Apple Processors Association
1750 K Street, NW, Ste. 700
Washington, DC 20006

May 3, 2023

Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, Maryland 20852

Submitted electronically at www.regulations.gov

RE: Docket No. FDA – 2022-D-0278 for Action Levels for Lead in Food Intended for Babies and Young Children: Draft Guidance for Industry

Dear Sirs and Madams:

Thank you for the opportunity to submit public comments regarding the Action Levels for Lead in Food Intended for Babies and Young Children: Draft Guidance for Industry

Background

The Apple Processors Association (APA) was founded in 1987 and is a national association of companies that manufacture quality food products, mainly from fresh apples, and the suppliers that provide goods and services to this important market. All members of APA stress quality, innovation and, by pasteurizing their juice products and hot filling their food containers, reinforce their commitment to safety during their food processing operations. APA is actively involved in monitoring, educating, and advocating for regulatory and legislative issues that affect our membership, the food industry, and the public. APA appreciates the opportunity to submit the following comments regarding the draft guidance for industry regarding action levels for lead in food intended for babies and young children. We believe this is an important initiative and appreciate the opportunity to provide the following comments.

Our members strictly follow the controls related to our supplier/vendor approval programs, including the management of heavy metals in all their ingredients and recipes. The main source of heavy metals in foods comes from levels found in fruits, vegetables, and grains due to absorption from soil and water during the growth process. The manufacturing processes and packaging processes used by our member companies are not a source of contamination.

We believe four areas will create challenges for our members based on the current draft standards.

1. **Agricultural Commodities and Supply Chain Issues:**
   As mentioned in the FDA draft guidance, there are several roots vegetable where lead is naturally present that could pose a challenge for agricultural commodities such as sweet potato, carrots, butternut squash etc.

   This could lead to tighter specifications if there is no proof of feasibility by the growers on 100% of their acreage. Depending on the mix in the product recipe, the 10ppb limit may be difficult to guarantee for an entire production batch and it will limit the product offerings in the marketplace. The Draft Guidance should also explicitly recognize that while lead may be present in soil across the United States, levels vary by geographic region and soil type. Additional data needs to be collected to map this variability more effectively before this strict guidance is imposed.

2. **Precision on Daily Intake Absorption:**
   Current guidelines do not show the difference that a 0–2-year-old could be exposed to due to different serving sizes. Therefore, we recommend revising the guidance to illustrate a level of exposure such as an absolute amount per serving. Not considering serving size when setting these standards could expose a consumer to different levels of lead depending on the serving size ingested.

3. **Methodology and Measure of Uncertainty**
   Current guidance does not contain a reference test methodology for lead testing. We recommend defining an approved and standard methodology by working with several accredited laboratories. This will make it possible to review the instrumentation and the method to be used while carrying out these tests. In this analysis, it is highly recommended to evaluate the measurement of uncertainty and its impact on the actual ranges mentioned by this draft guidance. In addition, taking in account the Product Matrix might be important as well in the methodology; various product textures could play a role in the analysis.

4. **Statistics Data – Stricter Range than EU Standards**
   If finalized without changes, these levels will be much stricter than the European standards of 20 ppb adopted by the EU in 2021 by the COMMISSION REGULATION (EC) No 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs, amended by Commission Regulation. (EU) 2021/1317 of 9 August 2021.Statistically. we recommend revising the panel by adding additional data and understanding why the EU 20 ppb limit could not be applied as well for fruits and vegetables products in USA (excluding root vegetable products at single ingredient). Table 3 of this draft guidance summarized the number of samples taken to be analyzed and as per below, statically the numbers do not reflect the number of products the market has, especially mixtures.

Table 3. Analysis of Lead Data from the Total Diet Study (FY2014-2020)[11] by Food Category for Babies and Young Children

Food Category for Babies and Young Children	Number of Samples	Mean ± std. dev (ppb)
Fruits (single type or combination)	231	0.17 ± 0.91
Mixtures	210	2.5 ± 3.9
Yogurts, custards/puddings, single-ingredient meats	83	0.49 ± 3.4
Vegetables (single type or combination)	139	4.9 ± 7.0
Vegetables (single type or combination excluding single-ingredient root vegetables products)	89	1.1 ± 2.3
Root vegetables	50	11.6 ± 7.6
Dry infant cereals	23	2.6 ± 2.9

Summary

We are committed to ensuring the highest quality products for our member companies and all consumers and appreciate the attention focused on providing healthy and nutritious food products for babies and young children. However, we strongly recommend that the agency review these four main keys points and consider partnering with the U.S. Industrial Board Committee on creating a standard that is safe and practical.

On behalf of all apple processors, we appreciate the opportunity to comment and share information with FDA. Should you have any questions or need additional input, APA would be happy to assist.

Sincerely,

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