

July 1, 2022

ATTORNEY GENERAL RAOUL DEMANDS SWIFT FEDERAL ACTION TO PROTECT CHILDREN FROM TOXIC METALS IN BABY FOODS

Chicago — Attorney General Kwame Raoul joined a multistate coalition of 22 attorneys general in calling on the heads of the U.S. Food and Drug Administration (FDA) and Department of Agriculture (USDA) to take swift action to eliminate toxic metals from baby food.

[In a letter](#) to FDA Commissioner Robert M. Califf, Deputy Commissioner Frank Yiannis, and USDA Secretary Tom Vilsack, the coalition outlines key strategies for the federal agencies that would allow them to take immediate and widespread action to drive down the levels of dangerous toxic metals in food for babies and young children. This is the latest action in a series of efforts in response to increasing alarm regarding the health hazards posed by lead, arsenic, cadmium and mercury in baby foods, including cereals, purees, and other products for babies and young children, aside from formula.

“Toxic heavy metals can cause developmental and other health concerns in babies and young children,” Raoul said. “I urge the FDA to expedite its actions to reduce the amounts of toxic heavy metals in baby and toddler foods, and to hold baby food manufacturers to higher standards that support the health and well-being of children in critical stages of their development.”

The FDA has set or proposed limits on toxic metals in a wide variety of other consumable products — such as bottled water, juice and candy — but the agency has failed to adequately regulate baby food. So far, the agency has established only one action level for one type of toxic metal, inorganic arsenic, in one type of baby food product, infant rice cereal, despite the FDA concluding years ago that babies’ and young children’s smaller bodies and metabolisms make them more vulnerable to the harmful neurological effects of these toxic metals. As a result, United States baby food manufacturers are left to self-regulate the amounts of lead and other toxic metals in their products. It remains up to the manufacturers to decide whether to even test their products for these contaminants.

In April 2021, FDA announced the “Closer to Zero” plan, under which the agency committed to proposing “action levels” for lead in various baby foods by April 2022, inorganic arsenic in various baby foods by April 2024, and cadmium and mercury sometime after April 2024. However, the coalition notes that the plan is already behind schedule since the FDA failed to propose lead action levels by the April deadline. This delay is both a public health concern and a matter of environmental justice, as low-income children and children of color are disproportionately impacted by lead through exposure to lead-based paint, lead in drinking water pipes and other sources. Lead in their food only exacerbates the existing inordinate and inequitable hazards these children face.

In their letter, Raoul and the coalition call on the federal government to adopt interim measures recommended in the coalition’s [October 2021 petition](#), which urged FDA to issue clear industry guidance for limiting toxic metals, such as:

- Propose interim limits for inorganic arsenic, lead, cadmium, and mercury in relevant categories of infant and toddler foods.
- Propose a lower limit for inorganic arsenic in infant rice cereal than that currently set in FDA guidance.
- Provide guidance to all baby food manufacturers to test their finished products for toxic metals.

The FDA denied the petition, but earlier this month, the coalition asked FDA to expeditiously reconsider its denial of that petition.

Joining Attorney General Raoul in sending this letter to FDA and USDA leadership are the attorneys general of New York, California, Colorado, Connecticut, Delaware, Hawaii, Iowa, Maine, Massachusetts, Maryland, Michigan, Minnesota, New Jersey, New Mexico, Nevada, North Carolina, Oregon, Pennsylvania, Vermont, Washington and Wisconsin.



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

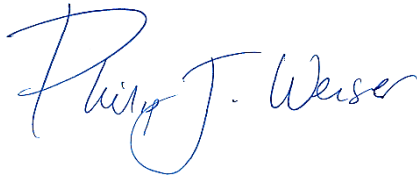
June 23, 2022



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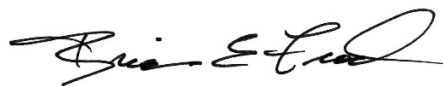
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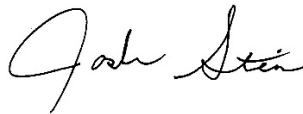
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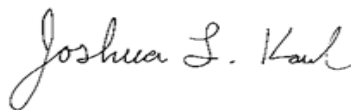
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Secretary Vilsack, Commissioner Califf, and Deputy Commissioner Yiannis
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Cc: Xavier Becerra, United States Secretary of Health and Human Services
Shalanda Young, Director of the Office of Management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



October 21, 2021

ATTORNEY GENERAL RAOUL URGES FDA TO PROTECT CHILDREN FROM TOXIC METALS IN BABY FOOD

Chicago — Attorney General Kwame Raoul, as part of a coalition of 23 attorneys general, today petitioned the U.S. Food and Drug Administration (FDA) to protect the health and well-being of babies across the United States by accelerating actions to remove toxic heavy metals found in infant and toddler foods. The petition responds to rising alarm about the health hazards posed by dangerous heavy metals in these foods and the failure of baby food brands and their suppliers to aggressively reduce these hazards.

“The levels of toxic heavy metals in several brands of baby food can cause developmental and other health concerns in babies and young children,” Raoul said. “I urge the FDA to expedite its actions to limit the amounts of toxic heavy metals in baby and toddler foods, and hold baby food manufacturers to higher standards that support the health and well-being of children in critical stages of their development.”

In February 2021, the U.S. House of Representatives’ Oversight and Reform Committee’s Subcommittee on Economic and Consumer Policy [published a report that determined that there are high levels of toxic heavy metals](#) – including arsenic, lead, cadmium, and mercury – in baby foods being sold by at least four of the nation’s seven largest manufacturers. The subcommittee issued a follow-up report last month that [urged the FDA “to move expeditiously to set limits for arsenic, lead, cadmium and mercury in baby foods.”](#)

Though the FDA does set limits on toxic metals in other consumable products – like bottled water, juice and candy – the agency has failed to adequately regulate baby food, and has, so far, established just one action level for one type of heavy metal (inorganic arsenic) in one type of baby food product (infant rice cereal). This lack of oversight comes despite the fact that the FDA has concluded that babies’ and young children’s smaller body sizes and metabolisms make them more vulnerable to the harmful neurotoxic effects of these metals.

[The petition](#) sent by Raoul and the attorneys general seeks to strengthen protections for young children by urging the FDA to issue interim action levels for limiting heavy metal contamination in baby food more swiftly than the timelines announced by the FDA in their “Closer to Zero plan,” announced this past April. Under that plan, the FDA would propose guidance on limiting lead in baby food by the middle of 2022, guidance for limiting inorganic arsenic by April 2024, and guidance for limiting cadmium and mercury sometime after April 2024. The members of the “Baby Food Council” – a group created in 2019 by four of the largest baby food brands – have not publicly committed to meeting any particular voluntary targets for reducing the levels of heavy metals in their products, pending FDA action.

Specifically, today’s petition calls on the FDA to:

- Propose science-based, achievability-focused interim limits for inorganic arsenic, lead, cadmium, and mercury in relevant categories of infant and toddler foods.
- Propose a lower limit for inorganic arsenic in infant rice cereal than that currently set forth in FDA guidance.
- Instruct all baby food manufacturers to test their finished products for toxic heavy metals.

Raoul and the coalition of attorneys general urge the FDA to take these actions no later than April 2022, the shortest timeframe for requesting FDA action on a petition under the agency’s regulations.

Joining Raoul in sending today’s petition to the FDA are the attorneys general of California, Colorado, Connecticut, Delaware, Hawaii, Iowa, Maine, Maryland, Massachusetts, Michigan, Minnesota, New Jersey, New Mexico, New York, Nevada, North Carolina, Oregon, Pennsylvania, Vermont, Virginia, Washington and Wisconsin.

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STATE OF NEW YORK
OFFICE OF THE ATTORNEY GENERAL

Via Electronic Submission on Regulations.gov

October 21, 2021

Division of Dockets Management
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Attn: Dr. Janet Woodcock, Acting Commissioner of FDA
Attn: Dr. Susan Mayne, Director, FDA, Center for Food Safety & Applied Nutrition

Re: Petition by State Attorneys General requesting that FDA issue interim proposed action levels for four toxic heavy metals in all relevant categories of infant and toddler food, together with related actions

Dear Dr. Woodcock and Dr. Mayne:

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, Virginia, Washington, and Wisconsin, submit this petition to the U.S. Federal Drug Administration (FDA), pursuant to 5 U.S.C. § 553(e) and 21 C.F.R. §§ 10.25(a)(2), 10.30(b), in their capacity as the chief legal officers of their respective states, and as the representatives of the people of their states. In this petition, the Attorneys General request that FDA take the following actions as expeditiously as possible, and by no later than April 18, 2022 (180 days from the submission date of this petition pursuant to 21 C.F.R. § 10.30(e)(2)(i)): (1) issue interim proposed action levels for four toxic heavy metals—inorganic arsenic, lead, cadmium, and mercury—in all relevant categories of infant and toddler (baby) foods in accordance with a science-based, data-driven, and achievability-focused methodology described in this petition; (2) propose an action level for inorganic arsenic in infant rice cereal that is lower than the existing action level of 100 parts per billion (ppb); and (3) issue guidance to industry that testing of finished baby food products for inorganic arsenic, lead, cadmium and mercury is a “preventive

control” that should be performed by baby food manufacturers to limit the concentration of these heavy metals in their products.

The Attorneys General have a strong interest in federal regulatory action to reduce the concentrations of toxic heavy metals in the food supply, particularly in baby food. FDA has recognized that lead, inorganic arsenic, cadmium and mercury “are present in many of the foods we eat, but can be especially harmful to children because of concerns about effects on their neurological development.”¹

Each year, approximately 220,000 babies are born in New York State, and approximately 2 million babies are born annually in all the states represented in this petition.² The impact of toxic heavy metals on the neurological and developmental health of the youngest residents of our states is an issue of paramount importance to the petitioning Attorneys General.

For decades, FDA regulations have required that any “manufacturer of food must at all times utilize quality control procedures which will reduce contamination to the lowest level currently feasible.”³ The Federal Food Safety Modernization Act of 2011, implemented in part through a 2015 FDA rule (the “Preventive Control Rule”)⁴, requires manufacturers of food for humans, including baby and toddler food manufacturers, to “identify and implement preventive controls to provide assurances that any hazards” requiring a preventive control—defined to include “chemical” hazards like toxic heavy metals—will be significantly minimized or prevented,” such that the food “will not be adulterated” under the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 342).⁵

FDA may establish an “action level” for an “added poisonous or deleterious substance” in any food “at a level at which the [FDA] may regard the food as

¹ <https://www.fda.gov/food/conversations-experts-food-topics/what-fda-doing-protect-consumers-toxic-metals-foods>

² <https://www.cdc.gov/nchs/fastats/state-and-territorial-data.htm>

³ 21 C.F.R. § 109.7(b); *Poisonous or Deleterious Substances in Food*, 42 Fed. Reg. 52, 813, 52,819 (Sept. 30, 1977) (Final Rule).

⁴ *Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Control for Human Food*, 80 Fed. Reg. 55,907 (Sept. 17, 2015) (Final Rule).

⁵ See 21 U.S.C. § 350g(c); 21 C.F.R. § 117.135(a)(1).

adulterated within the meaning of” 21 U.S.C. § 342(a)(1).⁶ As FDA has recognized, “[in] this context, ‘added’ does not mean added by the manufacturer, but rather resulting from the hand of man; for example, from previous pesticide use.”⁷ In August 2020, FDA finalized the only action level for baby food that currently exists: an action level of 100 ppb for inorganic arsenic in infant rice cereal.⁸

The Attorneys General laud FDA for announcing its “Closer to Zero” Action Plan for Baby Foods in April 2021.⁹ However, many of the timelines set in April 2021 are too far off and FDA must take swift and comprehensive action to reduce the concentration of heavy metals in baby foods in the near-term. Despite the mandates of the Food Safety Modernization Act of 2011, FDA’s implementing Preventive Control Rule, and the longstanding FDA requirement that food manufacturers “reduce contamination to the lowest level currently feasible,”¹⁰ baby food manufacturers are failing to effectively protect the most vulnerable of all consumers—our children—from the deleterious effects of these heavy metals. FDA should take the interim actions this petition requests, while the agency pursues its longer-term Closer to Zero plan.

The Attorneys General advocate for a science-based, data-driven, and achievability-focused methodology for determining interim proposed action levels for heavy metals in baby food. The methodology was developed based on a statistical evaluation by the New York Attorney General’s Office of available finished product sample data across multiple baby food categories, as illustrated by Appendices A through C attached hereto. Our proposal provides a transparent method that would facilitate lowering the levels of heavy metals in baby food going forward. FDA should expeditiously adopt this proposal and by doing so, FDA will

⁶ 21 C.F.R. §§ 109.4(c)(1), 109.6(d).

⁷ FDA, Guidance for Industry: Action Level for Inorganic Arsenic in Rice Cereals for Infants, August 2020, n.2 (citing *United States vs. Anderson Seafood, Inc.*, 622 F.2d 157 (5th Cir. 1980), available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-action-level-inorganic-arsenic-rice-cereals-infants>).

⁸ *See id.*

⁹ <https://www.fda.gov/food/metals-and-your-food/closer-zero-action-plan-baby-foods> (April 2021).

¹⁰ 21 C.F.R. § 109.7(b).

protect children and guide industry while the agency continues to develop and implement its Closer to Zero plan.

Over the past year, a growing chorus of concerned government officials and advocates have urged FDA to take expeditious action to protect children. The New York Attorney General previously wrote to the Acting Commissioner regarding this matter on February 8, 2021, urging FDA to “set standards [for heavy metals] across all baby foods” in order to remedy this “dangerous oversight in our nation’s regulatory framework when it comes to protecting our most vulnerable – our children.”¹¹ On March 25, 2021, legislation known as the “Baby Food Safety Act of 2021” was introduced in the U.S. House and Senate.¹² That legislation, were it to become law, would establish initial action levels for inorganic arsenic, lead, cadmium, and mercury in baby food within one year of the legislation’s passage, and require the Secretary of the U.S. Department of Health and Human Services to reduce the initial action levels within two years, and set final regulatory limits after three years.¹³ Several respected, science-based advocacy organizations, as well as a baby food manufacturer, have publicly supported the proposed legislation.¹⁴

In May 2021, over 100 organizations from across the country signed a letter to FDA’s Acting Commissioner pointing out that “[e]ach day, 10,000 babies start eating solid food” and that “[i]f the FDA waits until 2024 or later to set final levels food companies must meet, millions of babies will be exposed to metals that threaten their health and development.”¹⁵ On September 29, 2021, the U.S. House Oversight Committee’s Subcommittee on Economic and Consumer Policy—having

¹¹ https://ag.ny.gov/sites/default/files/oag_letter_to_fda_heavy_metals_baby_food_02.08.21_signed_002.pdf (February 8, 2021).

¹² <https://oversight.house.gov/news/press-releases/krishnamoorthi-klobuchar-c-rdenas-and-duckworth-introducing-bicameral-baby-food> (March 25, 2021).

¹³ <https://oversight.house.gov/sites/democrats.oversight.house.gov/files/Baby%20Food%20Safety%20Act%20-%20TEXT.pdf>.

¹⁴ <https://oversight.house.gov/sites/democrats.oversight.house.gov/files/Baby%20Food%20Safety%20Act%20-%20Endorsements.pdf>; <https://www.foodnavigator-usa.com/Article/2021/06/04/Yumi-backs-Baby-Food-Safety-Act-Heavy-metals-targets-are-challenging-but-feasible-says-COO> (June 4, 2021).

¹⁵ *Health and Safety Groups Petition FDA to Address Heavy Metals in Baby Foods*, May 5, 2021, <https://www.consumeraffairs.com/news/health-and-safety-groups-petition-fda-to-address-heavy-metals-in-baby-foods-050521.html>.

released its initial staff report on heavy metals in baby foods in February 2021—released a supplemental staff report recommending, *inter alia*, that FDA issue “an update to Closer to Zero’s proposed timelines for publishing draft and final limits for lead, arsenic, cadmium, and mercury.”¹⁶

A. Actions Requested

A.1 FDA Should Expeditiously Issue Guidance Setting Interim Proposed Action Levels for Inorganic Arsenic, Lead, Cadmium, and Mercury for All Baby Food Categories, Using an “Achievability” Benchmark Derived from the “Best Performer”

Baby Food Categories

The Attorneys General request that FDA, pursuant to its authority under 21 C.F.R. §§ 109.4(c)(1), 109.6(d) and in accordance with provisions of the Food Safety Modernization Act as codified at 21 U.S.C. § 2201(b),¹⁷ issue guidance to industry by no later than April 18, 2022 that includes interim proposed action levels for limiting inorganic arsenic, lead, cadmium, and mercury, to be applied to appropriate baby food categories. As a threshold matter, FDA should delineate the relevant baby food categories based on ingredient-driven criteria and analysis of finished product testing. FDA’s identification of applicable baby food categories should be informed by the agency’s knowledge about the correlation(s) of specific heavy metal contaminants with particular ingredients in common baby food products and any existing methods for reducing such heavy metal contamination, and should be validated by the agency’s rigorous statistical analysis of finished product testing that complies with data quality requirements discussed below.

¹⁶ <https://oversight.house.gov/sites/democrats.oversight.house.gov/files/ECP%20Second%20Baby%20Food%20Report%2009.29.21%20FINAL.pdf> (hereinafter, “September 29, 2021 House Subcommittee Report”).

¹⁷ The statute provides, *inter alia*, that “when appropriate to reduce the risk of serious illness or death to humans or animals or to prevent adulteration of the food under section 342 of this title . . . the Secretary [of the U.S. Department of Health and Human Services] shall issue contaminant-specific and science-based guidance documents, including guidance documents regarding action levels, or regulations. Such guidance, including guidance regarding action levels, or regulations—(1) shall apply to products or product classes” 21 U.S.C. § 2201(b)(1).

The Attorneys General thus agree with the recent public statement by FDA's Dr. Conrad Choiniere that when it comes to developing action levels for baby food, there is not "a one size fits all approach or one level you can establish across all groups."¹⁸

Identifying a "Best Performer" for Each Contaminant, Within Each Baby Food Category

To identify interim proposed action levels that are likely to be broadly achievable by the baby food industry in the near term, FDA should begin by statistically analyzing the results of heavy metal sampling of finished baby foods in the marketplace, and identify a company that currently is the "best performer" for each of the particular categories of baby food identified by FDA, as to each of the four heavy metals at issue. To the extent that FDA determines that it does not presently have access to sufficient finished product sampling data to cover all relevant categories of baby food, as an initial step FDA should undertake additional targeted sampling and analysis to supplement existing sample data and fill in any data gaps, while adhering to data quality criteria discussed below.

FDA regulations pertaining to "unavoidable" contaminants (including certain heavy metals that exist in the environment due to legacy contamination) already require manufacturers to "reduce contamination to the lowest level currently feasible,"¹⁹ which can be reasonably be regarded as the level that is currently feasible for at least one manufacturer within a market segment. Further, such a "best performer" methodology for identifying feasible action levels is not a novel regulatory principle. Development of new regulatory standards or limits based on levels of peak performance being achieved in the relevant category of performance is well-established in federal and state regulation of environmental contaminants.²⁰

¹⁸ <https://www.foodnavigator-usa.com/Article/2021/07/21/IFT-FIRST-FDA-official-weighs-in-on-heavy-metals-in-baby-food> (July 21, 2021).

¹⁹ 21 C.F.R. § 109.7(b).

²⁰ *E.g.*, 42 U.S.C. §§ 7475(a)(4), 7479(3) (Clean Air Act provisions requiring that any proposed major emitting facility be "subject to the best available control technology for each pollutant subject to regulation" in accordance with statutory definition of "best available control technology"); 42 U.S.C. § 7501(3)(B) (Clean Air Act provision defining the "lowest achievable emission rate" for any source of emissions to include "the most stringent emission limitation which is achieved in practice by such class or category of source"); 33

In this context, a “best performer” within a particular category of baby food, as to a particular heavy metal, is the company whose sample set(s) of finished product(s) (1) reflects a “normal distribution” for the concentration of the relevant heavy metal when applying parametric statistics, and (2) has the lowest *mean concentration* (in ppb) of the heavy metal in question, compared with all available and normally-distributed sample sets of other companies’ finished baby food product(s) within the same category of baby food, for the same heavy metal.

Data Quality Requirements of Sample Data Used to Inform Interim Proposed Action Levels

The sample data to be assessed by FDA in determining interim proposed action levels should be from finished products tested for heavy metals in September 2016 or later, and ideally within the past three years. Although all U.S. companies manufacturing baby food today are subject to FDA’s Preventive Control Rule,²¹ no U.S. company manufacturing baby food was subject to any regulatory requirement

U.S.C. § 1326(b) (Clean Water Act provision requiring that the development of “cooling water intake structures reflect the best technology available for minimizing adverse environmental impact”); U.S. Environmental Protection Agency, National Pollutant Discharge Elimination System (NPDES) Permit Writers’ Manual (Sept. 2010), Ch. 5, Technology-Based Effluent Limitations, *available at*, https://www.epa.gov/sites/default/files/2015-09/documents/pwm_chapt_05.pdf; New York State Department of Environmental Conservation, Division of Water Technical and Operational Guidance Series 1.2.1, Industrial Permit Writing (February 1998), Ch. B2, Developing Proposed Technology Limits/Projected Effluent Quality, *available at* https://www.dec.ny.gov/docs/water_pdf/togs121.pdf. Note that the Attorneys General’s citation to these examples of regulation of contaminants in air and water are illustrative of the “best performer” or “best technology” concept, and that the Attorneys General do not propose that FDA implement the specific methodologies employed in these examples in developing interim proposed action levels for heavy metals in baby food. For example, the NPDES Manual cited above (at page 5-47) states that “[a]ny treatment system can be described using the mean concentration of the parameter of interest (i.e., the long-term average) and the variance (or coefficient of variation) and by assuming a particular statistical distribution (usually lognormal).” While the methodology described in this petition focuses on mean concentrations of heavy metal contaminants achieved by the “best performer” within each relevant market segment utilizing normally-distributed sample data sets, the aspect of variability is addressed in the proposed methodology’s incorporation of the upper 95% confidence limit of the mean, discussed in footnote 31 below.

²¹ See <https://www.fda.gov/media/146423/download> (Mar. 5, 2021 FDA letter).

to implement “hazard analysis” or “preventive controls” for any heavy metal contaminants prior to September 2016.²² Accordingly, FDA should not base interim proposed action levels for baby food on earlier testing data, as they were generated from an era when no manufacturer was under any regulatory requirement to take steps to prevent or limit heavy metal contamination. Inclusion of such sample data in FDA’s analysis may improperly skew the proposed action levels upward and should therefore be avoided.

Further, it is critical that the analytical results included in the sample data utilized by FDA for identifying “best performers” be of consistent quality and achieve the lowest possible detection and quantitation limits. Therefore, FDA should only consider data produced by an accredited laboratory using the methods described in FDA’s analytical Method EAM 4.11 (Arsenic Speciation)²³ and analytical Method EAM 4.7 (Total Metals)²⁴ or equivalent analytical methods. Furthermore, given that our recommendations provide that FDA will be using the data in an iterative, statistically-based process for setting progressively lower action levels over time, FDA should tighten the quality control criteria and control limits detailed in that methodology, where practicable, to more broadly achieve analytical results with lower limits of quantitation (LOQs). Therefore, we recommend that FDA²⁵ coordinate the review of the analytical method used and consider updating

²² The compliance date for this rule was extended to September 2016 for businesses with more than 500 full-time equivalent employees (FTE), and to September 2017 for businesses with less than 500 FTE. See <https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-final-rule-preventive-controls-human-food>.

²³ FDA, Method EAM 4.11, Version 1.1 (Nov. 2012), <https://www.fda.gov/media/95197/download>. Arsenic Speciation in Rice and Rice Products Using High Performance Liquid Chromatography-Inductively Coupled Plasma-Mass Spectrometric Determination.

²⁴ FDA, Method EAM 4.7, Version 1.2 (Feb. 2020), <https://www.fda.gov/media/87509/download>. Inductively-Coupled-Plasma-Mass Spectrometric-Determination-of-Arsenic,Cadmium,Chromium,Lead.Mercury and other elements in Food Using Microwave Assisted Digestion. See also FDA, Method EAM 4.7, Version 1.1 (Mar. 2015), available at https://s27415.pcdn.co/wp-content/uploads/2020/01/64ER20-7/Heavy_Metals/1-FDA-EAM-4.7-Inductively-Coupled-Plasma-MS-Determination-of-Arsenic-Cadmium-Chromium-Lead-Mercury-etc.pdf.

²⁵ The process of generating, validating, and approving such methods is managed separately for the chemistry and microbiology disciplines through Research Coordination Groups (RCGs) and Method Validation Subcommittees (MVS). RCGs take overall leadership of the program and provide a coordinating role in developing and updating

the quality control criteria and control limits detailed in Methods EAM 4.7 and 4.11 to achieve the lowest possible LOQs and Limits of Detection (LODs).

Facilitating a “Race to the Top”

Once FDA identifies the mean concentration (in ppb) of a heavy metal concentration for a “best performer” within a normally-distributed sample set, FDA should use that statistic as the interim proposed action level for that entire category of baby food, for that particular heavy metal. If a manufacturer of baby food was able to achieve a certain level of control over a heavy metal in their finished baby food products within a given category, as demonstrated by the mean concentration of the particular metal in a normally-distributed sample set, then doing so consistently for all finished products entering the stream of commerce should also be considered achievable in the near-term for both that “best performer” and its competitors within that market segment.

In order to facilitate a “race to the top” rather than allow a “race to the bottom,” FDA should develop its guidance to industry around the principle that the current *best-performing* manufacturers—those currently limiting heavy metal concentrations in finished products to a greater extent than other manufacturers—should set the pace for all the rest.²⁶ When it comes to proposing action levels for baby food products, which are consumed by extremely sensitive segments of the population, FDA should recognize that “achievability” cannot be dictated by the level of heavy metal control that the *worst-performing* manufacturer is currently capable of consistently achieving. Such an approach would not be faithful to FDA’s mission to “ensure[] the safety of the nation’s food supply”²⁷ for the most vulnerable consumers of food.

guidelines and posting methods. *See also* <https://www.fda.gov/food/laboratory-methods-food/foods-program-methods-validation-processes-and-guidelines>.

²⁶ FDA need not disclose the identity of the “best performers”; any data that FDA releases when announcing interim proposed action level guidance can be brand-anonymized, consistent with FDA’s typical practice.

²⁷ *See* FDA Mission, <https://www.fda.gov/about-fda/what-we-do>.

Drawing on both its Total Diet Study data from recent years and other heavy metal sampling,²⁸ we expect that FDA already has sufficient finished product sample data to apply the statistical methodology described above and derive interim proposed action levels across the full spectrum of baby food categories. To the extent FDA presently lacks access to sufficient sample data, the agency should immediately procure and sample finished products in all baby food categories that are available through retail channels, sufficient to develop normal distributions and associated means for the four heavy metals in each baby food, for each manufacturer. This can be completed by the end of 2021.²⁹

FDA has explained that its “Closer to Zero” approach is an “iterative plan that will be updated as new data, information, and resources become available.”³⁰ The method described here for determining interim proposed action levels that the Attorneys General urge FDA to adopt is also intended to be iterative.

Because FDA’s data collection under its Total Diet Study is continuous and because FDA also has the ability to oversee targeted heavy metal sampling of baby foods in the development of action level guidance for heavy metals, FDA should re-evaluate each year (for example in April 2023, April 2024 and so on) which baby food manufacturer is the “best performer” in each baby food category, for each contaminant of concern. FDA should update its guidance to industry accordingly to the extent there is a basis grounded in the most recent data for reducing the interim proposed action level within any baby food category.

Attached hereto as Appendices A through C are three examples of the Attorneys General’s proposed methodology, applied to brand-anonymized analytical results from sampling of baby food products conducted in 2017 by Consumer Reports. The ingredient-based baby food categories in these examples (which the

²⁸ Analytical testing of heavy metals in baby food is also performed by accredited laboratories for manufacturers, State authorities, and science-based organizations.

²⁹ The Attorneys General note that while FDA’s website states that “the ongoing nature of the Total Diet Study enables [FDA] to track trends in the average U.S. diet,” the agency has not made its Total Diet Study analytical results for heavy metals available on its website (or elsewhere) for any year after 2017. See <https://www.fda.gov/food/total-diet-study/analytical-results-total-diet-study>. Thus, the Attorneys General have been unable to assess whether FDA requires additional sample data in order to proceed with the methodology recommended in this petition.

³⁰ <https://www.fda.gov/food/metals-and-your-food/closer-zero-action-plan-baby-foods>

New York Attorney General's Office developed together with analysis of finished product baby food sample data) were found to be consistent with statistical distributions observed in the data itself. Both the categories and the hypothetical interim proposed action levels that are derived in the appendices are for illustrative purposes only and the Attorneys General do not advocate for FDA to adopt those specific baby food categories, nor those interim proposed action levels.

The Attorneys General further propose that compliance with the interim proposed action level would be determined by requiring the upper 95% confidence limit of the average (the arithmetic mean) of a set of sample results from an individual lot of finished product to be less than or equal to the proposed interim action level applicable to the particular category of baby food.³¹

A.2 Following the Same “Best Performer”-Based Achievability Methodology, FDA Should Lower the Existing Action Level of 100 ppb for Inorganic Arsenic in Infant Rice Cereal

The Attorneys General urge FDA to apply a similar methodology for reducing heavy metals contamination in inorganic arsenic in infant rice cereal. The current 100 ppb action level, finalized by FDA in August 2020, can be lowered by

³¹ The Upper 95% Confidence Limit (95% UCL) is a probability statement common in statistics. In this context it means that one can be 95% confident that the true arithmetic mean of the concentration of a heavy metal within a production unit (lot) of baby food is less than or equal to the 95% UCL calculated from the analytical results of heavy metal contamination within a set of samples taken from that lot. Using the average of the results of a number of samples taken in one sampling event, with the addition of the upper 95% confidence limit, is a well-established statistical tool for addressing variability inherent in estimates of average concentration within decision units, such as production lots of baby food, when an average is used to determine compliance with a regulatory action level. To illustrate this concept, if a round of sampling and analysis of a given lot of finished product were performed 100 times, producing 100 average values of the concentration of a particular heavy metal within that lot, the likelihood that any one of those 100 averages would exceed the upper 95% confidence limit of the first sampling round is only 5%, with a likelihood of 95% that any one of those sampling rounds would be at or below that confidence limit. Accordingly, requiring the upper 95% confidence limit for the first (and typically only necessary) sampling round to determine the average concentration of a particular heavy metal in a lot of baby food to be equal to, or less than, the applicable proposed interim action level provides a high level of confidence that the average concentration of the heavy metal within that lot is highly unlikely to exceed that level.

application of the “best performer” approach, resulting in enhanced protection of children’s health.

In its March 2016 risk assessment for inorganic arsenic in rice products (see p.64 of PDF), combining FDA’s 2013 and 2016 sampling of infant rice cereal with Consumer Reports’ 2012 sampling, FDA found that the average concentration of inorganic arsenic in 65 samples of infant brown rice cereal was 119 ppb, and that the average concentration of inorganic arsenic in infant white rice cereal was 103 ppb.³² In evaluating hypothetical action levels of 50 ppb, 75 ppb, 100 ppb, and 150 ppb, FDA considered sample data that showed that 83.5% of infant white rice cereals were already below 100 ppb, and that nearly 61% of infant white rice cereals were already below 75 ppb.³³ For infant brown rice cereals, 79% of samples were already below 100 ppb, and 55% of samples were already below 75 ppb.³⁴ FDA stated in its April 2016 proposed action level guidance that “FDA testing found that the majority of infant rice cereal currently on the market either meets, or is close to, the proposed action level of 100 ppb inorganic arsenic” and that FDA “expects manufacturers can produce infant rice cereal that meet or are below the proposed limit with the use of good manufacturing practices, such as sourcing rice with lower inorganic arsenic levels.”³⁵

Yet in considering cancer risk, FDA’s March 2016 risk assessment for inorganic arsenic in rice products stated that “[l]imits of 50 ppb and 75 ppb were estimated to have significant reduction in the predicted risk of lung and bladder [cancer] estimates, compared with the baseline.”³⁶ FDA also identified non-cancer effects in infants and young children, such as neurodevelopmental effects. For example, FDA’s 2016 risk assessment states that “[t]here is also emerging evidence

³² <https://www.fda.gov/food/cfsan-risk-safety-assessments/arsenic-rice-and-rice-products-risk-assessment>.

³³ *Id.*

³⁴ *Id.*

³⁵ <https://www.fda.gov/news-events/press-announcements/fda-proposes-limit-inorganic-arsenic-infant-rice-cereal>.

³⁶ <https://www.fda.gov/food/cfsan-risk-safety-assessments/arsenic-rice-and-rice-products-risk-assessment>, p. 80.

that inorganic arsenic exposure during early childhood can have neurotoxic effects (for example, changes in IQ).”³⁷

For more than five and a half years, manufacturers have operated with the awareness of a 100 ppb action level (initially as a proposed action level, made final by FDA in August 2020) for inorganic arsenic in infant rice cereal.³⁸ In April 2021, when FDA released its “Closer to Zero” plan, the agency published an infographic stating that the “average concentration” of inorganic arsenic in infant rice cereal had dropped from 120 ppb in 2012, to 98 ppb in 2014, to 85 ppb in 2018.³⁹

FDA likely has additional sample data from recent years demonstrating that the prevailing average concentration of inorganic arsenic in infant rice cereals on the market today is lower than 100 ppb, and also likely lower than the 85 ppb average concentration that FDA sampling of 149 infant rice cereals detected in fiscal year 2018.⁴⁰

As an example of recent finished product sampling analysis of infant rice cereals available on the market, in May 2021 the Office of the New York State Attorney General had 21 products (3 samples of 7 different infant rice cereal products) from New York store shelves tested at the Brooks Applied Laboratory in Washington State. The analytical results received from the Brooks Applied Laboratory show the range of inorganic arsenic concentration was 31.4 ppb to 73.2 ppb, while 71% of infant rice cereal samples were below 62 ppb inorganic arsenic. Appendix D hereto presents the brand-anonymized and product-anonymized analytical results for these 21 samples of infant rice cereal.

³⁷ *Id.* p. 94.

³⁸ At least one major company was able to maintain an internal target four times lower than 100 ppb for inorganic arsenic in a range of its products—including infant rice cereal—for more than six years. According to information provided by Walmart Inc. (which sells its own “private brand of infant and baby food” in its U.S. stores) to the House Oversight Committee’s Subcommittee on Economic and Consumer Policy and discussed in the Subcommittee’s September 29, 2021 staff report, Walmart Inc. maintained a 23 ppb internal target for arsenic in rice cereal, oatmeal cereal, and puffed grains between September 12, 2012 and December 20, 2018, whereupon it increased its internal target for inorganic arsenic in these product categories to the 100 ppb level that FDA had proposed in its April 2016 guidance. See September 29, 2021 House Subcommittee Report, pp. 22-23.

³⁹ <https://www.fda.gov/media/147324/download>.

⁴⁰ <https://www.fda.gov/media/135552/download>.

Accordingly, FDA's data from 2018 and subsequent data on inorganic arsenic concentrations in infant rice cereals support a conclusion that reduction of the action level guidance from 100 ppb is warranted and that compliance with an action level below 100 ppb would appear to be readily achievable for the remaining manufacturers of infant rice cereal. This would offer additional protection to young children who consume infant rice cereal, and the Attorneys General urge FDA to take this action by no later than April 18, 2022.

A.3 FDA Should Provide Guidance to the Baby Food Industry That Finished Product Sampling is a “Preventive Control” That Manufacturers Should Perform

Since FDA action levels apply to finished products (not raw ingredients), FDA should issue guidance to industry on the application of the Preventive Control Rule to limiting toxic heavy metal contamination in the manufacture of baby food products.

When FDA issues guidance to industry that includes proposed or final action levels for toxic heavy metals, FDA guidance has stated, consistent with FDA's regulations, that an FDA action level for an added poisonous or deleterious substance defines the level of contamination in finished products at which FDA may regard a food as “adulterated” within the meaning of section 402(a)(1) of the federal Food, Drug, and Cosmetic Act.⁴¹ As FDA has pointed out in its April 2016 *proposed* action level guidance and August 2020 *final* action level guidance for inorganic arsenic in infant rice cereal, the agency “will consider action levels, in addition to other factors, when considering whether to bring enforcement action in a particular case.”⁴² FDA's “Closer to Zero” plan highlights this concept as well.⁴³

Under FDA's Preventive Control Rule, baby food manufactures “must identify and implement preventive controls to provide assurances that any hazards requiring a preventive control will be significantly minimized or prevented and the

⁴¹ See 21 C.F.R. §§ 109.4(c)(1), 109.6(d); <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-action-level-inorganic-arsenic-rice-cereals-infants>.

⁴² See *id.*; see also <https://www.fda.gov/news-events/press-announcements/fda-proposes-limit-inorganic-arsenic-infant-rice-cereal>.

⁴³ <https://www.fda.gov/food/metals-and-your-food/closer-zero-action-plan-baby-foods>.

food manufactured, processed, packed, or held by your facility will not be adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act” (21 U.S.C. § 342).⁴⁴ Under the Rule, a “preventive control” extends not only to “Critical Control Points” in the supply chain and/or manufacturing process but also includes controls other than those at such “Critical Control Points” that are “appropriate for food safety.”⁴⁵ Further, preventive controls include such “other procedures, practices, and processes necessary to satisfy the requirement” that heavy metal hazards in the food will be ‘significantly minimized or prevented” and that the food manufactured “will not be adulterated” under 21 U.S.C. § 342.⁴⁶

The Attorneys General urge FDA to provide clear guidance to the baby food industry that finished product sampling for heavy metals is a “preventive control” that baby food manufactures should perform.

Further, such FDA guidance should explain that, in weighing enforcement considerations in a given case, FDA will consider whether the manufacturer of a baby food product performed, or did not perform, appropriate finished product sampling on the production lot at issue prior to approving the subject lot for distribution into commerce.

As illustrated by the June 2021 nationwide recall of a production lot of single grain rice cereal based on inorganic arsenic contamination, testing a key ingredient (e.g. rice flour that goes into infant rice cereal) for heavy metals without also sampling the production lots of the finished product is not a reliable “preventive control” for the baby food industry.⁴⁷ It is of course vitally important for manufacturers to carefully source their ingredients to minimize the presence of heavy metals, to implement any available secondary processes to remove heavy metals from those ingredients, and to have good manufacturing practices in place that are also focused on heavy metals. However, manufacturers who do not perform finished product sampling on the relevant production lot, and instead rely solely on supplier-directed sampling of key ingredients for heavy metals (or some alternative indirect “preventive control” measure in the supply chain) should be on notice that

⁴⁴ 21 C.F.R. § 117.135(a)(1).

⁴⁵ 21 C.F.R. § 117.135(a)(2).

⁴⁶ 21 C.F.R. § 117.135(c)(6).

⁴⁷ <https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/beechnut-nutrition-company-issues-voluntary-recall-one-lot-beech-nut-single-grain-rice-cereal-and>.

FDA considers sampling of finished products for heavy metals prior to approving the production lot into the stream of commerce to be a “preventive control” that manufacturers should perform in satisfaction of the Food Safety Modernization Act and FDA regulations.

B. Statement of Grounds

B.1 Interim Proposed FDA Action Levels Will Drive Reduction of Heavy Metals by the Baby Food Industry, Providing a Stopgap Before FDA Can Fully Implement “Closer to Zero” Several Years From Now

- The Food Safety Modernization Act directs that the U.S. Department of Health and Human Services (operating through FDA), “when appropriate to reduce the risk of serious illness or death to humans or animals or to prevent adulteration of the food under section 402 of the Federal Food, Drug, or Cosmetic Act (21 U.S.C. 342) . . . shall issue contaminant-specific and science-based guidance documents, including guidance documents regarding action levels[.]”⁴⁸
- FDA’s “Closer to Zero” plan contemplates that action levels for lead will not be proposed until April 2022, that action levels for inorganic arsenic will not be proposed until April 2022 – April 2024, and that action levels for cadmium and mercury will not be proposed until April 2024 or beyond. FDA only expects to finalize the lead action levels by April 2024, and there is no expected date for finalizing inorganic arsenic, cadmium and mercury action levels.⁴⁹
- Such a timeline operates as a signal to baby food manufacturers that they can expect not to have to take aggressive measures to reduce inorganic arsenic, cadmium, and mercury concentrations in their products for several more years.
- Thus, stopgap measures are needed at least during the next three years that would communicate to industry a regulatory incentive to begin driving down levels of heavy metal contamination in all of their products.
- Manufacturers respond to proposed action levels, which is reflected in the reductions of inorganic arsenic in infant rice cereal between April 2016 and

⁴⁸ 21 U.S.C. § 2201(b)(1).

⁴⁹ <https://www.fda.gov/food/metals-and-your-food/closer-zero-action-plan-baby-foods> (April 2021).

August 2020. FDA testing of infant rice cereals showed reduction in average inorganic arsenic concentrations from 98 ppb in 2014 to 85 ppb in 2018 – after just a few years of proposed action levels at 100 ppb.⁵⁰

B.2 Interim Proposed FDA Action Levels and Compliance Criteria Will Facilitate More Effective Sampling and Recall Actions by State Authorities

- Some State authorities utilize recall manuals that incorporate the 100 ppb action level for inorganic arsenic in infant rice cereal, and other action level guidance on heavy metal contaminants that FDA has issued in either proposed or final form.
- In the absence of FDA action level guidance, some State authorities default to high thresholds for recalling food products based on heavy metal contamination.⁵¹
- State authorities, in consultation with FDA, can communicate exceedances of interim proposed action levels (and eventually proposed and final action levels implementing FDA’s Closer to Zero plan) in baby food products sold in interstate commerce to manufacturers and can work together with them constructively to identify ways to reduce heavy metal contamination in their products.

B.3 The Baby Food Industry Has Not Shown That Self-Regulation Is an Adequate Substitute for FDA Interim Proposed Action Levels

- Large baby food manufacturers have been subject to the Preventive Control Rule since September 2016 and smaller manufacturers have been subject to the Rule since September 2017. Yet only one major baby food company is known to routinely rely on finished product testing for the full range of baby food products distributed in the U.S.⁵² Many baby food companies continue to employ “preventive controls” at an earlier point in their supply chain.

⁵⁰ See <https://www.fda.gov/media/147324/download>.

⁵¹ See, e.g., New York State Department of Agriculture & Markets, Food Recall Manual (May 27, 2021) <https://agriculture.ny.gov/system/files/documents/2021/06/recallbook.pdf>.

⁵² House Subcommittee Report, p. 56
<https://oversight.house.gov/sites/democrats.oversight.house.gov/files/2021-02-04%20ECP%20Baby%20Food%20Staff%20Report.pdf>.

- In the absence of FDA action levels for most baby food, internal targets for heavy metal contaminant levels (referred to as “specifications”) utilized by some major baby food manufacturers have been set at arbitrarily high levels. For example, a baby food manufacturer had set an internal “specification” of 100 ppb for lead, inorganic arsenic, and cadmium for key ingredients in virtually all of its baby food products, apparently without any health-based justification, but seemingly to align—facially—with FDA’s 100 ppb then-proposed (now final) action level for *inorganic arsenic in infant rice cereal*.⁵³
- The one baby food company that is publicly known to have incorporated European Union (EU) regulatory limits for heavy metals in baby food into its internal targets will not necessarily reduce those internal targets for its U.S. manufacturing operations to track recent EU actions – for example the EU’s reduction of the regulatory limit in EU countries for lead in baby food from 50 ppb to 20 ppb, a level of lead contamination that the European Commission regulation of August 9, 2021 describes as “reasonably achievable” based on the “most recent occurrence data.”⁵⁴
- The Baby Food Council was formed in January 2019 to address heavy metal contamination in baby food. FDA is a technical consultant to the Council.⁵⁵ Publicly-available minutes of recent Baby Food Council meetings indicate that the Council’s Baby Food Standard in development will initially address only products with fruits or vegetables.⁵⁶

⁵³ See The Hain Celestial Group, Inc. testing data pulled November 26, 2019 and shared with House Subcommittee in December 2019, *available at* https://oversight.house.gov/sites/democrats.oversight.house.gov/files/3_0.pdf.

⁵⁴ Gerber Products Co. Letter to House Subcommittee dated Dec. 19, 2019, *available at* https://oversight.house.gov/sites/democrats.oversight.house.gov/files/7_Redacted.pdf. Compare with European Commission Regulation (EU) 2021/1317 of 9 August 2021 amending Regulation (EC) No 1881/2006 as regards maximum levels of lead in certain foodstuffs, *available at* <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32021R1317>.

⁵⁵ Baby Food Council, <https://www.foodchainid.com/babyfoodstandard/#:~:text=Created%20in%20January%202019%20in,reasonably%20achievable%20using%20best%2Din%2D>.

⁵⁶ Baby Food Council, Oversight Committee, Minutes of June 15, 2021 meeting, <https://1ilncn2ptox93ih9e41q8but-wpengine.netdna-ssl.com/media-library/wp-content/uploads/sites/24/2021/07/Baby-Food-Standard-Oversight-Committee-6-15-2021-Meeting-Minutes.pdf>.

- The Baby Food Council plans to release a Baby Food Standard by early 2022,⁵⁷ which presents the risk of consumer confusion regarding the relationship between products bearing the Baby Food Council’s seal and FDA standards and guidance. It is thus important for FDA to act swiftly to announce interim proposed action levels so that the Baby Food Council’s voluntary activities are not perceived by consumers as superseding or displacing FDA’s regulatory role.

B.4 The Risks of Adverse “Unintended Consequences” in the Marketplace for Baby Food Are Low

- FDA rightly considers whether consumer access to nutritious and affordable baby food may be impaired by aggressive FDA regulation of heavy metals.⁵⁸ Adopting the interim proposed action levels requested in this petition presents a low risk of these adverse consequences.
- The major baby food companies serving the U.S. market are owned by multinational corporations based in the European Union, which have been operating under lead, cadmium, and inorganic arsenic legal limits (not just non-binding guidance) for years.⁵⁹
- The CEO of one major baby food manufacturer (Hain Celestial Group, Inc.) said during a May 2021 earnings call that “[t]he only regulations that we have from the government are arsenic levels in rice cereal, and we are 100% compliant with the levels that they have specified. In fact, we rejected 12% of the finished goods last year to make sure that everything we have is compliant.”⁶⁰

⁵⁷ Baby Food Council, Baby Food Standard <https://www.foodchainid.com/babyfoodstandard/certification/>.

⁵⁸ <https://www.fda.gov/food/metals-and-your-food/closer-zero-action-plan-baby-foods> (“It is crucial to ensure that measures taken to limit toxic elements in foods do not have unintended consequences—like eliminating from the marketplace foods that have significant nutritional benefits or reducing the presence of one toxic element while increasing another.”).

⁵⁹ <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32015R1006>; https://eur-lex.europa.eu/eli/reg/2021/1323/oj#ntr5-L_2021288EN.01001301-E0005; <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32021R1317>.

⁶⁰ <https://www.fool.com/earnings/call-transcripts/2021/05/07/hain-celestial-group-inc-hain-q3-2021-earnings-cal/>.

- At least one major company, Walmart Inc., which utilizes “leading infant and baby food manufacturers” for its private brand, was able to maintain an internal target of 23 ppb for arsenic in its rice cereal, oatmeal cereal, and puffed grains products between September 12, 2012 and December 20, 2018, including for two-and-half years after FDA had proposed an action level of 100 ppb for inorganic arsenic in infant rice cereal.⁶¹
- Beech-Nut’s June 2021 exit from the market for infant rice cereal was tied in substantial part to its reliance on testing of rice flour as a substitute for infant rice cereal finished product testing,⁶² and is a basis for FDA to make clear in guidance that baby food companies should implement finished product testing as a “preventive control.”⁶³

C. No Environmental Impact

This petition is categorically excluded from the need to prepare an Environmental Assessment under 21 C.F.R. § 25.30(h) as an “Issuance, amendment, or revocation of procedural or administrative regulations and guidance documents, including procedures for submission of applications for product development, testing and investigational use, and approval.” The Attorneys General have identified no extraordinary circumstances as defined at 21 C.F.R. § 25.21 for the actions requested in this petition which would require the submission of an Environmental Assessment.

D. Economic Impact

FDA has not requested information about the economic impact of adopting the proposals in the Attorneys General’s petition.

Conclusion

For these reasons, the Attorneys General urge FDA as expeditiously as possible, and by no later than April 18, 2022 to: (1) issue guidance to industry that includes interim proposed action levels to limit inorganic arsenic, lead, cadmium,

⁶¹ See September 29, 2021 House Subcommittee Report, pp. 22-23; Letter dated February 25, 2021 from Walmart Inc. to Hon. Raja Krishnamoorthi, p. 1, <https://oversight.house.gov/sites/democrats.oversight.house.gov/files/Walmart%20Letter%202.25.21.pdf>.

⁶² See Beech-Nut Press Release dated June 8, 2021, <https://www.beechnut.com/ricecereal/>.

⁶³ <https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-final-rule-preventive-controls-human-food>.

and mercury contamination in a range of baby food categories based on the methodology proposed by the Attorneys General in this petition; (2) lower the existing FDA action level of 100 ppb for inorganic arsenic in infant rice cereal; and (3) issue guidance to industry stating that finished baby food product testing constitutes a “preventive control” to be performed by baby food manufacturers to limit the concentration of these heavy metals in their products.

E. Certification

The undersigned Attorneys General certify, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioners which are unfavorable to the petition.

Sincerely,

Letitia James



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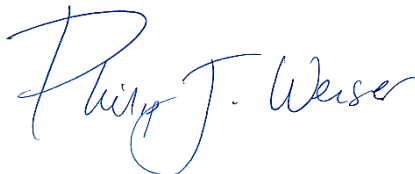
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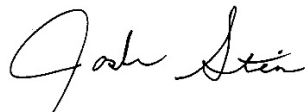
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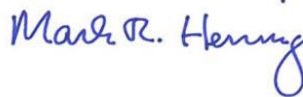
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Appendix A – First Example of Methodology for Establishing Interim Proposed Action Levels Described in Attorneys General Petition to FDA

For this example, we will look at data for **inorganic arsenic in the baby food category “Snacks with Rice or Rice Flour”**—baby food snack products in which rice or rice flour is listed as the first, second or third ingredient.

The testing data used in this example was obtained in brand-anonymized form from Consumer Reports sampling and testing of baby food products that Consumer Reports conducted in 2017 and later reported—publicly, and to FDA directly—in 2018.¹ The NY AG’s Office developed the baby food category “Snacks with Rice or Rice Flour” for illustrating their proposed methodology, and such a category was found to be consistent with statistical distributions observed in the data itself.²

Below is a graphic which contains histograms for inorganic arsenic in the category “Snacks with Rice or Rice Flour” whose finished products were sampled and tested by Consumer Reports, and are labeled below as companies “a” “f” “g” and “h.”

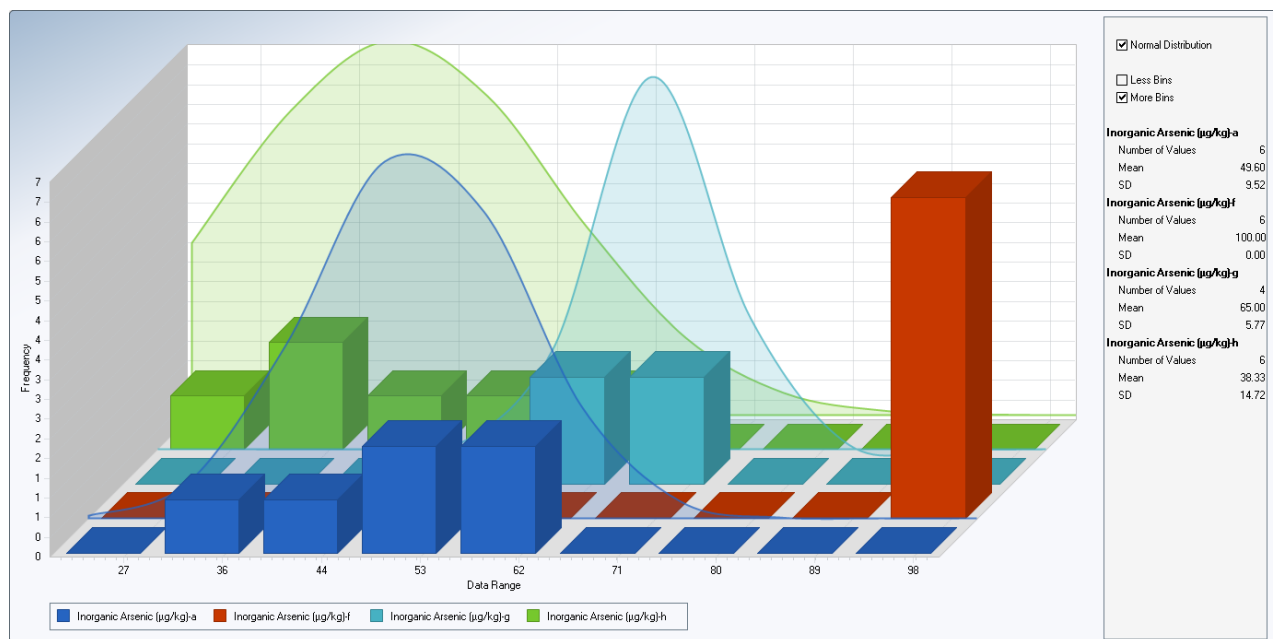


Figure 1: Multi-histogram plot of the frequency of inorganic arsenic detections in “Snacks with Rice or Rice Flour” for Companies a (dark blue), f (red), g (light blue) and h (green)

¹ Letter dated August 16, 2018 from Consumer Reports to FDA Commissioner Scott Gottlieb, with Enclosure, available at <https://article.images.consumerreports.org/prod/content/dam/CRO%20Images%202018/Health/August/Consumer%20Reports%20Letter%20to%20FDA%20on%20Heavy%20Metals%20in%20Baby%20and%20Toddler%20Food%208-16-18>; Jesse Hirsh, *Heavy Metals in Baby Food: What You Need to Know*: <https://www.consumerreports.org/food-safety/heavy-metals-in-baby-food/>. Consumer Reports also shared its underlying testing data, in brand-anonymized form, with FDA.

² Consumer Reports did not participate in the New York Attorney General’s Office’s analysis.

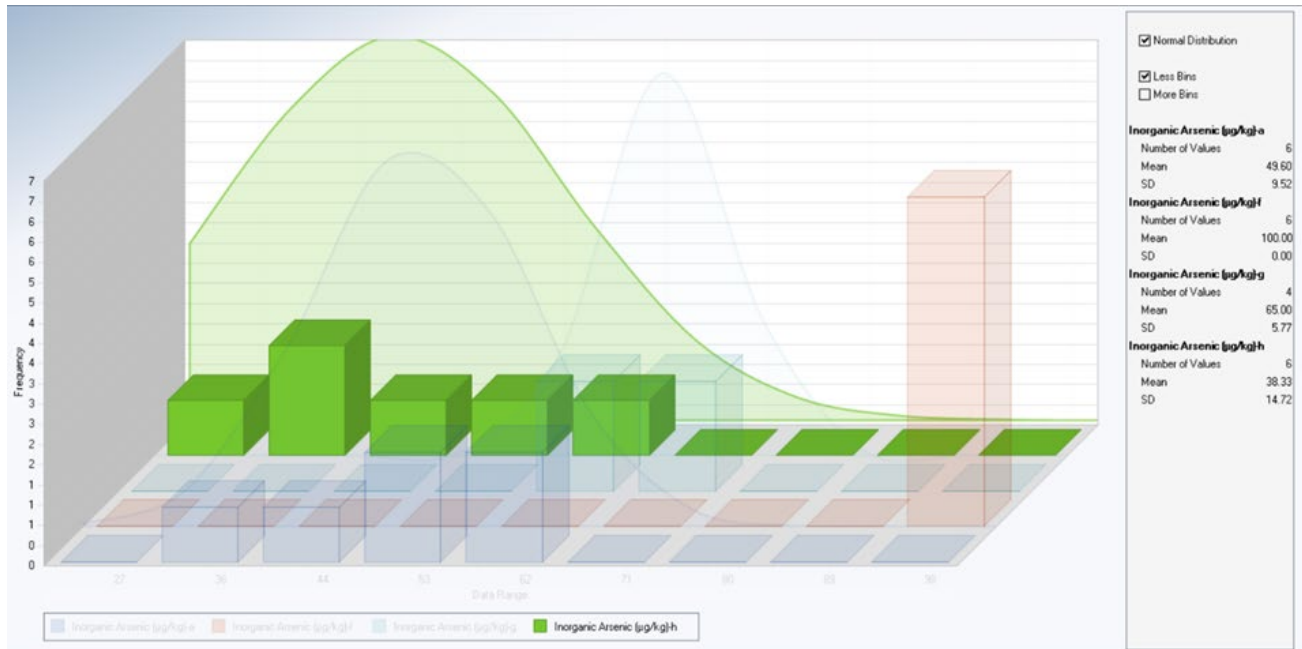


Figure 2: Multi-histogram plot of the frequency of inorganic arsenic detections in “Snacks with Rice or Rice Flour” for companies a, f, g and h, with company h data emphasized.

From these multi-histogram plots, we can identify company “h” as the best performer in this category, with a mean value of 38.33 ppb of inorganic arsenic “Snacks with Rice or Rice Flour.”

Now that we have identified from existing data the best performer for the category “Snacks with Rice or Rice Flour” for inorganic arsenic, we must consider if additional data are needed to create a roughly normal distribution (and a usable mean) for that company. In this example, company h’s data passes normality and thus additional data is not absolutely necessary for this example, but would be prudent with regard to setting a defensible action level (as it would be more robust to have more sampling data).

A normal probability plot and histogram plot showing only the analysis for company h are presented below.

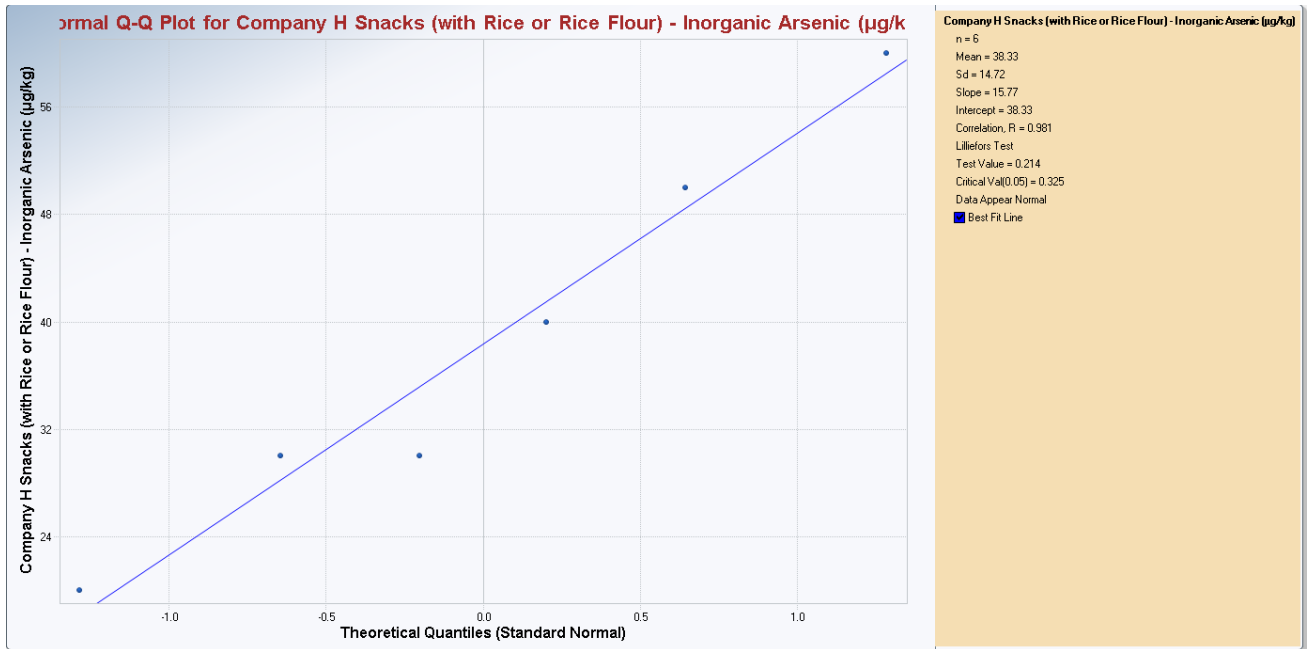


Figure 3: Normal probability plot for frequency of inorganic arsenic detections in “Snacks with Rice or Rice Flour” for company h showing good agreement of the data with what would be expected for normally distributed data (R value 0.981). Exact agreement would result in a correlation (R) value of 1.0 with all data points falling on the blue line.

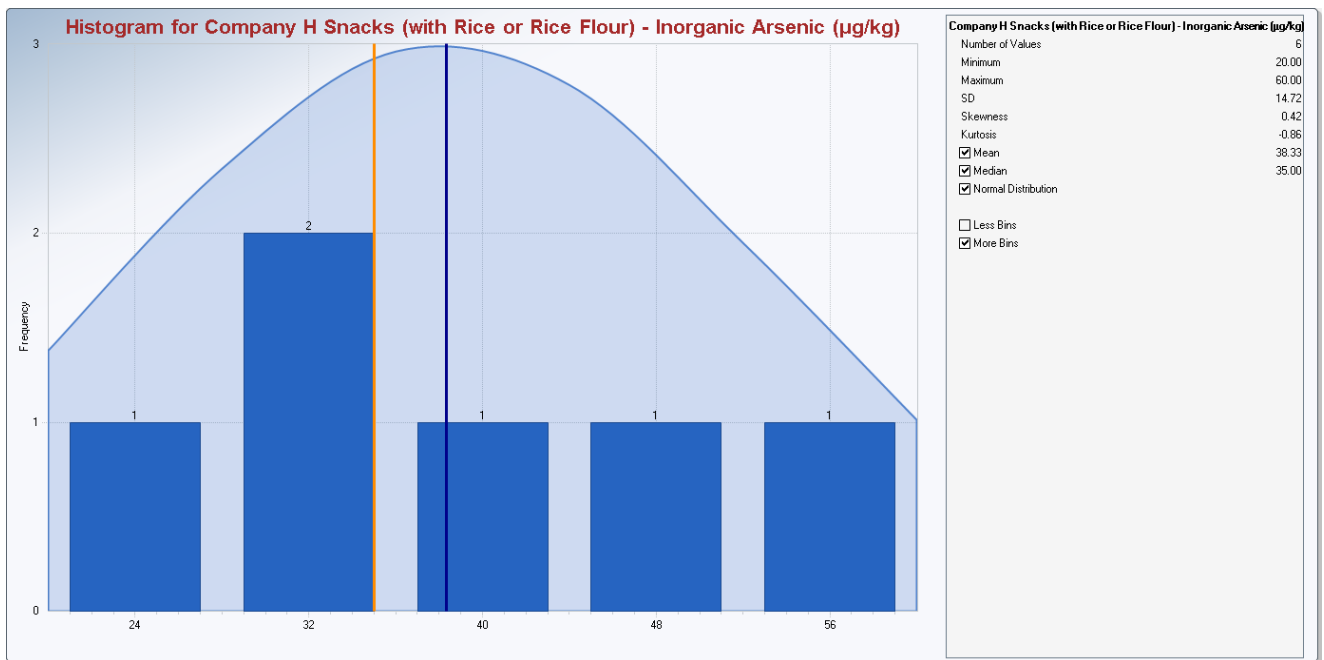


Figure 4: Histogram Plot of the frequency of inorganic arsenic detections in “Snacks with Rice or Rice Flour” for company h, with the corresponding normal distribution curve superimposed above the histogram. The orange and blue lines mark the values of the median (35 ppb) and the mean (38.33 ppb) of the corresponding normal distribution respectively.

In this example, 38.33 ppb (rounded to 38 ppb) would become the industry-wide interim proposed action level for inorganic arsenic in “Snacks with Rice or Rice Flour.” Below is a table that shows how this would compare with other existing and proposed limits/action levels for inorganic arsenic.

| Source | Level for Inorganic Arsenic | Proposed Level Applicable to Inorganic Arsenic in “Snacks with Rice or Rice Flour” |
|---|---|--|
| FDA | Currently no action levels, except for 100 ppb in infant rice cereal | Currently no action levels |
| EU (regulatory limit) | 100 ppb for “rice destined for the production of food for infants and young children” | 100 ppb |
| Baby Food Safety Act (initial levels in proposed legislation) | 10 ppb (15 ppb for cereals) | 10 ppb |
| “Best Performer” mean method in Attorneys General Petition | N/A | ~38 ppb (example) |

The histogram below shows that with an interim proposed action level of 38 ppb, up to one half of “Snacks with Rice or Rice Flour,” within the 2017 Consumer Reports data, would have exceeded the action level.

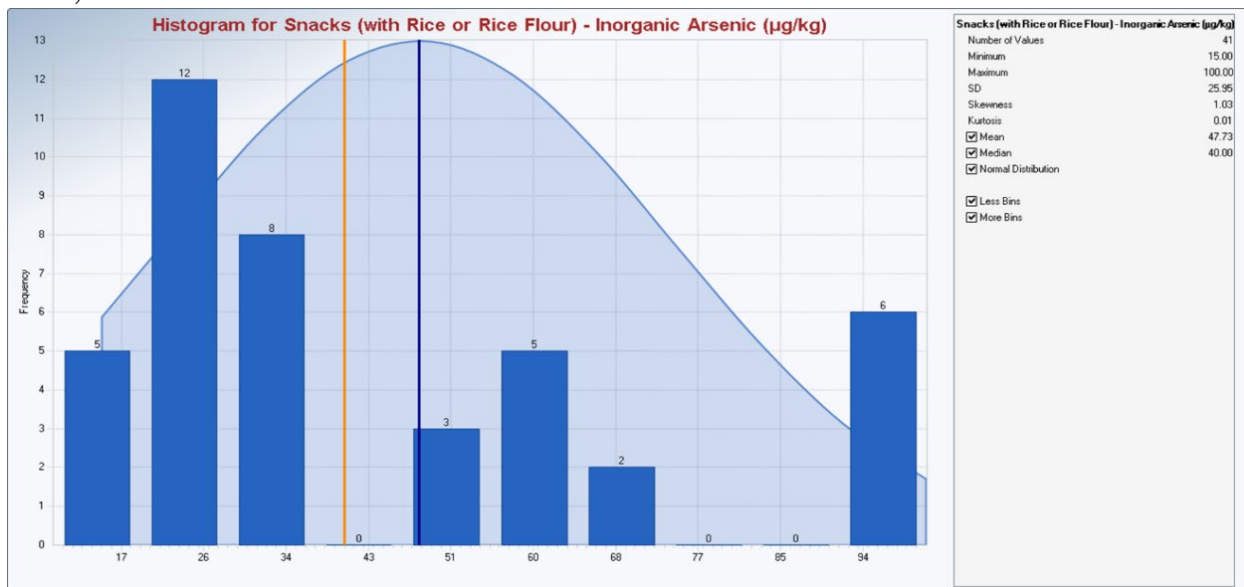


Figure 5: Histogram plot of the frequency of inorganic arsenic detections in Snacks with Rice or Rice Flour for all baby food companies whose products in this category were tested by Consumer Reports in 2017 (including data for companies b, d and e). The orange and blue lines mark the values of the median (40 ppb) and the mean (47.73 ppb), respectively, of the corresponding normal distribution. The values of the median and the mean in this data set suggest that using an action level of 38 ppb would result in between 50% and 39% of all “Snacks with Rice or Rice Flour” in this data set exceeding the interim proposed action level.

Appendix B – Second Example of Methodology for Establishing Interim Proposed Action Levels Described in Attorneys General Petition to FDA

For this example, we will look at data for **cadmium in the baby food category “Snacks with Rice or Rice Flour”**—baby food snack products in which rice or rice flour is listed as the first, second or third ingredient.

The testing data used in this example was obtained in brand-anonymized form from Consumer Reports sampling and testing of baby food products that Consumer Reports conducted in 2017 and later reported—publicly, and to FDA directly—in 2018.¹ The NY AG’s Office developed the baby food category “Snacks with Rice or Rice Flour” for the purpose of illustrating their proposed methodology, and such a category was found to be consistent with statistical distributions observed in the data itself.²

Below is a graphic which contains histograms for cadmium in the category “Snacks with Rice or Rice Flour” whose finished products were sampled and tested by Consumer Reports, and are labeled below as companies “a” “b” “d” “e” “f” “g” and “h.”

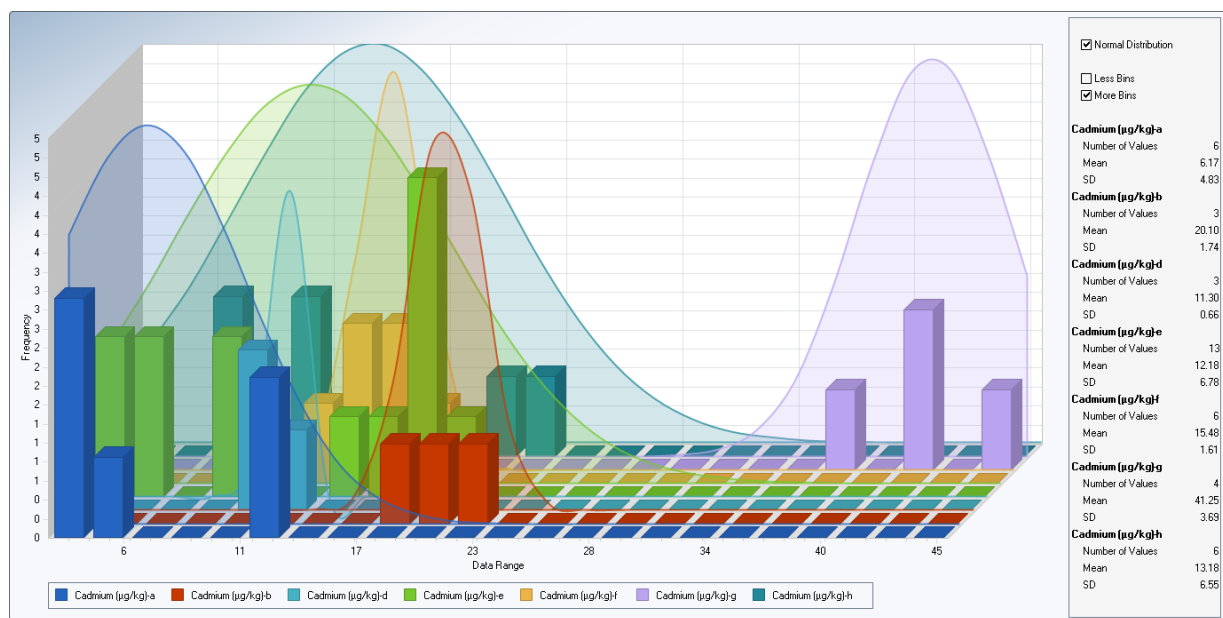


Figure 1: Multi-histogram plot of the frequency of inorganic arsenic detections in “Snacks with Rice or Rice Flour” for Companies a (dark blue), b (red), d (light blue), e (light green), f (orange), g (light purple) and h (dark green)

¹ Letter dated August 16, 2018 from Consumer Reports to FDA Commissioner Scott Gottlieb, with Enclosure, available at <https://article.images.consumerreports.org/prod/content/dam/CRO%20Images%202018/Health/August/Consumer%20Reports%20Letter%20to%20FDA%20on%20Heavy%20Metals%20in%20Baby%20and%20Toddler%20Food%208-16-18>; Jesse Hirsh, *Heavy Metals in Baby Food: What You Need to Know*: <https://www.consumerreports.org/food-safety/heavy-metals-in-baby-food/>. Consumer Reports also shared its underlying testing data, in brand-anonymized form, with FDA.

² Consumer Reports did not participate in the New York Attorney General’s Office’s analysis.

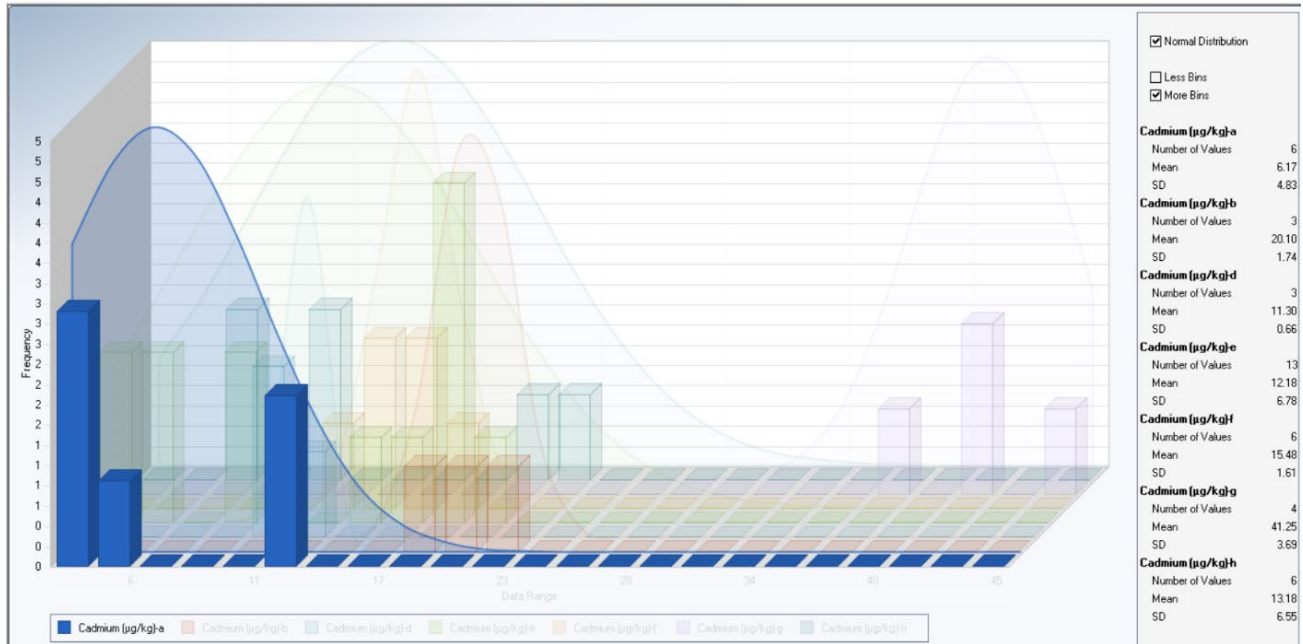


Figure 2: Multi-histogram plot of the frequency of cadmium detections in “Snacks with Rice or Rice Flour” for companies “a” “b” “d” “e” “f” “g” and “h” with company “a” emphasized.

From these multi-histogram plots, we can identify company “a” as the best performer in this category, with a mean value of 6.17 ppb cadmium in “Snacks with Rice or Rice Flour.”

Now that we have identified from existing data the best performer for the category “Snacks with Rice or Rice Flour” for cadmium, we must consider if additional data are needed to create a roughly normal distribution (and a usable mean) for that company. In this example, company a’s data passes normality and thus additional data is not absolutely necessary for this example, but would be prudent with regard to setting a defensible action level (as it would be more robust to have more sampling data).

A normal probability plot and histogram plot showing only the analysis for company a are presented below.

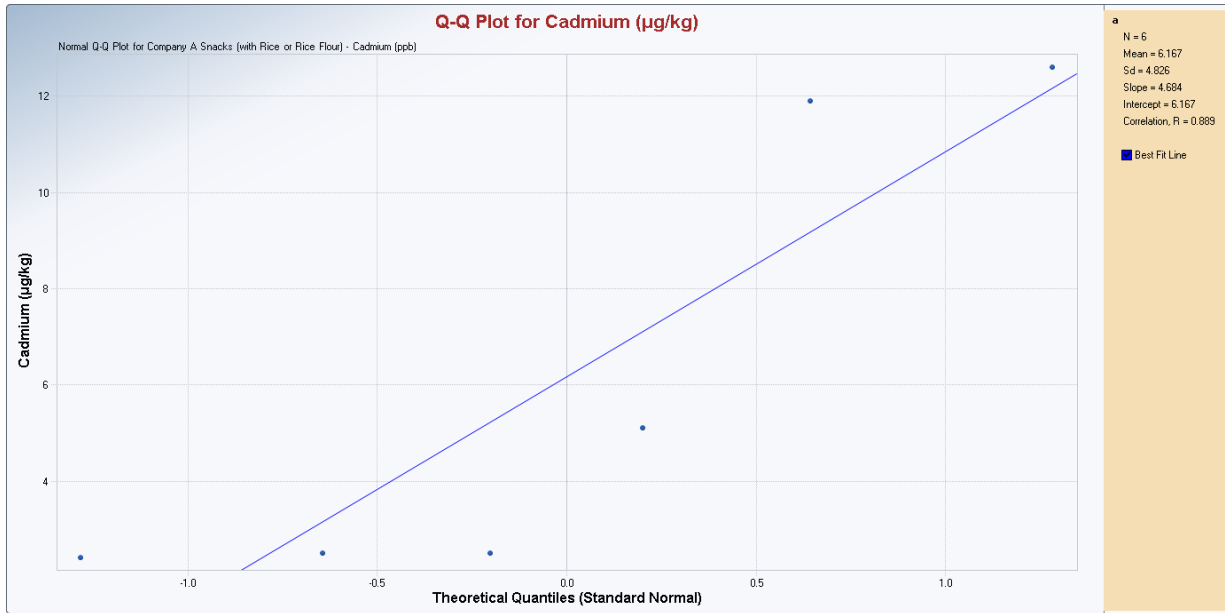


Figure 3: Normal probability plot for frequency of cadmium detections in “Snacks with Rice or Rice Flour” for company a showing good agreement of the data with what would be expected for normally distributed data (R value 0.889). Exact agreement would result in a correlation (R) value of 1.0 with all data points falling on the blue line.

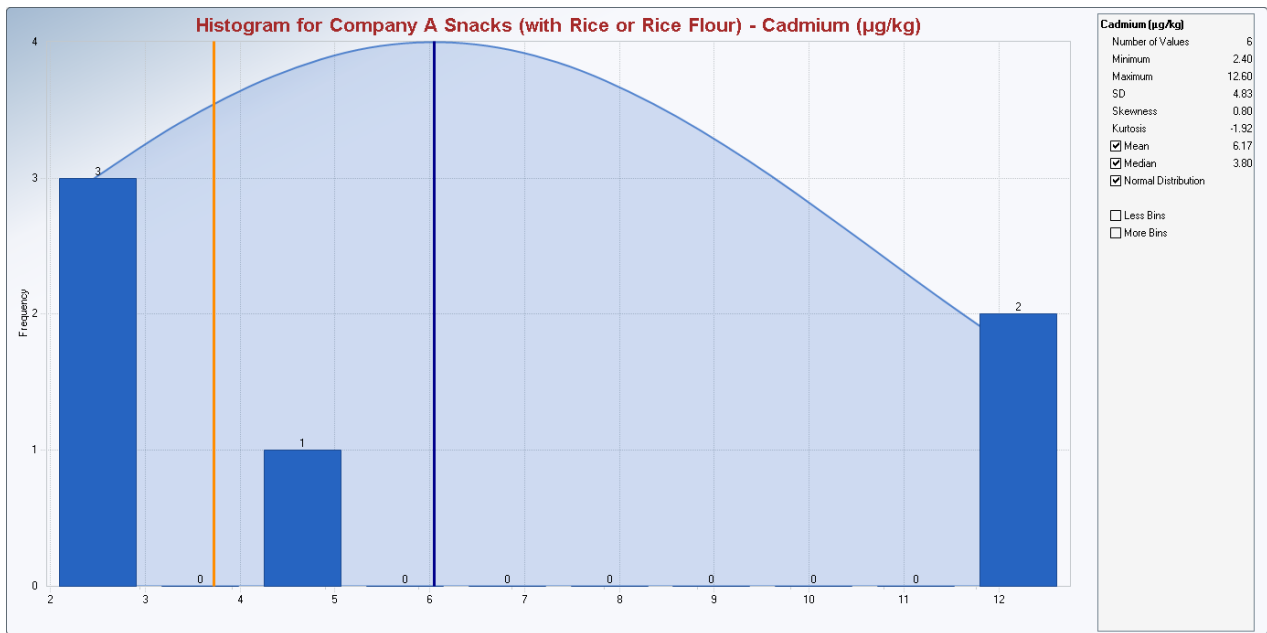


Figure 4: Histogram Plot of the frequency of cadmium detections in “Snacks with Rice or Rice Flour” for company a, with the corresponding normal distribution curve superimposed above the histogram. The orange and blue lines mark the values of the median (3.8 ppb) and the mean (6.17 ppb) of the corresponding normal distribution respectively.

In this example, 6.17 ppb (rounded down to 6 ppb) would become the industry-wide interim proposed action level for cadmium in “Snacks with Rice or Rice Flour.” Below is a table that shows how this would compare with other existing and proposed limits/action levels for cadmium.

| Source | Level for Cadmium | Proposed Level Applicable to Cadmium in “Snacks with Rice or Rice Flour” |
|---|----------------------------|--|
| FDA | Currently no action levels | Currently no action levels |
| EU (regulatory limit) | 40 ppb for baby foods | 40 ppb |
| Baby Food Safety Act (initial levels in proposed legislation) | 5 ppb (10 ppb for cereals) | 5 ppb |
| “Best Performer” mean method in Attorneys General Petition | N/A | ~6 ppb (example) |

The histogram below shows that with an interim proposed action level of 6 ppb, about 80% of “Snacks with Rice or Rice Flour,” within the 2017 Consumer Reports data, would have exceeded the action level.

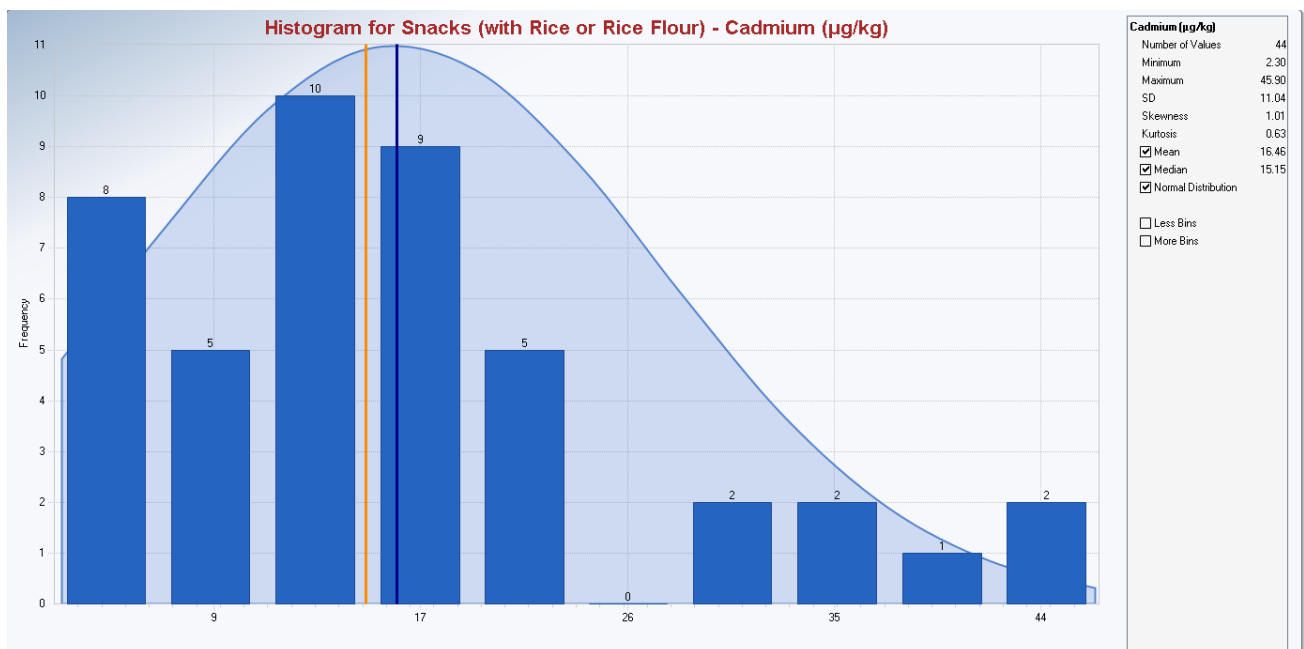


Figure 5: Histogram plot of the frequency of cadmium detections in “Snacks with Rice or Rice Flour” for all baby food companies whose products in this category were tested by Consumer Reports in 2017. The orange and blue lines mark the values of the median (15.15 ppb) and the mean (16.46 ppb), respectively, of the corresponding normal distribution. The values of the median and the mean in this data set suggest that using an action level of 6 ppb would result in approximately 80% of all “Snacks with Rice or Rice Flour” in this data set exceeding the interim proposed action level.

Appendix C – Third Example of Methodology for Establishing Interim Proposed Action Levels Described in Attorneys General Petition to FDA

For this example, we will look at data for **cadmium in the baby food category “Purees (with Sweet Potatoes or Carrots)”**—pureed products in which sweet potatoes or carrots are listed on the label as the first, second or third ingredient. The testing data used in this example was obtained in brand-anonymized form from Consumer Reports sampling and testing of baby food products that it conducted in 2017 and later reported—publicly, and to FDA directly—in 2018.¹ The Attorneys General developed the baby food category “Purees (with Sweet Potatoes or Carrots)” for illustrating their proposed methodology, and the use of such a category was found to be consistent with statistical distributions observed in the data itself.²

Below is a graphic which contains histograms for cadmium in the category “Purees (with Sweet Potatoes or Carrots)” for two companies whose finished products were sampled and tested by Consumer Reports, and are labeled below as companies “b” and “e”.

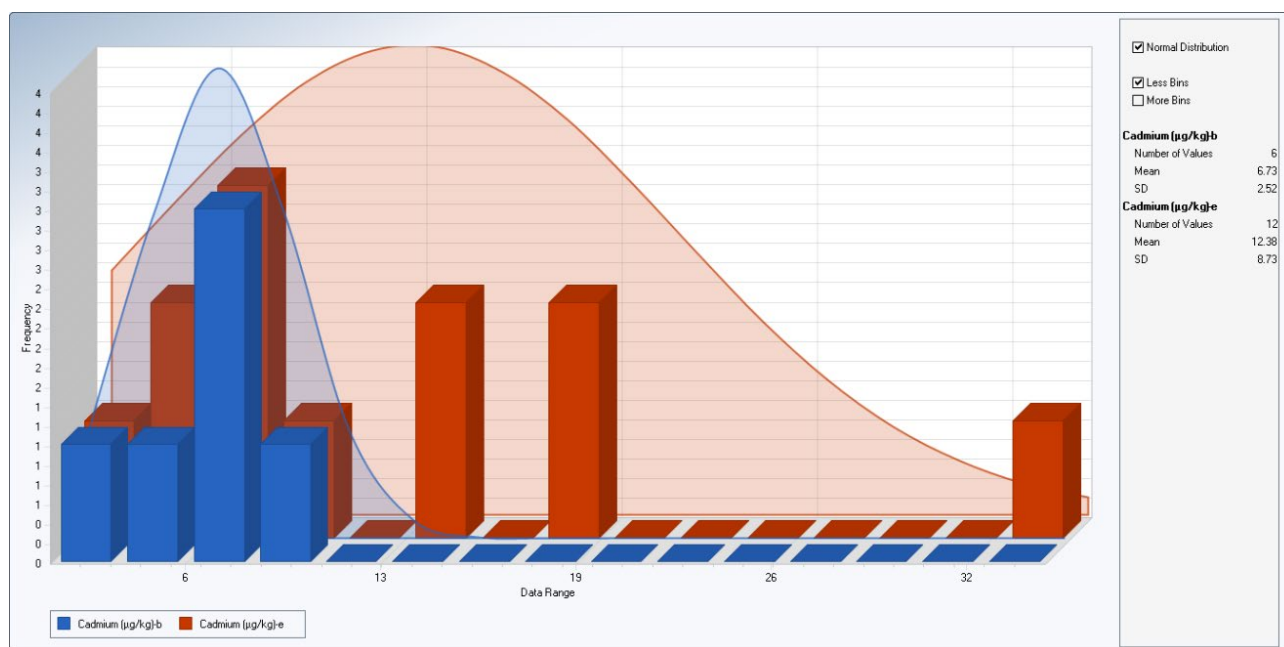


Figure 1: Multi-histogram plot of the frequency of cadmium detections in “Purees (With Sweet Potatoes or Carrots)” for companies b (blue) and e (red).

¹ Letter dated August 16, 2018 from Consumer Reports to FDA Commissioner Scott Gottlieb, with Enclosure, available at <https://article.images.consumerreports.org/prod/content/dam/CRO%20Images%202018/Health/August/Consumer%20Reports%20Letter%20to%20FDA%20on%20Heavy%20Metals%20in%20Baby%20and%20Toddler%20Food%208-16-18>; Jesse Hirsh, *Heavy Metals in Baby Food: What You Need to Know*: <https://www.consumerreports.org/food-safety/heavy-metals-in-baby-food/>. Consumer Reports also shared its underlying testing data, in brand-anonymized form, with FDA.

² Consumer Reports did not participate in the New York Attorney General’s Office’s analysis.

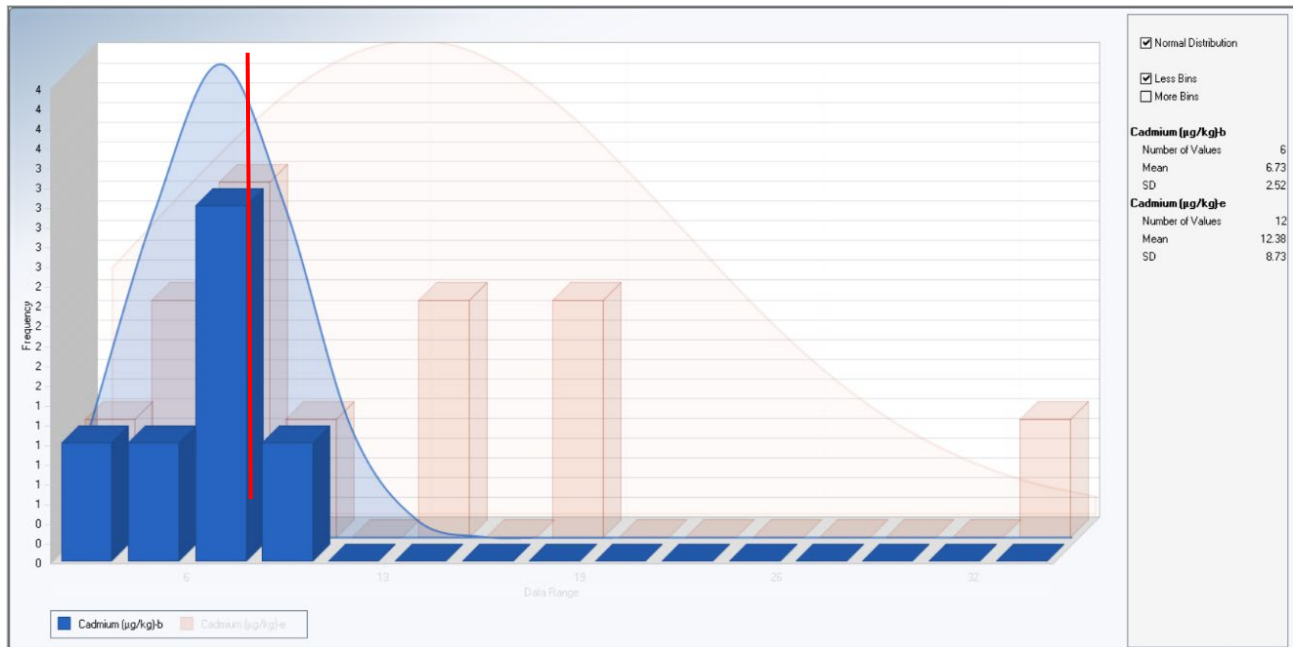


Figure 2: Multi-histogram plot of the frequency of cadmium detections in “Purees (with Sweet Potatoes or Carrots)” for companies b and e, with company b data emphasized. The location (i.e. value of the mean (6.73 ppb)) for company b is indicated by the red line.

From these multi-histogram plots, we can identify company “b” as the best performer in this category based on this data set, with a mean value of 6.73 ppb of cadmium in “Purees (with Sweet Potatoes or Carrots).”

Now that we have identified from existing data the best performer for the category “Purees (with Sweet Potatoes or Carrots)” for cadmium, we must consider if additional data are needed to create a roughly normal distribution (and a usable mean) for that company. In this example, company B’s data passes normality and thus additional data is not absolutely necessary for this example. However, obtaining additional data would be prudent with regard to setting a defensible action level (as it would be more robust to have more sampling data).

A normal probability plot and histogram plot showing only the analysis for company b are presented below.

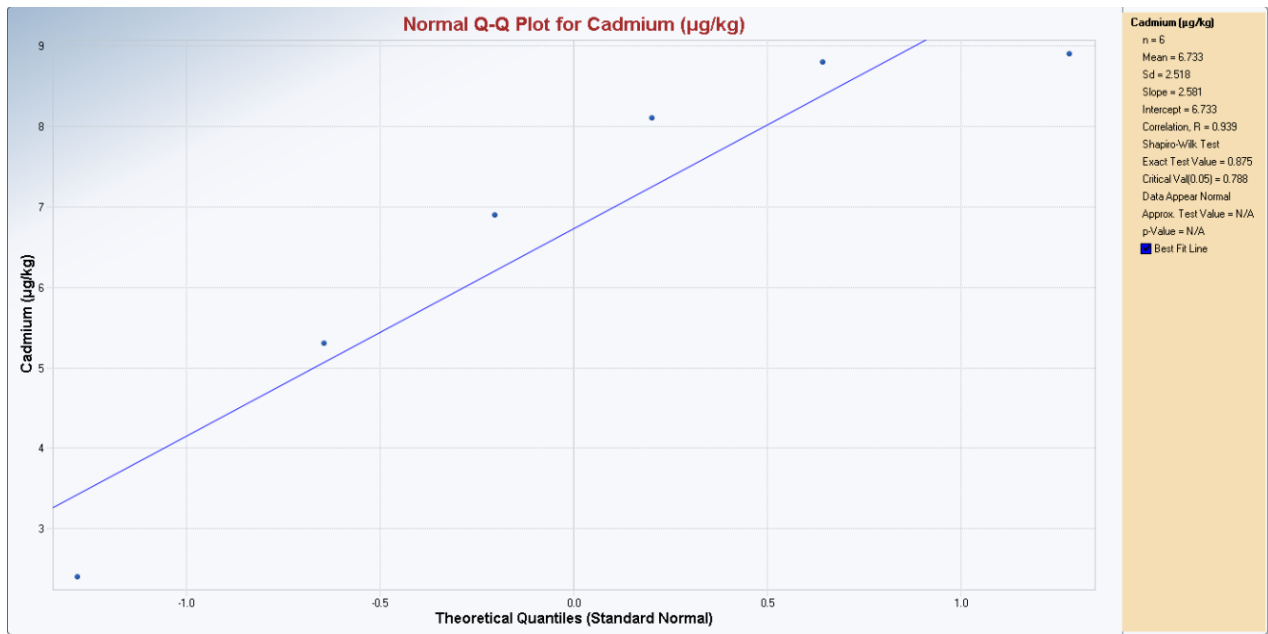


Figure 3: Normal probability plot for frequency of cadmium detections in “Purees (with Sweet Potatoes or Carrots)” for company b showing good agreement of the data with what would be expected for normally distributed data (R value 0.939). Exact agreement would result in a correlation (R) value of 1.0 with all data points falling on the blue line.

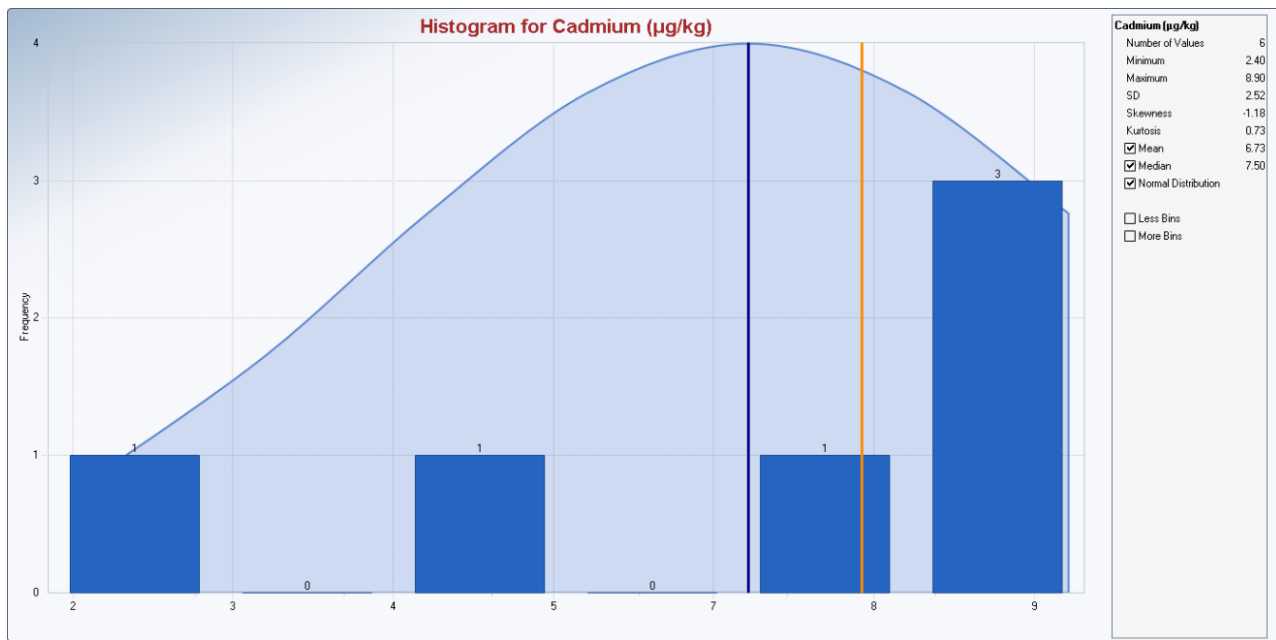


Figure 4: Histogram plot of the frequency of cadmium in “Purees (with Sweet Potatoes or Carrots)” for company b with the corresponding normal distribution curve superimposed above the histogram. The orange and blue lines mark the values of the median (7.50 ppb) and the mean (6.73 ppb) of the corresponding normal distribution respectively.

In this example, 6.73 ppb (which may be rounded up to 7 ppb) would become the industry-wide interim proposed action level for the category “Purees (with Sweet Potatoes or Carrots).” Below is a table that shows how this would compare with other existing and proposed limits/action levels for cadmium applicable to baby food purees (with sweet potatoes or carrots).

| Source | Level for Cadmium | Proposed Level Applicable to Cadmium in “Purees (with Sweet Potatoes or Carrots)” |
|---|----------------------------|---|
| FDA | Currently no action levels | Currently no action levels |
| EU (regulatory limit) | 40 ppb for baby foods | 40 ppb |
| Baby Food Safety Act (initial levels in proposed legislation) | 5 ppb (10 ppb for cereals) | 5 ppb |
| “Best Performer” mean method in Attorneys General Petition | N/A | ~7 ppb (example) |

The histogram below shows that with an interim proposed action level of 7 ppb, about one-third of products that would be classified as “Purees (with Sweet Potatoes or Carrots),” within the 2017 Consumer Reports data, would have exceeded the action level.

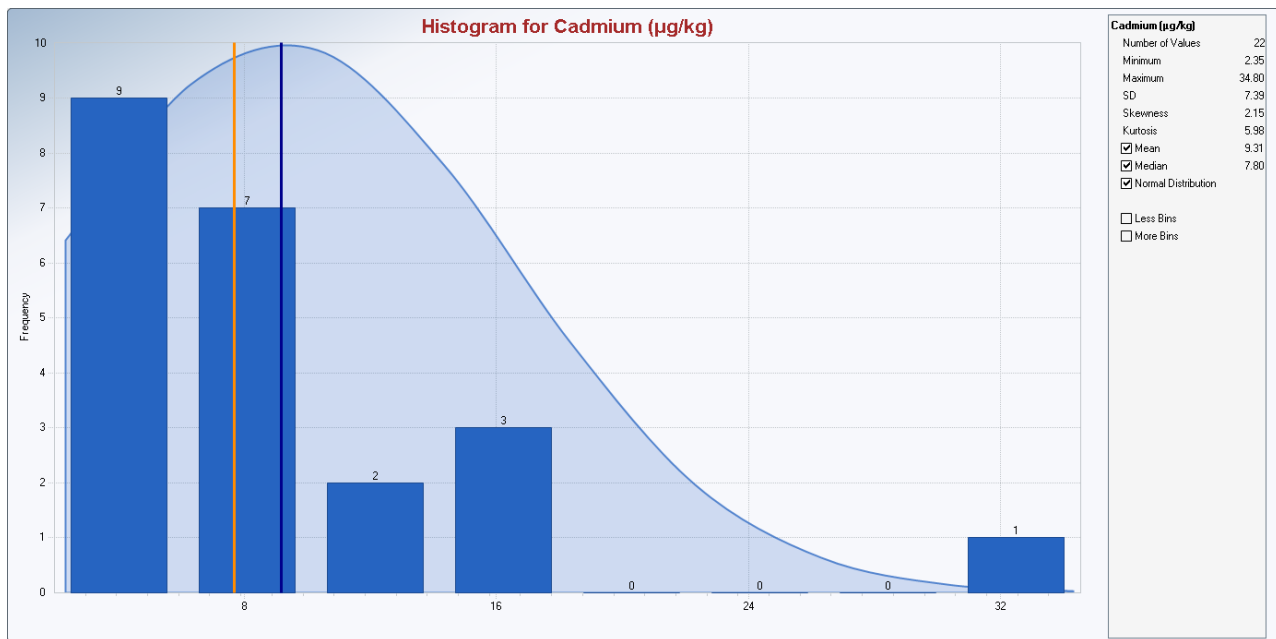


Figure 5: Histogram plot of the frequency of cadmium in “Purees (with Sweet Potatoes or Carrots)” for all baby food companies whose products in this category were tested by Consumer Reports in 2017 (including data for companies not previously shown in this example (i.e. companies d, f and h)). The orange and blue lines mark the values of the median (7.8 ppb) and the mean (9.31 ppb), respectively, of the corresponding normal distribution. The locations (i.e. values) of the median and the mean in this data set suggest that using an action level of 7 ppb would result in approximately 27% of all “Purees (with Sweet Potatoes or Carrots)” in this data set exceeding the interim proposed action level.

Results of NYSOAG Infant Rice Cereal Inorganic Arsenic Sampling (4 manufacturers, 7 products, 21 total samples)

Note: All products were purchased by NYSOAG from retailers in Nassau County, New York in April 2021 and analyzed by Brooks Applied Labs (Bothell, WA) in May 2021.*

| Product | Sample | Inorganic As (ug/kg)** |
|----------------|---------------|-------------------------------|
| 1 | a | 59.6 |
| | b | 60.3 |
| | c | 58.7 |
| 2 | a | 59.1 |
| | b | 57.3 |
| | c | 61.1 |
| 3 | a | 33.7 |
| | b | 31.5 |
| | c | 31.4 |
| 4 | a | 68.2 |
| | b | 67.6 |
| | c | 66.3 |
| 5 | a | 55.0 |
| | b | 55.9 |
| | c | 54.3 |
| 6 | a | 73.2 |
| | b | 69.0 |
| | c | 72.2 |
| 7 | a | 53.4 |
| | b | 53.3 |
| | c | 54.6 |

* Inorganic Arsenic speciation was performed using Brooks Analytical Method 4101 which is analagous to FDA EAM Method 4.11

** Level of Quantitation for Inorganic Arsenic - 1.1 ug/kg