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Dockets Management Staff (HFA-305) Re: Docket No. FDA-2021-N-0966

## Subject: IFT Comments to FDA on initial phase of Closer to Zero Initiative

The Institute of Food Technologists (IFT) appreciates the opportunity to provide input on the FDA Closer to Zero initiative and considers the Closer to Zero initiative on Baby Foods to be an important 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 a phased approach is appropriate to ensure the implementation of new regulations is purposeful and all stakeholders are engaged. However, the data from the US House ECP Staff Report from February 2021, as well as the earlier Consumer Reports data from 2018 (Baby Foods) and 2019 (Fruit Juices) indicates that in some cases, levels of these contaminants are high enough to be of concern in the near term. Therefore, IFT suggests that FDA consider leveraging the Codex Alimentarius standards for these contaminants in the near term while FDA continues the current phased approach to Closer to Zero. The Codex Standards were globally aligned through a rigorous scientific review by the United Nations reputable FAO/WHO JECFA body and take into account known health concern levels, food consumption rates, methods to reduce agricultural uptake of the contaminants, and reasonable expectations of manufacturers. By leveraging Codex standards initially, FDA could eliminate the most egregious contaminant risks that were indicated in the various reports, while continuing to progress the outlined phased approach for the long-term standards implementation. By leveraging standards derived from Codex in the short term and conducting enforcement testing when implemented, FDA would protect babies and young children from the most serious metal contaminant concerns in baby foods while it continues to finalize the acceptable US levels for

the contaminants to prevent health concerns in the 0-3 age range. In doing so, it would be asking US manufacturers to abide by global limits many of them already face with international trade in these products.

Regarding the implementation of the Closer to Zero process as it has been outlined, IFT believes that setting action levels with regard to the reasonably available analytical testing capabilities in the food matrix in question is an important consideration. IFT would note that the Codex Alimentarius limits on all of the contaminant metals in question exceed\* the analytical test capabilities in the food matrices by some margin.

During the FDA Webcast on November 18<sup>th</sup>, IFT noted that a number of the scientific presentations identified the importance of limiting heavy metal consumption throughout a child's growth from in-utero through at least to puberty, and since young children transition from baby food to standard food consumption in the age range of 1-3 years, it will be important to consider setting limitations within the Closer to Zero phase process on these contaminants across the food supply chain from farm to fork, not just within baby foods or their specific ingredient bases. Also, it highlights the importance of metal contaminants in the diet of the mother for both inutero and in the case of breast-feeding. It is important to consider the life cycle effects of these contaminants just as life stage has been a part of the development of nutrient intakes within the Dietary Guidelines for Americans (DGA).

Considering that some parents use fresh or frozen fruits and vegetables to prepare purees for their young children vs. pre-packaged products, IFT would highlight the importance of setting contaminant limits in foods like these that frequently are used as alternatives to pre-packaged baby foods. Additionally, IFT believes FDA will need to work with USDA regarding controls for items like fresh/frozen fruits and vegetables as control of these contaminants would almost entirely depend upon agricultural growing practices. Similarly, FDA might consider setting metal contaminant limits for products that go through limited processing (e.g., rice flour, oat flour, etc.) that are used frequently as ingredients by industry or parents at home as part of young children's diets. Young children transition to consuming simple formulated products as their consumption of breast-milk or baby formula declines (e.g. simple grain based RTE cereals in the beginning) and consideration should be given to setting metal contaminant standards related to such formulated products where a variety of ingredient options are available to industry to help limit intake (e.g., reduce use of rice flour with alternative grain flours less likely to contain significant inorganic arsenic).

IFT would also recommend that FDA consider the effects of micro-nutrients that combat the human uptake of these metal contaminants in the setting of maximum levels, as were discussed in the November 18<sup>th</sup> meeting. The example of folate mitigation of mercury uptake and magnesium counteracting cadmium uptake are important examples to consider in the diet of babies and young children to help prevent effects from metal contaminants.

Lastly, IFT would like to underscore the proposed 2022-2026 HHS strategy objective 3.2:

## Strengthen early childhood development and expand opportunities to help children and youth thrive equitably within their families and communities.

IFT believes the Closer to Zero work is a critical component in this proposed HHS effort to strengthen physical & cognitive development in early childhood to help US children to thrive.

IFT looks forward to continuing to engage with FDA in the Closer to Zero phase process as it proceeds in 2022. If there are any questions regarding our input, please do not hesitate to contact Bryan Hitchcock (VP Science, Policy and Learning) at <u>bhitchcock@ift.org</u> or me at <u>iruff@ift.org</u>.

Sincerely,

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\*Added for clarity: eg Codex at 100 ppb vs analytical capability at 10ppb