)) & Failed When Given the Opportunity to Require Sesame & Gluten Labeling

³² When food is poison: the history, consequences, and limitations of the Food Allergen Labeling and Consumer Protection Act of 2004, *Food Drug Law Journal*, 2006;61(1):65-165. PMID: 16838459, <https://www.jstor.org/stable/i26659390> .

³³ <https://www.congress.gov/108/crpt/srpt226/CRPT-108srpt226.pdf>

³⁴ <https://www.congress.gov/108/crpt/hrpt608/CRPT-108hrpt608.pdf>

³⁵ Food Allergy Safety, Treatment, Education, and Research Act of 2021, Pub. L. No. 117-11, § 8, 135 Stat. 230, 232-33 (2021).

According to the Center for Science in the Public Interest, “Despite the need for periodic, evidence-based updates, FDA actions following the passage of FALCPA have been slow, piecemeal, and largely driven by advocacy from outside stakeholders, including CSPI. For example, **the agency’s only use of section 403(x) was in 2009, when the agency cited this section as one of several authorities supporting mandatory labeling of carmine/cochineal extract as an allergenic color additive, an action taken in response to a petition that CSPI had submitted 11 years earlier.**”³⁶ See Listing of Color Additives Exempt from Certification; Food, Drug and Cosmetic Labeling, Cochineal Extract and Carmine Declaration, 74 FR 207, Jan. 5, 2009.³⁷

In response to the 2014 Citizen Petition to require the labeling of Sesame, the FDA’s 6 Year response was woefully late and wholly inadequate. According to the Center for Science in the Public Interest, “FDA deliberated for six years on a 2014 petition from CSPI requesting that sesame be labeled as an allergen. While the agency eventually issued a draft guidance in November 2020 providing voluntary recommendations to manufacturers regarding sesame labeling, **it never exercised its authorities under 403(x) or other provisions to require labeling and food safety controls for sesame.**”³⁸

³⁶ https://downloads.regulations.gov/FDA-2021-N-0553-1824/attachment_1.pdf

³⁷ <https://www.federalregister.gov/documents/2009/01/05/E8-31253/listing-of-color-additives-exempt-from-certification-food-drug-and-cosmetic-labeling-cochineal>

³⁸ https://downloads.regulations.gov/FDA-2021-N-0553-1824/attachment_1.pdf