

1 R. Brent Wisner (SBN: 276023)
2 rbwisner@baumhedlundlaw.com
3 Pedram Esfandiary (SBN 312569)
4 pesfandiary@baumhedlundlaw.com
5 **BAUM, HEDLUND, ARISTEI & GOLDMAN, P.C.**
6 10940 Wilshire Blvd., 17th Floor
7 Los Angeles, CA 90024
8 Tel: (310) 207-3233
9 Fax: (310) 820-7444

10 *Attorneys for Plaintiff*

11 **UNITED STATES DISTRICT COURT**
12 **NORTHERN DISTRICT OF CALIFORNIA**

13 AG; HG; and XG, individually and
14 represented by their mother and *guardian ad*
15 *litem* VALENCIA GIBSON,

16 Plaintiffs,

17 v.

18 PLUM, PBC; HAIN CELESTIAL GROUP,
19 INC.; GERBER PRODUCTS COMPANY;
20 NURTURE, INC; BEECH-NUT
21 NUTRITION COMPANY; AND SPROUT
22 FOODS INC.,

23 Defendants.

24 Case No.

25 **COMPLAINT**

26 **DEMAND FOR JURY TRIAL**

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INTRODUCTION

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2 1. This case involves a group of manufacturers—namely Plum, PBC; Hain Celestial
3 Group, Inc.; Gerber Products Company; Nurture, Inc; Beech-Nut Nutrition Company; and Sprout
4 Foods Inc. (“Defendants” or “Defendant Baby Food Manufacturers”)—that *knowingly* sold baby food
5 products (“Baby Foods”) which contain dangerous levels of toxic heavy metals—mercury, lead,
6 arsenic, and cadmium (collectively “Toxic Heavy Metals”), which are all known to be severe
7 neurotoxins—and how such toxic exposures substantially contributed to Plaintiffs developing
8 lifelong brain damage and neurodevelopmental disorders. Plaintiffs AG, HG, and XG (“Plaintiffs”)
9 are three small siblings who live with debilitating Autism Spectrum Disorder (“ASD”) because they
10 consumed poisonous Baby Foods manufactured and sold by these Defendants. This case seeks to
11 hold the Defendant Baby Food Manufacturers accountable for their reprehensible conduct and ensure
12 they are punished for permanently affecting Plaintiffs’ ability to live a fulfilling life.

13 2. That Defendants’ Baby Foods are laced with staggering amounts of Toxic Heavy
14 Metals recently made headlines following research and a Congressional investigation. In February
15 2021, the U.S. House of Representatives’ Subcommittee on Economic and Consumer Policy,
16 Committee on Oversight and Reform released a report containing shocking details of Defendants’
17 tainted Baby Foods based on the submission of internal test results and company documents.
18 Specifically, the Subcommittee found that Defendants sell Baby Foods containing as much as 180
19 parts per billion (“ppb”)¹ inorganic arsenic, 6441 ppb lead, 10 ppb mercury, and manufacture their
20 Baby Foods using ingredients containing as much as 913.4 ppb arsenic, 886.9 ppb lead, and 344.55
21 ppb cadmium, far eclipsing domestic and international regulatory standards. By way of comparison,
22 the U.S. Food and Drug Administration (“FDA”) has set the maximum allowable levels in bottled
23 water at 10 ppb inorganic arsenic, 5 ppb lead, and 5 ppb cadmium, and the U.S. Environmental
24 Protection Agency (“EPA”) has capped the allowable level of mercury in drinking water at 2 ppb.

25
26 _____
27 ¹ Ppb (or ppm) is used to measure the concentration of a contaminant in soils, sediments, and water.
28 1 ppb equals 1 µg (microgram) of substance per kg of solid (µg/kg). For the average baby weighing
approximately 3kg, the quantities of Toxic Heavy Metals found in Defendants’ Baby Foods, as
explained below, pose significant health risks.

1 With a chilling note the Subcommittee concluded that “[m]anufacturers *knowingly* sell these products
2 to unsuspecting parents, in spite of internal company standards and test results, and without any
3 warning labeling whatsoever.”² (emphasis added).

4 3. The high levels of Toxic Heavy Metals found in Defendants’ Baby Foods are, in part,
5 a function of the ingredients used by Defendants to manufacture their Baby Foods, the setting of
6 dangerously inflated internal limits which Defendants willingly flouted, disregard of regulatory
7 standards, and corporate policies which failed to test finished products before market distribution,
8 purchase by unknowing parents, and consumption by vulnerable infants.

9 4. Defendants’ malicious recklessness and callous disregard for human life has wreaked
10 havoc on the health of countless vulnerable children, all so that Defendants could maximize profits
11 while deliberately misleading parents regarding the safety of their Baby Foods. Accordingly, this
12 lawsuit will not only ensure that Plaintiffs are duly compensated for their tragic injuries and
13 Defendants punished, but that future generations are protected from the poisonous products that
14 Defendants pander as “food”.

15 **PARTIES**

16 **I. Plaintiffs**

17 5. Plaintiffs are citizens of Arizona and no other state.

18 **II. Defendants**

19 6. Defendant Plum, PBC (“Plum”) is a citizen of Delaware and California with its
20 principal place of business located at 1485 Park Avenue, Suite 200, Emeryville, California. Plum
21 sells Baby Foods under the brand name Plum Organics. Plum’s products are divided into groups
22 according to the targeted infant or toddler age and/or type of food product. For example, there are
23 five groups designated for the youngest infants: Stage 1 (4+ months old), Stage 2 (6+ months old),
24

25
26 ² Staff Report, Subcommittee on Economic and Consumer Policy Committee on Oversight and
27 Reform U.S. House of Representatives, *Baby Foods Are Tainted with Dangerous Levels of*
28 *Arsenic, Lead, Cadmium, and Mercury* (Feb. 4, 2021) (“Subcommittee Report”) at 59, available at:
<https://oversight.house.gov/sites/democrats.oversight.house.gov/files/2021-02-04%20ECP%20Baby%20Food%20Staff%20Report.pdf>.

1 Stage 3 (6+ months old), “Super Puffs”, and “Little Teethers”. At all relevant times, Plum has
2 conducted business and derived substantial revenue from its manufacturing, advertising, distributing,
3 selling, and marketing of Baby Foods within this judicial district.

4 7. Defendant Nurture, Inc (“Nurture”), is a citizen of Delaware and New York with its
5 principal place of business located at 40 Fulton St, 17th Floor, New York, NY 10038-1850. Nurture
6 owns Happy Family Brands (including Happy Family Organics) and sells Baby Foods under the
7 brand name HappyBaby. Nurture classifies its HappyBaby range of products according to three
8 categories: “baby”, “tot”, and “mama”. The “baby” category is comprised of foods, including
9 “starting solids”, intended for age groups 0-7+ months, the “tot” category covers 12+ months, and
10 “mama” includes infant formulas for newborn babies. At all relevant times, Nurture has conducted
11 business and derived substantial revenue from its manufacturing, advertising, distributing, selling,
12 and marketing of HappyBaby within this judicial district.

13 8. Defendant Beech-Nut Nutrition Company (“Beech-Nut”) is a citizen of Delaware and
14 New York with its principal place of business located at 1 Nutritious Pl., Amsterdam, NY 12010.
15 Beech-Nut sells Baby Foods under the brand name Beech-Nut. Beech-Nut produces Baby Foods
16 aimed at infants 4+ months up to 12+ months and includes a variety of cereals, “jars”, and “pouches”
17 for these age groups. At all relevant times, Beech-Nut has conducted business and derived substantial
18 revenue from its manufacturing, advertising, distributing, selling, and marketing of Baby Foods
19 within this judicial district.

20 9. Defendant Hain Celestial Group, Inc. (“Hain”) is a citizen of Delaware and New York
21 with its principal place of business located at 1111 Marcus Ave., Lake Success, NY 11042. Hain sells
22 Baby Foods under the brand name “Earth’s Best Organics”. Hain offers infant and baby formula and
23 foods as well as toddler foods covering products from “organic infant cereal” to “organic snacks for
24 toddlers and kids on the go”. At all relevant times, Hain has conducted business and derived
25 substantial revenue from its manufacturing, advertising, distributing, selling, and marketing of Baby
26 Foods within this judicial district.

27 10. Defendant Gerber Products Company (“Gerber”) is a citizen of Michigan with its
28 principal place of business located at 445 State Street, Fremont, MI 49413-0001. Gerber sells Baby

1 Foods under the brand name Gerber. Gerber organizes its products into broad categories of
2 “formula”, “baby cereal”, “baby food”, “snacks”, “meals & sides” “beverages” and “organic”. At all
3 relevant times, Gerber has conducted business and derived substantial revenue from its
4 manufacturing, advertising, distributing, selling, and marketing of Baby Foods within this judicial
5 district.

6 11. Defendant Sprout Foods, Inc. (“Sprout”) is a citizen of Delaware and New Jersey with
7 its principal place of business located at 50 Chestnut Ridge Rd, Montvale, NJ 07645. Sprout sells
8 Baby Foods under the brand name Sprout Organic Foods. Sprout organizes its Baby Foods selection
9 according to three categories: Stage 2 (6 months+); Stage 3 (8 months+); and Toddler. At all relevant
10 times, Sprout has conducted business and derived substantial revenue from its manufacturing,
11 advertising, distributing, selling, and marketing of Baby Foods within this judicial district.

12 **JURISDICTION AND VENUE**

13 12. This Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1332. There is
14 complete diversity of citizenship between the parties. In addition, Plaintiffs seek damages in excess
15 of \$75,000, exclusive of interest and costs.

16 13. This Court has personal jurisdiction over Plum because Plum is a citizen of the State
17 of California and resides within this judicial district. The Court has personal jurisdiction over Hain,
18 Nurture, Gerber, Beech-Nut, and Sprout insofar as each Defendant is authorized and licensed to
19 conduct business in the State of California, maintains and carries on systematic and continuous
20 contacts in this judicial district, regularly transacts business within this judicial district, and regularly
21 avails itself of the benefits of this judicial district.

22 14. Additionally, Defendants caused tortious injury by acts and omissions in this judicial
23 district and caused tortious injury in this district by acts and omissions outside this jurisdiction while
24 regularly doing and soliciting business, engaging in a persistent course of conduct, and deriving
25 substantial revenue from goods used or consumed and services rendered in this judicial district.

26 15. Venue is proper in this Court pursuant to 28 U.S.C. §1391 because all Defendants are
27 subject to the Court’s personal jurisdiction within this district. Plum is headquartered within this
28 judicial district and all Defendants maintain continuous, regular, and systematic contacts within this

1 judicial district.

2 16. Additionally, the Court has pendent personal jurisdiction over all Defendants.

3 **FACTUAL ALLEGATIONS**

4 **I. Rising Concerns Regarding the Presence of Toxic Heavy Metals in Baby Foods**

5 17. In October 2019, an alliance of nonprofit organizations, scientists and donors named
6 “Happy Babies Bright Futures” (“HBBF”), dedicated to designing and implementing “outcomes-
7 based programs to measurably reduce babies’ exposures to toxic chemicals”³, published a report
8 investigating the presence of Toxic Heavy Metals in baby foods.⁴ The HBBF Report tested 168
9 different baby foods sold on the U.S. market and concluded that “[n]inety-five percent of baby foods
10 tested were contaminated with one or more of four toxic heavy metals—arsenic, lead, cadmium and
11 mercury. All but nine of 168 baby foods contained at least one metal; most contained more than
12 one.”⁵ Specifically, the HBBF report identified “puffs and other snacks made with rice flour”,
13 “[t]eething biscuits and rice rusks”, “infant rice cereal”, “apple, pear, grape and other fruit juices”,
14 and “carrots and sweet potatoes” manufactured by baby food companies as particularly high in Toxic
15 Heavy Metals.⁶

16 18. The results of the HBBF report were consistent with that of the FDA which had, in
17 2017, detected one or more of the four Toxic Heavy Metals in 33 of 39 types of baby food tested.⁷
18 However, the HBBF reported that “[f]or 88 percent of baby foods tested by HBBF—148 of 168 baby
19 foods—FDA has failed to set enforceable limits or issue guidance on maximum safe amounts.”⁸ To
20 that end, the HBBF, along with other concerned stakeholders, urged the FDA to, among other
21

22 _____
23 ³ <https://www.hbbf.org/solutions>.

24 ⁴ Healthy Babies Bright Futures, *What’s in My Baby’s Food? A National Investigation Finds 95*
25 *Percent of Baby Foods Tested Contain Toxic Chemicals That Lower Babies’ IQ, Including Arsenic*
26 *and Lead* (Oct. 2019) (“HBBF Report”), available at:
www.healthybabyfood.org/sites/healthybabyfoods.org/files/2019-10/BabyFoodReport_FULLREPORT_ENGLISH_R5b.pdf.

27 ⁵ *Id.* at 6.

28 ⁶ *Id.* at 10-11

⁷ *Id.* at 6.

⁸ *Id.* at 6.

1 measures, “[s]et health-protective standards for heavy metals, prioritizing foods that offer FDA the
2 greatest opportunity to reduce exposure, considering additive effects of the multiple metals detected
3 in foods, and explicitly protecting against neurodevelopmental impacts... Implement a proactive
4 testing program for heavy metals in foods consumed by babies and toddlers...[and] [e]stablish a goal
5 of no measurable amounts of cadmium, lead, mercury, and inorganic arsenic in baby and children’s
6 food, in recognition of the absence of a known safe level of exposure, and work with manufacturers
7 to achieve steady progress.”⁹ The HBBF also invited baby food manufacturers to share its goal of
8 reducing “heavy metals in baby food to levels as low as reasonably achievable.”¹⁰

9 19. The HBBF’s findings were by no means an outlier. Eight months prior to publication
10 of the HBBF report, a study conducted by scientists at the University of Miami and the Clean Label
11 Project “examined lead and cadmium concentrations in a large convenience sample of US baby
12 foods.”¹¹ The study detected lead in 37% of samples, and cadmium in 57%.¹² This was consistent
13 with findings by researchers examining baby food products in other parts of the world. In December
14 2019, Brazilian researchers observed that “[i]norganic contaminants, including those commonly
15 known as ‘heavy metals’ (cadmium, arsenic, lead and mercury)...may be present in baby foods such
16 as infant formulas, cereals, snacks, prepared meals, and jarred fruits and vegetables.”¹³ And, in 2011
17 Swedish scientists from the renowned Karolinska Institute noted that that “[h]igh levels of arsenic in
18 [infant] rice-based foods are of concern.”¹⁴

19 **II. Congressional Investigation Finds Substantial Presence of Heavy Metals in Baby Foods**

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21 ⁹ *Id.* at 8-9.

22 ¹⁰ *Id.* at 9

23 ¹¹ Gardener, et al., *Lead and cadmium contamination in a large sample of United States infant*
24 *formulas and baby foods*, 651 SCI. TOTAL ENVIRON. 1, 822-827 (2019), available at:
<https://www.sciencedirect.com/science/article/abs/pii/S0048969718334442?via%3Dihub>.

25 ¹² *Id.*

26 ¹³ De Paiva, et al., *Occurrence and determination of inorganic contaminants in baby food and infant*
formula, 30 CURR. OPIN. FOOD SCI. (2019), available at:
<https://www.sciencedirect.com/science/article/abs/pii/S2214799318301565#!>.

27 ¹⁴ Bjorklund, et al., *High concentrations of essential and toxic elements in infant formula and infant*
foods - A matter of concern 127 FOOD. CHEM (2011), available at:
28 [https://www.researchgate.net/publication/228471005_High_concentrations_of_essential_and_toxic_e](https://www.researchgate.net/publication/228471005_High_concentrations_of_essential_and_toxic_elements_in_infant_formula_and_infant_foods_-_A_matter_of_concern/citation/download)
[lements_in_infant_formula_and_infant_foods_-_A_matter_of_concern/citation/download](https://www.researchgate.net/publication/228471005_High_concentrations_of_essential_and_toxic_elements_in_infant_formula_and_infant_foods_-_A_matter_of_concern/citation/download).

1 Sparking National Outrage

2 20. On February 4, 2021, the U.S. House of Representatives' Subcommittee on Economic
3 and Consumer Policy, Committee on Oversight and Reform, published a report detailing its findings
4 that Toxic Heavy Metals—including arsenic, cadmium, lead, and mercury—were present in
5 “significant levels” in numerous commercial baby food products.¹⁵ Four companies—Hain, Gerber,
6 Nurture, and Beech-Nut —produced internal testing policies, test results for ingredients and finished
7 products, and documentation about what the companies did with ingredients and/or finished products
8 that exceeded their internal testing limits. Three companies—Plum,¹⁶ Walmart, and Sprout—refused
9 to cooperate.¹⁷

10 21. The Subcommittee reported that the data submitted by the companies unequivocally
11 revealed that a substantial number of Defendants' finished products and/or ingredients used to
12 manufacture the Baby Foods are tainted with significant levels of Toxic Heavy Metals, namely
13 inorganic arsenic, lead, cadmium, and mercury.¹⁸

14 22. Specifically, the Subcommittee concluded that:

15 **ARSENIC** was present in baby foods made by all responding companies:

- 16 a. Nurture (HappyBABY) sold baby foods after tests showed they contained as
17 much as 180 parts per billion (ppb) inorganic arsenic. Over 25% of the
18 products Nurture tested before sale contained over 100 ppb inorganic arsenic.
19 Nurture's testing shows that the typical baby food product it sold contained 60
20 ppb inorganic arsenic.
- 21 b. Beech-Nut used ingredients after they tested as high as 913.4 ppb arsenic.
22 Beech-Nut routinely used high-arsenic additives that tested over 300 ppb
23

24 ¹⁵ See generally Subcommittee Rpt.

25 ¹⁶ Plum's parent corporation, Campbell's, responded to the Subcommittee's inquiries, and the
26 Subcommittee Report references the parent corporation as opposed to Plum. However, as Plum is the
27 Defendant in this lawsuit, any references to the Subcommittee's findings regarding Campbell are
28 attributed to Plum. The same Baby Foods are at issue.

¹⁷ Subcommittee Rpt. at 2.

¹⁸ *Id.* at 2-3.

1 arsenic to address product characteristics such as “crumb softness.”

- 2 c. Hain (Earth’s Best Organic) sold finished baby food products containing as
3 much as 129 ppb inorganic arsenic. Hain typically only tested its ingredients,
4 not finished products. Documents show that Hain used ingredients testing as
5 high as 309 ppb arsenic.
- 6 d. Gerber used high-arsenic ingredients, using 67 batches of rice flour that had
7 tested over 90 ppb inorganic arsenic.

8 **LEAD** was present in baby foods made by all responding companies:

- 9 a. Nurture (HappyBABY) sold finished baby food products that tested as high as
10 641 ppb lead. Almost 20% of the finished baby food products that Nurture
11 tested contained over 10 ppb lead.
- 12 b. Hain (Earth’s Best Organic) used ingredients containing as much as 352 ppb
13 lead. Hain used many ingredients with high lead content, including 88 that
14 tested over 20 ppb lead and six that tested over 200 ppb lead.
- 15 c. Beech-Nut used ingredients containing as much as 886.9 ppb lead. It used
16 many ingredients with high lead content, including 483 that contained over 5
17 ppb lead, 89 that contained over 15 ppb lead, and 57 that contained over 20
18 ppb lead.
- 19 d. Gerber used ingredients that tested as high as 48 ppb lead; and used many
20 ingredients containing over 20 ppb lead.

21 **CADMIUM** was present in baby foods made by all responding companies:

- 22 a. Beech-Nut used 105 ingredients that tested over 20 ppb cadmium. Some tested
23 much higher, up to 344.55 ppb cadmium.
- 24 b. Hain (Earth’s Best Organic) used 102 ingredients in its baby food that tested
25 over 20 ppb cadmium. Some tested much higher, up to 260 ppb cadmium.
- 26 c. Sixty-five percent of Nurture (HappyBABY) finished baby food products
27 contained more than 5 ppb cadmium.
- 28 d. Seventy-five percent of Gerber’s carrots contained cadmium in excess of 5

1 ppb, with some containing up to 87 ppb cadmium.

2 **MERCURY:**

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

5 b. Gerber rarely tests for mercury in its baby foods and Hain (Earth's Best
6 Organic) and Beech-Nut do not even test for mercury in baby food.¹⁹

7 However, independent testing by HBBF of Hain's Baby Foods confirm that
8 Hain's products contain as much as 2.4 ppb of mercury.²⁰

9 23. These levels greatly surpass the limits allowed by U.S. regulatory agencies. Upon
10 information and belief, there are no FDA regulations governing the presence of Toxic Heavy Metals
11 in Baby Foods specifically; to the extent such regulations exist, the quantities of Toxic Heavy Metals
12 in Defendants' Baby Foods far exceed any permissible FDA levels. To be sure, the FDA has set the
13 maximum contaminant levels ("MCL") in bottled water at 10 ppb inorganic arsenic, 5 ppb lead, and 5
14 ppb cadmium, and the EPA has capped the allowable level of mercury in drinking water at 2 ppb.
15 However, these limits were created in reference to *adult* exposure, not infants. Compared to these
16 thresholds, the test results of the Defendants' Baby Foods and their ingredients are 91 times (903
17 ppb) greater than permitted arsenic levels, 177 times (881 ppb) greater than permitted lead levels, 70
18 times (339 ppb) greater than permitted cadmium levels, and 5 times (8 ppb) greater than permitted
19 mercury levels.²¹

20 24. Moreover, compounding these troubling findings, the Defendants set internal limits
21 for the presence of Toxic Heavy Metals in their foods that were, themselves, dangerously high and
22 then routinely failed to abide by those inadequate standards. For example, the Subcommittee found
23 that Hain (Earth's Best Organic) set an internal standard of 200 ppb for arsenic, lead, and cadmium in
24 some of its ingredients. But Hain routinely exceeded its internal policies, using ingredients
25 containing 353 ppb lead and 309 ppb arsenic. Hain justified these deviations based on "theoretical

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27 ¹⁹ *Id.* at 2-4.

28 ²⁰ *See* HBBF Rpt. at 19.

²¹ Subcommittee Rpt. at 3-4.

1 calculations,” even after Hain admitted to the FDA that its testing *underestimated* final product toxic
2 heavy metal levels.²² Similarly, Beech-Nut set internal arsenic and cadmium standards at 3,000 ppb
3 in additives, such as vitamin mix, and 5,000 ppb lead for certain ingredients like BAN 800. The
4 Subcommittee observed that these standards are the highest of any responding manufacturer.²³

5 25. As found by the Subcommittee, Defendants have willfully sold—and continue to
6 sell—contaminated Baby Foods notwithstanding their full awareness of these unacceptably high
7 levels of Toxic Heavy Metals in their products. In August 2019, Hain held a closed-door meeting
8 with the FDA during which Hain delivered a presentation to the agency acknowledging the Toxic
9 Heavy Metal problem in its Baby Food.²⁴ In the PowerPoint slides presented during the meeting—
10 only made public by the Subcommittee—Hain confirmed that some of the ingredients in its Baby
11 Food contain as much as between 108 to 129 ppb of arsenic, specifically noting “[p]reliminary
12 investigation indicates Vitamin/Mineral Pre-Mix may be a major contributing factor”²⁵.

13 Additionally, the presentation revealed that:

- 14 a. Hain’s corporate policy to test only ingredients, not final products,
15 underrepresents the levels of toxic heavy metals in baby foods. In 100% of the
16 Hain baby foods tested, inorganic arsenic levels were higher in the finished
17 baby food than the company estimated they would be based on individual
18 ingredient testing. Inorganic arsenic was between 28% and 93% higher in the
19 finished products;
- 20 b. Many of Hain’s baby foods were tainted with high levels of inorganic
21 arsenic—half of its brown rice baby foods contained over 100 ppb inorganic
22 arsenic; its average brown rice baby food contained 97.62 ppb inorganic
23 arsenic; and

24
25 ²² *Id.* at 4-5.

26 ²³ Subcommittee Rpt. at 4.

27 ²⁴ Hain, *PowerPoint Presentation to Food and Drug Administration: FDA Testing Result*
Investigation (Aug. 1, 2019) (“2019 Hain & FDA Meeting”), available at:
28 <https://oversight.house.gov/sites/democrats.oversight.house.gov/files/2.pdf>.

²⁵ *Id.* at *9.

1 c. Naturally occurring toxic heavy metals may not be the only problem causing
2 the unsafe levels of toxic heavy metals in baby foods; rather, baby food
3 producers like Hain may be adding ingredients that have high levels of toxic
4 heavy metals into their products, such as vitamin/mineral pre-mix.²⁶

5 26. Moreover, although Plum and Sprout refused to cooperate with the Subcommittee's
6 investigation, independent data confirms that the Baby Food of these companies is similarly tainted.

7 27. Instead of producing any substantive information, Plum provided the Subcommittee
8 with a self-serving spreadsheet declaring that every one of its products "meets criteria",²⁷ while
9 declining to state what the criteria were. Plum's disingenuous testing summary speaks volumes since
10 the summary does not show the levels of Toxic Heavy Metals that the testing found or the levels that
11 would "meet criteria." Disturbingly, Plum admitted that, for mercury (a powerful neurotoxin), the
12 company has *no criterion* whatsoever, stating: "No specific threshold established because no high-
13 risk ingredients are used."²⁸ However, despite Plum having no mercury threshold, it still marked
14 every food as "meets criteria" for mercury. The Subcommittee noted that "[t]his misleading
15 framing—of meeting criteria that do not exist—raises questions about what [Plum's] other thresholds
16 actually are, and whether they exist."²⁹ Indeed, HBBF's independent testing confirms the presence of
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26 ²⁶ Subcommittee Report at 5-6

27 ²⁷ Campbell, *Product Heavy Metal Test Results* (Dec. 11, 2019), available at:
<https://oversight.house.gov/sites/democrats.oversight.house.gov/files/12.pdf>.

28 ²⁸ *Id.* at 00046.

29 ²⁹ Subcommittee Report at 45.

1 Toxic Heavy Metals in Plum's Baby Food:

Food	Arsenic (total, ppb)	Arsenic (inorganic, ppb)	Lead (ppb)	Cadmium (ppb)	Mercury (total, ppb)
Plum Organics Pumpkin Banana Papaya Cardamom, 6 months & up	2.4*	--	1.4*	2.4	<0.139
Plum Organics Apple, Raisin, & Quinoa Organic Baby Food- 2	5.6*	--	2.2	1.9	0.145*
Plum Organics Little Teethers Organic Multigrain Teething Wafers- Banana with Pumpkin- Baby Crawler	49.9	--	1.4*	6.3	0.726
Plum Organics Mighty Morning Bar- Blueberry Lemon- Tots, 15 months & up	40 ⁹	39	3.4	24.3	<0.137

14
15 28. Discovery will flesh out in greater detail the extent of Toxic Heavy Metals in Plum's
16 Baby Foods.

17 29. Sprout did not respond to the Subcommittee at all. Again, the testing conducted by
18 HBBF confirms that Sprout's Baby Foods are similarly tainted by substantial amounts of Toxic
19 Heavy Metals:

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	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

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24 30. As the Subcommittee noted, "[w]hether due to evasion or negligence, Sprout's failure
25 to respond raises serious concerns about the presence of toxic heavy metals in its baby foods, as even
26 limited independent testing has revealed the presence of toxic heavy metals in its products."³⁰

27
28 ³⁰ Subcommittee Rpt. at 46

1 Discovery will flesh out in greater detail the extent of Toxic Heavy Metals in Sprout’s Baby Foods.

2 **III. Pediatric ASD**

3 31. Autism spectrum disorder (“ASD”) is a developmental disability that can cause
4 significant social, communication and behavioral challenges, particularly for children diagnosed with
5 the disorder. ASD includes conditions that were previously considered separate—autism, Asperger’s
6 syndrome, childhood disintegrative disorder, and an unspecified form of pervasive developmental
7 disorder. The CDC estimates that, as of 2016, 1 in 54 U.S. children have ASD.³¹

8 32. There is often nothing about how individuals with ASD look that sets them apart from
9 other people, but those with ASD may communicate, interact, behave, and learn in ways that are
10 different from most other people. The learning, thinking, and problem-solving abilities of people
11 with ASD can range from gifted to severely challenged. Many people with ASD require substantial
12 support in their daily lives, many children with ASD have difficulty learning, and some have signs of
13 lower-than-normal intelligence.

14 33. A child with ASD may have problems with social interaction and communication
15 skills:

- 16 a. Fails to respond to his or her name or appears not to hear others;
- 17 b. Resists cuddling and holding, and seems to prefer playing alone, retreating into
18 his or her own world;
- 19 c. Has poor eye contact and lacks facial expression;
- 20 d. Does not speak or has delayed speech, or loses previous ability to say words or
21 sentences;
- 22 e. Cannot start a conversation or keep one going, or only starts one to make
23 requests or label items;
- 24 f. Speaks with an abnormal tone or rhythm and may use a singsong voice or
25 robot-like speech;
- 26

27
28 ³¹Centers for Disease Control and Prevention (“CDC”), *Data & Statistics on Autism Spectrum Disorder* (September 25, 2020), available at: <https://www.cdc.gov/ncbddd/autism/data.html>.

- 1 g. Repeats words or phrases verbatim, but does not understand how to use them;
- 2 h. Does not appear to understand simple questions or directions;
- 3 i. Does not express emotions or feelings and appears unaware of others' feelings;
- 4 j. Does not point at or bring objects to share interest;
- 5 k. Inappropriately approaches a social interaction by being passive, aggressive or
- 6 disruptive;
- 7 l. Has difficulty recognizing nonverbal cues, such as interpreting other people's
- 8 facial expressions, body postures or tone of voice;

9 34. Many children with ASD continue to have difficulty with language and social skills
10 throughout the course of their lives, and the teen years can bring worse behavioral and emotional
11 problems which may impose severe limitations to their quality of life.

12 35. Some children show signs of ASD in early infancy, such as reduced eye contact, lack
13 of response to their name or indifference to caregivers. Other children may develop normally for the
14 first few months or years of life, but then suddenly become withdrawn or aggressive or lose language
15 skills they have acquired.

16 36. Environmental factors—such as exposure to Toxic Heavy Metals—have been found to
17 play a key role in the development of ASD, with the CDC, Mayo Clinic and NIH all recognizing
18 early life exposure to environmental toxins (such as lead) as risk factors for ASD.³²

19 **IV. Dangers of Toxic Heavy Metals to Babies and Children**

20 37. According to the World Health Organization (“WHO”), Toxic Heavy Metals,
21 specifically arsenic, cadmium, lead, and mercury, pose a “major public health concern” for
22 children.³³ The Occupational Safety and Health Administration (“OSHA”) has warned that these

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25 ³² Mayo Clinic, *Autism spectrum disorder*, available at: <https://www.mayoclinic.org/diseases-conditions/autism-spectrum-disorder/symptoms-causes/syc-20352928>; CDC, *What is Autism Spectrum Disorder?*, available at: <https://www.cdc.gov/ncbddd/autism/facts.html>; NIH, *Autism Spectrum Disorder Fact Sheet*, available at: <https://www.ninds.nih.gov/Disorders/Patient-Caregiver-Education/Fact-Sheets/Autism-Spectrum-Disorder-Fact-Sheet>

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28 ³³ World Health Organization, *Children’s Health and the Environment WHO training Package for the Health Sector* (October 2011), available at: https://www.who.int/ceh/capacity/heavy_metals.pdf.

1 metals “may build up in biological systems and become a significant health hazard.”³⁴ Indeed, the
2 Department of Health and Human Services’ Agency for Toxic Substances and Disease Registry
3 (“ATSDR”) ranks arsenic as number *one* among substances present in the environment that pose the
4 most significant potential threat to human health, followed by lead (second), mercury (third), and
5 cadmium (seventh).³⁵

6 38. The threat presented by Toxic Heavy Metals to children’s health is widely shared by
7 the global scientific community. As one recent study observed, “[t]he implications of heavy metals
8 with regards to children’s health have been noted to be more severe compared to adults. The
9 elements’ harmful consequences on children health include mental retardation, neurocognitive
10 disorders, behavioral disorders, respiratory problems, cancer and cardiovascular diseases. Much
11 attention should be given to heavy metals because of their high toxicity potential, widespread use,
12 and prevalence.”³⁶ Children and, even more so, babies have higher exposure to metals compared to
13 adults because they consume more food in relation to their body weight and absorb metals more
14 readily than adults by 40 to 90%.³⁷ And, the mechanisms needed to metabolize and eliminate heavy
15 metals are comparatively undeveloped in childhood, with babies having weaker detoxifying
16 mechanisms and poorer immune systems than adults.³⁸ For example, liver pathways that in
17 adulthood metabolize absorbed arsenic do not mature until mid-childhood; un-excreted arsenic thus
18 continues to circulate and is deposited in other organs.³⁹ According to Linda McCauley, Dean of the
19 Nell Hodgson Woodruff School of Nursing at Emory University, who studies environmental health

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21 ³⁴ OSHA, *Toxic Metals*, available at: <https://www.osha.gov/toxic-metals>.

22 ³⁵ ATSDR, *ATSDR’s Substance Priority List* (2019), available at:
23 www.atsdr.cdc.gov/spl/index.html#2019spl.

24 ³⁶ Osman, et al., *Exposure routes and health effects of heavy metals on children*, 32 *BIOMETALS* 563–
25 573 (2019), available at: <https://link.springer.com/article/10.1007%2Fs10534-019-00193-5#citeas>.

26 ³⁷ Stein, et al., *In harm’s way: toxic threats to child development*, 23 *J DEV BEHAV PEDIATR* 1 S13–
27 S22 (2002).

28 ³⁸ Gorini, et al., *The Role of Heavy Metal Pollution in Neurobehavioral Disorders: a Focus on Autism*
1 *REV. J. AUTISM DEV. DISORD.* 1, 354–372 (2014), available at:
2 <https://link.springer.com/article/10.1007/s40489-014-0028-3>.

3 ³⁹ Del Rio, et al., *A comparison of arsenic exposure in young children and home water arsenic in two*
4 *rural West Texas communities* 17 *BMC PUBLIC HEALTH* 850 1-13 (2017), available at:
5 <https://bmcpublichealth.biomedcentral.com/articles/10.1186/s12889-017-4808-4>.

1 effects, “[n]o level of exposure to these [heavy] metals has been shown to be safe in vulnerable
2 infants.”⁴⁰ Thus, “the major windows of developmental vulnerability occur during infancy and early
3 childhood due to continuing brain development after birth.”⁴¹ In short, even small amounts of
4 exposure to Toxic Heavy Metals can have devastating health outcomes for babies and children.

5 **A. Exposure to Toxic Heavy Metals Has Been Consistently Associated with Autism**
6 **in Pediatric Populations**

7 39. Multiple studies, reviews, and meta-analyses conducted throughout various parts of
8 the world over the last decade have consistently observed a positive association between exposure to
9 Toxic Heavy Metals and the development of ASD in children and infant populations.

10 40. In 2019, researchers at the University of Buffalo conducted a systematic review and
11 meta-analysis of relevant published research on the association between children’s exposure to
12 inorganic arsenic and ASD.⁴² The meta-analysis concluded that there is consistent evidence
13 supporting a positive association between early life inorganic arsenic exposure and diagnosis of ASD,
14 with the authors noting that “it is in the best interest of policy makers and the public to reduce
15 exposures to [arsenic] among pregnant women and children.”⁴³

16 41. Similar results were observed in another systematic review and meta-analysis
17 published in 2020 by researchers at the State University of New York.⁴⁴ This follow-up meta-
18 analysis investigated the association of exposure to cadmium, mercury, and aluminum and ASD. The
19 authors stated that they selected these metals “because they are abundant in our environment, are
20 known to cause neurological problems in humans, and have multiple published studies examining
21

22 _____
23 ⁴⁰ Roni Caryn Rabin, *Some Baby Food May Contain Toxic Metals, U.S. Reports* (NY TIMES, Feb 4,
24 2021), available at: <https://www.nytimes.com/2021/02/04/health/baby-food-metals-arsenic.html>

25 ⁴¹ Gorini, et al. *supra*.

26 ⁴² Wang, et al., *Exposure to Inorganic Arsenic and Lead and Autism Spectrum Disorder in Children:
27 A Systematic Review and Meta-Analysis*, 21 CHEM. RES. TOXICOL. 32, 1904-1919 (2019), available at:
28 <https://pubmed.ncbi.nlm.nih.gov/31549506/>.

⁴³ *Id.*

⁴⁴ Sulaiman, et al., *Exposure to Aluminum, Cadmium, and Mercury and Autism Spectrum Disorder in
Children: A Systematic Review and Meta-Analysis*, 33 CHEM. RES. TOXICOL. 11, 2699-2718 (2020),
available at: <https://pubmed.ncbi.nlm.nih.gov/32990432/>.

1 their potential links with ASD.”⁴⁵ Specifically, the meta-analysis reviewed 18 studies on cadmium
2 and 23 studies on mercury. When the studies were integrated into the analysis, the authors found
3 significant associations between all the metals and ASD.⁴⁶ Notably, levels of mercury in hair, urine
4 and blood were all positively associated with ASD. Overall, the authors concluded, “these findings
5 support policies that advocate limiting exposure to neurotoxic metals, particularly for pregnant
6 women and young children, in order to help reduce the rising incidence of ASD.”⁴⁷

7 42. An earlier meta-analysis from 2014 similarly concluded that environmental exposures
8 to mercury in early infancy were significantly associated—almost a doubling of the risk—with the
9 development of ASD.⁴⁸ Notably, the authors found that the summary odds ratios (risk of disease)
10 were similar after excluding studies not adjusted for confounders. *Id.*

11 43. Similarly, a 2018 Chinese study observed that children with ASD had significantly
12 higher levels of mercury and arsenic in their blood compared with healthy controls.⁴⁹ The authors
13 proceeded to note “[t]he results of this study are consistent with numerous previous studies,
14 supporting an important role for heavy exposure, particularly mercury, in the etiology of ASD.”⁵⁰

15 44. A 2017 longitudinal cohort study of Korean children measured the levels of mercury
16 in the blood of children at ages 2 and 3.⁵¹ The study authors observed elevated mercury levels in the
17 blood of young children who were later diagnosed with ASD. Indeed, this study was specifically
18 cited by the Subcommittee for the proposition that Toxic Heavy Metals increase the risk of autistic
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20 ⁴⁵ *Id.*

21 ⁴⁶ *Id.*

22 ⁴⁷ *Id.*

23 ⁴⁸ Yoshimasu, et al., *A meta-analysis of the evidence on the impact of prenatal and early infancy*
exposures to mercury on autism and attention deficit/hyperactivity disorder in the childhood, 44
NEURO TOXICOL. 121-131 (2014), available at: <https://pubmed.ncbi.nlm.nih.gov/24952233/>.

24 ⁴⁹ Li, et al., *Blood Mercury, Arsenic, Cadmium, and Lead in Children with Autism Spectrum*
Disorder, 181 BIOL TRACE ELEM RES 31-37 (2018), available at:
25 <https://pubmed.ncbi.nlm.nih.gov/28480499/>.

26 ⁵⁰ *Id.*

27 ⁵¹ 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, 15 SCI. TOTAL
28 ENVIRON. 251-257 (2017), available at:
<https://www.sciencedirect.com/science/article/abs/pii/S0048969717316479>.

1 behaviors in pre-school children.⁵²

2 45. In 2016 a multidisciplinary team comprised of researchers from the University of
3 Texas, University of Utah, Johns Hopkins, University of South Florida, University of Alabama, and
4 Rutgers University analyzed data on 4,486 children with ASD residing in 2,489 census tracts in five
5 sites of the Centers for Disease Control and Prevention's Autism and Developmental Disabilities
6 Monitoring ("ADDM") Network to assess whether ambient lead, mercury, and arsenic concentrations
7 were associated with ASD prevalence.⁵³ Notably, as well as observing an association between
8 ambient lead concentrations and ASD prevalence, the results demonstrated that exposure to multiple
9 metals may have synergistic effects on ASD prevalence.⁵⁴ This is significant because children
10 consuming Defendants' Baby Foods are exposed to repeated, high doses of multiple Toxic Heavy
11 Metals, thereby compounding the risk of ASD. Indeed, recent research indicates that mercury has a
12 threshold effect (the minimum dose of exposure prior to onset of disease) of greater than 15 ppb for
13 the risk of ASD to manifest in a child, with one paper concluding that "[t]he weight of scientific
14 evidence supports [mercury] as a causal factor in subjects diagnosed with an ASD."⁵⁵ Indeed, the
15 available literature consistently observes a dose-response relationship between exposure to Toxic
16 Heavy Metals and ASD, with increased dose resulting in more severe forms of ASD.⁵⁶

17 46. Moreover, a 2015 study of lead and mercury levels in the bodies of Egyptian children
18 concluded that the mean levels of mercury and lead in the hair of children diagnosed with autism
19 were significantly higher than controls.⁵⁷ The authors specifically noted that "[e]nvironmental
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21 ⁵² Subcommittee Report at 13.

22 ⁵³ Dickerson, et al., *Autism spectrum disorder prevalence and associations with air concentrations of*
23 *lead, mercury, and arsenic*, 188 ENVIRON MONIT. ASSESS. 407 (2016).

24 ⁵⁴ *Id.*

25 ⁵⁵ Geier, et al., *Blood mercury levels in autism spectrum disorder:*
26 *Is there a threshold level?* 70 ACTA NEUROBIOL. EXP. 177–186 (2010), available at:
<https://pubmed.ncbi.nlm.nih.gov/20628441/>.

27 ⁵⁶ See Rossignol, et al., *Environmental toxicants and autism spectrum disorders: a systematic review*,
4 TRANSL. PSYCHIATRY 2, 1-23 (2014), available at: <https://pubmed.ncbi.nlm.nih.gov/24518398/>.

28 ⁵⁷ Mohamed, et al., *Assessment of Hair Aluminum, Lead, and Mercury in a Sample of Autistic*
Egyptian Children: Environmental Risk Factors of Heavy Metals in Autism BEHAV. NEUROL. (2015),
available at: <https://pubmed.ncbi.nlm.nih.gov/26508811/>.

1 exposure to these toxic heavy metals, at key times in development, may play a causal role in
2 autism.⁵⁸

3 47. A 2013 U.S. study investigated both the level of Toxic Heavy Metals in children with
4 ASD and the possible association of the metals with ASD severity.⁵⁹ 55 children with autism at ages
5 5-16 were compared to 44 controls with similar age and gender.⁶⁰ After measuring Toxic Heavy
6 Metals in whole blood, red blood cells and urine, the authors observed that the autism group had
7 higher levels of lead in red blood cells and higher urinary levels of lead.⁶¹ A stepwise, multiple linear
8 regression analysis found a strong association of levels of Toxic Heavy Metals with variation in the
9 degree of severity of autism for all the severity scales.⁶² Cadmium (whole blood) and mercury (whole
10 blood and RBC) were the most consistently significant variables.⁶³ The authors concluded that
11 overall, children with autism have higher average levels of several Toxic Heavy Metals, and levels of
12 several Toxic Heavy Metals are strongly associated with variations in the severity of autism.⁶⁴

13 48. In sum, the heavy weight of the literature, as supported by meta-analyses, multiple
14 studies employing varying methodologies and conducted in various countries, strongly supports a
15 causal relationship between exposure to Toxic Heavy Metals and the development of ASD in
16 children.

17 **V. Defendants Knowingly Sold Baby Foods Containing Dangerous Levels of Toxic Heavy**
18 **Metals and Knew or Should Have Known of the Risks of Such Exposures in Children**

19 49. During the time that Defendants manufactured and sold Baby Foods in the United
20 States, the weight of evidence showed that Defendants' Baby Foods exposed babies and children to
21 unsafe levels of Toxic Heavy Metals. Defendants failed to disclose this risk to consumers through
22

23 ⁵⁸ *Id.*

24 ⁵⁹ Adams, et al., *Toxicological Status of Children with Autism vs. Neurotypical Children and the*
25 *Association with Autism Severity*, 151 BIOL. TRACE ELEM. RES 171-180 (2013), available at:
<https://pubmed.ncbi.nlm.nih.gov/23192845/>.

26 ⁶⁰ *Id.*

27 ⁶¹ *Id.*

28 ⁶² *Id.*

⁶³ *Id.*

⁶⁴ *Id.*

1 any means.

2 50. As discussed above, both independent testing, Defendants' internal evaluations of
3 their Baby Food, and Defendants' representations and disclosures to the Subcommittee and FDA
4 reveal the presence of substantial amounts of Toxic Heavy Metals in Defendants' products. As such,
5 Defendants knew or should have known that their Baby Foods contain dangerous of Toxic Heavy
6 Metals.

7 51. Indeed, independent testing performed in early 2019 demonstrated elevated amounts
8 of such Toxic Heavy Metals in Baby Food products on the U.S. market,⁶⁵ and the HBBF Report
9 further confirmed such contamination of Defendants' Baby Food.⁶⁶ And, as the Subcommittee
10 found, Defendants continued to sell their Baby Food even after testing of both ingredients and
11 finished products revealed the presence of substantial amounts of Toxic Heavy Metals.⁶⁷

12 52. Moreover, the scientific literature on the dangers of Toxic Heavy Metals—particularly
13 as it relates to adverse effects on the neurodevelopment of children—have been well known for
14 decades. Defendants, as manufacturers of Baby Foods, are held to the standard of experts responsible
15 for keeping abreast of the latest scientific developments related to the dangers of contaminants in
16 their products. Defendants failed to take action in protecting vulnerable children from exposure to
17 the Toxic Heavy Metals in their foods and, thus, subjected them to the risk of developing
18 neurodevelopmental disorders such as ASD.

19 53. To be clear, Defendants are able to manufacture Baby Foods that do not pose such a
20 dangerous risk to the health of infants and children by using alternative ingredients, not adding
21 certain pre-mix minerals and vitamins high in Toxic Heavy Metals, or sampling their ingredients
22 from other sources, as specifically acknowledged by Hain in its August 2019 presentation to the
23 FDA: "Explore alternatives for Brown Rice ingredient to reduce risk."⁶⁸ At the very least,
24 Defendants were under a duty to warn unsuspecting parents of the presence of Toxic Heavy Metals in
25

26 ⁶⁵ See Gardener, et al., *supra*.

27 ⁶⁶ See HBBF Report, *supra*.

28 ⁶⁷ See, e.g., Subcommittee Report at 13-14.

⁶⁸ 2019 Hain & FDA Meeting at *10.

1 their Baby Foods. However, Defendants took no action, continued to sell their products with full
2 knowledge of the risks posed by their Baby Foods, and misled consumers regarding the safety of their
3 products, all to the harm of children.

4 **A. Nurture**

5 **1. Nurture Sells Products Even After Testing Confirms Their High Toxic Heavy**
6 **Metal Content and Regularly Uses Ingredients High in Toxic Heavy Metals in**
7 **its Baby Food**

8 54. According to internal company documents, Nurture sells products even after testing
9 confirms that they are dangerously high in inorganic arsenic. Nurture sold one such product, Apple
10 and Broccoli Puffs, despite tests results showing it contained 180 ppb inorganic arsenic.⁶⁹ An arsenic
11 level of 180 ppb is high by all standards, but it is 80% higher than Nurture’s own internal goal
12 threshold of 100 ppb. Nurture routinely sold products that exceeded its internal standards. Twenty-nine
13 other products that Nurture tested and sold registered over 100 ppb inorganic arsenic. In total, over 25%
14 of the products that Nurture tested for inorganic arsenic, and sold, had inorganic arsenic levels above 100
15 ppb.⁷⁰

16 55. Moreover, Nurture sold products that tested as high as 641 ppb lead—over six times
17 higher than its internal limit of 100 ppb lead.⁷¹ Nurture also sold five other products after they tested over
18 50 ppb lead.⁷² Of the 206 finished products that Nurture tested for lead, 16 products registered over 20
19 ppb lead—exceeding the EU standard. And 39 products, or 18.9%, tested over 10 ppb lead.⁷³ It is not
20 clear that even one of Nurture’s baby food products registered at or below 1 ppb lead, which should be the
21 upper limit for lead content according to health experts at Consumer Reports, the Environmental Defense
22 Fund, and the American Academy of Pediatrics.⁷⁴ The average amount of inorganic arsenic in the baby
23 _____

24 ⁶⁹ See Nurture, *Heavy Metal Test Results for Baby Food Products* (Dec. 18, 2019) (“Nurture Test
25 Results”), available at: <http://oversight.house.gov/sites/democrats.oversight.house.gov/files/1.xlsx>.

26 ⁷⁰ *Id.*

27 ⁷¹ *Id.*

28 ⁷² *Id.*

⁷³ *Id.*

⁷⁴ See Consumer Reports, *Consumer Reports letter to FDA on reducing heavy elements like arsenic, lead, and cadmium in fruit juices* (January 2019), available at:

1 foods that Nurture tested and sold was 59.54 ppb. That towers over existing and recommended standards,
2 including FDA's and EPA's water limits of 10 ppb. At least 89 of Nurture's final products—over 78% of
3 those products tested—tested at 9 ppb inorganic arsenic or above. For results under 9.54 ppb, Nurture did
4 not differentiate—it marked them all as “<9.54.” Because of this “less than” reporting format, there is no
5 way to confirm if any of Nurture's products were free of inorganic arsenic. Nurture sold multi-grain
6 cereal with 49 ppb cadmium; 125 products that tested over 5 ppb, which is the EPA's limit for drinking
7 water;⁷⁵ a finished baby food product that contained 10 ppb mercury; and two others that contained 9.8
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
9 total, Nurture sold 56 products that contained over 2 ppb mercury.

10 **2. Nurture Willfully and Recklessly Disregards Internal and Regulatory** 11 **Standards for Toxic Heavy Metals in is Baby Food.**

12 56. Nurture created internal standards but did not follow them. Nurture describes these
13 standards as “goal thresholds” that “are not used to make product disposition decisions and are not a pre-
14 condition to product release.”⁷⁶ Instead, its testing regime is limited to monitoring the supply chain as
15 opposed to ensuring that babies are not exposed to Toxic Heavy Metals. Nurture's thresholds are not
16 actually used to prevent products that contain high levels of toxic heavy metals from being sold.⁷⁷

17 57. Nurture does not even claim to be testing for safety. In its letter response to the
18 Subcommittee, Nurture stated: “our heavy metal testing is performed as part of our monitoring
19 program and not as a condition of product release, all of the products that were tested were sold into
20

21
22 [https://advocacy.consumerreports.org/research/consumer-reports-letter-to-fda-on-reducing-heavy-](https://advocacy.consumerreports.org/research/consumer-reports-letter-to-fda-on-reducing-heavy-elements-like-arsenic-lead-and-cadmium-in-fruit-juices/)
23 [elements-like-arsenic-lead-and-cadmium-in-fruit-juices/](https://advocacy.consumerreports.org/research/consumer-reports-letter-to-fda-on-reducing-heavy-elements-like-arsenic-lead-and-cadmium-in-fruit-juices/); ED, *FDA's outdated Lead Standards Put*
24 *the Public's Health at Risk* (December, 9 2020), available at: [https://www.edf.org/media/fdas-](https://www.edf.org/media/fdas-outdated-lead-standards-put-publics-health-risk)
25 [outdated-lead-standards-put-publics-health-risk](https://www.edf.org/media/fdas-outdated-lead-standards-put-publics-health-risk); American Academy of Pediatrics, *Lead Exposure in*
26 *Children* (2016), available at: [https://www.aap.org/en-us/advocacy-and-policy/aap-health-](https://www.aap.org/en-us/advocacy-and-policy/aap-health-initiatives/lead-exposure/Pages/Lead-Exposure-in-Children.aspx)
27 [initiatives/lead-exposure/Pages/Lead-Exposure-in-Children.aspx](https://www.aap.org/en-us/advocacy-and-policy/aap-health-initiatives/lead-exposure/Pages/Lead-Exposure-in-Children.aspx).

28 ⁷⁵ See Nurture Test Results, *supra*.

⁷⁶ *Letter from Nurture, Inc. to Chairman Raja Krishnamoorthi, Subcommittee on Economic and Consumer Policy, Committee on Oversight and Reform* (Dec. 18, 2019) (“Letter from Nurture”) at 3, available at: <https://oversight.house.gov/sites/democrats.oversight.house.gov/files/10.pdf>.

⁷⁷ *Id.* at 3-4.

1 commerce.”⁷⁸ Nurture sells the products it tests, regardless of their toxic heavy metal content. In total,
2 Nurture tested 113 final products and sold *every* product tested, regardless of how much inorganic
3 arsenic or lead the product contained, and regardless of whether those metals exceeded its own
4 internal standards. As a result of this policy of not testing for safety, Nurture released products
5 containing as much as 641 ppb lead and 180 ppb inorganic arsenic.⁷⁹ Nurture sold 29 products that
6 were above its internal arsenic limit of 100 ppb, including Apple & Broccoli Puffs that contained 180
7 ppb inorganic arsenic. Further, Nurture appears to have misled the Subcommittee about its testing
8 standards. Nurture conveyed to the Subcommittee that after January of 2019, it had a goal threshold of 50
9 ppb for lead in all of its baby food products—infant formula, cereals, and wet foods.⁸⁰ However, after the
10 date Nurture claims to have moved to a 50 ppb lead standard—January 2019—Nurture was still using a
11 “Goal Threshold” of 100 ppb for 53 baby food products, as demonstrated by Nurture’s internal tests.⁸¹
12 Nurture blatantly lied to the Subcommittee about these results. And, Nurture has also ignored the only
13 final standard that FDA has set. FDA set a 100 ppb inorganic arsenic limit for infant rice cereal. Rather
14 than comply with that limit, Nurture set its internal standards 15% higher, at 115 ppb inorganic arsenic.⁸²

15 **B. Hain**

16 **1. Hain Regularly Fails to Test its Finished Baby Food and Sells Baby Food**
17 **Notwithstanding High Content of Toxic Heavy Metals in Ingredients**

18 58. Hain does not regularly test finished baby food products for inorganic arsenic content.
19 It typically only tests ingredients. However, when Hain did test a small sample of finished product, it
20 found 129 ppb inorganic arsenic.⁸³ In August 2019, Hain presented the results of its testing to the
21 FDA in a closed-door meeting. During the presentation, Hain stated that its brown rice flour and
22 vitamin premix contained high amounts of Toxic Heavy Metals, specifically noting that “preliminary
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24 _____
25 ⁷⁸ *Id.* at 4.

26 ⁷⁹ Nurture Test Results, *supra*.

27 ⁸⁰ Letter from Nurture at 1, 3.

28 ⁸¹ Nurture Test Results, *supra*.

⁸² Letter from Nurture at 3.

⁸³ 2019 Hain & FDA Meeting at *9.

1 investigation indicates Vitamin/Mineral Pre-Mix may be a *major contributing factor*.⁸⁴ (emphasis
2 added). Indeed, this was later confirmed by Hain’s internal test results produced to the
3 Subcommittee, which showed that its rice flour had tested at 309 ppb arsenic; vitamin pre-mix at 223
4 ppb arsenic, and raisin and wheat flour containing 200 ppb arsenic.⁸⁵ To be clear, Hain continued
5 using these toxic ingredients even months *after* it had informed the FDA regarding its findings, as
6 demonstrated by the later testing produced to the Subcommittee. The testing data also shows that
7 Hain used at least 24 ingredients after testing found that they contained more than 100 ppb arsenic, its
8 already-dangerously-high internal standard for most ingredients.⁸⁶

9 59. Hain used six ingredients that tested above 200 ppb lead; 88 ingredients with lead
10 levels at or over 20 ppb—the EU’s standard for lead in infant formula; 115 ingredients that registered
11 at or over 15 ppb—EPA’s action level for drinking water; and at least 27% of Hain ingredients tested
12 at or over 5 ppb lead, FDA’s standard for lead in bottled water.⁸⁷ None of the test results showed an
13 ingredient below 1 ppb lead, the upper limit for lead content.⁸⁸ Hain used 14 ingredients that
14 contained more than 100 ppb cadmium, including barley flour that registered at 260 ppb cadmium.⁸⁹
15 That is thirteen times the EU’s upper limit on cadmium in baby food. Hain also tested and used 102
16 ingredients that registered at or above 20 ppb cadmium. Hain does not test its ingredients or finished
17 products for mercury.

18
19
20 ⁸⁴ 2019 Hain & FDA Meeting at *6, 9, 10.

21 ⁸⁵ Hain, *Raw Material Pre-Shipment Test Data History* (Dec. 11, 2019) (“Hain Test Results”) at
22 00033, 00029, available at:
https://oversight.house.gov/sites/democrats.oversight.house.gov/files/3_0.pdf.

23 ⁸⁶ See Hain Testing Results at 00029-52.

24 ⁸⁷ See, *id.*

25 ⁸⁸ See Consumer Reports, *Consumer Reports letter to FDA on reducing heavy elements like arsenic,*
26 *lead, and cadmium in fruit juices* (January 2019), available at:

27 [https://advocacy.consumerreports.org/research/consumer-reports-letter-to-fda-on-reducing-heavy-](https://advocacy.consumerreports.org/research/consumer-reports-letter-to-fda-on-reducing-heavy-elements-like-arsenic-lead-and-cadmium-in-fruit-juices/)
[elements-like-arsenic-lead-and-cadmium-in-fruit-juices/](https://www.edf.org/media/fdas-outdated-lead-standards-put-public-health-risk); ED, *FDA’s outdated Lead Standards Put*
28 *the Public’s Health at Risk* (December, 9 2020), available at: [https://www.edf.org/media/fdas-](https://www.edf.org/media/fdas-outdated-lead-standards-put-public-health-risk)
[outdated-lead-standards-put-public-health-risk](https://www.aap.org/en-us/advocacy-and-policy/aap-health-initiatives/lead-exposure/Pages/Lead-Exposure-in-Children.aspx); American Academy of Pediatrics, *Lead Exposure in*
Children (2016), available at: [https://www.aap.org/en-us/advocacy-and-policy/aap-health-](https://www.aap.org/en-us/advocacy-and-policy/aap-health-initiatives/lead-exposure/Pages/Lead-Exposure-in-Children.aspx)
[initiatives/lead-exposure/Pages/Lead-Exposure-in-Children.aspx](https://www.aap.org/en-us/advocacy-and-policy/aap-health-initiatives/lead-exposure/Pages/Lead-Exposure-in-Children.aspx).

⁸⁹ Hain Test Results at 00045.

2. Hain Set Dangerously High Internal Limits for Toxic Heavy Metals

60. 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.⁹⁰ 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.⁹¹ 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.⁹² Hain justified these variations by claiming that the “theoretical” final goods will not surpass its internal limits. In another example, Hain became aware that the vitamin pre-mix contained 223 ppb arsenic and 352 ppb lead.⁹³ And yet, 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.⁹⁴

61. 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.⁹⁵ However, Hain never tested the finished product. 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 products, which initially went undetected because Hain did

⁹⁰ 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).

⁹¹ *Id.*

⁹² *Id.*

⁹³ Hain, *Deviation Report, Vitamin Premix* (Nov. 26, 2019) at 000148, available at: https://oversight.house.gov/sites/democrats.oversight.house.gov/files/11_Redacted.pdf).

⁹⁴ *Id.*

⁹⁵ *Id.*

1 not test its finished products.⁹⁶ Hain made no effort to correct the problem.

2 C. Beech-Nut

3 1. Beech-Nut Does Not Test its Finished Baby Food for Toxic Heavy Metals and 4 Uses Ingredients Containing High Amounts of the Metals

5 62. Beech-Nut only tested arsenic content in its ingredients, not its final product. Beech-
6 Nut used ingredients containing as much as 913.4 ppb arsenic. Test results show that Beech-Nut used
7 at least fourteen other ingredients containing over 300 ppb arsenic. And it used at least 45 ingredients
8 containing over 100 ppb arsenic.⁹⁷ The six Beech-Nut ingredients with the highest arsenic levels—
9 Amylase, BAN 800, Alpha Amylase, and Sebamyl 100—are all enzymes that Beech-Nut adds to its
10 products. BAN 800 is an enzyme that reportedly “[i]ncreases crumb softness” in baked goods.⁹⁸
11 Amylase is an enzyme that is used in bread-making as an additive to improve the conversion of
12 complex sugars into simple sugars that yeast is then able to feed on and produce alcohol and CO₂.
13 Moreover, Beech-Nut used ingredients in its baby foods that contained high lead levels. For instance,
14 Beech-Nut used cinnamon that contained 886.9 ppb lead.⁹⁹ Beech-Nut tested and used 57 ingredients
15 that contained over 20 ppb lead, the EU’s standard for lead in infant formula; accepted 89 ingredients
16 that tested at or over 15 ppb lead, EPA’s action level for drinking water; and 483 ingredients that
17 tested at or over 5 ppb lead, FDA’s standard for lead in bottled water.¹⁰⁰ Beech-Nut used twenty
18 ingredients registering over 100 ppb cadmium, including cinnamon containing 344.5 ppb
19 cadmium.¹⁰¹ That is more than 17 times higher than the EU’s upper limit on cadmium in baby food.
20 At least 105 ingredients that Beech-Nut tested and used in baby foods registered at or over 20 ppb
21 cadmium—the EU’s infant formula upper limit.¹⁰² Beech-Nut does not test its ingredients or finished

22 _____
23 ⁹⁶ 2019 Hain & FDA Meeting at *9-10.

24 ⁹⁷ See generally, Beech-Nut, *Raw Material Heavy Metal Testing* (Dec. 6, 2019) (“Beech-Nut Tests”),
available at: <http://oversight.house.gov/sites/democrats.oversight.house.gov/files/4.xlsx>.

25 ⁹⁸ Novozymes, *Meet Consumer Demands with Enzymes that Support Organic Labeling* (May 2018)
26 (online at [www.novozymes.com/-/media/Project/Novozymes/Website/website/document-
library/Advance-your-business/Baking/Baking-Product-Range-for-Organic-Production.pdf](http://www.novozymes.com/-/media/Project/Novozymes/Website/website/document-library/Advance-your-business/Baking/Baking-Product-Range-for-Organic-Production.pdf)).

27 ⁹⁹ Beech-Nut Tests.

28 ¹⁰⁰ *Id.*

¹⁰¹ *Id.*

¹⁰² *Id.*

1 products for mercury.

2 **2. Beech-Nut Set Internal Limits for Toxic Heavy Metals Far Above Regulatory**
3 **Standards and Regularly Violated Its Own Limits**

4 63. Beech-Nut has set an internal specification limit of 3,000 ppb inorganic arsenic for
5 certain ingredients, including vitamin mix.¹⁰³ As a result of adopting this staggering and irresponsibly
6 high internal standard, Beech-Nut has used ingredients containing 710.9, 465.2, and 401.4 ppb
7 arsenic.¹⁰⁴ Beech-Nut also set internal guidelines of 3,000 ppb for cadmium and 5,000 ppb for lead
8 for certain ingredients.¹⁰⁵ These far surpass any existing regulatory standard in existence and Toxic
9 Heavy Metal levels for any other baby food manufacturer that responded to the Subcommittee
10 investigation. Beech-Nut sold eleven products that surpassed its own internal cadmium limits. By
11 doing so, Beech-Nut accepted dehydrated potato containing 119.6, 143.5, and 148.4 ppb cadmium,
12 far surpassing its own internal limit of 90 ppb for that ingredient.¹⁰⁶

13 64. Beech-Nut's explanation of why it accepted products over its own internal limits was
14 that it did so "rarely" and the ingredients were "generally restricted to a 20% variance of BNN's
15 allowable limits...."¹⁰⁷ However, as the cadmium examples show, Beech-Nut accepted certain
16 ingredients in spite of its own testing results which showed that they contained over 20% more
17 cadmium than their already-high internal limit. Beech-Nut's internal limit for cadmium in dehydrated
18 potato appears to be 90 ppb. A 20% variance would permit Beech-Nut to accept dehydrated potato
19 containing up to 108 ppb cadmium. Nevertheless, Beech-Nut accepted three shipments of dehydrated
20 potato containing cadmium in excess of its 20% variance allowance.¹⁰⁸ Beech-Nut failed to offer any
21 explanation to the Subcommittee.

22
23 ¹⁰³ *Id.*

24 ¹⁰⁴ *Id.*

25 ¹⁰⁵ *Id.*

26 ¹⁰⁶ *Id.*

27 ¹⁰⁷ *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 ("Letter from Beech-Nut") (Dec. 6, 2019) at 4, available at:
28 https://oversight.house.gov/sites/democrats.oversight.house.gov/files/6_0.pdf.

¹⁰⁸ *See* Beech Nut Test ("dehydrated potato").

D. Gerber

65. Test results for conventional rice flour revealed that Gerber routinely uses flour with over 90 ppb inorganic arsenic.¹⁰⁹ Gerber used five batches of rice flour that had 98 ppb inorganic arsenic, and 67 batches that contained more than 90 ppb.¹¹⁰ The results for Gerber 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 and twelve other batches of sweet potato that tested over 20 ppb for lead, the EU's lenient upper standard.¹¹¹ 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.¹¹² 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.¹¹³ Gerber only tests certain ingredients for mercury. Of the test results Gerber presented to the Subcommittee, it only tested carrots, sweet potatoes, and lemon juice concentrate.¹¹⁴

E. Plum and Sprout

66. As discussed above, although Plum and Sprout did not cooperate with the Subcommittee's investigation, the independent test results from HBBF's Report confirm that these two Defendants sold Baby Foods with substantial levels of Toxic Heavy Metals, and accordingly knew or should have known about the risk presented by such metals.¹¹⁵ As noted by the Subcommittee, the fact that these companies refused to produce testing results, internal company documents, or specific testing standards, strongly suggests that these companies "might be obscuring

¹⁰⁹ Gerber, *Gerber Products Company Test Results* (Dec. 9, 2019) ("Gerber Tests"), available at: https://oversight.house.gov/sites/democrats.oversight.house.gov/files/5_0.pdf.

¹¹⁰ *Id.* at *3-4, 7.

¹¹¹ *Id.* at *16,

¹¹² *Id.* at *9-11.

¹¹³ *Id.* at *15.

¹¹⁴ *Id.* at *15, 16, 18, 22-24.

¹¹⁵ *See* HBBF Report at 19-28.

1 the presence of even higher levels of toxic heavy metals in their baby food products than their
2 competitors' products."¹¹⁶

3 67. Indeed, even the limited testing conducted by HBBF demonstrates that Plum and
4 Sprout also acted out of callous disregard for human—specifically children's—health by selling Baby
5 Foods contaminated with substantial amounts of Toxic Heavy Metals. As the Subcommittee noted,
6 "[w]hether due to evasion or negligence, Sprout's failure to respond raises serious concerns about the
7 presence of toxic heavy metals in its baby foods, as even limited independent testing has revealed the
8 presence of toxic heavy metals in its products."¹¹⁷ Indeed, the HBBF testing reports that Sprout's
9 "organic Quinoa Puffs Baby Cereal Snack—Apple Kale contains 107 ppb arsenic, 47 ppb inorganic
10 arsenic, 39.3 ppb lead, 41.5 cadmium, and 1.31 ppb mercury; "Prunes Organic Baby Food starting
11 solids" contains 6.1 ppb lead; "Carrot Apple Mango Organic Baby Food" aimed at 6+ months
12 contains 2.1 ppb lead, 15.1 ppb cadmium; and "Garden Vegetables Brown Rice with Turkey" for 8+
13 months contains 7.2 ppb arsenic, 1.6 ppb lead, 2.5 ppb cadmium, among other foods with similarly
14 high contents of these Toxic Heavy Metals.¹¹⁸

15 68. Similarly, Plum refused to produce testing standards and the Subcommittee noted that
16 Plum "has hidden its policies and the actual level of toxic heavy metals in its products."¹¹⁹ The self-
17 serving spreadsheet produced by Plum wherein it declares, without any data, that its products "meet
18 criteria" (without identifying which criteria), poses more questions than it answers.¹²⁰ Indeed, Plum
19 has admitted that that it does not have a "specific threshold" established for the powerful neurotoxin
20 mercury because "no high-risk ingredients are used."¹²¹ As well as evincing Plum's reckless
21 disregard for the safety of children by refusing to establish a threshold for a toxin as dangerous as
22 mercury, the statement is also outright false. The limited testing performed by HBBF reveals that
23

24
25 ¹¹⁶ Subcommittee Report at 43.

26 ¹¹⁷ Subcommittee Report at 46.

27 ¹¹⁸ HBBF Report at 26, 23, 25.

28 ¹¹⁹ Subcommittee Report at 44.

¹²⁰ Campbell, *Product Heavy Metal Test Results* (Dec. 11, 2019) ("Plum Tests"), available at:
<https://oversight.house.gov/sites/democrats.oversight.house.gov/files/12.pdf>.

¹²¹ Plum Tests at 00046.

1 Plum’s “Little Teethers Organic Multigrain Teething Wafers—Banana with Pumpkin” intended for
2 crawling babies contains 0.726 ppb mercury, and Plum’s “Apple, Raisin, & Quinoa Organic Baby
3 Food” contain 0.145 ppb mercury, flatly contradicting Plum’s assertion that none of its products
4 contain mercury.¹²²

5 69. Although discovery will flesh out the full extent to which Plum and Sprout’s Baby
6 Foods are tainted with Toxic Heavy Metals, it is abundantly clear that these Defendants are no less
7 culpable in its wrongdoing than its competitors who provided data to the Subcommittee.

8 **VI. Exemplary / Punitive Damages Allegations**

9 70. Defendants’ conduct as alleged herein was done with reckless disregard for human
10 life, oppression, and malice. Defendants’ conduct is particularly reprehensible given that their toxic
11 foods were directed at vulnerable babies—a population group far more susceptible than adults to the
12 neurotoxic dangers of heavy metals.

13 71. Defendants were fully aware of the safety risks of Baby Foods, particularly the
14 dangerous potential of their Baby Foods given the high content of Toxic Heavy Metals that have all
15 been associated with neurodevelopmental disorders in children. Nonetheless, Defendants
16 deliberately crafted their label, marketing, and promotion to mislead consumers. Indeed, Defendants
17 repeatedly market their Baby Foods as safe for consumption and go so far as claiming that they
18 adhere to “the strictest standards in the world”; and provide “baby’s food full of nutrition while
19 meeting standards strict enough for tiny tummies.” In actual fact, as discussed above, Defendants
20 routinely sold Baby Foods containing astronomical amounts of Toxic Heavy Metals, regularly flouted
21 their own internal limits of Toxic Heavy Metals in Baby Foods and failed to disclose to consumers
22 that their products contained such dangerous contaminants.

23 72. This was not done by accident or through some justifiable negligence. Rather,
24 Defendants knew they could profit by convincing consumers that their Baby Foods were harmless to
25 humans, and that full disclosure of the true risks of the Toxic Heavy Metals present in the Baby
26 Foods would limit the amount of money Defendants would make selling the products. Defendants’

27
28 ¹²² HBBF Report at 27, 25.

1 object was accomplished not only through a misleading label, but through a comprehensive scheme
2 of selective misleading research and testing, failure to test, false advertising, and deceptive omissions
3 as more fully alleged throughout this pleading. Parents were denied the right to make an informed
4 decision about whether to purchase and Defendants' Baby Food for their children, knowing the full
5 risks attendant to that use. Such conduct was done with conscious disregard of Plaintiffs' rights.

6 73. Accordingly, Plaintiffs request punitive damages against the Manufacturer Defendants
7 for the harms caused to Plaintiffs.

8 **PLAINTIFF-SPECIFIC ALLEGATIONS**

9 74. Plaintiffs each consumed Baby Foods manufactured and sold by Plum, Hain, Nurture,
10 Beech-Nut, Gerber, and Sprout for approximately over 1 year and 1 year, respectively. Plaintiffs
11 consumed Defendants' Baby Foods during overlapping time periods and within the same household.

12 75. Upon information and belief, the baby foods consumed by Plaintiffs were
13 contaminated with substantial quantities of Toxic Heavy Metals, exceeding that of existing regulatory
14 limits.

15 76. As a direct and proximate result of consuming Defendants' Baby Foods, Plaintiffs
16 were diagnosed with ASD.

17 77. Based on prevailing scientific evidence, exposure to the Toxic Heavy Metals at the
18 levels contained in Defendants' Baby Foods can cause ASD in humans.

19 78. Had any Defendant warned Plaintiffs' parents that Defendants' Baby Foods could lead
20 to exposure to Toxic Heavy Metals or, in turn, ASD, Plaintiffs would not have consumed the Baby
21 Foods.

22 79. Plaintiffs allege that as a direct and proximate result of Plaintiffs' consumption of
23 Baby Foods supplied and distributed by Defendants, Plaintiffs suffered significant harm, conscious
24 pain and suffering, physical injury and bodily impairment including, but not limited to ASD and other
25 *sequelae*.

26 **CAUSES OF ACTION**

27 **COUNT I: STRICT PRODUCTS LIABILITY – FAILURE TO WARN**

28 80. Plaintiffs incorporate by reference each allegation set forth in preceding paragraphs as

1 if fully stated herein.

2 81. At all relevant times, Defendants engaged in the business of researching, testing,
3 developing, designing, manufacturing, labeling, marketing, selling, inspecting, distributing, and
4 promoting Baby Foods, which are defective and unreasonably dangerous to consumers, including
5 Plaintiffs, because they do not contain adequate warnings or instructions concerning the dangerous
6 characteristics of Baby Foods and Toxic Heavy Metals. These actions were under the ultimate
7 control and supervision of Defendants. At all relevant times, Defendants registered, researched,
8 manufactured, distributed, marketed, and sold Baby Foods and aimed at a consumer market.

9 82. Defendants researched, tested, developed, designed, manufactured, labeled, marketed,
10 sold, inspected, distributed, and promoted, and otherwise released into the stream of commerce their
11 Baby Foods, and in the course of same, directly advertised or marketed the products to consumers
12 and end users, including Plaintiffs, and therefore had a duty to warn of the risks associated with the
13 consumption of Baby Foods.

14 83. At all relevant times, Defendants had a duty to properly test, develop, design,
15 manufacture, inspect, package, label, market, promote, sell, and distribute, maintain, supply, provide
16 proper warnings, and take such steps as necessary to ensure their Baby Foods did not cause users and
17 consumers to suffer from unreasonable and dangerous risks. Defendants had a continuing duty to
18 warn Plaintiffs of dangers associated with Baby Foods. Defendants, as a manufacturer, seller, or
19 distributor of food, are held to the knowledge of an expert in the field.

20 84. At the time of manufacture, Defendants could have provided the warnings or
21 instructions regarding the full and complete risks of Baby Foods because they knew or should have
22 known of the unreasonable risks of harm associated with the use of and/or exposure to such products.

23 85. At all relevant times, Defendants failed and deliberately refused to investigate, study,
24 test, or promote the safety or to minimize the dangers to users and consumers of their product and to
25 those who would foreseeably use or be harmed by Defendants' Baby Foods.

26 86. Even though Defendants knew or should have known that Baby Foods posed a grave
27 risk of harm, they failed to exercise reasonable care to warn of the dangerous risks associated with
28 use and exposure to the products. The dangerous propensities of their products and the neurotoxic

1 characteristic of Toxic Heavy Metals contained in Defendants' Baby Foods, as described above, were
2 known to Defendants, or scientifically knowable to Defendants through appropriate research and
3 testing by known methods, at the time they distributed, supplied or sold the product, and were not
4 known to end users and consumers, such as the Plaintiffs. The product warnings for Baby Foods in
5 effect during the time period Plaintiffs consumed Baby Foods were vague, incomplete or otherwise
6 inadequate, both substantively and graphically, to alert consumers to the severe health risks
7 associated with Baby Foods consumption.

8 87. Defendants knew or should have known that their products created significant risks of
9 serious bodily harm to consumers, as alleged herein, and Defendants failed to adequately warn or
10 instruct consumers, i.e., the reasonably foreseeable users, of the risks of exposure to their products.
11 Defendants failed to warn and have wrongfully concealed information concerning the dangerous
12 level of Toxic Heavy Metals in their Baby Foods and the potential for consumed Baby Foods to
13 expose children to Toxic Heavy Metals, and further, have made false and/or misleading statements
14 concerning the safety of Baby Foods.

15 88. At all relevant times, Defendants' Baby Foods reached the intended consumers,
16 handlers, and users or other persons coming into contact with these products, including Plaintiffs,
17 without substantial change in their condition as designed, manufactured, sold, distributed, labeled,
18 and marketed by Defendants.

19 89. Plaintiffs were exposed to Defendants' Baby Foods without knowledge of their
20 dangerous characteristics.

21 90. At all relevant times, Plaintiffs were exposed to Defendants' Baby Foods while using
22 them for their intended or reasonably foreseeable purposes, without knowledge of their dangerous
23 characteristics.

24 91. Plaintiffs could not have reasonably discovered the defects and risks associated with
25 Baby Foods prior to or at the time of Plaintiffs consuming Baby Foods. Plaintiffs relied upon the
26 skill, superior knowledge, and judgment of Defendants to know about and disclose serious health
27 risks associated with using Defendants' products.

28 92. Defendants knew or should have known that the information disseminated with their

1 Baby Foods were inadequate, failed to communicate adequate information on the dangers
2 consumption, and failed to communicate warnings and instructions that were appropriate and
3 adequate to render the products safe for their ordinary, intended and reasonably foreseeable uses.

4 93. The information that Defendants did provide or communicate failed to contain
5 relevant warnings, hazards, and precautions that would have enabled consumers such as Plaintiffs to
6 avoid consuming the products. Instead, Defendants disseminated information that was inaccurate,
7 false, and misleading, and which failed to communicate accurately or adequately the comparative
8 severity, duration, and extent of the risk of injuries with use of and/or exposure to Baby Foods;
9 continued to aggressively promote the safety of their products, even after they knew or should have
10 known of the unreasonable risks from use or exposure; and concealed, downplayed, or otherwise
11 suppressed, through aggressive marketing and promotion, any information or research about the risks
12 and dangers of consuming Baby Foods.

13 94. This alleged failure to warn is not limited to the information contained on Baby Foods
14 labeling. The Defendants were able, in accord with federal law, to comply with relevant state law by
15 disclosing the known risks associated with Baby Foods through other non-labeling mediums, *i.e.*,
16 promotion, advertisements, public service announcements, and/or public information sources. But
17 the Defendants did not disclose these known risks through any medium.

18 95. Had Defendants provided adequate warnings and instructions and properly disclosed
19 and disseminated the risks associated with their Baby Foods, Plaintiffs could have avoided the risk of
20 developing injuries and could have obtained or used alternative products. However, as a result of
21 Defendants' concealment of the dangers posed by their Baby Foods, Plaintiffs could not have averted
22 their injuries.

23 96. Defendants' conduct, as described above, was reckless. Defendants risked the lives of
24 babies and children, including Plaintiffs, with knowledge of the safety problems associated with Baby
25 Foods, and suppressed this knowledge from the general public. Defendants made conscious decisions
26 not to redesign, warn or inform the unsuspecting public. Defendants' reckless conduct warrants an
27 award of punitive damages.

28 97. The Defendants' lack of adequate warnings and instructions accompanying their Baby

1 Foods were a substantial factor in causing Plaintiffs' injuries.

2 98. As a direct and proximate result of the Defendants' failure to provide an adequate
3 warning of the risks of Baby Foods, Plaintiffs have been injured, sustained severe and permanent
4 pain, suffering, disability, impairment, loss of enjoyment of life, economic loss and damages
5 including, but not limited to past and future medical expenses, lost income, and other damages.

6 99. **WHEREFORE**, Plaintiffs respectfully request this Court to enter judgment in
7 Plaintiffs' favor for damages, together with interest, costs herein incurred, attorneys' fees and all such
8 other and further relief as this Court deems just and proper.

9 **COUNT II: STRICT PRODUCTS LIABILITY – DESIGN DEFECT**

10 100. Plaintiffs incorporate by reference each allegation set forth in preceding paragraphs as
11 if fully stated herein.

12 101. At all times herein mentioned, Defendants designed, manufactured, tested, marketed,
13 sold, handled, and distributed the Baby Foods consumed by Plaintiffs. These actions were under the
14 ultimate control and supervision of Defendants.

15 102. At all relevant times, Defendants' Baby Food products were manufactured, designed,
16 and labeled in an unsafe, defective, and inherently dangerous manner that was dangerous for use by
17 or exposure to infants and babies, including Plaintiffs.

18 103. Defendants' Baby Food products as researched, tested, developed, designed, licensed,
19 manufactured, packaged, labeled, distributed, sold, and marketed by Defendants were defective in
20 design and formulation in that, when they were placed into the stream of commerce, they were
21 unreasonably dangerous and dangerous to an extent beyond that which an ordinary consumer would
22 contemplate.

23 104. Defendants' Baby Food products, as researched, tested, developed, designed, licensed,
24 manufactured, packaged, labeled, distributed, sold, and marketed by Defendants were defective in
25 design and formulation in that, when they left the hands of Defendants', the foreseeable risks
26 exceeded the alleged benefits associated with their design and formulation.

27 105. At all relevant times, the Baby Food products consumed by Plaintiffs were expected to
28 and did reach Plaintiffs without a substantial change in its condition as manufactured, handled,

1 distributed, and sold by Defendants.

2 106. At all relevant times, Defendants knew or had reason to know that their Baby Food
3 products were defective and were inherently dangerous and unsafe when used in the manner
4 instructed and provided by Defendants.

5 107. Therefore, at all relevant times, Defendants' Baby Food products, as researched,
6 tested, developed, designed, registered, licensed, manufactured, packaged, labeled, distributed, sold
7 and marketed by Defendants were defective in design and formulation, in one or more of the
8 following ways:

- 9 a. When placed in the stream of commerce, Defendants' Baby Food products
10 were unreasonably dangerous in that they were hazardous and posed a grave
11 risk of neurodevelopmental disorders—specifically ASD—when used in a
12 reasonably anticipated manner due to the substantial quantities of Toxic Heavy
13 Metals in the Baby Foods;
- 14 b. When placed in the stream of commerce, Defendants' Baby Food products
15 contained unreasonably dangerous design defects and were not reasonably safe
16 when used in a reasonably anticipated or intended manner;
- 17 c. Defendants did not sufficiently test, investigate, or study their Baby Food
18 products;
- 19 d. Exposure to the Toxic Heavy Metals in Defendants' Baby Food products
20 present a risk of harmful effects that outweigh any potential utility stemming
21 from their use;
- 22 e. Defendants knew or should have known at the time of marketing Baby Food
23 products that exposure to their Baby Food products could result in
24 neurodevelopmental disorders—specifically ASD—in children.
- 25 f. Defendants did not conduct adequate post-marketing surveillance of their Baby
26 Food products; and
- 27 g. Defendants could have employed safer alternative designs and formulations.

28 108. Plaintiffs consumed Defendants' Baby Food products in an intended or reasonably

1 foreseeable manner without knowledge of their dangerous characteristics.

2 109. Defendants' Baby Food products were and are more dangerous than alternative
3 products, and Defendants could have designed their Baby Food products to avoid harm to children.
4 Indeed, at the time Defendants designed the Baby Food products, the state of the industry's scientific
5 knowledge was such that a less risky design or formulation was attainable.

6 110. At the time the Baby Food products left Defendants' control, there was a practical,
7 technically feasible and safer alternative design that would have prevented the harm without
8 substantially impairing the reasonably anticipated or intended function of Defendants' Baby Foods,
9 as for example, demonstrated by Hain's presentation to the FDA wherein Hain acknowledges the risk
10 posed by specific ingredients in its Baby Foods.

11 111. Defendants have intentionally and recklessly defectively designed the Baby Foods
12 with wanton and willful disregard for the rights and health of the Plaintiffs, and with malice, placing
13 their economic interests above the health and safety of the Plaintiffs.

14 112. The design defects in Defendants' Baby Foods were substantial factors in causing
15 Plaintiffs' injuries.

16 113. As a direct and proximate result of the Defendants' defective design of the Baby
17 Foods, Plaintiffs have been injured, sustained severe and permanent pain, suffering, disability,
18 impairment, loss of enjoyment of life, economic loss and damages including, but not limited to
19 medical expenses, lost income, and other damages.

20 **WHEREFORE**, Plaintiffs respectfully request this Court to enter judgment in Plaintiffs'
21 favor for damages, together with interest, costs herein incurred, attorneys' fees and all such other and
22 further relief as this Court deems just and proper.

23 **COUNT III: STRICT PRODUCTS LIABILITY – MANUFACTURING DEFECT**

24 114. Plaintiffs incorporate by reference each allegation set forth in preceding paragraphs as
25 if fully stated herein.

26 115. At all times herein mentioned, Defendants designed, manufactured, tested, marketed,
27 sold, handled, and distributed the Baby Foods consumed by Plaintiffs.

28 116. At all relevant times, the Baby Foods consumed by Plaintiffs were expected to and did

1 reach Plaintiffs without a substantial change in its condition as manufactured, handled, distributed,
2 and sold by Defendants.

3 117. At all relevant times, the Baby Foods consumed by Plaintiffs were used in a manner
4 that was foreseeable and intended by Defendants.

5 118. The Baby Foods consumed by Plaintiffs were not reasonably safe for their intended
6 use and were defective with respect to their manufacture, as described herein, in that Defendants
7 deviated materially from their design and manufacturing specifications and/or such design and
8 manufacture posed an unreasonable risk of harm to Plaintiffs.

9 119. The Defendants' Baby Foods are inherently dangerous and defective, unfit and unsafe
10 for its intended and reasonably foreseeable uses, and do not meet or perform to the expectations of
11 parents or children.

12 120. The Baby Foods create risks to the health and safety of babies that are far more
13 significant and devastating than the risks posed by other baby food products, and which far outweigh
14 the utility of the Baby Foods products because of Defendants' manufacturing defects, which included
15 but were not limited to:

- 16 a. Failure to adequately inspect/test the Baby Foods during the manufacturing
17 process;
- 18 b. Failure to implement procedures that would reduce or eliminate the levels of
19 Toxic Heavy Metals in Baby Foods;
- 20 c. Failure to avoid using ingredients free from, or which contain far less, Toxic
21 Heavy Metals to manufacture Baby Foods.

22 121. Defendants have intentionally and recklessly manufactured the Baby Foods with
23 wanton and willful disregard for the rights and health of the Plaintiffs, and with malice, placing their
24 economic interests above the health and safety of the Plaintiffs.

25 122. The manufacturing defects in Defendants' Baby Foods were substantial factors in
26 causing Plaintiffs' injuries.

27 123. As a direct and proximate result of the Defendants' defective manufacture of the Baby
28 Foods, Plaintiffs have been injured, sustained severe and permanent pain, suffering, disability,

1 impairment, loss of enjoyment of life, economic loss and damages including, but not limited to
2 medical expenses, lost income, and other damages.

3 **WHEREFORE**, Plaintiffs respectfully request this Court to enter judgment in Plaintiffs'
4 favor for damages, together with interest, costs herein incurred, attorneys' fees and all such other and
5 further relief as this Court deems just and proper.

6 **COUNT IV: NEGLIGENCE – FAILURE TO WARN**

7 124. Plaintiffs incorporate by reference each allegation set forth in preceding paragraphs as
8 if fully stated herein.

9 125. At all relevant times, Defendants engaged in the business of testing, developing,
10 designing, manufacturing, marketing, selling, distributing, and promoting Baby Foods. Defendants
11 knew or by the exercise of reasonable care should have known that their Baby Foods are not
12 accompanied with adequate warnings concerning the dangerous characteristics of Baby Foods and
13 Toxic Heavy Metals. These actions were under the ultimate control and supervision of Defendants.

14 126. Defendants researched, developed, designed, tested, manufactured, inspected, labeled,
15 distributed, marketed, promoted, sold, and otherwise released into the stream of commerce their Baby
16 Foods, and in the course of same, directly advertised or marketed the products to consumers and end
17 users, including Plaintiffs, and therefore had a duty to warn of the risks associated with the use of
18 Baby Foods.

19 127. At all relevant times, Defendants had a duty to properly test, develop, design,
20 manufacture, inspect, package, label, market, promote, sell, distribute, maintain, supply, provide
21 proper warnings, and take such steps as necessary to ensure their Baby Foods did not cause users and
22 consumers to suffer from unreasonable and dangerous risks. Defendants had a continuing duty to
23 warn Plaintiffs of dangers associated with Baby Foods. Defendants, as a manufacturer, seller, or
24 distributor of food products, are held to the knowledge of an expert in the field.

25 128. At the time of manufacture, Defendants could have provided warnings regarding the
26 full and complete risks of Baby Foods and Toxic Heavy Metals because they knew or should have
27 known use of Baby Foods was dangerous, harmful and injurious when used by Plaintiffs in a
28 reasonably foreseeable manner.

1 129. At all relevant times, Defendants failed and deliberately refused to investigate, study,
2 test, or promote the safety or to minimize the dangers to users and consumers of their product and to
3 those who would foreseeably use or be harmed by Defendants' Baby Foods.

4 130. Defendants knew or should have known that Baby Foods posed a grave risk of harm,
5 but failed to exercise reasonable care to warn of the dangerous risks associated with use and exposure
6 to the products. The dangerous propensities of their products and the characteristics of Toxic Heavy
7 Metals contained in substantial amounts in their Baby Foods, as described above, were known to
8 Defendants, or scientifically knowable to Defendants through appropriate research and testing by
9 known methods, at the time they distributed, supplied or sold the product, and were not known to end
10 users and consumers, such as the Plaintiffs.

11 131. Defendants further breached their duty by failing to use reasonable care to adequately
12 warn or instruct consumers (*i.e.*, the reasonably foreseeable users) of the risks of exposure to their
13 products. Defendants failed to warn and have wrongfully concealed information concerning the
14 dangerous level of Toxic Heavy Metals in their Baby Foods and the potential for consumed Baby
15 Foods to expose babies and toddlers to Toxic Heavy Metals, and further, have made false and/or
16 misleading statements concerning the safety of Baby Foods.

17 132. At all relevant times, Plaintiffs were exposed to excessive levels of Toxic Heavy
18 Metals through consumption of Toxic Heavy Metals while using them for their intended or
19 reasonably foreseeable purposes, without knowledge of their dangerous characteristics.

20 133. Defendants knew or should have known that the minimal warnings disseminated with
21 their Baby Foods were inadequate, failed to communicate adequate information on the dangers and
22 safe use/exposure, and failed to communicate warnings and instructions that were appropriate and
23 adequate to render the products safe for their ordinary, intended and reasonably foreseeable uses.

24 134. The information that Defendants did provide or communicate failed to contain
25 relevant warnings, hazards, and precautions that would have enabled consumers such as Plaintiffs to
26 avoid using the product. Instead, Defendants disseminated information that was inaccurate, false, and
27 misleading, and which failed to communicate accurately or adequately the comparative severity,
28 duration, and extent of the risk of injuries with use of and/or exposure to Baby Foods; continued to

1 aggressively promote the efficacy of their products, even after they knew or should have known of
2 the unreasonable risks from use or exposure; and concealed, downplayed, or otherwise suppressed,
3 through aggressive marketing and promotion, any information or research about the risks and dangers
4 of consuming Baby Foods.

5 135. A reasonable company under the same or similar circumstance would have warned
6 and instructed of the dangers of Baby Foods and Toxic Heavy Metals contained therein.

7 136. This alleged failure to warn is not limited to the information contained on the labeling
8 of Defendants' Baby Foods. Defendants were able, in accord with federal law, to comply with
9 relevant state law by disclosing the known risks associated with Baby Foods and Toxic Heavy Metals
10 through other non-labeling mediums, *i.e.*, promotion, advertisements, public service announcements,
11 and/or public information sources. But the Defendants did not disclose these known risks through
12 any medium.

13 137. Had Defendants provided adequate warnings and instructions and properly disclosed
14 and disseminated the risks associated with their Baby Foods, Plaintiffs could have avoided the risk of
15 developing injuries and could have obtained or used alternative products. However, as a result of
16 Defendants' concealment of the dangers posed by their Baby Foods, Plaintiffs could not have averted
17 their injuries.

18 138. Defendants' conduct, as described above, was reckless. Defendants risked the lives of
19 consumers and users of their products, including Plaintiffs, with knowledge of the safety problems
20 associated with Baby Foods, and suppressed this knowledge from the general public. Defendants
21 made conscious decisions not to redesign, warn or inform the unsuspecting public. Defendants'
22 reckless conduct warrants an award of punitive damages.

23 139. The Defendants' lack of adequate warnings and instructions accompanying their Baby
24 Foods were a substantial factor in causing Plaintiffs' injuries.

25 140. As a direct and proximate result of the Defendants' failure to provide an adequate
26 warning of the risks of Baby Foods, Plaintiffs have been injured, sustained severe and permanent
27 pain, suffering, disability, impairment, loss of enjoyment of life, economic loss and damages
28 including, but not limited to past and future medical expenses, lost income, and other damages.

1 141. **WHEREFORE**, Plaintiffs respectfully request this Court to enter judgment in
2 Plaintiffs’ favor for damages, together with interest, costs herein incurred, attorneys’ fees and all such
3 other and further relief as this Court deems just and proper.

4 **COUNT V: NEGLIGENT PRODUCT DESIGN**

5 142. The Defendants knew or, by the exercise of reasonable care, should have known,
6 ordinary consumers such as Plaintiffs would not have realized the potential risks and dangers of Baby
7 Foods.

8 143. The Defendants owed a duty to all reasonably foreseeable users to design a safe
9 product.

10 144. The Defendants breached their duty by failing to use reasonable care in the design of
11 Baby Foods because the product exposed users to unsafe levels of Toxic Heavy Metals.

12 145. The Defendants breached their duty by failing to use reasonable care in the design of
13 Baby Foods by negligently designing the Baby Foods with ingredients and/or components high in
14 Toxic Heavy Metals.

15 146. The Defendants breached their duty by failing to use reasonable care in the design of
16 Baby Foods by negligently designing and formulation, in one or more of the following ways:

- 17 a. When placed in the stream of commerce, Defendants’ Baby Foods were
18 defective in design and formulation, and, consequently, dangerous to an extent
19 beyond that which an ordinary consumer would contemplate;
- 20 b. When placed in the stream of commerce, Defendants’ Baby Foods were
21 unreasonably dangerous in that they were hazardous and posed a grave risk of
22 neurodevelopmental disorders and other serious illnesses when used in a
23 reasonably anticipated manner;
- 24 c. When placed in the stream of commerce, Defendants’ Baby Foods contained
25 unreasonably dangerous design defects and were not reasonably safe when
26 used in a reasonably anticipated or intended manner;
- 27 d. Defendants did not sufficiently test, investigate, or study their Baby Foods and,
28 specifically, the content of Toxic Heavy Metals in the ingredients used to

1 manufacture the foods and/or the finished products;

2 e. Defendants did not sufficiently test, investigate, or study their Baby Foods and,
3 specifically, the ability for Baby Foods to expose babies to high amounts of
4 Toxic Heavy Metals;

5 f. Exposure to Baby Foods presents a risk of harmful effects that outweigh any
6 potential utility stemming from the use of the products;

7 g. Defendants knew or should have known at the time of marketing Baby Foods
8 that exposure to Toxic Heavy Metals contained in the Baby Foods could result
9 in neurodevelopmental disorders—specifically ASD—and other severe
10 illnesses and injuries;

11 h. Defendants did not conduct adequate post-marketing surveillance of their Baby
12 Foods; and

13 i. Defendants could have employed safer alternative designs and formulations.
14 For example, the Defendants could have avoided use of certain ingredients
15 high in Toxic Heavy Metals, avoided using pre-mix vitamins high in Toxic
16 Heavy Metals, and/or sampled their ingredients from other sources.

17 147. The Defendants breached their duty by failing to use reasonable care by failing to use
18 cost effective, reasonably feasible alternative designs. There was a practical, technically feasible, and
19 safer alternative design that would have prevented the harm without substantially impairing the
20 reasonably anticipated or intended function of Defendants' Baby Foods.

21 148. A reasonable company under the same or similar circumstances would have designed
22 a safer product.

23 149. Plaintiffs were harmed directly and proximately by the Defendants' failure to use
24 reasonable care in the design of their Baby Foods. Such harm includes significant exposure to a Toxic
25 Heavy Metals, which can cause or contribute to the development of neurodevelopmental disorders
26 such as ASD.

27 150. Defendants' defective design of Baby Foods was willful, wanton, malicious, and
28 conducted with reckless disregard for the health and safety of consumers of the Baby Foods,

1 including Plaintiffs.

2 151. The defects in Defendants' Baby Foods were substantial factors in causing Plaintiffs'
3 injuries.

4 152. As a direct and proximate result of the Defendants' defective design of the Baby
5 Foods, Plaintiffs have been injured, sustained severe and permanent pain, suffering, disability,
6 impairment, loss of enjoyment of life, economic loss and damages including, but not limited to past
7 and future medical expenses, lost income, and other damages.

8 153. **WHEREFORE**, Plaintiffs respectfully request this Court to enter judgment in
9 Plaintiffs' favor for damages, together with interest, costs herein incurred, attorneys' fees and all such
10 other and further relief as this Court deems just and proper.

11 **COUNT VI: NEGLIGENT MANUFACTURING**

12 154. Plaintiffs incorporate by reference each allegation set forth in preceding paragraphs as
13 if fully stated herein.

14 155. At all relevant times, the Defendants manufactured, tested, marketed, sold, and
15 distributed the Baby Foods that Plaintiffs consumed.

16 156. The Defendants had a duty to exercise reasonable care, in the manufacturing, testing,
17 marketing, sale, and distribution of Baby Foods.

18 157. The Defendants knew or, by the exercise of reasonable care, should have known, use
19 of Baby Foods were carelessly manufactured, dangerous, harmful and injurious when used by
20 Plaintiffs in a reasonably foreseeable manner.

21 158. The Defendants knew or, by the exercise of reasonable care, should have known,
22 ordinary consumers such as Plaintiffs would not have realized the potential risks and dangers of Baby
23 Foods improperly manufactured, tested, marketed, distributed, and sold.

24 159. Without limitation, examples of the manner in which Defendants breached their duty
25 to exercise reasonable care in manufacturing Baby Foods, included:

- 26 a. Failure to adequately inspect/test the Baby Foods during the manufacturing
27 process;
- 28 b. Failure to implement procedures that would reduce or eliminate levels of Toxic

1 Heavy Metals in Baby Foods; and

2 c. Failure to avoid using ingredients free from, or which contain far less, Toxic
3 Heavy Metals to manufacture Baby Foods.

4 160. A reasonable manufacturer under the same or similar circumstances would have
5 implemented appropriate manufacturing procedures to better ensure the quality and safety of their
6 product.

7 161. Plaintiffs were harmed directly and proximately by the Defendants' failure to use
8 reasonable care in the manufacture of their Baby Foods. Such harm includes significant exposure to a
9 Toxic Heavy Metals, which can cause or contribute the development of neurodevelopmental disorder
10 such as ASD.

11 162. Defendants' improper manufacturing of Baby Foods was willful, wanton, malicious,
12 and conducted with reckless disregard for the health and safety of users of the Baby Foods, including
13 Plaintiffs.

14 163. The defects in Defendants' Baby Foods were substantial factors in causing Plaintiffs'
15 injuries.

16 164. As a direct and proximate result of the Defendants' improper manufacturing of Baby
17 Foods, Plaintiffs have been injured, sustained severe and permanent pain, suffering, disability,
18 impairment, loss of enjoyment of life, economic loss and damages including, but not limited to past
19 and future medical expenses, lost income, and other damages.

20 165. **WHEREFORE**, Plaintiffs respectfully requests this Court to enter judgment in
21 Plaintiffs' favor for damages, together with interest, costs herein incurred, attorneys' fees and all such
22 other and further relief as this Court deems just and proper.

23 **COUNT VII: NEGLIGENT MISREPRESENTATION**

24 166. Plaintiffs incorporate by reference each allegation set forth in preceding paragraphs as
25 if fully stated herein.

26 167. At all relevant times, Defendants designed, manufactured, tested (or not), packaged,
27 labeled, marketed, advertised, promoted, supplied, distributed, sold and/or otherwise placed Baby
28 Foods into the stream of commerce, and therefore owed a duty of reasonable care to avoid causing

1 harm to those that consumed Baby Foods, such as Plaintiffs.

2 168. Defendants were negligent, reckless, and careless and owed a duty to Plaintiffs to
3 make accurate and truthful representations regarding Baby Foods, Defendants breached their duty,
4 thereby causing Plaintiffs to suffer harm.

5 169. Defendants represented to Plaintiffs via the media, advertising, website, social media,
6 packaging, and promotions, among other misrepresentations described herein that:

7 170. Baby Foods were both safe and effective for the lifetime of the product, when in fact,
8 the foods contain unsafe levels of Toxic Heavy Metals far in excess of regulatory standards; and

9 171. Consumption of Baby Foods would not expose babies to any harmful ingredients; and

10 172. Baby Foods were safe for their intended use when, in fact, Defendants knew or should
11 have known the products were not safe for their intended purpose.

12 173. These representations were false. Because of the presence and/or unsafe levels of
13 Toxic Heavy Metals in Baby Foods, the products presented an unacceptable risk of causing
14 neurodevelopmental disorders, specifically ASD.

15 174. Defendants knew or should have known these representations were false and
16 negligently made them without regard for their truth.

17 175. Defendants had a duty to accurately provide this information to Plaintiffs. In
18 concealing this information from Plaintiffs, Defendants breached their duty. Defendants also gained
19 financially from, and as a result of their breach.

20 176. Defendants intended for Plaintiffs to rely on these representations.

21 177. Each of these misrepresentations were material at the time they were made. In
22 particular, each of the misrepresentations concerned material facts that were essential to the analysis
23 undertaken by Plaintiffs as to whether to purchase or consume Baby Foods.

24 178. Defendants have yet to correct these misrepresentations about Baby Foods.

25 179. Plaintiffs reasonably relied on these representations and were harmed as described
26 herein. Plaintiffs' reliance on Defendants' representation was a substantial factor in causing
27 Plaintiffs' harms. Had Defendants told Plaintiffs the truth about the safety and composition of Baby
28 Foods, Plaintiffs would not have consumed or purchased them.

1 180. Defendants' acts and omissions as described herein were committed in reckless
2 disregard of Plaintiffs' rights, interests, and well-being to enrich Defendants.

3 181. Plaintiffs were injured as a direct and proximate result of Defendants' negligent
4 misrepresentations regarding Baby Foods as described herein.

5 182. **WHEREFORE**, Plaintiffs respectfully request this Court to enter judgment in
6 Plaintiffs' favor for damages, together with interest, costs herein incurred, attorneys' fees and all such
7 other and further relief as this Court deems just and proper.

8 **JURY TRIAL DEMAND**

9 183. Plaintiffs demand a trial by jury on all the triable issues within this pleading.

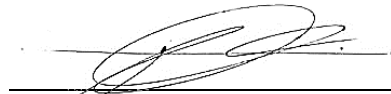
10 **PRAYER FOR RELIEF**

11 184. **WHEREFORE**, Plaintiffs request the Court to enter judgment in Plaintiffs' favor and
12 against the Defendants for:

- 13 a. actual or compensatory damages in such amount to be determined at trial and as
14 provided by applicable law;
15 b. exemplary and punitive damages sufficient to punish and deter the Defendants and
16 others from future wrongful practices;
17 c. pre-judgment and post-judgment interest;
18 d. costs including reasonable attorneys' fees, court costs, and other litigation expenses;
19 and
20 e. any other relief the Court may deem just and proper.

21 Dated: March 5, 2021

BAUM HEDLUND ARISTEI & GOLDMAN, P.C.

22 

23 Pedram Esfandiary (SBN 312569)

24 pesfandiary@baumhedlundlaw.com

25 R. Brent Wisner (SBN: 276023)

26 rbwisner@baumhedlundlaw.com

10940 Wilshire Blvd., 17th Floor

Los Angeles, CA 90024

Tel: (310) 207-3233 / Fax: (310) 820-7444

27 *Counsel for Plaintiffs*