April 22, 2026

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

RE: Docket No. FDA-2023-P-3942 for "Labeling and Preventing Cross-Contact of Gluten for Packaged Foods; Request for Information"

The Food Industry Association (FMI) appreciates the opportunity to comment on the U.S. Food and Drug Administration's (FDA's) Request for Information (RFI) on Labeling and Preventing Cross-Contact of Gluten in response to a Citizen Petition from Celiac Journey. We commend FDA for seeking public comment from stakeholders on this complex and important issue.

As the food industry association, FMI works with, and on behalf of, the entire industry to advance a safer, healthier, and more efficient consumer food supply chain. FMI brings together a wide range of members across the value chain — from retailers that sell to consumers, to producers that supply food and other products, as well as a wide variety of companies providing critical services — to amplify the collective work of the industry. Read more about us at www.FMI.org.

FMI and its members share a deep commitment to providing healthy, safe, and affordable food to all consumers. This includes the millions of individuals managing food allergies and celiac disease who rely on clear, accurate information to make safe choices every day. For years, FMI members have recognized the importance of understanding consumers' needs and helping them navigate the food environment with confidence.

FMI and its members take allergen labeling and allergen controls seriously. We are committed to ensuring that any products that contain a major food allergen are appropriately labeled as such and that controls are in place to manage allergen cross-contact. The Federal Food Drug and Cosmetic Act (FFDCA) defines "major food allergen" in part as an ingredient that is or contains protein derived from one of nine foods (milk, egg, fish, crustacean shellfish, tree nuts, wheat, peanuts, soybeans, and sesame).[1] We appreciate FDA's acknowledgment in the RFI that it is Congress, not FDA, that has the authority to alter the list.[2] Nevertheless, as food allergies have become more

[1] 21 USC 321(qq).

[2] 91 FR 2781, 2782 (Jan. 22, 2026).

prevalent—now affecting an estimated 8% of children and 10% of adults[3]—the industry's responsibility to provide transparent allergen information has only grown. Even though gluten is not currently defined as a major food allergen, and FDA does not require allergen labeling for gluten-containing grains other than wheat, many FMI members voluntarily label gluten-free products consistent with FDA's "gluten-free" labeling claim permitted under 21 CFR § 101.91 to support consumers seeking to avoid gluten. This reflects a longstanding industry commitment to transparency and to offering a variety of options for food-allergic and gluten-sensitive customers. As FDA considers the requests identified in the Citizen Petition, we urge FDA to maintain the current gluten-free labeling framework, as it has proven effective in assisting consumers with celiac disease and gluten intolerances. Any forthcoming regulatory measures should enhance the success of the framework, rather than complicate it. We address these among other related issues, in the comments that follow.

Gluten Labeling Should Focus on Information that Supports Transparency for Consumers

Section 403(a) of the FFDCA establishes the foundational requirement that food labeling must be truthful and not-misleading. FDA's implementing labeling regulations are based on this simple principle. As noted in the Request for Information, FDA has established clear standards regarding the use of "gluten-free" claims. More specifically, FDA regulations state that the labeling claim "gluten-free" means that the food does not contain any one of the following: (1) a gluten-containing grain (GCG); (2) an ingredient derived from a GCG that has not been processed to remove gluten; or (3) an ingredient derived from a GCG that has been processed to remove gluten, if the use of that ingredient results in the presence of 20 parts per million (ppm) or more gluten in the food.[4] A "gluten-free" claim is also permissible when the food inherently does not contain gluten.[5] Additionally, the unavoidable presence of gluten in any food bearing the "gluten-free" claim must be below 20 ppm.[6] Consumers have come to trust this standard and scientifically established threshold for gluten.

As the agency evaluates this complex issue, we recommend that the agency conduct quantitative and qualitative consumer research to evaluate messaging that will be most impactful to consumers and support decisions on foods to consume or avoid. In many cases, leading consumers to food they can consume is more helpful than pointing out foods to avoid. Consumers avoiding gluten should be the primary audience for surveys to evaluate possible labels and methods, including educational strategies that are the

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[3] Warren, C.M., Jiang, J., & Gupta, R.S. (2020). Epidemiology and Burden of Food Allergy. *Curr Allergy Asthma Rep*, *20*(2),6. https://doi.org/10.1007/s11882-020-0898-7

[4] 21 C.F.R. § 101.91(a)(3)(i)(A).

[5] 21 C.F.R. § 101.91(a)(3)(i)(B).

[6] 21 C.F.R. § 101.91(a)(3)(ii).

most beneficial and impactful. Support from Registered Dietitian Nutritionists (RDN) could be very helpful for consumers who are newly diagnosed or seeking to identify foods to consume or avoid. Professional advice and guidance from a RDN could assist consumers and patients in finding options to support their health and dietary needs that are consistent with lifestyle, culture and other needs.

FDA's Existing Framework for Gluten-Free Labeling Helps Eliminate Consumer Confusion and the Agency Should Continue to Support Clear Consumer Understanding Within This Framework

FMI strongly supports FDA's continued use of a single, science-based national definition of "gluten-free," anchored at less than 20 ppm gluten in finished products. This threshold is internationally recognized, aligns with Codex Alimentarius,[7] and has proven both protective for individuals with celiac disease and practical for industry to meet with appropriate process controls. Further, FDA took a thoughtful approach to determining the 20 ppm threshold, as demonstrated by the regulatory history of the gluten-free rule.[8] Although the 20 ppm threshold was based in part on the validated analytical methods of detection that were available, it also was based on a health hazard assessment that supported a conclusion that "most individuals with celiac disease can tolerate food that contains variable trace amounts and concentrations of gluten" and that "there is no evidence that consumption of food products containing less than 20 ppm gluten would pose a risk of adverse health effects for the large majority of individuals with celiac disease."[9]

Furthermore FDA rejected comments asking FDA to adopt a lower gluten level, stating that establishing a threshold to lower than 20 ppm "would not offer additional protection or clinical benefits to individuals with celiac disease" because "epidemiological evidence [] suggest[s] that variable trace amounts and concentrations of gluten in foods can be tolerated by most individuals with celiac disease without causing adverse health effects."[10] Additionally, lowering the threshold or eliminating it entirely ultimately could harm the very gluten intolerant population that the framework is intended to protect because it would result in the removal from the market of many products that currently meet the criterion of < 20 ppm gluten in the definition of

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[7] Standard For Foods For Special Dietary Use For Persons Intolerant To Gluten, CXS 118-1979, Revised in 2008.

[8] Food Labeling; Gluten-Free Labeling of Foods; Proposed Rule, 72 FR 2795, 2803 (Jan. 23, 2007); Food Labeling; Gluten-Free Labeling of Foods; Proposed Rule, Reopening of the Comment Period, 76 FR 46671 (Aug. 3, 2011); Food Labeling; Gluten-Free Labeling of Foods, Final Rule, 78 Fed. Reg. 47154, 47159 and 47167 (Aug. 5, 2013).

[9] Food Labeling; Gluten-Free Labeling of Foods, Final Rule, 78 Fed. Reg. 47154, 47159 and 47167 (Aug. 5, 2013).

[10] *Id.*

"gluten-free" and bear the claim, or discourage the introduction of new foods labeled as "gluten-free". Limiting the availability of the number and variety of foods labeled "gluten-free" would be detrimental to individuals with celiac disease who are already challenged by the complexities of adhering long term to a gluten-free diet.[11]

The success of gluten-free labeling over the past decade is rooted in transparency and consistency, and we are not aware of any public health concerns with this existing regulatory framework. If FDA concludes that changes to the gluten-free framework are necessary, it should pursue those changes through notice-and-comment rulemaking.

As FDA considers potential changes to gluten-related labeling, it is important to recognize the complexity of gluten as a potential allergenic protein. Unlike the major food allergens, which are all foods, gluten spans multiple grains, including grains that elicit immune responses that include IgE-mediated and non-IgE-mediated reactions.[12] Regulatory changes must therefore be approached carefully to avoid unintended consequences. A regulatory framework that encourages over-labeling, excessive precautionary allergen labeling, and ambiguous "may contain" statements can reduce consumer trust and limit food choices without improving safety.

FMI does not support adding mandatory qualifiers—such as parts per million (ppm) disclosures or new categories like "low-gluten"—to gluten-free labels. Although consumers trust and understand that FDA's current standard for "gluten-free" claims means they can safely consume the product, they generally do not understand more nuanced disclosures (e.g., interpreting what "low" or a numerical ppm means for their ability to consume a product).[13] Newly diagnosed individuals are especially vulnerable to confusion. Adding technical information to labels risks overcrowding, redundancy, and mixed messages—particularly when consumers already struggle with statements that could be contradictory, such as "gluten-free" appearing alongside "may contain wheat." FDA can best support consumers by keeping front-of-pack claims simple and providing more detailed explanations through off-label channels, such as FDA.gov or through educational information provided by health care professionals.

We also encourage continued coordination between FDA and USDA-FSIS labeling policies so that gluten-free rules apply consistently across all foods, regardless of which

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[11] 78 FR at 47159.

[12] National Academies of Sciences, Engineering, and Medicine. (2017). *Finding a Path to Safety in Food Allergy: Assessment of the Global Burden, Causes, Prevention, Management, and Public Policy*. Washington, DC: The National Academies Press. https://doi.org/10.17226/23658

[13] Graham, F., Waserman, S., Gerdts, J., Povolo, B., Bonvalot, Y., & La Vieille, S. (2025). A Survey of Allergic Consumers and Allergists on Precautionary Allergen Labelling: Where Do We Go from Here? *Nutrients*, *17*(9), 1556. https://doi.org/10.3390/nu17091556

agency regulates them. Consistency across the food supply is critical for consumer understanding.

Additional Considerations

Gluten-Free Third-Party Certifications

In order to provide additional reassurances for consumers with celiac disease and gluten sensitivities, many manufacturers voluntarily seek third-party certifications that utilize icons on food packaging to communicate and provide additional assurances that a product is "gluten free" (i.e., below the 20 ppm FDA standard).

As no single product or consumer is the same, flexibility remains essential. FMI supports flexibility in the voluntary use of gluten-free icons or symbols rather than mandating a single standardized icon. While the terminology and threshold are defined, there are multiple ways to accurately convey information to consumers on food packages.

Oats

As noted above, it is important to recognize the complexity of gluten. Oats are a particularly important example of potential complexities. Oats are naturally gluten-free and should not be classified as a gluten-containing grain. However, cross-contact can occur due to unavoidable commingling through farming, transportation, and manufacturing processes. Yet such challenges may be addressed through preventive controls and risk-based assessments—not through the reclassification of an ingredient. Further, the gluten-free framework considers the adventitious presence of gluten in oats, by requiring that any presence of gluten in the food bearing the claim is below 20 ppm gluten.

Importantly, labeling inherently gluten-free foods – such as oats – as a gluten containing grain simply because cross-contact is possible is inconsistent with the ingredient labeling provisions of the FFDCA. Section 403(i)(2) states that it applies to substances used to "fabricate" a food.[14] This requirement does not extend to substances that are not *added* to a food, but are present due to inadvertent cross-contact. Furthermore, even though gluten is not defined as a major food allergen, requiring the labeling of oats as a gluten-containing grain due to cross contact also conflicts with the Food Allergen Labeling and Consumer Protection Act (FALCPA), which does not require labeling when a major food allergen is unintentionally present due to agricultural commingling.[15] The ingredient list and the "Contains" statement may only be used to declare the presence of major food allergen ingredients that have been intentionally

[14] 21 U.S. Code § 343(i)(2).

[15] 21 U.S. Code § 343(w).

added to a food.[16] FDA has underscored this point stating that "allergens present due to cross-contact are not to be declared in the ingredients list or the 'Contains' statement."[17]

Not only is the proposal inconsistent with the statute, it also would mislead consumers and unnecessarily restrict access to grains on which many gluten-sensitive individuals rely as part of a healthy diet. For these reasons, FDA should maintain its current approach and not treat oats as a gluten-containing grain, as requested by the Citizen Petition.

Consumers with celiac disease and gluten sensitivities have limited options for grains, especially whole grain foods. Oats are an important food nutritionally, and provide additional dietary options for consumers avoiding gluten.

Flavors, Colors, and Spices

Regarding flavors, colors, and spices, the food industry is already required to complete allergen risk assessments when products are derived from one of the major food allergens, including wheat. In addition, many of these ingredients are highly refined ingredients that do not contain allergenic proteins. In other instances, these ingredients are added in very small quantities and would be accounted for in the 20 ppm threshold, should a "gluten-free" claim be used. FDA has the authority to require declaration of non-major food allergens and has done so in limited circumstances for specific ingredients.[18] For example, FDA relied on its Section 403(x) authority to require that the color additives cochineal extract and carmine be declared in the ingredient statement.[19] However, FDA explained in the preamble to the final rule that it relied primarily on its authority under 721(b) of the FFDCA (i.e., the authority to prescribe conditions under which a color additive may be safely used), and that Section 403(x) was an "additional legal authority."[20] Furthermore, the action was limited to labeling and did not impose new allergen control requirements with respect to the color additives in manufacturing environments. The Section 403(x) authority is narrow in scope, and this example indicates that Congress did not intend for it to be used to bypass the Congressional action needed to revise the defined list of major food allergens.

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[16] *Id.*

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

[18] 21 U.S. Code § 343(x)

[19] 74 FR 207 (Jan. 5, 2009).

[20] *Id.* at 210.

Given the significant policy implications and need for clarity and predictability for industry and consumers alike, if FDA determines that the public health concerns are sufficiently high that gluten labeling and/or controls for gluten-containing grains are necessary, such an action must be pursued through notice and comment rulemaking.[21]

If FDA pursues rulemaking, we recommend that the agency consider the outcome of the *FAO/WHO Expert Consultation on Reference Doses for Cereals containing Gluten*, and consultation to incorporate that into the *General Standard for the Labelling of Prepackaged Foods* (GSLPF),[22] before proposing any rule-making or guidance on this matter, and if FDA decides to implement a gluten labeling requirement, it would be beneficial to align with established global practices, where applicable. Global harmonization of allergen labelling enhances consumer safety, reduces food industry burdens, and facilitates international trade.[23]

Analytical methods

FMI also supports FDA's ongoing work to strengthen analytical methods for detecting gluten, especially in foods where current methods have limitations such as fermented foods and hydrolyzed proteins.[24] Continued investment in method development will improve consistency and reduce unnecessary precautionary labeling. Methods should be validated and available to the industry to use for verification activities.

Scientific Framework for Evaluating Gluten

Further, FDA has established a process for determining whether an allergen other than the major food allergens is an allergen of public health importance through its guidance document "Evaluating the Public Health Importance of Food Allergens Other Than the Major Food Allergens Listed in the Federal Food, Drug, and Cosmetic Act: Guidance for FDA Staff and Interested parties."[25] The guidance establishes a flexible, science-based

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[21] *See* 21 USC 343(x); 5 USC 553.

[22] WHO. (2025, November 7). *Ad hoc Joint FAO/WHO Expert Consultation on Risk Assessment of Food Allergens – reference dose(s) for cereals containing gluten or gluten*. https://www.who.int/publications/m/item/ad-hoc-joint-fao-who-expert-consultation-on-risk-assessment-of-food-allergens-reference-dose(s)-for-cereals-containing-gluten-or-gluten

[23] Ham, J.H., Suh, S.M., Cha, J.E, Ahn, K., Sohn, M.G., & Kim, H.Y. (2025). Global Perspectives on Allergen Labeling: Harmonization of Regulations and Practices. *Allergy Asthma Immunol Res. 17*(3), 288-303. https://doi.org/10.4168/aair.2025.17.3.288

[24] 85 FR 157 (August 13, 2020)

[25] FDA. (2025, January). *Evaluating the Public Health Importance of Food Allergens Other Than the Major Food Allergens Listed in the Federal Food, Drug, and Cosmetic Act: Guidance for FDA Staff and Interested Parties*. https://www.fda.gov/regulatory-information/search-fda-

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framework that allows FDA to evaluate gluten and other compounds of public health concern, even when they fall outside traditional IgE-mediated allergen models.

The guidance appropriately recognizes celiac disease as a serious population-level health concern and offers a thoughtful approach for considering gluten within FDA's broader allergen policy. FMI encourages FDA to continue applying this framework as it evaluates non-listed food allergens of public health concern, as well as other substances, such as gluten.

Process Considerations

Should FDA determine additional labeling provisions are required for gluten containing grains, the agency must undertake rulemaking to establish regulatory expectations, rather than implementing them through guidance. Furthermore, adequate implementation time, clear guidance, and sell-through provisions would assist the industry with compliance and reduce operational impacts. The food industry would strongly prefer a single coordinated label change rather than rolling updates, which add cost, create confusion for consumers and throughout the supply chain, and reduce the effectiveness of consumer education efforts.

Consumer Research and Education

Finally, FMI urges FDA to conduct consumer research before adopting new approaches or changes to existing labeling requirements. Understanding how consumers interpret proposed changes—and whether those changes actually help them manage gluten exposure—is essential. Education, developed in partnership with healthcare providers, advocacy organizations, and industry, will also play a critical role in ensuring that consumers can use gluten-related information effectively and select foods that will support their health.

Conclusion

Across all the issues raised in this RFI, several principles remain central:

- Labeling must be clear and simple;
- Regulatory decisions must be grounded in science and real-world risk;
- Flexibility is necessary to reflect the diversity of food production systems; and
- Unintended consequences must be avoided.

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The existing gluten-free labeling framework has been highly effective in supporting consumers with celiac disease and gluten intolerance, and any future regulatory action should build on this success rather than complicate it.

FMI appreciates FDA's thoughtful consideration of these issues and looks forward to continued engagement to ensure that gluten-related labeling supports consumer health, maintains clarity, and remains feasible for industry to implement.

Sincerely,

Hilary S. Thesmar

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