



AMERICAN SPICE TRADE ASSOCIATION, INC.

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

Re: American Spice Trade Association Comments to Docket No. FDA-2021-N-0966 for “Closer to Zero Action Plan: Impacts of Toxic Element Exposure and Nutrition at Different Crucial Developmental Stages”

To Whom It May Concern:

The American Spice Trade Association (ASTA) appreciates the opportunity to comment on FDA’s Closer to Zero initiative.

ASTA was founded in 1907 and represents the interests of approximately 200 members, including companies that grow, dehydrate, and process spices. ASTA’s members include U.S. based agents, brokers and importers, companies based outside of the U.S. that grow spices and ship them to the U.S., and other companies associated with the U.S. spice industry. ASTA members manufacture and market the majority of spices sold in the U.S. for industrial, food service and consumer use. ASTA and our members’ highest priority is ensuring the supply of pure, safe spice to American consumers.

We are submitting this letter to express support for FDA’s mission to decrease childhood toxic element exposure through establishment of science-based federal action levels.

ASTA supports FDA’s mission to decrease childhood dietary toxic element exposure

The spice industry supports FDA’s efforts to establish toxic element limits for food products for babies and young children. ASTA shares FDA’s commitment to ensuring public health and safety and stands ready to work with the FDA on the important goal of reducing toxic elements in childhood foods. ASTA further applauds the many successes that the public health community can claim in reducing childhood exposure to toxic elements over the past several decades. Considering the significant reductions that have already been made, the focus is now shifting to more minor sources of exposure.

ASTA supports the goal of moving “closer to zero” and appreciates FDA’s acknowledgement that trace amounts of these elements are largely unavoidable in the environment and food supply. Like many agricultural commodities, spices can absorb toxic elements from their environment through soil, water, and air. The introduction of these toxic elements into the growing environment can be driven by their



natural presence, environmental pollution, fossil fuel emissions, and volcanic eruptions. The concentration of these elements naturally varies due to where and how agricultural commodities are grown. Imported commodities grown in developing nations may face unique environmental challenges based on local air and water quality conditions. The botanical nature of the commodity will also influence uptake of these elements. For example, levels may differ depending on the part of a plant from which a food product is derived (e.g. roots, seeds, bark, fruit, or leaves). ASTA appreciates FDA's recognition that federal limits should consider naturally occurring background levels of toxic elements in various food commodities.

Despite the unavoidable presence of toxic elements in growing environments, ASTA is committed to ensuring the supply of pure, safe spices to consumers. The U.S. spice industry works to ensure toxic elements in spices are as low as possible and has undertaken numerous efforts to reduce toxic elements in spices. One of ASTA's goals is to limit toxic element levels in spices to as low as feasible. In furtherance of this goal, ASTA publishes a guide on Good Agricultural Practices to educate spice producers on how to best grow crops, manage irrigation, monitor soils, and safely transport product to minimize toxic element uptake from the environment. Additionally, suppliers and sellers typically institute quality control, monitoring, and testing protocols to achieve the safest supply of spices to consumers.

Furthermore, ASTA works with producers and other partners, such as the Sustainable Spice Initiative, around the world to provide training on these practices. Additionally, ASTA is investing in ongoing research to mitigate toxic elements in the spice supply chain. For example, ASTA has an ongoing research project in Vietnam to understand sources of toxic elements and mitigation strategies to reduce natural toxic element uptake by cinnamon trees. While this work will hopefully provide promising new tools to further minimize toxic element levels, it will take the industry many years to implement. A cinnamon tree takes 10-15 years to reach maturity, which illustrates how much time is needed to reap the benefit of interventions intended to reduce toxic element uptake. This is why we particularly appreciate FDA's recognition that any limits that are established need to be achievable and that the limits may need to be revised over time.

ASTA supports federal leadership on the establishment of toxic element action levels

ASTA supports the establishment of federal action levels for toxic elements in baby and young childhood foods that strike the balance of being protective of consumers and achievable for industry. It is ideal for these action levels to be in line with applicable global regulations.

Due to the global nature of the supply chain, particularly for commodities like spices, discrepancies between regulatory bodies have the potential to create significant barriers to global trade. Harmonization with international regulations fosters compliance and mitigates barriers to trade. As such, ASTA is supportive of FDA's approach to establish federal toxic element action levels, and requests that the agency explore harmonizing levels with those established by international bodies, such as Codex Alimentarius and regulations established by key trading partners.



Additionally, the establishment of federal action levels for toxic elements in foods will help address problems presented by the lack of alignment among state authorities within the United States. As an example of how the lack of alignment can play out, New York state recently announced limits for toxic elements in spices that do not align with other established limits. This type of action is increasingly likely in the absence of federal direction, regardless of the role of legal preemption. Differences in state-by-state requirements are extraordinarily burdensome for the industry due to the national food distribution system. A patchwork of state laws has the potential to significantly impact the ability of American consumers to obtain safe, abundant, and affordable food. ASTA requests that FDA take a leadership role in the establishment of federal action levels and work with state partners on the implementation of federal standards. In this regard, it is helpful for FDA to explicitly communicate exposures that it does not find to be of concern so that the public is not unduly alarmed about the safety of the food supply.

Federal action levels should be established on a risk-based approach

The safety assessments used to underpin federal action levels should not simply be hazard based but should include assessments of exposure risk based on consumption patterns. The risk to American children from chemical contaminants such as toxic elements is driven by overall exposure. As such, the determination of action levels should take into account the exposure from particular foods. This would result in relatively lower levels being instituted for foods consumed in larger quantities, and relatively higher levels for those consumed in small amounts.

ASTA supports FDA's plan to engage with stakeholders and consider industry achievability concerns

ASTA is supportive of FDA's action plan to engage with stakeholders and industry input throughout the Closer to Zero evaluation cycle. Partnering with industry can lead to meaningful reductions in exposure to toxic elements and allows for the joint creation of best practices which can be implemented more expeditiously through partnership with industry stakeholders. Stakeholder engagement further allows for feasibility and achievability to be considered in the establishment of new action levels. This consideration allows for companies to develop tools and controls to limit exposure without being forced to remove products from the market due to trace levels of toxic elements from their ubiquitous presence in the environment. Lastly, it will allow for both government and industry to jointly identify analytical testing methodologies that are accessible to industry in their efforts to monitor toxic element levels in food products.

ASTA is supportive of FDA's cyclical evaluation approach

ASTA is supportive of FDA's iterative evaluation approach because it is grounded in science and allows for the re-evaluation of new data and stakeholder engagement to propose targeted action levels. There is interest in certain quarters in evaluating the cumulative impacts of multiple toxic elements and the impact of certain nutrients on toxic element risk. While there is value in understanding these important questions, at this time, the body of scientific evidence has not advanced to be able to quantitatively



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evaluate these combined risks. Until the scientific evidence evolves to this point, levels should be based on risk assessments of the individual elements.

ASTA supports FDA's holistic approach of balancing nutritional benefits with the potential presence of low-levels of toxic elements

Lastly, ASTA supports FDA's recognition that there are nutritional benefits of foods that may contain toxic elements, and thus that a holistic approach needs to be taken to ensure that children and others continue to have access to foods that aid in health and development. For example, spices have the potential to compensate for loss of flavor in foods lower in added fat, sugars, and sodium. In fact, the Dietary Guidelines for Americans cites the use of spices as a potential strategy to influence consumer behavior to reduce sodium intake, which may help consumers adhere to a lower sodium diet while also increasing the consumption of foods such as fruits, vegetables, and healthy grains by making them more appealing and taste better. Additionally, there is a growing body of research on the potential for certain spices to improve health. For example, there is interest in the impact of spice consumption on improving cardiovascular and metabolic health, providing antioxidants, and supporting the gut microbiome. Spices are healthful ingredients that promote healthy eating patterns and play an important role in the celebration of cultural heritage.

Conclusion

In conclusion, ASTA supports the FDA's Closer to Zero initiative and the establishment of science-based action levels for toxic elements in foods for babies and young children that are protective, feasible, and established using a risk-based approach. Federal action levels should align with global standards. ASTA stands ready to work with FDA on the implementation of this important initiative.

Sincerely,

Laura Shumow
Executive Director
American Spice Trade Association