June 28, 2022

Dockets Management Staff (HFA305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Submitted electronically via www.regulations.gov

Re: Action Levels for Lead in Juice; Draft Guidance for Industry; Availability
Docket No. FDA-2019-D-5609

Dear Sir or Madam:

FMI - The Food Industry Association (FMI) appreciates the opportunity to provide comments on the *Action Levels for Lead in Juice; Draft Guidance for Industry*. 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 the wide variety of companies providing critical services — to amplify the collective work of the industry. www.FMI.org

FMI Supports the FDA Closer to Zero Framework and Science-based Process

FMI and its members fully support the approach outlined in FDA's Closer to Zero Action Plan, which includes the Agency thoroughly evaluating the science, consulting with stakeholders through a transparent process, and developing policy to reduce the exposure to heavy metals naturally occurring in the food supply. We think FDA is the appropriate agency to work through this process and has the internal expertise as well as access to external experts to accomplish these goals. We support the process outlined and strongly encourage transparency and collaboration with all stakeholders including medical professionals, toxicologists, food scientists, farmers, producers, processors, manufacturers and the entire food industry.

Importance of Achievability in the Existing Food Supply

As the FDA and all stakeholders work through this process, it is imperative that we consider realistic and practical achievability of the action levels in the current food supply. We need to be mindful of unintended consequences of food waste, limited supplies from specific regions, the

availability of products and the economic impact of setting standards that are not consistent with availability of commodities in the global supply chain. Limiting supply and/or increasing food waste would be unfortunate unintended outcomes if commodities or finished products are deemed out of compliance and not usable. Determining achievability is dependent on availability of accurate data. Therefore, it is critical for the analytical methods used by FDA for the detection of lead and other toxic elements in juice and other foods are statistically valid and based on published, globally recognized standards (e.g., AOAC).

FDA has indicated in its Closer to Zero plan that the Agency is "sensitive to the fact that requiring levels that are not currently feasible could result in significant reductions in the availability of nutritious, affordable foods that many families rely on for their children." We appreciate FDA's recognition of these challenges and encourage FDA to continue to consider potential effects on the food supply as the Agency moves forward in this process.

At least one manufacturer of infant rice cereal has exited the industry due to challenges with procuring product in line with existing industry standards. We encourage FDA to work with scientists, medical professionals, the food industry, risk managers and economists to evaluate the costs and benefits of having standards that deter companies from making products that were once staples in the diets of infants.

We also encourage FDA and USDA to invest in research and education programs for farmers, processors, and manufacturers to reduce levels when metals are naturally occurring in soil. Working directly to provide resources to each step of the supply chain on reducing heavy metals will help ensure the feasibility of FDA's action levels in the finished products when consumed in a balanced diet.

Clarification is Needed on the Role and Scope of Guidance and Statements from FDA regarding Determination of Adulteration

Guidance is not binding and the statement in the introductory paragraphs of the document "Action Levels for Lead in Juice; Draft Guidance for Industry" states the following:

> *"The contents of this document do not have the force and effect of law and are not meant to bind the public in any way, unless specifically incorporated into a contract. This document is intended only to provide clarity to the public regarding existing requirements under the law. FDA guidance documents, including this guidance, should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word* should *in FDA guidance means that something is suggested or recommended, but not required."*[1]

[1] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/draft-guidance-industry-action-levels-lead-juice

Yet, in the Constituent Update announcing the guidance, the following statement indicates that adulteration can be determined based on FDA action levels.

> *"The FDA issues action levels according to our regulations to inform industry on the levels of contamination at which FDA may regard specific foods to be adulterated."*[2]

These statements are seemingly contradictory, and clarification is needed for the industry. We ask FDA to clarify, in writing, the role of guidance and exactly how adulteration will be determined for product categories with draft or final guidance on action levels.

FDA Should Align Action Levels with CODEX Recommendations

We also want to encourage FDA to consider the levels set by CODEX and other international food safety bodies. Our food supply today is truly global in nature. Therefore, it is important to consider international requirements affecting the fruits, vegetables, and grains that become the basis for these foods, as well as those for finished products. Many manufacturers operate on a global basis producing foods for multiple markets. For decades, the US has participated in and supported CODEX standards.

The current standard for contaminants is:

> GENERAL STANDARD FOR CONTAMINANTS AND TOXINS IN FOOD AND FEED CXS 193-1995

With a global supply chain, current production practices and the importance of international trade, we encourage FDA to reconsider aligning with CODEX for standards for lead in juice. There is no compelling reason why the action levels for lead in juice should differ from international levels established by CODEX.

Additionally, FDA stated that US data was used to determine the action levels in the draft guidance. A document was posted as a draft but does not include information that has been peer reviewed and is not presented in a standard scientific format.

> Draft Supporting Document for Establishing FDA's Action Levels for Lead in Juice DRAFT-NOT FOR IMPLEMENTATION April 2022
> https://www.fda.gov/media/157944/download

We request that FDA clearly identify and make available the data that was used for determining the action levels in this draft guidance.

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[2] https://www.fda.gov/food/cfsan-constituent-updates/fda-issues-draft-guidance-industry-action-levels-lead-juice

According to the draft supporting document, "FDA considers the action levels for lead in juice to be achievable by industry when control measures are taken to minimize the presence of this contaminant" yet a reference for the mentioned control measures is not provided. We request FDA to share these control measures with stakeholders. Furthermore, we encourage FDA to work with stakeholders to identify industry best practices for controlling lead in juice and ensure growers and producers of all sizes are aware of best practices and have access to the necessary resources to implement effective control measures.

Urgent Need for Transparency and Access to Federally Funded Research on all Aspects of Heavy Metals in Agriculture and Food Production

A Public Meeting was hosted by USDA ARS on April 27, 2022. This meeting was very informative but referenced a workshop/forum for which the proceedings are not available and referenced research that is not available to the industry. There is an imperative need for transparency in research funded by all government agencies (FDA, USDA NIFA, USDA ARS). The results and publications should be shared widely and there is a need for scientific translation of findings and recommendations to all target audiences. We need to identify and engage experts in science translation and communications, so that industry stakeholders can fully understand and contribute to scientific findings utilized in the Closer to Zero process.

We appreciate the opportunity to submit comments on this guidance document and the FDA Closer to Zero program. We encourage the agency to continue to work closely with all stakeholders on this important and complex issue and welcome follow-up discussions.

Sincerely,

Hilary S. Thesmar

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