



Institute of Food Technologists

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March 23, 2023

Dockets Management Staff (HFA-305) Re: Docket #: FDA-2022-D-0278

Subject: IFT Comments to FDA on Action Levels for Lead in Food Intended for Babies and Young Children; Draft Guidance for Industry

The Institute of Food Technologists (IFT) appreciates the opportunity to provide input on the FDA Closer to Zero initiative Action Levels for Lead in Food Intended for Babies and Young Children. The proposed action levels are an important first step for further protecting foods for infants and young children from contaminants such as arsenic, lead, cadmium and mercury, which are all known to be harmful to healthy growth and development.

IFT is a global organization of approximately 12,000 individual members from 95 countries who are committed to advancing the science of food. Since 1939, IFT has engaged experts in food science, technology and related professions from academia, government, and industry to help solve many of the world's greatest food related challenges. IFT provides scientific, technical and career development resources for advancing the science of food and its application across global food and agricultural systems. Our primary mission is to connect global food system communities to promote and advance the science of food and its applications. We believe that science is essential to ensuring a global food supply that is sustainable, safe, nutritious, and accessible to all.

IFT believes that while the proposed guidance is a good first step, additional steps are needed to protect the most vulnerable of the US population from the potential for significant health effects from exposure to lead in food. The latest scientific research continues to indicate that there is no known safe level of lead intake for humans, and particularly for those most vulnerable to its effects, such as pregnant women, infants, and young children. Therefore, while seeking zero exposure is impossible, lead exposure should be minimized to the greatest extent for these most vulnerable groups.

IFT believes that the FDA focus on select categories of foods for infants and young children in the draft guidance for industry should be elaborated on to protect these vulnerable populations and needs to quickly be followed up by assessing the need and if indicated, developing broader guidance on lead in additional categories of infant and young child targeted foods, as well as in the broader food supply, to account for the transition period for babies to toddlers in the 6 month to 18 month age range. IFT's own review of US Early Head Start Program menus indicates that at the FDA maximum levels, a 12-18 month-old child could easily consume over the current 2.2 ug/day of lead recommended maximum, depending upon the selected menu day. Assessing the risk of exposure across frequently consumed foods in 6-18 month age range and developing



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risk-mitigating guidance is essential to protect to most vulnerable. Additionally, FDA should collaborate with other agencies to ensure public health nutrition guidelines and programs derived from these guidelines, including but not limited to Head Start and WIC, are similarly mitigating toxic element exposure through their programs.

IFT recognizes the important consideration of balancing nutrient needs while mitigating toxic element exposure. This was highlighted during the NICHD-FDA February workshop. Many pregnant women, infants and young children in the US population have iron and other vitamin and mineral deficiencies that are of concern regarding the uptake of toxic elements. With almost 50% of US infants and young children being supported in some way by the USDA WIC program, IFT believes it is imperative that the FDA and the USDA incorporate toxic element considerations into the WIC program. Likewise, IFT recommends a thorough review of the Dietary Guidelines for Americans (DGA), the Early Head Start menus, and the Standard Head Start menus and other programs with recommended dietary patterns for children 6-36 months be undertaken by HHS/FDA and USDA.

Additionally, IFT recommends that FDA evaluate frequently consumed transition foods, as infants start consuming food from the general food supply between 6 months to 18 months of age, and then for young children still at heightened risk in the 18-36 month range. While IFT agrees with the concept discussed in multiple FDA webinars that having children eat a varied diet during these age ranges is helpful to reduce lead intake in this vulnerable portion of the population, communicating to parents and caregivers and nutrition and health professionals with transparency and risk mitigation recommendations would provide a major step in reducing consumption of concerning foods during this timeframe and substantially reduce exposure. IFT recommends this concept be expanded to all four of the target toxic elements as a tool for parents, caretakers, nutritionists and health professionals.

The complexity of the issue with lead and the other toxic elements is very high and requires a strong, coordinated federal effort by HHS/FDA & USDA across multiple fronts. Research data continues to unfold on the long-term human health consequences of toxic element consumption, and IFT believes it demands a stronger urgency of action. It is also clear that the government resources currently dedicated to accomplishing this task are limited within the various agencies, as well as the focus of federally funded research efforts to help mitigate it both short and longer term. IFT recommends that FDA discuss with the various federal research funding organizations (USDA-NIFA, NIH/CDC, FFAR, NSF) the urgency of new research needed, including on the following topics:

- Lack of focused research on toxic element health impacts and mechanisms of action for pregnant women, infants, and young children
- Short-term toxic element mitigation in food production systems (e.g., sorting and removal technologies from food & food ingredients).
- Short & longer-term agricultural research to reduce toxic element uptake in plants with a



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focus on the most consumed foods for infants and young children.

- Assessment of US Dietary Guidelines, Early and Standard Head Start menus, USDA school menus and other federal, state and local feeding programs for young children for implications of toxic element consumption and modification to reduce exposure and enhance intake of relevant mineral and vitamin deficiencies, potentially including possible fortification of foods.
- Deeper assessment of both US produced and internationally produced food growing region soil to identify potential shifts in where foods are grown to reduce toxic elements in the food supply.

IFT is encouraged by this next step of the FDA's Closer to Zero program on Action Levels for Lead in Food for Babies and Young children, and notes that there is a tremendous amount of work yet to be done to address this challenging issue. IFT looks forward to continuing to work with the FDA, other federal and state agencies, the food industry, and academia on solutions to the food safety hazards posed by toxic elements in our food supply.

If there are any questions regarding our input, please do not hesitate to contact me at bhitchcock@ift.org.

Sincerely,

Bryan Hitchcock
Chief Science & Technology Officer, IFT