



January 21, 2025

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

Re: Docket Number FDA-2024-N-3609 – Development of an Enhanced Systematic Process for FDA’s Post-Market Assessment of Chemicals in Food

Dear Sir/Madam,

The American Spice Trade Association (ASTA) appreciates the opportunity to provide comments on the Food and Drug Administration’s (FDA’s) August 2024 Discussion Paper *Development of an Enhanced Systematic Process for FDA’s Post-Market Assessment of Chemicals in Food*.

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. The highest priority for ASTA and our members is ensuring the supply of pure, safe spices to American consumers.

ASTA commends the FDA’s initiative to launch a systematic process for the post-market assessment of chemicals in food to ensure that existing approvals for these chemicals are grounded in the latest scientific findings and risk assessments to maintain the safety for their intended and authorized uses. Nevertheless, ASTA advises that the evaluation of contaminants should be addressed using a modified approach from that used for intentionally added substances (whether introduced directly or indirectly), given the unique complexities and supply chain realities associated with contaminants, which require holistic consideration. Furthermore, as the agency moves toward implementing the post market assessment process and its Closer to Zero initiative, we urge the agency to provide industry with additional guidance regarding contaminants and tools for establishing appropriate safety thresholds. We address these points in more detail below.

Environmental contaminants are unique and should be addressed using a separate or modified approach to that used for intentionally added chemicals.

Unlike chemicals that are intentionally added directly/indirectly to food, contaminants are unintentionally incorporated into agricultural products from the environments where they are grown and produced, with varying degrees of mitigation feasibility. Spices, for example, originate from different parts of a variety of plant crops grown in various countries around the world. The presence of contaminants such as mycotoxins, agricultural chemicals, and heavy metals in the environment vary

considerably by climate, geography, and the length of time each plant needs to reach maturation for harvest, as well as the physiological propensity of the crop to uptake and accumulate contaminants from their surroundings. At the same time, a holistic approach needs to be taken to ensure that Americans continue to have access to healthful foods. Specifically, as it relates to spices, FDA's recent final rule updating the definition of "healthy" notes that: *"herbs and spices can play an important role in the diet by replacing seasonings and ingredients that contribute sodium, saturated fat, and added sugars to the diet. They can also help increase the palatability of nutrient-dense foods."* Beyond their role in promoting a healthy diet, spices also hold significant cultural importance in ethnic cuisines, particularly for diverse populations living in the U.S.

To this end, ASTA encourages FDA to establish a separate pathway for the assessment of contaminants within the post-market assessment program and provide additional detail for how it plans to conduct assessments of unavoidable contaminants. This pathway should take into account not only the risk to consumers based on exposure, but also consideration of the availability of nutritious products, the feasibility of mitigation measures, and existing international standards to promote regulatory compliance and global trade. We also ask FDA to consider how the agency will allocate resources between contaminant assessments and post-market assessments of intentionally added chemicals.

Additional guidance from FDA is needed to assist industry with setting appropriate thresholds.

Furthermore, it is our understanding that the Closer to Zero initiative will be housed and managed within FDA's Office of Post-Market Assessment. ASTA supports the Closer to Zero initiative and believes that FDA has done a commendable job in taking a considered and methodological approach to that initiative. In alignment with FDA's goal to reduce childhood lead exposure, ASTA has published industry guidance levels for lead in spices¹, as well as 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 uptake of heavy metals and other contaminants from the environment.

ASTA recognizes that it is infeasible for FDA to evaluate and establish limits for every contaminant and commodity pair. However, as FDA moves forward with the post-market assessment process and Closer to Zero initiative, ASTA encourages FDA to provide tools and resources to assist industry groups in setting safety thresholds and specifications in the absence of federal limits and outline a mechanism by which FDA can provide feedback on industry guidance levels. Guidance related to consideration of exposure based on consumption patterns and naturally-occurring levels of contaminants in foods would be helpful. Specifically, it would be helpful to understand FDA's input on what consumption data should be used for exposure assessment purposes, and how to determine consumption for ingredients such as spices that may not be directly included in national dietary intake surveys, such as What We Eat in America.

Thank you for your consideration.

¹ <https://astaspice.org/resources/asta-guidance-levels-for-heavy-metals-in-spices>

Sincerely,

A handwritten signature in cursive script that reads "Laura Shumow". The signature is written in black ink and includes a long horizontal flourish at the end.

Laura Shumow
Executive Director
American Spice Trade Association