



August 16, 2018

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

Dear Commissioner Gottlieb:

Consumer Reports, an independent, nonprofit organization that works side by side with consumers to create a fairer, safer, and healthier world, writes regarding our recently completed testing of baby and toddler food for elements commonly known as “heavy metals,” including cadmium, lead, and inorganic arsenic. Based on our findings, we urge the Food and Drug Administration (FDA) to take several steps to protect the public from these potentially harmful contaminants in the food supply.

As the FDA is aware, exposure to even small amounts of these elements may, over time, increase the risk of several serious health problems, including those involving carcinogenic, cognitive, and reproductive effects. Babies and young children are the most at risk, particularly given the potential harms of heavy metal exposure on developing brains in the form of lower IQ and behavior problems.

As we report in a major story published today on CR.org, Consumer Reports’ food safety team analyzed 50 nationally distributed foods made for babies and toddlers, including baby cereals, packaged fruits and vegetables, packaged entrées, and packaged snacks. We found:

- Every product had measurable levels of at least one of these heavy metals: cadmium, lead, or inorganic arsenic.
- Around two-thirds (68%) had worrisome levels of at least one heavy metal.
- Among the 50 foods tested, 15 would pose potential health risks to a child regularly eating just one serving or less per day.
- Snacks and products containing rice and/or sweet potatoes were particularly likely to have high levels of heavy metals.
- Certified organic foods were as likely to contain heavy metals as conventional ones.

We are concerned by these results, especially because a recent nationwide survey we conducted of over 3,000 respondents found misconceptions among parents about the safety of baby food. Four in 10 of the parents we surveyed believe children’s packaged foods are lower in heavy metals than other packaged foods. This is despite our testing that showed worrisome levels in many children’s food products. About half of respondents think baby food is already regulated more stringently than other packaged food, and an even larger 72% think it should be.

Accordingly, as a part of our published story, Consumer Reports provides several recommendations to parents. We lay out several steps parents can take to reduce heavy metals exposure, including to eat a broad array of healthful whole foods; limit intake of infant rice cereal and packaged snacks and be conscious of intake of fruit juices; and to choose rice that generally contains less inorganic arsenic. We also encourage them not to panic, and to remember that significant exposure to heavy metals does not guarantee that a child will have health problems, merely that it increases the chance of them.

As parents seek to reduce children's exposure to heavy metals and its associated risks, they should not be left to fend for themselves. Food companies and the FDA have essential roles to play, particularly given another, more encouraging finding of ours: among the 50 products tested, 16 had less concerning levels of the heavy metals. Indeed, for some products, there were some of the metals that were not measurable at all. This suggests that baby food manufacturers across the industry should be able to achieve similar results. We encourage these companies to implement strong, recognized best practices—such as the Codex Alimentarius Code of Practice for the Prevention and Reduction of Lead Contamination in Foods—and urge the FDA to ensure they do so. We appreciate the important, ongoing work of the FDA's Toxic Elements Working Group in this area, and recognize the agency's ability to take enforcement action on a case-by-case basis and its efforts to prevent contaminated food from being imported.

However, we also recognize that the FDA has no specific limits in place to restrict contaminants in the vast majority of children's food. With the agency's own data and the work of Consumer Reports and other public interest groups in mind, it is critically important for the FDA to take the following additional steps to protect the public and assist parents nationwide:

- **Establish aggressive targets.** Because there are no established safe levels of heavy metals like lead, we urge the FDA to set a goal of having no measurable amounts of cadmium, lead, or inorganic arsenic in baby and children's food—and to use the most sensitive testing methods to determine the presence of those elements.
- **Create and enforce benchmarks.** To limit heavy metals in baby and children's food, the FDA should set incremental targets for industry to meet along the way, while continually recognizing that the end goal must be always to have no measurable amounts. The agency also should insist that manufacturers meet strong, recognized best practices as described above.
- **Finalize proposed guidelines.** By the end of 2018, the agency's planned deadline, the FDA should finalize its guidances limiting inorganic arsenic in apple juice to 10 ppb, and limiting inorganic arsenic in infant rice cereal to 100 ppb. Also, it should revise existing guidance for lead in fruit juice to reduce the limit from 50 to 5 ppb, the standard for bottled water.

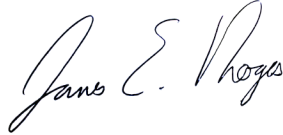
We appreciate your consideration of these critical issues, and kindly request your response to this letter at your earliest convenience. Consumer Reports looks forward to working

with you to prevent contamination, reduce levels of heavy metals in food made for babies and children, and limit the risk of food safety harm to consumers nationwide.

Sincerely,



Jean Halloran
Director of Food Policy Initiatives
Consumers Union¹



James E. Rogers, Ph.D.
Director, Food Safety Research and Testing
Consumer Reports

Enclosure:

“Heavy Metals in Baby Food: What You Need To Know,” Consumer Reports (Aug. 16, 2018)

¹ Consumers Union is the advocacy division of Consumer Reports.