

Congress of the United States
Washington, DC 20515

January 27, 2023

VIA ELECTRONIC DELIVERY

Dr. Robert Califf
Commissioner
Food and Drug Administration
10903 New Hampshire Ave
Silver Spring, MD 20993

Dear Commissioner Califf:

We write as a follow-up on our June 2022 letter to express our continued concerns regarding the recent reports of high levels of toxic heavy metals in baby foods, as published in Bloomberg Law, that found many storebought baby food products to contain unacceptable levels of toxic heavy metals such as arsenic, lead and cadmium. We also write to thank the Food and Drug Administration (FDA) for issuing draft guidance on proposed action levels for lead in processed baby foods and juices. While we believe issuing this draft guidance is an important step forward, more must be done to ensure the safety of foods consumed by babies and young children.

Despite the establishment of the *Closer to Zero* initiative and FDA's additional actions to regulate the presence of toxic heavy metals in baby foods, it appears that unacceptable levels of toxic heavy metals persist in these foods. Their continued presence poses a threat to the Nation's public health and food supply. When the FDA announced its *Closer to Zero* initiative in 2021, the plan sought to "identify actions the agency will take to reduce exposure to toxic elements from foods eaten by babies and young children – to as low as possible" and included timelines to set standards for each of the four toxic metals (arsenic, lead, cadmium and mercury). However, to date, no standards have been established, and the FDA remains behind its own schedule. As you know, FDA's schedule called for the release of proposed action levels of lead in foods intended for babies and young children in April 2022, yet its guidance was only released a few days ago. It is alarming that little tangible progress has been made on the *Closer to Zero* action plan, despite the seriousness and severity of this issue, and that to date, FDA has only issued draft guidance on one of the heavy metals.

A recent report from Bloomberg Law detailing the unacceptable levels of toxic heavy metals in baby foods is just the latest of this nature. In 2021, the House Oversight Subcommittee on Economic and Consumer Policy issued a report revealing that many popular baby foods contain dangerously high levels of arsenic, lead, cadmium and mercury. Given the lack of clear standards for baby food—part of the issue we seek to address—the Subcommittee compared the heavy metal content found in baby foods to the standards for bottled water. Data obtained by the Subcommittee identified baby foods containing up to 91 times, 177 times, 69 times and 5 times the limits of arsenic, lead, cadmium and mercury permitted in bottled drinking water, respectively. In 2018, a Consumer Reports investigation also found concerning levels of arsenic, cadmium and lead in nationally distributed baby food products.

As you know, arsenic, lead, cadmium and mercury, while present in many of the foods we eat, can be especially harmful to children. These toxic heavy metals have a range of negative effects on a child's health, particularly on neurological development, and can result in behavioral disorders and lower academic achievement. According to the Centers for Disease Control and Prevention, there is no safe blood level for lead in children. Even low levels of lead in a child's blood can negatively affect that child's development in one of the most critical stages of growth. It is well documented that exposure to lead can damage a child's brain and nervous system, slow growth and development, increase the likelihood of difficulty with hearing and speech and more. Similar neurological effects also occur when children are exposed to high levels of mercury, as studies have shown that children who consumed high levels of mercury in their diets had difficulties with learning, sensory perception and movement.

It is deeply concerning that high levels of toxic heavy metals remain in our Nation's manufactured baby foods. Given the severity of the potential dangers posed by this, we urge FDA to expeditiously finalize guidance documents for industry on proposed action levels for lead in foods consumed by babies and children under the age of two. We also encourage FDA to continue working to fulfill, if not expedite, its Phase 2 and Phase 3 commitments as highlighted in the *Closer to Zero* plan. Lastly, we request that FDA respond to these questions no later than February 20, 2023.

1. When will FDA finalize action levels for lead in juices and processed baby foods?
2. When does FDA expect to release draft guidance on arsenic levels in foods consumed by babies and children under the age of two?
3. When does FDA expect to submit draft guidance on mercury levels in all foods intended for babies and children under the age of two?
4. What steps will FDA take in the interim to address the high levels of toxic heavy metals found in the baby foods tested in the recent Bloomberg Law report and other similar reports?

Thank you in advance for your response to our concerns on this important topic.

Sincerely,



Tammy Duckworth
United States Senator



Raja Krishnamoorthi
Member of Congress



Amy Klobuchar
United States Senator



Tony Cárdenas
Member of Congress