



New Disclosures Show Dangerous Levels of Toxic Heavy Metals in Even More Baby Foods



Staff Report

**Subcommittee on Economic and Consumer Policy
Committee on Oversight and Reform
U.S. House of Representatives**

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EXECUTIVE SUMMARY

On February 4, 2021, the Subcommittee on Economic and Consumer Policy released its staff report entitled “Baby Foods Are Tainted with Dangerous Levels of Arsenic, Lead, Cadmium, and Mercury.” The staff report exposed dangerous levels of toxic heavy metals in baby foods produced by: Nurture, Inc., which sells Happy Family Organics, including under the brand name HappyBABY; Beech-Nut Nutrition Company; Hain Celestial Group, Inc., which sells baby food products under the brand name Earth’s Best Organic; and Gerber.

At the time of the February 4, 2021, staff report, three companies had failed to provide the Subcommittee with the documents and information that it had requested, causing concern about whether they were concealing higher levels of toxic heavy metals in their products than were found in their competitors’ products. Those three companies were: Campbell, the maker of Plum Organics (Plum); Walmart; and Sprout Foods, Inc.

Following publication of the staff report, the three companies began cooperating to varying degrees. Plum provided its test results, which confirmed the Subcommittee’s concerns about the danger of some of its products. Walmart provided documents revealing a concerning lack of attention to toxic heavy metal levels in baby food and an abandonment of its previously more protective standards. The handful of documents that Sprout provided displayed a lax approach to testing for toxic heavy metals in its baby foods.

In June, Beech-Nut announced a recall of some of its baby foods due to the presence of toxic heavy metals found by public health officials in the State of Alaska. The Subcommittee obtained the State of Alaska’s test results for both Beech-Nut and Gerber products, which have not been publicly disclosed before or after the Beech-Nut recall. They reveal dangerous levels of toxic inorganic arsenic in additional Beech-Nut infant rice cereal products that the company did *not* recall, *and* in Gerber infant rice cereal products. Beech-Nut’s recall appears to have been incomplete. Gerber, despite its products’ having similar inorganic arsenic levels to those of the Beech-Nut products, failed to take any action.

Findings

1. Food and Drug Administration (FDA)-funded testing conducted by the State of Alaska found that multiple samples of Beech-Nut’s and Gerber’s infant rice cereals contained more inorganic arsenic than FDA’s 100 parts per billion (ppb) limit (an already-dangerously-high standard that FDA is now lowering). Beech-Nut issued a recall but limited it to product codes associated with only two of the six samples that Alaska’s testing found contained over 100 ppb. Its recall was therefore too narrow. Gerber failed to recall product associated with either of its two infant rice cereal samples that tested over 100 ppb. The Subcommittee’s review of Alaska’s test results revealed that:
 - Beech-Nut rice cereal tested up to 125 ppb inorganic arsenic and averaged 85.47 ppb inorganic arsenic;

- Beech-Nut’s practice of testing ingredients, rather than finished products, for toxic heavy metals appears to have contributed to its failure to detect the dangerous inorganic arsenic levels in its recalled products;
 - Gerber’s rice cereal tested up to 116 ppb inorganic arsenic, and its average rice cereal product contained 87.43 ppb inorganic arsenic, which is even higher than the amount contained in Beech-Nut’s average rice cereal product. While Beech-Nut recalled some of its products and completely discontinued sales of its rice cereal, Gerber has taken no such actions to protect consumers; and
 - Gerber’s organic rice cereal is dangerous and has been found to contain up to 76 ppb inorganic arsenic and to average 65.6 ppb inorganic arsenic.
2. The testing practices for toxic heavy metals used by most of the baby food industry are flawed and underestimate the toxic heavy metal content of their products. In the February 4, 2021, staff report, the Subcommittee found that most baby food manufacturers do not test their finished products at all. Instead, they test only individual ingredients and use those results to estimate the toxic heavy metal levels in their finished products. One manufacturer, Hain, underestimated those levels 100% of the time. Its estimates were grossly wrong: toxic heavy metal levels were underestimated by 28% to 93% in its finished products. The Subcommittee recommended that all manufacturers adopt finished product testing.
- The circumstances surrounding the Beech-Nut recall provide further evidence that estimates based on individual ingredient testing are inaccurate and dangerous for consumers. Beech-Nut used the ingredient-testing method and failed to detect high levels of inorganic arsenic in its infant rice cereal. Finished product testing found that Beech-Nut’s products contained up to 125 ppb inorganic arsenic.
 - Sprout, which is now owned by Neptune Wellness Solutions, a Canadian cannabis company, also uses ingredient testing. It relies on its ingredient suppliers to test their ingredients for toxic heavy metals, but it only asks them to do so *once per year*. Sprout’s testing practices appear to be the most reckless among baby food manufacturers.
3. According to internal company documents and test results obtained by the Subcommittee, Plum Organics baby foods are tainted with high levels of toxic heavy metals. Specifically, the Subcommittee found high levels of the following toxic heavy metals:
- Arsenic: 100% of Plum’s Super Puff rice-based products tested between 2017 and 2019 contained in excess of 200 ppb arsenic. Plum’s average Super Puff product had 233.74 ppb arsenic, including 79 ppb inorganic arsenic. Plum’s products contained up to 470 ppb arsenic, and up to 225 ppb inorganic arsenic. For comparison, the maximum level of inorganic arsenic that FDA allows in bottled water is 10 ppb, and the Baby Food Safety Act would impose a maximum level of 15 ppb inorganic arsenic for infant cereals.

- Lead: 54.5% of Plum Organics products exceed 5 ppb lead, the maximum amount FDA allows in bottled water.
 - Cadmium: 38.3% of Plum Organics products exceed 5 ppb cadmium, the maximum amount FDA allows in bottled water.
4. In 2018, Walmart took a giant step backwards in protecting babies from toxic heavy metals. For six years, Walmart set an internal maximum inorganic arsenic limit of 23 ppb for its finished baby foods. However, in 2018, Walmart abandoned that more-protective standard, more than quadrupling it to a standard allowing 100 ppb inorganic arsenic in its baby foods. Walmart offered no justification for its extreme course reversal on protecting babies' neurological development.
5. The Subcommittee recommends the following:
- FDA:
 - Issue Maximum Toxic Heavy Metal Levels Sooner: The recent Beech-Nut and Gerber test results show the need for action sooner rather than later. In response to the Subcommittee's February 4, 2021, staff report, FDA created the Closer to Zero Action Plan, setting timelines by which it will publish draft and final limits for lead, arsenic, cadmium, and mercury in baby foods. However, FDA's timelines are far in the future. FDA should accelerate its proposed timelines for publishing final limits for these toxic heavy metals.
 - Mandate Finished-Product Testing: The Subcommittee's investigation has demonstrated that it is dangerous to estimate toxic heavy metal levels based on inaccurate individual-ingredient tests, because these tests underestimate toxic heavy metal levels. FDA should require baby food manufacturers to test their finished products.
 - Industry:
 - Adopt Finished-Product Testing: If FDA does not require baby food manufacturers to test their finished products for toxic heavy metals, then industry should voluntarily adopt that practice. This is an easy step toward rebuilding public trust in their products.
 - Voluntarily Phase Out Toxic Ingredients: Baby food manufacturers should voluntarily find substitutes for ingredients that are high in toxic heavy metals, or, if they cannot find appropriate substitutes, should phase out products that have high amounts of ingredients that frequently test high in toxic heavy metals, such as rice.

I. FDA-FUNDED TESTING RECENTLY FOUND MULTIPLE BEECH-NUT AND GERBER INFANT RICE CEREAL SAMPLES CONTAINED MORE INORGANIC ARSENIC THAN FDA’S 100 PPB LIMIT, BUT COMPANIES FAILED TO RECALL SEVERAL DANGEROUS PRODUCTS.

FDA has set the maximum allowable level of inorganic arsenic in infant rice cereal at 100 parts per billion (ppb).¹

Through its Laboratory Flexible Funding Model Cooperative Agreement Program, FDA provides funding to state laboratories to conduct sample testing to “strengthen FDA’s efforts to minimize foodborne exposure.”² Within the program “FDA prioritized testing infant rice cereals for inorganic arsenic” to see if they comply with FDA’s 100 ppb standard.³ The State of Alaska’s Department of Environmental Health Laboratory was awarded a grant through the program in order to test inorganic arsenic levels in infant rice cereal.⁴

Alaska’s Department of Environmental Health Laboratory collected infant rice cereal samples for inorganic arsenic testing on March 31, 2021; April 7, 2021; and April 27, 2021. The samples collected were “products randomly selected from customer shel[ves]” at various retail locations around Anchorage, Alaska.⁵

Alaska began testing the inorganic arsenic content of the samples on May 3, 2021. Alaska reported the test results to FDA as they became available, providing reports on May 6, 2021; May 18, 2021; and May 24, 2021.⁶ FDA officials confirmed, in a Subcommittee staff briefing, that when FDA received the reports, Alaska had already provided the results to Beech-Nut and Gerber.⁷

Beech-Nut asked FDA to review Alaska’s testing results. FDA did so and confirmed that Alaska’s methods were sound and that the data supported a food safety violation. Beech-Nut

¹ Food and Drug Administration, *Guidance for Industry: Action Level for Inorganic Arsenic in Rice Cereals for Infants* (Aug. 2020) (online at www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-action-level-inorganic-arsenic-rice-cereals-infants).

² Food and Drug Administration, *Laboratory Flexible Funding Model Cooperative Agreement Program* (online at www.fda.gov/federal-state-local-tribal-and-territorial-officials/grants-and-cooperative-agreements/laboratory-flexible-funding-model-cooperative-agreement-program) (accessed Sept. 2, 2021).

³ Email from Staff, Food and Drug Administration, to Staff, Subcommittee on Economic and Consumer Policy, Committee on Oversight and Reform (June 9, 2021).

⁴ *Id.*

⁵ Alaska State Environmental Health Laboratory, *Analytical Reports* (May 6, 2021, to June 3, 2021) (online at https://oversight.house.gov/sites/democrats.oversight.house.gov/files/Test_Results.pdf).

⁶ Email from Staff, Alaska State Environmental Health Laboratory, to Staff, Subcommittee on Economic and Consumer Policy, Committee on Oversight and Reform (June 28, 2021) (online at <https://oversight.house.gov/sites/democrats.oversight.house.gov/files/Alaska%20Email%20re%20Report%20Timelines.pdf>).

⁷ Briefing by Center for Food Safety and Applied Nutrition, Food and Drug Administration, for Majority Staff, Subcommittee on Economic and Consumer Policy, Committee on Oversight and Reform (July 7, 2021).

also provided additional data to FDA that further supported a food safety violation. As part of its food safety plan, Beech-Nut keeps samples from each lot sold. It tested samples from the relevant lots, and its own findings supported food safety violations.⁸ Alaska's reporting of Beech-Nut's test results led to a recall of Beech-Nut infant rice cereal.

Alaska also reported troubling findings about Gerber rice cereal, but Gerber has failed to recall this product.

A. Beech-Nut Recalled Only Product Codes Associated with the Two Samples That Contained the Most Inorganic Arsenic (up to 125 ppb) but Failed to Recall the Product Codes Associated with the Other Four Samples That Contained over 100 ppb Inorganic Arsenic.

On June 8, 2021, Beech-Nut announced that it was voluntarily recalling tainted rice cereal bearing two specific product codes, 103470XXXX and 093470XXXX, and bearing an expiration date of 01MAY2022. These product codes are numbers that can be found on the bottom of the Beech-Nut Rice Cereal canister.



Beech-Nut also announced that it would stop selling infant rice cereal.⁹ Both of these actions make babies safer because those products were harmful to infant neurological development.

⁸ *Id.*

⁹ Food and Drug Administration, *Company Announcement: Beech-Nut Nutrition Company Issues a Voluntary Recall of One Lot of Beech-Nut Single Grain Rice Cereal and Also Decides to Exit the Rice Cereal Segment* (June 8, 2021) (online at www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/beech-nut-nutrition-company-issues-voluntary-recall-one-lot-beech-nut-single-grain-rice-cereal-and).

Alaska tested three samples associated with the two product codes subject to the recall and found inorganic arsenic levels of 125 ppb, 122 ppb, and 116 ppb. Each was well in excess of FDA's 100 ppb limit for inorganic arsenic in infant rice cereal.¹⁰

The sample bearing product code 103470XXXX tested at 125 ppb inorganic arsenic:

Analytical Data									
Client: AKDEC Food Safety & Sanitation Program Project: LFFM - Surveillance					Work Order: 2104096 Report Date: 05/24/21 18:20				
Client Sample ID: Rice Cereal 8oz Lab Sample ID: 2104096-10 Date Collected: 04/27/21 17:52 Date Received: 04/29/21 14:50 Sampled By: [REDACTED] Temperature at Receipt: 20.6 degrees C					Product Lot Code: 103470 Brand Name: BEECH-NUT Product Lot Size: 21 Sample Description: CEREAL IN PLASTIC : FDA FEI# State Code: AK				
Analyte	Result	Reporting Limit	Units	Dilution	Batch	Prepared	Analyzed	Method	Notes
Arsenic (III)	97.4	37.4	ug/kg	1	B21E021	13-May-21	14-May-21	SOP-Chemistry-036	
Arsenic (V)	27.1	37.4	ug/kg	"	"	"	"	"	J
Inorganic Arsenic Total	125	37.4	ug/kg	"	"	"	"	"	
Inorganic Arsenic	125	37.4	ug/kg	1	[CALC]	"	14-May-21	[CALC]	

Two separate samples bearing product code 093470XXXX were tested. One contained 122 ppb inorganic arsenic, and the other contained 116 ppb:

Analytical Data									
Client: AKDEC Food Safety & Sanitation Program Project: LFFM - Surveillance					Work Order: 2104024 Report Date: 05/18/21 12:12				
Client Sample ID: Rice Cereal (8 oz) Lab Sample ID: 2104024-12 Date Collected: 04/07/21 11:28 Date Received: 04/07/21 15:22 Sampled By: [REDACTED] Temperature at Receipt: 17.6 degrees C					Product Lot Code: 093470 Brand Name: BEECH-NUT Product Lot Size: 8 Bottles Sample Description: CEREAL IN PLASTIC : FDA FEI# State Code: AK				
Analyte	Result	Reporting Limit	Units	Dilution	Batch	Prepared	Analyzed	Method	Notes
Arsenic (III)	102	37.4	ug/kg	1	B21E017	10-May-21	12-May-21	SOP-Chemistry-036	
Arsenic (V)	19.9	37.4	ug/kg	"	"	"	"	"	J
Inorganic Arsenic Total	122	37.4	ug/kg	"	"	"	"	"	
Inorganic Arsenic	122	37.4	ug/kg	1	[CALC]	"	12-May-21	[CALC]	

¹⁰ Alaska State Environmental Health Laboratory, *Analytical Reports* (May 6, 2021, to June 3, 2021) (online at https://oversight.house.gov/sites/democrats.oversight.house.gov/files/Test_Results.pdf).

Analytical Data

Client: AKDEC Food Safety & Sanitation Program
Project: LFFM - Surveillance

Work Order: 2104025
Report Date: 05/24/21 17:43

Client Sample ID: Rice Cereal (8 oz)
Lab Sample ID: 2104025-08
Date Collected: 04/07/21 13:33
Date Received: 04/07/21 15:46
Sampled By: [REDACTED]
Temperature at Receipt: 17.6 degrees C

Product Lot Code: 093476
Brand Name: BEECH-NUT
Product Lot Size: 3
Sample Description: CEREAL IN PLASTIC : FDA FEI#
State Code: AK

Analyte	Result	Reporting Limit	Units	Dilution	Batch	Prepared	Analyzed	Method	Notes
Arsenic (III)	88.8	37.4	ug/kg	1	B21E019	13-May-21	14-May-21	SOP-Chemistry-036	
Arsenic (V)	27.2	37.4	ug/kg	"	"	"	"	"	J
Inorganic Arsenic Total	116	37.4	ug/kg	"	"	"	"	"	
Inorganic Arsenic	116	37.4	ug/kg	1	[CALC]	"	14-May-21	[CALC]	

The recall followed regulatory meetings between Beech-Nut, FDA, and state regulators, which occurred between June 4 and June 7, 2021.¹¹ Having made the determination that there was a reasonable probability that Beech-Nut products were “adulterated” and that exposure to them would “cause serious adverse health consequences,” FDA allowed Beech-Nut the opportunity to issue a voluntary recall pursuant to federal law.¹² Beech-Nut exercised that option for two product codes.

i. Beech-Nut Should Voluntarily Recall Four Additional Product Codes that Also Tested over FDA’s 100 ppb Arsenic Limit.

In addition to the two recalled product codes, Alaska reported five additional Beech-Nut Rice Cereal samples (across four product codes) that tested in excess of FDA’s 100 ppb inorganic arsenic limit:¹³

Product Code	Company	Product	Inorganic Arsenic Content in ppb	Date Reported to FDA
013470XXXX	Beech-Nut	Rice Cereal (8oz)	104	May 6, 2021

¹¹ Email from State of Alaska employee to Staff, Subcommittee on Economic and Consumer Policy, Committee on Oversight and Reform (July 9, 2021).

¹² 21 U.S.C. § 350L(a) (“If the Secretary determines ... that there is a reasonable probability that an article of food ... is adulterated under section 342 of this title ... and the use of or exposure to such article will cause serious adverse health consequences or death to humans or animals, the Secretary shall provide the responsible party ... with an opportunity to cease distribution and recall such article.”).

¹³ Alaska State Environmental Health Laboratory, *Analytical Reports* (May 6, 2021, to June 3, 2021) (online at https://oversight.house.gov/sites/democrats.oversight.house.gov/files/Test_Results.pdf).

013351XXXX	Beech-Nut	Rice Cereal (8oz)	104	May 24, 2021
243470XXXX	Beech-Nut	Rice Cereal (8oz)	103	May 24, 2021
243470XXXX	Beech-Nut	Rice Cereal (8oz)	101	May 24, 2021
113470XXXX	Beech-Nut	Rice Cereal (8oz)	101	May 6, 2021

Each of these products exceeds FDA’s maximum limit for inorganic arsenic in infant rice cereal.¹⁴ Beech-Nut should have, but did not, voluntarily recall each of these products.

Notably, the two highlighted test results were from separate product samples with the same product code (243470XXXX) in the same lot. This replication of dangerous results in multiple samples provides even more compelling evidence that Beech-Nut should have voluntarily recalled this lot.

According to FDA staff, the agency did not press Beech-Nut over its failure to voluntarily recall these four additional product codes because of the difficulty of proving adulteration with products that test so close to the maximum limit, and because of Beech-Nut’s decisions to recall its worst products and discontinue sales of rice cereal. While FDA’s decision not to pursue further action may have been a reasonable exercise of discretion, Beech-Nut’s failure to voluntarily do the right thing was not. Beech-Nut knowingly concealed the danger of violative products and allowed parents to unwittingly keep feeding them to their babies.

ii. Beech-Nut’s Call to Discontinue Infant Rice Cereal Sales Was Necessary Because All Beech-Nut Rice Cereal Samples Tested Were Dangerously High in Inorganic Arsenic, Averaging 85.47 ppb.

Alaska tested 26 Beech-Nut Rice Cereal products. Beyond just the eight samples that tested above FDA’s 100 ppb inorganic arsenic limit on infant rice cereal, *all* of Beech-Nut’s Rice Cereal samples tested dangerously high in inorganic arsenic.

As outlined in this Subcommittee’s February 4, 2021, staff report on baby food safety, FDA’s current 100 ppb limit is far too high and does not protect babies from neurological impairment. FDA set the limit at 100 ppb because it was focused on the level of inorganic arsenic that would cause cancer. It disregarded the risk of neurological damage, which happens at a much lower level.¹⁵

¹⁴ 85 Fed. Reg. 47797 (Aug. 6, 2020).

¹⁵ Staff Report, Subcommittee on Economic and Consumer Policy, Committee on Oversight and Reform, *Baby Foods Are Tainted with Dangerous Levels of Arsenic, Lead, Cadmium, and Mercury* (Feb. 4, 2021) (online at <https://oversight.house.gov/sites/democrats.oversight.house.gov/files/2021-02-04%20ECP%20Baby%20Food%20Staff%20Report.pdf>).

In response to the Subcommittee’s staff report, FDA created the Closer to Zero initiative, and as part of that program, FDA plans to lower the allowable limit of inorganic arsenic in baby food.¹⁶ The Subcommittee supports a maximum level of 10 ppb inorganic arsenic in most baby foods, with a 15 ppb limit for infant cereal, as proposed in the Baby Food Safety Act.¹⁷ These proposed standards were developed in consultation with experts to be more protective of babies’ neurological development than current levels, and research shows that industry could meet these standards today.

Each of the 26 Beech-Nut Rice Cereal samples that was pulled off store shelves contained far in excess of the proposed 15 ppb inorganic arsenic level. The average Beech-Nut product tested at 85.47 ppb inorganic arsenic.¹⁸ Even the Beech-Nut sample with the lowest level of inorganic arsenic contained more than three times the standard proposed in the Baby Food Safety Act. The results of the Beech-Nut Rice Cereal testing for inorganic arsenic conducted by Alaska are as follows:¹⁹

<u>Product Code</u>	<u>Company</u>	<u>Product</u>	<u>Inorganic Arsenic (ppb)</u>	<u>Date Reported to FDA</u>
103470XXXX	Beech-Nut	Rice Cereal (8oz)	125	May 24, 2021
093470XXXX	Beech-Nut	Rice Cereal (8oz)	122	May 18, 2021
093470XXXX	Beech-Nut	Rice Cereal (8oz)	116	May 24, 2021
013470XXXX	Beech-Nut	Rice Cereal (8oz)	104	May 6, 2021
013351XXXX	Beech-Nut	Rice Cereal (8oz)	104	May 24, 2021
243470XXXX	Beech-Nut	Rice Cereal (8oz)	103	May 24, 2021
243470XXXX	Beech-Nut	Rice Cereal (8oz)	101	May 24, 2021
113470XXXX	Beech-Nut	Rice Cereal (8oz)	101	May 6, 2021
243470XXXX	Beech-Nut	Rice Cereal (8oz)	93.3	May 24, 2021

¹⁶ Food and Drug Administration, *Closer to Zero: Action Plan for Baby Foods* (online at www.fda.gov/food/metals-and-your-food/closer-zero-action-plan-baby-foods) (accessed Sept. 2, 2021).

¹⁷ Baby Food Safety Act of 2021, H.R. 2229.

¹⁸ Alaska State Environmental Health Laboratory, *Analytical Reports* (May 6, 2021, to June 3, 2021) (online at https://oversight.house.gov/sites/democrats.oversight.house.gov/files/Test_Results.pdf).

¹⁹ *Id.*

203470XXXX	Beech-Nut	Rice Cereal (8oz)	88.9	May 6, 2021
133470XXXX	Beech-Nut	Rice Cereal (8oz)	88.8	May 24, 2021
203470XXXX	Beech-Nut	Rice Cereal (8oz)	88.4	May 6, 2021
083470XXXX	Beech-Nut	Rice Cereal (8oz)	86.5	May 6, 2021
073470XXXX	Beech-Nut	Rice Cereal (8oz)	84.2	May 18, 2021
083470XXXX	Beech-Nut	Rice Cereal (8oz)	82.8	May 6, 2021
083470XXXX	Beech-Nut	Rice Cereal (8oz)	82.5	May 6, 2021
113470XXXX	Beech-Nut	Rice Cereal (8oz)	81.8	May 6, 2021
203470XXXX	Beech-Nut	Rice Cereal (8oz)	72.1	May 6, 2021
193470XXXX	Beech-Nut	Rice Cereal (8oz)	66.9	May 24, 2021
183470XXXX	Beech-Nut	Rice Cereal (8oz)	61.8	May 6, 2021
183470XXXX	Beech-Nut	Rice Cereal (8oz)	60.9	May 6, 2021
243470XXXX	Beech-Nut	Rice Cereal (8oz)	58.6	May 6, 2021
293470XXXX	Beech-Nut	Rice Cereal (8oz)	57.1	May 6, 2021
243470XXXX	Beech-Nut	Rice Cereal (8oz)	54	May 6, 2021
193470XXXX	Beech-Nut	Rice Cereal (8oz)	52.2	May 6, 2021
		Average:	85.47	

Beech-Nut’s decision to stop selling rice cereal was appropriate in light of these results and the prior testing data released in the Subcommittee’s February 4, 2021, report. In that report, the Subcommittee called on Beech-Nut to “voluntarily find substitutes for ingredients that are high in toxic heavy metals, or phase out products that have high amounts of ingredients that frequently test high in toxic heavy metals, *such as rice*.” In warning Beech-Nut that it should stop using rice in its baby foods, the Subcommittee specifically pointed to the fact that, “for Beech-Nut, the majority of its ingredients that tested over 100 ppb inorganic arsenic (27 of 45) were rice-based (containing either rice, rice flour, or organic rice).”²⁰

²⁰ Staff Report, Subcommittee on Economic and Consumer Policy, Committee on Oversight and Reform, *Baby Foods Are Tainted with Dangerous Levels of Arsenic, Lead, Cadmium, and Mercury* (Feb. 4, 2021) (online at

Unfortunately, Beech-Nut ignored the Subcommittee’s call for four months, only deciding to discontinue its rice cereal product after Alaska’s test results forced the company to recall two products. In those four months, Beech-Nut was knowingly harming babies.

B. Gerber Should Recall Two Infant Rice Cereal Product Codes and Consider Discontinuing Sales of Its Rice Cereal

Alaska’s test results found that, like Beech-Nut, Gerber was also selling tainted baby food. Unlike Beech-Nut, however, Gerber has failed to voluntarily recall any of its product.

Alaska tested both Beech-Nut and Gerber rice cereal products in the same time period. Alaska reported the results to FDA at the same time. The results were nearly identical. In fact, the average Gerber product tested *higher* in inorganic arsenic than the average Beech-Nut product.²¹

Gerber’s Rice Cereal averaged 87.43 ppb inorganic arsenic—2 ppb higher than Beech-Nut’s 85.47 ppb average that led to a recall and discontinuation of sales of the product. Gerber’s test results show two samples exceeding FDA’s current 100 ppb inorganic arsenic limit, and many just below that level. Even the Gerber Rice Cereal that tested lowest in inorganic arsenic contained four times the limit on inorganic arsenic proposed in the Baby Food Safety Act.²² The full list of Gerber’s Rice Cereal results is as follows:²³

<u>Product Code</u>	<u>Company</u>	<u>Product</u>	<u>Inorganic Arsenic (ppb)</u>	<u>Date Reported to FDA</u>
035251XXXX	Gerber	Rice Cereal (8oz)	116	May 24, 2021
035151XXXX	Gerber	Rice Cereal (8oz)	101	May 6, 2021
013551XXXX	Gerber	Rice Cereal (8oz)	95	May 18, 2021
022551XXXX	Gerber	Rice Cereal (16oz)	94.9	May 24, 2021

<https://oversight.house.gov/sites/democrats.oversight.house.gov/files/2021-02-04%20ECP%20Baby%20Food%20Staff%20Report.pdf> (emphasis added).

²¹ Alaska State Environmental Health Laboratory, *Analytical Reports* (May 6, 2021, to June 3, 2021) (online at https://oversight.house.gov/sites/democrats.oversight.house.gov/files/Test_Results.pdf).

²² Baby Food Safety Act of 2021, H.R. 2229.

²³ Alaska State Environmental Health Laboratory, *Analytical Reports* (May 6, 2021 to June 3, 2021) (online at https://oversight.house.gov/sites/democrats.oversight.house.gov/files/Test_Results.pdf).

021851XXXX	Gerber	Rice Cereal (8oz)	93.8	May 24, 2021
034451XXXX	Gerber	Rice Cereal (16oz)	93.1	May 6, 2021
027651XXXX	Gerber	Rice Cereal (16oz)	92.3	May 6, 2021
030851XXXX	Gerber	Rice Cereal (16oz)	90.8	May 24, 2021
102051XXXX	Gerber	Rice Cereal (16oz)	89.5	May 24, 2021
030051XXXX	Gerber	Rice Cereal (16oz)	88.3	May 24, 2021
020451XXXX	Gerber	Rice Cereal (8oz)	87.5	May 24, 2021
102251XXXX	Gerber	Rice Cereal (16oz)	86.7	May 24, 2021
012251XXXX	Gerber	Rice Cereal (8oz)	83.4	May 6, 2021
033851XXXX	Gerber	Rice Cereal (8oz)	83.2	May 18, 2021
030251XXXX	Gerber	Rice Cereal (8oz)	82.7	May 6, 2021
033751XXXX	Gerber	Rice Cereal (8oz)	82.7	May 6, 2021
030451XXXX	Gerber	Rice Cereal (16oz)	82.5	May 24, 2021
030151XXXX	Gerber	Rice Cereal (8oz)	79.5	May 6, 2021
105351XXXX	Gerber	Rice Cereal (16oz)	77.5	May 24, 2021
031751XXXX	Gerber	Rice Cereal (8oz)	76.5	May 18, 2021
102151XXXX	Gerber	Rice Cereal (16oz)	59.1	May 18, 2021
		Average:	87.43	

i. Based on the Similarities Between Gerber's and Beech-Nut's Test Results, and the Identical Reporting Timeline, There Is No Excuse for Gerber's Delay in Recalling Its Dangerous Products.

In May and June 2021, Alaska provided FDA with several batches of testing data on Beech-Nut and Gerber baby foods. Each batch showed that Gerber products presented at least as much danger to babies as Beech-Nut products, however Gerber has taken no action to protect babies that could be harmed by its products.

On May 6, 2021, Alaska provided Beech-Nut Rice Cereal test results to FDA: fifteen samples averaging 67.2 ppb inorganic arsenic, two of which exceeded 100 ppb. The same day, Alaska also provided Gerber Rice Cereal test results to FDA: seven samples averaging 87.8 ppb inorganic arsenic, one of which exceeded 100 ppb.²⁴

On May 18, 2021, Alaska provided Beech-Nut Rice Cereal test results to FDA: two samples averaging 103.1 ppb inorganic arsenic, one of which exceeded 100 ppb. The same day, Alaska also provided Gerber Rice Cereal test results to FDA: four samples averaging 78.45 ppb inorganic arsenic, one of which contained 95 ppb inorganic arsenic.²⁵

On May 24, 2021, Alaska provided Beech-Nut Rice Cereal test results to FDA: eight samples averaging 99.75 ppb inorganic arsenic, five of which exceeded 100 ppb. The same day, Alaska also provided Gerber Rice Cereal test results to FDA: ten samples averaging 90.75 ppb inorganic arsenic, one of which exceeded 100 ppb.²⁶

On June 8, 2021, Beech-Nut announced its action recalling some of its infant rice cereal and discontinuing sales of the product.²⁷ That was 15 days after Alaska's last report. It has been more than 115 days since Alaska's last report, and Gerber has still taken no action.

ii. Despite Its Higher Price Tag, Gerber's Organic Rice Cereal Also Contains Dangerous Inorganic Arsenic Levels, Exceeding Proposed Limits by Four Times, on Average.

Gerber's Organic Rice Cereal also registered dangerous levels of inorganic arsenic. Gerber's organic product tested up to 76 ppb inorganic arsenic and contained, on average, 65.6 ppb inorganic arsenic:²⁸

<u>Product Code</u>	<u>Company</u>	<u>Product</u>	<u>Inorganic Arsenic (ppb)</u>	<u>Date Reported to FDA</u>

²⁴ Alaska State Environmental Health Laboratory, *Analytical Reports* (May 6, 2021, to June 3, 2021) (online at https://oversight.house.gov/sites/democrats.oversight.house.gov/files/Test_Results.pdf); Email from Staff, Alaska State Environmental Health Laboratory, to Staff, Subcommittee on Economic and Consumer Policy, Committee on Oversight and Reform (June 28, 2021) (online at <https://oversight.house.gov/sites/democrats.oversight.house.gov/files/Alaska%20Email%20re%20Report%20Timelines.pdf>).

²⁵ *Id.*

²⁶ *Id.*

²⁷ Food and Drug Administration, *Company Announcement: Beech-Nut Nutrition Company Issues a Voluntary Recall of One Lot of Beech-Nut Single Grain Rice Cereal and Also Decides to Exit the Rice Cereal Segment* (June 8, 2021) (online at www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/beech-nut-nutrition-company-issues-voluntary-recall-one-lot-beech-nut-single-grain-rice-cereal-and).

²⁸ Alaska State Environmental Health Laboratory, *Analytical Reports* (May 6, 2021, to June 3, 2021) (online at https://oversight.house.gov/sites/democrats.oversight.house.gov/files/Test_Results.pdf).

015515912	Gerber	Organic Rice Cereal (8 oz)	76	May 18, 2021
0154515912	Gerber	Organic Rice Cereal (8 oz)	69.2	May 18, 2021
0072515912	Gerber	Organic Rice Cereal (8 oz)	63.3	May 18, 2021
0260515912	Gerber	Organic Rice Cereal (8 oz)	53.9	May 18, 2021
		Average:	65.6	

Despite these dangerous levels of inorganic arsenic, Gerber charges consumers 36.4% more for its organic offering than for its standard offering.²⁹



ORGANIC SINGLE-GRAIN CEREAL

Rice

8 oz Container (Pack of 6)

★★★★☆

\$22.49



SINGLE GRAIN CEREAL

Rice

8 oz Container (Pack of 6)

★★★★☆

\$16.49

²⁹ Gerber, Company Website, Search Results for “Rice Cereal” (online at www.gerber.com/catalogsearch/result/?q=rice+cereal) (accessed Sept. 2, 2021).

iii. **Another Gerber Rice Cereal Product Tested (Probiotic Rice Banana Apple Cereal) Is Equally Concerning.**

One other Gerber rice cereal product was tested by Alaska: probiotic rice banana apple cereal. It contained 62.9 ppb inorganic arsenic.³⁰ This is over four times the inorganic arsenic limit for cereal proposed in the Baby Food Safety Act.³¹

<u>Product Code</u>	<u>Company</u>	<u>Product</u>	<u>Inorganic Arsenic (ppb)</u>	<u>Date Reported to FDA</u>
032551XXXX	Gerber	Probiotic Rice Banana Apple Cereal (8 oz)	62.9	May 6, 2021

II. **THE TESTING PRACTICES FOR TOXIC HEAVY METALS USED BY MOST OF THE BABY FOOD INDUSTRY ARE FLAWED AND UNDERESTIMATE THE TOXIC HEAVY METAL CONTENT OF ITS PRODUCTS.**

On February 4, 2021, the Subcommittee issued a staff report that found that industry practice of testing the ingredients in baby foods, as opposed to testing finished baby food products, understates the toxic heavy metal levels in baby foods and exposes babies to dangerous levels of toxic heavy metals. The majority of the baby food industry, including Beech-Nut, followed the ingredient-testing method. After testing ingredients, the companies make estimates of the levels of toxic heavy metals that their baby foods might contain. The Subcommittee made public an internal assessment conducted by Hain, the maker of Earth's Best Organic, that found that the company's estimates underestimate toxic heavy metal levels 100% of the time. A comparison of company estimates to the results of actual finished-product testing shows that inorganic arsenic was between 28% and 93% higher in the finished products than in industry's guesses based on ingredient testing.³²

The Subcommittee recommended that baby food manufacturers, such as Beech-Nut, should be required to test their **finished products** for toxic heavy metals, not just their ingredients.³³

³⁰ Alaska State Environmental Health Laboratory, *Analytical Reports* (May 6, 2021, to June 3, 2021) (online at https://oversight.house.gov/sites/democrats.oversight.house.gov/files/Test_Results.pdf).

³¹ Baby Food Safety Act of 2021, H.R. 2229.

³² Staff Report, Subcommittee on Economic and Consumer Policy, Committee on Oversight and Reform, *Baby Foods Are Tainted with Dangerous Levels of Arsenic, Lead, Cadmium, and Mercury* (Feb. 4, 2021) (online at <https://oversight.house.gov/sites/democrats.oversight.house.gov/files/2021-02-04%20ECP%20Baby%20Food%20Staff%20Report.pdf>).

³³ *Id.*

A. The Beech-Nut Recall Provides Further Evidence that Baby Food Companies Must Be Required to Test Their Finished Products for Toxic Heavy Metals; the Industry Practice of Testing Only Ingredients Leads to Underreporting of Heavy Metal Content.

Beech-Nut failed to heed the Subcommittee's recommendation. As a result of the company's willful disregard for safety, infant rice cereal containing up to 125 ppb inorganic arsenic was found on the market by the State of Alaska and was recalled by Beech-Nut *four months after the Subcommittee's warning*.

In announcing the recall, Beech-Nut made clear that its ingredient-testing method is insufficient. Beech-Nut's Vice President of Food Safety and Quality, Jason Jacobs, stated:

We are issuing this voluntary recall, because we learned through routine sampling by the State of Alaska that a limited quantity of Beech-Nut Single Grain Rice Cereal products had levels of naturally-occurring inorganic arsenic above the FDA guidance level, *even though the rice flour used to produce these products tested below the FDA guidance level for inorganic arsenic*.³⁴

In other words, Beech-Nut had tested the ingredients and failed to detect a problem. It did not test its finished product. When Alaska tested Beech-Nut's finished product, it found inorganic arsenic in excess of FDA's 100 ppb limit. Beech-Nut's ingredient testing underreported toxic heavy metal levels and endangered babies.

B. Sprout Only Requires Toxic Heavy Metal Testing of Its Ingredients Once per Year, the Most Reckless Testing Practice Among Manufacturers on the Market.

Sprout Foods, Inc., which is now owned by Neptune Wellness Solutions, a Canadian cannabis company, also follows the ingredient-testing method. It relies on its ingredient suppliers to test their ingredients for toxic heavy metals and only asks them to do so *once per year*. In an April 30, 2021, letter to the Subcommittee, Sprout stated that "Sprout's current policy requires annual heavy metal testing by its suppliers." In explaining why it could only provide 11 toxic heavy metal test results, it stated that "[b]ecause Sprout requires annual testing for heavy metals for its ingredients, rather than by lot, Sprout is unable to provide testing information for each lot as requested."³⁵

Based on the Subcommittee's study of the baby food industry, the testing practices of Sprout appear to be the most reckless among baby foods sellers on the market. For comparison,

³⁴ Food and Drug Administration, *Company Announcement: Beech-Nut Nutrition Company Issues a Voluntary Recall of One Lot of Beech-Nut Single Grain Rice Cereal and Also Decides to Exit the Rice Cereal Segment* (June 8, 2021) (online at www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/beech-nut-nutrition-company-issues-voluntary-recall-one-lot-beech-nut-single-grain-rice-cereal-and) (emphasis added).

³⁵ Letter from Counsel for Sprout Foods, Inc., to Chairman Raja Krishnamoorthi, Subcommittee on Economic and Consumer Policy, Committee on Oversight and Reform (Apr. 30, 2021) (online at https://oversight.house.gov/sites/democrats.oversight.house.gov/files/Sprout%20Letter%204.30.21_Redacted.pdf).

Beech-Nut tested its ingredients 1,745 times between September 2016 and November 2019, including 807 tests of a single ingredient: pears.³⁶

III. PLUM ORGANICS' OWN TESTS SHOW THAT ITS BABY FOODS ARE TAINTED WITH HIGH LEVELS OF TOXIC HEAVY METALS

Internal company test results obtained by the Subcommittee confirm that Plum Organics sold baby foods tainted by high levels of toxic heavy metals.

A. Arsenic: All of Plum's Super Puffs Tested Between 200 ppb and 470 ppb Arsenic and Contained an Average of 79 ppb Inorganic Arsenic

FDA has not yet set a standard for inorganic arsenic for all baby foods. The only standard FDA has set is a limit of 100 ppb on inorganic arsenic in infant rice cereal,³⁷ even though a product containing 100 ppb is dangerous to infant neurological development. The limit was set at its current high value because FDA was focused on protecting children only from cancer, not from neurological impacts. As part of its "Closer to Zero" program, FDA is in the process of lowering the limit.

FDA has set a more appropriate maximum inorganic arsenic level of 10 ppb for bottled water.³⁸ The Environmental Protection Agency (EPA) has similarly set a 10 ppb inorganic arsenic cap on drinking water, as have the European Union and the World Health Organization.³⁹

The Baby Food Safety Act, H.R. 2229, would set a 10 ppb inorganic arsenic cap on baby food and a 15 ppb inorganic arsenic cap on infant cereal.⁴⁰

³⁶ Beech-Nut, Raw Material Heavy Metal Testing (Dec. 6, 2019) (online at <http://oversight.house.gov/sites/democrats.oversight.house.gov/files/4.xlsx>).

³⁷ Food and Drug Administration, *Guidance for Industry: Action Level for Inorganic Arsenic in Rice Cereals for Infants* (Aug. 2020) (online at www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-action-level-inorganic-arsenic-rice-cereals-infants).

³⁸ Food and Drug Administration, *Arsenic in Food and Dietary Supplements* (online at www.fda.gov/food/metals-and-your-food/arsenic-food-and-dietary-supplements) (accessed Sept. 2, 2021).

³⁹ Environmental Protection Agency, *Drinking Water Requirements for States and Public Water Systems* (online at www.epa.gov/dwreginfo/chemical-contaminant-rules) (accessed Sept. 2, 2021); European Food Information Council, *Arsenic (Q&A)* (online at www.eufic.org/en/food-safety/article/arsenic-qa) (accessed Sept. 2, 2021); World Health Organization, *Arsenic* (Feb. 15, 2018) (online at www.who.int/news-room/fact-sheets/detail/arsenic).

⁴⁰ Baby Food Safety Act of 2021, H.R. 2229.



Plum tested its Super Puffs products 19 times between October 28, 2017, and the present.⁴¹

Reference Criteria				FDA 100 ppb inorganic arsenic limit for rice cereal and/or EU 300 ppb for rice crackers **
Product Name	Testing Date	Serving size in grams	Total ppb Arsenic (As)	ppb Arsenic (inorganic)
Plum Organics® Super Puffs® Apple with Spinach, 1.5oz	10/28/2017	7	201	53
Plum Organics® Super Puffs® Mango with Sweet Potato, 1.5oz	10/28/2017	7	222	52
Plum Organics® Super Puffs® Blueberry with Purple Sweet Potato, 1.5oz	10/28/2017	7	218	49
Plum Organics® Super Puffs® Strawberry with Beet, 1.5oz	10/29/2017	7	228	62
Plum Organics® Super Puffs® Apple with Spinach, 1.5oz	3/16/2018	7	243	61
Plum Organics® Super Puffs® Apple with Spinach, 1.5oz	3/16/2018	7	462	80
Plum Organics® Super Puffs® Apple with Spinach, 1.5oz	3/16/2018	7	384	85
Plum Organics® Super Puffs® Blueberry with Purple Sweet Potato, 1.5oz	3/16/2018	7	245	63
Plum Organics® Super Puffs® Blueberry with Purple Sweet Potato, 1.5oz	3/16/2018	7	277	70
Plum Organics® Super Puffs® Blueberry with Purple Sweet Potato, 1.5oz	3/16/2018	7	422	83
Plum Organics® Super Puffs® Blueberry with Purple Sweet Potato, 1.5oz	3/16/2018	7	389	89
Plum Organics® Super Puffs® Blueberry with Purple Sweet Potato, 1.5oz	3/16/2018	7	470	86
Plum Organics® Super Puffs® Mango with Sweet Potato, 1.5oz	3/16/2018	7	246	62
Plum Organics® Super Puffs® Mango with Sweet Potato, 1.5oz	3/16/2018	7	456	83
Plum Organics® Super Puffs® Mango with Sweet Potato, 1.5oz	3/16/2018	7	388	85
Plum Organics® Super Puffs® Strawberry with Beet, 1.5oz	3/16/2018	7	217	57
Plum Organics® Super Puffs® Strawberry with Beet, 1.5oz	3/16/2018	7	468	83
Plum Organics® Super Puffs® Strawberry with Beet, 1.5oz	3/16/2018	7	410	74
Plum Organics® Super Puffs® Strawberry with Beet, 1.5oz	10/29/2017	7	225	not speciated

Every test returned high levels of total arsenic, each in excess of 200 ppb arsenic, including six that tested over 400 ppb (470, 468, 462, 456, 422, and 410 ppb).⁴²

According to Plum, it initially tests for total arsenic, and “[w]here total ppb is less than the more stringent FDA standard of 100 ppb, we do not speciate” (i.e., check for inorganic arsenic).⁴³ Each of the Super Puffs products were far in excess of 100 ppb arsenic, causing Plum to test 18 of the 19 samples for inorganic arsenic. Once speciated, the average amount of

⁴¹ Plum Organics, Baby Food Product Testing Results (2017–2019) (online at <https://oversight.house.gov/sites/democrats.oversight.house.gov/files/Plum%20Organics%20Test%20Results.pdf>).

⁴² *Id.*

⁴³ *Id.*

inorganic arsenic in those products was 79 ppb inorganic arsenic, nearly eight times the amount FDA allows in bottled water.⁴⁴

According to Plum Organics' own testing, 100% of its puff products exceeded 200 ppb total arsenic. Its average puff product had 233.74 ppb arsenic. Its worst puff product contained 470 ppb arsenic.

B. Lead: Most Plum Baby Foods Contain in Excess of 5 ppb Lead, with Some Containing up to 73 ppb Lead.

There is no federal standard for lead in baby food. However, FDA has set a 5 ppb lead standard for bottled water.⁴⁵ The Baby Food Safety Act, H.R. 2229, would set a 5 ppb lead cap on baby food, and a 10 ppb lead cap on infant cereal.⁴⁶

The Subcommittee's investigation has found that the majority of Plum's baby food products—54.5%—contain in excess of 5 ppb lead, with 25.8% of products containing over 10 ppb lead. Certain Plum products tested up to 73 ppb lead.⁴⁷

*Excerpted Results from Plum's Testing Data*⁴⁸

<u>Product Name</u>	<u>Testing Date</u>	<u>Lead Level (ppb)</u>
Plum Organics Mighty Morning Bar Blueberry Lemon, 4.02oz (Pack of 5)	September 25, 2019	73
Plum Organics Super Puffs Mango with Sweet Potato, 1.5oz	March 16, 2018	49
Plum Organics Super Puffs Strawberry with Beet, 1.5oz	March 16, 2018	48
Plum Organics Mighty Sticks Apple Carrot, 2.1oz	October 28, 2017	43
Plum Organics Teensy Snacks Berry, 1.75oz	October 29, 2017	35
Plum Organics Super Puffs Apple with Spinach, 1.5oz	March 16, 2018	31
Plum Organics Grow Well Tummy, 3.5oz	October 29, 2017	31
Plum Organics Grow Well Muscle, 3.5oz	October 29, 2017	29

⁴⁴ *Id.*

⁴⁵ *Id.*

⁴⁶ Baby Food Safety Act of 2021, H.R. 2229.

⁴⁷ Plum Organics, Baby Food Product Testing Results (2017–2019) (online at <https://oversight.house.gov/sites/democrats.oversight.house.gov/files/Plum%20Organics%20Test%20Results.pdf>).

⁴⁸ *Id.* (Showing test results exceeding 25 ppb lead).

Plum Organics Little Teethers Blueberry, 3.17oz (Pack of 6)	October 28, 2017	29
Plum Organics Mighty Snack Bars Strawberry, 4.02oz (Pack of 6)	October 29, 2017	29
Plum Organics Super Puffs Blueberry with Purple Sweet Potato, 1.5oz	March 16, 2018	28

C. Cadmium: Almost 40% of Plum Baby Foods Contain in Excess of 5 ppb Cadmium, with Some Containing up to 43 ppb Cadmium.

EPA limits the level of cadmium permitted in drinking water to 5 ppb, and FDA has set a limit of 5 ppb in bottled water.⁴⁹ The Baby Food Safety Act would set a 5 ppb cadmium cap on baby food and a 10 ppb cadmium cap on infant cereal.⁵⁰

The Subcommittee found that Plum sold many products with much higher cadmium contents: 38.3% of Plum products tested—80 of 209 products—exceeded 5 ppb cadmium. Seven of the products tested exceeded 25 ppb cadmium. One product contained 43 ppb cadmium: Plum Organics Mighty Morning Bar Apple Cinnamon, 4.02oz (Pack of 5).⁵¹

IV. WALMART CHANGED LONG-STANDING POLICY, RESULTING IN A QUADRUPLING IN THE LEVEL OF ARSENIC ALLOWED IN ITS BABY FOOD. WALMART DOES NOT TEST ITS OWN BABY FOOD FOR HEAVY METALS.

Prior to the issuance of the Subcommittee’s February 4, 2021, staff report, Walmart had failed to produce any documents showing its internal testing policies, its testing results, or how Walmart treats ingredients or products that surpass any internal standards.

After the Subcommittee issued its staff report, Walmart provided information on its internal heavy metal standards. The results are troubling.

Walmart does not appear to conduct any testing of its baby food products for toxic heavy metals. Instead, it sets maximum toxic heavy metal levels and asks the manufacturer of Walmart’s private label to self-certify that products meet those levels. It does not appear that Walmart collects any test data on the toxic heavy metal levels of its baby foods to check the accuracy of the certifications. In a February 25, 2021, letter to the Subcommittee, Walmart stated, “we do not require our private brand suppliers (or their suppliers of raw materials) to

⁴⁹ Environmental Protection Agency, *Ground Water and Drinking Water* (online at www.epa.gov/ground-water-and-drinking-water/national-primary-drinking-water-regulations) (accessed Jan. 26, 2021); 21 C.F.R. § 165 (2019).

⁵⁰ Baby Food Safety Act of 2021, H.R. 2229.

⁵¹ Plum Organics, Baby Food Product Testing Results (2017–2019) (online at <https://oversight.house.gov/sites/democrats.oversight.house.gov/files/Plum%20Organics%20Test%20Results.pdf>).

submit all test reports or test results to our Company in the ordinary course of business.” Instead, it asks them to self-certify that they “meet the finished good specifications, including for heavy metals in baby foods, that Walmart establishes.”⁵² While Walmart’s statement implies that it might see some test results, that does not appear to be the case. The Subcommittee requested all toxic heavy metal test data but received none.

A. In 2018, Walmart More than Quadrupled Its Allowable Limit of Inorganic Arsenic in Its Baby Foods, from 23 ppb to 100 ppb Inorganic Arsenic.

In its February 25, 2021, letter to the Subcommittee, Walmart explained:

In the absence of guidance from FDA on these other types of baby food products, Walmart’s Food Safety and Compliance team, working with a third-party microbiology expert in food safety, has independently established heavy metal limits by category of infant and baby food.

According to Walmart, these toxic heavy metal limits are “included in the finished goods specifications which Walmart’s baby food suppliers are required to meet.”⁵³

Prior to September 14, 2012, Walmart’s internal standard for arsenic in rice cereal, oatmeal cereal, and puffed grains was 100 ppb arsenic.⁵⁴ On that date, Walmart created a more protective standard, allowing no more than 23 ppb arsenic in its rice cereal, oatmeal cereal, and puffed grains.⁵⁵

Chemical Properties* (Chemical properties required by the Walmart Quality & Product Development teams, not listed below, must also be met)					
Property Analysis Type	Method Reference	n	Accept (m)	Reject (M)	Frequency
Arsenic ¹	EPA Method 200.8	3	<23 ppb	≥23 ppb	Per lot
Lead ¹	AOAC 982.27	3	<50 ppb	≥50 ppb	Per lot
Melamine ²	FDA LIB 4423	3	<0.25 ppm	≥0.25 ppm	Per lot
Sulfite ³	AOAC 990.28	3	<10 ppm	≥10 ppm	Per lot

¹Required for products that contain juice or nectars (fresh or from concentrate) from apples, pears, grapes, apple sauce or pear puree
²Required only for products containing gluten or milk powder ingredients sourced from China
³Required for all products containing dried fruit

WHERE:
n = Number of sample units to be tested
m = Maximum number of bacteria that are allowable in this product
c = Maximum number of samples which may have bacterial concentrations between m and M (Marginal samples)
M = Maximum contaminated levels allowable in any one sample. No sample may exceed this value

⁵² Letter from Scott Morris, Senior Vice President, Food/Consumables—Private Brands, Walmart, to Chairman Raja Krishnamoorthi, Subcommittee on Economic and Consumer Policy, Committee on Oversight and Reform (Feb. 25, 2021) (online at <https://oversight.house.gov/sites/democrats.oversight.house.gov/files/Walmart%20Letter%202.25.21.pdf>).

⁵³ *Id.*

⁵⁴ Walmart, Food Safety Guidelines, Infant Dry Food (Jan. 14, 2011) (online at https://oversight.house.gov/sites/democrats.oversight.house.gov/files/Walmart-ECP-0000003_Redacted.pdf).

⁵⁵ Walmart, Food Safety Guidelines, Infant/Adult Nutrition—Infant Dry Foods (Sept. 14, 2012) (online at https://oversight.house.gov/sites/democrats.oversight.house.gov/files/Walmart-ECP-0000004_Redacted.pdf).

Walmart kept in place this more-protective 23 ppb arsenic standard for six years. However, in 2018, Walmart abandoned this protection and began subjecting babies to more dangerous levels of toxic heavy metals. On December 20, 2018, Walmart loosened its standards, allowing more than quadruple the previous amount of arsenic in rice cereal, oatmeal cereal, and puffed grains—moving from 23 ppb to 100 ppb.⁵⁶ This was a drastic retreat in safety standards.

CHEMICAL PROPERTIES*						
(Additional chemical properties required by the Walmart/Sam's Club Product Development team, not listed below, must also be met)						
Property Analysis Type	Method Reference	n	UOM	Accept (m)	Reject (M)	Frequency
Inorganic Arsenic	AOAC 2013.06 (SMPR 2015.006)	3	ppb	≤100	>100	Per Lot
Lead ²	AOAC 982.27	3	ppb	≤50	>50	Per Lot
Melamine, Ammeline, Ammelide, Cyanuric Acid ³	FDA LIB 4423	3	ppm	≤0.25	>0.25	Per Lot
Sulfites ⁴	AOAC 990.28	3	ppm	≤10	>10	Per Lot

² Required testing for products that contain juice or nectars (fresh or from concentrate) from apples, pears, grapes, applesauce, or pear puree.

³ Required testing for all products containing glutens or milk powder ingredients sourced from China. Test limits are total for melamine and all metabolites.

⁴ Required testing for all products containing dried fruit.

WHERE:
n = Number of sample units to be tested
m = Maximum number of bacteria that are allowable in this product (acceptable)
M = Maximum contaminated levels allowable in any one sample. No sample may exceed this value.
c = Maximum number of samples which may have bacterial concentrations between m and M (marginal samples)

Walmart's retreat from safety does not appear to have been caused by FDA's adoption of a 100 ppb limit for inorganic arsenic in infant rice cereal: the timeline does not match. Walmart began using a 23 ppb arsenic standard on September 14, 2012. FDA's draft guidance, allowing up to 100 ppb inorganic arsenic in infant rice cereal, came three and a half years later: April 6, 2016. For the next two years, Walmart kept its standard at 23 ppb, well below the FDA's lax guidance. Then on December 20, 2018, Walmart quadrupled its arsenic standard, loosening protections all the way up to FDA's ill-advised 100 ppb standard. FDA did not finalize its guidance until 2020, so that was not the reason for Walmart's retreat from safety.⁵⁷

Walmart does not have any standards for cadmium or mercury and does not require any cadmium or mercury testing.⁵⁸

⁵⁶ Walmart, Food Safety Guidelines, Infant/Adult Nutrition—Infant Dry Foods (Dec. 20, 2018) (online at https://oversight.house.gov/sites/democrats.oversight.house.gov/files/WM-ECP-0000009_Redacted.pdf).

⁵⁷ Food and Drug Administration, *Guidance for Industry: Action Level for Inorganic Arsenic in Rice Cereals for Infants* (Aug. 2020) (online at www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-action-level-inorganic-arsenic-rice-cereals-infants).

⁵⁸ Letter from Scott Morris, Senior Vice President, Food/Consumables—Private Brands, Walmart, to Chairman Raja Krishnamoorthi, Subcommittee on Economic and Consumer Policy, Committee on Oversight and Reform (Feb. 25, 2021) (online at <https://oversight.house.gov/sites/democrats.oversight.house.gov/files/Walmart%20Letter%202.25.21.pdf>).

V. FDA’S “CLOSER TO ZERO” PROGRAM, CREATED IN RESPONSE TO THE SUBCOMMITTEE’S REPORT, MUST ACCELERATE ITS TIMELINES FOR DEVELOPING TOXIC HEAVY METAL LIMITS AND REQUIRE BABY FOOD COMPANIES TO TEST THEIR FINISHED PRODUCTS, NOT JUST THEIR INGREDIENTS.

Following the Subcommittee’s February 4, 2021, staff report, FDA has worked quickly to address the deficiencies and dangers it raised. Within two weeks of the staff report, on February 16, 2021, FDA issued a Constituent Update entitled “FDA Response to Questions About Levels of Toxic Elements in Baby Food, Following Congressional Report,” stating that the goal should be “to reduce exposure to toxic elements in foods to the greatest extent feasible.”⁵⁹ On April 8, 2021, FDA announced the creation of the “Closer to Zero” program. Closer to Zero set timelines by which FDA would establish maximum levels for lead, inorganic arsenic, cadmium, and mercury.⁶⁰

FDA has made Closer to Zero a commissioner-level priority. FDA staff has provided Subcommittee staff with regular progress updates on the program. The Subcommittee commends the progress being made.

However, Closer to Zero’s timelines are far too slow. FDA has committed to the following:

- Lead: publishing a draft lead limit by April 2022 and a final lead limit by April 2024;
- Arsenic: publishing a draft arsenic limit by April 2022 and a final arsenic limit in a time period designated as “April 2024–beyond”; and
- Cadmium and Mercury: publishing draft cadmium and mercury limits in the time period designated as “April 2024–beyond.”⁶¹

The Subcommittee recommends that FDA:

- **Issue Toxic Heavy Metal Levels Sooner**: The recent Beech-Nut and Gerber test results show the need for action now. If baby food safety is truly a commissioner-level priority, FDA can show that by issuing an update to Closer to Zero’s proposed timelines for publishing draft and final limits for lead, arsenic, cadmium, and mercury.

⁵⁹ Food and Drug Administration, *FDA Response to Questions About Levels of Toxic Elements in Baby Food, Following Congressional Report* (Feb. 14, 2021) (online at www.fda.gov/food/cfsan-constituent-updates/fda-response-questions-about-levels-toxic-elements-baby-food-following-congressional-report).

⁶⁰ Food and Drug Administration, *Closer to Zero: Action Plan for Baby Foods* (Apr. 8, 2021) (online at www.fda.gov/food/metals-and-your-food/closer-zero-action-plan-baby-foods#action-items-timeline).

⁶¹ *Id.*

- **Mandate Finished-Product Testing:** The Subcommittee's staff reports have demonstrated the clear danger in allowing industry to test only its ingredients and not its finished products for toxic heavy metals. Ingredient testing regularly leads to underestimation of toxic heavy metal levels. Baby food manufacturers should be required by FDA to test their finished products for toxic heavy metals, not just their ingredients.

VI. RECOMMENDATIONS TO INDUSTRY

The Subcommittee recommends the following:

- **Finished-Product Testing:** If FDA does not require manufacturers to test their finished products for toxic heavy metals instead of testing only ingredients, then industry should take that action voluntarily. This is an easy step toward rebuilding public trust in their products.
- **Voluntary Phase-Out of Toxic Ingredients:** Manufacturers should voluntarily find substitutes for ingredients that are high in toxic heavy metals or phase out products that have high amounts of ingredients that frequently test high in toxic heavy metals, such as rice.

VII. CONCLUSION

The Subcommittee's investigation continues to reveal that commercial baby foods contain dangerous levels of arsenic, lead, mercury, and cadmium. These toxic heavy metals pose serious health risks to babies and toddlers. Manufacturers knowingly sell these products to unsuspecting parents, in spite of internal company standards and test results, and without any warning label.

We encourage FDA to move expeditiously to set limits for arsenic, lead, cadmium, and mercury in baby foods.