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

April 20, 2026

Re: Docket Number FDA-2023-P-3942 – Labeling and Preventing Cross-Contact of Gluten for Packaged Foods; Request for Information

Dear Sir/Madam,

The North American Millers' Association (NAMA) respectfully submits these comments in response to the citizen petition submitted by Jonathan H. Bari, individually, on behalf of Jax Bari, and Celiac Journey (the Celiac Journey Petition) and the Food and Drug Administration's (FDA) subsequent request for information (RFI) titled "Labeling and Preventing Cross-Contact of Gluten for Packaged Foods, Request for Information" Docket Number FDA-2023-P-3942.[1]

NAMA represents millers of wheat, corn, oats, and rye. Our members take raw grain and, through grinding and crushing, create flour and other products that are used to make favorite foods, such as bread, cereals, pasta, tortillas, cookies, cakes, and snack foods. We're proud to be the indispensable link between raw grain and healthy and delicious products that have sustained and enriched people's lives for centuries.

The current regulatory framework provides familiarity and consistency for both consumers with celiac disease and industry, and FDA should carefully examine how potential changes would impact these stakeholders. As noted in the RFI, the Celiac Journey Petition asks FDA to categorize oats as a gluten-containing grain (GCG) due to the potential for cross-contact and to add gluten to the list of allergens in Compliance Policy Guide Sec. 555.250 (the CPG), "Statement of Policy for Labeling and Preventing Cross-contact of Common Food Allergens." If adopted, a food product containing undeclared gluten could be deemed misbranded, and failure to control for cross-contact with gluten could render a food product adulterated even if it is not intended to be marketed as "gluten-free." Below we offer our preliminary comments in response to the petition and RFI.

[1] 91 Fed. Reg. 2,781 (Jan. 22, 2026).

1. **Any new requirements must be clearly authorized under the FD&C Act.**

It is critical that any new regulatory requirements pertaining to gluten be clearly authorized under the Federal Food, Drug, and Cosmetic Act (FD&C Act) to minimize the likelihood of legal challenges and the uncertainty that would result. Through the Food Allergen Labeling and Consumer Protection Act (FALCPA), Congress granted FDA clear authority to require labeling of major food allergens. Notably, the FD&C Act defines "major food allergen" in part as an ingredient that is or contains protein derived from one of nine specifically enumerated foods,[2] and, as FDA has acknowledged in the RFI, "Congress established the list of 'major food allergens' and the FDA does not have the authority to alter the list."[3] The recent history of the FASTER Act, through which Congress was required to pass legislation to add sesame to the list of major food allergens, further illustrates that changes to the major food allergen list require congressional action.[4]

We recognize that FALCPA disclaimed any intent to affect FDA's authority to require a label or labeling for food allergens other than major food allergens[5] and that certain pre-existing provisions of the FD&C Act could, in theory, be brought to bear on that issue. However, such a use of those provisions has not been tested, and any such use would need to satisfy the criteria established by the Supreme Court's decision in *Loper Bright Enterprises v. Raimondo*.[6] Relatedly, the Compliance Policy Guide Sec. 555.250, which Celiac Journey seeks to amend, is not a vehicle for enacting policy changes by functionally bypassing FALCPA.[7] This CPG provides direction for FDA staff on the agency's enforcement policy regarding major food allergen labeling and cross-contact. The CPG limits the "list of

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[2] 21 U.S.C. § 321(qq).

[3] 91 Fed. Reg. 2,781, 2,782 (Jan. 22, 2026).

[4] Food Allergy Safety, Treatment, Education, and Research (FASTER) Act of 2021, Pub. L. No. 117-11, 135 Stat. 309 (2021).

[5] Food Allergen Labeling and Consumer Protection Act of 2004 § 203(b), Pub. L. No. 108-282, 118 Stat. 905, 908, states: ''The amendments made by this section that require a label or labeling for major food allergens do not alter the authority of the Secretary of Health and Human Services under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) to require a label or labeling for other food allergens.''

[6] 603 U.S. 369 (2024).

[7] FDA, CPG Sec. 555.250 DRAFT: Major Food Allergen Labeling and Cross-contact (May 2023), https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cpg-sec-555250-draft-major-food-allergen-labeling-and-cross-contact.

allergens" to the major food allergens as defined by statute, and adding gluten to the CPG's list of allergens would functionally expand, from a practical standpoint, the scope of what Congress has defined as a major food allergen through a guidance document rather than through legislation. Furthermore, any actions pursued through FDA's authority under Section 403(x) of the FD&C Act regarding non-major food allergens must be accomplished through notice-and-comment rulemaking, which would provide clarity and predictability by engaging industry as part of the process.

Congress also granted FDA clear authority to issue a regulation to define and permit use of the term "gluten-free," and FDA arrived at its current definition by accounting for potential impacts to both consumers and industry. Industry and consumers have come to rely on FDA's regulatory definition; thus, any change that could increase the expense or decrease the availability of gluten-free oats must be carefully considered. In its proposed rule for the gluten-free definition, FDA recognized that allowing a gluten-free claim for oats that do not contain gluten from wheat, rye, barley, or any of their cross-bred hybrids "would make them easier to identify and perhaps would encourage…manufacturers to produce such oats."[8]

This has been the case, and gluten-free oats are now an important source of nutrients to consumers with celiac disease; changes to the current scheme could affect the availability of this important ingredient.[9] In the recently released Dietary Guidelines, "[w]hole grains are encouraged" and "[f]oods like oats, rice, and true sourdough are preferred."[10] Oats caryopsis offer relatively high amounts of fiber (12 – 14%) and beta glucans (5%), and are rich in unsaturated fatty acids, polyunsaturated fatty acids, essential amino acids, antioxidants, vitamins, and minerals. Moreover, consumption of oat grain or oat bran can decrease total plasma cholesterol and LDL-cholesterol levels.

Several factual distinctions warrant excluding oats from the definition of a GCG. Oats caryopsis do not inherently contain gluten proteins (such as gliadin and glutenin), which are responsible for triggering the immune response in consumers with celiac disease.[11] Gluten-free oat products on the market are made from raw oats that have been extensively

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8 72 Fed. Reg. 2,795, 2,802 (Jan. 23, 2007).

9 Iva Hoffmanová et al., The Pros and Cons of Using Oat in a Gluten-Free Diet for Celiac Patients, 11 Nutrients 2345 (2019).

10 *Real* Food Wins, https://www.realfood.gov.

11 Hoffmanová et al., *supra* note 9.

purified via robust production and milling systems. In its prior rulemaking for the gluten-free claim, FDA also acknowledged a concern that including oats in the definition of GCG could disincentivize "manufacturers to produce oats free of gluten from other grains because those manufacturers would have no way of distinguishing their products in the marketplace."[12]

Additionally, the Celiac Journey Petition's request to treat oats as GCGs is premised not on the *inherent properties* of oats, but rather on the *potential* for cross-contact. Defining an ingredient by its potential for cross-contact strains the purpose of defining such an ingredient when, under the same logic, many ingredients would also qualify for the same definition; the same logic would classify wheat as a "soy-containing grain" because both crops are sometimes grown in rotation on the same land, and especially because this is also a known issue. Also, if FDA defines "allergen cross-contact" to be the "unintentional incorporation of a food allergen into a food," this implicitly requires the food itself to not inherently contain the food allergen.[13] Oats cannot be a GCG and also be at risk of gluten contamination, and a definition allowing this would create confusing regulatory requirements. Further, defining oats as a GCG would be inconsistent with the definition used by the United States Department of Agriculture (USDA), which has separately developed a grading standard for "oats" that reflects the inherent characteristics of oats commingling with other grains.[14]

FALCPA does not require allergen labeling when an allergen is unintentionally present due to agricultural commingling; the use of both the ingredient list and the "Contains" statement for declaration of major food allergens is limited to ingredients that are intentionally added.[15] FDA has emphasized that "allergens present due to cross-contact are not to be declared in the ingredients list or the 'Contains' statement."[16] Therefore, designating oats as a GCG would be scientifically inaccurate and inconsistent with both USDA's definition and FDA's original reasoning for excluding oats from the definition.

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12 72 Fed. Reg. 2,795, 2,802 (Jan. 23, 2007).

13 21 C.F.R. § 117.3.

14 USDA, 7 C.F.R. pt. 810 (last visited Mar. 12, 2024).

15 21 U.S.C. § 343(w).

16 FDA, Guidance for Industry: Questions and Answers Regarding Food Allergen Labeling (Edition 5) (Jan. 2025), https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-questions-and-answers-regarding-food-allergen-labeling-edition-5.

To the extent that FDA is considering designating oats or gluten as a food allergen, that decision could also be vulnerable to challenge. Celiac disease is an autoimmune condition triggered by gluten ingestion; it is not an IgE-mediated allergic response and does not result in anaphylaxis. Gluten is not generally considered a food allergen within the scientific community.[17] Furthermore, Congress deliberately treated food allergens and gluten protein separately under FALCPA and limited the definition of "major food allergen" to a defined set of foods responsible for the vast majority of IgE-mediated allergic reactions. Congress specifically discussed celiac disease and gluten as one of the six findings in FALCPA, acknowledging that celiac disease is an immune-mediated disease and that avoidance of glutens in certain foods is the current recommended treatment.[18] Even with this finding in the statute, Congress omitted gluten from the list of major food allergens; this approach clearly indicates that FALCPA requirements were not intended to extend to gluten as an allergen.

Finally, if there are to be any changes to FDA's existing regulatory framework for allergens and gluten, it is important that the states agree to adhere to that framework. A patchwork of state labeling laws and regulations, particularly regarding gluten, would impose heavy compliance burdens on industry and would prove confusing to consumers.

2. The changes requested by Celiac Journey would disrupt the grain supply chain without providing a clear benefit to consumers with celiac disease.

The existing regulatory framework—notably, the "gluten-free" regulation and its corresponding requirements—provides a reliable option for consumers avoiding gluten in oats while also giving suppliers the ability to deliver affordable products meeting different consumer needs. It is important to note that, while the realities of the agricultural production and handling system virtually always lead to the commingling of oats with low levels of GCGs in field-run oats (oats taken straight from the field), specific production and/or milling protocols can reliably remove the presence of these GCGs. However, this is not feasible at scale across the entire oat supply chain. Treating gluten as a major food allergen would limit supplier options by imposing extraordinary burdens at every stage of the milling supply chain starting at the farm level and proceeding through harvest, storage, milling, and distribution of GCGs, even for supply chains not intended for gluten-free

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[17] See Food Allergy Research & Resource Program, Celiac Disease, available at https://farrp.unl.edu/farrp-resources/general-information-food-allergies-sensitivities/celiac-disease/ (last visited Mar. 10, 2026).

[18] Food Allergen Labeling and Consumer Protection Act of 2004, Pub. L. No. 108-282, Title II, 118 Stat. 905 (2004).

finished food products. Those burdens would extend into the subsequent manufacture of finished food products that contain GCGs.

It is one thing for producers to voluntarily undertake these burdens for purposes of qualifying their products as "gluten-free." It is quite another to make these burdens mandatory across the food supply and generate additional costs for industry and downstream consumers not seeking gluten-free products. Notably, FDA's regulatory impact analysis for the gluten-free labeling regulation did not consider the costs associated with these types of extensive controls. The totality of these burdens could make operations untenable for some millers and food manufacturers, limiting grain-based food options for both consumers seeking gluten-free products and general consumers.

Commingling of raw agricultural commodities (RACs) starts at the farm level, and classifying gluten as a major allergen would add another complication to planting decisions for farmers. Commingling, which occurs at the RAC level, is distinct from cross-contact, which is mainly a risk at the processing and manufacturing stage. The primary risk of gluten contamination in oats comes from commingling, as oats and wheat are typically processed on different lines with different types of equipment during manufacturing.

It is common for crops to be grown in fields with volunteer plants from prior plantings of GCGs or in close proximity to fields in which GCGs are growing or have been grown. For example, research conducted by Iowa State University[19] suggests that GCGs, particularly cereal rye and winter wheat, are being more prevalently used as cover crops in areas where corn and soy are being grown. Cover crops such as these play an important role in erosion control, soil cover, and weed suppression; regulatory requirements that add commingling considerations could force farmers to prioritize those considerations in planting decisions over cover crop functions and the long-term health of their farms.

As producers of oats labeled as gluten-free have learned, mitigating these sources of cross-contact requires the implementation of specific farm-level controls that significantly increase the complexity and expense of production. It may not be feasible for some farms to maintain dedicated harvesting, transport, and storage equipment or conduct full allergen cleans of equipment between use; thus, cross-contact can still occur.

The reality of commingling is recognized in several regulations that either provide for a tolerance of commingled grains or exempt RACs entirely from certain requirements. Under

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[19] Mark Licht & Zachary Clemens, *Most Commonly Used Cover Crops in Iowa*, Iowa State Univ. Extension & Outreach, https://crops.extension.iastate.edu/blog/mark-licht-zachary-clemens/most-commonly-used-cover-crops-iowa.

7 C.F.R. pt. 810, Official United States Standards for Grain (Grain Standards),[20] a tolerance of 10% other grains is allowed in a sample before the lot is considered "*Mixed Grain*." Further, the Grain Standards also allow for foreign material, which includes other grains. The amount of foreign material ranges from 0.4% to 15%, depending on the commodity and the grade number. Most RAC grains bought and sold in the U.S. are grade No. 2, which, for oats, allows up to 3% of foreign material.

Congress acknowledged commingling in the language of FALCPA Section 203(a)(1), which added section 403(w) to the FD&C Act and states: "A food shall be deemed to be misbranded… If it is **not a raw agricultural commodity** [emphasis added] and it is, or it contains an ingredient that bears or contains, a major food allergen…." Consistent with that statutory exclusion, FDA's guidance acknowledges that RACs are not subject to the food allergen labeling requirements of the FD&C Act.[21]

Beyond implementing additional controls, the need to verify the effectiveness of those controls could pressure industry into conducting additional, and sometimes unnecessary, testing. While 21 C.F.R. § 117.165 provides flexibility for facilities to determine when testing is necessary,[22] changing the current paradigm to treat gluten as an allergen would compel industry to implement some level of testing. FDA should formally recognize that allergen management can be (and is) adequately controlled through existing food safety plan prerequisite programs and preventive controls.

These systems are individually catered to specific manufacturing facilities and products produced by each site. Many of these programs inherently rely on supplier qualification and verification after determining appropriate risk levels for intended ingredients. Introducing an additional layer of potentially unreliable testing complexity would afford little additional benefit.

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[20] USDA, 7 C.F.R. pt. 810 (last visited Mar. 12, 2024).

[21] See FDA, Questions and Answers Regarding Food Allergens, Including the Food Allergen Labeling Requirements of the Federal Food, Drug, and Cosmetic Act (Edition 5): Guidance for Industry (last visited Mar. 12, 2024); FDA, Sec. 555.250 Major Food Allergen Labeling and Cross-contact Draft Compliance Policy Guide (last visited Mar. 12, 2024).

[22] "[T]he actual decision as to whether product testing and environmental monitoring are warranted depend on the actual facility and its food product, as well as the nature of the preventive control and its role in the facility's food safety system, and a slight variation on circumstances that would lead one facility to conclude that such testing programs were not required could lead a different facility to the opposite conclusion." 80 Fed. Reg. 55,908, 56,061 (Sept. 17, 2015).

To make matters more complex, testing may be infeasible in some instances. While some manufacturers use testing to verify the effectiveness of sanitation controls and equipment cleaning, there are no commercially available validated test kits to test for residual gluten from fermented or hydrolyzed foods. FDA's Final Rule on Gluten-Free Labeling of Fermented and Hydrolyzed Foods acknowledges that there are no recognized methods that detect gluten in fermented and hydrolyzed foods because gluten proteins in such foods are no longer intact, and current methodologies do not adequately detect and quantify those nonintact proteins. However, it is important to note that the final rule permits the use of record keeping and manufacturing controls to support a "gluten-free" claim in the absence of a valid method. Such an approach should be considered in the context of the Celiac Journey petition, as well as the requested data and associated burdens of FDA's RFI.

3. Any new requirements should be predicated on a threshold of 20 ppm gluten.

FDA established a threshold of 20 ppm gluten in the gluten-free labeling regulation based on a careful consideration of several factors, including the need to balance protection of individuals with celiac disease with the need to ensure the availability and affordability of foods labeled as "gluten-free."[23] The food industry has made considerable investments in developing and implementing production systems and technologies based on that threshold. Further, that threshold is consistent with the threshold for gluten-free labeling in multiple jurisdictions, thereby facilitating trade while protecting the health of individuals with celiac disease. Thus, there should be no change to that threshold unless there is a compelling scientific and policy rationale for that change. Further, any such change must be preceded by ample notice so that manufacturers can update their production systems and labeling accordingly.

4. Conclusion

The current framework for regulating allergens is well-understood by both consumers and industry, and regulations for "gluten-free" labeling serve to protect consumers with celiac disease while maintaining consumer choice. Any new requirements must be authorized under the FD&C Act and should take into account burdens on the agricultural supply chain in the context of consumer benefit. The Agency should carefully consider the precedential effect of defining oats as a GCG based solely on agricultural commingling, upending a core FALCPA principle. The 20 ppm threshold for "gluten-free" is internationally recognized and

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[23] Food Labeling; Gluten-Free Labeling of Foods, 78 Fed. Reg. 47,154, at 47,159 (Aug. 5, 2013), https://www.govinfo.gov/content/pkg/FR-2013-08-05/pdf/2013-18813.pdf.

well understood by consumers, and industry has developed sophisticated, validated methods for processing oats to remove gluten present via commingling.

NAMA respectfully submits the above comments and looks forward to continued engagement with FDA on related issues.