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Via Electronic Transmission

August 17, 2022

Dockets Management Staff
Food and Drug Administration
5630 Fishers Lane
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Rockville, MD 20852

Re: Food and Drug Administration; *Evaluating the Public Health Importance of Food Allergens Other Than the Major Food Allergens Listed in the Federal Food, Drug, and Cosmetic Act*; *Draft Guidance for FDA Staff and Stakeholders*, 87 Fed. Reg 23181 (April 19, 2022); Docket No. FDA-2021-N-0553

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(ASTA) appreciates the opportunity to submit comments in response to the U.S. Food and Drug Administration's (FDA) *Draft Guidance for FDA Staff and Stakeholders: Evaluating the Public Health Importance of Food Allergens Other Than the Major Food Allergens Listed in the Federal Food, Drug, and Cosmetic Act* (Draft Guidance). This Draft Guidance is important in establishing a framework for protecting public health with respect to allergen issues and we support FDA's efforts on this initiative.

Introduction

ASTA was established in 1907 and is the voice of the U.S. spice industry in the global market. Our members include companies involved in all aspects of the spice trade – importing, growing, processing, and marketing at the wholesale and retail levels. We represent our members' U.S. interests by supporting regulatory compliance and maintaining relationships with U.S. agencies. ASTA shares FDA's commitment to food safety. Our highest priority is ensuring the supply of pure, safe spices to American consumers. Additionally, ASTA has consistently advocated to ensure that FDA is adequately resourced and is a member of the Alliance for a Stronger FDA.

ASTA has a long history of working with food regulatory authorities, including FDA. We are pleased to provide the following comments in response to the FDA's Draft Guidance on the consideration of food allergens other than the major food allergens listed in the Federal Food, Drug, and Cosmetic Act (FD&C Act). ASTA supports science-based policies pertaining to allergens and believes that decisions to identify food allergens of public health importance should be based strictly on the best available science. If credible research identifies a food substance as an allergen of public health importance in the United States, based on prevalence, potency, and severity data, ASTA supports the classification of the evaluated substance as such. For example, ASTA supported the passage of the FASTER Act and the disclosure of sesame as an allergen.[1]

ASTA is submitting comments on the *Draft Guidance for FDA Staff and Stakeholders: Evaluating the Public Health Importance of Food Allergens Other Than the Major Food Allergens Listed in the Federal Food, Drug, and Cosmetic Act* on one key issue. Although the framework outlined by FDA in the Draft Guidance is an excellent step toward increased transparency on the agency's strategy, the document also should establish clear scientific and legal standards for which a food or food protein may be classified as an allergen of public health importance. ASTA recognizes FDA's need to evaluate food and food proteins on a case-by-case basis; however, ASTA is concerned by the lack of clearly defined standards for which FDA considers as a sufficient body of evidence to determine whether a food allergen is of public health importance.

We expand on these comments below.

The FDA Framework Should Establish Clear Scientific and Legal Standards for Which a Food or Food Protein May Be Classified As an Allergen of Public Health Importance

ASTA supports the creation of a regulatory framework to evaluate potential allergens of public health importance that is clear, scientifically based, and consistent with the approaches undertaken by other regulatory bodies. The current Draft Guidance outlines a framework that calls for the consideration of prevalence, potency, and severity of potential allergens, which is largely consistent with the criteria agreed upon by the ad hoc FAO/WHO joint expert consultation on food allergen risk assessment.[2]

[1] While ASTA is supportive of the labeling of sesame as an allergen, we are still concerned that there is confusion regarding the current policy and labeling practices pertaining to sesame being labeled under the generic declaration of "spices". In FDA's *Draft Guidance for FDA Staff and Stakeholders: Evaluating the Public Health Importance of Food Allergens Other Than the Major Food Allergens Listed in the Federal Food, Drug, and Cosmetic Ac*, FDA states that *Voluntary Disclosure of Sesame as an Allergen: Guidance for Industry (Draft Guidance)* is reflective of FDA's current views of sesame disclosure. However, as asserted in ASTA's comments, the voluntary guidance is misleading and inconsistent with FDA's existing Compliance Policy Guide (CPG) Sec. 525.750, which affirms that sesame seeds are not spices and that sesame seeds should be labeled by their common or usual name, not listed under "spice(s)" on a label. As such, it is current industry policy and practice that sesame included in a spice blend already be labeled with the term "sesame" in line with the current FDA CPG guidance. This is confirmed by a study by the Food Allergy Research and Resource Program (FAARP), which found that undeclared sesame under the generic term "spices" was not reported on any ingredients and only reported in 0.01% finished food products included in the survey.

[2] FAO and WHO. 2022. Risk Assessment of Food Allergens. Part 1 – Review and validation of Codex Alimentarius priority allergen list through risk assessment. Meeting Report. Food Safety and Quality Series No. 14. Rome. https://doi.org/10.4060/cb9070en

Although the general framework allows for improved transparency between the Agency and stakeholders, the Draft Guidance would be more helpful if it also establishes scientific or legal standards that would apply during the evaluation of non-major food allergens, as is referenced in the FAO/WHO allergen risk assessment report. In the Draft Guidance, FDA provides a thorough review of the types of data, studies, and scientific information that it would find most relevant in its consideration of a non-listed food allergen. FDA states it will rate the strength of the various types of evidence for each of the scientific factors on a GRADE system, and that it will generally consider food with high or medium evidence to be considered allergens of public health importance. However, the Agency does not establish a "threshold" or "bar" that must be met for FDA to consider a commodity as a food allergen of public health importance, such as the actual prevalence in the population of the allergy or severity of the reactions. Reference doses and approaches to allergen risk assessment are not yet harmonized in any jurisdiction, even in the European Union where a legislative framework exists. Absence of agreement on what risk is tolerable has made it difficult to set quantitative limits to manage risk and protect allergic consumers effectively. This lack of regulation also drives confusion in Precautionary Allergen Labeling.

Although ASTA recognizes FDA's need for flexibility to evaluate non-listed food allergens on a case-by-case basis, the Agency should be transparently promoting harmonization and driving for consensus in the approaches to defining tolerable risk thresholds. Notably, the scientific basis for the evaluation of a potential allergen of public health importance should be distinct from the consideration of whether the ingredient must be listed on the ingredient statement by its common or usual name. In the Draft Guidance, FDA indicates that allergens may be "undisclosed" on labeling information if regulations permit that a commodity may declared under a collective term. Manufacturers are permitted to list certain ingredients under generic disclosures (such as the term "spices") to protect their confidential trade secret recipes and formulas. Any requirement to label an ingredient as an allergen should be based solely on an evaluation of its public health risk and should not take into account if the ingredient may be listed under a generic declaration. Compelling manufacturers to divulge trade secret information without a strong and consistent public health basis is a violation of important confidentiality rights.

In addition to a clearly established scientific standard, ASTA requests that as part of its evaluation framework, FDA establish a notice and comment period and publish its full assessment for non-listed food allergens of public health importance. The publication of FDA's assessment would allow for both increased transparency and a better understanding of the application of FDA's guidance framework in the consideration of certain potential food allergens of public health importance.

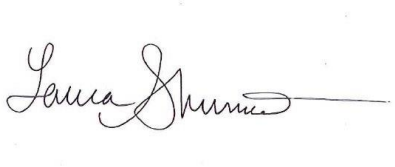
Conclusion

ASTA appreciates the opportunity to submit comments to the FDA on the *Draft Guidance for FDA Staff and Stakeholders: Evaluating the Public Health Importance of Food Allergens Other Than the Major Food Allergens Listed in the Federal Food, Drug, and Cosmetic Act*. In summary, ASTA is supportive of efforts to evaluate non-listed allergens of public health importance. However, the approach outlined in the Draft Guidance raises questions and concerns regarding the consistent application of the framework in addition to clearly defined thresholds. Specifically, a consistent evaluation of public health risk should be applied to the evaluation of a potential allergen, regardless of whether or not the ingredient must be labeled by its common or usual name or is permitted to be listed under a generic disclosure, such as "spices." Furthermore, ASTA requests that FDA publish their risk assessments for potential food

allergens of public health importance and establish a notice and comment period to remain transparent and provide the opportunity for additional scientific discourse with relevant stakeholders. Finally, ASTA wants to reiterate that the spice industry remains committed to proper labeling of allergens per existing federal regulations and guidance.

Please feel free to reach out to ASTA with any questions or follow up.

Sincerely,



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