

**UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF NEW YORK**

LAURA PEEK, Individually and on Behalf
of All Others Similarly Situated,

Plaintiff,

v.

BEECH-NUT NUTRITION COMPANY,

Defendant.

Case No. 1:21-cv-0167 (TJM/ML)

CLASS ACTION COMPLAINT

DEMAND FOR JURY TRIAL

1. Plaintiff Laura Peek (“Plaintiff”), individually and on behalf of all others similarly situated, by and through her undersigned attorneys, brings this Class Action Complaint against Defendant Beech-Nut Nutrition Company (“Beech-Nut” or “Defendant”), for its negligent, reckless, and/or intentional practice of misrepresenting and failing to fully disclose the presence (or material risk of) heavy metals in its baby food sold throughout the United States. Plaintiff seeks both injunctive and monetary relief on behalf of the proposed Class (as defined herein), including requiring full disclosure of all such substances in its marketing, advertising, and labeling and restoring monies to the members of the proposed Class. Plaintiff alleges the following based upon personal knowledge as well as investigation by her counsel, and as to all other matters, upon information and belief (Plaintiff believes that substantial evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery).

NATURE OF THE ACTION

2. Parents like Plaintiff trust manufacturers like Defendant to sell baby food that is safe, nutritious, and free from harmful toxins, contaminants, and chemicals. They certainly expect

the food they feed their infants and toddlers to be free from Heavy Metals and Perchlorate, substances known to have significant and dangerous health consequences.¹

3. Consumers lack the scientific knowledge necessary to determine whether the Defendant's products do in fact contain (or have a material risk of) Heavy Metals and Perchlorate or to know or ascertain the true nature of the ingredients and quality of the Products. Reasonable consumers therefore must and do rely on Defendant to honestly report what its products contain.

4. A recent report by the U.S. House of Representatives' Subcommittee on Economic and Consumer Policy, Committee on Oversight and Reform reveals that parents' trust has been violated (the "Subcommittee's investigation"). Ex. 1. The Subcommittee's investigation of the seven largest baby food manufacturers in the United States, including Defendant, was spurred by "reports alleging high levels of toxic heavy metals in baby foods" and the knowledge that "[e]ven low levels of exposure can cause serious and often irreversible damage to brain development." Ex. 1 at 2.

5. As the Subcommittee noted, its investigation disclosed Defendant's "reckless disregard for the health of babies." *Id.* at 43.

6. Defendant knows that its customers trust the quality of its products and that they expect Defendant's products to be free of Heavy Metals and Perchlorate. It also knows that certain consumers seek out and wish to purchase premium baby foods that possess high quality ingredients free of toxins, contaminants, or chemicals and that these consumers will pay more for baby foods they believe possess these qualities than for baby foods they do not believe possess these qualities.

7. As such, Defendant's promises, warranties, pricing, statements, claims, packaging, labeling, marketing, advertising, and material nondisclosures (hereinafter collectively referred to

¹ As used herein, the phrase "Heavy Metals" is defined as arsenic, cadmium, lead, and mercury.

as “Marketing” or “Claims”) (hereinafter collectively referred to as “Marketing” or “Claims”) center on representations and pictures that are intended to, and do, convey to consumers that their baby food, including its Contaminated Baby Foods,² possess certain qualities and characteristics that justify a premium price.

8. No reasonable consumer seeing Defendant’s Marketing would expect the Contaminated Baby Foods to contain Heavy Metals, Perchlorate, or other undesirable toxins or contaminants. Furthermore, reasonable consumers, like Plaintiff, would consider the mere inclusion of Heavy Metals, Perchlorate, or other undesirable toxins or contaminants a material fact when considering what baby food to purchase.

9. Defendant intended for consumers to rely on its Marketing, and reasonable consumers did in fact so rely. However, Defendant’s Marketing is deceptive, misleading, unfair, and/or false because, among other things, the Contaminated Baby Foods include undisclosed Heavy Metals, Perchlorate, or other undesirable toxins or contaminants.

10. Defendant’s Contaminated Baby Foods do not have a disclaimer regarding the presence of Heavy Metals or other undesirable toxins or contaminants that would inform consumers that the Contaminated Baby Food contain Heavy Metals and Perchlorate and/or that Heavy Metals and Perchlorate can accumulate over time in a child’s body to the point where poisoning, injury, and/or disease can occur.

² The phrase “Contaminated Baby Foods” collectively refers to products sold under the “Beech-Nut Naturals,” “Beech-Nut Organics,” and “Beech-Nut” brands, including but not limited to the products listed in paragraph 20. These products include purees of fruit, vegetables, meat broths, cereals, fruit and vegetable purees, bars, crisps, and dissolving snacks marketed as “melties.” Plaintiff reserves her right to include in this action any products sold by Defendant deemed to contain Heavy Metals and Perchlorate following discovery.

11. Defendant's wrongful Marketing, which includes misleading, deceptive, unfair, and false Marketing and omissions, allowed it to capitalize on, and reap enormous profits from, consumers who paid the purchase price or a price premium for Contaminated Baby Food that was not sold as advertised. And Defendant continues to wrongfully induce consumers to purchase its Contaminated Baby Food that are not as advertised.

12. Plaintiff brings this proposed consumer class action individually and on behalf of all other members of the Class (as defined herein) who, from the applicable limitations period up to and including the present, purchased for use and not resale any of Defendant's Contaminated Baby Foods.

JURISDICTION AND VENUE

13. This Court has original jurisdiction over all causes of action asserted herein under the Class Fairness Act, 28 U.S.C. § 1332(d)(2), because the matter in controversy exceeds the sum or value of \$5,000,000 exclusive of interest and costs and more than two-thirds of the Class resides in states other than the state in which Defendant is a citizen and in which this case is filed, and therefore any exemptions to jurisdiction under 28 U.S.C. §1332(d)(2) do not apply.

14. Venue is proper in this Court pursuant to 28 U.S.C. § 1391, because Plaintiff suffered injury as a result of Defendant's acts in this district, many of the acts and transactions giving rise to this action occurred in this district, and Defendant conducts substantial business in this district and is headquartered in this district. Defendant has intentionally availed itself of the laws and markets of this district, and Defendant is subject to personal jurisdiction in this district.

THE PARTIES

15. Plaintiff is, and at all times relevant hereto has been, a citizen of the state of Wisconsin. She purchased the Contaminated Baby Foods, various flavors of Defendant's organic jarred purees, such as the Beech-Nut Organics Banana & Cinnamon & Granola, and of

Defendant's pouches, such as the Beech-Nut Organic Apple, Sweet Potato, Pineapple & Oat, for her children generally from Target. Plaintiff first purchased the Contaminated Baby Foods in approximately 2009 and last purchased the Contaminated Baby Foods in approximately May 2019.

16. Plaintiff believed she was feeding her children healthy, nutritious food during the time she purchased and fed her children the Contaminated Baby Foods. Due to the false and misleading claims and omissions by Defendant, she was unaware the Contaminated Baby Foods contained any level of Heavy Metals or Perchlorate and would not have purchased the food if that information had been fully disclosed.

17. As the result of Defendant's negligent, reckless, and/or knowingly deceptive conduct as alleged herein, Plaintiff was injured when she paid the purchase price or a price premium for the Contaminated Baby Foods that did not deliver what they promised. She paid the purchase price on the assumption that the labeling of the Contaminated Baby Foods was accurate and that it was free of Heavy Metals and Perchlorate and safe to ingest. Plaintiff would not have paid the money had she known that the Contaminated Baby Foods contained excessive degrees of Heavy Metals and Perchlorate. Further, should Plaintiff encounter the Contaminated Baby Foods in the future, she could not rely on the truthfulness of the Marketing, absent corrective changes to the packaging and advertising of the Contaminated Baby Foods. Damages can be calculated through expert testimony at trial.

18. Defendant Beech-Nut Nutrition Company is incorporated in Delaware with its principal place of business located at 1 Nutritious Place, Amsterdam, New York. Defendant formulates, develops, manufactures, labels, distributes, markets, advertises, and sells the Contaminated Baby Foods under the Beech-Nut name throughout the United States. Defendant

created, allowed, negligently oversaw, and/or authorized the unlawful, fraudulent, unfair, misleading, and/or deceptive labeling and advertising for the Contaminated Baby Foods.

19. The Marketing for the Contaminated Baby Foods, relied upon by Plaintiff, was prepared, reviewed, and/or approved by Defendant and its agents at its headquarters in New York and was disseminated by Defendant and its agents through marketing, advertising, packaging, and labeling that contained the misrepresentations alleged herein. The Marketing for the Contaminated Baby Foods was designed to encourage consumers to purchase the Contaminated Baby Foods and reasonably mislead the reasonable consumer, i.e., Plaintiff and the Class members, into purchasing the Contaminated Baby Foods. Moreover, the quality control, manufacturing and packaging of the Contaminated Baby Food occurred in New York as Defendant's production facility was located in New York throughout the Class Period.

20. The Contaminated Baby Foods include all flavor profiles or varieties in the following product lines:

- a) Beech-Nut Naturals® Purees, which includes 24 different types of purees of fruits and vegetables, including:



- b) Beech-Nut® Organics, which includes 16 different types of purees of fruits, vegetables and grains, including:



- c) Beech-Nut® Stage 1 and Stage 2 Purees, which includes 26 different purees of fruit, vegetables, broth, meats and grains, including:



- d) Beech-Nut® Naturals Pouches, which includes 6 types of fruit and vegetable purees sold in squeezable pouch form, including:



- e) Beech-Nut® and Beech-Nut Organics Cereals, which includes 4 types of infant cereal blends under Beech-Nut® and Beech-Nut Organics brand names, including:



- f) Beech-Nut® Fruities, Veggies and Breakfast Pouches, which includes 14 different types of baby food pouches as “Fruities,” “Veggies” and “Breakfast” purees that contain various combinations of fruits, vegetables, and yogurt, including:



- g) Beech-Nut Naturals® Bars, which includes 4 types of toddler snack bars containing combinations of fruit, grain and vegetables under the Beech-Nut Naturals® Brand, including:



- h) Beech-Nut® and Beech-Nut Naturals® “Melties,” which includes 4 types of dissolving baby snacks as “melties” under the Beech-Nut® and Beech-Nut Naturals® brands, including:



- i) Beech-Nut Naturals® Baked Cheese Bites and Baked Veggie Crisps:



FACTUAL ALLEGATIONS

I. A Congressional Investigation Found the Presence of Heavy Metals in Baby Foods

21. On February 4, 2021, the U.S. House of Representatives’ Subcommittee on Economic and Consumer Policy, Committee on Oversight and Reform, published a report

detailing its findings that Heavy Metals—including arsenic, cadmium, lead, and mercury—were present in “significant levels” in numerous commercial baby food products. Ex. 1.

22. Defendant was one of the baby food manufacturers from whom the Subcommittee requested and obtained internal documents and test results. The investigation found the following with respect to heavy metals:

- a) **Arsenic:** Defendant “used ingredients after they tested as high as 913.4 ppb arsenic” and “routinely used high-arsenic additives that tested over 300 ppb arsenic to address product characteristics such as ‘crumb softness.’” *Id.* at 3. “Beech-Nut set internal arsenic and cadmium standards at 3,000 ppb in additives, such as vitamin mix, and 5,000 ppb lead for certain ingredients like BAN 800. These standards are the highest of any responding manufacturer.” *Id.* at 4.
- b) **Lead:** Defendant “used ingredients containing as much as 886.9 ppb lead. It used many ingredients with high lead content, including 483 that contained over 5 ppb lead, 89 that contained over 15 ppb lead, and 57 that contained over 20 ppb lead.” *Id.* “Internal testing data from Gerber, Nurture, **Beech-Nut**, and Hain demonstrate that all four companies sold products or used ingredients with significant amounts of lead. Only Nurture routinely tested its finished product for lead. Hain, **Beech-Nut**, and Gerber did not test their finished products, only their ingredients. All companies, whether they test their final products or merely their ingredients, sold baby foods even when they or their ingredients contained unsafe levels of lead.” Ex. 1 at 22 (emphasis added).
- c) **Cadmium:** Defendant “used 105 ingredients that tested over 20 ppb cadmium. Some tested much higher, up to 344.55 ppb cadmium.” *Id.*

d) **Mercury:** Defendant “do[es] not even test for mercury in baby food.” *Id.* at 4.

23. The investigation found that, when baby food manufacturers were left to self-regulate and establish their own Heavy Metals standards, they routinely failed to abide by their own standards and that the “[i]nternal company standards permit dangerously high levels of toxic heavy metals,” and manufacturers, like Defendant, “have often sold foods that exceeded those levels.” *Id.*

24. Indeed, Defendant’s “standards [were] the highest [i.e., least stringent] of any responding manufacturer.” *Id.*

25. In its conclusion, the Subcommittee stressed the danger associated with the presence of Heavy Metals in baby food: “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 labeling whatsoever.” *Id.* at 58.

II. Perchlorate Presents Additional Serious Risks to Infants and Children

26. Perchlorate “is a rocket fuel component used since the Cold War.”³ The dangers of perchlorate in human food are recognized by the FDA.⁴ It “disrupts thyroid functions crucial to brain development,” yet “[l]evels in children’s food [have] increased dramatically” in recent years.⁵

³ Healthy Babies Bright Futures Report, at 8. Available at: https://www.healthybabyfood.org/sites/healthybabyfoods.org/files/2020-04/BabyFoodReport_ENGLISH_R6.pdf (last visited Feb. 9, 2021).

⁴ FDA, Exploratory Survey Data on Perchlorate in Food 2004-2005, <https://www.fda.gov/food/chemicals/exploratory-survey-data-perchlorate-food-2004-2005>

⁵ Healthy Babies Bright Futures Report, at 8.

27. Test “results suggest a prevalence that could pose risks during pregnancy and infancy.”⁶ One lab “detected it in 19 of 25 foods tested,”⁷ including in food manufactured and sold by Defendant.⁸

Brand	Food	Food type	Arsenic (total, ppb)	Arsenic (inorganic, ppb)	Lead (ppb)	Cadmium (ppb)	Mercury (total, ppb)	Metro area where purchased	Retailer
Infant cereal: rice									
Beech-Nut	Rice Single Grain Baby Cereal - Stage 1, from about 4 months	Cereal - rice	117	86	3.5	5.4	0.582	Charlottesville, VA	Wegmans

Vegetable - single, sweet potato									
Beech-Nut	Naturals Just Sweet Potatoes - Stage 1, from about 4 months	Veggie - single - sweet potato	2.4 *	--	14.1	4	< 0.136	Albany, NY	buybuyBABY
Beech-Nut	Organics Just Sweet Potatoes - Stage 1, from about 4 months	Veggie - single - sweet potato	3.8 *	--	7.3	2.7	< 0.142	Cincinnati, OH	Kroger
Beech-Nut	Classics Sweet Potatoes - Stage 2, from about 6 months	Veggie - single - sweet potato	2.8 *	--	24.1	3.4	< 0.138	Portland, OR	Fred Meyer

28. Despite the presence, or ever increasing risk of presence, of Perchlorate in its Contaminated Baby Foods, the cornerstone of Defendant’s labels and marketing is its “Natural” ingredients. The presence, or risk of presence, of Perchlorate is directly contrary to Defendant’s “Naturals” promise.

III. Defendant Falsely Marketed Its Contaminated Baby Foods as Healthy While Omitting Any Mention of Heavy Metals or Perchlorate

29. Defendant packages, labels, markets, advertises, formulates, manufactures, distributes, and sells its Contaminated Baby Foods throughout the United States, including New York.

30. Defendant is aware that “parents know that what they feed their baby will have a **lifelong** impact” and touts that it is aware of “scientific research” that “confirm[s] those instincts.”⁹

⁶ *Id.*

⁷ *Id.*

⁸ *Id.* at 19, 20.

⁹ <https://www.beechnut.com/blog/baby-eats-now-matters-lot/> (last accessed Feb. 9, 2021).

31. Defendant's uses its trademarked slogan "Real Food For Babies" because Defendant knows that parents desire to serve healthy, uncontaminated food to their infants and children.¹⁰ Defendant repeatedly touts its commitment to and use of organic and non-GMO ingredients in its products, including the Contaminated Baby Foods.

32. While Defendant encourages consumers to "read the front AND the back of the label, so you know exactly what's inside your baby's food,"¹¹ it fails to disclose the inclusion of Heavy Metals or Perchlorate altogether on its packaging.

33. Based on Defendant's decision to advertise, label, and market its Contaminated Baby Foods as appropriate for various "stages" of development, it had a duty to ensure that the statements and messaging portrayed on the labels were true and not misleading.

34. The Contaminated Baby Foods are available at numerous retail and online outlets. The Contaminated Baby Foods are widely advertised, and Defendant even publishes a blog that it links to on its site for "Infant Nutrition." That blog includes the claim: "We know how important it is for parents to feel good about what they feed their babies, so Beech-Nut goes the extra mile."¹²

35. As discussed above, the Marketing of the Contaminated Baby Foods during the Class period also failed to disclose that they contain or are at risk or containing any level of Heavy Metals, Perchlorate, or other undesirable toxins or contaminants. Defendant intentionally omitted these contaminants in order to induce and mislead reasonable consumers to purchase its Contaminated Baby Foods.

¹⁰ <https://www.beechnut.com/> (last accessed Feb. 9, 2021).

¹¹ <https://www.beechnut.com/blog/label-decoder-natural-organic-means-babys-food/> (last accessed Feb. 9, 2021)

¹² <https://www.beechnut.com/blog/label-decoder-natural-organic-means-babys-food/> (last accessed Feb. 9, 2021)

36. Defendant claims that they have been testing their ingredients for Heavy Metals and other contaminants since 1985, are “aware of no higher standards in the industry than [theirs], and that it goes “above and beyond ‘the standard.’”¹³

37. However, Defendant does not test its food for mercury and has among the lowest standards in the industry for lead and cadmium. Ex. 1 at 33, 37-38.

38. As a result of Defendant’s omissions, a reasonable consumer would have no reason to suspect the presence of Heavy Metals or Perchlorate in the Contaminated Baby Foods without conducting his or her own scientific tests or reviewing third party scientific testing of these products.

IV. Defendant’s Marketing Misled and Deceived Consumers

39. Defendant’s Marketing wrongfully conveys to consumers that its Contaminated Baby Foods have certain superior quality and characteristics that they do not actually possess.

40. For instance, although Defendant misleadingly causes consumers to believe its Contaminated Baby Foods do not contain Heavy Metals or Perchlorate through its Marketing and omissions, the Contaminated Baby Foods do in fact contain undisclosed Heavy Metals, which is material information to reasonable consumers.

41. For example, the following foods were tested and found to contain undisclosed Heavy Metals at the following levels:¹⁴

¹³ <https://www.beechnut.com/food-quality-safety/> (last accessed Feb. 9, 2021).

¹⁴ The following chart represents the levels of Heavy Metals in Defendant’s products included in the Healthy Babies Bright Futures Report, dated October 2019. Available at: https://www.healthybabyfood.org/sites/healthybabyfoods.org/files/2020-04/BabyFoodReport_ENGLISH_R6.pdf (last accessed Feb. 8, 2021).

Food	Arsenic (total, ppb)	Arsenic (inorganic, ppb)	Lead (ppb)	Cadmium (ppb)	Mercury (total, ppb)
Rice Single Grain Baby Cereal - Stage 1, from about 4 months	117	86	3.5	5.4	0.582
Classics Sweet Carrots - 2	<2.1	--	27.2 ^{15*}	6.8	0.15
Classics Sweet Carrots - Stage 2	<2.2	--	23.5	8	0.212*
Organics Just Carrots - Stage 1	2.8*	--	1.3*	1.4*	0.142*
Naturals Just Sweet Potatoes - Stage 1, from about 4 months	2.4*	--	14.1	4	0.136
Organics Just Sweet Potatoes - Stage 1, from about 4 months	3.8*	--	7.3*	2.7	<0.142
Classics Sweet Potatoes - Stage 2, from about 6 months	2.8*	--	24.1	3.4	<0.138
Classics Sweet Peas - Stage 2	6.3*	--	1.1*	1.6*	< 0.138
Beechnut Naturals Just Butternut Squash - Stage 1	< 2.2	--	1.3*	1.2*	< 0.139
Organic Just Pumpkin - Stage 1, from about 4 months	2.6*	--	4	1.1*	< 0.139
Organic Just Apples - Stage 1, from about 4 months	< 2	--	< 0.5	< 0.5	< 0.126
Naturals Bananas - Stage 1, from about 4 months	< 2.1	--	< 0.5	< 0.5	< 0.136

¹⁵ An “*” indicates that test results were estimated, between the limit of detection and the limit of quantitation.

Food	Arsenic (total, ppb)	Arsenic (inorganic, ppb)	Lead (ppb)	Cadmium (ppb)	Mercury (total, ppb)
Naturals Beets, Pear & Pomegranate - 2	< 2.2	--	0.9*	4.7	< 0.139
Classics Mixed Vegetables - Stage 2	< 2.2	--	17.9	8.6	< 0.139
Classics Chicken & Chicken Broth - 1	< 2.2	--	< 0.5	< 0.5	< 0.137
Classics Turkey and Turkey Broth - Stage One	< 2	--	1*	< 0.5	< 0.128
Breakfast On-the-Go Yogurt, Banana & Mixed Berry Blend - Stage 4 from about 12 months	< 2.2	--	0.7*	< 0.5	< 0.139

42. Defendant's Marketing wrongfully fails to disclose to consumers the presence of Heavy Metals and Perchlorate in its Contaminated Baby Foods.

43. Based on Defendant's Marketing, a reasonable consumer would not suspect the presence of Heavy Metals or Perchlorate, nor would a reasonable consumer be able to detect the presence of Heavy Metals or Perchlorate in the Contaminated Baby Foods without conducting his or her own scientific tests or reviewing scientific testing conducted on the Products.

44. Reasonable consumers must and do rely on Defendant to honestly report what its Contaminated Baby Foods contain.

45. In light of Defendant's Marketing, including its "comprehensive" quality controls, Defendant knew or should have known the Contaminated Baby Foods contained Heavy Metals and Perchlorate.

46. Defendant intended for consumers to rely on its Marketing, and reasonable consumers did in fact so rely.

47. Defendant had a duty to ensure the Contaminated Baby Foods were as they were represented and not deceptively, misleadingly, unfairly, and falsely marketed.

48. Pursuant to the foregoing, Defendant's Marketing is deceptive, misleading, unfair, and false to Plaintiff and other consumers, including under the consumer protection laws of California.

49. Defendant acted negligently, recklessly, unfairly, and/or intentionally with its deceptive, misleading, unfair, and false Marketing and omissions.

V. Why Defendant's Marketing and Omissions are Misleading

50. At all times during the Class Period, Defendant knew or should have known the Contaminated Baby Foods contained Heavy Metals and Perchlorate and were not sufficiently tested for the presence of Heavy Metals and Perchlorate.

51. Defendant's Contaminated Baby Foods had a risk of containing Heavy Metals and Perchlorate due to Defendant's failure to monitor for their presence in the ingredients and finished products, and Defendant's use of ingredients that exceed its own lax internal guidelines for some Heavy Metals. Defendant was aware of this risk and failed to disclose it to Plaintiff and the Class.

52. Defendant knew that Heavy Metals and Perchlorate are potentially dangerous contaminants that poses health risks to humans.

53. A sampling of raw material sampling shows Defendant utilizes ingredients containing Heavy Metals:

Date	Commodity	Preshipment	Arsenic result (ppb)	Spec.	Cadmium result (ppb)	Spec.	Lead result (ppb)	Spec.	Acceptance (Y/N)
12/20/2017	BAN 800	786	465.20	<3000	6.30	<500	<58	<5000	Y
1/23/2019	ascorbic acid	80	<5	<3000	<1	<3000	<5	<3000	Y
10/7/2017	BAN 800	673	710.90	<3000	8.30	<500	<5	<5000	Y
10/23/2017	BAN 800	712	401.40	<3000	6.10	<500	<5	<5000	Y
2/19/2018	BAN 800	120	382.00	<3000	<5	<500	<5	<5000	Y
6/12/2018	Ban 800	292	353.80	<3000	<5	<500	<5	<5000	Y
3/12/2018	BAN 800	164	29.70	<3000	<5	<500	<5	<5000	Y
2/6/2017	Vitamin Mix	76	106.90	<3000	60.30	<3000	24.6	<10	Y
1/31/2017	Vitamin Mix	72	89.40	<3000	48.20	<3000	18	≤20	Y
10/10/2019	BAN 800	680	91.10	<3000	28.40	<500	7.5	<5000	Y
12/5/2018	ascorbic acid	1084	<5	<3000	<5	<3000	6	<3000	Y
9/4/2019	BAN 800	442	59.70	<3000	11.00	<500	5.8	<5000	Y

54. Defendant knew or should have known that it owed consumers a duty of care to prevent, or at the very least, minimize the presence of Heavy Metals and Perchlorate in the Contaminated Baby Foods to the extent reasonably possible.

55. Defendant knew or should have known it owed consumers a duty of care to adequately test for Heavy Metals and Perchlorate in the Contaminated Baby Foods.

56. Defendant knew consumers purchased the Contaminated Baby Foods based on the reasonable expectation that Defendant manufactured the Contaminated Baby Foods to the highest standards. Based on this expectation, Defendant knew or should have known consumers reasonably inferred that Defendant would hold the Contaminated Baby Foods to the highest standards for preventing the inclusion of Heavy Metals and Perchlorate in the Contaminated Baby Foods and for the Heavy Metals and Perchlorate testing of the ingredients in the Contaminated Baby Foods as well as the final product.

57. Arsenic is an odorless and tasteless element that does not degrade or disappear. Arsenic occurs in the environment and can be found in rocks, soil, water, air, plants, and animals. Inorganic arsenic is highly toxic and a known cause of human cancers. Arsenic exposure can also cause respiratory, gastrointestinal, hematological, hepatic, renal, skin, neurological and

immunological effects, and damage children’s central nervous systems and cognitive development. Ex. 1 at 9-10. Based on the risks associated with exposure to higher levels of arsenic, both the U.S. Environmental Protection Agency (“EPA”) and U.S. Food and Drug Administration (“FDA”) have set limits concerning the allowable limit of arsenic at 10 parts per billion (“ppb”) for human consumption in apple juice (regulated by the FDA) and drinking water (regulating by the EPA).

58. Defendant tests for arsenic contents only in its ingredients, not its final product. Ex. 1 at 17. The Subcommittee’s investigation determined that Defendant “used ingredients containing as much as 913.4 ppb arsenic. Test results show that Beech-Nut used at least fourteen other ingredients containing over 300 ppb arsenic. And it used at least 45 ingredients containing over 100 ppb arsenic.” *Id.*

59. The “six ingredients with the highest arsenic levels—Amylase, Amylase, BAN 800, Alpha Amylase, and Sebamyl 100—are all enzymes that Beech-Nut adds to its products. BAN 800 is an enzyme that reportedly “increases crumb softness” in baked goods. Amylase is an enzyme that is used in bread-making as an additive to improve the conversion of complex sugars into simple sugars.” *Id.* (internal quotations omitted).

60. The Subcommittee’s investigation determined that Defendant’s use of “high-arsenic additives to address issues like crumb softness” are unnecessary. *Id.*

61. The Subcommittee’s investigation also determined that Defendant had the highest internal standard for arsenic levels of any of the responding manufacturers. In fact, Defendant “set an internal specification limit [] of 3,000 ppb inorganic arsenic for certain ingredients, including vitamin mix.” *Id.* at 37. “As a result of adopting this high internal standard, Beech-Nut has used ingredients containing 710.9, 465.2, and 401.4 ppb arsenic.” *Id.* at 37-38.

62. Lead is a carcinogen and developmental toxin known to cause health problems in children such as behavioral problems, decreased cognitive performance, delayed puberty, and reduced postnatal growth. Because lead can build up in the body over time as one is exposed to and/or ingests it, even a low level of chronic exposure can become toxic and seriously injurious to one's health. The FDA has set standards that regulate the maximum parts per billion of lead permissible in water: bottled water cannot contain more than 5 ppb of total lead or 10 ppb of total arsenic. *See* 21 C.F.R. § 165.110(b)(4)(iii)(A).

63. The Subcommittee's investigation found that baby food manufacturers, like Defendant, "are selling baby food with higher levels of lead than what is allowed by existing standards for water, juice, and candy. Internal testing data from [] Beech-Nut [] [it]sold products or used ingredients with significant amounts of lead." Ex. 1 at 22. Further, the Subcommittee's investigation determined that Defendant did not even test its finished product for lead, and "sold baby foods even when they or their ingredients contained unsafe levels of lead." *Id.*

64. Defendant uses ingredients, like cinnamon, that contained as much as 886.9 ppb lead. *Id.* at 23. It also "routinely used ingredients with high lead content," including (a) "57 ingredients that contained over 20 ppb lead," which is the European Union's "lax standard for lead in infant formula," (b) "89 ingredients that contained over 15 ppb lead, [the] EPA's action level of drinking water, and (c) 483 ingredients that contained over 5 ppb lead, the FDA's standard for lead in bottled water." *Id.*

65. The Subcommittee's investigation also determined that Defendant had the highest internal standard for lead levels of any of the responding manufacturers. In fact, Defendant "set internal guidelines of 5,000 ppb for lead for certain ingredients," which "far surpass[es] any

existing regulatory standard in existence and toxic heavy metal levels for any other baby food manufacturer that responded to the Subcommittee’s inquiry.” *Id.* at 37-38.

66. Cadmium is associated with decreases in IQ and the development of ADHD. The U.S. Department of Health and Human Services has determined that cadmium and cadmium compounds are known human carcinogens and the EPA has likewise determined that cadmium is a probable human carcinogen. It has been specifically noted that “Kidney and bone effects have ... been observed in laboratory animals ingesting cadmium.”

67. The Subcommittee investigation determined that Defendant uses “twenty ingredients registering over 100 ppb cadmium, including cinnamon containing 344.5 ppb cadmium,” levels that are “more than 17 times higher than the EU’s lax upper limit on cadmium in baby food.” Ex. 1 at 28-29. It also uses “[a]t least 105 ingredients that [] registered at or over 20 ppb cadmium—the EU’s lax infant formula upper limit.” *Id.* at 29.

68. The Subcommittee’s investigation also determined that Defendant had the highest internal standard for cadmium levels of any of the responding manufacturers. In fact, Defendant “set internal guidelines of 3,000 ppb for cadmium” for certain ingredients, which “far surpass[es] any existing regulatory standard in existence and toxic heavy metal levels for any other baby food manufacturer that responded to the Subcommittee’s inquiry.” *Id.* at 37-38.

69. Despite its own lax internal guideline for cadmium, Defendant “sold eleven products that surpassed its own internal cadmium limits. By doing so, Beech-Nut accepted dehydrated potato containing 119.6, 143.5, and 148.4 ppb cadmium, far surpassing its own internal limit of 90 ppb for that ingredient[:.]”

Date	Commodity	Preshipment	Arsenic result (ppb)	Spec.	Cadmium result (ppb)	Spec.	Lead result (ppb)	Spec.	Acceptance (Y/N)
1/11/2018	Oat Flour	38	47.00	≤40	21.80	≤20	<5	≤20	Y
1/16/2018	Coarse Oat Flour	45	45.60	≤40	20.70	≤20	<5	≤20	Y
6/22/2018	Org. Oat Flour	299	24.00	≤40	20.80	≤20	<5	≤20	Y
7/5/2018	oat flour	299	24.00	≤40	20.80	≤20	<5	≤20	
3/13/2018	Coarse Oat Flour	168	23.40	≤40	20.70	≤20	<5	≤20	Y
10/1/2019	Oat Flour	645	20.90	≤40	20.90	≤20	<5	≤20	Y
9/13/2019	Oat Flour	554	18.20	≤40	22.30	≤20	<5	≤20	Y
10/10/2018	Dehydrated Potat	816	11.30	<75	143.50	<90	32.4	<75	Y - ER
11/29/2017	Dehydrated Potat	760	9.30	<75	148.40	<90	10.1	<75	Y - ER
1/30/2018	Org. Oat Flour	73	8.50	≤40	21.70	≤20	<5	≤20	Y - ER
11/29/2017	Dehydrated Potat	749	7.60	<75	119.60	<90	<5	<75	Y - ER

Id. at 39.

70. The Subcommittee indicated that “Beech-Nut’s explanation of why it accepted products over its own internal limits was that it did so ‘rarely’ and the ingredients were ‘generally restricted to a 20% variance of BNN’s allowable limits....’ *Id.* However, testing revealed that Defendant “accepted certain ingredients in spite of their own testing results which showed that they contained over 20% more cadmium than their already-high internal limit.” *Id.* For example, Defendant’s “internal limit for cadmium in dehydrated potato appears to be 90 ppb. A 20% variance would permit Beech-Nut to accept dehydrated potato containing up to 108 ppb cadmium. Nevertheless, Beech-Nut accepted three shipments of dehydrated potato containing cadmium in excess of its 20% variance allowance.” *Id.* Defendant “did not offer any explanation” as to why this ingredient exceeded the 20% variance. *Id.*

71. Mercury is a known toxin, and pre-natal exposure has been associated with affected neuro-development, a lowered IQ, and autistic behaviors. The impact of the various ways humans and animals are exposed and ingest mercury has been studied for years. In fact, in as early as 1997, the EPA issued a report to Congress that detailed the health risks to both humans and animals.

Based on the toxicity and risks of mercury, regulations have been enacted at both the Federal and state level.

72. Defendant does not test its ingredients nor its finished baby food products for mercury. *Id.* at 33.

73. While federal regulations regarding levels of Heavy Metals in most baby foods are non-existent, it is not due to a lack of risk. According to Linda McCauley, Dean of the Nell Hodgson Woodruff School of Nursing at Emory University, who studies environmental health effects, stated, “No level of exposure to these [heavy] metals has been shown to be safe in vulnerable infants.”¹⁶

74. Based on the foregoing, reasonable consumers, like Plaintiff, would consider the inclusion of Heavy Metals and Perchlorate a material fact when considering what baby food to purchase.

75. Defendant knew that properly and sufficiently monitoring for Heavy Metals and Perchlorate in its ingredients and Contaminated Baby Foods was not only important but critical.

76. Defendant also knew that monitoring Heavy Metals and Perchlorate was likewise important to its health-conscious consumers.

77. Finally, Defendant knew or should have known it could control the levels of Heavy Metals and Perchlorate in the Contaminated Baby Foods by properly monitoring its ingredients for Heavy Metals and Perchlorate and adjusting any formulation or diet to reduce ingredients that contained higher levels of Heavy Metals and Perchlorate.

¹⁶ <https://www.nytimes.com/2021/02/04/health/baby-food-metals-arsenic.html> (last accessed Feb. 9, 2021).

78. However, Defendant also knew it was not properly and sufficiently testing for Heavy Metals and Perchlorate in the Contaminated Baby Foods. Defendant knew its failure to properly and sufficiently test for Heavy Metals and Perchlorate in the Contaminated Baby Foods continued throughout the Class Period.

79. Defendant's Marketing was misleading due to its failure to properly and sufficiently monitor for and to disclose the risk of the presence of Heavy Metals and Perchlorate in the Contaminated Baby Foods.

80. Defendant knew or should have known consumers paid premium prices and expected Defendant to regularly test for Heavy Metals and Perchlorate and sufficiently monitor the presence of Heavy Metals and Perchlorate in the Contaminated Baby Foods and ingredients.

81. At all times during the Class Period, Defendant did not consistently monitor or test for Heavy Metals and Perchlorate in the Contaminated Baby Foods and ingredients. In fact, as the Subcommittee investigation revealed, Defendant never tests its finished product, Ex. 1 at 56 and does not test its ingredients at all for mercury, *id.* at 33. "That policy recklessly endangers babies and children and prevents the companies from even knowing the full extent of the danger presented by their products." *Id.* at 56-57. Indeed, "only testing ingredients gives the false appearance of lower-than-actual toxic heavy metal levels." *Id.*

82. Defendant knew or should have known that consumers reasonably expected it to test for and monitor the presence of Heavy Metals and Perchlorate in the Contaminated Baby Foods and ingredients.

83. Defendant knew or should have known the Contaminated Baby Foods contained unmonitored levels of Heavy Metals and Perchlorate that were inconsistent with their Marketing.

84. Defendant knew or should have known that consumers expected it to ensure the Contaminated Baby Foods were monitored and tested for Heavy Metals and Perchlorate to ensure compliance with their Marketing.

85. Defendant knew, yet failed to disclose, its lack of regular testing and knowledge of the risk or presence of Heavy Metals and Perchlorate in the Contaminated Baby Foods and ingredients.

86. Defendant's above-referenced statements, representations, partial disclosures, and omissions are false, misleading, and crafted to deceive the public as they create an image that the Contaminated Baby Foods are healthy, nutritious, and made from the best ingredients, are subject to stringent quality control, and are free of Heavy Metals and Perchlorate.

87. Moreover, reasonable consumers, such as Plaintiff and the Class members, would have no reason to doubt Defendant's statements regarding the quality of the Contaminated Baby Foods. Defendant's nondisclosure and/or concealment of the toxins in the Contaminated Baby Foods coupled with the misrepresentations alleged herein that were intended to and did, in fact, cause consumers like Plaintiff and the members of the Class, to purchase products they would not have if the true quality and ingredients were disclosed or would not have paid a premium price for such baby food.

88. As a result of Defendant's wrongful Marketing, which includes misleading, deceptive, unfair, and false statements and omissions, Defendant has generated substantial sales of the Contaminated Baby Foods.

89. Defendant's wrongful Marketing, which includes misleading, deceptive, unfair, and false representations and omissions, allowed it to capitalize on, and reap enormous profits

from, consumers who paid the purchase price or premium for the Products that were not as advertised.

90. This is not surprising given that, for example, that the baby food market in the United States was valued at \$12.9 billion in 2018 and was expected to increase to \$17.2 billion by 2026,¹⁷ and organic baby food was valued at \$1.9 billion in the U.S. in 2018 and is expected to reach \$3.32 billion by 2024.¹⁸

91. The incredible rise in consumer demand for organic baby food is “driven by the growing awareness among consumers to limit that baby’s exposure to the harmful chemicals used in conventional food production and the awareness of the benefits of organic products.”¹⁹

DEFENDANT’S STATEMENTS AND OMISSIONS VIOLATE NEW YORK LAWS

92. New York law is designed to ensure that a company’s claims about its products are truthful and accurate.

93. Defendant violated New York law by negligently, recklessly, and/or intentionally incorrectly claiming that the Contaminated Baby Foods are healthy, nutritious, and “made from the best ingredients,” appropriate for various “stages” of development, and by not accurately detailing that the products contain Heavy Metals and Perchlorate.

¹⁷ <https://www.globenewswire.com/news-release/2020/01/16/1971596/0/en/U-S-Baby-Food-Market-by-Product-Type-and-Distribution-Channel-Opportunity-Analysis-and-Industry-Forecast-2019-2026.html> (last accessed Feb. 9, 2021).

¹⁸ <https://www.businesswire.com/news/home/20200120005436/en/North-America-Organic-Baby-Food-Market-Expected-to-Reach-a-Value-of-3.32-Billion-by-2024-with-a-CAGR-of-9.6---ResearchAndMarkets.com> (last accessed Feb. 8, 2021).

¹⁹ <https://www.mordorintelligence.com/industry-reports/organic-baby-food-market> (last accessed Feb. 9, 2021).

94. Defendant's marketing and advertising campaign has been sufficiently lengthy in duration, and widespread in dissemination, that it would be unrealistic to require Plaintiff to plead relying upon each advertised misrepresentation.

95. Defendant has engaged in this long-term advertising campaign to convince potential customers that the Contaminated Baby Foods were healthy, nutritious, and "made from the best ingredients," appropriate for various "stages" of development, and did not contain harmful ingredients, such as Heavy Metals and Perchlorate.

PLAINTIFF'S RELIANCE WAS REASONABLE AND FORESEEN BY DEFENDANT

96. Plaintiff reasonably relied on Defendant's claims, warranties, representations, advertisements, and other marketing concerning the particular qualities and benefits of the Contaminated Baby Food.

97. Plaintiff read and relied upon the labels and packaging of the Contaminated Baby Foods when making her purchasing decisions. Had she known Defendant omitted the presence of Heavy Metals and Perchlorate from its packaging, she would not have purchase it.

98. A reasonable consumer would consider the labeling of a product when deciding whether to purchase. Here, Plaintiff relied on the specific statements and omissions on the Contaminated Baby Foods' labeling that led her to believe it was healthy, nutritious, and free of Heavy Metals and Perchlorate.

DEFENDANT'S KNOWLEDGE AND NOTICE OF ITS BREACHES OF ITS EXPRESS AND IMPLIED WARRANTIES

99. Defendant had sufficient notice of its breaches of express and implied warranties. Defendant has, and had, exclusive knowledge of the physical and chemical make-up of the Contaminated Baby Foods. Moreover, Defendant was put on notice by the Healthy Babies Bright

Future Report about the inclusion of Heavy Metals, Perchlorate, or other undesirable toxins or contaminants in the Contaminated Baby Foods.²⁰

PRIVITY EXISTS WITH PLAINTIFF AND THE PROPOSED CLASS

100. Defendant knew that consumers such as Plaintiff and the proposed Class would be the end purchasers of the Contaminated Baby Foods and the target of its advertising and statements.

101. Defendant intended that the warranties, advertising, labeling, statements, and representations would be considered by the end purchasers of the Contaminated Baby Foods, including Plaintiff and the proposed Class.

102. Defendant directly marketed to Plaintiff and the proposed Class through statements on its website, labeling, advertising, and packaging.

103. Plaintiff and the proposed Class are the intended beneficiaries of the expressed and implied warranties.

CLASS ACTION ALLEGATIONS

104. Plaintiff brings this action individually and on behalf of the following Class pursuant to Rules 23(a) and 23(b)(2) and (3) of the Federal Rules of Civil Procedure:

All persons who, from February 10, 2015, to the present, purchased the Contaminated Baby Foods for household or business use, and not for resale (the “Class”).

105. Plaintiff also brings this action individually and on behalf of the following Subclass pursuant to Rules 23(a) and 23(b)(2) and (3) of the Federal Rules of Civil Procedure:

²⁰ Nonprofit organization, Healthy Babies Bright Futures, published a report based on a scientific study of the presence of Heavy Metals in baby foods. https://www.healthybabyfood.org/sites/healthybabyfoods.org/files/2020-04/BabyFoodReport_ENGLISH_R6.pdf (last accessed Feb. 9, 2021).

All persons who are citizens of Wisconsin who, from February 10, 2015, to the present, purchased the Contaminated Baby Foods for household or business use, and not for resale (the “Wisconsin Class” or “Subclass”).

106. Excluded from the Class and Subclass (collectively, “Classes”) is the Defendant; any parent companies, subsidiaries, and/or affiliates, officers, directors, legal representatives, and employees; co-conspirators; all governmental entities; and any judge, justice, or judicial officer presiding over this matter.

107. This action is brought and may be properly maintained as a class action. There is a well-defined community of interests in this litigation and the members of the Class are easily ascertainable.

108. The members in the proposed Class are so numerous that individual joinder of all members is impracticable, and the disposition of the claims of the members of all Classes in a single action will provide substantial benefits to the parties and Court.

109. Questions of law and fact common to Plaintiff and the Class include, but are not limited to, the following:

- a) whether Defendant owed a duty of care;
- b) whether Defendant knew or should have known that the Contaminated Baby Foods contained Heavy Metals and Perchlorate;
- c) whether Defendant represented and continue to represent that the Contaminated Baby Foods are healthy, nutritious, made from the best ingredients, appropriate for various “stages” of development, and safe for consumption;
- d) whether Defendant represented and continues to represent that the manufacturing of its Products is subjected to rigorous quality standards;
- e) whether Defendant failed to disclose that the Contaminated Baby Foods contained Heavy Metals and Perchlorate;

- f) whether Defendant's representations in advertising, warranties, packaging, and/or labeling are false, deceptive, and misleading;
- g) whether those representations are likely to deceive a reasonable consumer;
- h) whether Defendant had knowledge that those representations were false, deceptive, and misleading;
- i) whether Defendant continues to disseminate those representations despite knowledge that the representations are false, deceptive, and misleading;
- j) whether a representation that a product is healthy, nutritious, made from the best ingredients, appropriate for various "stages" of development, and safe for consumption and does not contain Heavy Metals or Perchlorate is material to a reasonable consumer;
- k) whether Defendant's Marketing of the Contaminated Baby Foods are likely to mislead, deceive, confuse, or confound consumers acting reasonably;
- l) whether Defendant violated the Wisconsin Deceptive Trade Practices Act, Wis. Stat. § 100.18, *et seq.*; and
- m) whether Plaintiff and the members of the Class are entitled to declaratory and injunctive relief.

110. Defendant engaged in a common course of conduct giving rise to the legal rights sought to be enforced by Plaintiff individually and on behalf of the other members of the Class. Identical statutory violations and business practices and harms are involved. Individual questions, if any, are not prevalent in comparison to the numerous common questions that dominate this action.

111. Plaintiff's claims are typical of those of the members of the Class in that they are based on the same underlying facts, events, and circumstances relating to Defendant's conduct.

112. Plaintiff will fairly and adequately represent and protect the interests of the Class, has no interests incompatible with the interests of the Class, and has retained counsel competent and experienced in class action, consumer protection, and false advertising litigation.

113. Class treatment is superior to other options for resolution of the controversy because the relief sought for each member of the Class is small such that, absent representative litigation, it would be infeasible for members of the Class to redress the wrongs done to them.

114. Questions of law and fact common to the Class predominate over any questions affecting only individual members of the Class.

115. As a result of the foregoing, class treatment is appropriate.

COUNT I

(Negligent Misrepresentation Against Defendant on Behalf of the Class, or alternatively the Subclass pursuant to state law)

116. Plaintiff incorporates by reference and realleges each and every allegation contained above, as though fully set forth herein.

117. Plaintiff reasonably placed her trust and reliance in Defendant's representations that the Contaminated Baby Foods were as Marketed to her and the Class, and were healthy, nutritious, made from the best ingredients, appropriate for various "stages" of development, and safe for consumption, and did not contain Heavy Metals and Perchlorate.

118. Because of the relationship between the parties, the Defendant owed a duty to use reasonable care to impart correct and reliable disclosures concerning the presence of Heavy Metals and Perchlorate in the Contaminated Baby Foods or, based upon its superior knowledge, having spoken, to say enough to not be misleading.

119. Defendant breached its duty to Plaintiff and the Class by providing false, misleading, and/or deceptive information regarding the nature of the Contaminated Baby Foods.

120. Plaintiff and the Class reasonably and justifiably relied upon the information supplied to them by the Defendant. A reasonable consumer would have relied on Defendant's own warranties, statements, representations, advertising, packaging, labeling, and other marketing as to the quality, make-up, and included ingredients of the Contaminated Baby Foods.

121. As a result of these misrepresentations, Plaintiff and the Class purchased the Contaminated Baby Foods at a premium.

122. Defendant failed to use reasonable care in its communications and representations to Plaintiff and the Class, especially in light of its knowledge of the risks and importance of considering ingredients to consumers when purchasing the Contaminated Baby Foods.

123. By virtue of Defendant's negligent misrepresentations, Plaintiff and the Class have been damaged in an amount to be proven at trial or alternatively, seek rescission and disgorgement under this Count.

COUNT II

(Violations of New York's Deceptive Acts and Practices, N.Y. Gen. Bus. Law § 349, Against Defendant on Behalf of the Class or alternatively the Subclass pursuant to state law)

124. Plaintiff incorporates by reference and realleges each and every allegation contained above, as though fully set forth herein.

125. New York General Business Law § 349 prohibits deceptive acts or practices in the conduct of any business, trade, or commerce.

126. In its sale of goods throughout New York, Defendant conducts business and trade within the meaning and intendment of New York General Business Law § 349.

127. Defendant violated N.Y. Gen. Bus. Law. § 349 by representing that its Contaminated Baby Foods were healthy, nutritious, “real food for babies,” and safe baby foods as promised, which was deceptive because the Contaminated Baby Foods instead had a risk of and/or actual inclusion of Heavy Metals and Perchlorate, including levels that exceed FDA and EPA guidance.

128. Defendant intentionally represented that the Contaminated Baby Foods were of a particular standard, grade, or quality when they in fact had a risk and/or actual inclusion of Heavy Metals and Perchlorate and were not safe for consumption.

129. The facts that Defendant concealed or misrepresented were material in that any Plaintiff and any other reasonable consumer would have considered them when deciding whether to purchase the Contaminated Baby Foods.

130. Defendant’s conduct and omissions described herein repeatedly occurred in the course of Defendant’s business and were capable of deceiving a substantial portion of the consuming public.

131. Defendant has engaged and continues to engage in deceptive conduct in violation of the New York General Business Law.

132. Defendant’s misrepresentations and deceptive acts or practices resulted in Plaintiff and other reasonable consumers suffering actual damages when they purchased the Contaminated Baby Foods that were worth less than the price paid and that they would not have purchased at all had they known of the risk and/or actual inclusion of Heavy Metals and Perchlorate.

133. Defendant intended for Plaintiff and other reasonable consumers to rely on its deceptive misrepresentations and conduct when purchasing its Contaminated Baby Foods.

134. As a direct and proximate result of these violations, Plaintiff and other reasonable consumers have been harmed, and that harm will continue unless Defendant is enjoined from misrepresenting the quality and ingredients of its Contaminated Baby Foods described herein.

135. Pursuant to N.Y. Gen. Bus. Law § 349(h), Plaintiff and the Class and/or Subclass seek injunctive and declaratory relief, full refund, actual and punitive damages, and attorneys' fees.

COUNT III

(Violations of New York False Advertising Law, N.Y. Gen. Bus. Law § 350, Against Defendant on Behalf of the Class or alternatively the Subclass pursuant to state law)

136. Plaintiff incorporates by reference and realleges each and every allegation contained above, as though fully set forth herein.

137. New York General Business Law § 350 prohibits false advertising in the conduct of any business, trade, or commerce.

138. Pursuant to N.Y. Gen. Bus. Law § 350, false advertising is defined as “advertising, including labeling, or a commodity... if such advertising is misleading in a material respect.”

139. Defendant's claims that the Contaminated Baby Foods were healthy, nutritious, “real food for babies,” and safe baby foods as promised were untrue or misleading because such claims failed to disclose that the Contaminated Baby Foods instead had a risk of and/or actual inclusion of Heavy Metals and Perchlorate, including levels that exceed FDA and EPA guidance.

140. Defendant knew or should have known that such claims were false or misleading.

141. Such false and misleading claims and representations made by Defendant were material in that Plaintiff and any reasonable consumer would have considered them when deciding to purchase the Contaminated Baby Foods.

142. Defendant, including its agents and distributors, made untrue, deceptive, and misleading assertions and representations about the alleged quality, characteristics, and nature of the Contaminated Baby Foods.

143. Defendant's conduct caused Plaintiff and the Class to suffer actual damages when they purchased the Contaminated Baby Foods that were worth less than the price paid and that they would not have purchased at all had they known of the risk and/or actual inclusion of Heavy Metals and Perchlorate, including levels that exceed FDA and EPA guidance.

144. As a direct and proximate result of Defendant's violation of N.Y. Gen. Bus. Law § 350, Plaintiff and the Class have been injured, and that harm will continue unless Defendant is enjoined from misrepresenting the quality, ingredients, standards, and suitability for consumption of its Contaminated Baby Foods.

145. Pursuant to N.Y. Gen. Bus. Law § 350, *et seq.*, Plaintiff and the Class and/or Subclass seek injunctive and declaratory relief, full refund, actual and punitive damages, and attorneys' fees.

COUNT IV

(Violations of the Wisconsin Deceptive Trade Practices Act ("WDTPA"), Wis. Stat. § 100.18, *et seq.*, Against Defendant on Behalf of the Wisconsin Subclass)

146. Plaintiff incorporates by reference and realleges each and every allegation contained above, as though fully set forth herein.

147. Plaintiff brings this cause of action on behalf of herself and on behalf of the members of the Wisconsin Subclass against Defendant.

148. Defendant willingly engaged in deceptive trade practices, in violation of the ("WDTPA") by:

- (a) Representing its Contaminated Baby Foods have characteristics, ingredients, uses, and benefits they do not have;
- (b) Representing its Contaminated Baby Foods are of a superior standard, quality, and grade when they contain levels of Heavy Metals, Perchlorate, and/or unnatural or other ingredients that do not conform to the products' labels, packaging, advertising, and statements; and
- (c) Representing its Contaminated Baby Foods as natural when they contain Perchlorate and other unnatural ingredients; and
- (d) Representing its Contaminated Baby Foods are appropriate for the advertised "stage" when they contain Heavy Metals, Perchlorates, and other ingredients that are not appropriate for that "stage" of development.

149. Defendant knew or should have known that the Contaminated Baby Foods did not have the ingredients, uses, and benefits described herein because they contain levels of Heavy Metals, Perchlorate, and/or unnatural or other ingredients that do not conform to the products' labels, packaging, advertising, and statements.

150. Defendant knew or should have known the Contaminated Baby Foods were not of a superior standard, quality, or grade because they contain levels of Heavy Metals, Perchlorate, and/or unnatural or other ingredients that do not conform to the products' labels, packaging, advertising, and statements that a reasonable consumer would consider material.

151. Defendant knew or should have known the Contaminated Baby Foods were not natural because they contain material levels of Perchlorate and other unnatural ingredients.

152. Defendant knew or should have known that the Contaminated Baby Foods were not appropriate for the advertised "stage" because they contain material levels of Heavy Metals, Perchlorates, and other ingredients not appropriate for the advertised "stage."

153. Defendant's misrepresentations, concealment, omissions, and other deceptive conduct were likely to deceive or cause misunderstanding and did in fact deceive Plaintiff and the

Subclass with respect to the Contaminated Baby Foods' ingredients, uses, benefits, standards, quality, grade, and suitability for consumption by infants and children.

154. Defendant intended for Plaintiff and the Subclass to rely on Defendant's misrepresentations, concealment, warranties, deceptions, and/or omissions regarding the Contaminated Baby Foods' ingredients, uses, benefits, standards, quality, grade, and suitability for consumption by infants and children.

155. Defendant's conduct and omissions described herein occurred repeatedly in Defendant's trade or business and were capable of deceiving a substantial portion of the consuming public.

156. The facts concealed or not disclosed by Defendant were material facts in that Plaintiff and any reasonable consumer would have considered them when deciding whether to purchase the Contaminated Baby Foods. Had Plaintiff known the Contaminated Baby Foods did not have the quality and ingredients advertised by Defendant, she would not have purchased the Contaminated Baby Foods.

157. Defendant intended for Plaintiff and the Subclass to rely on the deception by purchasing the Contaminated Baby Foods, unaware of the undisclosed material facts. This conduct constitutes consumer fraud.

158. Defendant's unlawful conduct is continuing, with no indication that Defendant intends to cease this fraudulent course of conduct.

159. As a result of Defendant's conduct, Plaintiff and the Subclass have suffered actual damages in that they purchased Contaminated Baby Foods that were worth less than the price they paid, and that they would not have purchased at all had they known of the levels of Heavy Metals, Perchlorate, toxins, and/or unnatural or other ingredients that do not conform to the products'

labels, packaging, advertising, and statements. There is an association between Defendant's acts and omissions as alleged herein and the damages suffered by Plaintiff.

160. As a direct and proximate result of Defendant's violations of the WDTPA, Plaintiff and the Subclass have been injured, and that harm is likely to continue unless Defendant is enjoined from misrepresenting the ingredients, uses, benefits, standards, quality, grade, and suitability for consumption by infants and children of its Contaminated Baby Foods described herein.

161. Pursuant to Wis. Stat. Ann. § 100.18, Plaintiff and the Subclass seek actual damages, injunctive and declaratory relief, attorneys' fees, costs, and any other just and proper relief available thereunder for Defendant's violation of the WDTPA.

COUNT V

(Breach of Express Warranty Against Defendant on Behalf of the Class or alternatively the Subclass pursuant to state law)

162. Plaintiff incorporates by reference and realleges each and every allegation contained above, as though fully set forth herein.

163. As set forth herein, Defendant made express representations to Plaintiff and the Class that the Contaminated Baby Foods were healthy, nutritious, "real food for babies," and safe baby foods.

164. These promises became part of the basis of the bargain between the parties and thus constituted express warranties.

165. There was a sale of goods from Defendant to Plaintiff and the Class members.

166. On the basis of these express warranties, Defendant sold to Plaintiff and the Class members the Contaminated Baby Foods.

167. Defendant knowingly breached the express warranties by including Heavy Metals and Perchlorate in the Contaminated Baby Foods.

168. Defendant was on notice of this breach as it was aware of the included Heavy Metals and Perchlorate in the Contaminated Baby Foods, and based on the public investigation by the nonprofit organization, Healthy Babies Bright Futures, that showed its baby food products as containing Heavy Metals and Perchlorate.

169. Privity exists because Defendant expressly warranted to Plaintiff and the Class that the Contaminated Baby Foods were healthy, nutritious, “real food for babies,” and safe baby foods.

170. Plaintiff and the Class members reasonably relied on the express warranties by Defendant.

171. As a result of Defendant’s breaches of its express warranties, Plaintiff and the Class sustained damages as they paid money for the Contaminated Baby Foods that were not what Defendant represented.

172. Plaintiff, on behalf of herself and the Class, seek actual damages for Defendant’s breach of warranty.

COUNT VI

(Breach of Implied Warranty of Merchantability Against Defendant on Behalf of the Class or, alternatively the Subclass pursuant to state law)

173. Plaintiff incorporates by reference and realleges each and every allegation contained above, as though fully set forth herein.

174. Defendant is a merchant engaging in the sale of goods to Plaintiff and the Class members.

175. There was a sale of goods from Defendant to Plaintiff and the Class members.

176. At all times mentioned herein, Defendant manufactured and/or sold the Contaminated Baby Foods, prior to the time the Contaminated Baby Foods were purchased by Plaintiff and the Class, Defendant impliedly warranted to Plaintiff, and to the Class, that the

Contaminated Baby Foods were of merchantable quality and fit for the use for which they were intended.

177. Plaintiff and the Class relied on the skill and expertise of Defendant in purchasing and feeding the Contaminated Baby Foods to their children.

178. The Contaminated Baby Foods were unfit for their intended use and were not of merchantable quality, as warranted by Defendant. Instead, the Contaminated Baby Foods had the risk of and/or actual inclusion of Heavy Metals and Perchlorate, including levels that exceed FDA and EPA guidance.

179. Defendant breached the implied warranty of merchantability because of the risk and/or actual inclusion of Heavy Metals and Perchlorate, including levels that exceed FDA and EPA guidance in the Contaminated Baby Foods.

180. Defendant was on notice of this breach as it was aware of the inclusion of Heavy Metals and Perchlorate in the Contaminated Baby Foods, and based on the public investigation by the nonprofit organization, Healthy Babies Bright Futures, that showed its baby food products as containing Heavy Metals and Perchlorate.

181. Privity exists because Defendant impliedly warranted to Plaintiff and the Class members through the warranting, packaging, advertising, marketing, and labeling that the Contaminated Baby Foods were healthy, nutritious, “real food for babies,” and safe baby foods, and by failing to make any mention of Heavy Metals and Perchlorate.

182. As a result of Defendant’s breach of its implied warranties of merchantability, Plaintiff and the Class sustained damages as they paid money for the Contaminated Baby Foods that were not what Defendant represented, in an amount to be determined at trial.

COUNT VII

(Breach of Implied Warranty of Fitness for a Particular Purpose Against Defendant on Behalf of the Class alternatively the Subclass pursuant to state law)

183. Plaintiff incorporates by reference and realleges each and every allegation contained above, as though fully set forth herein.

184. At the time of contracting, Defendant had reason to know of Plaintiff's and Class members' particular purpose for purchasing the Contaminated Baby Foods.

185. Plaintiff and the Class relied on Defendant's skill or judgment to select or furnish suitable goods, thereby creating an implied warranty that the goods would be fit for such purpose.

186. The Contaminated Baby Foods were not fit for these purposes, thereby causing injuries to Plaintiff and the Class members.

COUNT VIII

(Unjust Enrichment Against Defendant on Behalf of the Class or alternatively the Subclass pursuant to state law)

187. Plaintiff incorporates by reference and realleges each and every allegation contained above, as though fully set forth herein.

188. Substantial benefits have been conferred on Defendant by Plaintiff and the Classes through the purchase of the Contaminated Baby Foods. Defendant knowingly and willingly accepted and enjoyed these benefits.

189. Defendant either knew or should have known that the payments rendered by Plaintiff were given and received with the expectation that the Contaminated Baby Foods would have the qualities, characteristics, ingredients, and suitability for consumption represented and warranted by Defendant. As such, it would be inequitable for Defendant to retain the benefit of the payments under these circumstances.

190. Defendant's acceptance and retention of these benefits under the circumstances alleged herein make it inequitable for Defendant to retain the benefits without payment of the value to Plaintiff and the Classes.

191. Plaintiff and the Classes are entitled to recover from Defendant all amounts wrongfully collected and improperly retained by Defendant, plus interest thereon.

192. Plaintiff and the Classes seek actual damages, injunctive and declaratory relief, attorneys' fees, costs, and any other just and proper relief available under the laws.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff, individually and on behalf of all others similarly situated, pray for judgment against the Defendant as to each and every count, including:

A. An order declaring this action to be a proper class action, appointing Plaintiff and her counsel to represent the Class, and requiring Defendant to bear the costs of class notice;

B. An order enjoining Defendant from selling the Contaminated Baby Foods until the higher and/or unsafe levels of Heavy Metals and Perchlorate are removed;

C. An order enjoining Defendant from selling the Contaminated Baby Foods in any manner suggesting or implying that they are healthy, nutritious, and safe for consumption;

D. An order requiring Defendant to engage in a corrective advertising campaign and engage in any further necessary affirmative injunctive relief, such as recalling existing products;

E. An order awarding declaratory relief, and any further retrospective or prospective injunctive relief permitted by law or equity, including enjoining Defendant from continuing the unlawful practices alleged herein, and injunctive relief to remedy Defendant's past conduct;

F. An order requiring Defendant to pay restitution to restore all funds acquired by means of any act or practice declared by this Court to be an unlawful, unfair, or fraudulent business

act or practice, untrue or misleading advertising, or a violation of the WDTPA, plus pre- and post-judgment interest thereon;

G. An order requiring Defendant to disgorge or return all monies, revenues, and profits obtained by means of any wrongful or unlawful act or practice;

H. An order requiring Defendant to pay all actual and statutory damages permitted under the counts alleged herein;

I. An order requiring Defendant to pay punitive damages on any count so allowable;

J. An order awarding attorneys' fees and costs to Plaintiff and the Class; and

K. An order providing for all other such equitable relief as may be just and proper.

JURY DEMAND

Plaintiff hereby demands a trial by jury on all issues so triable.

Dated: February 11, 2021

Respectfully submitted,

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EXHIBIT 1



Baby Foods Are Tainted with Dangerous Levels of Arsenic, Lead, Cadmium, and Mercury



Staff Report

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

February 4, 2021

oversight.house.gov

EXECUTIVE SUMMARY

Inorganic arsenic, lead, cadmium, and mercury are toxic heavy metals. The Food and Drug Administration and the World Health Organization have declared them dangerous to human health, particularly to babies and children, who are most vulnerable to their neurotoxic effects. Even low levels of exposure can cause serious and often irreversible damage to brain development.

On November 6, 2019, following reports alleging high levels of toxic heavy metals in baby foods, the Subcommittee on Economic and Consumer Policy requested internal documents and test results from seven of the largest manufacturers of baby food in the United States, including both makers of organic and conventional products:

- Nurture, Inc. (Nurture), which sells Happy Family Organics, including baby food products under the brand name HappyBABY
- Beech-Nut Nutrition Company (Beech-Nut)
- Hain Celestial Group, Inc. (Hain), which sells baby food products under the brand name Earth's Best Organic
- Gerber
- Campbell Soup Company (Campbell), which sells baby food products under the brand name Plum Organics
- Walmart Inc. (Walmart), which sells baby food products through its private brand Parent's Choice
- Sprout Foods, Inc. (Sprout Organic Foods)

Four of the companies—Nurture, Beech-Nut, Hain, and Gerber—responded to the Subcommittee's requests. They produced their internal testing policies, test results for ingredients and/or finished products, and documentation about what the companies did with ingredients and/or finished products that exceeded their internal testing limits.

Walmart, Campbell, and Sprout Organic Foods refused to cooperate with the Subcommittee's investigation. The Subcommittee is greatly concerned that their lack of cooperation might be obscuring the presence of even higher levels of toxic heavy metals in their baby food products than their competitors' products.

FINDINGS

1. According to internal company documents and test results obtained by the Subcommittee, commercial baby foods are tainted with significant levels of toxic heavy metals, including arsenic, lead, cadmium, and mercury. Exposure to toxic heavy metals causes permanent decreases in IQ, diminished future economic productivity, and increased risk of future criminal and antisocial behavior in children. Toxic heavy metals endanger infant neurological development and long-term brain function. Specifically, the Subcommittee reports that:

ARSENIC was present in baby foods made by all responding companies.

- Nurture (HappyBABY) sold baby foods after tests showed they contained as much as 180 parts per billion (ppb) inorganic arsenic. Over 25% of the products Nurture tested before sale contained over 100 ppb inorganic arsenic. Nurture's testing shows that the typical baby food product it sold contained 60 ppb inorganic arsenic.
- Hain (Earth's Best Organic) sold finished baby food products containing as much as 129 ppb inorganic arsenic. Hain typically only tested its ingredients, not finished products. Documents show that Hain used ingredients testing as high as 309 ppb arsenic.
- Beech-Nut used ingredients after they tested as high as 913.4 ppb arsenic. Beech-Nut routinely used high-arsenic additives that tested over 300 ppb arsenic to address product characteristics such as "crumb softness."
- Gerber used high-arsenic ingredients, using 67 batches of rice flour that had tested over 90 ppb inorganic arsenic.

LEAD was present in baby foods made by all responding companies.

- Nurture (HappyBABY) sold finished baby food products that tested as high as 641 ppb lead. Almost 20% of the finished baby food products that Nurture tested contained over 10 ppb lead.
- Beech-Nut used ingredients containing as much as 886.9 ppb lead. It used many ingredients with high lead content, including 483 that contained over 5 ppb lead, 89 that contained over 15 ppb lead, and 57 that contained over 20 ppb lead.
- Hain (Earth's Best Organic) used ingredients containing as much as 352 ppb lead. Hain used many ingredients with high lead content, including 88 that tested over 20 ppb lead and six that tested over 200 ppb lead.
- Gerber used ingredients that tested as high as 48 ppb lead; and used many ingredients containing over 20 ppb lead.

CADMIUM was present in baby foods made by all responding companies.

- Beech-Nut used 105 ingredients that tested over 20 ppb cadmium. Some tested much higher, up to 344.55 ppb cadmium.
- Hain (Earth's Best Organic) used 102 ingredients in its baby food that tested over 20 ppb cadmium. Some tested much higher, up to 260 ppb cadmium.

- Sixty-five percent of Nurture (HappyBABY) finished baby food products contained more than 5 ppb cadmium.
- Seventy-five percent of Gerber's carrots contained cadmium in excess of 5 ppb, with some containing up to 87 ppb cadmium.

MERCURY was detected in baby food of the only responding company that tested for it.

- Nurture (HappyBABY) sold finished baby food products containing as much as 10 ppb mercury.
- Beech-Nut and Hain (Earth's Best Organic) do not even test for mercury in baby food.
- Gerber rarely tests for mercury in its baby foods.

These results are multiples higher than allowed under existing regulations for other products. For example, the Food and Drug Administration has set the maximum allowable levels in bottled water at 10 ppb inorganic arsenic, 5 ppb lead, and 5 ppb cadmium, and the Environmental Protection Agency has capped the allowable level of mercury in drinking water at 2 ppb. The test results of baby foods and their ingredients eclipse those levels: including results up to 91 times the arsenic level, up to 177 times the lead level, up to 69 times the cadmium level, and up to 5 times the mercury level.

2. Internal company standards permit dangerously high levels of toxic heavy metals, and documents revealed that the manufacturers have often sold foods that exceeded those levels.
 - Nurture (HappyBABY) sold all products tested, regardless of how much toxic heavy metal the baby food contained. By company policy, Nurture's toxic heavy metal testing is not intended for consumer safety. The Food and Drug Administration (FDA) has only finalized one standard—100 ppb inorganic arsenic in infant rice cereal—and Nurture set its internal standard for that product 15% higher than the FDA limit, at 115 ppb.
 - Beech-Nut set internal arsenic and cadmium standards at 3,000 ppb in additives, such as vitamin mix, and 5,000 ppb lead for certain ingredients like BAN 800. These standards are the highest of any responding manufacturer.
 - Hain (Earth's Best Organic) set an internal standard of 200 ppb for arsenic, lead, and cadmium in some of its ingredients. But Hain exceeded its internal policies, using ingredients containing 353 ppb lead and 309 ppb arsenic. Hain justified deviations above its ingredient testing

standards based on “theoretical calculations,” even after Hain admitted to FDA that its testing underestimated final product toxic heavy metal levels.

3. The Subcommittee has grave concerns about baby food products manufactured by Walmart (Parent’s Choice), Sprout Organic Foods, and Campbell (Plum Organics). These companies refused to cooperate with the Subcommittee’s investigation. The Subcommittee is greatly concerned that their lack of cooperation might obscure the presence of even higher levels of toxic heavy metals in their baby food products, compared to their competitors’ products.
 - Walmart sells Parent’s Choice and Parent’s Choice Organic products for babies as young as four months.
 - Sprout Organic Foods sells organic products for babies as young as six months. It is owned by North Castle Partners, a Greenwich, Connecticut–based private equity firm.
 - Campbell sells Plum Organics products for babies as young as four months.
 - Independent testing of Walmart, Sprout Organic Foods, and Campbell products has confirmed that their baby foods contain concerning levels of toxic heavy metals.

4. The Trump administration ignored a secret industry presentation to federal regulators revealing increased risks of toxic heavy metals in baby foods. On August 1, 2019, FDA received a secret slide presentation from Hain (Earth’s Best Organic), which revealed that:
 - Corporate policies to test only ingredients, not final products, underrepresent the levels of toxic heavy metals in baby foods. In 100% of the Hain baby foods tested, inorganic arsenic levels were higher in the finished baby food than the company estimated they would be based on individual ingredient testing. Inorganic arsenic was between 28% and 93% higher in the finished products;
 - Many of Hain’s baby foods were tainted with high levels of inorganic arsenic—half of its brown rice baby foods contained over 100 ppb inorganic arsenic; its average brown rice baby food contained 97.62 ppb inorganic arsenic; and
 - Naturally occurring toxic heavy metals may not be the only problem causing the unsafe levels of toxic heavy metals in baby foods; rather, baby food producers like Hain may be adding ingredients that have high levels of toxic heavy metals into their products, such as vitamin/mineral pre-mix.

This presentation made clear that ingredient testing is inadequate, and that only final product testing can measure the true danger posed by baby foods.

The Trump FDA took no new action in response. To this day, baby foods containing toxic heavy metals bear no label or warning to parents. Manufacturers are free to test only ingredients, or, for the vast majority of baby foods, to conduct no testing at all. FDA has only finalized one metal standard for one narrow category of baby food, setting a 100 ppb inorganic arsenic standard for infant rice cereal. But this FDA standard is far too high to protect against the neurological effects on children.

5. The Subcommittee makes the following recommendations:
 - **Mandatory testing**—Baby food manufacturers should be required by FDA to test their finished products for toxic heavy metals, not just their ingredients;
 - **Labeling**—Manufacturers should be required by FDA to report levels of toxic heavy metals on food labels;
 - **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;
 - **FDA standards**—FDA should set maximum levels of toxic heavy metals permitted in baby foods. One level for each metal should apply across all baby foods. And the level should be set to protect babies against the neurological effects of toxic heavy metals; and
 - **Parental vigilance**—Parents should avoid baby foods that contain ingredients testing high in toxic heavy metals, such as rice products. Instituting recommendations one through four will give parents the information they need to make informed decisions to protect their babies.
6. Baby food manufacturers hold a special position of public trust. Consumers believe that they would not sell products that are unsafe. Consumers also believe that the federal government would not knowingly permit the sale of unsafe baby food. As this staff report reveals, baby food manufacturers and the Trump administration's federal regulators have broken the faith.

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I. THE DANGER OF TOXIC HEAVY METALS TO CHILDREN'S HEALTH

Children's exposure to toxic heavy metals causes permanent decreases in IQ, diminished future economic productivity, and increased risk of future criminal and antisocial behavior.¹

Babies' developing brains are "exceptionally sensitive to injury caused by toxic chemicals, and several developmental processes have been shown to be highly vulnerable to chemical toxicity."² The fact that babies are small, have other developing organ systems, and absorb more of the heavy metals than adults, exacerbates their risk from exposure to heavy metals.³

Exposure to heavy metals at this developmental stage can lead to "untreatable and frequently permanent" brain damage, which may result in "reduced intelligence, as expressed in terms of lost IQ points, or disruption in behavior."⁴ For example, a recent study estimates that exposure to environmental chemicals, including lead, are associated with 40,131,518 total IQ points loss in 25.5 million children (or roughly 1.57 lost IQ points per child)—more than the total IQ losses associated with preterm birth (34,031,025), brain tumors (37,288), and traumatic brain injury (5,827,300) combined.⁵ For every one IQ point lost, it is estimated that a child's lifetime earning capacity will be decreased by \$18,000.⁶

Well-known vectors of child exposure to toxic heavy metals include lead paint in old housing and water pollution from landfills. Over the decades, a range of federal and state laws and regulations have been passed to protect child health through emissions standards, among other things.

The Food and Drug Administration (FDA) has declared that inorganic arsenic, lead, cadmium, and mercury are dangerous, particularly to infants and children. They have "no established health benefit" and "lead to illness, impairment, and in high doses, death." According to FDA, "even low levels of harmful metals from individual food sources, can

¹ Miguel Rodríguez-Barranco et al., *Association of Arsenic, Cadmium and Manganese Exposure with Neurodevelopment and Behavioural Disorders in Children: A Systematic Review and Meta-Analysis* (Apr. 9, 2013) (online at www.sciencedirect.com/science/article/abs/pii/S0048969713003409?via%3Dihub).

² Philippe Grandjean and Philip J. Landrigan, *Neurobehavioural Effects of Developmental Toxicity* (Mar. 13, 2014) (online at www.ncbi.nlm.nih.gov/pmc/articles/PMC4418502/).

³ Consumer Reports, *Heavy Metals in Baby Food: What You Need to Know* (Aug. 16, 2018) (online at www.consumerreports.org/food-safety/heavy-metals-in-baby-food/).

⁴ Philippe Grandjean and Philip J. Landrigan, *Neurobehavioural Effects of Developmental Toxicity* (Mar. 13, 2014) (online at www.ncbi.nlm.nih.gov/pmc/articles/PMC4418502/).

⁵ David C. Bellinger, *A Strategy for Comparing the Contributions of Environmental Chemicals and Other Risk Factors to Neurodevelopment of Children* (Dec. 19, 2011) (online at www.ncbi.nlm.nih.gov/pmc/articles/PMC3339460/).

⁶ Martine Bellanger et al., *Economic Benefits of Methylmercury Exposure Control in Europe: Monetary Value of Neurotoxicity Prevention* (Jan. 17, 2013) (online at <https://pubmed.ncbi.nlm.nih.gov/23289875/>).

sometimes add up to a level of concern.” FDA cautions that infants and children are at the greatest risk of harm from toxic heavy metal exposure.⁷

The Subcommittee on Economic and Consumer Policy’s investigation has found another source of exposure: baby foods. According to documents obtained from baby food manufacturers, toxic heavy metals, such as arsenic, cadmium, lead, and mercury are present at substantial levels in both organic and conventional baby foods. Currently, there is no federal standard on, or warning to parents and caregivers about, these toxins.

A. Inorganic Arsenic

Arsenic is ranked number one among substances present in the environment that pose the most significant potential threat to human health, according to the Department of Health and Human Services’ Agency for Toxic Substances and Disease Registry (ATSDR).⁸ The known health risks of arsenic exposure include “respiratory, gastrointestinal, haematological, hepatic, renal, skin, **neurological and immunological effects, as well as damaging effects on the central nervous system and cognitive development in children.**”⁹

Studies have concluded that arsenic exposure has a “significant negative effect on neurodevelopment in children.”¹⁰ This negative effect is most pronounced in Full Scale IQ, and more specifically, in verbal and performance domains as well as memory. For every 50% increase in arsenic levels, there is an approximately “0.4 decrease in the IQ of children.”¹¹

A study of Maine schoolchildren exposed to arsenic in drinking water found that children exposed to water with an arsenic concentration level greater than 5 parts per billion (ppb) “showed significant reductions in Full Scale IQ, Working Memory, Perceptual Reasoning and Verbal Comprehension scores.” The authors pegged 5 ppb as an important threshold.¹²

Likewise, a study of children in Spain found that increasing arsenic exposure led to a decrease in the children’s global motor, gross motor, and fine motor function scores. Boys in particular were more susceptible to arsenic’s neurotoxicity.¹³

⁷ Food and Drug Administration, *Metals and Your Food* (online at www.fda.gov/food/chemicals-metals-pesticides-food/metals-and-your-food) (accessed Jan. 26, 2021).

⁸ Agency for Toxic Substances and Disease Registry, *ATSDR’s Substance Priority List* (2019) (online at www.atsdr.cdc.gov/spl/index.html#2019spl).

⁹ Miguel Rodríguez-Barranco et al., *Association of Arsenic, Cadmium and Manganese Exposure with Neurodevelopment and Behavioural Disorders in Children: A Systematic Review and Meta-Analysis* (June 1, 2013) (online at <https://pubmed.ncbi.nlm.nih.gov/23570911/>) (emphasis added).

¹⁰ *Id.*

¹¹ *Id.*

¹² Gail A. Wasserman et al., *A Cross-Sectional Study of Well Water Arsenic and Child IQ in Maine Schoolchildren* (Apr. 1, 2014) (online at <https://ehjournal.biomedcentral.com/articles/10.1186/1476-069X-13-23>).

¹³ Antonio J. Signes-Pastor et al., *Inorganic Arsenic Exposure and Neuropsychological Development of Children of 4-5 Years of Age Living in Spain* (Apr. 29, 2019) (online at www.ncbi.nlm.nih.gov/pmc/articles/PMC6541502/).

B. Lead

Lead is number two on ATSDR's list of substances present in the environment that pose the most significant potential threat to human health.¹⁴ Even small doses of lead exposure are hazardous, particularly to children.¹⁵ Lead is associated with a range of bad health outcomes, including behavioral problems, decreased cognitive performance, delayed puberty, and reduced postnatal growth. According to FDA, lead is especially dangerous to "infants" and "young children." FDA acknowledges that:

High levels of lead exposure can seriously harm children's health and development, specifically the brain and nervous system. Neurological effects from high levels of lead exposure during early childhood include learning disabilities, behavior difficulties, and lowered IQ. Because lead can accumulate in the body, even low-level chronic exposure can be hazardous over time.¹⁶

Lead exposure severely affects academic achievement in children. Even at low levels, early childhood lead exposure has a negative impact on school performance. Two separate studies of schoolchildren in Detroit and Chicago public schools found a strong inverse relationship between lead exposure and test scores. In the Detroit study, there was a "significant association" between early childhood lead exposure and decreased standardized test performance, with lead exposure strongly linked to an adverse effect on academic achievement.¹⁷ The Chicago study found that higher blood lead concentrations were associated with lower reading and math scores in 3rd grade children. Increased blood lead concentrations correlated with a 32% increase in the risk of failing reading and math.¹⁸

The cognitive effects of early childhood lead exposure appear to be permanent. In one study, adults who previously had lead-associated developmental delays continued to show persisting cognitive deficits, demonstrating the long-lasting damage of lead exposure.¹⁹

¹⁴ Agency for Toxic Substances and Disease Registry, *ATSDR's Substance Priority List* (2019) (online at www.atsdr.cdc.gov/spl/index.html#2019spl).

¹⁵ Philippe Grandjean, *Even Low-Dose Lead Exposure Is Hazardous* (Sept. 11, 2010) (online at <https://pubmed.ncbi.nlm.nih.gov/20833288/>).

¹⁶ Food and Drug Administration, *Lead in Food, Foodwares, and Dietary Supplements* (online at www.fda.gov/food/metals-and-your-food/lead-food-foodwares-and-dietary-supplements) (accessed Jan. 26, 2021).

¹⁷ Nanhua Zhang et al., *Early Childhood Lead Exposure and Academic Achievement: Evidence From Detroit Public Schools* (Mar. 2013) (online at <http://mediad.publicbroadcasting.net/p/michigan/files/201302/AJPH.2012.pdf>).

¹⁸ Anne Evens et al., *The Impact of Low-Level Lead Toxicity on School Performance Among Children in the Chicago Public Schools: A Population-Based Retrospective Cohort Study* (Apr. 7, 2015) (online at <https://ehjournal.biomedcentral.com/articles/10.1186/s12940-015-0008-9>).

¹⁹ Maitreyi Mazumdar et al., *Low-Level Environmental Lead Exposure in Childhood and Adult Intellectual Function: A Follow-Up Study* (Mar. 30, 2011) (online at www.ncbi.nlm.nih.gov/pmc/articles/PMC3072933/).

Studies have also established a significant association between lead exposure and Attention-Deficit/Hyperactivity Disorder (ADHD).²⁰

C. Cadmium

Cadmium is number seven on ATSDR's list of substances present in the environment that pose the most significant potential threat to human health.²¹ Cadmium is associated with decreases in IQ, as well as the development of ADHD.

A 2018 study found that cadmium exposure negatively affected children's Full Scale IQ, particularly among boys. Boys exhibiting higher amounts of cadmium exposure had seven fewer IQ points than those exhibiting less cadmium exposure.²² A 2015 study similarly found a significant inverse relationship between early cadmium exposure and IQ.²³

A 2018 study linked cadmium exposure to ADHD, finding that the disorder was more common among children with the highest levels of cadmium exposure as compared to a control group.²⁴

D. Mercury

Mercury is number three on ATSDR's list of substances present in the environment that pose the most significant potential threat to human health.²⁵ Studies of mercury's effect on childhood development have primarily been conducted by considering the mother's exposure to mercury while pregnant. In these instances, "pre-natal mercury exposure has been consistently associated with adverse subsequent neuro-development."²⁶ And pre-natal mercury exposure is also related to poorer estimated IQ.²⁷ Beyond prenatal exposure, higher blood mercury levels at

²⁰ Gabriele Donzelli et al., *The Association Between Lead and Attention-Deficit/Hyperactivity Disorder: A Systematic Review* (Jan. 29, 2019) (online at www.mdpi.com/1660-4601/16/3/382/htm).

²¹ Agency for Toxic Substances and Disease Registry, *ATSDR's Substance Priority List* (2019) (online at www.atsdr.cdc.gov/spl/index.html#2019spl).

²² Klara Gustin et al., *Cadmium Exposure and Cognitive Abilities and Behavior at 10 Years Off Age: A Prospective Cohort Study* (Apr. 2018) (online at www.sciencedirect.com/science/article/pii/S0160412017321025).

²³ Alison P. Sanders et al., *Perinatal and Childhood Exposure To Cadmium, Manganese, And Metal Mixtures And Effects On Cognition And Behavior: A Review Of Recent Literature* (July 5, 2015) (online at www.ncbi.nlm.nih.gov/pmc/articles/PMC4531257/).

²⁴ Min-Jing Lee et al., *Heavy Metals' Effect on Susceptibility to Attention-Deficit/Hyperactivity Disorder: Implication of Lead, Cadmium, and Antimony* (June 10, 2018) (online at www.ncbi.nlm.nih.gov/pmc/articles/PMC6025252/).

²⁵ Agency for Toxic Substances and Disease Registry, *ATSDR's Substance Priority List* (2019) (online at www.atsdr.cdc.gov/spl/index.html#2019spl).

²⁶ Margaret R. Karagas et al., *Evidence on the Human Health Effects of Low-Level Methylmercury Exposure* (June 1, 2012) (online at <https://ehp.niehs.nih.gov/doi/10.1289/ehp.1104494>).

²⁷ Joseph Jacobson et al., *Relation of Prenatal Methylmercury Exposure from Environmental Sources to Childhood IQ* (Aug. 1, 2015) (online at <https://ehp.niehs.nih.gov/doi/10.1289/ehp.1408554>).

“2 and 3 years of age were positively associated with autistic behaviors among preschool-age children.”²⁸

II. TOP BABY FOODS ARE TAINTED WITH DANGEROUS LEVELS OF INORGANIC ARSENIC, LEAD, CADMIUM, AND MERCURY.

Internal company test results obtained by the Subcommittee confirm that all responding baby food manufacturers sold baby foods tainted by high levels of toxic heavy metals.

A. Inorganic Arsenic

There is no established safe level of inorganic arsenic consumption for babies. Organizations such as Healthy Babies Bright Futures have called for a goal of no measurable amount of inorganic arsenic in baby food.²⁹ Consumer Reports suggests setting inorganic arsenic levels as low as 3 parts per billion (ppb).³⁰ FDA has already set maximum inorganic arsenic levels at 10 ppb for bottled water.³¹ The Environmental Protection Agency (EPA) has similarly set a 10 ppb inorganic arsenic cap on drinking water, as have the European Union (EU) and the World Health Organization (WHO).³²

1. Nurture (HappyBABY) sold finished baby foods after testing showed they contained as much as 180 ppb inorganic arsenic; over 25% of the tested baby food sold by Nurture exceeded 100 ppb inorganic arsenic; on average, Nurture baby food on store shelves has nearly 60 ppb inorganic arsenic.

Nurture is the only baby food manufacturer that appears to regularly tests its finished baby food products for inorganic arsenic content (the others only test ingredients).

²⁸ Jia Ryu et al., *Associations of Prenatal and Early Childhood Mercury Exposure with Autistic Behaviors at 5 Years of Age: The Mothers and Children's Environmental Health (MOCEH) Study* (Dec. 15, 2017) (online at www.sciencedirect.com/science/article/pii/S0048969717316479).

²⁹ Healthy Babies Bright Futures, *What's in My Baby's Food? A National Investigation Finds 95 Percent of Baby Foods Tested Contain Toxic Chemicals That Lower Babies' IQ, Including Arsenic and Lead* (Oct. 2019) (online at www.healthybabyfood.org/sites/healthybabyfoods.org/files/2019-10/BabyFoodReport_FULLREPORT_ENGLISH_R5b.pdf).

³⁰ Consumer Reports, *Arsenic in Some Bottled Water Brands at Unsafe Levels, Consumer Reports Says* (June 28, 2019) (online at www.consumerreports.org/water-quality/arsenic-in-some-bottled-water-brands-at-unsafe-levels/); Consumer Reports, *Arsenic and Lead Are in Your Fruit Juice: What You Need to Know* (Jan. 30, 2019) (online at www.consumerreports.org/food-safety/arsenic-and-lead-are-in-your-fruit-juice-what-you-need-to-know/).

³¹ 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 Jan. 26, 2021).

³² Environmental Protection Agency, *Drinking Water Requirements for States and Public Water Systems* (online at www.epa.gov/dwreginfo/chemical-contaminant-rules) (accessed Jan. 26, 2021); The European Food Information Council, *Arsenic (Q&A)* (online at www.eufic.org/en/food-safety/article/arsenic-qa) (accessed Jan. 26, 2021); World Health Organization, *Arsenic* (Feb. 15, 2018) (online at www.who.int/news-room/fact-sheets/detail/arsenic).

According to internal company documents, Nurture sells products even after testing confirms that they are dangerously high in inorganic arsenic. Nurture sold one such product, Apple and Broccoli Puffs, despite tests results showing it contained 180 ppb inorganic arsenic.³³ An arsenic level of 180 ppb is high by all standards, but it is 80% higher than Nurture's own internal goal threshold of 100 ppb.

Nurture's Heavy Metal Test Results for Baby Food Products (Excerpted Entries)³⁴

Product Name	Category	Best Before Date	Parameter	Goal	Result		Unit	Date of Test Report	Disposition
				Thresh old					
Apple & Broccoli Puffs	Baby 7+ Months	9/7/2018	Inorganic Arsenic	100	180	180	ppb	11/01/17	Sell - Testing For Monitoring & Supply Chain Improvement Purposes Only
Banana & Pumpkin Puffs	Baby 7+ Months	10/11/2018	Inorganic Arsenic	100	160	160	ppb	10/31/17	Sell - Testing For Monitoring & Supply Chain Improvement Purposes Only
Strawberry & Beet Puffs	Baby 7+ Months	7/24/2018	Inorganic Arsenic	100	160	160	ppb	10/31/17	Sell - Testing For Monitoring & Supply Chain Improvement Purposes Only

Nurture routinely sold products that exceeded its internal standards. Twenty-nine other products that Nurture tested and sold registered over 100 ppb inorganic arsenic. In total, over 25% of the products that Nurture tested for inorganic arsenic, and sold, had inorganic arsenic levels above 100 ppb.³⁵

Nurture's Heavy Metal Test Results for Baby Food Products (Excerpted Entries)³⁶

Product Name	Goal Threshold	Result	Date of Test Report	Disposition
Apple & Broccoli Puffs	100	180	11/01/17	Sell
Banana & Pumpkin Puffs	100	160	10/31/17	Sell
Strawberry & Beet Puffs	100	160	10/31/17	Sell
Kale & Spinach Puffs	100	150	10/31/17	Sell
Kale & Spinach Puffs	100	150	10/31/17	Sell
Purple Carrot & Blueberry Puffs	100	150	11/17/17	Sell
Sweet Potato & Carrot Puffs	100	150	10/31/17	Sell
Sweet Potato & Carrot Puffs	100	150	10/31/17	Sell
Apple Rice Cakes	100	130	02/08/17	Sell
Apple Rice Cakes	100	130	02/08/17	Sell
Sweet Potato & Carrot Puffs	100	122	09/13/18	Sell
Apple Rice Cakes	100	120	02/08/17	Sell

³³ Nurture, *Heavy Metal Test Results for Baby Food Products* (Dec. 18, 2019) (online at <http://oversight.house.gov/sites/democrats.oversight.house.gov/files/1.xlsx>).

³⁴ *Id.*

³⁵ *Id.*

³⁶ *Id.*

Blueberry Beet Rice Cakes	100	120	02/08/17	Sell
Purple Carrot & Blueberry Puffs	100	120	10/31/17	Sell
Apple & Broccoli Puffs	100	115	10/15/18	Sell
Strawberry & Beet Puffs	100	114	03/21/19	Sell
Purple Carrot & Blueberry Puffs	100	112	06/05/18	Sell
Apple Rice Cakes	100	110	07/28/17	Sell
Blueberry Beet Rice Cakes	100	110	02/08/17	Sell
Blueberry Beet Rice Cakes	100	110	02/08/17	Sell
Strawberry & Beet Puffs	100	108	12/10/18	Sell
Strawberry & Beet Puffs	100	108	09/21/18	Sell
Apple & Broccoli Puffs	100	107	05/30/19	Sell
Strawberry & Beet Puffs	100	107	05/22/19	Sell
Strawberry & Beet Puffs	100	105	09/21/18	Sell
Strawberry & Beet Puffs	100	104	08/22/18	Sell
Banana & Pumpkin Puffs	100	103	04/24/19	Sell
Sweet Potato & Carrot Puffs	100	103	04/24/19	Sell
Banana & Pumpkin Puffs	100	101	09/21/18	Sell

The average amount of inorganic arsenic in the baby foods that Nurture tested and sold was 59.54 ppb. That towers over existing and recommended standards, including FDA's and EPA's water limits of 10 ppb.

At least 89 of Nurture's final products—over 78% of those products tested—tested at 9 ppb inorganic arsenic or above.

For results under 9.54 ppb, Nurture did not differentiate—it marked them all as “<9.54.” Because of this “less than” reporting format, there is no way to know if any of Nurture's products were free of inorganic arsenic.

Summary of Nurture's Inorganic Arsenic Results

180 ppb – Nurture's product with the highest amount of inorganic arsenic: Apple & Broccoli Puffs.
>100 ppb – Over 25% of the baby food products that were tested for inorganic arsenic had over 100 ppb inorganic arsenic.
59.54 ppb – Average amount of inorganic arsenic in all baby food products tested for inorganic arsenic.
>50 ppb – Over 50% of Nurture's baby food products that were tested for inorganic arsenic contained over 50 ppb inorganic arsenic.

- 2. Hain (Earth's Best Organic) produced finished baby foods that contained as much as 129 ppb inorganic arsenic; Hain used ingredients in its baby foods with as much as 309 ppb total arsenic.**

Hain does not regularly test finished baby food products for inorganic arsenic content. It typically only tests ingredients. However, when Hain did test a small sample of finished product, it found 129 ppb inorganic arsenic.³⁷

Hain Celestial, FDA Testing Result Investigation, August 1, 2019 (Excerpted Entries)³⁸

FDA Data					Estimate % Avg FG Increase from Avg Raw	Track & Trace Data					
FDA Sample Number	Best By Date	Lot number	FDA FG Inorganic Arsenic (ppb)	Avg FG Result		Packaging Date	WIP Batch	Rice Flour Lot #s	Type of Arsenic Test	Raw Material Results (ppb)	Avg Raw Result
1024309	4/27/19	BN I 2216	129	129.0	93%	11/3/17	204146	B160005305	Total Arsenic	69	67.0
								B160005306	Total Arsenic	76	
								B160005512	Total Arsenic	62	
								B160005152	Total Arsenic	61	

The Subcommittee's review of the ingredient test results reveals that Hain routinely used ingredients with high levels of arsenic. Hain used brown rice flour that had tested at 309 ppb arsenic.³⁹ Hain likewise used a vitamin pre-mix containing 223 ppb arsenic, and raisin and wheat flour containing 200 ppb arsenic.⁴⁰ The testing data shows that Hain used at least 24 ingredients after testing found that they contained more than 100 ppb arsenic, its already-dangerously-high internal standard for most ingredients.⁴¹

Hain, Raw Material Pre-Shipment Test Data History (Excerpted Entries)⁴²

Lab Results Date	Product Description	Status	Arsenic Spec Limit (ppb)	Arsenic Result (ppb)
Jun/19/2019	Org Brown Rice Flour	Deviation Approved	100	309
Nov/26/2019	Vitamin Pre-Mix	Deviation Approved	100	223
Jul/10/2018	Org Whole Raisins	Accepted	100	200
Sep/29/2017	Org Soft White Wheat Flour	Accepted	200	200
Dec/14/2017	Org Spelt Flour	Accepted	100	190
Jan/8/2018	Organic Barley Malt Extract	Accepted	100	180
Dec/5/2017	Org Yellow Split Pea Powder	Accepted	100	160
Jul/13/2017	Medium Grain Whole Rice	Accepted	200	150
Oct/3/2017	Org Brown Rice Flour	Accepted	100	140
Sep/4/2019	Org Brown Rice Flour	Deviation Approved	100	134
Dec/5/2017	Org Butternut Squash Puree	Accepted	100	130
Oct/31/2017	Org Brown Rice Flour	Accepted	100	130

³⁷ Hain, *PowerPoint Presentation to FDA: FDA Testing Result Investigation* (Aug. 1, 2019) (online at <https://oversight.house.gov/sites/democrats.oversight.house.gov/files/2.pdf>).

³⁸ *Id.*

³⁹ Hain, *Raw Material Pre-Shipment Test Data History* (Dec. 11, 2019) (online at https://oversight.house.gov/sites/democrats.oversight.house.gov/files/3_0.pdf).

⁴⁰ *Id.*

⁴¹ *Id.*

⁴² *Id.*

Oct/31/2017	Org Brown Rice Flour	Accepted	100	130
Oct/31/2017	Org Brown Rice Flour	Accepted	100	129
Oct/31/2017	Org Brown Rice Flour	Accepted	100	129
Oct/31/2017	Org Brown Rice Flour	Accepted	100	129
Oct/31/2017	Org Brown Rice Flour	Accepted	100	127
Oct/31/2017	Org Brown Rice Flour	Accepted	100	126
Dec/13/2017	Org Blueberry Puree	Accepted	100	120
Dec/27/2017	Org Barley Flour	Accepted	100	120
Oct/31/2017	Org Brown Rice Flour	Accepted	100	119
Nov/29/2017	Org Blueberry Puree	Accepted	100	110
Nov/3/2017	Org Cinnamon Powder	Accepted	100	110
Jul/11/2019	Org Brown Rice Flour	Accepted	100	101

3. Beech-Nut used ingredients in its baby foods with as much at 913.4 ppb arsenic; Beech-Nut routinely used ingredients that exceeded 300 ppb total arsenic; Beech-Nut unnecessarily uses high-arsenic additives to address issues like “crumb softness.”

Beech-Nut only tested arsenic content in its ingredients, not its final product. The Subcommittee has determined that Beech-Nut used ingredients containing as much as 913.4 ppb arsenic.⁴³ Test results show that Beech-Nut used at least fourteen other ingredients containing over 300 ppb arsenic.⁴⁴ And it used at least 45 ingredients containing over 100 ppb arsenic.

Beech-Nut, Raw Material Heavy Metal Testing (Excerpted Entries)⁴⁵

Date	Commodity	Arsenic Result (ppb)	Spec.	Acceptance (Y/N)
9/19/2018	Amylase	913.40	N/A	Y
4/26/2018	Amylase	741.10	N/A	Y
10/7/2017	BAN 800	710.90	<3000	Y
11/29/2017	Alpha Amylase	679.00	N/A	Y
10/12/2017	Amylase	645.10	N/A	Y
8/20/2019	Sebamyl 100	583.60	N/A	Y
3/6/2018	Org. Rice Flour	570.00	≤100(inorg)	Y
6/7/2019	Enzyme	499.30	N/A	Y
12/20/2017	BAN 800	465.20	<3000	Y
1/14/2019	Enzyme	442.30	N/A	Y
10/23/2017	BAN 800	401.40	<3000	Y

⁴³ Beech-Nut, *Raw Material Heavy Metal Testing* (Dec. 6, 2019) (online at <http://oversight.house.gov/sites/democrats.oversight.house.gov/files/4.xlsx>).

⁴⁴ *Id.*

⁴⁵ *Id.*

2/19/2018	BAN 800	382.00	<3000	Y
6/12/2018	Ban 800	353.80	<3000	Y
5/21/2018	Org. Cumin	322.70	≤1000	Y
4/13/2018	Org. Rice	237.40	≤100(inorg)	Y
4/12/2018	Rice Flour	170.00	≤100(inorg)	Y
4/6/2018	Rice Flour	170.00	≤100(inorg)	Y
7/14/2017	Org. Cumin	168.50	≤1000	y
7/31/2018	rice flour	162.00	≤100(inorg)	Y
2/28/2018	Rice Flour	161.00	≤100(inorg)	y
3/30/2017	Cumin	160.50	≤1000	Y
3/27/2018	Rice Flour	160.00	≤100(inorg)	Y
5/30/2018	Rice Flour	160.00	≤100(inorg)	Y
6/12/2018	Rice Flour	160.00	≤100(inorg)	Y
7/20/2018	Rice Flour	160.00	≤100(inorg)	Y
10/11/2016	Oregano	158.10	<1000	Y
1/15/2018	Rice Flour	150.00	≤100(inorg)	Y
1/15/2018	Rice Flour	150.00	≤100(inorg)	Y
2/15/2018	Rice Flour	150.00	≤100(inorg)	Y
5/31/2018	Rice Flour	150.00	≤100(inorg)	Y
2/22/2018	Rice Flour	140.00	≤100(inorg)	Y
1/6/2018	Rice Flour	140.00	≤100(inorg)	Y
4/6/2018	Rice Flour	140.00	≤100(inorg)	Y
9/4/2019	Org. rice	132.30	≤200	Y
11/3/2017	Org.Cumin	130.20	≤1000	Y
2/15/2018	Rice Flour	130.00	≤100(inorg)	Y
2/5/2018	Rice Flour	130.00	≤100(inorg)	Y
2/8/2018	Rice Flour	130.00	≤100(inorg)	Y
1/5/2018	Rice Flour	122.30	≤100(inorg)	Y
1/5/2018	Rice Flour	120.80	≤100(inorg)	Y
2/8/2018	Rice Flour	120.00	≤100(inorg)	Y
1/18/2017	Org.Rice	110.00	≤200	Y
5/8/2018	Rice Flour	110.00	≤100(inorg)	Y
5/17/2017	Rice	110.00	≤200	Y
2/6/2017	Vitamin Mix	106.90	<3000	Y

The six Beech-Nut ingredients with the highest arsenic levels—Amylase, BAN 800, Alpha Amylase, and Sebamyl 100—are all enzymes that Beech-Nut adds to its products. BAN 800 is an enzyme that reportedly “[i]ncreases crumb softness” in baked goods.⁴⁶ Amylase is an

⁴⁶ Novozymes, *Meet Consumer Demands with Enzymes that Support Organic Labeling* (May 2018) (online at www.novozymes.com/-/media/Project/Novozymes/Website/website/document-library/Advance-your-business/Baking/Baking-Product-Range-for-Organic-Production.pdf).

enzyme that is “used in bread-making as an additive to improve the conversion of complex sugars into simple sugars that yeast are then able to feed on and produce alcohol and CO₂.”⁴⁷

4. Gerber used 67 batches of rice flour that had more than 90 ppb inorganic arsenic.

Gerber did not provide inorganic arsenic results for all of its ingredients. However, test results for conventional rice flour revealed that Gerber routinely used flour with over 90 ppb inorganic arsenic.⁴⁸ Gerber used five batches of rice flour that had 98 ppb inorganic arsenic, and 67 batches that contained more than 90 ppb.

Gerber Products Company Test Results (Excerpted Entries)⁴⁹

Year	Ingredient	Total Arsenic (ppb)	Inorganic Arsenic (ppb)
2018	Flour Rice Long Grain Tote NGM InfG Kshr	105	98
2018	Flour Rice Long Grain Tote NGM InfG Kshr	105	98
2018	Flour Rice Long Grain Tote NGM InfG Kshr	105	98
2018	Flour Rice Long Grain Tote NGM InfG Kshr	105	98
2018	Flour Rice Long Grain Tote NGM InfG Kshr	105	98
2018	Flour Rice Long Grain Tote NGM InfG Kshr	107	97
2018	Flour Rice Long Grain Tote NGM InfG Kshr	107	97
2018	Flour Rice Long Grain Tote NGM InfG Kshr	107	97
2018	Flour Rice Long Grain Tote NGM InfG Kshr	107	97
2018	Flour Rice Long Grain Tote NGM InfG Kshr	107	97
2019	Flour Rice Long Grain Tote NGM InfG Kshr	105	96
2019	Flour Rice Long Grain Tote NGM InfG Kshr	105	96
2019	Flour Rice Long Grain Tote NGM InfG Kshr	105	96
2019	Flour Rice Long Grain Tote NGM InfG Kshr	105	96
2019	Flour Rice Long Grain Tote NGM InfG Kshr	105	96
2019	Flour Rice Long Grain Tote NGM InfG Kshr	105	96
2019	Flour Rice Long Grain Tote NGM InfG Kshr	105	96
2019	Flour Rice Long Grain Tote NGM InfG Kshr	105	96
2019	Flour Rice Long Grain Tote NGM InfG Kshr	105	96

⁴⁷ ChefSteps, *Amylase* (online at www.chefsteps.com/ingredients/amylase) (accessed Jan. 26, 2021).

⁴⁸ Gerber, *Gerber Products Company Test Results* (Dec. 9, 2019) (online at https://oversight.house.gov/sites/democrats.oversight.house.gov/files/5_0.pdf).

⁴⁹ *Id.*

2019	Flour Rice Long Grain Tote NGM InfG Kshr	105	96
2018	Flour Rice Long Grain Tote NGM InfG Kshr	123	95
2018	Flour Rice Long Grain Tote NGM InfG Kshr	123	95
2018	Flour Rice Long Grain Tote NGM InfG Kshr	95	95
2018	Flour Rice Long Grain Tote NGM InfG Kshr	123	95
2018	Flour Rice Long Grain Tote NGM InfG Kshr	123	95
2018	Flour Rice Long Grain Tote NGM InfG Kshr	124	95
2018	Flour Rice Long Grain Tote NGM InfG Kshr	124	95
2018	Flour Rice Long Grain Tote NGM InfG Kshr	124	95
2018	Flour Rice Long Grain Tote NGM InfG Kshr	124	95
2017	Flour Rice Long Grain Tote NGM InfG Kshr	118	94
2017	Flour Rice Long Grain Tote NGM InfG Kshr	118	94
2017	Flour Rice Long Grain Tote NGM InfG Kshr	94	94
2017	Flour Rice Long Grain Tote NGM InfG Kshr	118	94
2017	Flour Rice Long Grain Tote NGM InfG Kshr	118	94
2018	Flour Rice Long Grain Tote NGM InfG Kshr	111	94
2018	Flour Rice Long Grain Tote NGM InfG Kshr	111	94
2018	Flour Rice Long Grain Tote NGM InfG Kshr	111	94
2018	Flour Rice Long Grain Tote NGM InfG Kshr	111	94
2018	Flour Rice Long Grain Tote NGM InfG Kshr	111	94
2018	Flour Rice Long Grain Tote NGM InfG Kshr	111	94
2018	Flour Rice Long Grain Tote NGM InfG Kshr	111	94
2018	Flour Rice Long Grain Tote NGM InfG Kshr	111	94
2018	Flour Rice Long Grain Tote NGM InfG Kshr	111	94
2018	Flour Rice Long Grain Tote NGM InfG Kshr	111	94
2018	Flour Rice Long Grain Tote NGM InfG Kshr	111	94
2018	Flour Rice Long Grain Tote NGM InfG Kshr	111	94
2018	Flour Rice Long Grain Tote NGM InfG Kshr	121	93
2017	Flour Rice Long Grain Tote NGM InfG Kshr	123	92
2017	Flour Rice Long Grain Tote NGM InfG Kshr	123	92
2017	Flour Rice Long Grain Tote NGM InfG Kshr	123	92
2017	Flour Rice Long Grain Tote NGM InfG Kshr	123	92
2017	Flour Rice Long Grain Tote NGM InfG Kshr	108	92
2017	Flour Rice Long Grain Tote NGM InfG Kshr	92	92
2017	Flour Rice Long Grain Tote NGM InfG Kshr	108	92
2017	Flour Rice Long Grain Tote NGM InfG Kshr	108	92
2017	Flour Rice Long Grain Tote NGM InfG Kshr	108	92
2018	Flour Rice Long Grain Tote NGM InfG Kshr	120	92

2018	Flour Rice Long Grain Tote NGM InfG Kshr	120	92
2018	Flour Rice Long Grain Tote NGM InfG Kshr	120	92
2018	Flour Rice Long Grain Tote NGM InfG Kshr	120	92
2018	Flour Rice Long Grain Tote NGM InfG Kshr	120	92
2018	Flour Rice Long Grain Tote NGM InfG Kshr	120	92
2019	Flour Rice Long Grain Tote NGM InfG Kshr	138	91
2019	Flour Rice Long Grain Tote NGM InfG Kshr	138	91
2019	Flour Rice Long Grain Tote NGM InfG Kshr	138	91
2019	Flour Rice Long Grain Tote NGM InfG Kshr	138	91
2019	Flour Rice Long Grain Tote NGM InfG Kshr	138	91

B. Lead

There is a growing consensus among health experts that lead levels in baby foods should not exceed 1 ppb. The American Academy for Pediatrics, the Environmental Defense Fund, and Consumer Reports have all, in some form, called for a 1 ppb level in food and drinks that babies and children consume.⁵⁰ Healthy Babies Bright Futures has called for a goal of no measurable amount of lead in baby food.⁵¹

There is no federal standard for lead in baby food. However, FDA has set a 5 ppb lead standard for bottled water, WHO has set 10 ppb lead as a provisional guideline for drinking water, and EPA has set an action level of 15 ppb for lead in drinking water. FDA has also set standards for lead in juice (50 ppb) and candy (100 ppb). The European Union has set the maximum lead level in infant formula to 20 ppb.⁵²

⁵⁰ American Academy of Pediatrics, *Prevention of Childhood Lead Toxicity* (May 5, 2016) (online at <https://pediatrics.aappublications.org/content/pediatrics/early/2016/06/16/peds.2016-1493.full.pdf>); Environmental Defense Fund, *Lead in Food: A Hidden Health Threat* (June 15, 2017) (online at www.edf.org/sites/default/files/edf_lead_food_report_final.pdf); Consumer Reports, *Consumer Reports Letter to FDA on Reducing Heavy Elements Like Arsenic, Lead, and Cadmium in Fruit Juices* (Jan. 30, 2019) (online at <https://advocacy.consumerreports.org/research/consumer-reports-letter-to-fda-on-reducing-heavy-elements-like-arsenic-lead-and-cadmium-in-fruit-juices/>).

⁵¹ Healthy Babies Bright Futures, *What's in My Baby's Food? A National Investigation Finds 95 Percent of Baby Foods Tested Contain Toxic Chemicals That Lower Babies' IQ, Including Arsenic and Lead* (Oct. 2019) (online at www.healthybabyfood.org/sites/healthybabyfoods.org/files/2019-10/BabyFoodReport_FULLREPORT_ENGLISH_R5b.pdf).

⁵² World Health Organization, *Lead in Drinking-Water* (2011) (online at www.who.int/water_sanitation_health/dwq/chemicals/lead.pdf); Environmental Protection Agency, *Drinking Water Requirements for States and Public Water Systems* (online at www.epa.gov/dwreginfo/lead-and-copper-rule) (accessed Jan. 26, 2021); European Union, *Setting Maximum Levels for Certain Contaminants in Foodstuffs* (Dec. 19, 2006) (online at <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:02006R1881-20150521>).

Proposed and Existing Lead Standards

Group or Agency	Standard
Environmental Defense Fund	1 ppb, especially for baby food
Consumer Reports	1 ppb in fruit juices
American Academy of Pediatrics (AAP)	1 ppb for water fountains in schools
FDA	5 ppb for bottled water
World Health Organization	10 ppb provisional guideline
EPA	15 ppb for drinking water (action level)
European Union (EU)	20 ppb for “infant formulae and follow-on formulae”
FDA	50 ppb for juice
	100 ppb for candy

The Subcommittee’s investigation has found that baby food manufacturers are selling baby food with higher levels of lead than what is allowed by existing standards for water, juice, and candy. Internal testing data from Gerber, Nurture, Beech-Nut, and Hain demonstrate that all four companies sold products or used ingredients with significant amounts of lead. Only Nurture routinely tested its finished product for lead. Hain, Beech-Nut, and Gerber did not test their finished products, only their ingredients. All companies, whether they test their final products or merely their ingredients, sold baby foods even when they or their ingredients contained unsafe levels of lead.

- 1. Nurture (HappyBABY) sold finished baby food products after testing confirmed they contained as much as 641 ppb lead, over six times its already-dangerously-high internal standard.**

Nurture sold products that tested as high as 641 ppb lead—over six times higher than its internal limit of 100 ppb lead.⁵³ Nurture also sold five other products after they tested over 50 ppb lead.⁵⁴

⁵³ Nurture, *Heavy Metal Test Results for Baby Food Products* (Dec. 18, 2019) (online at <http://oversight.house.gov/sites/democrats.oversight.house.gov/files/1.xlsx>).

⁵⁴ *Id.*

*Nurture's Heavy Metal Test Results for Baby Food Products (Excerpted Entries)*⁵⁵

Product Name	Category	Best Before Date	Parameter	Goal Threshold	Result	Unit	Date of Test Report	Disposition
Blueberry Purple Carrot	Baby 7+ Months	10/25/2017	Lead	100	641	ppb	01/27/17	Sell - Testing For Monitoring & Supply Chain Improvement Purposes Only
Multi-Grain Cereal Canister	Baby 6+ Months	11/16/2018	Lead	100	580	ppb	08/30/17	Sell - Testing For Monitoring & Supply Chain Improvement Purposes Only
Apple Spinach Kiwi Cre	Baby 7+ Months	8/4/2018	Lead	100	86	ppb	07/28/17	Sell - Testing For Monitoring & Supply Chain Improvement Purposes Only
Blueberry Beet Rice Ca	Baby 7+ Months	5/22/2018	Lead	100	61	ppb	07/28/17	Sell - Testing For Monitoring & Supply Chain Improvement Purposes Only
Pea Spinach Teether	Baby 7+ Months	10/24/2019	Lead	100	55	ppb	12/12/18	Sell - Testing For Monitoring & Supply Chain Improvement Purposes Only
Pea Spinach Teether	Baby 7+ Months	05/07/2019	Lead	100	50	ppb	12/12/18	Sell - Testing For Monitoring & Supply Chain Improvement Purposes Only

Of the 206 finished products that Nurture tested for lead, 16 products registered over 20 ppb lead—exceeding the lenient EU standard. And 39 products, or 18.9%, tested over 10 ppb lead.⁵⁶ It is not clear that even one of Nurture's baby food products registered at or below 1 ppb lead, which should be the upper limit for lead content according to the health experts at Consumer Reports, the Environmental Defense Fund, and the American Academy of Pediatrics.

- Beech-Nut used ingredients containing as much as 886.9 ppb lead; Beech-Nut routinely used ingredients with high lead content, including 483 ingredients that contained over 5 ppb lead, 89 ingredients that contained over 15 ppb lead, and 57 ingredients that contained over 20 ppb lead.**

Beech-Nut used ingredients in its baby foods that contained high lead levels. For instance, Beech-Nut used cinnamon that contained 886.9 ppb lead.⁵⁷

*Beech-Nut's Raw Materials Heavy Metal Testing (Excerpted Entry)*⁵⁸

Date	Commodity	Preshipment Lot	Arsenic result (ppb)	Spec.	Cadmium result (ppb)	Spec.	Lead result (ppb)	Spec.	Acceptance (Y/N)
10/19/2016	cinnamon	762	18.8	≤1000	344.5	≤1000	886.9	≤1000	Y

Beech-Nut tested and used 57 ingredients that contained over 20 ppb lead, the EU's lax standard for lead in infant formula. Beech-Nut accepted 89 ingredients that tested at or over 15 ppb lead, EPA's action level for drinking water, and 483 ingredients that tested at or over 5 ppb lead, FDA's standard for lead in bottled water.⁵⁹

⁵⁵ *Id.*

⁵⁶ *Id.*

⁵⁷ Beech-Nut, *Raw Material Heavy Metal Testing* (Dec. 6, 2019) (online at <http://oversight.house.gov/sites/democrats.oversight.house.gov/files/4.xlsx>).

⁵⁸ *Id.*

⁵⁹ *Id.*

Beech-Nut's Raw Materials Heavy Metal Testing (Excerpted Entries)⁶⁰

Date	Commodity	Lead result (ppb)	Spec.	Acceptance (Y/N)
10/19/2016	Cinnamon	886.9	≤1000	Y
5/21/2018	Org. Cumin	644.9	≤1000	Y
8/11/2017	Org. Coriander	603.5	<1000	Y
10/11/2016	Oregano	570.4	<1000	Y
7/14/2017	Org. Cumin	231.2	≤1000	y
5/31/2017	Cinnamon	203.9	≤1000	Y
3/30/2017	Cumin	177.7	≤1000	Y
11/3/2017	Org. Cumin	167.7	≤1000	Y
12/5/2017	Org. Cinnamon	126.2	≤1000	Y
11/29/2017	Alpha Amylase	114.5	<300	Y
9/19/2018	Amylase	108.8	<300	Y
7/11/2017	Org. Lemon	102	≤160	Y
7/8/2019	Org. Cinnamon	100	≤1000	Y
7/12/2019	Org. Cinnamon	100	≤1000	Y
10/12/2017	Amylase	95.8	<300	Y
4/26/2018	Amylase	91	<300	Y
4/12/2017	Turmeric	76.3	≤1000	Y
8/27/2018	Sunflower Lecithin	71.6	≤100	Y
8/3/2017	Org. Lemon	63.7	≤160	Y

⁶⁰ *Id.*

4/11/2018	Org. Cinnamon	59	≤1000	Y
11/2/2018	S. Potato	55.3	≤15	Y
4/21/2017	Sunflower Lecithin	54.9	≤100	Y
8/15/2018	Quinoa Flour	51.6	<75	Y
11/2/2018	S. Potato	50.1	≤15	Y
10/25/2016	Lemon	47.5	≤160	Y
1/14/2019	Enzyme	47.3	<300	Y
5/31/2018	Prune Puree	41.5	≤40	Y - ER
11/6/2018	S. Potato	40.3	≤15	Y
9/29/2017	Org. Turmeric	39.3	≤1000	Y
9/13/2019	Org. Cinnamon	37.8	≤1000	Y
8/11/2017	Org. Cinnamon	36.7	≤1000	y
11/6/2018	S. Potato	35.2	≤15	Y
11/2/2018	S. Potato	34.9	≤15	Y
10/10/2018	Dehydrated Potato	32.4	<75	Y - ER
8/2/2018	Mango	32.3	≤20	Y
11/2/2018	S. Potato	31.8	≤15	Y
6/11/2018	Sunflower Lecithin	31.7	≤100	Y
8/6/2018	Prune	31.1	≤40	
8/20/2019	Sebamyl 100	30.6	<300	Y
3/19/2018	Org. Prune	30	≤40	Y
9/20/2016	Apricot	28	≤20	Y - ER
2/13/2019	Org. Prune	27.9	≤40	Y - ER

6/7/2019	Enzyme	26.3	<300	Y
6/19/2018	Org. Quinoa Flour	25.3	<75	Y - ER
2/6/2017	Vitamin Mix	24.6	<10	Y
9/28/2017	Org. Quinoa Seeds	24.2	<75	Y
9/28/2017	Org. Quinoa Seeds	24.2	<75	Y
2/1/2019	Blueberry	22.7	<25	Y
11/6/2018	S. Potato	22	≤15	Y
3/18/2019	Org. Pears	21.7	<10	
6/14/2019	Sunflower Lecithin	21	≤100	Y
3/20/2018	Carrots	20	<25	Y - ER
3/20/2018	Carrots	20	<25	Y - ER
3/19/2018	Carrots	20	<25	Y - ER
3/19/2018	Carrots	20	<25	Y - ER
3/16/2017	Sunflower Lecithin	20	≤100	Y
3/1/2019	Org. Cinnamon	20	≤1000	Y

3. Hain (Earth's Best Organic) used ingredients containing as much as 352 ppb lead; Hain consistently used baby food ingredients with high lead content, including 88 ingredients that tested over 20 ppb lead and six ingredients that tested over 200 ppb lead.

Hain used an ingredient called vitamin pre-mix in its baby food that contained as much as 352 ppb lead.⁶¹

⁶¹ Hain, *Raw Material Pre-Shipment Test Data History* (Dec. 11, 2019) (online at https://oversight.house.gov/sites/democrats.oversight.house.gov/files/3_0.pdf).

Hain's Raw Material Pre-Shipment Test Data History (Excerpted Entry)⁶²

Lab Results Date	Vendor Name	Item Number	Product Description	Status	Comments on Status	Lab	Spec Based On	Arsenic Spec Limit (ppb)	Arsenic Result (ppb)	Lead Spec Limit (ppb)	Lead Result (ppb)
Nov/26/2019	Wright Enrichment	5316067	Vitamin Pre Mix	Deviation Approved	Accepted on deviation 20190236	Eurofins/C	As Purchased ovance	100	223	100	352

Hain used six ingredients that tested above 200 ppb lead. Hain used 88 ingredients with lead levels at or over 20 ppb—the EU's standard for lead in infant formula. Hain accepted 115 ingredients that registered at or over 15 ppb—EPA's action level for drinking water. And at least 27% of Hain ingredients tested at or over 5 ppb lead, FDA's standard for lead in bottled water. None of the test results showed an ingredient below 1 ppb lead, which should be the upper limit for lead content according to the health experts at Consumer Reports, the Environmental Defense Fund, and the American Academy of Pediatrics.

Hain's Raw Material Pre-Shipment Test Data History (Excepted Entries for Ingredients Above 200 ppb Lead)⁶³

Lab Results Date	Vendor Name	Item Number	Product Description	Status	Comments on Status	Lab	Spec Based On	Arsenic Spec Limit (ppb)	Arsenic Result (ppb)	Cadmium Spec Limit (ppb)	Cadmium Result (ppb)	Lead Spec Limit (ppb)	Lead Result (ppb)
Nov/26/2019	Wright Enrichment	5316067	Vitamin Pre Mix	Deviation Approved	Accepted on deviation 20190236	Eurofins/C	As Purchased ovance	100	223	100	60.5	100	352
Jan/19/2018	Grain Millers	471138	Org Whole Wheat Fine Flour	Accepted	Calculated Levels on consumed basis	Deibel	As consumed	100	<100	100	160	100	250
Dec/28/2017	Grain Millers	471011	Org Quick Oats	Accepted	Calculated Levels on consumed basis	Deibel	As consumed	100	<100	100	<100	100	230
Dec/27/2017	Grain Millers	55300	Org Barley Flour	Accepted	Calculated Levels on consumed basis	Deibel	As consumed	100	120	100	<100	100	230
Nov/3/2017	Starwest Botanicals	40500	Org Cinnamon Powder	Accepted	Calculated Levels on consumed basis	Deibel	As consumed	100	110	100	200	100	230
Jan/22/2018	Jewel Date	14300	Org Date Paste	Accepted	Calculated Levels on consumed basis	Deibel	As consumed	100	<100	100	190	100	220

4. Gerber used ingredients that tested as high as 48 ppb lead; and routinely accepted ingredients containing over 20 ppb lead.

Gerber produced limited lead testing results. The results for its sweet potatoes and juices demonstrated its willingness to use ingredients that contained dangerous lead levels. Gerber used an ingredient, conventional sweet potatoes, with 48 ppb lead. Gerber also used twelve other batches of sweet potato that tested over 20 ppb for lead, the EU's lenient upper standard.⁶⁴

⁶² *Id.*

⁶³ *Id.*

⁶⁴ Gerber, *Gerber Products Company Test Results* (Dec. 9, 2019) (online at https://oversight.house.gov/sites/democrats.oversight.house.gov/files/5_0.pdf).

Gerber Products Company Test Results (Excerpted Entries)⁶⁵

Year	Ingredient	Lead Level (ppb)
2017	Conventional	48
2017	Organic	35
2017	Organic	34
2017	Organic	34
2018	Conventional	34
2019	Conventional	34
2019	Conventional	34
2018	Organic	25
2019	Organic	25
2018	Organic	22
2018	Organic	22
2018	Organic	21
2019	Conventional	21

The average amount of lead in Gerber's tested juice concentrates was 11.2 ppb—more than FDA's limit for lead in bottled water. Over 83% of the juice concentrates tested showed greater than 1 ppb lead, which is Consumer Reports' recommended limit for fruit juices.

Gerber Products Company Test Results (Excerpted Entries)⁶⁶

GERBER Products Company Test Results		Confidential Business Information	
		19-Dec-19	
Juice Concentrate Ingredients (Lead Results)			
Year	Ingredient		Lead (ppb)
2018	Grape Juice White 68 Bx Asp Tote AR InfG	Supplier 1	29
2018	Grape Juice White 68 Bx Asp Tote AR InfG	Supplier 1	26
2018	Grape Juice White 68 Bx Asp Tote AR InfG	Supplier 1	25

⁶⁵ *Id.*

⁶⁶ *Id.*

C. Cadmium

Outside the context of baby food, some regulation has taken action against cadmium. For example, EPA has a limit of 5 ppb in drinking water, and FDA has set a limit of 5 ppb in bottled water.⁶⁷ These standards approach WHO's 3 ppb limit for cadmium in drinking water.⁶⁸

Groups like Healthy Babies Bright Futures have set a goal of no measurable amount of cadmium in baby food.⁶⁹ Consumer Reports has called for a limit of 1 ppb cadmium in fruit juices.⁷⁰ And the EU has set a limit ranging from 5–20 ppb cadmium for infant formula.

The Subcommittee found that baby food manufacturers sold many products with much higher cadmium content.

Proposed and Existing Cadmium Standards

Group or Agency	Standard
Consumer Reports	1 ppb in all fruit juices
World Health Organization	3 ppb for drinking water
EPA	5 ppb for drinking water
FDA	5 ppb for drinking water
European Union (EU)	5-20 ppb for infant formulae

1. Beech-Nut used ingredients in its baby food containing up to 344.55 ppb cadmium; 105 Beech-Nut ingredients tested over 20 ppb cadmium.

Beech-Nut used twenty ingredients registering over 100 ppb cadmium, including cinnamon containing 344.5 ppb cadmium.⁷¹ That is more than 17 times higher than the EU's lax

⁶⁷ 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) (online at www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?fr=165.110).

⁶⁸ World Health Organization, *Cadmium in Drinking-Water* (2011) (online at www.who.int/water_sanitation_health/water-quality/guidelines/chemicals/cadmium.pdf?ua=1).

⁶⁹ Healthy Babies Bright Futures, *What's in My Baby's Food? A National Investigation Finds 95 Percent of Baby Foods Tested Contain Toxic Chemicals That Lower Babies' IQ, Including Arsenic and Lead* (Oct. 2019) (online at www.healthybabyfood.org/sites/healthybabyfoods.org/files/2019-10/BabyFoodReport_FULLREPORT_ENGLISH_R5b.pdf).

⁷⁰ Consumer Reports, *Consumer Reports Letter To FDA On Reducing Heavy Elements Like Arsenic, Lead, and Cadmium in Fruit Juices* (Jan. 30, 2019) (online at <https://advocacy.consumerreports.org/research/consumer-reports-letter-to-fda-on-reducing-heavy-elements-like-arsenic-lead-and-cadmium-in-fruit-juices/>); European Union, *Setting Maximum Levels for Certain Contaminants in Foodstuffs* (Dec. 19, 2006) (online at <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:02006R1881-20150521>).

⁷¹ Beech-Nut, *Raw Material Heavy Metal Testing* (Dec. 6, 2019) (online at <http://oversight.house.gov/sites/democrats.oversight.house.gov/files/4.xlsx>).

upper limit on cadmium in baby food. At least 105 ingredients that Beech-Nut tested and used in baby foods registered at or over 20 ppb cadmium—the EU’s lax infant formula upper limit.⁷²

Beech-Nut’s Raw Materials Heavy Metal Testing (Excerpted Entries)⁷³

Date	Commodity	Cadmium Result (ppb)	Spec.	Acceptance (Y/N)
10/19/2016	Cinnamon	344.50	≤1000	Y
4/11/2018	Org. Cinnamon	225.10	≤1000	Y
5/31/2017	Cinnamon	194.30	≤1000	Y
6/8/2018	Org. Garlic	186.00	≤1000	Y
8/11/2017	Org. Cinnamon	178.20	≤1000	y
10/11/2016	Oregano	176.50	<1000	Y
12/5/2017	Org. Cinnamon	163.40	≤1000	Y
11/29/2017	Dehydrated Potato	148.40	<90	Y - ER
10/10/2018	Dehydrated Potato	146.00	<90	Y
10/10/2018	Dehydrated Potato	143.50	<90	Y - ER
7/10/2019	Spinach Puree	143.00	<180	Y
7/2/2018	Fresh Spinach	142.30	<180	Y
7/8/2019	Org. Cinnamon	140.00	≤1000	Y
7/12/2019	Org. Cinnamon	140.00	≤1000	Y
3/1/2019	Org. Cinnamon	120.00	≤1000	Y
11/29/2017	Dehydrated Potato	119.60	<90	Y - ER
9/13/2019	Org. Cinnamon	117.30	≤1000	Y
7/15/2019	Spinach	117.00	<180	Y
7/15/2019	Spinach	101.00	<180	Y
7/15/2019	Spinach	101.00	<180	Y

2. Hain (Earth’s Best Organic) used ingredients in its baby food containing up to 260 ppb cadmium; 102 Hain ingredients tested over 20 ppb cadmium.

Hain used 14 ingredients that contained more than 100 ppb cadmium, including barley flour that registered at 260 ppb cadmium.⁷⁴ That is thirteen times the EU’s lax upper limit on cadmium in baby food. Hain tested and used 102 ingredients that registered at or above 20 ppb cadmium—the EU’s lax upper limit.

⁷² *Id.*

⁷³ *Id.*

⁷⁴ Hain, *Raw Material Pre-Shipment Test Data History* (Dec. 11, 2019) (online at https://oversight.house.gov/sites/democrats.oversight.house.gov/files/3_0.pdf).

*Hain’s Raw Material Pre-Shipment Test Data History (Excerpted Entries)*⁷⁵

Lab Results Date	Products Description	Status	Cadmium Spec. limit (ppb)	Cadmium Result (ppb)
Jan/19/2018	Org Barley Flour	Accepted	100	260
Jan/22/2018	IQF Org Chopped Broccoli	Accepted	100	250
Jan/23/2018	Org Date Paste	Accepted	100	220
Nov/3/2017	Org Cinnamon Powder	Accepted	100	200
Aug/21/2017	Org Brown Flax Milled	Accepted	100	190
Jan/22/2018	Org Date Paste	Accepted	100	190
Jan/18/2018	Org Yellow Papaya Puree	Accepted	100	170
Jan/19/2018	Org Whole Wheat Fine Flour	Accepted	100	160
Aug/17/2017	Org Red Lentils	Accepted	100	130
Jan/15/2018	Org Oat Flakes	Accepted	100	130
Jun/13/2018	Org Brown Flax Milled	Accepted	100	121
Jan/12/2018	Org Barley Flour	Accepted	100	110
Jun/25/2018	Org Oat Flour	Accepted	100	102
Feb/19/2019	Org Cinnamon Powder	Deviation Approved	100	102

3. Sixty-five percent of Nurture (HappyBABY) finished baby food products contained more than 5 ppb cadmium, the EPA’s limit for drinking water.

Nurture sold multi-grain cereal with 49 ppb cadmium. Nurture sold another 125 products that tested over 5 ppb, which is the EPA’s limit for drinking water.⁷⁶

*Nurture’s Heavy Metal Test Results for Baby Food Products (Excerpted Entries)*⁷⁷

Product Name	Category	Best Before Date	Parameter	Goal Thresh old	Result	Unit	Date of Test	Disposition
Multi-Grain Cereal Canister	Baby 6+ Months	11/16/2018	Cadmium	50	49	ppb	08/30/17	Sell - Testing For Monitoring & Supply Chain Improvement Purposes Only
Strawberry Raspberj	Baby 7+ Months	1/18/2019	Cadmium	50	36	ppb	12/06/17	Sell - Testing For Monitoring & Supply Chain Improvement Purposes Only
Kale & Spinach Puffs	Baby 7+ Months	12/4/2020	Cadmium	50	35	ppb	10/09/19	Sell - Testing For Monitoring & Supply Chain Improvement Purposes Only
Strawberry Raspberj	Baby 7+ Months	11/10/2019	Cadmium	50	31	ppb	10/23/18	Sell - Testing For Monitoring & Supply Chain Improvement Purposes Only
Strawberry Raspberj	Baby 7+ Months	11/10/2019	Cadmium	50	30	ppb	10/31/18	Sell - Testing For Monitoring & Supply Chain Improvement Purposes Only

⁷⁵ *Id.*

⁷⁶ Nurture, *Heavy Metal Test Results for Baby Food Products* (Dec. 18, 2019) (online at <http://oversight.house.gov/sites/democrats.oversight.house.gov/files/1.xlsx>).

⁷⁷ *Id.*

4. Gerber used carrots containing as much as 87 ppb cadmium; 75% of Gerber’s carrots contain cadmium in excess of 5 ppb.

Gerber does not test all its ingredients for cadmium. Of those it does test, it accepts ingredients with high levels of cadmium. Gerber used multiple batches of carrots containing as much as 87 ppb cadmium, and 75% of the carrots Gerber used had more than 5 ppb cadmium—the EPA’s drinking water standard.⁷⁸

Gerber Products Company Test Results (Excerpted Entries)⁷⁹

Year	Ingredient	Supplier	Arsenic (ppb)	Cadmium (ppb)	Mercury (ppb)	Lead (ppb)
2018	Conventional	Supplier 1		87		
2018	Conventional	Supplier 4		53		
2019	Conventional	Supplier 4		42		
2017	Conventional	Supplier 1	<2	40	<1	4

D. Mercury

Outside the context of baby food, some regulation has taken action against mercury. EPA, for example, has capped mercury in drinking water at 2 ppb.⁸⁰ Consumer advocates urge even stricter standards for baby food. For example, Health Babies Bright Futures has called for a goal of no measurable amount of mercury in baby food.⁸¹

1. Nurture (HappyBABY) sold finished baby food products containing as much as 10 ppb mercury.

Nurture sold a finished baby food product that contained 10 ppb mercury, and two others that contained 9.8 and 7.3 ppb. A level of 10 ppb is five times more than the EPA’s 2 ppb standard for drinking water. In total, Nurture sold 56 products that contained over 2 ppb mercury.⁸²

⁷⁸ Gerber, *Gerber Products Company Test Results* (Dec. 9, 2019) (online at https://oversight.house.gov/sites/democrats.oversight.house.gov/files/5_0.pdf).

⁷⁹ *Id.*

⁸⁰ 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).

⁸¹ Healthy Babies Bright Futures, *What’s in My Baby’s Food? A National Investigation Finds 95 Percent of Baby Foods Tested Contain Toxic Chemicals That Lower Babies’ IQ, Including Arsenic and Lead* (Oct. 2019) (online at www.healthybabyfood.org/sites/healthybabyfoods.org/files/2019-10/BabyFoodReport_FULLREPORT_ENGLISH_R5b.pdf).

⁸² Nurture, *Heavy Metal Test Results for Baby Food Products* (Dec. 18, 2019) (online at <http://oversight.house.gov/sites/democrats.oversight.house.gov/files/1.xlsx>).

*Nurture's Heavy Metal Test Results for Baby Food Products (Excerpted Entries)*⁸³

Product Name	Category	Best Before Date	Parameter	Goal Threshold	Result	Unit	Date of Test Report	Disposition
Brown Rice Cereal Canister	Baby 6+ Months	08/16/2019	Mercury	10	10	ppb	08/20/18	Sell - Testing For Monitoring & Supply Chain Improvement Purposes Only
Banana Sweet Potato Tee	Baby 7+ Months	6/9/2019	Mercury	10	9.8	ppb	04/16/18	Sell - Testing For Monitoring & Supply Chain Improvement Purposes Only
Brown Rice Cereal Canister	Baby 6+ Months	04/17/2019	Mercury	10	7.3	ppb	12/04/18	Sell - Testing For Monitoring & Supply Chain Improvement Purposes Only

2. Beech-Nut and Hain (Earth's Best Organic) did not even test for mercury in baby food; Gerber barely tests for it.

From the documents produced to this Subcommittee, it appears that neither Beech-Nut nor Hain tests their ingredients or their finished products for mercury.

Gerber only tests certain ingredients for mercury. Of the test results they presented to the Subcommittee, they only tested carrots, sweet potatoes, and lemon juice concentrate.

III. INDUSTRY SELF-REGULATION FAILS TO PROTECT CONSUMERS: NURTURE, BEECH-NUT, HAIN, AND GERBER SET THEIR OWN DANGEROUSLY HIGH INTERNAL STANDARDS FOR TOXIC HEAVY METAL LEVELS AND ROUTINELY IGNORED THEM TO SELL PRODUCTS WITH HIGHER HEAVY METAL LEVELS.

Baby food manufacturers are free to set their own internal standards for toxic heavy metal content of their products. They have set those standards at dangerously high levels and have often sold foods that exceed even those levels.

A. Nurture (HappyBABY) sets high internal standards and regularly exceeds them. Nurture admits that its toxic heavy metal testing is not for safety—it sells all products tested, regardless of its toxic heavy metal content. FDA has finalized only one standard—100 ppb inorganic arsenic in infant rice cereal—Nurture has ignored it, setting its internal standard for that product at 115 ppb.

Nurture created internal standards but did not follow them. Nurture describes these standards as “goal thresholds” that “are not used to make product disposition decisions and are not a pre-condition to product release.”⁸⁴ Instead, its testing regime is limited to monitoring the supply chain. Nurture’s thresholds are not actually used to prevent products that contain high levels of toxic heavy metals from being sold.⁸⁵

⁸³ *Id.*

⁸⁴ Letter from Nurture, Inc. to Chairman Raja Krishnamoorthi, Subcommittee on Economic and Consumer Policy, Committee on Oversight and Reform (Dec. 18, 2019) (online at <https://oversight.house.gov/sites/democrats.oversight.house.gov/files/10.pdf>).

⁸⁵ *Id.*

Nurture does not even claim to be testing for safety—it made clear in its letter response to this Subcommittee that all products will be sold regardless of testing result: **“our heavy metal testing is performed as part of our monitoring program and not as a condition of product release, all of the products that were tested were sold into commerce.”**⁸⁶

Nurture sells the products it tests, regardless of their toxic heavy metal content. In total, Nurture tested 113 final products and sold every product tested, regardless of how much inorganic arsenic or lead the product contained, and regardless of whether those metals exceeded its own internal standards.

As a result of this policy of not testing for safety, Nurture released products containing as much as 641 ppb lead and 180 ppb inorganic arsenic.⁸⁷

Nurture sold 29 products that were above its internal arsenic limit of 100 ppb, including Apple & Broccoli Puffs that contained 180 ppb inorganic arsenic. Nurture’s standards “are not used to make product disposition decisions and are not a pre-condition to product release.” Instead, their testing regime is limited to monitoring the supply chain.⁸⁸

Nurture’s Heavy Metal Test Results for Baby Food Products (Excerpted Entries)⁸⁹

Product Name	Category	Best Before Date	Parameter	Goal Thresh		Unit	Date of Test Report	Disposition
				old	Result			
Apple & Broccoli Puffs	Baby 7+ Months	9/7/2018	Inorganic Arsenic	100	180	ppb	11/01/17	Sell - Testing For Monitoring & Supply Chain Improvement Purposes Only
Banana & Pumpkin Puffs	Baby 7+ Months	10/11/2018	Inorganic Arsenic	100	160	ppb	10/31/17	Sell - Testing For Monitoring & Supply Chain Improvement Purposes Only
Strawberry & Beet Puffs	Baby 7+ Months	7/24/2018	Inorganic Arsenic	100	160	ppb	10/31/17	Sell - Testing For Monitoring & Supply Chain Improvement Purposes Only
Kale & Spinach Puffs	Baby 7+ Months	3/16/2019	Inorganic Arsenic	100	150	ppb	10/31/17	Sell - Testing For Monitoring & Supply Chain Improvement Purposes Only
Kale & Spinach Puffs	Baby 7+ Months	11/16/2018	Inorganic Arsenic	100	150	ppb	10/31/17	Sell - Testing For Monitoring & Supply Chain Improvement Purposes Only
Purple Carrot & Blueberry Puffs	Baby 7+ Months	2/15/2019	Inorganic Arsenic	100	150	ppb	11/17/17	Sell - Testing For Monitoring & Supply Chain Improvement Purposes Only
Sweet Potato & Carrot Puffs	Baby 7+ Months	1/19/2019	Inorganic Arsenic	100	150	ppb	10/31/17	Sell - Testing For Monitoring & Supply Chain Improvement Purposes Only

⁸⁶ *Id.*

⁸⁷ Nurture, *Heavy Metal Test Results for Baby Food Products* (Dec. 18, 2019) (online at <http://oversight.house.gov/sites/democrats.oversight.house.gov/files/1.xlsx>).

⁸⁸ Letter from Nurture, Inc. to Chairman Raja Krishnamoorthi, Subcommittee on Economic and Consumer Policy, Committee on Oversight and Reform (Dec. 18, 2019) (online at <https://oversight.house.gov/sites/democrats.oversight.house.gov/files/10.pdf>).

⁸⁹ Nurture, *Heavy Metal Test Results for Baby Food Products* (Dec. 18, 2019) (online at <http://oversight.house.gov/sites/democrats.oversight.house.gov/files/1.xlsx>).

Further, Nurture appears to have misled the Subcommittee about its testing standards. As seen from Nurture’s goal thresholds pictured below, Nurture conveyed to the Subcommittee that after January of 2019, it had a goal threshold of 50 ppb for lead in all of its baby food products—infant formula, cereals, and wet foods.⁹⁰ However, in the test results that Nurture provided to this Subcommittee, it was still using 100 ppb as an internal guideline after January 2019.

This image is from Nurture’s December 18, 2019, response to the Subcommittee, stating that after January of 2019, its lead threshold was 50 ppb in all baby food products:⁹¹

All of our specific goal thresholds for the referenced contaminants⁸ are set forth in the chart below.

<u>Product Type</u>	<u>Contaminant</u>	<u>Analytical Matrix</u>	<u>Goal Threshold</u>	<u>Unit</u>
Infant Formula	Cadmium	As Sold	10	ppb
Infant Formula	Inorganic Arsenic	As Sold	75	ppb
Infant Formula	Lead	As Sold	50	ppb
Cereals	Cadmium	As Consumed	50	ppb
Cereals with <75% Rice	Inorganic Arsenic	As Sold	100	ppb
Cereals with >75% Rice	Inorganic Arsenic	As Sold	115	ppb
Cereals	Lead	As Consumed	50*	ppb
Cereals	Mercury	As Consumed	10	ppb
Wet Foods	Cadmium	As Consumed	50	ppb
Wet Foods	Inorganic Arsenic	As Sold	100	ppb
Wet Foods	Lead	As Consumed	50*	ppb
Wet Foods	Mercury	As Consumed	10	ppb

*Threshold lowered from 100ppb to 50ppb in January, 2019.

However, the chart below appears to show that after the date Nurture claims to have moved to a 50 ppb lead standard—January 2019—Nurture was still using a “Goal Threshold” of 100 ppb for 53 baby food products. The fact that Nurture appears to have continued using a higher standard up to nine months after it claimed to the Subcommittee to have lowered the threshold casts serious doubt on Nurture’s candor in this matter.

*Nurture’s Heavy Metal Test Results for Baby Food Products (Excerpted Entries)*⁹²

⁹⁰ Letter from Nurture, Inc. to Chairman Raja Krishnamoorthi, Subcommittee on Economic and Consumer Policy, Committee on Oversight and Reform (Dec. 18, 2019) (online at <https://oversight.house.gov/sites/democrats.oversight.house.gov/files/10.pdf>).

⁹¹ *Id.*

⁹² Nurture, *Heavy Metal Test Results for Baby Food Products* (Dec. 18, 2019) (online at <http://oversight.house.gov/sites/democrats.oversight.house.gov/files/1.xlsx>).

Product Name	Parameter	Goal Threshold	Result	Unit	Date of Test Report
Blueberry Beet Rice Cakes	Lead	100	<4.0	ppb	10/14/19
Stage 3 Root Vegetable and Turkey	Lead	100	<4.0	ppb	10/11/19
Apple & Broccoli Puffs	Lead	100	5.8	ppb	10/10/19
Apple Cinnamon Oat Jar	Lead	100	<4.0	ppb	10/09/19
Apple Spinach Jar	Lead	100	<4.0	ppb	10/09/19
Kale & Spinach Puffs	Lead	100	9.7	ppb	10/09/19
Apple Mango Beet	Lead	100	<4.0	ppb	08/22/19
Pear Prune Jar	Lead	100	<4.0	ppb	08/22/19
Apple Spinach Pea & Kiwi	Lead	100	43	ppb	08/22/19
Pea Spinach Teether	Lead	100	18	ppb	08/16/19
Strawberry Yogis	Lead	100	<4.0	ppb	08/13/19
Sweet Potato & Carrot Puffs	Lead	100	7.7	ppb	07/25/19
Banana & Pumpkin Puffs	Lead	100	6.2	ppb	07/25/19
Apples Blueberries & Oats	Lead	100	<4.0	ppb	07/24/19
CC Oats & Quinoa Cereal	Lead	100	<4.0	ppb	07/24/19
Green Beans Jar	Lead	100	<4.0	ppb	07/24/19
Pears Mangoes & Spinach	Lead	100	<4.0	ppb	07/24/19
Carrots	Lead	100	<4.0	ppb	07/20/19
Pea Spinach Teether	Lead	100	23	ppb	07/11/19
Apple & Broccoli Puffs	Lead	100	11	ppb	07/11/19
Kale & Spinach Puffs	Lead	100	11	ppb	07/11/19
Mangoes	Lead	100	<4.0	ppb	07/03/19
Sweet Potatoes Jar	Lead	100	<4.0	ppb	07/03/19
CC Oats & Quinoa Cereal	Lead	100	<4.0	ppb	07/02/19
Harvest Vegetables & Chicken	Lead	100	<4.0	ppb	07/02/19
Apple Rice Cakes	Lead	100	7.2	ppb	07/02/19
Blueberry Purple Carrot Greek Yogis	Lead	100	4.3	ppb	07/02/19
Apple & Broccoli Puffs	Lead	100	9.9	ppb	05/30/19
Strawberry & Beet Puffs	Lead	100	10	ppb	05/22/19
Apples & Spinach	Lead	100	<4.0	ppb	05/15/19
Clearly Crafted Apple Guava Beet	Lead	100	<4.0	ppb	05/10/19
Sweet Potato Jar	Lead	100	<4.0	ppb	05/10/19
Banana & Pumpkin Puffs	Lead	100	13	ppb	04/24/19
Sweet Potato & Carrot Puffs	Lead	100	7.7	ppb	04/24/19
Apple Pumpkin Carrots	Lead	100	<4.0	ppb	04/12/19
Pea Spinach Teether	Lead	100	23	ppb	04/12/19
Multi-Grain Cereal Canister	Lead	100	5.2	ppb	04/12/19
Carrots	Lead	100	<4.0	ppb	04/11/19
Sweet Potato Jar	Lead	100	<4.0	ppb	04/11/19
Apple Spinach Pea & Kiwi	Lead	100	34	ppb	03/29/19
Strawberry & Beet Puffs	Lead	100	7.8	ppb	03/21/19

Banana & Pumpkin Puffs	Lead	100	5.5	ppb	03/21/19
CC Oatmeal Cereal	Lead	100	<4.0	ppb	03/18/19
Carrots & Peas	Lead	100	<4.0	ppb	03/13/19
CC Prunes	Lead	100	<4.0	ppb	03/13/19
Pears & Kale Jar	Lead	100	<4.0	ppb	03/13/19
Vegetable & Beef Medley	Lead	100	<4.0	ppb	03/07/19
Banana Sweet Potato Teether	Lead	100	12	ppb	02/19/19
Banana & Pumpkin Puffs	Lead	100	11	ppb	02/19/19
Blueberry Purple Carrot Teether	Lead	100	10	ppb	02/19/19
Mangoes	Lead	100	<4.0	ppb	02/13/19
Apple Mango Beet	Lead	100	<4.0	ppb	02/12/19
Strawberry Banana Greek Yogis	Lead	100	<4.0	ppb	02/12/19

Nurture has also ignored the only final standard that FDA has set. FDA set a 100 ppb inorganic arsenic limit for infant rice cereal. Rather than comply with that limit, Nurture set its internal standards 15% higher, at 115 ppb inorganic arsenic.⁹³

*Excerpt of December 18, 2019, Letter from Nurture, Inc. to Chairman Raja Krishnamoorthi*⁹⁴

<u>Product Type</u>	<u>Contaminant</u>	<u>Analytical Matrix</u>	<u>Goal Threshold</u>	<u>Unit</u>
Infant Formula	Cadmium	As Sold	10	ppb
Infant Formula	Inorganic Arsenic	As Sold	75	ppb
Infant Formula	Lead	As Sold	50	ppb
Cereals	Cadmium	As Consumed	50	ppb
Cereals with <75% Rice	Inorganic Arsenic	As Sold	100	ppb
Cereals with >75% Rice	Inorganic Arsenic	As Sold	115	ppb

B. Beech-Nut set internal arsenic and cadmium standards at 3,000 ppb in dangerous additives, such as vitamin mix, and 5,000 ppb lead for certain ingredients like BAN 800. These standards are the highest of any responding manufacturer.

Beech-Nut has set an internal specification limit (listed in the chart below as “spec.”) of 3,000 ppb inorganic arsenic for certain ingredients, including vitamin mix.⁹⁵ As a result of

⁹³ Letter from Nurture, Inc. to Chairman Raja Krishnamoorthi, Subcommittee on Economic and Consumer Policy, Committee on Oversight and Reform (Dec. 18, 2019) (online at <https://oversight.house.gov/sites/democrats.oversight.house.gov/files/10.pdf>).

⁹⁴ *Id.*

⁹⁵ Beech-Nut, *Raw Material Heavy Metal Testing* (Dec. 6, 2019) (online at <http://oversight.house.gov/sites/democrats.oversight.house.gov/files/4.xlsx>).

adopting this high internal standard, Beech-Nut has used ingredients containing 710.9, 465.2, and 401.4 ppb arsenic.⁹⁶ Beech-Nut also set internal guidelines of 3,000 ppb for cadmium and 5,000 ppb for lead for certain ingredients.⁹⁷ These far surpass any existing regulatory standard in existence and toxic heavy metal levels for any other baby food manufacturer that responded to the Subcommittee's inquiry.

Beech-Nut's Raw Materials Heavy Metal Testing (Excerpted Entries)⁹⁸

Date	Commodity	Preshipment	Arsenic result (ppb)	Spec.	Cadmium result (ppb)	Spec.	Lead result (ppb)	Spec.	Acceptance (Y/N)
12/20/2017	BAN 800	786	465.20	<3000	6.30	<500	<58	<5000	Y
1/23/2019	ascorbic acid	80	<5	<3000	<1	<3000	<5	<3000	Y
10/7/2017	BAN 800	673	710.90	<3000	8.30	<500	<5	<5000	Y
10/23/2017	BAN 800	712	401.40	<3000	6.10	<500	<5	<5000	Y
2/19/2018	BAN 800	120	382.00	<3000	<5	<500	<5	<5000	Y
6/12/2018	Ban 800	292	353.80	<3000	<5	<500	<5	<5000	Y
3/12/2018	BAN 800	164	29.70	<3000	<5	<500	<5	<5000	Y
2/6/2017	Vitamin Mix	76	106.90	<3000	60.30	<3000	24.6	<10	Y
1/31/2017	Vitamin Mix	72	89.40	<3000	48.20	<3000	18	≤20	Y
10/10/2019	BAN 800	680	91.10	<3000	28.40	<500	7.5	<5000	Y
12/5/2018	ascorbic acid	1084	<5	<3000	<5	<3000	6	<3000	Y
9/4/2019	BAN 800	442	59.70	<3000	11.00	<500	5.8	<5000	Y

Beech-Nut sold eleven products that surpassed its own internal cadmium limits. By doing so, Beech-Nut accepted dehydrated potato containing 119.6, 143.5, and 148.4 ppb cadmium, far surpassing its own internal limit of 90 ppb for that ingredient.⁹⁹

⁹⁶ *Id.*

⁹⁷ *Id.*

⁹⁸ *Id.*

⁹⁹ *Id.*

Beech-Nut's Raw Materials Heavy Metal Testing (Excerpted Entries)¹⁰⁰

Date	Commodity	Preshipment	Arsenic result (ppb)	Spec.	Cadmium result (ppb)	Spec.	Lead result (ppb)	Spec.	Acceptance (Y/N)
1/11/2018	Oat Flour	38	47.00	≤40	21.80	≤20	<5	≤20	Y
1/16/2018	Coarse Oat Flour	45	45.60	≤40	20.70	≤20	<5	≤20	Y
6/22/2018	Org. Oat Flour	299	24.00	≤40	20.80	≤20	<5	≤20	Y
7/5/2018	oat flour	299	24.00	≤40	20.80	≤20	<5	≤20	
3/13/2018	Coarse Oat Flour	168	23.40	≤40	20.70	≤20	<5	≤20	Y
10/1/2019	Oat Flour	645	20.90	≤40	20.90	≤20	<5	≤20	Y
9/13/2019	Oat Flour	554	18.20	≤40	22.30	≤20	<5	≤20	Y
10/10/2018	Dehydrated Potato	816	11.30	<75	143.50	<90	32.4	<75	Y - ER
11/29/2017	Dehydrated Potato	760	9.30	<75	148.40	<90	10.1	<75	Y - ER
1/30/2018	Org. Oat Flour	73	8.50	≤40	21.70	≤20	<5	≤20	Y - ER
11/29/2017	Dehydrated Potato	749	7.60	<75	119.60	<90	<5	<75	Y - ER

Beech-Nut's explanation of why it accepted products over its own internal limits was that it did so "rarely" and the ingredients were "generally restricted to a 20% variance of BNN's allowable limits...."¹⁰¹ However, as the cadmium examples show, Beech-Nut accepted certain ingredients in spite of their own testing results which showed that they contained over 20% more cadmium than their already-high internal limit. Beech-Nut's internal limit for cadmium in dehydrated potato appears to be 90 ppb. A 20% variance would permit Beech-Nut to accept dehydrated potato containing up to 108 ppb cadmium. Nevertheless, Beech-Nut accepted three shipments of dehydrated potato containing cadmium in excess of its 20% variance allowance.¹⁰² Beech-Nut did not offer any explanation.

C. Hain (Earth's Best Organic) set an internal standard of 200 ppb for arsenic, lead, and cadmium in some of its ingredients. Hain justified deviations above its ingredient testing standards based on "theoretical calculations," even after Hain admitted to FDA that its testing underestimated final product toxic heavy metal levels.

Hain set an internal standard of 200 ppb arsenic for 12 ingredients, most of which were different kinds of flours. By setting this high internal standard, Hain justified accepting wheat flour and rice that contained 200 and 150 ppb arsenic.¹⁰³

¹⁰⁰ *Id.*

¹⁰¹ Letter from the President and Chief Executive Officer of Beech-Nut Nutrition Company to Chairman Raja Krishnamoorthi, Subcommittee on Economic and Consumer Policy, Committee on Oversight and Reform (Dec. 6, 2019) (online at https://oversight.house.gov/sites/democrats.oversight.house.gov/files/6_0.pdf).

¹⁰² Beech-Nut, *Raw Material Heavy Metal Testing* (Dec. 6, 2019) (online at <http://oversight.house.gov/sites/democrats.oversight.house.gov/files/4.xlsx>).

¹⁰³ Hain, *Raw Material Pre-Shipment Test Data History* (Dec. 11, 2019) (online at https://oversight.house.gov/sites/democrats.oversight.house.gov/files/3_0.pdf).

*Hain’s Raw Material Pre-Shipment Test Data History (Excerpted Entries)*¹⁰⁴

Lab Results Date	Product Description	Status	Arsenic Spec Limit (ppb)	Arsenic Result (ppb)
Aug/3/2017	Org Kamut Flour	Accepted	200	<100
Aug/3/2017	Org Spelt Flour	Accepted	200	<100
Jul/6/2017	Org Yellow Split Pea Powder	Accepted	200	<100
Jul/5/2017	Org Quinoa Flour	Accepted	200	<100
May/26/2017	Org Soft White Wheat Flour	Accepted	200	<100
Aug/1/2017	Org Fiber Oat	Accepted	200	<100
Sep/25/2017	Org Quinoa Flour	Accepted	200	<100
Sep/12/2017	Org Spelt Flour	Accepted	200	<100
Aug/4/2017	Org Spelt Flour	Accepted	200	<100
Jul/19/2017	Org Green Lentil Flour	Accepted	200	<100
Sep/29/2017	Org Soft White Wheat Flour	Accepted	200	200
Jul/13/2017	Medium Grain Whole Rice	Accepted	200	150

Similarly, Hain set an internal limit of 200 ppb for lead in five ingredients—forty times higher than FDA’s guidance for bottled water. By doing so, Hain justified accepting lentil flour with 110 ppb lead and quinoa flour with 120 ppb lead. These surpass every existing regulatory standard for lead.¹⁰⁵

*Hain’s Raw Material Pre-Shipment Test Data History (Excerpted Entries)*¹⁰⁶

Lab Results Date	Vendor Name	Item Number	Product Description	Status	Comments on Status	Lab	Spec Based On	Lead Spec Limit (ppb)	Lead Result (ppb)
Aug/3/2017	Montana Flour & Grains	5303053	Org Kamut Flour	Accepted		Deibel	As consumed	200	<100
Jul/19/2017	Firebird Artisan Mills	57200	Org Green Lentil Flour	Accepted	Calculated Levels on consumed basis	Deibel	As consumed	200	110
Aug/21/2017	Grain Millers	5308029	Org Brown Flax Milled	Accepted	Calculated Levels on consumed basis	Deibel	As consumed	200	<100
Jul/15/2017	Firebird Artisan Mills	5303042	Org Quinoa Flour	Accepted		Deibel	As consumed	200	<100
Feb/03/2017	Firebird Artisan Mills	5303042	Org Quinoa Flour	Accepted	spec for lead was 200ppb	Deibel	As consumed	200	120

¹⁰⁴ *Id.*

¹⁰⁵ *Id.*

¹⁰⁶ *Id.*

Hain used four products that surpassed its internal toxic heavy metal limits. For example, it accepted cinnamon that contained 102 ppb cadmium, vitamin pre-mix that had 223 ppb arsenic and 353 ppb lead, and two rice flours that had 134 and 309 ppb arsenic.¹⁰⁷

Hain’s Raw Material Pre-Shipment Test Data History (Excerpted Entries)¹⁰⁸

Lab Results Date	Vendor Name	Item Number	Product Description	Status	Comments on Status	Lab	Spec Based On	Arsenic Spec Limit (ppb)	Arsenic Result (ppb)	Cadmium Spec Limit (ppb)	Cadmium Result (ppb)	Lead Spec Limit (ppb)	Lead Result (ppb)
Feb/19/2019	Red Ape Cinnamon	40500	Org Cinnamon Powder	Deviation Approved	Accepted on deviation 20190045	Deibel	As Purchased	100	20	100	102	100	40
Nov/26/2019	Wright Enrichment	5316067	Vitamin Pre Mix	Deviation Approved	Accepted on deviation 20190236	Eurofins/Covance	As Purchased	100	223	100	60.5	100	352
Jun/19/2019	Firebird Artisan Mills	57600	Org Brown Rice Flour	Deviation Approved	Accepted on deviation 20190127	Eurofins/Covance	As Purchased	100	309	100	23	100	<10
Sep/4/2019	Firebird Artisan Mills	57600	Org Brown Rice Flour	Deviation Approved	Accepted on deviation 2019030 and 20190234	Eurofins/Covance	As Purchased	100	134	100	12.8	100	5

Hain justified these variations by claiming that the “theoretical” final goods will not surpass its internal limits. For example, Hain became aware that the vitamin pre-mix contained 223 ppb arsenic and 352 ppb lead.¹⁰⁹

Hain Deviation Report, Vitamin Premix (Nov. 26, 2019)¹¹⁰

Ingredient Exp. Date		
Lot Code	19090122P	
Specification	Arsenic: 100 ppb Lead: 100 ppb	Arsenic: 223 ppb Lead: 352 ppb
Highest Percentage in Finished Good(s)	2.08%	

Despite having dangerously high levels of toxic heavy metals, Hain approved the use of this vitamin pre-mix based on a “theoretical” calculation of toxic heavy metals in the final good.¹¹¹

¹⁰⁷ *Id.*

¹⁰⁸ *Id.*

¹⁰⁹ Hain, *Deviation Report, Vitamin Premix* (Nov. 26, 2019) (online at https://oversight.house.gov/sites/democrats.oversight.house.gov/files/11_Redacted.pdf).

¹¹⁰ *Id.*

¹¹¹ *Id.*

*Hain Deviation Report, Vitamin Premix (Nov. 26, 2019)*¹¹²

QUALITY & FOOD SAFETY REVIEW		
Reviewed Date	11/26/2019	Select one: <input checked="" type="radio"/> Approved <input type="radio"/> Rejected <input type="radio"/> Revisions Requested
Reviewed By	[REDACTED]	
Comments	Vitamin premix is used at 2.08% in the rice cereal finished good C90001. Upon theoretical calculations including the 10% variation, the arsenic and lead levels in the finished product are below 100 ppb. Attached calculations.	

To calculate the estimated quantity of lead and arsenic in the finished good, Hain considered the percentage of rice flour and vitamin pre-mix in the finished goods, and their projected amounts of arsenic and lead. Ultimately, Hain predicted that the finished good would have roughly 85 ppb arsenic and 25 ppb lead.¹¹³

*Hain Deviation Report, Vitamin Premix (Nov. 26, 2019)*¹¹⁴

Item	Lot Code	Heavy Metal	Test Value (ppb)	% in formula	Hypothetical Level in finished product (ppb)	
Rice Flour	B160007680	Inorganic Arsenic	81.9	97.8	80.0982	
		Lead	17.6	97.8	17.2128	
		Cadmium	18.6	97.8	18.1908	
Vitamin Premix	19090122P	Inorganic Arsenic	223	2.08	4.6384	
		Lead	352	2.08	7.3216	
		Cadmium	60.5	2.08	1.2584	
			Theoretical Arsenic		84.7366	93.21026
			Theoretical Lead		24.5344	26.98784
			Theoretical Cadmium		19.4492	21.39412

However, it is not clear that Hain ever tested the finished good. Hain appears to have used this vitamin pre-mix with dangerously high levels of toxic heavy metals without ever confirming the finished good was actually safe to consume.

Hain made this decision four months *after* it had made a secret presentation to FDA admitting that heavily tainted vitamin premix caused dangerous levels of arsenic in its finished

¹¹² *Id.*

¹¹³ *Id.*

¹¹⁴ *Id.*

products, which initially went undetected because Hain did not test its finished products.¹¹⁵ Hain made no effort to correct the problem. *Note: Full discussion of Hain's secret presentation to FDA appears in Section V., Parts D. and E., below.*

IV. WALMART, SPROUT ORGANIC FOODS, AND CAMPBELL REFUSED TO COOPERATE WITH THE SUBCOMMITTEE'S INVESTIGATION

Nurture, Beech-Nut, Hain, and Gerber cooperated with the Subcommittee's investigation, despite the fact that doing so exposed their reckless disregard for the health of babies. With that in mind, the Subcommittee questions why Walmart (Parent's Choice), Sprout Organic Foods, and Campbell (Plum Organics) would refuse to comply with the investigation. None of them produced testing results or specific testing standards and Sprout never even responded to the Subcommittee's repeated inquiries. The Subcommittee is greatly concerned that these companies might be obscuring the presence of even higher levels of toxic heavy metals in their baby food products than their competitors' products.

A. Walmart (Parent's Choice Brand)

Walmart refused to produce any documents showing its internal testing policies, its testing results, or how Walmart treats ingredients and/or products that surpass any internal standards.

Walmart's evasion is concerning, as even limited independent testing has revealed the presence of toxic heavy metals in its baby food.

*Data from Healthy Babies Bright Futures Report: What's in My Baby's Food?*¹¹⁶

Brand	Food	Food type	Arsenic (total, ppb)	Arsenic (inorganic, ppb)	Lead (ppb)	Cadmium (ppb)	Mercury (total, ppb)	Metro area where purchased	Retailer
Parent's Choice (Walmart)	Little Hearts Strawberry Yogurt Cereal Snack - Stage 3, 9+ months	Snack - other	56.1	--	5.2	26.1	0.941	Charlottesville, VA	Walmart
Parent's Choice (Walmart)	Organic Strawberry Rice Rusks - Stage 2, 6+ months	Snack - teething biscuits & rice rusks/cakes	108	66	26.9	2.4	2.05	Charlottesville, VA	Walmart

¹¹⁵ Hain, PowerPoint Presentation to Food and Drug Administration: *FDA Testing Result Investigation* (Aug. 1, 2019) (online at <https://oversight.house.gov/sites/democrats.oversight.house.gov/files/2.pdf>).

¹¹⁶ Healthy Babies Bright Futures, *What's in My Baby's Food? A National Investigation Finds 95 Percent of Baby Foods Tested Contain Toxic Chemicals That Lower Babies' IQ, Including Arsenic and Lead* (Oct. 2019) (online at www.healthybabyfood.org/sites/healthybabyfoods.org/files/2019-10/BabyFoodReport_FULLREPORT_ENGLISH_R5b.pdf).

Walmart (Parent's Choice) Baby Food that Tested High in Toxic Heavy Metals¹¹⁷



B. Campbell (Plum Organics Brand)

Campbell refused to produce its testing standards and specific testing results to the Subcommittee. Campbell has hidden its policies and the actual level of toxic heavy metals in its products.

Instead of producing any substantive information, Campbell provided a spreadsheet self-declaring that every one of its products “meets criteria.”¹¹⁸ Campbell declined to state what those criteria are.

***Campbell’s Product Heavy Metal Test Results (Excerpted Entries)*¹¹⁹**

Product Name	Testing Date	ARSENIC	CADMIUM	LEAD	MERCURY
Plum Organics® Stage 2 Apple & Carrot, 4oz	11/1/2017	Meets Criteria	Meets Criteria	Meets Criteria	Meets Criteria
Plum Organics® Stage 2 Banana & Pumpkin, 4oz	11/1/2017	Meets Criteria	Meets Criteria	Meets Criteria	Meets Criteria
Plum Organics® Mighty 4® Blends Strawberry Banana, Greek Yogurt, Kale, Oat & Amaranth, 4oz	11/1/2017	Meets Criteria	Meets Criteria	Meets Criteria	Meets Criteria
Plum Organics® Mighty Snack Bars® Strawberry, 4.02oz (Pack of 6)	10/29/2017	Meets Criteria	Meets Criteria	Meets Criteria	Meets Criteria
Plum Organics® Mighty Nut Butter Bar™ Almond Butter (Pack of 5)	8/29/2018	Meets Criteria	Meets Criteria	Meets Criteria	Meets Criteria

¹¹⁷ Walmart, *Parent’s Choice Organic Strawberry Rice Rusks* (online at www.walmart.com/ip/Parent-s-Choice-Organic-Baby-Rusks-Strawberry-Flavored/171533478) (accessed on Jan. 26, 2021).

¹¹⁸ Campbell, *Product Heavy Metal Test Results* (Dec. 11, 2019) (online at <https://oversight.house.gov/sites/democrats.oversight.house.gov/files/12.pdf>).

¹¹⁹ *Id.*

Campbell’s testing summary hides more than it reveals, since it does not show the levels of heavy metals that the testing found or the levels of heavy metals that would “meet criteria.”

The Subcommittee was disturbed that, for mercury, which is a powerful neurotoxin, Campbell notes with asterisks that it has no criterion whatsoever, stating: “No specific threshold established because no high-risk ingredients are used.”¹²⁰ However, despite Campbell having no mercury threshold, Campbell still marked every food as “meets criteria” for mercury.¹²¹ This misleading framing—of meeting criteria that do not exist—raises questions about what Campbell’s other thresholds actually are, and whether they exist.

Campbell’s evasion is concerning, as even limited independent testing has revealed the presence of toxic heavy metals in its baby food.

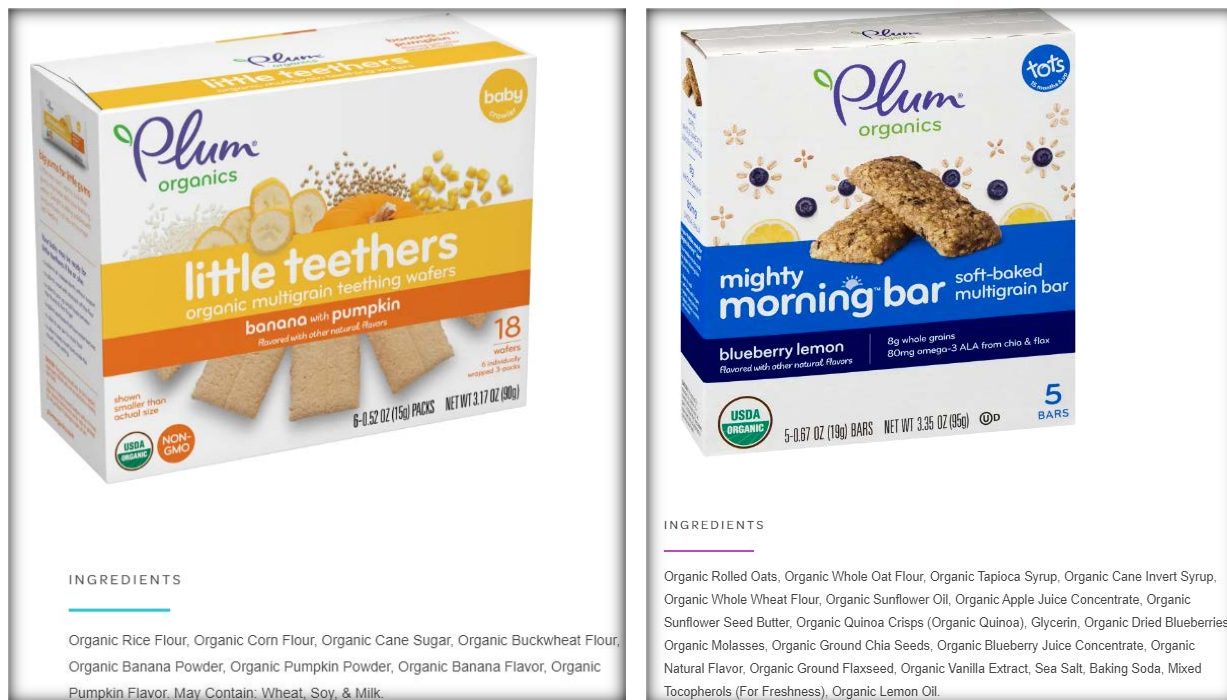
Data from Healthy Babies Bright Futures Report: What’s in My Baby’s Food?¹²²

Brand	Food	Food type	Arsenic (total, ppb)	Arsenic (inorganic, ppb)	Lead (ppb)	Cadmium (ppb)	Mercury (total, ppb)	Metro area where purchased	Retailer
Plum Organics	Mighty Morning Bar - Blueberry Lemon - Tots: 15 months & up	Snack - other	40*	39	3.4	24.3	<0.137	Cincinnati, OH	Kroger
Plum Organics	Little Teethers Organic Multigrain Teething Wafers - Banana with Pumpkin - Baby Crawler	Snack - teething biscuits & rice rusks/cakes	49.9	--	1.4*	6.3	0.726	Columbia, SC	Publix

¹²⁰ *Id.*

¹²¹ *Id.*

¹²² Healthy Babies Bright Futures, *What’s in My Baby’s Food? A National Investigation Finds 95 Percent of Baby Foods Tested Contain Toxic Chemicals That Lower Babies’ IQ, Including Arsenic and Lead* (Oct. 2019) (online at www.healthybabyfood.org/sites/healthybabyfoods.org/files/2019-10/BabyFoodReport_FULLREPORT_ENGLISH_R5b.pdf).

Plum Organics' Foods That Tested High in Toxic Heavy Metals¹²³**C. Sprout Organic Foods**

Sprout Organic Foods did not respond to the Subcommittee at all. Despite numerous emails to executives and its general information email address, as well as numerous attempts to reach the Sprout central office by telephone, Sprout never responded or made contact with the Subcommittee.

Sprout Organic Foods was acquired by North Castle Partners, a Greenwich, Connecticut private equity firm, in 2015. North Castle Partners also owns such well-known brands as Curves International/Jenny Craig, Palladio Beauty Group, Mineral Fusion, Red Door Spas, Performance Bicycles, Octane Fitness, Ibex Outdoor Clothing, and Doctor's Best.¹²⁴

Whether due to evasion or negligence, Sprout's failure to respond raises serious concerns about the presence of toxic heavy metals in its baby foods, as even limited independent testing has revealed the presence of toxic heavy metals in its products.

¹²³ Plum Organics, *Little Teethers, Banana with Pumpkin* (online at www.plumorganics.com/products/banana-with-pumpkin-wafers/) (accessed Jan. 26, 2021); Plum Organics, *Mighty Morning Bar, Blueberry Lemon* (online at www.plumorganics.com/products/blueberry-lemon-bar/) (accessed Jan. 26, 2021).

¹²⁴ North Castle Partners, *Press Release: North Castle Partners Invests in Sprout Organic Foods, Inc.* (June 29, 2015) (online at www.northcastlepartners.com/wp-content/uploads/2016/01/North-Castle_Sprout-Press-Release.pdf).

Data from Healthy Babies Bright Futures Report: What's in My Baby's Food?¹²⁵

Brand	Food	Food type	Arsenic (total, ppb)	Arsenic (inorganic, ppb)	Lead (ppb)	Cadmium (ppb)	Mercury (total, ppb)	Metro area where purchased	Retailer
Sprout	Organic Quinoa Puffs Baby Cereal Snack - Apple Kale	Snack - puffs, contains rice	107	47	39.3	41.5	1.31	Washington, DC	amazon.com

Sprout Organic Food That Tested High in Toxic Heavy Metals¹²⁶

V. FDA HAS FAILED TO CONFRONT THE RISKS OF TOXIC HEAVY METALS IN BABY FOOD. THE TRUMP ADMINISTRATION IGNORED A SECRET INDUSTRY PRESENTATION ABOUT HIGHER AMOUNTS OF TOXIC HEAVY METALS IN FINISHED BABY FOODS.

Despite the well-known risks of harm to babies from toxic heavy metals, FDA has not taken adequate steps to decrease their presence in baby foods. FDA has not issued thresholds for the vast majority of toxic heavy metals in baby foods and does not require warning labels on any baby food products. In the summer of 2019, FDA received a secret presentation from a baby

¹²⁵ Healthy Babies Bright Futures, *What's in My Baby's Food? A National Investigation Finds 95 Percent of Baby Foods Tested Contain Toxic Chemicals That Lower Babies' IQ, Including Arsenic and Lead* (Oct. 2019) (online at www.healthybabyfood.org/sites/healthybabyfoods.org/files/2019-10/BabyFoodReport_FULLREPORT_ENGLISH_R5b.pdf).

¹²⁶ Sprout Organic Foods, *Quinoa Puffs, Apple Kale* (online at www.sproutorganicfoods.com/babies/6-months-and-up/plant-power-puffs/apple-kale-plant-power-puffs) (accessed Jan. 26, 2021).

food manufacturer that revealed that the commercial process of preparing finished baby foods increases their levels of toxic heavy metals. For that manufacturer, Hain (HappyBABY), the process increased inorganic arsenic levels between 28% and 93%. Yet, FDA took no apparent action.

In May 2017, FDA established the Toxic Elements Working Group with the goal of reducing exposure to toxic elements in food, cosmetics, and dietary supplements. FDA claims that the Toxic Elements Working Group is focusing on metals “because high levels of exposure to those metals are likely to have the most significant impact on public health,” and “can be especially harmful to children because of concerns about effects on their neurological development.”¹²⁷ But the working group has not resulted in new or stronger regulations to protect babies from toxic heavy metals in their food.

A. Mercury and Cadmium

FDA has acknowledged the dangers of mercury. Mercury has “no established health benefit” and has been “shown to lead to illness, impairment, and in high doses, death.”¹²⁸ FDA has acknowledged the added risk to babies and children, noting that it is: “paying special attention to children because their smaller body sizes and metabolism may make them more susceptible to the harmful effects of these metals,” including mercury.¹²⁹

Despite these statements, FDA has taken no action to limit mercury in baby food. Instead, FDA has only set mercury standards for wheat, and fish, shellfish, and crustaceans, and they are high—1,000 ppb.¹³⁰ There are no FDA protections for mercury in baby food.

The lack of FDA action on mercury standards stands in contrast to other regulators. The EPA, for example, set a limit of 2 ppb mercury in drinking water, even after taking into account the cost of attainment for industry.¹³¹

¹²⁷ Food and Drug Administration, *Metals and Your Food* (online at www.fda.gov/food/chemicals-metals-pesticides-food/metals-and-your-food) (accessed Jan. 26, 2021); Food and Drug Administration, *What FDA Is Doing to Protect Consumers from Toxic Metals in Foods* (Apr. 20, 2018) (online at www.fda.gov/food/conversations-experts-food-topics/what-fda-doing-protect-consumers-toxic-metals-foods).

¹²⁸ Food and Drug Administration, *Metals and Your Food* (online at www.fda.gov/food/chemicals-metals-pesticides-food/metals-and-your-food) (accessed Jan. 26, 2021).

¹²⁹ *Id.*

¹³⁰ Food and Drug Administration, *Guidance for Industry: Action Levels for Poisonous or Deleterious Substances in Human Food and Animal Feed* (Aug. 2000) (online at www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-action-levels-poisonous-or-deleterious-substances-human-food-and-animal-feed).

¹³¹ 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).

Similarly, FDA has taken no action on cadmium in baby food. FDA has issued only one guideline for cadmium, and that is a limit of 5 ppb for bottled water.¹³² The EU has instituted a limit of 10-15 ppb for infant formula.¹³³

B. Lead

FDA acknowledges that there is “no identified safe blood lead level” and that lead is especially dangerous to children:

Lead is especially harmful to vulnerable populations, including infants, young children, pregnant women and their fetuses, and others with chronic health conditions. High levels of lead exposure can seriously harm children’s health and development, specifically the brain and nervous system. Neurological effects from high levels of lead exposure during early childhood include learning disabilities, behavior difficulties, and lowered IQ. Because lead can accumulate in the body, even low-level chronic exposure can be hazardous over time.¹³⁴

FDA has taken action on bottled water, limiting lead to 5 ppb.¹³⁵ FDA has also taken steps toward regulating lead content in products for older children. FDA has released guidance recommending a maximum lead level of 100 ppb in candy likely to be consumed by children, and 50 ppb in some juices.¹³⁶ It is not sound logic to say that water is unsafe to drink if it contains over 5 ppb lead, but candy and fruit juice can be ten and twenty times higher than that limit.

Unfortunately, it appears that FDA designed these limits to be protective of industry. In its “Supporting Document for Recommended Maximum Level for Lead in Candy,” FDA repeatedly emphasizes achievability by industry, as opposed to safety for children:

- “FDA believes that sugar-based candy products *can be made* with lead levels below” [100 ppb].”
- “We believe *that if milk chocolate manufacturers source their raw materials appropriately, lead levels in their finished products will not exceed* [100 ppb] lead.”
- “We believe that, *if dark chocolate manufacturers source their raw materials appropriately, lead levels in their finished products will not exceed* [100 ppb].”

¹³² 21 C.F.R. § 165 (2019) (online at www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?fr=165.110).

¹³³ European Union, *Setting Maximum Levels for Certain Contaminants in Foodstuffs* (Dec. 19, 2006) (online at <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:02006R1881-20150521>).

¹³⁴ Food and Drug Administration, *Lead in Food, Foodwares, and Dietary Supplements* (online at www.fda.gov/food/metals-and-your-food/lead-food-foodwares-and-dietary-supplements) (accessed Jan. 26, 2021).

¹³⁵ *Id.*

¹³⁶ *Id.*

- “[E]ven for high-chili-content candy and powdered snack mix products, *we believe that candy with appropriately sourced ingredients will not exceed* [100 ppb] lead.”
- “We believe that *if manufacturers source salt to minimize lead levels, finished, high-salt- content powdered snack mix products will not exceed* [100 ppb] lead.”¹³⁷

But FDA has failed to regulate lead levels in baby foods. Manufacturers are free to set their own limits. Hain, for example, used internal soft limits of 100 and 200 ppb lead for the majority of its ingredients.

FDA *has* created what it calls an Interim Reference Level (IRL) for lead, but this standard does not apply to manufacturers and is unhelpful for parents purchasing baby food. An Interim Reference Level is what FDA calls a calculation of “the maximum daily intake for lead from food.”¹³⁸ Above this limit, a person or baby’s blood level would reach a “point of concern.” FDA’s current IRL is 3 µg per day for children. This standard, though perhaps helpful to FDA in researching and evaluating how lead affects our nation’s children, is unworkable for parents. For this standard to be useful to a parent, they would need to know:

- what a µg is (it stands for a microgram);
- how much lead is in each product they are serving their baby;
- how much lead their child is exposed to through tap water; and
- how much lead is in their local environment, such as through lead-based paints.

Obtaining this information is currently impossible for parents because baby food manufacturers do not publicly provide information on the amount of lead in their products. Given the information gaps parents face, it would be most appropriate for FDA to promulgate clear rules for baby food manufacturers that limit the amount of lead in baby food.

C. Arsenic

In the context of arsenic in baby food, there are only two FDA regulations for specific products—an unenforceable draft guidance issued in July 2013, but never finalized, recommending an action level of 10 ppb for inorganic arsenic in single-strength (ready to drink) apple juice, and an August 2020 final guidance, setting an action level for inorganic arsenic in infant rice cereals at 100 ppb.¹³⁹

¹³⁷ Food and Drug Administration, *Supporting Document for Recommended Maximum Level for Lead in Candy Likely to Be Consumed Frequently by Small Children* (Nov. 2006) (online at www.fda.gov/food/metals-and-your-food/supporting-document-recommended-maximum-level-lead-candy-likely-be-consumed-frequently-small) (emphasis added).

¹³⁸ Food and Drug Administration, *Lead in Food, Foodwares, and Dietary Supplements* (online at www.fda.gov/food/metals-and-your-food/lead-food-foodwares-and-dietary-supplements) (accessed Jan. 26, 2021).

¹³⁹ Food and Drug Administration, *Draft Guidance for Industry: Action Level for Arsenic in Apple Juice* (July 2013) (online at www.fda.gov/regulatory-information/search-fda-guidance-documents/draft-guidance-industry-action-level-arsenic-apple-juice); Food and Drug Administration, *Guidance for Industry: Action Level for*

The first problem with these standards is that they cover only a small sliver of the foods babies eat.

The second problem is that they are far too lax to be protective of babies. There is no established safe level of inorganic arsenic consumption for babies. Arsenic exposure has a “significant negative effect on neurodevelopment.”¹⁴⁰ FDA acknowledged that “Low-to-moderate levels of inorganic arsenic appear to be associated with adverse health effects during childhood.”¹⁴¹ Children exposed to water with an arsenic concentration of just 5 ppb “showed significant reductions in Full Scale, Working Memory, Perceptual Reasoning and Verbal Comprehension scores.”¹⁴² This suggests that 5 ppb may be an important threshold, or that the threshold of safety may fall far below that.

Healthy Babies Bright Futures has called for a goal of no measurable amount of inorganic arsenic in baby food.¹⁴³ Consumer Reports suggests that the level of inorganic arsenic should be set as low as 3 ppb for water and fruit juices.¹⁴⁴

FDA has already set inorganic arsenic levels at 10 ppb for bottled water.¹⁴⁵ EPA has similarly set a 10 ppb inorganic arsenic cap on water, as have the European Union and the World Health Organization.¹⁴⁶

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).

¹⁴⁰ Miguel Rodríguez-Barranco et al., *Association of Arsenic, Cadmium and Manganese Exposure with Neurodevelopment and Behavioural Disorders in Children: A Systematic Review and Meta-Analysis* (Apr. 9, 2013) (online at www.sciencedirect.com/science/article/abs/pii/S0048969713003409?via%3Dihub).

¹⁴¹ Food and Drug Administration, *Arsenic in Rice and Rice Products Risk Assessment Report* (Mar. 2016) (online at www.fda.gov/files/food/published/Arsenic-in-Rice-and-Rice-Products-Risk-Assessment-Report-PDF.pdf).

¹⁴² Gail A. Wasserman et al., *A Cross-Sectional Study of Well Water Arsenic and Child IQ in Maine Schoolchildren* (Apr. 1, 2014) (online at <https://ehjournal.biomedcentral.com/articles/10.1186/1476-069X-13-23>).

¹⁴³ Healthy Babies Bright Futures, *What’s in My Baby’s Food? A National Investigation Finds 95 Percent of Baby Foods Tested Contain Toxic Chemicals That Lower Babies’ IQ, Including Arsenic and Lead* (Oct. 2019) (online at www.healthybabyfood.org/sites/healthybabyfoods.org/files/2019-10/BabyFoodReport_FULLREPORT_ENGLISH_R5b.pdf).

¹⁴⁴ Consumer Reports, *Arsenic in Some Bottled Water Brands at Unsafe Levels, Consumer Reports Says* (June 28, 2019) (online at www.consumerreports.org/water-quality/arsenic-in-some-bottled-water-brands-at-unsafe-levels/); Consumer Reports, *Arsenic and Lead Are in Your Fruit Juice: What You Need to Know* (Jan. 30, 2019) (online at www.consumerreports.org/food-safety/arsenic-and-lead-are-in-your-fruit-juice-what-you-need-to-know/).

¹⁴⁵ 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 Jan. 26, 2021).

¹⁴⁶ Environmental Protection Agency, *Drinking Water Requirements for States and Public Water Systems* (online at www.epa.gov/dwreginfo/chemical-contaminant-rules) (accessed Jan. 26, 2021); The European Food Information Council, *Arsenic (Q&A)* (online at www.eufic.org/en/food-safety/article/arsenic-qa) (accessed Jan. 26, 2021); World Health Organization, *Arsenic* (Feb. 15, 2018) (online at www.who.int/news-room/fact-sheets/detail/arsenic).

FDA is fully aware of the dangers that inorganic arsenic presents to young children, stating that:

There is growing evidence ... that exposure to inorganic arsenic during...infancy...may increase the risk of adverse health effects, including impaired development during...childhood and neurodevelopmental toxicity in infants and young children, and that these adverse effects may persist later in life [C]hildren may likewise be particularly susceptible to neurotoxic effects of inorganic arsenic, e.g., as manifested in intelligence test results in children Also, children three years and younger have the highest exposure to inorganic arsenic because they have 2-3-fold higher intakes of food on a per body mass basis as compared to adults. Therefore, a child's daily exposure to contaminants in food, such as inorganic arsenic in rice, could potentially be much higher than that of adults.¹⁴⁷

Yet, in the one category of baby food for which FDA has finalized a standard—infant rice cereal—it set the maximum inorganic arsenic content at the dangerous level of 100 ppb.

Why did FDA set its level so high? Because in developing the limit, FDA was focused on the level of inorganic arsenic that would cause cancer. FDA disregarded the risk of neurological damage, which happens at a much lower level. In its 2016 Risk Assessment Report, FDA was able to quantify the risk of lung and bladder cancer that inorganic arsenic presents. It was not able to quantify the risks of neurological development for infants.¹⁴⁸ As a result, the 100 ppb limit is too high to adequately protect infants and children from the effects of inorganic arsenic.

The third problem is that FDA's piecemeal approach of setting different inorganic arsenic standards for different products is logically unsound. There can be only one safe level for inorganic arsenic in the foods that babies consume. All finished baby food products should accord with this safe level.

Aside from these guidance documents for infant rice cereal and apple juice, FDA does not regulate toxic heavy metals in other baby food products.

One example of how this approach is failing is with FDA's decision to release draft guidance for apple juice, but not any other fruits juices. Based on the testing results the Subcommittee reviewed, baby food companies routinely exceed this draft limit of 10 ppb in other types of commonly consumed juices. Gerber, for example, used grape juice concentrate registering at 39 ppb inorganic arsenic. But because it was grape juice, as opposed to apple

¹⁴⁷ Food and Drug Administration, *Supporting Document For Action Level For Inorganic Arsenic In Rice Cereals For Infants* (Aug. 2020) (online at www.fda.gov/food/chemical-metals-natural-toxins-pesticides-guidance-documents-regulations/supporting-document-action-level-inorganic-arsenic-rice-cereals-infants#introduction).

¹⁴⁸ Food and Drug Administration, *Arsenic in Rice and Rice Products Risk Assessment Report* (Mar. 2016) (online at www.fda.gov/files/food/published/Arsenic-in-Rice-and-Rice-Products-Risk-Assessment-Report-PDF.pdf).

juice—which, from a safety perspective, is a distinction without a difference—Gerber incorporated in its products juice concentrate with high arsenic levels.

The fourth problem with FDA’s piecemeal approach is that it appears designed to be protective of baby food manufacturers. In developing the infant rice cereal limit of 100 ppb, FDA considered an “achievability assessment.” The achievability assessment considered “manufacturers’ ability to achieve hypothetical maximum limits for inorganic arsenic in infant rice cereals....”¹⁴⁹ FDA considered samples taken from three time periods: 2011-2013, 2014, and 2018. As shown below, over time, the number of samples that tested under 100 ppb inorganic arsenic increased from 36% to 76% of the total number of samples. FDA noted that this increase meant “alternate sources of rice are available to enable infant rice cereal manufacturers to supply the market and meet the” 100 ppb level.¹⁵⁰ In short, FDA’s standard reflects manufacturers’ ease of compliance, rather than babies’ safety.

If it is not possible, or it is exceedingly costly, to source ingredients like rice that achieve a safe level, then baby food manufacturers should find substitutes for those ingredients. Our nation’s children should not bear lifelong health burdens because of a manufacturer’s preference for tainted ingredients.

D. The Trump Administration Ignored A Secret Industry Presentation About Higher Risks Of Toxic Heavy Metals In Baby Foods.

On August 1, 2019, the Trump administration received a secret industry presentation that disclosed higher risks of toxic heavy metals in finished baby food products. Hain (Earth’s Best Organic) revealed the finding in a presentation to FDA entitled “FDA Testing Result Investigation.”¹⁵¹

¹⁴⁹ Food and Drug Administration, *Supporting Document for Action Level for Inorganic Arsenic in Rice Cereals for Infants* (Aug. 2020) (online at www.fda.gov/food/chemical-metals-natural-toxins-pesticides-guidance-documents-regulations/supporting-document-action-level-inorganic-arsenic-rice-cereals-infants#introduction).

¹⁵⁰ *Id.*

¹⁵¹ Hain, *PowerPoint Presentation to Food and Drug Administration: FDA Testing Result Investigation* (Aug. 1, 2019) (online at <https://oversight.house.gov/sites/democrats.oversight.house.gov/files/2.pdf>).



Hain revealed that half (10 of 21) of the finished rice products that Hain tested contained 100 ppb or more of inorganic arsenic—exceeding FDA’s standard for infant rice cereal. One product contained almost 30% more, registering at 129 ppb inorganic arsenic.

FDA Data					Estimate % Avg FG Increase from Avg Raw	Track & Trace Data					
FDA Sample Number	Best By Date	Lot number	FDA FG Inorganic Arsenic (ppb)	Avg FG Result		Packaging Date	WIP Batch	Rice Flour Lot #s	Type of Arsenic Test	Raw Material Results (ppb)	Avg Raw Result
1024309	4/27/19	BN 2216	129	129.0	93%	11/3/17	204146	B160005305	Total Arsenic	69	67.0
								B160005306	Total Arsenic	76	
								B160005512	Total Arsenic	62	
								B160005152	Total Arsenic	61	

Hain’s average level of inorganic arsenic in its finished rice foods was 97.62 ppb, which nearly matches FDA’s dangerously high 100 ppb level for inorganic arsenic for infant rice cereal.

Hain claims that it “revised its internal policies and testing standards to conform to FDA’s non-binding recommendations.”¹⁵² In 2016, FDA instituted draft guidance (which is now final) for inorganic arsenic in infant rice cereal at the dangerously high level of 100 ppb. However, Hain has not consistently abided by those limits.

FDA also learned that Hain’s policy to test ingredients underrepresented the levels of toxic heavy metals in its finished baby foods. Hain’s finished products contained between 28% and 93% more inorganic arsenic than Hain estimated they would based on Hain’s ingredient

¹⁵² Letter from Kelly B. Kramer, Counsel for The Hain Celestial Group, Inc. to Chairman Raja Krishnamoorthi, Subcommittee on Economic and Consumer Policy, Committee on Oversight and Reform (Dec. 11, 2019) (online at https://oversight.house.gov/sites/democrats.oversight.house.gov/files/9_Redacted.pdf).

testing method.¹⁵³ Hain found higher levels of arsenic in *all* finished foods tested for this FDA presentation than were reflected in tests of individual raw ingredients. This revelation means that every single finished good containing brown rice had more arsenic than the company's estimates, which were based on testing the raw ingredients.

After seeing these results, FDA was put on notice that finished baby foods pose an even higher risk to babies than reflected in company tests of the raw ingredients that go into those finished products.

Final Product Data Compared to Raw Ingredient Data, From Hain's Presentation to FDA¹⁵⁴

FDA Data					Estimate % Avg FG Increase from Avg Raw	Track & Trace Data									
FDA Sample Number	Best By Date	Lot number	FDA FG Inorganic Arsenic (ppb)	Avg FG Result		Packaging Date	WIP Batch	Rice Flour Lot #s	Type of Arsenic Test	Raw Material Results (ppb)	Avg Raw Result				
1017814	3/2/19	BN A 0636	94	80.3	43%	9/8/17	199987	B160004661	Total Arsenic	54	56.3				
1038929		BN C 1139	83					B160004870	Total Arsenic	58					
1039633		BN F 1648	64					B160004759	Total Arsenic	57					
	B160004659			Total Arsenic	54										
	197594	B160004870	Total Arsenic	58											
		B160004759	Total Arsenic	57											
1039750	3/8/19	BN E	74	74.0	29%	9/14/17	200408	B160004871	Total Arsenic	60	57.3				
1041752	3/20/19	BN G	92	96.0	57%	9/26/17	200651	B160005149	Total Arsenic	65	61.3				
1037933		BN E 1536	67					B160004873	Total Arsenic	58					
1041751	3/21/19	BN B 0832	108	B160005157	Total Arsenic	62									
1038677		BN B 0932	116	B160004871	Total Arsenic	60									
1026932		BN D 1248	97	B160005148	Total Arsenic	61									
				B160004872	Total Arsenic	55									
1044380	4/11/19	BH C	100	100.0	69%	10/18/17	201873	B160005152	Total Arsenic	61	59.0				
1024309	4/27/19	BN I 2216	129	129.0	93%	11/3/17	204146	B160005305	Total Arsenic	69	67.0				
1024210	6/6/19	BN I 2241	94	101.0	61%	12/13/17	206697	B160005150	Total Arsenic	65					
547103		BN I 2339	115					B160005513	Total Arsenic	60					
1013927	6/7/19	BN E 1540	92	B160005150	Total Arsenic	65									
1026516		BN H 2123	104	1047511	6/27/19	BN C 1142	100	100.0	56%	1/3/18	208226	B160006190	Inorganic Arsenic	73	64.0
1074288		6/8/19	BNE 1406	105	B160005581	Total Arsenic	55								
1035738	6/13/19	BN J 0000	96	115.0	43%	1/25/18	208594	B160006191	Inorganic Arsenic	80	80.5				
1027437	8/18/19	BN A 0703	97	97.0	28%	2/24/18	210374	B160006203	Inorganic Arsenic	77	75.7				
784399	11/23/19	BN K 0305	108	108.0	31%	6/1/18	215305	B160006263	Inorganic Arsenic	74					
								B160006260	Inorganic Arsenic	76					
								B160007235	Inorganic Arsenic	66	82.5				
								B160006755	Inorganic Arsenic	99					

Hain admitted to FDA in its presentation that "Brown Rice Flour testing results do not appear to be correlated to finished good results data."¹⁵⁵ They are not correlated because the finished goods can contain as much as double the amount of arsenic as the raw ingredients.

¹⁵³ Hain, *PowerPoint Presentation to Food and Drug Administration: FDA Testing Result Investigation* (Aug. 1, 2019) (online at <https://oversight.house.gov/sites/democrats.oversight.house.gov/files/2.pdf>).

¹⁵⁴ *Id.*

¹⁵⁵ *Id.*

What can account for this increase in inorganic arsenic from the time the ingredients are tested to the time the products are finished? Hain conveyed to FDA that the cause of the increase was Hain's use of a dangerous additive, stating: "Preliminary investigation indicates Vitamin/Mineral Pre-Mix may be a major contributing factor." Although this additive may only make up roughly 2% of the final good, Hain suggested it was still responsible for the spike in the levels of inorganic arsenic in the finished baby food.¹⁵⁶

Hain's finding accords with the Subcommittee's own. In the test results we reviewed, Hain used vitamin pre-mix that contained 223 ppb arsenic.¹⁵⁷ This ingredient also contained 352 ppb lead, a matter not even addressed in the FDA presentation.

Hain's Raw Material Pre-Shipment Test Data History (Excerpted Entry)¹⁵⁸

Lab Results Date	Vendor Name	Item Number	Product Description	Status	Comments on Status	Lab	Spec Based On	Arsenic Spec Limit (ppb)	Arsenic Result (ppb)	Lead Spec Limit (ppb)	Lead Result (ppb)
Nov/26/2019	Wright Enrichment	5316067	Vitamin Pre Mix	Deviation Approved	Accepted on deviation 20190236	Eurofins/Covance	As Purchased	100	223	100	352

Therefore, naturally occurring toxic heavy metals may not be the only problem causing dangerous levels of toxic heavy metals in baby foods; rather, baby food producers like Hain are adding ingredients that have high levels of toxic heavy metals into their products, such as vitamin/mineral pre-mix.

FDA did not appear to take any unplanned actions on behalf of babies' safety after it received Hain's presentation. FDA did finalize a previously planned guidance, setting a limit of 100 ppb inorganic arsenic in infant rice cereal. But it did not initiate regulation of additives like Hain's vitamin/mineral pre-mix. Moreover, it has not mandated that baby food manufacturers test finished goods.

E. Corporate Testing Policies Hide the Truth: In Addition to Hain, Beech-Nut and Gerber Also Fail to Test Finished Product, Risking an Undercount of Toxic Heavy Metals in Their Finished Baby Foods.

Hain (Earth's Best Organic) revealed to FDA that its policy to test only its ingredients, and not its final product, is underrepresenting the levels of toxic heavy metals in its baby foods. Unfortunately, Hain is not alone. The majority of baby food manufacturers, including Beech-Nut and Gerber, employ the same policy of testing only ingredients.¹⁵⁹ That policy recklessly

¹⁵⁶ *Id.*

¹⁵⁷ Hain, Raw Material Pre-Shipment Test Data History (Dec. 11, 2019) (online at https://oversight.house.gov/sites/democrats.oversight.house.gov/files/3_0.pdf).

¹⁵⁸ *Id.*

¹⁵⁹ Letter from the President and CEO of Beech-Nut Nutrition Company to Chairman Raja Krishnamoorthi, Subcommittee on Economic and Consumer Policy, Committee on Oversight and Reform (Dec. 6, 2019) (online at https://oversight.house.gov/sites/democrats.oversight.house.gov/files/6_0.pdf) ("we do not test finished goods"); Letter from the Chief Executive Officer of Gerber Products Company to Chairman Raja Krishnamoorthi, Subcommittee on Economic and Consumer Policy, Committee on Oversight and Reform (Dec. 19,

endangers babies and children and prevents the companies from even knowing the full extent of the danger presented by their products.

As the Hain presentation lays bare, ingredient testing does not work. Hain's finished baby foods had more arsenic than their ingredients 100% of the time—28-93% more inorganic arsenic.¹⁶⁰ That means that only testing ingredients gives the false appearance of lower-than-actual toxic heavy metal levels.

VI. RECOMMENDATIONS AND CONSIDERATIONS FOR INDUSTRY, PARENTS, AND REGULATORS: DO HIGHLY TAINTED INGREDIENTS LIKE RICE BELONG IN BABY FOOD?

Baby food manufacturers hold a special position of public trust. Consumers believe that they would not sell unsafe products. Consumers also believe that the federal government would not knowingly permit the sale of unsafe baby food. As this staff report reveals, baby food manufacturers and federal regulators have broken the faith.

Step one to restoring that trust is for manufacturers to voluntarily and immediately reduce the levels of toxic heavy metals in their baby foods to as close to zero as possible. If that is impossible for foods containing certain ingredients, then those ingredients should not be included in baby foods.

One example of an ingredient that might not be suitable for baby foods is rice. Throughout this report, rice appeared at or near the top of every list of dangerous baby foods.

- For Hain (Earth's Best Organic), organic brown rice was the ingredient that tested highest in inorganic arsenic—309 ppb. Indeed, the majority of Hain ingredients that exceeded 100 ppb inorganic arsenic in testing (13 of 24) were organic brown rice flour.¹⁶¹
- For Beech-Nut, the majority of its ingredients that tested over 100 ppb inorganic arsenic (27 of 45) were rice-based (either rice, rice flour, or organic rice).¹⁶²

2019) (online at https://oversight.house.gov/sites/democrats.oversight.house.gov/files/7_Redacted.pdf) (Gerber's policy is to "regularly test our ingredients, and periodically test... finished goods"); Hain, *Testing And Release Procedure For Baby Food Ingredients* (Dec. 11, 2019) (online at https://oversight.house.gov/sites/democrats.oversight.house.gov/files/8_Redacted.pdf) (Hain only tests raw ingredients; their testing policy applies only to ingredients and the vast majority of the testing information they provided to the Subcommittee was raw ingredient testing.).

¹⁶⁰ Hain, *PowerPoint Presentation to Food and Drug Administration: FDA Testing Result Investigation* (Aug. 1, 2019) (online at <https://oversight.house.gov/sites/democrats.oversight.house.gov/files/2.pdf>).

¹⁶¹ *Id.*

¹⁶² Beech-Nut, *Raw Material Heavy Metal Testing* (Dec. 6, 2019) (online at <http://oversight.house.gov/sites/democrats.oversight.house.gov/files/4.xlsx>).

- A significant number of the Nurture products that exceeded 100 ppb inorganic arsenic were rice products.¹⁶³
- Gerber used 67 batches of rice flour with over 90 ppb inorganic arsenic.¹⁶⁴

Further, rice and rice flour constitute a large proportion by volume of the baby foods that contain them. Therefore, increased toxic heavy metal levels in rice and rice flour could have a significant impact on the safety of the finished product.

If certain ingredients, like rice, are highly tainted, the answer is not to simply lower toxic heavy metal levels as much as possible for those ingredients, the answer is to stop including them in baby foods. The Subcommittee urges manufacturers to make this change voluntarily.

Similar considerations must be made for other ingredients that consistently contain higher levels of toxic heavy metals—ingredients like cinnamon, amylase, BAN 800, and vitamin premix. Manufacturers suggest that these additives, though high in toxic heavy metals, are not a concern because they make up a low percentage of the final food product. However, those manufacturers do not test their final food products, which is the only way to determine safety. Manufacturers should voluntarily commit to testing all of their finished baby food products, as opposed to just the ingredients. If they refuse, FDA should require them to do so.

The Subcommittee recommends the following:

- **Mandatory Testing**: Only one of the companies reviewed by the Subcommittee routinely tests its finished baby foods, even though the industry is aware that toxic heavy metals levels are higher after food processing. Baby food manufacturers should be required by FDA to test their finished products for toxic heavy metals, not just their ingredients.
- **Labeling**: Manufacturers should be required by FDA to report levels of toxic heavy metals on food labels.
- **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.
- **FDA Standards**: FDA should set maximum levels of inorganic arsenic, lead, cadmium, and mercury permitted in baby foods. One level for each metal should apply across all baby foods. The level should be set to protect babies against the neurological effects of toxic heavy metals.
- **Parental Vigilance**: Parents should avoid baby food products that contain ingredients testing high in heavy metals, such as rice products. The implementation of recommendations one through four will give parents the information they need to make informed decisions to protect their babies.

¹⁶³ Nurture, *Heavy Metal Test Results For Baby Food Products* (Dec. 18, 2019) (online at <http://oversight.house.gov/sites/democrats.oversight.house.gov/files/1.xlsx>).

¹⁶⁴ Gerber, *Raw Material Heavy Metal Testing* (Dec. 9, 2019) (online at https://oversight.house.gov/sites/democrats.oversight.house.gov/files/5_0.pdf).

VII. CONCLUSION

The Subcommittee's investigation proves 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 labeling whatsoever.

Last year, the Trump administration ignored new information contained in a secret industry presentation to federal regulators about toxic heavy metals in baby foods. On August 1, 2019, FDA received a secret slide presentation from Hain, the maker of Earth's Best Organic baby food, which revealed that finished baby food products contain even higher levels of toxic heavy metals than estimates based on individual ingredient test results. One heavy metal in particular, inorganic arsenic, was repeatedly found to be present at 28-93% higher levels than estimated.

The time is now for FDA to determine whether there is any safe exposure level for babies to inorganic arsenic, lead, cadmium, and mercury, to require manufacturers to meet those levels, and to inform consumers through labels.

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CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. (SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)

I. (a) PLAINTIFFS

Jonathan Wooden

(b) County of Residence of First Listed Plaintiff Atlantic County, NJ (EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorneys (Firm Name, Address, and Telephone Number) Charles J. LaDuca, Cuneo Gilbert & LaDuca LLP 4725 Wisconsin Ave NW, Ste 200, Washington, DC 20016 202-789-3960

DEFENDANTS

Beech-Nut Nutrition Company

County of Residence of First Listed Defendant (IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

Attorneys (If Known)

II. BASIS OF JURISDICTION (Place an "X" in One Box Only)

- 1 U.S. Government Plaintiff, 2 U.S. Government Defendant, 3 Federal Question (U.S. Government Not a Party), 4 Diversity (Indicate Citizenship of Parties in Item III)

III. CITIZENSHIP OF PRINCIPAL PARTIES (Place an "X" in One Box for Plaintiff and One Box for Defendant)

Table with columns for Plaintiff (PTF) and Defendant (DEF) citizenship and incorporation status. Includes options for Citizen of This State, Citizen of Another State, and Citizen or Subject of a Foreign Country.

IV. NATURE OF SUIT (Place an "X" in One Box Only)

Click here for: Nature of Suit Code Descriptions.

Large table with categories: CONTRACT, REAL PROPERTY, CIVIL RIGHTS, PRISONER PETITIONS, TORTS, FORFEITURE/PENALTY, LABOR, IMMIGRATION, BANKRUPTCY, SOCIAL SECURITY, FEDERAL TAX SUITS, OTHER STATUTES. Includes various legal codes and descriptions.

V. ORIGIN (Place an "X" in One Box Only)

- 1 Original Proceeding, 2 Removed from State Court, 3 Remanded from Appellate Court, 4 Reinstated or Reopened, 5 Transferred from Another District (specify), 6 Multidistrict Litigation - Transfer, 8 Multidistrict Litigation - Direct File

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing (Do not cite jurisdictional statutes unless diversity): 28 U.S.C. § 1332. Brief description of cause: Consumer class action alleging fraudulent and misleading advertising

VII. REQUESTED IN COMPLAINT:

CHECK IF THIS IS A CLASS ACTION UNDER RULE 23, F.R.Cv.P. DEMAND \$ CHECK YES only if demanded in complaint: JURY DEMAND: [X] Yes [] No

VIII. RELATED CASE(S) IF ANY

(See instructions): JUDGE Thomas J. McAvoy DOCKET NUMBER 1:21-cv-00133

DATE February 11, 2021 SIGNATURE OF ATTORNEY OF RECORD /s/ Charles J. LaDuca

FOR OFFICE USE ONLY ANYNDC-5417592

RECEIPT # AMOUNT \$402.00 APPLYING IFP JUDGE TJM MAG. JUDGE ML

INSTRUCTIONS FOR ATTORNEYS COMPLETING CIVIL COVER SHEET FORM JS 44

Authority For Civil Cover Sheet

The JS 44 civil cover sheet and the information contained herein neither replaces nor supplements the filings and service of pleading or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. Consequently, a civil cover sheet is submitted to the Clerk of Court for each civil complaint filed. The attorney filing a case should complete the form as follows:

- I.(a) Plaintiffs-Defendants.** Enter names (last, first, middle initial) of plaintiff and defendant. If the plaintiff or defendant is a government agency, use only the full name or standard abbreviations. If the plaintiff or defendant is an official within a government agency, identify first the agency and then the official, giving both name and title.
- (b) County of Residence.** For each civil case filed, except U.S. plaintiff cases, enter the name of the county where the first listed plaintiff resides at the time of filing. In U.S. plaintiff cases, enter the name of the county in which the first listed defendant resides at the time of filing. (NOTE: In land condemnation cases, the county of residence of the "defendant" is the location of the tract of land involved.)
- (c) Attorneys.** Enter the firm name, address, telephone number, and attorney of record. If there are several attorneys, list them on an attachment, noting in this section "(see attachment)".
- II. Jurisdiction.** The basis of jurisdiction is set forth under Rule 8(a), F.R.Cv.P., which requires that jurisdictions be shown in pleadings. Place an "X" in one of the boxes. If there is more than one basis of jurisdiction, precedence is given in the order shown below.
 United States plaintiff. (1) Jurisdiction based on 28 U.S.C. 1345 and 1348. Suits by agencies and officers of the United States are included here. United States defendant. (2) When the plaintiff is suing the United States, its officers or agencies, place an "X" in this box.
 Federal question. (3) This refers to suits under 28 U.S.C. 1331, where jurisdiction arises under the Constitution of the United States, an amendment to the Constitution, an act of Congress or a treaty of the United States. In cases where the U.S. is a party, the U.S. plaintiff or defendant code takes precedence, and box 1 or 2 should be marked.
 Diversity of citizenship. (4) This refers to suits under 28 U.S.C. 1332, where parties are citizens of different states. When Box 4 is checked, the citizenship of the different parties must be checked. (See Section III below; **NOTE: federal question actions take precedence over diversity cases.**)
- III. Residence (citizenship) of Principal Parties.** This section of the JS 44 is to be completed if diversity of citizenship was indicated above. Mark this section for each principal party.
- IV. Nature of Suit.** Place an "X" in the appropriate box. If there are multiple nature of suit codes associated with the case, pick the nature of suit code that is most applicable. Click here for: [Nature of Suit Code Descriptions](#).
- V. Origin.** Place an "X" in one of the seven boxes.
 Original Proceedings. (1) Cases which originate in the United States district courts.
 Removed from State Court. (2) Proceedings initiated in state courts may be removed to the district courts under Title 28 U.S.C., Section 1441.
 Remanded from Appellate Court. (3) Check this box for cases remanded to the district court for further action. Use the date of remand as the filing date.
 Reinstated or Reopened. (4) Check this box for cases reinstated or reopened in the district court. Use the reopening date as the filing date.
 Transferred from Another District. (5) For cases transferred under Title 28 U.S.C. Section 1404(a). Do not use this for within district transfers or multidistrict litigation transfers.
 Multidistrict Litigation – Transfer. (6) Check this box when a multidistrict case is transferred into the district under authority of Title 28 U.S.C. Section 1407.
 Multidistrict Litigation – Direct File. (8) Check this box when a multidistrict case is filed in the same district as the Master MDL docket. **PLEASE NOTE THAT THERE IS NOT AN ORIGIN CODE 7.** Origin Code 7 was used for historical records and is no longer relevant due to changes in statute.
- VI. Cause of Action.** Report the civil statute directly related to the cause of action and give a brief description of the cause. **Do not cite jurisdictional statutes unless diversity.** Example: U.S. Civil Statute: 47 USC 553 Brief Description: Unauthorized reception of cable service.
- VII. Requested in Complaint.** Class Action. Place an "X" in this box if you are filing a class action under Rule 23, F.R.Cv.P.
 Demand. In this space enter the actual dollar amount being demanded or indicate other demand, such as a preliminary injunction.
 Jury Demand. Check the appropriate box to indicate whether or not a jury is being demanded.
- VIII. Related Cases.** This section of the JS 44 is used to reference related pending cases, if any. If there are related pending cases, insert the docket numbers and the corresponding judge names for such cases.

Date and Attorney Signature. Date and sign the civil cover sheet.

ClassAction.org

This complaint is part of ClassAction.org's searchable [class action lawsuit database](#)
