

CASE NO: A-21-830390-B  
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12 **DISTRICT COURT**  
13 **CLARK COUNTY, NEVADA**

14 NATHANIEL BENITEZ, a Minor Child, by  
and through his Guardian Ad Litem,  
15 SAGRARIO BENITEZ, SAGRARIO  
BENITEZ, on her own behalf; ANDRE  
16 HAYNES JR., a Minor Child by and through  
his Guardian Ad Litem, ANDRE HAYNES,  
17 ANDRE HAYNES, on his own behalf; LUIS  
MATTHEW VILLALOBOS, a Minor Child,  
18 by and through his Guardian Ad Litem, LUIZ  
VILLALOBOS, on his own behalf; BRAXON  
19 COHEE, by and through his Guardian Ad  
Litem, ERIC COHEE, ERIC COHEE, on his  
20 own behalf; NATHAN HEAD, a Minor Child,  
by and through his Guardian Ad Litem,  
21 BROOKE HEAD, BROOKE HEAD, on her  
own behalf; JANCARLO ARELLANES and  
22 EMMA ARELLANES, both Minor Children,  
by and through their Guardian Ad Litem,  
23 MARLA GARCIA, and MARLA GARCIA,  
on her own behalf,

24 Plaintiffs

25 vs.

26 BEECH-NUT NUTRITION COMPANY  
27 INC., HAIN CELESTIAL GROUP INC.,  
GERBER PRODUCTS CO. INC.,  
28 NURTURE INC, MARIANA's  
ENTERPRISES, d/b/a MARIANA'S

Case No.:  
Dept. No.:

**COMPLAINT AND DEMAND FOR  
JURY TRIAL**

**REQUEST FOR BUSINESS COURT  
PURSUANT TO EDCR 1.61**

**EXEMPT FROM ARBITRATION:**

**Damages in Excess of \$50,000**

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1 SUPERMARKETS, ANAYA  
2 ENTERPRISES d/b/a MARIANAS  
3 SUPERMARKETS, and LA BONITA  
4 GROCERY AND MEAT MARKET d/b/a LA  
5 BONITA SUPERMARKETS.

6 Defendants.

7 Plaintiffs by and through their counsel of record, and for their Complaint against  
8 Defendants, hereby allege as follows:

9 **Introduction**

10 1. The United States of America ('America') has one of the best medical health  
11 systems in the world. Yet, it has some of the worse statistics for unhealthy children in the world,  
12 including a high number of children with autism.

13 2. Over the past decade, many scientific and medical studies have been conducted  
14 to determine why one of six children in America has a developmental disability.

15 3. In October, 2019 the "Healthy Babies Bright Futures" organization ('HBBF'),  
16 which is a not for profit dedicated to improving the lives of American children, published a  
17 study and report captioned: What's in my baby's food? That report disclosed that after testing  
18 168 baby foods, scientists commissioned by the HBBF found toxic metals in 95% of the 168  
19 baby foods that were tested. Moreover, its testing found that one in four baby foods contained  
20 all four of the following dangerous metals - arsenic, lead, cadmium and mercury- and even in  
21 the "trace amounts found in food, these contaminants can alter the developing brain and erode a  
22 child's IQ. The impacts add up with each meal or snack a baby eats". A copy of this report is  
23 attached as Exhibit 1.

24 4. Many of the baby foods tested by HBBF were manufactured by the defendants in  
25 this case that produce these products.

26 5. On February 4, 2021, the United States House of Representatives Committee on  
27 Oversight and Reform's Subcommittee on Economic and Consumer Policy (the "House  
28 Subcommittee") released a report entitled "Baby Foods Are Tainted with Dangerous Levels of  
Arsenic, Lead, Cadmium, and Mercury" (the "Subcommittee Report"). *See generally,*

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1 Subcommittee Report, attached hereto as Exhibit 2. According to the Subcommittee Report,  
2 several brands of baby food sold in the United States contain unsafe levels of toxic heavy  
3 metals, including those sold by Defendants. *See* Subcommittee Report, p. 2.

4 6. Given the health risks associated with high levels of toxic heavy metals,  
5 including arsenic, cadmium, lead and mercury, the presence of these substances in baby food is  
6 a material fact to consumers. Indeed, consumers such as Plaintiffs are unwilling to purchase  
7 baby food that contains unsafe levels of toxic heavy metals.

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

10 8. Accordingly, Plaintiffs bring this suit for damages resulting from Defendants'  
11 sale of baby food products that contained unsafe levels of toxic heavy metals.

12 **Parties**

13 9. Plaintiff NATHANIEL BENITEZ is a minor child residing in Clark County,  
14 Nevada. Plaintiff SAGRARIO BENITEZ is the Guardian Ad Litem over NATHANIEL  
15 BENITEZ and brings this action on his behalf and individually. She is a resident of Nevada and  
16 purchased toxic baby food from the Defendants for her three children.

17 10. Plaintiff ANDRE HAYNES JR., is a minor child residing in Clark County,  
18 Nevada. Plaintiff ANDRE HAYNES is the Guardian Ad Litem over ANDRE HAYNES JR.,  
19 and brings this action on his behalf and individually. He is a resident of Nevada and purchased  
20 toxic baby food from the Defendants for his child.

21 11. Plaintiff LUIS MATTHEW VILLALOBOS is a minor child residing in Clark  
22 County, Nevada. Plaintiff LUIZ VILLALOBOS is the Guardian Ad Litem over LUIS  
23 MATTHEW VILLALOBOS, and brings this action on his behalf and individually. He is a  
24 resident of Nevada and purchased toxic baby food from the Defendants for his child.

25 12. Plaintiff BRAXON COHEE is a minor child residing in Clark County, Nevada.  
26 Plaintiff ERIC COHEE is the Guardian Ad Litem over BRAXON COHEE and brings this  
27 action on his behalf and individually. He is a resident of Nevada and purchased toxic baby food  
28 from the Defendants for his child.

1           13. Plaintiff NATHAN HEAD is a minor child residing in Clark County, Nevada.  
2 Plaintiff BROOKE HEAD is the Guardian Ad Litem over NATHAN HEAD and brings this  
3 action on his behalf and individually. She is a resident of Nevada and purchased toxic baby  
4 food from the Defendants for her child.

5           14. Plaintiffs JANCARLO ARELLANES and EMMA ARELLANES are minors  
6 residing in Clark County, Nevada. Plaintiff MARLA GARCIA is the Guardian Ad Litem over  
7 JANCARLO ARELLANES and EMMA ARELLANES and brings this action on their behalf  
8 and individually. She is a resident of Nevada and purchased toxic baby food from the  
9 Defendants for her children.

10           15. Defendant BEECH-NUT NUTRITION COMPANY INC. (“Beech”) is  
11 incorporated in New York. Beech sells its baby food under the “Beach Nut” brand name.  
12 Beech’s Baby Food is sold nationwide, including throughout the state of Nevada.

13           16. Defendant HAIN CELESTIAL GROUP INC. (“Hain”) is an American  
14 Corporation with its headquarters located in Lake Success, New York and it sells its baby food  
15 products under the brand name “Earth’s Best Organic” nationwide, including throughout the  
16 state of Nevada.

17           17. Defendant GERBER PRODUCTS CO. INC is a Michigan corporation with its  
18 principal place of business in Virginia. Gerber sells its baby food under the eponymous  
19 “Gerber” brand name (“Gerber Brand Baby Food”). Gerber Brand Baby Food is sold  
20 nationwide, including throughout the state of Nevada.

21           18. Defendant NURTURE INC. (“Nurture”) is a Delaware Corporation with its  
22 principal place of business in White Plains, New York and it sells its baby food products under  
23 the brand name “Happy Baby” nationwide, including throughout the state of Nevada.

24           19. Defendants MARIANA ENTERPRISES INC. d/b/a MARIANA’S  
25 SUPERMARKETS (“Mariana’s”), and ANAYA ENTERPRISES are Nevada Corporations with  
26 five supermarket locations in Clark County, which sold the Defendants’ toxic baby food  
27 products to Plaintiffs.  
28

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1           20. Defendant LA BONITA GROCERY AND MEAT MARKET is a Nevada  
2 corporation with a supermarket location in Clark County which sold the toxic baby food  
3 products to Plaintiffs.

### 4                                   Jurisdiction and Venue

5           21. Exercise of jurisdiction by this Court over each and every Defendant in this  
6 action is appropriate because each and every Defendant has done, and continues to do business  
7 in the State of Nevada, and sold toxic baby food products to Nevada residents and violated  
8 Nevada laws.

9           22. Defendants do business in Nevada, and sold toxic baby food products to Nevada  
10 residents and made money from these residents.

11           23. Defendants sold their toxic baby food products to Plaintiffs while Plaintiffs  
12 resided in Clark County, Nevada.

13           24. Exercise of jurisdiction by this Court is further appropriate because the Plaintiffs  
14 currently reside in the County of Clark, State of Nevada.

15           25. This Court has jurisdiction over the subject matter of this action. Exercise of  
16 jurisdiction by this Court over the Defendants in this action is appropriate because they have  
17 done, and continue to do, business in Clark County, State of Nevada, and committed the  
18 wrongdoings alleged in this Complaint in the State of Nevada. Additionally, this Court has  
19 jurisdiction over the claims alleged herein as they arise out of sales made to Nevada residents,  
20 the defendants' actions violate Nevada law and some of the claims arise under the Uniform  
21 Commercial Code (i.e., the warranty of merchantability) or are such that the Code will supply  
22 the rule of decision.

### 23                                   General Allegations

#### 24                                   *The U.S. Subcommittee Report*

25           26. Inorganic arsenic, lead, cadmium, and mercury are toxic heavy metals. The U.S.  
26 Food and Drug Administration (“FDA”) and the World Health Organization (“WHO”) have  
27 declared these toxic heavy metals dangerous to human health. Specifically, the FDA states that  
28 these toxic heavy metals have “no established health benefit,” “lead to illness, impairment, and

1 in high doses, death,” and because of bioaccumulation, “even low levels of harmful metals from  
2 individual food sources, can sometimes add up to a level of concern.”<sup>1</sup>

3 27. The dangerous effects of these toxins are exacerbated and can be indelible in  
4 damaging the vulnerable bodies and brains of babies and children, which FDA explains are at  
5 the greatest risk of harm. *See* Subcommittee Report, p. 2. Exposure, such as ingestion, of toxic  
6 heavy metals by babies and children leads to untreatable and permanent brain damage, resulting  
7 in reduced intelligence and behavioral problems. For instance, scientific studies have connected  
8 exposure to lead to a substantial decrease in children’s total IQ points and their lifetime earning  
9 capacity. *See* Subcommittee Report, p. 9.

10 28. “Exposure to toxic heavy metals [such as arsenic, lead, cadmium, and mercury]  
11 causes permanent decreases in IQ, diminished future economic productivity, and increased risk  
12 of future criminal and antisocial behavior in children. Toxic heavy metals endanger infant  
13 neurological development and long-term brain function.” *See* Subcommittee Report, p. 2.

14 29. Given these risks, and in response to several reports alleging high levels of toxic  
15 heavy metals in baby foods sold in the United States, the House Subcommittee launched an  
16 investigation into the presence of toxic heavy metals in certain brands of baby foods, including  
17 Gerber Brand Baby Food, Beech’s Brand Baby Food, Hain and Nature Baby Food Products. *See*  
18 Subcommittee Report, p. 2. The results of the House Subcommittee’s investigation were set  
19 forth in the Subcommittee Report, which was released on February 4, 2021 and is attached  
20 hereto as Exhibit 2.

21 ***Arsenic in Defendants’ Baby Food***

22 30. According to the Subcommittee Report, arsenic was present in all brands of baby  
23 foods subject to the House Subcommittee’s investigation. Gerber Brand Baby Food used high-  
24 arsenic ingredients, including rice flour that contained over 90 ppb arsenic; Beech used  
25 ingredients that tested as high as 913.4 ppb arsenic and used high arsenic additives that tested  
26 above 300 ppb arsenic to address product characteristics such as “crumb softness”; Nurture sold  
27

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

1 baby foods after tests showed they contained as much as 180 parts per ppb of arsenic; and Hain  
2 sold finished baby food products containing as much as 129 ppb of arsenic. *See* Subcommittee  
3 Report, p. 3.

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

6 32. Arsenic is the most dangerous of the toxic heavy metals at issue and poses the  
7 most significant risk to human health. *See* Subcommittee Report, p. 10. Currently known risks  
8 of arsenic to health include respiratory, gastrointestinal, hematological, hepatic, renal, skin,  
9 neurological and immunological effects, as well as damaging effects on the central nervous  
10 system and cognitive development in children.”<sup>2</sup>

11 33. One study found negative effects in cognitive development of schoolchildren  
12 exposed to concentrations of arsenic over 5 ppb. For the authors of the study, 5 ppb was an  
13 important threshold for small children. Consumer reports has recommended setting the limit of  
14 arsenic at 3 ppb.<sup>3</sup>

15 34. Gerber agreed to provide only limited data to the House Subcommittee, but the  
16 data it provided shows that Gerber routinely used ingredients in Gerber Brand Baby Food that  
17 contained over 90 ppb arsenic, including 67 batches of rice flour. *See* Subcommittee Report, p.  
18 19. Gerber used grape juice concentrate in Gerber Brand Baby Food containing 39 ppb  
19 inorganic arsenic. For apple juice concentrate, FDA has issued draft guidance requiring less  
20 than 10 ppb in organic arsenic. *See* Subcommittee Report, p. 52.

### 21 *Lead in Defendants’ Baby Food*

22 35. Lead was also present in all brands of baby foods subject to the House  
23 Subcommittee’s investigation. *See* Subcommittee Report, p. 3. In particular, Beech sold Baby  
24 Food to contain as much as 886.9 ppb lead, and used many ingredients that contained high lead

25  
26 <sup>2</sup> Agency for Toxic Substances and Disease Registry, ATSDR’s Substance Priority List (2019),  
available at <http://www.atsdr.cdc.gov/spl/index.html#2019spl>.

27 <sup>3</sup> Miguel Rodriguez-Barranco *et al.*, Association of Arsenic, Cadmium and  
28 Manganese (<https://pubmed.ncbi.nlm.nih.gov/23570911/>); *see* Exposure with Neurodevelopment and Behavioral Disorders in  
Children: A Systematic Review and Meta-Analysis (June 1, 2013) (online at  
<https://pubmed.ncbi.nlm.nih.gov/23570911/>).

1 content. *See* Subcommittee Report, p. 3. Gerber Brand Baby Food also used high-lead  
2 ingredients in Gerber Brand Baby Food, including some that contained over 48 ppb lead. *See*  
3 Subcommittee Report, p. 3.

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

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

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

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

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24 <sup>4</sup> FDA, Metals and Your Food, available at [https://www.fda.gov/food/chemicals-metals-pesticides-](https://www.fda.gov/food/chemicals-metals-pesticides-food/metals-and-your-food)  
25 [food/metals-and-your-food](https://www.fda.gov/food/chemicals-metals-pesticides-food/metals-and-your-food).

26 <sup>5</sup> Namhua Zhang *et al.*, Early Childhood Lead Exposure and Academic Achievement: Evidence From  
27 Detroit Public Schools, available at:  
28 <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/s12940-015-008-9>; Maitreyi Mazumdar *et al.*,  
Low-Level Environmental Lead Exposure in Childhood and Adult Intellectual Function: A Follow-



*Cadmium in Defendants' Baby Food*

1  
2 40. Cadmium was another toxic heavy metal found to be present in all brands of  
3 baby foods subject to the House Subcommittee's investigation. *See* Subcommittee Report, p. 3.  
4 In particular, Beech Food used 105 ingredients that contained over 20 ppb cadmium, with some  
5 of those ingredients containing up to 344.55 ppb cadmium. *See*, Subcommittee Report, p. 3.  
6 Certain Gerber Brand Baby Foods were made with ingredients that contained over 87 ppb  
7 cadmium. *See* Subcommittee Report, p. 4. Hain used 102 ingredients in its baby food products  
8 that tested over 20 ppb cadmium. *See* Subcommittee Report, p.3. Regarding Nurture, 65% of  
9 this company's finished baby products contained more than 5 ppb cadmium. *See* Subcommittee  
10 Report, p. 4.

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

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

18 43. Beech used twenty ingredients registering over 100 ppb cadmium, including  
19 cinnamon containing 344.5 ppb cadmium. This is more than 17 times higher than the EU's lax  
20 upper limit on cadmium in baby foods. At least 105 ingredients that Beech tested and used in  
21 baby foods registered at or over 20 ppb cadmium – which is the European Union's lax infant  
22 formula upper limit. *See* Subcommittee Report, p. 29-30.

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

25 45. Hain used 14 ingredients that contained more than 100 ppb cadmium, including  
26 barley flour that registered at 260 ppb cadmium, which is thirteen times the EU's lax upper limit  
27 on cadmium in food. *See* Subcommittee Report, p. 30.

28

1 46. Nurture sold multi-grain cereal with 49 ppb cadmium. *See* Subcommittee Report,  
2 p. 31.

3 ***Defendants’ Internal Testing***

4 47. The House Subcommittee also sought to investigate the presence of mercury in  
5 baby food. It found that Beech and Hain did not even test for mercury in Baby Food; that  
6 Gerber “rarely” tested for mercury in Gerber Brand Baby Food; and Nurture sold a finished  
7 baby product that contained 10 ppb mercury, and two other products that contained 9.8 and 7.3  
8 ppb. *See* Subcommittee Report, pp. 4, 32 and 33.

9 ***Defendants’ Baby Food***

10 48. Defendants Beech, Hain, Nurture, and Gerber each manufacture, distribute,  
11 advertise, market, and sell brands of baby food evaluated in the Subcommittee Report.

12 49. Defendants Beech, Hain, Nurture, and Gerber each direct, control, and  
13 participate in the manufacturing and packaging of the brands of baby food that they sell. As part  
14 of that direction, control, and participation, Defendants each determine and are responsible for  
15 the ingredients used in their baby food products.

16 50. Defendants Beech, Hain, Nurture, and Gerber each know and are responsible for  
17 the ingredients in the brands of baby food that they sell to the public, including the Plaintiffs.

18 51. Defendants Beech, Hain, Nurture, and Gerber each created, developed, reviewed,  
19 authorized, and are responsible for the textual and graphic content on the packaging of the  
20 brands of baby food that they sell. This is supported by the fact that the labels on Gerber Brand  
21 Baby Food contain Gerber’s corporate logo and trademark, and note that Gerber Brand Baby  
22 Food is distributed by Gerber. Similarly, the labels on the Beech, Nurture and Hain Baby Food  
23 products contain each of the companies’ registered trademarks—and note that the Baby Food  
24 product is distributed by each of the respective companies.

25 52. Each package of Beech’s Baby Food contains standardized labeling created,  
26 developed, reviewed, and authorized by Beech. The packaging of all types of Beech’s Baby  
27 Food is the same or substantially similar. The same is true for the food products of Gerber,  
28 Nurture and Hain.

1 53. Defendants Beech, Hain, Nurture, and Gerber each know, created, developed,  
2 reviewed and are responsible for the representations contained on each package of the baby  
3 food products that they sell.

4 54. The labels on some of the varieties of Gerber Brand Baby Food—including some  
5 of those that Plaintiffs purchased—state that the product contains “iron to help support learning  
6 ability.”

7 55. The labels on some of the varieties of Beech’s Baby Food—including those that  
8 Plaintiffs purchased—state that the product contains “Real Food for Babies” and its packaging  
9 omitted the presence or risks associated with heavy metals. Beech intentionally omitted  
10 disclosure of the presence or risk of these substances in order to induce reasonable consumers  
11 like the Plaintiffs to purchase their Baby Foods at premium prices.

12 56. The labels on Hain’s baby products boasted that its products were derived from  
13 ingredients that are “Earth Best”, “organic” and “nurturing baby the purest way.”

14 57. Nurture’s labels on its baby products boasted that its products were from  
15 “organics”, “Happy Baby” and “Superfood.”

16 58. The labels on many varieties of Gerber Brand Baby Food and Beech’s Baby  
17 Food—including some of those that Plaintiffs purchased—also tout those products as being free  
18 of GMO—which stands for “genetically modified organism”—ingredients – and emphasized  
19 they were “natural.” Like BPA, GMOs are also believed to be associated with health risks,  
20 “including infertility, immune problems, accelerated aging, faulty insulin regulation and  
21 changes in major organs and the gastrointestinal system.”<sup>6</sup> As such, these varieties of Gerber  
22 Brand Baby Food and Beech’s Baby Food are marketed as *lacking* a particular dangerous  
23 substance that can negatively affect consumers of the product.

24 59. Despite touting the lack of certain dangerous substances in their respective  
25 brands of baby food, the Defendants Gerber, Beech, Nurture and Hain each failed to disclose  
26 elevated levels of dangerous metals in their Baby Food products.

27  
28 <sup>6</sup> CNN, 10 Ways to Keep Your Diet GMO-Free, available at  
<https://www.cnn.com/2014/03/25/health/ipwave-gmo-free-diet/index.html>.

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

4 61. While Defendants’ respective omissions regarding the material fact that their  
5 brands of baby food contain elevated levels of toxic heavy metals are legally significant on their  
6 own, Defendants’ respective representations regarding the presence of “iron to help support  
7 learning ability” and the lack of BPA and GMOs are also significant. Although these  
8 representations may be true, a statement that is technically true may nevertheless be fraudulent  
9 where it omits qualifying material since a ‘half-truth’ is sometimes more misleading than an  
10 outright lie. *See* W. Prosser, Law of Torts § 106, at 696 (4th ed. 1971) (“half the truth may  
11 obviously amount to a lie, if it is understood to be the whole.”).

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

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

22 ***Consumer Expectations Regarding Baby Food***

23 64. Parents’ instinctive desire to protect and ensure the healthy development of their  
24 children is well-known. As such, the safety of baby food is of paramount importance, and is a  
25 material fact, to consumers such as Plaintiffs.

26 65. More specifically, given the negative effects of toxic heavy metals (such as  
27 arsenic, lead, cadmium, and mercury) on child development, the presence of these substances in  
28 baby food is a material fact to consumers like Plaintiffs. Indeed, consumers—including

1 Plaintiffs—are unwilling to purchase baby food that contains elevated levels of toxic heavy  
2 metals.

3 66. Defendants know that the safety of their respective brands of baby food (as a  
4 general matter) is a material fact to consumers. This is exemplified by the fact that Beech’s  
5 Brand Baby Food and Gerber Brand Baby Food are both marketed and labeled as *lacking*  
6 certain substances (*e.g.*, BPA, GMOs) that consumers believe would be harmful to the health of  
7 children.

8 67. Defendants also know that consumers (such as Plaintiffs) are unwilling to  
9 purchase their respective brands of baby food that contain elevated levels of toxic heavy metals.

10 68. As such, Defendants Beech, Hain, Nurture, and Gerber also know that the  
11 presence of toxic heavy metals in their respective brands of baby food is a material fact to  
12 consumers such as Plaintiffs.

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

16 70. Defendants Beech, Hain, Nurture, and Gerber each knew that if the elevated  
17 levels of toxic heavy metals in their respective brands of baby food was disclosed to the  
18 Plaintiffs, then Plaintiffs would be unwilling to purchase their Baby Food products.

19 71. In light of Defendants’ respective knowledge that consumers, including Plaintiffs  
20 would be unwilling to purchase Beech’s Brand Baby Food and Gerber Brand Baby Food if they  
21 knew that those brands of baby food contained elevated levels of toxic heavy metals,  
22 Defendants intentionally and knowingly concealed this fact from Plaintiffs, and did not disclose  
23 the presence of these toxic heavy metals on the labels of Beech’s Brand Baby Food and Gerber  
24 Brand Baby Food (respectively).

25 72. Defendants knew that Plaintiffs would rely upon the representations and  
26 omissions contained on the packages of Beech’s Brand Baby Food and Gerber Brand Baby  
27 Food (respectively), and intended for them to do so.  
28

1           73. Defendants knew that in relying upon the representations and omissions  
2 contained on the packages of Beech’s Brand Baby Food and Gerber Brand Baby Food  
3 (respectively), Plaintiffs and other consumers would view those products as being safe for  
4 consumption, given their represented lack of certain deleterious substances (*e.g.*, BPA, GMOs),  
5 and were “natural,” and Defendants’ concealment of the fact that those brands of baby food  
6 contained elevated levels of toxic heavy metals.

7           74. Prior to purchasing the Beech, Hain, Nurture, and Gerber Brand Baby Food  
8 products, Plaintiffs were exposed to, saw, read, and understood Defendants’ respective  
9 representations and omissions regarding the safety of their baby food, and relied upon them.

10           75. As a result of Defendants’ respective representations regarding the safety of their  
11 baby food, and the lack of certain deleterious substances (*e.g.*, BPA, GMOs), and Defendants’  
12 statements that the products were “natural”, and the Defendants’ concealment of the fact that  
13 those brands of baby food contained elevated levels of toxic heavy metals, Plaintiffs reasonably  
14 believed that Beech’s Brand Baby Food and Gerber Brand Baby Food were free from  
15 substances that would negatively affect children’s development.

16           76. In reliance upon Defendants’ Gerber, Beech, Nurture and Hain respective  
17 representations and omissions, Plaintiffs purchased Beech’s Brand Baby Food and Gerber  
18 Brand Baby Food.

19           77. Had Plaintiffs known the truth—*i.e.*, that Defendants’ Gerber, Beech, Nurture  
20 and Hain’s respective brands of baby food contained elevated levels of toxic heavy metals,  
21 rendering them unsafe for consumption by children—Plaintiffs would not have purchased them  
22 at all.

23           78. Therefore, as a direct and proximate result of Defendants’ misrepresentations and  
24 omissions concerning their respective brands of baby food, Plaintiffs purchased Beech’s Brand  
25 Baby Food and/or Gerber Brand Baby Food.

26           79. Plaintiffs were harmed in the form of the monies they paid for Defendants’  
27 Beech, Hain, Nurture, and Gerber Baby Food products, which they would not otherwise have  
28 paid had they known the truth. Since the presence of elevated levels of toxic heavy metals in

1 baby food renders these products unsafe for human consumption, Gerber, Beech, Nurture and  
2 Hain Baby Food products that Plaintiffs purchased is worthless and harmful.

3 **Facts Relevant to Plaintiffs**

4 80. Between 2000 and until recently, one or the other of Plaintiffs purchased several  
5 different varieties of Beech Brand Baby Food, Gerber Brand Baby Food, Hain's baby products  
6 and Nurture's baby products from several Nevada stores. Many of the varieties of the Gerber,  
7 Beech, Nurture and Hain Baby Food products contained ingredients (and contaminants)  
8 discussed in the Subcommittee Report. Plaintiffs' relevant purchases include:

- 9 a. Beech's, Beech-Nut Rice; Organics Oatmeal whole Grain baby  
10 cereal; organics pear, kale & Cucumber; organics apple, raspberries  
11 & avocado; organics apple, kiwi & spinach; organics banana,  
12 cinnamon & granola; organic sweet potato; organic sweet carrots;  
13 organics carrots; classics sweet pea; organics apple; naturals banana;  
14 naturals green beans and naturals mango.
- 15 b. Gerber's purchased products are: Gerber Toddler Mashed Potatoes  
16 & Gravy with Roasted Chicken Meal, Gerber Toddler Pick-ups  
17 Chicken & Carrot Ravioli Meal; Gerber Toddler Spaghetti Rings in  
18 meat Sauce Meal, Gerber Toddler Spiral Paste in Turkey, Gerber  
19 Sitter 2nd Foods Apple Chicken Dinner Plastic Tub, Gerber Sitter  
20 2nd Foods Vegetable Beef Dinner Plastic Tub and Gerber Toddler  
21 Mashed Potatoes & Gravy with Roasted Chicken Meal.
- 22 c. Nurture's purchased products are: "Happy Baby Superfood Puffs,"  
23 Brown Rice cereal, and Apple & Broccoli Puffs.
- 24 d. Hain's purchased products are: Organic barley flour, organic  
25 chopped broccoli, organic date paste, organic whole raisins, medium  
26 grain whole rice, and sweet potato and chicken dinner.

27 81. Prior to purchasing baby food products from Gerber, Beech, Nurture and Hain,  
28 Plaintiffs were exposed to, saw, read, and understood Defendants' respective representations  
and omissions regarding the safety of their baby food, as well as their omissions regarding the  
presence of elevated levels of toxic heavy metals therein, and relied upon them.

82. Plaintiffs were only willing to purchase the baby food products of Beech, Hain,  
Nurture and Gerber because Plaintiffs 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, and their  
representations that their products were "natural."

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83. In reliance upon Defendants’ respective representations and omissions, Plaintiffs purchased Beech’s Brand Baby Food and Gerber Brand Baby Food.

84. Had Plaintiffs 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—Plaintiffs would not have purchased them.

85. The presence of elevated levels of toxic heavy metals in the baby food products of Gerber, Beech, Nurture and Hain made the baby food that Plaintiffs purchased worthless, because it was unsafe for human consumption.

86. Plaintiffs bring this action seeking recovery of the damages they incurred as a result of Defendants’ misrepresentations, omissions, deceptions and actions.

**Causes of Action**  
**FIRST CAUSE OF ACTION**  
**(Strict Liability – Failure to Warn)**

87. Plaintiffs incorporate by reference the allegations set forth in paragraphs 1 through 86 above.

88. Defendants’ baby food was defective and unreasonably dangerous in that Defendants failed to provide warnings about elevated levels of dangerous, toxic metals in their Baby Food products, the existence of which Defendants either knew or should have known about.

89. If adequately warned, Plaintiffs would have taken precautions to avoid the injury.

90. As a direct and proximate result of the defective nature of the Defendants’ lack of warning instructions on their baby food products, Plaintiffs have suffered substantial, adverse health consequences, including a diagnosis with autism of the minor plaintiffs, which is a neurological developmental disorder.

91. As a direct and proximate result of the minor Plaintiffs’ consumption of Defendants’ toxic heavy metals in their baby food products, they now require medical monitoring to evaluate, test, and/or remedy the neurological developmental disorders caused by



1 said consumption and exposure, with costs for the same in excess of Fifteen Thousand Dollars  
2 (\$15,000.00).

3 92. The equitable remedy of medical monitoring is appropriate equitable relief in  
4 light of Defendants' conduct since the prospective medical evaluation, testing and medical for  
5 neurological developmental disabilities would have been completely unnecessary had the  
6 Defendants warned Plaintiffs of toxic heavy metals in their baby food products.

7 93. As a direct and proximate result of these acts and omissions, Plaintiffs have  
8 incurred, and will incur, present and future medical expenses, in excess of Fifteen Thousand  
9 Dollars (\$15,000.00).

10 94. As a direct and proximate result of the acts and omissions of Defendants,  
11 Plaintiffs minor children have incurred permanent injuries, in excess of Fifteen Thousand  
12 Dollars (\$15,000.00).

13 95. As a direct and proximate result of these negligent acts and omissions, Plaintiffs'  
14 minor children will suffer future lost wages, in excess of Fifteen Thousand Dollars  
15 (\$15,000.00).

16 96. In carrying out its responsibilities for the design, manufacturer, testing, labeling,  
17 distribution, marketing, and sale of their baby food, Defendants acted with fraud, malice,  
18 express or implied, oppression and/or conscious disregard of the safety of others. As a direct  
19 and proximate result of the conduct of Defendants, Plaintiffs are entitled to punitive damages in  
20 excess of Fifteen Thousand Dollars (\$15,000.00).

21 97. Plaintiffs have been required to retain legal counsel to prosecute this action, and  
22 are therefore entitled to reasonable attorney's fees and costs of suit incurred in this action.

23  
24 **SECOND CAUSE OF ACTION**  
**(Breach of Implied Warranty of Merchantability)**

25 98. Plaintiffs incorporate by reference the allegations set forth in paragraphs 1  
26 through 97 above.

27 99. An implied warranty of merchantability existed between Plaintiffs and  
28 Defendants under Nevada Law, i.e., NRS 104.2314.

1           100. The Defendants sold toxic baby food products to Plaintiffs.

2           101. The Defendants breached the implied warranty of merchantability when they  
3 sold toxic baby food products to Plaintiffs.

4           102. As a direct result of the Defendants' breach of implied warranty of  
5 merchantability, Plaintiffs have been damaged.

6           103. As a direct and proximate result of the breach of warranty, Plaintiffs have  
7 suffered substantial, adverse health consequences, including a diagnosis with autism, which is a  
8 neurological developmental disorder.

9           104. As a direct and proximate result of the minor Plaintiffs consumption of  
10 Defendants' toxic heavy metals in their baby food products, they now require medical  
11 monitoring to evaluate, test, and/or remedy the neurological developmental disorders caused by  
12 said consumption and exposure, with costs for the same in excess of Fifteen Thousand Dollars  
13 (\$15,000.00).

14           105. The equitable remedy of medical monitoring is appropriate equitable relief in  
15 light of Defendants' conduct since the prospective medical evaluation, testing and medical care  
16 for neurological developmental disabilities would have been completely unnecessary had  
17 Defendants warned Plaintiffs of toxic heavy metals in their baby food.

18           106. As a direct and proximate result of the breach of warranty, Plaintiffs have  
19 incurred, and will incur, present and future medical expenses, in excess of Fifteen Thousand  
20 Dollars (\$15,000.00).

21           107. As a direct and proximate result of the breach of warranty, Plaintiffs minor  
22 children have incurred permanent injuries, in excess of Fifteen Thousand Dollars (\$15,000.00).

23           108. It has been necessary for Plaintiffs to retain the services of counsel to represent  
24 them in bringing this action, and Plaintiffs are entitled to recovery of attorneys' fees and costs  
25 incurred herein.

26 ////

27 ////

28 ////

**THIRD CAUSE OF ACTION  
(Negligence Per Se - Adulterated Product)**

109. Plaintiffs incorporate by reference the allegations set forth in paragraphs 1 through 108 above.

110. NRS 585.300 provides in pertinent part that “[a] food shall be deemed to be adulterated if: 1. It bears or contains any poisonous or deleterious substance which may render it injurious to health unless the substance is not ad added substance and the quantity of the substance does not ordinarily render it injurious to health . . . .”

111. NRS 585.310 provides in pertinent part that “[a] food shall be deemed to be adulterated . . . 3. If damage or inferiority has been concealed in any manner . . . .”

112. NRS 585.320 provides in pertinent part that “[a] good shall be deemed to be adulterated if it falls below the standard of purity, quality or strength which it purports or is represented to possess.”

113. NRS 585.520 provides in pertinent part that “[t]he following acts and the causing thereof within the State of Nevada are hereby prohibited: 1. The manufacture, sale or delivery, holding or offering for sale of any good, drug, device or cosmetic that is adulterated or misbranded.”

114. NRS 585.550 provides that a person who violates the foregoing provisions is “guilty of a gross misdemeanor.”

115. The Nevada Supreme Court has held that knowledge is not a necessary element for a violation of NRS 585.520. See Duchess Business Services, Inc. v. Nevada State Board of Pharmacy, 181 P.2d 1159, 1169 (2008) (“we conclude that NRS 585.520(1) contains no knowledge requirement and that liability may be imposed under that section absent consciousness of any wrongdoing.”)

116. Defendants breached their duty of care by manufacturing, selling, delivering, holding, or offering to sell adulterated baby food products to Plaintiff.

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1 117. As a direct and proximate result of these negligent acts and omissions, Plaintiffs  
2 minor children suffered substantial, adverse medical consequences in the form of contracting a  
3 neurological developmental disorder, specifically autism.

4 118. As a direct and proximate result of these negligent acts and omissions, Plaintiffs  
5 minor children consumed and were therefore exposed to toxic heavy metals in the baby food  
6 products and now require medical monitoring to evaluate, test, and/or remedy the neurological  
7 developmental disorders caused by said consumption and exposure, with costs for the same far  
8 in excess of Fifteen Thousand Dollars (\$15,000.00).

9 119. The equitable remedy of medical monitoring is appropriate equitable relief in  
10 light of Defendants' conduct since the prospective medical evaluation, testing and medical for  
11 neurological developmental disabilities would have been completely unnecessary had Plaintiffs  
12 minor children not been exposed to toxic heavy metals caused by Defendants' conduct.

13 120. As a direct and proximate result of these acts and omissions, Plaintiffs have  
14 incurred, and will incur, present and future medical expenses, in excess of Fifteen Thousand  
15 Dollars (\$15,000.00).

16 121. As a direct and proximate result of the acts and omissions of Defendants,  
17 Plaintiffs' minor children have incurred permanent injuries, in excess of Fifteen Thousand  
18 Dollars (\$15,000.00).

19 122. As a direct and proximate result of these acts and omissions, Plaintiffs minor  
20 children will suffer future lost wages, in excess of Fifteen Thousand Dollars (\$15,000.00).

21 123. Plaintiffs have been required to retain legal counsel to prosecute this action, and  
22 are therefore entitled to reasonable attorney's fees and costs of suit incurred in this action.

23 **FOURTH CAUSE OF ACTION**  
24 **(Negligence)**

25 124. Plaintiffs incorporate by reference the allegations set forth in paragraphs 1  
26 through 123 above.

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125. Defendants owed a duty of care to Plaintiffs in the design, manufacture, construction, assembly, testing, labeling, distribution, marketing and sale of their baby food products and breached that duty of care.

126. As a direct and proximate result of these negligent acts and omissions, Plaintiffs minor children suffered substantial, adverse medical consequences in the form of contracting a neurological developmental disorder, specifically autism.

127. As a direct and proximate result of these negligent acts and omissions, Plaintiffs' minor children consumed and were therefore exposed to toxic heavy metals in the baby food products they consumed, and now require medical monitoring to evaluate, test, and/or remedy the neurological developmental disorders caused by said consumption and exposure, with costs for the same far in excess of Fifteen Thousand Dollars (\$15,000.00).

128. The equitable remedy of medical monitoring is appropriate equitable relief in light of Defendants' conduct since the prospective medical evaluation, testing and medical care for neurological developmental disabilities would have been completely unnecessary had the Plaintiffs minor children not been exposed to toxic heavy metals caused by Defendants' negligent and reckless conduct.

129. As a direct and proximate result of these negligent acts and omissions, Plaintiffs have incurred, and will incur, present and future medical expenses, in excess of Fifteen Thousand Dollars (\$15,000.00).

130. As a direct and proximate result of the acts and omissions of Defendants, the Plaintiffs minor children have incurred permanent injuries, in excess of Fifteen Thousand Dollars (\$15,000.00).

131. As a direct and proximate result of these negligent acts and omissions, Plaintiffs minor children will suffer future lost wages, in excess of Fifteen Thousand Dollars (\$15,000.00).

132. Plaintiffs have been required to retain legal counsel to prosecute this action, and are therefore entitled to reasonable attorney's fees and costs of suit incurred in this action.

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**FIFTH CAUSE OF ACTION**  
**(Violation of Nevada Deceptive Trade Practices Act – NRS §§ 598.0903 to 598.0999)**

133. Plaintiffs incorporate by reference the allegations set forth in paragraphs 1 through 132 above.

134. At all times relevant herein, Defendants violated the Nevada Deceptive Trade Practices Act, §§ 598.0903 to 598.0999, by representing to its Nevada baby food customers and consumers that their manufactured and sold baby food products were safe, and failed to take into consideration the damages consumers of their unsafe products would sustain throughout Nevada.

135. Defendants made false or misleading statements of fact concerning the safety of their products and intentionally omitted reference to the dangerous metals contained in their products in violation of NRS 598.0915(13) and otherwise knowingly made false representations in their communications with Nevada consumers by representing that their products were “natural and healthy.”

136. As a direct result of the Defendants’ conduct, Plaintiffs have been deprived of fair and adequate baby food products for which they paid, and to which they were fairly and lawfully entitled.

137. As a direct and proximate result of these acts and omissions, Plaintiffs’ minor children suffered substantial, adverse medical consequences in the form of contracting a neurological developmental disorder, specifically autism.

138. As a direct and proximate result of these acts and omissions, Plaintiffs’ minor children consumed and were therefore exposed to toxic heavy metals in the baby food products and now require medical monitoring to evaluate, test, and/or remedy the neurological developmental disorders caused by said consumption and exposure, with costs for the same far in excess of Fifteen Thousand Dollars (\$15,000.00).

139. The equitable remedy of medical monitoring is appropriate equitable relief in light of Defendants’ conduct since the prospective medical evaluation, testing and medical for

1 neurological developmental disabilities would have been completely unnecessary had Plaintiffs'  
2 minor children not been exposed to toxic heavy metals caused by Defendants' conduct.

3 140. As a direct and proximate result of these acts and omissions, Plaintiffs have  
4 incurred, and will incur, present and future medical expenses, in excess of Fifteen Thousand  
5 Dollars (\$15,000.00).

6 141. As a direct and proximate result of the acts and omissions of Defendants,  
7 Plaintiffs minor children have incurred permanent injuries, in excess of Fifteen Thousand  
8 Dollars (\$15,000.00).

9 142. As a direct and proximate result of these negligent acts and omissions,  
10 Plaintiffs' minor children will suffer future lost wages, in excess of Fifteen Thousand Dollars  
11 (\$15,000.00).

12 143. Plaintiffs have been required to retain legal counsel to prosecute this action, and  
13 are therefore entitled to reasonable attorney's fees and costs of suit incurred in this action.

14 **SIXTH CAUSE OF ACTION**  
15 **(Strict Liability – Unreasonably Dangerous)**

16 144. Plaintiffs incorporate by reference the allegations set forth in paragraphs 1  
17 through 143 above.

18 145. Defendants' baby food products are further defective and unreasonably  
19 dangerous because their elevated levels of the dangerous toxic metals render them unsuited to  
20 perform reasonably as expected in light of their nature and intended function.

21 146. Defendants' baby food products are more dangerous than would be contemplated  
22 by the ordinary user having the ordinary knowledge available in the community given the  
23 presence of toxic heavy metals therein.

24 147. Plaintiffs minor children were exposed to Defendants' baby food products  
25 through retail purchases and consumption of the same, as was intended by Defendants.

26 148. Safer alternative ingredients, materials, and/or designs were available at all  
27 relevant times, beginning when Plaintiffs first purchased Defendants' baby food products.  
28

1           149. As a direct and proximate result of the elevated levels of toxic heavy metals in  
2 Defendants' baby food products, Plaintiffs have suffered substantial, adverse health  
3 consequences, including a diagnosis with autism, which is a neurological developmental  
4 disorder.

5           150. As a direct and proximate result of the Plaintiffs' minor children consumption of  
6 Defendants' toxic heavy metals, which were in their baby food products, Plaintiffs now require  
7 medical monitoring to evaluate, test, and/or remedy the neurological developmental disorders  
8 caused by said consumption and exposure, with costs for the same in excess of Fifteen  
9 Thousand Dollars (\$15,000.00).

10           151. The equitable remedy of medical monitoring is appropriate equitable relief in  
11 light of Defendants' conduct since the prospective medical evaluation, testing and medical for  
12 neurological developmental disabilities would have been completely unnecessary had Plaintiffs  
13 not been exposed to toxic heavy metals in Defendants' baby food products.

14           152. As a direct and proximate result of these acts and omissions, Plaintiffs have  
15 incurred, and will incur, present and future medical expenses, in excess of Fifteen Thousand  
16 Dollars (\$15,000.00).

17           153. As a direct and proximate result of the acts and omissions of Defendants, the  
18 Plaintiffs minor children incurred permanent injuries, in excess of Fifteen Thousand Dollars  
19 (\$15,000.00).

20           154. As a direct and proximate result of these acts and omissions, the Plaintiffs minor  
21 children have suffered future lost wages, in excess of Fifteen Thousand Dollars (\$15,000.00).

22           155. As a direct and proximate result of the acts and omissions of Defendants,  
23 Plaintiffs will incur medical expenses and been required to provide care and comfort, in excess  
24 of Fifteen Thousand Dollars (\$15,000.00).

25           156. In carrying out its responsibilities for the design, manufacture, testing, labeling,  
26 distribution, marketing, and sale of their baby food products, Defendants acted with fraud,  
27 malice, express or implied, oppression and/or conscious disregard of the safety of others. As a  
28



1 direct and proximate result of the conduct of Defendants, the Plaintiffs are entitled to punitive  
2 damages in excess of Fifteen Thousand Dollars (\$15,000.00).

3 157. Plaintiffs have been required to retain legal counsel to prosecute this action, and  
4 are therefore entitled to reasonable attorney's fees and costs of suit incurred in this action.

5 **SEVENTH CAUSE OF ACTION**  
6 **(Unjust Enrichment)**

7 158. Plaintiffs incorporate by reference the allegations set forth in paragraphs 1  
8 through 157 above.

9 159. Plaintiffs have conferred a monetary benefit upon Defendants by purchasing  
10 their baby food products, which monetary benefit the Defendants substantially.

11 160. Defendants have accepted and retained these monetary benefits despite knowing  
12 that the sale of their baby food products containing elevated levels of toxic heavy metals to  
13 unknowing consumers, such as Plaintiffs, which Defendants entirely failed to warn about.

14 161. In light of Defendants' egregious conduct, it would be inequitable for Defendants  
15 to retain the value of Plaintiffs conferred monetary benefits without paying Plaintiffs for the  
16 value of the same.

17 162. As a direct and proximate result of Defendants' retention of said monetary  
18 benefits, the Plaintiffs have expended significant sums of money on routine retail purchases of  
19 Defendants' baby food products in an amount to be determined at trial, all of which rightfully  
20 belong to Plaintiffs.

21 163. As a direct and proximate result of the Defendants being unjustly enriched,  
22 Plaintiffs have been required to retain the services of an attorney and are entitled to an award of  
23 reasonable attorneys' fees and costs incurred in the litigation of this claim.

24 **PRAYER FOR RELIEF**

25 **WHEREFORE**, Plaintiffs, pray for relief and damages as follows, that the court:

- 26 1. Order the equitable remedy of medical monitoring to evaluate, test, treat, and  
27 remedy the minor Plaintiffs neurological developmental disorders;  
28

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2. Award compensatory damages to Plaintiffs for the Defendants' wrongful conduct detailed above in excess of Fifteen Thousand;
3. Award punitive damages in excess of Fifteen Thousand;
4. Award to Plaintiff all attorneys' fees and costs; and
5. Award such other and further relief, as this Court deems just and appropriate.

DATED this 2nd day of March 2021.

**KEMP JONES, LLP**

**EGLET ADAMS**

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# **EXHIBIT 1**



# 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

Report includes safer choices for parents, manufacturers  
and retailers seeking healthy foods for infants

IN PARTNERSHIP WITH



## ACKNOWLEDGEMENTS

**Authors: Jane Houlihan, MSCE, Research Director, and Charlotte Brody, RN, National Director, Healthy Babies Bright Futures**

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The opinions expressed in this report are those of HBBF and do not necessarily reflect the views of the supporters and reviewers listed above. HBBF is responsible for any errors of fact or interpretation contained in this report.

Report design: Winking Fish

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# What's in my Baby's Food?

Our findings show what parents, baby food companies and FDA should do to get toxic heavy metals out of babies' diets

## EXECUTIVE SUMMARY

Parents shop for baby food expecting the nutrition, convenience and baby-tested flavors of store-bought brands. But nearly every jar, pouch and canister also offers something unexpected for a baby's mealtime—traces of heavy metals, including arsenic and lead.

The problem, uncovered nearly a decade ago, is far from solved. New tests of 168 baby foods commissioned by Healthy Babies Bright Futures (HBBF) found toxic heavy metals in 95 percent of containers tested. One in four baby foods contained all four metals assessed by our testing lab—arsenic, lead, cadmium, and mercury. Even in the trace amounts found in food, these contaminants can alter the developing brain and erode a child's IQ. The impacts add up with each meal or snack a baby eats.

Fresh research continues to confirm widespread exposures and troubling risks for babies, including cancer and lifelong deficits in intelligence from exposures to these common food contaminants. Despite the risks, with few exceptions there are no specific limits for toxic heavy metals in baby food.

### PROMISING SIGNS OF PROGRESS MUST ACCELERATE TO PROTECT BABIES.

The government, parents and baby food companies are paying attention. In 2017 the U.S. Food and Drug Administration charged a team of top agency scientists with “reducing exposures... to the greatest extent possible” by prioritizing and modernizing FDA's approaches (FDA 2018a,b). In early 2019 leading baby food companies supported by non-profit organizations, including HBBF, formed a new Baby Food Council that is “seeking to reduce heavy metals in the companies' products to as low as reasonably achievable using best-in-class management practices” (BFC 2019). And since 2011 public health advocates have regularly tested baby foods and educated parents on issues ranging from arsenic and lead in fruit juice (CR 2011,2019a) to arsenic in infant rice cereal (HBBF 2017a, CR 2012) and heavy metals in a range of baby foods (CR 2018, EDF 2017a, Gardener 2018).

Children are better off for the efforts: Current arsenic contamination levels in rice cereal and juice are 37 and 63 percent lower, respectively, than amounts measured a decade ago because of companies' success in reducing metals levels in their food ingredients to comply with draft FDA guidance. They have shifted growing and processing methods, switched plant varieties, and sourced from cleaner fields.

Despite the gains, 19 of every 20 baby foods tested had detectable levels of one or more heavy metals, according to new tests detailed in this study. Only a dramatically accelerated pace at FDA and the fruition of the new Baby Food Council's pursuit of industry-wide change will be enough to finally solve the problem.



#### TEST RESULTS: 168 BABY FOODS

**95 percent of baby foods tested contained one or more toxic heavy metals**

*1 in 4 baby foods contained all 4 toxic heavy metals assessed by our testing lab, including arsenic and lead.*

#### How many baby foods had multiple heavy metals in a single container?

4 metals	26% of baby foods
3 metals	40%
2 metals	21%
1 metal	8%
0 metals	5% (9 foods)

#### In how many baby foods was each heavy metal found?

Arsenic	73% of baby foods
Lead	94%
Cadmium	75%
Mercury	32%

## WHAT'S NEW ABOUT THIS STUDY?

Reports of heavy metals in baby food span nearly a decade. HBBF's study advances this work in 4 ways:

**Many brands tested:** We report on tests of a wider variety of brands than past studies - 61 brands, from big names to niche brands.

**First-ever look at IQ loss for babies:** We include a new study HBBF commissioned from Abt Associates to quantify for the first time the health impacts posed by heavy metals in baby food. This work gives first-ever estimates of the population-wide decline in IQ from children's exposures to lead and arsenic in food, from birth to 24 months of age. It also gives food-by-food rankings to show the 15 foods commonly consumed by babies and young children that drive more than half of the risk (see Findings section of this report).

**Optimized actions for parents:** We streamline advice for parents to cover foods posing the greatest risk to babies, based on the newly released IQ loss findings (Abt 2019b). This allows parents to focus on five actions estimated to provide the greatest benefit for babies' brains.

**New data on industrial pollutants and additive risks:** We also include new data for the industrial chemical perchlorate in baby food. It adds to the risk of IQ loss posed by heavy metals, increasing the urgency for actions to lower the levels of neurotoxic contaminants in baby food.

### PARENTS CAN MAKE FIVE SAFER BABY FOOD CHOICES FOR 80 PERCENT LESS TOXIC METAL RESIDUE.

In the meantime, HBBF's new tests help parents navigate the baby food aisle. We found that simple changes can significantly lower a baby's exposures to heavy metal contamination. Parents shopping for baby food can choose five types of safer items, all readily available, over more contaminated foods (see table below). The safer choices contain 80 percent less arsenic, lead and other toxic heavy metals, on average, than the riskier picks.

Notably, parents can't shop their way out of these exposures by choosing organic foods or by switching from store-bought brands to homemade purees. Heavy metals are naturally occurring in soil and water and are found

at elevated levels in fields polluted by pesticides, contaminated fertilizer, airborne contaminants and industrial operations. Food crops uptake these metals naturally. Leafy greens and root crops like carrots and sweet potatoes retain more than most other types of fruits and vegetables. How the food is processed may also affect the levels. Organic standards do not address these contaminants, and foods beyond the baby food aisle are equally affected.



### Our tests show that simple actions for 5 foods can help lower your babies' exposures to arsenic, lead and other toxic heavy metals

	Higher risk foods for heavy metal exposure	Safer alternative	Toxic heavy metal level
<b>Snacks</b>	Puff snacks (rice)	Rice-free snacks	<b>93% less</b>
<b>Teething Foods</b>	Teething biscuits and rice rusks	Other soothing foods for teething—frozen banana or chilled cucumber	<b>91% less</b>
<b>Cereal</b>	Infant rice cereal	Other infant cereals like multi-grain and oatmeal	<b>84% less</b>
<b>Drinks</b>	Fruit juice	Tap water	<b>68% less</b>
<b>Fruits &amp; Veggies</b>	Carrots and sweet potatoes	Variety: A variety of fruits and veggies that includes carrots, sweet potatoes, and other choices	<b>Up to 73% less</b>

Source: HBBF analysis of tests of 168 baby foods by Brooks Applied Labs, Bothell Washington and FDA market basket data, 2014-2017. Exposures reductions consider average total heavy metal levels in each food (inorganic arsenic, lead, cadmium, mercury) except for cereal, which considers inorganic arsenic only.



## FIFTEEN FOODS ACCOUNT FOR MORE THAN HALF OF THE RISK. RICE-BASED FOODS TOP THE LIST.

Our research substantiates the widespread presence of toxic heavy metals in baby foods found in prior studies, almost no enforceable limits or guidelines on what's allowed, and the common occurrence of arsenic and lead in excess of recommended levels to protect children's health (Table 1, page 12).

Although many foods are contaminated, a few stand out: 15 foods consumed by children under 2 years of age account for 55 percent of the risk to babies' brains, according to a new study commissioned by HBBF and detailed in this report (see Findings section and Appendix E). These include apple and grape juice, oat ring cereal, macaroni and cheese, puff snacks and 10 other foods.

But topping the list are rice-based foods—infant rice cereal, rice dishes and rice-based snacks. These popular baby foods are not only high in inorganic arsenic, the most toxic form of arsenic, but also are nearly always contaminated with all four toxic metals. The new study, completed by the nationally recognized toxicology and economic research firm Abt Associates, estimates that lead and arsenic in rice-based foods account for one-fifth of the more than 11 million IQ points children lose from birth to 24 months of age from all dietary sources. This concentrated risk underscores the need for swift action from FDA and baby food companies to reduce arsenic levels in rice-based foods.

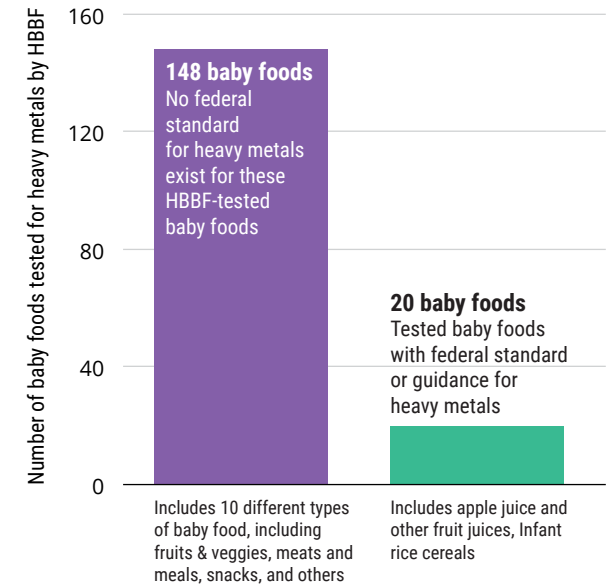
## PARENTS, BABY FOOD COMPANIES, FARMERS, AND FDA ALL HAVE A ROLE IN MEASURABLY REDUCING BABIES' EXPOSURES.

A number of baby food companies are setting their own standards in the absence of enforceable federal limits or guidance. As these initiatives advance, packaged baby foods may be increasingly likely to have lower amounts of heavy metals than homemade varieties.

Our findings raise concerns, but on the spectrum from worry to action, parents can choose to act. While no amount of heavy metals is considered safe, less is better, and parents can lower their babies' exposures by serving a variety of foods and by following the five safer choices for baby foods provided above.

Many factors can influence a child's IQ, from nutrition and genetics to environmental toxins like heavy metals (e.g., Makharia 2016). And many sources ratchet up children's exposures to heavy metals, from drinking water and old plastic toys to lead in dust from chipping paint and soil tracked into the house. But among these factors and sources, heavy metals in food constitute both a significant and a solvable problem. The government, companies and parents can all act — and are, in many cases, already acting — to measurably lower levels in food and to lessen exposures for babies.

## 88 percent of baby foods we tested have no enforceable federal safety limit for arsenic, lead and other heavy metals



## RECOMMENDATIONS

### Baby food companies

Our research shows that baby food companies need to take additional steps to reduce heavy metals in their products. This action is especially important for foods posing the greatest risk to baby's development, with arsenic in rice topping the list, based on a new analysis of children's IQ loss from lead and arsenic in baby food detailed in this study.

To reduce arsenic levels, solutions suggested by FDA and other experts include sourcing rice from fields with lower arsenic levels in soil, growing it with natural soil additives that reduce arsenic uptake by the roots, growing rice strains less prone to arsenic uptake, altering irrigation practices, preparing rice with excess water that is poured off, and blending it with lower arsenic grains in multi-grain products.



We found no evidence to suggest that any brand has reduced heavy metals levels in rice to amounts comparable to those found in other types of grains, despite at least 10 years of significant public attention to the issue that has included widespread consumer alerts and a proposed federal action level (Consumer Reports 2012 and 2014, HBBF 2017, FDA 2016). Four of seven infant rice cereals tested in this study contained inorganic arsenic in excess of FDA's action level.

### FDA

FDA should establish and finalize health-protective standards for heavy metals, prioritizing foods that offer the greatest opportunity to reduce exposure, considering additive effects of the multiple metals detected in foods, and explicitly protecting against neurodevelopmental impacts.

FDA should implement a proactive testing program for heavy metals in foods consumed by babies and toddlers, similar to the Consumer Product Safety Commission's program for children's toys (CPSC 2019).

Because inorganic arsenic in rice is a top source of neurodevelopmental risk for children, FDA should act immediately to establish a health-based limit for this chemical in infant rice cereal and other rice-based foods. In setting its 2016 proposed action level, the agency did not consider IQ loss or other forms of neurological impact, allowed cancer risks far outside of protective limits, and failed to account for children who have unusually high exposures to arsenic in rice (HBBF 2016). Rapid action by FDA to set a protective level will protect children from high levels of arsenic in rice.



### Parents

HBBF encourages parents to follow our simple actions for five foods to lower children's exposures to toxic heavy metals, shown in the Executive Summary and in the report section entitled "What parents can do." The safer choices we list contain 80 percent less arsenic, lead and other toxic heavy metals, on average, than the riskier foods.

# BABY FOOD PURCHASED FOR THE STUDY: STORES, BRANDS, AND FOOD TYPES

We selected 168 individual containers of 13 different food types under 61 baby food brand names. Testing for 4 toxic heavy metals—arsenic, lead, cadmium, and mercury—was performed at Brooks Applied Labs in Bothell, Washington. Only 9 of 168 samples had no detected toxic metals.

**4**  
toxic heavy  
metals tested

**168**  
containers

**61**  
baby food  
brands



and 50 other brands

**13**  
types of baby food



Fruit



Infant formula



Puffs and other snacks



Vegetables



Apple juice



Teething biscuits,  
including rice rusks



Mixed fruits & veggies



100% fruit juice



Infant rice cereal



Meat (jars)



Other drinks for  
toddlers/babies



Infant cereal: multi-  
and non-rice grains



Meals (veggies,  
grains, pasta, meat  
combos)

**14 metropolitan areas**  
and **17 retailers** from whom  
the foods were purchased:

- supermarkets
- dollar stores
- baby stores
- superstores



## SUMMARY: EIGHT FINDINGS FROM NEW BABY FOOD TESTS

HBBF and a national, volunteer network of seven other non-profit organizations purchased baby food from stores in 14 metropolitan areas across the country. We purchased foods from 15 retail chains - supermarkets, dollar stores, baby stores, superstores - and two online-only retailers.

We commissioned a nationally recognized laboratory with expertise in heavy metal analysis, Brooks Applied Labs (BAL) near Seattle Washington, to test for four toxic heavy metals—arsenic, lead, cadmium and mercury—in the 168 baby food containers included in this study. We also commissioned this lab to test 25 of those foods, those with the highest arsenic levels, for the specific form of arsenic most toxic to people, inorganic arsenic.

We commissioned a second laboratory, Southwest Research Institute, to test 25 of those foods for an additional neurotoxic contaminant called perchlorate, to further illustrate the need for standards that consider the wide range of neurotoxins in food. Test results, analytical methods and quality control procedures are in Appendices A, C and D. HBBF's analysis of test results shows:

### 1. TOXIC HEAVY METALS WERE FOUND IN NEARLY EVERY BABY FOOD TESTED.

Ninety-five percent of baby foods tested were contaminated with one or more of four toxic heavy metals—arsenic, lead, cadmium and mercury. All but nine of 168 baby foods contained at least one metal; most contained more than one. One in four foods had detectable levels of all four metals, in the same baby food container. We tested a wider range of foods than FDA includes in their annual market basket studies, but our results are consistent with the agencies' findings. In 2017 FDA detected one or more of these four metals in 33 of 39 types of baby food tested (FDA 2019c).

### 2. BABIES ARE EXPOSED DAILY, WITH IMPACTS TO HEALTH.

The four heavy metals we found in baby food have a unique significance: All are developmental neurotoxins (e.g., Grandjean and Landrigan 2006, Sanders 2015). They can harm a baby's developing brain and nervous system, both *in utero* and after birth, for impacts that include the permanent loss of intellectual capacity and behavioral problems like attention-deficit hyperactivity disorder (ADHD). All four metals are linked to IQ loss from exposures early in life. The scientific evidence spans decades and continues to build: at least 23 studies published in the past seven years confirm these four heavy metals' impacts to a child's healthy development (Appendix B). These metals are so prevalent in foods eaten by babies and toddlers that every child could be exposed daily to all three of the most common heavy metals detected in food - lead, arsenic, and cadmium - based on an analysis of federal surveys of children's dietary patterns and heavy metals levels in food (Abt 2019b).

### 3. FEW SAFETY STANDARDS EXIST.

For 88 percent of baby foods tested by HBBF—148 of 168 baby foods—FDA has failed to set enforceable limits or issue guidance on maximum safe amounts. In 2016 FDA proposed limiting inorganic arsenic in infant rice cereal to 100 ppb (FDA 2016). Inorganic arsenic exceeded this amount in four of the seven infant rice cereals tested by HBBF (Appendix A). FDA has also proposed limiting inorganic arsenic in apple juice and has issued guidance for limiting lead in fruit juice, but has failed to set specific limits for metals in any other type of baby food (FDA 2013,2014).



**Baby food:**  
Cases of excessive heavy metal contamination, but few safety standards

#### **Four of seven rice cereals tested:**

Contain inorganic arsenic in excess of FDA's proposed limit of 100 ppb.

#### **88 percent of foods tested:**

Lack any federal standards or guidance on maximum safe levels of toxic heavy metals like arsenic and lead.

#### 4. RECOMMENDED LIMITS ARE OFTEN EXCEEDED.

Arsenic exceeded FDA’s guidance level in four of seven infant rice cereals tested. In the absence of protective federal standards for other baby foods, public health organizations have recommended limits and urged their adoption by companies and FDA. Eighty-three percent of baby foods tested had more lead than the 1-ppb limit endorsed by public health advocates (EDF 2017). Recent FDA tests also found heavy metals in baby food above safe limits, including maximum allowable amounts for children established by the European Food Safety Authority and the U.S. Agency for Toxic Substances and Disease Registry (Spungen 2019). Table 1 (page 12) shows other exceedances.

#### 5. POPULAR BABY FOODS ESTIMATED TO POSE THE GREATEST RISK ARE AMONG THE MANY FOODS THAT LACK SPECIFIC LIMITS FOR HEAVY METALS.

HBBF commissioned a new analysis from Abt Associates, a nationally recognized toxicology and economic research group, to accompany our laboratory tests. The work included an assessment of IQ loss attributed to lead and arsenic in baby food and provided food-by-food rankings to show which foods are driving the bulk of the risk. Abt’s analysis estimates that children age 0 to 24 months lose more than 11 million IQ points from exposure to arsenic and lead in food. Just 15 foods consumed by these children account for 55 percent of the total estimated IQ loss. Heavy metals in 10 of these foods are unregulated, lacking any FDA guidance or regulation to limit the levels. Abt’s analysis is described in Appendix E. The analysis considers all foods consumed by children under 2, from store-bought and homemade foods for babies to the wider range of packaged and homemade foods that toddlers eat.

Milk and infant formula appear on the list of 15 foods not because of high metals levels—arsenic and lead concentrations are relatively low in both compared to some other types of baby food, according to HBBF and FDA tests—but because American children drink so much of them. These are nutritious foods, and there is no action needed

#### Results of IQ analysis: 15 foods account for 55% of total IQ loss from children’s dietary exposures to arsenic and lead in baby food

Food consumed by child age 0 - 24 months	Percent of total harm (fraction of total IQ points lost for children under 2, from lead and arsenic in food)	Primary toxic metal of concern
Rice dishes, including with beans & veggies	10.0%	Arsenic
Milk, whole*	8.4%	Arsenic
Rice, white and brown	7.0%	Arsenic
Apple juice	6.1%	Arsenic
Infant formula*	5.3%	Lead
Fruit juice blend (100% juice)	4.1%	Arsenic
Infant rice cereal	2.7%	Arsenic
Grape juice	2.0%	Lead and arsenic
Cheerios and other oat ring cereals	1.6%	Arsenic
Sweet potato (baby food)	1.6%	Lead and arsenic
Soft cereal bars and oatmeal cookies	1.4%	Arsenic
Macaroni and cheese	1.4%	Lead and arsenic
Puffs and teething biscuits	1.3%	Lead and arsenic
Bottled drinking water	1.2%	Arsenic
Fruit yogurt	1.2%	Lead

\*Note: Milk and infant formula appear on the list not because of high metals levels — arsenic and lead concentrations are relatively low in both compared to some other types of baby food, according to HBBF and FDA tests — but because American children drink so much of them. These are nutritious foods, and there is no action needed by parents to change what they serve their children.

Source: HBBF-commissioned analysis of federal data in national surveys of food contamination and consumption (see Appendix E and Abt 2019b for details).

by parents to change what they serve their children. But FDA action to set limits in milk and formula for arsenic and lead—and cadmium as well, which is often detected—would create benefits extending to millions of children.

Similarly, bottled water appears on the list not because high metals levels are common, but because so many children drink it. Bottled water is no safer than filtered tap water and generates plastic waste that is easily avoided by choosing tap water.

Two results stand out from the IQ analysis. First, during the first two years of life, American children lose four times more IQ points from arsenic contamination in food than from lead contamination. Second, rice-based foods—including infant rice cereal, rice dishes and rice-based snacks—contribute nearly one-fifth of the total estimated IQ loss. These results show a crucial need for swift action from FDA and baby food companies to dramatically reduce arsenic levels in rice-based foods.

## 6. ADDITIONAL BABY FOOD TESTS BY HBBF DETECTED ANOTHER NEUROTOXIC CONTAMINANT—PERCHLORATE.

HBBF's tests uncovered one additional neurotoxin in food. We sent new containers of 25 of the foods tested for heavy metals to a separate laboratory, to be analyzed for a neurotoxic pollutant called perchlorate. The lab detected it in 19 of 25 foods tested (Appendix D and SWRI 2019). All 19 foods with detectable perchlorate also contained heavy metals, and 12 contained all four heavy metals included in our tests.

Perchlorate disrupts thyroid functions crucial to brain development and has been linked to IQ loss among children born to mothers with thyroid dysfunction, who are more vulnerable to perchlorate toxicity (Taylor 2014). It is a rocket fuel component used since the Cold War. In 2005 FDA approved its use as an antistatic in plastic food packaging, and in 2016 expanded the approval to cover dry food handling equipment. Perchlorate is also a degradation product of hypochlorite used to disinfect food processing equipment. Levels in children's food increased dramatically from 2005 to 2012 (Abt 2016, EDF 2017b).

Our tests did not find the high spikes seen previously (EDF 2017b), but our results suggest a prevalence that could pose risks during pregnancy and infancy. The results support the need for FDA to ban all food uses, especially given that perchlorate adds to neurodevelopmental risks already imposed by the heavy metal contamination in baby food.

## 7. EXPOSURES AND IMPACTS ADD UP, INCREASING URGENCY FOR ACTION.

Heavy metals and perchlorate are not the only food contaminants raising the specter of IQ loss and other neurodevelopmental deficits for babies. Among recent examples, apples and spinach are often tainted with organophosphate pesticides, cheeses including mac 'n' cheese powder contain phthalate plasticizers, and

## New tests by HBBF find perchlorate contamination in 19 of 25 baby foods

### Number of baby foods with perchlorate, of total tested (and maximum level found):

Infant rice cereal:	2 of 5 - 7.1 ppb
Other infant cereals:	9 of 9 - 7.8 ppb
Infant formula:	2 of 3 - 11.4 ppb
Fruits & vegetables:	4 of 4 - 19.8 ppb
Snacks:	2 of 4 - 4.6 ppb

See Appendix D for details. "ppb" = parts per billion, or micrograms per kilogram.

a wide range of breakfast cereals, grains and beans are contaminated with the pesticide glyphosate (Roundup). All of these pollutants and pesticides are neurotoxic or linked to babies being born small (from mothers' exposures), with resulting risks for lower IQ and other neurological or behavioral impacts (e.g., Flensburg-Madsen 2017, Parvez 2018, Gillam 2017, FOE 2019, EWG 2019 and 2020, CSFPP 2017).

## 8. ACTIONS NEEDED BY FDA AND BABY FOOD COMPANIES GO BEYOND HEAVY METALS.

Exposures and impacts add up. The new analysis of children's IQ loss (Abt 2019b) provides a starting point for understanding these combined impacts. It considers one health impact—IQ loss—associated with 2 metals in food, arsenic and lead. Mercury in baby food would also contribute to IQ loss, and preliminary data suggests that cadmium would as well; for these metals, data were not

yet available to assess the IQ drop expected with each successive exposure for a child. Those data are urgently needed. And other neurotoxic pollutants in food would add to the cumulative impacts, each time a child eats.

For parents, the answer is not switching to homemade purees instead of store-bought baby foods. Federal data shows that baby food sometimes has higher levels and sometimes lower levels of heavy metals, compared to comparable fresh or processed foods purchased outside the baby food aisle. For example, peaches and green beans from the baby food aisle are less likely to contain detectable levels of lead than canned versions of these foods, while carrot and sweet potato baby foods have higher lead detection rates than their peeled, fresh counterparts (EDF 2019b).

In most cases it's not the amount of a particular contaminant in baby food that causes concern. Our tests show that most metals are at low levels and by themselves in any given food raise little concern. It's babies' daily exposures to the many neurotoxins in baby foods that drive the urgency for action. When FDA and baby food companies address one contaminant in one type of food, children benefit. But truly protecting children necessitates addressing the many contaminants that collectively harm a child's healthy development. HBBF supports the FDA's and baby food companies' efforts to continually lower the levels of heavy metals and other neurotoxic contaminants in all baby foods. Specific recommendations include:

### FDA:

HBBF agrees with the mission of FDA's Toxic Elements Working Group to reduce exposures to the greatest extent possible. We urge the agency to:

- Set health-protective standards for heavy metals, prioritizing foods that offer FDA the greatest opportunity to reduce exposure, considering additive effects of the multiple metals detected in foods, and explicitly protecting against neurodevelopmental impacts.

- Strengthen and finalize standards for arsenic in apple juice and infant rice cereal, and expand the range of foods covered. HBBF supports recommendations for a 3-ppb inorganic arsenic standard and 1-ppb lead standard that apply to all fruit juice, and a health-protective standard for arsenic in infant rice cereal and all other rice-based foods.
- Implement a proactive testing program for heavy metals in foods consumed by babies and toddlers, similar to the Consumer Product Safety Commission's program for children's toys (CPSC 2019).
- Ensure lead is not present in food contact materials where it could get into food.
- Establish a goal of no measurable amounts of cadmium, lead, mercury, and inorganic arsenic in baby and children's food, in recognition of the absence of a known safe level of exposure, and work with manufacturers to achieve steady progress.

#### **Baby food companies:**

HBBF is a member of the Baby Food Council and supports its goal to reduce heavy metals in baby food to levels as low as reasonably achievable. Other companies can join this effort, as described below from the organization's charter:

*The Baby Food Council is a group of infant and toddler food companies, supported by key stakeholders, seeking to reduce heavy metals in the companies' products to as low as reasonably achievable usage best-in-class management practices. The Council was created in January 2019 in partnership with Cornell University and*

*the Environmental Defense Fund. All companies that source ingredients, manage the upstream supply chain, and nationally market foods for children six to 24 months of age in the United States are welcome to participate in the Council. Since its creation, Healthy Babies Bright Futures has joined the Council as a member and the American Academy of Pediatrics and the Food and Drug Administration have agreed to serve as technical advisors to the effort. For more information, contact Randy Worobo of Cornell University at [rww8@cornell.edu](mailto:rww8@cornell.edu).*

*- The Baby Food Council, 2019*

HBBF urges all baby food companies to establish a goal of no measurable amounts of cadmium, lead, mercury, and inorganic arsenic in baby and children's food, in recognition of the absence of a known safe level of exposure, and to achieve steady progress toward that goal.

# WHAT PARENTS CAN DO

THE SAFER FOOD CHOICES OUTLINED HERE HAVE 80 PERCENT LOWER HEAVY METAL LEVELS, ON AVERAGE, THAN THE HIGHER RISK FOODS.

An abundance of online advice instructs parents on ways to reduce children’s exposures to heavy metals in foods. HBBF has streamlined those tips down to simple actions that cover five foods posing high risks to babies’ neurological development, based on Abt’s new analysis (Abt 2019b). This allows parents to focus on changes that are estimated to provide the greatest benefit for babies’ brains.

*Note: For each pair of foods shown, concentrations shown and the comparative term “less toxic metals” are based on the average of the sum of four metals (inorganic arsenic, lead, cadmium and mercury) for the available samples of each food, unless noted otherwise. Averages were computed using data from the current study combined with data from FDA’s market basket study (the Total Diet Study, FDA 2014-2017). The abbreviation “ppb” refers to parts per billion.*

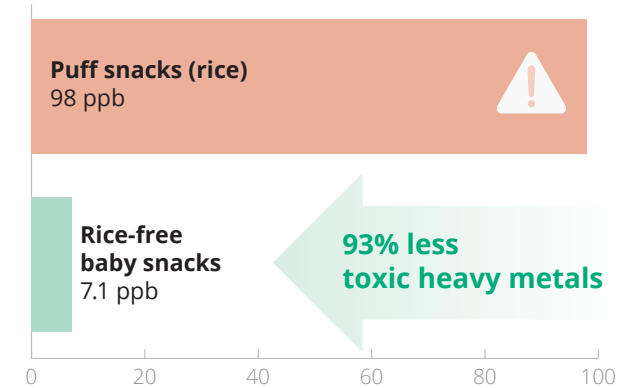
**1 Puffs and other snacks made with rice flour** contain arsenic, lead and cadmium at relatively high levels compared to other baby foods. Parents can reduce children’s exposures by choosing rice-free packaged snacks instead, which have 93 percent less toxic metal residues, on average. Multi-grain snacks that include rice would also have lower levels than snacks containing rice as the only grain. Other alternatives come from Consumer Reports, which recommends snacks that are rich in nutrients and low in metals, and that can be prepared and served to be appropriate for young children (such as soft-cooked, diced or mashed): **apples, applesauce (unsweetened), bananas, barley with diced vegetables, beans, cheese, grapes (cut lengthwise), hard-boiled eggs, peaches, and yogurt** (CR 2018). A caveat for non-rice snacks—HBBF tests showed lower metals levels in non-rice snacks, including crackers, bars and yogurt snacks, but federal data shows relatively high arsenic in a popular snack we did not test: oat ring cereals like Cheerios (FDA 2019c). We recommend avoiding this choice for snacks.

**2 Teething biscuits and rice rusks** often contain arsenic, lead, and cadmium. They also lack nutrients and can cause tooth decay. Doctors and dentists recommend other solutions for baby teething pain (Colgate 2020, AAP 2020). Options include **a frozen banana, a peeled and chilled cucumber, a clean, cold wet washcloth or spoon**. Healthcare professionals advise parents to stay with their baby to watch for any choking.

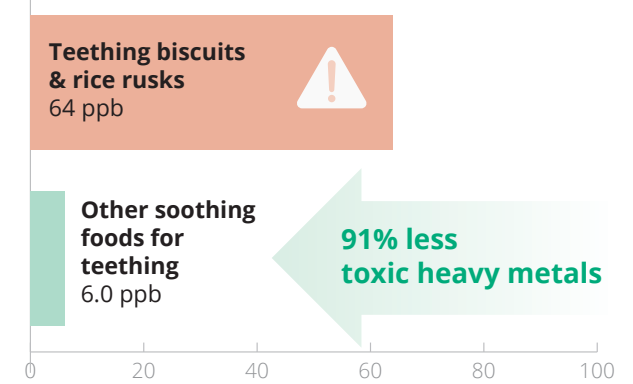
**3 Infant rice cereal** is the top source of arsenic in infant’s diets. HBBF’s 2017 study of infant cereals found that **non-rice and multi-grain varieties** on grocery shelves nationwide—including **oatmeal, corn, barley, quinoa, and others**—contain 84 percent less inorganic arsenic than leading brands of infant rice cereal, on average. Federal data shows 64 percent less total heavy metals, on average, in infant non-rice cereals compared to rice varieties. The alternates include reliable and affordable choices for parents seeking to reduce infants’ exposures to arsenic (HBBF 2017a).

**Rice** is a leading source of arsenic exposure for young children. Parents can serve other grains like oats, wheat and barley instead of rice to help cut their family’s exposures. Cooking rice in extra water that is poured off before serving can cut the arsenic levels by up to 60 percent, according to FDA studies (FDA 2016). The lowest arsenic levels are found in basmati rice grown in California, India, and Pakistan. White rice has less arsenic than brown rice. Rice from Arkansas, Louisiana, Texas, or simply “U.S.” has the highest levels, according to testing by Consumer Reports (CR 2014).

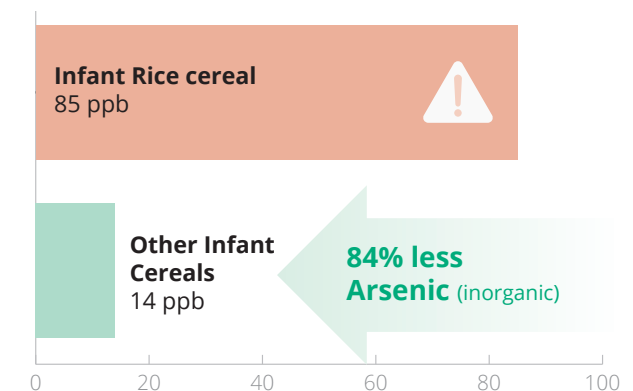
## 1 SNACKS



## 2 TEETHING FOODS

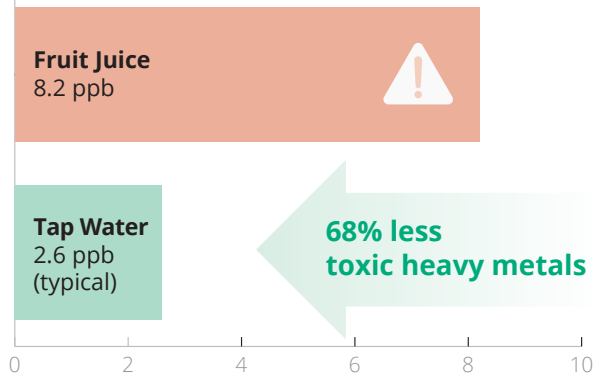


## 3 CEREAL



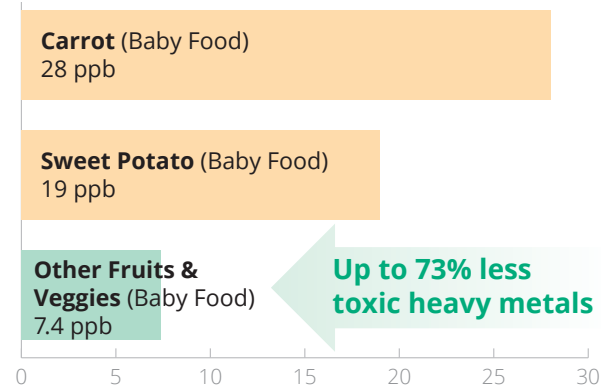


#### 4 DRINKS



**4 Apple, pear, grape and other fruit juices** contain traces of lead and arsenic. Levels aren't as high as in some other foods, but toddlers drink juice often, so it's a top exposure source. **Tap water** is a better drink for thirsty toddlers. Another alternative is **whole or pureed fruits** (like applesauce), which offer more fiber and nutrients than juice. The American Academy of Pediatrics warns parents of juice's high caloric and sugar content. It advises no fruit juice for children under 1 year of age, and half a cup or less daily for children under 3. AAP recommends that if fruit juice is given, it should be offered as part of a meal, not diluted with water and sipped over time, because of tooth decay risks (AAP 2017b, Heyman 2017).

#### 5 FRUITS & VEGGIES



**5 Carrots and sweet potatoes** are a great source of Vitamin A and other nutrients your baby needs. But they also contain higher levels of lead and cadmium than other fruits and vegetables, on average. Yet they are an important part of a child's diet, and a common baby food ingredient. **Variety is the solution:** parents can serve these vegetables along with other fruits and vegetables during the week, for benefits without the excess risk.

**Table 1: Three take-aways:**

Our research substantiated the widespread presence of four toxic heavy metals in baby foods, almost no enforceable federal standards to limit what’s allowed, and the common occurrence of arsenic and lead in excess of recommended levels to protect children’s health.

**What did our tests of 168 baby foods find?**

	<b>1. Widespread detections of toxic heavy metals</b> 95 percent of baby foods tested were contaminated with one or more toxic heavy metals, including arsenic and lead. No food type was free of contamination.				<b>2. Few enforceable limits for baby food</b> For 10 of 13 baby food types tested, there is no FDA guidance on safe limits for toxic heavy metals.				<b>3. Gaps in protecting babies’ health</b> 83% of baby foods tested had more lead than the 1-ppb limit endorsed by public health advocates. Arsenic exceeded FDA’s guidance level in 4 of 7 infant rice cereals tested.			
	Our tests found four toxic heavy metals in baby food (▲ = detected)				Has FDA issued a safe limit for toxic heavy metals in the baby foods we tested? Limits endorsed by health organizations are also shown.				Did our test results exceed recommended safe limits for baby food? (▲ = safe level exceeded in HBBF tests)			
	Arsenic	Lead	Cadmium	Mercury	Arsenic (inorganic)	Lead	Cadmium	Mercury	Arsenic	Lead	Cadmium	Mercury
<b>Puffs and other snacks</b>	▲ 19 of 21 foods	▲ 21 of 21 foods	▲ 19 of 21 foods	▲ 14 of 21 foods	No	No 1 ppb (EDF)	No	No	No limit exists	▲ All 21 foods exceed 1 ppb limit.	No limit exists	No limit has been set for mercury in baby food, but levels are low compared to amounts in canned tuna and other seafood.
<b>Teething biscuits, including rice rusks</b>	▲ 10 of 10 foods	▲ 10 of 10 foods	▲ 10 of 10 foods	▲ 10 of 10 foods	No	No 1 ppb (EDF)	No	No	No limit exists	▲ All 10 foods exceed 1 ppb limit.	No limit exists	
<b>Infant formula</b>	▲ 8 of 13 containers	▲ 13 of 13 containers	▲ 8 of 13 containers	▲ 1 of 13 containers	No	No 1 ppb (EDF)	No	No	No limit exists	▲ 12 of 13 containers exceed 1 ppb limit.	No limit exists	
<b>Infant rice cereal</b>	▲ 7 of 7 cereals	▲ 7 of 7 cereals	▲ 7 of 7 cereals	▲ 7 of 7 cereals	Yes - limits: 100 ppb (FDA) 25 ppb (HBBF)	No 1 ppb (EDF)	No	No	▲ 7 cereals tested. 4 exceed FDA limit. 7 exceed HBBF limit.	▲ All 7 cereals exceed 1 ppb limit.	No limit exists	
<b>Infant cereal - multi &amp; single non-rice grains</b>	▲ 11 of 11 cereals	▲ 10 of 11 cereals	▲ 11 of 11 cereals	▲ 2 of 11 cereals	No	No 1 ppb (EDF)	No	No	No limit exists	▲ 9 of 11 cereals exceed 1 ppb limit.	No limit exists	
<b>Meals (veggies, grains, pasta, meat combos)</b>	▲ 7 of 10 foods	▲ 10 of 10 foods	▲ 10 of 10 foods	▲ 2 of 10 foods	No	No 1 ppb (EDF)	No	No	No limit exists	▲ All 10 meals exceed 1 ppb limit.	No limit exists	
<b>Veggies</b>	▲ 25 of 38 containers	▲ 38 of 38 containers	▲ 34 of 38 containers	▲ 9 of 38 containers	No	No 1 ppb (EDF)	No	No	No limit exists	▲ 33 of 38 containers exceed 1 ppb limit.	No limit exists	
<b>Fruits</b>	▲ 8 of 16 containers	▲ 10 of 16 containers	▲ 5 of 16 containers	▲ 3 of 16 containers	No	No 1 ppb (EDF)	No	No	No limit exists	▲ 8 of 16 containers exceed 1 ppb limit.	No limit exists	
<b>Mixed fruits and veggies</b>	▲ 10 of 14 containers	▲ 14 of 14 containers	▲ 12 of 14 containers	▲ 3 of 14 containers	No	No 1 ppb (EDF)	No	No	No limit exists	▲ 11 of 14 containers exceed 1 ppb limit.	No limit exists	
<b>Meat (jars)</b>	▲ 1 of 6 jars	▲ 5 of 6 jars	▲ 1 of 6 jars	▲ 1 of 6 jars	No	No 1 ppb (EDF)	No	No	No limit exists	▲ 2 of 6 jars exceed 1 ppb limit.	No limit exists	
<b>Apple juice</b>	▲ 3 of 4 juices	▲ 4 of 4 juices	None found 0 of 4 juices	None found 0 of 4 juices	Yes - limits: 10 ppb (FDA) 3 ppb (CR)	Yes - limits: 50 ppb (FDA) 1 ppb (AAP)	No 1 ppb (CR)	No	▲ 4 juices tested. 0 exceed FDA’s 10 ppb limit. 2 exceed a 3 ppb limit.	▲ 4 juices tested. 0 exceed FDA’s 50 ppb limit. 1 exceeds 1 ppb limit.	★ 4 juices tested. 0 exceed 1 ppb limit.	
<b>Juice - 100% fruit, non-apple</b>	▲ 4 of 5 juices	▲ 4 of 5 juices	▲ 2 of 5 juices	None found 0 of 5 juices	No 3 ppb (CR)	Yes - limits: 50 ppb (FDA) 1 ppb (AAP)	No 1 ppb (CR)	No	▲ 5 juices tested. 2 exceed 3 ppb limit.	▲ 5 juices tested. 0 exceed FDA’s 50 ppb limit. 3 exceed AAP limit.	★ 5 juices tested. 0 exceed 1 ppb limit.	
<b>Other drinks for babies and toddlers</b>	▲ 3 of 5 drinks	▲ 4 of 5 drinks	▲ 2 of 5 drinks	None found 0 of 5 drinks	No	No 1 ppb (EDF)	No	No	No limit exists	▲ 2 of 5 drinks exceed 1 ppb limit.	No limit exists	

Information on safety standards and recommended limits can be found in these references: FDA – 100 ppb arsenic in infant rice cereal (FDA 2016); HBBF (Healthy Babies Bright Futures) – 25 ppb arsenic in infant rice cereal (HBBF 2017a,b); FDA – 10 ppb arsenic in apple juice (FDA 2013); CR (Consumer Reports) – 3 ppb arsenic in apple and other fruit juice (CR 2019a,b); FDA – 50 ppb limit for lead in fruit juice (FDA 2004); CR and EDF (Environmental Defense Fund) – endorsement of AAP (American Academy of Pediatrics) 1-ppb lead-in-water limit to apply to fruit juice (CR 2019a,b; AAP 2017a); EDF – goal of 1 ppb for lead in baby food (EDF 2017a).

## HEALTH RISKS: THE SCIENTIFIC EVIDENCE

Fresh research continues to confirm widespread exposures and troubling risks for babies exposed to the four heavy metals included in this study, including at least 23 peer-reviewed studies published in the past seven years revealing IQ loss, attention deficits, and other learning and behavioral impacts among children who are exposed through food and other sources (Appendix B). Three of the metals, arsenic, lead and cadmium, are also potent human carcinogens.

Widespread exposure to toxic heavy metals shifts the population-wide IQ curve down. It nudges more children into special education, and ratchets down the IQ of the most creative and intellectually gifted children. For an individual child, the harm appears to be permanent (e.g., Grandjean and Landrigan 2014, Wasserman 2007 and 2016, Hamadani 2011).

Instead of overt poisoning, the low, daily exposures children face from heavy metals in food and other sources create “subclinical decrements in brain function” with impacts on a global scale. Scientists write that the exposures “diminish quality of life, reduce academic achievement, and disturb behaviour, with profound consequences for the welfare and productivity of entire societies” (Grandjean and Landrigan 2014).



### ARSENIC

Arsenic widely contaminates food and drinking water from its long-time use as a pesticide and an additive in animal feed, from its release at mining and industrial operations, and from natural sources. Arsenic causes bladder, lung and skin cancer and also harms the developing brain and nervous system. In the peer-reviewed scientific literature, at least 13 studies link arsenic to IQ loss for children exposed in utero or during the first few years of life (Rodriguez-Barranco 2013).

Among evidence supporting arsenic’s ability to harm the brain is a 2014 assessment of nearly 300 third to fifth graders in Maine, finding an average loss of 5-6 IQ points among those who drank well water contaminated with arsenic at or above 5 parts per billion. This level is common in some parts of the U.S. and is lower than the legal limit in public water supplies (10 parts per billion) (Wasserman 2014). Studies find lasting impacts when children are exposed to arsenic early in life, including persistent IQ deficits in children two years after their polluted drinking water was replaced, cognitive deficits among school-age children exposed early in life, and neurological problems in adults who were exposed to arsenic-poisoned milk as infants (Wasserman 2007 and 2016, Hamadani 2011, Tanaka 2010). There is no evidence that the harm caused by arsenic is reversible.

### LEAD

Over the past 40 years lead has been restricted in children’s toys and phased out of gasoline, pesticides, paint, and food contact surfaces, including lead solder from cans. But lead that lingers in homes, soil, and water remains a festering problem. The toxic metal continues to contaminate the blood of nearly every child tested. Although exposures are lower now than in the past, lead-induced brain damage still accounts for an estimated 23 million IQ points lost among children under five (Bellinger 2012). Even very low exposure

levels cause lower academic achievement, attention deficits and behavior problems. No safe level of exposure has been identified.

Evidence of lead’s toxicity spans decades. Among recent studies are two that included 80,000 Detroit and Chicago school children, 3rd grade through middle school, whose standardized math and reading tests were correlated to their blood lead levels measured at birth or early childhood. “Early childhood lead exposure is associated with poorer achievement... even at very low blood lead levels,” concluded one of the research teams (Zhang 2013, Evens 2015).

Lead widely contaminates food from its long-time use as a pesticide, its presence in food processing equipment (in older brass, bronze, plastic, and coated materials), and its presence at elevated levels in soil, either natural or accumulated from industrial pollution. In October 2018 FDA cut in half its maximum daily intake limit for lead in children’s food. An estimated 2.2 million children six years or younger exceed the new intake limit (EDF 2019a).

### Beyond Food: Other sources of lead exposure

For many children the biggest source of lead exposure is not food, but lead paint in homes built before 1978. Lead from chipping and peeling paint builds up in house dust and sticks to children’s hands. It also flakes off of a home’s exterior to contaminate soil in the yard.

To learn if you have lead paint, have your home inspected by a licensed lead inspector. You can also use a simple test kit sold at many hardware stores. Learn more: <https://www.epa.gov/lead/protect-your-family-exposures-lead>

## CADMIUM

Cadmium is a heavy metal linked to neurotoxicity and cancer, and to kidney, bone and heart damage. It has many industrial uses and is a common contaminant in food and the environment. It lacks the name recognition of arsenic and lead, but may deserve an equal share of attention from parents, companies, and regulators, since it also displays a troubling ability to cause harm at low levels of exposure.

A 2015 review of recent scientific literature identified 16 studies on the neurotoxic impacts of cadmium on children. Among these is research by Harvard scientists reporting a tripling of risk for learning disabilities and special education among children with higher cadmium exposures, at levels common among U.S. children and previously thought to be safe (Ciesielski 2012).

A 2019 study by FDA found that cadmium in food exceeds amounts safe for children: In its 2014-2016 market basket tests, FDA detected cadmium in 65 percent of nearly 3000 food samples tested, and estimated that children's average exposures exceed safe limits established by both the European Food Safety Authority and the U.S. Agency for Toxic Substances and Disease Registry (Spungen 2019).

## MERCURY

Mercury is a global pollutant released from coal-fired power plants, mining operations and other sources. It contaminates the biosphere and the food chain. Seafood is the dominant source of mercury exposure for children and adults. It contains a particularly toxic form of mercury called methylmercury that increases risk for cardiovascular disease for adults and poor performance on tests of vision, intelligence, and memory for children exposed in utero.

Evidence that the developing brain is particularly sensitive to mercury extends back decades, covering two mass poisonings and major longitudinal studies of lower exposures from seafood, among other research (NAS 2000). Recently, scientists found a four-fold higher risk for IQ scores under 80, the clinical cut-off for borderline intellectual disability, among school-age children exposed to high levels of mercury in utero (Jacobsen 2015).

Although mercury was detected in 32 percent of the 168 baby foods tested in this study, levels were far lower than typical amounts in tuna and other seafood. FDA and EPA's joint advisory gives safer seafood choices for pregnant women and young children (EPA and FDA 2019). A number of NGOs have published more conservative advice to protect women who eat seafood frequently (EWG 2014, MBASW 2020). Mercury levels in canned tuna exceed the legal limit under California's Proposition 65, but an attempt to require the law's mandated warnings on canned tuna failed in 2006 when an appeals court found that the California law was preempted by the FDA/EPA seafood advisory (Kone 2006).

## SAFETY STANDARDS

The four toxic metals covered in this study—arsenic, lead, cadmium and mercury—were regulated decades ago in sources as wide-ranging as drinking water, gasoline and children’s toys.

Regulations have also eliminated lead from food contact surfaces, including lead solder from food cans (Bolger 1996). But they remain without an enforceable limit or guideline in nearly every type of baby food, despite being widely acknowledged as toxic during a child’s development and prevalent in popular baby and toddler foods.

All four metals are neurotoxic. Three—arsenic, lead and mercury—have been shown to permanently reduce children’s IQ. Three are also human carcinogens, arsenic, cadmium and lead.

FDA can use its testing programs, recall authority, and guidance to industry, among other tools, to characterize and control heavy metal levels in food. The agency tests a fraction of imported food in their Import Program, prioritizing food likely to pose risks to consumers, including those with high heavy metals levels. Federal law gives FDA the authority to require a recall of food it deems to be adulterated, that “bears or contains any poisonous or deleterious substance which may render it injurious to health,” including heavy metals. In the past three years FDA has issued recalls for eight foods with excessive lead or arsenic, none of which were baby foods (FDA 2019d). In September 2019 the agency issued an import alert for lead and arsenic in grape and pear juice concentrates, advising their inspectors to target these products for testing (FDA 2019e).

FDA also tests a variety of foods on store shelves in their Total Diet Study market basket program, focusing on foods that are commonly eaten or likely to have high levels of metals (FDA 2019c). FDA’s compliance program conducts occasional testing programs that target select, high-risk foods. These data have helped FDA prioritize its work to reduce heavy metals levels in baby food.

In 2016 FDA proposed limiting inorganic arsenic in infant rice cereal to 100 ppb (FDA 2016). Inorganic arsenic exceeded this amount in four of the seven infant rice cereals tested by HBBF.

FDA has also proposed limiting inorganic arsenic in apple juice and has issued guidance for limiting lead in fruit juice (FDA 2004, 2013), but has failed to set limits for metals in any other type of baby food.

Despite FDA’s many areas of authority and its recent emphasis on reducing exposures to heavy metals, for 88 percent of baby foods tested by HBBF—148 of 168 baby foods—FDA has failed to set enforceable limits or issue guidance on maximum safe amounts.

And none of the agency’s existing guidance considers the additive neurological impacts of multiple metals in baby food.

### FDA’S PROPOSED GUIDANCE FOR ARSENIC IN INFANT RICE CEREAL REMAINS UNFINALIZED DESPITE PROMISES TO COMPLETE IN 2018.

FDA’s 2016 proposed limit for inorganic arsenic in infant rice cereal—its 100 parts-per-billion “action level”—falls short of what is needed to protect children. In proposing the level, FDA did not consider IQ loss or other forms of neurological impact, allowed cancer risks far outside of protective limits, and failed to account for children who have unusually high exposures to arsenic in rice (HBBF 2016, HBBF 2017a).

And if the agency finalizes the action level, it will serve only as guidance to the infant cereal industry, not as a standard that FDA is required to enforce. Instead, FDA can choose whether or not to enforce an action level, at its own discretion.

HBBF has advocated that FDA finalize a more protective standard that protects against neurological harm during development and that applies to all rice-based foods eaten by babies and pregnant women. HBBF has also called on cereal companies to reduce levels to 25 ppb, an amount typical of levels in multi-grain cereals (HBBF 2017a,b).

Altogether, six of 30 rice-based baby foods tested by HBBF contained inorganic arsenic above the 100-ppb limit proposed for infant rice cereal—four infant rice cereals and two puff snacks (Appendix A).

## FDA'S PROPOSED GUIDANCE FOR ARSENIC IN APPLE JUICE REMAINS UNFINALIZED DESPITE PROMISES TO COMPLETE IN 2018.

In 2013 FDA proposed limiting inorganic arsenic in apple juice to 10 ppb, the federal government's standard for arsenic in drinking water (FDA 2013). This limit still has not been finalized. Consumer Reports, a long-time advocate for reducing toxic metals in food, has argued for a more protective limit of 3 ppb, and for inclusion of other high-arsenic juices, like grape and pear juice (CR 2019a,b).

Arsenic in juice exceeded CR's recommended limit of 3 ppb in two of nine juices tested by HBBF, a white grape juice and an apple juice.

FDA has also issued guidance to limit lead in fruit juice (FDA 2004). This level, 50 ppb, is 3.3 times higher than the federal drinking-water action level, 10 times more than the FDA's bottled-water standard, and 50 times higher than the American Academy of Pediatrics' recommended lead-in-water limit for school drinking fountains.

Experts at Consumer Reports and the Environmental Defense Fund back a far lower limit, arguing for a 1-ppb cap to match the American Academy of Pediatrics' recommended maximum for lead in school drinking fountains (CR 2019a,b; AAP 2017).

While none of the fruit juices tested by HBBF topped FDA's 50-ppb limit, four of nine juices contained more lead than the recommended 1 ppb cap, with a maximum of over 11 ppb in a white grape juice marketed for toddlers. At these levels, the many children who regularly drink juice are getting too much lead. Eighty percent of American families with toddlers and babies serve juice to children. Three-quarters of those families serve it daily; their children face the highest risks (CR 2019b).

## PROMISING PROGRESS AT FDA

In April 2017 FDA's Center for Food Safety and Applied Nutrition (CFSAN) announced it had established a Toxic Elements Working Group to modernize safety standards for the toxic metal mixtures Americans are exposed to, including in food. The working group is charged with "achieving the public health goal of reducing exposure... to the greatest extent possible" (FDA 2017, 2018a,b).

Although FDA has not yet introduced new standards as a result of the initiative, it has made progress. It has lowered the maximum allowed daily lead intake for children from 6 to 3 micrograms per day (ug/day) and set a cap of 12.5 ug/day for women who are pregnant or nursing. These new "Interim Reference Levels" are a critical first step for lowering allowable lead levels in food (FDA 2019b). FDA has also launched new research to understand children's exposures to combinations of metals, and the impacts of these mixtures on the developing brain and nervous system (e.g., Spungen 2019). The agency missed its commitment to finalize the arsenic guidelines for infant rice cereal and apple juice by the end of 2018.

Heavy metal mixtures like those found in baby food pose risks to the developing brain. Setting protective, health-based limits for these contaminants presents an opportunity to make a significant difference in children's health.

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## APPENDIX A: LABORATORY TEST RESULTS FOR HEAVY METALS

Results for analysis of heavy metals in a variety of baby foods are listed below. Foods were tested for total recoverable arsenic; speciated arsenic (total inorganic arsenic is shown below); and total recoverable lead, cadmium, and mercury. Testing was commissioned by HBBF and performed by Brooks Applied Labs in Bothell, Washington in 2019. Appendix C provides a summary of analytical methods.

The qualifier “<” indicates that the concentration was below the method detection limit, while The symbol “\*” indicates test results that are estimated, that fall between the limit of detection and the limit of quantification. The qualifier “--” indicates that the analysis was not performed.

About estimated values: The table below shows results for all target analytes detected by the lab’s instruments. Estimated values shown with the qualifier “\*” have greater uncertainty than other results. The starred (\*) values are the lab’s best estimates of concentration, but the actual amounts may be higher or lower than these best estimates. These estimated test results are near the test’s detection limit. They are higher than the detection limit but lower than the test’s quantitation limit. In contrast, test results above the quantification limit don’t carry the J qualifier - they have lower uncertainty and are not considered to be estimates. The laboratory’s detailed reports that accompany this study give detection and quantification limits for each individual test result shown below.

Brand	Food	Food type	Arsenic (total, ppb)	Arsenic (inorganic, ppb)	Lead (ppb)	Cadmium (ppb)	Mercury (total, ppb)	Metro area where purchased	Retailer
<b>Infant cereal: rice</b>									
Beech-Nut	Rice Single Grain Baby Cereal - Stage 1, from about 4 months	Cereal - rice	117	86	3.5	5.4	0.582	Charlottesville, VA	Wegmans
BioKinetics	BioKinetics Brown Rice Organic Sprouted Whole Grain Baby Cereal	Cereal - rice	353	144	3.1 *	31.7	2.32	Washington, DC	amazon.com
Earth’s Best	Whole Grain Rice Cereal	Cereal - rice	138	113	22.5	14.7	2.41	San Diego, CA	99 Cents Only Stores
Earth’s Best	Whole Grain Rice Cereal	Cereal - rice	126	107	17.8	13.4	2.19	Portland, ME	Hannaford
Gerber	Rice Single Grain Cereal	Cereal - rice	106	74	3.9	11.1	1.79	Gambell, AK	ANICA Native Store
Healthy Times	Organic Brown Rice Cereal - 4+ months	Cereal - rice	153	133	67.4	12.1	1.53	Washington, DC	amazon.com
Kitchdee Organic	Baby Cereal Rice and Lentil - 6+ months	Cereal - rice	79.3	78	10.9	13.1	4.06	Washington, DC	amazon.com
<b>Infant cereal: multi- and single non-rice grain</b>									
Gerber	MultiGrain Cereal - Sitter 2nd Foods	Cereal - mixed and multi-grain	37	31	5.3	26.2	0.367 *	Detroit, MI	Meijer
HappyBABY	Oats & Quinoa Baby Cereal Organic Whole Grains with Iron - Sitting baby	Cereal - mixed and multi-grain	10.2	--	0.9 *	12.4	< 0.14	Minneapolis, MN	Target
Beech-Nut	Oatmeal Whole Grain Baby Cereal - Stage 1, from about 4 months	Cereal - oatmeal	23.8	--	2.2	13	< 0.139	Portland, OR	Fred Meyer
Earth’s Best	Whole Grain Oatmeal Cereal	Cereal - oatmeal	29.5	27	2 *	20.1	< 0.277	Portland, ME	Hannaford
Gerber	Oatmeal Single Grain Cereal	Cereal - oatmeal	26.9	--	3 *	13	< 0.281	Washington, DC	Safeway
HappyBABY	Oatmeal Baby Cereal, Clearly Crafted - Organic Whole Grains - for sitting baby	Cereal - oatmeal	6.3 *	--	< 0.5	10	< 0.14	Albany, NY	buybuyBABY
Harvest Hill	Instant Oatmeal, Maple & Brown Sugar	Cereal - oatmeal	13.5	--	8.1	5.8	< 0.14	Houston, TX	Dollar Tree
Cream of Wheat	Cream of Wheat Instant Original Flavor	Cereal - other single-grain	19.5	--	21.8	36.7	< 0.14	San Diego, CA	99 Cents Only Stores

APPENDIX A: Laboratory Test Results for Heavy Metals (continued)

Brand	Food	Food type	Arsenic (total, ppb)	Arsenic (inorganic, ppb)	Lead (ppb)	Cadmium (ppb)	Mercury (total, ppb)	Metro area where purchased	Retailer
Gerber	Barley Single Grain Cereal- Supported Sitter 1st Foods	Cereal - other single-grain	10.6 *	--	3 *	13.7	< 0.279	Detroit, MI	Meijer
Gerber	Whole Wheat Whole Grain Cereal - Sitter 2nd Foods	Cereal - other single-grain	40.6	39	5.5	50.8	< 0.14	Cincinnati, OH	Kroger
NurturMe	Organic Quinoa Cereals - Quinoa + Sweet Potato + Raisin	Cereal - other single-grain	35.9	26	39.8	20.3	0.389 *	San Diego, CA	99 Cents Only Stores
<b>Infant formula</b>									
365 organic (Whole Foods)	Organic Milk Based Powder Infant Formula with Iron	Formula	4.1 *	--	2.7	0.7 *	< 0.139	Boulder, CO	Whole Foods Market
Baby's Only Organic	Organic Non-GMO Dairy Toddler Formula	Formula	3.8 *	--	1.6 *	< 0.5	< 0.139	Boulder, CO	Whole Foods Market
Earth's Best	Organic Sensitivity - DHR/ARA Infant Formula with Iron Organic Milk-Based Powder	Formula	< 4.4	--	1.6 *	1.4 *	< 0.278	Portland, ME	Hannaford
Enfamil	ProSobee Soy Infant Formula, Milk-Free Lactose-Free Powder with Iron	Formula	6.2 *	--	7.8	6.9	< 0.14	Columbia, SC	Publix
Enfamil	Infant - Infant Formula Milk-Based with Iron - 0-12 months	Formula	< 2.2	--	2	0.7 *	< 0.138	Charlottesville, VA	Wegmans
Gerber	Good Start Gentle HM-O and Probiotics Infant Formula with iron; Milk Based Powder - Stage 1, birth to 12 months	Formula	5.2 *	--	0.9 *	< 0.5	< 0.14	Cincinnati, OH	Kroger
HappyBABY	Organic Infant Formula with Iron, Milk Based Powder - 0-12 months	Formula	< 4.5	--	3.7	< 1.1	< 0.286	Washington, DC	amazon.com
Meijer	Meijer Baby, Infant Formula - Milk-Based Powder with Iron - Birth - 12 months	Formula	< 4.4	--	2.3 *	3.1 *	0.417 *	Detroit, MI	Meijer
Parent's Choice (Walmart)	Organic Infant With Iron Milk-Based Powder - Stage 1 through 12 months	Formula	3.2 *	--	3.9	0.7 *	< 0.134	Charlottesville, VA	Walmart
Plum Organics	Gentle Organic Infant Formula with Iron, Milk-Based Powder - 0-12 months <sup>†</sup>	Formula	4.6 *	--	4.7	< 1.1	< 0.278	Washington, DC	amazon.com
Similac	Similac Advance OptiGRO Powder - Milk-Based	Formula	4.6 *	--	2	< 0.5	< 0.139	Gambell, AK	ANICA Native Store
Simple Truth Organic (Kroger)	Infant Formula with Iron, Organic Milk-Based Powder	Formula	3.6 *	--	2.7	0.6 *	< 0.135	Portland, OR	Fred Meyer
up & up (Target)	Infant - Infant Formula with Iron, Milk-Based Powder, DHA and Dual Prebiotics	Formula	< 2.2	--	1.5 *	3.1	< 0.138	Minneapolis, MN	Target
<b>Vegetable - single, carrot</b>									
Beech-Nut	Classics Sweet Carrots - 2	Veggie - single - carrot	< 2.1	--	27.2	6.8	0.15 *	Washington, DC	Safeway
Beech-Nut	Classics Sweet Carrots - Stage 2	Veggie - single - carrot	< 2.2	--	23.5	8	0.212 *	Portland, ME	Hannaford
Beech-Nut	Organics Just Carrots - Stage 1	Veggie - single - carrot	2.8 *	--	1.3 *	1.4 *	0.142 *	Minneapolis, MN	Target

APPENDIX A: Laboratory Test Results for Heavy Metals (continued)

Brand	Food	Food type	Arsenic (total, ppb)	Arsenic (inorganic, ppb)	Lead (ppb)	Cadmium (ppb)	Mercury (total, ppb)	Metro area where purchased	Retailer
Earth's Best	Carrots Organic Baby Food - 2, 6 months +	Veggie - single - carrot	4.1 *	--	1.1 *	< 0.5	0.224 *	Boulder, CO	Whole Foods Market
Earth's Best	Carrots Organic Baby Food 2 - 6 months+	Veggie - single - carrot	3.5 *	--	1.6 *	5.2	0.24 *	Columbia, SC	Publix
Earth's Best	First Carrots Organic Baby Food - 1, 4 months+	Veggie - single - carrot	5.2 *	--	1.6 *	4.4	0.222 *	Charlottesville, VA	Wegmans
Gerber	Diced Carrots Veggie Pick-Ups™	Veggie - single - carrot	< 2.2	--	11.8	27.7	0.223 *	Washington, DC	Safeway
Gerber	Carrot - Sitter 2nd food	Veggie - single - carrot	< 2.2	--	9.4	31.4	0.214 *	Minneapolis, MN	Target
Gerber	Carrot - Supported Sitter 1st Foods	Veggie - single - carrot	< 2.2	--	11	42.2	0.248 *	Columbia, SC	Publix
Meijer	True Goodness Organic Carrots Baby Food	Veggie - single - carrot	< 2.2	--	1.4 v	7.7	< 0.141	Detroit, MI	Meijer
O Organics (Albertson/Safeway)	Organic Carrots Baby Food - 2	Veggie - single - carrot	3.3 *	--	1.9	5.2	< 0.14	Washington, DC	Safeway
Parent's Choice (Walmart)	Carrot - Stage 2, 6+ months	Veggie - single - carrot	< 2	--	2.3	11.2	< 0.128	Charlottesville, VA	Walmart
<b>Vegetable - single, sweet potato</b>									
Beech-Nut	Naturals Just Sweet Potatoes - Stage 1, from about 4 months	Veggie - single - sweet potato	2.4 *	--	14.1	4	< 0.136	Albany, NY	buybuyBABY
Beech-Nut	Organics Just Sweet Potatoes - Stage 1, from about 4 months	Veggie - single - sweet potato	3.8 *	--	7.3	2.7	< 0.142	Cincinnati, OH	Kroger
Beech-Nut	Classics Sweet Potatoes - Stage 2, from about 6 months	Veggie - single - sweet potato	2.8 *	--	24.1	3.4	< 0.138	Portland, OR	Fred Meyer
Earth's Best	Sweet Potatoes Organic Baby Food - 1, 4 months +	Veggie - single - sweet potato	3.3 *	--	14.7	4.6	< 0.136	Boulder, CO	Whole Foods Market
Earth's Best	Sweet Potatoes Organic Baby Food 2 - from about 6 months	Veggie - single - sweet potato	3.1 *	--	12.9	3	< 0.136	Portland, OR	Fred Meyer
Earth's Best	Sweet Potatoes Organic Baby Food 2 - 6 months+	Veggie - single - sweet potato	4.3 *	--	6.9	1.6 *	< 0.138	Columbia, SC	Publix
Gerber	Sweet Potato Supported Sitter 1st Foods Tub	Veggie - single - sweet potato	2.4 *	--	20.3	4.7	< 0.139	Washington, DC	Safeway
Gerber	Sweet Potato - Sitter 2nd Food	Veggie - single - sweet potato	3.9 *	--	29.3	5.8	< 0.138	Minneapolis, MN	Target
Gerber	Sweet Potato - Supported Sitter 1st Foods	Veggie - single - sweet potato	6.9	--	14.6	3.5	< 0.138	Cincinnati, OH	Kroger
HappyBABY	Organics Sweet Potatoes - Stage 1	Veggie - single - sweet potato	5.8 *	--	1.5 *	1 *	< 0.142	Portland, ME	Hannaford

APPENDIX A: Laboratory Test Results for Heavy Metals (continued)

Brand	Food	Food type	Arsenic (total, ppb)	Arsenic (inorganic, ppb)	Lead (ppb)	Cadmium (ppb)	Mercury (total, ppb)	Metro area where purchased	Retailer
HappyBABY	Organics Sweet Potatoes - Stage 1	Veggie - single - sweet potato	6 *	--	2.2	0.8 *	< 0.14	Detroit, MI	Meijer
HappyBABY	Sweet Potatoes - Stage 1	Veggie - single - sweet potato	27.5	29**	2	1.6 *	< 0.141	Columbia, SC	Publix
Meijer	Meijer Baby Sweet Potatoes - 2nd Stage	Veggie - single - sweet potato	11.9	--	1.3 *	0.8 *	< 0.14	Portland, ME	Hannaford
Meijer	True Goodness Organic Sweet Potatoes Baby Food - Stage 2	Veggie - single - sweet potato	2.6 *	--	0.8 *	0.6 *	< 0.14	Detroit, MI	Meijer
Parent's Choice (Walmart)	Sweet Potato - Stage 1, 4-6 months	Veggie - single - sweet potato	4.3 *	--	4.3	1.4 *	< 0.141	Charlottesville, VA	Walmart
Plum Organics	Just Sweet Potato Organic Baby Food - 1, 4 months & up	Veggie - single - sweet potato	3.1 *	--	5.6	2.3	< 0.142	Boulder, CO	Whole Foods Market
Plum Organics	Just Sweet Potato Organic Baby Food - 1, 4 months & up	Veggie - single - sweet potato	2.3 *	--	14	2.7	< 0.14	Washington, DC	Safeway
<b>Vegetable - single (other than carrot, sweet potato)</b>									
Beech-Nut	Classics Sweet Peas - Stage 2	Veggie - single - other	6.3 *	--	1.1 *	1.6 *	< 0.138	Portland, ME	Hannaford
Beech-Nut	Beechnut Naturals Just Butternut Squash - Stage 1	Veggie - single - other	< 2.2	--	1.3 *	1.2 *	< 0.139	Detroit, MI	Meijer
Beech-Nut	Organic Just Pumpkin - Stage 1, from about 4 months	Veggie - single - other	2.6 *	--	4	1.1 *	< 0.139	Portland, OR	Fred Meyer
Earth's Best	Winter Squash Organic Baby Food - 2, 6 months +	Veggie - single - other	< 2.2	--	0.8 *	< 0.5	< 0.137	Cincinnati, OH	Kroger
Earth's Best	First Peas Organic Baby Food 1 - 4 months+	Veggie - single - other	5.9 *	--	3.8	< 0.5	< 0.14	Columbia, SC	Publix
Gerber	Pea - Sitter 2nd foods	Veggie - single - other	< 2.2	--	0.7 *	< 0.5	< 0.14	Gambell, AK	ANICA Native Store
Gerber	Green Bean - Sitter 2nd Food	Veggie - single - other	< 2.1	--	0.8 *	2.8	< 0.135	Minneapolis, MN	Target
Gerber	Green Bean - Supported Sitter 1st Foods	Veggie - single - other	< 2.2	--	0.7 *	0.6 *	< 0.142	Cincinnati, OH	Kroger
Parent's Choice (Walmart)	Organic Butternut Squash Vegetable Puree - Stage 2, 6+ months	Veggie - single - other	< 2.2	--	4.2	0.9 *	< 0.138	Charlottesville, VA	Walmart

APPENDIX A: Laboratory Test Results for Heavy Metals (continued)

Brand	Food	Food type	Arsenic (total, ppb)	Arsenic (inorganic, ppb)	Lead (ppb)	Cadmium (ppb)	Mercury (total, ppb)	Metro area where purchased	Retailer
<b>Fruit - single</b>									
Applesnax	Applesauce with Cinnamon	Fruit - single - apple	< 2.1	--	1.7	< 0.5	< 0.134	Dallas, TX	Dollar Tree
Beech-Nut	Organic Just Apples - Stage 1, from about 4 months	Fruit - single - apple	< 2	--	< 0.5	< 0.5	< 0.126	Charlottesville, VA	Wegmans
Earth's Best	Apples Organic Baby Food 2 - from about 6 months	Fruit - single - apple	6.5	--	1.5 *	< 0.5	< 0.141	Portland, OR	Fred Meyer
Mott's	Mott's Applesauce Apple	Fruit - single - apple	< 2.2	--	< 0.5	< 0.5	< 0.139	San Diego, CA	Family Dollar
Seneca	Cinnamon Apple Sauce	Fruit - single - apple	5.6 *	--	3.7	0.7 *	< 0.138	San Diego, CA	99 Cents Only Stores
Beech-Nut	Naturals Bananas - Stage 1, from about 4 months	Fruit - single - banana	< 2.1	--	< 0.5	< 0.5	< 0.136	Albany, NY	buybuyBABY
Gerber	Banana - Sitter 2nd Foods	Fruit - single - banana	< 2.1	--	< 0.5	< 0.5	< 0.135	Gambell, AK	ANICA Native Store
Meijer	Meijer Baby Bananas - 2nd Stage	Fruit - single - banana	< 2.2	--	< 0.5	< 0.5	< 0.138	Detroit, MI	Meijer
Gerber	Peach - Sitter 2nd Foods	Fruit - single - other	7.3	--	2.4	2.1	0.142 *	Gambell, AK	ANICA Native Store
Orchard Naturals	Mandarin Oranges in Light Syrup	Fruit - single - other	< 2.2	--	< 0.5	< 0.5	< 0.139	Houston, TX	Dollar Tree
Plum Organics	Just peaches - organic baby food - for 4+ months (stage 1)	Fruit - single - other	7.2	--	0.9 *	< 0.5	< 0.139	Albany, NY	buybuyBABY
Earth's Best	First pears - 1, 4 months+	Fruit - single - pear	4.3 *	--	1.2 *	1.5 *	< 0.135	Houston, TX	99 Cents Only Stores
Gerber	Pear - Sitter 2nd foods	Fruit - single - pear	4.2 *	--	1.1 *	2.5	0.169 *	Gambell, AK	ANICA Native Store
HappyBABY	Organic Pears - Stage 1	Fruit - single - pear	7.4	--	1 *	0.8 *	< 0.138	Boulder, CO	Whole Foods Market
HappyBABY	Clearly Crafted Prunes Organic Baby Food, 1, 4+ months	Fruit - single - prune	< 2.1	--	2	< 0.5	< 0.136	Charlottesville, VA	Wegmans
Sprout	Prunes Organic Baby Food - 1 starting solids	Fruit - single - prune	3.9 *	--	6.1	< 0.5	0.245 *	Albany, NY	buybuyBABY
<b>Fruit &amp; Veggie, Mixed</b>									
Beech-Nut	Naturals Beets, Pear & Pomegranate - 2	Fruit and veggie - mixed	< 2.2	--	0.9 *	4.7	< 0.139	Washington, DC	Safeway
Gerber	Organic Mango Apple Carrot Kale - Sitter 2nd foods	Fruit and veggie - mixed	3.3 *	--	1.1 *	11.4	0.212 *	Gambell, AK	ANICA Native Store
Gerber	Carrot Pear Blackberry - Sitter 2nd Foods	Fruit and veggie - mixed	2.7 *	--	3.6	18.2	< 0.141	Washington, DC	gerber.com
Gerber	Organic Apple Blueberry Spinach - Sitter 2nd Food	Fruit and veggie - mixed	5 *	--	1.5 *	1.8	< 0.141	Houston, TX	99 Cents Only Stores

APPENDIX A: Laboratory Test Results for Heavy Metals (continued)

Brand	Food	Food type	Arsenic (total, ppb)	Arsenic (inorganic, ppb)	Lead (ppb)	Cadmium (ppb)	Mercury (total, ppb)	Metro area where purchased	Retailer
HappyBABY	Simple Combos Apples, Spinach & Kale - 2	Fruit and veggie - mixed	3 *	--	4.3	4.9	0.182 *	Portland, ME	Hannaford
O Organics (Albertson/Safeway)	Organic Apple, Sweet Potato & Carrot Baby Food	Fruit and veggie - mixed	2.6 *	--	0.7 *	1.1 *	<0.142	Washington, DC	Safeway
Plum Organics	Just Prunes Organic Baby Food - 1, 4 months & up	Fruit and veggie - mixed	7.6	--	2.5	<0.5	0.194 *	Boulder, CO	Whole Foods Market
Sprout	Carrot Apple Mango Organic Baby Food - 2, 6 months & up	Fruit and veggie - mixed	6.1	--	2.1	15.1	<0.131	Charlottesville, VA	Wegmans
up & up (Target)	Apple and Carrot Baby Food, Fruit + Vegetable Blend, 6+ months	Fruit and veggie - mixed	<2.3	--	0.7 *	<0.6	<0.146	Minneapolis, MN	Target
Gerber	Apple Sweet Potato with Cinnamon - Toddler 12+ months	Fruit and veggie - mixed	<2.2	--	3.1	0.7 *	<0.139	Houston, TX	99 Cents Only Stores
Plum Organics	Pumpkin Banana Papaya Cardmom - 6 months and up	Fruit and veggie - mixed	2.4 *	--	1.4 *	2.4	<0.139	San Diego, CA	99 Cents Only Stores
Beech-Nut	Classics Mixed Vegetables - Stage 2	Veggie - mixed	<2.2	--	17.9	8.6	<0.139	Portland, ME	Hannaford
Earth's Best	Spinach and Potato Organic Baby Food - 2, 6+ months	Veggie - mixed	6.4	--	1.4 *	3	<0.13	Charlottesville, VA	Wegmans
Gerber	Carrot Sweet Potato Pea - Sitter 2nd Foods	Veggie - mixed	2.4 *	--	6.7	2.1	<0.137	Gambell, AK	ANICA Native Store
<b>Juice - 100% apple</b>									
365 organic (Whole Foods)	100% Juice - Apple from Concentrate	Juice - 100% fruit	2.5 *	--	0.7 *	<0.5	<0.13	Boulder, CO	Whole Foods Market
Gerber	Apple Juice from Concentrate - Toddler 12+ months	Juice - 100% fruit	3.1 *	--	2.1	<0.5	<0.137	Portland, ME	Hannaford
Juicy Juice	Juicy Juice 100% Juice - Apple	Juice - 100% fruit	3.6 *	--	1 *	<0.5	<0.14	Dallas, TX	Dollar Tree
Kidgits	Toddler Apple Juice from Concentrate	Juice - 100% fruit	<2.2	--	0.6 *	<0.5	<0.141	San Diego, CA	Family Dollar
<b>Juice - 100% fruit juice, non-apple or mixed</b>									
Apple & Eve	Elmo's Punch - 100% Juice Organics	Juice - 100% fruit	<2.1	--	<0.5	<0.5	<0.137	Boulder, CO	Whole Foods Market
Gerber	Apple Prune Juice from Concentrate - Toddler 12+ months	Juice - 100% fruit	5.6 *	--	3.3	<0.5	<0.136	Cincinnati, OH	Kroger
Gerber	Variety Pack Juices from Concentrate - White Grape	Juice - 100% fruit	9.9	--	11.1	<0.5	<0.135	Portland, OR	Fred Meyer
Gerber	Pear Juice from Concentrate 100% Juice - Toddler 12+ months	Juice - 100% fruit	4 *	--	1.1 *	0.9 *	<0.136	Charlottesville, VA	Wegmans
Juicy Juice	100% Juice Fruit Punch	Juice - 100% fruit	2.5 *	--	0.6 *	0.6 *	<0.139	San Diego, CA	Family Dollar
<b>Drinks - not 100% fruit juice</b>									
Good2Grow	Fortified Water - Orange Mango	Drink - not 100% fruit	<2.1	--	1.8	<0.5	<0.136	Dallas, TX	99 Cents Only Stores

APPENDIX A: Laboratory Test Results for Heavy Metals (continued)

Brand	Food	Food type	Arsenic (total, ppb)	Arsenic (inorganic, ppb)	Lead (ppb)	Cadmium (ppb)	Mercury (total, ppb)	Metro area where purchased	Retailer
Orgain	Kids Protein Organic Nutritional Shake Vanilla Flavor - Ages 1 to 13	Drink - not 100% fruit	3.9 *	--	0.6 *	< 0.5	< 0.14	Charlottesville, VA	Wegmans
Pediasure	Grow & Gain Chocolate Shake	Drink - not 100% fruit	3 *	--	1.3 *	2	< 0.136	Portland, ME	Hannaford
Repone	Suero/Electrolyte Solution with Zinc Fruit Flavor	Drink - not 100% fruit	< 2.2	--	< 0.5	< 0.5	< 0.139	San Diego, CA	Family Dollar
Yoo-hoo	Yoo-hoo Chocolate Drink	Drink - not 100% fruit	2.6 *	--	0.8 *	1.1 *	< 0.134	Houston, TX	Dollar Tree
<b>Meals, including fruits &amp; veggies with grains</b>									
Deluxe Pasta	Macaroni & cheese, Original Flavor	Meal	6.7	--	7	25	< 0.14	Houston, TX	Dollar Tree
Earth's Best	Chicken and Brown Rice Organic Baby Food - 2, 6+ months	Meal	34.4	13	18.3	1.9	0.232 *	Washington, DC	amazon.com
Earth's Best	Organic Turkey Quinoa Apple Sweet Potato Homestyle Meal Puree	Meal	< 2.2	--	1.9	1.9	< 0.139	Columbia, SC	Publix
Earth's Best	Organic Chicken Pot Pie Homestyle Meal Puree	Meal	< 2.2	--	1.2 *	2.1	< 0.139	Columbia, SC	Publix
Gerber	Mashed Potatoes & Gravy with Roasted Chicken and a Side of Carrots - Toddler	Meal	< 2.2	--	2.4	17.5	< 0.139	Portland, ME	Hannaford
Gerber	Chicken Rice Dinner - Sitter 2nd Foods	Meal	19.1	--	2.3 *	8.9	< 0.236	Washington, DC	gerber.com
Gerber	Turkey Rice Dinner - Sitter 2nd Foods	Meal	6.2 *	--	5.2	3.4	< 0.139	Washington, DC	gerber.com
Happy Tot	Love My Veggies Bowl - Cheese & Spinach Ravioli with Organic Marinara Sauce - for tots and tykes	Meal	4.8 *	--	8.5	19.6	0.148 *	Columbia, SC	Publix
Kraft	Macaroni & Cheese Dinner, Original Flavor	Meal	8.1	--	2	38.6	< 0.139	Houston, TX	Dollar Tree
Sprout	Garden Vegetables Brown Rice with Turkey - for 8 months & up, Stage 3	Meal	7.2	--	1.6 *	2.5	< 0.138	Albany, NY	buybuyBABY
Earth's Best	Organic Sweet Potato Cinnamon Flax & Oat - Wholesome Breakfast Puree - 2, for 6+ months	Fruit and veggie - with grain/meat/dairy/legume	< 2.2	--	4.4	4.3	< 0.138	Albany, NY	buybuyBABY
HappyBABY	Apples, Sweet Potatoes & Granola Clearly Crafted Organic Baby Food - 2	Fruit and veggie - with grain/meat/dairy/legume	3.6 *	--	5.2	1.5 *	< 0.142	Washington, DC	Safeway
Parent's Choice (Walmart)	Organic Strawberry Carrot and Quinoa Fruit & Veg Puree - Stage 2, 6+ months	Fruit and veggie - with grain/meat/dairy/legume	2.5 *	--	3.6	1.8	< 0.125	Charlottesville, VA	Walmart
Plum Organics	Apple, Raisin & Quinoa Organic Baby Food - 2 †	Fruit and veggie - with grain/meat/dairy/legume	5.6 *	--	2.2	1.9	0.145 *	Washington, DC	Safeway
Sprout	Butternut Chickpea Quinoa & Dates Organic Baby Food	Fruit and veggie - with grain/meat/dairy/legume	2.3 *	--	0.8 *	< 0.5	< 0.137	Columbia, SC	Publix

APPENDIX A: Laboratory Test Results for Heavy Metals (continued)

Brand	Food	Food type	Arsenic (total, ppb)	Arsenic (inorganic, ppb)	Lead (ppb)	Cadmium (ppb)	Mercury (total, ppb)	Metro area where purchased	Retailer
<b>Meat</b>									
Beech-Nut	Classics Chicken & Chicken Broth - 1	Meat	< 2.2	--	< 0.5	< 0.5	< 0.137	Washington, DC	Safeway
Beech-Nut	Classics Turkey and Turkey Broth - Stage One	Meat	< 2	--	1 *	< 0.5	< 0.128	Charlottesville, VA	Wegmans
Gerber	Lil' Sticks Chicken Sticks - Toddler	Meat	< 2.2	--	3.5	2.3	< 0.138	Washington, DC	Safeway
Gerber	Beef and Gravy 2nd foods	Meat	< 2.1	--	2.1	< 0.5	0.251 *	Columbia, SC	Publix
Gerber	Ham and Gravy 2nd foods	Meat	< 2.2	--	1 *	< 0.5	< 0.141	Columbia, SC	Publix
O Organics (Albertson/Safeway)	Strained Organic Turkey and Turkey Gravy Baby Food - 2	Meat	2.7 *	--	1 *	< 0.5	< 0.137	Washington, DC	Safeway
<b>Snacks - Puffs</b>									
Comforts (Kroger)	Blueberry Little Puffs Cereal Snack	Snack - rice puffs	83.3	61	8.5	36.9	0.835	Cincinnati, OH	Kroger
Earth's Best	Sesame Street Organic Peanut Butter Baked Corn Puffs	Snack - puffs, non-rice	< 4.4	--	1.3 *	26	< 0.278	Washington, DC	amazon.com
HappyBABY	Superfood Puffs - Apple & Broccoli Organic Grain Snack - for crawling baby	Snack - rice puffs	266	83	8.2	11	2.16	Albany, NY	buybuyBABY
HappyBABY	Superfood Puffs Organic Grain Snack - Sweet Potato & Carrot	Snack - rice puffs	295	91	3.7	12.2	1.94	Washington, DC	amazon.com
Gerber	Puffs Banana Cereal Snack - Crawler 8+ months	Snack - rice puffs	44.5	--	9.2	16	0.376 *	Houston, TX	99 Cents Only Stores
O Organics (Albertson/Safeway)	Organic Puffs - Apple Strawberry	Snack - rice puffs	309	133	7.5	15.2	3.29	Washington, DC	Safeway
Simple Truth Organic (Kroger)	Whole Grain Puffs Broccoli & Spinach	Snack - rice puffs	307	126	9.8	13.5	3.68	Cincinnati, OH	Kroger
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
<b>Snacks - Teething biscuits &amp; rice rusks/cakes</b>									
Baby Mum-Mum	Banana Rice Rusks	Snack - teething biscuits & rice rusks/cakes	104	53	5.2	2.3	1.72	Cincinnati, OH	Kroger
HappyBABY	Organic Rice Cakes Puffed Rice Snack - Apple	Snack - teething biscuits & rice rusks/cakes	455	47	1.7	5.4	3.18	Boulder, CO	Whole Foods Market
Meijer	Apple Rice Rusks Baked Rice Snack	Snack - teething biscuits & rice rusks/cakes	50.2	--	3.2 *	3.9	1.99	Detroit, MI	Meijer
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
Simple Truth Organic (Kroger)	Mini Rice Cakes Apple - 7+ months	Snack - teething biscuits & rice rusks/cakes	65.9	--	8.7	0.8 *	1.1	Cincinnati, OH	Kroger



APPENDIX A: Laboratory Test Results for Heavy Metals (continued)

Brand	Food	Food type	Arsenic (total, ppb)	Arsenic (inorganic, ppb)	Lead (ppb)	Cadmium (ppb)	Mercury (total, ppb)	Metro area where purchased	Retailer
Cué tara	Animalitos Galleta Crackers (Animal Crackers)***	Snack - teething biscuits & rice rusks/cakes	4.1 *	--	6.4	25.5	< 0.139	San Diego, CA	99 Cents Only Stores
Gerber	Teether Wheels - Apple Harvest - Crawlers	Snack - teething biscuits & rice rusks/cakes	51.5	--	2.1 *	3.8	0.588 *	Washington, DC	Safeway
HappyBABY	Organic Teethers Blueberry & Purple Carrot - Sitting baby	Snack - teething biscuits & rice rusks/cakes	67	--	6	8.2	2.26	Charlottesville, VA	Wegmans
Lil' Dutch Maid	Saltine Crackers***	Snack - teething biscuits & rice rusks/cakes	10.1	--	1.5 *	19.1	< 0.138	San Diego, CA	99 Cents Only Stores
Meijer	True Goodness Organic Teethers Baked Rice Snack - Vegetable	Snack - teething biscuits & rice rusks/cakes	65	36	3.9	6.7	2.41	Detroit, MI	Meijer
Nosh!	Baby Munchables Organic Teething Wafers - Banana & Mango	Snack - teething biscuits & rice rusks/cakes	110	62	6.6	3.1 *	3.44	Detroit, MI	Meijer
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
<b>Snacks - Other (yogurt, biscuits, bars)</b>									
Beech-Nut	Breakfast On-the-Go Yogurt, Banana & Mixed Berry Blend - Stage 4 from about 12 months	Snack - other	< 2.2	--	0.7 *	< 0.5	< 0.139	Charlottesville, VA	Wegmans
Earth's Best	Sesame Street Organic Fruit Yogurt Smoothie - Apple Blueberry	Snack - other	4.4 *	--	2.5	< 0.5	< 0.135	Portland, OR	Fred Meyer
Earth's Best	Sunny Days Snack Bars - Sweet Potato Carrot	Snack - other	13.9	--	3.8	10.5	0.161 *	Boulder, CO	Whole Foods Market
Ella's Kitchen	Organic Nibbly Fingers - Apples and Strawberries, 1+	Snack - other	27	--	3	7.8	0.216 *	Boulder, CO	Whole Foods Market
Gerber	Yogurt Blends Strawberry Snack - Crawler 8+ months	Snack - other	< 2.1	--	1 *	< 0.5	< 0.135	Gambell, AK	ANICA Native Store
Gerber	Fruit & Veggie Melts - Truly Tropical Blend - Freeze-Dried Fruit & Vegetable Snack - Crawler, 8+ months	Snack - other	22.6	--	12.2	26.8	0.455	Albany, NY	buybuyBABY
Gerber	Arrowroot Biscuits - Crawler 10+ months	Snack - other	13.1	--	12.5	25.9	< 0.279	Washington, DC	walmart.com
Little Duck Organics	100% Pressed Fruit Snacks + Probiotics - Pomegranate, Blueberry & Acai	Snack - other	13.6	--	15	1 *	< 0.138	Albany, NY	buybuyBABY
Nostalgia	Marias Cookies Galletas	Snack - other	3.8 *	--	6.6	22	0.14 *	San Diego, CA	99 Cents Only Stores
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
Plum Organics	Mighty Morning Bar - Blueberry Lemon - Tots: 15 months & up	Snack - other	40 *	39	3.4	24.3	< 0.137	Cincinnati, OH	Kroger

APPENDIX A: Laboratory Test Results for Heavy Metals (continued)

Brand	Food	Food type	Arsenic (total, ppb)	Arsenic (inorganic, ppb)	Lead (ppb)	Cadmium (ppb)	Mercury (total, ppb)	Metro area where purchased	Retailer
SOBISK	Breakfast Biscuits - Golden Oats	Snack - other	9	--	60.1	9.6	0.143 *	Dallas, TX	Dollar Tree
Sprout	Organic Crispy Chews Red Fruit Beet & Berry with Crispy Brown Rice Toddler Fruit Snack	Snack - other	19.2	--	7.7	1.2 *	0.185 *	Charlottesville, VA	Wegmans
<b>Supplement</b>									
Gerber	Soothe Probiotic Colic Drops	Supplement	4.4 *	--	< 0.5	< 0.5	< 0.139	Washington, DC	walmart.com

Notes
<p>The symbol “&lt;” indicates no detection, with a test result less than the indicated limit of detection.</p> <p>The symbol “**” indicates test results that are estimated, between the limit of detection and the limit of quantitation.</p> <p>The symbol “--” indicates that no test was performed.</p> <p>** Total arsenic value is higher than inorganic arsenic value but falls within the allowable and expected analytical error. For example, this ratio of inorganic to total arsenic of 105% falls within the FDA method for arsenic speciation in rice, which allows this ratio to range from 65 – 135%.</p> <p>*** This food was purchased from a dollar store and is not marketed specifically as a baby food. Because dollar stores carry so few standard baby foods, this food is purchased by parents as an alternative, according to information from HBBF’s local partner participating in this study.</p> <p>† Food is no longer manufactured.</p> <p>‡ This value is the average of 3 tests of total arsenic (44, 37, and 39 ppb). The original homogenized bar was tested twice, and homogenate of a second, separate bar from the same box was tested once..</p>

## APPENDIX B: RECENT SCIENCE ON THE IMPACT OF HEAVY METALS TO CHILDREN'S BRAIN DEVELOPMENT

The table below details 23 recent studies on the impact of arsenic, cadmium, lead and mercury on the development of children's brains. Evidence in the scientific literature spans decades; the studies below are a sampling of publications over the past seven years.

Study number	Study	What did the study find?
<b>Metals combinations: Recent studies of children's exposures to toxic-metal combinations and impacts to the developing brain</b>		
1	Grandjean and Landrigan 2014	In this update to their 2006 systematic review, the authors added six chemicals to their earlier review of the science on the toxicity to the developing brain and nervous system of lead, methylmercury, polychlorinated biphenyls, arsenic, and toluene. The authors provide an estimate of 24 million IQ points lost from combined exposures to lead and mercury.
2	Freire 2018	In a study of the cognitive development of 302 Spanish 4 and 5 year old children, researchers found lower scores on pre-school neurodevelopmental tests among children who had been exposed to higher levels of arsenic and mercury during pregnancy, as measured in the placenta at birth. The study also found a synergistic effect between arsenic and lead indicated by lower general cognitive scores.
3	Kim 2018	A study of 140 Korean 1- and 2-year-olds and their mothers compared the chemicals in pregnant women's blood or urine, or in breast milk after delivery, with standard pre-school tests of neurodevelopmental performance. The mothers' blood lead levels were inversely associated with psychomotor development in their children. Pregnant women with higher levels of a combination of heavy metals in their blood also had children with more behavior problems.
4	Pan 2018	Researchers tested the blood and urine of 530 children ages 9-11 living near an industrialized area and 264 from another town in the same city in South China as a reference. A significant decrease in IQ scores was identified in children from the industrialized town, who had statistically higher geometric mean concentrations of lead, cadmium, and mercury. Blood lead had a significant negative association by itself, and the additive impact of all four metals raised concerns.
5	Lucchini 2019	Scientists studied the effect of co-exposures to socio-economic stressors and arsenic, cadmium, lead, mercury and other metals in schoolchildren in Taranto, Italy. Biomonitoring and an analysis of the distance between the residence of 299 children ages 6 to 12 and point sources of industrial emissions were done along with tests of children's cognitive functions. The researchers found that metal levels in the children's blood and urine had a negative cognitive impact. Lead exposure was shown to have a neurocognitive effect even at very low levels of blood lead concentration for children of low socio-economic status.
<b>Arsenic: Recent studies of children's exposures to arsenic and impacts to the developing brain</b>		
6	Rodríguez-Barranco 2013	This meta-analysis details 13 articles reporting "a significant negative effect on neurodevelopment and behavioural disorders" from arsenic exposure during pregnancy and early childhood.
7	Wasserman 2014	Columbia University researchers report on their assessment of 272 third to fifth graders in Maine who lived in homes with well water. The study found an average loss of 5-6 IQ points among those who drank well water contaminated with arsenic at or above 5 parts per billion. This level is common in some parts of the U.S. and is lower than the legal limit in public water supplies (10 parts per billion).
8	Tsuji 2015	This 2015 literature review identifies 24 studies linking low-level arsenic exposure to neurological harm in children.
9	Signes-Pastor 2019	This study focused on the impact of arsenic exposure from food. The urine of 400 4- and 5-year-olds was tested for arsenic. The children took tests that measure neuropsychological development. Children with higher arsenic levels performed worse on tests of motor function. Boys showed diminished working memory with higher arsenic exposures.
<b>Cadmium: Recent studies of children's exposures to cadmium and impacts to the developing brain</b>		
10	Sanders 2015	This review of recent scientific literature found 16 studies on cadmium's neurotoxic impacts to children. In these studies, lower IQ scores and more learning disorders and special education needs were correlated to higher cadmium levels in children.
11	Gustin 2018	A study of 1500 mother and child pairs in Bangladesh associated prenatal and childhood cadmium exposure with lower intelligence in boys. In girls, there were indications of altered behavior for both prenatal and childhood exposure.
12	Lee 2018	A study of 76 children with ADHD and 46 control children found cadmium levels negatively correlated with Full Scale Intelligence Quotient.
13	Al Osman 2019	This scientific review references studies that link children's cadmium exposure to IQ loss and other health endpoints, including kidney disease, osteoporosis, cardiovascular disease, stunted growth, and pediatric cancer.

APPENDIX B: Recent Science on the Impact of Heavy Metals on Children's Brain Development (continued)

Study number	Study	What did the study find?
<b>Lead: Recent studies of children's exposures to lead and impacts to the developing brain</b>		
14	NTP 2012	The National Institutes of Health's National Toxicology Program evaluation of the toxicity of low-level lead exposure concludes that such exposures are responsible for intellectual deficits, diminished academic abilities, attention deficits, and problem behaviors, including impulsivity, aggression, and hyperactivity in children.
15	Zhang 2013	An analysis of the blood lead tests recorded before the age of 6 and the standardized test scores in grades 3, 5 and 8 of 21,281 students in the Detroit Public Schools found that early childhood lead exposure was negatively associated with academic achievement in elementary and junior high school.
16	Evens 2015	The study compared Chicago's birth registry, the blood lead registry and the scores on 3rd grade iSAT tests for 58,650 children. After adjusting for poverty, race/ethnicity, gender, maternal education and very low birth weight or preterm birth, the study concluded "Early childhood lead exposure is associated with poorer achievement on standardized reading and math tests in the third grade, even at very low blood lead levels."
17	Liu 2014	A study of 1341 children in the Jiangsu province of China compared blood lead at ages 3 to 5 with behavioral problems at age 6 and found a significant association. The authors report that the risk of clinical-level behavioral problems increased with blood lead concentration.
18	Lewis 2018	This study's 278 study participants were drawn from a large longitudinal study in Cleveland, Ohio that is examining the developmental effects of prenatal cocaine exposure. The children's blood was tested for lead at age 4, and their language skills were assessed at 4, 6, 10 and 12 years of age. The researchers found that lead exposure harmed both receptive and expressive language skills. Prenatal drug exposure was not related to the effects of lead on language skills.
19	Donzelli 2019	A systematic review of studies on the relationship between lead exposure and the diagnosis of ADHD identified 17 studies reporting an association between lead and ADHD.
<b>Mercury: Recent studies of children's exposures to mercury and impacts to the developing brain</b>		
20	Karagas 2012	A review of the literature on the health effects of low-level exposure to methylmercury concentrated on studies that include measurement of this toxic chemical in blood and hair of pregnant women and their children. The consistent finding in the researchers' review of the science on neurocognitive and behavior outcomes was the connection between prenatal mercury levels and psychomotor function, memory, verbal skills cognition in 7- to 14-year-old children.
21	Jacobson 2015	A 2015 study in Environmental Health Perspectives compared the IQs of 282 school-age children with the levels of mercury in umbilical cord blood taken at birth. The researchers found that prenatal mercury levels were associated with lower scores on school-age IQ tests.
22	Ryu 2017	A study of 458 mother child pairs in Korea found that blood mercury levels during late pregnancy and early childhood were associated with more autistic behaviors in children at 5 years of age, as assessed using the Social Responsiveness Scale.
23	Bellinger 2019	To derive an estimate of the global burden of intellectual disability from prenatal exposure to mercury, scientists conducted a meta-analysis of the available science and determined a dose-effect relationship of IQ reductions to increases in maternal hair mercury levels.

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# APPENDIX C: LABORATORY ANALYSIS – SUMMARY OF METHODS FOR HEAVY METALS TESTING

## BACKGROUND

HBBF commissioned a national laboratory recognized for its expertise in heavy metals analysis, Brooks Applied Labs (BAL) near Seattle Washington (<http://brooksapplied.com/>), to test 168 containers of baby food for total recoverable arsenic, lead, cadmium, and mercury; and speciated arsenic for a subset of samples.

BAL is accredited through the National Environmental Accreditation Program (NELAC), the Department of Defense (DOD), and the International Organization for Standardization (ISO). It has also earned state accreditations for a variety of metals analyses, including arsenic and mercury. It uses the most current microwave digestion and ICP-MS technologies, and specializes in heavy metals testing (including arsenic, lead, cadmium, and mercury). BAL's clients include local governments, industry, the federal government, and engineering consulting firms.

BAL specializes in low-level metal analysis, including analysis in food. It has tested a wide range of baby foods. Its sensitive methods can detect heavy metals in a wide range of baby food types, including grains, dairy, fruits and vegetables, and meat.

For the heavy metals analyses used in this study, BAL is accredited according to the ISO 17025 standard. BAL's methods are comparable to FDA methods (FDA 2012,2015), with two notable differences: 1) The extraction acid used by BAL gives optimum results specifically for the food type being analyzed, according to tests of a range of acids and other solvents; and 2) BAL achieves a lower limit of quantification (LOQ) for the analysis of inorganic arsenic than FDA. Other major analytical techniques are comparable: for example, both BAL and FDA rely on chromatography methods to separate arsenic species, and ICP-MS methods to detect heavy metals.

## SAMPLE PREPARATION

**Baby food receipt and storage:** BAL received 168 baby food containers in April and May 2019. BAL logged in samples for the analysis of total recoverable arsenic [As], cadmium [Cd], lead [Pb], and mercury [Hg].

BAL received and stored all samples according to BAL Standard Operating Procedures (SOPs) and EPA methodology. Samples were stored at ambient temperature, maintaining the shipping temperature of the samples. Once containers were opened and aliquots obtained for testing, samples were frozen.

**Sample homogenization:** Any foods which were heterogeneous (e.g., snack bars) were thoroughly homogenized prior to sample digestion. All equipment used for the homogenization process was pre-cleaned beforehand and subject to routine testing to ensure the accuracy of sample data.

**Sample digestion:** BAL prepared samples by the addition of hydrogen peroxide (H<sub>2</sub>O<sub>2</sub>) and concentrated nitric acid (HNO<sub>3</sub>) to a microwave digestion vessel, via method AOAC 2015.01, modified. BAL digested samples at a precise pressure and temperature in a controlled microwave digestion program.

## TOTAL METALS ANALYSIS BY AOAC 2015.01, MOD.

BAL developed method AOAC 2015.01, Mod (Heavy Metals in Food: Inductively Coupled Plasma-Mass Spectrometry) for analysis of total recoverable metals. The method was accepted as a First Action Method by the consensus standards developing organization AOAC, placing it in AOAC's process leading to formal method adoption.

BAL analyzed total recoverable As, Cd, and Pb according to this method, using inductively coupled plasma triple

quadrupole mass spectrometry (ICP-QQQ-MS). The ICPQQQ-MS method uses advanced interference removal techniques to ensure accuracy of the sample results. This technology allows for the removal of polyatomic and doubly-charged ions that can interfere with an isotope. This is a critical step for arsenic analysis, since arsenic is a monoisotopic element. For more information, visit the Interference Reduction Technology section on BAL's website, [brooksapplied.com](http://brooksapplied.com).

## TOTAL MERCURY ANALYSIS BY EPA METHOD 1631

BAL prepared samples for Hg analysis using the AOAC 2015.01, modified method, as described above. BAL analyzed sample preparations with stannous chloride (SnCl<sub>2</sub>) reduction, single gold amalgamation, and cold vapor atomic fluorescence spectroscopy (CVAFS) detection using a Brooks Rand Instruments MERX-T CVAFS Mercury Automated-Analyzer. The laboratory then blank corrected the Hg results as described in the relevant BAL SOP and evaluated results using adjusted reporting limits to account for sample aliquot size.

## ARSENIC SPECIATION ANALYSIS

**Sample digestion:** BAL digested baby food samples for arsenic speciation using a solution of trifluoroacetic acid (TFA). The TFA digestion method typically induces conversion of As(V) to As(III) in the samples and matrix spikes and induces conversion of As(III) to As(V) in the blank spikes. (This is also a characteristic of FDA's method.) Therefore, the accurate measurement resulting from this method is total inorganic arsenic (the sum of As(V) and As(III)), rather than results from individual valence states.

**Analysis of arsenic speciation:** Extracts from digestion were analyzed for total inorganic arsenic [InorgAs] (sum of As(III) and As(V)), monomethylarsonic acid [MMAs], and

dimethylarsinic acid [DMAs] using ion chromatography inductively coupled plasma collision reaction cell mass spectrometry (IC-ICP-CRC-MS). This method uses chromatography to separate the different arsenic species and ICP-CRC-MS to detect the arsenic. The CRC is an interference reduction technology to remove polyatomic ions that can interfere with arsenic.

## QA/QC AND CERTIFICATION

**Quality Assurance and Quality Control:** All analyses were conducted in accordance with BAL's Standard Operating Procedures. Each preparation batch also included four method blanks (BLKs), a laboratory fortified blank (BS), a certified reference material (SRM), a laboratory duplicate (DUP), and a matrix spike/matrix spike duplicate (MS/MSD) set. Post-preparation spikes (PS) were also included in the arsenic speciation batches. The sample results were reviewed and evaluated in relation to the QA/QC samples worked up at the same time. The BS recoveries, SRM recoveries, PS recoveries, and method blanks were evaluated against method criteria to ensure data quality.

**BAL certification:** BAL is ISO certified for elemental analyses (including arsenic, lead, cadmium, and mercury) and arsenic speciation analysis in food.

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## APPENDIX D: LABORATORY TEST RESULTS FOR PERCHLORATE

Results for analysis of perchlorate in a limited number of baby foods are listed below. Testing was commissioned by HBBF and performed by Southwest Research Institute, San Antonio, TX. The detailed laboratory report (SWRI 2019) is provided under “Resources” in HBBF’s online version of this heavy metals study, at [healthybabyfood.org](http://healthybabyfood.org).

Twenty-five foods were tested for perchlorate, with containers purchased from supermarkets near Washington DC and from online retailers. These 25 foods were also included in the heavy metals testing described in this report, but perchlorate testing was performed using food samples extracted from a separate container. The table below also lists the number of heavy metals detected in each of these foods, from Appendix A, to provide information on the full range of neurotoxic contaminants covered in this study and detected in the foods chosen for testing. This limited perchlorate testing is intended to spur further testing and research on perchlorate in baby food. It is not necessarily representative of perchlorate levels across the baby food market, but instead provides a snapshot of levels in containers of these 25 foods.

The qualifier “<” indicates that the perchlorate concentration was below the method detection limit, while “(\*)” indicates that the arsenic concentration was near the method detection limit and was estimated.

Brand	Food	Food type	Perchlorate (ppb)	Number of heavy metals detected in this food**
Healthy Times	Organic Brown Rice Cereal - 4+ months	Cereal - rice	7.1	4
Gerber	Rice Single Grain Cereal	Cereal - rice	4.6	4
BioKinetics	BioKinetics Brown Rice Organic Sprouted Whole Grain Baby Cereal	Cereal - rice	< 3.2	4
Beech-Nut	Rice Single Grain Baby Cereal - Stage 1, from about 4 months	Cereal - rice	< 3.2	4
Earth’s Best	Whole Grain Rice Cereal	Cereal - rice	< 3.2	4
Gerber	Oatmeal Single Grain Cereal	Cereal - oatmeal	7.7	3
Beech-Nut	Oatmeal Whole Grain Baby Cereal - Stage 1, from about 4 months	Cereal - oatmeal	4.2	3
Earth’s Best	Whole Grain Oatmeal Cereal	Cereal - oatmeal	2.7 *	3
HappyBABY	Oatmeal Baby Cereal, Clearly Crafted - Organic Whole Grains - for sitting baby	Cereal - oatmeal	1.6 *	2
Gerber	MultiGrain Cereal - Sitter 2nd Foods	Cereal - mixed and multi-grain	8.7	4
HappyBABY	Oats & Quinoa Baby Cereal Organic Whole Grains with Iron - Sitting baby	Cereal - mixed and multi-grain	2.4 *	3
Gerber	Whole Wheat Whole Grain Cereal - Sitter 2nd Foods	Cereal - other single-grain	4.2	3
NurturMe	Organic Quinoa Cereals - Quinoa + Sweet Potato + Raisin	Cereal - other single-grain	3.5	4
Gerber	Barley Single Grain Cereal- Supported Sitter 1st Foods	Cereal - other single-grain	3.3	3
Similac	Similac Advance OptiGRO Powder - Milk-Based	Formula	11.4	2
Earth’s Best	Organic Sensitivity - DHR/ARA Infant Formula with Iron Organic Milk-Based Powder	Formula	1.5 *	2
Enfamil	ProSobee Soy Infant Formula, Milk-Free Lactose-Free Powder with Iron	Formula	< 3.2	3
Earth’s Best	Spinach and Potato Organic Baby Food - 2, 6+ months	Veggie - mixed	19.8	3
Beech-Nut	Organics Just Carrots - Stage 1	Veggie - single - carrot	2.3	4
Parent’s Choice (Walmart)	Carrot - Stage 2, 6+ months	Veggie - single - carrot	0.64 *	2
HappyBABY	Simple Combos Apples, Spinach & Kale - 2	Fruit and vegetable - mixed	3.7	4



APPENDIX D: Laboratory Test Results for Perchlorate (continued)

Brand	Food	Food type	Perchlorate (ppb)	Number of heavy metals detected in this food**
Plum Organics	Mighty Morning Bar - Blueberry Lemon - Tots: 15 months & up	Snack - bar	1.8 (J)	3
HappyBABY	Superfood Puffs - Apple & Broccoli Organic Grain Snack - for crawling baby	Snack - puffs	< 3.2	4
Baby Mum-Mum	Banana Rice Rusks	Snack - rice rusks and rice cakes	4.6	4
HappyBABY	Organic Rice Cakes Puffed Rice Snack - Apple	Snack - rice rusks and rice cakes	< 3.2	4

Notes
<p>The symbol “&lt;” indicates no detection, with a test result less than the indicated limit of detection.</p> <p>The symbol “*” indicates test results that are estimated, between the limit of detection and the limit of quantification.</p> <p>** Heavy metal test data can be found in Appendix A. Perchlorate and metals tests used food from separate containers for each food, not a single container.</p>

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# APPENDIX E: RESULTS OF IQ ANALYSIS: 15 FOODS ACCOUNT FOR OVER HALF OF TOTAL IQ LOSS FROM CHILDREN'S EXPOSURES TO ARSENIC AND LEAD IN BABY FOOD

Healthy Babies Bright Futures (HBBF) commissioned a new study from Abt Associates (Abt) to quantify the health impacts posed by multiple heavy metals in baby food. This work gives first-ever estimates of the population-wide decline in IQ from children's exposures to lead and arsenic in food, from birth to 24 months of age. It also gives the 15 baby foods that collectively account for 55 percent of the total IQ loss from these exposures.

## DATA USED IN IQ LOSS ANALYSIS

The analysis relies on two data sources published by the federal government:

**Foods babies eat:** What We Eat in America (WWEIA) data – 24-hour food recall data collected as part of The National Health and Nutrition Examination Survey (NHANES) – contains dietary intake measurements for the U.S. population, including babies. Dietary data are collected for up to two days for each respondent, including food type and quantity consumed. NHANES is run by the CDC's National Center for Health Statistics (NCHS) and was designed to collect information on the health and nutritional status of the U.S. civilian, non-institutionalized population through in-home interviews and physical examinations. Abt used this data to represent babies' daily food intake in this analysis.

**Arsenic and lead levels in baby food:** FDA's Total Diet Study (TDS), an ongoing FDA program, collects information on levels of various contaminants, including arsenic and lead, that occur in food and beverages commonly consumed by the U.S. population. FDA buys these foods as a consumer would, prepares them as directed, and then

analyzes the prepared foods for levels of the contaminants of interest. This process yields nationally representative estimates of contaminant levels in approximately 280 kinds of food and beverages. Abt used TDS arsenic and lead data to represent contaminant levels in the foods babies eat.

## ESTIMATING CHILDREN'S INTAKE OF ARSENIC AND LEAD

Steps and assumptions in estimating children's arsenic and lead intake include:

**Mapping the food intake and concentration datasets:** A mapping file<sup>1</sup> pairs TDS foods with similar foods included in the WWEIA dataset. The mapping file covers 2014-2016 TDS data cycles; Abt used all three of these years of data to represent the lead and arsenic levels in foods children eat. For WWEIA, FDA's mapping file covers 2003-2014. Abt used a subset of those years, WWEIA data cycles from 2009-2014, to represent the foods children eat. The earlier years of WWEIA data covered in FDA's mapping file (2003-2008) were considered less representative of children's current eating habits than the more recent data, and were therefore excluded from the analysis.

**Method used to account for arsenic and lead levels below detection limits:** Abt performed the Xue et al. (2010) method for summarizing values of TDS data that fall below the limit of detection (LOD), assigning half the LOD to values below the LOD if there was at least one detection among the many samples taken of each particular food; otherwise a value of 0 was assigned.

**Estimating children's intake of lead and arsenic:** Abt matched mean values for each TDS food with each food consumed in the WWEIA dataset according to the mapping file. The intake of arsenic and lead for each food consumed was calculated as the product of the concentration of each metal and the mass of each food consumed during the survey's period of record.

**Criteria for inclusion of surveyed children:** Abt included in the analysis all children with two days of dietary data from WWEIA, and used the mean lead/arsenic consumption value between the two days to represent each child's average daily lead/arsenic intake.

## ESTIMATING INORGANIC ARSENIC CONCENTRATIONS

FDA tests TDS foods for total arsenic, as opposed to inorganic arsenic. Inorganic arsenic is the form considered in studies of arsenic exposure and IQ loss, and for which concentration-response functions have been developed. Studies indicate that inorganic arsenic is more toxic than other forms (Abt 2017). Therefore, it was necessary to scale the total arsenic consumed by children to represent the portion that was inorganic. In the absence of more specific information, Abt assumed that 70 percent of total arsenic consumed in food was comprised of inorganic arsenic, as was done by the European Food Safety Authority in their 2014 report entitled "Dietary exposure to inorganic arsenic in the European population" (EFSA 2014). In certain cases, exceptions to the application of this rule were made using information about the arsenic makeup of particular foods as specified in Cubadda et al. (2017).

<sup>1</sup> provided by FDA to Abt (via personal correspondence)

Using this information, Abt assumed:

- 95% of total arsenic is inorganic in beverages, and 100% of total arsenic is inorganic in bottled water.
- 80% of total arsenic is inorganic in fruit.
- 60% of total arsenic is inorganic in rice.
- 95% of total arsenic is inorganic in wheat.
- 5% of total arsenic is inorganic in fish and shellfish, including New England clam chowder and tuna casserole.
- 90% of total arsenic is inorganic in vegetables.

In addition, Abt assumed the following inorganic arsenic compositions based on independent testing from data provided by HBBF, from laboratory results presented in HBBF (2017):

- 61% of total arsenic is inorganic in infant rice cereal.
- 53% of total arsenic is inorganic in infant multi-grain and non-rice cereals.

Abt also assumed the following inorganic arsenic compositions based on testing performed by FDA, from analysis of data from FDA (2014) provided by EDF (2018):

- 73% of total arsenic is inorganic in grape juice.
- 59% of total arsenic is inorganic in oat ring cereal.
- 56% of total arsenic is inorganic in teething biscuits.

All other foods not specifically mentioned were assumed to have 70% of total arsenic as inorganic arsenic, per EFSA (2014).

## ESTIMATING IQ LOSS FROM LEAD

Abt used the following steps to estimate IQ loss from lead intake:

1. Calculated baseline concurrent childhood lead uptake for each year of age from 0 to 7. Other sources of lead were accounted for by using U.S. Environmental Protection Agency's (EPA's) default levels for air, drinking water, and soil/dust lead exposure, as outlined in the agency's User's Guide for the Integrated Exposure Uptake Biokinetic model for Lead in Children (IEUBK), excluding the contribution from food (EPA 2007). These estimates were input into approximation equations from EPA's IEUBK model that were derived by Zartarian et al. (2017) to convert this baseline lead uptake to blood lead level (without food intake).

2. Estimated the lead consumption from WWEIA's contribution to the child's blood lead level by converting lead consumption to lead uptake (assuming 50% lead uptake from dietary ingestion), and the same estimation equations of EPA's IEUBK model described in Step 1 to convert the baseline lead uptake estimated above plus the additional lead uptake from food to blood lead level (with food intake).

3. Assumed each child's daily lead intake from food was equal to their survey-specific lead intake for the entire year of their age in the WWEIA data, and equal to the population-wide mean lead intake from food for every other year of life.. For example, the estimated mean lead intake for a child when they were one year old (assuming they are not one year old in the WWEIA data) is represented by calculating the mean lead intake of all one-year-olds in the dataset.

4. Calculated lifetime blood lead without food by taking the average of the baseline concurrent blood lead levels for each year of life as estimated by the Zartarian et al. (2017) IEUBK estimation equations (in Step 1). Calculated lifetime blood lead with food by taking the average of the mean value of blood leads with both other sources of lead and food in the data (from step 2) for each year of life, except

for the year of each child's age in the WWEIA data, which is represented by their personal blood lead level with the added contribution from food (as described above).

5. Used the Crump et al. (2013) concentration-response function to estimate the lifetime IQ loss due to the difference in lifetime blood lead level based on the contribution of lead in food using the following equation:

$$IQ\ Loss = \beta \times \ln\left(\frac{PbB_1 + 1}{PbB_2 + 1}\right)$$

where:

Beta = -3.25

$PbB_1$  = Baseline lifetime blood lead level without food

$PbB_2$  = Baseline lifetime blood lead level including food contribution

## ESTIMATING IQ LOSS FROM INORGANIC ARSENIC

Abt used the following steps to estimate IQ loss as a result of inorganic arsenic intake:

1. Assumed each child's inorganic arsenic intake was equal to their personal inorganic arsenic intake for the entire of their current age, and equal to the population-wide mean inorganic arsenic intake for every other year of life specific to that year of life and the study population. For example, the mean inorganic arsenic intake for a child when they were one year old (assuming they are not one year old in the WWEIA data) is represented by calculating the mean inorganic arsenic intake of all one-year-olds in the dataset.

2. Calculated lifetime inorganic arsenic consumption from food by taking the average of the mean inorganic arsenic consumption figures from the dataset for each year of life, except for the year of each child's age in the WWEIA data, which is represented by their personal mean daily inorganic arsenic intake (as described above).

3. Used a concentration-response function based on a study by Wasserman et al. (2004), as described in Abt 2017, to estimate lifetime IQ loss based on arsenic drinking water concentration:

$$IQ\ Loss = \beta \times \Delta AsDW$$

where:

Beta = 0.44

$\Delta AsDW$  = Change in arsenic drinking water concentration

4. Converted lifetime inorganic arsenic consumption from food (from Step 2) to an approximate drinking water concentration by assuming that each child in the Wasserman et al. (2004) consumes 1 Liter of water per day, as was done by CalEPA when deriving a chronic Reference Exposure Level for inorganic arsenic consumption in 2008 (CalEPA, 2008). This was necessary to match the concentration-response function in Step 3.

Because the Wasserman et al. (2004) concentration-response function for IQ loss is linear, the approximate equivalent drinking water concentration calculated in Step 4 represents the change in arsenic drinking water concentration used in the equation in Step 3. In other words, the IQ loss for a population with any background level of arsenic exposure using the Wasserman et al. (2004) function will always be equal to the change in arsenic concentration from the calculation in Step 4 multiplied by the beta. This differs from the lead analysis, where the background exposure from other sources matters due to the log transformation of lead in the concentration-response function.

### ESTIMATING TOTAL LIFETIME IQ LOSS FROM LEAD AND ARSENIC IN FOODS BABIES EAT

Total IQ loss from food was estimated as the sum of the lifetime IQ loss due to lead consumption from food with the lifetime IQ loss due to inorganic arsenic consumption from food.

### DEFINING THE CONTRIBUTION OF EACH FOOD TO IQ LOSS

Total IQ loss was estimated for each food from the TDS based on lead consumption alone, arsenic consumption alone, and lead consumption and arsenic consumption combined. It was necessary to calculate the lifetime IQ loss for each instance that a food was consumed individually, since the method for calculating lead uptake is specific to age. Thus, an instance of food consumption of the same food in the same amount could be responsible for two different magnitudes of IQ loss due to lead if the two children who consumed the food were of different ages.

Lifetime IQ loss from lead was calculated for each instance of food consumption using the IQ Loss equation as above. However, PbB2 was assumed equal to baseline lifetime blood lead level plus the additional blood lead from the consumption of that one food for the current year of their life. All other years of blood lead averaged into the lifetime blood lead equation for PbB2 are assumed equal to the baseline. Each of these incremental IQ losses due to each instance of a particular food being consumed were multiplied by their respective survey weight, and summed to estimate the total IQ loss attributable to each food across the population of children.

Lifetime IQ loss from arsenic was calculated using the concentration response function above for each food consumption instance, but was then multiplied by the survey weight, and summed to estimate the total IQ loss attributable to each food across the population of children.

These two IQ losses for each food were then added together to estimate the total IQ loss from each food due to both lead and arsenic combined.

### ESTIMATING POPULATION-WIDE TOTAL LIFETIME IQ LOSS DUE TO LEAD, ARSENIC, AND LEAD AND ARSENIC COMBINED

Total IQ loss due to lead, arsenic, and lead and arsenic combined were calculated by multiplying each child's estimated lifetime IQ loss from each of these sources by the corresponding survey weight, and summed together for all children aged zero to less than two in the survey data.

### LIMITATIONS

A baseline level of inorganic arsenic could not be estimated; it was necessary for us to use a linear concentration-response function relating inorganic arsenic to IQ loss. Thus, Abt was unable to provide a range of results related to the many concentration response functions presented in Abt's previous arsenic analysis (Abt 2017). There is a great deal of uncertainty in the inorganic arsenic dose conversions, and it should be noted that Abt is assuming that the linear extrapolation holds for different population and lower doses compared to the original studies. Estimates of IQ loss from lead in food are considered to be lower-bound estimates, from Abt's experience applying a range of accepted concentration-response functions from other studies. HBBF recommends that future work to estimate IQ loss from heavy metals in food include a full range of accepted functions, for a more comprehensive view of potential health impacts for children.

## INTERPRETATION OF RESULTS: LIFETIME CONSUMPTION AND IQ LOSS

Results are presented in Abt (2019b) for children under the age of two. The results reflect lifetime consumption / IQ loss, and are focused on the group of children in the WWEIA data who are ages 0 to 2 at the time of the survey.

## RESULTS OF THE ANALYSIS

Results are detailed in Abt 2019b. Abt estimates more than 11 million IQ points lost among children ages 0-24 months from exposure to arsenic and lead in food. The table below shows the top 15 foods contributing to IQ loss for those children, from an analysis of all WWEIA foods that are matched to TDS foods.

Food consumed by child age 0 - 24 months	Percent of total harm (fraction of total IQ points lost for children under 2, from lead and arsenic in food)	Primary toxic metal of concern	Of these foods: Rank for potency (considering average IQ points lost per child eating the food; 1=highest, 15=lowest)	Food name from FDA's Total Diet Study (TDS) - source of As/Pb concentration data	Food name(s) from What We Eat in America survey (WWEIA)*, source of data on food types and amounts that children eat
Rice dishes, including with beans & veggies	10.0%	Arsenic	1	Fried rice, meatless, from Chinese carry-out	SPANISH RICE; RICE W/ BEANS; FLAVORED RICE&PASTA MIXTURE (INCL RICE-A-RONI); and other rice dishes
Milk, whole	8.4%	Arsenic	7	Milk, whole, fluid	MILK, COW'S, FLUID, WHOLE
Rice, white and brown	7.0%	Arsenic	6	Rice, white, enriched, cooked	Rice, white, cooked, fat not added in cooking; Rice, white, cooked, fat added in cooking, made with oil; RICE, WHITE, COOKED, REGULAR, NO FAT ADD IN COOKING
Apple juice	6.1%	Arsenic	10	Apple juice, bottled; BF, juice, apple	APPLE JUICE; APPLE JUICE, BABY
Infant formula	5.3%	Lead	4	BF, Infant formula, milk-based, iron fortified RTF	ENFAMIL LIPIL, W/ IRON, INFANT FORMULA, PREP FROM PDR; SIMILAC ADVANCE, W/ IRON, INFANT FORMULA, PREP FROM PDR; Similac Advance, infant formula, prepared from powder, made with baby water; and other infant formulas
Fruit juice blend (100% juice)	4.1%	Arsenic	8	Fruit juice blend (100% juice), canned/bottled	FRUIT JUICE BLEND, 100% JUICE
Infant rice cereal	2.7%	Arsenic	3	BF, cereal, rice, dry, prepared w/ water	RICE CEREAL, BABY, DRY, INSTANT
Grape juice	2.0%	Lead and arsenic	5	Grape juice, frozen conc, reconstituted; BF, juice, grape	GRAPE JUICE
Cheerios and other oat ring cereals	1.6%	Arsenic	12	Oat ring cereal	CHEERIOS; HONEY NUT CHEERIOS
Sweet potato (baby food)	1.6%	Lead and arsenic	2	BF, sweet potatoes	SWEETPOTATOES, BABY, STRAINED; SWEETPOTATOES, BABY, JUNIOR
Soft cereal bars and oatmeal cookies	1.4%	Arsenic	11	Granola bar, w/ raisins	Kellogg's Nutri-Grain Cereal Bar; COOKIE, OATMEAL; COOKIE, OATMEAL, W/ RAISINS OR DATES

Food consumed by child age 0 - 24 months	Percent of total harm (fraction of total IQ points lost for children under 2, from lead and arsenic in food)	Primary toxic metal of concern	Of these foods: Rank for potency (considering average IQ points lost per child eating the food; 1=highest, 15=lowest)	Food name from FDA's Total Diet Study (TDS) - source of As/Pb concentration data	Food name(s) from What We Eat in America survey (WWEIA)*, source of data on food types and amounts that children eat
Macaroni and cheese	1.4%	Lead and arsenic	13	Macaroni and cheese, prepared from box mix	Macaroni or noodles with cheese, made from packaged mix; MACARONI OR NOODLES W/ CHEESE; MACARONI/NOODLES W/ CHEESE, MADE FROM DRY MIX
Puffs and teething biscuits	1.3%	Lead and arsenic	9	BF, teething biscuits	GERBER FINGER FOODS, PUFFS, BABY FOOD; Cookie, teething, baby; Cookie, fruit, baby food; Finger Foods, Puffs, baby food
Bottled drinking water	1.2%	Arsenic	15	Bottled drinking water (mineral/spring), not carbonated or flavored	WATER, BOTTLED, UNSWEETENED; Water, baby, bottled, unsweetened
Fruit yogurt	1.2%	Lead	14	Yogurt, lowfat, fruit-flavored	YOGURT, FRUIT VARIETY, WHOLE MILK; YOGURT, FRUIT VARIETY, LOWFAT MILK

Notes

\* What We Eat in America (WWEIA) dataset: Many foods are matched to a single TDS food in Abt's calculation method (per FDA's mapping file). Foods shown above are those most commonly consumed by children 0-24 mo, from among the WWEIA foods matched to each listed TDS food.

Results shown above for IQ loss and potency ranking correspond to children from 0-24 months old

BF = baby food, in TDS food names

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## ADDENDUM - REVISIONS TO FDA'S MAPPING FILE

In calculations described above, Abt assumed the following matches that differed from the FDA's original mapping file, to provide more representative concentration estimates where inexact FDA matches yielded inappropriate estimates. In these cases, high arsenic levels in clam chowder from the TDS dataset were inconsistent with arsenic levels typical for the matched foods from WWEIA listed below.

**TDS food from FDA mapping file:** Clam chowder, New England, canned, cond, prepared w/ whole milk

- **WWEIA matched foods:** CHICKEN NOODLE SOUP, CREAM OF; CHICKEN SOUP, CREAM OF, PREPARED W/ WATER; CHICKEN/TURKEY SOUP, CM OF, CAN, RED SOD, W/ MILK; CHICKEN SOUP, CREAM OF, NS AS TO MILK OR WATER
- **Revised TDS food:** Assume 50/50 mixture of these 2 TDS foods: TDS food #1: Soup, chicken noodle, canned, cond, prepared w/ water; and TDS food #2: Milk, whole, fluid
- **WWEIA matched foods:** POTATO SOUP, CREAM OF, W/ MILK; POTATO SOUP, NS AS TO MADE W/MILK OR WATER; POTATO & CHEESE SOUP
- **Revised TDS food:** Assume 50/50 mixture of these 2 TDS foods: TDS food #1: Potato, boiled (w/out peel); and TDS food #2: Milk, whole, fluid
- **WWEIA matched food:** CORN SOUP, CREAM OF, PREPARED W/ WATER
- **Revised TDS food:** Assume 50/50 mixture of these 2 TDS foods: TDS food #1: Corn, fresh/frozen, boiled); and TDS food #2: Milk, whole, fluid
- **WWEIA matched foods:** MUSHROOM SOUP, CREAM OF, PREP W/ MILK; MUSHROOM SOUP, CREAM OF, PREPARED W/ WATER; MUSHROOM SOUP, NFS
- **Revised TDS food:** Assume 50/50 mixture of these 2 TDS foods: TDS food #1: Mushrooms, raw; and TDS food #2: Milk, whole, fluid
- **WWEIA matched food:** CHEDDAR CHEESE SOUP
- **Revised TDS food:** Assume 50/50 mixture of these 2 TDS foods: TDS food #1: Cheese, cheddar, natural (sharp/mild); TDS food #2: Milk, whole, fluid
- **WWEIA matched food:** WHITE SAUCE, MILK SAUCE
- **Revised TDS food:** Milk, whole, fluid

## APPENDIX F: DATA AND CALCULATIONS—AVERAGE HEAVY METALS LEVELS FOR HIGHER-RISK FOODS AND SAFER ALTERNATIVES

The table below summarizes test results from HBBF and FDA for foods highlighted in this report’s charts on higher-risk baby foods and safer alternatives. The tables are the basis of the finding in our study that the safer food choices we list contain 80 percent less arsenic, lead and other toxic heavy metals, on average, than the higher-risk foods. That number is calculated as the average reduction for the 5 food categories shown on the Executive Summary chart entitled “What Parents Can Do.” The foods shown on that chart, and the average total heavy metals levels that are the basis of that calculation, are indicated in the table below.

Study	Food	Number of samples	Metal concentration, parts per billion (ppb)						Source of inorganic arsenic level, and average ratio of inorganic to total arsenic		This food's data is shown in safer-choices food charts in this study	Reference for ratio of inorganic to total arsenic
			Lead	Cadmium	Mercury	Arsenic, total	Arsenic, inorganic	Total metals	Measured - ratio of inorganic to total arsenic is shown below	Calculated - Assumed ratio of inorganic to total arsenic is shown below		
<b>Infant rice cereal (dry, white and brown rice)</b>												
HBBF 2019 Baby Food Study (see Appendix A of this document)	Infant rice cereal (dry, white and brown rice)	7	18.44	14.50	2.13	153.19	105.00	140.07	0.77			HBBF 2019 Baby Food study
HBBF 2017 Arsenic in Infant Cereal Study (HBBF 2017)	Infant rice cereal (dry, white and brown rice)	42					85.00		0.61		X	HBBF 2017
FDA testing, 2013 and 2014 (FDA 2016, Abt 2017)	Infant rice cereal (dry, white and brown rice)	76						103.00				
<b>Other cereals (dry)</b>												
HBBF 2019 Baby Food Study (see Appendix A of this document)	Other cereals (non-rice)	11	8.35	20.18	0.14	23.07	12.23	40.91		0.53		HBBF 2017
HBBF 2017 Arsenic in Infant Cereal Study (HBBF 2017)	Other cereals (non-rice)	63					14.00		0.53		X	HBBF 2017
<b>Infant rice cereal (dry, prepared)</b>												
FDA's Total Diet Study 2014-2017 (FDA 2019)	BF, cereal, rice, dry, prepared with water	14	0.50	3.10	0.17	26.60	16.83	20.60		0.63	X	HBBF 2017 and this study (see Note 6)
<b>Other cereals (dry, prepared)</b>												
FDA's Total Diet Study 2014-2017 (FDA 2019)	BF, cereal, oatmeal, dry, prepared with water	14	0.00	3.20	0.00	3.60	1.91	5.11		0.53		HBBF 2017
FDA's Total Diet Study 2014-2017 (FDA 2019)	BF, cereal, mixed, dry, prepared with water	14	0.88	7.30	0.00	6.50	3.45	11.63		0.53		HBBF 2017
FDA's Total Diet Study 2014-2017 (FDA 2019)	BF, cereal, oatmeal with fruit, prepared with water	14	0.00	3.30	0.00	4.00	2.12	5.42		0.53		HBBF 2017
FDA's Total Diet Study 2014-2017 (FDA 2019)	Average of the 3 TDS Other Cereals above	14	0.29	4.60	0.00	4.70	2.49	7.38			X	



APPENDIX F: Data and Calculations—Average Heavy Metals Levels for Higher-Risk Foods and Safer Alternatives (continued)

Study	Food	Number of samples	Metal concentration, parts per billion (ppb)						Source of inorganic arsenic level, and average ratio of inorganic to total arsenic		This food's data is shown in safer-choices food charts in this study	Reference for ratio of inorganic to total arsenic
			Lead	Cadmium	Mercury	Arsenic, total	Arsenic, inorganic	Total metals	Measured - ratio of inorganic to total arsenic is shown below	Calculated - Assumed ratio of inorganic to total arsenic is shown below		
<b>Carrot, baby food</b>												
HBBF 2019 Baby Food Study (see Appendix A of this document)	Carrots, baby food	12	7.84	12.62	0.17	2.20	1.98	22.62		0.90		Cubadda 2016
FDA's Total Diet Study 2014-2017 (FDA 2019)	BF, carrots	14	8.70	19.00	0.00	1.50	1.35	29.05		0.90		Cubadda 2016
HBBF and FDA studies listed above	Sample-weighted average	26	8.51	17.58	0.04	1.66	1.49	27.62			X	
<b>Sweet potato, baby food</b>												
HBBF 2019 Baby Food Study (see Appendix A of this document)	Sweet potato, baby food	17	10.35	2.62	0.07	5.67	5.10	18.14		0.90		Cubadda 2016
FDA's Total Diet Study 2014-2017 (FDA 2019)	BF, sweet	14	13.70	3.60	0.00	1.90	1.71	19.01		0.90		Cubadda 2016
HBBF and FDA studies listed above	Sample-weighted average	31	12.73	3.32	0.02	2.99	2.69	18.76			X	
<b>Other fruits and vegetables, baby food</b>												
HBBF 2019 Baby Food Study (see Appendix A of this document)	Other fruits and vegetables, baby food (excludes carrots and sweet potatoes)	39	2.27	2.41	0.09	3.13	2.66	7.42		0.85	X	Cubadda 2016 (see Note 7)
<b>Fruit juice</b>												
HBBF 2019 Baby Food Study (see Appendix A of this document)		9	2.31	0.36	0.07	3.71	0.83	3.56		0.95		Cubadda 2016
FDA's Total Diet Study 2014-2017 (FDA 2019)	BF, juice, apple	14	0.25	0.00	0.00	3.30	3.14	3.39				
FDA's Total Diet Study 2014-2017 (FDA 2019)	BF, juice, grape	14	2.70	0.00	0.00	13.60	12.92	15.62				
FDA's Total Diet Study 2014-2017 (FDA 2019)	BF, juice, pear	14	1.30	0.75	0.00	4.70	4.47	6.52				
HBBF and FDA studies listed above	Sample-weighted average	51	1.48	0.26	0.00	6.97	6.44	8.18			X	
<b>Alternative to fruit juice - Tap water</b>												
HBBF's Lead in Water Testing Program (HBBF 2019)	Tap water	743	2.00	0.09	NT	0.50	0.50	2.59		1.00	X	Cubadda 2016 (see Note 8)
<b>Puffs (rice)</b>												
HBBF 2019 Baby Food Study (see Appendix A of this document)		7	12.31	20.90	1.94	201.69	81.00	116.16	0.44			EDF 2018 and HBBF 2019 Baby Food Study (see Note 9)
FDA testing, 2013 and 2014 (EDF 2018)		31	19.10	19.30	0.00	119.00	54.90	93.30	0.58			EDF 2018 (see Note 10)
HBBF and FDA studies listed above	Sample-weighted average	38	17.85	19.59	0.36	134.23	59.71	97.51			X	

APPENDIX F: Data and Calculations—Average Heavy Metals Levels for Higher-Risk Foods and Safer Alternatives (continued)

Study	Food	Number of samples	Metal concentration, parts per billion (ppb)						Source of inorganic arsenic level, and average ratio of inorganic to total arsenic		This food's data is shown in safer-choices food charts in this study	Reference for ratio of inorganic to total arsenic
			Lead	Cadmium	Mercury	Arsenic, total	Arsenic, inorganic	Total metals	Measured - ratio of inorganic to total arsenic is shown below	Calculated - Assumed ratio of inorganic to total arsenic is shown below		
<b>Teething biscuits (rice) and rice rusks</b>												
HBBF 2019 Baby Food Study (see Appendix A of this document)	Teething biscuits and rice rusks	10	6.57	4.29	1.95	68.68	41.80	54.61	0.47			EDF 2018 and HBBF 2019 Baby Food Study (see Note 11)
FDA testing, 2013 and 2014 (EDF 2018)	Teething biscuits and rice rusks	27	12.00	9.20	0.00	84.80	46.40	67.60	0.54			EDF 2018 (see Note 12)
HBBF and FDA studies listed above	Sample-weighted average		10.53	7.87	0.53	80.44	45.16	64.09			X	
<b>Alternatives to teething biscuits</b>												
FDA's Total Diet Study 2014-2017 (FDA 2019)	Banana, raw	14	0.00	0.00	0.00	0.00	0.00	0.00				
FDA's Total Diet Study 2014-2017 (FDA 2019)	Cucumber, peeled, raw	14	0.00	1.23	0.00	11.95	10.76	11.99		0.90		Cubadda 2016
FDA studies listed above	Sample-weighted average	28	0.00	0.62	0.00	5.98	5.38	5.99			X	
<b>Non-rice snacks and teethers</b>												
HBBF 2019 Baby Food Study (see Appendix A of this document)	Non-rice snacks and teethers (biscuits, cookies, teethers)	10	8.90	14.20	0.20	15.30	10.71	34.01		0.70		EFSA 2014
<b>Other snacks recommended as alternatives to rice-based snacks</b>												
FDA's Total Diet Study 2014-2017 (FDA 2019)	Apple (red), raw (with peel)	14	0.53	0.00	0.00	2.10	1.68	2.21		0.80		Cubadda 2016
FDA's Total Diet Study 2014-2017 (FDA 2019)	Applesauce: Applesauce, bottled	14	0.00	0.00	0.00	0.59	0.47	0.47		0.80		Cubadda 2016
FDA's Total Diet Study 2014-2017 (FDA 2019)	Bananas	14	0.00	0.00	0.00	0.00	0.00	0.00		0.80		Cubadda 2016
FDA's Total Diet Study 2014-2017 (FDA 2019)	Barley with diced veggies: No data available											
FDA's Total Diet Study 2014-2017 (FDA 2019)	Beans: White beans, dry, boiled	14	0.00	2.60	0.00	0.97	0.68	3.28		0.70		EFSA 2014
FDA's Total Diet Study 2014-2017 (FDA 2019)	Cheese: Cheese, cheddar, natural (sharp/mild)	14	0.59	0.22	0.00	0.00	0.00	0.81		0.70		EFSA 2014
FDA's Total Diet Study 2014-2017 (FDA 2019)	Grapes: Grapes (red/green), raw	14	2.94	0.47	0.00	3.99	3.19	6.60		0.80		Cubadda 2016
FDA's Total Diet Study 2014-2017 (FDA 2019)	Hard-boiled egg	14	0.00	0.00	0.00	0.72	0.50	0.50		0.70		EFSA 2014
FDA's Total Diet Study 2014-2017 (FDA 2019)	Peaches: Peach, raw/frozen	14	0.00	0.54	0.00	4.39	3.51	4.05		0.80		Cubadda 2016
FDA's Total Diet Study 2014-2017 (FDA 2019)	Yogurt: Yogurt, lowfat, fruit-flavored	14	2.65	0.00	0.00	0.00	0.00	2.65		0.70		EFSA 2014

APPENDIX F: Data and Calculations—Average Heavy Metals Levels for Higher-Risk Foods and Safer Alternatives (continued)

Study	Food	Number of samples	Metal concentration, parts per billion (ppb)						Source of inorganic arsenic level, and average ratio of inorganic to total arsenic		This food's data is shown in safer-choices food charts in this study	Reference for ratio of inorganic to total arsenic
			Lead	Cadmium	Mercury	Arsenic, total	Arsenic, inorganic	Total metals	Measured - ratio of inorganic to total arsenic is shown below	Calculated - Assumed ratio of inorganic to total arsenic is shown below		
FDA's Total Diet Study 2014-2017 (FDA 2019)	Average for the snacks listed above	126	0.75	0.43	0.00	1.42	0.00	1.17				
FDA's Total Diet Study 2014-2017 (FDA 2019) and HBBF 2019 Baby Food Study	Average for snacks listed above and the non-rice snacks from this study		1.49	1.68	0.02	2.68	1.89	5.07			X	

Notes
<p>* Sample-weighted averages account for the 3 individual samples that comprise each TDS composite sample.</p> <ol style="list-style-type: none"> <li>1. NT = not tested</li> <li>2. "HBBF 2019 Baby Food Study" refers to this study; individual sample data are shown in Appendix A.</li> <li>3. Zero is shown for metals levels from FDA's Total Diet Study for results that fall below the limit of quantitation. For mercury, a zero may also indicate that the test was not conducted.</li> <li>4. Average inorganic arsenic is calculated from average total arsenic value in cases where HBBF lacked access to data for individual samples.</li> <li>5. Calculations of average levels for FDA TDS data are calculated using the Xue (2010) method for treatment of results below the quantitation limit.</li> <li>6. Ratio of inorganic to total arsenic is the sample-weighted average of data from HBBF 2017 and this study.</li> <li>7. From Cubadda 2017: Inorganic arsenic is 90% total for vegetables, 80% total for fruit. 85% is used here.</li> <li>8. Metals levels shown are averages from HBBF tap water testing from over 700 homes in 43 states.</li> <li>9. Inorganic arsenic for one puffs sample was not measured, and was instead calculated from the change FDA 2013-14 study ratio (EDF 2018).</li> <li>10. Averages are derived from sample data available at EDF 2018.</li> <li>11. Inorganic arsenic for 4 samples were not measured, and were instead calculated from the FDA 2013-14 study ratio (EDF 2018).</li> <li>12. Averages are derived from sample data available at EDF 2018.</li> </ol>

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Healthy Babies Bright Futures (HBBF) is an alliance of scientists, nonprofit organizations and donors working to create and support initiatives that measurably reduce exposures to neurotoxic chemicals in the first thousand days of development.

Our efforts are inspired and supported by science and data, and designed to help restore the chance for a full life to children who would otherwise face brain-diminishing exposures to toxic chemicals beginning in utero.

Learn more at [hbbf.org](http://hbbf.org)

# **EXHIBIT 2**

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

**February 4, 2021**

**[oversight.house.gov](https://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.

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

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

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."<sup>2</sup> 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.<sup>3</sup>

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."<sup>4</sup> 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.<sup>5</sup> For every one IQ point lost, it is estimated that a child's lifetime earning capacity will be decreased by \$18,000.<sup>6</sup>

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

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<sup>1</sup> 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](http://www.sciencedirect.com/science/article/abs/pii/S0048969713003409?via%3Dihub)).

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

<sup>3</sup> 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/](http://www.consumerreports.org/food-safety/heavy-metals-in-baby-food/)).

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

<sup>5</sup> 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/](http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3339460/)).

<sup>6</sup> 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.<sup>7</sup>

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).<sup>8</sup> 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.**”<sup>9</sup>

Studies have concluded that arsenic exposure has a “significant negative effect on neurodevelopment in children.”<sup>10</sup> 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.”<sup>11</sup>

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.<sup>12</sup>

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.<sup>13</sup>

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

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

<sup>9</sup> 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).

<sup>10</sup> *Id.*

<sup>11</sup> *Id.*

<sup>12</sup> 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>).

<sup>13</sup> 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/](http://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.<sup>14</sup> Even small doses of lead exposure are hazardous, particularly to children.<sup>15</sup> 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.<sup>16</sup>

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.<sup>17</sup> 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.<sup>18</sup>

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.<sup>19</sup>

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

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

<sup>16</sup> 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](http://www.fda.gov/food/metals-and-your-food/lead-food-foodwares-and-dietary-supplements)) (accessed Jan. 26, 2021).

<sup>17</sup> 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>).

<sup>18</sup> 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>).

<sup>19</sup> 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/](http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3072933/)).



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

### **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.<sup>21</sup> 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.<sup>22</sup> A 2015 study similarly found a significant inverse relationship between early cadmium exposure and IQ.<sup>23</sup>

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.<sup>24</sup>

### **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.<sup>25</sup> 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."<sup>26</sup> And pre-natal mercury exposure is also related to poorer estimated IQ.<sup>27</sup> Beyond prenatal exposure, higher blood mercury levels at

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<sup>20</sup> 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](http://www.mdpi.com/1660-4601/16/3/382/htm)).

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

<sup>22</sup> 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](http://www.sciencedirect.com/science/article/pii/S0160412017321025)).

<sup>23</sup> 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/](http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4531257/)).

<sup>24</sup> 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/](http://www.ncbi.nlm.nih.gov/pmc/articles/PMC6025252/)).

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

<sup>26</sup> 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>).

<sup>27</sup> 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.”<sup>28</sup>

## **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.<sup>29</sup> Consumer Reports suggests setting inorganic arsenic levels as low as 3 parts per billion (ppb).<sup>30</sup> FDA has already set maximum inorganic arsenic levels at 10 ppb for bottled water.<sup>31</sup> 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).<sup>32</sup>

#### **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).

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<sup>28</sup> 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](http://www.sciencedirect.com/science/article/pii/S0048969717316479)).

<sup>29</sup> 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](http://www.healthybabyfood.org/sites/healthybabyfoods.org/files/2019-10/BabyFoodReport_FULLREPORT_ENGLISH_R5b.pdf)).

<sup>30</sup> 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/](http://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/](http://www.consumerreports.org/food-safety/arsenic-and-lead-are-in-your-fruit-juice-what-you-need-to-know/)).

<sup>31</sup> 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](http://www.fda.gov/food/metals-and-your-food/arsenic-food-and-dietary-supplements)) (accessed Jan. 26, 2021).

<sup>32</sup> Environmental Protection Agency, *Drinking Water Requirements for States and Public Water Systems* (online at [www.epa.gov/dwreginfo/chemical-contaminant-rules](http://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](http://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](http://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.<sup>33</sup> 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)***<sup>34</sup>

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

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.<sup>35</sup>

***Nurture’s Heavy Metal Test Results for Baby Food Products (Excerpted Entries)***<sup>36</sup>

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

<sup>33</sup> 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>).

<sup>34</sup> *Id.*

<sup>35</sup> *Id.*

<sup>36</sup> *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***

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

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

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

***Hain Celestial, FDA Testing Result Investigation, August 1, 2019 (Excerpted Entries)***<sup>38</sup>

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.<sup>39</sup> Hain likewise used a vitamin pre-mix containing 223 ppb arsenic, and raisin and wheat flour containing 200 ppb arsenic.<sup>40</sup> 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.<sup>41</sup>

***Hain, Raw Material Pre-Shipment Test Data History (Excerpted Entries)***<sup>42</sup>

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

<sup>37</sup> 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>).

<sup>38</sup> *Id.*

<sup>39</sup> 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](https://oversight.house.gov/sites/democrats.oversight.house.gov/files/3_0.pdf)).

<sup>40</sup> *Id.*

<sup>41</sup> *Id.*

<sup>42</sup> *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.<sup>43</sup> Test results show that Beech-Nut used at least fourteen other ingredients containing over 300 ppb arsenic.<sup>44</sup> And it used at least 45 ingredients containing over 100 ppb arsenic.

***Beech-Nut, Raw Material Heavy Metal Testing (Excerpted Entries)***<sup>45</sup>

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

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

<sup>44</sup> *Id.*

<sup>45</sup> *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.<sup>46</sup> Amylase is an

<sup>46</sup> 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](http://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 CO<sub>2</sub>.”<sup>47</sup>

**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.<sup>48</sup> 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)***<sup>49</sup>

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

<sup>47</sup> ChefSteps, *Amylase* (online at [www.chefsteps.com/ingredients/amylase](http://www.chefsteps.com/ingredients/amylase)) (accessed Jan. 26, 2021).

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

<sup>49</sup> *Id.*





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.<sup>50</sup> Healthy Babies Bright Futures has called for a goal of no measurable amount of lead in baby food.<sup>51</sup>

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.<sup>52</sup>

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<sup>50</sup> 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](http://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/>).

<sup>51</sup> 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](http://www.healthybabyfood.org/sites/healthybabyfoods.org/files/2019-10/BabyFoodReport_FULLREPORT_ENGLISH_R5b.pdf)).

<sup>52</sup> World Health Organization, *Lead in Drinking-Water* (2011) (online at [www.who.int/water\\_sanitation\\_health/dwq/chemicals/lead.pdf](http://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](http://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.<sup>53</sup> Nurture also sold five other products after they tested over 50 ppb lead.<sup>54</sup>

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<sup>53</sup> 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>).

<sup>54</sup> *Id.*

*Nurture’s Heavy Metal Test Results for Baby Food Products (Excerpted Entries)*<sup>55</sup>

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	590	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.<sup>56</sup> 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.<sup>57</sup>

*Beech-Nut’s Raw Materials Heavy Metal Testing (Excerpted Entry)*<sup>58</sup>

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.<sup>59</sup>

<sup>55</sup> *Id.*

<sup>56</sup> *Id.*

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

<sup>58</sup> *Id.*

<sup>59</sup> *Id.*

*Beech-Nut's Raw Materials Heavy Metal Testing (Excerpted Entries)<sup>60</sup>*

<b>Date</b>	<b>Commodity</b>	<b>Lead result (ppb)</b>	<b>Spec.</b>	<b>Acceptance (Y/N)</b>
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

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<sup>60</sup> *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.<sup>61</sup>

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<sup>61</sup> 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](https://oversight.house.gov/sites/democrats.oversight.house.gov/files/3_0.pdf)).

**Hain’s Raw Material Pre-Shipment Test Data History (Excerpted Entry)<sup>62</sup>**

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)<sup>63</sup>**

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 Cinamon 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.<sup>64</sup>

<sup>62</sup> *Id.*

<sup>63</sup> *Id.*

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



**Gerber Products Company Test Results (Excerpted Entries)<sup>65</sup>**

<b>Year</b>	<b>Ingredient</b>	<b>Lead Level (ppb)</b>
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)<sup>66</sup>**

<b>GERBER Products Company Test Results</b>		<b>Confidential Business Information</b>	
		<b>19-Dec-19</b>	
<b>Juice Concentrate Ingredients (Lead Results )</b>			
<b>Year</b>	<b>Ingredient</b>		<b>Lead (ppb)</b>
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

<sup>65</sup> *Id.*

<sup>66</sup> *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.<sup>67</sup> These standards approach WHO's 3 ppb limit for cadmium in drinking water.<sup>68</sup>

Groups like Healthy Babies Bright Futures have set a goal of no measurable amount of cadmium in baby food.<sup>69</sup> Consumer Reports has called for a limit of 1 ppb cadmium in fruit juices.<sup>70</sup> 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.<sup>71</sup> That is more than 17 times higher than the EU's lax

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<sup>67</sup> Environmental Protection Agency, *Ground Water and Drinking Water* (online at [www.epa.gov/ground-water-and-drinking-water/national-primary-drinking-water-regulations](http://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](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?fr=165.110)).

<sup>68</sup> World Health Organization, *Cadmium in Drinking-Water* (2011) (online at [www.who.int/water\\_sanitation\\_health/water-quality/guidelines/chemicals/cadmium.pdf?ua=1](http://www.who.int/water_sanitation_health/water-quality/guidelines/chemicals/cadmium.pdf?ua=1)).

<sup>69</sup> 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](http://www.healthybabyfood.org/sites/healthybabyfoods.org/files/2019-10/BabyFoodReport_FULLREPORT_ENGLISH_R5b.pdf)).

<sup>70</sup> 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>).

<sup>71</sup> 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.<sup>72</sup>

***Beech-Nut’s Raw Materials Heavy Metal Testing (Excerpted Entries)***<sup>73</sup>

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.<sup>74</sup> 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.

<sup>72</sup> *Id.*

<sup>73</sup> *Id.*

<sup>74</sup> 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](https://oversight.house.gov/sites/democrats.oversight.house.gov/files/3_0.pdf)).

**Hain's Raw Material Pre-Shipment Test Data History (Excerpted Entries)<sup>75</sup>**

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.<sup>76</sup>

**Nurture's Heavy Metal Test Results for Baby Food Products (Excerpted Entries)<sup>77</sup>**

Product Name	Category	Best Before Date	Parameter	Goal Thresh old	Result	Unit	Date of Test Report	Disposition
Multi-Grain Cereal Canister	Baby 6+ Months	11/16/2018	Cadmium	50	49	ppb	09/30/17	Sell - Testing For Monitoring & Supply Chain Improvement Purposes Only
Strawberry Raspberry	Baby 7+ Months	1/16/2019	Cadmium	50	36	ppb	12/05/17	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 Raspberry	Baby 7+ Months	11/10/2019	Cadmium	50	31	ppb	10/23/18	Sell - Testing For Monitoring & Supply Chain Improvement Purposes Only
Strawberry Raspberry	Baby 7+ Months	11/10/2019	Cadmium	50	30	ppb	10/31/18	Sell - Testing For Monitoring & Supply Chain Improvement Purposes Only

<sup>75</sup> *Id.*

<sup>76</sup> 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>).

<sup>77</sup> *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.<sup>78</sup>

***Gerber Products Company Test Results (Excerpted Entries)***<sup>79</sup>

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.<sup>80</sup> 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.<sup>81</sup>

**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.<sup>82</sup>

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

<sup>79</sup> *Id.*

<sup>80</sup> Environmental Protection Agency, *Ground Water and Drinking Water* (online at [www.epa.gov/ground-water-and-drinking-water/national-primary-drinking-water-regulations](http://www.epa.gov/ground-water-and-drinking-water/national-primary-drinking-water-regulations)) (accessed Jan. 26, 2021).

<sup>81</sup> 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](http://www.healthybabyfood.org/sites/healthybabyfoods.org/files/2019-10/BabyFoodReport_FULLREPORT_ENGLISH_R5b.pdf)).

<sup>82</sup> 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)*<sup>83</sup>

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	8.8	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.”<sup>84</sup> 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.<sup>85</sup>

<sup>83</sup> *Id.*

<sup>84</sup> 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>).

<sup>85</sup> *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.”**<sup>86</sup>

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.<sup>87</sup>

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.<sup>88</sup>

***Nurture’s Heavy Metal Test Results for Baby Food Products (Excerpted Entries)***<sup>89</sup>

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	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	11/18/2018	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

<sup>86</sup> *Id.*

<sup>87</sup> 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>).

<sup>88</sup> 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>).

<sup>89</sup> 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.<sup>90</sup> 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:<sup>91</sup>

**All of our specific goal thresholds for the referenced contaminants<sup>8</sup> 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
<b>Infant Formula</b>	<b>Lead</b>	<b>As Sold</b>	<b>50</b>	<b>ppb</b>
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>Cereals</b>	<b>Lead</b>	<b>As Consumed</b>	<b>50*</b>	<b>ppb</b>
Cereals	Mercury	As Consumed	10	ppb
Wet Foods	Cadmium	As Consumed	50	ppb
Wet Foods	Inorganic Arsenic	As Sold	100	ppb
<b>Wet Foods</b>	<b>Lead</b>	<b>As Consumed</b>	<b>50*</b>	<b>ppb</b>
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)<sup>92</sup>***

<sup>90</sup> 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>).

<sup>91</sup> *Id.*

<sup>92</sup> 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.<sup>93</sup>

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

<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.<sup>95</sup> As a result of

<sup>93</sup> 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>).

<sup>94</sup> *Id.*

<sup>95</sup> 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.<sup>96</sup> Beech-Nut also set internal guidelines of 3,000 ppb for cadmium and 5,000 ppb for lead for certain ingredients.<sup>97</sup> 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)***<sup>98</sup>

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.<sup>99</sup>

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<sup>96</sup> *Id.*

<sup>97</sup> *Id.*

<sup>98</sup> *Id.*

<sup>99</sup> *Id.*

***Beech-Nut’s Raw Materials Heavy Metal Testing (Excerpted Entries)***<sup>100</sup>

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	146.40	<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...”<sup>101</sup> 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.<sup>102</sup> 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.<sup>103</sup>

<sup>100</sup> *Id.*

<sup>101</sup> 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](https://oversight.house.gov/sites/democrats.oversight.house.gov/files/6_0.pdf)).

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

<sup>103</sup> 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](https://oversight.house.gov/sites/democrats.oversight.house.gov/files/3_0.pdf)).

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

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.<sup>105</sup>

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

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/1/2017	Grain Millers	5308029	Org Brown Flax Milled	Accepted	Calculated Levels on consumed basis	Deibel	As consumed	200	<100
Jul/19/2017	Firebird Artisan Mills	5303042	Org Quinoa Flour	Accepted		Deibel	As consumed	200	<100
Sep/29/2017	Firebird Artisan Mills	5303042	Org Quinoa Flour	Accepted	spec for lead was 200ppb	Deibel	As consumed	200	120

<sup>104</sup> *Id.*

<sup>105</sup> *Id.*

<sup>106</sup> *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.<sup>107</sup>

***Hain’s Raw Material Pre-Shipment Test Data History (Excerpted Entries)***<sup>108</sup>

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.<sup>109</sup>

***Hain Deviation Report, Vitamin Premix (Nov. 26, 2019)***<sup>110</sup>

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

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

<sup>107</sup> *Id.*

<sup>108</sup> *Id.*

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

<sup>110</sup> *Id.*

<sup>111</sup> *Id.*

*Hain Deviation Report, Vitamin Premix (Nov. 26, 2019)*<sup>112</sup>

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.<sup>113</sup>

*Hain Deviation Report, Vitamin Premix (Nov. 26, 2019)*<sup>114</sup>

Item	Lot Code	Heavy Metal	Test Value (ppb)	% in formula	Hypothetical Level in finished product (ppb)	
Rice Flour	B160007580	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		84.7966	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

<sup>112</sup> *Id.*

<sup>113</sup> *Id.*

<sup>114</sup> *Id.*

products, which initially went undetected because Hain did not test its finished products.<sup>115</sup> 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?*<sup>116</sup>**

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

<sup>115</sup> 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>).

<sup>116</sup> 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](http://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 Metals<sup>117</sup>**



**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.”<sup>118</sup> Campbell declined to state what those criteria are.

***Campbell’s Product Heavy Metal Test Results (Excerpted Entries)<sup>119</sup>***

Product Name	Testing Date	Aspartame	Lead	Cadmium	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 5)	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

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

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

<sup>119</sup> *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.”<sup>120</sup> However, despite Campbell having no mercury threshold, Campbell still marked every food as “meets criteria” for mercury.<sup>121</sup> 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?***<sup>122</sup>

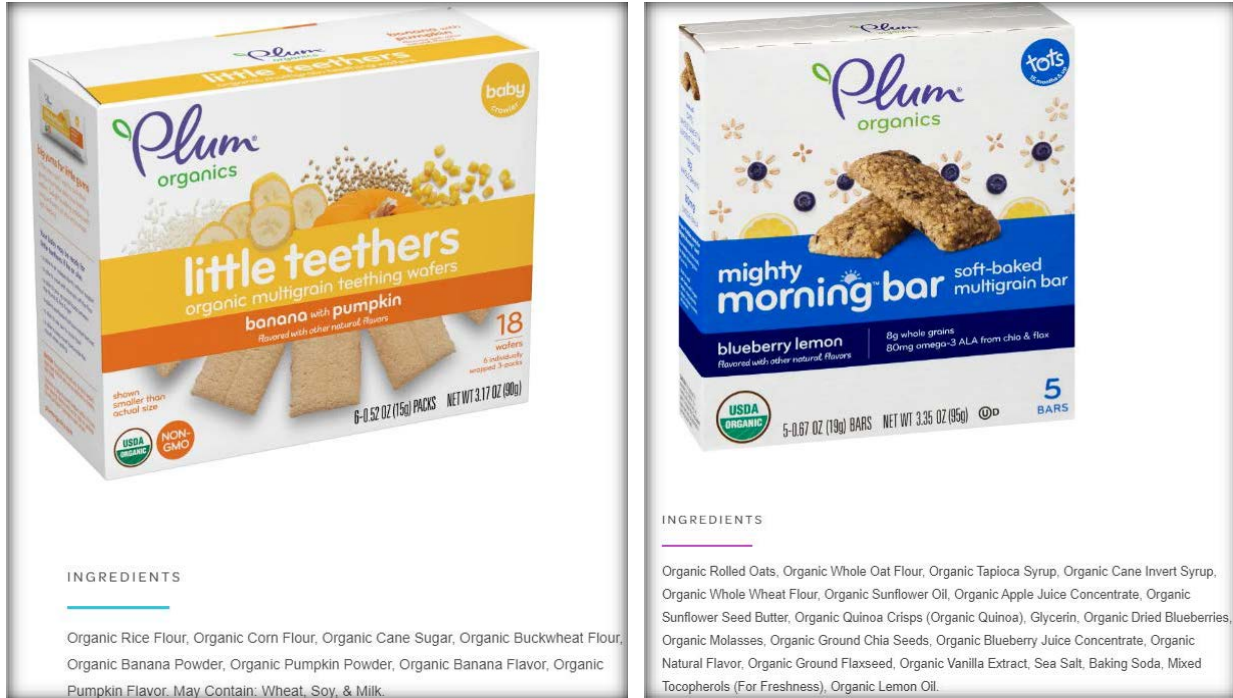
Brand	Food	Food type	Arsenic (total, ppb)	Arsenic (inorganic, ppb)	Lead (ppb)	Cadmium (ppb)	Mercury (total, ppb)	Metro area where purchased	Retailer
Plum Organics	Mighty Morning Bar - Blueberry Lemon - Tots: 15 months & up	Snack - other	40*	39	3.4	24.3	< 0.137	Cincinnati, OH	Kroger
Plum Organics	Little 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

<sup>120</sup> *Id.*

<sup>121</sup> *Id.*

<sup>122</sup> 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](http://www.healthybabyfood.org/sites/healthybabyfoods.org/files/2019-10/BabyFoodReport_FULLREPORT_ENGLISH_R5b.pdf)).

## Plum Organics' Foods That Tested High in Toxic Heavy Metals<sup>123</sup>



### 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.<sup>124</sup>

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.

<sup>123</sup> Plum Organics, *Little Teethers, Banana with Pumpkin* (online at [www.plumorganics.com/products/banana-with-pumpkin-wafers/](http://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/](http://www.plumorganics.com/products/blueberry-lemon-bar/)) (accessed Jan. 26, 2021).

<sup>124</sup> 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](http://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?**<sup>125</sup>

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	1.51	Washington, DC	amazon.com

**Sprout Organic Food That Tested High in Toxic Heavy Metals**<sup>126</sup>



**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

<sup>125</sup> 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](http://www.healthybabyfood.org/sites/healthybabyfoods.org/files/2019-10/BabyFoodReport_FULLREPORT_ENGLISH_R5b.pdf)).

<sup>126</sup> 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](http://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.”<sup>127</sup> 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.”<sup>128</sup> 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.<sup>129</sup>

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.<sup>130</sup> 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.<sup>131</sup>

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<sup>127</sup> Food and Drug Administration, *Metals and Your Food* (online at [www.fda.gov/food/chemicals-metals-pesticides-food/metals-and-your-food](http://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](http://www.fda.gov/food/conversations-experts-food-topics/what-fda-doing-protect-consumers-toxic-metals-foods)).

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

<sup>129</sup> *Id.*

<sup>130</sup> 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](http://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-action-levels-poisonous-or-deleterious-substances-human-food-and-animal-feed)).

<sup>131</sup> Environmental Protection Agency, *Ground Water and Drinking Water* (online at [www.epa.gov/ground-water-and-drinking-water/national-primary-drinking-water-regulations](http://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.<sup>132</sup> The EU has instituted a limit of 10-15 ppb for infant formula.<sup>133</sup>

## **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.<sup>134</sup>

FDA has taken action on bottled water, limiting lead to 5 ppb.<sup>135</sup> 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.<sup>136</sup> 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].”

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

<sup>133</sup> 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>).

<sup>134</sup> 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](http://www.fda.gov/food/metals-and-your-food/lead-food-foodwares-and-dietary-supplements)) (accessed Jan. 26, 2021).

<sup>135</sup> *Id.*

<sup>136</sup> *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.”<sup>137</sup>

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.”<sup>138</sup> 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.<sup>139</sup>

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<sup>137</sup> 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](http://www.fda.gov/food/metals-and-your-food/supporting-document-recommended-maximum-level-lead-candy-likely-be-consumed-frequently-small)) (emphasis added).

<sup>138</sup> 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](http://www.fda.gov/food/metals-and-your-food/lead-food-foodwares-and-dietary-supplements)) (accessed Jan. 26, 2021).

<sup>139</sup> 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](http://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.”<sup>140</sup> FDA acknowledged that “Low-to-moderate levels of inorganic arsenic appear to be associated with adverse health effects during childhood.”<sup>141</sup> 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.”<sup>142</sup> 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.<sup>143</sup> Consumer Reports suggests that the level of inorganic arsenic should be set as low as 3 ppb for water and fruit juices.<sup>144</sup>

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

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*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](http://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-action-level-inorganic-arsenic-rice-cereals-infants)).

<sup>140</sup> 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](http://www.sciencedirect.com/science/article/abs/pii/S0048969713003409?via%3Dihub)).

<sup>141</sup> 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](http://www.fda.gov/files/food/published/Arsenic-in-Rice-and-Rice-Products-Risk-Assessment-Report-PDF.pdf)).

<sup>142</sup> 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>).

<sup>143</sup> 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](http://www.healthybabyfood.org/sites/healthybabyfoods.org/files/2019-10/BabyFoodReport_FULLREPORT_ENGLISH_R5b.pdf)).

<sup>144</sup> 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/](http://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/](http://www.consumerreports.org/food-safety/arsenic-and-lead-are-in-your-fruit-juice-what-you-need-to-know/)).

<sup>145</sup> 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](http://www.fda.gov/food/metals-and-your-food/arsenic-food-and-dietary-supplements)) (accessed Jan. 26, 2021).

<sup>146</sup> Environmental Protection Agency, *Drinking Water Requirements for States and Public Water Systems* (online at [www.epa.gov/dwreginfo/chemical-contaminant-rules](http://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](http://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](http://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.<sup>147</sup>

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.<sup>148</sup> 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

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<sup>147</sup> 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](http://www.fda.gov/food/chemical-metals-natural-toxins-pesticides-guidance-documents-regulations/supporting-document-action-level-inorganic-arsenic-rice-cereals-infants#introduction)).

<sup>148</sup> 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](http://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...”<sup>149</sup> 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.<sup>150</sup> 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.**

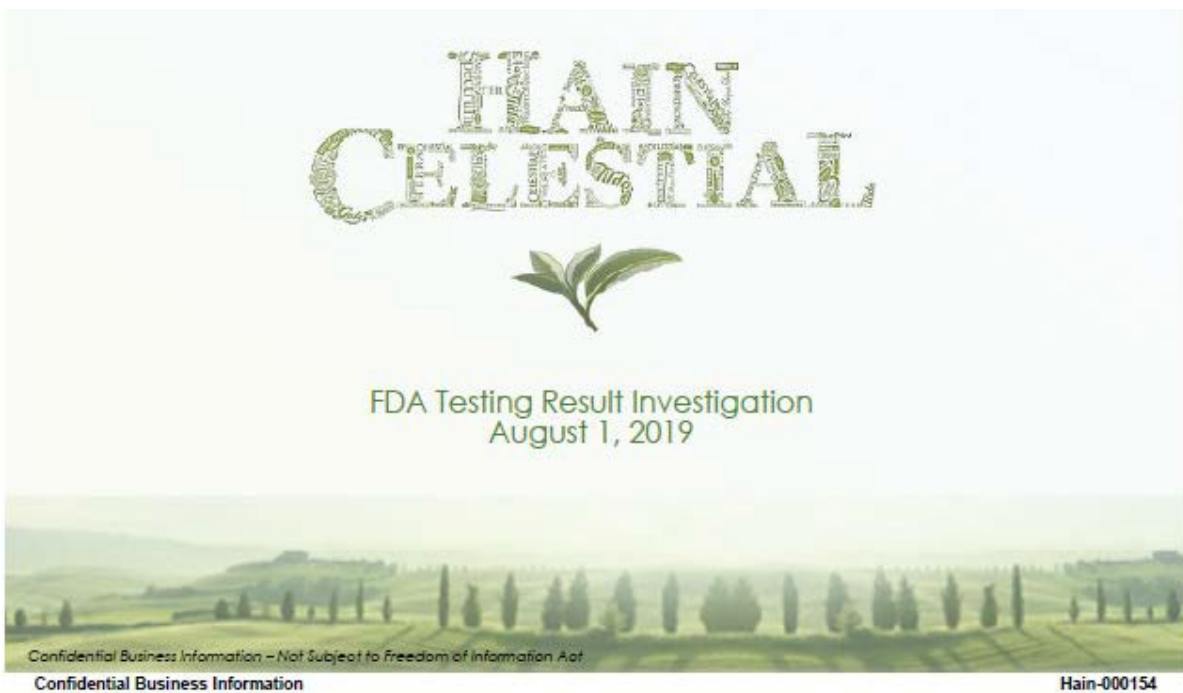
On August 1, 2019, the Trump administration received a secret industry presentation that disclosed higher risks of toxic heavy metals in finished baby food products. Hain (Earth’s Best Organic) revealed the finding in a presentation to FDA entitled “FDA Testing Result Investigation.”<sup>151</sup>

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<sup>149</sup> 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](http://www.fda.gov/food/chemical-metals-natural-toxins-pesticides-guidance-documents-regulations/supporting-document-action-level-inorganic-arsenic-rice-cereals-infants#introduction)).

<sup>150</sup> *Id.*

<sup>151</sup> 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 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	

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.”<sup>152</sup> 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

<sup>152</sup> 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](https://oversight.house.gov/sites/democrats.oversight.house.gov/files/9_Redacted.pdf)).

testing method.<sup>153</sup> 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 FDA***<sup>154</sup>

FDA Data					Estimate % Avg FG Increase from Avg Raw	Track & Trace Data					
FDA Sample Number	Best By Date	Lot number	FDA FG Inorganic Arsenic (ppb)	Avg FG Result		Packaging Date	WIP Batch	Rice Flour Lot #s	Type of Arsenic Test	Raw Material Results (ppb)	Avg Raw Result
1017814	3/2/19	BN A 0636	94	80.3	43%	9/8/17	199987	B160004661	Total Arsenic	54	56.3
1038929		BN C 1139	83					B160004870	Total Arsenic	58	
1039633		BN F 1648	64					B160004759	Total Arsenic	57	
	B160004659			Total Arsenic	54						
	197594	B160004870	Total Arsenic	58							
		B160004759	Total Arsenic	57							
1039750	3/8/19	BN E	74	74.0	29%	9/14/17	200408	B160004871	Total Arsenic	60	57.3
1041752	3/20/19	BN G	92	96.0	57%	9/26/17	200651	B160005149	Total Arsenic	65	61.3
1037933		BN E 1536	67					B160004873	Total Arsenic	58	
1041751	3/21/19	BN B 0832	108	B160005157	Total Arsenic	62					
1038677		BN B 0932	116	B160004871	Total Arsenic	60					
1026932		BN D 1248	97	B160005148	Total Arsenic	61					
				B160004872	Total Arsenic	55					
1044380	4/11/19	BH C	100	100.0	69%	10/18/17	201873	B160005152	Total Arsenic	61	59.0
1024309	4/27/19	BN I 2216	129	129.0	93%	11/3/17	204146	B160005305	Total Arsenic	69	67.0
1024210	6/6/19	BN I 2241	94	101.0	61%	12/13/17	206697	B160005515	Total Arsenic	63	62.7
		547103	BN I 2339					115	B160005513	Total Arsenic	
	1013927	BN E 1540	92			12/15/17		B160005150	Total Arsenic	65	
	1026516	BN H 2123	104								
	1074288	BNE 1406	105								
	1035738	BN J 0000	96								
1047511	6/27/19	BN C 1142	100	100.0	56%	1/3/18	208226	B160006190	Inorganic Arsenic	73	64.0
1063061	7/19/19	BN J	115	115.0	43%	1/25/18	208594	B160005581	Total Arsenic	55	80.5
								B160006189	Inorganic Arsenic	81	
1027437	8/18/19	BN A 0703	97	97.0	28%	2/24/18	210374	B160006191	Inorganic Arsenic	80	75.7
								B160006205	Inorganic Arsenic	77	
								B160006263	Inorganic Arsenic	74	
784399	11/23/19	BN K 0305	108	108.0	31%	6/1/18	215305	B160006260	Inorganic Arsenic	76	82.5
								B160007235	Inorganic Arsenic	66	
								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.”<sup>155</sup> They are not correlated because the finished goods can contain as much as double the amount of arsenic as the raw ingredients.

<sup>153</sup> 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>).

<sup>154</sup> *Id.*

<sup>155</sup> *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.<sup>156</sup>

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.<sup>157</sup> 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)***<sup>158</sup>

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.<sup>159</sup> That policy recklessly

<sup>156</sup> *Id.*

<sup>157</sup> 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](https://oversight.house.gov/sites/democrats.oversight.house.gov/files/3_0.pdf)).

<sup>158</sup> *Id.*

<sup>159</sup> 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](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.<sup>160</sup> 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.<sup>161</sup>
- 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).<sup>162</sup>

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2019) (online at [https://oversight.house.gov/sites/democrats.oversight.house.gov/files/7\\_Redacted.pdf](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](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.).

<sup>160</sup> 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>).

<sup>161</sup> *Id.*

<sup>162</sup> 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.<sup>163</sup>
- Gerber used 67 batches of rice flour with over 90 ppb inorganic arsenic.<sup>164</sup>

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.

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<sup>163</sup> 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>).

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