

**IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION**

AILEEN GARCES , individually, and)	
on behalf of all others similarly situated,)	
)	
Plaintiff,)	
)	
v.)	No. 21 cv 719
)	
GERBER PRODUCTS CO. , and)	
THE HAIN CELESTIAL GROUP, INC. ,)	
)	
Defendants.)	Jury Trial Demanded

CLASS ACTION COMPLAINT

Plaintiff AILEEN GARCES (“Plaintiff”), individually, and on behalf of all others similarly situated, by and through counsel at Zimmerman Law Offices, P.C., brings this Class Action Complaint (“Complaint”) against Defendants GERBER PRODUCTS CO. (“Gerber”) and THE HAIN CELESTIAL GROUP, INC. (“Hain”) (collectively, “Defendants”), as follows:

INTRODUCTION

1. On February 4, 2021, the United States House of Representatives Committee on Oversight and Reform’s Subcommittee on Economic and Consumer Policy (the “House Subcommittee”) released a report entitled “Baby Foods Are Tainted with Dangerous Levels of Arsenic, Lead, Cadmium, and Mercury” (the “Subcommittee Report”). *See generally*, Subcommittee Report, attached hereto as Exhibit 1. According to the Subcommittee Report, several brands of baby food sold in the United States contain unsafe levels of toxic heavy metals, including those sold by Defendants. *See*, Subcommittee Report, p. 2.

2. Given the health risks associated with high levels of toxic heavy metals, the presence of these substances in baby food is a material fact to consumers. Indeed, consumers—

such as Plaintiff and members of the Class (defined below)—are unwilling to purchase baby food that contains unsafe levels of toxic heavy metals.

3. Defendants knew that the presence of toxic heavy metals in their baby food was a material fact to consumers, yet omitted and concealed that fact from consumers.

4. Accordingly, Plaintiff brings this suit on behalf of herself and a Class of similarly situated individuals for damages resulting from Defendants' sale of baby food that contained unsafe levels of toxic heavy metals.

PARTIES

5. Plaintiff AILEEN GARCES is a natural person and resident and citizen of Illinois.

6. Defendant GERBER PRODUCTS CO. is a Michigan corporation with its principal place of business in Virginia. Gerber sells its baby food under the eponymous "Gerber" brand name ("Gerber Brand Baby Food"). Gerber Brand Baby Food is sold nationwide, including throughout the state of Illinois.

7. Defendant THE HAIN CELESTIAL GROUP, INC. is a Delaware corporation with its principal place of business in New York. Hain sells its baby food under the "Earth's Best Organic" brand name ("Earth's Best Brand Baby Food"). Earth's Best Brand Baby Food is sold nationwide, including throughout the state of Illinois.

JURISDICTION AND VENUE

8. This Court has personal jurisdiction over Defendants pursuant to 735 ILCS 5/2-209(a)(1) (transaction of any business within this State), section 2-209(a)(7) (the making or performance of any contract or promise substantially connected with this State), section 2-209(b)(4) (corporation doing business within this State), and section 2-209(c) (any other basis now or hereafter permitted by the Illinois Constitution and the Constitution of the United States).

9. This Court has original jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1332(d). As set forth below, the proposed Class involves more than 100 individuals, and the amount of controversy, in the aggregate, exceeds the sum of \$5,000,000 exclusive of interest and costs, given Defendants' market reach and the approximate number of potential Class members in the United States. Some members of the proposed Class are citizens of states different from Defendants.

10. Venue is proper in this district under 28 U.S.C. § 1391, because a substantial part of the events and omissions giving rise to the claims occurred in this district.

FACTUAL ALLEGATIONS

The Subcommittee Report

11. Inorganic arsenic, lead, cadmium, and mercury are toxic heavy metals. The United States Food and Drug Administration ("FDA") and the World Health Organization ("WHO") have declared these toxic heavy metals dangerous to human health. Specifically, the FDA states that these toxic heavy metals have "no established health benefit," "lead to illness, impairment, and in high doses, death," and because of bioaccumulation, "even low levels of harmful metals from individual food sources, can sometimes add up to a level of concern."¹

12. The dangerous effects of these toxins are exacerbated and can be indelible in developing and vulnerable bodies and brains of babies and children, who FDA explains are at the greatest risk of harm. Subcommittee Report, p. 2. Exposure, such as ingestion, of toxic heavy metals by babies and children leads to untreatable and permanent brain damage, resulting in reduced intelligence and behavioral problems. For instance, scientific studies have connected

¹ FDA, *Metals and Your Food*, available at: <https://www.fda.gov/food/chemicals-metals-pesticides-food/metals-and-your-food>.

exposure to lead to a substantial decrease in children's total IQ points and their lifetime earning capacity. Subcommittee Report, p. 9.

13. "Exposure to toxic heavy metals [such as arsenic, lead, cadmium, and mercury] 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." *See*, Subcommittee Report, p. 2.

14. Given these risks, and in response to reports alleging high levels of toxic heavy metals in baby foods sold in the United States, the House Subcommittee launched an investigation into the presence of toxic heavy metals in certain brands of baby foods, including Gerber Brand Baby Food and Earth's Best Brand Baby Food. *See*, Subcommittee Report, p. 2. The results of the House Subcommittee's investigation were set forth in the Subcommittee Report, which was released on February 4, 2021.

Arsenic in Defendants' Baby Food

15. According to the Subcommittee Report, arsenic was present in all brands of baby foods subject to the House Subcommittee's investigation. *See*, Subcommittee Report, p. 3. In particular, Earth's Best Brand Baby Food was found to contain as much as 129 parts per billion—abbreviated as "ppb"—arsenic, and was made with ingredients that contained as high as 309 ppb arsenic. *See*, Subcommittee Report, p. 3. Gerber Brand Baby Food used high-arsenic ingredients, including rice flour that contained over 90 ppb arsenic. *See*, Subcommittee Report, p. 3.

16. For comparison, the FDA has set the maximum level of arsenic in bottled water at 10 ppb. *See*, Subcommittee Report, p. 4.

17. Arsenic is the most dangerous of the toxic heavy metals at issue and poses the most significant risk to human health. *See*, Subcommittee Report, p. 10. Currently known risks of

arsenic to health 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.”²

18. One study found negative effects in cognitive development of schoolchildren exposed to concentrations of arsenic over 5 ppb. For the authors of the study, 5 ppb was an important threshold for small children.³ Consumer reports has recommended setting the limit of arsenic at 3 ppb.

19. Hain sold finished baby food products using ingredients (such as organic brown rice flour) containing as much as 309 ppb arsenic, finished products contained as much as 129 ppb arsenic. Subcommittee Report, p. 3.

20. Hain exceeded its own unreasonable and excessive internal standards. For many ingredients in Earth’s Best Brand Baby Food, Hain set a standard for certain ingredients of 100 and up to 200 ppb for arsenic. Subcommittee Report, p. 16. Nevertheless, it approved and used a vitamin pre-mix with arsenic levels of 223 ppb, more than twice the specific limit Hain itself set at 100 ppb for this ingredient, which is itself way too high. *See*, Subcommittee Report, p. 16. Numerous other ingredients were used in Earth’s Best Brand Baby Food that contained excessive levels of arsenic according to Hain’s own testing, including organic whole raisins, organic soft white wheat flour, organic spelt flour, organic barley malt extract, organic yellow split pea powder, medium grain whole rice, organic brown rice flour, organic blueberry puree, organic barley flour, organic cinnamon powder, and organic butternut squash puree.

² Agency for Toxic Substances and Disease Registry, *ATSDR’s Substance Priority List* (2019), available at <http://www.atsdr.cdc.gov/spl/index.html#2019spl>.

³ 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/>).

21. Gerber agreed to provide only limited data to the House Subcommittee, but the data it provided shows that Gerber routinely used ingredients in Gerber Brand Baby Food that contained over 90 ppb arsenic, including 67 batches of rice flour. Subcommittee Report, p. 19.

22. Gerber used grape juice concentrate in Gerber Brand Baby Food containing 39 ppb inorganic arsenic. For apple juice concentrate, FDA has issued draft guidance requiring less than 10 ppb in organic arsenic. Subcommittee Report, p. 52.

Lead in Defendants' Baby Food

23. Lead was also present in all brands of baby foods subject to the House Subcommittee's investigation. *See*, Subcommittee Report, p. 3. In particular, Earth's Best Brand Baby Food was found to contain as much as 352 ppb lead, and was made with ingredients that contained as high as 200 ppb lead. *See*, Subcommittee Report, p. 3. Gerber Brand Baby Food also used high-lead ingredients in Gerber Brand Baby Food, including some that contained over 48 ppb lead. *See*, Subcommittee Report, p. 3

24. For comparison, the FDA has set the maximum level of lead in bottled water at 5 ppb. *See*, Subcommittee Report, p. 4.

25. Lead is the second most dangerous of the toxic heavy metals at issue. Because lead can accumulate in the body, even small doses of lead have deleterious effects on children, including health, behavioral, cognitive, and development issues. The FDA states that “[h]igh levels of lead exposure can seriously harm children’s health and development, specifically the brain and nervous system.”⁴ There is a growing consensus that lead levels in baby foods should not exceed 1 ppb.

⁴ FDA, *Metals and Your Food*, available at: <https://www.fda.gov/food/chemicals-metals-pesticides-food/metals-and-your-food>.

26. Two studies have established a significant association between early childhood exposure to lead and decreased standardized test scores, academic achievement, and diseases such as attention-deficit/hyperactivity disorder (“ADHD”). These effects last into adulthood according to other studies.⁵

27. Hain, under its Earth’s Best Organic label, used ingredients (such as vitamin pre-mix) containing as much as 352 ppb lead. 88 different ingredients in Earth’s Best Brand Baby Food tested over 20 ppb lead and six ingredients tested over 200 ppb lead, including organic whole wheat fine flour, organic quick oats, organic barley flour, organic cinnamon powder, and organic date paste. Subcommittee Report, p. 26.

28. All of Hain’s ingredients contained 1 or more ppb of lead, the limit recommended by some groups.

29. Gerber agreed to provide only limited data to the House Subcommittee, but the data it provided shows that Gerber used ingredients in Gerber Brand Baby Food that tests show contained as much as 48 ppb lead, and Gerber used many ingredients containing over 20 ppb lead, including its juice ingredients and sweet potatoes. Subcommittee Report, p. 27. Gerber’s tested juice concentrate measured an average of 11.2 ppb lead, which exceeds the 10 ppb standard for bottled water set by FDA.

⁵ Nanhua Zhang et al., *Early Childhood Lead Exposure and Academic Achievement: Evidence From Detroit Public Schools*, available at: <http://mediad.publicbroadcasting.net/p/michigan/files/201302/AJPH.2012.pdf>; 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*, available at: <https://ehjournal.biomedcentral.com/articles/10.1186/s12940-015-0008-9>; Maitreyi Mazumdar et al., *Low-Level Environmental Lead Exposure in Childhood and Adult Intellectual Function: A Follow-Up Study*, available at: www.ncbi.nlm.nih.gov/pmc/articles/PMC3072933/.

Cadmium in Defendants' Baby Food

30. Cadmium was another toxic heavy metal found to be present in all brands of baby foods subject to the House Subcommittee's investigation. *See*, Subcommittee Report, p. 3. In particular, Earth's Best Brand Baby Food used 102 ingredients that contained over 20 ppb cadmium, with some of those ingredients containing up to 260 ppb cadmium. *See*, Subcommittee Report, p. 3.

31. Certain Gerber Brand Baby Foods were made with ingredients that contained over 87 ppb cadmium. *See*, Subcommittee Report, p. 4.

32. For comparison, the FDA has set the maximum level of cadmium in bottled water at 5 ppb. *See*, Subcommittee Report, p. 4.

33. Cadmium is the seventh most dangerous heavy metal toxin according to the ATSDR. Exposure to cadmium is linked with decreases in IQ and development of ADHD. The EPA and FDA set the limit at 5 ppb of cadmium in drinking water and bottled water, respectively. The WHO limits cadmium in drinking water at 3 ppb. Certain experts recommend an upper limit of 1 ppb of cadmium in fruit juices.

34. In Earth's Best Brand Baby Food, Hain used 102 ingredients with 20 ppb cadmium or higher. Some ingredients (such as organic barley flour) tested as high as 260 ppb cadmium. Subcommittee Report, pp. 30–31. Other individual ingredients in Earth's Best Brand Baby Food containing excessive cadmium include: a product described as IQF⁶ organic chopped broccoli, organic date past, organic cinnamon powder, organic brown flax milled, organic yellow papaya puree, organic whole wheat fine flour, organic red lentils, organic oat flakes, and organic oat flour.

⁶ IQF likely means individually quick-frozen, a method for freezing foods that prevents ice crystals.

35. Gerber used carrots in Gerber Brand Baby Food, 75% of which contained between 5 and 87 ppb cadmium. Subcommittee Report, p. 4.

Defendants' Internal Testing

36. The House Subcommittee also sought to investigate the presence of mercury in baby food, but found that Hain did not even test for mercury in Earth's Best Brand Baby Food, and that Gerber "rarely" tested for mercury in Gerber Brand Baby Food. *See*, Subcommittee Report, p. 4.

37. The Subcommittee Report also noted that Hain routinely exceeded its own internal limits relative to the use of ingredients with arsenic, lead, and cadmium in Earth's Best Brand Baby Food. *See*, Subcommittee Report, p. 4. Although Hain attempted to justify these deviations from its internal standards, it "admitted to FDA that its testing underestimated final product toxic heavy metal levels." *See*, Subcommittee Report, pp. 4-5.

Defendants' Baby Food

38. Defendants each manufacture, distribute, advertise, market, and sell brands of baby food evaluated in the Subcommittee Report. Gerber manufactures, distributes, advertises, markets, and sells Gerber Brand Baby Food, and Hain manufactures, distributes, advertises, markets, and sells Earth's Best Brand Baby Food.

39. Defendants each direct, control, and participate in the manufacturing and packaging of the brands of baby food that they sell. As part of that direction, control, and participation, Defendants each determine and are responsible for the ingredients used in their baby food.

40. Defendants each know and are responsible for the ingredients in the brands of baby food that they sell.

41. Defendants each created, developed, reviewed, authorized, and are responsible for the textual and graphic content on the packaging of the brands of baby food that they sell. This is supported by the fact that the labels on Gerber Brand Baby Food contain Gerber’s corporate logo and trademark, and note that Gerber Brand Baby Food is distributed by Gerber. Similarly, the labels on Earth’s Best Brand Baby Food contain the Earth’s Best trademark—which is one of Hain’s federally registered trademarks—and note that Earth’s Best Brand Baby Food is distributed by Hain.

42. Each package of Earth’s Best Brand Baby Food contains standardized labeling created, developed, reviewed, and authorized by Hain. The packaging of all types of Earth’s Best Brand Baby Food is the same or substantially similar.

43. Each package of Gerber Brand Baby Food contains standardized labeling created, developed, reviewed, and authorized by Gerber. The packaging of all types of Gerber Brand Baby Food is the same or substantially similar.

44. Defendants each know, created, developed, reviewed and are responsible for the representations contained on each package of baby food that they sell.

45. The labels on some of the varieties of Gerber Brand Baby Food—including some of those that Plaintiff and Class members purchased—state that the product contains “iron to help support learning ability.”

46. The labels on some of the varieties of Earth’s Best Brand Baby Food—including some of those that Plaintiff and Class members purchased—state that the product contains used “non-BPA packaging.” BPA stands for bisphenol A, “an industrial chemical that has been used to make certain plastics and resins since the 1960s” that is linked to certain health issues.⁷ In other

⁷ Mayo Clinic, *What is BPA, and What Are the Concerns About BPA?*, available at: <https://www.mayoclinic.org/healthy-lifestyle/nutrition-and-healthy-eating/expert-answers/bpa/faq-20058331> (“Some

words, these varieties of Earth's Best Brand Baby Food are marketed as *lacking* a particular dangerous substance that can negatively affect brain development and children's behavior.

47. The labels on many varieties of Gerber Brand Baby Food and Earth's Best Brand Baby Food—including some of those that Plaintiff and Class members purchased—also tout those products as being free of GMO—which stands for “genetically modified organism”—ingredients. Like BPA, GMOs are also believed to be associated with health risks, “including infertility, immune problems, accelerated aging, faulty insulin regulation and changes in major organs and the gastrointestinal system.”⁸ As such, these varieties of Gerber Brand Baby Food and Earth's Best Brand Baby Food are marketed as *lacking* a particular dangerous substance that can negatively affect consumers of the product.

48. Despite touting the lack of certain dangerous substances in their respective brands of baby food, Defendants each fail to disclose elevated levels of toxic heavy metals on the labels of Earth's Best Brand Baby Food and Gerber Brand Baby Food.

49. Similarly, despite touting the presence of “iron to help support learning ability” in Gerber Brand Baby Food, Gerber fails to disclose the fact that its baby food contains other substances—toxic heavy metals—that have the exact opposite effect.

50. While Defendants' respective omissions regarding the material fact that their brands of baby food contain elevated levels of toxic heavy metals are legally significant on their own, Defendants' respective representations regarding the presence of “iron to help support learning ability” and the lack of BPA and GMOs are also significant. Although these

research has shown that BPA can seep into food or beverages from containers that are made with BPA,” which “is a concern because of possible health effects of BPA on the brain and prostate gland of fetuses, infants and children. It can also affect children's behavior. Additional research suggests a possible link between BPA and increased blood pressure.”).

⁸ CNN, *10 Ways to Keep Your Diet GMO-Free*, available at: <https://www.cnn.com/2014/03/25/health/upwave-gmo-free-diet/index.html>.

representations may be true, “a statement that is technically true may nevertheless be fraudulent where it omits qualifying material since a ‘half-truth’ is sometimes more misleading than an outright lie.” *Abazari v. Rosalind Franklin Univ. of Med. & Sci.*, 2015 IL App (2d) 140952, ¶ 33 (citing cases); *see also Heider v. Leewards Creative Crafts, Inc.*, 245 Ill.App.3d 258, 265 (2nd Dist. 1993) (“A statement which is technically true as far as it goes may nonetheless be fraudulent if it is misleading because it does not state matters which materially qualify that statement.”); W. Prosser, *Law of Torts* § 106, at 696 (4th ed. 1971) (“half the truth may obviously amount to a lie, if it is understood to be the whole.”).

51. For example, in representing that Earth’s Best Brand Baby Food and Gerber Brand Baby Food lack BPA and GMOs, Defendants represent that their respective brands of baby food lack substances that consumers would consider to be deleterious to human health. This is, however, only a “half-truth” as Earth’s Best Brand Baby Food and Gerber Brand Baby Food do, in fact, contain deleterious substances—*i.e.*, toxic heavy metals.

52. Gerber’s representations regarding the presence of “iron to help support learning ability” in Gerber Brand Baby Food is also a “half-truth,” as it fosters the understanding that the ingredients in Gerber Brand Baby Food will *promote* childhood brain development, when, in fact, Gerber Brand Baby Food contains toxic heavy metals, which are proven to *impede* childhood brain development.

Consumer Expectations Regarding Baby Food

53. Parents’ instinctive desire to protect and ensure the healthy development of their children is well-known. As such, the safety of baby food is of paramount importance, and is a material fact, to consumers (such as Plaintiff and Class members).

54. More specifically, given the negative effects of toxic heavy metals (such as arsenic, lead, cadmium, and mercury) on child development, the presence of these substances in baby food is a material fact to consumers (such as Plaintiff and members of the Class). Indeed, consumers—such as Plaintiff and members of the Class—are unwilling to purchase baby food that contains elevated levels of toxic heavy metals.

55. Defendants each know that the safety of their respective brands of baby food (as a general matter) is a material fact to consumers. This is exemplified by the fact that Earth's Best Brand Baby Food and Gerber Brand Baby Food are both marketed and labeled as *lacking* certain substances (e.g., BPA, GMOs) that consumers believe would be deleterious to the health of children.

56. Defendants each also know that consumers (such as Plaintiff and members of the Class) are unwilling to purchase their respective brands of baby food that contain elevated levels of toxic heavy metals.

57. As such, Defendants also know that the presence of toxic heavy metals in their respective brands of baby food is a material fact to consumers (such as Plaintiff and Class members).

58. Baby food manufacturers (such as Defendants) hold a special position of public trust. Consumers believe that they would not sell products that are unsafe. *See*, Subcommittee Report, p. 6.

59. Defendants each knew that if the elevated levels of toxic heavy metals in their respective brands of baby food was disclosed to Plaintiff and Class members, then Plaintiff and Class members would be unwilling to purchase Earth's Best Brand Baby Food and/or Gerber Brand Baby Food.

60. In light of Defendants' respective knowledge that Plaintiff and Class members would be unwilling to purchase Earth's Best Brand Baby Food and/or Gerber Brand Baby Food if they knew that those brands of baby food contained elevated levels of toxic heavy metals, Defendants intentionally and knowingly concealed this fact from Plaintiff and Class members, and did not disclose the presence of these toxic heavy metals on the labels of Earth's Best Brand Baby Food and Gerber Brand Baby Food (respectively).

61. Defendants knew that Plaintiff and Class members would rely upon the representations and omissions contained on the packages of Earth's Best Brand Baby Food and Gerber Brand Baby Food (respectively), and intended for them to do so.

62. Defendants knew that in relying upon the representations and omissions contained on the packages of Earth's Best Brand Baby Food and Gerber Brand Baby Food (respectively), Plaintiff and Class members would view those products as being safe for consumption, given their represented lack of certain deleterious substances (*e.g.*, BPA, GMOs), and Defendants' concealment of the fact that those brands of baby food contained elevated levels of toxic heavy metals.

63. Prior to purchasing Earth's Best Brand Baby Food and Gerber Brand Baby Food, Plaintiff and Class members were exposed to, saw, read, and understood Defendants' respective representations and omissions regarding the safety of their baby food, and relied upon them.

64. As a result of Defendants' respective representations regarding the safety of their baby food, and the lack of certain deleterious substances (*e.g.*, BPA, GMOs), and Defendants' concealment of the fact that those brands of baby food contained elevated levels of toxic heavy metals, Plaintiff and Class members reasonably believed that Earth's Best Brand Baby Food and

Gerber Brand Baby Food were free from substances that would negatively affect children's development.

65. In reliance upon Defendants' respective representations and omissions, Plaintiff and Class members purchased Earth's Best Brand Baby Food and/or Gerber Brand Baby Food.

66. Had Plaintiff and Class members known the truth—*i.e.*, that Defendants' respective brands of baby food contained elevated levels of toxic heavy metals, rendering them unsafe for consumption by children—they would not have been willing to purchase them at all.

67. Therefore, as a direct and proximate result of Defendants' misrepresentations and omissions concerning their respective brands of baby food, Plaintiff and Class members purchased Earth's Best Brand Baby Food and/or Gerber Brand Baby Food.

68. Plaintiff and Class members were harmed in the form of the monies they paid for Earth's Best Brand Baby Food and/or Gerber Brand Baby Food which they would not otherwise have paid had they known the truth. Since the presence of elevated levels of toxic heavy metals in baby food renders it unsafe for human consumption, the Earth's Best Brand Baby Food and/or Gerber Brand Baby Food that Plaintiff and Class members purchased is worthless.

Facts Relevant to Plaintiff

69. Between November 2020 and February 4, 2021, Plaintiff purchased several different varieties of Earth's Best Brand Baby Food and Gerber Brand Baby Food from Amazon.com and Target. Many of the varieties of Earth's Best Brand Baby Food and Gerber Brand Baby Food contained ingredients (and contaminants) discussed in the Subcommittee Report. Plaintiff's relevant purchases include:

- a. Earth's Best Brand Baby Food from Hain containing organic raisins, organic rice flour, organic blueberry puree, organic whole grain barley flour, organic brown flax milled, organic cinnamon, organic whole grain oat flour with excessive levels of arsenic, including: Earth's Best Organic

Blueberry Banana Flax & Oat Wholesome Breakfast Puree on February 4, 2021; Earth's Best Organic Apple Peach Oatmeal Wholesome Breakfast Puree on January 23, 2021; Earth's Best Apple Raisin Flax & Oat Wholesome Breakfast Puree on January 1, 9, 15 and 21, 2021; Earth's Best Sweet Potato Cinnamon Flax & Oat Wholesome Breakfast Puree on January 9, 15, 21 and 23, 2021; and Earth's Best Organic Rice Cereal on November 22, 2020.

- b. Earth's Best Brand Baby Food from Hain containing organic raisins, organic barley flour, organic cinnamon powder, and vitamin pre-mix with excessive levels of lead, including: Earth's Best Organic Blueberry Banana Flax & Oat Wholesome Breakfast Puree on February 4, 2021; Earth's Best Apple Raisin Flax & Oat Wholesome Breakfast Puree on January 1, 9, 15 and 21, 2021; and Earth's Best Sweet Potato Cinnamon Flax & Oat Wholesome Breakfast Puree on January 15, 21 and 23, 2021.
- c. Earth's Best Brand Baby Food from Hain containing organic barley flour, organic cinnamon powder, and organic brown flax with excessive levels of cadmium, including: Earth's Best Apple Raisin Flax & Oat Wholesome Breakfast Puree on January 1, 9, 15 and 21, 2021; and Earth's Best Sweet Potato Cinnamon Flax & Oat Wholesome Breakfast Puree on January 15, 21 and 23, 2021.
- d. Gerber's Teethers Strawberry Apple Spinach Wafers containing dried apple juice with excessive levels of lead on February 2, 2021.
- e. Gerber's Teethers Banana Peach Wafers and Strawberry Apple Spinach Wafers containing rice flour with excessive levels of toxic heavy metals on February 2, 2021.

70. Prior to purchasing Earth's Best Brand Baby Food and Gerber Brand Baby Food, Plaintiff and Class members were exposed to, saw, read, and understood Defendants' respective representations and omissions regarding the safety of their baby food, as well as the presence of elevated levels of toxic heavy metals therein, and relied upon them.

71. Plaintiff was only willing to purchase Earth's Best Brand Baby Food and Gerber Brand Baby Food because she believed that they did *not* contain elevated levels of toxic heavy metals. This belief was bolstered by Defendants' representations regarding the presence of iron, and the *lack* of BPA and GMOs, in their respective brands of baby food.

72. In reliance upon Defendants' respective representations and omissions, Plaintiff purchased Earth's Best Brand Baby Food and Gerber Brand Baby Food.

73. Had Plaintiff known the truth—*i.e.*, that Defendants' respective brands of baby food contained elevated levels of toxic heavy metals, rendering them unsafe for consumption by children—she would not have been willing to purchase them at all.

74. The presence of elevated levels of toxic heavy metals in Earth's Best Brand Baby Food and Gerber Brand Baby Food renders the baby food that Plaintiff purchased worthless, as it is unsafe for human consumption.

75. Therefore, as a direct and proximate result of Defendants' misrepresentations and omissions concerning their respective brands of baby food, Plaintiff was harmed in the form of the monies she paid for Earth's Best Brand Baby Food and/or Gerber Brand Baby Food which she would not otherwise have paid had she known the truth.

76. Plaintiff brings this action on behalf of herself, and a Class of similar situated individuals, seeking recovery of the damages they incurred as a result of Defendants' deception.

CLASS ALLEGATIONS

77. **Class Definition:** Plaintiff brings this action pursuant to Fed. R. Civ. P. 23, on behalf of a nationwide class of similarly situated individuals and entities ("the Class"), defined as follows:

All persons in the United States who purchased Earth's Best Brand Baby Food and/or Gerber Brand Baby Food.

Excluded from the Class are: (1) Defendants, Defendants' agents, subsidiaries, parents, successors, predecessors, and any entity in which Defendants or their parents have a controlling interest, and those entities' current and former employees, officers, and directors; (2) the Judge to whom this case is assigned and the Judge's immediate family; (3) any person who executes and files a timely request for exclusion from the Class; (4) any persons who have had their claims in this matter finally adjudicated and/or otherwise released; and (5) the legal representatives, successors and assigns of any such excluded person.

78. **Illinois Subclass Definition:** Plaintiff also brings this action pursuant to Fed. R. Civ. P. 23, on behalf of a subclass of similarly situated individuals and entities (“Illinois Subclass”), defined as follows:

All persons in Illinois who purchased Earth’s Best Brand Baby Food and/or Gerber Brand Baby Food.

Excluded from the Illinois Subclass are: (1) Defendants, Defendants’ agents, subsidiaries, parents, successors, predecessors, and any entity in which Defendants or their parents have a controlling interest, and those entities’ current and former employees, officers, and directors; (2) the Judge to whom this case is assigned and the Judge’s immediate family; (3) any person who executes and files a timely request for exclusion from the Illinois Subclass; (4) any persons who have had their claims in this matter finally adjudicated and/or otherwise released; and (5) the legal representatives, successors and assigns of any such excluded person.

79. **Numerosity:** The Class and Illinois Subclass are each so numerous that joinder of individual members would be impracticable. While the exact number of Class members and Illinois Subclass members is presently unknown and can only be ascertained through discovery, Plaintiff believes that there are thousands of Class and Illinois Subclass members, if not more, as Gerber and Hain are two of the seven largest manufacturers of baby food in the United States. *See*, Subcommittee Report, p. 2.

80. **Commonality and Predominance:** There are several questions of law and fact common to the claims of the Plaintiff and members of the Class, which predominate over any individual issues, including:

- a. Whether the Earth’s Best Brand Baby Food and/or Gerber Brand Baby Food contain unsafe levels of toxic heavy metals;
- b. Whether Defendants misrepresented to Plaintiff and Class members that Earth’s Best Brand Baby Food and/or Gerber Brand Baby Food was safe for human consumption and did not contain elevated levels of toxic heavy metals;
- c. Whether Defendants omitted and concealed the fact that Earth’s Best Brand Baby Food and/or Gerber Brand Baby Food contained elevated levels of toxic heavy metals;

- d. Whether the presence of elevated levels of toxic heavy metals in Earth's Best Brand Baby Food and/or Gerber Brand Baby Food was a material fact to Plaintiff and Class members;
- e. The extent and amount of Plaintiff's and Class members' damages;
- f. Whether Defendants' conduct constitutes unfair or deceptive business practices under the Illinois Consumer Fraud and Deceptive Trade Practices Act;
- g. Whether Defendants violated the Consumer Fraud and Deceptive Trade Practices Acts of the fifty states and the District of Columbia;
- h. Whether Defendants' conduct constitutes fraudulent concealment;
- i. Whether Defendants' conduct violates the Illinois Food, Drug, and Cosmetic Act;
- j. Whether Defendants' conduct resulted in Defendants unjustly retaining a benefit to the detriment of Plaintiff and Class members, and violated the fundamental principles of justice, equity, and good conscience.

81. **Typicality:** Plaintiff's claims are typical of the claims of the proposed Class. All claims are based on the same legal and factual issues, to wit: Defendants' misrepresentations and omissions concerning the presence of elevated levels of toxic heavy metals in Earth's Best Brand Baby Food and/or Gerber Brand Baby Food.

82. **Adequacy:** Plaintiff will fairly and adequately represent and protect the interests of the proposed Class, and Plaintiff does not have any interests antagonistic to those of the proposed Class. Plaintiff has retained competent counsel experienced in the prosecution of this type of litigation.

83. **Superiority:** A class action can best secure the economies of time, effort and expense, and promote uniformity. A class action is superior to other available methods for the fair and efficient adjudication of this controversy. The expense and burden of individual litigation would make it impracticable or impossible for proposed Class members to prosecute their claims individually. Individual actions are not economically feasible and it is unlikely that individual

members of the Class will prosecute separate actions. The trial and the litigation of Plaintiff's claims are manageable.

COUNT I
(on Behalf of Plaintiff and the Illinois Subclass)
Violation of the Illinois Consumer Fraud and Deceptive Trade Practices Act
(815 ILCS 505/1, *et seq.*)

84. Plaintiff repeats and re-alleges the allegations of the paragraphs 1-83 with the same force and effect as though fully set forth herein.

85. The Illinois Consumer Fraud and Deceptive Business Practices Act (“ICFA”), 815 ILCS 505/1, *et seq.*, provides protection to consumers by mandating fair competition in commercial markets for goods and services.

86. The ICFA prohibits any deceptive, unlawful, unfair, or fraudulent business acts or practices including using deception, fraud, false pretenses, false promises, false advertising, misrepresentation, or the concealment, suppression, or omission of any material fact, or the use or employment of any practice described in Section 2 of the “Uniform Deceptive Trade Practices Act”. 815 ILCS 505/2.

87. The ICFA applies to Defendants’ acts as described herein because it applies to transactions involving the sale of goods or services to consumers.

88. Defendants are each a “person,” as defined by 815 ILCS 505/1(c).

89. Plaintiff and each member of the Illinois Subclass are “consumers,” as defined by 815 ILCS 505/1(e), because they purchased Earth’s Best Brand Baby Food and/or Gerber Brand Baby Food.

90. Earth’s Best Brand Baby Food and Gerber Brand Baby Food are “merchandise,” as defined by 815 ILCS 505/1(b).

91. Defendants each made false and fraudulent statements, and misrepresented, concealed, and omitted material facts regarding Earth's Best Brand Baby Food and/or Gerber Brand Baby Food, including the misrepresentation that their brands of baby food were safe for human consumption and the omission that their brands of baby food contained unsafe levels of toxic heavy metals.

92. Defendants' respective misrepresentations and omissions regarding Earth's Best Brand Baby Food and Gerber Brand Baby Food constitute deceptive and unfair acts or practices prohibited by the ICFA.

93. Defendants' aforementioned misrepresentations and omissions possess the tendency or capacity to mislead and create the likelihood of consumer confusion. *Unique Concepts, Inc. v. Manuel*, 669 F. Supp. 185, 191 (N.D. Ill. 1987).

94. Defendants' aforementioned misrepresentations and omissions were used or employed in the conduct of trade or commerce, namely, the marketing, sale, and distribution of Earth's Best Brand Baby Food and Gerber Brand Baby Food (respectively) to Plaintiff and the Illinois Subclass.

95. Defendants' aforementioned misrepresentations and omissions are unfair business practices because they offend public policy and/or cause substantial injury to consumers. *Robinson v. Toyota Motor Credit Corp.*, 201 Ill.2d 403, 417-18 (2002).

96. Defendants' aforementioned conduct is deceptive and unlawful because it violated section 343(a)(i) of the FDCA and section 620/11(a) of the IFDCA.

97. Defendants intended that Plaintiff and Illinois Subclass members rely on their respective aforementioned false statements, misrepresentations, and omissions of material fact in purchasing Earth's Best Brand Baby Food and/or Gerber Brand Baby Food.

98. Plaintiff and Illinois Subclass members reasonably relied on Defendants' respective misrepresentations and omissions when they purchased Earth's Best Brand Baby Food and/or Gerber Brand Baby Food.

99. Acting as reasonable consumers, had Plaintiff and Illinois Subclass members been aware of the true facts regarding the presence of toxic heavy metals in Earth's Best Brand Baby Food and Gerber Brand Baby Food, they would have declined to purchase Earth's Best Brand Baby Food and Gerber Brand Baby Food.

100. Plaintiff and Illinois Subclass members suffered injuries in fact—*i.e.*, the loss of the money that they paid for Earth's Best Brand Baby Food and/or Gerber Brand Baby Food under the belief that they were safe for human consumption and did not contain unsafe levels of toxic heavy metals.

101. Acting as reasonable consumers, Plaintiff and Illinois Subclass members could not have avoided the injuries suffered by purchasing Earth's Best Brand Baby Food and/or Gerber Brand Baby Food because they did not have any reason to suspect that those brands of baby food contained elevated levels of toxic heavy metals. Moreover, the detection of toxic heavy metals in food requires rigorous and specialized scientific testing that goes well beyond the level of inquiry a reasonable consumer would make into the issue, and, in any event, such testing was not readily available to Plaintiff and Illinois Subclass members at the time they purchased Earth's Best Brand Baby Food and/or Gerber Brand Baby Food.

102. As a direct and proximate result of Defendants' unfair and deceptive acts or practices, Plaintiff and members of the Illinois Subclass suffered damages by purchasing Earth's Best Brand Baby Food and/or Gerber Brand Baby Food because they would not have purchased

those brands of baby food had they known the truth, and they received a product that was worthless because it contains unsafe levels of toxic heavy metals.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff AILEEN GARCES, individually, and on behalf of the Illinois Subclass, prays for an Order as follows:

- A. Finding that this action satisfies the prerequisites for maintenance as a class action set forth in Fed. R. Civ. P. 23, and certifying the Illinois Subclass defined herein;
- B. Designating Plaintiff as representative of the Illinois Subclass and her undersigned counsel as Class Counsel;
- C. Entering judgment in favor of Plaintiff and the Illinois Subclass and against Defendants;
- D. Awarding Plaintiff and the Illinois Subclass damages equal to the amount of actual damages that they sustained;
- E. Awarding Plaintiff and the Illinois Subclass attorneys' fees and costs, including interest thereon, as allowed or required by law; and
- F. Granting all such further and other relief as the Court deems just and appropriate.

COUNT II

(on Behalf of Plaintiff and the Class)

Violation of the Consumer Fraud and Deceptive Trade Practices Acts of the Various States and District of Columbia

103. Plaintiff repeats and re-alleges the allegations in Paragraphs 1-83 with the same force and effect as though fully set forth herein.

104. Plaintiff brings this Count individually, and on behalf of all similarly situated residents of each of the 50 states and the District of Columbia for violations of the respective statutory consumer protection laws, as follows:

- a. the Alabama Deceptive Trade Practices Act, Ala.Code 1975, § 8-19-1, *et seq.*;

- b. the Alaska Unfair Trade Practices and Consumer Protection Act, AS § 45.50.471, *et seq.*;
- c. the Arizona Consumer Fraud Act, A.R.S §§ 44-1521, *et seq.*;
- d. the Arkansas Deceptive Trade Practices Act, Ark.Code §§ 4-88-101, *et seq.*;
- e. the California Unfair Competition Law, Bus. & Prof. Code §§17200, *et seq.* and 17500 *et seq.*;
- f. the California Consumers Legal Remedies Act, Civil Code §1750, *et seq.*;
- g. the Colorado Consumer Protection Act, C.R.S.A. §6-1-101, *et seq.*;
- h. the Connecticut Unfair Trade Practices Act, C.G.S.A. § 42-110, *et seq.*;
- i. the Delaware Consumer Fraud Act, 6 Del. C. § 2513, *et seq.*;
- j. the D.C. Consumer Protection Procedures Act, DC Code § 28-3901, *et seq.*;
- k. the Florida Deceptive and Unfair Trade Practices Act, FSA § 501.201, *et seq.*;
- l. the Georgia Fair Business Practices Act, OCGA § 10-1-390, *et seq.*;
- m. the Hawaii Unfair Competition Law, H.R.S. § 480-1, *et seq.*;
- n. the Idaho Consumer Protection Act, I.C. § 48-601, *et seq.*;
- o. the Illinois Consumer Fraud and Deceptive Business Practices Act, 815 ILCS 501/1 *et seq.*;
- p. the Indiana Deceptive Consumer Sales Act, IN ST § 24-5-0.5-2, *et seq.*;
- q. The Iowa Private Right of Action for Consumer Frauds Act, Iowa Code Ann. § 714H.1, *et seq.*;
- r. the Kansas Consumer Protection Act, K.S.A. § 50-623, *et seq.*;
- s. the Kentucky Consumer Protection Act, KRS 367.110, *et seq.*;
- t. the Louisiana Unfair Trade Practices and Consumer Protection Law, LSA-R.S. 51:1401, *et seq.*;
- u. the Maine Unfair Trade Practices Act, 5 M.R.S.A. § 205-A, *et seq.*;
- v. the Maryland Consumer Protection Act, MD Code, Commercial Law, § 13-301, *et seq.*;

- w. the Massachusetts Regulation of Business Practices for Consumers Protection Act, M.G.L.A. 93A, *et seq.*;
- x. the Michigan Consumer Protection Act, M.C.L.A. 445.901, *et seq.*;
- y. the Minnesota Prevention of Consumer Fraud Act, Minn. Stat. § 325F.68, *et seq.*;
- z. the Mississippi Consumer Protection Act, Miss. Code Ann. § 75-24-1, *et seq.*;
- aa. the Missouri Merchandising Practices Act, V.A.M.S. § 407, *et seq.*;
- bb. the Montana Unfair Trade Practices and Consumer Protection Act of 1973, Mont. Code Ann. § 30-14-101, *et seq.*;
- cc. the Nebraska Consumer Protection Act, Neb.Rev.St. §§ 59-1601, *et seq.*;
- dd. the Nevada Deceptive Trade Practices Act, N.R.S. 41.600, *et seq.*;
- ee. the New Hampshire Regulation of Business Practices for Consumer Protection, N.H.Rev.Stat. § 358-A:1, *et seq.*;
- ff. the New Jersey Consumer Fraud Act, N.J.S.A. 56:8, *et seq.*;
- gg. the New Mexico Unfair Practices Act, N.M.S.A. §§ 57-12-1, *et seq.*;
- hh. the New York Consumer Protection from Deceptive Acts and Practices, N.Y. GBL (McKinney) § 349, *et seq.*;
- ii. the North Carolina Unfair and Deceptive Trade Practices Act, N.C. Gen Stat. § 75-1.1, *et seq.*;
- jj. the North Dakota Consumer Fraud Act, N.D. Cent.Code Chapter 51-15, *et seq.*;
- kk. the Ohio Consumer Sales Practices Act, R.C. 1345.01, *et seq.*;
- ll. the Oklahoma Consumer Protection Act, 15 O.S.2001, §§ 751, *et seq.*;
- mm. the Oregon Unlawful Trade Practices Act, ORS 646.605, *et seq.*;
- nn. the Pennsylvania Unfair Trade Practices and Consumer Protection Law, 73 P.S. § 201-1, *et seq.*;
- oo. the Rhode Island Deceptive Trade Practices Act, G.L.1956 § 6-13.1-5.2(B), *et seq.*;

- pp. the South Carolina Unfair Trade Practices Act, SC Code 1976, §§ 39-5-10, *et seq.*;
- qq. the South Dakota Deceptive Trade Practices and Consumer Protection Act, SDCL § 37-24-1, *et seq.*;
- rr. the Tennessee Consumer Protection Act, T.C.A. § 47-18-101, *et seq.*;
- ss. the Texas Deceptive Trade Practices-Consumer Protection Act, V.T.C.A., Bus. & C. § 17.41, *et seq.*;
- tt. the Utah Consumer Sales Practices Act, UT ST § 13-11-1, *et seq.*;
- uu. the Vermont Consumer Fraud Act, 9 V.S.A. § 2451, *et seq.*;
- vv. the Virginia Consumer Protection Act of 1977, VA ST § 59.1-196, *et seq.*;
- ww. the Washington Consumer Protection Act, RCWA 19.86.010, *et seq.*;
- xx. the West Virginia Consumer Credit And Protection Act, W.Va.Code § 46A-1-101, *et seq.*;
- yy. the Wisconsin Deceptive Trade Practices Act, WIS.STAT. § 100.18, *et seq.*; and
- zz. the Wyoming Consumer Protection Act, WY ST § 40-12-101, *et seq.*

105. Earth's Best Brand Baby Food and Gerber Brand Baby Food are each a consumer good.

106. Defendants each made false and fraudulent statements, and misrepresented, concealed, and omitted material facts regarding Earth's Best Brand Baby Food and/or Gerber Brand Baby Food, including the misrepresentation that their brands of baby food were safe for human consumption and the omission that their brands of baby food contained unsafe levels of toxic heavy metals.

107. Defendants' aforementioned misrepresentations and omissions were used or employed in the conduct of trade or commerce, namely, the marketing, sale, and distribution of Earth's Best Brand Baby Food and Gerber Brand Baby Food (respectively) to Plaintiff and the Class.

108. Defendants' aforementioned misrepresentations and omissions possess the tendency or capacity to mislead and create the likelihood of confusion.

109. Defendants' aforementioned misrepresentations and omissions are unfair and unlawful business practices because they offend public policy and cause substantial injury to consumers.

110. Defendants intended that Plaintiff and Class members rely on the aforementioned false statements, misrepresentations, and omissions of material fact in purchasing Earth's Best Brand Baby Food and Gerber Brand Baby Food.

111. Plaintiff and Class members reasonably relied on Defendants' misrepresentations and omissions when they purchased Earth's Best Brand Baby Food and Gerber Brand Baby Food.

112. Acting as reasonable consumers, had Plaintiff and Class members been aware of the true facts regarding the Earth's Best Brand Baby Food and Gerber Brand Baby Food, they would have declined to purchase those brands of baby food.

113. Plaintiff and Class members suffered injuries in fact—*i.e.*, the loss of the money that they paid for Earth's Best Brand Baby Food and/or Gerber Brand Baby Food under the belief that they were safe for human consumption and did not contain unsafe levels of toxic heavy metals.

114. Acting as reasonable consumers, Plaintiff and Class members could not have avoided the injuries suffered by purchasing Earth's Best Brand Baby Food and/or Gerber Brand Baby Food because they did not have any reason to suspect that those brands of baby food contained elevated levels of toxic heavy metals. Moreover, the detection of toxic heavy metals in food requires rigorous and specialized scientific testing that goes well beyond the level of inquiry a reasonable consumer would make into the issue, and, in any event, such testing was not readily

available to Plaintiff and Class members at the time they purchased Earth's Best Brand Baby Food and/or Gerber Brand Baby Food.

115. As a direct and proximate result of Defendants' unfair and deceptive acts or practices, Plaintiff and members of the Class suffered damages by purchasing Earth's Best Brand Baby Food and/or Gerber Brand Baby Food because they would not have purchased those brands of baby food had they known the truth, and they received a product that was worthless because it contains unsafe levels of toxic heavy metals.

116. Plaintiff and Class members reasonably relied on Defendants' respective misrepresentations and omissions when they purchased Earth's Best Brand Baby Food and/or Gerber Brand Baby Food.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff AILEEN GARCES, individually, and on behalf of the Class, prays for an Order as follows:

- A. Finding that this action satisfies the prerequisites for maintenance as a class action set forth in Fed. R. Civ. P. 23, and certifying the Class defined herein;
- B. Designating Plaintiff as representative of the Class and her undersigned counsel as Class Counsel;
- C. Entering judgment in favor of Plaintiff and the Class and against Defendants;
- D. Awarding Plaintiff and the Class damages equal to the amount of actual damages that they sustained;
- E. Awarding Plaintiff and the Class attorneys' fees and costs, including interest thereon, as allowed or required by law; and
- F. Granting all such further and other relief as the Court deems just and appropriate.

COUNT III
(on Behalf of Plaintiff and the Class)
Fraudulent Concealment

117. Plaintiff repeats and re-alleges the allegations of the paragraphs 1-83 with the same force and effect as though fully set forth herein.

118. “The elements needed to prove fraudulent concealment are (1) concealment of a material fact, (2) intent to induce a false belief where there exists a duty to speak, (3) that the other party could not have discovered the truth through reasonable inquiry and relied upon the silence as an indication that the concealed fact did not exist, (4) that the other party would have acted differently had it known of the concealed information, and (5) that its reliance resulted in its injury.” *Vandenberg v. Brunswick Corp.*, 2017 IL App (1st) 170181, ¶ 31 (citing *Schrager v. North Community Bank*, 328 Ill.App.3d 696, 706-07 (1st Dist. 2002).

119. As noted above, the presence of elevated levels of toxic heavy metals in baby food is a material fact to consumers.

120. Defendants each knew that the presence of elevated levels of toxic heavy metals in Earth’s Best Brand Baby Food and Gerber Brand Baby Food (respectively) was a material fact to consumers, such as Plaintiff and members of the Class.

121. Because Defendants are each responsible for, and control, the manufacturing, marketing, distribution, and sale of Earth’s Best Brand Baby Food and Gerber Brand Baby Food (respectively), Defendants knew and intended that their omissions and concealment of the presence of elevated levels of toxic heavy metals in their respective brands of baby food would mislead Plaintiff and Class members, and induce them to buy products that they would otherwise not have been willing to purchase.

122. Acting as reasonable consumers, had Plaintiff and Class members been aware of the true facts regarding the Earth's Best Brand Baby Food and Gerber Brand Baby Food, they would have declined to purchase those brands of baby food.

123. Plaintiff and Class members suffered injuries in fact—*i.e.*, the loss of the money that they paid for Earth's Best Brand Baby Food and/or Gerber Brand Baby Food under the belief that they were safe for human consumption and did not contain unsafe levels of toxic heavy metals.

124. Acting as reasonable consumers, Plaintiff and Class members could not have avoided the injuries suffered by purchasing Earth's Best Brand Baby Food and/or Gerber Brand Baby Food because they did not have any reason to suspect that those brands of baby food contained elevated levels of toxic heavy metals. Moreover, the detection of toxic heavy metals in food requires rigorous and specialized scientific testing that goes well beyond the level of inquiry a reasonable consumer would make into the issue, and, in any event, such testing was not readily available to Plaintiff and Class members at the time they purchased Earth's Best Brand Baby Food and/or Gerber Brand Baby Food.

125. As a direct and proximate result of Defendants' fraudulent concealment, Plaintiff and members of the Class suffered damages by purchasing Earth's Best Brand Baby Food and/or Gerber Brand Baby Food because they would not have purchased those brands of baby food had they known the truth, and they received a product that was worthless because it contains unsafe levels of toxic heavy metals.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff AILEEN GARCES, individually, and on behalf of the Class, prays for an Order as follows:

- A. Finding that this action satisfies the prerequisites for maintenance as a class action set forth in Fed. R. Civ. P. 23, and certifying the Class defined herein;

- B. Designating Plaintiff as representative of the Class and her undersigned counsel as Class Counsel;
- C. Entering judgment in favor of Plaintiff and the Class and against Defendants;
- D. Awarding Plaintiff and the Class damages equal to the amount of actual damages that they sustained;
- E. Awarding Plaintiff and the Class attorneys' fees and costs, including interest thereon, as allowed or required by law; and
- F. Granting all such further and other relief as the Court deems just and appropriate.

COUNT IV
(on Behalf of Plaintiff and the Illinois Subclass)
Violation of the Illinois Food, Drug and Cosmetic Act
(410 ILCS 620/1, *et seq.*)

126. Plaintiff repeats and re-alleges the allegations of the paragraphs 1-83 with the same force and effect as though fully set forth herein.

127. At all relevant times, the Illinois Food, Drug, and Cosmetic Act (“IFDCA”)—codified as 410 ILCS 620/1, *et seq.*—was in full force and effect.

128. The IFDCA prohibits the “manufacture, sale or delivery, holding or offering for sale of any food...that is adulterated or misbranded,” the “adulteration or misbranding of any food,” and “the delivery or proffered delivery thereof for pay or otherwise.” 410 ILCS 620/3 (incorporating 410 ILCS 620/3.1, 410 ILCS 620/3.2, and 410 ILCS 620/3.3).

129. Under the IFDCA, “a food is adulterated if it bears or contains any poisonous or deleterious substance which may render it injurious to health...if the quantity of such substance in such food [would] render it injurious to health.” 410 ILCS 620/10.

130. Defendants each violated the IFDCA by manufacturing, distributing, marketing, and selling Gerber Brand Baby Food and Earth’s Best Brand Baby Food (respectively) because

the presence of unsafe levels of toxic heavy metals in those brands of baby food render them injurious to health.

131. Plaintiff and Illinois Subclass members reasonably relied on Defendants' respective misrepresentations and omissions when they purchased Earth's Best Brand Baby Food and/or Gerber Brand Baby Food.

132. Acting as reasonable consumers, had Plaintiff and Illinois Subclass members been aware of the true facts regarding the presence of toxic heavy metals in Earth's Best Brand Baby Food and Gerber Brand Baby Food, they would have declined to purchase Earth's Best Brand Baby Food and Gerber Brand Baby Food.

133. Plaintiff and Illinois Subclass members suffered injuries in fact—*i.e.*, the loss of the money that they paid for Earth's Best Brand Baby Food and/or Gerber Brand Baby Food under the belief that they were safe for human consumption and did not contain unsafe levels of toxic heavy metals.

134. Acting as reasonable consumers, Plaintiff and Illinois Subclass members could not have avoided the injuries suffered by purchasing Earth's Best Brand Baby Food and/or Gerber Brand Baby Food because they did not have any reason to suspect that those brands of baby food contained elevated levels of toxic heavy metals. Moreover, the detection of toxic heavy metals in food requires rigorous and specialized scientific testing that goes well beyond the level of inquiry a reasonable consumer would make into the issue, and, in any event, such testing was not readily available to Plaintiff and Illinois Subclass members at the time they purchased Earth's Best Brand Baby Food and/or Gerber Brand Baby Food.

135. As a direct and proximate result of Defendants' violations of the IFDCA, Plaintiff and members of the Illinois Subclass suffered damages by purchasing Earth's Best Brand Baby

Food and/or Gerber Brand Baby Food because they would not have purchased those brands of baby food had they known the truth, and they received a product that was worthless because it contains unsafe levels of toxic heavy metals.

136. Therefore, Plaintiff and members of the Illinois Subclass were damaged as a direct result of Defendants' violation of the IFDCA.

137. "A private cause of action is found to exist under a statute where: (1) the plaintiff falls within the class of persons sought to be protected; (2) the plaintiff's injury is one intended to be prevented; (3) the cause of action is consistent with the underlying purpose of the statute; and (4) the private cause of action is necessary to effectuate the purpose of the statute, *i.e.*, a civil remedy is needed." *Reuben H. Donnelley Corp. v. Brauer*, 275 Ill.App.3d 300, 311 (1st Dist. 1995).

138. Plaintiff and Illinois Subclass members fall within the class of persons sought to be protected by the IFDCA because they unknowingly purchased adulterated baby food as a result of Defendants' respective misrepresentations and omissions. The IFDCA was designed to regulate the manner in which food, drugs, and cosmetics could be manufactured, prepared, advertised, and sold to consumers. Specifically, section 620/10 of the IFDCA was designed to prohibit food manufacturers and sellers from selling food to consumers which contain unsafe levels of "any poisonous or deleterious substance which may render it injurious to health." The sale of adulterated food is prohibited under the IFDCA so that consumers, such as Plaintiff and Illinois Subclass members, do not purchase and/or ingest foods that are be injurious to their health.

139. Plaintiff's and Illinois Subclass members' common injury is one intended to be prevented by the IFDCA. Section 620/10 of the IFDCA prohibits food manufacturers and sellers from selling food to consumers which contain unsafe levels of "any poisonous or deleterious

substance which may render it injurious to health.” The sale of adulterated food is prohibited under the IFDCA so that consumers, such as Plaintiff and Illinois Subclass members, do not purchase and/or ingest foods that are injurious to their health.

140. Granting Plaintiff and Illinois Subclass members a private right of action under the IFDCA is consistent with the underlying purpose of the IFDCA. The underlying purpose of section 620/10 of the IFDCA is to prevent consumers from purchasing and/or ingesting foods that will be injurious to their health. Allowing Plaintiff and Illinois Subclass members to hold Defendants liable for their violations of the IFDCA is consistent with that purpose.

141. Granting Plaintiff and Illinois Subclass members a private right of action under the IFDCA is necessary to effectuate the purpose of the IFDCA because the statute would be rendered meaningless if it could not be enforced. There would be no incentive keeping food manufacturers and sellers from selling adulterated food products to consumers if they could not be held liable to consumers for their actions.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff AILEEN GARCES, individually, and on behalf of the Illinois Subclass, prays for an Order as follows:

- A. Finding that this action satisfies the prerequisites for maintenance as a class action set forth in Fed. R. Civ. P. 23, and certifying the Illinois Subclass defined herein;
- B. Designating Plaintiff as representative of the Illinois Subclass and her undersigned counsel as Class Counsel;
- C. Entering judgment in favor of Plaintiff and the Illinois Subclass and against Defendants;
- D. Awarding Plaintiff and the Illinois Subclass damages equal to the amount of actual damages that they sustained;
- E. Awarding Plaintiff and the Illinois Subclass attorneys’ fees and costs, including interest thereon, as allowed or required by law; and

- F. Granting all such further and other relief as the Court deems just and appropriate.

COUNT V
(on Behalf of Plaintiff and the Class)
Unjust Enrichment

142. Plaintiff repeats and re-alleges the allegations in Paragraphs 1-83 with the same force and effect as though fully set forth herein.

143. When a specific contract does not govern the relationship of the parties, and, therefore, no adequate remedy at law is applicable, an equitable remedy under a theory of unjust enrichment is available. *See, e.g., Guinn v. Hoskins Chevrolet*, 361 Ill.App.3d 575, 604 (1st Dist. 2005) (internal citations omitted).

144. Unjust enrichment “is a condition that may be brought about by unlawful or improper conduct as defined by law[.]” *See, e.g., Gagnon v. Schickel*, 2012 IL App (1st) 120645, ¶ 25 (quoting *Martis v. Grinnell Mutual Reinsurance Co.*, 388 Ill.App.3d 1017, 1024 (3rd Dist. 2009); *Alliance Acceptance Co. v. Yale Insurance Agency, Inc.*, 271 Ill.App.3d 483, 492 (1st Dist. 1995)).

145. To prevail on a claim of unjust enrichment, a plaintiff must prove: (1) “that the defendant has unjustly retained a benefit to the plaintiff’s detriment,” and (2) “that defendant’s retention of the benefit violates the fundamental principles of justice, equity, and good conscience.” *See, e.g., Cleary v. Philip Morris Inc.*, 656 F.3d 511, 518 (7th Cir.2011) (quoting *HPI Health Care Servs., Inc. v. Mt. Vernon Hosp., Inc.*, 131 Ill.2d 145, 160 (1989)).

146. As noted above, the presence of elevated levels of toxic heavy metals in baby food is a material fact to consumers.

147. Defendants each knew that the presence of elevated levels of toxic heavy metals in Earth's Best Brand Baby Food and Gerber Brand Baby Food (respectively) was a material fact to consumers, such as Plaintiff and members of the Class.

148. Because Defendants are each responsible for, and control, the manufacturing, marketing, distribution, and sale of Earth's Best Brand Baby Food and Gerber Brand Baby Food (respectively), Defendants knew and intended that their omissions and concealment of the presence of elevated levels of toxic heavy metals in their respective brands of baby food would mislead Plaintiff and Class members, and induce them to buy products that they would otherwise not have been willing to purchase.

149. Acting as reasonable consumers, had Plaintiff and Class members been aware of the true facts regarding the Earth's Best Brand Baby Food and Gerber Brand Baby Food, they would have declined to purchase those brands of baby food.

150. Acting as reasonable consumers, Plaintiff and Class members could not have avoided the injuries suffered by purchasing Earth's Best Brand Baby Food and/or Gerber Brand Baby Food because they did not have any reason to suspect that those brands of baby food contained elevated levels of toxic heavy metals. Moreover, the detection of toxic heavy metals in food requires rigorous and specialized scientific testing that goes well beyond the level of inquiry a reasonable consumer would make into the issue, and, in any event, such testing was not readily available to Plaintiff and Class members at the time they purchased Earth's Best Brand Baby Food and/or Gerber Brand Baby Food.

151. As a direct and proximate result of Defendants' misrepresentations and omissions, Plaintiff and members of the Class conferred a benefit on Defendants—*i.e.*, the money that they

paid for Earth's Best Brand Baby Food and/or Gerber Brand Baby Food under the belief that they were safe for human consumption and did not contain unsafe levels of toxic heavy metals.

152. Defendants each acquired and retained money belonging to Plaintiff and the Class as a result of their wrongful conduct—*i.e.*, misrepresenting that Earth's Best Brand Baby Food and/or Gerber Brand Baby Food were safe for human consumption, and concealing the fact that those brands of baby food contained unsafe levels of toxic heavy metals. Defendants profited at the expense of Plaintiff and Class members in connection with each individual sale of Earth's Best Brand Baby Food and Gerber Brand Baby Food (respectively) because Plaintiff and Class members paid money for products that were worthless due to the fact that they are not safe for human consumption.

153. Defendants each have unjustly received and retained a benefit at the expense of Plaintiff and the Class because Defendants unlawfully acquired their profits for worthless (and unsafe) baby food products while appreciating and knowing that Earth's Best Brand Baby Food and Gerber Brand Baby Food (respectively) was unsafe for human consumption, contrary to their misrepresentations and omissions.

154. Defendants' retention of that benefit violates the fundamental principles of justice, equity, and good conscience because Defendants misled Plaintiff and the Class into falsely believing that Earth's Best Brand Baby Food and Gerber Brand Baby Food (respectively) was safe and did *not* contain unsafe levels of toxic heavy metals in order to unjustly receive and retain a benefit.

155. Under the principles of equity, Defendants should not be allowed to keep the money belonging to Plaintiff and the members of the Class because Defendants have unjustly received it as a result of Defendants' unlawful actions described herein.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff AILEEN GARCES, individually, and on behalf of the Class, prays for an Order as follows:

- A. Finding that this action satisfies the prerequisites for maintenance as a class action set forth in Fed. R. Civ. P. 23, and certifying the Class defined herein;
- B. Designating Plaintiff as representative of the Class and her undersigned counsel as Class Counsel;
- C. Entering judgment in favor of Plaintiff and the Class and against Defendants;
- D. Ordering disgorgement of any of Defendants' ill-gotten gains and awarding those amounts to Plaintiff and the Class members as compensatory damages;
- E. Awarding Plaintiff and the Class attorneys' fees and costs, including interest thereon, as allowed or required by law; and
- F. Granting all such further and other relief as the Court deems just and appropriate.

JURY DEMAND

Plaintiff demands a trial by jury on all counts so triable.

Plaintiff AILEEN GARCES, individually, and
on behalf of all others similarly situated,

By: s/ Thomas A. Zimmerman, Jr.

Thomas A. Zimmerman, Jr.

tom@attorneyzim.com

Sharon A. Harris

sharon@attorneyzim.com

Matthew C. De Re

matt@attorneyzim.com

Jeffrey D. Blake

jeff@attorneyzim.com

ZIMMERMAN LAW OFFICES, P.C.

77 W. Washington Street, Suite 1220

Chicago, Illinois 60602

(312) 440-0020 telephone

(312) 440-4180 facsimile
www.attorneyzim.com

Counsel for Plaintiff and the putative Class



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

EXHIBIT 1

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.

TABLE OF CONTENTS

I. THE DANGER OF TOXIC HEAVY METALS TO CHILDREN’S HEALTH..... 9

A. Inorganic Arsenic..... 10

B. Lead..... 11

C. Cadmium 12

D. Mercury 12

II. TOP BABY FOODS ARE TAINTED WITH DANGEROUS LEVELS OF INORGANIC ARSENIC, LEAD, CADMIUM, AND MERCURY. 13

A. Inorganic Arsenic..... 13

B. Lead..... 21

C. Cadmium 29

D. Mercury 32

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..... 33

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..... 33

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..... 37

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. 39

IV. WALMART, SPROUT ORGANIC FOODS, AND CAMPBELL REFUSED TO COOPERATE WITH THE SUBCOMMITTEE’S INVESTIGATION..... 43

A.	Walmart (Parent’s Choice Brand)	43
B.	Campbell (Plum Organics Brand).....	44
C.	Sprout Organic Foods.....	46
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.....	47
A.	Mercury and Cadmium.....	48
B.	Lead.....	49
C.	Arsenic	50
D.	The Trump Administration Ignored A Secret Industry Presentation About Higher Risks Of Toxic Heavy Metals In Baby Foods.....	53
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.....	56
VI.	RECOMMENDATIONS AND CONSIDERATIONS FOR INDUSTRY, PARENTS, AND REGULATORS: DO HIGHLY TAINTED INGREDIENTS LIKE RICE BELONG IN BABY FOOD?	57
VII.	CONCLUSION	59

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.

- 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	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)	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/Covance	As Purchased	100	223	100	60.5	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/Covance	As Purchased	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/5/2017	Firebird Artisan Mills	5303042	Org Quinoa Flour	Accepted		Deibel	As consumed	200	<100
Jul/13/2017	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
Highest Percentage in Finished Good(s)		2.08%
		Arsenic: 223 ppb Lead: 352 ppb

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.

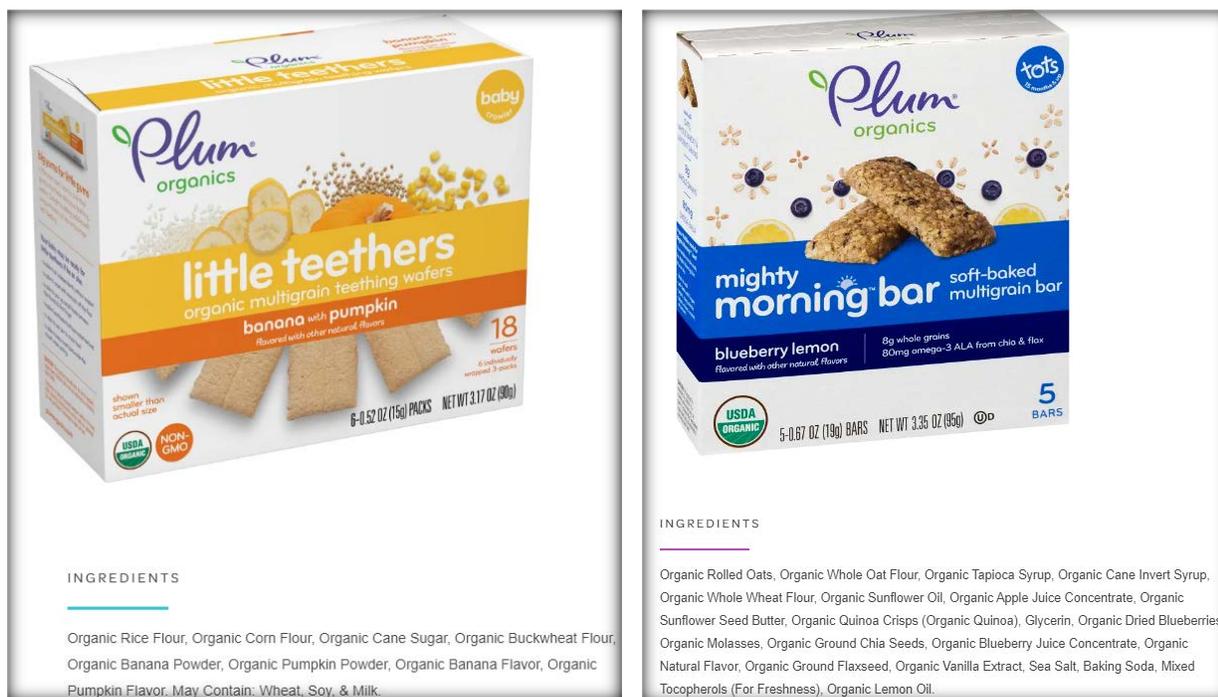
Data from Healthy Babies Bright Futures Report: What’s in My Baby’s Food?¹²²

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					197594	B160004759	Total Arsenic	
	B160004659			Total Arsenic	54						
	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	B160005306	Total Arsenic	76	
547103		BN I 2339	115					B160005512	Total Arsenic	62	
1013927	6/7/19	BN E 1540	92	B160005150	Total Arsenic	65					
1026516		BN H 2123	104	12/15/17	208226	B160006190	Inorganic Arsenic	73	64.0		
1074288		BNE 1406	105			B160005581	Total Arsenic	55			
1035738	6/13/19	BN J 0000	96	100.0	56%	1/3/18	208594	B160006191	Inorganic Arsenic	80	80.5
1047511	6/27/19	BN C 1142	100	115.0	43%	1/25/18	210374	B160006203	Inorganic Arsenic	77	75.7
1063061	7/19/19	BN J	115	97.0	28%	2/24/18		B160006263	Inorganic Arsenic	74	
1027437	8/18/19	BN A 0703	97	B160006260	Inorganic Arsenic	76					
784399	11/23/19	BN K 0305	108	108.0	31%	6/1/18	215305	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.

ClassAction.org

This complaint is part of ClassAction.org's searchable class action lawsuit database and can be found in this post: [More Class Actions Say Baby Food Products Are Tainted by Toxic Heavy Metals](#)
