STATE OF NEW YORK
OFFICE OF THE ATTORNEY GENERAL

Via Electronic Submission on Regulations.gov

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Dr. Susan Mayne, Director
Dr. Conrad Choiniere
Dr. Paul South
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Food and Drug Administration
5001 Campus Drive
College Park, MD 20740

Re: Comments of State Attorneys General on *FDA's Action Levels for Lead in Food Intended for Babies and Young Children: Draft Guidance for Industry*
[Docket No. FDA-2022-D-0278]

Dear Dr. Susan Mayne, Dr. Conrad Choiniere, and Dr. Paul South:

The Attorneys General of New York, Arizona, California, Colorado, Connecticut, Delaware, Hawaii, Illinois, Maine, Maryland, Massachusetts, Michigan, Minnesota, Nevada, New Jersey, North Carolina, Oregon, Pennsylvania, Vermont, Washington and Wisconsin submit these comments to the Food and Drug Administration (FDA) on the agency's Draft Guidance to Industry on Action Levels for Lead in Food Intended for Babies and Young Children, published on January 24, 2023 (the "Lead Guidance") as part of FDA's "Closer to Zero" initiative to "reduce childhood exposure to contaminants from foods."[1]

The Attorneys General believe that FDA's release of the draft Lead Guidance is a welcome and important step that advances the goal for industry to "reduce levels of lead in products for babies and young children to as low as possible."[2] Through the Food Safety Modernization Act of 2011, Congress directed the U.S. Department of Health and Human Services (through FDA) to "issue contaminant-specific and science-based guidance documents, including guidance documents

[1] https://www.fda.gov/food/environmental-contaminants-food/closer-zero-reducing-childhood-exposure-contaminants-foods (last visited Mar. 27, 2023).

[2] https://www.fda.gov/food/cfsan-constituent-updates/fda-issues-guidance-industry-action-levels-lead-baby-foods ("Lead Guidance"), page 5.

regarding action levels, or regulations" "when appropriate to reduce the risk of serious illness or death to humans or animals or to prevent adulteration of the food under [21 U.S.C. § 342]."[3]

Lead hazards are a scourge on the health and welfare of young children, the most vulnerable residents of our states. As the Lead Guidance acknowledges, "[n]o safe level of lead exposure has been identified for protecting children's health."[4] Specifically, the "neurological effects of lead exposure during early childhood include learning disabilities, behavior difficulties, and lowered IQ. Lead exposures also may be associated with immunological, cardiovascular, renal, and reproductive and/or developmental effects."[5] FDA recognizes that "[b]ecause lead can accumulate in the body, even low-level chronic exposure can be hazardous over time."[6]

Additionally, lead poisoning is a core environmental justice issue.[7] Communities of color are disproportionately exposed to lead-polluting sources.[8] The EPA has recognized that "[c]hildren living in communities overburdened by pollution and other health and social stressors, often communities of color and lower socioeconomic status, are at greater risk."[9]

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[3] Pub. L. 111–353, title I, § 104, Jan. 4, 2011, 124 Stat. 3899, codified at 21 U.S.C. § 2201(b).

[4] Lead Guidance, page 5.

[5] *Id.* page 4.

[6] *Id.*

[7] *See generally EPA Strategy to Reduce Lead Exposures and Disparities in U.S. Communities*, October 2022 ("EPA Lead Strategy"), https://www.epa.gov/system/files/documents/202211/Lead%20Strategy_1.pdf (last accessed Mar. 27, 2023).

[8] A 2020 study concluded that race was the second strongest predictor for elevated blood lead levels. *See* Yeter D. et al. (2020), *Disparity in Risk Factor Severity for Early Childhood Blood Lead Among Predominantly African-American Black Children: The 1999 to 2010 US NHANES*, International Journal of Environmental Research and Public Health 17(5) at 19, https://doi.org/10.3390/ijerph17051552. Another study found that Black and Hispanic children have higher rates of lead poisoning than white children, even when accounting for socioeconomic status. Environmental Injustice: Lead Poisoning in Indiana (A Report of the Indiana Advisory Committee to the U.S. Commission on Civil Rights, November 2020), page 41, https://www.usccr.gov/files/2020/2020-11-12-Report-Lead-Poisoning-in-Indiana.pdf.

[9] EPA Lead Strategy, page 11.

We therefore urge FDA to expand and strengthen the Lead Guidance to protect more children from the serious, long-term health risks of lead exposure through store-bought foods marketed to babies and toddlers. Specifically, the Lead Guidance would be more protective of children's health with the following revisions:

- FDA should expand the Lead Guidance to include foods intended for children 36 months old and younger, rather than include only foods intended for children 24 months old and younger.
- FDA should extend the Lead Guidance to include grain-based snacks, which are commonly consumed by babies and toddlers, and have demonstrated elevated lead concentrations.
- FDA should expressly state that manufacturers whose products are covered by the Lead Guidance should perform finished product testing for lead.
- FDA should consider evaluating action levels based on lead intake at the 97.5th percentile consumption level, as the Centers for Disease Control (CDC) does for assessing elevated blood lead levels, or explain why it is prudent for FDA to apply a lower (i.e., 90th percentile) consumption level when setting action levels for lead in baby and toddler foods.
- FDA should reconsider its use of FDA testing data collected prior to September 2016, because FDA's Preventive Controls Rule had not yet gone into effect, and because the pre-2016 data were analyzed with higher limits of detection and quantitation than are currently available.
- FDA's "achievability" assessment should not presume that lower achievability rates associated with more protective action levels are prohibitive to industry.

I. FDA Should Expand the Lead Guidance to Cover Foods Intended for Children 36 Months Old and Younger, Rather Than for Children 24 Months Old and Younger.

The Lead Guidance covers processed food intended for "babies and young children." But FDA has limited the definition of this category of food to "food packaged in jars, pouches, tubs, and boxes represented or purported to be specifically for *babies and young children less than two years old*."[10] When

[10] Lead Guidance, page 3 n.2.

finalizing the Lead Guidance, FDA should modify the definition to cover packaged foods represented or purported to be specifically for babies and young children up to 36 months old.

The Lead Guidance does not explain why FDA has decided that the Guidance should cover foods intended only for children younger than 2 years old. Plainly, lead exposure is a concern for infants, toddlers, and preschoolers with developing brain and organ systems.[11] This is why the CDC's Blood Lead Reference Value is based on the 97.5th percentile of blood lead values of children ages 1-5 years old.[12]

When FDA announced the Closer to Zero plan almost two years ago, in April 2021, the agency suggested that the agency's guidance to industry under Closer to Zero would address foods intended for babies and young children from infancy through the age of three or four. For example, a Closer to Zero infographic that FDA released in April 2021 and that still appears on Closer to Zero's website today includes a graph showing the decline in "average daily dietary exposures to lead for *1-3 year olds*" between 1980 and 2016.[13] Dr. Susan Mayne of FDA discussed this same criteria (i.e. dietary lead exposures in 1-3 year olds) when introducing a public meeting on Closer to Zero on November 18, 2021.[14] In the same Closer to Zero public meeting, Dr. Conrad Choiniere of FDA—addressing the issue of "what ages [FDA] should be targeting and what foods"—analyzed national dietary consumption data for children ages 0-12 months, 1 to 2 years old, and 3 to 4 years old, and noted that consumption data for children 5 years and older were not relevant to Closer to Zero.[15] FDA's presentations and discussions thus strongly indicated that foods marketed to children ages 2 to 3 years old would fall within the scope of the Closer to Zero plan for reducing toxic elements in young children's food.

Applying the Closer to Zero program to infants and young children up to 36 months old makes sense based on existing FDA regulations and guidelines from other authorities on pediatrics and public health. FDA's regulations on daily nutrient values (% DV), last updated in 2016, establish a category for "infants up to

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[11] *See* Lead Guidance, page 6 ("[We place particular emphasis on foods consumed by babies and young children, who are especially sensitive to lead's adverse health effects because of their smaller body sizes and rapid development.").

[12] https://www.cdc.gov/nceh/lead/data/blood-lead-reference-value.htm.

[13] https://www.fda.gov/media/147324/download (emphasis added).

[14] Transcript of Nov. 18, 2021 "Closer to Zero" public meeting, page 19, https://www.fda.gov/media/155396/download

[15] *Id.* at pages 33-39.

12 months of age" and for "children 1 through 3 years of age."[16] When adopting those regulations, FDA explained that "[b]ecause the growth velocity in height is most similar for children 1 through 3 years of age, we consider it appropriate to revise the age range to include children of these ages into a single category for food labeling purposes."[17] And more recently, FDA wrote in a proposed rule on "healthy" food labeling that children 1 through 3 years old have "specific nutritional needs."[18] The CDC has information for parents that groups infants and toddlers ages 0-3 years old into one category in terms of health and development.[19] And the American Academy of Pediatrics' website defines "toddler" as ages 1-3 years old.[20]

The Lead Guidance also does not explain how foods targeted for children between the ages of 1 and 2 years old are meaningfully different from foods intended for children between 2 and 3 years old. FDA's recent proposed rule on updating regulations governing labeling of food as "healthy," on which many of the undersigned Attorneys General submitted comments to FDA,[21] lists "fruit pouches" and "toddler snack puffs" as examples of foods that are both "intended specifically for use by infants and children less than 2 years of age" and as falling within the "subset of foods specifically directed to children 2 to 3 years of age."[22] FDA's own example indicates that "fruit pouches" (a type of food covered by the Lead Guidance)[23] are marketed to children who are younger than 2 years old as well as to children who are between 2 and 3 years old. This is also true of other commercially packaged foods intended for young children, such as vegetable purees, meat purees, mixed purees, and yogurts, which are also covered by FDA's Lead Guidance.[24]

As FDA is aware, the Codex Alimentarius Commission's Committee on Contaminants in Food, of which the United States is a member is considering a proposal for maximum levels of lead in "ready-to-eat meals for infants and young

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[16] *See* 21 C.F.R. § 101.12(a)(2).

[17] FDA, *Food Labeling: Revision of the Nutrition and Supplement Facts Labels*, 81 Fed. Reg. 33,742, 33916 (May 27, 2016) (Final Rule).

[18] FDA, *Food Labeling: Nutrient Content Claims; Definition of Term "Healthy,"* 87 Fed. Reg. 59,168, 59,181 (Sept. 29, 2022) (Proposed Rule).

[19] https://www.cdc.gov/parents/infants/index.html.

[20] https://www.healthychildren.org/English/ages-stages/Pages/default.aspx.

[21] https://www.regulations.gov/comment/FDA-2016-D-2335-1587.

[22] 87 Fed. Reg. at 59,178, 59,181.

[23] https://www.fda.gov/media/164684/download. See page 3 n.2.

[24] See *id.*

children" at a meeting next month. In that proposal, the definition for "infants" is "up to 12 months" and the definition of young children is "12 to 36 months."[25] Many Codex proposals and documents have defined "young children" in this context as going up to 36 months, and it does not appear that this has been a controversial definition for the U.S. Codex Office. It would be incongruous for the United States to support international lead reduction initiatives that expressly include children up to 36 months old, while issuing guidance on action levels for lead to the U.S. baby and toddler food industry that only include "young children" up to 24 months, as the proposed Lead Guidance does.

Modifying the Lead Guidance to apply to packaged food products intended for children up to 36 months old will help reduce dietary lead exposures to many more U.S children.

II. FDA Should Extend the Lead Guidance to Grain-Based Snacks, Which Are Commonly Consumed by Babies and Toddlers and Contain Elevated Lead Concentrations.

The Lead Guidance includes a footnote disclosing that "grain-based snacks (e.g., arrowroot cookies, puffs, rusks, teething biscuits) also were analyzed; however, they are not addressed in this guidance."[26] FDA adds that it "is seeking additional information on this category of foods to inform whether an action level would be appropriate."[27] FDA fails to provide an adequate explanation for why this category of packaged food, commonly consumed by children under 2 years old (and also by children between 2 and 3 years old), is being excluded from coverage under the Lead Guidance. Unlike infant formula, which FDA notes was sampled in its Total Diet Study (TDS) and where it was determined that most samples collected contain no lead (albeit at a Limit of Detection of 4 parts per billion),[28] various forms of grain-based snacks test higher in lead across various FDA sources of sample data.

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[25] Joint FAO/WHO Food Standards Programme, Codex Committee on Contaminants in Foods, Maximum Levels for Lead in Certain Food Categories, February 2023, page 7, https://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FMeetings%252FCX-735-16%252FWDs%252Fcf16_03e.pdf.

[26] Lead Guidance, page 7 n.6.

[27] *Id.*

[28] *Id.*

Approximately 58 grain-based snacks were tested as part of FDA's Toxic Elements Program (TEP) sampling between fiscal years 2016 and 2021.[29] Lead was not detected in 10 of those samples, though the Limit of Detection is not disclosed in that data set. For reasons discussed below, data from fiscal year (FY) 2016[30] should not be relied upon since such data were collected prior to the first compliance date for FDA's Preventive Control Rule.[31] Thus, focusing on the 51 samples collected for the TEP from FY 2017 through FY 2021, the mean lead concentration detected was roughly 8 parts per billion (ppb), with a 90th percentile of roughly 16 ppb, and a 97.5th percentile approaching 19 ppb. These lead levels are among the highest of the categories that FDA analyzed in the Lead Guidance, with mean and 90th percentile levels comparable to all vegetable products (including root vegetables) for babies/toddlers.[32] Those 51 samples do not appear to show a material difference between lead levels in different kinds of grain-based snacks (teething biscuits, puffs, rusks, or cookies), however teething biscuits seem to have slightly higher mean lead levels than other sub-categories of grain-based snacks.[33]

Additionally, FDA's evaluation of its TDS data for FY 2018 through 2020 identified "baby food teething biscuits" as the food category with the second-highest levels of lead, after "baby food sweet potatoes."[34] Attorneys General in this coalition brought these concerning TDS results about high lead concentrations in teething biscuits (as well as baby food sweet potatoes) to FDA's attention in an August 18,

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[29] https://www.regulations.gov/document/FDA-2022-D-0278-0014.

[30] Fiscal Year 2016 corresponds to calendar year October 2015 through September 2016.

[31] *Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Control for Human Food*, 80 Fed. Reg. 55,907 (Sept. 17, 2015) (Final Rule).

[32] *See* Lead Guidance, at page 15, Table 2.

[33] Approximately 120 samples of grain-based snacks were also analyzed as part of FDA's FY 2013-14 survey, and found to have elevated lead levels, with roughly 18 ppb of lead at the 90th percentile. However, the Attorneys General would not support FDA proposing or establishing an action level for grain-based snacks on the basis of data from a decade ago, for reasons discussed below.

[34] *See* FDA Total Diet Study Report, July 2022, page 20, https://www.fda.gov/media/159745/download.

2022 letter filed in further support of their Reconsideration Petition, which remains before FDA.[35]

We are concerned that if FDA excludes grain-based snacks from being subject to an action level when the agency finalizes the Lead Guidance, this may signal to manufacturers that FDA is not concerned with the concentrations of lead in those finished products. That signal makes it less likely that manufacturers will take diligent steps to control for lead in these products. Even where a manufacturer attempts to limit lead in its products intended for babies and young children, the lack of directly-applicable FDA guidance may lead the manufacturer to establish internal targets that are too lax to protect public health. For example, a 2021 congressional report revealed that at least one major baby food brand previously set an internal lead "specification" level of 100 ppb for key ingredients in their products, while another major baby food brand previously maintained an "internal limit of 100 ppb lead."[36] These high internal targets for lead—up to ten times higher than the action levels FDA has proposed in the Lead Guidance—were presumably based on the 100 ppb then-proposed FDA action level for inorganic arsenic in infant rice cereal, or the 100 ppb FDA action level for lead in candy—neither of which action levels apply to lead in food intended for babies and toddlers.[37] It is thus critical that FDA address grain-based snacks in the current version of the Lead Guidance.

The Attorneys General urge FDA to revise the Lead Guidance to include an appropriate lead action level for grain-based snacks of 15 ppb or lower, based on FDA sampling data from the agency's TEP (after September 2016) and other

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[35] Letter from Attorneys General to FDA dated Aug. 18, 2022, https://www.regulations.gov/comment/FDA-2021-P-1144-0015

[36] U.S. House Subcommittee on Economic and Consumer Policy Staff Report, Baby Foods Are Tainted with Dangerous Levels of Arsenic, Lead, Cadmium, and Mercury, Feb. 4, 2021 ("February 2021 U.S. House Subcommittee Report") page 22 (referring to Nurture Inc's "internal limit of 100 ppb lead"), page 27 (excerpting data produced by the Hain Celestial Group, Inc. showing a "Lead Spec" of 100 ppb, i.e., an internal lead "specification" of 100 ppb), https://oversightdemocrats.house.gov/sites/democrats.oversight.house.gov/files/20210204%20ECP%20Baby%20Food%20Staff%20Report.pdf.

[37] *See* https://www.fda.gov/news-events/press-announcements/fda-proposes-limit-inorganic-arsenic-infant-rice-cereal; https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-lead-candy-likely-be-consumed-frequently-small-children.

sampling data from more recent years that FDA may have obtained. This will protect young children from an important source of lead exposures in their diets.

III. FDA Should Expressly State That Manufacturers Whose Products Are Covered By the Lead Guidance Should Perform Finished Product Testing for Lead, In Addition to Testing of Key Ingredients.

In the Lead Guidance, FDA encourages manufacturers to "consider" increased "testing of ingredients or finished products that are historically known to contain elevated lead levels."[38] FDA adds that this is "particularly important" for "ingredients or finished products intended for babies and young children."[39] While the testing of key ingredients for lead is of crucial importance, FDA's reference to finished product testing in the Lead Guidance is a step forward compared with prior FDA guidance documents that set or proposed action levels to limit toxic elements without mention of finished product testing.[40] But FDA would advance its objective of reducing lead in baby and toddler foods by providing a clear statement to industry that finished product testing for lead is a control measure that manufacturers in this particular subset of the processed food industry *should* employ, in addition to testing of key ingredients for lead in the supply chain.

As a congressional report revealed in 2021, many major baby and toddler food manufacturers perform no systematic testing of many of their finished products for lead or other toxic elements before distribution into commerce.[41] Nor, as far as the Attorneys General are aware, does FDA obtain in any systematic way the results of testing for lead that is voluntarily performed by some manufacturers of baby and toddler foods.

FDA is seeking an express statutory mandate for baby and toddler food manufacturers to perform finished product testing for lead and other toxic elements, and for FDA to be able to seamlessly access the analytical results of such testing.

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[38] Lead Guidance, page 4.

[39] *Id.*

[40] *See Inorganic Arsenic in Rice Cereals for Infants: Action Level Guidance for Industry*, https://www.fda.gov/media/97234/download (referring only to testing of incoming rice and rice-based ingredients); *Draft Supporting Document for Establishing FDA's Action Levels for Lead in Juice*, https://www.fda.gov/media/157944/download (referring vaguely to the taking of "control measures")

[41] February 2021 U.S. House Subcommittee Report, pages 56-57 ("The majority of baby food manufacturers . . . employ the same policy of testing only ingredients.").

This is evident from FDA's Fiscal Year 2024 Legislative Proposals Executive Summary document (released earlier this month), which states that "FDA is seeking to amend the [Food, Drugs and Cosmetics Act] to: (1) require industry to conduct toxic element testing of final products marketed for consumption by infants and young children and maintain such records of these testing results for FDA inspection; and (2) provide FDA with new authority to remotely access records of these test results and to review these test results whenever necessary."[42] FDA explains that "this new authority would help FDA understand levels of toxic elements in such products, allow FDA to monitor industry progress in reducing levels of these toxic elements over time, and identify where FDA should devote more time and resources to better protect infants and young children."[43]

In light of FDA's publicly stated interest in requiring finished product testing by manufacturers of baby and toddler food, as expressed in FDA's Fiscal Year 2024 Legislative Proposals Executive Summary, FDA should not miss the opportunity to advance finished product testing as part of the instant guidance. There is nothing to stop FDA from explicitly recommending in the Lead Guidance that baby and toddler food manufacturers *should* employ finished product testing to assess the levels of lead in the products they distribute into commerce. The Lead Guidance already includes FDA's standard disclaimer that "FDA's guidance documents do not establish legally enforceable responsibilities," but rather "describe FDA's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited."[44] More specifically, FDA already advises in the Lead Guidance that "[t]he use of the word *should* in FDA guidances means that something is suggested or recommended, but not required."[45] Thus, with this clear caveat, there is little risk that an FDA recommendation to baby and toddler food manufacturers in the Lead Guidance that they *should* be performing finished product testing for lead will be misinterpreted as anything other than a recommendation. Additionally, the Lead Guidance recommends that "manufacturers could consider examining their facilities, processes, and equipment to ensure that they are not contributing to lead in their products."[46] Manufacturers should test their products at the end of their production process, given that FDA

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[42] FDA Summary of FY 2024 Legislative Proposals, page 3 https://www.fda.gov/media/166049/download.

[43] *Id.*

[44] Lead Guidance, page 4.

[45] *Id.* (emphasis added to the word "should").

[46] Food Guidance, page 4.

has indicated that the production process itself could be a source of additional lead contamination beyond ingredients that are agricultural commodities.

IV. FDA Should Evaluate a More Health-Protective Action Level Based on the 97.5th Percentile Level of Consumption, as CDC Does for the Blood Lead Reference Value, Or Should More Transparently Explain Its Selection of the 90th Percentile Consumption Level.

The Lead Guidance Relies on a 90th Percentile Level of Consumption Without Explanation.

The Lead Guidance explains that a key consideration of FDA in developing action levels for lead in baby food is that "the action level should minimize the likelihood that a consumer will be exposed to lead levels exceeding the IRL," referring to the lead Interim Reference Level ("IRL") of 2.2 µg/day for children that FDA updated in 2022. "The IRL represents the maximum daily dietary intake of lead from food that corresponds to the CDC's BLRV [Blood Lead Reference Value] of 3.5 µg/dl, with an additional 10x safety factor applied." In order to identify the maximum lead concentration in baby foods that would not cause the IRL to be exceeded, in the Lead Guidance FDA "consider[ed] intake at the 90th percentile consumption level for the food/food category."

An FDA guidance document from 2006 on *Estimating Dietary Intake on Substances in Food* states that FDA "estimates upper percentile intakes of substances in the diet to account for individuals who are considered 'high level' consumers of specific foods that contain these substances."[47] That 2006 guidance states that "[t]he 90th, 95th and 97.5th percentile intakes are used by various regulatory bodies in the world to represent 'high level' consumers."[48]

In the context of developing action levels for contaminants like lead, a 90th percentile consumption level means that 90% of the entire target population is expected, based on their food consumption, to be exposed to lead in the covered foods at levels below the action level, while 10% of the target population will be expected, based on their food consumption rate, to be exposed to lead in the covered foods in excess of the action level. Alternatively, an action level for lead based on consumption at the 97.5th percentile is intended to protect all but the 2.5% of the target population with the highest consumption rate of the covered foods.

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[47] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-estimating-dietary-intake-substances-food

[48] *Id.*

Other than a footnote explaining the sources of consumption data from which the 90th percentile consumption level was calculated, the Lead Guidance does not explain why FDA chose the 90th percentile as the "upper bound" consumption level. The 90th percentile of intake does not match the CDC's standard for assessing elevated blood lead levels based on an upper bound intake at the 97.5th percentile. Other risk assessment guidelines from the World Health Organization indicate that FDA should at least explain its reliance on the 90th percentile for modeling high dietary lead exposures in the youngest children.

The CDC Uses the 97.5th Percentile to Model High Blood Lead Levels

The CDC's Blood Lead Reference Value "is based on the 97.5th percentile of the blood lead values among U.S. children ages 1-5 years from 2015-2016 and 2017-2018 National Health and Nutrition Examination Survey (NHANES) cycles."[49] In other words, "[c]hildren with blood lead levels at or above the Blood Lead Reference Value represents those at the top 2.5% with the highest blood lead levels."[50] CDC estimates that approximately 500,000 children ages 1-5 in the U.S. have a blood lead level at or above the Blood Lead Reference Value.[51] According to the CDC's Lead Exposure and Prevention Advisory Committee, the CDC Blood Lead Reference Value "is not a clinical reference level defining an acceptable range of blood lead levels in children nor is it a health-based toxicity threshold; rather it is a policy tool that helps target children in the upper end of the population blood lead distribution in order to prioritize prevention efforts and evaluate their effectiveness."[52]

Thus, while the FDA may have validly derived a daily Interim Reference Level for children's lead exposure from food of 2.2 µg/day based on the CDC Blood Lead Reference Value of 3.5 µg/dL, the logical starting point of consumption estimates for developing FDA's action levels would appear to be the 97.5th percentile, which is the upper consumption threshold used by the CDC. This choice could have significant consequences. An action level based on exposure at the 90th percentile instead of at the 97.5th percentile will protect fewer U.S. children under 2 years old from the harmful effects of lead exposure. Since there are roughly 11.2

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[49] https://www.cdc.gov/nceh/lead/data/blood-lead-reference-value.htm

[50] *Id.*

[51] https://www.cdc.gov/nceh/lead/overview.html#:~:text=CDC%20uses%20a%20blood%20lead,at%20or%20above%20the%20BLRV.

[52] Lead Exposure and Prevention Advisory Committee, Annual Report to U.S. Department of Health & Human Services, August 2022, page 3, https://www.cdc.gov/nceh/lead/docs/lepac/lepac-2021-annual-report-h.pdf.

million children in the U.S. under two years old (based on 2021 U.S. Census data),[53] choosing the 90th percentile as the "upper bound" consumption threshold would at the outset provide less than adequate protection to 7.5 percent, or roughly 840,000, more babies and toddlers (under two years old) each year than would be the case if FDA used the 97.5th percentile.[54] In short, by choosing a 90th percentile consumption level FDA is essentially relaxing its objective of protecting as many children as possible from potentially dangerous dietary sources of lead exposures.

Global Public Health Guidance Advises Transparency in Explaining the Selection of an Upper Bound Percentile for Dietary Exposure Assessments

The Food and Agriculture Organization of the United Nations and the World Health Organization have jointly published the *Principles and Methods for the Risk Assessment of Chemicals in Food* (2009) (the "WHO Principles").[55] In the chapter on Dietary Exposure Assessment of Chemicals in Food, the WHO Principles state that in every dietary exposure assessment, "[t]he method applied should be clearly described" and that "the model and data sources used, assumptions, limitations and uncertainties should also be documented."[56] Most relevant here, the WHO Principles state that "[t]he percentiles (e.g. 90th, 95th or 97.5th) used to represent highly exposed consumers should be clearly stated and their derivation described."[57] Here, FDA's draft Lead Guidance does not, but should, clearly explain and justify the agency's selection of the less protection 90th percentile upper bound if FDA adheres to that threshold.

The WHO advises that "[i]deally, the food consumption values in the GEMS/Food LP [Large Portion] database should be based on the 97.5th percentile of individual consumer days from national surveys."[58] Here, the WHO Principles refer to the WHO's Global Environmental Monitoring System for food contaminants at higher exposure levels. The WHO Principles also note that "[t]he choice of the upper

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[53] https://www.kidsdata.org/topic/34/child-population-age-gender/table#fmt=141&loc=1&tf=141&ch=1433,926,927,1434,1435,372,78,77,79&sortColumnId=0&sortType=asc

[54] 7.5% of 11.2 million children under 2 years old is roughly 840,000 children.

[55] FAO and WHO, Principles and Methods for the Risk Assessment of Chemicals in Food (2009) ("WHO Principles"), http://apps.who.int/iris/bitstream/handle/10665/44065/WHO_EHC_240_9_eng_Chapter6.pdf;jsessionid=54FB5FC9F36757CE2F2C754CEEAD00BD?sequence=9.

[56] WHO Principles, Chapter 6, page 6-6.

[57] *Id.*

[58] *Id.* Chapter 6, page 6-38.

percentile of dietary exposure that represents a high consumer is . . . dependent on the purpose of the dietary exposure and the data available to the risk assessor and risk manager."[59] FDA's Lead Guidance is intended to reduce health risks to children and, given that there is no safe level of lead exposure for young children, an objective that favors a more health-protective approach is needed. Nor has FDA raised any issues about the availability of consumption data at higher percentiles, such as the 95th percentile or the 97.5th percentile.

Accordingly, FDA should reevaluate its selection of a 90th percentile upper bound for modeling high consumption given that the objective of the Lead Guidance is to protect a highly susceptible population from a chemical contaminant for which there is no safe level of exposure. Moreover, the choice of the 90th percentile does not match the CDC's more protective 97.5th percentile for the Blood Lead Reference Value. At a minimum, FDA's Lead Guidance should clearly explain and justify why the agency selected the less protective 90th percentile if FDA adheres to that threshold.

V. FDA Should Reconsider its Use of FDA Testing Data From Periods Prior to September 2016, When Compliance with FDA's Preventive Controls Rule Began, and Because the Pre-2016 Data Were Analyzed With Higher Limits of Detection and Quantitation Than Are Currently Available.

The Lead Guidance is principally based on FDA sampling of baby and toddler foods from three sources: FDA's Toxic Element Program (TEP) testing conducted between federal fiscal years 2008 and 2021, and two FDA surveys targeting baby and toddler foods in 2013-14 and 2021.[60] FDA combined data from these sources and used it to evaluate both the baseline levels at which babies and young children are exposed to lead in various categories of baby and toddler food, and the percentages for industry-wide achievability at the proposed action levels.[61] FDA explained that it considered the TDS 2014-2020 data, but that the "compositing" (i.e., combining several samples into one sample) of TDS samples collected from different retail locations prevents the TDS data from being used in the achievability assessment.[62]

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[59] *Id.* Chapter 6, page 6-56.

[60] Lead Guidance, page 6, page 15 (Table 1).

[61] *Id.* page 6, page 17 (Table 4) n.13.

[62] *Id.* page 7.

Of the testing data that directly informs FDA's development of action levels—the TEP data and the two FDA surveys—there are a total of 863 samples.[63] Of these, 147 samples were from FDA's survey in 2013-14, and roughly 40 samples were collected by FDA's Toxic Element Program between October 2008 and September 2016 (federal fiscal years 2009-2016).[64] Thus, about 187 samples on which FDA relied—representing over 21% of the total data set that informed FDA's achievability assessments—were collected prior to September 2016.

This is alarming because FDA's Preventive Control Rule did not go into effect until September 2016.[65] That rule requires U.S. companies manufacturing baby and toddler food, to implement "hazard analysis" and "preventive controls" for any heavy metal contaminants.[66] Accordingly, samples collected during fiscal year 2016 and before are from an era when no manufacturer of baby and toddler food was under any regulatory requirement to take steps to prevent or limit lead contamination in their products.[67] For that reason, the 147 analytical results for lead that FDA collected in its 2013-14 survey, and the other samples collected prior to September 2016 are not representative of the baseline levels of lead in baby and toddler food products on the market today and should therefore be excluded from FDA's analysis.

This is not a harmless error. The inclusion of the older sample data in FDA's development of the action levels tends to skew the sample data's means upward and tends to push the achievability percentages downward.[68] If only sample data from fiscal years 2017 through 2021 were included in FDA's analysis, FDA might not have needed to propose action levels two times higher than 10 ppb for single-ingredient root vegetables and dry infant cereals based solely on FDA's

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[63] *Id.* page 15 (Table 1).

[64] *See* https://www.regulations.gov/document/FDA-2022-D-0278-0014.

[65] *Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Control for Human Food*, 80 Fed. Reg. 55,907 (Sept. 17, 2015) (Final Rule).

[66] *See* https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-final-rule-preventive-controls-human-food (identifying September 19, 2016 as the first compliance date for the Preventive Controls Rule).

[67] The FDA's action level for "Lead in Candy Likely to Be Consumed Frequently by Small Children" was set in 2006, but manufacturers of candy generally do not also manufacturer foods intended for babies and toddlers.

[68] Achievability percentage is the % of the combined samples for a particular category of baby and toddler food that fall below a hypothetical action level.

achievability assessment.[69] To the extent that excluding older samples from FDA's operative data sets would produce a lower quantity of samples for each relevant category—such as single-ingredient root vegetables and dry infant cereals—then FDA could have collected and analyzed more samples of baby and toddler food in fiscal year 2022 to utilize in developing the Lead Guidance. FDA can still expeditiously collect more sample data in fiscal year 2023 and incorporate any relevant sample data from fiscal year 2022 when finalizing the Lead Guidance.

Additionally, the older data may present a distorted and incomplete picture of lead concentrations because laboratory proficiency with lower Limits of Detection and Limits of Quantitation has advanced since the 2009-2014 period.

In the data from FDA's survey in FY 2021, a footnote states that the "Limits of Detection (LODs) ranged from 0.3 to 1.2 ppb" and that the "Limits of Quantitation (LOQs)[70] ranged from 3.1 to 10.9 ppb."[71] This is compared with FDA's survey in FY 2013-14, where the LODs for lead ranged from 0.8 ppb to 6.5 ppb, and the LOQs for lead ranged from 7.0 ppb to 58.4 ppb.[72] Sample data from the TEP (covering fiscal years 2008 through 2021) includes an even wider range of LOQs of 0.2 ppb to 100 ppb, and notes that LODs were not consistently reported.[73]

These comparisons demonstrate that the data FDA collected and analyzed in FY 2021 has a far narrower and lower range of LODs and LOQs than data sets from 2013-14 and earlier. This may also help explain why the FY 2013-14 FDA survey data reflect a high rate of non-detect samples for lead (as much as 30% of all solid food samples in that survey).[74] This is compared with the far lower level of non-

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[69] Lead Guidance, page 9.

[70] The Limit of Detection (LOD), or detection limit, is the lowest concentration of an analyte (chemical) at which the laboratory is able to detect the presence of the analyte in the sample, but not necessarily to quantify the exact value of the analyte. The Limit of Quantitation (LOQ), or quantitation limit, is the lowest concentration of an analyte at which the laboratory is able to quantitatively determine the precise concentration of the analyte in the sample with accuracy. The LOQ must be greater than the LOD. *See* FDA *Guidelines for the Validation of Chemical Methods for the FDA Foods Program*, 3rd Ed., page 19, https://www.fda.gov/media/81810/download.

[71] https://www.regulations.gov/document/FDA-2022-D-0278-0016.

[72] https://www.fda.gov/media/100386/download.

[73] https://www.regulations.gov/document/FDA-2022-D-0278-0014.

[74] The FY 2013-14 FDA survey also characterizes many lead sample results as having "trace" quantities of lead—meaning above the LOD but below the LOQ—

detect samples for lead in the FY 2021 FDA survey (approximately 6% non-detects of the 360 samples that FDA used for the Lead Guidance).

Based on a comparison of the various data sets, it is fair to conclude that FDA today utilizes laboratories with a more consistent ability to detect and quantify lead in food at very low concentrations, compared with a decade ago. This is an additional reason why FDA's inclusion of older data may be less appropriate when proposing action levels intended to limit and drive down lead in baby and toddler foods.

VI. FDA's "Achievability" Assessment Should Not Presume That More Protective Action Levels Are Prohibitive to Industry.

The Attorneys General recognize that industry achievability is a legitimate consideration for FDA when setting action levels for unavoidable contaminants as provided in 21 C.F.R. § 109.6(d). FDA interprets "achievability" to mean the percentage of samples in a given FDA data set (which are typically based on a market basket and are brand-anonymous) that would fall under a hypothetical action level. But FDA does not explain why the prospective "achievability" of proposed action levels should necessarily be evaluated based on the same historic market-basket data that informs the development of action levels for different categories of baby and toddler food.

Achievability is an iterative and evolving concept that may depend on the quality of a manufacturer's food safety processes, safety culture, supply-chain management, and on the proficiency and accuracy of the laboratories that the manufacturer contracts to perform testing for lead and other toxic elements in finished products and key ingredients. This is why FDA emphasizes "continuous improvement" in the Closer to Zero program, and why FDA action levels, as opposed to FDA tolerances which are static, are premised on the concept that "technological or other changes" might "affect the appropriateness" of the action level "in the near future."[75] In other words, the level of lead concentrations in the baby and toddler food industry *en masse* based on sample data from years ago, before there was any proposed FDA action level applicable to those foods, is hardly an indicator of the industry's ability to achieve the action levels now being proposed by FDA.

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even for results that would exceed the 10 ppb and 20 ppb action levels that FDA has now proposed.

[75] 21 C.F.R. § 109.6(d).

The Lead Guidance presumes that an achievability threshold of at least 90% (or close to 90%) is appropriate.[76] FDA assumes, without providing any empirical evidence, that achievability rates between 70% and 90% are prohibitive. This is evident from FDA's discussion of root vegetables, where FDA considered an action level of 10 ppb (to match the action level being proposed for other kinds of vegetables) but rejected the lower action level, observing that "at an action level of 10 ppb (the action level provided in this guidance for other vegetable products), root vegetable achievability was only 71%."[77] In some respects, this is a departure from FDA's approach to achievability in developing an action level of 100 ppb for infant rice cereal. There, FDA's supporting document confirmed that a 100 ppb action level assumed an achievability rate of 76% based on FY 2018 testing data.[78]

There is thus no clear basis for FDA to presume that the baby and toddler food industry would be gravely disrupted by more protective action levels. The Attorneys General understand, at the same time, that it is important to be mindful of potential unintended consequences, such as impacts of FDA regulatory actions on the availability and affordability of products in the baby and toddler food segment. Still, FDA has not pointed to any evidence of economic impacts, such as retail price increases or supply shortages, that would be expected from setting more health-protective action levels.

Conclusion

The Attorneys General applaud FDA's release of proposed guidance for industry on lead action levels for a range of packaged foods marketed to babies and young children. Because FDA correctly recognizes that no "safe" level of lead exposure for children has been identified by any U.S. public health authority, the Attorneys General urge FDA to strengthen the proposed Lead Guidance so that it broadly covers the market for commercially sold foods directed towards infants and toddlers, is as protective of children's health as possible, and will apply an iterative and prospective concept of achievability, without presuming that industry cannot make significant strides towards bringing all of their products within health-protective FDA action levels for lead in the near future.

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[76] *See* Lead Guidance, at page 17, Table 4 (showing achievability rates of 95%, 88% and 90% for the three proposed action levels).

[77] Lead Guidance, page 8.

[78] FDA, Supporting Document for Action Level for Inorganic Arsenic in Rice Cereals for Infants, August 2020, page 9, https://www.fda.gov/media/97121/download.

Many of the Attorneys General in this coalition continue to await FDA's decision on their Reconsideration Petition from June 1, 2022, and, as always, are open to meeting with you and other FDA officials to discuss these comments, and the pace of further activities under FDA's Closer to Zero plan.

Respectfully Submitted,

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