



STATE OF NEW YORK
OFFICE OF THE ATTORNEY GENERAL

Via UPS and E-Mail

June 23, 2022

Dr. Robert M. Califf, Commissioner
Frank Yiannis, Deputy Commissioner
For Food Policy and Response
Food and Drug Administration
10903 New Hampshire Ave
Silver Spring, MD 20993-0002

The Honorable Tom Vilsack
Secretary
U.S. Department of
Agriculture
1400 Independence Ave., S.W.
Washington, DC 20250

Re: Prioritizing Actions to Protect Babies and Young Children from Exposures to Toxic Heavy Metals in Their Food

Dear Secretary Vilsack, Commissioner Califf and Deputy Commissioner Yiannis:

The Attorneys General of New York, California, Colorado, Connecticut, Delaware, Hawaii, Illinois, Iowa, Maine, Maryland, Massachusetts, Michigan, Minnesota, New Jersey, New Mexico, Nevada, North Carolina, Oregon, Pennsylvania, Vermont, Washington, and Wisconsin write on behalf of our states' residents to underscore our concern that the Food and Drug Administration (FDA) and the United States Department of Agriculture (USDA) are not sufficiently prioritizing a public health problem long overdue for robust action: children's exposure to neurotoxic heavy metals (lead, arsenic, cadmium, and mercury) through foods specifically designed and marketed for babies and young children. We call on your leadership to address this critical food safety issue with the urgency it requires.

As FDA Commissioner Califf recently stated: "Exposure of our most vulnerable populations, especially children, to elevated levels of toxic elements from foods is unacceptable."¹ We fully agree. But without your bold and timely leadership to accelerate protective actions by your agencies, American families with young children will be asked to accept this "unacceptable" status quo for several more years before FDA proposes limits on arsenic, cadmium and mercury in baby

¹ U.S. FDA, Twitter, Apr. 27, 2022, https://twitter.com/US_FDA/status/1519403059851538433/photo/1 (last viewed June 23, 2022).

food, and finalizes limits on lead in baby food, under the agency’s “Closer to Zero” Plan, on which USDA is partnering.

Addressing the need for swift action, the Attorneys General submitted a detailed Citizen Petition to FDA in October 2021 urging FDA to adopt science-based, data-driven interim guidance measures within six months to drive improvements in the safety of food intended for babies and young children, including through a best performer standard-setting methodology designed to drive a race to the top by the baby food industry.² Several weeks ago, Attorneys General in this coalition asked FDA to expeditiously reconsider its denial of our Petition.³ Our Petition received support from diverse stakeholders including the health advocacy group Environmental Defense Fund, and a national baby food brand.⁴ Our Petition presents a key set of interim measures that FDA can and should implement in the coming months that would meet the urgent need to reduce this ongoing exposure while implementation of Closer to Zero moves forward.

Toxics in Baby Food Is a Pressing Public Health and Equity Issue

FDA has long acknowledged that toxic elements like lead and arsenic present serious long-term health risks to young children, and that baby food products are an exposure pathway for such toxic contaminants.

In 2017, Dr. Conrad Choiniere of FDA stated that excessive exposure to lead, inorganic arsenic, cadmium, and mercury can be “especially harmful” to children’s “neurological development.”⁵ FDA’s website states that “[r]esearch has shown that reducing exposure to toxic elements is important to minimizing any potential long-term effects on the developing brains of infants and children.”⁶ More recently, Dr. Michael Aschner, Chair of the FDA National Center for Toxicological Research

² The Attorneys General did not, and do not, consider our Petition’s definition of “baby foods” to include “infant formula” defined at 21 U.S.C. § 321(z) and regulated under 21 U.S.C. § 350a.

³ Petition for Reconsideration dated June 1, 2022 Regarding October 21, 2021 Petition to FDA, <https://www.regulations.gov/document/FDA-2021-P-1144-0012>

⁴ See e.g. <https://www.regulations.gov/docket/FDA-2021-P-1144/comments>

⁵ <https://www.fda.gov/food/conversations-experts-food-topics/what-fda-doing-protect-consumers-toxic-metals-foods>

⁶ <https://www.fda.gov/food/cfsan-constituent-updates/fda-letter-industry-chemical-hazards-including-toxic-elements-food-and-update-fda-efforts-increase>

Science Advisory Board, submitted an expert report concluding that lead, arsenic, and mercury can be a substantial factor in causing developmental disabilities.⁷

Additionally, given that cumulative lead exposure pathways already disproportionately impact low-income children and children of color from sources such as lead-based paint and water service lines containing lead, exposure to lead and other toxic metals in food has a disproportionate and inequitable cumulative effect on those children. USDA's administration of the federal WIC program⁸ provides that agency with a clear mandate to help speed the reduction of lead levels and concentrations of other toxic metals in baby food products.

The Closer to Zero Plan Lacks Urgency and Is Already Behind Schedule

While commendable in purpose and goals, FDA's Closer to Zero Plan has been widely criticized for its lengthy and vague timelines, which now extend to mid-2024 and beyond. Even more troubling, implementation of the plan is already behind schedule. FDA did not publish proposed action levels for lead in various baby foods in April 2022, a milestone it committed to meeting within the first year of the Closer to Zero Plan's implementation.⁹

As a result of this and other agency delays, U.S. baby food manufacturers continue to largely self-regulate the amount of lead (and other toxic elements) that is contained within their products. Indeed, it remains up to the manufacturers to decide whether even to test their products for these contaminants.¹⁰ With the continuing absence of FDA action levels and product testing guidance, the lack of

⁷ *N.C. v. Hain Celestial Group, Inc. et al.*, No. 21STCV22822 (Cal. Sup. Ct.), Expert Report of Dr. Michael Aschner, Ph.D in Support of General Causation, November 12, 2021, at <https://www.baumhedlundlaw.com/documents/Aschner-Expert-Report.pdf>.

⁸ See USDA, Special Supplemental Nutrition Program for Women, Infants, and Children (WIC), <https://www.fns.usda.gov/wic>

⁹ <https://www.fda.gov/food/metals-and-your-food/closer-zero-action-plan-baby-foods>. FDA apparently submitted its proposed lead guidance for inter-agency review to the White House Office of Management and Budget in April 2022 but, given the delays associated with that process, FDA's website now offers the vague timeline of "later this year" for release of FDA's proposed lead action levels. <https://www.fda.gov/food/metals-and-your-food/lead-food-foodwares-and-dietary-supplements>

¹⁰ The Baby Food Council—established in 2019 as a collaborative NGO/industry group—now discloses on its website that it has ceased its operations. See Baby Food Council, <https://www.foodchainid.com/babyfoodstandard/> To the extent FDA and USDA had expected the Council's work to contribute to an industry-led reduction in heavy metals in baby food, no such collective action by industry is forthcoming.

transparency about these toxic metals in specific foods brings unnecessary worry and confusion for American families with young children, who continue to face the risks of exposure to heavy metals in the foods marketed to them.

Conclusion

Today's infants and young children need just as much protection from heavy metals in the food they are eating now as do babies born two or more years in the future. Immediate FDA guidance to baby food manufacturers, based on a progressive achievability metric as sought in our Petition, is the most expedient way for the federal government to reduce toxic heavy metal contamination in the foods eaten by *today's* babies and young children. Additionally, we ask FDA and USDA to accelerate the timelines of the Closer to Zero Plan. On behalf of our most vulnerable residents, we call on you to collaborate on accelerating federal actions necessary to help meaningfully drive down the levels of lead, arsenic, cadmium and mercury in food for babies and young children without further delay.

Sincerely,

Letitia James



Attorney General
State of New York

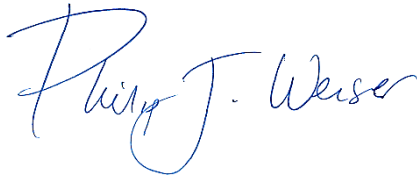
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Rob Bonta
Attorney General
State of California



William Tong
Attorney General
State of Connecticut



Philip J. Weiser
Attorney General
State of Colorado



Kathleen Jennings
Attorney General
State of Delaware



Holly Shikada
Attorney General
State of Hawaii



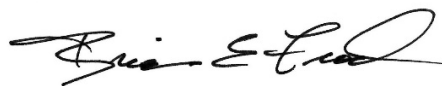
Kwame Raoul
Attorney General
State of Illinois



Tom Miller
Attorney General
State of Iowa



Aaron Frey
Attorney General
State of Maine



Brian E. Frosh
Attorney General
State of Maryland



Maura Healey
Attorney General
Commonwealth of Massachusetts

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Dana Nessel
Attorney General
State of Michigan



Keith Ellison
Attorney General
State of Minnesota



Matthew J. Platkin
Acting Attorney General
State of New Jersey



Hector Balderas
Attorney General
State of New Mexico



Aaron D. Ford
Attorney General
State of Nevada



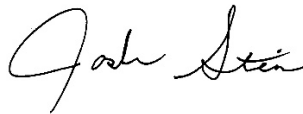
Ellen Rosenblum
Attorney General
State of Oregon



Josh Shapiro
Attorney General
Commonwealth of Pennsylvania



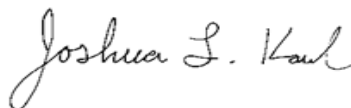
Justin R. Diamond
Acting Attorney General
State of Vermont



Joshua H. Stein
Attorney General
State of North Carolina



Bob Ferguson
Attorney General
State of Washington



Joshua L. Kaul
Attorney General
State of Wisconsin

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Cc: Xavier Becerra, United States Secretary of Health and Human Services
Shalanda Young, Director of the Office of Management and Budget