

# United States Senate

WASHINGTON, DC 20510

October 2, 2018

The Honorable Scott Gottlieb, M.D.  
Commissioner  
United States Food and Drug Administration  
10903 New Hampshire Avenue  
Silver Spring, Maryland 20993

Dear Commissioner Gottlieb:

We write to you with serious concerns regarding recent findings of heavy metals at potentially harmful levels in baby and toddler food products. Parents who purchase and rely on these prepared food products to feed and nourish their children expect these products to be safe and we agree. Children deserve nothing short of the highest standard of safety. As such, we strongly urge the U.S. Food and Drug Administration (FDA) to set performance standards for heavy metals, which do not currently have a known safe level of exposure.

A recent study<sup>1</sup> by Consumer Reports tested 50 different popular, widely distributed baby and toddler food products—including packaged cereals, fruits, vegetables, and snacks—and found troubling levels of heavy metals including inorganic arsenic, cadmium, and lead. Exposure to heavy metals, even at low levels, may have harmful health impacts on consumers of all ages.

Babies and young children are particularly vulnerable to exposure to heavy metals during their critical developmental years and are at an increased risk for serious, potentially irreversible health issues, including cognitive and reproductive problems, cancer, and type 2 diabetes. Additionally, exposure to heavy metals has also been linked to autism, attention deficit hyperactivity disorder, behavioral issues, and lower IQ.

It is unconscionable that infants and toddlers are exposed to dangerous heavy metals in conventional and organic foods alike. Therefore, we strongly urge the FDA to prioritize the health of our most vulnerable population by taking the following actions:

- Use the Agency's explicit authority under 21 U.S. Code § 2201 to initiate a rulemaking for heavy metals for which there is no known safe exposure level, including lead, inorganic arsenic, and cadmium—to remove any measurable amount of these dangerous elements from children's food.
- Evaluate the merits of promoting the Codex Alimentarius Commission's Code of Practice for the Prevention and Reduction of Lead Contamination in Foods and the Code of Practice for the Prevention and Reduction of Arsenic Contamination in Rice to companies to accelerate improvement on lead and arsenic.

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<sup>1</sup> Hirsch, Jesse. "Heavy Metals in Baby Food: What You Need to Know." Consumer Reports. August 16, 2018. <https://www.consumerreports.org/food-safety/heavy-metals-in-baby-food/>.

- Until a rulemaking can be completed, swiftly finalize proposed guidance to provide industry with a clear action limit that would limit arsenic in apple juice<sup>2</sup> and inorganic arsenic in rice cereals for infants.<sup>3</sup>
- Promptly issue a new maximum exposure limit for lead in food and make this public.
- Set interim goals and recall limits for heavy metals in all food types children commonly eat.

Thank you for your attention to this important matter. We respectfully request a response by November 2, 2018 detailing the steps FDA will take to protect our children from unnecessary exposure to heavy metals that continue to persist in our food supply.

Sincerely,



Richard Blumenthal  
United States Senate



Cory A. Booker  
United States Senate



Edward J. Markey  
United States Senate

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<sup>2</sup> "Draft Guidance for Industry: Arsenic in Apple Juice - Action Level." U. S. Food and Drug Administration. July 2013. <https://www.fda.gov/RegulatoryInformation/Guidances/ucm360020.htm>.

<sup>3</sup> "Draft Guidance for Industry: Arsenic in Apple Juice - Action Level." U. S. Food and Drug Administration. July 2013. <https://www.fda.gov/RegulatoryInformation/Guidances/ucm360020.htm>.