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Attorneys for Plaintiff LAUREN SMITH, individual, on behalf of herself and others similarly situated,

**UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO DIVISION**

**LAUREN SMITH, individual, on
behalf of herself and others similarly
situated,**

Plaintiff,

v.

**PLUM, PBC,
PLUM, INC., D/B/A PLUM
ORGANICS,
CAMPBELL SOUP COMPANY,
BEECH-NUT NUTRITION
COMPANY,
GERBER PRODUCTS COMPANY,
NURTURE, INC., D/B/A
HAPPYFAMILY ORGANICS,
SAFEWAY INC.,**

Defendants.

) Case No.

) **COMPLAINT
CLASS ACTION**

) 1. Racketeer Influenced & Corrupt
Organizations Act (RICO)

) 2. Express Warranty

) 3. Implied Warranty

) 4. Negligent Testing & Inspection

) 5. Negligent Misrepresentation

) 6. Medical Monitoring

) 7. Unjust Enrichment

) 8. Common Law Fraud

) 9. Colorado Consumer Protection Act

) 10. Kansas Consumer Protection Act

) **DEMAND FOR JURY TRIAL**

Plaintiff LAUREN SMITH on behalf of herself and all others similarly situated,
sue Defendants Plum, PBC, Plum, Inc., d/b/a Plum Organics, Campbell Soup
Company, Beech-Nut Nutrition Company, Gerber Products Company, Nurture, Inc.,

1 d/b/a HappyFamily Organics, and Safeway Inc. for selling, marketing, advertising,
2 distributing, and manufacturing baby food products containing dangerous levels of
3 heavy metals and alleges as follows:

4 **INTRODUCTION**

5 1. Food fraud is a crime that siphons millions of dollars every year from
6 unsuspecting American consumers. Food fraud not only results in injury and
7 sometimes death to the person who consumes the altered food, but it also deprives
8 the purchaser of the value of their purchase—i.e., they overpaid for a product,
9 sometimes the full amount of the purchase price.¹ As PwC has explained, “Food
10 fraud is simply defined as intentional deception using food for economic gain.”²

11 2. “Food fraud” occurs when bad actors cut corners “to profit financially.
12 It is that intent to profit that separates food fraud from failures in food safety and
13 food quality.”³

14 3. Food fraud’s economic toll is growingly rapidly both in America and
15 globally: “today’s estimates of the global financial cost of food fraud range from
16 \$6.2 billion to a massive \$40 billion per year.”⁴

17 4. The roots of food fraud run deep in the American economy. In 1906,
18 Upton Sinclair published a novel, *The Jungle*, to expose the horrors that were
19 occurring in the American meat-packing industry, including the sickness and death

20
21 ¹ Arun Chauhan, *Food fraud – an evolving crime with profit at its heart*, NEW FOOD
22 (Apr. 23, 2020) (“Loss can also be paying a premium for goods that are presented as
23 being of superior quality, when in reality they have been made cheaply with
contaminated or substitute ingredients. This is loss through overpayment and loss
caused by the use of a sub-standard or altered product.”).

24 ² Julia Leong & Tan Hwee Ching, *Tackling food fraud*, PWC.com,
25 <https://www.pwc.com/sg/en/services/food-supply-integrity/tackling-food-fraud.html>
(last visited Mar. 11, 2021).

26 ³ Luke Cridland, *Food Fraud | When Does Food Become Criminal*, FOOD UNFOLDED
(Dec. 17, 2020).

27 ⁴ Luke Cridland, *Food Fraud | When Does Food Become Criminal*, FOOD UNFOLDED
28 (Dec. 17, 2020).

1 of children caused by contamination during manufacturing and processing. The
2 food manufacturers and suppliers cut corners to increase their profits, putting
3 safety and honesty behind profits and greed.

4 5. Unfortunately, more than a century later, profiteering among food
5 companies remains a major problem in America. In particular, contamination of
6 baby food with toxic heavy metals is a key issue that is concealed and
7 misrepresented to the purchasers of baby food products.

8 6. The greed of executives at baby food companies has caused them to
9 engage long-running, ongoing schemes to defraud involving premium baby food.
10 Several companies have promised and reassured parents that their baby food
11 products are pure, natural, safe, and healthy; in reality, these products contain
12 heavy metals that are not pure, unnatural, unsafe, and pose a major risk to babies
13 and infants.

14 7. Had parents (or guardians)⁵ been fully informed about the contents of
15 the baby food they purchased, they would not have bought the premium baby
16 food—or would have paid far less for less-than-premium products.

17 8. The baby food fraud alleged in this case occurred in multiple stages.
18 Executives at these companies devised a scheme to defraud in which baby food
19 would be represented as something different than what it was, which made the
20 food their companies produced and manufactured not safe for consumption. Then,
21 once their food fraud was exposed to the public, Defendants also engaged in
22 additional fraudulent acts to cover up, conceal, and continue their ongoing schemes
23 to defraud.

24 9. The mail and wire fraud statutes have a long-established meaning: each
25 mailing and each use of the wires *in furtherance of* a scheme to defraud is a
26

27 ⁵ This Complaint uses the term “parents” at times instead of “guardians”; any
28 purchaser of baby food within the scope of the class definition is a class member.

1 separate criminal act. In turn, given the scope of the advertising and marketing and
2 constant use of the Internet and email by Defendants, each Defendant has engaged
3 in a pattern of wire and mail fraud since at least January 2019, when Defendants
4 formed and began using the Baby Food Council as a vessel for fraud.

5 10. This ongoing fraud was only recently revealed. On February 4, 2021,
6 the U.S. House of Representatives Committee on Oversight and Reform released
7 the explosive report, “*Baby Foods Are Tainted with Dangerous Levels of Arsenic,
8 Lead, Cadmium, and Mercury.*” (hereinafter “the House Staff Report” or
9 “Congressional Report”). The House Staff Report exposed rampant fraud,
10 misrepresentations, half-truths, and fraud by omission committed by the nation’s
11 seven leading baby food manufacturers in selling food to the most vulnerable in
12 our population: infants and toddlers.⁶

13 11. The House Staff Report highlighted the high levels of toxic heavy
14 metals present in numerous baby foods produced by Defendants, namely
15 Defendant Beech-Nut, Defendant Nurture, Defendant Gerber, and Hain who
16 cooperated with Congress’s investigation.

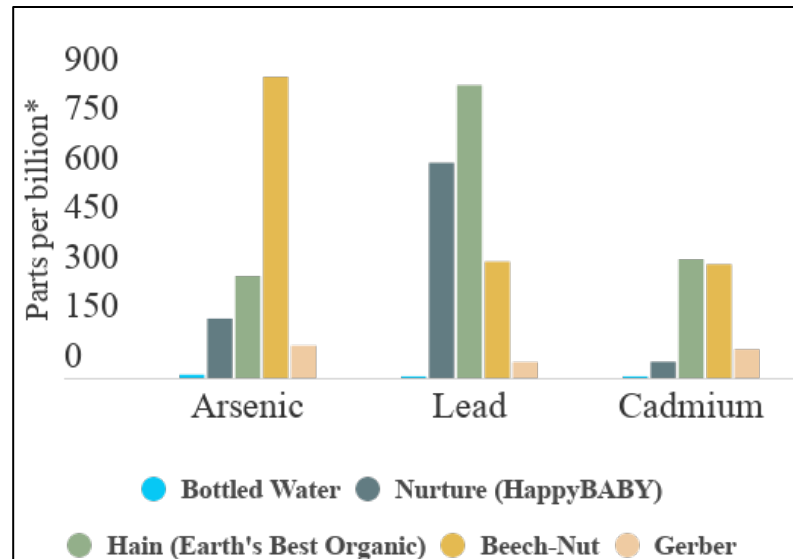
17 12. Defendants Campbell and Plum refused cooperation along with
18 Walmart and Sprout,⁷ which suggested their misconduct was even more nefarious
19 (particularly because it is unusual for corporations not to cooperate with federal
20 regulators).

21 13. Although there has been no conclusion about a safe level of these
22 hazardous heavy metals in baby foods, the FDA sets the maximum allowable

23
24 ⁶ Staff Report, Subcommittee on Economic and Consumer Policy of the Committee
25 on Oversight and Reform, U.S. House of Representatives, *Baby Foods Are Tainted
26 with Dangerous Levels of Arsenic, Lead, Cadmium, and Mercury* (Feb. 4, 2021)
27 [https://oversight.house.gov/sites/democrats.oversight.house.gov/files/2021-02-
28 04%20ECP%20Baby%20Food%20Staff%20Report.pdf](https://oversight.house.gov/sites/democrats.oversight.house.gov/files/2021-02-04%20ECP%20Baby%20Food%20Staff%20Report.pdf) (hereinafter “House Staff
Report”) (attached as Ex. A).

⁷ *Id.* at 2.

1 levels of these toxic heavy metals in water bottles safe for consumption at 10 parts
 2 per billion (ppb) inorganic arsenic, 5 ppb lead, and 5 ppb cadmium.⁸ Similarly, the
 3 EPA only allows up to 10 ppb of arsenic, 10 ppb of lead, 5 ppb of cadmium, and 2
 4 ppb of mercury in public drinking water.



15 14. The levels of these toxic heavy metals that would pose health risks to
 16 infants and children are likely far less than those set for a bottle of water because
 17 the bottled water limits are set assuming adult consumption—not that of an infant
 18 or toddler.

19 15. The baby food at issue, examined in the House Staff Report, showed
 20 levels as high as **91 times** as much arsenic, **177 times** as much lead, **69 times** as
 21 much cadmium, and **5 times** as much mercury than levels allowed in bottled
 22 water.⁹

23 16. All of these toxins are harmful to the babies and children who ingested
 24 them. Exposure to these heavy metals can result in:

- 25 a. Permanent decreases in IQ;

27 ⁸ *Id.* at 4.

28 ⁹ *Id.*

- b. Diminished future economic productivity;
- c. Increased risk of future criminal and antisocial behavior in children;
- d. Affected neurological development and brain function in infants;¹⁰
- e. Other unknown and harmful effects to children.

17. But baby food is big business and these companies feared that billions of dollars of revenue might slip away if they took the precaution, time, and necessary steps to get their products into healthy and safe-for-consumption baby food. So, Defendants cut corners, covered up their schemes, and have failed to recall their products or stop their campaign of lies and misrepresentations.

18. This criminal behavior among several of America’s top baby food manufacturers remains ongoing and must be stopped. Fortunately, Congress passed the Racketeer Influenced and Corrupt Organizations Act (“RICO”) Act in 1970 to address situations precisely like this. Situations of interstate, nationwide fraud that no state can tackle on its own and situations where federal prosecutors and agencies either lack the resources or priorities to stop immediately (that is not to say indictments will not follow, but indictments typically come many years later—not immediately).

19. This case seeks to hold these baby food producers and manufacturers accountable where government enforcement has not (at least not yet). Defendants should be required to repay the consumers they lied to and stole from—and be subject whatever regulatory action and criminal indictments that follow in the wake of this case.

I. Parties

A. Plaintiff

20. Plaintiff Lauren Smith currently resides in the state of Kansas and purchased baby foods produced by Defendants for her children in Kansas and

¹⁰ *Id.* at 2.

1 Colorado. From December 2018 until October 2020, Plaintiff Smith resided in the
2 state of Colorado and during that time purchased Defendants’ baby food products
3 at Safeway.

4 a. Plaintiff Smith purchased products from Defendant Beech-Nut, namely
5 Organics Apple Jar, Organics Carrots Jar, Organics Sweet Potato Jar,
6 Organics Prunes Jar, Organics Pumpkin Jar, Naturals Green Beans Jar,
7 Naturals Banana Jar and other jarred baby food purees. Plaintiff Smith
8 purchased Beech-Nut products approximately twenty (20) times from
9 December 2018 – March 2019 for her first child and August 2020 –
10 October 2020 for her second child. Plaintiff Smith purchased Beech-
11 Nut products at Safeway, and specifically recalls it being “prevalent” at
12 the grocery store. She relied on Beech-Nut’s representations and labels
13 that their products were healthy and all natural.

14 b. Plaintiff Smith purchased products from Defendant Gerber, namely
15 jarred baby food purees, pouches, puffs, and snacks. Plaintiff Smith
16 purchased Gerber approximately twenty (20) times between December
17 2018- March 2019 based on Gerber’s representations in advertisements
18 that its’ products only contained simple ingredients. Further, Plaintiff
19 Smith relied on the labels affixed on the Gerber foods she bought her
20 children and trusted the labels were accurate about what was contained
21 inside.

22 c. Plaintiff Smith purchased products from Defendant Nurture, namely
23 HappyBABY, Happy Tot Organic Blueberry Pear & Beet Stage 4
24 Pouch, Happy Tot Organic Apples Spinach Pea & Broccoli Blend Stage
25 4 Pouch, Happy Tot Organic Pear Raspberry Squash & Carrot Fiber &
26 Protein Blend Stage 4 Pouch, Happy Tot Organic Pear Blueberry &
27 Spinach Fiber & Protein Blend Stage 4 Pouch, Happy Baby Blueberry
28

1 & Purple Carrot Teethers, Happy Baby Sweet Potato & Banana
2 Teethers, Happy Baby Apple & Broccoli Puffs, Happy Baby Sweet
3 Potato & Carrot Puffs, Happy Baby Purple Carrot & Blueberry Puffs,
4 Love My Veggies Carrots, Bananas, Mangos & Sweet Potatoes Pouch,
5 Love My Veggies Zucchini, Pears, Chickpeas & Kale Pouch, Love My
6 Veggies Bananas, Beets, Squash & Blueberries Pouch, Fiber & Protein
7 Pears, Kiwi & Kale Toddler Pouch, Happy Tot Pears Mangos &
8 Spinach with Super Chia, and other snacks. Plaintiff Smith purchased
9 HappyBABY products approximately eighty (80) times, every month
10 between December 2018- January 2021 and believe HappyBABY's
11 representations online that the products only contained simple, organic,
12 "clearly-crafted" and high quality, non-GMO ingredients.

13 d. Plaintiff Smith purchased products from Defendant Campbell, namely
14 Plum Organics, Stage 1 Pouches: Just Prunes, Just Sweet Potato, Stage
15 2 Pouches: Apple & Broccoli, Apple & Carrot, Apple, Raspberry,
16 Spinach & Greek Yogurt, Banana & Pumpkin, Pear Spinach & Pea,
17 Pear Purple Carrot & Blueberry, Peach Banana & Apricot, Pumpkin,
18 Spinach, Chickpea & Broccoli, Butternut Squash, Carrot, Chickpea &
19 Corn, Carrots, Beans, Spinach & Tomato, Stage 3 Pouches: Carrot
20 Spinach Turkey Corn Apple & Potato with Celery & Onion, Mighty 4
21 Pouches: Banana Blueberry Sweet Potato Carrot Greek Yogurt &
22 Millet, Strawberry Banana Greek Yogurt Kale Amaranth & Oat, Apple,
23 Blackberry, Purple Carrot, Greek Yogurt & Oat, Tots Pouches: Mighty
24 Protein & Fiber Banana, White Bean Strawberry & Chia, Mighty 4
25 Blends Pear Cherry Blackberry Strawberry, Black Bean Spinach & Oat,
26 Mighty 4 Banana Kiwi Spinach Greek Yogurt & Barley, Mighty
27 Veggie Sweet Potato Apple Banana Carrot, Mighty 4 Organic Mango
28

1 Pineapple, White Bean Butternut Squash Oat, Mighty 4 Spinach Kiwi
2 Barley Greek Yogurt Pouch, Mighty Protein & Fiber Pear White Bean
3 Blueberry Date & Chia, Mighty 4 Strawberry Kale Amaranth. Plaintiff
4 Smith purchased these baby foods over 100 times, every month,
5 multiple times a month, for her children, between December 2018 and
6 January 2021. Based on representations on the Plum website, when
7 making purchasing decisions, Plaintiff Smith trusted the labels and
8 advertisements that these products were safe for her children.

9 21. Prior to purchasing these baby foods, Plaintiff Smith saw Defendants'
10 advertisements, claims on the packaging alleging the food was nutritious, healthy,
11 and safe. Plaintiff Smith relied on these representations in purchasing food for her
12 daughter. During that time, based on Defendants' omissions, false and misleading
13 claims, warranties, representations, advertisements and other fraudulent marketing,
14 Plaintiff Smith was unaware that these products contained any level of heavy
15 metals, chemicals, or toxins, and would not have purchased the food if that was
16 fully disclosed. Further, she would not have paid the premium price for the baby
17 foods if the information of toxins was fully disclosed. Plaintiff Smith was injured
18 by paying a premium for the baby foods that have no or very little value—or
19 whose value was at least less than what she paid—based on the presence of the
20 heavy metals, chemicals, and toxins. Plaintiff Smith suffered anguish and concern
21 for her daughter since learning that these products contain high levels of heavy
22 metals.

23 22. Through counsel, Plaintiff Smith notified Manufacturer Defendants of
24 her intention to file suit by letter dated March 26, 2021.

25 23. Through counsel, Plaintiff Smith notified Defendant Safeway of her
26 intention to file suit by letter dated March 29, 2021.

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1 24. Plaintiff brings this action individually and on behalf of all consumers
2 who purchased baby foods manufactured by Defendants to cause the disclosure of
3 the presence and/or risk of the presence of heavy metals and/or other toxins that do
4 not conform to the labels, packaging, advertising, and statements in the baby food
5 products; to correct the false and misleading perception that Defendants created in
6 the minds of consumers that their products are high quality, healthy, and safe for
7 infant consumption; and to obtain redress for those who have purchased the baby
8 food.

9 **B. Defendants**

10 25. Defendant Beech-Nut Nutrition Company (“Beech-Nut”) is
11 incorporated in New York. Its headquarters and principal place of business is
12 located at One Nutritious Place, Amsterdam, New York 12010.

13 26. Defendant Beech-Nut formulates, develops, manufactures, labels,
14 distributes, markets, advertises, and sells under the baby food brand names Beech-
15 Nut throughout the United States, including in this District, during the Class Period
16 (defined below). The advertising, labeling, and packaging for these products, relied
17 upon by Plaintiff were prepared, reviewed, and/or approved by Defendant Beech-
18 Nut and its agents, and were disseminated by Defendant Beech-Nut and its agents
19 through marketing, advertising, packaging, and labeling that contained the
20 misrepresentations alleged herein. The marketing, advertising, packaging, and
21 labeling for these baby foods were designed to encourage consumers to purchase
22 them and reasonably misled the reasonable consumer, i.e., Plaintiff and the Class,
23 into purchasing them. Defendant Beech-Nut owns, manufactures, and distributes
24 the baby foods, and created, allowed, negligently oversaw, and/or authorized the
25 unlawful, fraudulent, unfair, misleading, and/or deceptive labeling and advertising
26 for the baby foods. Defendant Beech-Nut is responsible for sourcing ingredients,
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1 manufacturing the products, and conducting all relevant quality assurance
2 protocols, including testing, for the ingredients and finished baby foods.

3 27. Defendant Campbell Soup Company (“Campbell”) is incorporated in
4 Delaware. Its headquarters and principal place of business is located at 1 Campbell
5 Place, Camden, NJ 08103-1701.

6 28. Defendant Plum, Inc., d/b/a Plum Organics, is a Delaware corporation.
7 In 2013, it was reincorporated as a public benefit corporation (Plum, PBC) in
8 Delaware. Until February 2021, its headquarters were located at 1485 Park
9 Avenue, Suite 200, Emeryville, California. Plum, Inc. holds the Plum intellectual
10 property and brands. As recently as January 27, 2021, Plum, Inc. reported to the
11 Secretary of State for the State of California that its Principal Executive Office,
12 Chief Executive Officer, Secretary, and Chief Financial Officer were all located at
13 1485 Park Avenue, Suite 200, Emeryville, California. On February 22, 2021, days
14 after Plum Organics began facing suit in California, Plum, Inc. surrendered its right
15 to do business in California and revoked its designation of agent for service of
16 process in California. Plum, Inc. consented to service through the California
17 Secretary of State for actions based upon any liability or obligation incurred within
18 the State of California prior to the filing of the Certificate of Surrender. Based on
19 the Certificate of Surrender, Plaintiff believes Plum, Inc. now claims its
20 headquarters and principal place of business is located at 1 Campbell Place,
21 Camden, NJ.

22 29. Defendant Campbell, Defendant Plum, PBC, and Defendant Plum, Inc.
23 (together, “Plum”) formulate, develop, manufacture, label, distribute, market,
24 advertise, and sell under the baby food brand name Plum Organics throughout the
25 United States, including in this District, during the Class Period (defined below).
26 The advertising, labeling, and packaging for these products, relied upon by
27 Plaintiff were prepared, reviewed, and/or approved by Plum Defendants and their
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1 agents, and were disseminated by Plum Defendants and its agents through
2 marketing, advertising, packaging, and labeling that contained the
3 misrepresentations alleged herein. The marketing, advertising, packaging, and
4 labeling for these baby foods were designed to encourage consumers to purchase
5 them and reasonably misled the reasonable consumer, *i.e.*, Plaintiff and the Class,
6 into purchasing them. Plum Defendants own, manufacture, and distribute the baby
7 foods, and created, allowed, negligently oversaw, and/or authorized the unlawful,
8 fraudulent, unfair, misleading, and/or deceptive labeling and advertising for the
9 baby foods. Plum Defendants are responsible for sourcing ingredients,
10 manufacturing the products, and conducting all relevant quality assurance
11 protocols, including testing, for the ingredients and finished baby foods.

12 30. Defendant Gerber Products Company (“Gerber”) (a/k/a Nestle
13 Nutrition, Nestle Infant Nutrition or Nestle Nutrition North America) is
14 incorporated in Michigan. Its headquarters and principal place of business is
15 located at 1812 North Moore Street, Arlington, VA.

16 31. Defendant Gerber formulates, develops, manufactures, labels,
17 distributes, markets, advertises, and sells under the baby food brand name Gerber
18 throughout the United States, including in this District, during the Class Period
19 (defined below). The advertising, labeling, and packaging for these products, relied
20 upon by Plaintiffs were prepared, reviewed, and/or approved by Defendant Gerber
21 and its agents, and were disseminated by Defendant Gerber and its agents through
22 marketing, advertising, packaging, and labeling that contained the
23 misrepresentations alleged herein. The marketing, advertising, packaging, and
24 labeling for these baby foods were designed to encourage consumers to purchase
25 them and reasonably misled the reasonable consumer, *i.e.*, Plaintiffs and the Class,
26 into purchasing them. Defendant Gerber owns, manufactures, and distributes the
27 baby foods, and created, allowed, negligently oversaw, and/or authorized the
28

1 unlawful, fraudulent, unfair, misleading, and/or deceptive labeling and advertising
2 for the baby foods. Defendant Gerber is responsible for sourcing ingredients,
3 manufacturing the products, and conducting all relevant quality assurance
4 protocols, including testing, for the ingredients and finished baby foods.

5 32. Defendant Nurture, Inc. (“Nurture”) is incorporated in Delaware. Its
6 headquarters and principal place of business is located at 1 Maple Avenue, White
7 Plains, New York.

8 33. Defendant Nurture formulates, develops, manufactures, labels,
9 distributes, markets, advertises, and sells under the baby food brand names Happy
10 Baby and Happy Family throughout the United States, including in this District,
11 during the Class Period (defined below). The advertising, labeling, and packaging
12 for these products, relied upon by Plaintiff were prepared, reviewed, and/or
13 approved by Defendant and its agents, and were disseminated by Defendant
14 Nurture and its agents through marketing, advertising, packaging, and labeling that
15 contained the misrepresentations alleged herein. The marketing, advertising,
16 packaging, and labeling for these baby foods were designed to encourage
17 consumers to purchase them and reasonably misled the reasonable consumer, *i.e.*,
18 Plaintiff and the Class, into purchasing them. Defendant Nurture owns,
19 manufactures, and distributes the baby foods, and created, allowed, negligently
20 oversaw, and/or authorized the unlawful, fraudulent, unfair, misleading, and/or
21 deceptive labeling and advertising for the baby foods. Defendant Nurture is
22 responsible for sourcing ingredients, manufacturing the products, and conducting
23 all relevant quality assurance protocols, including testing, for the ingredients and
24 finished baby foods.

25 34. Collectively, Defendants Beech-Nut, Campbell, Plum, Gerber, and
26 Nurture are referred to in this Complaint as “Manufacturer Defendants.”
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1 35. Defendant Safeway Inc. is incorporated in Delaware. Its headquarters
2 and principal place of business is located at 11555 Dublin Canyon Rd., Pleasanton,
3 California.

4 36. Defendant Safeway markets, distributes, advertises, and sells
5 Manufacturer Defendants' baby food products throughout the United States,
6 including in this District, during the Class Period (defined below). Defendant
7 Safeway and its agents reviewed and disseminated the advertising, marketing,
8 labeling, and packaging for Manufacturer Defendants' products including the
9 materials relied upon by Plaintiff. The marketing and advertising for these baby
10 foods were designed to encourage consumers to purchase them and reasonably
11 misled the reasonable consumer into purchasing them. Defendant Safeway sells
12 and distributes the baby foods, and created, allowed, negligently oversaw, and/or
13 authorized the unlawful, fraudulent, unfair, misleading, and/or deceptive labeling
14 and advertising for the baby foods.

15 **II. Jurisdiction**

16 37. This Court has subject matter jurisdiction over this class action pursuant
17 to 18 U.S.C. § 1964(a) (civil RICO jurisdiction), 18 U.S.C. § 1331 (federal
18 question jurisdiction), and 28 U.S.C. § 1332(d)(2)(A) (CAFA jurisdiction).

19 38. Venue is proper in this Court pursuant to 28 U.S.C. § 1391, because
20 Plaintiff has suffered injury as a result of Defendants' acts in this District, many of
21 the acts and transactions giving rise to this action occurred in this District,
22 Defendants conduct substantial business in this District, Defendants have
23 intentionally availed themselves of the laws, protections, and markets of this
24 District, and Defendants are subject to personal jurisdiction in this District.

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1 **III. Factual Background**

2 **A. The baby food industry is a large, lucrative market driven by**
3 **consumer demand for convenience and reassurances of safety.**

4 39. Baby food manufacturers know that there are few things as precious as
5 a newborn baby and that parents want the very best for their children. Baby food
6 manufacturers also know that many parents are willing to pay premium dollars to
7 ensure the quality and healthiness of the products they feed their babies.

8 40. Given this demand, the world market for infant formula and baby food
9 is large, growing, and very competitive with a forecast market value of almost \$99
10 billion by 2024.¹¹

11 41. In the United States, the baby food market size was valued at \$12.9
12 billion in 2018 and is projected to reach \$17.2 billion by 2026.¹²

13 42. Baby food is the most purchased baby product category in U.S.
14 supermarkets.

15 43. A market research group notes that “[i]n the recent years, packaged
16 baby food has been widely adopted by parents since it provides convenience and
17 higher nutrition level. In addition, the rise in awareness among people about the
18 numerous health advantages of feeding baby food to infants has significantly
19 fueled the growth of the baby food market.”¹³

20 44. The growth in the baby food market is also driven by rising numbers of
21 women working outside the home. “As many working mothers return to their jobs
22

23 ¹¹ Emma Bedford, *U.S. baby food market - statistics & facts*, STATISTA (Nov. 20,
24 2020), <https://www.statista.com/topics/1218/baby-food-market/>.

25 ¹² *U.S. Baby Food Market Expected to Grow with a CAGR of 3.7% from 2019 to*
26 *2026*, BUSINESS WIRE (Mar. 3, 2020, 05:44 AM),
27 [https://www.businesswire.com/news/home/20200303005477/en/U.S.-Baby-Food-](https://www.businesswire.com/news/home/20200303005477/en/U.S.-Baby-Food-Market-Expected-to-Grow-with-a-CAGR-of-3.7-from-2019-to-2026---)
[Market-Expected-to-Grow-with-a-CAGR-of-3.7-from-2019-to-2026---](https://www.businesswire.com/news/home/20200303005477/en/U.S.-Baby-Food-Market-Expected-to-Grow-with-a-CAGR-of-3.7-from-2019-to-2026---)
28 [ResearchAndMarkets.com](https://www.businesswire.com/news/home/20200303005477/en/U.S.-Baby-Food-Market-Expected-to-Grow-with-a-CAGR-of-3.7-from-2019-to-2026---).

¹³ *Id.*

1 shortly after giving birth, prepared baby foods and formulas provide an appealing
2 alternative for working mothers, bridging their desires for healthy, nutritious food
3 with their need for convenience.”¹⁴

4 45. The cereal segment of the baby food market has the largest revenue
5 because infants consume these products on a regular basis as their high protein and
6 vitamin content is necessary for overall growth.¹⁵

7 46. A growing segment of this baby food market is baby food labeled as
8 organic. In North America, the organic baby food market had a value of \$1.9
9 billion in 2018. One market researcher concluded that the growth in the North
10 America organic baby food market was driven in part by the “increasing awareness
11 among parents regarding the baby’s nutrition, coupled with the health benefits
12 associated with organic food products is driving the market growth in the region”
13 and “the rising consumer awareness about the harmful effects of chemicals on the
14 infant’s health.”¹⁶

15 47. Another market research group noted that the strong growth of the
16 organic market in North America: “Consumers are increasingly health conscious
17 and looking for natural, minimally-processed foods, and the stakes are even higher
18

19 ¹⁴ *Oh, Baby! Trends in the Global Baby Food and Diaper Markets*, NIELSEN (Aug.
20 2015) [https://www.nielsen.com/wp-](https://www.nielsen.com/wp-content/uploads/sites/3/2019/04/Global20Baby20Care20Report20Revised20FINAL-2.pdf)
21 [content/uploads/sites/3/2019/04/Global20Baby20Care20Report20Revised20FINAL-](https://www.nielsen.com/wp-content/uploads/sites/3/2019/04/Global20Baby20Care20Report20Revised20FINAL-2.pdf)
22 [2.pdf](https://www.nielsen.com/wp-content/uploads/sites/3/2019/04/Global20Baby20Care20Report20Revised20FINAL-2.pdf).

23 ¹⁵ *U.S. Baby Food Market Expected to Grow with a CAGR of 3.7% from 2019 to*
24 *2026*, BUSINESS WIRE (Mar. 3, 2020, 05:44 AM),
25 [https://www.businesswire.com/news/home/20200303005477/en/U.S.-Baby-Food-](https://www.businesswire.com/news/home/20200303005477/en/U.S.-Baby-Food-Market-Expected-to-Grow-with-a-CAGR-of-3.7-from-2019-to-2026---ResearchAndMarkets.com)
26 [Market-Expected-to-Grow-with-a-CAGR-of-3.7-from-2019-to-2026---](https://www.businesswire.com/news/home/20200303005477/en/U.S.-Baby-Food-Market-Expected-to-Grow-with-a-CAGR-of-3.7-from-2019-to-2026---ResearchAndMarkets.com)
27 [ResearchAndMarkets.com](https://www.businesswire.com/news/home/20200303005477/en/U.S.-Baby-Food-Market-Expected-to-Grow-with-a-CAGR-of-3.7-from-2019-to-2026---ResearchAndMarkets.com).

28 ¹⁶ *U.S. Baby Food Market Expected to Grow with a CAGR of 3.7% from 2019 to*
2026, BUSINESS WIRE (Mar. 3, 2020, 05:44 AM),
[https://www.businesswire.com/news/home/20200303005477/en/U.S.-Baby-Food-](https://www.businesswire.com/news/home/20200303005477/en/U.S.-Baby-Food-Market-Expected-to-Grow-with-a-CAGR-of-3.7-from-2019-to-2026---ResearchAndMarkets.com)
[Market-Expected-to-Grow-with-a-CAGR-of-3.7-from-2019-to-2026---](https://www.businesswire.com/news/home/20200303005477/en/U.S.-Baby-Food-Market-Expected-to-Grow-with-a-CAGR-of-3.7-from-2019-to-2026---ResearchAndMarkets.com)
[ResearchAndMarkets.com](https://www.businesswire.com/news/home/20200303005477/en/U.S.-Baby-Food-Market-Expected-to-Grow-with-a-CAGR-of-3.7-from-2019-to-2026---ResearchAndMarkets.com).

1 when it comes to their babies.” “More parents are seeking foods that set their
2 children up for a healthy life—even if it comes at a premium. We expect this
3 segment will continue to grow as more parents can afford to trade up.”¹⁷

4 48. According to a Consumer Reports survey, 39 percent of parents who
5 purchased packaged foods sometimes bought organic food for their children, and
6 they cited avoiding lead, arsenic, and other heavy metals as their primary reason
7 for doing it.¹⁸

8 49. While many millennial parents may have less children, market research
9 shows they adopt a quality over quantity approach to the baby products they
10 purchase. These parents prioritize organic and chemical-free baby products and are
11 willing to pay a premium for healthy and high nourishment meals.¹⁹

12 50. Even for value purchasers, these parents expect that all baby foods they
13 buy will be safe and nutritious.²⁰

14 51. Parents look to endorsements from trusted sources like health experts in
15 choosing baby food.

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18 ¹⁷ *Oh, Baby! Trends in the Global Baby Food and Diaper Markets*, NIELSEN (Aug.
19 2015) [https://www.nielsen.com/wp-](https://www.nielsen.com/wp-content/uploads/sites/3/2019/04/Global20Baby20Care20Report20Revised20FINAL-2.pdf)
20 [content/uploads/sites/3/2019/04/Global20Baby20Care20Report20Revised20FINAL-](https://www.nielsen.com/wp-content/uploads/sites/3/2019/04/Global20Baby20Care20Report20Revised20FINAL-2.pdf)
21 [2.pdf](https://www.nielsen.com/wp-content/uploads/sites/3/2019/04/Global20Baby20Care20Report20Revised20FINAL-2.pdf).

22 ¹⁸ Jesse Hirsch, *Heavy Metals in Baby Food: What You Need to Know*, CONSUMER
23 REPORTS (Aug. 16, 2018) [https://www.consumerreports.org/food-safety/heavy-](https://www.consumerreports.org/food-safety/heavy-metals-in-baby-food/)
24 [metals-in-baby-food/](https://www.consumerreports.org/food-safety/heavy-metals-in-baby-food/).

25 ¹⁹ *U.S. Baby Food Market Expected to Grow with a CAGR of 3.7% from 2019 to*
26 *2026*, BUSINESS WIRE (Mar. 3, 2020, 05:44 AM),
27 [https://www.businesswire.com/news/home/20200303005477/en/U.S.-Baby-Food-](https://www.businesswire.com/news/home/20200303005477/en/U.S.-Baby-Food-Market-Expected-to-Grow-with-a-CAGR-of-3.7-from-2019-to-2026---ResearchAndMarkets.com)
28 [Market-Expected-to-Grow-with-a-CAGR-of-3.7-from-2019-to-2026---](https://www.businesswire.com/news/home/20200303005477/en/U.S.-Baby-Food-Market-Expected-to-Grow-with-a-CAGR-of-3.7-from-2019-to-2026---ResearchAndMarkets.com)
[ResearchAndMarkets.com](https://www.businesswire.com/news/home/20200303005477/en/U.S.-Baby-Food-Market-Expected-to-Grow-with-a-CAGR-of-3.7-from-2019-to-2026---ResearchAndMarkets.com).

²⁰ *Oh, Baby! Trends in the Global Baby Food and Diaper Markets*, NIELSEN (Aug.
2015) [https://www.nielsen.com/wp-](https://www.nielsen.com/wp-content/uploads/sites/3/2019/04/Global20Baby20Care20Report20Revised20FINAL-2.pdf)
[content/uploads/sites/3/2019/04/Global20Baby20Care20Report20Revised20FINAL-](https://www.nielsen.com/wp-content/uploads/sites/3/2019/04/Global20Baby20Care20Report20Revised20FINAL-2.pdf)
[2.pdf](https://www.nielsen.com/wp-content/uploads/sites/3/2019/04/Global20Baby20Care20Report20Revised20FINAL-2.pdf).

1 **B. Arsenic, lead, cadmium, and mercury are toxic, hazardous**
2 **substances.**

3 52. Heavy metals such as arsenic, lead, cadmium, and mercury are
4 extremely toxic and dangerous to babies and young children.

5 53. All four of the heavy metals (arsenic, lead, cadmium, and mercury) are
6 defined by the Environmental Protection Agency as hazardous substances that may
7 endanger public health and subject companies to strict liability clean-up and
8 reporting requirements under the Comprehensive Environmental Response,
9 Compensation, and Liability Act. Designation of Hazardous Substances, 40 C.F.R.
10 § 302.4 (2019).

11 54. Except for inorganic arsenic in infant rice cereal, no federal agency has
12 determined that there is a safe level of these toxic heavy metals in baby food.

13 55. The lack of any federal FDA mandated maximum contaminant level for
14 baby food does not allow Defendants to simply ignore what research says about the
15 harm associated with these high levels of heavy metals in baby food. Indeed,
16 without action by the FDA, there has been no federal government determination of
17 what levels of these hazardous neurotoxins (arsenic, lead, cadmium, and mercury)
18 can be safely consumed by infants and children through regular consumption of
19 baby food and snacks. Standards for these hazardous substances from other
20 contexts indicates that the levels in Manufacturer Defendants' baby foods are not
21 safe or healthy.

22 56. This contamination, even in small amounts, can be especially dangerous
23 for young children: "Infants are especially vulnerable because their bodies are so
24 small, and on a per-pound basis, they're getting much higher exposure than anyone
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1 else in the population,” according to Jane Houlihan, research director for Healthy
2 Babies Bright Futures, discussing arsenic exposure in baby food in 2017.²¹

3 57. A Healthy Babies 2019 Report also concluded that the exposure to
4 these four heavy metals was particularly harmful for infants and children:²²

- 5 a. Arsenic, lead, mercury, and cadmium, four heavy metals found in the
6 baby foods, are neurotoxins.
- 7 b. Exposures to these four heavy metals “diminish quality of life, reduce
8 academic achievement, and disturb behavior, with profound
9 consequences for the welfare and productivity of entire societies.”
- 10 c. These four toxins “can harm a baby’s developing brain and nervous
11 system” and cause negative impacts such as “the permanent loss of
12 intellectual capacity and behavioral problems like attention-deficit
13 hyperactivity disorder (ADHD).”
- 14 d. Even in trace amounts found in food, these heavy metals can alter the
15 developing brain and erode a child’s IQ.
- 16 e. These four heavy metals pose “troubling risks for babies, including
17 cancer and lifelong deficits in intelligence”

18 58. The risk of exposure to heavy metals is exacerbated in babies and
19 toddlers because they are small, have other developing organ systems, and absorb
20 more of the heavy metals than adults.

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23 ²¹ Roni Caryn Rabin, *Should You be Worried About the Arsenic in Your Baby Food?*,
24 THE NEW YORK TIMES (Dec. 7, 2017)

25 <https://www.nytimes.com/2017/12/07/well/eat/should-you-be-worried-about-the-arsenic-in-your-baby-food.html>.

26 ²² Jane Houlihan & Charlotte Brody, *What’s In My Baby’s Food?*, HEALTHY BABIES
27 BRIGHT FUTURES (Oct. 2019),

28 [https://www.healthybabyfood.org/sites/healthybabyfoods.org/files/2019-](https://www.healthybabyfood.org/sites/healthybabyfoods.org/files/2019-10/BabyFoodReport_FULLREPORT_ENGLISH_R5b.pdf)

[10/BabyFoodReport_FULLREPORT_ENGLISH_R5b.pdf](https://www.healthybabyfood.org/sites/healthybabyfoods.org/files/2019-10/BabyFoodReport_FULLREPORT_ENGLISH_R5b.pdf) (attached as Ex. B).

1 59. Because of how the effects of exposure to these heavy metals manifest,
2 the potentially catastrophic effects on children who ate food produced by
3 Manufacturer Defendants that contains these heavy metals might not be discovered
4 for years to come.

5 ***1. Arsenic***

6 60. *Arsenic* is ranked number one among substances present in the
7 environment that pose the most significant potential threat to human health,
8 according to the Department of Health and Human Services' Agency for Toxic
9 Substances and Disease Registry (ATSDR).²³

10 61. The known health risks of arsenic exposure include “respiratory,
11 gastrointestinal, haematological, hepatic, renal, skin, neurological and
12 immunological effects, as well as damaging effects on the central nervous system
13 and cognitive development in children.”²⁴

14 62. A study of Maine schoolchildren exposed to arsenic in drinking water
15 found that children exposed to water with an arsenic concentration level greater
16 than 5 parts per billion (ppb) “showed significant reductions in Full Scale IQ,
17 Working Memory, Perceptual Reasoning and Verbal Comprehension scores.” The
18 authors noted that 5 ppb was an important exposure threshold.²⁵

21 ²³ *ATSDR's Substance Priority List*, AGENCY FOR TOXIC SUBSTANCES AND DISEASE
22 REGISTRY, (2019), www.atsdr.cdc.gov/spl/index.html#2019spl (last visited Mar. 3,
23 2021).

24 ²⁴ The House Staff Report at 10, (citing Miguel Rodríguez-Barranco et al.,
25 *Association of arsenic, cadmium and manganese exposure with neurodevelopment*
26 *and behavioural disorders in children: a systematic review and meta-analysis*,
27 NATIONAL LIBRARY OF MEDICINE (June 1, 2013),
28 <https://pubmed.ncbi.nlm.nih.gov/23570911/>).

²⁵ *Id.* (citing Gail A. Wasserman et al., A cross-sectional study of well water arsenic
and child IQ in Maine schoolchildren, BIOMED CENTRAL, INC. (Apr. 1, 2014),
<https://ehjournal.biomedcentral.com/articles/10.1186/1476-069X-13-23>)).

1 63. The FDA acknowledged the grave dangers in consumption of high
2 levels of arsenic by infants: “FDA’s risk assessment shows that inorganic arsenic
3 exposure during fetal development, infancy, and childhood may contribute to
4 neurodevelopmental effects, as well as increase lifetime cancer risk, and that
5 establishing an action level will reduce inorganic arsenic exposure and risk.”²⁶

6 64. The Environmental Protection Agency has set the maximum
7 contaminant level (MCL) for arsenic to 10 micrograms per liter (or 10 ppb) for
8 public drinking water systems, as have the European Union and the World Health
9 Organization.

10 65. The FDA has already set maximum inorganic arsenic levels at 10 ppb
11 for bottled water. FDA has also set the maximum amount of inorganic arsenic in
12 infant rice cereals at 100 ppb.²⁷

13 66. Consumer Reports suggests setting inorganic arsenic levels as low as 3
14 ppb.

15 67. Organizations such as Healthy Babies Bright Futures have called for a
16 goal of no measurable amount of inorganic arsenic in baby food.

17 **2. Lead**

18 68. **Lead** is number two on ATSDR’s list of substances present in the
19
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21 ²⁶ *Supporting Document for Action Level for Inorganic Arsenic in Rice Cereals for*
22 *Infants*, U.S. FOOD & DRUG ADMINISTRATION (Aug. 5, 2020)
23 [https://www.fda.gov/food/chemical-metals-natural-toxins-pesticides-guidance-](https://www.fda.gov/food/chemical-metals-natural-toxins-pesticides-guidance-documents-regulations/supporting-document-action-level-inorganic-arsenic-rice-cereals-infants)
24 [documents-regulations/supporting-document-action-level-inorganic-arsenic-rice-](https://www.fda.gov/food/chemical-metals-natural-toxins-pesticides-guidance-documents-regulations/supporting-document-action-level-inorganic-arsenic-rice-cereals-infants)
25 [cereals-infants](https://www.fda.gov/food/chemical-metals-natural-toxins-pesticides-guidance-documents-regulations/supporting-document-action-level-inorganic-arsenic-rice-cereals-infants).

26 ²⁷ *Drinking Water Requirements for States and Public Water Systems*,
27 ENVIRONMENTAL PROTECTION AGENCY, [www.epa.gov/dwreginfo/chemical-](http://www.epa.gov/dwreginfo/chemical-contaminant-rules)
28 [contaminant-rules](http://www.epa.gov/dwreginfo/chemical-contaminant-rules) (last visited Mar. 3, 2021); *Arsenic (Q&A)*, THE EUROPEAN FOOD
INFORMATION COUNCIL (Dec. 8, 2014) [www.eufic.org/en/food-safety/article/arsenic-](http://www.eufic.org/en/food-safety/article/arsenic-qa)
[qa](http://www.eufic.org/en/food-safety/article/arsenic-qa)); *Arsenic*, WORLD HEALTH ORGANIZATION (Feb. 15, 2018)
<https://www.who.int/news-room/fact-sheets/detail/arsenic>.

1 environment that pose the most significant potential threat to human health.²⁸

2 69. Even small doses of lead exposure are hazardous, particularly to
3 children.²⁹ “Lead exposure is a particular health concern for fetuses, infants, and
4 children because of their developing nervous system. In addition, infants and
5 young children exhibit greater percentage of dietary lead absorption than do
6 adults.”³⁰

7 70. The Centers for Disease Control and Prevention maintains there is no
8 known safe blood lead level in children. Even low levels of lead in blood have
9 been shown to affect IQ, ability to pay attention, and academic achievement.³¹

10 71. The FDA acknowledges that “even low-level chronic exposure” to lead
11 “can be hazardous over time” because “lead can accumulate in the body.”³²

12 72. Lead is associated with a range of negative health outcomes, including
13 behavioral problems, decreased cognitive performance, delayed puberty, and
14 reduced postnatal growth.

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19 ²⁸ *ATSDR’s Substance Priority List*, AGENCY FOR TOXIC SUBSTANCES AND DISEASE
20 REGISTRY, (2019), www.atsdr.cdc.gov/spl/index.html#2019spl (last visited Mar. 3,
21 2021).

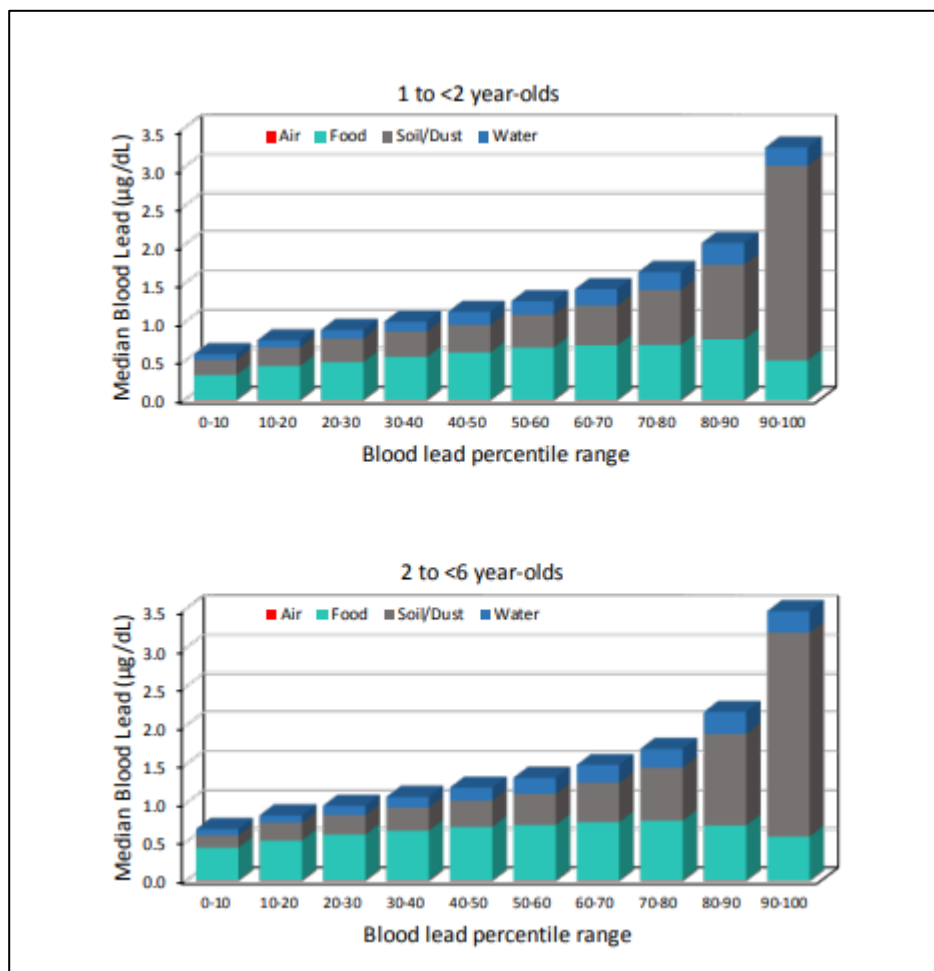
22 ²⁹ The House Staff Report at 11 (citing Philippe Grandjean, *Even low-dose lead*
23 *exposure is hazardous*, NATIONAL LIBRARY OF MEDICINE (Sept. 11, 2010)
24 <https://pubmed.ncbi.nlm.nih.gov/20833288/>).

25 ³⁰ Brenna Flannery et al., *U.S. Food & Drug Administration’s interim reference levels*
26 *for dietary lead exposure in children and women of childbearing age*, 110
27 REGULATORY TOXICOLOGY & PHARMACOLOGY 104516 (2020).

28 ³¹ *Blood Levels in Children*, CENTERS FOR DISEASE CONTROL & PREVENTION (last
reviewed Feb. 9, 2021), [https://www.cdc.gov/nceh/lead/prevention/blood-lead-
levels.htm](https://www.cdc.gov/nceh/lead/prevention/blood-lead-levels.htm) (last visited Mar. 8, 2021).

³² *Lead in Food, Foodwares, and Dietary Supplements*, U.S. FOOD & DRUG
ADMINISTRATION (Feb. 27, 2020) [https://www.fda.gov/food/metals-and-your-
food/lead-food-foodwares-and-dietary-supplements](https://www.fda.gov/food/metals-and-your-food/lead-food-foodwares-and-dietary-supplements).

1 73. Half of blood lead exposure for most children between the ages of 1 and
 2 6 comes from food.³³



18 74. FDA has set a 5-ppb lead standard for bottled water, WHO has set 10
 19 ppb lead as a provisional guideline for drinking water, and EPA has set an action
 20 level of 15 ppb for lead in drinking water. FDA has also set standards for lead in
 21 juice (50 ppb) and candy (100 ppb). The European Union has set the maximum
 22 lead level in infant formula to 20 ppb.

23 75. The FDA has also set an Interim Reference Level, the maximum daily
 24 intake level from food, of 3ppb for lead in children. The FDA also again noted that
 25

26 ³³ Valerie Zartarian, Jianping Xue, Rogelio Tornero-Velez, and James Brown,
 27 *Supplemental Material, Children’s Lead Exposure: A Multimedia Modeling Analysis*
 28 *to Guide Public Health Decision-Making*, ENV’L HEALTH PERSPECTIVES 97009-1
 (Sept. 12, 2017).

1 there has been “no safe level of lead exposure” yet “identified for children’s
2 health.”³⁴

3 76. There is a growing consensus among health experts that lead levels in
4 baby foods should not exceed 1 ppb. The American Academy for Pediatrics, the
5 Environmental Defense Fund, and Consumer Reports have all, in some form,
6 called for a 1 ppb level in food and drinks that babies and children consume.

7 77. Healthy Babies Bright Futures has called for a goal of no measurable
8 amount of lead in baby food.

9 78. Most children with any lead in their blood have no obvious immediate
10 symptoms. Blood tests are a simple and readily available way to assess a person’s
11 exposure to lead. According to the CDC, early identification of elevated blood lead
12 levels is key to reducing the long-term effects of lead exposure.³⁵

13 79. While regulation can minimize dietary lead exposure, it can also be
14 minimized “through surveillance of lead concentrations in food, and adjustment of
15 manufacturing processes.”³⁶

16 3. *Cadmium*

17 80. *Cadmium* is number seven on ATSDR’s list of substances present in
18 the environment that pose the most significant potential threat to human health.³⁷

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21 ³⁴ Brenna Flannery et al., *U.S. Food & Drug Administration’s interim reference levels
22 for dietary lead exposure in children and women of childbearing age*, 110
REGULATORY TOXICOLOGY & PHARMACOLOGY 104516 (2020).

23 ³⁵ *Blood Levels in Children*, CENTERS FOR DISEASE CONTROL & PREVENTION (last
24 reviewed Feb. 9, 2021), [https://www.cdc.gov/nceh/lead/prevention/blood-lead-
25 levels.htm](https://www.cdc.gov/nceh/lead/prevention/blood-lead-levels.htm) (last visited Mar. 8, 2021).

26 ³⁶ Brenna Flannery et al., *U.S. Food & Drug Administration’s interim reference levels
27 for dietary lead exposure in children and women of childbearing age*, 110
REGULATORY TOXICOLOGY & PHARMACOLOGY 104516 (2020).

28 ³⁷ *ATSDR’s Substance Priority List*, AGENCY FOR TOXIC SUBSTANCES AND DISEASE
REGISTRY, (2019), www.atsdr.cdc.gov/spl/index.html#2019spl (last visited Mar. 3,
2021).

1 81. Cadmium is associated with decreases in IQ, as well as the
2 development of attention deficit hyperactivity disorder (ADHD).

3 82. EPA has a limit of 5 ppb of cadmium in drinking water, and FDA
4 similarly has set a limit of 5 ppb in bottled water. The World Health Organization
5 has set its limit for cadmium in drinking water at 3 ppb. The EU has set a limit
6 ranging from 5–20 ppb cadmium for infant formula.

7 83. Groups like Healthy Babies Bright Futures have set a goal of no
8 measurable amount of cadmium in baby food. Consumer Reports has called for a
9 limit of 1 ppb cadmium in fruit juices.

10 4. *Mercury*

11 84. *Mercury* is number three on ATSDR’s list of substances present in the
12 environment that pose the most significant potential threat to human health.

13 85. EPA has capped mercury in drinking water at 2 ppb.

14 86. Consumer advocates urge even stricter standards for baby food. For
15 example, Health Babies Bright Futures has called for a goal of no measurable
16 amount of mercury in baby food.

17 C. **Defendants have known for years that their baby food products 18 contained or could contain unsafe levels of heavy metals.**

19 87. For years, Defendants have been aware that Manufacturer Defendants’
20 products contained dangerous levels of heavy metals, yet they failed to take action
21 to minimize the amount of toxins in foods that would eventually be consumed by
22 young children, toddlers, and infants.³⁸

23 88. On June 15, 2017, the Environmental Defense Fund released a report
24 demonstrating that lead had been frequently detected in baby foods. In fact, 20% of
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26 ³⁸ See Sally Kuzemchak, *Everything You Need to Know About Heavy Metals and*
27 *Contaminants in Baby Food*, PARENTS (Feb. 4, 2021)
28 <https://www.parents.com/recipes/scoop-on-food/clean-label-project-study-finds-contaminants-in-formula-baby-food/>.

1 baby food samples tested by the Food and Drug Administration from 2003 to 2013
2 contained lead.³⁹ Lead was most commonly found in grape (89%), mixed fruit
3 (67%), apple (55%), and pear (45%) juices; sweet potatoes (86%); carrots (43%);
4 arrowroot cookies (64%); and teething biscuits (47%).

5 89. In October 2017, a non-profit organization called Clean Label Project (a
6 nonprofit focused on “bring[ing] truth and transparency to food and consumer
7 product labeling”⁴⁰) released findings from a study showing contaminants such as
8 arsenic, lead, and mercury in leading brands of infant formula and baby foods.
9 Clean Label Project purchased baby foods available in grocery stores across
10 America and independently tested them. The Clean Label Project report noted:

- 11 a. Over 30 percent of infant formulas and baby foods contained lead as
12 well as many other contaminants including arsenic and mercury;
 - 13 b. Over 20 percent of all products tested exceeded at least one state or
14 federal guideline for contaminants;
 - 15 c. Some products labeled “certified organic” actually had higher amounts
16 of mercury and lead than conventional baby foods, although the organic
17 baby foods had fewer pesticides;
 - 18 d. Rice-based “puff” snacks had on average over 5 times as much arsenic
19 as other baby snacks.⁴¹
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24 ³⁹ Press Release, Environmental Defense Fund, EDF Report Finds Lead in 1 in 5
25 Baby Food Samples (June 15, 2017), available at [https://www.edf.org/media/edf-
report-finds-lead-1-5-baby-food-samples](https://www.edf.org/media/edf-report-finds-lead-1-5-baby-food-samples).

26 ⁴⁰ *Our Mission*, CLEAN LABEL PROJECT, [https://cleanlabelproject.org/about-us/#our-
mission](https://cleanlabelproject.org/about-us/#our-mission) (last visited Mar. 3, 2021).

27 ⁴¹ *What are You Really Feeding Your Baby?*, CLEAN LABEL PROJECT (Oct. 25, 2017)
28 <https://cleanlabelproject.org/blog-post/clp-infant-formula-baby-food-test/>.

1 90. The products of Manufacturer Defendants and non-Defendant, co-
2 conspirators were included as the worst in the baby food categories:⁴²

3 a. Plum Defendants: Plum Organics Stage 2 Apple & Carrot Organic
4 Baby Food was identified as one of the bottom five pouches.

5 b. Defendant Nurture: Happy Baby Organic Teethers Sweet Potato and
6 Banana Gentle Teething Wafers was identified as one of the bottom
7 five snacks.

8 c. Defendant Gerber: (1) Gerber DHA & Probiotic Rice Cereal with
9 Vitablocks was identified as one of the bottom five baby cereals; (2)
10 Gerber 3rd Foods Banana Apple Strawberry with Lil' Bits and 3rd
11 Foods Mixed Carrots, Corn and Butternut Squash with Lil' Bits were
12 identified as two of the bottom five jar meals; (3) Gerber Graduates
13 Grabbers Apple & Sweet Potato with Cinnamon Squeezable Fruit &
14 Veggies was identified as one of the bottom five pouches; (4) Gerber
15 Graduates Lil' Biscuits Vanilla Wheat Biscuits was identified as one of
16 the bottom five snacks.

17 d. Hain: (1) Earth's Best Organic Whole Grain Rice Cereal was identified
18 as one of the bottom five baby cereals; (2) Earth's Best Stage 2-
19 Organic Apple Raisin Flax & Oat Wholesome Breakfast was identified
20 as one of the bottom five pouches.

21 91. The following year, in 2018, *Consumer Reports* analyzed 50 nationally
22 distributed baby and toddler foods for arsenic, lead, cadmium, and mercury.

23 Consumer Reports tested products from Defendant Beech-Nut, Defendant Plum,
24 Defendant Nurture, Defendant Gerber, and Hain. It found that 68 percent of tested
25

26 _____
27 ⁴² *Infant Formula and Baby Food Project Summary*, CLEAN LABEL PROJECT,
28 <https://web.archive.org/web/20171027011929/http://www.cleanlabelproject.org/product-ratings/infant-formula-baby-food/#top-ten> (last visited Mar. 3, 2021).

1 products had worrisome levels of at least one of these metals, and over 25 percent
2 would pose a risk to a child who only ate one serving or less per day.⁴³

3 92. Consumer Reports' testing showed that all the samples of Defendant
4 Beech-Nut's Classics Sweet Potatoes, Hain's Earth's Best Organic Sweet Potatoes,
5 and Defendant Gerber's Turkey & Rice had concerning levels of lead. Consumer
6 Reports sent its findings to these Defendants. Defendant Gerber went back and
7 tested samples of its turkey and rice dinner from the same three batches CR tested.
8 The company said it got similar results and that it was "reviewing our protocols for
9 further improvement." Defendant Beech-Nut did not detect lead in its independent
10 testing but noted that based on an internal investigation, the company was
11 upgrading the requirements for its third-party lab testing.⁴⁴

12 93. Consumer Reports also calculated a daily limit for certain of
13 Manufacturer Defendants' products to determine the number of servings a child
14 would need to eat for the food to pose potential health risks from exposure to the
15 three heavy metals. All Manufacturer Defendants as well as non-Defendant co-
16 conspirators Hain had products where the daily limit for that product was less than
17 one serving per day.⁴⁵

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20 ⁴³ Jesse Hirsch, *Heavy Metals in Baby Food: What You Need to Know*, CONSUMER
21 REPORTS (Aug. 16, 2018) [https://www.consumerreports.org/food-safety/heavy-](https://www.consumerreports.org/food-safety/heavy-metals-in-baby-food/)
22 *metals-in-baby-food/*; *see also*, *CR renews call for FDA and manufacturers to take*
23 *action to keep infants and children safe from heavy metals in foods*, CONSUMER
24 REPORT (Feb. 4, 2021) [https://advocacy.consumerreports.org/press_release/cr-](https://advocacy.consumerreports.org/press_release/cr-renews-call-for-fda-and-manufacturers-to-take-action-to-keep-infants-and-children-safe-from-heavy-metals-in-foods/)
25 *renews-call-for-fda-and-manufacturers-to-take-action-to-keep-infants-and-children-*
26 *safe-from-heavy-metals-in-foods/*.

25 ⁴⁴ Jesse Hirsch, *Heavy Metals in Baby Food: What You Need to Know*, CONSUMER
26 REPORTS (Aug. 16, 2018) [https://www.consumerreports.org/food-safety/heavy-](https://www.consumerreports.org/food-safety/heavy-metals-in-baby-food/)
27 *metals-in-baby-food/*.

27 ⁴⁵ Jesse Hirsch, *Heavy Metals in Baby Food: What You Need to Know*, CONSUMER
28 REPORTS (Aug. 16, 2018) [https://www.consumerreports.org/food-safety/heavy-](https://www.consumerreports.org/food-safety/heavy-metals-in-baby-food/)
metals-in-baby-food/.

1 94. The Consumer Reports study indicated that products with rice were
2 particularly susceptible to dangerous heavy metal contamination. Additionally, as a
3 category, snack foods—bars, cookies, crackers, crunches, crisps, puffs, and rice
4 rusks and other teething biscuits—were the most problematic. Consumer Reports
5 noted that this was particularly concerning because “snacks are also the most
6 common type of packaged product that babies and toddlers eat, according to CR’s
7 recent survey. Seventy-two percent of parents said they feed their child at least one
8 of the types of snack foods we tested.”⁴⁶

9 95. Consumer Reports also found that organic baby foods were just as
10 likely to contain heavy metals as those from conventional farms.

11 96. The Consumer Reports’ researchers noted: “Babies and toddlers are
12 particularly vulnerable due to their smaller size and developing brains and organ
13 systems. They also absorb more of the heavy metals that get into their bodies than
14 adults do.”⁴⁷

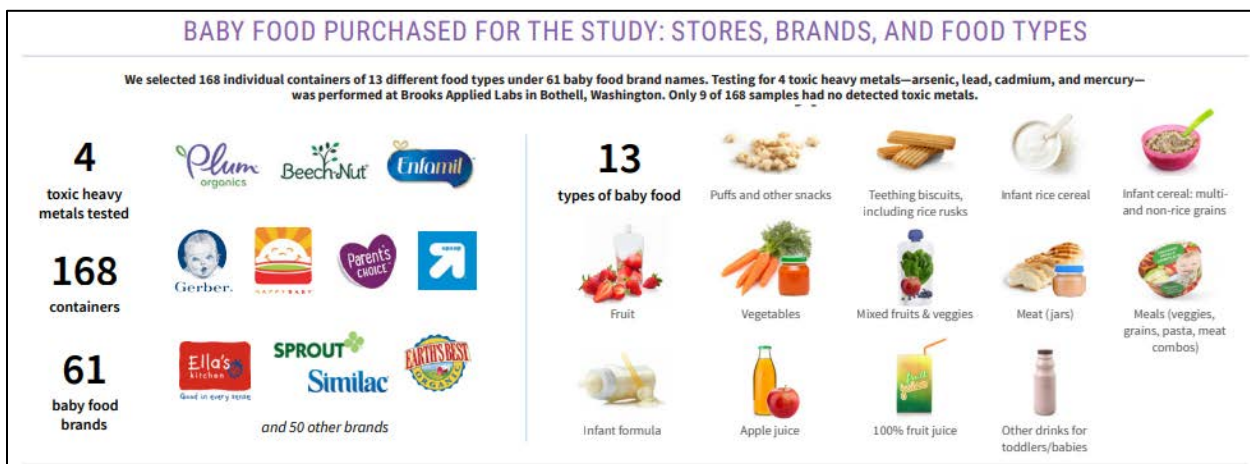
15 97. In its 2018 report, Consumer Reports also concluded that children’s
16 food manufacturers could reduce the heavy metal content of their products.

17 98. These alarm bells sounded again in October 2019 when Healthy Babies
18 Bright Futures released a report detailing that dangerous levels of toxic heavy
19 metals were found in **95 percent of baby food**.⁴⁸ The Healthy Baby study tested
20 products from all Manufacturer Defendants and provided their findings publicly.
21

22
23 ⁴⁶ Jesse Hirsch, *Heavy Metals in Baby Food: What You Need to Know*, CONSUMER
24 REPORTS (Aug. 16, 2018) [https://www.consumerreports.org/food-safety/heavy-](https://www.consumerreports.org/food-safety/heavy-metals-in-baby-food/)
25 [metals-in-baby-food/](https://www.consumerreports.org/food-safety/heavy-metals-in-baby-food/).

26 ⁴⁷ Jesse Hirsch, *Heavy Metals in Baby Food: What You Need to Know*, CONSUMER
27 REPORTS (Aug. 16, 2018) [https://www.consumerreports.org/food-safety/heavy-](https://www.consumerreports.org/food-safety/heavy-metals-in-baby-food/)
28 [metals-in-baby-food/](https://www.consumerreports.org/food-safety/heavy-metals-in-baby-food/)

⁴⁸ Jane Houlihan & Charlotte Brody, *What’s In My Baby’s Food?*, HEALTHY BABIES
BRIGHT FUTURES (Oct. 2019),
<https://www.healthybabyfood.org/sites/healthybabyfoods.org/files/2019->



99. The Healthy Baby Report showed concerning levels of these toxic heavy metals in products from all Manufacturer Defendants as well as non-Defendant, co-conspirator Hain including:

- a. Defendant Beech-Nut: rice cereal (>100ppb arsenic, >5ppb cadmium)
- b. Plum Defendants: Snacks - Other (>35ppb arsenic, >20ppb cadmium)
- c. Defendant Nurture: snacks – puffs (>80ppb arsenic, >5ppb lead, >10ppb cadmium, >2ppb mercury)
- d. Defendant Gerber: rice cereal (>100ppb arsenic, >10ppb cadmium, >2ppb mercury)
- e. Hain: rice cereal (>100ppb arsenic, >15ppb lead, >10ppb cadmium, >2ppb mercury)

100. Four of seven infant rice cereals tested in the Healthy Baby study contained inorganic arsenic in excess of FDA’s action level.

101. The Healthy Baby Report noted that a study by a nationally-recognized toxicology and economic research firm estimated 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. Based on this risk,

10/BabyFoodReport_FULLREPORT_ENGLISH_R5b.pdf (attached as Ex. B) (emphasis added).

1 Healthy Babies Bright Futures concluded that baby food companies needed to—
2 and could—take swift action to reduce arsenic levels in rice-based foods.

3 102. In August 2020, the Clean Label Project released an updated report,
4 finding that nothing had changed. Of the 530 baby and toddler food products
5 tested, “[t]he results of the baby food study were shocking”: lead was detected in
6 36 percent of products, cadmium in 58 percent, arsenic in 65 percent.⁴⁹ Certified
7 organic products were found to have twice the amount of arsenic than conventional
8 products.

9 103. In its August 2020 report, the Clean Label Project again called for
10 manufacturers to test for heavy metals “to ensure that their product is safe and
11 wholesome.”⁵⁰

12 **D. Despite Defendants’ knowledge of heavy metal contamination, they**
13 **misled consumers about the safety of their products and the**
14 **veracity of watchdog reports through press releases, the creation of**
15 **industry groups, and advertising.**

16 104. Knowing that consumers valued the quality and safety of the baby food
17 products they fed their children, Defendants misrepresented the health, safety, and
18 contents of their products and omitted information about the testing that showed
19 risky levels of toxic heavy metals.

20 105. Each Defendant engaged in false representations, fraud by omission,
21 fraud by half-truth, and/or fraudulent concealment.

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26 ⁴⁹ *Baby Food: A Puree of Plasticizers and Heavy Metals*, CLEAN LABEL PROJECT
27 (Aug. 10, 2020) <https://cleanlabelproject.org/baby-food-white-paper/>. Attached as
28 Exhibit C.

⁵⁰ *Id.*

1 *1. After consumer watchdog reports broke, Defendants released*
2 *intentionally misleading statements to lull consumers and*
3 *regulators into inaction.*

4 106. On December 11, 2017, after the release of the Clean Label Project
5 report, Plum Defendants stated: “**We believe that Plum’s products are safe to**
6 **eat.** Our testing confirmed that the **averaged results** for heavy metals in all tested
7 Plum products gave concentrations that are typical for those ingredients – whether
8 that’s a leafy green grown in your own garden or a bunch of carrots purchased at
9 the farmer’s market. The results also demonstrate our tested products are below
10 exposure limits set by **certain** domestic and international regulatory bodies.”⁵¹

11 107. Notably, however, Plum Defendants purposefully did not state which of
12 these “certain domestic and international regulatory bodies” it was referring to, and
13 its reference to “averaged results” was deliberately misleading and fraud by half-
14 truth because it did not explain what exact numbers were averaged together.

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27 ⁵¹ *Plum’s Updated Response to Clean Label Project Report*, PLUM ORGANICS (Dec.
28 11, 2017) <https://www.plumorganics.com/plums-response-clean-label-report/>
(emphasis added).

1 108. In 2018, when Consumer Reports reported on its independent testing
2 showing Beech-Nut baby foods also included worrisome levels of toxic heavy
3 metals, **Beech-Nut** sought to downplay the reports and assured parents that its
4 baby foods were “healthy, nutritious and safe” and that it had already taken the
5 recommended actions. It also inaccurately stated that “no government standard or
6 recommendation exists for lead.”⁵² On August 16, 2018, this press release was also
7 picked up by news media sites and relayed to the public.⁵³

8 **Beech-Nut Response to the Recent Consumer Reports** 9 **Article on Baby Food**

10 We want to reassure parents that Beech-Nut’s real food for babies is healthy, nutritious and safe. Our focus is on the safety and
11 quality of the food we prepare for infants and toddlers.

12 The Consumer Reports baby food article recommends specific actions for manufacturers, including sourcing produce from areas
13 less likely to be contaminated, and ensuring water and equipment used for manufacturing don’t contribute to contamination. These
14 actions have been an important part of Beech-Nut’s quality and safety process for many years. We also want to assure parents that
15 there is not a recall on any of our products, and we have high confidence in the quality and standards we use in making our food.

16 All produce – even the highest quality, organic and non-GMO fruits and vegetables you buy at the grocery store or a farmer’s
17 market – contain very tiny levels, or trace amounts, of lead and other elements because they exist naturally in soil, air and water.
18 Our goal is and always has been to minimize the trace amounts of heavy metals in our products. Certain ingredients, like sweet
19 potatoes and rice, are especially vulnerable because of their growing conditions.

20 Currently, no government standard or recommendation exists for lead. We continue to advocate for a government standard or
21 recommendation for lead level, and we would welcome the opportunity to work with the FDA on science-based standards that
22 food suppliers can implement across our industry.

23 Please visit our Food Quality & Safety page for more information on our food quality standards.

19 109. Similarly, in 2018, as Consumer Reports revealed its independent
20 testing showing Gerber baby foods also included worrisome levels of toxic heavy
21 metals, Defendant Gerber sought to downplay the reports and assured parents in a
22 statement that was published on August 16, 2018: “All of our foods meet our
23

24 ⁵² *Beech-Nut Response to the Recent Consumer Reports Article on Baby Food*,
25 BEECH-NUT, <https://www.beechnut.com/response-recent-consumer-reports-article/>
(last visited Mar. 3, 2021).

26 ⁵³ Thomas Barrabi, *Baby food brands contain ‘worrisome’ level of toxic metals:*
27 *Gerber, Beech-Nut respond*, FOX BUSINESS (Aug. 16, 2018),
28 [https://www.foxbusiness.com/markets/baby-food-brands-contain-worrisome-level-of-](https://www.foxbusiness.com/markets/baby-food-brands-contain-worrisome-level-of-toxic-metals-gerber-beech-nut-respond)
[toxic-metals-gerber-beech-nut-respond](https://www.foxbusiness.com/markets/baby-food-brands-contain-worrisome-level-of-toxic-metals-gerber-beech-nut-respond).

1 safety and quality standards, which are among the strictest in the world.” “Our
 2 rigorous standards are developed by evaluating the latest food safety guidance –
 3 from sources like the Food and Drug Administration, Environmental Protection
 4 Agency, and international health authorities. Gerber also partners with our farmers
 5 and our ingredient and packaging suppliers to control, reduce and limit
 6 contaminants in all our foods.”⁵⁴

7 110. The 2019 Health Baby report prompted another deceptive statement
 8 sent through the interstate wires to consumers by Defendant Beech-Nut across the
 9 country. Defendant Beech-Nut represented to consumers that “[o]ur process starts
 10 with high-quality fruits and vegetables that meet BNN’s own standards, which in
 11 some cases are **10 times stricter than those of the U.S. government. For**
 12 **example, we test for 255 common contaminants, such as lead, other heavy**
 13 **metals and pesticides, to confirm that all the ingredients delivered to us and**
 14 **used in our products comply with our standards. If they don’t, we send them**
 15 **back.”⁵⁵**

16 **2. *Using Big Tobacco’s playbook, Manufacturer Defendants rush***
 17 ***to create the Baby Food Council and each uses it as a vessel for***
 18 ***fraud.***

19 111. As Congress began to investigate Manufacturer Defendants’
 20 wrongdoing in late 2018, Manufacturer Defendants turned to one of Big Tobacco’s
 21 proven tricks: creating a seemingly independent and pro-consumer entity that
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 25 ⁵⁴ Thomas Barrabi, *Baby food brands contain ‘worrisome’ level of toxic metals: Gerber, Beech-Nut respond*, FOX BUSINESS (Aug. 16, 2018),
 26 <https://www.foxbusiness.com/markets/baby-food-brands-contain-worrisome-level-of-toxic-metals-gerber-beech-nut-respond>.

27 ⁵⁵ *Baby Food Council Commits to Food Safety*, BEECH-NUT (Oct. 17, 2019),
 28 <https://www.beechnut.com/baby-food-council/> (emphasis added).

1 suggested they were actually committed to stopping the very fraud they were
2 directing and perpetrating. This new entity was called the Baby Food Council.

3 112. The Baby Food Council was created in January 2019 only after
4 congressional investigations began. It was put together quickly as a front
5 organization by Manufacturer Defendants to mislead and deflect attention away
6 from their ongoing fraud.

7 113. This deceptive maneuver was borrowed directly from the playbook of
8 Big Tobacco, which decades earlier had employed public relations experts,
9 lawyers, and lobbyists who worked to deceive the American public regarding the
10 dangers of smoking:

11 In December 1953, the CEOs of the major tobacco companies met
12 secretly in New York City. Their purpose was to counter the damage
13 from studies linking smoking to lung cancer. A year earlier Reader's
14 Digest—then the public's leading source of medical information—had
15 printed an article entitled “Cancer by the Carton” (Norr 1952). After it
16 appeared, cigarette sales plummeted for two years, the first such
17 decline of the century except during the Great Depression.

18 Working closely with John Hill, the founder of the public relations
19 giant Hill & Knowlton, the industry created “A Frank Statement to
20 Cigarette Smokers” and paid to have it published in 448 newspapers
21 on January 4, 1954. To give the industry a human face, the statement
22 included the signatures of the nation's top tobacco executives and
23 assured Americans that “we accept an interest in people's health as a
24 basic responsibility, paramount to every other consideration in our
25 business.” Furthermore, they promised that “we always have and
26 always will cooperate closely with those whose task it is to safeguard
27 the public's health” (Tobacco Industry Research Committee 1954).

28 The “Frank Statement” was a charade, the first step in a concerted,
half-century-long campaign to mislead Americans about the
catastrophic effects of smoking and to avoid public policy that might
damage sales. Unearthed later, industry documents showed the
repeated duplicity of its executives. Everything was at stake. The
industry wanted desperately to prevent, or at least delay, shifts in
public opinion that would permit a barrage of legislative, regulatory,
and legal actions that would erode sales and profits.⁵⁶

⁵⁶ Kelly D. Brownell & Kenneth E. Warner, *The Perils of Ignoring History: Big Tobacco Played Dirty and Millions Died. How Similar Is Big Food?*, MILBANK QUARTERLY (Mar. 2009), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2879177/>.

1 114. Tobacco executives deliberately engineered deception using a pro-
 2 consumer front group as a form of misdirection and concealment; they would give
 3 money to seemingly independent universities so they could control the research
 4 and, more important, any results that were released. Big Tobacco realized that the
 5 “best public relations approach was for the industry to become a major sponsor of
 6 medical research. This tactic offered several essential advantages. The call for new
 7 research implied that existing studies were inadequate or flawed. It made clear that
 8 there was more to know, and it made the industry seem a committed participant in
 9 the scientific enterprise rather than a self-interested critic.”⁵⁷

10 115. In other words, Big Tobacco created “a research program that would be
 11 controlled by the industry yet promoted as independent. This was a public relations
 12 masterstroke. [Big Tobacco executives] understood that simply giving money to
 13 scientists—through the National Institutes of Health or some other entity, for
 14 example—offered little opportunity to shape the public relations environment.
 15 However, offering funds **directly to university-based scientists** would **enlist**
 16 **their support and dependence**. Moreover, it would have the added benefit of
 17 making academic institutions ‘partners’ with the tobacco industry in its moment of
 18 crisis.”⁵⁸

19 116. The food industry has already been exposed for following the Big
 20 Tobacco playbook:

21 The tobacco team had a **playbook—a master plan and script that**
 22 **directed the behavior of industry executives, lobbyists, lawyers,**
 23 **scientists, and government officials friendly to the industry.** In *A*
Question of Intent, a former FDA commissioner, David Kessler (2001,
 p. xiii), wrote:

24 Devised in the 1950s and '60s, the tobacco industry's
 strategy was embodied in a script written by the lawyers.

25
 26 ⁵⁷ Allan Brandt, *Inventing Conflicts of Interest: A History of Tobacco Industry*
 27 *Tactics*, AM. J. PUBLIC HEALTH (Jan. 2012),
<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3490543/>.

28 ⁵⁸ *Id.* (emphasis added).

1 Every tobacco company executive in the public eye was
2 told to learn the script backwards and forwards, no
3 deviation was allowed. The basic premise was simple—
4 smoking had not been proved to cause cancer. Not proven,
5 not proven, not proven—this would be stated insistently
6 and repeatedly. Inject a thin wedge of doubt, create
7 controversy, never deviate from the prepared line. It was a
8 simple plan and it worked.

9 The **food industry appears to have a strategy as well**, repeatedly
10 carried to the public by spokespersons from food companies, trade
11 associations, and their political allies.⁵⁹

12 117. The baby food industry has taken these same techniques, proven to
13 work by Big Tobacco and already used by the overall food industry to beat back
14 proof that bad foods cause obesity, and applied them to baby food manufacturing,
15 sales, and marketing.

16 118. Big Tobacco was stopped only by a civil RICO claim that broke apart
17 the corrupt, coordinated corporate behavior that centered on fraudulent sales,
18 marketing, and advertising of tobacco products to American purchasers. In an
19 August 2006 judgment, a federal court ruled that several tobacco companies
20 “systematically defrauded the American people by lying for decades about, among
21 other things, the health effects of smoking and their marketing to children.”⁶⁰

22 **i. Manufacturer Defendants Use of the Baby Food**
23 **Council to Inappropriately Lull Consumers and**
24 **Regulators into Inaction**

25 119. Defendant Beech-Nut, Plum Defendants, Defendant Nurture, Defendant
26 Gerber along with non-Defendant co-conspirator Hain are mimicking Big Tobacco
27 through the establishment and use of the Baby Food Council. Until the site was
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24 ⁵⁹ Kelly D. Brownell & Kenneth E. Warner, *The Perils of Ignoring History: Big*
25 *Tobacco Played Dirty and Millions Died. How Similar Is Big Food?*, MILBANK
26 QUARTERLY (Mar. 2009), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2879177/>
(emphasis added).

27 ⁶⁰ *Big Tobacco finally forced to tell the truth about its deadly products through court-*
28 *ordered ads*, TRUTH INITIATIVE (Nov. 27, 2017), [https://truthinitiative.org/press/press-](https://truthinitiative.org/press/press-release/big-tobacco-finally-forced-tell-truth-about-its-deadly-products-through-court)
[release/big-tobacco-finally-forced-tell-truth-about-its-deadly-products-through-court.](https://truthinitiative.org/press/press-release/big-tobacco-finally-forced-tell-truth-about-its-deadly-products-through-court)

1 recently scrubbed, a website hosted on the food science department of Cornell
2 University claimed: “the Baby Food Council is a group of infant and toddler food
3 companies” (supported by other entities) that was “created in January 2019.”⁶¹

4 120. According to the Baby Food Council charter from May 21, 2019, its
5 members as of April 15, 2019, included Cornell University and the Manufacturer
6 Defendants: Beech-Nut, Campbell, Hain, Gerber, and Nurture’s brand, Happy
7 Family Organics.

8 121. Through the charter, these members agreed to “[t]reat the heavy metals
9 as an unavoidable contaminant that should be manageable by admitting their
10 presence, acknowledging no safe level in the food supply, and striving to drive the
11 levels as low as reasonably achievable using best-in-class management practices.”

12 122. The members also acknowledged that FDA had previously suggested
13 not looking at one food at a time but looking at overall exposure based on a child’s
14 complete diet.

15 123. When it was formed, Manufacturer Defendants and Hain stressed their
16 involvement in a joint press release issued on October 17, 2019, through the
17 Environmental Defense Fund.⁶²

- 18 a. Jason Jacobs, Vice President of Food Safety & Quality for Defendant
19 Beech-Nut, stated: ““Being a dad, I understand the need for safe food.
20 Beech-Nut cares deeply about the safety of all food – not just baby food
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23 ⁶¹ *CIFS-IPP Councils*, Cornell College of Agriculture & Life Sciences, Industry
24 Engagement, [https://foodscience.cals.cornell.edu/industry-partnership-program/cifs-
25 ipp-councils/](https://foodscience.cals.cornell.edu/industry-partnership-program/cifs-ipp-councils/); archived Feb. 25, 2021 at WAYBACK MACHINE,
[https://web.archive.org/web/20210225020557/https://foodscience.cals.cornell.edu/ind
26 ustry-partnership-program/cifs-ipp-councils/](https://web.archive.org/web/20210225020557/https://foodscience.cals.cornell.edu/industry-partnership-program/cifs-ipp-councils/).

26 ⁶² Press Release, Baby Food Council, The Baby Food Council is taking on the
27 challenge of reducing heavy metals in young kids’ food (Oct. 17, 2019),
28 [https://www.edf.org/media/baby-food-council-taking-challenge-reducing-heavy-
metals-young-kids-food](https://www.edf.org/media/baby-food-council-taking-challenge-reducing-heavy-metals-young-kids-food).

1 – and that’s why we were a founding member of the Baby Food
2 Council. We’re committed to working together to bring sustainable
3 change in this important environmental issue.”

4 b. Annalisa Fornarelli, Vice President of Global Food Safety and Quality
5 for Defendant Campbell, stated: “Plum Organics is proud to be a
6 member of the Baby Food Council. As part of the Council, we share the
7 same overall goal of our industry partners, and that is to provide safe
8 and high-quality products to babies and toddlers. Plum’s mission is to
9 provide all little ones with the very best food from the very first bite.”

10 c. Joel Lim, M.D., Medical Director for Gerber, stated: “Gerber has
11 always put babies and toddlers first, but we never stop asking ourselves,
12 ‘Can we do more?’ This question inspires our commitment to
13 continuously raise our high standards and improve our methods to
14 reduce and limit contaminants in all our foods. We’re excited to be
15 partnering with like-minded organizations who are also committed to
16 improving the safety and quality of food for little ones.”

17 d. Raul Fajardo, Senior Vice President of Technical Services for Hain,
18 stated: “Although heavy metals are naturally occurring in the
19 environment, we are always looking to reduce their presence in food.
20 Earth’s Best is excited to partner with the members of the Baby Food
21 Council to support this important initiative.”

22 e. Jason Rosecast, Vice President of Quality and Food Safety for
23 Defendant Nurture, stated: “At Happy Family Organics, our mission is,
24 and always has been, to change the trajectory of children’s health
25 through nutrition. Being a founding member of and contributor to the
26 Baby Food Council reinforces our commitment to create the best
27 possible foundation for young children to realize their potential to lead
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1 a happy and healthy life. This is a great challenge in which many
2 stakeholders across our industry need to work together, and we all share
3 in the responsibility to do so.”

4 124. Including Cornell University as a member (and having it host the
5 website) is directly in line with Big Tobacco by using university-based scientists
6 and partnering with academic institutions to further Manufacturer Defendants’
7 schemes. Further, there is good reason to infer that the baby food industry is
8 paying significant money to either Cornell University’s food science department
9 and/or the professors at Cornell who are running the Baby Food Council.

10 125. Despite being involved in the Baby Food Council, Manufacturer
11 Defendants knowingly violate several of the stated tenets of the Baby Food
12 Council and take positions contradicted by the Council:

13 a. First, the Baby Food Council affirmatively states that any exposure to
14 contaminated foods is unacceptable because “there is no known safe
15 level of exposure” for babies:

16 **Analysis of Baby Food Products for Heavy Metals**

17 A best practice to reduce heavy metals in vegetable and fruit purees is to regularly test ingredients and products for
18 low levels of arsenic, cadmium, and lead to be able to identify and resolve potential problems. Accordingly, the FDA
19 and food industry regularly test foods for various heavy metals, including arsenic, cadmium, and lead. These
20 common food contaminants occur naturally or from pollution in the environment. Organic and conventional crops
alike absorb them from soil and water. Their presence in baby food raises is a concern because babies are more
sensitive to their harmful impacts. There is no known safe level of exposure to these metals; hence even low levels of
contamination are a concern.

21 b. Second, the Baby Food Council website states that it is also important
22 to test “ingredients **and products**”—not simply each ingredient in
23 isolation. Manufacturer Defendants violate this tenant by willfully
24 testing only individual ingredients in isolation as an effort to sidestep
25 the contamination of the products. Of course, babies ingest products,
26 not ingredients in isolation, which renders this type of testing a sham.

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1 c. Third, the website refers to proper procedures for testing for “arsenic,
2 cadmium, and lead”—yet Manufacturer Defendants did not follow
3 these guidelines when knowingly manufacturing products with
4 contaminants.

5 126. Because of their financial contributions, Manufacturer Defendants were
6 able to influence the content of the Council’s website, however, in at least two
7 ways:

8 a. First, the Baby Food Council website falsely states that “contaminants
9 naturally occur”—an obviously false statement that was included to
10 mislead purchasers into believing the contamination in their food
11 cannot be mitigated when in fact it can. Indeed, “[t]oxic metals might
12 be more common in baby foods because of the vitamins and minerals
13 added to those foods during processing,” according to Michael Hansen,
14 senior staff scientist at Consumer Reports.

15 b. Second, the website ignores mercury as a dangerous heavy metal that is
16 included in baby food as a contaminant. The Council website speaks
17 only to arsenic, cadmium, and lead—it leaves out mercury entirely,
18 even though mercury is a well-known toxin present in baby food.

19 127. Prior to 2021, Defendant Campbell left the Baby Food Council for
20 unexplained reasons.

21 **ii. A Dormant Entity**

22 128. If it was not created by Manufacturer Defendants as a vessel for fraud,
23 the Baby Food Council appears to have been infiltrated and taken over by
24 Manufacturer Defendants. Several factors suggest this has occurred.

25 129. First, despite being formed in January 2019, the Council has taken no
26 meaningful steps toward solving the issue of heavy metals in baby food. Further,
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1 the Council cannot point to any activity it has taken that is contrary to the corporate
2 interests of its members, including Manufacturer Defendants.

3 130. Second, if the Baby Food Council were legitimately concerned with
4 baby food, it would have, at a minimum, commented upon the practices of
5 Manufacturer Defendants following the release of the February 2021 congressional
6 study. Or, at the very least, it would have issued some statement regarding this
7 bombshell, front page national news event. But the Baby Food Council, as of
8 March 11, 2021, has said nothing about these recent congressional findings.

9 131. Third, its website is hosted by the Food Science Department of Cornell
10 University, which is odd because Cornell is merely a member of the Baby Food
11 Council but does not own or operate the entity on its own. Further discovery is
12 needed for Plaintiff to uncover the financial payments made by Manufacturer
13 Defendants to Cornell and its faculty and any other connections between
14 Manufacturer Defendants and Cornell and its food science department, including
15 the professor listed on the Baby Food Council webpage (Professor Rui Hai Liu).

16 132. Fourth, the Council has virtually no online presence. Its members
17 frequently tout their membership as a defense to the fact they are engaging in food
18 fraud, but the Council does nothing. It issues no press releases, no guidance, no
19 newsletter, no updates, no safety alerts—nothing.

20 133. Fifth, the Council waited 10 months (from January to October 2019)
21 before doing or saying anything, and that occurred only because it knew that its
22 food manufacturer members (Manufacturer Defendants) were about to be
23 hammered for major food fraud violations:

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October 17, 2019

FOR IMMEDIATE RELEASE

(Washington, D.C. – October 17, 2019) Today, the [Baby Food Council](#), a broad-based group of companies and other organizations formed in January 2019, announced its efforts to take on the challenge of reducing heavy metals in young children’s food. This news comes as [Healthy Babies Bright Futures \(HBBF\)](#), a children’s health advocacy group and member of the Council, released a [new report](#) demonstrating that tests on over 150 foods consumed by babies and toddlers found that 95% of the products tested had detectable levels of heavy metals. Recognizing that heavy metals are widely present in the environment and can get into food, the Council seeks to reduce levels of heavy metals in food products to as low as reasonably achievable using best-in-class management techniques.

134. This press release directly connects the Baby Food Council’s activity to the incriminating Healthy Baby Bright Futures report that was about to be issued. Had the Healthy Baby Bright Futures report not been released, the Council would have taken no action. And even then, from October 2019 to present, nothing has changed. The Council and Defendants have not alerted purchasers that their food is contaminated, nor have they corrected their false advertising, recalled any of their defective products, or disproven the allegations that they are engaging in food fraud.

135. This 2019 release was not news to Defendants or the Council. At least by 2018, Defendants and the Council knew there was a systemic problem of contamination with baby food:

In 2018, [Consumer Report’s] food safety team analyzed 50 nationally distributed packaged foods made for babies and toddlers, checking for cadmium, lead, mercury, and inorganic arsenic, the type most harmful to health. Those tests found that about two-thirds (68 percent) had worrisome levels of at least one heavy metal. Fifteen of the foods would pose potential health risks to a child regularly eating just one serving or

1 less per day. Snacks and products containing rice and/or sweet potatoes
2 were particularly likely to have high levels of heavy metals.⁶³

3 **3. Throughout this time, Defendants continue to falsely reassure**
4 **consumers that their products are healthy, safe, pure, and**
5 **natural.**

6 136. Despite knowing their products posed a significant risk to the
7 developing minds and bodies of babies and young children, Defendants continue to
8 warrant, promise, represent, mislead, label, and/or advertise that their baby food
9 products are free of any heavy metals, and/or unnatural ingredients by making
10 assurances that the foods are natural, pure, healthy, and safe for infant
11 consumption.

12 **i. Beech-Nut**

13 137. Beech-Nut advertises its products as being “natural” and including only
14 “simple” ingredients and “nothing artificial.” But Beech-Nut omits that the
15 ingredients like dehydrated potato, sweet potato, prunes, carrots, spinach,
16 cinnamon, oat flour, and rice flour contain high levels of arsenic, lead, and
17 cadmium—all inorganic heavy metals.⁶⁴ Beech-Nut has made similar
18 representations on its product pages since at least July 10, 2017. In fact, on July 10,
19

20 ⁶³ *CR Renews call for FDA and manufacturers to take action*, CONSUMER REPORTS
21 (Feb. 4, 2021), [https://advocacy.consumerreports.org/press_release/cr-renews-call-](https://advocacy.consumerreports.org/press_release/cr-renews-call-for-fda-and-manufacturers-to-take-action-to-keep-infants-and-children-safe-from-heavy-metals-in-foods/)
22 [for-fda-and-manufacturers-to-take-action-to-keep-infants-and-children-safe-from-](https://advocacy.consumerreports.org/press_release/cr-renews-call-for-fda-and-manufacturers-to-take-action-to-keep-infants-and-children-safe-from-heavy-metals-in-foods/)
23 [heavy-metals-in-foods/](https://advocacy.consumerreports.org/press_release/cr-renews-call-for-fda-and-manufacturers-to-take-action-to-keep-infants-and-children-safe-from-heavy-metals-in-foods/).

24 ⁶⁴ *beech-nut natural*® *banana, cinnamon & granola pouch*, BEECH-NUT,
25 <https://www.beechnut.com/product/naturals-banana-cinnamon-granola-pouch/> (last
26 visited Mar. 3, 2021); *beech-nut naturals*® *sweet potato baked veggie crisps*, BEECH-
27 NUT, <https://www.beechnut.com/product/sweet-potato-baked-veggie-crisps/> (last
28 visited Mar. 3, 2021); *beech-nut naturals*® *carrots jar*, BEECH-NUT,
<https://www.beechnut.com/product/naturals-just-carrots-jar/> (last visited Mar. 3,
2021); *beech-nut naturals*® *spinach, zucchini & peas jar*, BEECH-NUT,
<https://www.beechnut.com/product/naturals-just-spinach-zucchini-peas-jar/> (last
visited Mar. 3, 2021).

1 2017, Beech-Nut represented to consumers that its Carrot jars were “just carrots”
 2 and “just real vegetables” “nothing artificial.”⁶⁵

3 **naturals sweet potato**
 4 **baked veggie crisps**

5 Beech-Nut Naturals® Baked Veggie Crisps sweet potato are a simple and tasty snack your toddler will love. Made with just 6 ingredients, and baked (not fried!) to create a crunchy texture that will help your little one continue to learn to love the taste and texture of real food. This gluten-free snack is Non-GMO Project verified and contains real veggies without any added sugar. Each box contains five on-the-go packs that are perfect for lunchboxes, car rides, and all-day snacking. Look for more toddler snacks and baby food pouches from Beech-Nut Naturals® to supply the simple ingredients and natural nutrition your little one will love.

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included inside

- Pea Flour
- Potato Starch
- Rice Flour
- Sweet Potatoes

- 5, 0.25 oz Packs
- Toddler Snack
- Made with just 6 ingredients
- Non-GMO Project verified
- Nothing artificial added
- Baked, not fried

12 **naturals banana,**
 13 **cinnamon & granola**
 14 **pouch**

15 Beech-Nut Naturals® is made with real ingredients, gently cooked™. And with Beech-Nut Naturals® baby food pouches, you can conveniently take that real food on-the-go. For this Non-GMO Project verified pouch, we puree banana, cinnamon, and grains and gently cook it with indirect heat to preserve flavor and nutrients. The result is a hearty puree so delicious we had to show it off in a clear pouch. This Stage 2 Beech-Nut Naturals® banana, cinnamon & granola baby food pouch is ideal for your 6 month old baby. No sugar added and nothing artificial.

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included inside

- Bananas
- Cinnamon
- Oat Flour
- Rice Flour

- Single, 3.5 oz Pouch
- Stage 2: for 6 months and up
- Real ingredients, gently cooked™
- Non-GMO Project verified
- Nothing artificial added
- Squeezable pouch for on-the-go

⁶⁵ *beech-nut naturals® carrots jar*, BEECH-NUT, <https://www.beechnut.com/product/naturals-just-carrots-jar/>; archived from July 10, 2017 at WAYBACK MACHINE, <https://web.archive.org/web/20170710011140/http://www.beechnut.com/product/naturals-just-carrots-jar/>.

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naturals spinach, zucchini & peas jar

Beech-Nut Naturals® baby food is made with real ingredients, gently cooked™. For Stage 2 Beech-Nut Naturals® spinach, zucchini & peas baby food, we start with non-GMO vegetables and gently cook them over indirect heat to preserve color, flavor and nutrients. The hearty texture of this puree helps introduce your growing baby to new tastes and textures of real food. As a Stage 2 puree, Beech-Nut Naturals® spinach, zucchini & peas is an ideal food for babies 6 months and up. All Beech-Nut® baby food jars are vacuum-sealed for freshness. This jar can be stored in the refrigerator for up to 3 days after opening.

- Single, 4 oz Jar
- Stage 2: for 6 months and up
- Real Ingredients, gently cooked™
- Non-GMO Project verified
- Nothing artificial added
- Made with real vegetables

naturals carrots jar

Beech-Nut Naturals® baby food is made with real ingredients, gently cooked™. This Non-GMO Project verified Stage 1 carrots puree is easy to spot when you're at the grocery store due to its vibrant orange color. We start with non-gmo carrots then gently cook this veggie over indirect heat to preserve color, flavor and nutrients. It's a perfect way to offer baby real veggies without any chopping! As a Stage 1 puree, this puree is ideal for babies first starting solids at around 4 months. All Beech-Nut® baby food jars are vacuum-sealed for freshness. This jar can be stored in the refrigerator for up to 2 days after opening.

- Single, 4 oz Jar
- Stage 1: for 4 months and up
- Real Ingredients, gently cooked™
- Non-GMO Project verified
- Nothing artificial added
- Made with real carrots



138. Beech-Nut also knows that its consumers care about “what’s inside” their baby food and stresses that the content “matters.” It represents to customers that it “conduct[s] over 20 rigorous tests on our purees, testing for up to 255 pesticides and heavy metals (like lead, cadmium and other nasty stuff). Just like

1 you would, we send the produce back if it's not good enough.”⁶⁶ But Beech-Nut
2 does not tell consumers that it has accepted ingredients that have failed its own
3 internal standards as well as national guidelines on heavy metal content. Beech-
4 Nut has made these representations on its website since at least July 13, 2019.⁶⁷ In
5 a previous version of this page, as early as May 30, 2017, Beech-Nut told
6 consumers that its baby food was “clean food” and “classic, natural and organic
7 real food for babies and toddlers” “with just real, simple ingredients.”⁶⁸

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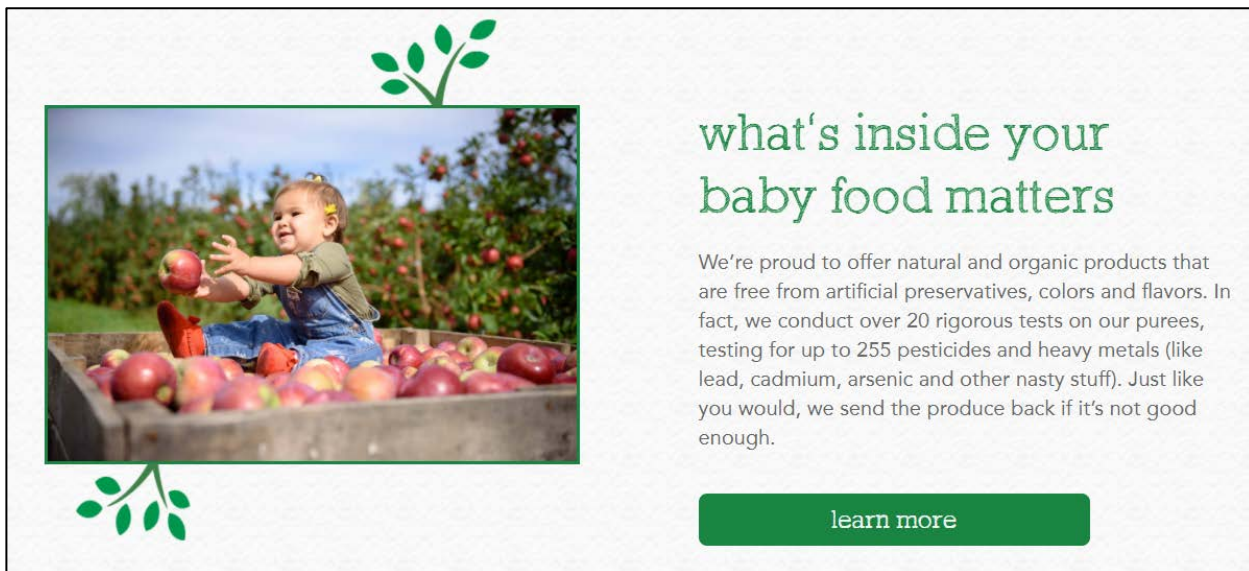
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what's inside your
baby food matters

We're proud to offer natural and organic products that are free from artificial preservatives, colors and flavors. In fact, we conduct over 20 rigorous tests on our purees, testing for up to 255 pesticides and heavy metals (like lead, cadmium, arsenic and other nasty stuff). Just like you would, we send the produce back if it's not good enough.

learn more

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23 ⁶⁶ *Our Purpose*, BEECH-NUT, <https://www.beechnut.com/our-story/> (last visited Mar. 3, 2021).

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25 ⁶⁷ *Our Purpose*, BEECH-NUT, <https://www.beechnut.com/our-story/>; archived from July 13, 2019 at Wayback Machine, <https://web.archive.org/web/20190713000457/https://www.beechnut.com/our-story/>.

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27 ⁶⁸ *Our Purpose*, BEECH-NUT, <https://www.beechnut.com/our-story/>; archived from July 13, 2019 at Wayback Machine, <https://web.archive.org/web/20190713000457/https://www.beechnut.com/our-story/>

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1 139. Repeatedly, Beech-Nut stresses that it only uses “real,” “quality”
2 ingredients.⁶⁹ Beech-Nut Hain has made these representations on its website since
3 at least June 14, 2020.⁷⁰



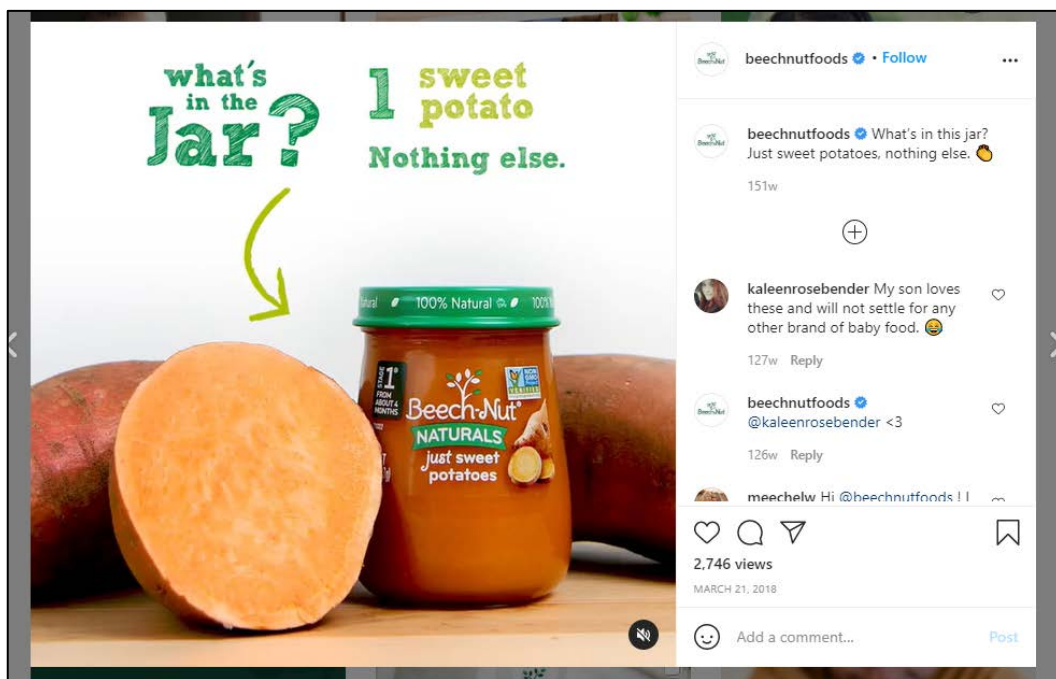
23
24 ⁶⁹ *Real Ingredients, Gently Cooked*TM, BEECH-NUT, <https://www.beechnut.com/our-story-naturals/> (last visited Mar. 3, 2021).

25 ⁷⁰ *Real Ingredients, Gently Cooked*TM, BEECH-NUT, <https://www.beechnut.com/our-story-naturals/> (last visited Mar. 3, 2021); archived from June 14, 2020 at Wayback
26 Machine,
27 [https://web.archive.org/web/20200614085439/https://www.beechnut.com/our-story-](https://web.archive.org/web/20200614085439/https://www.beechnut.com/our-story-naturals/)
28 [naturals/](https://web.archive.org/web/20200614085439/https://www.beechnut.com/our-story-naturals/).

1 140. On social media on March 28, 2019, Beech-Nut advertised that its
2 products are for consumers who are “label readers” and look for “natural
3 ingredients only.”



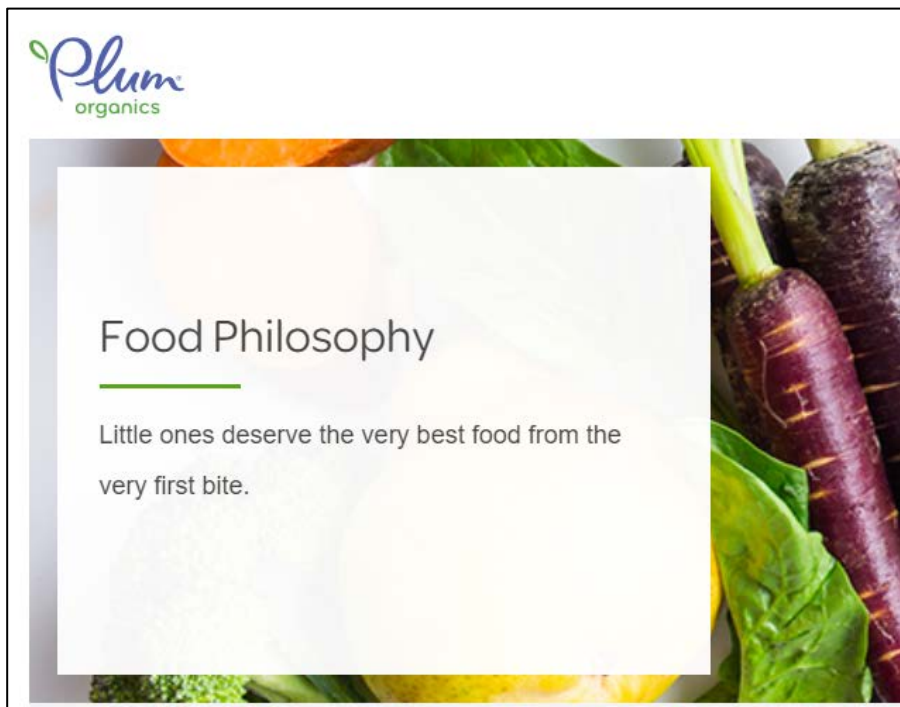
16 141. Similarly, on March 21, 2018, Beech-Nut represented to consumers that
17 its products contain “nothing else” but the listed ingredient.



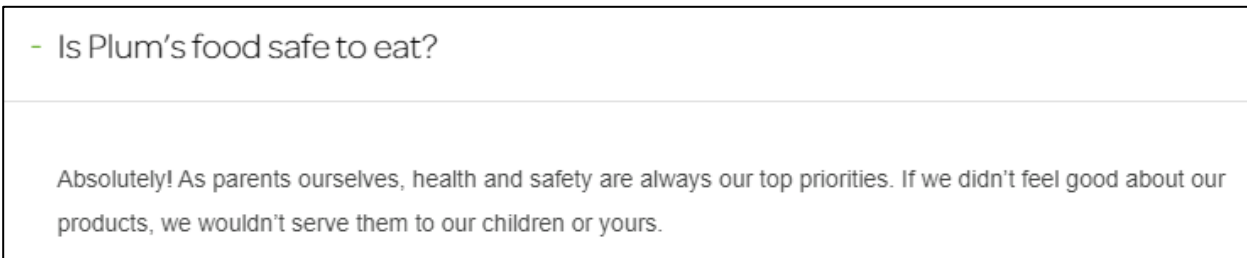
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ii. Plum Organics

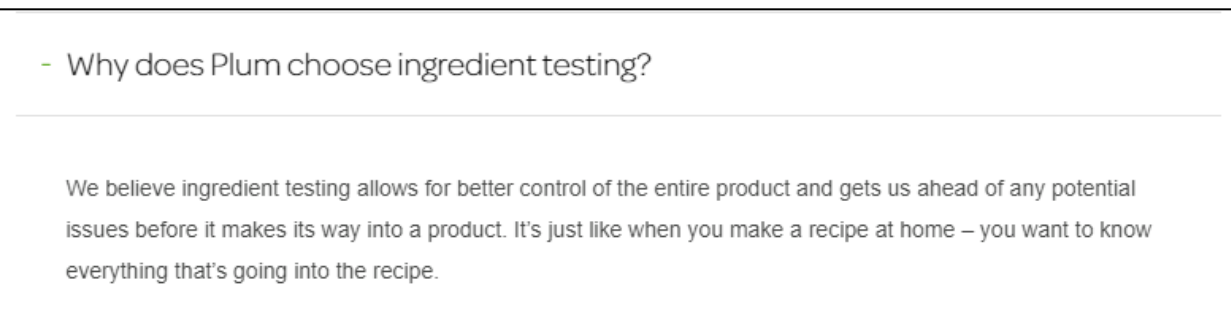
142. The Plum Organics’ mission promises that the company will provide “little ones” with “the very best food from the first bite.” This message was relayed to the public over the wires and disseminated further on the internet on February 12, 2018 on social media.



1 143. Plum represents to consumers that its baby foods are “absolutely” “safe
2 to eat” and that “health and safety are always” its “top priorities.”⁷¹ Plum has made
3 these representations on its website since at least August 12, 2020.⁷²



8 144. Plum understands that parents “want to know everything” that is in their
9 child's foods. Plum acknowledges this parental desire for transparency and
10 represents to consumer that it performs ingredient testing.⁷³ Plum has made these
11 representations on its website since at least August 12, 2020.⁷⁴



18 145. Plum knows that the ingredients in baby food impact child development
19 and these ingredients can be “critical” in healthy eating.

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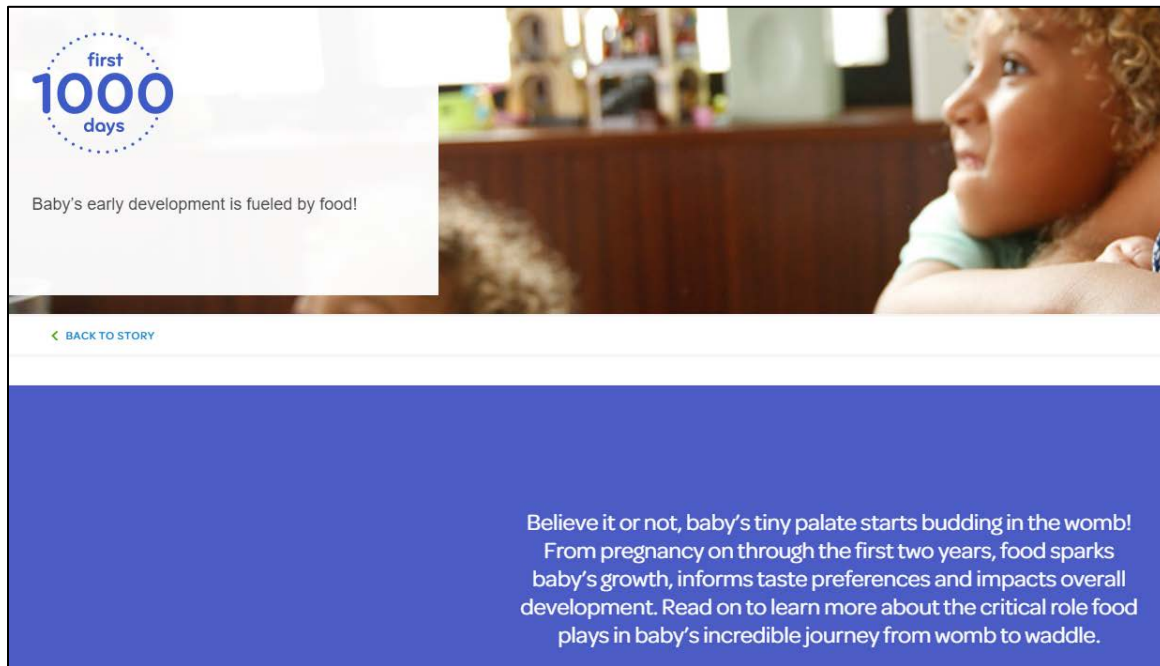
23 ⁷¹ FAQs, PLUM ORGANICS, <https://www.plumorganics.com/faqs/> (last visited Mar. 3,
24 2021).

25 ⁷² <https://web.archive.org/web/20200812160036/https://www.plumorganics.com/faqs/>.

26 ⁷³ FAQs, PLUM ORGANICS, <https://www.plumorganics.com/faqs/> (last visited Mar. 3,
27 2021).

28 ⁷⁴ <https://web.archive.org/web/20200812160036/https://www.plumorganics.com/faqs/>.

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146. Plum misleadingly tells consumers that the heavy metals in its products and ingredients meet “applicable government standards.” But then Plum goes on to claim that “there is no federal standard on heavy metals in baby food.”⁷⁵

147. On social media, Plum represented to customers on June 7, 2019, that the back of the pouch lets customers “find out exactly what [you are] getting!”



⁷⁵ FAQs, PLUM ORGANICS, <https://www.plumorganics.com/faqs/> (last visited Mar. 9, 2021).

1 **iii. Nurture**

2 148. Nurture and its Happy Family Organics brand promise customers that
 3 they can have “peace of mind” because it “source[s] high-quality organic
 4 ingredients” and has “rigorous and uncompromising quality standards” so
 5 consumers “can feel confident” in what they are feeding their family.⁷⁶ Nurture has
 6 made these representations on its website since at least August 13, 2020.⁷⁷



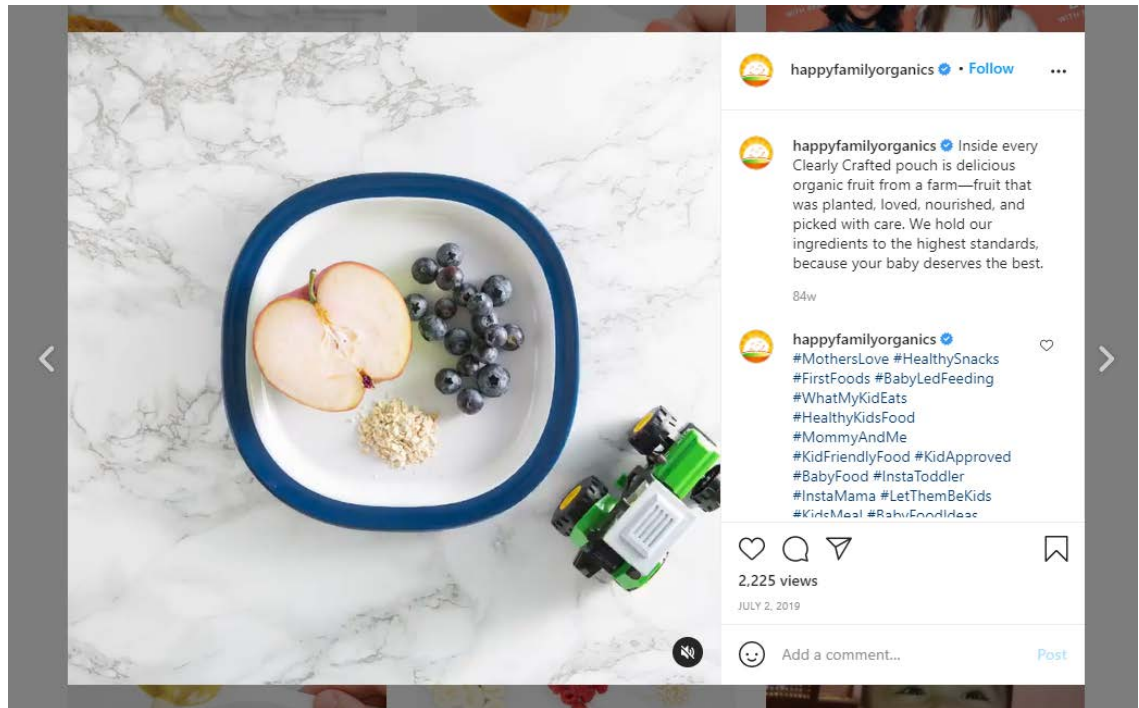
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17 149. Nurture emphasizes that it goes beyond USDA organic standards
 18 because it knows that what children eat in the first few years of life is “crucial.”
 19 Nurture assures parents that it holds itself to “strict standards” to help children
 20 “grow healthy and strong” through “test[ing] and thoroughly analyz[ing] every
 21
 22

23 ⁷⁶ *Our Commitment to Organic*, NURTURE,
 24 <https://www.happyfamilyorganics.com/our-mission/going-beyond-organic-standards/>
 (last visited Mar. 3, 2021).

25 ⁷⁷ *Our Commitment to Organic*, Nurture, [https://www.happyfamilyorganics.com/our-](https://www.happyfamilyorganics.com/our-mission/going-beyond-organic-standards/)
 26 [mission/going-beyond-organic-standards/](https://www.happyfamilyorganics.com/our-mission/going-beyond-organic-standards/); archived from Aug. 13, 2020 at Wayback
 27 Machine,
 28 [https://web.archive.org/web/20200813062006/https://www.happyfamilyorganics.com](https://web.archive.org/web/20200813062006/https://www.happyfamilyorganics.com/our-mission/going-beyond-organic-standards/)
[/our-mission/going-beyond-organic-standards/](https://web.archive.org/web/20200813062006/https://www.happyfamilyorganics.com/our-mission/going-beyond-organic-standards/).

1 batch of food.”⁷⁸ Nurture has made these representations on its website since at
2 least August 13, 2020.⁷⁹

3 150. On social media, Nurture assured consumers on July 2, 2019 that it
4 holds its “ingredients to the highest standards, because your baby deserves the
5 best.”



17 151. Nurture also asserts that parents can “trust” its organic food because
18 Nurture “partner[s] with pediatricians, dietitians, and children’s health experts.”⁸⁰

21 ⁷⁸ *Our Commitment to Organic*, NURTURE,
22 <https://www.happyfamilyorganics.com/our-mission/going-beyond-organic-standards/>
23 (last visited Mar. 3, 2021).

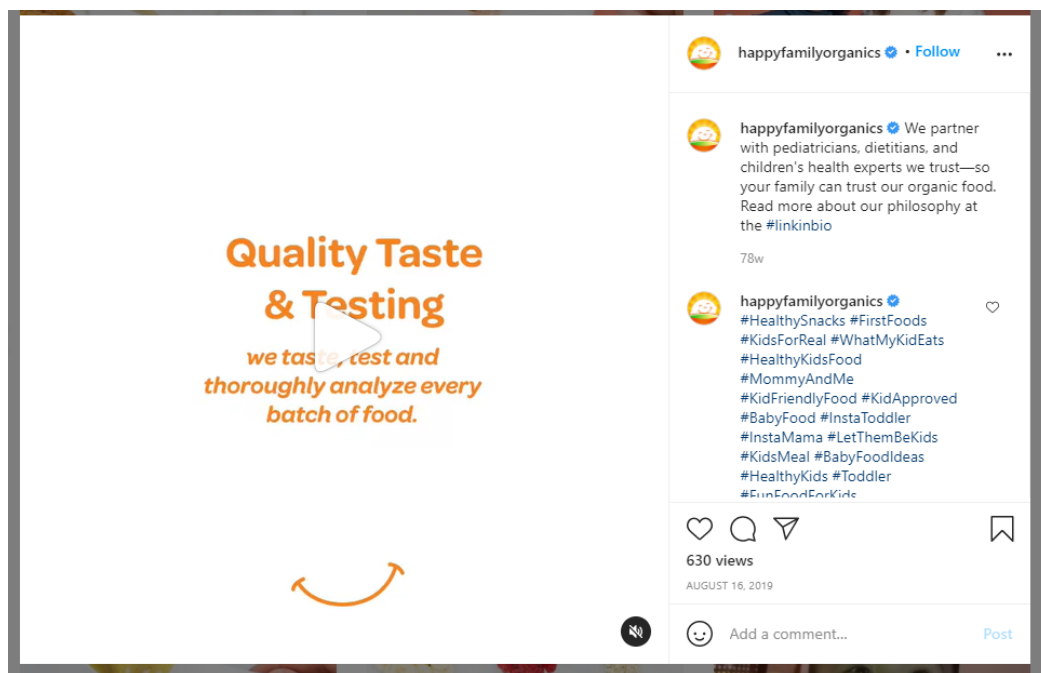
24 ⁷⁹ *Our Commitment to Organic*, Nurture, [https://www.happyfamilyorganics.com/our-](https://www.happyfamilyorganics.com/our-mission/going-beyond-organic-standards/)
25 [mission/going-beyond-organic-standards/](https://www.happyfamilyorganics.com/our-mission/going-beyond-organic-standards/); archived from Aug. 13, 2020 at Wayback
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[https://web.archive.org/web/20200813062006/https://www.happyfamilyorganics.com](https://web.archive.org/web/20200813062006/https://www.happyfamilyorganics.com/our-mission/going-beyond-organic-standards/)
27 [/our-mission/going-beyond-organic-standards/](https://web.archive.org/web/20200813062006/https://www.happyfamilyorganics.com/our-mission/going-beyond-organic-standards/).

28 ⁸⁰ *Our Commitment to Organic*, NURTURE,
<https://www.happyfamilyorganics.com/our-mission/going-beyond-organic-standards/>
(last visited Mar. 3, 2021).

1 Nurture has made these representations on its website since at least August 13,
 2 2020.⁸¹



13 152. On August 16, 2019, Nurture made similar promises about its health
 14 partners and the fact that parents can trust its organic food on its social media sites.



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82 [https://web.archive.org/web/20200813062006/https://www.happyfamilyorganics.com/our-mission/going-beyond-organic-standards/.](https://web.archive.org/web/20200813062006/https://www.happyfamilyorganics.com/our-mission/going-beyond-organic-standards/)

1 153. Nurture claims that its Happy Baby puffs are “superfood” made by “a
 2 team of real parents, pediatricians, and nutritionists” to ensure “health and
 3 happiness to our little ones.”⁸² But they omit that these superfoods also include
 4 dangerously high levels of arsenic, lead, and cadmium that have even failed lenient
 5 internal standards.⁸³

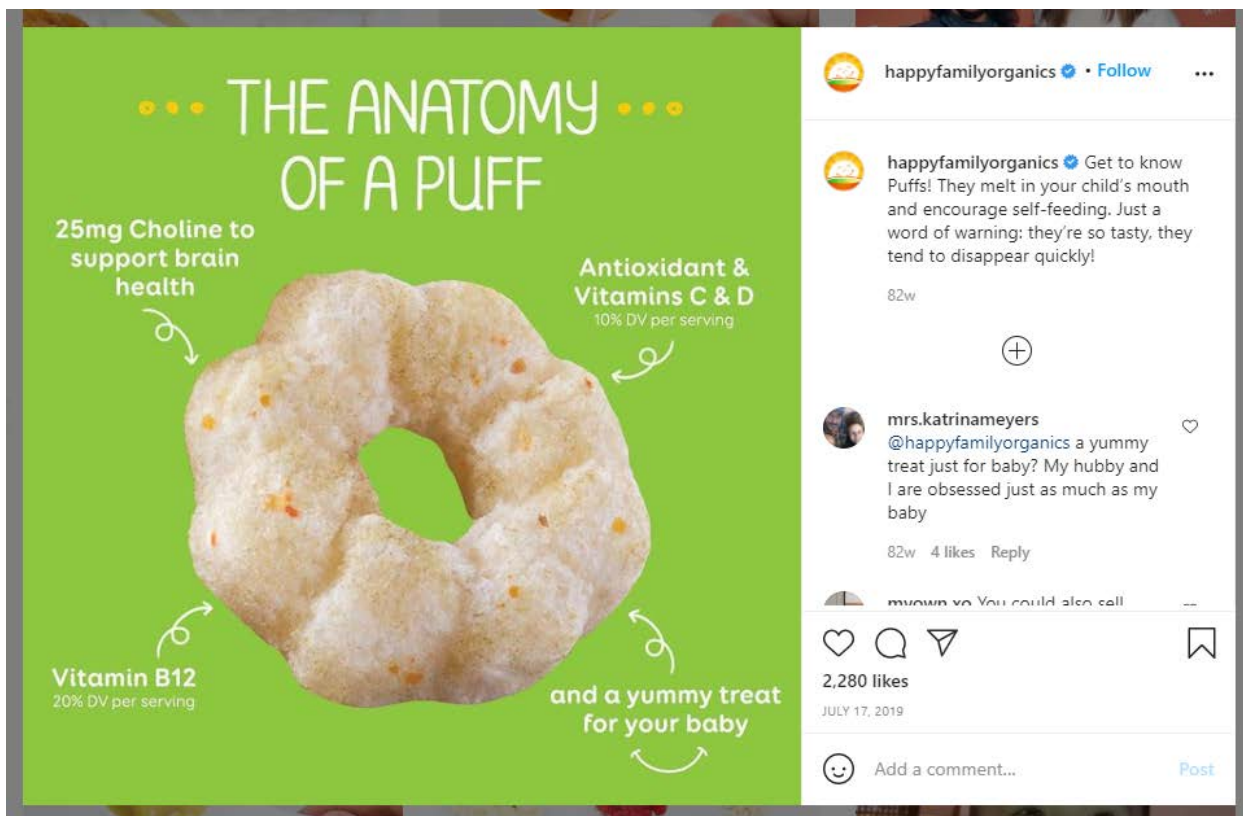


23 154. On social media, Nurture claimed on July 17, 2019, that these puffs
 24 “support brain health” but do not mention the levels of arsenic, lead, and cadmium
 25 that can cause developmental issues.

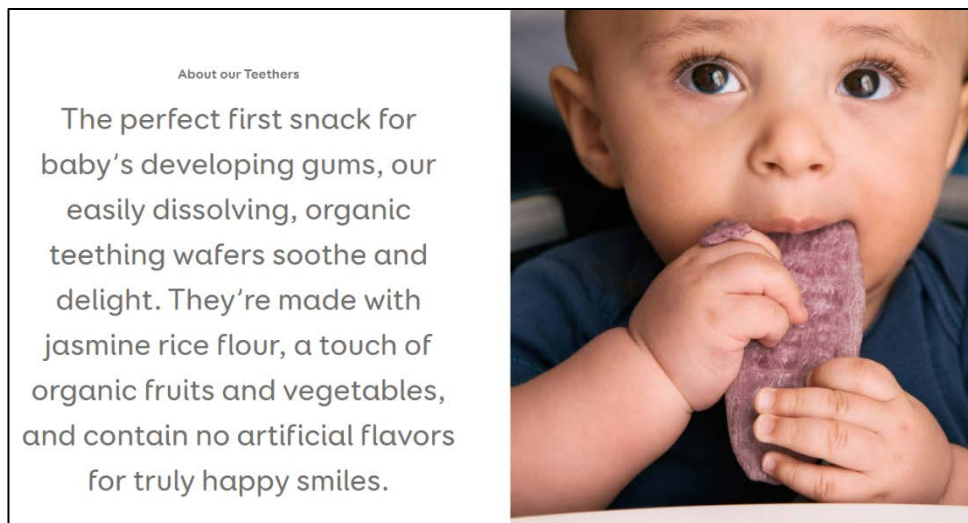
27 ⁸² <https://www.happyfamilyorganics.com/shop/baby/apple-broccoli-finger-food/>

28 ⁸³ House Staff Report at 2-4, 13-15, 22-23, 31-37.

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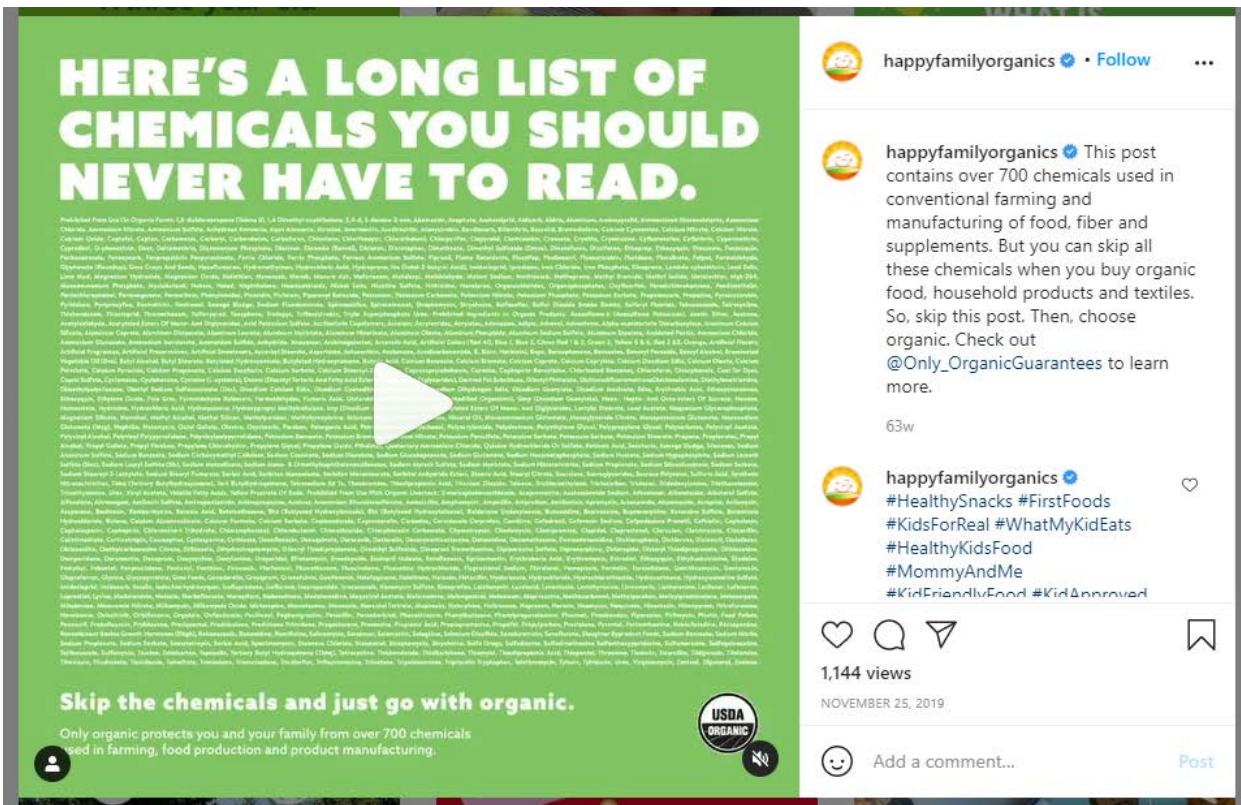


155. Similarly, Nurture claims that its teethers are “the perfect first snack” but it omits that teethers have been sold with levels of lead higher than even lenient internal standards.⁸⁴



⁸⁴ *Blueberry & Purple Carrot Teether*, NURTURE, <https://www.happyfamilyorganics.com/shop/baby/blueberry-purple-carrot-teething-wafer/> (last visited Mar. 11, 2021).

1 156. On social media on November 25, 2019, Nurture asserted that parents
 2 can skip the chemicals by purchasing its organic foods. But it does not mention
 3 that inorganic heavy metals are still present in its baby foods.



17
 18 **iv. Gerber**

19 157. Defendant Gerber knows that parents want “the very best for [their]
 20 little one to ensure she reaches her full potential, and so do we.” It represents to
 21 parents that it has adopted “super strict” farming practices “to ensure that their fruit
 22 and vegetable purees are not only nutritious, but also wholesome and safe for even
 23 the littlest bodies.” Gerber also misleadingly asserts its belief “that little ones
 24 deserve the highest standards set just for them” guides its mission to “deliver the
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1 very best fruits and veggies.”⁸⁵ Gerber has made these representations on its
2 website since at least November 25, 2020.⁸⁶



10 **Clean Field Farming™: Big Standards for Tiny Tummies**

11 You want the very best for your little one to ensure she reaches her full potential, and so do we.
12 That’s why we use super strict Clean Field Farming™ practices to ensure that our fruit & veggie
13 purees are not only nutritious, but also wholesome and safe for even the littlest bodies.

14 These unique practices guide the way we thoughtfully select our seeds and land, sustainably care
15 for the soil, and trace our harvested crops not only to the farms, but to the very fields where they
16 were grown. That’s why we only partner with a select group of farms that meet our strict Clean
17 Field Farming™ practices.

18 We think little ones deserve the highest standards set just for them. That’s why we take our
19 mission to deliver the very best fruits and veggies so seriously.

20 158. Gerber also knows that parents do not want high levels of heavy metals
21 in their baby foods, and it represents that its growing standards are the “strictest in
22 the world” to ensure “quality control” because “what you get out is what you put
23

24 ⁸⁵ *Clean Field Farming™: Big Standards for Tiny Tummies*, NESTLE,
25 <https://www.gerber.com/big-standards-for-tiny-tummies> (last visited Mar. 3, 2021).

26 ⁸⁶ *Clean Field Farming™: Big Standards for Tiny Tummies*, Nestle,
27 <https://www.gerber.com/big-standards-for-tiny-tummies>; archived from Nov. 25,
28 2020 at Wayback Machine,
<https://web.archive.org/web/20201125013258/https://www.gerber.com/big-standards-for-tiny-tummies>.

1 in.”⁸⁷ Gerber has made these representations on its website since at least November
2 25, 2020.⁸⁸



11 **Keeping Soil in the Family**

12 Some soil can have naturally high levels of nitrates and heavy metals, which you don't want in your
13 baby's food. That's why we created requirements for growing our fruits and veggies that are
14 among the strictest in the world.

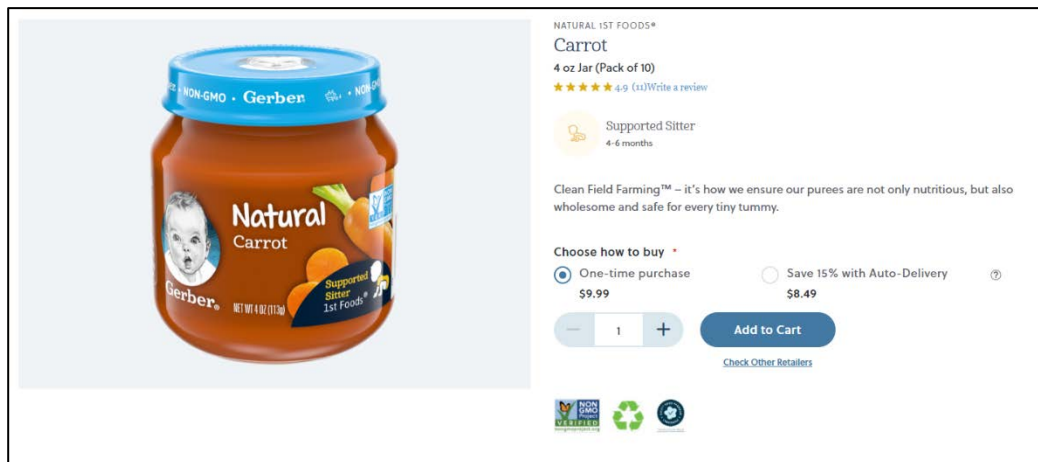
15 The Karnemaats have been working their farm in Michigan, perfecting techniques that maintain
16 Gerber's high soil standards, for generations. To say quality control runs in the family would be an
17 understatement. Dan Gerber, the founder of Gerber, used to walk the fields with great-
18 grandfather Karnemaat. So they know that when it comes to soil, what you get out is what you put
19 in.

20 159. On its product pages, Gerber claims that its Clean Field Farming
21 process “ensure[s] our purees are not only nutritious, but also wholesome and safe
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25 ⁸⁷ *Keeping Soil in the Family*, NESTLE, <https://www.gerber.com/keeping-soil-in-the-family> (last visited Mar. 3, 2021).

26 ⁸⁸ *Keeping Soil in the Family*, Nestle, <https://www.gerber.com/keeping-soil-in-the-family>;
27 archived from Nov. 25, 2020 at Wayback Machine,
28 <https://web.archive.org/web/20201125021145/https://www.gerber.com/keeping-soil-in-the-family>.

1 for every tiny tummy.”⁸⁹ Gerber has made these representations on its website
2 since at least November 25, 2020.⁹⁰



26 ⁸⁹ *Carrot*, NESTLE, <https://www.gerber.com/carrot-0> (last visited Mar. 3, 2021).

27 ⁹⁰ *Carrot*, Nestle, <https://www.gerber.com/carrot-0>; archived from Nov. 25, 2020 at
28 <https://web.archive.org/web/20201125014630/https://www.gerber.com/carrot-0>.

1 160. Gerber claims that its rice cereals will help support “learning ability”
2 but they omit that these cereals can contain levels of heavy metals that can cause
3 development issues. And, again, Gerber conveys to consumers that they can rely
4 on its Clean Field Farming practices to ensure that its baby foods are “safe and
5 wholesome.”⁹¹ Gerber has made these representations on its website since at least
6 September 30, 2020.⁹²

7
8 Following Clean Field Farming™ practices, we keep our grains
9 safe and wholesome from farm to kitchen.



24
25 ⁹¹ *Rice*, NESTLE, <https://www.gerber.com/gerber-organic-single-grain-cereal-rice> (last visited Mar. 3, 2021).

26 ⁹² *Rice*, Nestle, <https://www.gerber.com/gerber-organic-single-grain-cereal-rice>;
27 archived from Sept. 30, 2020 at Wayback Machine,
28 <https://web.archive.org/web/20200930035221/https://www.gerber.com/gerber-organic-single-grain-cereal-rice>.

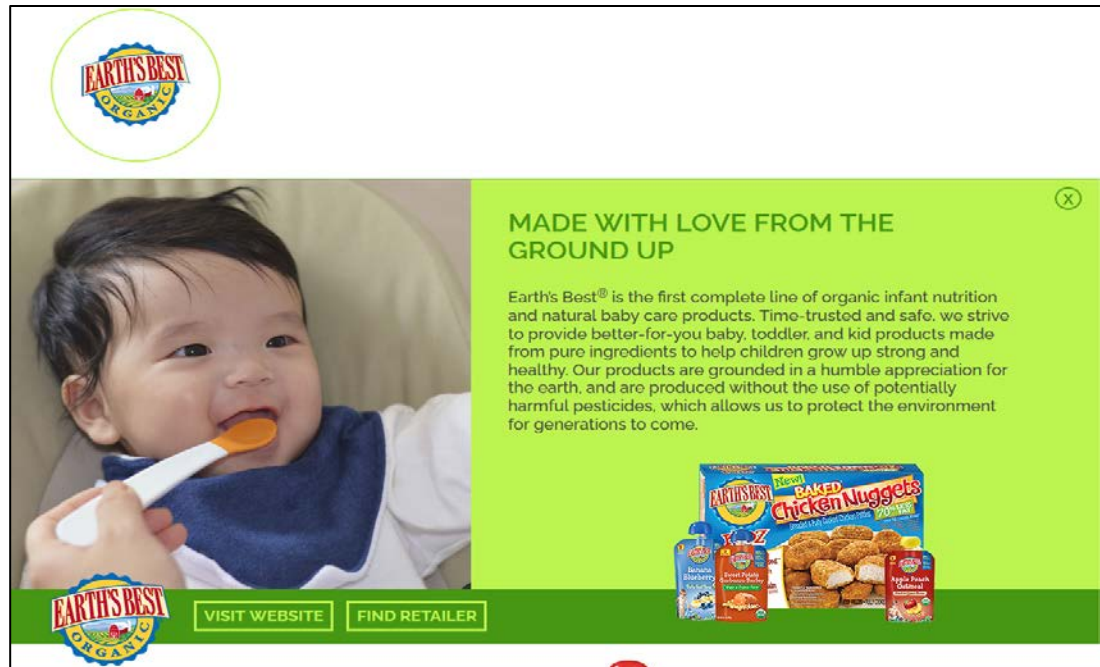
1
2 161. On social media, Gerber stressed to consumers on October 12, 2020,
3 that its Clean Field Farming Standards allows it to “ensure that [our produce is]
4 safe and wholesome for baby.”



18
19 **v. The Hain Celestial Group**

20 162. In promoting its Earth's Best Organic baby food products, non-
21 Defendant co-conspirator Hain tells parents that its products are “time-trusted and
22 safe” and “made from pure ingredients to help children grow up strong and
23 healthy.” Hain knew that parents cared about whether the “potentially harmful”
24 contaminants were in their products because it noted that its food is “produced
25 without the use of potentially harmful pesticides” but Hain omits that the products
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1 *do* contain other “potentially harmful” contaminants, namely toxic heavy metals.⁹³
2 Hain has made these representations on its website since at least May 16, 2016.⁹⁴

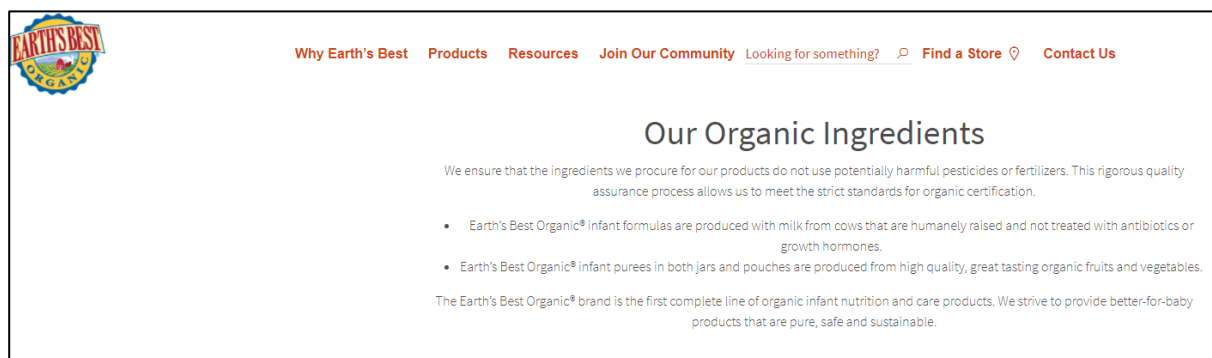
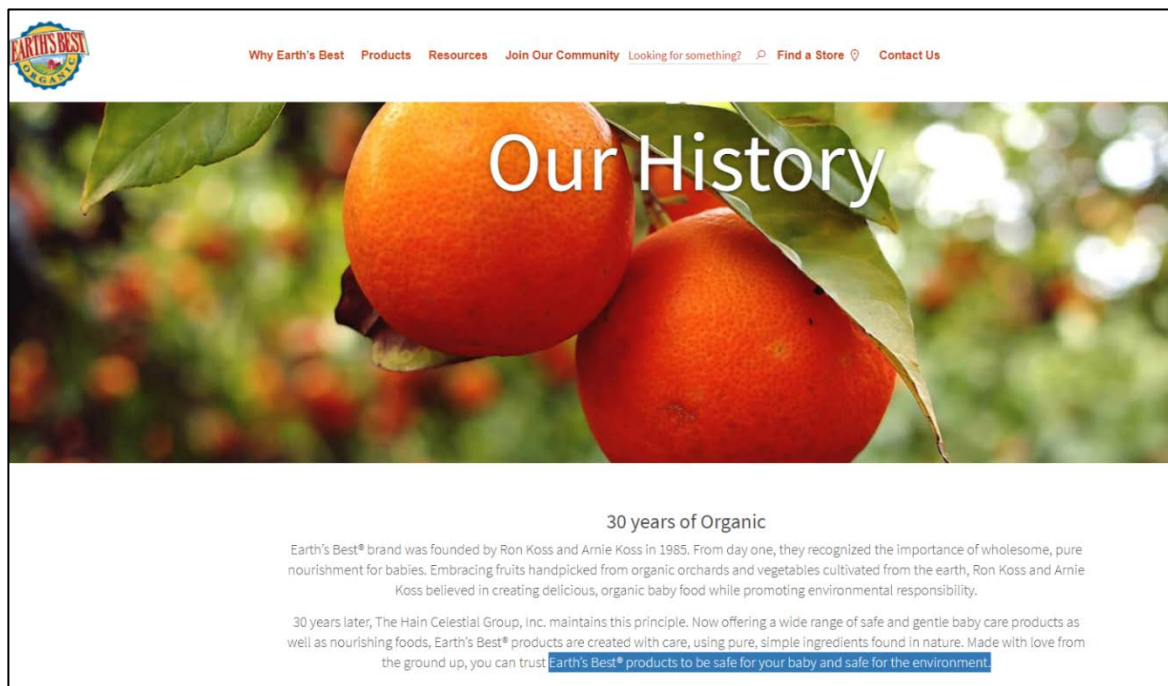


14 163. Hain also represents to consumers that from day one, it has “recognized
15 the importance of wholesome, pure nourishment for babies” so its products are
16 “created with care, using pure, simple ingredients found in nature.” Because of this
17 “principle,” Hain tells parents that they “can trust Earth’s Best® products to be

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23 ⁹³ *Brands Available in the US*, HAIN CELESTIAL,
24 <http://www.hain.com/brandcats/baby-food/#c1> (click “Baby Food” from the
dropdown menu; the click “Earth’s Best Organic”) (last visited Mar. 3, 2021).

25 ⁹⁴ *Brands Available in the US*, Hain Celestial, [http://www.hain.com/brandcats/baby-](http://www.hain.com/brandcats/baby-food/#c1)
26 [food/#c1](http://www.hain.com/brandcats/baby-food/#c1) (click “Baby Food” from the dropdown menu; the click “Earth’s Best
Organic”); archived from May 22, 2016 at WAYBACK MACHINE,
27 [https://web.archive.org/web/20160522102854/http://www.hain.com/brandcats/baby-](https://web.archive.org/web/20160522102854/http://www.hain.com/brandcats/baby-food/#c1)
28 [food/#c1](https://web.archive.org/web/20160522102854/http://www.hain.com/brandcats/baby-food/#c1) (last visited Mar. 11, 2021).

1 safe for your baby and safe for the environment.”⁹⁵ Hain has made these
2 representations on its website since at least June 1, 2019.⁹⁶



20 164. In discussing its organic ingredients, Hain claims that it has a “rigorous
21 quality assurance process” which allows it to provide “better-for-baby products
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25 ⁹⁵ *Our History*, THE HAIN CELESTIAL GROUP, <https://www.earthsbest.com/why-earths-best/our-history/> (last visited Mar. 3, 2021).

26 ⁹⁶ *Our History*, THE HAIN CELESTIAL GROUP, <https://www.earthsbest.com/why-earths-best/our-history/>; archived from June 1, 2019 at WAYBACK MACHINE
27 <https://web.archive.org/web/20190719084543/https://www.earthsbest.com/why-earths-best/our-history/> (last visited Mar. 11, 2021).
28

1 that are pure, safe and sustainable.”⁹⁷ Hain has made these representations on its
2 website since at least July 18, 2019.⁹⁸

3 165. Hain repeatedly used this “rigorous product testing” as a “guarantee” to
4 parents of the “quality and safety” of its products.⁹⁹ Hain has made these
5 representations on its website since at least July 18, 2019.¹⁰⁰

6

7 The Earth’s Best Organic® Difference

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- Organic ingredients grown without potentially harmful pesticides
- Unsweetened, unsalted, and no added modified starches
- Kosher certified products (excluding meat varieties)

- No genetically modified ingredients
- No artificial flavors, colors, or preservatives
- Rigorous product testing to guarantee quality and safety

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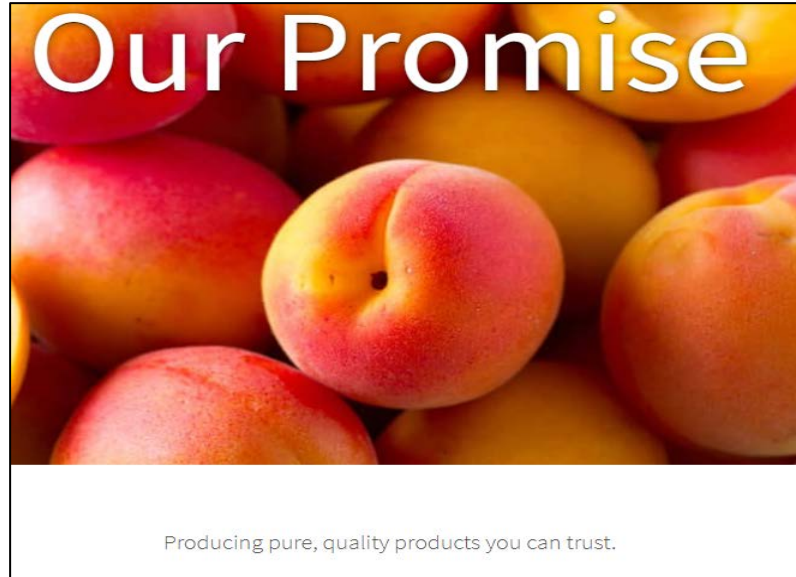
22 ⁹⁷ *Our Promise*, THE HAIN CELESTIAL GROUP, [https://www.earthsbest.com/why-](https://www.earthsbest.com/why-earths-best/our-promise/)
23 [earths-best/our-promise/](https://www.earthsbest.com/why-earths-best/our-promise/) (last visited Mar. 3, 2021)

24 ⁹⁸ *Our Promise*, THE HAIN CELESTIAL GROUP,
25 <https://www.earthsbest.com/why-earths-best/our-promise/>; archived from July 18,
26 2019 at Wayback Machine.

27 ⁹⁹ *Our Promise*, THE HAIN CELESTIAL GROUP, [https://www.earthsbest.com/why-](https://www.earthsbest.com/why-earths-best/our-promise/)
28 [earths-best/our-promise/](https://www.earthsbest.com/why-earths-best/our-promise/) (last visited Mar. 3, 2021).

¹⁰⁰ *Our Promise*, THE HAIN CELESTIAL GROUP,
<https://www.earthsbest.com/why-earths-best/our-promise/>; archived from July 18,
2019 at Wayback Machine.

1 166. At the heart of its representations to parents about its products was
2 Hain’s “Promise” to produce “pure, quality products you can trust.”¹⁰¹ Hain has
3 made these representations on its website since at least July 18, 2019.¹⁰²



13
14 **E. Despite Defendants knowledge of risks and representations to**
15 **consumers, the recent Congressional Report demonstrates through**
16 **internal documentation that nothing has changed, and Defendants**
17 **continue to put children at risk.**

18 167. Despite the findings made by Clean Label Project, Consumer Report
19 and Healthy Babies Bright Futures, Manufacturer Defendants refused to cease their
20 perilous practice of producing baby foods full of dangerous toxins and continued to
21 expose millions of babies to these harmful, dangerous ingredients.

22 168. Following years of dissemination of misinformation by Defendants and
23 their front group about what was contained in baby foods, the U.S. House of
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25 ¹⁰¹ *Our Promise*, THE HAIN CELESTIAL GROUP, [https://www.earthsbest.com/why-](https://www.earthsbest.com/why-earths-best/our-promise/)
26 [earths-best/our-promise/](https://www.earthsbest.com/why-earths-best/our-promise/) (last visited Mar. 3, 2021).

27 ¹⁰² *Our Promise*, THE HAIN CELESTIAL GROUP,
28 <https://www.earthsbest.com/why-earths-best/our-promise/>; archived from July 18,
2019 at Wayback Machine.

1 Representatives Subcommittee on Economic and Consumer Policy finally
2 intervened and conducted their own investigation into what America's babies were
3 ingesting. The results were shocking.

4 169. The Report by the U.S. House of Representatives recently confirmed
5 that Defendants and non-Defendant co-conspirator Hain continue to sell, distribute,
6 and market baby foods contaminated with dangerous levels of toxic heavy metals.
7 The House Staff Report demonstrated that Defendants were knowingly, recklessly,
8 and/or negligently selling baby foods containing arsenic, mercury, cadmium, lead,
9 and other high levels of toxic heavy metals.

10 170. At the onset of their investigation, the Subcommittee reached out to the
11 offending manufacturers, requesting information about their processes and what
12 they knew about the containments in their products fed to babies.

13 171. Manufacturer Defendants responded, each making detailed, specific
14 representations to Congress that have since been disputed.¹⁰³ Three Manufacturer
15 Defendants (Beech-Nut, Gerber, and Nurture) cooperated and provided the
16 Subcommittee with testing results. Non-Defendant co-conspirator Hain also
17 provided the Subcommittee with testing results.

18 172. The Congressional Report concluded that for the cooperating entities
19 (Defendant Beech-Nut, Defendant Nurture, Defendant Gerber, and Hain):

- 20 a. All sold baby food with dangerously high levels of lead,¹⁰⁴
21 b. All sold baby food with dangerously high levels of arsenic,¹⁰⁵
22 c. All sold baby food with dangerously high levels of cadmium,¹⁰⁶
23 d. All four of the Defendants that cooperated with Congress not only set
24 their internal standards for heavy metals in ingredients and final

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26 ¹⁰³ See Exhibits D-H attached hereto.

27 ¹⁰⁴ The House Staff Report at 3.

28 ¹⁰⁵ *Id.*

¹⁰⁶ *Id.*

1 products at dangerously high levels, but then sold products that
2 exceeded those already too lenient internal levels,¹⁰⁷

3 e. Three of the four Defendants that cooperated with Congress did not
4 even test for mercury,¹⁰⁸

5 f. Three of the four Defendants that cooperated with Congress only tested
6 ingredients, but not the final product, for lead.¹⁰⁹

7 ***I. Arsenic findings***

8 173. While there has been no determination of a safe level of arsenic
9 contamination in most baby foods, government agencies have set maximum
10 contaminant levels for inorganic arsenic between 10 ppb and 100 ppb for other
11 exposure paths. Consumer groups that have investigated levels for baby food
12 exposure suggest either a non-detect level or 3 ppb for inorganic arsenic.

13 174. With respect to the arsenic contamination, the Subcommittee found that
14 Defendant Beech-Nut:

- 15 a. Used ingredients that tested as high as 913.4 ppb arsenic;¹¹⁰
16 b. “Routinely used” high-arsenic additives testing over 300 ppb;¹¹¹
17 c. Only tested arsenic content in its ingredients, not its final product.¹¹²

18 175. With respect to the arsenic contamination, the Subcommittee found that
19 Defendant Nurture (manufacturer of Happy Baby foods) sold finished baby food
20 products that tested as high as 180 ppb for inorganic arsenic.¹¹³

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24 ¹⁰⁷ *Id.* at 33-42.

25 ¹⁰⁸ *Id.* at 4.

26 ¹⁰⁹ *Id.* at 22.

27 ¹¹⁰ *Id.* at 3.

28 ¹¹¹ *Id.*

¹¹² *Id.* at 17.

¹¹³ *Id.* at 13.

1 176. With respect to the arsenic contamination, the Subcommittee found that
2 Defendant Gerber routinely included flour with over 90 ppb inorganic arsenic and
3 juice concentrate with high arsenic levels in its baby food products.¹¹⁴

4 177. With respect to the arsenic contamination, the Subcommittee found that
5 non-Defendant, co-conspirator Hain (manufacturer of Earth's Organics) sold
6 finished baby food products testing as high 129 ppb of inorganic arsenic.¹¹⁵

7 178. The Subcommittee also found that Hain had used vitamin pre-mix and
8 two rice flours that had surpassed its internal toxic heavy metal limits. Internally,
9 Hain had set a 100ppb limit for its ingredients, but the vitamin pre-mix had 223
10 ppb and the rice flours lots had 309 ppb and 134 ppb.¹¹⁶

11 179. Despite having dangerously high levels of toxic heavy metals, Hain
12 approved the use of this vitamin pre-mix based on a "theoretical" calculation of
13 toxic heavy metals in the final good of 85ppb of arsenic and 25ppb of lead.¹¹⁷ But
14 the Subcommittee could not tell that Hain had ever confirmed the *actual* levels in
15 the final product. This is especially troubling because the Subcommittee found that
16 Hain had previously told the FDA in a secret presentation that vitamin pre-mix had
17 caused dangerous levels of arsenic in its finished product.

18 180. The Subcommittee obtained the secret presentation Hain made on
19 August 1, 2019, which revealed their corporate policies to test only ingredients, not
20 final products, underrepresents the levels of toxic heavy metals in its baby foods.¹¹⁸
21 Hain presented the FDA with a PowerPoint presentation, noting higher levels of
22 arsenic in all finished foods tested for the presentation than were reflected in tests
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24

25 ¹¹⁴ *Id.* at 19, 52.

26 ¹¹⁵ *Id.* at 54.

27 ¹¹⁶ *Id.* at 41.

28 ¹¹⁷ *Id.*

¹¹⁸ *Id.* at 5, 53-56.

1 of individual raw ingredients.¹¹⁹ The Subcommittee noted, “This revelation means
2 that every single finished good containing brown rice had more arsenic than the
3 company’s estimates, which were based on testing the raw ingredients.”¹²⁰

4 **2. Lead findings**

5 181. While there has been no determination of a safe level of lead
6 contamination in baby foods, government agencies have set maximum contaminant
7 levels for lead between 10 ppb and 100 ppb for other exposure paths. Consumer,
8 environmental, and medical groups that have investigated levels for baby food
9 exposure have suggested either non-detect or 1 ppb for lead.

10 182. With respect to the lead contamination, the House Staff Report found
11 that Defendant Beech-Nut:

- 12 a. Used ingredients as high as 886.9 ppb lead;¹²¹
13 b. Only tested lead content in its ingredients, not its final product.¹²²

14 183. With respect to the lead contamination, the Subcommittee found that
15 Defendant Nurture (manufacturer of Happy Baby foods) sold finished baby food
16 products that tested as high as 641 ppb for lead—over six times higher than its
17 internal limit of 100 ppb lead.¹²³ Almost 20 percent of the baby food products that
18 Defendant Nurture tested contained over 10 ppb lead.¹²⁴

19 184. With respect to the lead contamination, the House Staff Report found
20 Defendant Gerber used ingredients testing as high as 48 ppb lead.¹²⁵

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23 ¹¹⁹ *FDA Testing Result Investigation*, HAIN CELESTIAL (Aug. 1, 2019) (Attached as
24 Exhibit I).

25 ¹²⁰ House Staff Report at 53.

26 ¹²¹ *Id.* at 3.

27 ¹²² *Id.* at 22.

28 ¹²³ *Id.* at 22.

¹²⁴ *Id.* at 3.

¹²⁵ *Id.* at 27.

1 185. The Subcommittee also found non-Defendant, co-conspirator Hain had
 2 used vitamin pre-mix that had surpassed its internal lead limits of 100ppb. The
 3 vitamin pre-mix accepted and used had 352 ppb of lead.¹²⁶ Despite having
 4 dangerously high levels of toxic heavy metals, Hain approved the use of this
 5 vitamin pre-mix based on a “theoretical” calculation of toxic heavy metals in the
 6 final good of 85 ppb of arsenic and 25 ppb of lead.¹²⁷ But the Subcommittee could
 7 not tell that Hain had ever confirmed the *actual* levels in the final product.

8 3. *Cadmium findings*

9 186. While there has been no determination of a safe level of cadmium
 10 contamination in baby foods, government agencies have set maximum contaminant
 11 levels for cadmium between 5 ppb and 20 ppb for other exposure paths. Consumer
 12 groups that have investigated levels for baby food exposure have suggested either
 13 non-detect or 1 ppb for cadmium.

14 187. With respect to the cadmium contamination, the Subcommittee found
 15 that Defendant Beech-Nut:

- 16 a. Used 105 ingredients testing over 20 ppb cadmium, some testing as
 17 high as 344.55 ppb;¹²⁸
- 18 b. Sold eleven products that surpassed its own internal (already-too-high)
 19 cadmium limits.¹²⁹

20 188. With respect to the cadmium contamination, the Subcommittee found
 21 that almost 65 percent of Defendant Nurture’s finished baby food contained over 5
 22 ppb of cadmium.

26 ¹²⁶ *Id.* at 41.

27 ¹²⁷ *Id.*

28 ¹²⁸ *Id.*

¹²⁹ *Id.* at 38-39.

1 189. With respect to the cadmium contamination, the Subcommittee found
2 Defendant Gerber does not test all its ingredients for cadmium. Of those it does
3 test, it accepted ingredients with as much as 87 ppb of cadmium.¹³⁰

4 190. With respect to the cadmium contamination, the Subcommittee found
5 non-Defendant, co-conspirator Hain had used 102 ingredients in its baby food that
6 tested over 20 ppb cadmium, with some testing up to 260 ppb (much higher than
7 its internal 100 ppb cadmium limit).¹³¹

8 4. *Mercury findings*

9 191. While there has been no determination of a safe level of mercury
10 contamination in baby foods, government agencies have set maximum contaminant
11 levels for mercury at 2 ppb for other exposure paths. Consumer groups that have
12 investigated levels for baby food exposure have suggested non-detect threshold for
13 mercury.

14 192. With respect to the mercury contamination, the Subcommittee found
15 that Defendant Beech-Nut and non-Defendant, co-conspirator Hain do not even
16 test for mercury in its ingredients or finished baby food.¹³² Defendant Gerber only
17 presented the Subcommittee with mercury testing results for three ingredients.

18 193. With respect to the mercury contamination, the Subcommittee found
19 that Defendant Nurture (manufacturer of Happy Baby foods) sold finished baby
20 food products that contained as much as 10 ppb of mercury.¹³³

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26 ¹³⁰ *Id.* at 32.

27 ¹³¹ *Id.* at 3, 41.

28 ¹³² *Id.* at 4, 33.

¹³³ *Id.* at 4.

1 5. *Uncooperative Manufacturer Defendants hide their*
2 *contamination.*

3 194. Plum Defendants refused to cooperate with the Subcommittee.¹³⁴ The
4 House Staff Report concludes: “The Subcommittee is greatly concerned that their
5 lack of cooperation might be obscuring the presence of even higher levels of toxic
6 heavy metals in their baby food products than their competitors’ products.”¹³⁵

7 195. The Subcommittee noted that Plum Defendants’ parent company,
8 Campbell, refused to produce its testing standards and specific testing results. The
9 Subcommittee concluded that Defendant Campbell (manufacturer of Plum
10 Organics) “has hidden its policies and the actual level of toxic heavy metals in its
11 products.”¹³⁶ The Subcommittee further noted its great concern that Defendant
12 Campbell’s “lack of cooperation might obscure the presence of even higher levels
13 of toxic heavy metals in their baby food products, compared to their competitors’
14 products.”¹³⁷

15 196. Based on a letter from Plum Defendants’ parent company, Campbell, to
16 the Subcommittee, they do not routinely test all products or ingredients for the
17 presence of heavy metals. Rather, they conducted *ad hoc* testing (most recently in
18 September 2019) when they “reexamined” only the Plum Organics foods featured
19 in the Healthy Babies Bright Futures report.¹³⁸ Currently, Plum Defendants only do
20 testing on new ingredients or finished product testing on new products.¹³⁹ As such,
21 they do no routine testing of all ingredients or products.

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23 ¹³⁴ *Id.* at 2.

24 ¹³⁵ *Id.* at 5.

25 ¹³⁶ *Id.* at 44.

26 ¹³⁷ *Id.* at 5.

27 ¹³⁸ Letter from attorney Thomas Perrelli on behalf of Campbell to Chairman Raja
Krishnamoorthi, Subcommittee on Economic and Consumer Policy, Committee on
Oversight and Reform (Dec. 11, 2019) (emphasis added). Attached as Exhibit H.

28 ¹³⁹ *Id.*

1 **6. Beyond specific testing results, the Subcommittee noted serious**
2 **shortcomings in Manufacturer Defendants' overall**
3 **manufacturing, testing, and sale of the products.**

4 197. As reported by Congress, Defendant Beech-Nut, Defendant Nurture,
5 Defendant Gerber, and Hain knew these heavy metals posed a threat and set their
6 own internal standards for how much of these toxins were present in their product.
7 However, these Defendants and non-Defendant co-conspirators then proceeded to
8 continue to turn a blind eye to their dangers by selling food that contained heavy
9 metals that far exceeded these levels.

10 198. Based on a review of internal documents from Manufacturer
11 Defendants and non-Defendant co-conspirators, the Subcommittee concluded that
12 corporate policies to test only ingredients, not final products, underrepresents the
13 levels of toxic heavy metals in baby foods.

14 199. For example, Defendant Hain tested a limited number of finished baby
15 food products for inorganic arsenic. In 100 percent of the products tested, the
16 inorganic arsenic levels were 28 percent to 93 percent higher than their estimates
17 based on individual ingredient testing.¹⁴⁰

18 200. The Subcommittee went on to note that “only testing ingredients gives
19 the false appearance of lower-than-actual toxic heavy metal levels.” For this
20 reason, “ingredient testing is inadequate, and [] only final product testing can
21 measure the true danger posed by baby foods.”¹⁴¹ The Subcommittee concluded
22 that a policy of testing only ingredients “recklessly endangers babies and children
23 and prevents the companies from even knowing the full extent of the danger
24 presented by their products.”

27 ¹⁴⁰ *Id.* at 5.

28 ¹⁴¹ *Id.* at 6.

1 201. The Congressional Report also documented that for the companies that
2 did test final products, they routinely sold products that had exceeded internal
3 company guidelines that these companies assured consumers were being met.

4 202. For example, Defendant Hain had an internal 100 ppb spec limit on
5 inorganic arsenic. While Defendant Hain did not routinely test finished products,
6 when it did, it found finished goods that contained as much as 129 ppb inorganic
7 arsenic.

8 203. As another example, Defendant Nurture set internal thresholds for toxic
9 heavy metals at 100 ppb for inorganic arsenic, 100 ppb for lead, 50 ppb for
10 cadmium, and 10 ppb for mercury. But Defendant Nurture (manufacturer of Happy
11 Baby products) sold all the finished products it tested “regardless of how much
12 toxic heavy metal the baby food contained.”¹⁴² Those products sold included baby
13 food that contained as much as 180 ppb of inorganic arsenic, 641 ppb of lead, and
14 10 ppb of mercury. More than a 25 percent of the food Defendant Hain sold had
15 over its internal limit of 100 ppb inorganic arsenic.

16 204. Defendant Nurture also produced inaccurate data during the
17 investigation in what the Subcommittee concluded was an attempt to mislead it:
18 **Further, Nurture appears to have misled the Subcommittee about**
19 **its testing standards.** As seen from Nurture’s goal thresholds pictured
20 below, Nurture conveyed to the Subcommittee that after January of
21 2019, it had a goal threshold of 50 ppb for lead in all of its baby food
22 products—infant formula, cereals, and wet foods. However, in the test
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28 ¹⁴² *Id.* at 4.

1 results that Nurture provided to this Subcommittee, it was still using
2 100 ppb as an internal guideline after January 2019.¹⁴³

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

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

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

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

8 However, the chart below appears to show that after the date Nurture claims to have
9 moved to a 50 ppb lead standard—January 2019—Nurture was still using a “Goal Threshold” of
10 100 ppb for 53 baby food products. The fact that Nurture appears to have continued using a
11 higher standard up to nine months after it claimed to the Subcommittee to have lowered the
12 threshold casts serious doubt on Nurture's candor in this matter.

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18 205. The House Staff Report—coupled with the lack of cooperation from
19 some Defendants—revealed that babies across the United States and beyond
20 consume food that contains high levels of toxins and heavy metals. Further, the
21 House Staff Report demonstrated that Defendants knowingly sold these products to
22 unsuspecting families, displaying little regard for the health and wellbeing of the
23 innocent children.¹⁴⁴

24 206. Manufacturer Defendants knowingly manufactured baby foods with
25 high levels of heavy metals, even though they were aware of the danger posed by
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27 ¹⁴³ *Id.* at 35 (emphasis added).

28 ¹⁴⁴ *See* The House Staff Report.

1 these toxic ingredients. Defendants displayed a reckless disregard or complete
2 indifference to the probable consequences of the actions to the babies and children
3 who ingested their products.

4 207. Defendants were clearly aware that Plaintiff, members of the putative
5 class, and consumers repeatedly purchased products that did not conform to the
6 standard Defendants advertised these products as satisfying. The fact that these
7 food products contained potential toxins and could lead to cognitive and health
8 problems for infants constituted wantonness on the behalf of Defendants.

9 **F. After the Congressional Report, Defendants again presented the**
10 **public with misleading half-truths to avoid having to eliminate**
11 **harmful contamination and avoid further regulation.**

12 208. When confronted by the U.S. House of Representatives regarding the
13 heavy doses of these toxins in these baby foods, Defendants boasted that their
14 products conforming with regulations. But Defendants were well aware that there
15 were no such regulatory standards because the FDA had not determined that any
16 level of lead, cadmium, or mercury were safe in baby foods and snacks. And while
17 FDA has set an inorganic arsenic standard of 100 ppb for infant cereal, most
18 Defendants do not test their final products to determine compliance and Defendant
19 Nurture sets a higher internal threshold (115 ppb) for final goods for sale than what
20 was allowed by the FDA.¹⁴⁵

21 209. The Congressional Report also documented that for Defendants that did
22 test final products, they routinely sold products that had exceeded internal
23 company guidelines that these companies assured consumers were being met.

24 210. When originally confronted with the inquiry about these products
25 containing high levels of heavy metal, Defendant Beech-Nut represented to the
26 Subcommittee in a December 6, 2019 letter that it applied “rigorous testing
27

28 ¹⁴⁵ *Id.* at 37.

1 protocols and heavy metal testing standards which are continuously reviewed and
 2 strengthened.”¹⁴⁶ Defendant Beech-Nut did concede that it used products over its
 3 own internal limits—“generally” up to 20% over those limits.¹⁴⁷

4 211. Defendant Campbell misleadingly told the Congressional
 5 Subcommittee by letter dated December 11, 2019: “Campbell has conducted
 6 testing on every Plum Organics product on the market to ensure **none exceed**
 7 **acceptable levels of arsenic, lead, cadmium, or mercury** To date, no Plum
 8 Organics foods have been found to be above exposure limits set by available
 9 domestic and international regulatory bodies”¹⁴⁸

10 212. In February 2021 after the release of the Congressional Report,
 11 Defendant Nurture doubled-down about the safety and health of its products by
 12 misleadingly referencing non-existent FDA standards: “We can say with the
 13 **utmost confidence** that **all** Happy Family Organics products are safe for babies
 14 and toddlers to enjoy and we are proud to have **best-in-class testing protocols** in
 15 our industry. We only sell products that have been rigorously tested and **we do not**
 16 **have products in-market with contaminant ranges outside of the limits set by**
 17 **the FDA.**”¹⁴⁹

20 ¹⁴⁶ Letter from the President and CEO of Beech-Nut Nutrition Company to Chairman
 21 Raja Krishnamoorthi, Subcommittee on Economic and Consumer Policy, Committee
 22 on Oversight and Reform (Dec. 6, 2019)
https://oversight.house.gov/sites/democrats.oversight.house.gov/files/6_0.pdf.

23 Attached as Exhibit E.

¹⁴⁷ *Id.*

24 ¹⁴⁸ Letter from attorney Thomas Perrelli on behalf of Campbell to Chairman Raja
 25 Krishnamoorthi, Subcommittee on Economic and Consumer Policy, Committee on
 Oversight and Reform (Dec. 11, 2019) (emphasis added). Attached as Exhibit H.

26 ¹⁴⁹ *Quality and Safety of Our Products*, NURTURE,
 27 <https://www.happyfamilyorganics.com/quality-and-safety-of-our-products/> (last
 28 visited Mar. 3, 2021) (emphasis added). The first capture on the Wayback Internet
 Archive is on February 5, 2021.

1 213. Since the release of the Congressional Report, Defendant Beech-Nut
2 has continued to misleadingly assure parents and consumers that its products are
3 “safe and nutritious” in a message provided to the press and carried over the wires
4 on February 5, 2021.¹⁵⁰

5 214. Plum Defendants continue to obfuscate the truth from the public.
6 Notably, after the release of the Congressional Report, it stated to the press in a
7 message carried over the wires on February 5, 2021: “Campbell has conducted
8 testing on every Plum Organics product on the market to ensure none exceed
9 acceptable levels of arsenic, lead, cadmium, or mercury.”¹⁵¹ However, Plum
10 Defendants have never clarified what “acceptable levels” are or provides any
11 substantive information about heavy metals in their food.

12 215. As these specific misrepresentations by each Defendant show, each was
13 more interested in protecting profits than making meaningful changes to eliminate
14 toxic heavy metal contamination. Once Congress illustrated Defendants’ continued
15 manufacturing, testing, and distribution practices that led to contaminated baby
16 food, Defendants engaged in a whole new round of fraud to conceal and prolong
17 their schemes to defraud.

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20
21 <https://web.archive.org/web/20210205034954/https://www.happyfamilyorganics.com/quality-and-safety-of-our-products/>

22 ¹⁵⁰ Elaine Watson, *Baby food brands defend protocols as congressional report alleges*
23 *‘highly dangerous’ levels of heavy metals in infant foods; expect lawsuits, stays*
24 *attorney*, FOOD NAVIGATOR (Feb. 5, 2021), <https://www.foodnavigator-usa.com/Article/2021/02/05/Baby-food-brands-defend-protocols-as-congressional-report-alleges-highly-dangerous-levels-of-heavy-metals>.

25 ¹⁵¹ Elaine Watson, *Baby food brands defend protocols as congressional report alleges*
26 *‘highly dangerous’ levels of heavy metals in infant foods; expect lawsuits, stays*
27 *attorney*, FOOD NAVIGATOR (Feb. 5, 2021), <https://www.foodnavigator-usa.com/Article/2021/02/05/Baby-food-brands-defend-protocols-as-congressional-report-alleges-highly-dangerous-levels-of-heavy-metals>.

1 216. Defendants’ actions and inactions have likely caused irreparable harm
2 to hundreds of thousands of families across the nation.

3 217. Plaintiff and members of the putative class have also suffered
4 significant economic damages, to the tune of billions of dollars,¹⁵² because they
5 paid for what was represented as healthy, nutritious baby food for their children,
6 devoid of contaminants, but received foods containing harmful levels of heavy
7 metals.

8 **G. Equitable Tolling, Discovery Rule, and Fraudulent Concealment**

9 218. Plaintiff repeats and re-alleges the allegations set forth above. At all
10 times relevant to this Complaint, Defendants took active steps to conceal their
11 unlawful activities.

12 219. **Discovery Rule:** Plaintiff and the members of the Class had no
13 knowledge or reason to know of Defendants’ knowing concealment of toxic heavy
14 metals in their products until on or about (at the earliest) February 4, 2021, when
15 the U.S. House of Representatives Committee on Oversight and Reform released
16 its explosive report, “*Baby Foods Are Tainted with Dangerous Levels of Arsenic,*
17 *Lead, Cadmium, and Mercury.*”

18 220. Plaintiff and the Class are consumers who do not have the training or
19 means from which they could have discovered Defendants’ knowing concealment
20 of toxic heavy metals in their products until on or about (at the earliest) February 4,
21 2021, if then.

22 221. Information regarding the unlawful conduct described herein was not
23 available to Plaintiff and members of the Class prior to Defendants’ knowing
24 concealment of toxic heavy metals in their products until on or about (at the
25 earliest) February 4, 2021. Plaintiff and members of the Class had no previous,
26

27 ¹⁵² Emma Bedford, *U.S. baby food market - statistics & facts*, STATISTA (Nov. 20,
28 <https://www.statista.com/topics/1218/baby-food-market/>).

1 reasonable means of obtaining the facts or information concerning the Defendants’
2 unlawful activities, all of which were purposefully concealed by Defendants.

3 222. For these reasons, the statute of limitations as to Plaintiff’s and the
4 Class’ claims did not begin to run and has been tolled with respect to the claims
5 that Plaintiff and the members of the Class have alleged in this Complaint.

6 223. **Fraudulent Concealment and/or Equitable Tolling:** In the
7 alternative, application of the doctrine of fraudulent concealment and/or equitable
8 tolling tolled the statute of limitations on the claims asserted herein by Plaintiff and
9 the Class. Plaintiff and the members of the Class did not discover, and could not
10 have reasonably discovered, Defendants’ knowing concealment of toxic heavy
11 metals in their products alleged herein until on or about (at the earliest) February 4,
12 2021, when the U.S. House of Representatives Committee on Oversight and
13 Reform released its explosive report, “*Baby Foods Are Tainted with Dangerous*
14 *Levels of Arsenic, Lead, Cadmium, and Mercury.*”

15 224. Before that time, Plaintiff and the members of the Class were unaware
16 of Defendants’ unlawful conduct and did not know before then about Defendants’
17 knowing concealment of toxic heavy metals in their products. Defendants provided
18 no information, actual or constructive, to Plaintiff and members of the Class.

19 225. The affirmative acts of Defendants alleged herein were wrongfully
20 concealed and carried out in a manner that precluded detection.

21 226. Accordingly, a reasonable person under the circumstances would not
22 have been alerted to begin to investigate Defendants’ knowing concealment of
23 toxic heavy metals in their products before February 4, 2021.

24 227. Plaintiff and the members of the Classes could not have discovered the
25 alleged unlawful activity at an earlier date by the exercise of reasonable diligence
26 because of the deceptive practices and techniques of secrecy employed by the
27 Defendants to avoid detection of, and fraudulently conceal, their unlawful conduct.
28

1 228. Because the alleged unlawful conduct, alleged herein was self-
2 concealing and affirmatively concealed by Defendants, Plaintiff and members of
3 the Classes had no knowledge of the alleged unlawful conduct, or of any facts or
4 information that would have caused a reasonably diligent person to investigate,
5 before February 4, 2021.

6 229. For these reasons, the statute of limitations applicable to Plaintiff's and
7 the Classes' claims was tolled and did not begin to run until February 4, 2021.

8 230. **Continuing Tort:** Defendants are estopped from relying on any statute
9 of limitations defense because their illegal, deceptive, and fraudulent practices as
10 alleged herein, which are continuing, have created continuing and repeated injuries
11 to Plaintiff and the Class.

12 **IV. Class Action Allegations**

13 231. Plaintiff brings this action individually and on behalf of the following
14 Classes pursuant to Rules 23(a) and 23(b)(2) and (3) of the Federal Rules of Civil
15 Procedure:

16 RICO Class for all persons with standing to prosecute Count I:

17 All persons in the United States who, from January 1, 2019, to the present,
18 purchased foods for babies, toddlers or children manufactured by Defendants
19 for household or business use, and not for resale (the "RICO Class").

20
21 State Law Class for all persons with standing to prosecute Counts II - VIII:

22 All persons in the United States who, from June 15, 2017, to the present,
23 purchased foods for babies, toddlers or children manufactured by Defendants
24 named herein for household or business use, and not for resale (the "State
25 Law Class").

1 Colorado Class for all persons with standing to prosecute Count IX:

2 All persons in the state of Colorado, who, from June 15, 2017, to the present,
3 purchased foods for babies, toddlers or children manufactured by Defendants
4 named herein for household or business use, and not for resale (the
5 “Colorado Class”).

6
7 Kansas Class for all persons with standing to prosecute Count X:

8 All persons in the state of Kansas, who, from June 15, 2017, to the present,
9 purchased foods for babies, toddlers or children manufactured by any
10 Defendants named herein for household or business use, and not for resale
11 (the “Kansas Class”).

12
13 232. Excluded from the Classes are the Defendants, any parent companies,
14 subsidiaries, and/or affiliates, officers, directors, legal representatives, employees,
15 co-conspirators, all governmental entities, and any judge, justice, or judicial officer
16 presiding over this matter.

17 233. This action is brought and may be properly maintained as a class action.
18 There is a well-defined community of interests in this litigation and the members
19 of the Classes are easily ascertainable. Purchasers of these products can identify
20 their purchases through receipts, store rewards programs, and their own testimony.

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

25 235. Questions of law and fact common to Plaintiff and the Classes include,
26 but are not limited to, the following:

27 a. whether Defendants owed a duty of care to Plaintiff and the Classes;

28

- 1 b. whether Defendants knew or should have known that the baby foods
- 2 contained or may contain heavy metals;
- 3 c. whether Defendants wrongfully represented and continue to represent
- 4 that the baby foods are natural and safe for human infant and child
- 5 consumption;
- 6 d. whether Defendants misrepresent their baby foods as healthy, superior
- 7 quality, nutritious, and safe for consumption;
- 8 e. whether Defendants wrongfully represented and continue to represent
- 9 that these products are natural;
- 10 f. whether Defendants wrongfully represented and continue to represent
- 11 that the manufacturing of baby foods are subjected to rigorous
- 12 standards, including testing for heavy metals and government
- 13 regulation;
- 14 g. whether Defendants wrongfully failed to disclose that their baby foods
- 15 contained, or may contain, heavy metals;
- 16 h. whether Defendants' representations in advertising, warranties,
- 17 packaging, and/or labeling are false, deceptive, and misleading;
- 18 i. whether those representations are likely to deceive a reasonable
- 19 consumer;
- 20 j. whether a reasonable consumer would consider the presence, or risk of,
- 21 heavy metals as a material fact in purchasing baby food;
- 22 k. whether Defendants had knowledge that those representations were
- 23 false, deceptive, and misleading;
- 24 l. whether Defendants continue to disseminate those representations
- 25 despite knowledge that the representations are false, deceptive, and
- 26 misleading;
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- 1 m. whether a representation that a product is healthy, superior quality,
- 2 nutritious and safe for consumption and does not contain arsenic,
- 3 mercury, cadmium, lead and/or other heavy metals is material to a
- 4 reasonable consumer;
- 5 n. whether Defendants' representations and descriptions on the labeling of
- 6 their baby foods are likely to mislead, deceive, confuse, or confound
- 7 consumers acting reasonably;
- 8 o. whether Defendants violated 18 U.S.C. § 1964(a);
- 9 p. whether Defendants violated the laws of the State of Kansas;
- 10 q. whether Defendants violated the laws of the State of Colorado;
- 11 r. whether Defendants violated the laws of other states;
- 12 s. whether Defendants breached express warranties;
- 13 t. whether Defendants breached implied warranties;
- 14 u. whether Defendants made negligent and/or fraudulent
- 15 misrepresentations and/or omissions;
- 16 v. whether Plaintiff and the members of the Class are entitled to actual,
- 17 statutory, and punitive damages; and
- 18 w. whether Plaintiff and members of the Class are entitled to declaratory
- 19 and injunctive relief.

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

25 237. Plaintiff's claims are typical of those of the members of the Classes in
26 that they are based on the same underlying facts, events, and circumstances
27 relating to Defendants' conduct.

1 238. Plaintiff will fairly and adequately represent and protect the interests of
2 the Classes, have no interests incompatible with the interests of the Classes, and
3 have retained counsel competent and experienced in class action, consumer
4 protection, and false advertising litigation.

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

9 240. Questions of law and fact common to the Classes predominate over
10 any questions affecting only individual members of the Class.

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

12 **COUNT ONE:**
13 **Violation of The Racketeer Influenced and Corrupt Organizations Act (Civil**
14 **RICO) under 18 U.S.C. § 1962(c) and (d)**
15 (As to Defendant Beech-Nut, Plum Defendants, Defendant Gerber, and Defendant
16 Nurture)

17 242. Plaintiff realleges and incorporates by reference each and every
18 allegation contained in the preceding paragraphs as if fully set forth herein.

19 243. At all relevant times, the RICO Defendants (for purposes of this claim
20 only, “RICO Defendants” refers only to the five Defendants sued for RICO and not
21 all Defendants as a whole) and non-Defendant, co-conspirator Hain have been
22 “persons” under 18 U.S.C. § 1961(3).

23 244. Section 1962(c) makes it “unlawful for any person employed by or
24 associated with any enterprise engaged in, or the activities of which affect,
25 interstate or foreign commerce, to conduct or participate, directly or indirectly, in
26 the conduct of such enterprise’s affairs through a pattern of racketeering activity.”
27 18 U.S.C. § 1962(c).

1 245. Section 1962(d) makes it unlawful for “any person to conspire to
2 violate,” among other provisions, Section 1962(c). See 18 U.S.C. § 1962(d).

3 246. Each RICO Defendant (as well as non-Defendant, co-conspirator Hain)
4 is a participant in the multi-billion-dollar baby food industry. Finding it difficult to
5 achieve their ambitious goals lawfully and to outsell their competitors by playing by
6 the rules, each RICO Defendant and non-Defendant, co-conspirator Hain resorted to
7 cheating through a scheme to defraud that included four types of fraud: false
8 representations, fraud by omission, fraudulent concealment, and fraud by half-truth.

9 247. Each RICO Defendant and non-Defendant, co-conspirator Hain knew
10 that American parents and purchasers are closely focused on the ingredients in baby
11 food. They designed marketing and advertising campaigns around food safety and
12 purity. The whole time they did so, RICO Defendants and non-Defendant, co-
13 conspirator Hain knew their products were not as advertised—the products were
14 contaminated (not pure), included foreign substances (not natural), and were
15 dangerous to highly vulnerable babies and toddlers (not safe).

16 248. This RICO claim is for the compensatory damages (on behalf of the
17 purchasers) that resulted from the baby food companies’ interstate, nationwide,
18 schemes to fraud. It does not seek to recovery for personal injuries, nor does it rely
19 upon any personal injuries occurring. Instead, the baby food that was sold was
20 “essentially worthless” because it did not contain the very essence of what was
21 advertised. Parents and purchasers bought this baby food because it was natural,
22 pure, and safe—thus, because it was not, and each RICO Defendant and non-
23 Defendant, co-conspirator Hain either concealed or omitted facts or spoke in half-
24 truths—the very purpose of these purchases was fraudulently induced.

25 249. Worse, RICO Defendants and non-Defendant, co-conspirator Hain have
26 prolonged their fraud by covering up and actively speaking out to falsely deny their
27 underlying fraud occurred. To this day, they have not recalled the contaminated
28

1 products and are using the pretext of the Baby Food Council to avoid taking
2 responsibility for their fraud.

3 250. Consumers and purchasers are not highly knowledgeable about food
4 manufacturing or processing and lack any ability to uncover the fraud that is
5 occurring. RICO Defendants and non-Defendant, co-conspirator Hain aggravated
6 this information asymmetry by using the Baby Food Council to lull purchasers and
7 further obscure their fraud and to falsely suggest they are committed to baby food
8 safety.

9 **A. The Baby Food Council Is Infiltrated by Each RICO Defendant**
10 **and Used as An Enterprise for Fraud**

11 251. At all relevant times, RICO Defendants and non-Defendant, co-
12 conspirator Hain each engaged in food fraud using the Baby Food Council as an
13 enterprise, or in the alternative, forming an association in fact enterprise with the
14 Baby Food Council and/or the other RICO Defendants. At this stage, without access
15 to discovery to see the private communications between RICO Defendants and non-
16 Defendant, co-conspirator Hain, Plaintiff pleads in the alternative. They will later
17 clarify their allegations once discovery has occurred, and they obtain the emails and
18 other documents needed to explain the precise structure among RICO Defendants as
19 well as with non-Defendant, co-conspirator Hain.

20 252. According to its website, the Baby Food Council, as an entity, has
21 existed since January 2019. Discovery is needed to confirm when it was actually
22 created, who created it, how RICO Defendants and non-Defendant, co-conspirator
23 Hain worked together to create it, the financial payments that were made, the
24 finances of the entity, and so forth. These documents and records are not publicly
25 available and are kept confidential by RICO Defendants, non-Defendant, co-
26 conspirator Hain, the Council, and the members of the Council.

27
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1 253. Each RICO Defendant as well as non-Defendant, co-conspirator Hain
2 infiltrated and used the Baby Food Council as a vessel for fraud so that each could
3 sell contaminated baby food products to purchasers without incurring the expense
4 and time required to properly manufacture and process these foods. Alternatively,
5 RICO Defendants and non-Defendant, co-conspirator Hain formed and infiltrated
6 the Baby Food Council to use it as a vessel for fraud and worked together to
7 accomplish their schemes to defraud.

8 254. Once the American media uncovered the massive food fraud scheme
9 that had been ongoing since January 2019, each RICO Defendant as well as non-
10 Defendant, co-conspirator Hain hid behind its membership and status in the Baby
11 Food Council as a decoy and shield, as well as to lull victims of their food fraud
12 into not believing what Congress had publicly exposed.

13 255. RICO Defendants and non-Defendant, co-conspirator Hain falsely
14 suggested and implied that membership in the Baby Food Council membership was
15 a defense to the fraud and that they were committed to baby safety and health and
16 best practices.

17 256. Each RICO Defendant as well as non-Defendant, co-conspirator Hain
18 also used its membership in the Baby Food Council as a pretext for not adopting
19 standards for baby food manufacturing. Each RICO Defendant as well as non-
20 Defendant, co-conspirator Hain did not disclose that it was co-opting the push for
21 FDA standards by promising that baby food manufacturers would regulate
22 themselves and work to adopt food standards. Although they claim the FDA is a
23 member of the Baby Food Council, they took no action with the FDA and steered
24 the FDA away from adopting standards. Thus, the lack of standards by the FDA is
25 part of the scheme to defraud. Each RICO Defendant as well as non-Defendant, co-
26 conspirator Hain worked to defeat the adoption of FDA standards using the Baby
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1 Food Council as an instrument to do so. This tactic is straight out of the playbook
2 used by Big Tobacco for decades.

3 257. Each RICO Defendant's claim of membership was also false and
4 misleading because the Baby Food Council has not done anything to help American
5 babies and to date has been kept dormant. Rather, it has been set up so RICO
6 Defendants and non-Defendant, co-conspirator Hain can use it to avoid liability. As
7 set forth above, the Council has engaged in no meaningful activity in the 25 months
8 since it was created. The Baby Food Council is a shell entity that has only been
9 used to cover up the food fraud committed by RICO Defendants and non-
10 Defendant, co-conspirator Hain.

11 258. Each RICO Defendant as well as non-Defendant, co-conspirator Hain
12 has dragged out the adoption of standards and any manufacturing and processing
13 reform by using the diversion and distraction of the Baby Food Council, despite
14 willfully knowing that the Baby Food Council would take no action and would
15 serve only as a lifeless scarecrow.

16 259. The Baby Food Council has also served as an anchor for RICO
17 Defendants and non-Defendant, co-conspirator Hain to coordinate, work together,
18 and unify their cover-up and concealment of their food fraud—to work together,
19 aligned through the auspices of the Baby Food Council, as an association in fact
20 enterprise. RICO Defendants and non-Defendant, co-conspirator Hain use the Baby
21 Food Council to coordinate and synchronize their fraudulent marketing and sales
22 strategy and manufacturing processes.

23 260. Without the Baby Food Council, each RICO Defendant and co-
24 conspirator would be exposed and forced to defend its food fraud on its own. With
25 the Baby Food Council, RICO Defendants and non-Defendant, co-conspirator Hain
26 are all able to band together, point to each other's shared industry-wide
27 commitment, and defraud and defend consistently as a united group. This, too,
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1 confirms the Baby Food Council is an essential part of each RICO Defendant's
2 scheme to defraud Plaintiff and the RICO Class.

3 261. Discovery is needed to uncover the confidential emails and
4 communications among RICO Defendants and non-Defendant, co-conspirator Hain
5 showing how they worked together as an association-in-fact enterprise, and
6 collectively worked together using the Baby Food Council. They worked together,
7 rather than against each other to compete in the marketplace on this issue, as
8 competitors usually do.

9 262. In addition to RICO Defendants and non-Defendant, co-conspirator
10 Hain forming an association-in-fact enterprise with the Baby Food Council, in the
11 alternative, the Baby Food Council is an enterprise and each RICO Defendant as
12 well as each co-conspirator has operated or participated, directly or indirectly, in the
13 affairs of the Baby Food Council through a pattern of racketeering activity—*i.e.*,
14 wire fraud, mail fraud, and the corruption of an official proceeding before Congress.

15 263. Indeed, RICO Defendants and non-Defendant, co-conspirator Hain had
16 no legitimate or lawful use for becoming members of the Baby Food Council other
17 than to use it to commit fraud. They engaged in repeated acts of wire fraud and mail
18 fraud, and they sought to cover up and explain away this fraud using their
19 membership in the Baby Food Council and statements it made as an alibi for their
20 food fraud. If they had a legitimate interest in protecting babies and infants, they
21 would have either adopted standards and complied with them, not sold defective
22 products, or recalled their defective products and apologized (offering refunds) once
23 the 2021 Congressional Report came down. That they are continuing to use the
24 Baby Food Council as part of their concealment strategy, citing their membership in
25 the hollow Baby Food Council as a way to lull victims and Congress into believing
26 they are not guilty of fraud, further shows the Baby Food Council is integral to the
27 pattern of mail and wire fraud, which remains ongoing.

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1 264. The Baby Food Council’s inactivity and failure to engage in any
2 substantive activity for over 25 months confirms it has been infiltrated by RICO
3 Defendants and non-Defendant, co-conspirator Hain and used by them as a vessel
4 for fraud.

5 265. If the Baby Food Council were a legitimate organization actually
6 committed to baby food health and safety, it would have taken active steps to
7 combat baby food contamination and speak out against the widely established,
8 industry-wide baby food fraud that was exposed in February 2021. But the Baby
9 Food Council said and did nothing.

10 266. It is necessary to hold RICO Defendants accountable for their
11 racketeering so that the Baby Food Council can be cleansed of these bad actors.
12 Freed from the fraud and nefarious influences of RICO Defendants and non-
13 Defendant, co-conspirator Hain, the Baby Food Council can actually take steps to
14 help combat baby food contamination—or it can wind down its affairs if it was
15 never anything more than a front group for RICO Defendants and non-Defendant,
16 co-conspirator Hain, modeled after the tactics of Big Tobacco.

17 267. Discovery is needed to ascertain and confirm the facts regarding the
18 creation, intentions, internal activities, and internal communications among RICO
19 Defendants as well as with non-Defendant, co-conspirator Hain. Without access to
20 the private, non-public, confidential documents, Plaintiff has no way of pleading
21 these details.

22 **B. The Enterprise**

23 268. The enterprise is the Baby Food Council, which each RICO Defendant
24 infiltrated and used as a vessel for fraud. Alternatively, the Baby Food Council,
25 RICO Defendants, and non-Defendant, co-conspirator Hain formed an association-
26 in-fact enterprise.

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1 269. At all relevant times, the Baby Food Council had an existence separate
2 and distinct from each of the RICO Defendants and their co-conspirators and was
3 separate and distinct from the pattern of racketeering in which RICO Defendants
4 and their co-conspirators engaged. Likewise, each RICO Defendant and their co-
5 conspirator Hain was separate and apart from the Baby Food Council and every
6 other RICO Defendant as well as non-Defendant, co-conspirator Hain.

7 270. Each of the RICO Defendants made its membership in the Baby Food
8 Council a central part of their scheme to defraud. RICO Defendants and non-
9 Defendant, co-conspirator Hain ordinarily are competitors and should be
10 competitors who compete for market share; instead, RICO Defendants and non-
11 Defendant, co-conspirator Hain used the Baby Food Council as a mechanism to
12 conspire and work together to deflect, deny, and conceal their collective food fraud
13 against baby food purchasers.

14 271. Likewise, baby food has been sold for decades in America. The Baby
15 Food Council was created only in January 2019 because RICO Defendants and non-
16 Defendant, co-conspirator Hain knew they were running out of time to conceal their
17 fraud—they became desperate to create a new entity (Baby Food Council) to help
18 deflect and deny their fraud was occurring. The timing of the Baby Food Council's
19 creation in January 2019 further confirms it was created for the purpose of
20 facilitating the ongoing food fraud.

21 272. Through their collective membership in the Baby Food Council, each
22 RICO Defendant along with non-Defendant, co-conspirator Hain worked side-by-
23 side (rather than in competition) with the common purpose of furthering the illegal
24 baby food fraud scheme. RICO Defendants and non-Defendant, co-conspirator Hain
25 further shared the common purposes of blocking food standards from being adopted
26 and preventing purchasers and the American public from uncovering the massive
27 food fraud scheme they were engaged in. RICO Defendants and non-Defendant, co-
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1 conspirator Hain have formed long-term, ongoing relationships through the Baby
2 Food Council and have demonstrated they are aligned and working together.

3 273. RICO Defendants and non-Defendant, co-conspirator Hain made sure
4 to include legitimate entities, like Cornell University, as members of the Baby Food
5 Council and made sure the website for the Baby Food Council is hosted on
6 Cornell's Food Science Department to lend a false aura of legitimacy. Discovery
7 is needed to obtain the financial payments and other contributions made by RICO
8 Defendants and non-Defendant, co-conspirator Hain to Cornell and its professors
9 who agree to be listed on the Baby Food Council.

10 274. The ordinary business of RICO Defendants and non-Defendant, co-
11 conspirator Hain is to engage in the manufacture and sales of baby food products. It
12 is not part of their routine business to engage in acts of mail and wire fraud to
13 mislead purchasers about the contents of their products and their steps to combat
14 food contamination. Nor is it part of the ordinary business to form a Baby Food
15 Council, which was created only in January 2019, despite decades of baby food
16 manufacturers never forming a conspiracy. It was the public release of the
17 bombshell Consumer Reports article in 2018 that prompted RICO Defendants and
18 non-Defendant, co-conspirator Hain to scramble and quickly erect the Baby Food
19 Council as a vessel for their ongoing fraud.

20 275. RICO Defendants have also made mail and wire fraud part of the
21 ordinary business activities by routinely selling contaminated food products and
22 engaging in advertising and marketing that is knowingly and willfully false and
23 fraud by omission or fraud by half-truth.

24 276. Each RICO Defendant as well as non-Defendant, co-conspirator Hain
25 has a separate existence separate and apart from the enterprise, including distinct
26 legal statuses, different offices and roles, bank accounts, officers, directors,
27

1 employees, individual personhood, reporting requirements, and financial
2 statements.

3 277. The Baby Food Council website is a separate website that identifies the
4 Baby Food Council as an independent entity to which each RICO Defendant as well
5 as non-Defendant, co-conspirator Hain is a member. That website is hosted by
6 Cornell's Food Science Department, further creating distinctiveness and separation
7 from each RICO Defendant (and also the false halo of legitimacy).

8 278. RICO Defendants and non-Defendant, co-conspirator Hain have used
9 the very independent status of the Baby Food Council as an integral part of their
10 fraud schemes—suggesting that they are members of an independent, legitimate
11 third-party entity that is working to combat baby food fraud contamination.

12 279. The Baby Food Council might be dormant and not engaging in real
13 activity, but RICO Defendants and non-Defendant, co-conspirator Hain have
14 conveyed to purchasers, Congress, and the American public the opposite and are
15 bound by those representations. By publicly touting their membership in the Baby
16 Food Council as proof of their benevolence and commitment to baby food safety
17 (when, in fact, the opposite is true, and they have used the Baby Food Council to
18 co-opt reforms and conceal their fraud), RICO Defendants and non-Defendant, co-
19 conspirator Hain have committed to the Baby Food Council being a real entity
20 engaged in independent, legitimate activity.

21 **C. The Pattern of Racketeering: Mail Fraud and Wire Fraud and**
22 **Corruption of an Official Proceeding**

23 280. To carry out their schemes to defraud, RICO Defendants and non-
24 Defendant, co-conspirator Hain knowingly participated, directly or indirectly, and
25 conducted the affairs of the Baby Food Council through a pattern of racketeering
26 activity within the meaning of 18 U.S.C. §§ 1961(1), 1961(5) and 1962(c).

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1 281. From at least 2019 to the present, each RICO Defendant as well as non-
2 Defendant, co-conspirator Hain has worked to execute a scheme to defraud by
3 infiltrating and using the Baby Food Council as a vessel for fraud to (1) coordinate
4 the suppression of information revealing the widespread contamination of baby
5 food during manufacturing; (2) delay the adoption of governmental standards for
6 baby food manufacturers while falsely suggesting a commitment to adopt those
7 very standards; (3) falsely suggest that contamination of baby food products is
8 “natural” and to omit “mercury” as a heavy metal dangerous to babies; (4) falsely
9 suggest that they were committed to improving baby food safety, when in fact the
10 Baby Food Council has done nothing to solve this problem since January 2019 and
11 serves only to help RICO Defendants and non-Defendant, co-conspirator Hain
12 prolong their fraud; (5) work to share information on heavy metals and how to
13 deceive purchasers into believing that baby food with heavy metals is “safe” and
14 not in violation of “standards” given that the RICO Defendants worked to make
15 sure no standards were adopted through the Baby Food Council co-option of this
16 effort; and (6) conceal, camouflage, and prolong their ongoing food fraud by
17 specifically referencing their active involvement in the Baby Food Council as proof
18 of their commitment to baby food safety (when in fact the opposite has been proven
19 true) as part of statements made by interstate wire (detailed in this Complaint).

20 282. Contrary to public statements made by RICO Defendants and non-
21 Defendant, co-conspirator Hain, the Baby Food Council was designed to falsely lull
22 purchasers of contaminated baby food (Plaintiff and the Class) and Congress into
23 believing that food companies are actively working to fix the food fraud that is
24 occurring.

25 283. The Baby Food Council has done nothing other than serve as a shiny
26 distraction. Despite being formed in January 2019, the Baby Food Council has done
27 nothing substantive to address the lack of food standards or to regulate its members.

1 The Council has not issued any demands for product recalls, nor has it assisted its
2 members or the public with anything. It has sat dormant merely to deflect attention
3 and serve as a false hope that RICO Defendants and non-Defendant, co-conspirator
4 Hain are doing something, when in fact they are not.

5 284. The five baby food companies that joined the Baby Food Council did so
6 because they knew their scheme to defraud would soon be exposed, and they
7 wanted to have a handy diversion ready to convince purchasers and the government
8 that they were actively addressing the concerns.

9 285. This was a fraudulent pretext—these companies have known for several
10 years that their products are contaminated, and they did nothing to stop these
11 problems—either in January 2019 or any time before.

12 286. When Congress began its inquiry into allegations that baby food was
13 contaminated with heavy metals and sought information from RICO Defendants
14 and non-Defendant, co-conspirator Hain, they were quickly met with proclamations
15 from RICO Defendants and non-Defendant, co-conspirator Hain that membership
16 in the Baby Food Council meant they were dedicated to fixing the problem. *See*
17 Exhibits D, E, F, and G.

18 a. On December 6, 2019, Defendant Beech-Nut represented to Congress
19 that after the Health Babies Bright Future report, it encouraged the
20 creation of the Baby Food Council to “conduct research and work to
21 achieve a long-term reduction of heavy metals in the baby food supply
22 chain” and that its current “top priority is to reduce heavy metals in the
23 products manufactured and marketed by the member companies
24 [including Defendant Beech-Nut] using best-in-class management
25 practices.”

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1 In October of 2018 we encouraged Cornell University to establish a coalition of academia, baby
2 food companies, governmental and non-governmental organizations (“NGO”), including Health
3 Babies Bright Futures, to conduct research and work to achieve a long-term reduction of heavy
4 metals in the baby food supply chain.

5 Shortly thereafter, The Baby Food Council (BFC) was formed in January of 2019. Its top priority
6 is to reduce heavy metals in the products manufactured and marketed by the member companies
7 using best-in-class management practices. The council members meet monthly with our non-
8 governmental organization and regulatory agencies to discuss past actions and set the agenda for
9 future research and testing.

10 b. On December 19, 2019, Defendant Gerber represented to Congress that
11 along with its internal programs and procedures, it was “also a founding
12 member of the Baby Food Council,” whose objective is “reducing
13 heavy metals in the products manufactured by the member companies
14 to as low as reasonably achievable using best-in-class management
15 practices.” Gerber claimed that its “efforts with the Council represent
16 our commitment to the safety of the baby food category.”

17 In addition to the Nestlé internal programs and procedures to manage contaminants described above,
18 Gerber is also a founding member of the Baby Food Council, which is comprised of leading companies and
19 academic, government, and NGO partners and advisors. The Council was created in January of 2019 with
20 the objective of reducing heavy metals in the products manufactured by the member companies to as low
21 as reasonably achievable using best-in-class management practices.

22 Early efforts of the Council have focused on identifying those foods and ingredients with the highest
23 potential to contribute to heavy metal exposure in young children. We will also be identifying and
24 evaluating best practices that can be used to further lower heavy metal levels in these foods. Recognizing
25 that heavy metals are widely present in the environment and can get into food, this work will initially
26 focus on the impact of the environment and growing conditions but will also extend to other aspects of
27 the supply chain including handling and processing. Our efforts with the Council represent our
28 commitment to the safety of the baby food category.

c. On December 11, 2019, Hain responded to Congress by pointing to its
membership in the Baby Food Council as an indicator of its

1 commitment “to producing safe, nutritious, high-quality baby food
2 products.”

3
4 Hain is a member of the Baby Food Council (“Council”), a group of companies organized by
5 Cornell University and the Environmental Defense Fund. The Council’s mission is supported by
6 the U.S. Department of Agriculture, the Food and Drug Administration (“FDA”), and other
7 stakeholders, including Healthy Babies Bright Futures, the organization that authored the report
8 that prompted the Subcommittee’s request. Like all of the Council’s member companies, Hain is
9 committed to producing safe, nutritious, high-quality baby food products. Moreover, Hain
10 supports the FDA finalizing guidance limiting inorganic arsenic in baby food products, and it
11 supports the development of additional guidance limits as supported by the scientific evidence.

12 Heavy metals occur naturally in the environment, but their prevalence varies widely depending
13 on food types and sources. Hain supports the Council’s efforts to identify foods and ingredients
14 with the highest potential to contribute to heavy metal exposure in children, as well as its efforts
15 to develop effective mitigation strategies. Hain further supports the Council’s decision to focus
16 initially on environmental factors, including growing conditions and farming techniques,
17 understanding that the Council will also assess ways to improve manufacturing and handling
18 processes.

19
20 d. On December 18, 2019, Defendant Nurture responded to Congress by
21 pointing to its membership in the Baby Food Council as an indication
22 of its commitment to “reduce heavy metals in baby food products as
23 low as reasonably achievable using best-in-class management
24 practices.”

25 Furthermore, we believe our approach is better than, or at least consistent with, that taken
26 by others in our industry. Indeed, we joined the Baby Food Council, which was created this year
27 with the objective to reduce heavy metals in baby food products as low as reasonably achievable
28 using best-in-class management practices. This Council includes the leading baby food
 manufacturers as well as the Environmental Defense Fund (EDF).⁷

29
30 287. RICO Defendants and non-Defendant, co-conspirator Hain sent these
31 fraudulent statements, via mail and e-mail, to members of the United States
32 Congress in order to corrupt the ongoing investigation by Congress of baby food
33 contamination.

1 288. And once the February 2021 congressional report was released, RICO
2 Defendants and non-Defendant, co-conspirator Hain were again quick to tout their
3 commitment to child safety as proven by their membership in the Baby Food
4 Council—using its membership to lull victims into not pursuing and correcting the
5 fraud.

6 289. For example, Defendant Gerber stated on its website on or around Feb.
7 4, 2021, that as a Baby Food Council member, it has “been working together with
8 other industry members, the Environmental Defense Fund, Healthy Babies Bright
9 Futures and Cornell University” to identify “best agricultural practices” and create
10 “a voluntary industry standard to reduce heavy metal levels in baby foods to the
11 lowest level possible.”

12 "As stated in our 2019 response to the Congressional Inquiry, we take many steps to minimise their presence. We
13 prioritise growing locations based on climate and soil composition. We approve fields before crops are planted
based on soil testing," the statement read.

14 It continued: "As a member of the Baby Food Council, we have been working together with other industry members,
15 the Environmental Defense Fund, Healthy Babies Bright Futures and Cornell University in the identification of best
16 agricultural practices and creating a voluntary industry standard to reduce heavy metal levels in baby foods to the
lowest levels possible."

17
18 290. While actively selling their products in January 2019 to present, RICO
19 Defendants and non-Defendant, co-conspirator Hain kept secret their knowledge of
20 the massive contamination in their products. They committed fraud by omission and
21 fraud by half-truth by advertising their products from January 2019 to present as
22 safe, nutritious, pure, and natural—despite knowing that these representations were
23 false and that their products were contaminated with several heavy metals.

24 291. Regardless of whether the Baby Food Council was working on food
25 standards, that lack of consensus did not grant it permission to misrepresent facts,
26 conceal facts, omit facts, and speak in half-truths.

1 292. In February 2021, when caught committing fraud, RICO Defendants
2 and non-Defendant, co-conspirator Hain try to defend by claiming there are no
3 standards, and they cannot be held accountable as a result. They advertised and
4 made promises that were far higher and more demanding, and it is these promises
5 and representations that they are held to under the federal fraud laws. RICO
6 Defendants and non-Defendant, co-conspirator Hain cannot advertise and promise
7 under one standard, and then defend and deflect under a much lower one.

8 293. The denial and deflection by RICO Defendants and non-Defendant, co-
9 conspirator Hain are a second stage of their ongoing scheme to defraud—the cover-
10 up stage. RICO Defendants and non-Defendant, co-conspirator Hain knew all along
11 that there are no baby food standards identifying safe levels for baby food exposure,
12 but they did not disclose this when they advertised their products. Having chosen to
13 advertise that their foods are pure, safe, natural, and held to the highest standards, it
14 was a fraudulent omission or fraud by half-truth to now claim that they have no
15 obligation to minimize or eliminate exposure to these toxic heavy metals. This was
16 not disclosed to purchasers at any time prior to February 4, 2021.

17 294. According to Brian Ronholm, director of food policy at Consumer
18 Reports, the recent uncovering of the food fraud scheme is “especially troubling”
19 because RICO Defendants and non-Defendant, co-conspirator Hain “knew of the
20 high levels of heavy metal contamination and still sold the products.”¹⁵³

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24 ¹⁵³ Jesse Hirsch, *Heavy Metals in Baby Food: What You Need to Know*, CONSUMER
25 REPORTS (Aug. 16, 2018) [https://www.consumerreports.org/food-safety/heavy-metals-](https://www.consumerreports.org/food-safety/heavy-metals-in-baby-food/)
26 *in-baby-food/*; *see also*, *CR renews call for FDA and manufacturers to take action to*
27 *keep infants and children safe from heavy metals in foods*, CONSUMER REPORT (Feb. 4,
28 2021) [https://advocacy.consumerreports.org/press_release/cr-renews-call-for-fda-and-](https://advocacy.consumerreports.org/press_release/cr-renews-call-for-fda-and-manufacturers-to-take-action-to-keep-infants-and-children-safe-from-heavy-metals-in-foods/)
manufacturers-to-take-action-to-keep-infants-and-children-safe-from-heavy-metals-
in-foods/.

1 295. RICO Defendants and non-Defendant, co-conspirator Hain have
2 engaged in acts of lulling as a cover-up and to continue their ongoing schemes to
3 defraud, as evidenced by the statements alleged throughout this Complaint, and by
4 way of further example:

5 296. In a February 4, 2021, article in the Washington Post that was
6 disseminated nationwide, Beech-Nut spoke directly to purchasers and “assured
7 parents its baby food is ‘safe and nutritious.’”¹⁵⁴ This statement was knowingly
8 false and attempted to cover-up the crimes that Beech-Nut committed. It effectively
9 doubled down on its ongoing food fraud and sought to convince purchasers and
10 parents that they could continue to purchase and have their children consume unsafe
11 food.

12 297. In a February 4, 2021 article in the Wall Street Journal that was widely
13 disseminated, Defendant Gerber spoke directly to purchasers and stated that “all of
14 its food meets its safety standards, which it says are among the strictest in the
15 world.”¹⁵⁵

16 298. In a February 4, 2021 press release that was widely disseminated and
17 posted by Good Morning America¹⁵⁶ and other news outlets, Hain spoke directly to
18 purchasers, stating: “Nothing is more important to Earth’s Best than the trust and
19

20
21 ¹⁵⁴ Dee-Ann Durbin, *Congressional Report Finds Toxic Metals in Baby Food Brands*,
22 U.S. NEWS (Feb. 4, 2021), <https://www.usnews.com/news/politics/articles/2021-02-04/congressional-report-finds-toxic-metals-in-baby-food-brands>.

23 ¹⁵⁵ Annie Gasparro & Sharon Terlep, *Toxic Heavy Metals Found in Some Baby Food*,
24 *Congressional Report Says*, WALL STREET JOURNAL (Feb. 4, 2021),
25 <https://www.wsj.com/articles/toxic-heavy-metals-found-in-some-baby-food-congressional-report-says-11612451332>.

26 ¹⁵⁶ Katie Kindelan and Kelly McCarthy, *Some popular baby foods contain 'significant*
27 *levels' of toxic heavy metals, report says*, GOOD MORNING AMERICA (Feb. 5, 2021),
28 <https://www.goodmorningamerica.com/wellness/story/popular-baby-foods-significant-levels-toxic-heavy-metals-75685913>.

1 confidence of parents that our organic products provide safe nutrition for healthy
2 babies. Our rigorous internal standards and testing procedures ensure Earth’s Best
3 products meet or exceed the current federal guidelines.”¹⁵⁷

4 299. In a February 5, 2021 article in People that was widely disseminated,
5 Nurture spoke directly to purchasers, “We can say with the utmost confidence that
6 all Happy Family Organics products are safe for babies and toddlers to enjoy, and
7 we are proud to have best-in-class testing protocols in our industry.”¹⁵⁸

8 300. The predicate acts of racketeering (18 U.S.C. § 1961(1)) engaged in by
9 RICO Defendants and non-Defendant, co-conspirator Hain include, but are not
10 limited to:

- 11 a. Mail Fraud: RICO Defendants and non-Defendant, co-conspirator Hain
12 violated 18 U.S.C. § 1341 by engaging in an unlawful scheme to
13 defraud involving false pretenses, misrepresentations, promises, half-
14 truths, and omissions. In furtherance of this scheme, RICO Defendants
15 and non-Defendant, co-conspirator Hain used the mails:
- 16 i. RICO Defendants and non-Defendant, co-conspirator Hain
17 shipped, or caused to ship, via interstate mail the baby food
18 products that were purchased by Plaintiff and the Class.
 - 19 ii. RICO Defendants and non-Defendant, co-conspirator Hain used
20 the mails to send letters to the U.S. House of Representatives in
21

22
23 ¹⁵⁷ February 4, 2021 Press Release, HAIL CELESTIAL (Feb. 4, 2021)
24 <https://ir.hain.com/news-releases/news-release-details/statement-behalf-earths-best-organic-response-congressional>.

25
26 ¹⁵⁸ Benjamin VanHoose, *Investigation Finds Baby Food Products 'Tainted with*
27 *Significant Levels of Toxic Heavy Metals'*, People, PEOPLE.COM (Feb. 5, 2021),
28 <https://people.com/parents/baby-food-found-tainted-dangerous-levels-toxic-heavy-metals-congressional-investigation-report/>.

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December 2019 to perpetuate their false pretenses, misrepresentations, promises, half-truths, and omissions;

iii. RICO Defendants and non-Defendant, co-conspirator Hain used the mails in furtherance of their scheme to defraud and, in fact, could not have accomplished their scheme to defraud without using the mails to ship their products to all fifty states.

iv. Further discovery will likely uncover additional uses of the mail.

b. Wire Fraud: RICO Defendants and non-Defendant, co-conspirator Hain violated 18 U.S.C. § 1343 by engaging in an unlawful scheme to defraud involving false pretenses, misrepresentations, promises, half-truths, and omissions. In furtherance of this scheme, RICO Defendants and non-Defendant, co-conspirator Hain used the interstate wires, including the Internet, email, and use of the telephone across state lines.

i. RICO Defendants and non-Defendant, co-conspirator Hain have engaged in extensive, nationwide (interstate) advertising campaigns using Facebook, email, and the Internet to reach consumers in all 50 states with false pretenses, misrepresentations, promises, half-truths, and omissions. *See also* Factual Background, Section IV.D.3.

| Defendant | Date | Representation in Furtherance of the Scheme to Defraud |
|------------------|--------------------------|---|
| Beech-Nut | Since at least 5/30/2017 | Beech-Nut baby food is “clean food” and “classic, natural and organic real food for babies and toddlers” “with just real, simple ingredients” |
| | ~8/16/2018 | “We want to reassure parents that Beech-Nut’s real food for babes is healthy, nutritious and safe.” |

| Defendant | Date | Representation in Furtherance of the Scheme to Defraud |
|-----------|--------------------------|---|
| | | <p>“We want to assure parents that . . . we have high confidence in the quality and standards we use in making our food.”</p> <p>“Currently, no government standard or recommendation exists for lead.”</p> |
| | 3/21/2018 | Beech-Nut products contain “nothing else” but the listed ingredient |
| | 3/28/2019 | Beech-Nut products are for consumers who are “label readers” and look for “natural ingredients only.” |
| | Since at least 7/13/2019 | <p>“what’s inside your baby food matters”</p> <p>Beech-Nut “offer[s] natural and organic products”</p> <p>“In fact, we conduct over 20 rigorous tests on our purees, testing for up to 255 pesticides and heavy metals (like lead, cadmium and other nasty stuff). Just like you would, we send the produce back if it’s not good enough.”</p> |
| | 10/17/2019 | <p>“Our process starts with high-quality fruits and vegetables that meet BNN’s own standards, which in some cases are 10 times stricter than those of the U.S. government. For example, we test for 255 common contaminants, such as lead, other heavy metals and pesticides, to confirm that all the ingredients delivered to us and used in our</p> |

| Defendant | Date | Representation in Furtherance of the Scheme to Defraud |
|-------------|--------------------------|--|
| | | products comply with our standards. If they don't, we send them back." |
| | 12/6/2019 | Beech-Nut applied "rigorous testing protocols and heavy metal testing standards which are continuously reviewed and strengthened." Beech-Nut encouraged the creation of the Baby Food Council to "conduct research and work to achieve a long-term reduction of heavy metals in the baby food supply chain" and that its current "top priority is to reduce heavy metals in the products manufactured and marketed by the member companies [including Defendant Beech-Nut] using best-in-class management practices." |
| | Since at least 6/14/2020 | Beech-Nut "only" uses "real," "quality" ingredients |
| | 2/4/2021 | Beech-Nut "assured parents its baby food is 'safe and nutritious.'" |
| | ~2/5/2021 | Beech-Nut products are "safe and nutritious" |
| | ~2/5/2021 | "We want to reassure parents Beech-Nut products are safe and nutritious.... We look forward to continuing to work with the FDA, in partnership with the Baby Food Council..." |
| Plum | 12/11/2017 | "We believe that Plum's products are safe to eat. Our testing confirmed that the averaged results for |

| Defendant | Date | Representation in Furtherance of the Scheme to Defraud |
|-----------|--------------------------|--|
| | | heavy metals in all tested Plum products gave concentrations that are typical for those ingredients – whether that’s a leafy green grown in your own garden or a bunch of carrots purchased at the farmer’s market. The results also demonstrate our tested products are below exposure limits set by certain domestic and international regulatory bodies.” |
| | 2/12/2018 | The mission that Plum Organics promises is that it will provide “little ones” with “the very best food from the first bite.” |
| | 6/7/2019 | The back of the Plum Organics’ pouch lets customers “find out exactly what [you are] getting!” |
| | 12/11/2019 | “Campbell has conducted testing on every Plum Organics product on the market to ensure none exceed acceptable levels of arsenic, lead, cadmium, or mercury... To date, no Plum Organics foods have been found to be above exposure limits set by available domestic and international regulatory bodies” |
| | Since at least 8/12/2020 | Plum Organics baby foods are “absolutely” “safe to eat” and that “health and safety are always” its “top priorities.” |

| Defendant | Date | Representation in Furtherance of the Scheme to Defraud |
|---------------|------------|--|
| | | <p>“We believe ingredient testing allows for better control of the entire product and gets us ahead of any potential issues before it makes its way into a product. It’s just like when you make a recipe at home – you want to know everything that’s going into the recipe.”</p> |
| | 2/5/2021 | <p>“Campbell has conducted testing on every Plum Organics product on the market to ensure none exceed acceptable levels of arsenic, lead, cadmium, or mercury.”</p> |
| Gerber | ~8/16/2018 | <p>“All of our foods meet our safety and quality standards, which are among the strictest in the world.”</p> <p>“Our rigorous standards are developed by evaluating the latest food safety guidance – from sources like the Food and Drug Administration, Environmental Protection Agency, and international health authorities. Gerber also partners with our farmers and our ingredient and packaging suppliers to control, reduce and limit contaminants in all our foods.”</p> |
| | 12/19/2019 | <p>Gerber “takes all concerns related to safety very seriously, which is why all of our foods and beverages meet our safety and quality standards</p> |

| Defendant | Date | Representation in Furtherance of the Scheme to Defraud |
|-----------|----------------------------------|---|
| | | <p>and conform to all regulatory compliance guidelines.”</p> <p>Gerber was “also a founding member of the Baby Food Council,” whose objective is “reducing heavy metals in the products manufactured by the member companies to as low as reasonably achievable using best-in-class management practices.” Defendant Gerber claimed that its “efforts with the Council represent our commitment to the safety of the baby food category.”</p> |
| | <p>Since at least 9/30/2020</p> | <p>Gerber rice cereals will help support “learning ability”</p> <p>Gerber Clean Field Farming practices ensure that its baby foods are “safe and wholesome.”</p> |
| | <p>10/12/2020</p> | <p>Gerber Clean Field Farming Standards allows it to “ensure that [our produce is] safe and wholesome for baby.”</p> |
| | <p>Since at least 11/25/2020</p> | <p>Gerber knows that parents want “the very best for your little one to ensure she reaches her full potential, and so do we.”</p> <p>Gerber represents to parents that it has adopted “super strict” farming practices “to ensure that their fruit and vegetable purees are not only</p> |

| Defendant | Date | Representation in Furtherance of the Scheme to Defraud |
|-----------|-----------|--|
| | | <p data-bbox="750 325 1474 430">nutritious, but also wholesome and safe for even the littlest bodies.”</p> <p data-bbox="750 451 1523 625">Gerber believes “that little ones deserve the highest standards set just for them” guides its mission to “deliver the very best fruits and veggies.”</p> <p data-bbox="750 646 1523 821">Gerber represents that its growing standards are the “strictest in the world” to ensure “quality control” because “what you get out is what you put in.”</p> <p data-bbox="750 842 1484 1016">Gerber’s Clean Field Farming process “ensure[s] our purees are not only nutritious, but also wholesome and safe for every tiny tummy.”</p> |
| | ~2/4/2021 | <p data-bbox="750 1039 1516 1470">Gerber has “been working together with other industry members, the Environmental Defense Fund, Healthy Babies Bright Futures and Cornell University” to identify “best agricultural practices” and create “a voluntary industry standard to reduce heavy metal levels in baby foods to the lowest level possible.”</p> <p data-bbox="750 1491 1490 1665">Gerber stated that “all of its food meets its safety standards, which it says are among the strictest in the world.”</p> |
| | 2/5/2021 | <p data-bbox="750 1690 1490 1923">Gerber’s standards “are among the strictest in not just the US, but the world... where government standards don’t currently exist, we develop our own rigorous standards.”</p> |

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| Defendant | Date | Representation in Furtherance of the Scheme to Defraud |
|-------------|--------------------------|--|
| Hain | Since at least 5/16/2016 | <p>Products are “time-trusted and safe” and “made from pure ingredients to help children grow up strong and healthy”</p> <p>Hain knew that parents cared about the whether “potentially harmful” contaminants were in their products because it noted that its food is “produced without the use of potentially harmful pesticides” but Hain omits that the products <i>do</i> contain other “potentially harmful” contaminants, namely toxic heavy metals</p> |
| | Since at least 6/1/2019 | <p>Hain “recognized the importance of wholesome, pure nourishment for babies” so its products are “created with care, using pure, simple ingredients found in nature.” Because of this “principle,” Hain tells parents that they “can trust Earth’s Best® products to be safe for your baby and safe for the environment.”</p> |
| | Since at least 7/18/2019 | <p>Hain has a “rigorous quality assurance process” which allows them to provide “better-for-baby products that are pure, safe and sustainable.”</p> <p>“rigorous product testing” as a “guarantee” to parents of the “quality and safety” of Earth’s Best products</p> <p>Hain’s “Promise” to produce “pure, quality products you can trust.”</p> |

| Defendant | Date | Representation in Furtherance of the Scheme to Defraud |
|----------------|------------|--|
| | 12/11/2019 | Hain’s membership in the Baby Food Council is an indicator of its commitment “to producing safe, nutritious, high-quality baby food products.” |
| | 2/4/2021 | <p>“Our rigorous internal standards and testing procedures ensure Earth’s Best products meet or exceed the current federal guidelines.”</p> <p>“Nothing is more important to Earth’s Best than the trust and confidence of parents that our organic products provide safe nutrition for healthy babies.”</p> |
| Nurture | 7/2/2019 | Nurture holds its “ingredients to the highest standards, because your baby deserves the best.” |
| | 7/17/2019 | Nurture’s Happy Baby superfood Puffs “support brain health” |
| | 8/16/2019 | Nurture “partner[s] with pediatricians, dietitians, and children’s health experts [it] trust[s]—so your family can trust our organic food.” |
| | 11/25/2019 | Nurture represented that consumers “can skip all these chemicals when you buy organic food” |
| | 12/18/2019 | Nurture’s membership in the Baby Food Council is an indication of its commitment to “reduce heavy metals in baby food products as low as reasonably achievable using best-in-class management practices.” |

| Defendant | Date | Representation in Furtherance of the Scheme to Defraud |
|-----------|---------------------------------|---|
| | <p>Since at least 8/13/2020</p> | <p>Customers can have “peace of mind” because Nurture “source[s] high-quality organic ingredients” and has “rigorous and uncompromising quality standards” so consumers “can feel confident” in what they are feeding their family.</p> <p>Nurture emphasizes that it goes beyond USDA organic standards because it knows that what children eat in the first few years of life is “crucial.” Nurture assures parents that it holds itself to “strict standards” to help children “grow healthy and strong” through “test[ing] and thoroughly analyz[ing] every batch of food.”</p> <p>Parents can “trust” its organic food because Nurture “partner[s] with pediatricians, dietitians, and children’s health experts.”</p> |
| | <p>2/5/2021</p> | <p>“We can say with the utmost confidence that all Happy Family Organics products are safe for babies and toddlers to enjoy, and we are proud to have best-in-class testing protocols in our industry.”</p> |
| | <p>Since at least 2/5/2021</p> | <p>“We can say with the utmost confidence that all Happy Family Organics products are safe for babies and toddlers to enjoy and we are proud to have best-in-class testing protocols in our industry.”</p> |

| Defendant | Date | Representation in Furtherance of the Scheme to Defraud |
|-----------|------|---|
| | | We only sell products that have been rigorously tested and we do not have products in-market with contaminant ranges outside of the limits set by the FDA.” |

- ii. RICO Defendants and non-Defendant, co-conspirator Hain used the interstate wires to communicate with one another via email or telephone regarding the Baby Food Council.
- iii. The Baby Food Council website was created on or around January 2019. This website uses the interstate wires to suggest a legitimate entity that is engaged in meaningful activity.
- iv. RICO Defendants and non-Defendant, co-conspirator Hain used email and interstate wires to send letters to the U.S. House of Representatives in December 2019 to perpetuate their false pretenses, misrepresentations, promises, half-truths, and omissions.
- v. RICO Defendants and non-Defendant, co-conspirator Hain used email and interstate wires to issue press releases, set forth above, on or around February 4, 2021, to deny the food fraud that Congress uncovered and to lull their victims into believing this fraud had stopped. Without use of the interstate wires, RICO Defendants and non-Defendant, co-conspirator Hain could not have communicated with Plaintiff or the class either when marketing and advertising their products or when denying and covering up their scheme to defraud.

1 vi. RICO Defendants and non-Defendant, co-conspirator Hain have
2 coordinated their cover-up schemes with each other and the Baby
3 Food Council over email and telephone calls throughout
4 February 2021.

5 vii. Because the emails and telephone calls of RICO Defendants and
6 non-Defendant, co-conspirator Hain are in their exclusive
7 possession and are not publicly available, discovery is needed for
8 Plaintiff to plead the exact dates and names of the persons who
9 made these communications.

10 301. This pattern of racketeering is open-ended and remains ongoing to this
11 day. Only by pursuing this lawsuit and financially punishing RICO Defendants will
12 the pattern of racketeering at issue here finally cease. RICO Defendants and non-
13 Defendant, co-conspirator Hain continue to deny their ongoing food fraud and have
14 not recalled the dangerous baby food products that they have sold and continue to
15 sell in interstate commerce in all 50 states.

16 302. The predicate acts are all related because they were all done in
17 furtherance of the same overall goal and common purpose of the RICO enterprise:
18 to allow RICO Defendants and non-Defendant, co-conspirator Hain to sell baby
19 food without engaging in safe (and more costly) food production, manufacturing,
20 and processing. The predicate acts allowed RICO Defendants and non-Defendant,
21 co-conspirator Hain to cut corners and save millions of dollars, which translated
22 into bigger bonuses for their executives, higher stock prices, and more dividends
23 and distributions for their companies.

24 303. The predicate acts have not ceased and will continue until this Court
25 awards relief. By pursuing this RICO claim, Plaintiff further hopes to prompt
26 criminal investigations and prosecutions by state and federal prosecutors.

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1 **D. Causation and Damages**

2 304. There is a direct and straight line from the scheme to defraud to the
3 damages suffered. RICO Defendants marketed and advertised directly to the
4 purchasers and parents in the Class. No other group was the focus of this
5 advertising, and no other group can sue for this RICO claim. Likewise, once their
6 schemes to defraud were exposed by Congress, RICO Defendants and non-
7 Defendant, co-conspirators Hain continued to speak through press releases and
8 newspapers to consumers.

9 305. There are no intervening steps or causes that could have prevented or
10 altered, or even interfered, with the fraud RICO Defendants and non-Defendant, co-
11 conspirator Hain committed using the Baby Food Council as an enterprise.

12 306. Plaintiff and all members in the class purchased contaminated baby
13 food in reasonable reliance upon the market conduct, representations, statements,
14 promises, and suggestions made in the advertisements and marketing campaigns of
15 RICO Defendants.

16 307. RICO Defendants and non-Defendant, co-conspirator Hain not only
17 made specific material misstatements of fact, but they also engaged by fraud by
18 omission, fraud by half-truth, and fraudulent concealment. Every member of the
19 class was a victim of the schemes to defraud through one of these forms of fraud.

20 308. But for the fraudulent marketing and advertising, and but for the
21 fraudulent cover-up campaign (using the Baby Food Council as proof of the
22 legitimacy of the efforts of RICO Defendants and non-Defendant, co-conspirator
23 Hain), the purchasers and parents in the Class would not have bought the
24 contaminated products and would not continue to buy them today.

25 309. By reason of, and as a result of the conduct of RICO Defendants,
26 Plaintiff and Class members have been injured in their property (money is property)
27 by purchasing “essentially worthless” products that failed to meet their essential
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1 and marketed/advertised purpose: being healthy, pure, natural, and safe. Given that
2 the product is baby food, and children and babies are particularly vulnerable, RICO
3 Defendants knew that the safety, contents, and purity of the food being sold was
4 especially important. Indeed, they tailored their marketing and sales
5 communications directly to this issue, preying on the purchasers' vulnerability and
6 desperation as parents to do everything possible to feed their children healthy and
7 safe food. RICO Defendants exploited that vulnerability, knowing that Plaintiff and
8 the class had (and have) no way of uncovering the fraud at issue.

9 310. It was foreseeable—and, indeed, fully known—to RICO Defendants
10 that Plaintiff and the Class members would not have purchased the contaminated
11 food products had RICO Defendants fully disclosed all known facts about the baby
12 food products. RICO Defendants purposefully omitted material facts from their
13 advertisements and made sure that Plaintiff and the Class never were fully aware of
14 all facts and circumstances.

15 311. The violations of 18 U.S.C. § 1962(c) and (d) by RICO Defendants
16 have directly and proximately caused injuries and damages to Plaintiff and Class
17 members. Plaintiff and Class members are entitled to bring this action for three
18 times their actual damages, as well as costs and reasonable attorneys' fees pursuant
19 to 18 U.S.C. § 1964(a) and (c).

20 312. If a RICO Defendant is not guilty as a primary RICO violator under §
21 1962(c), it is liable for conspiring to violate RICO by engaging in the same schemes
22 to defraud set forth above.

23 313. Each RICO Defendant violated § 1962(d) by agreeing to participate,
24 directly or indirectly, in the schemes to defraud outlined above.

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COUNT TWO:
Breach of Express Warranty
 (As to All Defendants)

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314. Plaintiffs, on behalf of themselves and those similarly situated, re-allege and incorporate by reference each and every allegation set forth in the preceding paragraphs as though alleged in full herein.

315. Defendants utilized false and deceptive product labels as well as marketing and advertising to promote, encourage, and urge the use, purchase, and utilization of these baby foods by representing the quality and safety to parents and purchasers, Plaintiff, and the public in such a way as to induce their purchase or use.

316. As set out in Section III.D.3, Defendants expressly warranted that their foods were safe, natural, healthy, pure, and real food. Defendants also expressly warranted about extensive testing measure deployed internally to ensure their products met these standards.

| Defendant | Date | Representations |
|------------------|-----------------------------|---|
| Beech-Nut | Since at least 5/30/2017 | Beech-Nut baby food is “clean food” and “classic, natural and organic real food for babies and toddlers” “with just real, simple ingredients” |
| | ~8/16/2018 | “We want to reassure parents that Beech-Nut’s real food for babes is healthy, nutritious and safe.” “We want to assure parents that . . . we have high confidence in the quality and standards we use in making our food.” “Currently, no government standard or recommendation exists for lead.” |
| | 3/21/2018 | Beech-Nut products contain “nothing else” but the listed ingredient |

| Defendant | Date | Representations |
|-----------|--------------------------|---|
| | 3/28/2019 | Beech-Nut products are for consumers who are “label readers” and look for “natural ingredients only.” |
| | Since at least 7/13/2019 | “what’s inside your baby food matters” Beech-Nut “offer[s] natural and organic products” “In fact, we conduct over 20 rigorous tests on our purees, testing for up to 255 pesticides and heavy metals (like lead, cadmium and other nasty stuff). Just like you would, we send the produce back if it’s not good enough.” |
| | 10/17/2019 | “Our process starts with high-quality fruits and vegetables that meet BNN’s own standards, which in some cases are 10 times stricter than those of the U.S. government. For example, we test for 255 common contaminants, such as lead, other heavy metals and pesticides, to confirm that all the ingredients delivered to us and used in our products comply with our standards. If they don’t, we send them back.” |
| | 12/6/2019 | Beech-Nut applied “rigorous testing protocols and heavy metal testing standards which are continuously reviewed and strengthened.” Beech-Nut encouraged the creation of the Baby Food Council to “conduct research and work to achieve a long-term reduction of heavy metals in the baby food supply chain” and that its current |

| Defendant | Date | Representations |
|--------------------|---------------------------------|---|
| | | <p>“top priority is to reduce heavy metals in the products manufactured and marketed by the member companies [including Defendant Beech-Nut] using best-in-class management practices.”</p> |
| | <p>Since at least 6/14/2020</p> | <p>Beech-Nut “only” uses “real,” “quality” ingredients</p> |
| | <p>2/4/2021</p> | <p>Beech-Nut “assured parents its baby food is ‘safe and nutritious.’”</p> |
| | <p>~2/5/2021</p> | <p>“We want to reassure parents Beech-Nut products are safe and nutritious.... We look forward to continuing to work with the FDA, in partnership with the Baby Food Council...”</p> |
| | <p>~2/5/2021</p> | <p>Beech-Nut products are “safe and nutritious”</p> |
| <p>Plum</p> | <p>12/11/2017</p> | <p>“We believe that Plum’s products are safe to eat. Our testing confirmed that the averaged results for heavy metals in all tested Plum products gave concentrations that are typical for those ingredients – whether that’s a leafy green grown in your own garden or a bunch of carrots purchased at the farmer’s market. The results also demonstrate our tested products are below exposure limits set by certain domestic and international regulatory bodies.”</p> |

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| Defendant | Date | Representations |
|-----------|--------------------------|--|
| | 2/12/2018 | The mission that Plum Organics promises is that it will provide “little ones” with “the very best food from the first bite.” |
| | 6/7/2019 | The back of the Plum Organics’ pouch lets customers “find out exactly what [you are] getting!” |
| | 12/11/2019 | “Campbell has conducted testing on every Plum Organics product on the market to ensure none exceed acceptable levels of arsenic, lead, cadmium, or mercury... To date, no Plum Organics foods have been found to be above exposure limits set by available domestic and international regulatory bodies” |
| | Since at least 8/12/2020 | Plum Organics baby foods are “absolutely” “safe to eat” and that “health and safety are always” its “top priorities.” “We believe ingredient testing allows for better control of the entire product and gets us ahead of any potential issues before it makes its way into a product. It’s just like when you make a recipe at home – you want to know everything that’s going into the recipe.” |
| | 2/5/2021 | “Campbell has conducted testing on every Plum Organics product on the market to ensure none exceed acceptable levels of arsenic, lead, cadmium, or mercury.” |

| Defendant | Date | Representations |
|---------------|------------|--|
| Gerber | ~8/16/2018 | <p>“All of our foods meet our safety and quality standards, which are among the strictest in the world.”</p> <p>“Our rigorous standards are developed by evaluating the latest food safety guidance – from sources like the Food and Drug Administration, Environmental Protection Agency, and international health authorities. Gerber also partners with our farmers and our ingredient and packaging suppliers to control, reduce and limit contaminants in all our foods.”</p> |
| | 12/19/2019 | <p>Gerber “takes all concerns related to safety very seriously, which is why all of our foods and beverages meet our safety and quality standards and conform to all regulatory compliance guidelines.”</p> <p>Gerber was “also a founding member of the Baby Food Council,” whose objective is “reducing heavy metals in the products manufactured by the member companies to as low as reasonably achievable using best-in-class management practices.” Defendant Gerber claimed that its “efforts with the Council represent our commitment to the safety of the baby food category.”</p> |

| Defendant | Date | Representations |
|-----------|------------------------------|--|
| | Since at least 9/30/2020 | Gerber rice cereals will help support “learning ability” Gerber Clean Field Farming practices ensure that its baby foods are “safe and wholesome.” |
| | 10/12/2020 | Gerber Clean Field Farming Standards allows it to “ensure that [our produce is] safe and wholesome for baby.” |
| | Since at least 11/25/2020 | Gerber knows that parents want “the very best for your little one to ensure she reaches her full potential, and so do we.” Gerber represents to parents that it has adopted “super strict” farming practices “to ensure that their fruit and vegetable purees are not only nutritious, but also wholesome and safe for even the littlest bodies.” Gerber believes “that little ones deserve the highest standards set just for them” guides its mission to “deliver the very best fruits and veggies.” Gerber represents that its growing standards are the “strictest in the world” to ensure “quality control” because “what you get out is what you put in.” Gerber’s Clean Field Farming process “ensure[s] our purees are not only nutritious, but also wholesome and safe for every tiny tummy.” |
| | ~2/4/2021 | Gerber has “been working together with other industry members, the Environmental Defense |

| Defendant | Date | Representations |
|----------------|------------|--|
| | | <p data-bbox="751 264 1515 558">Fund, Healthy Babies Bright Futures and Cornell University” to identify “best agricultural practices” and create “a voluntary industry standard to reduce heavy metal levels in baby foods to the lowest level possible.”</p> <p data-bbox="751 590 1490 747">Gerber stated that “all of its food meets its safety standards, which it says are among the strictest in the world.”</p> |
| | 2/5/2021 | Gerber’s standards “are among the strictest in not just the US, but the world... where government standards don’t currently exist, we develop our own rigorous standards.” |
| Nurture | 7/2/2019 | Nurture holds its “ingredients to the highest standards, because your baby deserves the best.” |
| | 7/17/2019 | Nurture’s Happy Baby superfood Puffs “support brain health” |
| | 8/16/2019 | Nurture “partner[s] with pediatricians, dietitians, and children’s health experts [it] trust[s]—so your family can trust our organic food.” |
| | 11/25/2019 | Nurture represented that consumers “can skip all these chemicals when you buy organic food” |
| | 12/18/2019 | Nurture’s membership in the Baby Food Council is an indication of its commitment to “reduce heavy metals in baby food products as low as reasonably achievable using best-in-class management practices.” |

| Defendant | Date | Representations |
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| | <p>Since at least 8/13/2020</p> | <p>Customers can have “peace of mind” because Nurture “source[s] high-quality organic ingredients” and has “rigorous and uncompromising quality standards” so consumers “can feel confident” in what they are feeding their family.</p> <p>Nurture emphasizes that it goes beyond USDA organic standards because it knows that what children eat in the first few years of life is “crucial.” Nurture assures parents that it holds itself to “strict standards” to help children “grow healthy and strong” through “test[ing] and thoroughly analyz[ing] every batch of food.”</p> <p>Parents can “trust” its organic food because Nurture “partner[s] with pediatricians, dietitians, and children’s health experts.”</p> |
| | <p>2/5/2021</p> | <p>“We can say with the utmost confidence that all Happy Family Organics products are safe for babies and toddlers to enjoy, and we are proud to have best-in-class testing protocols in our industry.”</p> |
| | <p>Since at least 2/5/2021</p> | <p>“We can say with the utmost confidence that all Happy Family Organics products are safe for babies and toddlers to enjoy and we are proud to have best-in-class testing protocols in our industry. We only sell products that have been rigorously</p> |

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| Defendant | Date | Representations |
|-----------|------|---|
| | | tested and we do not have products in-market with contaminant ranges outside of the limits set by the FDA.” |

317. Through these representations, Defendants made express warranties that these foods would conform to the representations. More specifically, Defendants represented that these foods, when ingested by babies and children in the manner foreseen by Defendants, were safe and effective. Defendants also represented that these foods were safe and effective for use by individuals such as Plaintiff for feeding their children.

318. Defendants represented that their products only contained the ingredients disclosed on the label. These specific misrepresentations went beyond mere puffery.

319. Given that the product is baby food, and children and babies are particularly vulnerable, Defendants knew that the safety, contents, and purity of the food being sold was especially important. Indeed, they tailored their marketing and sales communications directly to this issue, preying on the purchasers’ vulnerability and desperation as parents to do everything possible to feed their children healthy and safe food.

320. The representations, as set forth above, contained, or constituted affirmations of fact or promises made by the seller to the buyer which related to the goods and became part of the basis of the bargain creating an express warranty that the goods shall conform to the affirmations of fact or promises.

321. The foods ingested by Plaintiff’s infants and children did not conform to the representations made by Defendants, because these foods contained toxic levels of heavy metals and ingredients not safe for human ingestion and contained undisclosed contaminants.

1 322. Plaintiff, by use of reasonable care, could not have discovered the
2 breached warranty and realized the hidden increased risks and unreasonable dangers
3 of allowing their children to ingest these foods.

4 323. As a direct or proximate result of Defendants' conduct, Plaintiff and the
5 putative State Law Class have suffered actual damages in the purchase of these
6 baby foods that were worth significantly less than the price paid and because they
7 would not have purchased the product had they known of the presence of heavy
8 metals, entitling them to compensatory and equitable damages, attorneys' fees and
9 costs and declaratory relief in an amount to be proven at trial.

10 324. Further, Plaintiff and the putative State Law Class shall be entitled to an
11 award of punitive damages, as is clear from the facts herein that Defendants' actions
12 were performed with a realization of the imminence of danger and a reckless
13 disregard and complete indifference to the probable consequences of their actions.
14 By Defendants' putting their own pecuniary interests ahead of all else, they sacrificed
15 the safety, health, and wellbeing of innocent babies, toddlers, and children.
16 Defendants also unfairly profited off the unsuspecting parents and purchasers who
17 believed they were buying healthy food for their children. The only way to prevent
18 this type of egregious indifference again is to assess punitive damages against
19 Defendants.

20 **COUNT THREE:**
21 **BREACH OF IMPLIED WARRANTY**
22 (As to All Defendants)

23 325. Plaintiff realleges and incorporates by reference each and every
24 allegation contained in the preceding paragraphs as if fully set forth herein.

25 326. At all relevant times, Defendants were merchants with respect to baby
26 foods.
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1 327. A warranty that Defendants’ baby food products were in merchantable
2 condition was implied by law in the transactions when Plaintiff and the putative
3 Class purchased Defendants’ baby food products.

4 328. When sold, and at all times thereafter, the baby foods at issue were not
5 reasonably fit for the ordinary purposes for which such goods are used and did not
6 meet the expectations for the performance of the product when used in the
7 customary, usual, and reasonably foreseeable manner. Nor were these products
8 minimally safe for their expected purpose.

9 329. Specifically, and unbeknownst to Plaintiff, these baby food products
10 had unsafe levels of toxic heavy metals at the time Plaintiff purchased them.

11 330. The products at issue, even if they served their purpose in serving as
12 food and sustenance for babies and children, cannot create a benefit of the bargain
13 because the heavy metals, and their dangerous effects were never bargained for.

14 331. Because of the presence of these heavy metals, these products create a
15 present economic injury to Plaintiff and the putative class as their sale should never
16 have occurred.

17 332. As a direct or proximate result of Defendants’ conduct, Plaintiff and the
18 putative Class have suffered actual damages in the purchase of these baby foods
19 that were worth significantly less than the price paid and because they would not
20 have purchased the product had they known of the presence of heavy metals,
21 entitling them to compensatory and equitable damages, attorneys’ fees and costs
22 and declaratory relief in an amount to be proven at trial.

23 333. Further, Plaintiff and the putative State Law Class shall be entitled to an
24 award of punitive damages, as is clear from the facts herein that Defendants’ actions
25 were performed with a realization of the imminence of danger and a reckless
26 disregard and complete indifference to the probable consequences of their actions.
27 By Defendants’ putting their own pecuniary interests ahead of all else, they sacrificed
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1 the safety, health, and wellbeing of innocent babies, toddlers, and children.
2 Defendants also unfairly profited off the unsuspecting parents and purchasers who
3 believed they were buying healthy food for their children. The only way to prevent
4 this type of egregious indifference again is to assess punitive damages against
5 Defendants.

6 **COUNT FOUR:**

7 **NEGLIGENT TESTING AND INSPECTION**

8 (As to Defendant Beech-Nut, Plum Defendants, Defendant Gerber, and Defendant
9 Nurture)

10 334. Plaintiff realleges and incorporates by reference each and every
11 allegation contained in the preceding paragraphs as if fully set forth herein.

12 335. At all relevant times, Manufacturer Defendants were manufacturers of
13 the baby food at issue and had a duty to make such tests and inspections, during and
14 after the process of manufacture, to ensure these baby foods were safe for ingestion.

15 336. Manufacturer Defendants failed to use reasonable care in making such
16 tests and inspections, and instead, oftentimes only tested the ingredients of the baby
17 food individually, never testing the finished product that was put on store shelves
18 for purchase by the Plaintiff and the putative Class.

19 337. Further, Manufacturer Defendants failed to use reasonable care in
20 making such tests and inspections by sometimes not even testing for heavy metals
21 like mercury at all in their products and/or ingredients that were then sold to
22 Plaintiff and the putative Class.

23 338. Had Manufacturer Defendants properly and effectively tested their
24 finished products, the foods that would actually be consumed by babies as young as
25 four months old, they would have been alerted to the fact that the finished products
26 contained dangerously high levels of arsenic, lead, cadmium or mercury.

27 339. By failing to exercise this reasonable care, Manufacturer Defendants
28 manufactured harmful and toxic baby foods.

1 340. Plaintiff's children have experienced cellular, subcellular, or subclinical
2 injury due to the clinically demonstrable presence of toxins in the children's
3 bloodstream.

4 341. As a direct or proximate result of Manufacturer Defendants' conduct,
5 Plaintiff and the putative Class have incurred monitoring expenses, will incur
6 monitoring expenses, or would incur the monitoring expenses if they could afford
7 it. Plaintiff and the putative class are entitled to compensatory and equitable
8 damages, medical monitoring, attorneys' fees and costs and declaratory relief in an
9 amount to be proven at trial.

10 342. Further, Plaintiff and the putative State Law Class shall be entitled to an
11 award of punitive damages, as is clear from the facts herein that Manufacturer
12 Defendants' actions were performed with a realization of the imminence of danger
13 and a reckless disregard and complete indifference to the probable consequences of
14 their actions. By Manufacturer Defendants putting their own pecuniary interests
15 ahead of all else, they sacrificed the safety, health, and wellbeing of innocent babies,
16 toddlers, and children. Manufacturer Defendants also unfairly profited off the
17 unsuspecting parents and purchasers who believed they were buying healthy food for
18 their children. The only way to prevent this type of egregious indifference again is to
19 assess punitive damages against Manufacturer Defendants.

20 **COUNT FIVE:**
21 **NEGLIGENT MISREPRESENTATION**

22 (As to Defendant Beech-Nut, Plum Defendants, Defendant Gerber, and Defendant
23 Nurture)

24 343. Plaintiff realleges and incorporates by reference each and every
25 allegation contained in the preceding paragraphs as if fully set forth herein.

26 344. Because Plaintiff reasonably relied on Manufacturer Defendants as
27 longstanding manufacturers of baby food and Manufacturer Defendants had a
28 relationship vis-à-vis consumers seeking to purchase healthy foods for their

1 children, Manufacturer Defendants had a duty to alert Plaintiff about what was
2 actually contained in their products.

3 345. Manufacturer Defendants have known for years, as indicated by the
4 Clean Label Report in 2017, the Consumer Report in 2018, the inception of the
5 Baby Food Council in January 2019, and the Healthy Babies Bright Futures report
6 in October 2019 that their products contained *inter alia* mercury, lead, cadmium,
7 and arsenic.

8 346. When Manufacturer Defendants were unequivocally confronted with
9 these facts, they had a duty to speak and inform Plaintiff and members of the
10 putative class.

11 347. Manufacturer Defendants each had a duty to disclose that their baby
12 food products were defective and unsafe in that they contained unsafe levels of
13 toxic heavy metals including arsenic, cadmium, lead, and mercury, because Plaintiff
14 relied on Manufacturer Defendants' representations that the baby food they were
15 purchasing was safe and free from defects. Manufacturer Defendants also had a
16 duty to disclose because they: (1) Possessed exclusive knowledge of the defects; (2)
17 Intentionally concealed the presence of unsafe levels of toxic heavy metals through
18 their deceptive marketing campaign that they designed to hide the presence of these
19 hazardous substances from the State Law Class; and/or (3) Made incomplete
20 representations about the safety of their baby food products while purposefully
21 withholding material facts from the State Law Class that contradicted these
22 representations.

23 348. But instead, Manufacturer Defendants put their own profits over the
24 health and safety of children, and actively withheld the fact that these containments
25 were contained in the food, at high levels, far exceeding that allowed in regular
26 bottled water and omitted these ingredients and containments from the labels and
27 packaging of these products.

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1 349. Decisionmakers, executives, and every employee in the marketing
2 and/or labeling departments of these Manufacturer Defendants had the choice to
3 expose the contaminants to Plaintiff and members of the putative class, and they all
4 chose to ignore it.

5 350. As set out in Section III.D, Manufacturer Defendants continued to
6 represent their products as safe, natural, healthy, and even good for learning ability
7 when they knew about the unsafe levels of heavy metals.

| 8 Defendant | Date | Representations |
|--------------------|-----------------------------------|--|
| 9 Beech-Nut | 10 Since at least 11 5/30/2017 | Beech-Nut baby food is “clean food” and “classic, natural and organic real food for babies and toddlers” “with just real, simple ingredients” |
| | 12 ~8/16/2018 | 13 “We want to reassure parents that Beech-Nut’s real food for babes is healthy, nutritious and safe.” 14 “We want to assure parents that . . . we have high confidence in the quality and standards we use in making our food.” 15 16 “Currently, no government standard or recommendation exists for lead.” |
| | 17 3/21/2018 | 18 Beech-Nut products contain “nothing else” but the listed ingredient |
| | 19 3/28/2019 | 20 Beech-Nut products are for consumers who are “label readers” and look for “natural ingredients only.” |
| | 21 Since at least 22 7/13/2019 | 23 “what’s inside your baby food matters” 24 Beech-Nut “offer[s] natural and organic products” 25 “In fact, we conduct over 20 rigorous tests on our purees, testing for up to 255 pesticides and heavy 26 27 |

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| Defendant | Date | Representations |
|-----------|--------------------------|--|
| | | metals (like lead, cadmium and other nasty stuff). Just like you would, we send the produce back if it's not good enough." |
| | 10/17/2019 | "Our process starts with high-quality fruits and vegetables that meet BNN's own standards, which in some cases are 10 times stricter than those of the U.S. government. For example, we test for 255 common contaminants, such as lead, other heavy metals and pesticides, to confirm that all the ingredients delivered to us and used in our products comply with our standards. If they don't, we send them back." |
| | 12/6/2019 | Beech-Nut applied "rigorous testing protocols and heavy metal testing standards which are continuously reviewed and strengthened." Beech-Nut encouraged the creation of the Baby Food Council to "conduct research and work to achieve a long-term reduction of heavy metals in the baby food supply chain" and that its current "top priority is to reduce heavy metals in the products manufactured and marketed by the member companies [including Defendant Beech-Nut] using best-in-class management practices." |
| | Since at least 6/14/2020 | Beech-Nut "only" uses "real," "quality" ingredients |

| Defendant | Date | Representations |
|-------------|------------|--|
| | 2/4/2021 | Beech-Nut “assured parents its baby food is ‘safe and nutritious.’” |
| | ~2/5/2021 | “We want to reassure parents Beech-Nut products are safe and nutritious.... We look forward to continuing to work with the FDA, in partnership with the Baby Food Council...” |
| | ~2/5/2021 | Beech-Nut products are “safe and nutritious” |
| Plum | 12/11/2017 | “We believe that Plum’s products are safe to eat. Our testing confirmed that the averaged results for heavy metals in all tested Plum products gave concentrations that are typical for those ingredients – whether that’s a leafy green grown in your own garden or a bunch of carrots purchased at the farmer’s market. The results also demonstrate our tested products are below exposure limits set by certain domestic and international regulatory bodies.” |
| | 2/12/2018 | The mission that Plum Organics promises is that it will provide “little ones” with “the very best food from the first bite.” |
| | 6/7/2019 | The back of the Plum Organics’ pouch lets customers “find out exactly what [you are] getting!” |
| | 12/11/2019 | “Campbell has conducted testing on every Plum Organics product on the market to ensure none exceed acceptable levels of arsenic, lead, cadmium, |

| Defendant | Date | Representations |
|---------------|--------------------------|--|
| | | or mercury... To date, no Plum Organics foods have been found to be above exposure limits set by available domestic and international regulatory bodies” |
| | Since at least 8/12/2020 | Plum Organics baby foods are “absolutely” “safe to eat” and that “health and safety are always” its “top priorities.” “We believe ingredient testing allows for better control of the entire product and gets us ahead of any potential issues before it makes its way into a product. It’s just like when you make a recipe at home – you want to know everything that’s going into the recipe.” |
| | 2/5/2021 | “Campbell has conducted testing on every Plum Organics product on the market to ensure none exceed acceptable levels of arsenic, lead, cadmium, or mercury.” |
| Gerber | ~8/16/2018 | “All of our foods meet our safety and quality standards, which are among the strictest in the world.” “Our rigorous standards are developed by evaluating the latest food safety guidance – from sources like the Food and Drug Administration, Environmental Protection Agency, and international health authorities. Gerber also partners with our farmers and our ingredient and |

| Defendant | Date | Representations |
|-----------|---------------------------|--|
| | | packaging suppliers to control, reduce and limit contaminants in all our foods.” |
| | 12/19/2019 | <p>Gerber “takes all concerns related to safety very seriously, which is why all of our foods and beverages meet our safety and quality standards and conform to all regulatory compliance guidelines.”</p> <p>Gerber was “also a founding member of the Baby Food Council,” whose objective is “reducing heavy metals in the products manufactured by the member companies to as low as reasonably achievable using best-in-class management practices.” Defendant Gerber claimed that its “efforts with the Council represent our commitment to the safety of the baby food category.”</p> |
| | Since at least 9/30/2020 | <p>Gerber rice cereals will help support “learning ability”</p> <p>Gerber Clean Field Farming practices ensure that its baby foods are “safe and wholesome.”</p> |
| | 10/12/2020 | Gerber Clean Field Farming Standards allows it to “ensure that [our produce is] safe and wholesome for baby.” |
| | Since at least 11/25/2020 | Gerber knows that parents want “the very best for your little one to ensure she reaches her full potential, and so do we.” |

| Defendant | Date | Representations |
|-----------|-----------|---|
| | | <p>Gerber represents to parents that it has adopted “super strict” farming practices “to ensure that their fruit and vegetable purees are not only nutritious, but also wholesome and safe for even the littlest bodies.”</p> <p>Gerber believes “that little ones deserve the highest standards set just for them” guides its mission to “deliver the very best fruits and veggies.”</p> <p>Gerber represents that its growing standards are the “strictest in the world” to ensure “quality control” because “what you get out is what you put in.”</p> <p>Gerber’s Clean Field Farming process “ensure[s] our purees are not only nutritious, but also wholesome and safe for every tiny tummy.”</p> |
| | ~2/4/2021 | <p>Gerber has “been working together with other industry members, the Environmental Defense Fund, Healthy Babies Bright Futures and Cornell University” to identify “best agricultural practices” and create “a voluntary industry standard to reduce heavy metal levels in baby foods to the lowest level possible.”</p> <p>Gerber stated that “all of its food meets its safety standards, which it says are among the strictest in the world.”</p> |
| | 2/5/2021 | Gerber’s standards “are among the strictest in not just the US, but the world... where government |

| Defendant | Date | Representations |
|----------------|--------------------------|--|
| | | standards don't currently exist, we develop our own rigorous standards." |
| Nurture | 7/2/2019 | Nurture holds its "ingredients to the highest standards, because your baby deserves the best." |
| | 7/17/2019 | Nurture's Happy Baby superfood Puffs "support brain health" |
| | 8/16/2019 | Nurture "partner[s] with pediatricians, dietitians, and children's health experts [it] trust[s]—so your family can trust our organic food." |
| | 11/25/2019 | Nurture represented that consumers "can skip all these chemicals when you buy organic food" |
| | 12/18/2019 | Nurture's membership in the Baby Food Council is an indication of its commitment to "reduce heavy metals in baby food products as low as reasonably achievable using best-in-class management practices." |
| | Since at least 8/13/2020 | Customers can have "peace of mind" because Nurture "source[s] high-quality organic ingredients" and has "rigorous and uncompromising quality standards" so consumers "can feel confident" in what they are feeding their family. Nurture emphasizes that it goes beyond USDA organic standards because it knows that what children eat in the first few years of life is "crucial." Nurture assures parents that it holds |

| Defendant | Date | Representations |
|-----------|-------------------------|--|
| | | itself to “strict standards” to help children “grow healthy and strong” through “test[ing] and thoroughly analyz[ing] every batch of food.” Parents can “trust” its organic food because Nurture “partner[s] with pediatricians, dietitians, and children’s health experts.” |
| | 2/5/2021 | “We can say with the utmost confidence that all Happy Family Organics products are safe for babies and toddlers to enjoy, and we are proud to have best-in-class testing protocols in our industry.” |
| | Since at least 2/5/2021 | “We can say with the utmost confidence that all Happy Family Organics products are safe for babies and toddlers to enjoy and we are proud to have best-in-class testing protocols in our industry. We only sell products that have been rigorously tested and we do not have products in-market with contaminant ranges outside of the limits set by the FDA.” |

351. Manufacturer Defendants grossed billions of dollars in revenue in the sale of these products, which would have been significantly diminished if Plaintiff and members of the putative class had known about the toxins contained in the baby foods.

352. Given that the product is baby food, and children and babies are particularly vulnerable, Manufacturer Defendants knew that the safety, contents, and purity of the food being sold was especially important. Indeed, they tailored

1 their marketing and sales communications directly to this issue, preying on the
2 purchasers' vulnerability and desperation as parents to do everything possible to
3 feed their children healthy and safe food.

4 353. Plaintiff's reliance on Manufacturer Defendants' representations that
5 the baby food they produced was as advertised and labeled was reasonable, because
6 consumers expect food producers, especially food made for vulnerable, developing
7 babies and children, not to contain heavy metals at toxic levels.

8 354. Plaintiff's children have experienced cellular, subcellular, or subclinical
9 injury due to the clinically demonstrable presence of toxins in the children's
10 bloodstream.

11 355. As a direct or proximate result of Manufacturer Defendants' conduct,
12 Plaintiff and the putative Class have incurred monitoring expenses, will incur
13 monitoring expenses, or would incur the monitoring expenses if they could afford
14 it. Plaintiff and the putative class are entitled to compensatory and equitable
15 damages, medical monitoring, attorneys' fees and costs and declaratory relief in an
16 amount to be proven at trial.

17 356. As a direct or proximate result of Manufacturer Defendants' conduct,
18 Plaintiff and the putative Class also suffered actual damages from purchasing baby
19 foods that they would not have purchased without the intentional or negligent
20 misrepresentations or at least would have paid significantly less for Manufacturer
21 Defendants' baby food products.

22 357. Further, Plaintiff and the putative Class shall be entitled to an award of
23 punitive damages, as is clear from the facts herein that Manufacturer Defendants'
24 actions were performed with a realization of the imminence of danger and a reckless
25 disregard and complete indifference to the probable consequences of their actions.
26 By Manufacturer Defendants' putting their own pecuniary interests ahead of all else,
27 they sacrificed the safety, health, and wellbeing of innocent babies, toddlers, and
28

1 children. Manufacturer Defendants also unfairly profited off the unsuspecting parents
2 and purchasers who believed they were buying healthy food for their children. The
3 only way to prevent this type of egregious indifference again is to assess punitive
4 damages against Manufacturer Defendants.

5
6 **COUNT SIX:**
7 **MEDICAL MONITORING**

8 (As to Defendant Beech-Nut, Plum Defendants, Defendant Gerber, and Defendant
9 Nurture)

10 358. Plaintiff reallege and incorporate by reference each and every allegation
11 contained in the preceding paragraphs as if fully set forth herein.

12 359. Due to non-specific signs and symptoms of toxicity, as well as the fact
13 that the duration and extent of exposure is often not known, diagnosis of most toxic
14 element exposures depends on laboratory testing.¹⁵⁹

15 360. According to scientists, laboratory testing is an important tool for
16 detecting and managing exposure to toxic heavy metals like arsenic, cadmium, lead,
17 and mercury.

18 361. Several analytical methods are available.

19 362. While the effects of lead poisoning are permanent, if caught early, there
20 are measures parents can do to prevent further exposure and reduce damage to their
21 child's health.

22 363. Most children with any lead in their blood have no obvious immediate
23 symptoms. Blood tests are a simple and readily available way to assess a person's
24 exposure to lead.

25
26 _____
27 ¹⁵⁹ Deborah E. Keil, Jennifer Berger-Ritchie, Gwendolyn A. McMillin, *Testing for*
28 *Toxic Elements: A Focus on Arsenic, Cadmium, Lead, and Mercury*, 42 LAB. MED.
735 (Dec. 2011).

1 364. According to the CDC, early identification of elevated blood lead levels
2 is key to reducing the long-term effects of lead exposure.

3 365. Testing provides parents and medical professionals with the necessary
4 information to provide guidance on follow-up services.

5 366. Medical monitoring is reasonably necessary to enable Plaintiff and the
6 Class to obtain diagnostic testing for their exposed children to allow early detection
7 and treatment of latent injuries or disease that may have developed or will develop
8 as a result of exposure to toxic heavy metals in Manufacturer Defendants’ baby
9 food products.

10 367. Plaintiff and the Class therefore seek an injunction and/or other equitable
11 relief from this Court to create a Court-supervised, Defendant-funded,
12 comprehensive medical monitoring program for exposed children of class members
13 and notification to all Class Members of the necessity and importance of medical
14 monitoring.

15 **COUNT SEVEN:**
16 **UNJUST ENRICHMENT**
17 (As to All Defendants)

18 368. Plaintiff reallege and incorporate by reference each and every allegation
19 contained in the preceding paragraphs as if fully set forth herein.

20 369. Manufacturer Defendants here are the leading seven producers of baby
21 foods in this country, an extremely lucrative industry.

22 370. Defendants received a benefit to the tune of tens of billions of dollars in
23 purchases of this defective, dangerous baby food.

24 371. Defendants retained these billions of dollars in revenue.

25 372. Under the circumstances and the fact that these Defendants did produce
26 and sell baby foods to Plaintiff and the putative State Law Class which contained
27

1 dangerous levels of toxic, heavy metals, it is unjust and unequitable for Defendants
2 to retain the money paid for these baby foods.

3 373. As a direct or proximate result of Defendants' conduct, Plaintiff and the
4 putative State Law Class have suffered actual damages in the purchase of these
5 baby foods that were worth significantly less than the price paid and because they
6 would not have purchased the product had they known of the presence of heavy
7 metals, entitling them to compensatory and equitable damages, attorneys' fees and
8 costs and declaratory relief in an amount to be proven at trial.

9 374. Further, Plaintiff and the putative State Law Class shall be entitled to an
10 award of punitive damages, as is clear from the facts herein that Defendants' actions
11 were performed with a realization of the imminence of danger and a reckless
12 disregard and complete indifference to the probable consequences of their actions.
13 By Defendants' putting their own pecuniary interests ahead of all else, they sacrificed
14 the safety, health, and wellbeing of innocent babies, toddlers, and children.
15 Defendants also unfairly profited off the unsuspecting parents and purchasers who
16 believed they were buying healthy food for their children. The only way to prevent
17 this type of egregious indifference again is to assess punitive damages against
18 Defendants.

19 **COUNT EIGHT:**
20 **COMMON LAW FRAUD**

21 (As to All Defendants)

22 375. Plaintiff realleges and incorporates by reference each and every
23 allegation contained in the preceding paragraphs as if fully set forth herein.

24 376. Defendants have known for years, as indicated by the Environmental
25 Defense Fund report in 2017, the Clean Label Report in 2017, the Consumer Report
26 in 2018, the inception of the Baby Food Council in January 2019, and the Healthy
27

1 Babies Bright Futures report in October 2019 that their products contained *inter*
 2 *alia* mercury, lead, cadmium, and arsenic.

3 377. Each Defendant has worked to defraud consumers by: (1) suppressing
 4 of information revealing the widespread contamination of baby food during
 5 manufacturing; (2) delaying the adoption of governmental standards for baby food
 6 manufacturers while falsely suggesting a commitment to adopt those very
 7 standards; (3) falsely suggesting that contamination of baby food products is
 8 “natural”; (4) falsely suggesting that they were committed to improving baby food
 9 safety as a way to prolong their fraud; (5) deceiving purchasers into believing that
 10 baby food with heavy metals is “safe,” “healthy,” and “pure”; and (6) conceal,
 11 camouflage, and prolong their ongoing food fraud.

12 378. As set out in Section III.D.3, when Defendants were unequivocally
 13 confronted with these facts, they continued to falsely market their products as
 14 “healthy,” “safe,” “pure,” even good for learning ability, and failed to exercise
 15 reasonable care to inform Plaintiff and members of the putative class of what was
 16 actually contained in the product. Defendants also expressly assured consumers
 17 about extensive testing measure deployed internally to ensure their products met
 18 these standards and purported governmental standards.

| Defendant | Date | Representation in Furtherance of Fraud |
|------------------|--------------------------|---|
| Beech-Nut | Since at least 5/30/2017 | Beech-Nut baby food is “clean food” and “classic, natural and organic real food for babies and toddlers” “with just real, simple ingredients” |
| | ~8/16/2018 | “We want to reassure parents that Beech-Nut’s real food for babes is healthy, nutritious and safe.” “We want to assure parents that . . . we have high confidence in the quality and standards we use in making our food.” |

| Defendant | Date | Representation in Furtherance of Fraud |
|--------------------------|------------|---|
| | | “Currently, no government standard or recommendation exists for lead.” |
| | 3/21/2018 | Beech-Nut products contain “nothing else” but the listed ingredient |
| | 3/28/2019 | Beech-Nut products are for consumers who are “label readers” and look for “natural ingredients only.” |
| Since at least 7/13/2019 | | “what’s inside your baby food matters” Beech-Nut “offer[s] natural and organic products” “In fact, we conduct over 20 rigorous tests on our purees, testing for up to 255 pesticides and heavy metals (like lead, cadmium and other nasty stuff). Just like you would, we send the produce back if it’s not good enough.” |
| | 10/17/2019 | “Our process starts with high-quality fruits and vegetables that meet BNN’s own standards, which in some cases are 10 times stricter than those of the U.S. government. For example, we test for 255 common contaminants, such as lead, other heavy metals and pesticides, to confirm that all the ingredients delivered to us and used in our products comply with our standards. If they don’t, we send them back.” |
| | 12/6/2019 | Beech-Nut applied “rigorous testing protocols and heavy metal testing standards which are continuously reviewed and strengthened.” |

| Defendant | Date | Representation in Furtherance of Fraud |
|-------------|--------------------------|---|
| | | Beech-Nut encouraged the creation of the Baby Food Council to “conduct research and work to achieve a long-term reduction of heavy metals in the baby food supply chain” and that its current “top priority is to reduce heavy metals in the products manufactured and marketed by the member companies [including Defendant Beech-Nut] using best-in-class management practices.” |
| | Since at least 6/14/2020 | Beech-Nut “only” uses “real,” “quality” ingredients |
| | 2/4/2021 | Beech-Nut “assured parents its baby food is ‘safe and nutritious.’” |
| | ~2/5/2021 | “We want to reassure parents Beech-Nut products are safe and nutritious.... We look forward to continuing to work with the FDA, in partnership with the Baby Food Council...” |
| | ~2/5/2021 | Beech-Nut products are “safe and nutritious” |
| Plum | 12/11/2017 | “We believe that Plum’s products are safe to eat. Our testing confirmed that the averaged results for heavy metals in all tested Plum products gave concentrations that are typical for those ingredients – whether that’s a leafy green grown in your own garden or a bunch of carrots purchased at the farmer’s market. The results also demonstrate our tested products are below exposure limits set by |

| Defendant | Date | Representation in Furtherance of Fraud |
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| | | certain domestic and international regulatory bodies.” |
| | 2/12/2018 | The mission that Plum Organics promises is that it will provide “little ones” with “the very best food from the first bite.” |
| | 6/7/2019 | The back of the Plum Organics’ pouch lets customers “find out exactly what [you are] getting!” |
| | 12/11/2019 | “Campbell has conducted testing on every Plum Organics product on the market to ensure none exceed acceptable levels of arsenic, lead, cadmium, or mercury... To date, no Plum Organics foods have been found to be above exposure limits set by available domestic and international regulatory bodies” |
| | Since at least 8/12/2020 | Plum Organics baby foods are “absolutely” “safe to eat” and that “health and safety are always” its “top priorities.” “We believe ingredient testing allows for better control of the entire product and gets us ahead of any potential issues before it makes its way into a product. It’s just like when you make a recipe at home – you want to know everything that’s going into the recipe.” |
| | 2/5/2021 | “Campbell has conducted testing on every Plum Organics product on the market to ensure none |

| Defendant | Date | Representation in Furtherance of Fraud |
|---------------|------------|---|
| | | exceed acceptable levels of arsenic, lead, cadmium, or mercury.” |
| Gerber | ~8/16/2018 | <p>“All of our foods meet our safety and quality standards, which are among the strictest in the world.”</p> <p>“Our rigorous standards are developed by evaluating the latest food safety guidance – from sources like the Food and Drug Administration, Environmental Protection Agency, and international health authorities. Gerber also partners with our farmers and our ingredient and packaging suppliers to control, reduce and limit contaminants in all our foods.”^{42F}</p> |
| | 12/19/2019 | <p>Gerber “takes all concerns related to safety very seriously, which is why all of our foods and beverages meet our safety and quality standards and conform to all regulatory compliance guidelines.”</p> <p>Gerber was “also a founding member of the Baby Food Council,” whose objective is “reducing heavy metals in the products manufactured by the member companies to as low as reasonably achievable using best-in-class management practices.” Defendant Gerber claimed that its “efforts with the Council represent our</p> |

| Defendant | Date | Representation in Furtherance of Fraud |
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| | | commitment to the safety of the baby food category.” |
| | Since at least 9/30/2020 | Gerber rice cereals will help support “learning ability” Gerber Clean Field Farming practices ensure that its baby foods are “safe and wholesome.” |
| | 10/12/2020 | Gerber Clean Field Farming Standards allows it to “ensure that [our produce is] safe and wholesome for baby.” |
| | Since at least 11/25/2020 | Gerber knows that parents want “the very best for your little one to ensure she reaches her full potential, and so do we.” Gerber represents to parents that it has adopted “super strict” farming practices “to ensure that their fruit and vegetable purees are not only nutritious, but also wholesome and safe for even the littlest bodies.” Gerber believes “that little ones deserve the highest standards set just for them” guides its mission to “deliver the very best fruits and veggies.” Gerber represents that its growing standards are the “strictest in the world” to ensure “quality control” because “what you get out is what you put in.” Gerber’s Clean Field Farming process “ensure[s] our purees are not only nutritious, but also wholesome and safe for every tiny tummy.” |

| Defendant | Date | Representation in Furtherance of Fraud |
|----------------|------------|---|
| | ~2/4/2021 | <p>Gerber has “been working together with other industry members, the Environmental Defense Fund, Healthy Babies Bright Futures and Cornell University” to identify “best agricultural practices” and create “a voluntary industry standard to reduce heavy metal levels in baby foods to the lowest level possible.”</p> <p>Gerber stated that “all of its food meets its safety standards, which it says are among the strictest in the world.”</p> |
| | 2/5/2021 | Gerber’s standards “are among the strictest in not just the US, but the world... where government standards don’t currently exist, we develop our own rigorous standards.” |
| Nurture | 7/2/2019 | Nurture holds its “ingredients to the highest standards, because your baby deserves the best.” |
| | 7/17/2019 | Nurture’s Happy Baby superfood Puffs “support brain health” |
| | 8/16/2019 | Nurture “partner[s] with pediatricians, dietitians, and children’s health experts [it] trust[s]—so your family can trust our organic food.” |
| | 11/25/2019 | Nurture represented that consumers “can skip all these chemicals when you buy organic food” |
| | 12/18/2019 | Nurture’s membership in the Baby Food Council is an indication of its commitment to “reduce heavy metals in baby food products as low as reasonably |

| Defendant | Date | Representation in Furtherance of Fraud |
|-----------|--------------------------|---|
| | | achievable using best-in-class management practices.” |
| | Since at least 8/13/2020 | <p>Customers can have “peace of mind” because Nurture “source[s] high-quality organic ingredients” and has “rigorous and uncompromising quality standards” so consumers “can feel confident” in what they are feeding their family.</p> <p>Nurture emphasizes that it goes beyond USDA organic standards because it knows that what children eat in the first few years of life is “crucial.” Nurture assures parents that it holds itself to “strict standards” to help children “grow healthy and strong” through “test[ing] and thoroughly analyz[ing] every batch of food.”</p> <p>Parents can “trust” its organic food because Nurture “partner[s] with pediatricians, dietitians, and children’s health experts.”</p> |
| | 2/5/2021 | “We can say with the utmost confidence that all Happy Family Organics products are safe for babies and toddlers to enjoy, and we are proud to have best-in-class testing protocols in our industry.” |
| | Since at least 2/5/2021 | “We can say with the utmost confidence that all Happy Family Organics products are safe for babies and toddlers to enjoy and we are proud to |

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| Defendant | Date | Representation in Furtherance of Fraud |
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| | | <p>have best-in-class testing protocols in our industry. We only sell products that have been rigorously tested and we do not have products in-market with contaminant ranges outside of the limits set by the FDA.”</p> |

379. Knowing that consumers valued the quality and safety of the baby food products they fed their children, Defendants misrepresented the health, safety, and contents of their products and omitted information about the testing that showed risky levels of toxic heavy metals.

380. Each Defendant engaged in false representations, fraud by omission, fraud by half-truth, and/or fraudulent concealment.

381. Each Defendant knew these representations were false when made.

382. The baby food purchased by Plaintiff was, in fact, defective and unsafe, because the baby food contained unsafe levels of toxic heavy metals including arsenic, cadmium, lead, and mercury.

383. Defendants each had a duty to disclose that their baby food products were defective and unsafe in that they contained unsafe levels of toxic heavy metals including arsenic, cadmium, lead, and mercury, because Plaintiff relied on Defendants’ representations that the baby food they were purchasing was safe and free from defects. Defendants also had a duty to disclose because they: (1) Possessed exclusive knowledge of the defects; (2) Intentionally concealed the presence of unsafe levels of toxic heavy metals through their deceptive marketing campaign that they designed to hide the presence of these hazardous substances from the State Law Class; and/or (3) Made incomplete representations about the safety of their baby food products while purposefully withholding material facts from the State Law Class that contradicted these representations.

1 384. These representations were also material because they were facts that
2 would typically be relief on by a person purchasing baby food. Given that the
3 product is baby food, and children and babies are particularly vulnerable,
4 Defendants knew that the safety, contents, and purity of the food being sold was
5 especially important. Indeed, they tailored their marketing and sales
6 communications directly to this issue, preying on the purchasers' vulnerability and
7 desperation as parents to do everything possible to feed their children healthy and
8 safe food.

9 385. Defendants exploited that vulnerability, knowing that Plaintiff and the
10 class had (and have) no way of uncovering the fraud at issue.

11 386. Plaintiff relied on Defendants' reputation (along with their failure to
12 disclose and affirmative representations) in purchasing Defendants' baby food
13 products.

14 387. Plaintiff and members of the putative class relied on Defendants'
15 representations that the foods were safe for consumption by babies and children.

16 388. Plaintiff's reliance on Defendants' representations that the baby food
17 they produced was as advertised and labeled was reasonable, because consumers
18 expect food producers, especially food made for vulnerable, developing babies and
19 children, not to contain heavy metals at toxic levels.

20 389. Plaintiff and members of the putative class, as consumers of baby food
21 for their babies and children were the exact people for whose benefit and guidance
22 the information was supplied.

23 390. Defendants each had a duty to disclose the true facts about their baby
24 food products because these facts were known and/or accessible only to Defendants
25 who had superior knowledge and access to the facts, and the facts were not known
26 to or reasonably discoverable by Plaintiff and the Class.

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28

1 391. As a direct or proximate result of Defendants’ conduct, Plaintiff and the
 2 putative Class have suffered actual damages in the purchase of these baby foods
 3 that were worth significantly less than the price paid and because they would not
 4 have purchased the product had they known of the presence of heavy metals,
 5 entitling them to compensatory and equitable damages, attorneys’ fees and costs
 6 and declaratory relief in an amount to be proven at trial.

7 392. Further, Plaintiff and the putative Class shall be entitled to an award of
 8 punitive damages, as is clear from the facts herein that Defendants’ conduct was
 9 knowing, intentional, with malice, demonstrated a complete lack of care, and was in
 10 reckless disregard and complete indifference to the probable consequences of their
 11 actions. By Defendants’ putting their own pecuniary interests ahead of all else, they
 12 sacrificed the safety, health, and wellbeing of innocent babies, toddlers, and children.
 13 Defendants also unfairly profited off unsuspecting parents and purchasers who
 14 believed they were buying healthy food for their children. The only way to prevent
 15 this type of egregious indifference again is to assess punitive damages against
 16 Defendants.

17 **COUNT NINE:**
 18 **VIOLATIONS OF COLORADO CONSUMER PROTECTION ACT**
 19 **COL. REV. STAT. § 6-1-101, et seq.**

20 (As to All Defendants)

21 393. Plaintiff realleges and incorporates by reference each and every
 22 allegation contained in the preceding paragraphs as if fully set forth herein.

23 394. This claim is on behalf of the Colorado Class.

24 395. Defendants are “persons” under § 6-1-102(6) of the Colorado
 25 Consumer Protection Act (“Colorado CPA”).

26 396. The Colorado Class members are “consumers” for purposes of § 6-1-
 27 113(1)(a) who purchased one or more of Manufacturer Defendants’ baby food
 28 products including from Defendant Safeway.

1 397. The Colorado CPA prohibits deceptive trade practices in the course of a
2 person's business. By failing to disclose and actively concealing the dangerous
3 levels of toxic heavy metals contained in their baby foods, Defendants engaged in
4 unfair or deceptive practices prohibited by the Colorado CPA including (1)
5 knowingly making a false representation as to the characteristics, uses, and benefits
6 of their baby food products that had a capacity or tendency to deceive Colorado
7 Class members; (2) representing that the baby foods are of a particular standard,
8 quality, and grade when Defendants knew or should have known they did not have
9 meet those standards; (3) advertising the baby foods with the intent not to sell them
10 as advertised; (4) failing to disclose material information concerning Defendants'
11 baby food products that was known to Defendants at the time of advertisement or
12 sale with the intent to induce Colorado Class members to purchase the defective
13 baby food products..

14 398. Defendants' activities set forth above occurred in the conduct of trade
15 or commerce.

16 399. In the course of their business, Defendants willfully failed to disclose
17 and actively concealed the dangerous levels of toxic heavy metals contained in their
18 baby foods. Defendants also engaged in unlawful trade practices by employing
19 deception; deceptive acts or practices; fraud; misrepresentations; concealment,
20 suppression, or omission of any material fact with intent that others rely upon such
21 concealment, suppression, or omission, in connection with the sale of Defendants'
22 baby food products.

23 400. As alleged above, Defendants knew of the heavy metal contamination
24 in their baby food products, while the Colorado Class was deceived by Defendants'
25 omission into believing the baby food products were safe, and the information
26 could not have reasonably been known by the consumer.

27
28

1 401. Defendants knew or should have known that their conduct violated the
 2 Colorado CPA.

3 402. Each Defendant has worked to defraud consumers by: (1) suppressing
 4 of information revealing the widespread contamination of baby food during
 5 manufacturing; (2) delaying the adoption of governmental standards for baby food
 6 manufacturers while falsely suggesting a commitment to adopt those very
 7 standards; (3) falsely suggesting that contamination of baby food products is
 8 “natural”; (4) falsely suggesting that they were committed to improving baby food
 9 safety as a way to prolong their fraud; (5) deceiving purchasers into believing that
 10 baby food with heavy metals is “safe,” “healthy,” and “pure”; and (6) conceal,
 11 camouflage, and prolong their ongoing food fraud.

12 403. As set out in Section III.D.3, when Defendants were unequivocally
 13 confronted with these facts, they continued to falsely market their products as
 14 “healthy,” “safe,” “pure,” even good for learning ability, and failed to exercise
 15 reasonable care to inform Plaintiff and members of the putative class of what was
 16 actually contained in the product. Defendants also expressly assured consumers
 17 about extensive testing measure deployed internally to ensure their products met
 18 these standards and purported governmental standards.

| Defendant | Date | Representation in Furtherance of Fraud |
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| Beech-Nut | Since at least 5/30/2017 | Beech-Nut baby food is “clean food” and “classic, natural and organic real food for babies and toddlers” “with just real, simple ingredients” |
| | ~8/16/2018 | “We want to reassure parents that Beech-Nut’s real food for babes is healthy, nutritious and safe.” “We want to assure parents that . . . we have high confidence in the quality and standards we use in making our food.” |

| Defendant | Date | Representation in Furtherance of Fraud |
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| | | “Currently, no government standard or recommendation exists for lead.” |
| | 3/21/2018 | Beech-Nut products contain “nothing else” but the listed ingredient |
| | 3/28/2019 | Beech-Nut products are for consumers who are “label readers” and look for “natural ingredients only.” |
| Since at least 7/13/2019 | | “what’s inside your baby food matters” Beech-Nut “offer[s] natural and organic products” “In fact, we conduct over 20 rigorous tests on our purees, testing for up to 255 pesticides and heavy metals (like lead, cadmium and other nasty stuff). Just like you would, we send the produce back if it’s not good enough.” |
| | 10/17/2019 | “Our process starts with high-quality fruits and vegetables that meet BNN’s own standards, which in some cases are 10 times stricter than those of the U.S. government. For example, we test for 255 common contaminants, such as lead, other heavy metals and pesticides, to confirm that all the ingredients delivered to us and used in our products comply with our standards. If they don’t, we send them back.” |
| | 12/6/2019 | Beech-Nut applied “rigorous testing protocols and heavy metal testing standards which are continuously reviewed and strengthened.” |

| Defendant | Date | Representation in Furtherance of Fraud |
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| | | Beech-Nut encouraged the creation of the Baby Food Council to “conduct research and work to achieve a long-term reduction of heavy metals in the baby food supply chain” and that its current “top priority is to reduce heavy metals in the products manufactured and marketed by the member companies [including Defendant Beech-Nut] using best-in-class management practices.” |
| | Since at least 6/14/2020 | Beech-Nut “only” uses “real,” “quality” ingredients |
| | 2/4/2021 | Beech-Nut “assured parents its baby food is ‘safe and nutritious.’” |
| | ~2/5/2021 | “We want to reassure parents Beech-Nut products are safe and nutritious.... We look forward to continuing to work with the FDA, in partnership with the Baby Food Council...” |
| | ~2/5/2021 | Beech-Nut products are “safe and nutritious” |
| Plum | 12/11/2017 | “We believe that Plum’s products are safe to eat. Our testing confirmed that the averaged results for heavy metals in all tested Plum products gave concentrations that are typical for those ingredients – whether that’s a leafy green grown in your own garden or a bunch of carrots purchased at the farmer’s market. The results also demonstrate our tested products are below exposure limits set by |

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| Defendant | Date | Representation in Furtherance of Fraud |
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| | | certain domestic and international regulatory bodies.” |
| | 2/12/2018 | The mission that Plum Organics promises is that it will provide “little ones” with “the very best food from the first bite.” |
| | 6/7/2019 | The back of the Plum Organics’ pouch lets customers “find out exactly what [you are] getting!” |
| | 12/11/2019 | “Campbell has conducted testing on every Plum Organics product on the market to ensure none exceed acceptable levels of arsenic, lead, cadmium, or mercury... To date, no Plum Organics foods have been found to be above exposure limits set by available domestic and international regulatory bodies” |
| | Since at least 8/12/2020 | Plum Organics baby foods are “absolutely” “safe to eat” and that “health and safety are always” its “top priorities.” “We believe ingredient testing allows for better control of the entire product and gets us ahead of any potential issues before it makes its way into a product. It’s just like when you make a recipe at home – you want to know everything that’s going into the recipe.” |
| | 2/5/2021 | “Campbell has conducted testing on every Plum Organics product on the market to ensure none |

| Defendant | Date | Representation in Furtherance of Fraud |
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| | | exceed acceptable levels of arsenic, lead, cadmium, or mercury.” |
| Gerber | ~8/16/2018 | <p>“All of our foods meet our safety and quality standards, which are among the strictest in the world.”</p> <p>“Our rigorous standards are developed by evaluating the latest food safety guidance – from sources like the Food and Drug Administration, Environmental Protection Agency, and international health authorities. Gerber also partners with our farmers and our ingredient and packaging suppliers to control, reduce and limit contaminants in all our foods.”</p> |
| | 12/19/2019 | <p>Gerber “takes all concerns related to safety very seriously, which is why all of our foods and beverages meet our safety and quality standards and conform to all regulatory compliance guidelines.”</p> <p>Gerber was “also a founding member of the Baby Food Council,” whose objective is “reducing heavy metals in the products manufactured by the member companies to as low as reasonably achievable using best-in-class management practices.” Defendant Gerber claimed that its “efforts with the Council represent our</p> |

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| Defendant | Date | Representation in Furtherance of Fraud |
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| | | commitment to the safety of the baby food category.” |
| | Since at least 9/30/2020 | Gerber rice cereals will help support “learning ability” Gerber Clean Field Farming practices ensure that its baby foods are “safe and wholesome.” |
| | 10/12/2020 | Gerber Clean Field Farming Standards allows it to “ensure that [our produce is] safe and wholesome for baby.” |
| | Since at least 11/25/2020 | Gerber knows that parents want “the very best for your little one to ensure she reaches her full potential, and so do we.” Gerber represents to parents that it has adopted “super strict” farming practices “to ensure that their fruit and vegetable purees are not only nutritious, but also wholesome and safe for even the littlest bodies.” Gerber believes “that little ones deserve the highest standards set just for them” guides its mission to “deliver the very best fruits and veggies.” Gerber represents that its growing standards are the “strictest in the world” to ensure “quality control” because “what you get out is what you put in.” Gerber’s Clean Field Farming process “ensure[s] our purees are not only nutritious, but also wholesome and safe for every tiny tummy.” |

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| Defendant | Date | Representation in Furtherance of Fraud |
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| | ~2/4/2021 | <p>Gerber has “been working together with other industry members, the Environmental Defense Fund, Healthy Babies Bright Futures and Cornell University” to identify “best agricultural practices” and create “a voluntary industry standard to reduce heavy metal levels in baby foods to the lowest level possible.”</p> <p>Gerber stated that “all of its food meets its safety standards, which it says are among the strictest in the world.”</p> |
| | 2/5/2021 | Gerber’s standards “are among the strictest in not just the US, but the world... where government standards don’t currently exist, we develop our own rigorous standards.” |
| Nurture | 7/2/2019 | Nurture holds its “ingredients to the highest standards, because your baby deserves the best.” |
| | 7/17/2019 | Nurture’s Happy Baby superfood Puffs “support brain health” |
| | 8/16/2019 | Nurture “partner[s] with pediatricians, dietitians, and children’s health experts [it] trust[s]—so your family can trust our organic food.” |
| | 11/25/2019 | Nurture represented that consumers “can skip all these chemicals when you buy organic food” |
| | 12/18/2019 | Nurture’s membership in the Baby Food Council is an indication of its commitment to “reduce heavy metals in baby food products as low as reasonably |

| Defendant | Date | Representation in Furtherance of Fraud |
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| | | achievable using best-in-class management practices.” |
| | Since at least 8/13/2020 | <p>Customers can have “peace of mind” because Nurture “source[s] high-quality organic ingredients” and has “rigorous and uncompromising quality standards” so consumers “can feel confident” in what they are feeding their family.</p> <p>Nurture emphasizes that it goes beyond USDA organic standards because it knows that what children eat in the first few years of life is “crucial.” Nurture assures parents that it holds itself to “strict standards” to help children “grow healthy and strong” through “test[ing] and thoroughly analyz[ing] every batch of food.”</p> <p>Parents can “trust” its organic food because Nurture “partner[s] with pediatricians, dietitians, and children’s health experts.”</p> |
| | 2/5/2021 | “We can say with the utmost confidence that all Happy Family Organics products are safe for babies and toddlers to enjoy, and we are proud to have best-in-class testing protocols in our industry.” |
| | Since at least 2/5/2021 | “We can say with the utmost confidence that all Happy Family Organics products are safe for babies and toddlers to enjoy and we are proud to |

| Defendant | Date | Representation in Furtherance of Fraud |
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| | | have best-in-class testing protocols in our industry. We only sell products that have been rigorously tested and we do not have products in-market with contaminant ranges outside of the limits set by the FDA.” |

404. Knowing that consumers valued the quality and safety of the baby food products they fed their children, Defendants misrepresented the health, safety, and contents of their products and omitted information about the testing that showed risky levels of toxic heavy metals.

405. Each Defendant engaged in false representations, fraud by omission, fraud by half-truth, and/or fraudulent concealment.

406. At the time of sale, each Defendant knew these representations were false, misleading, and/or omitted material facts.

407. Each Defendant deliberately withheld the information about the presence of toxic heavy metals in their baby food products to ensure that consumers would purchase their baby foods and to induct consumers to enter into a transaction.

408. The baby food purchased by Plaintiff was, in fact, defective and unsafe, because the baby food contained unsafe levels of toxic heavy metals including arsenic, cadmium, lead, and mercury.

409. Defendants each had a duty to disclose that their baby food products were defective and unsafe in that they contained unsafe levels of toxic heavy metals including arsenic, cadmium, lead, and mercury, because Defendants: (1) Possessed exclusive knowledge of the defects; (2) Intentionally concealed the presence of unsafe levels of toxic heavy metals through their deceptive marketing campaign that they designed to hide the presence of these hazardous substances from the Colorado Class; and/or (3) Made incomplete representations about the safety of their baby

1 food products while purposefully withholding material facts from the Colorado
2 Class that contradicted these representations.

3 410. These representations were also material because they were facts that
4 would typically be relied on by a person purchasing baby food. Given that the
5 product is baby food, and children and babies are particularly vulnerable,
6 Defendants knew that the safety, contents, and purity of the food being sold was
7 especially important. Indeed, they tailored their marketing and sales
8 communications directly to this issue, preying on the purchasers' vulnerability and
9 desperation as parents to do everything possible to feed their children healthy and
10 safe food.

11 411. Defendants' unfair or deceptive acts or practices were likely to deceive
12 reasonable consumers, including the Colorado Class, about the true safety and
13 reliability of Defendants' baby food products. Defendants intentionally and
14 knowingly misrepresented material facts regarding their baby food products with an
15 intent to mislead the Colorado Class.

16 412. The presence of unsafe levels of heavy metals in Defendants' baby food
17 products was material to the Colorado Class. Had the Colorado Class known that
18 their baby food had these serious safety defects, they would either not have
19 purchased Defendants' baby food, or would have paid less for them than they did.

20 413. All members of the Colorado Class suffered ascertainable loss caused
21 by Defendants' failure to disclose material information. The Colorado Class
22 overpaid for Defendants' baby food products and did not receive the benefit of their
23 bargain.

24 414. As a direct and proximate result of Defendants' violations of the
25 Colorado CPA, the Colorado Class has suffered injury-in-fact and/or actual
26 damage.

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1 415. Pursuant to Colo. Rev. Stat. § 6-1-113, the Colorado Class seeks
2 monetary relief against Defendants measured as the greater of (a) actual damages in
3 an amount to be determined at trial and discretionary trebling of such damages, or
4 (b) statutory damages in the amount of \$500 for each Colorado Class Member.

5 416. The Colorado Class also seeks attorneys’ fees and any other just and
6 proper relief available under the Colorado CPA.

7 **COUNT TEN:**
8 **VIOLATIONS OF KANSAS CONSUMER PROTECTION ACT**
9 **Kan. Stat. Ann. § 50-623, et seq.**

10 (As to All Defendants)

11 417. Plaintiff realleges and incorporates by reference each and every
12 allegation contained in the preceding paragraphs as if fully set forth herein.

13 418. This claim is on behalf of the Kansas Class.

14 419. Defendants are “suppliers” within the meaning of Kansas Consumer
15 Protection Act (“Kansas CPA”), Kan. Stat. Ann. § 50-624(1).

16 420. Kansas Class members are “consumers,” as defined by Kan. Stat. Ann.
17 § 50-624(b), who purchased Defendants’ baby food products.

18 421. The sale of the defective baby food products was a “consumer
19 transaction” within the meaning of Kan. Stat. Ann. § 50-624(c).

20 422. The Kansas CPA states “[n]o supplier shall engage in any deceptive act
21 or practice in connection with a consumer transaction,” KAN. STAT. ANN. § 50-
22 626(a), and that deceptive acts or practices include: (1) knowingly making
23 representations or with reason to know that “(A) Property or services have
24 sponsorship, approval, accessories, characteristics, ingredients, uses, benefits or
25 quantities that they do not have;” and “(D) property or services are of particular
26 standard, quality, grade, style or model, if they are of another which differs
27 materially from the representation;” “(2) the willful use, in any oral or written
28 representation, of exaggeration, falsehood, innuendo or ambiguity as to a material

1 fact;” and “(3) the willful failure to state a material fact, or the willful concealment,
2 suppression or omission of a material fact.” The Kansas CPA also provides that
3 “[n]o supplier shall engage in any unconscionable act or practice in connection with
4 a consumer transaction.” KAN. STAT. ANN. § 50-627(a).

5 423. In the course of their business, Defendants willfully failed to disclose
6 and actively concealed the dangerous levels of toxic heavy metals contained in their
7 baby foods. Defendants also engaged in unlawful trade practices by employing
8 deception; deceptive acts or practices; fraud; misrepresentations; concealment,
9 suppression, or omission of any material fact with intent that others rely upon such
10 concealment, suppression, or omission, in connection with the sale of Defendants’
11 baby food products.

12 424. As alleged above, Defendants knew of the heavy metal contamination
13 in their baby food products, while the Kansas Class was deceived by Defendants’
14 omission into believing the baby food products were safe, and the information
15 could not have reasonably been known by the consumer.

16 425. Defendants participated in misleading, false, or deceptive acts that
17 violated the Kansas CPA. By failing to disclose and actively concealing the
18 dangerous levels of toxic heavy metals contained in their baby foods, Defendants
19 engaged in unfair or deceptive practices prohibited by the Kansas CPA including
20 (1) representing that the baby foods had characteristics, uses, benefits, and qualities
21 which they do not have; (2) representing that the baby foods are of a particular
22 standard and quality when they were not; (3) advertising the baby foods with the
23 intent not to sell them as advertised; (4) willfully using, in any oral or written
24 representation, of exaggeration, falsehood, innuendo or ambiguity as to a material
25 fact; (5) willfully failing to state a material fact, or the willfully concealing,
26 suppressing or omitting a material fact; and (6) otherwise engaging in an
27 unconscionable act or practice in connection with a consumer transaction.

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1 426. Defendants knew or should have known that their conduct violated the
 2 Kansas CPA.

3 427. As set out above, Defendants made material statements about the safety
 4 of their baby food products that were either false or misleading.

5 428. Each Defendant has worked to defraud consumers by: (1) suppressing
 6 of information revealing the widespread contamination of baby food during
 7 manufacturing; (2) delaying the adoption of governmental standards for baby food
 8 manufacturers while falsely suggesting a commitment to adopt those very
 9 standards; (3) falsely suggesting that contamination of baby food products is
 10 “natural”; (4) falsely suggesting that they were committed to improving baby food
 11 safety as a way to prolong their fraud; (5) deceiving purchasers into believing that
 12 baby food with heavy metals is “safe,” “healthy,” and “pure”; and (6) conceal,
 13 camouflage, and prolong their ongoing food fraud.

14 429. As set out in Section III.D.3, when Defendants were unequivocally
 15 confronted with these facts, they continued to falsely market their products as
 16 “healthy,” “safe,” “pure,” even good for learning ability, and failed to exercise
 17 reasonable care to inform Plaintiff and members of the putative class of what was
 18 actually contained in the product. Defendants also expressly assured consumers
 19 about extensive testing measure deployed internally to ensure their products met
 20 these standards and purported governmental standards.

| Defendant | Date | Representation in Furtherance of Fraud |
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| Beech-Nut | Since at least 5/30/2017 | Beech-Nut baby food is “clean food” and “classic, natural and organic real food for babies and toddlers” “with just real, simple ingredients” |
| | ~8/16/2018 | “We want to reassure parents that Beech-Nut’s real food for babes is healthy, nutritious and safe.” |

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| Defendant | Date | Representation in Furtherance of Fraud |
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| | | <p>“We want to assure parents that . . . we have high confidence in the quality and standards we use in making our food.”</p> <p>“Currently, no government standard or recommendation exists for lead.”</p> |
| | 3/21/2018 | Beech-Nut products contain “nothing else” but the listed ingredient |
| | 3/28/2019 | Beech-Nut products are for consumers who are “label readers” and look for “natural ingredients only.” |
| | Since at least 7/13/2019 | <p>“what’s inside your baby food matters”</p> <p>Beech-Nut “offer[s] natural and organic products”</p> <p>“In fact, we conduct over 20 rigorous tests on our purees, testing for up to 255 pesticides and heavy metals (like lead, cadmium and other nasty stuff). Just like you would, we send the produce back if it’s not good enough.”</p> |
| | 10/17/2019 | <p>“Our process starts with high-quality fruits and vegetables that meet BNN’s own standards, which in some cases are 10 times stricter than those of the U.S. government. For example, we test for 255 common contaminants, such as lead, other heavy metals and pesticides, to confirm that all the ingredients delivered to us and used in our products comply with our standards. If they don’t, we send them back.”</p> |

| Defendant | Date | Representation in Furtherance of Fraud |
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| | 12/6/2019 | <p>Beech-Nut applied “rigorous testing protocols and heavy metal testing standards which are continuously reviewed and strengthened.”</p> <p>Beech-Nut encouraged the creation of the Baby Food Council to “conduct research and work to achieve a long-term reduction of heavy metals in the baby food supply chain” and that its current “top priority is to reduce heavy metals in the products manufactured and marketed by the member companies [including Defendant Beech-Nut] using best-in-class management practices.”</p> |
| | Since at least 6/14/2020 | Beech-Nut “only” uses “real,” “quality” ingredients |
| | 2/4/2021 | Beech-Nut “assured parents its baby food is ‘safe and nutritious.’” |
| | ~2/5/2021 | “We want to reassure parents Beech-Nut products are safe and nutritious.... We look forward to continuing to work with the FDA, in partnership with the Baby Food Council...” |
| | ~2/5/2021 | Beech-Nut products are “safe and nutritious” |
| Gerber | ~8/16/2018 | <p>“All of our foods meet our safety and quality standards, which are among the strictest in the world.”</p> <p>“Our rigorous standards are developed by evaluating the latest food safety guidance – from</p> |

| Defendant | Date | Representation in Furtherance of Fraud |
|-----------|--------------------------|---|
| | | sources like the Food and Drug Administration, Environmental Protection Agency, and international health authorities. Gerber also partners with our farmers and our ingredient and packaging suppliers to control, reduce and limit contaminants in all our foods.” |
| | 12/19/2019 | Gerber “takes all concerns related to safety very seriously, which is why all of our foods and beverages meet our safety and quality standards and conform to all regulatory compliance guidelines.” Gerber was “also a founding member of the Baby Food Council,” whose objective is “reducing heavy metals in the products manufactured by the member companies to as low as reasonably achievable using best-in-class management practices.” Defendant Gerber claimed that its “efforts with the Council represent our commitment to the safety of the baby food category.” |
| | Since at least 9/30/2020 | Gerber rice cereals will help support “learning ability” Gerber Clean Field Farming practices ensure that its baby foods are “safe and wholesome.” |

| Defendant | Date | Representation in Furtherance of Fraud |
|-----------|---------------------------|---|
| | 10/12/2020 | Gerber Clean Field Farming Standards allows it to “ensure that [our produce is] safe and wholesome for baby.” |
| | Since at least 11/25/2020 | <p>Gerber knows that parents want “the very best for your little one to ensure she reaches her full potential, and so do we.”</p> <p>Gerber represents to parents that it has adopted “super strict” farming practices “to ensure that their fruit and vegetable purees are not only nutritious, but also wholesome and safe for even the littlest bodies.”</p> <p>Gerber believes “that little ones deserve the highest standards set just for them” guides its mission to “deliver the very best fruits and veggies.”</p> <p>Gerber represents that its growing standards are the “strictest in the world” to ensure “quality control” because “what you get out is what you put in.”</p> <p>Gerber’s Clean Field Farming process “ensure[s] our purees are not only nutritious, but also wholesome and safe for every tiny tummy.”</p> |
| | ~2/4/2021 | Gerber has “been working together with other industry members, the Environmental Defense Fund, Healthy Babies Bright Futures and Cornell University” to identify “best agricultural practices” and create “a voluntary industry standard to reduce |

| Defendant | Date | Representation in Furtherance of Fraud |
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| | | <p>heavy metal levels in baby foods to the lowest level possible.”</p> <p>Gerber stated that “all of its food meets its safety standards, which it says are among the strictest in the world.”</p> |
| | 2/5/2021 | Gerber’s standards “are among the strictest in not just the US, but the world... where government standards don’t currently exist, we develop our own rigorous standards.” |
| Plum | 12/11/2017 | <p>“We believe that Plum’s products are safe to eat. Our testing confirmed that the averaged results for heavy metals in all tested Plum products gave concentrations that are typical for those ingredients – whether that’s a leafy green grown in your own garden or a bunch of carrots purchased at the farmer’s market. The results also demonstrate our tested products are below exposure limits set by certain domestic and international regulatory bodies.”</p> |
| | 2/12/2018 | The mission that Plum Organics promises is that it will provide “little ones” with “the very best food from the first bite.” |
| | 6/7/2019 | The back of the Plum Organics’ pouch lets customers “find out exactly what [you are] getting!” |

| Defendant | Date | Representation in Furtherance of Fraud |
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| | 12/11/2019 | “Campbell has conducted testing on every Plum Organics product on the market to ensure none exceed acceptable levels of arsenic, lead, cadmium, or mercury... To date, no Plum Organics foods have been found to be above exposure limits set by available domestic and international regulatory bodies” |
| | Since at least 8/12/2020 | Plum Organics baby foods are “absolutely” “safe to eat” and that “health and safety are always” its “top priorities.” “We believe ingredient testing allows for better control of the entire product and gets us ahead of any potential issues before it makes its way into a product. It’s just like when you make a recipe at home – you want to know everything that’s going into the recipe.” |
| | 2/5/2021 | “Campbell has conducted testing on every Plum Organics product on the market to ensure none exceed acceptable levels of arsenic, lead, cadmium, or mercury.” |
| Nurture | 7/2/2019 | Nurture holds its “ingredients to the highest standards, because your baby deserves the best.” |
| | 7/17/2019 | Nurture’s Happy Baby superfood Puffs “support brain health” |

| Defendant | Date | Representation in Furtherance of Fraud |
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| | 8/16/2019 | Nurture “partner[s] with pediatricians, dietitians, and children’s health experts [it] trust[s]—so your family can trust our organic food.” |
| | 11/25/2019 | Nurture represented that consumers “can skip all these chemicals when you buy organic food” |
| | 12/18/2019 | Nurture’s membership in the Baby Food Council is an indication of its commitment to “reduce heavy metals in baby food products as low as reasonably achievable using best-in-class management practices.” |
| | Since at least 8/13/2020 | <p>Customers can have “peace of mind” because Nurture “source[s] high-quality organic ingredients” and has “rigorous and uncompromising quality standards” so consumers “can feel confident” in what they are feeding their family.</p> <p>Nurture emphasizes that it goes beyond USDA organic standards because it knows that what children eat in the first few years of life is “crucial.” Nurture assures parents that it holds itself to “strict standards” to help children “grow healthy and strong” through “test[ing] and thoroughly analyz[ing] every batch of food.”</p> <p>Parents can “trust” its organic food because Nurture “partner[s] with pediatricians, dietitians, and children’s health experts.”</p> |

| Defendant | Date | Representation in Furtherance of Fraud |
|-----------|-------------------------|--|
| | 2/5/2021 | “We can say with the utmost confidence that all Happy Family Organics products are safe for babies and toddlers to enjoy, and we are proud to have best-in-class testing protocols in our industry.” |
| | Since at least 2/5/2021 | “We can say with the utmost confidence that all Happy Family Organics products are safe for babies and toddlers to enjoy and we are proud to have best-in-class testing protocols in our industry. We only sell products that have been rigorously tested and we do not have products in-market with contaminant ranges outside of the limits set by the FDA.” |

430. Knowing that consumers valued the quality and safety of the baby food products they fed their children, Defendants misrepresented the health, safety, and contents of their products and omitted information about the testing that showed risky levels of toxic heavy metals.

431. Each Defendant engaged in false representations, fraud by omission, fraud by half-truth, and/or fraudulent concealment.

432. At the time of sale, each Defendant knew these representations were false, misleading, and/or omitted material facts.

433. Each Defendant deliberately withheld the information about the presence of toxic heavy metals in their baby food products to ensure that consumers would purchase their baby foods and to induct consumers to enter into a transaction.

1 434. The baby food purchased by Plaintiff was, in fact, defective and unsafe,
2 because the baby food contained unsafe levels of toxic heavy metals including
3 arsenic, cadmium, lead, and mercury.

4 435. Defendants each had a duty to disclose that their baby food products
5 were defective and unsafe in that they contained unsafe levels of toxic heavy metals
6 including arsenic, cadmium, lead, and mercury, because Defendants: (1) Possessed
7 exclusive knowledge of the defects; (2) Intentionally concealed the presence of
8 unsafe levels of toxic heavy metals through their deceptive marketing campaign that
9 they designed to hide the presence of these hazardous substances from the Kansas
10 Class; and/or (3) Made incomplete representations about the safety of their baby
11 food products while purposefully withholding material facts from the Kansas Class
12 that contradicted these representations.

13 436. These representations were also material because they were facts that
14 would typically be relief on by a person purchasing baby food. Given that the
15 product is baby food, and children and babies are particularly vulnerable,
16 Defendants knew that the safety, contents, and purity of the food being sold was
17 especially important. Indeed, they tailored their marketing and sales
18 communications directly to this issue, preying on the purchasers' vulnerability and
19 desperation as parents to do everything possible to feed their children healthy and
20 safe food.

21 437. Defendants' unfair or deceptive acts or practices were likely to deceive
22 reasonable consumers, including the Kansas Class, about the true safety and
23 reliability of Defendants' baby food products. Defendants intentionally and
24 knowingly misrepresented material facts regarding their baby food products with an
25 intent to mislead the Kansas Class.

26 438. The presence of unsafe levels of heavy metals in Defendants' baby food
27 products was material to the Kansas Class. Had the Kansas Class known that their
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1 baby food had these serious safety defects, they would either not have purchased
2 Defendants' baby food, or would have paid less for them than they did.

3 439. All members of the Kansas Class suffered ascertainable loss caused by
4 Defendants' failure to disclose material information. The Kansas overpaid for
5 Defendants' baby food products and did not receive the benefit of their bargain.

6 440. As a direct and proximate result of Defendants' violations of the
7 Kansas CPA, the Kansas Class has suffered injury-in-fact and/or actual damage.

8 441. Pursuant to KAN. STAT. ANN. § 50-634, the Kansas Class seeks
9 monetary relief against Defendant measured as the greater of (a) actual damages in
10 an amount to be determined at trial and (b) statutory damages in the amount of
11 \$10,000 for each Kansas Class Member.

12 442. The Kansas Class also seeks attorneys' fees and any other just and proper
13 relief available under the Kansas CPA.

14 **DEMAND FOR JURY TRIAL**

15 443. Plaintiff is entitled to and hereby demand a jury trial in this matter.

16 **PRAYER FOR RELIEF**

17 Wherefore, Plaintiff respectfully requests that this Court will:

- 18 1. Enter judgment against Defendants, jointly and severally, in such
19 amounts as will fully and adequately compensate Plaintiff for the
20 damages they have suffered, in an amount to be determined at trial;
- 21 2. Award Plaintiff punitive damages against Defendants, jointly and
22 severally, in an amount to be determined by the jury for Defendants'
23 violations of federal and state law;
- 24 3. Award Plaintiff damages and treble damages under the RICO Act;
- 25 4. Award Plaintiff injunctive relief that requires Manufacturer Defendants
26 to test and inspect final baby food prior to sale and establish
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1 supervision and compliance protocols that prevent the sale of baby food
2 products contaminated with unsafe levels of toxic heavy metals;

- 3 5. Award Plaintiff pre-judgment and post-judgment interest;
4 6. Award Plaintiff their actual expenses of litigation, including reasonable
5 attorney's fees;
6 7. Appoint Plaintiff as class representatives;
7 8. Appoint Plaintiff's counsel as counsel for the class;
8 9. Award Plaintiff such other and further relief as the Court deems just
9 and proper.

10
11 Dated: April 7, 2021

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13 Respectfully submitted,

14 Attorneys for Plaintiffs

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16 _____
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18 (CSBN 126246)
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20 Westlake Village, CA 91361
21 Telephone: 310-849-3135
22 keith.robinson@karlawgroup.com

23 /s/ Ruth Anne French-Hodson

24 Ruth Anne French-Hodson, *pro hac vice* forthcoming
25 Sharp Law, LLP
26 5301 West 75th Street
27 Prairie Village, Kansas 66208
28 Telephone: 913-901-0505
Facsimile: 913-901-0419
rafrenchhodson@midwest-law.com

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DEMAND FOR JURY TRIAL

Plaintiff on behalf of herself and others similarly situated demands a trial by jury for all issues so triable under the law.

Dated: April 7, 2021

Respectfully submitted,

By: /s/ Keith A. Robinson
Keith A. Robinson
Attorney for Plaintiff

EXHIBIT A



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



Staff Report

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

February 4, 2021

oversight.house.gov

EXECUTIVE SUMMARY

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

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

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

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

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

FINDINGS

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

5. The Subcommittee makes the following recommendations:

- **Mandatory testing**—Baby food manufacturers should be required by FDA to test their finished products for toxic heavy metals, not just their ingredients;
- **Labeling**—Manufacturers should be required by FDA to report levels of toxic heavy metals on food labels;
- **Voluntary phase-out of toxic ingredients**—Manufacturers should voluntarily find substitutes for ingredients that are high in toxic heavy metals, or phase out products that have high amounts of ingredients that frequently test high in toxic heavy metals, such as rice;
- **FDA standards**—FDA should set maximum levels of toxic heavy metals permitted in baby foods. One level for each metal should apply across all baby foods. And the level should be set to protect babies against the neurological effects of toxic heavy metals; and
- **Parental vigilance**—Parents should avoid baby foods that contain ingredients testing high in toxic heavy metals, such as rice products. Instituting recommendations one through four will give parents the information they need to make informed decisions to protect their babies.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

A. Inorganic Arsenic

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

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

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

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

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

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

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

¹⁰ *Id.*

¹¹ *Id.*

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

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

B. Lead

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

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

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

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

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

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

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

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

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

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

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

C. Cadmium

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

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

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

D. Mercury

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

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

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

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

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

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

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

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

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

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

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

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

A. Inorganic Arsenic

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

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

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

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

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

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

³¹ Food and Drug Administration, *Arsenic in Food and Dietary Supplements* (online at www.fda.gov/food/metals-and-your-food/arsenic-food-and-dietary-supplements) (accessed Jan. 26, 2021).

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

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

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

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

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

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

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

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

³⁴ *Id.*

³⁵ *Id.*

³⁶ *Id.*

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

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

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

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

Summary of Nurture’s Inorganic Arsenic Results

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

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

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

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

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

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

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

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

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

³⁸ *Id.*

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

⁴⁰ *Id.*

⁴¹ *Id.*

⁴² *Id.*

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

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

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

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

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

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

⁴⁴ *Id.*

⁴⁵ *Id.*

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

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

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

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

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

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

Gerber Products Company Test Results (Excerpted Entries)⁴⁹

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

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

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

⁴⁹ *Id.*

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

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

B. Lead

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

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

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

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

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

Proposed and Existing Lead Standards

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

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

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

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

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

⁵⁴ *Id.*

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

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

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

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

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

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

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

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

⁵⁵ *Id.*

⁵⁶ *Id.*

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

⁵⁸ *Id.*

⁵⁹ *Id.*

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

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

⁶⁰ *Id.*

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

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

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

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

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

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

| Lab Results Date | Vendor Name | Item Number | Product Description | Status | Comments on Status | Lab | Spec Based On | Arsenic Spec Limit (ppb) | Arsenic Result (ppb) | Cadmium Spec Limit (ppb) | Cadmium Result (ppb) | Lead Spec Limit (ppb) | Lead Result (ppb) |
|------------------|-------------------|-------------|---------------------|--------------------|--------------------------------|------------------|---------------|--------------------------|----------------------|--------------------------|----------------------|-----------------------|-------------------|
| Nov/26/2019 | Wright Enrichment | 5316067 | Vitamin Pre Mix | Deviation Approved | Accepted on deviation 20190236 | Eurofins/Covance | As Purchased | 100 | 223 | 100 | 60.5 | 100 | 352 |

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

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

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

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

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

⁶² *Id.*

⁶³ *Id.*

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

Gerber Products Company Test Results (Excerpted Entries)⁶⁵

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

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

Gerber Products Company Test Results (Excerpted Entries)⁶⁶

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

⁶⁵ *Id.*

⁶⁶ *Id.*

C. Cadmium

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

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

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

Proposed and Existing Cadmium Standards

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

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

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

⁶⁷ Environmental Protection Agency, *Ground Water and Drinking Water* (online at www.epa.gov/ground-water-and-drinking-water/national-primary-drinking-water-regulations) (accessed Jan. 26, 2021); 21 C.F.R. § 165 (2019) (online at www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?fr=165.110).

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

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

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

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

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

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

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

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

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

⁷² *Id.*

⁷³ *Id.*

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

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

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

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

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

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

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

⁷⁵ *Id.*

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

⁷⁷ *Id.*

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

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

Gerber Products Company Test Results (Excerpted Entries)⁷⁹

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

D. Mercury

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

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

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

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

⁷⁹ *Id.*

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

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

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

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

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

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

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

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

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

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

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

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

⁸³ *Id.*

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

⁸⁵ *Id.*

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

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

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

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

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

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

⁸⁶ *Id.*

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

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

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

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

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

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

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

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

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

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

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

⁹¹ *Id.*

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

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

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

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

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

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

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

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

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

⁹⁴ *Id.*

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

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

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

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

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

⁹⁶ *Id.*

⁹⁷ *Id.*

⁹⁸ *Id.*

⁹⁹ *Id.*

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

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

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

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

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

¹⁰⁰ *Id.*

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

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

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

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

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

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

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

| Lab Results Date | Vendor Name | Item Number | Product Description | Status | Comments on Status | Lab | Spec Based On | Lead Spec Limit (ppb) | Lead Result (ppb) |
|------------------|------------------------|-------------|------------------------|----------|-------------------------------------|--------|---------------|-----------------------|-------------------|
| Aug/3/2017 | Montana Flour & Grains | 5303053 | Org Kamut Flour | Accepted | | Deibel | As consumed | 200 | <100 |
| Jul/19/2017 | Firebird Artisan Mills | 57200 | Org Green Lentil Flour | Accepted | Calculated Levels on consumed basis | Deibel | As consumed | 200 | 110 |
| Aug/21/2017 | Grain Millers | 5308029 | Org Brown Flax Milled | Accepted | Calculated Levels on consumed basis | Deibel | As consumed | 200 | <100 |
| Jul/15/2017 | Firebird Artisan Mills | 5303042 | Org Quinoa Flour | Accepted | | Deibel | As consumed | 200 | <100 |
| Jul/13/2017 | Firebird Artisan Mills | 5303042 | Org Quinoa Flour | Accepted | spec for lead was 200ppb | Deibel | As consumed | 200 | 120 |

¹⁰⁴ *Id.*

¹⁰⁵ *Id.*

¹⁰⁶ *Id.*

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

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

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

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

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

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

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

¹⁰⁷ *Id.*

¹⁰⁸ *Id.*

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

¹¹⁰ *Id.*

¹¹¹ *Id.*

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

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

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

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

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

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

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

¹¹² *Id.*

¹¹³ *Id.*

¹¹⁴ *Id.*

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

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

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

A. Walmart (Parent’s Choice Brand)

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

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

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

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

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

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

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



B. Campbell (Plum Organics Brand)

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

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

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

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

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

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

¹¹⁹ *Id.*

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

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

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

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

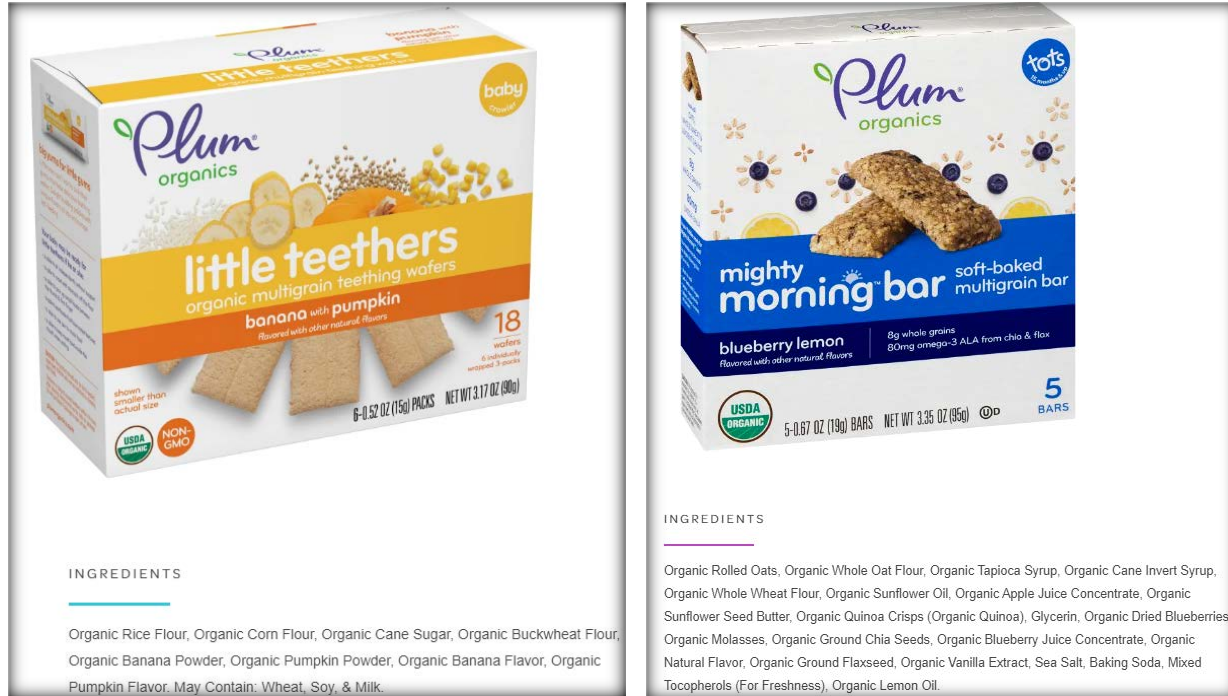
| Brand | Food | Food type | Arsenic (total, ppb) | Arsenic (inorganic, ppb) | Lead (ppb) | Cadmium (ppb) | Mercury (total, ppb) | Metro area where purchased | Retailer |
|---------------|---|--|----------------------|--------------------------|------------|---------------|----------------------|----------------------------|----------|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

¹²⁰ *Id.*

¹²¹ *Id.*

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

*Plum Organics' Foods That Tested High in Toxic Heavy Metals*¹²³



C. Sprout Organic Foods

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

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

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

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

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

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

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

Sprout Organic Food That Tested High in Toxic Heavy Metals¹²⁶



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

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

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

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

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

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

A. Mercury and Cadmium

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

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

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

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

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

¹²⁹ *Id.*

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

¹³¹ Environmental Protection Agency, *Ground Water and Drinking Water* (online at www.epa.gov/ground-water-and-drinking-water/national-primary-drinking-water-regulations) (accessed Jan. 26, 2021).

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

B. Lead

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

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

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

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

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

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

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

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

¹³⁵ *Id.*

¹³⁶ *Id.*

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

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

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

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

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

C. Arsenic

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

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

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

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

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

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

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

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

Inorganic Arsenic in Rice Cereals for Infants (Aug. 2020) (online at www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-action-level-inorganic-arsenic-rice-cereals-infants).

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

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

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

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

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

¹⁴⁵ Food and Drug Administration, *Arsenic in Food and Dietary Supplements* (online at www.fda.gov/food/metals-and-your-food/arsenic-food-and-dietary-supplements) (accessed Jan. 26, 2021).

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

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

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

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

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

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

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

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

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

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

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

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

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

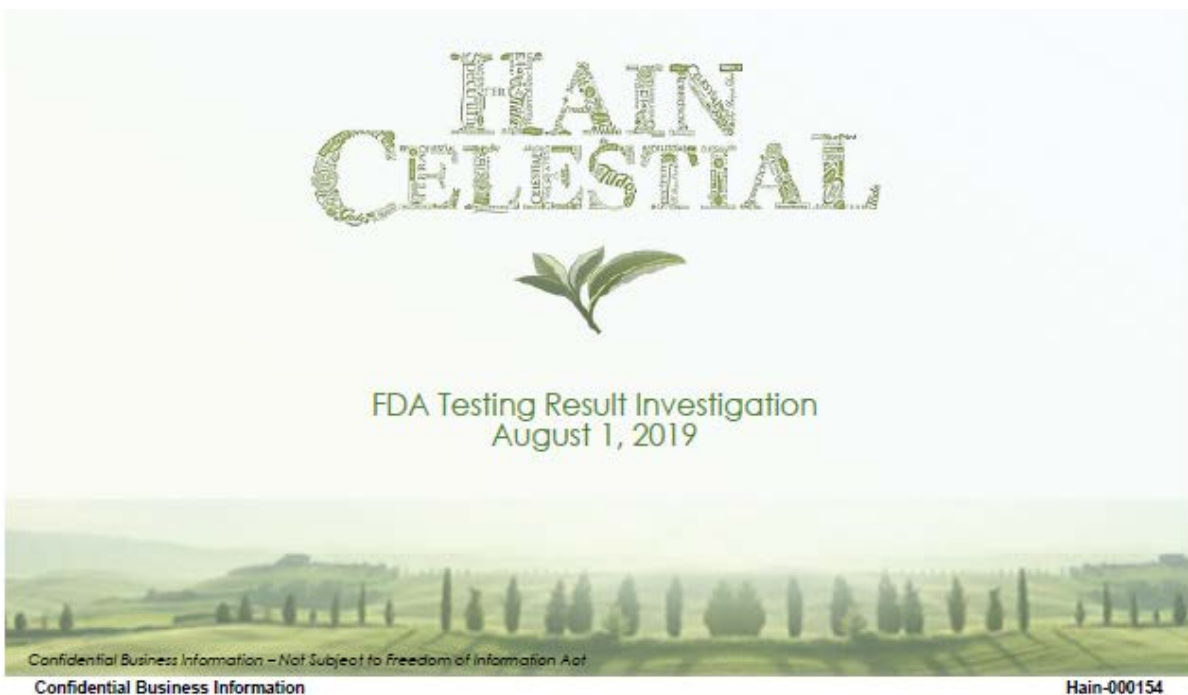
D. The Trump Administration Ignored A Secret Industry Presentation About Higher Risks Of Toxic Heavy Metals In Baby Foods.

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

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

¹⁵⁰ *Id.*

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



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

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

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

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

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

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

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

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

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

| FDA Data | | | | | Estimate % Avg FG Increase from Avg Raw | Track & Trace Data | | | | | |
|-------------------|--------------|------------|--------------------------------|---------------|---|--------------------|-----------|-------------------|----------------------|----------------------------|----------------|
| FDA Sample Number | Best By Date | Lot number | FDA FG Inorganic Arsenic (ppb) | Avg FG Result | | Packaging Date | WIP Batch | Rice Flour Lot #s | Type of Arsenic Test | Raw Material Results (ppb) | Avg Raw Result |
| 1017814 | 3/2/19 | BN A 0636 | 94 | 80.3 | 43% | 9/8/17 | 199987 | B160004661 | Total Arsenic | 54 | 56.3 |
| 1038929 | | BN C 1139 | 83 | | | | | B160004870 | Total Arsenic | 58 | |
| 1039633 | | BN F 1648 | 64 | | | | | B160004759 | Total Arsenic | 57 | |
| | B160004659 | | | Total Arsenic | 54 | | | | | | |
| | 197594 | B160004870 | Total Arsenic | 58 | | | | | | | |
| | | B160004759 | Total Arsenic | 57 | | | | | | | |
| 1039750 | 3/8/19 | BN E | 74 | 74.0 | 29% | 9/14/17 | 200408 | B160004871 | Total Arsenic | 60 | 57.3 |
| 1041752 | 3/20/19 | BN G | 92 | 96.0 | 57% | 9/26/17 | 200651 | B160005149 | Total Arsenic | 65 | 61.3 |
| 1037933 | | BN E 1536 | 67 | | | | | B160004873 | Total Arsenic | 58 | |
| 1041751 | 3/21/19 | BN B 0832 | 108 | B160005157 | Total Arsenic | 62 | | | | | |
| 1038677 | | BN B 0932 | 116 | B160004871 | Total Arsenic | 60 | | | | | |
| 1026932 | | BN D 1248 | 97 | B160005148 | Total Arsenic | 61 | | | | | |
| | | | | B160004872 | Total Arsenic | 55 | | | | | |
| 1044380 | 4/11/19 | BH C | 100 | 100.0 | 69% | 10/18/17 | 201873 | B160005152 | Total Arsenic | 61 | 59.0 |
| 1024309 | 4/27/19 | BN I 2216 | 129 | 129.0 | 93% | 11/3/17 | 204146 | B160005305 | Total Arsenic | 69 | 67.0 |
| 1024210 | 6/6/19 | BN I 2241 | 94 | 101.0 | 61% | 12/13/17 | 206697 | B160005306 | Total Arsenic | 76 | |
| | | | | | | | | B160005512 | Total Arsenic | 62 | |
| | | | | | | | | B160005152 | Total Arsenic | 61 | |
| 547103 | 6/7/19 | BN I 2339 | 115 | 101.0 | 61% | 12/14/17 | 206697 | B160005515 | Total Arsenic | 63 | 62.7 |
| 1013927 | | BN E 1540 | 92 | | | | | B160005513 | Total Arsenic | 60 | |
| 1026516 | | BN H 2123 | 104 | | | | | B160005150 | Total Arsenic | 65 | |
| 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 | |
| 1063061 | 7/19/19 | BN J | 115 | 115.0 | 43% | 1/25/18 | 208594 | B160005581 | Total Arsenic | 55 | |
| | | | | | | | | 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 |
| | | | | | | | | B160006203 | 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 | |
| | | | | | | | | 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.”¹⁵⁵ They are not correlated because the finished goods can contain as much as double the amount of arsenic as the raw ingredients.

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

¹⁵⁴ *Id.*

¹⁵⁵ *Id.*

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

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

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

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

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

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

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

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

¹⁵⁶ *Id.*

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

¹⁵⁸ *Id.*

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

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

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

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

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

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

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

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

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

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

¹⁶¹ *Id.*

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

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

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

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

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

The Subcommittee recommends the following:

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

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

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

VII. CONCLUSION

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

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

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

EXHIBIT B



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

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.

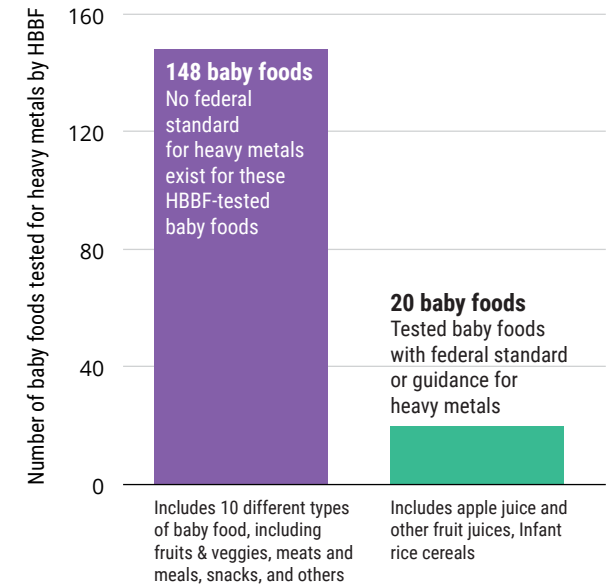
PARENTS, BABY FOOD COMPANIES, FARMERS, AND FDA ALL HAVE A ROLE IN MEASURABLY REDUCING BABIES' EXPOSURES.

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



13
types of baby food



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.

- 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.

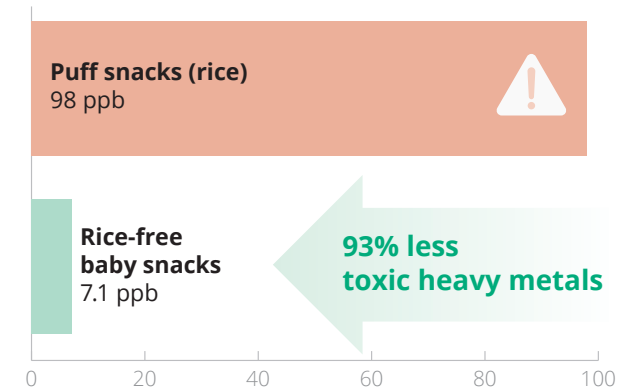
1 Puffs and other snacks made with rice flour contain arsenic, lead and cadmium at relatively high levels compared to other baby foods. Parents can reduce children’s exposures by choosing rice-free packaged snacks instead, which have 93 percent less toxic metal residues, on average. Multi-grain snacks 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.

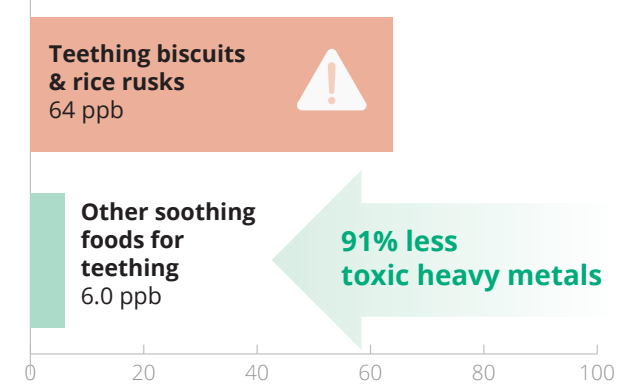
3 Infant rice cereal is the top source of arsenic in infant’s diets. HBBF’s 2017 study of infant cereals found that **non-rice and multi-grain varieties** on grocery shelves nationwide—including **oatmeal, corn, barley, quinoa, and others**—contain 84 percent less inorganic arsenic than leading brands 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).

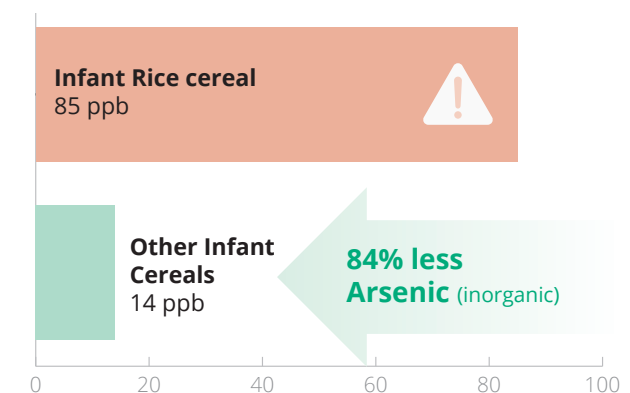
1 SNACKS



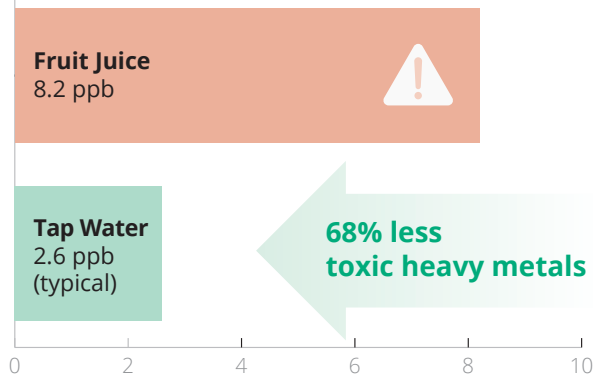
2 TEETHING FOODS



3 CEREAL

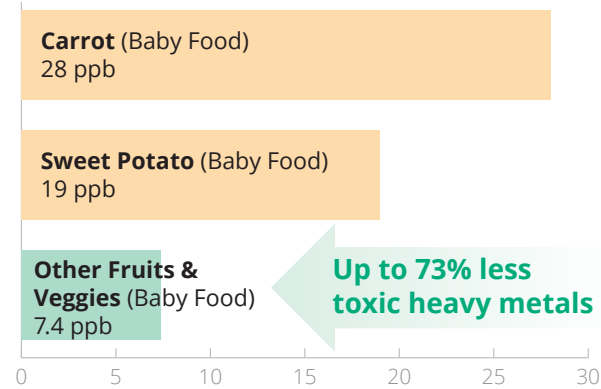


4 DRINKS



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?

| What did our tests of 168 baby foods find? | 1. Widespread detections of toxic heavy metals 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. | | | | 2. Few enforceable limits for baby food For 10 of 13 baby food types tested, there is no FDA guidance on safe limits for toxic heavy metals. | | | | 3. Gaps in protecting babies’ health 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 |
| Puffs and other snacks | ▲ 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. |
| Teething biscuits, including rice rusks | ▲ 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 | |
| Infant formula | ▲ 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 | |
| Infant rice cereal | ▲ 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 | |
| Infant cereal - multi & single non-rice grains | ▲ 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 | |
| Meals (veggies, grains, pasta, meat combos) | ▲ 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 | |
| Veggies | ▲ 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 | |
| Fruits | ▲ 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 | |
| Mixed fruits and veggies | ▲ 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 | |
| Meat (jars) | ▲ 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 | |
| Apple juice | ▲ 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. | |
| Juice - 100% fruit, non-apple | ▲ 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. | |
| Other drinks for babies and toddlers | ▲ 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 |
|--|--|--------------------------------|----------------------|--------------------------|------------|---------------|----------------------|----------------------------|----------------------|
| Infant cereal: rice | | | | | | | | | |
| Beech-Nut | Rice Single Grain Baby Cereal - Stage 1, from about 4 months | Cereal - rice | 117 | 86 | 3.5 | 5.4 | 0.582 | Charlottesville, VA | Wegmans |
| 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 |
| Infant cereal: multi- and single non-rice grain | | | | | | | | | |
| 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 |
| Infant formula | | | | | | | | | |
| 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 [†] | 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 |
| Vegetable - single, carrot | | | | | | | | | |
| 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 |
| Vegetable - single, sweet potato | | | | | | | | | |
| Beech-Nut | Naturals Just Sweet Potatoes - Stage 1, from about 4 months | Veggie - single - sweet potato | 2.4 * | -- | 14.1 | 4 | < 0.136 | Albany, NY | buybuyBABY |
| Beech-Nut | Organics Just Sweet Potatoes - Stage 1, from about 4 months | Veggie - single - sweet potato | 3.8 * | -- | 7.3 | 2.7 | < 0.142 | Cincinnati, OH | Kroger |
| Beech-Nut | Classics Sweet Potatoes - Stage 2, from about 6 months | Veggie - single - sweet potato | 2.8 * | -- | 24.1 | 3.4 | < 0.138 | Portland, OR | Fred Meyer |
| 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 |
| Vegetable - single (other than carrot, sweet potato) | | | | | | | | | |
| 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 |
|----------------------------------|--|--------------------------|----------------------|--------------------------|------------|---------------|----------------------|----------------------------|----------------------|
| Fruit - single | | | | | | | | | |
| 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 |
| Fruit & Veggie, Mixed | | | | | | | | | |
| 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 |
| Juice - 100% apple | | | | | | | | | |
| 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 |
| Kidgets | Toddler Apple Juice from Concentrate | Juice - 100% fruit | <2.2 | -- | 0.6 * | <0.5 | <0.141 | San Diego, CA | Family Dollar |
| Juice - 100% fruit juice, non-apple or mixed | | | | | | | | | |
| 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 |
| Drinks - not 100% fruit juice | | | | | | | | | |
| 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 Nutrituional 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 |
| Meals, including fruits & veggies with grains | | | | | | | | | |
| 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 |
|--|--|--|----------------------|--------------------------|------------|---------------|----------------------|----------------------------|----------------------|
| Meat | | | | | | | | | |
| 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 |
| Snacks - Puffs | | | | | | | | | |
| 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 |
| Snacks - Teething biscuits & rice rusks/cakes | | | | | | | | | |
| 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 |
| Snacks - Other (yogurt, biscuits, bars) | | | | | | | | | |
| 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 |
| Supplement | | | | | | | | | |
| Gerber | Soothe Probiotic Colic Drops | Supplement | 4.4 * | -- | < 0.5 | < 0.5 | < 0.139 | Washington, DC | walmart.com |

| Notes |
|---|
| <p>The symbol "<" 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? |
|--|------------------------------|--|
| Metals combinations: Recent studies of children’s exposures to toxic-metal combinations and impacts to the developing brain | | |
| 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. |
| Arsenic: Recent studies of children’s exposures to arsenic and impacts to the developing brain | | |
| 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. |
| Cadmium: Recent studies of children’s exposures to cadmium and impacts to the developing brain | | |
| 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? |
|---|----------------|--|
| Lead: Recent studies of children’s exposures to lead and impacts to the developing brain | | |
| 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. |
| Mercury: Recent studies of children’s exposures to mercury and impacts to the developing brain | | |
| 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://brooksupplied.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 (H₂O₂) and concentrated nitric acid (HNO₃) 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, brooksupplied.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 (SnCl₂) 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.

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 “<” 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 file¹ 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).

¹ 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 | | |
| Infant rice cereal (dry, white and brown rice) | | | | | | | | | | | | |
| 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 | | | | |
| Other cereals (dry) | | | | | | | | | | | | |
| 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 |
| Infant rice cereal (dry, prepared) | | | | | | | | | | | | |
| 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) |
| Other cereals (dry, prepared) | | | | | | | | | | | | |
| 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 | | |
| Carrot, baby food | | | | | | | | | | | | |
| 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 | |
| Sweet potato, baby food | | | | | | | | | | | | |
| 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 | |
| Other fruits and vegetables, baby food | | | | | | | | | | | | |
| 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) |
| Fruit juice | | | | | | | | | | | | |
| 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 | |
| Alternative to fruit juice - Tap water | | | | | | | | | | | | |
| 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) |
| Puffs (rice) | | | | | | | | | | | | |
| 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 | | |
| Teething biscuits (rice) and rice rusks | | | | | | | | | | | | |
| 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 | |
| Alternatives to teething biscuits | | | | | | | | | | | | |
| 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 | |
| Non-rice snacks and teethers | | | | | | | | | | | | |
| 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 |
| Other snacks recommended as alternatives to rice-based snacks | | | | | | | | | | | | |
| 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 |
|--|
| * Sample-weighted averages account for the 3 individual samples that comprise each TDS composite sample. 1. NT = not tested 2. "HBBF 2019 Baby Food Study" refers to this study; individual sample data are shown in Appendix A. 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. 4. Average inorganic arsenic is calculated from average total arsenic value in cases where HBBF lacked access to data for individual samples. 5. Calculations of average levels for FDA TDS data are calculated using the Xue (2010) method for treatment of results below the quantitation limit. 6. Ratio of inorganic to total arsenic is the sample-weighted average of data from HBBF 2017 and this study. 7. From Cubadda 2017: Inorganic arsenic is 90% total for vegetables, 80% total for fruit. 85% is used here. 8. Metals levels shown are averages from HBBF tap water testing from over 700 homes in 43 states. 9. Inorganic arsenic for one puffs sample was not measured, and was instead calculated from the change FDA 2013-14 study ratio (EDF 2018). 10. Averages are derived from sample data available at EDF 2018. 11. Inorganic arsenic for 4 samples were not measured, and were instead calculated from the FDA 2013-14 study ratio (EDF 2018). 12. Averages are derived from sample data available at EDF 2018. |

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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

EXHIBIT C

Baby Food: *A Puree of Plasticizers and Heavy Metals*

Introduction

There is nothing in the world more vulnerable and sensitive to the harsh environment than a baby. Though they may appear complete on the outside, on the inside their immune system and brain functions are still developing. The events immediately following birth all the way to three years old can affect a child's health and well-being for the rest of his or her life¹. The immune system is all of the cells and proteins in the body that fight off infections within the body². Brain functions are essential to control body movements, learn about the outside world, and to communicate³. These unique sensitivities need to be protected, especially in terms of nutrition and what enters a baby's body. Parents are given the important responsibility of introducing the first outside foods to their baby in the form of "baby food." Baby food can come in many types: cereals, jars, pouches, formulas, drinks, and snacks⁴. While many parents still feed their babies conventional baby food, there is an increasing shift to organic baby food and hand-making baby food in the home. In fact, the market for organic baby food in North America is projected to become increasingly popular in the next four years due to concerns about

farming practices and fear of dangerous chemicals reaching the food supply⁵. On the other side of the spectrum, some parents have started to make purees with fruits and vegetables in their own kitchens. This eliminates the worries of harmful preservatives, dyes, and possible food allergies from a baby's diet⁶. However, it can be costly and time consuming to prepare. Conventional store-bought baby food is a cheaper or more convenient option, but can still hold dangers of its own. Imported baby food and formulas might pose serious health risks when not reviewed by the FDA⁷. This means they may be tainted with additives that are prohibited by FDA standards or are not meeting FDA food safety guidelines⁷.

Increase in Attention to Heavy Metals

Being a parent to a baby is stressful enough without worrying if the food you are feeding is contaminated with heavy metals. However, guidelines regarding heavy metal content and food safety in baby foods didn't always exist. The first regulation made specifically for baby foods was the Infant Formula Act of 1980 that ensured the quality of formulas produced and the nutritional value⁸. Another major milestone for baby food safety was in the 1990s when President Clinton signed the Food Quality Inspection Act⁹. This unique act required the EPA to disclose all food exposures to pesticides and ensure that baby and infant food was safe and free of these residues⁹. Following this act, many pesticides have been banned in food production and their residues substantially lessened⁹. Now, in the modern age, food safety quality for babies and infants is still a problem. An organization

“The events immediately following birth all the way to three years old can affect a child's health and well-being for the rest of his or her life¹.”

“The Healthy Babies Bright Futures 2019 of 168 baby foods revealed that 95% of baby foods contained at least one heavy metals, and 25% contained all four.”

called the Healthy Babies Bright Futures released a study in 2019 that shocked the world and terrified parents. Their investigation of 168 different baby foods found that 95% contained at least one heavy metal¹⁰. The Healthy Babies Bright Futures 2019 of 168 baby foods revealed that 95% of baby foods contained at least one heavy metals, and 25% contained all four. Even scarier, they found that one in four baby foods contained all four heavy metals: arsenic, lead, mercury, and cadmium¹⁰. Healthy Babies Bright Futures urged parents to push for more FDA regulations in regards to the production of foods for infants and babies. Many Americans do not yet understand the dangers of heavy metal exposure and the long-term effect. In 2014, after switching from the Detroit water system to receiving water from the Flint River, residents of Flint, Michigan were poisoned with lead-contaminants coming through their taps¹¹. This horrible crisis was the result of poor water testing and quality control systems¹¹. For 18 months, the complaints from residents of rashes, hair loss, and skin irritations were discredited. The long-term effects of the Flint, Michigan lead exposure has been reduced IQ and a variety of cognitive and

“The long-term effects of the Flint, Michigan lead exposure has been reduced IQ and a variety of cognitive and behavioral issues.”

behavioral issues. For children, long term effects of the lead exposure has led to lower IQ levels as well as a variety of cognitive and behavioral issues¹².

Health Risks Associated with Dietary and Heavy Metal Exposure in Children

Children and babies are vulnerable to bodily harm caused by exposure to heavy metals. These effects can appear in many forms depending on the length of time and potency of exposure. The “big four” of heavy metals are lead, arsenic, cadmium, and mercury. The impact of heavy metal exposure on children differs from adults because children are still developing. Lead exposure affects children by impairing their cognitive and mental capabilities, kidney damage, and anemia¹³. Arsenic exposure, commonly caused by contaminated water, has been linked to long-term effects such as cancers, cardiovascular disease, and impaired cognitive ability¹⁴. Cadmium, which is difficult for the body to

“Mercury is highly toxic to all systems of the body, but a child’s central nervous system is most vulnerable to mercury poisoning¹⁶.”

eliminate, can cause impaired immunity and motor skills in children¹⁵. As the children grow into adults with continued exposure, the results can develop into kidney toxicity and osteoporosis¹⁵. The last heavy metal, mercury, can be the most dangerous and highly toxic¹⁶. Mercury is highly toxic to all systems of the body, but a child’s central nervous system is most vulnerable to mercury poisoning¹⁶, the impacts of which are likely to be

permanent. No safe level of Mercury is known to exist¹⁶. In the past, heavy metals were used in our daily lives and the adverse effects were not known. Since then, these elements are extremely regulated for public health and safety reasons.

Health Risks Associated with Pesticide and Plasticizer Exposure in Children

Heavy metals are not the only contaminant in foods that have been known to cause long-term health defects. Pesticides are used to control and eliminate pests and weeds which could carry diseases from crops¹⁷. However, pesticide use can also cause residues to linger within the crops and enter the body through the human consumption of agricultural products. An example is glyphosate, which is used as a major herbicide with the tradename Roundup. While very effective at controlling weeds, exposure to residues found in foods have been linked to the development of cancers, kidney and liver damage, and reproductive issues¹⁸. Eating just one tomato contaminated with glyphosate residues is unlikely to cause immediate affects; instead, it is the constant consumption of contaminated foods which compounds the negative impact over time. Many foods can be contaminated with glyphosate. Over 250 million pounds of glyphosate is used each year on crops¹⁹ such as corn, soybeans, oats, as well as various fruits, nuts, and veggies²⁰. There are also many other pesticides, herbicides, and insecticides out there that can leave residues. According the World Health Organization, "Insecticides tend to be more toxic to humans than herbicides²¹," meaning that not all pesticides were created equal and they have varying levels of toxicity.

On the other end of the spectrum are acrylamides and plasticizers. Acrylamides are a chemical compound that forms during high temperature cooking such as baking and frying as the byproduct of sugars and amino acids that were already present in the foods²². Unfortunately, acrylamides do have negative health risks. Organizations such as the US National Toxicity Program and the EPA list acrylamides as reasonably likely to be a carcinogen, or cancer-causing substance²³.

“Over 250 million pounds of glyphosate is used each year on crops¹⁹ such as corn, soybeans, oats, as well as various fruits, nuts, and veggies²⁰.”

However, even with the severity of the side effects, the FDA does not have regulations in place to protect consumers, only recommendations²⁴. Another high-risk threat to consumers is plasticizers which are components added to plastics to make them more flexible and increase their overall strength²⁵. Sometimes, food and beverages come into contact and are contaminated with plasticizers; either in the production process or through their packaging²⁶. Plasticizers have been linked to endocrine disruption and the formation of cancers²⁷.

How Our Study Was Conducted

Clean Label Project conducted a study of over 530 baby and toddler food products such as formulas, cereals, jars, pouches, juices, drinks, and snacks. These products were chosen because they were the most commonly purchased by consumers. Both

Methodology

| Contaminant | Instrumentation | Test Method | LOD/LOQ |
|---|-----------------|--------------------------|----------|
| Heavy Metals (Total Arsenic, Cadmium, Lead, and Mercury) | ICP-MS | EPA 6020 modified | ≤ 4 ppb |
| Pesticides | LC-MSMS | AOAC 2007.01 modified | ≤ 10 ppb |
| Acrylamide | LC-MSMS | EA_AC02 | ≤ 40 ppb |
| BPA/BPS | LC-MSMS | EA_BP02 | ≤ 40 ppb |

the conventional and organic products were chosen for the study. Instead of requesting product from the various companies to test, Clean Label Project follows the consumer chain of custody; which means purchasing samples in the same way that the consumer buys their baby foods: in the grocery store and online marketplaces. By doing this, the results are more accurate and authentic as to what is in spoonfuls at highchairs across the country. The main points the study focused on was heavy metal content, acrylamide content, and presence of plasticizers.

Overview of the Findings

The results of the baby food study were shocking. Heavy metal content was concerning in the products tested. Lead was detectable in 36% of the products. Cadmium, also found in batteries, was detected in 58% of the products. Soy-based formulas contained 7 times the amount of cadmium as compared to other formulas. Among all of the products tested, arsenic was detected in 65% of them. However, arsenic was found in nearly 80% of all formulas tested. Even more surprising, certified organic products contained 2 times more arsenic than the conventional products tested. A plasticizer called BPA was found in 60% of the products claiming to be “BPA-free.” The last finding, acrylamides, were found in only 10% of the products tested.

How Did Heavy Metals and Pesticides Get into Baby Food and Formulas?

So how did these harmful chemicals and metals get into the baby food in the first place? There are actually several ways this happens. The first and most prevalent is water and soil contamination. Water is extremely susceptible to contamination which can happen through

“A plasticizer called BPA was found in 60% of the products claiming to be “BPA-free.”

pesticides runoff into the water source, industrial waste, and oil pollution²⁸. Soil can also be a source of contamination through pesticide use, oil spills, construction, and erosion²⁹. The use of leaded paints and leaded gasoline have increased the lead content in today’s soil²⁹. Processes such as industrial farming and fracking/mining can also contaminate the surrounding water and soil. Industrial farming involves the large-scale use of fertilizer, pesticides, and other chemicals to grow primarily one crop in a short amount of time³⁰. The

“The use of leaded paints and leaded gasoline have increased the lead content in today’s soil²⁹.”

chemicals used in these industrial practices can seep into the soil and cause contamination. Fracking is a process where millions on gallons of water are pumped into air pockets within the earth to extract natural gas or oil³¹. These high-pressure systems can also force contaminated water through unpredictable fissures through the Earth’s crust into the human and agricultural water supplies³². Finally, the soil can already have naturally occurring heavy metals within it because these metals are part of the earth’s crust with varying levels around the world³³.

What Should a Concerned Consumer Do?

1. If a consumer is concerned about the safety of the food he/she is feeding his/her baby, it is always best to ask questions. Going to the company’s website can give insight to their current testing protocols and their food safety programs. If something is not listed on the website but is important to you, contact the company and ask them to test for it or add it to their procedures.

2. Look for verifications and certifications. Clean Label Project is a great source because their certifications are backed by laboratory results and studies.

3. Talk to your pediatrician about what brands are best for your baby to ensure all nutrition needs are met and that you are introducing something safe into your baby's diet.

What Should a Concerned Brand Do?

1. Given the statistics of contaminated baby food it is justly that a brand should be concerned about the safety of the products they produce. A brand should trust their products but still test for heavy metals, pesticide residues, acrylamides, and plasticizers to ensure that their product is safe and wholesome.

2. Consider Clean Label Project as a certifier. CLP offers certificates that verify the safety of the product and the purity of the contents. Also, it is a great marketing tool that shows parents that you care about the quality and safety of your products.

3. Stay up to date on regulations regarding food production for babies and infants. If new regulations are made, the production practices should be changed accordingly to accommodate.

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EXHIBIT D



DEC 12 2019

December 6, 2019

Dear Mr. Raja Krishnamoorthi
Chairman Subcommittee on Economic and Consumer Policy

The following is the response of Beech-Nut Nutrition Company (BNN) to the Subcommittee's request for documents and information dated November 6, 2019 (the "Request"). As set forth in the Request, our responses and production pertain to the period July 1, 2017 through the present unless otherwise indicated. Certain Trade Secret and/or Confidential Commercial Information being provided has been designated as such and BNN respectfully requests that the Subcommittee maintain its confidentiality throughout this process.

We share the Subcommittee's concern for maintaining a safe food supply and we appreciate you reaching out to us to learn more about our actions, industry best practices and commitments in the area of heavy metals.

First, we want to confirm that the products that we provide are healthy, nutritious and safe – and we proudly stand behind them. As we prepare food for infants and toddlers, our focus is on industry best practices to help ensure safety and quality.

Regarding your letter and request, we have a shared goal of minimizing naturally occurring heavy metals in our products. We also recognize that heavy metals are an environmental contaminant found in nearly all soil and present in all foods, not just baby foods. We recognize the risk of heavy metal consumption in infants. We apply rigorous testing protocols and heavy-metal testing standards which are continuously reviewed and strengthened.

Contaminant testing has been part of our food safety policy since the 1970's. Our current standard for pesticide residue is 1/10th the level of pesticides allowed by EPA regulations. We were the first baby food company to remove sugar and salt from its baby food in 1979.

We have been testing ingredients for heavy metals since the 1980's. At the time, there was no FDA requirement or maximum allowable level this continues as of today. We understood then, as now, that different fruits and vegetables naturally uptake from the soil heavy metals at different rates. Additionally, heavy metal levels in fruits and vegetables can also be impacted by the environments/regions in which the foods are grown. Controlling those heavy metal levels at the ingredient level before manufacturing them into food has been a core part of our food safety program.

We established internal standards for all fruits, vegetables and grains in the 1980's by using historical testing data and the FDA's Total Diet Study. We implemented our own testing program at that time with the use of an Inductively Coupled Plasma Mass Spectrometer (or ICP-



MS for short). Through the following decades, this technology has improved, increasing in sensitivity and enhancing our ability to detect reliably the levels of heavy metals in foods, which has enabled us to lower the allowable levels under our internal standards.

In 2015, we were contacted by FDA to discuss inorganic arsenic (the harmful form of arsenic) in infant rice cereal. The FDA proposed a level of 100 ppb of inorganic arsenic in all rice cereal products. Since the April 1, 2016 draft guidance proposal by FDA (to limit the inorganic arsenic in infant rice cereal to 100 ppb) we have been in compliance as verified through our ingredient testing program and confirmed in the recent Healthy Babies Bright Futures Report (the "HBBF Report").

In 2015 the Food Safety Modernization Act's (FSMA) Preventive Controls for Human Food (PCHF) was published by the FDA.¹ It requires that companies identify all hazards in food ingredients. In 2016 our newly developed Food Safety Plan identified heavy metals as a hazard that required supply chain preventive controls. Overwhelmingly, the risk we identified was due to ingredients being contaminated in the ground. No risk of ingredients being contaminated during manufacturing was identified. Therefore, we have focused our efforts on ingredient testing before manufacturing and try to source materials from regions that have historically experienced lower heavy metal levels. While the compliance date for the PCHF rules was September 17, 2017, we have been testing for heavy metals, establishing limits and verifying compliance to our limits for over 30 years.

In October of 2018 we encouraged Cornell University to establish a coalition of academia, baby food companies, governmental and non-governmental organizations("NGO"), including Health Babies Bright Futures, to conduct research and work to achieve a long-term reduction of heavy metals in the baby food supply chain.

Shortly thereafter, The Baby Food Council (BFC) was formed in January of 2019. Its top priority is to reduce heavy metals in the products manufactured and marketed by the member companies using best-in-class management practices. The council members meet monthly with our non-governmental organization and regulatory agencies to discuss past actions and set the agenda for future research and testing.

Early efforts of the BFC have focused on identifying foods and ingredients that have the highest potential to contribute to heavy metal exposure in infants and toddlers. The BFC will be identifying and evaluating best practices that can be used to lower heavy metal levels in foods. Recognizing that heavy metals are widely present in ground soil which exposes all food to potential contamination, this work will initially focus primarily on the impact of the soil, water and growing conditions.

One of the key aspects of the BFC's mission has been to work with NGOs to help guide and focus our work. We have been working with Healthy Babies Bright Futures, the author of the Report you reference in your letter. We would like to draw your attention to key aspects of the

¹ <https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-final-rule-preventive-controls-human-food>



HBBF Report that may have been overlooked in some of the media coverage, as well as actions taken by the BFC that have been proactive on these issues:

- Heavy metals are in the soil and water and become part of crops as they grow – these substances cannot be avoided by making foods at home or by switching to organic products.
- While more progress is needed, baby food companies and FDA have been working to establish limits and to reduce heavy metals – achieving significant reductions in levels of inorganic arsenic in rice-based foods and juices. The Baby Food Council members support finalizing the FDA proposed guidance limiting inorganic arsenic in these food categories and supports the development of additional guidance limits, where supported by the scientific evidence.
- FDA conducts routine testing of foods and beverages for heavy metals to inform regulatory and public health efforts – and recently improved their testing methods. One of the Council’s related objectives is to conduct a proficiency study to facilitate consistent evaluation of data collected across the supply chain and by regulators.
- The HBBF Report provides some advice on how to limit the exposure to heavy metals for consumers such as eating a wide variety of foods. The Baby Food Council and the American Academy of Pediatricians endorse this advice and are committed to helping educate consumers more on this point.
- In general, the levels of heavy metals in the HBBF Report were low but we all want to do more to drive levels even lower.
- The Baby Food Council members are Campbell’s Soup Company, Beech-Nut Nutrition, Environmental Defense Fund, Gerber Products Company, The Hain Celestial Group, Happy Family Organics, Healthy Babies Bright Future with FDA and Cornell University serving as advisors.

In addition, we adhere to the Codex Alimentarius Code of Practice for the Prevention and Reduction of Lead Contamination and the Code of Practice for the Prevention and Reduction of Arsenic Contamination in Rice.

You have forwarded eight specific documentation requests regarding our testing and policies around heavy metals in our food products. Below is a description of the documents and procedures you will receive, and any explanations needed for these requests.

1. “All policies and procedures regarding testing baby food products for the presence of contaminants, including maximum levels of each of those contaminants that you allow in your products, and the actions your company takes if testing reveals that those levels are exceeded in a product;”
 - a. As noted, we conduct raw ingredient testing as part of our Food Safety Plan’s Preventive Controls program. We will provide testing results of those ingredients with our internal maximum levels for each of those contaminants from Jan 1, 2017 through the most recent data collected.



- I. We do not make apple juices.
- iii. *"Lead in fruit juice as a result of FDA's 2004 guidance entitled, Guidance for Industry: Juice Hazard Analysis Critical Control Point Hazards and Controls Guidance, First Edition:"*
 - I. We do not make fruit juices.
7. *"All documents related to the negative neurological effects on babies of contaminants"*
 - a. We will provide you all the research information we have collected on the risks of heavy metals on infant development that was used in our risk assessment and hazard analysis when we created our Food Safety Plan.
 - b. We have not done any primary research on this topic nor tested any of its food for its effects on the neurological development on infants. All research collected was published by other entities not related to or funded by BNN.
8. *"A description of whether you support FDA promptly:"*
 - a. *Finalizing draft guidelines for inorganic arsenic in apple juice.*
 - b. *Finalizing draft guidelines for inorganic arsenic in infant rice cereal.*
 - c. *Issue guidelines for heavy metals in all baby foods.*
 - d. *Considering neurological harms in setting guidelines.*

We support all scientific and risk-based standards for heavy metals in all foods. We have adopted the FDA's draft guidelines for infant rice cereal and anticipate we would do the same for any other risk-based guidance or rule that was established.

This is an environmental contamination issue. Therefore, we along with the members of the Baby Food Council, recognize that addressing the issue at the soil level will take time and that a measurable reduction over time is a good goal and valuable starting point for the industry. There are many questions and gaps in research knowledge on this issue that need to be resolved so we can continue to work towards achieving the lowest levels possible.

Funding of studies through the USDA would be one way to close the knowledge gaps and lower the levels and risks to infants. It would also help speed up the implementation of real solutions. We are committed to helping find solutions and believe the creation of the Baby Food Council and persistently working closely with FDA and other NGOs, such as Healthy Babies Bright Futures, are ways we can ensure we are taking the right steps to resolve this issue.

We appreciate you contacting us understanding its importance to parents who want to provide their children with safe and nutritious food. We share this goal and are willing to work with any agency or organization who can help in this process.

Best Regards;

Mark S. Rodriguez
President and CEO, Beech-Nut Nutrition Company

EXHIBIT E

Response to Subcommittee Request to Nurture, Inc., December 18, 2019

General Information Regarding Nurture & Scope of Response

We set forth below the questions in your November 6, 2019 letter followed by our response, to the best of our knowledge based on our search of Nurture's records, with additional detail provided as appropriate.

At the outset, we believe it is critical that the Committee's questions and our responses below be understood in the proper regulatory context. Currently, the FDA does not require baby food manufacturers to establish "maximum levels" for heavy metals (see Request Nos. 1-2) or to conduct heavy metal "detection tests" (see Request No. 2), though many in the industry, like Nurture, have voluntarily done so. Given this framework, it follows that there are also no federal guidelines concerning recalls of such products specifically in response to heavy metal contamination (Request Nos. 3-5).¹ The FDA's guidance to industry instead reflects the reality that a generally-applicable rule limiting heavy metal content in baby foods is simply not possible given the chronic, i.e. non-acute, characterization of heavy metal toxicity, the naturally-occurring etymology of heavy metal presence in many foods, both inter- and intra-lot variability in concentration levels, and the lack of reliable, product-specific consumption data.

Nurture, for its part, is nevertheless continuously working with its suppliers and co-manufacturers to go beyond federal requirements, adhere to the "as low as reasonably practical" principle, and drive heavy metal levels further downward. We engage in significant supply chain monitoring and improvement efforts, which includes independent screening by Nurture for heavy metals, among other initiatives. Nurture makes these efforts even though its contract manufacturers often assume responsibility for ingredient sourcing and compliance with FDA manufacturing regulations generally. Nurture also has goal threshold levels for heavy metal content that we have set for ourselves as part of our commitment to reduce heavy metals.

More specifically, our efforts to further reduce heavy metal exposures have recently prioritized our infant rice cereal products, which we evaluate against the level articulated in FDA's draft guidance of 100 ppb for inorganic arsenic, published in 2016.² Since that time, we have made considerable progress in this regard, as we now have adjusted our supply chain so that our current testing for our infant rice cereal products is consistently below the draft FDA level. Additionally, for lead, our prior 100 ppb goal threshold, which was based on a global standard for all Danone subsidiaries, was recently updated to 50 ppb and is based on FDA's new Interim Reference Level of 3 mcg Pb/day for children, which was previously 6 mcg Pb/day.³

Overall, contrary to some statements in the October, 2019 Healthy Babies report and other media accounts, we are aware of no survey or study finding that Nurture's products, or

¹ 21 C.F.R. § 106.150 broadly requires notification of recalls where infant formulas regulated pursuant to 21 C.F.R. § 106.1 "[m]ay be otherwise adulterated or misbranded."

² Note that pursuant to Cal. OEHHA regulations, 27 CCR § 25501.1, 80ppb of inorganic arsenic in white rice and 170 ppb in brown rice should be treated as naturally-occurring, further underscoring the conservative nature of Nurture's 100ppb goal for arsenic.

³ *Lead in Food, Foodwares, and Dietary Supplements*, FDA, <https://www.fda.gov/food/metals/lead-food-foodwares-and-dietary-supplements> (last updated Feb. 19, 2019).

products with similar concentrations of naturally-occurring heavy metals,⁴ have been shown to “alter the developing brain and erode a child’s IQ”⁵ or otherwise increase risks to consumers or their children from heavy metals.⁶ To the extent the Healthy Babies report encourages reduced infant formula consumption or calls into question a scientific consensus in favor of promoting plant-based foods to babies generally, it may in fact be doing the public a disservice.

Furthermore, we believe our approach is better than, or at least consistent with, that taken by others in our industry. Indeed, we joined the Baby Food Council, which was created this year with the objective to reduce heavy metals in baby food products as low as reasonably achievable using best-in-class management practices. This Council includes the leading baby food manufacturers as well as the Environmental Defense Fund (EDF).⁷

Finally, Nurture has made a good faith effort to provide documents responsive to this inquiry. Please do not hesitate to contact us if we can provide any additional information or clarifications regarding the information provided. With that background, we will now turn to your specific questions.

1. *All policies and procedures regarding testing baby food products for the presence of contaminants, including the maximum levels of each of those contaminants that you allow in your products, and the actions your company takes if testing reveals that those maximum levels are exceeded in a product*

We conduct heavy metal testing in order to evaluate our supply chain and make adjustments, if necessary, to ensure we are receiving the quality ingredients we expect. This data is a part of our continuous improvement efforts based on what is achievable in the marketplace. To evaluate the data, we rely on internal global goal levels and work with suppliers and co-manufacturers to address results that exceed our goals so we can drive levels downward.

⁴ Like the natural ingredients from which they are derived, Nurture’s products contain arsenic, lead, cadmium, and mercury resulting inescapably and almost entirely, if not completely so, from omnipresent environmental pollution. Heavy metal exposure to Nurture consumers is comparable to or below exposures from dietary alternatives such as raw fruits, vegetables, juices, and other healthy plant-based foods. *See Potter v. Firestone Tire & Rubber Co.*, 6 Cal. 4th 965, 989 (1993) (“A carcinogenic or other toxic ingestion or exposure, without more, does not provide a basis for fearing future physical injury or illness which the law is prepared to recognize as reasonable . . . nearly everybody is exposed to carcinogens which appear naturally in all types of foods.”) (citing Ames & Gold, *Too Many Rodent Carcinogens: Mitogenesis Increases Mutagenesis* (1990) 249 *Science* 970, 971, fn. 10).

⁵ Jane Houlihan & Charlotte Brody, *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*, HEALTHY BABIES BRIGHT FUTURES, Oct. 15, 2019, at 1.

⁶ Heavy metal levels found in Nurture products are within relevant safety thresholds and are low enough not to require a warning under the conservative standards established by California’s Office of Environmental Health Hazard Assessment for purposes of California Proposition 65, pursuant to which a warning may be required if exposures to reproductive toxicants exceed an amount 1,000 times below the level at which no reproductive harm is observed. As further illustration, Nurture’s formula products, for example, uniformly test below the EPA’s 15 ppb action level for lead in drinking water.

⁷ Early efforts of the Council have focused on identifying those foods and ingredients with the highest potential to contribute to heavy metal exposure in young children. The Council will also be identifying and evaluating best practices that can be used to lower heavy metal levels in these foods. Recognizing that heavy metals are widely present in the environment and can get into food, this work will initially focus on the impact of the environment and growing conditions but will also extend to other aspects of the supply chain including handling and processing.

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

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

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

Importantly, as noted above and consistent with applicable regulations, these goal thresholds are not used to make product disposition decisions and are not a pre-condition to product release. Instead, we perform routine testing for contaminants to monitor the supply chain and promote improvements.

2. *A spreadsheet specifying for each baby food product:

 - a. *The maximum allowable level of each contaminant in that product; and*
 - b. *The dates of all detection tests, specifying the contaminant(s) for which the test was searching**

The attached spreadsheet provides a summary of all relevant contaminant testing in baby foods (products for children aged 0-9 months) from January 1, 2017 to October 27, 2019.

3. *For each test identified in response to Request 2(b) that indicated the presence of a contaminant, the test report and a description of what your company did with the food (i.e., sell, dispose, recall, etc.)*

⁸ Nurture’s goal threshold, like the FDA’s Draft Guidance, is specific to inorganic arsenic. *See Inorganic Arsenic in Rice Cereals for Infants*, FDA, <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/draft-guidance-industry-action-level-inorganic-arsenic-rice-cereals-infants> (last updated Sept. 16, 2018).

The second sheet in the attached spreadsheet provides a summary of all test results in excess of our goal levels. As discussed above, nearly all foods will test positive for the presence of heavy metals. Further, Nurture's testing is performed for supply chain monitoring and improvement purposes and not as a condition to product release.

Excluding the recently introduced goal level for inorganic arsenic, only two outlier results have been obtained for the products in question, all of which were for products made by a contract manufacturer, not Nurture. Our responses to each were as follows:

- First, an outlier result, which was for lead in Multi-Grain Cereal, was obtained by Nurture after we had already switched to a new manufacturer. Testing of the new manufacturer's production runs resulted in consistently below-goal results.
- Second, an outlier lead result was obtained for Blueberry Purple Carrot Greek Yogis. In response, we tested batch retention samples from an earlier and later production date, which did not replicate the high lead results. As a confirmed outlier, no further action was taken.

In sum, we believe these two results were historical anomalies which had already been corrected by changes in the supply chain. Nevertheless, we include them in the chart for completeness.

Finally, as mentioned above, when FDA reduced its reference intake level for lead in food intended for children from 6 mcg Pb/day to 3 mcg Pb/day, Nurture began a process to reduce its own lead goal threshold from 100ppb to 50ppb. Nearly all products, including all infant formulas, were already well below that level. For one product, the Pea Spanish Teether, which tested at 55 ppb in December of 2018, we had to engage with spinach powder suppliers to implement lower ingredient limits for lead. Through those efforts, we were able to lower the lead levels in the product significantly.

4. *All documents related to specific positive test results for the presence of contaminants in your company's baby food products, including documents related to deciding what to do with the specific product that tested positive (e.g., whether to conduct a recall)*

As noted earlier, our heavy metal testing is performed as part of our monitoring program and not as a condition to product release, all of the products that were tested were sold into commerce. We are providing copies of the analytical reports for these results, and do not have any further documents regarding this data.

5. *A list of all baby food products your company recalled due to the presence of contaminants*

We have not conducted any product recall due to the presence of contaminants.

6. *All changes your company made, if any, to its policies and procedures on testing for:*

- a. *Inorganic arsenic in infant rice cereal as a result of Food and Drug Administration's (FDA) 2016 draft guidance entitled, Inorganic Arsenic in rice Cereals for Infants: Action Level guidance for Industry*

We discontinued a brown rice baby cereal, in part based on FDA's draft guidance and uncertainty about whether we could consistently source brown rice that met FDA's draft guidance levels. We also undertook an evaluation of our other rice-based products and undertook reformulation efforts. In 2018, we worked with our supplier of rice cakes to reduce the amount of brown rice in the recipe to consistently meet FDA's draft guidance level. This year, we have been working with the supplier of our Puff products to similarly reduce the amount of brown rice in the recipe to consistently meet FDA's draft guidance level. The final formula from these efforts is scheduled for its first production in December 2019. Both Nurture and the manufacturer of the product have had discussions with FDA on these products and our efforts to reformulate to consistently be below FDA's draft guidance level.

- b. *Inorganic arsenic in apple juice as a result of FDA's 2013 draft guidance entitled, Guidance for Industry Arsenic in Apple Juice: Action Level; and*

This draft guidance is not directly applicable to Nurture because we do not sell juice products.

- c. *Lead in fruit juice as a result of FDA's 2004 guidance entitled, Guidance for Industry: Juice Hazard Analysis Critical Control Point Hazards and Controls Guidance, First Edition*

This guidance is not directly applicable to Nurture because we do not sell juice products, although this guidance is used industry-wide as a reference.

7. *All documents related to the negative neurological effects on babies of contaminants*

We did not locate any relevant documents to this request. We have never commissioned or directly participated in any studies related to potential neurological effects of these contaminants.

8. *A description of whether you support FDA promptly:*

- a. *Finalizing draft guidelines for inorganic arsenic in apple juice*

Nurture has no position as such guidelines do not directly impact our business.

- b. *Finalizing draft guidelines for inorganic arsenic in infant rice cereal*

Nurture supports FDA finalizing guidelines for inorganic arsenic in infant rice cereal. FDA's issuance of the draft guidance empowered us in our discussions with suppliers and co-

manufacturers, and facilitated collaboration in the supply chain to address sourcing and formulation issues. We are confident that our supply chain for rice is well-controlled to ensure all of our infant rice cereal products are compliant with FDA's draft guidance, and support finalizing this guidance.

- c. *Issuing guidelines for heavy metals in all baby foods and*
- d. *Considering neurological harms in setting guidelines*

Our goal is to provide healthy, organic foods for the families who depend on us, and we would gladly participate in the development of guidelines for heavy metals in the categories of baby foods we offer. We joined the Baby Food Council, which was created with the objective to reduce heavy metals in baby food products as low as reasonably achievable using best-in-class management practices. Nurture recognizes the importance of decreasing the levels of heavy metals in baby food, and we support guidelines based on sound science, informed by the health needs of babies and reputable research on potential for neurological harm, as well as what is feasible in the supply chain using best-practice management strategies.

EXHIBIT F

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December 11, 2019

BY COURIER

DEC 16 2019

Kelly B. Kramer

[REDACTED]
Subcommittee on Economic and Consumer Policy
Committee on Oversight and Reform
2157 Rayburn House Office Building
Washington, DC 20515

Re: Response to Request for Information

Dear Mr. [REDACTED]

We write on behalf of our client, The Hain Celestial Group, Inc. (“Hain”), to respond to the Subcommittee’s November 6, 2019 request for information regarding Hain’s baby food products.

Hain is a member of the Baby Food Council (“Council”), a group of companies organized by Cornell University and the Environmental Defense Fund. The Council’s mission is supported by the U.S. Department of Agriculture, the Food and Drug Administration (“FDA”), and other stakeholders, including Healthy Babies Bright Futures, the organization that authored the report that prompted the Subcommittee’s request. Like all of the Council’s member companies, Hain is committed to producing safe, nutritious, high-quality baby food products. Moreover, Hain supports the FDA finalizing guidance limiting inorganic arsenic in baby food products, and it supports the development of additional guidance limits as supported by the scientific evidence.

Heavy metals occur naturally in the environment, but their prevalence varies widely depending on food types and sources. Hain supports the Council’s efforts to identify foods and ingredients with the highest potential to contribute to heavy metal exposure in children, as well as its efforts to develop effective mitigation strategies. Hain further supports the Council’s decision to focus initially on environmental factors, including growing conditions and farming techniques, understanding that the Council will also assess ways to improve manufacturing and handling processes.

Hain is committed to reducing heavy metals in its baby food products using best-in-class management practices. To that end, Hain has taken, and will continue to take, proactive steps to reduce the presence of heavy metals in its baby food products. By way of example, when the FDA issued draft guidance in March 2016 regarding arsenic levels in rice and rice products, Hain revised its internal policies and testing standards to conform to the FDA’s non-binding recommendations. In an effort further to reduce arsenic levels in its rice cereals, Hain is currently testing a new formulation of its rice-cereal product. Validation testing of the new formulation is ongoing, but Hain’s testing to date suggests that the new formulation will

Mayer Brown LLP

[REDACTED]
December 11, 2019

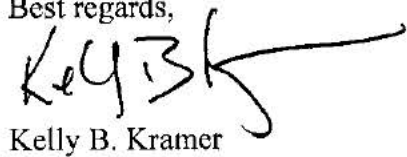
Page 2

meaningfully reduce arsenic levels. Hain expects to complete validation testing by January 2020 and, if it is successful, to introduce the new formulation to the marketplace.

Hain is pleased to provide you with the enclosed CD, which contains documents responsive to the Subcommittee's requests, as modified by agreement during our November 21, 2019 discussion, as well as the attached index. Because this letter and the enclosed documents contain confidential business information, we respectfully request that the Subcommittee maintain them in confidence to the greatest extent possible.

Please do not hesitate to contact me if you have any follow up questions or requests.

Best regards,

Handwritten signature of Kelly B. Kramer in black ink, consisting of the letters 'K', 'B', and 'K' in a stylized, cursive font.

Kelly B. Kramer

Enclosure

December 11, 2019

Page 3

Attachment A: Index to Document Production

1. Policies and Procedures Regarding Baby Food Product Testing

Hain-000001--000028

2. Specifications and Test Results

Hain-000029--000114

3. Rice Cereal Validation Report and Deviation Reports

Hain—000115--000152

4. All Documents Relating to Positive Test Results

N/A

5. List of Recalled Products

N/A

6. Implementation of FDA Draft Guidance for Rice Cereal

Hain-000153--000166

7. Scientific Research on Impact

Hain-000167--000685

8. Description of Position on FDA Activity

N/A

EXHIBIT G



Gerber Products Company

1812 N Moore Street,
Arlington, VA 22209

William Partyka
Chief Executive Officer
Email: [REDACTED]

December 19, 2019

Dear Chairman Krishnamoorthi,

Thank you for your letter of November 6, 2019 in which you request information on the presence of certain contaminants in baby food products. As the CEO of Gerber Products Company¹, I want to assure you that Gerber's top priority is the health and safety of children above everything else. For over 90 years this commitment is one of the reasons Gerber is the trusted leader in Infant Nutrition. We take your inquiry seriously and will cooperate fully with the Committee's request.

The potential for certain contaminants to be present in foods is well documented and, while progress has been made in reducing the level of contaminants, to date there is no known way to completely eliminate the risk. Because heavy metals occur in the environment, it is possible that trace amounts may get into fruits, vegetables and grains as part of the normal growing process. For this reason, Gerber takes a comprehensive and multifaceted approach to minimizing contaminants in foods and ingredients to the lowest levels reasonably achievable also referred to as ALARA (as low as reasonably achievable). Our approach is informed and guided by the food safety expertise of the Nestlé Research Center (NRC), the largest private food and nutrition research center in the world. NRC's network includes upwards of 4,800 scientists and researchers including a dedicated food safety and quality network with partners from industry, scientific institutions and academia across the globe.

A first step in our approach is understanding the foods children eat through our Feeding Infants and Toddlers Study (FITS) the largest and most comprehensive dietary intake study focused on infants, toddlers and pre-schoolers in the United States. From this study, conducted in 2002, 2008 and most recently in 2016, we have a database of food and nutrient intakes for approximately 10,000 children between the ages of birth to forty-eight months. FITS informs our product design, services and education leading to healthier food options that promote adequate nutrient intake as well as the development of healthy eating habits for young children. FITS has resulted in over 50 peer-reviewed publications and is widely referenced by nutrition and feeding experts and organizations including the American Academy of Pediatrics and the Institute of Medicine². Most recently we have used FITS data to evaluate the

¹ Gerber Products Company d/b/a Nestlé Infant Nutrition

² American Academy of Pediatrics Committee on Nutrition. Kleinman RE, Greer FR, Ed. Pediatric Nutrition. 8th edition, Itaca, IL

Institute of Medicine. 2006. WIC Food Packages: Time for a Change. Washington, DC: The National Academies Press.

Lott M, Callahan E, Welker Duffy E, Story M, Daniels S. Healthy Beverage Consumption in Early Childhood: Recommendations from Key National Health and Nutrition Organizations. Technical Scientific Report. Durham, NC: Healthy Eating Research, 2019.



predominant fruits and vegetables consumed by infants and young children and the format they were consumed as – either commercial baby food or non-baby food formats. These data were analyzed in the context of evaluating and prioritizing the contaminant risk posed by fruits and vegetables in the diet of young children. The accompanying publication presented a call-to-action and methodology to assess the important balance between contaminant risk and nutrition³. It is worth noting that those foods associated with a healthy diet - fruits, vegetables and grains - are the same foods often associated with the presence of heavy metals.

A second step in our approach is our in-depth knowledge of which ingredients and foods have the potential for presence of heavy metals and other contaminants. Nestlé maintains a global sourcing and contaminant management strategy that identifies food ingredients and crops at risk for the presence of heavy metals and other contaminants, including emerging contaminants. We identify areas of risk through published data, food safety assessments by government organizations and through our own extensive monitoring and testing of crops globally. To facilitate management of these identified and emerging contaminant risks, Nestlé establishes global contaminant guidance levels for many substances across our baby food product categories. These contaminant guidance levels are based on an evaluation of the latest food safety science and regulatory guidance – from sources like the Food and Drug Administration, Environmental Protection Agency, the European Food Safety Authority, the World Health Organization as well as the published scientific literature. Our guidance levels also take into consideration what is achievable and known about current agricultural practices and mitigation strategies.

Finally, we incorporate our product design, sourcing and supplier strategies, as well as testing requirements into our approach. Given the scope of what we purchase this is a major undertaking. During any given year, we purchase just under 200,000 tons of nine fruits and vegetables from dozens of U.S. growers and suppliers. This is in addition to the many other minor fruits and vegetables we purchase in smaller volumes. For grains, we purchase over 30,000 tons of rice, oat and wheat ingredients from several millers across North America. These materials are used to produce over 71,000 metric tons of infant cereals and baby food purees and almost 8,000 metric tons of juice. Given these volumes, having a robust grower and supplier program as well as controlling and monitoring contaminants upstream in the supply chain is necessary to ensure a consistent source of supply and forms the foundation for our continuous improvement programs.

With the above overview as context, our answers to the questions posed are provided below.

- 1. All policies and procedures regarding testing baby food products for the presence of contaminants, including the maximum levels of each of those contaminants that you allow in your products, and the actions your company takes if testing reveals that those maximum levels are exceeded in a product;**

Perez-Escamilla R, Segura-Perez S, Lott M, on behalf of the RWJF HER Expert Panel on Best Practices for Promoting Healthy Nutrition, Feeding Patterns, and Weight Status for Infants and Toddlers from Birth to 24 Months. Feeding Guidelines for Infants and Young Toddlers: A Responsive Parenting Approach. Durham, NC: Healthy Eating Research, 2019.

³ Callen C, Bhatia J, Czerkies L, Klish W, Gray G. Challenges and Considerations When Balancing the Risk of Contaminants with the Benefits of Fruits and Vegetables for Infants and Toddlers. *Nutrients* 2018, 10,1572.



Nestlé has established contaminant guidance levels for all baby food product categories globally. These guidance levels are based on an evaluation of the latest food safety and regulatory guidance – from sources like the Food and Drug Administration, Environmental Protection Agency, the European Food Safety Authority and the World Health Organization. Guidance levels also take into consideration what is achievable given current and evolving agricultural practices. This concept is often referred to as ALARA or “as low as reasonably achievable”.

Presented below is a comparison of Nestlé contaminant guidance levels for heavy metals compared to the U.S. Food and Drug Administration (FDA) guidance. Other sources of information are considered in setting our contaminant guidance levels, therefore, we are also providing a comparison of FDA and European Union contaminant limits. Values are reported in parts per billion (ppb).

| Product Category | FDA Guidance or Limits | | | | Nestlé Global Contaminant Guidance Levels for finished food products | | | |
|--------------------------|--------------------------|-------------|----------------|----------------|--|-------------|----------------|----------------|
| | <i>Inorganic Arsenic</i> | <i>Lead</i> | <i>Cadmium</i> | <i>Mercury</i> | <i>Inorganic Arsenic</i> | <i>Lead</i> | <i>Cadmium</i> | <i>Mercury</i> |
| Apple Juice | 10 ppb | 50 ppb | NA† | NA† | 10 ppb | 40 ppb | 40 ppb | 10 ppb |
| Other juices | NA† | 50 ppb | NA† | NA† | 15 ppb | 40 ppb | 40 ppb | 10 ppb |
| Fruit/vegetable purees | NA† | 50 ppb | NA† | NA† | 20 ppb | 40 ppb | 40 ppb | 10 ppb |
| Infant rice cereal | 100 ppb | NA† | NA† | NA† | 100 ppb | 40 ppb | 40 ppb | 10 ppb |
| Infant cereals, non-rice | NA† | NA† | NA† | NA† | 100 ppb‡ | 40 ppb | 40 ppb | 10 ppb |
| Grain based snacks | NA† | NA† | NA† | NA† | 100 ppb | 50 ppb | 40 ppb | 10 ppb |

NA† - FDA conducts testing of foods and can take enforcement action if a food is deemed to be adulterated with high levels of lead, cadmium, arsenic or mercury.
 ‡total arsenic.

| Product Category | FDA Guidance or Limits | | | | European Union Limits | | | |
|--------------------------|--------------------------|-------------|----------------|----------------|--------------------------|---------------|-----------------|----------------|
| | <i>Inorganic Arsenic</i> | <i>Lead</i> | <i>Cadmium</i> | <i>Mercury</i> | <i>Inorganic Arsenic</i> | <i>Lead ‡</i> | <i>Cadmium‡</i> | <i>Mercury</i> |
| Apple Juice | 10 ppb | 50 ppb | NA† | NA† | NA† | 40 ppb | 40 ppb | NA† |
| Other juices | NA† | 50 ppb | NA† | NA† | NA† | 40 ppb | 40 ppb | NA† |
| Fruit /vegetable purees | NA† | 50 ppb | NA† | NA† | NA† | 40 ppb | 40 ppb | NA† |
| Infant rice cereal | 100 ppb | NA† | NA† | NA† | 100 ppb | 40 ppb | 40 ppb | NA† |
| Infant cereals, non-rice | NA† | NA† | NA† | NA† | NA† | 40 ppb | 40 ppb | NA† |
| Grain based snacks | NA† | NA† | NA† | NA† | NA† | 40 ppb | 40 ppb | NA† |

NA† - FDA conducts testing of foods, and can take enforcement action if a food is deemed to be adulterated with high levels of lead, cadmium arsenic or mercury

‡EU limits are for processed cereal based foods for infants and baby foods

Note: Both the US FDA and the EU have established limits for mercury in fish. Other foods have not been shown to represent a potential risk for increased exposure to mercury.



As evidenced from the charts above, Nestlé's contaminant guidance levels for heavy metals are equivalent to or stricter than regulatory guidance in both the U.S and the European Union (EU). Many of our guidance levels are established in the absence of regulatory requirements. We use these guidance levels to monitor the contaminant levels in our ingredients and foods and to identify areas of concern with the goal of implementing corrective actions and continuous improvement plans.

Our growers and suppliers are key partners in helping to maintain our high-quality standards and continual drive for improvement. Some of these improvements have a long-time horizon since they often are required to correspond to annual growing seasons. Improvements in agricultural practices, sourcing and production techniques may take months to years to see their full potential. We are able to invest the needed time because many of our Gerber growers have been growing for Gerber for multiple generations. The relationships we have with our growers is a source of pride for Gerber and we are happy to extend an invitation and encourage interested Committee members to visit one or more of our Gerber growers and to see Gerber agricultural sourcing practices in action.

Our Gerber team works directly with our growers to advise on soil testing prior to planting, developing best-in-class crop rotation practices, minimizing pesticide use and identifying optimal application timing to minimize pesticide residues on crops at harvest, and finally optimizing harvest, storage and transportation conditions. Gerber also hosts annual Grower meetings where we bring our growers together to discuss best practices and share the latest techniques for growing safe produce.

Our gold standard is to be able to trace our produce to the farms and fields where they are grown. These programs are the foundation for continuous improvement and offer the opportunity to control and monitor contaminants upstream in the supply chain. We find our growers are inspired by our mission to do "Anything for Baby" and work diligently to comply with our strict standards.

In order to meet changing consumer needs, we are constantly evaluating new crops and ingredients. Sometimes these can be sourced from our current growers and suppliers. More often, these new ingredients are sourced from growers or suppliers that are new to Gerber. Before any new crop or ingredient is used in a Gerber product, the ingredient, as well as the grower or supplier, must go through an extensive review and on-boarding process. For the grower or supplier, this entails an extensive assessment process to ensure the supplier or grower has the capabilities necessary to deliver crops and ingredients that consistently comply with Nestlé requirements. We offer advice and assistance to suppliers who may need additional help in meeting Nestlé standards. For the crop or ingredient, this includes a preliminary assessment by our food safety team to determine inherent or suspected risks such as anti-nutritional factors and contaminants. Finally, prior to use, each new material goes through a rigorous testing process to confirm the nutritional profile and contaminants profile relative to Nestlé contaminant guidance levels.

In addition to shaping our growing practices, supplier specifications, and supplier selection, our contaminant guidance levels inform product formulation, design and testing requirements. We regularly test our ingredients, and periodically test our finished foods. The majority of our contaminant testing is focused on incoming ingredients, to ensure ingredients meet our requirements before they enter our



manufacturing facility. Finished product testing is considered as a verification activity and is done less frequently. The majority of our analytical testing is conducted by the Nestle Quality Assurance Center (NQAC) located in Dublin, Ohio. NQAC is an ISO-accredited laboratory, meaning they follow international standards for analytical reliability. They use the latest technologies, validated methods, and provide some of the lowest detection limits relative to other highly respected laboratories in the U.S. While NQAC is a Nestlé facility, they also conduct analytical testing for other companies and institutions.

Analytical results are reviewed by our internal technical team to determine compliance with Nestlé contaminant guidance levels. If any test result exceeds our established guidance levels, a food safety assessment and root cause analysis is conducted to determine the appropriate actions to be taken. These actions may include rejection of the material, approval to use the material as intended, or approval to use the material under specified and limited conditions. Materials that exceed a regulatory requirement, such as lead in juice, would be unconditionally rejected.

- 2. A spreadsheet specifying for each baby food product:**
- a. the maximum allowable level of each contaminant in that product; and**
 - b. the dates of all detection tests, specifying the contaminant(s) for which the test was searching;**

Nestlé has established contaminant guidance levels across all baby food product categories. These guidance levels inform product design, grower and supplier selection and testing protocols. These contaminant guidance levels are established based on an evaluation of the latest food safety and regulatory guidance – from sources like the Food and Drug Administration, Environmental Protection Agency, the European Food Safety Authority and the World Health Organization. They also take into consideration what is achievable with the agricultural practices of the market. A summary of our contaminant guidance levels is provided in response to question number one above.

Regarding test results, the following are provided in the accompanying Appendix:

- 2017/2018/2019 test results for arsenic in rice flour used for infant rice cereal
- 2017/2018/2019 test results for lead and arsenic in juice concentrates used to make our finished juice products
- 2017/ 2018/2019 test results for lead and cadmium in sweet potatoes and carrots – two vegetable crops recognized for their potential risk for low levels of heavy metals.
- 2017/2018/2019 test results for other fruits and vegetables commonly consumed by young children

A short summary of the results is below:

Rice Flour for Infant rice cereal

Inorganic arsenic is controlled in the incoming rice ingredient to ensure the finished infant rice cereal complies with the FDA proposed 100 ppb inorganic arsenic limit for infant rice cereal. Gerber works closely with our supplier based in Arkansas. Our supplier tests rice at the field level to identify rice that will meet Gerber requirements beginning with preliminary testing after harvest. Testing is conducted two more



times throughout the milling process to ensure each rice cereal batch will be compliant with the FDA proposed guidance level. Through these efforts, we have achieved significant reductions in levels of inorganic arsenic in rice-based foods.



Juice Concentrates

All test results for juice concentrate ingredients (pear, apple, white grape) supported manufacture of finished products compliant with the FDA proposed lead guidance limit for apple juice. Testing is conducted on the juice concentrate ingredients. These ingredients are reconstituted with water to make single strength juice products. The water used to make our juice is treated with reverse osmosis to ensure the water source does not contribute to heavy metal levels in finished juice. Results reported are on the concentrate ingredient. Arsenic is reported as either total arsenic, inorganic arsenic or both. Inorganic arsenic is a subset of total arsenic. To determine the level equivalent to single strength juice from the data provided: divide the value by the Brix in concentrate and then multiply by the Brix for single strength juice.

For example:

$40\text{ppb lead} \div 68 \text{ Brix concentrate} = 0.588 \text{ ppb}$

$0.588\text{ppb} \times 16 \text{ Brix in single strength juice} = 9.4 \text{ ppb in single strength juice.}$

| Juice Type | Brix Single Strength Juice | Brix Concentrate ingredient |
|-------------|----------------------------|-----------------------------|
| Apple | 11.5 | 70 |
| White Grape | 16 | 68 |



Carrots and sweet potatoes

Carrots and sweet potatoes are root crops recognized to be a potential risk for heavy metals, specifically cadmium and lead. Data from 2017, 2018, and 2019 were consistent with Nestlé contaminant guidance levels with two exceptions – one result from 2018 for cadmium in carrots and one result from 2017 for a slightly elevated lead level in sweet potatoes. As mentioned elsewhere in this response, the Gerber team works with our growers and suppliers, helping them to institute the practices necessary to ensure our guidance levels are met. All other data on carrots and sweet potatoes were consistent with Nestlé contaminant guidance levels.

As additional background, Gerber has had soil standards in place for carrots since 2007. This includes soil testing for lead and cadmium prior to planting carrots at each growing season. Our growing history with carrots suggests that soil testing can be a useful tool for predicting the level of heavy metals in peeled root vegetables.

As part of our continuous improvement program for sweet potatoes, we changed our sourcing practices in 2018. Prior to 2018, we did not have the capability to establish a correlation between soil test results for lead and cadmium and levels in peeled sweet potatoes. The change implemented in 2018 improved our ability to trace to the field level and, as a result, we initiated a soil testing program with standards similar to those instituted for carrots. This was based on the theory that these heavy metal limits in soil should result in sweet potatoes consistent with Nestlé guideline levels. Our first year of data indicates that uptake of heavy metals from soils by vegetables is species specific and, as a result, the standard used for soil testing for carrots may not be transferrable to sweet potatoes. A study to better understand heavy metal translocation in sweet potatoes is being implemented during the 2019 growing season which will inform best practices for further reductions in heavy metal levels.

Other fruits and vegetables

Nestlé maintains a global sourcing and contaminant management strategy that identifies food ingredients and crops at risk for the presence of heavy metals and other contaminants, including emerging contaminants. Risks are identified through published data, food safety assessments by government organizations and through our own extensive monitoring and testing of crops globally. This data is evaluated by our experts at the Nestlé Research Center who assign a risk level for each potential contaminant monitored by Nestlé according to a specific crop or ingredient. Once sufficient data exists to support that an ingredient is not likely to be a source of a contaminant, it is designated as “low risk” and testing is reduced or eliminated. This is the case for heavy metals in many fruits and vegetables and is why we have relatively few data points on peas and green beans among other ingredients.

3. For each test identified in response to 2(b) that indicated the presence of a contaminant, the test report and a description of what your company did with the food (i.e. sell, dispose, recall, etc.)

Trace amounts of many elements occur naturally in the environment. They are in the water and soil – so it is possible they can get into fruits, vegetables and grains as they grow. The mere presence of heavy



metals is not an indication that the product is unsafe. All test results provided in response to question 2b represent ingredients used in our production.

4. All documents related to specific positive test results for the presence of contaminants in your company's baby food products, including documents related to deciding what to do with the specific products that tested positive (e.g. whether to conduct a recall);

Trace amounts of many elements occur naturally in the environment. They are in the water and soil – so it is possible they can get into fruits, vegetables and grains as they grow. The mere presence of heavy metals is not an indication that the product is unsafe – therefore recalls are not based solely on detection of a heavy metal in a food product.

Nestlé has established contaminant guidance levels for all baby food product categories. These guidance levels are based on an evaluation of the latest food safety and regulatory guidance – from sources like the Food and Drug Administration, Environmental Protection Agency, the European Food Safety Authority and the World Health Organization.

This response provides details on Nestlé contaminant guidance levels and analytical results for certain contaminants, namely the heavy metals, in Gerber ingredients. Our supplier, grower and raw material sourcing programs are designed to control for heavy metals throughout the supply chain starting at the field level. Contaminant levels may also vary based on growing conditions and other environmental factors. If any test result indicates an ingredient may result in a product exceeding our established guidance levels, we conduct a food safety assessment as well as a root cause analysis to determine the appropriate actions to be taken. These actions may include rejection of the material, approval to use the material as intended, or approval to use the material under specified and limited conditions. Materials that exceed a regulatory requirement, such as lead in juice, would be unconditionally rejected.

5. A list of all baby food products your company recalled due to the presence of contaminants;

There have been no recalls of Gerber products due to elevated levels of heavy metals.

6. All changes your company made, if any, to its policies and procedures on testing for:
a. Inorganic arsenic in infant rice cereal as a result of the FDA 2016 draft guidance entitled, Inorganic Arsenic in rice Cereals for Infants: Action Level Guidance for Industry;

Prior to the publication of the FDA proposed guidance limit for inorganic arsenic in infant rice cereal, Gerber was actively working on a sourcing program to procure US grown rice flour with a lower inorganic arsenic. At the time of the 2016 FDA publication, Gerber was producing infant rice cereal in compliance with the FDA proposed limit of 100 ppb inorganic arsenic. We work closely with our rice supplier to ensure all rice flour received for the manufacture of infant rice cereal meets or is below the FDA proposed limit. Preliminary testing begins after harvest to identify rice that will comply with Nestle standards. Testing is conducted two more times throughout the milling process to ensure each rice cereal batch will be compliant with the FDA guidance level. Through these efforts, we have achieved significant reductions in levels of arsenic in rice-based foods.



Since weather and growing conditions have an impact on inorganic arsenic levels in rice, Gerber has also invested in research with the University of Arkansas to identify growing practices that may reduce the uptake of inorganic arsenic from the soil. This research conducted between 2012 and 2015 resulted in adoption of irrigation strategies that can reduce arsenic uptake close to rice harvest while maintaining yields.

- b. Inorganic arsenic in apple juice as a result of FDA's 2013 draft guidance entitled, Guidance for Industry Arsenic in Apple Juice: Action level; and lead in fruit juice as a result of FDA's 2004 guidance entitled, Guidance for Industry: Juice Hazard Analysis Critical Control Point Hazards and Controls Guidance, First Edition;**

Gerber has had processes in place for many years to ensure levels of heavy metals are as low as possible. As part of this plan, we have strict guidance limits for contaminants in juices, make our juice only from healthy, clean, mature and undamaged fruit, and ensure every batch of concentrate is tested prior to use in making juice.

Gerber is committed to meeting the FDA draft guidance limiting inorganic arsenic in apple juice. We require our apple juice to meet the 10ppb inorganic arsenic level proposed by FDA and the lead level specified in the Juice HACCP guidance. Compliance is managed through testing on every batch of juice concentrate prior to making our juice. We also use water treated with reverse osmosis, a type of purification process. This ensures the water does not contribute to heavy metal content in the finished juice product.

7. All documents related to the negative neurological effects on babies of contaminants; and

We are not aware of any confirmed reports of infants or children becoming sick from lead or arsenic in baby foods. We take all concerns related to safety very seriously, which is why all of our foods and beverages meet our safety and quality standards and conform to all regulatory compliance guidelines.

- 8. A description of whether you support FDA promptly:**
 - a. finalizing draft guidelines for inorganic arsenic in apple juice;**
 - b. finalizing draft guidelines for inorganic arsenic in infant rice cereal;**
 - c. issuing guidelines for heavy metals in all baby foods;**
 - d. considering neurological harms in setting guidelines**

Gerber prioritizes the safety, health, and well-being of babies. We have publically supported FDA finalizing the draft guidance for inorganic arsenic in apple juice and infant rice cereal. We are also supportive of FDA considering proposed guidelines for heavy metals in additional foods based on the scientific evidence for health risks, including neurological risks as applicable, at current levels of exposure.



In addition to the Nestlé internal programs and procedures to manage contaminants described above, Gerber is also a founding member of the Baby Food Council, which is comprised of leading companies and academic, government, and NGO partners and advisors. The Council was created in January of 2019 with the objective of reducing heavy metals in the products manufactured by the member companies to as low as reasonably achievable using best-in-class management practices.

Early efforts of the Council have focused on identifying those foods and ingredients with the highest potential to contribute to heavy metal exposure in young children. We will also be identifying and evaluating best practices that can be used to further lower heavy metal levels in these foods. Recognizing that heavy metals are widely present in the environment and can get into food, this work will initially focus on the impact of the environment and growing conditions but will also extend to other aspects of the supply chain including handling and processing. Our efforts with the Council represent our commitment to the safety of the baby food category.

I trust this letter addresses your request. Please let me know if we can be of any further help to you in this investigation.

Sincerely,

A handwritten signature in blue ink, appearing to read "W. Partyka". The signature is fluid and cursive, with a large initial "W" and a long, sweeping underline.

William Partyka, CEO

EXHIBIT H

1099 NEW YORK AVENUE, NW SUITE 900 WASHINGTON, DC 20001-4412

JENNER & BLOCK LLP

December 11, 2019

Thomas J. Perrelli
Tel 202/639-6004
tperrelli@jenner.com

The Honorable Raja Krishnamoorthi, Chairman
Subcommittee on Economic and Consumer Policy
Committee on Oversight and Reform
United States House of Representatives
Washington, D.C. 20515-6216

Confidential/Includes Confidential Business Information

Re: Response to Letter Dated November 6, 2019

Dear Chairman Krishnamoorthi:

I write in response to the Subcommittee's November 6, 2019 letter addressed to Adam Ciongoli requesting that Campbell Soup Company ("Campbell") provide certain documents and information as part of the Subcommittee's investigation into the occurrence of certain materials in baby foods. Campbell, through its Plum Organics brand, is committed to its mission of serving babies the very best food from the first bite. Accordingly, Campbell supports the Subcommittee's efforts to ensure that the foods we feed our babies are safe and nourishing.

Campbell provides responses to the Subcommittee's requests below and in the documents accompanying this letter. This response and the documents Campbell is producing today contain confidential business information and are marked as such. Campbell requests that the Committee treat these materials accordingly.

Background

Founded in 1869, Campbell Soup Company is headquartered in Camden, New Jersey. Campbell makes a range of high-quality soups, simple meals, beverages, and snacks. Campbell has distributed Plum Organics baby foods since it acquired the brand in 2013. As the Subcommittee is aware, the U.S. Food and Drug Administration ("FDA") does not regulate or provide guidelines concerning heavy metals in baby foods other than certain cereals and juices, as well as baby formula. Heavy metals occur naturally in the environment, including in soil and water. These naturally occurring substances will, accordingly, often be present in foods to some extent, whether grown in the backyard or procured from a farmers' market or supermarket.

In October 2017, a group called the Clean Label Project made claims about the presence of heavy metals in many brands of baby food, including Plum Organics. Although the report

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was neither peer reviewed nor supported by publicly available data, Campbell took its findings seriously and responded by doing its own testing.

Given the lack of specific FDA guidance on baby food, Campbell used standards from California's Proposition 65, the European Union, and the World Health Organization—along with general guidance from the FDA on lead not specific to baby foods—to develop a testing protocol for evaluating whether heavy metals in Plum Organics' products exceeded levels that independent authorities had determined to be acceptable. For instance, Campbell adopted the Proposition 65 "safe harbor" daily intake level for arsenic—that is, the level under which the substance is deemed to pose no significant risk and thus is free from regulation—of 10 micrograms per day. Standards were similarly derived from the previously identified sources for other heavy metals. Campbell tested each of the Plum Organics foods featured in the Clean Label Project report and confirmed that none of the products exceeded the levels discussed above.

Nevertheless, when a group called Healthy Babies Bright Futures released a report earlier this year that again made claims about a handful of Plum Organics' products, Campbell undertook another round of testing. The results were consistent with the previous rounds: Each product was well within levels deemed acceptable by independent authorities.

Request No. 1

Campbell is committed to the safety of Plum Organics' products. That is why it takes a multi-level approach to ensuring the safety of its supply chain. With specific respect to heavy metals, Campbell has also conducted finished-product and ingredient testing.

Campbell co-manufactures its Plum Organics baby food products. That means that Campbell contracts with suppliers, some of which contract with many baby food companies, to manufacture and package Plum Organics' products. In the case of dry foods, suppliers procure ingredients themselves; with respect to Plum's wide range of pouch products, Campbell specifically directs the co-manufacturers as to which sources they must use for their ingredients.

In either case, Campbell requires that the co-manufacturers of Plum Organics' products adhere to strict standards for ingredients. For instance, under Campbell's Supply Base Requirements and Expectation Manual—standards to which suppliers and co-manufacturers agree and against which they are periodically audited—co-manufacturers must obtain heavy metals warranties from suppliers for their ingredients and certain packaging materials. Campbell's Supply Base Requirements and Expectations ¶ 26[B].

Campbell itself also tests Plum Organics' products for heavy metals. Indeed, Campbell has conducted testing on every Plum Organics product on the market to ensure none exceed

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Page 3

acceptable levels of arsenic, lead, cadmium, or mercury.¹ This testing has occurred in waves, most recently in September 2019, when Campbell reexamined the Plum Organics foods featured in the Healthy Babies Bright Futures report. Moreover, currently, all new products added to the Plum Organics line are subjected to finished-product testing. In addition, Campbell follows a policy of testing new ingredients before introducing them to the supply chain for Plum Organics' baby food pouches. That screening includes testing for heavy metals.

Request No. 2

A spreadsheet with information regarding Campbell testing of its Plum Organics products accompanies this letter.

Requests Nos. 3, 4, and 5

To date, no Plum Organics foods have been found to be above exposure limits set by available domestic and international regulatory bodies, which, as noted above, Campbell used as reference points in the absence of relevant FDA guidance. Campbell has thus never needed to recall a baby food product due to the presence of heavy metals.

Request No. 6

Request No. 6 asks about FDA guidance concerning rice cereal and certain kinds of juice. Plum Organics does not sell either rice cereal or juice.

Request No. 7

A reasonable search has produced no additional relevant documents beyond those that gave rise to this inquiry and related public materials.

Request No. 8

Plum Organics does not manufacture rice cereal or juice and thus does not take a position on the FDA's consideration of guidelines for those products. Campbell does support the FDA developing clear and specific guidance for baby food manufacturers on appropriate levels of heavy metals, based on scientific consensus. We look forward to working with the Subcommittee and the FDA on these issues.

¹ The only product that Campbell has not tested is baby formula, which Campbell has discontinued, effective January 2020. Such additional testing was unnecessary because the baby formula co-manufacturer thoroughly tests its products pursuant to applicable regulations. *See, e.g.*, 21 C.F.R. § 106.40. Campbell has enclosed a letter from the co-manufacturer, PBM Nutritionals, certifying its compliance with all relevant regulations. *See* Certification from PBM Nutritionals Regarding Infant Formula Regulatory Compliance (Dec. 2, 2019).

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Thank you for your partnership in ensuring that babies get the food they need to support healthy growth in their early years. Campbell looks forward to continuing to engage with the Subcommittee. Please contact me if you have any questions.

Sincerely,



Thomas J. Perrelli

EXHIBIT I



FDA Testing Result Investigation August 1, 2019



Confidential Business Information – Not Subject to Freedom of Information Act



QUALITY INGREDIENTS, SIMPLY PACKAGED.

Agenda



- Earth's Best Background
- Earth's Best Rice Cereal Manufacturing
 - Components
 - Supply Chain
- Organic Brown Rice Flour Testing History
- Investigation of FDA Results
- Hain Action Items and Next Steps

Understanding the Earth's Best Mission



We have been cultivating the organic movement for more than 30 years, from responsibly raised protein to sustainably sourced purees. All this with the goal of making better food available to more moms.



At Earth's Best we believe that
Organic Baby Food is a RIGHT, not a privilege.



Earth's Best Portfolio Overview: Birth to Backpack



Formula

Diapers

Cereal

Jars

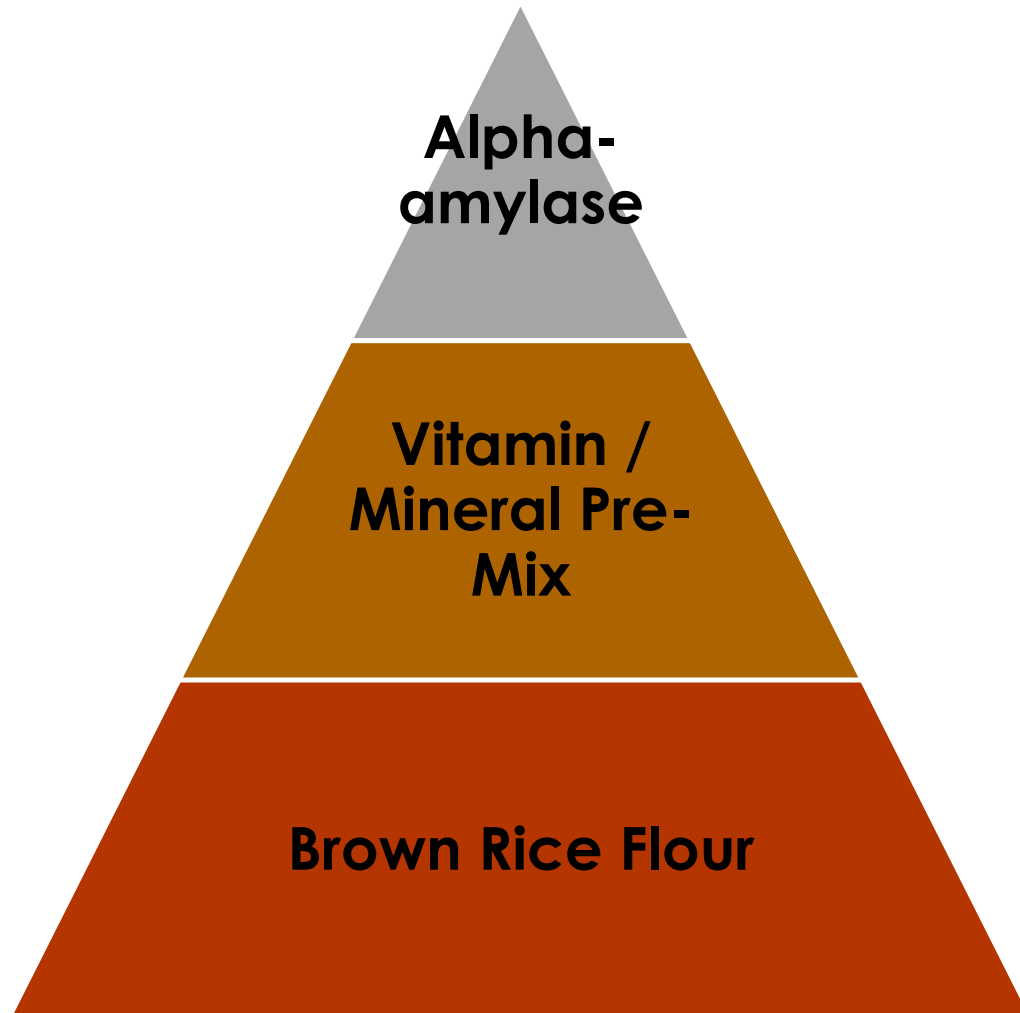
Pouches

Toddler
Pouches

Snacks

Meals

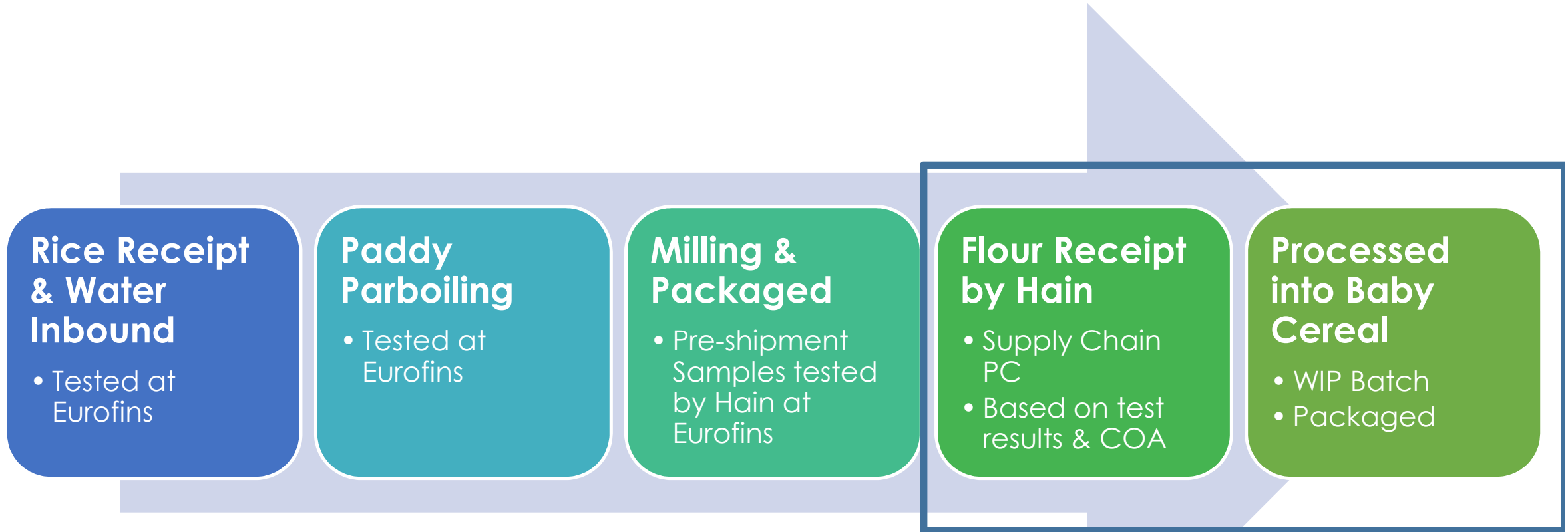
Earth's Best Organic Brown Rice Cereal



- Testing focused on Brown Rice Flour
 - Ingredient Hazard Analysis
 - High Risk of Arsenic presence
 - Dominance in formula (~98%)
 - Sourcing region
- Partnership with key Brown Rice supplier
 - 5+ years
 - Training on food safety management principles throughout the supply chain
 - Strong sustainability programs



Processing and Testing of Rice Cereal



Organic Brown Rice Flour Testing History



- **Brown Rice Flour spec revised based on FDA Guidance in 2016**
 - Decreased pre-shipment acceptance due to Arsenic
 - Decrease in average amount of Arsenic found in pre-shipment samples

| Arsenic Spec Compliance | # Samples Evaluated | Arsenic Spec Acceptance Rate | Avg Arsenic In Spec Samples |
|-------------------------------------|---------------------|------------------------------|-----------------------------|
| Pre-Guidance (2015-2016) | 88 | 98% | 98.5 ppb |
| Post-Guidance (2016-2019) | 142 | 82% | 69.3 ppb |

Note: Actual Acceptance Rates are lower; these exclude rejections for non-Arsenic related issues

Investigation of FDA Results By Lot Code



| 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 | | |
| 1039750 | 3/8/19 | BN E | 74 | 74.0 | 29% | 9/14/17 | 200408 | B160004659 | Total Arsenic | 54 | | |
| | | | | | | | | B160004870 | Total Arsenic | 58 | | |
| | | | | | | | | B160004759 | Total Arsenic | 57 | | |
| 1041752 | 3/20/19 | BN G | 92 | 96.0 | 57% | 9/26/17 | 200651 | B160004871 | Total Arsenic | 60 | 61.3 | |
| 1037933 | | BN E 1536 | 67 | | | | | B160004870 | Total Arsenic | 58 | | |
| 1041751 | 3/21/19 | BN B 0832 | 108 | 97.0 | 69% | 9/27/17 | 201873 | B160005149 | Total Arsenic | 65 | | |
| 1038677 | | BN B 0932 | 116 | | | | | B160004873 | Total Arsenic | 58 | | |
| 1026932 | | BN D 1248 | 97 | | | | | B160005157 | Total Arsenic | 62 | | |
| 1044380 | 4/11/19 | BH C | 100 | 100.0 | 69% | 10/18/17 | 201873 | B160004871 | Total Arsenic | 60 | | 59.0 |
| 1024309 | 4/27/19 | BN I 2216 | 129 | 129.0 | 93% | 11/3/17 | 204146 | B160005148 | Total Arsenic | 61 | | |
| | | | | | | | | B160004872 | Total Arsenic | 55 | | |
| | | | | | | | | B160005152 | Total Arsenic | 61 | | |
| 1024210 | 6/6/19 | BN I 2241 | 94 | 101.0 | 61% | 12/13/17 | 206697 | B160005305 | Total Arsenic | 69 | 62.7 | |
| 547103 | | BN I 2339 | 115 | | | | | B160005306 | Total Arsenic | 76 | | |
| 1013927 | 6/7/19 | BN E 1540 | 92 | 105.0 | 56% | 12/14/17 | 208226 | B160005512 | Total Arsenic | 62 | | |
| 1026516 | | BN H 2123 | 104 | | | | | B160005150 | Total Arsenic | 65 | | |
| 1074288 | 6/8/19 | BNE 1406 | 105 | 105.0 | 56% | 12/15/17 | 208594 | B160006190 | Inorganic Arsenic | 73 | | 64.0 |
| 1035738 | 6/13/19 | BN J 0000 | 96 | 96.0 | 43% | 12/20/17 | | B160005581 | Total Arsenic | 55 | | |
| 1047511 | 6/27/19 | BN C 1142 | 100 | 100.0 | 56% | 1/3/18 | 208594 | B160006189 | Inorganic Arsenic | 81 | 80.5 | |
| 1063061 | 7/19/19 | BN J | 115 | 115.0 | 43% | 1/25/18 | 210374 | B160006191 | Inorganic Arsenic | 80 | | |
| 1027437 | 8/18/19 | BN A 0703 | 97 | 97.0 | 28% | 2/24/18 | 215305 | B160006265 | Inorganic Arsenic | 77 | 75.7 | |
| | | | | | | | | B160006263 | Inorganic Arsenic | 74 | | |
| | | | | | | | | B160006260 | Inorganic Arsenic | 76 | | |
| 784399 | 11/23/19 | BN K 0305 | 108 | 108.0 | 31% | 6/1/18 | 215305 | B160007235 | Inorganic Arsenic | 66 | 82.5 | |
| | | | | | | | | B160006755 | Inorganic Arsenic | 99 | | |

- Variation amongst Finished Good manufacturing date results
- Brown Rice Flour testing results do not appear to be correlated to finished good results data
- Preliminary investigation indicates Vitamin/Mineral Pre-Mix may be a major contributing factor
- Hain is committed to revalidating all components and processing steps to meet FDA guidance

Confidential Business Information –
 Not Subject to Freedom of Information Act



Action Items



- **Review entire supply chain testing and methodologies**
- **Validate minor ingredients impact to Food Safety Plan Hazard Analysis**
- **Explore alternatives for Brown Rice ingredient to reduce risk**
- **Revalidation of processing impact on finished goods**



Appendix

Laboratory Methodology Capabilities



- **Eurofins – *current testing lab***

Arsenic Speciation by IC/ICP-MS (AS_SPEC_S)

Food Integrity Innovation-Madison

Arsenobetaine represents unretained organic arsenic species. Sums represent the quantifiable results plus the estimated results of any species below LOQ.

FDA Elemental Analysis Manual [Internet]. Silver Spring (MD): Food and Drug Administration (US); Section 4.11 [Version 1.1; 2012 November]. Arsenic Speciation in Rice and Rice Products Using High Performance Liquid Chromatography-Inductively Coupled Plasma-Mass Spectrometric Determination.

Kutscher, D., McSheehy, S., Wills, J., Jensen, D., “IC-ICP-MS Speciation Analysis of As in Apple Juice using the Thermo Scientific iCAP Q ICP-MS,”. Thermo Scientific Application Note 43099, (2012).

- **Covance – *Lab purchased by Eurofins, previously NFL***

Arsenic Speciation by IC/ICP-MS (AS_SPEC_S)

Covance Laboratories - Madison

Arsenobetaine represents unretained organic arsenic species. Sums represent the quantifiable results plus the estimated results of any species below LOQ.

FDA Elemental Analysis Manual [Internet]. Silver Spring (MD): Food and Drug Administration (US); Section 4.11 [Version 1.1; 2012 November]. Arsenic Speciation in Rice and Rice Products Using High Performance Liquid Chromatography-Inductively Coupled Plasma-Mass Spectrometric Determination.

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Laboratory Methodology Capabilities



- **Certified Labs - *historic lab***

- Total Arsenic

| | | |
|------------------|---------|---------------------|
| ARSENIC (ICP-MS) | 120 ppb | ICP-MS, FDA EAM 4.7 |
|------------------|---------|---------------------|

- Speciation of Arsenic

ARSENIC SPECIATION

| | | |
|----------------------------|---------|---------------------|
| AS (III) | 85 ppb | EAM: SEC 4: ARSENIC |
| AS (V) | 35 ppb | EAM: SEC 4: ARSENIC |
| TOTAL INORGANIC | 120 ppb | EAM: SEC 4: ARSENIC |
| DIMETHYLARSINIC ACID - DMA | <25 ppb | EAM: SEC 4: ARSENIC |
| MONOMETHYLARSONIC ACID | <25 ppb | EAM: SEC 4: ARSENIC |
| TOTAL ORGANIC | <25 ppb | EAM: SEC 4: ARSENIC |

- **Deibel Labs – *approved back-up lab***

- Total Arsenic

| | | | |
|---------|-----------|--------|---------|
| Arsenic | 0.098 ppm | ICP-MS | PE-2118 |
|---------|-----------|--------|---------|

- Speciation of Arsenic

| | | | |
|-----------------------------|--------|-----------|-----|
| Arsenic Inorganic ICP (ppb) | 95 ppb | IC-ICP-MS | n/a |
|-----------------------------|--------|-----------|-----|