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

Re: Food and Drug Administration; *Labeling and Preventing Cross-Contact of Gluten for Packaged Foods; Request for Information*, 91 Fed. Reg. 2781 (Jan. 22, 2026); Docket No. FDA-2023-P-3942

To Whom It May Concern,

The American Spice Trade Association (ASTA) appreciates the opportunity to submit comments in response to the U.S. Food and Drug Administration's (FDA) *Labeling and Preventing Cross-Contact of Gluten for Packaged Foods; Request for Information* (RFI).

ASTA was established in 1907 and is the voice of the U.S. spice industry in the global market. Our members include approximately 250 companies involved in all aspects of the spice trade – importing, growing, processing, and marketing at the wholesale and retail levels. ASTA's highest priority is ensuring the supply of pure, safe spices to American consumers.

1. Introduction

ASTA has a longstanding commitment to food ingredient safety, transparency, and consumer confidence. To that end, ASTA supports the use of a regulatory framework for gluten labeling that is protective of individuals with celiac disease, is grounded in science, consistent with existing regulatory approaches, and is achievable, recognizing the complexities of agricultural supply chains for spices.

Specifically, our comments focus on the following:

- Spices do not inherently contain gluten and are not derived from gluten-containing grains such as wheat, barley, and rye. Although low, unavoidable levels well below the 20-ppm threshold of gluten may occasionally be present in spices due to agricultural commingling, given the extremely small quantities in which spices are used, such trace amounts would contribute negligibly to overall dietary gluten exposure in finished foods.

- ASTA supports a scientific risk-based approach to unintended gluten presence and potential labeling requirements. Such approaches help ensure protection for individuals with celiac disease while keeping regulatory requirements achievable and practical.

- ASTA supports consistency with existing FDA requirements, specifically gluten-free labeling claims, and harmonization with international standards for gluten-free labeling.

2. Spices do not inherently contain gluten

FDA's RFI specifically seeks information regarding the potential presence of gluten in spices. These ingredients are permitted to be declared collectively under the generic term "spices," without listing the specific common or usual name in ingredient statements, in accordance with FDA labeling regulations under 21 CFR 101.22(h)(1). *Importantly, no spices inherently contain gluten or are derived from gluten-containing grains such as wheat, barley, or rye.*

Spices are defined in 21 CFR 101.22(a)(2), CFR 182.10, 21 CFR Part 184, and FDA's Compliance Policy Guide (CPG) 525.750 as aromatic vegetables used primarily for seasoning. Cereals containing gluten do not meet this definition and therefore would not qualify for declaration under the generic term "spices." No spices listed in any FDA regulations, policies, or guidance, nor any of the spices on ASTA's spice list[1], are derived from gluten-containing grains and none of these ingredients inherently contain gluten.

As with many agricultural commodities, commingling can occur at early stages of spice supply chains. Spices are often grown on small farms, near other crops, including, in some instances, commodities that contain gluten. During harvesting, transport, or storage, spices may be handled within shared agricultural systems, which can occasionally result in the unavoidable adventitious presence of gluten. This is distinct from cross-contact that may occur during manufacturing or food processing.

[1] The ASTA Splice List is a list developed to assist our member spice companies in determining if an ingredient is considered to be a spice by regulatory authorities in the U.S., how it may be labeled, and if it is permitted to be used in foods.

Any potential presence of gluten in spices due to agricultural commingling generally occurs at low levels, in the hundreds of parts per million (ppm) or less. Subsequent processing and cleaning further reduce these levels. In finished foods, spices are typically used in very small quantities, generally at less than one percent of food formulations. As a result, the potential contribution of trace gluten from spices would be expected to fall well below established risk levels, such as the Food and Agriculture Organization (FAO)/World Health Organization (WHO)'s reference dose of 4 mg for cereals containing gluten, which was published in 2025 to inform risk-based decisions regarding gluten.[2] As discussed in more detail below, FDA has an existing regulatory framework that considers the adventitious presence of gluten due to agricultural commingling and cross-contact through its final rule on gluten-free labeling of food.[3]

Given the realities of agricultural production in global spice supply chains, achieving an absolute zero presence of gluten in spices is not feasible. A regulatory approach grounded in scientific risk assessment is the most effective way to protect individuals with celiac disease while ensuring that requirements remain practical and achievable.

3. ASTA supports consistency with FDA's existing gluten-free standard and harmonization with international standards for gluten labeling

Importantly, an effective regulatory framework already exists to help consumers with celiac disease identify appropriate foods. FDA's existing "gluten-free" labeling rule established in 2013 under 21 CFR 101.91 sets a limit of less than 20 ppm gluten for foods bearing a gluten-free claim. This standard aligns with the Codex standard developed in 2008, which was informed by clinical data indicating that this threshold is unlikely to cause clinically significant intestinal damage in most individuals with celiac disease.[4] This 20-ppm limit has been widely adopted internationally, including in the European Union, United Kingdom, Canada, and many other jurisdictions.

ASTA supports maintaining the existing 20-ppm threshold for gluten-free claims. Reducing the threshold is not supported by the available scientific evidence and could create significant technical and analytical challenges without providing additional meaningful health benefits.

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[2] FAO/WHO. 2025. *Ad hoc Joint FAO/WHO Expert Consultation on Risk Assessment of Food Allergens – Reference Dose(s) for Cereals Containing Gluten or Gluten*. Meeting Summary and Conclusions. Available at: https://openknowledge.fao.org/server/api/core/bitstreams/520eaa21-b6dc-46eb-91f6-e3974a98b85b/content.

[3] 78 FR 47178 (Aug. 5, 2013).

[4] Codex Standard for Foods for Special Dietary Use for Persons Intolerant to Gluten (CODEX STAN 118-1979, revised 2008).

Indeed, FDA explained the risks of establishing an overly stringent gluten-free framework in the gluten-free rulemaking:

> "To the extent it is possible to do so and protect public health, we believe that we should set a gluten threshold level for 'gluten free' labeling that best assists most individuals with celiac disease in adhering life-long to a 'gluten-free' diet without causing adverse health consequences. If the prevalence of persons with celiac disease not following a 'gluten-free' diet increases because there are fewer foods labeled 'gluten-free' to choose from (because the criteria for making 'gluten-free' labeling claims are too stringent for most food manufacturers to meet) or such foods become more expensive (because any changes made by manufacturers to enable them to meet more stringent criteria to make foods labeled 'gluten-free' may increase their production costs), then these individuals could be at a higher risk of developing serious health complications and other diseases associated with celiac disease. In other words, moving to a definition of 'gluten-free' that adopts a criterion that is much lower than < 20 ppm gluten could have an adverse impact on the health of Americans with celiac disease."[5]

As FDA considers whether to develop or revise its regulatory framework for GCGs, we urge the agency to ensure it remains consistent with the existing gluten-free labeling framework that consumers know and trust.

4. ASTA supports the use of a scientific risk-based approach for gluten labeling requirements

It is not scientifically appropriate to regulate gluten as a food allergen under the framework established by the Food Allergen Labeling and Consumer Protection Act (FALCPA). Gluten does not cause IgE-mediated allergic reactions such as anaphylaxis but rather is a protein of concern for individuals with celiac disease. This distinction between IgE-mediated food allergies and autoimmune conditions such as celiac disease is well documented in the scientific literature, including research summarized by the Food Allergy Research and Resource Program (FARRP).[6] Because its mechanism of response and risk profile differ substantially from food allergens, gluten should not be regulated or managed as an allergen.

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

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[5] 78 FR 47160 (quoting 76 FR 46671 at 46675 (Aug. 3, 2011)).

[6] Food Allergy Research & Resource Program (FARRP). *Celiac Disease.* University of Nebraska–Lincoln. Available at: https://farrp.unl.edu/farrp-resources/general-information-food-allergies-sensitivities/celiac-disease/ (accessed March 2026).

shellfish, tree nuts, wheat, peanuts, soybeans, and sesame).[7] Because gluten is a sensitivity and not an IgE mediated allergen, it should not be considered under FALCPA. Furthermore, the addition of allergens to the list of major food allergens requires congressional action. Indeed, Congressional legislation was required through the Food Allergy Safety, Treatment, Education, and Research (FASTER) Act to add sesame to the definition of major food allergen in 2021. We appreciate FDA's acknowledgment in the RFI that it is Congress, not FDA, that has the authority to alter the list of major food allergens.[8]

Additionally, treating gluten as a major food allergen, even though it is a sensitivity, could create unintended consequences for consumers with celiac disease. For example, it could lead to widespread use of advisory allergen statements related to gluten. Such labeling would likely increase confusion for consumers, diminish the clarity provided by the existing gluten-free claim standard, and reduce the availability of nutritious foods for individuals with celiac disease that currently meet the definition of "gluten-free" under the current regulatory framework. The U.S. allergen regulatory framework is intentionally limited to the most common allergens in order to balance public health protections with practical implementation in the food supply. Managing gluten as an allergen across supply chains and manufacturing environments could impose substantial burdens on the food sector without improving consumer safety outcomes, and would not be consistent with the public health risk.

Conclusion

ASTA supports a science-based and transparent regulatory approach to gluten labeling that protects individuals with celiac disease while remaining practical for agricultural supply chains.

Spices do not inherently contain gluten. While unavoidable agricultural commingling may result in the presence of gluten in spices, these levels contribute negligibly to gluten exposure given the very small quantities in which spices are used in finished foods.

It is not appropriate from a scientific or regulatory framework to regulate gluten as an allergen, since it is a food sensitivity rather than a true allergen. Maintaining FDA's current 20-ppm gluten-free threshold, which is supported by scientific evidence and widely adopted internationally, will continue to promote transparency, consistency, and consumer confidence while ensuring regulatory requirements remain achievable.

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[7] 21 USC 321(qq).

[8] 91 FR 2781, 2782 (Jan. 22, 2026).

As FDA considers potential next steps, it is important that any future policy changes continue to reflect real-world agricultural practices and consider the potential unintended consequences of implementing overly burdensome standards.

Sincerely,

Laura Shumow
Executive Director
American Spice Trade Association