Testimony of Michael Hansen, PhD
Senior Scientist

FDA Public Meeting: Closer To Zero Action Plan:
Impacts of Toxic Element Exposure and Nutrition at Different Crucial Developmental Stages for Babies and Young Children
November 18, 2021

Thank you for the opportunity to talk about the FDA Closer to Zero Program. My name is Michael Hansen, Senior Scientist for Consumer Reports. Consumer Reports has been testing a variety of baby foods and fruit juices for heavy metal for a number of years.

Consumer Reports is an independent, nonprofit organization - - that works with consumers for truth, transparency, and fairness in the marketplace through rigorous, independent testing and research. We empower and inform consumers, incentivize corporations to act responsibly, and help policymakers prioritize the rights and interests of consumers in order to shape a truly consumer-driven marketplace.

We note that in recent years, more and more studies are coming out to show that heavy metals, but especially inorganic arsenic (iAs), lead, and cadmium, are more hazardous than previously thought with new studies finding adverse effects, particularly neurobehavioral effects, at lower and lower levels. Consequently, we think there are enough data on the toxicity of heavy metals for the FDA to set mandatory standards or limits on baby foods and fruit juices for infants and children, and so think that the timeline for the Closer to Zero program is too prolonged.

Based on CR testing, we think the FDA could take action immediately on various heavy metals in baby foods, especially fruit juices. For instance, rather than wait till April 2024, FDA should immediately finalize the inorganic arsenic (iAS) apple juice draft action level of 10 parts per billion (ppb). Next, FDA should set a new limit of iAs in fruit juice of 3 ppb. Our testing of heavy metals in fruit juices, published in the January 2019 issue of *Consumer Reports*, found that the majority (58%) of samples were below 3 ppb of iAs, indicating such a limit is achievable to meet. We therefore urge the FDA to set a new 3 ppb limit for inorganic arsenic that is applicable to all affected types of juice, in the form of a mandatory standard or, at a minimum, an action level.

For lead, FDA should set a mandatory standard of lead in fruit juice of 1 ppb. Although there is a 5 ppb limit for lead in bottled water, the American Academy of Pediatrics advocates for a 1 ppb lead limit for school drinking water fountains. Our testing of fruit juices found that a majority of juice samples could meet this 1 ppb limit, which demonstrates that this is an achievable standard.

For cadmium, whose risks are similar to lead, FDA should set a mandatory standard of cadmium in fruit juice of 1 ppb. Our testing of fruit juices found that over 90% of juice samples could meet this 1 ppb limit, so establishing a mandatory limit of 1 ppb cadmium for fruit juices would not be disruptive.

Finally, we urge the FDA to move more quickly in setting action levels or limits for a range of baby foods. In developing the action levels/limits for lead, we note that FDA determined an interim reference level (IRL), for dietary lead intake, of 3 µg (micrograms)/day for children and 12.5 µg/day for adults. FDA's IRL was based on CDC's blood reference level for lead of 5 µg/dL (deciliter) of whole blood. However, last month the CDC updated/lowered the blood reference level from 5 µg/dL to 3.5 µg/dL of whole blood, representing a 30% decrease. Thus, we urge FDA to revise their IRLs using the new blood reference level--to roughly 2.1 µg/day for children and 8.3 µg/day for adults--prior to developing action levels/limits for lead in baby foods.