

Plaintiff, Leiba Baumgarten (hereinafter “Plaintiff”), individually and on behalf of all others similarly situated, by her attorneys, alleges the following upon information and belief, except for those allegations pertaining to Plaintiff, which are based on personal knowledge:

NATURE OF THE ACTION

1. This action seeks to remedy the deceptive and misleading business practices of The Hain Celestial Group, Inc. (hereinafter “Defendant”) with respect to the marketing and sales of Defendant Hain Celestial Group, Inc.’s Earth’s Best Organic and Earth’s Best product line throughout the State of New York and throughout the country. The Earth’s Best Organic products include the following products (hereinafter the “Products”):

- Earth’s Best Organic Organic Dairy Infant Formula with Iron Milk-Based Powder;
- Earth’s Best Organic Organic Sensitivity Infant Formula with Iron Milk-Based Powder;
- Earth’s Best Organic Organic Gentle Infant Formula with Iron Milk-Based Powder;
- Earth’s Best Organic Organic Toddler Milk Drink Powder;
- Earth’s Best Non-GMO Plant Based Infant Formula with Iron Soy-Based Powder;
- Earth’s Best Organic Whole Grain Oatmeal Cereal;
- Earth’s Best Organic Rice Cereal;
- Earth’s Best Organic Whole Grain Multi-Grain Cereal;
- Earth’s Best Organic Organic Banana Blueberry Baby Food Puree Pouch;
- Earth’s Best Organic Organic Apple Strawberry Baby Food Puree Pouch;

- Earth's Best Organic Organic Sweet Potato Cinnamon Flax & Oat Wholesome Breakfast Pouch;
- Earth's Best Organic Organic Blueberry Banana Flax & Oat Wholesome Breakfast Puree Pouch;
- Earth's Best Organic Organic Peach Mango Baby Food Puree Pouch;
- Earth's Best Organic Organic Apple Peach Oatmeal Fruit & Grain Puree Pouch;
- Earth's Best Organic Organic Carrots & Broccoli Veggie Puree Pouch;
- Earth's Best Organic Organic Sweet Potato & Apple Baby Food Puree Pouch;
- Earth's Best Organic Organic Orange Banana Baby Food Puree Pouch;
- Earth's Best Organic Organic Butternut Squash Pear Baby Food Puree Pouch;
- Earth's Best Organic Organic Apple Raisin Flax & Oat Wholesome Breakfast Puree Pouch;
- Earth's Best Organic Organic Pumpkin & Spinach Veggie Puree Pouch;
- Earth's Best Organic Organic Squash & Sweet Peas Baby Food Puree Pouch;
- Earth's Best Organic Organic Sweet Potato Garbanzo Barley Veggie & Protein Puree Pouch;
- Earth's Best Organic Organic Sweet Potato & Beets Veggie Puree Pouch;
- Earth's Best Organic Organic Banana Raspberry & Brown Rice Fruit & Grain Puree Pouch;
- Earth's Best Organic Organic Apple Sweet Potato Pumpkin & Blueberry Baby Food Puree Pouch;

- Earth's Best Organic Organic Pasta with Tomato & White Bean made with Olive Oil Pouch;
- Earth's Best Organic Organic Banana Apricot Pumpkin with Yogurt, Oat and Quinoa Wholesome Breakfast Puree Pouch;
- Earth's Best Organic Organic Strawberry Peach Pear with Yogurt, Oat and Quinoa Wholesome Breakfast Puree Pouch;
- Earth's Best Organic Organic Spinach Lentil Brown Rice Veggie & Protein Puree Pouch;
- Earth's Best Organic Organic Chicken Casserole with Vegetables & Rice Homestyle Meal Puree Pouch;
- Earth's Best Organic Organic Pear Carrot Apricot Baby Food Puree Pouch;
- Earth's Best Organic Organic Pumpkin Cranberry Apple Baby Food Puree Pouch;
- Earth's Best Organic Organic Cheesy Pasta with Veggies Homestyle Meal Pouch;
- Earth's Best Organic Organic Turkey Quinoa Apple Sweet Potato Homestyle Meal Pouch;
- Earth's Best Organic Organic Chicken Pot Pie Homestyle Meal Pouch;
- Earth's Best Organic Organic Beef Medley with Vegetables Homestyle Meal Puree Pouch;
- Earth's Best Organic Turkey & Turkey Broth Organic Baby Food Stage 1;
- Earth's Best Organic Chicken & Chicken Broth Organic Baby Food Stage 1;
- Earth's Best Organic Sweet Potato & Chicken Organic Baby Food Stage 2;

- Earth's Best Organic Apple Apricot Organic Baby Food Stage 2;
- Earth's Best Organic Apple & Plums Organic Baby Food Stage 2;
- Earth's Best Organic Pears & Mangos Organic Baby Food Stage 2;
- Earth's Best Organic Sweet Potato Apricot Organic Baby Food Stage 2;
- Earth's Best Organic Vegetable Turkey Dinner Organic Baby Food Stage 2;
- Earth's Best Organic Sweet Potatoes Organic Baby Food Stage 2;
- Earth's Best Organic Peach Oatmeal Banana Organic Baby Food Stage 2;
- Earth's Best Organic Banana Mango Organic Baby Food Stage 2;
- Earth's Best Organic Apple Butternut Squash Organic Baby Food Stage 2;
- Earth's Best Organic Banana Peach Raspberry Organic Baby Food Stage 2;
- Earth's Best Organic Apples & Blueberries Organic Baby Food Stage 2;
- Earth's Best Organic Corn & Butternut Squash Organic Baby Food Stage 2;
- Earth's Best Organic Chicken & Rice Organic Baby Food Stage 2;
- Earth's Best Organic Pears & Raspberries Organic Baby Food Stage 2;
- Earth's Best Organic Sweet Potato & Chicken Organic Baby Food Stage 2;
- Earth's Best Organic Winter Squash Organic Baby Food Stage 2;
- Earth's Best Organic Pears Organic Baby Food Stage 2;
- Earth's Best Organic Bananas Organic Baby Food Stage 2;
- Earth's Best Organic Carrots Organic Baby Food Stage 2;
- Earth's Best Organic Apples Organic Baby Food Stage 2;
- Earth's Best Organic Peas Organic Baby Food Stage 2;

- Earth's Best Organic Tender Chicken & Stars Organic Baby Food Stage 3;
- Earth's Best Organic Apple Cinnamon Oatmeal Organic Baby Food Stage 3;
- Earth's Best Organic Organic Fruit Yogurt Smoothie Strawberry Banana Pouch;
- Earth's Best Organic Organic Fruit Yogurt Smoothie Peach Banana Pouch;
- Earth's Best Organic Organic Fruit Yogurt Smoothie Pineapple Orange Banana Pouch;
- Earth's Best Organic Organic Fruit Yogurt Smoothie Mixed Berry Pouch;
- Earth's Best Organic Organic Fruit Yogurt Smoothie Pear Mango Pouch;
- Earth's Best Organic Organic Fruit Yogurt Smoothie Apple Blueberry Pouch;
- Earth's Best Organic Organic Veggie Red Lentil Bake with Olive Oil Protein Puree Pouch;
- Earth's Best Organic Organic Four Bean Feast with Vegetables Protein Puree Pouch.

2. Caregivers like Plaintiff trust manufacturers like Defendant to sell food for babies/children that is nutritious, safe, and free from harmful toxins, contaminants, and chemicals. Caregivers certainly expect that the food that they feed their infants and toddlers will be free from heavy metals, harmful toxins, and contaminants.

3. Plaintiff and those similarly situated ("Class Members") relied on Defendant's misrepresentations when purchasing the Products. Plaintiff and Class Members paid a premium for the Products based upon their representations. Given that Plaintiff and Class Members paid a

premium for the Products based on Defendant's misrepresentations, Plaintiff and Class Members suffered an injury in the amount of the premium paid.

4. Defendant's conduct violated and continues to violate, *inter alia*, New York General Business Law §§ 349 and 350, and the Magnuson-Moss Warranty Act. Defendant breached and continues to breach its warranties regarding the Products. Defendant fraudulently concealed material facts regarding the Products. Defendant has been and continues to be unjustly enriched. Accordingly, Plaintiff brings this action against Defendant on behalf of herself and Class Members who purchased the Products during the applicable statute of limitations period (the "Class Period").

FACTUAL BACKGROUND

5. Consumers lack the scientific knowledge necessary to determine whether the Defendant's products contain heavy metals or to know or ascertain the true nature of the ingredients and quality of the Products. Reasonable consumers therefore must and do rely on Defendant to honestly report what its products contain.

6. Defendant did not list heavy metals as an ingredient on its Products' labels, nor did it warn of the potential presence of toxic heavy metals in its Products.

7. A recent report by the U.S. House of Representatives' Subcommittee on Economic and Consumer Policy, Committee on Oversight and Reform reveals that caregivers' trust has been violated. Ex. 1. The Subcommittee's investigation of the seven largest baby food manufacturers in the United States, including Defendant, was spurred by "reports alleging high levels of toxic heavy metals in baby foods" and the knowledge that

"[e]ven low levels of exposure can cause serious and often irreversible damage to brain development." Ex. 1 at pg. 2.

8. The Subcommittee's report revealed that "[i]nternal company standards permit dangerously high levels of toxic heavy metals, and ... that the manufacturers have often sold foods that exceeded these levels." Ex. 1 at pg. 4.

9. The investigation found that, when baby food manufacturers were left to self-regulate and establish their own heavy metals standards, they routinely failed to abide by their own standards. Ex. 1.

10. The Subcommittee also revealed that baby foods are "tainted with significant levels of toxic heavy metals, including arsenic, lead, cadmium, and mercury." Ex. 1 at pg. 2.

11. The Subcommittee's investigation has found that baby food manufacturers are selling baby food with higher levels of lead than what is allowed by existing standards for water, juice, and candy. Ex. 1 at pg. 22.

12. Defendant's own internal testing data demonstrates that Defendant sold baby foods even when they or their ingredients contained unsafe levels of lead. Ex. 1 at pg. 22.

13. Specific to Defendant, the report noted that "Hain typically only tested its ingredients, not finished products." Ex. 1 at pg. 3.

14. Defendant's egregious lack of quality control led to the following findings by the Subcommittee:

a. Defendant 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. Ex. 1 at pg. 39;

- b. Defendant 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, Defendant justified accepting lentil flour with 110 ppb lead and quinoa flour with 120 ppb lead. These surpass every existing regulatory standard for lead. In fact, Defendant used ingredients that contained as much as 352 ppb lead, used 88 ingredients with lead levels at or over 20 ppb (the EU's standard for lead in infant formula), accepted 115 ingredients that registered at or over 15 ppb (EPA's action level for drinking water), and at least 27% of Defendant's ingredients tested at or over 5 ppb lead (FDA's standard for lead in bottled water). None of the test results showed an ingredient below 1 ppb lead, which should be the upper limit for lead content according to the health experts at Consumer Reports, the Environmental Defense Fund, and the American Academy of Pediatrics. Ex. 1 at pgs. 26-27;
- c. Defendant used 14 ingredients that contained more than 100 ppb cadmium, including barley flour that registered at 260 ppb cadmium (which is thirteen times the EU's lax upper limit on cadmium in baby food). Defendant tested and used 102 ingredients that registered at or

- above 20 ppb cadmium (the EU's lax upper limit). Ex. 1 at pg. 30;
- d. Defendant did not even test for mercury in baby food. Ex. 1 at pg. 4;
- e. These results are multiples higher than allowed under existing regulations for other products. For example, the FDA has set the maximum allowable levels in bottled water at 10 ppb inorganic arsenic, 5 ppb lead, and 5 ppb cadmium, and the EPA has capped the allowable level of mercury in drinking water at 2 ppb. Ex. 1 at pg. 4;
- f. Defendant set an internal standard of 200 ppb for arsenic, lead, and cadmium in some of its ingredients. But Hain exceeded its internal policies, using ingredients containing 353 ppb lead and 309 ppb arsenic. Hain justified deviations above its ingredient testing standards based on "theoretical calculations," even after Defendant admitted to the FDA that its testing underestimated final product toxic heavy metal levels. Ex. 1 at pgs. 4-5.
- g. On August 1, 2019, the FDA received a secret slide presentation from Defendant, which revealed that:
- Corporate policies to test only ingredients, not final products, underrepresent the levels of toxic heavy metals in baby foods. In 100% of the Hain baby foods tested, inorganic arsenic levels were higher in the finished baby food than the company estimated they would be based on individual ingredient testing. Inorganic arsenic was between 28% and

93% higher in the finished products;

- Many of Defendant's baby foods were tainted with high levels of inorganic arsenic—half of its brown rice baby foods contained over 100 ppb inorganic arsenic; its average brown rice baby food contained 97.62 ppb inorganic arsenic;
- Naturally occurring toxic heavy metals may not be the only problem causing the unsafe levels of toxic heavy metals in baby foods; rather, baby food producers like Defendant may be adding ingredients that have high levels of toxic heavy metals into their products, such as vitamin/mineral pre-mix. Ex. 1 at pgs. 5, 43; and
- Even four months after it had made the secret presentation to the FDA admitting that the heavily tainted vitamin premix caused dangerous levels of arsenic in its finished products (which initially went undetected because Defendant did not test its finished products), Defendant made no effort to correct the problem. Ex. 1 at pgs. 42-43.

15. In its conclusion, the Subcommittee stressed the danger associated with the presence of heavy metals in baby food: "These toxic heavy metals pose serious health risks to babies and toddlers. Manufacturers knowingly sell these products to unsuspecting caregivers, in spite of internal company standards and test results, and without any warning labeling whatsoever." Ex. 1 at pg. 59.

16. Defendant's deceptive representations and omissions are material in that a reasonable person would attach importance to such information and would be induced to act upon such information in making purchase decisions.

17. Even after they were fully aware (and made a secret presentation to the FDA about it), Defendant still willfully failed to warn Plaintiff and the Class of the elevated levels of toxic heavy metals in the Products.

18. Defendant also knows that consumers, such as Plaintiff and the Class, are unwilling to purchase baby food that contain elevated levels of toxic heavy metals.

19. Defendant knew that if the elevated levels of toxic heavy metals in their respective brands of baby food was disclosed to Plaintiff and Class members, then Plaintiff and Class members would be unwilling to purchase the Products.

20. Defendant has thus violated, *inter alia*, NY General Business Law § 392-b by: a) putting upon an article of merchandise, bottle, wrapper, package, label or other thing, containing or covering such an article, or with which such an article is intended to be sold, or is sold, a false description or other indication of or respecting the kind of such article or any part thereof; and b) selling or offering for sale an article, which to its knowledge is falsely described or indicated upon any such package, or vessel containing the same, or label thereupon, in any of the particulars specified.

21. Plaintiff and the Class members reasonably relied to their detriment on Defendant's misleading representations and omissions.

22. Defendant's false, misleading, and deceptive misrepresentations and omissions are likely to continue to deceive and mislead reasonable consumers and the general public, as they have already deceived and misled Plaintiff and the Class members.

23. As an immediate, direct, and proximate result of Defendant's false, misleading, and deceptive representations and omissions, Defendant injured Plaintiff and the Class members in that they:

- a. Paid a sum of money for Products that were not what Defendant represented;
- b. Paid a premium price for Products that were not what Defendant represented;
- c. Were deprived of the benefit of the bargain because the Products they purchased were different from what Defendant warranted;
- d. Were deprived of the benefit of the bargain because the Products they purchased had less value than what Defendant represented;
- e. Ingested a substance that was of a different quality than what Defendant promised; and
- f. Were denied the benefit of the beneficial properties of the natural foods Defendant promised.

24. Had Defendant not made the false, misleading, and deceptive representations and omissions, Plaintiff and the Class members would not have been willing to pay the same amount for the Products they purchased.

25. Plaintiff and the Class members all paid money for the Products; however, Plaintiff and the Class members did not obtain the full value of the advertised Products due to Defendant's misrepresentations and omissions. Plaintiff and the Class members purchased, purchased more of, and/or paid more for the Products than they would have had they known the truth about the

Products. Consequently, Plaintiff and the Class members have suffered injury in fact and lost money as a result of Defendant's wrongful conduct.

JURISDICTION AND VENUE

26. This Court has subject matter jurisdiction under the Class Action Fairness Act, 28 U.S.C. section 1332(d) in that: (1) this is a class action involving more than 100 class members; (2) Plaintiff is a citizen of the State of New York, Defendant The Hain Celestial Group is a citizen of the State of New York; more than two-thirds of the class members reside outside the State of New York; and (3) the amount in controversy is in excess of \$5,000,000, exclusive of interests and costs.

27. This Court has personal jurisdiction over Defendant because Defendant conducts and transacts business in the State of New York, contracts to supply goods within the State of New York, and supplies goods within the State of New York.

28. Venue is proper because Plaintiff and many Class Members reside in the Eastern District of New York, and throughout the State of New York. A substantial part of the events or omissions giving rise to the classes' claims occurred in this District.

PARTIES

Plaintiff

29. Plaintiff is an individual consumer who, at all times material hereto, was a citizen of New York State. Plaintiff purchased the Products during the Class Period. The packaging of the Products Plaintiff purchased did not contain the representation that the Products contained

harmful contaminants and heavy metals. If the Products actually were free of harmful contaminants and heavy metals, Plaintiff would purchase the Products in the immediate future.

30. Had Defendant not made the false, misleading, and deceptive representations and omissions regarding the Products, Plaintiff would not have been willing to pay the same amount for the Products, and, consequently, would not have been willing to purchase the Products. Plaintiff purchased, purchased more of, and/or paid more for the Products than she would have had she known the truth about the Products. The Products Plaintiff received were worth less than the Products for which she paid. Plaintiff was injured in fact and lost money as a result of Defendant's improper conduct.

Defendant

31. Defendant The Hain Celestial Group, Inc. is a corporation with its principal place of business in Lake Success, New York. Defendant manufactures, markets, advertises, and distributes the Products throughout the United States. Defendant created and/or authorized the false, misleading, and deceptive advertisements, packaging, and labeling for the Products.

CLASS ALLEGATIONS

32. Plaintiff brings this matter on behalf of herself and those similarly situated. As detailed at length in this Complaint, Defendant orchestrated deceptive marketing and labeling practices. Defendant's customers were uniformly impacted by and exposed to this misconduct. Accordingly, this Complaint is uniquely situated for class-wide resolution, including injunctive relief.

33. The Class is defined as all consumers who purchased the Products anywhere in the United States during the Class Period (the “Class”).

34. Plaintiff also seeks certification, to the extent necessary or appropriate, of a subclass of individuals who purchased the Products in the State of New York at any time during the Class Period (the “New York Subclass”).

35. The Class and New York Subclass shall be referred to collectively throughout the Complaint as the Class.

36. The Class is properly brought and should be maintained as a class action under Rule 23(a), satisfying the class action prerequisites of numerosity, commonality, typicality, and adequacy because:

37. Numerosity: Class Members are so numerous that joinder of all members is impracticable. Plaintiff believes that there are thousands of consumers who are Class Members described above who have been damaged by Defendant's deceptive and misleading practices.

38. Commonality: The questions of law and fact common to the Class Members which predominate over any questions which may affect individual Class Members include, but are not limited to:

- a. Whether Defendant are responsible for the conduct alleged herein which was uniformly directed at all consumers who purchased the Products;
- b. Whether Defendant's misconduct set forth in this Complaint demonstrates that Defendant has engaged in unfair, fraudulent, or unlawful business practices with respect to the advertising, marketing, and sale of their Products;

- c. Whether Defendant made false and/or misleading statements to the Class and the public concerning the contents of its Products;
- d. Whether Defendant's false and misleading statements concerning its Products were likely to deceive the public;
- e. Whether Plaintiff and the Class are entitled to injunctive relief; and
- f. Whether Plaintiff and the Class are entitled to money damages under the same causes of action as the other Class Members?

39. Typicality: Plaintiff is a member of the Class. Plaintiff's claims are typical of the claims of each Class Member in that every member of the Class was susceptible to the same deceptive, misleading conduct and purchased the Defendant's Products. Plaintiff is entitled to relief under the same causes of action as the other Class Members.

40. Adequacy: Plaintiff is an adequate Class representative because her interests do not conflict with the interests of the Class Members she seeks to represent, her consumer fraud claims are common to all members of the Class and she has a strong interest in vindicating her rights, she has retained counsel competent and experienced in complex class action litigation, and counsel intends to vigorously prosecute this action.

41. Predominance: Pursuant to Rule 23(b)(3), common issues of law and fact identified above predominate over any other questions affecting only individual members of the Class. The Class issues fully predominate over any individual issue because no inquiry into individual conduct is necessary; all that is required is a narrow focus on Defendant's deceptive and misleading marketing and labeling practices.

42. Superiority: A class action is superior to the other available methods for the fair and efficient adjudication of this controversy because:

- a. The joinder of thousands of individual Class Members is impracticable, cumbersome, unduly burdensome, and a waste of judicial and/or litigation resources;
- b. The individual claims of the Class Members may be relatively modest compared with the expense of litigating the claim, thereby making it impracticable, unduly burdensome, and expensive—if not totally impossible—to justify individual actions;
- c. When Defendant's liability has been adjudicated, all Class Members' claims can be determined by the Court and administered efficiently in a manner far less burdensome and expensive than if it were attempted through filing, discovery, and trial of all individual cases;
- d. This class action will promote orderly, efficient, expeditious, and appropriate adjudication and administration of Class claims;
- e. Plaintiff knows of no difficulty to be encountered in the management of this action that would preclude its maintenance as a class action;
- f. This class action will assure uniformity of decisions among Class Members;
- g. The Class is readily definable and prosecution of this action as a class action will eliminate the possibility of repetitious litigation;

- h. Class Members' interests in individually controlling the prosecution of separate actions is outweighed by their interest in efficient resolution by single class action; and
- i. It would be desirable to concentrate in this single venue the litigation of all plaintiffs who were induced by Defendant's uniform false advertising to purchase its Products.

43. Accordingly, this Class is properly brought and should be maintained as a class action under Rule 23(b)(3) because questions of law or fact common to Class Members predominate over any questions affecting only individual members, and because a class action is superior to other available methods for fairly and efficiently adjudicating this controversy.

INJUNCTIVE CLASS RELIEF

44. Rules 23(b)(1) and (2) contemplate a class action for purposes of seeking class-wide injunctive relief. Here, Defendant has engaged in conduct resulting in misleading consumers about ingredients in its Products. Since Defendant's conduct has been uniformly directed at all consumers in the United States, and the conduct continues presently, injunctive relief on a class-wide basis is a viable and suitable solution to remedy Defendant's continuing misconduct. Plaintiff would purchase the Products again if the ingredients were changed.

45. The injunctive Class is properly brought and should be maintained as a class action under Rule 23(a), satisfying the class action prerequisites of numerosity, commonality, typicality, and adequacy because:

- a. Numerosity: Individual joinder of the injunctive Class Members would be wholly impracticable. Defendant's Products have been purchased by thousands of people throughout the United States;
- b. Commonality: Questions of law and fact are common to members of the Class. Defendant's misconduct was uniformly directed at all consumers. Thus, all members of the Class have a common cause against Defendant to stop its misleading conduct through an injunction. Since the issues presented by this injunctive Class deal exclusively with Defendant's misconduct, resolution of these questions would necessarily be common to the entire Class. Moreover, there are common questions of law and fact inherent in the resolution of the proposed injunctive class, including, *inter alia*:
 - i. Resolution of the issues presented in the 23(b)(3) class;
 - ii. Whether members of the Class will continue to suffer harm by virtue of Defendant's deceptive product marketing and labeling; and
 - iii. Whether, on equitable grounds, Defendant should be prevented from continuing to deceptively mislabel its Products?
- c. Typicality: Plaintiff's claims are typical of the claims of the injunctive Class because her claims arise from the same course of conduct (i.e. Defendant's deceptive and misleading marketing, labeling, and advertising practices). Plaintiff is a typical representative of the Class because, like all members of the injunctive

Class, she purchased Defendant's Products which were sold unfairly and deceptively to consumers throughout the United States.

- d. Adequacy: Plaintiff will fairly and adequately represent and protect the interests of the injunctive Class. Her consumer protection claims are common to all members of the injunctive Class and she has a strong interest in vindicating her rights. In addition, Plaintiff and the Class are represented by counsel who is competent and experienced in both consumer protection and class action litigation.

46. The injunctive Class is properly brought and should be maintained as a class action under Rule 23(b)(2) because Plaintiff seeks injunctive relief on behalf of the Class Members on grounds generally applicable to the entire injunctive Class. Certification under Rule 23(b)(2) is appropriate because Defendant has acted or refused to act in a manner that applies generally to the injunctive Class (i.e. Defendant has marketed its Products using the same misleading and deceptive labeling to all of the Class Members). Any final injunctive relief or declaratory relief would benefit the entire injunctive Class as Defendant would be prevented from continuing its misleading and deceptive marketing practices and would be required to honestly disclose to consumers the nature of the contents of its Products. Plaintiff would purchase the Products again if the ingredients were changed.

FIRST CAUSE OF ACTION
VIOLATION OF NEW YORK GBL § 349
(On Behalf of Plaintiff and New York Subclass Members)

47. Plaintiff repeats and realleges each and every allegation contained in all the foregoing paragraphs as if fully set forth herein.

48. New York General Business Law Section 349 (“GBL § 349”) declares unlawful “[d]eceptive acts or practices in the conduct of any business, trade, or commerce or in the furnishing of any service in this state . . .”

49. The conduct of Defendant alleged herein constitutes recurring, “unlawful” deceptive acts and practices in violation of GBL § 349, and as such, Plaintiff and the New York Subclass Members seek monetary damages and the entry of preliminary and permanent injunctive relief against Defendant, enjoining them from inaccurately describing, labeling, marketing, and promoting the Products.

50. There is no adequate remedy at law.

51. Defendant misleadingly, inaccurately, and deceptively advertise and market its Products to consumers.

52. Defendant's improper consumer-oriented conduct is misleading in a material way in that it, *inter alia*, induced Plaintiff and the New York Subclass Members to purchase and pay a premium for Defendant's Products and to use the Products when they otherwise would not have. Defendant made its untrue and/or misleading statements and representations willfully, wantonly, and with reckless disregard for the truth.

53. Plaintiff and the New York Subclass Members have been injured inasmuch as they paid a premium for products that were contrary to Defendant's representations. Accordingly, Plaintiff and the New York Subclass Members received less than what they bargained and/or paid for.

54. Defendant's advertising and Products' packaging and labeling induced the Plaintiff and the New York Subclass Members to buy Defendant's Products and to pay a premium price for them.

55. Defendant's deceptive and misleading practices constitute a deceptive act and practice in the conduct of business in violation of New York General Business Law §349(a) and Plaintiff and the New York Subclass Members have been damaged thereby.

56. As a result of Defendant's recurring, "unlawful" deceptive acts and practices, Plaintiff and the New York Subclass Members are entitled to monetary, statutory, compensatory, treble and punitive damages, injunctive relief, restitution, and disgorgement of all moneys obtained by means of Defendant's unlawful conduct, interest, and attorneys' fees and costs.

SECOND CAUSE OF ACTION
VIOLATION OF NEW YORK GBL § 350
(On Behalf of Plaintiff and the New York Subclass Members)

57. Plaintiff repeats and realleges each and every allegation contained in all the foregoing paragraphs as if fully set forth herein.

58. N.Y. Gen. Bus. Law § 350 provides, in part, as follows:

False advertising in the conduct of any business, trade, or commerce or in the furnishing of any service in this state is hereby declared unlawful.

59. N.Y. Gen. Bus. Law § 350a(1) provides, in part, as follows:

The term 'false advertising, including labeling, of a commodity, or of the kind, character, terms or conditions of any employment opportunity if such advertising is misleading in a material respect. In determining whether any advertising is misleading, there shall be taken into account (among other things) not only representations made by statement, word, design, device, sound or any combination

thereof, but also the extent to which the advertising fails to reveal facts material in the light of such representations with respect to the commodity or employment to which the advertising relates under the conditions proscribed in said advertisement, or under such conditions as are customary or usual . . .

60. Defendant's labeling and advertisements contain untrue and materially misleading statements concerning Defendant's Products inasmuch as they misrepresent the Products.

61. Plaintiff and the New York Subclass Members have been injured inasmuch as they relied upon the labeling, packaging, and advertising and paid a premium for the Products which were contrary to Defendant's representations. Accordingly, Plaintiff and the New York Subclass Members received less than what they bargained and/or paid for.

62. Defendant's advertising, packaging, and products' labeling induced the Plaintiff and the New York Subclass Members to buy Defendant's Products.

63. Defendant made its untrue and/or misleading statements and representations willfully, wantonly, and with reckless disregard for the truth.

64. Defendant's conduct constitutes multiple, separate violations of N.Y. Gen. Bus. Law § 350.

65. Defendant made the material misrepresentations described in this Complaint in Defendant's advertising and on the Products' packaging and labeling.

66. Defendant's material misrepresentations were substantially uniform in content, presentation, and impact upon consumers at large. Moreover, all consumers purchasing the Products were and continue to be exposed to Defendant's material misrepresentations.

67. As a result of Defendant's recurring, "unlawful" deceptive acts and practices, Plaintiff and New York Subclass Members are entitled to monetary, statutory, compensatory, treble and punitive damages, injunctive relief, restitution, and disgorgement of all moneys obtained by means of Defendant's unlawful conduct, interest, and attorneys' fees and costs.

THIRD CAUSE OF ACTION
BREACH OF EXPRESS WARRANTY
(On Behalf of Plaintiff and All Class Members)

68. Plaintiff repeats and realleges each and every allegation contained in the foregoing paragraphs as if fully set forth herein.

69. Defendant provided the Plaintiff and Class Members with an express warranty in the form of written affirmations of fact.

70. The above affirmations of fact were not couched as "belief" or "opinion," and were not "generalized statements of quality not capable of proof or disproof."

71. These affirmations of fact became part of the basis for the bargain and were material to the Plaintiff's and Class Members' transactions.

72. Plaintiff and Class Members reasonably relied upon Defendant's affirmations of fact and justifiably acted in ignorance of the material facts omitted or concealed when they decided to buy Defendant's Products.

73. Within a reasonable time after they knew or should have known of Defendant's breach, Plaintiff, on behalf of herself and Class Members, placed Defendant on notice of its breach, giving Defendant an opportunity to cure its breach, which it refused to do.

74. Defendant breached the express warranty because the Products contain heavy metals and contaminants.

75. As a direct and proximate result of Defendant's breach of the express warranty, Plaintiff and Class Members were damaged in the amount of the price they paid for the Products, in an amount to be proven at trial.

FOURTH CAUSE OF ACTION
VIOLATION OF THE MAGNUSON-MOSS
WARRANTY ACT, 15 U.S.C. § 2301 *et seq.*
(On Behalf of Plaintiff and All Class Members)

76. Plaintiff repeats and realleges each and every allegation contained in the foregoing paragraphs as if fully set forth herein.

77. Plaintiff brings this claim individually and on behalf of all members of the Class. Upon certification, the Class will consist of more than 100 named Plaintiffs.

78. The Magnuson-Moss Warranty Act provides a federal remedy for consumers who have been damaged by the failure of a supplier or warrantor to comply with any obligation under a written warranty or implied warranty, or other various obligations established under the Magnuson-Moss Warranty Act, 15 U.S.C. § 2301 *et seq.*

79. The Products are “consumer products” within the meaning of the Magnuson-Moss Warranty Act, 15 U.S.C. § 2301(1).

80. Plaintiff and other members of the Class are “consumers” within the meaning of the Magnuson-Moss Warranty Act, 15 U.S.C. § 2301(3).

81. Defendant are “suppliers” and “warrantors” within the meaning of the Magnuson-Moss Warranty Act, 15 U.S.C. §§ 2301(4) & 2301(5).

82. Defendant did not represent in writing that the Products contained heavy metals and contaminants.

83. These statements were made in connection with the sale of the Products and relate to the nature of the Products and affirm and promise that the Products are as represented and defect free and, as such, are “written warranties” within the meaning of the Magnuson-Moss Warranty Act, 15 U.S.C. § 2301(6)(A).

84. As alleged herein, Defendant breached the written warranty by selling consumers Products that contain heavy metals and contaminants.

85. The Products do not conform to Defendant's written warranty and therefore violate the Magnuson-Moss Warranty Act, 15 U.S.C. § 2301 *et seq.* Consequently, Plaintiff and the other members of the Class have suffered injury and are entitled to damages in an amount to be proven at trial.

FIFTH CAUSE OF ACTION
FRAUDULENT CONCEALMENT
(On Behalf of Plaintiff and All Class Members)

86. Plaintiff repeats and realleges each and every allegation contained in the foregoing paragraphs as if fully set forth herein.

87. Defendant concealed and failed to disclose the material fact the Products contained, or were at risk of containing, elevated levels of toxic heavy metals, that they were not

testing the amount of toxic heavy metals in their finished products, and that the products were not safe or healthy for consumption.

88. Defendants had knowledge that the Products contained, or were at risk of containing, elevated levels of toxic heavy metals, that they were not testing the amount of toxic heavy metals in their finished products, and that the products were not safe or healthy for consumption.

89. Defendants had a duty to disclose that the Products contained, or were at risk of containing, elevated levels of toxic heavy metals, that they were not testing the amount of toxic heavy metals in their finished products, and that the products were not safe or healthy for consumption.

90. Defendants had superior knowledge or means of knowledge available to them and knew that Plaintiff and the Class would rely upon the representations and omissions of Defendant regarding the quality of its products. Consumers lack the meaningful ability to test or independently ascertain or verify whether a product contains elevated levels of toxic heavy metals, especially at the point of sale.

91. Defendant's concealment was material and intentional because caregivers are concerned with what they are feeding to the children in their care. Caregivers are influenced by the ingredients listed, as well as any warnings (or lack thereof) on the products they buy and feed to the children in their care. Defendant knows that if it had not omitted that the Products contained, or were at risk of containing, elevated levels of toxic heavy metals, that they were not testing the amount of toxic heavy metals in their finished products, and that the products were

not safe or healthy for consumption then Plaintiff and the Class would not have paid a premium for the Products (or purchased them at all) and Defendant wanted to increase sales/profits.

92. Defendant's concealment misled Plaintiff and the Class as to the true nature of what they were buying and feeding to children.

93. Defendant fraudulently concealed that the Products contained, or were at risk of containing, elevated levels of toxic heavy metals, that they were not testing the amount of toxic heavy metals in their finished products, and that the products were not safe or healthy for consumption. Consequently, Plaintiff and the other members of the Class have suffered injury and are entitled to damages in an amount to be proven at trial.

SIXTH CAUSE OF ACTION
UNJUST ENRICHMENT

(On Behalf of Plaintiff and All Class Members in the Alternative)

94. Plaintiff repeats and realleges each and every allegation contained in the foregoing paragraphs as if fully set forth herein.

95. Plaintiff, on behalf of herself and consumers nationwide, brings a claim for unjust enrichment.

96. Defendant's conduct violated, *inter alia*, state and federal law by manufacturing, advertising, marketing, and selling its Products while misrepresenting and omitting material facts.

97. Defendant's unlawful conduct as described in this Complaint allowed Defendant to knowingly realize substantial revenues from selling its Products at the expense of, and to the detriment or impoverishment of, Plaintiff and Class Members, and to Defendant's benefit and enrichment. Defendant has thereby violated fundamental principles of justice, equity, and good

conscience.

98. Plaintiff and Class Members conferred significant financial benefits and paid substantial compensation to Defendant for the Products, which were not as Defendant represented them to be.

99. Under New York's common law principles of unjust enrichment, it is inequitable for Defendant to retain the benefits conferred by Plaintiff and Class Members' overpayments.

100. Plaintiff and Class Members seek disgorgement of all profits resulting from such overpayments and establishment of a constructive trust from which Plaintiff and Class Members may seek restitution.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff, on behalf of herself and the Class, prays for judgment as follows:

- (a) Declaring this action to be a proper class action and certifying Plaintiff as the representative of the Class under Rule 23 of the FRCP;
- (b) Enjoining Defendant from continuing its unlawful practices described herein;
- (c) Awarding monetary damages and treble damages;
- (d) Awarding statutory damages of \$50 per transaction, and treble damages for knowing and willful violations, pursuant to N.Y. GBL § 349;
- (e) Awarding statutory damages of \$500 per transaction pursuant to N.Y. GBL § 350;
- (f) Awarding punitive damages;
- (g) Awarding Plaintiff and Class Members their costs and expenses incurred in this action, including reasonable allowance of fees for Plaintiff's attorneys and experts, and

reimbursement of Plaintiff's expenses; and

(h) Granting such other and further relief as the Court may deem just and proper.

JURY DEMAND

Plaintiff demands a trial by jury.

Respectfully submitted,

Dated: February 22, 2021

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EXHIBIT 1



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



Staff Report

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

February 4, 2021

oversight.house.gov

EXECUTIVE SUMMARY

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

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

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

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

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

FINDINGS

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

5. The Subcommittee makes the following recommendations:

- **Mandatory testing**—Baby food manufacturers should be required by FDA to test their finished products for toxic heavy metals, not just their ingredients;
- **Labeling**—Manufacturers should be required by FDA to report levels of toxic heavy metals on food labels;
- **Voluntary phase-out of toxic ingredients**—Manufacturers should voluntarily find substitutes for ingredients that are high in toxic heavy metals, or phase out products that have high amounts of ingredients that frequently test high in toxic heavy metals, such as rice;
- **FDA standards**—FDA should set maximum levels of toxic heavy metals permitted in baby foods. One level for each metal should apply across all baby foods. And the level should be set to protect babies against the neurological effects of toxic heavy metals; and
- **Parental vigilance**—Parents should avoid baby foods that contain ingredients testing high in toxic heavy metals, such as rice products. Instituting recommendations one through four will give parents the information they need to make informed decisions to protect their babies.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

A. Inorganic Arsenic

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

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

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

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

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

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

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

¹⁰ *Id.*

¹¹ *Id.*

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

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

B. Lead

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

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

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

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

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

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

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

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

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

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

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

C. Cadmium

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

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

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

D. Mercury

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

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

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

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

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

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

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

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

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

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

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

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

A. Inorganic Arsenic

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

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

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

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

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

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

³¹ Food and Drug Administration, *Arsenic in Food and Dietary Supplements* (online at www.fda.gov/food/metals-and-your-food/arsenic-food-and-dietary-supplements) (accessed Jan. 26, 2021).

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

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

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

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

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

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

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

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

³⁴ *Id.*

³⁵ *Id.*

³⁶ *Id.*

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

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

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

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

Summary of Nurture's Inorganic Arsenic Results

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

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

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

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

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

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

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

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

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

³⁸ *Id.*

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

⁴⁰ *Id.*

⁴¹ *Id.*

⁴² *Id.*

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

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

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

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

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

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

⁴⁴ *Id.*

⁴⁵ *Id.*

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

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

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

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

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

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

Gerber Products Company Test Results (Excerpted Entries)⁴⁹

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

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

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

⁴⁹ *Id.*

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

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

B. Lead

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

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

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

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

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

Proposed and Existing Lead Standards

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

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

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

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

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

⁵⁴ *Id.*

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

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

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

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

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

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

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

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

⁵⁵ *Id.*

⁵⁶ *Id.*

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

⁵⁸ *Id.*

⁵⁹ *Id.*

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

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

⁶⁰ *Id.*

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

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

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

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

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

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

| Lab Results Date | Vendor Name | Item Number | Product Description | Status | Comments on Status | Lab | Spec Based On | Arsenic Spec Limit (ppb) | Arsenic Result (ppb) | Cadmium Spec Limit (ppb) | Cadmium Result (ppb) | Lead Spec Limit (ppb) | Lead Result (ppb) |
|------------------|-------------------|-------------|---------------------|--------------------|--------------------------------|------------------|---------------|--------------------------|----------------------|--------------------------|----------------------|-----------------------|-------------------|
| Nov/26/2019 | Wright Enrichment | 5316067 | Vitamin Pre Mix | Deviation Approved | Accepted on deviation 20190236 | Eurofins/Covance | As Purchased | 100 | 223 | 100 | 60.5 | 100 | 352 |

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

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

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

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

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

⁶² *Id.*

⁶³ *Id.*

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

*Gerber Products Company Test Results (Excerpted Entries)*⁶⁵

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

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

*Gerber Products Company Test Results (Excerpted Entries)*⁶⁶

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

⁶⁵ *Id.*

⁶⁶ *Id.*

C. Cadmium

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

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

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

Proposed and Existing Cadmium Standards

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

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

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

⁶⁷ Environmental Protection Agency, *Ground Water and Drinking Water* (online at www.epa.gov/ground-water-and-drinking-water/national-primary-drinking-water-regulations) (accessed Jan. 26, 2021); 21 C.F.R. § 165 (2019) (online at www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?fr=165.110).

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

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

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

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

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

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

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

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

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

⁷² *Id.*

⁷³ *Id.*

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

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

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

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

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

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

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

⁷⁵ *Id.*

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

⁷⁷ *Id.*

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

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

Gerber Products Company Test Results (Excerpted Entries)⁷⁹

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

D. Mercury

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

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

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

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

⁷⁹ *Id.*

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

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

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

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

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

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

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

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

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

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

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

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

⁸³ *Id.*

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

⁸⁵ *Id.*

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

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

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

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

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

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

⁸⁶ *Id.*

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

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

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

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

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

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

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

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

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

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

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

⁹¹ *Id.*

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

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

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

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

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

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

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

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

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

⁹⁴ *Id.*

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

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

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

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

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

⁹⁶ *Id.*

⁹⁷ *Id.*

⁹⁸ *Id.*

⁹⁹ *Id.*

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

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

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

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

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

¹⁰⁰ *Id.*

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

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

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

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

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

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

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

| Lab Results Date | Vendor Name | Item Number | Product Description | Status | Comments on Status | Lab | Spec Based On | Lead Spec Limit (ppb) | Lead Result (ppb) |
|------------------|------------------------|-------------|------------------------|----------|-------------------------------------|--------|---------------|-----------------------|-------------------|
| Aug/3/2017 | Montana Flour & Grains | 5303053 | Org Kamut Flour | Accepted | | Deibel | As consumed | 200 | <100 |
| Jul/19/2017 | Firebird Artisan Mills | 57200 | Org Green Lentil Flour | Accepted | Calculated Levels on consumed basis | Deibel | As consumed | 200 | 110 |
| Aug/21/2017 | Grain Millers | 5308029 | Org Brown Flax Milled | Accepted | Calculated Levels on consumed basis | Deibel | As consumed | 200 | <100 |
| Jul/15/2017 | Firebird Artisan Mills | 5303042 | Org Quinoa Flour | Accepted | | Deibel | As consumed | 200 | <100 |
| Jul/13/2017 | Firebird Artisan Mills | 5303042 | Org Quinoa Flour | Accepted | spec for lead was 200ppb | Deibel | As consumed | 200 | 120 |

¹⁰⁴ *Id.*¹⁰⁵ *Id.*¹⁰⁶ *Id.*

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

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

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

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

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

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

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

¹⁰⁷ *Id.*

¹⁰⁸ *Id.*

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

¹¹⁰ *Id.*

¹¹¹ *Id.*

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

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

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

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

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

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

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

¹¹² *Id.*

¹¹³ *Id.*

¹¹⁴ *Id.*

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

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

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

A. Walmart (Parent’s Choice Brand)

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

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

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

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

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

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

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



B. Campbell (Plum Organics Brand)

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

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

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

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

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

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

¹¹⁹ *Id.*

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

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

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

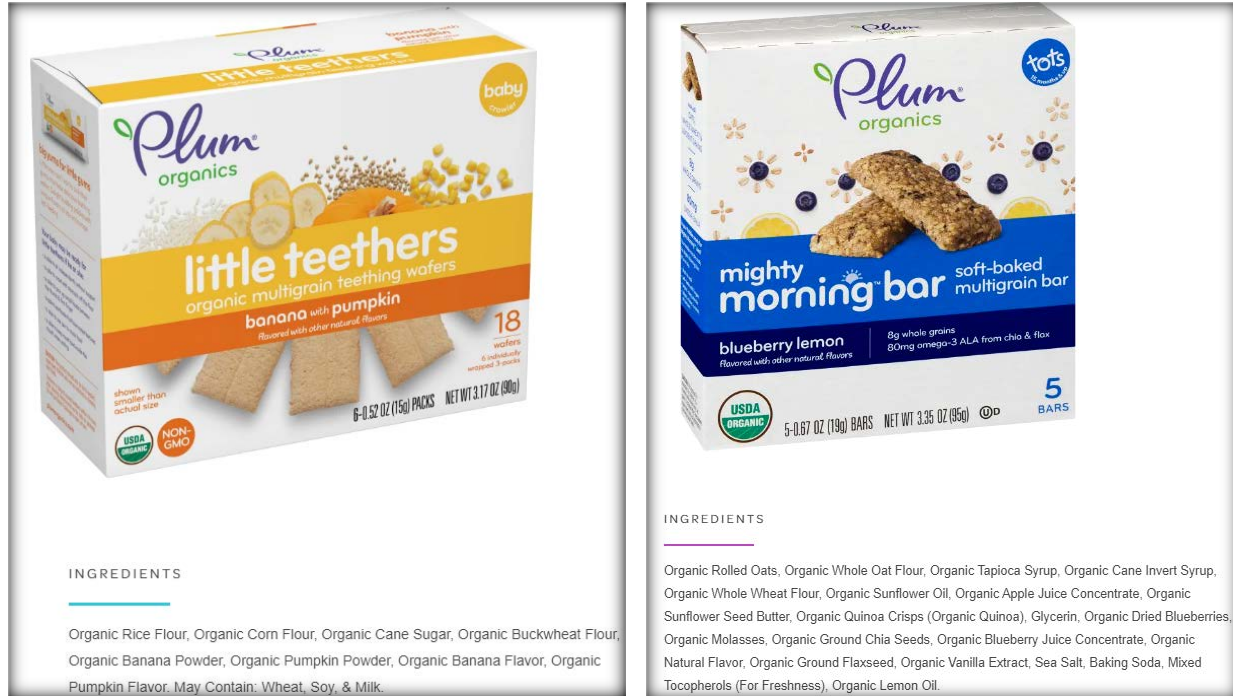
Data from Healthy Babies Bright Futures Report: What’s in My Baby’s Food?¹²²

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

¹²⁰ *Id.*

¹²¹ *Id.*

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

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

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

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

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

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

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

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

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

Sprout Organic Food That Tested High in Toxic Heavy Metals¹²⁶



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

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

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

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

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

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

A. Mercury and Cadmium

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

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

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

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

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

¹²⁹ *Id.*

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

¹³¹ Environmental Protection Agency, *Ground Water and Drinking Water* (online at www.epa.gov/ground-water-and-drinking-water/national-primary-drinking-water-regulations) (accessed Jan. 26, 2021).

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

B. Lead

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

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

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

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

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

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

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

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

¹³⁵ *Id.*

¹³⁶ *Id.*

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

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

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

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

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

C. Arsenic

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

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

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

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

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

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

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

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

Inorganic Arsenic in Rice Cereals for Infants (Aug. 2020) (online at www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-action-level-inorganic-arsenic-rice-cereals-infants).

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

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

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

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

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

¹⁴⁵ Food and Drug Administration, *Arsenic in Food and Dietary Supplements* (online at www.fda.gov/food/metals-and-your-food/arsenic-food-and-dietary-supplements) (accessed Jan. 26, 2021).

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

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

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

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

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

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

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

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

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

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

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

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

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

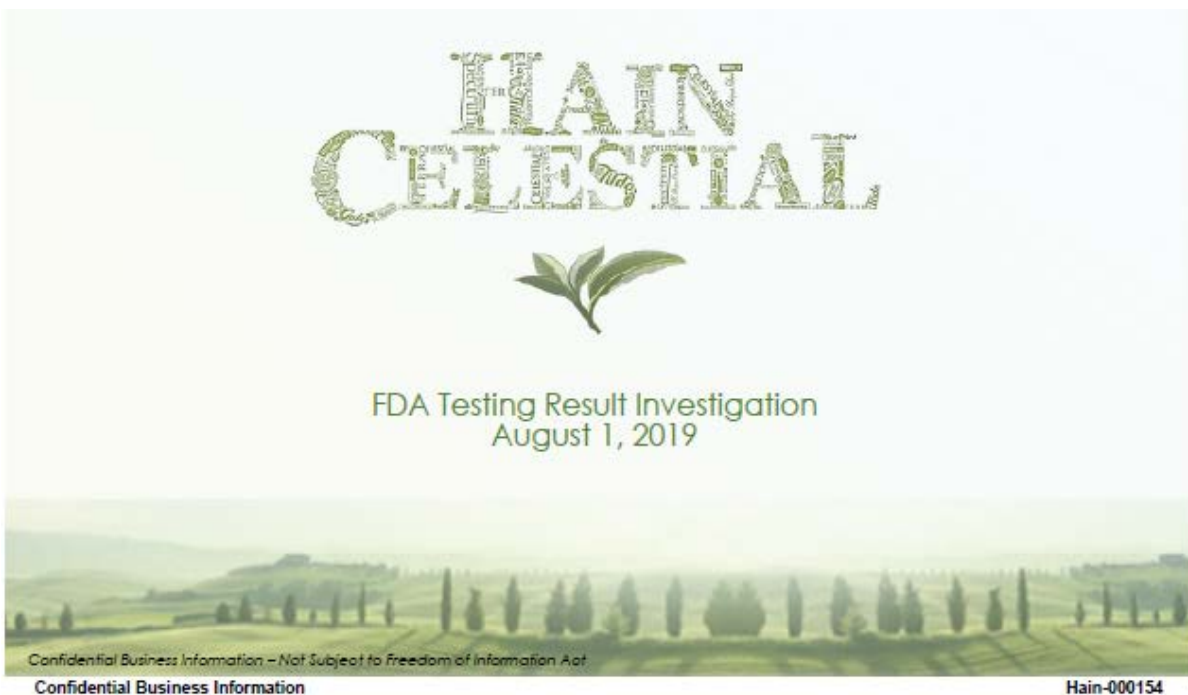
D. The Trump Administration Ignored A Secret Industry Presentation About Higher Risks Of Toxic Heavy Metals In Baby Foods.

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

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

¹⁵⁰ *Id.*

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



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

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

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

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

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

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

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

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

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

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

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

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

¹⁵⁴ *Id.*

¹⁵⁵ *Id.*

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

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

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

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

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

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

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

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

¹⁵⁶ *Id.*

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

¹⁵⁸ *Id.*

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

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

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

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

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

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

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

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

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

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

¹⁶¹ *Id.*

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

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

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

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

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

The Subcommittee recommends the following:

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

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

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

VII. CONCLUSION

The Subcommittee's investigation proves that commercial baby foods contain dangerous levels of arsenic, lead, mercury, and cadmium. These toxic heavy metals pose serious health risks to babies and toddlers. Manufacturers knowingly sell these products to unsuspecting parents, in spite of internal company standards and test results, and without any warning labeling whatsoever.

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

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

CIVIL COVER SHEET

JS 44 (Rev. 10/20)

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

I. (a) PLAINTIFFS

Leiba Baumgarten, individually and on behalf of all others similarly situated

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

(c) Attorneys (Firm Name, Address, and Telephone Number)

The Sultzter Law Group P.C. Jason P. Sultzter, Esq.
85 Civic Center Plaza, Suite 200 (845) 483-7100
Poughkeepsie, NY 12601

DEFENDANTS

The Hain Celestial Group, Inc.

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

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

Attorneys (If Known)

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

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

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

| | PTF | DEF | | PTF | DEF |
|-----------------------------------------|---------------------------------------|----------------------------|---------------------------------------------------------------|----------------------------|---------------------------------------|
| Citizen of This State | <input checked="" type="checkbox"/> 1 | <input type="checkbox"/> 1 | Incorporated or Principal Place of Business In This State | <input type="checkbox"/> 4 | <input checked="" type="checkbox"/> 4 |
| Citizen of Another State | <input type="checkbox"/> 2 | <input type="checkbox"/> 2 | Incorporated and Principal Place of Business In Another State | <input type="checkbox"/> 5 | <input type="checkbox"/> 5 |
| Citizen or Subject of a Foreign Country | <input type="checkbox"/> 3 | <input type="checkbox"/> 3 | Foreign Nation | <input type="checkbox"/> 6 | <input type="checkbox"/> 6 |

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

Click here for: Nature of Suit Code Descriptions.

| CONTRACT | TORTS | FORFEITURE/PENALTY | BANKRUPTCY | OTHER STATUTES | |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <input type="checkbox"/> 110 Insurance <input type="checkbox"/> 120 Marine <input type="checkbox"/> 130 Miller Act <input type="checkbox"/> 140 Negotiable Instrument <input type="checkbox"/> 150 Recovery of Overpayment & Enforcement of Judgment <input type="checkbox"/> 151 Medicare Act <input type="checkbox"/> 152 Recovery of Defaulted Student Loans (Excludes Veterans) <input type="checkbox"/> 153 Recovery of Overpayment of Veteran's Benefits <input type="checkbox"/> 160 Stockholders' Suits <input type="checkbox"/> 190 Other Contract <input type="checkbox"/> 195 Contract Product Liability <input type="checkbox"/> 196 Franchise | PERSONAL INJURY <input type="checkbox"/> 310 Airplane <input type="checkbox"/> 315 Airplane Product Liability <input type="checkbox"/> 320 Assault, Libel & Slander <input type="checkbox"/> 330 Federal Employers' Liability <input type="checkbox"/> 340 Marine <input type="checkbox"/> 345 Marine Product Liability <input type="checkbox"/> 350 Motor Vehicle <input type="checkbox"/> 355 Motor Vehicle Product Liability <input type="checkbox"/> 360 Other Personal Injury <input type="checkbox"/> 362 Personal Injury - Medical Malpractice | <input type="checkbox"/> 365 Personal Injury - Product Liability <input type="checkbox"/> 367 Health Care/Pharmaceutical Personal Injury Product Liability <input type="checkbox"/> 368 Asbestos Personal Injury Product Liability PERSONAL PROPERTY <input checked="" type="checkbox"/> 370 Other Fraud <input type="checkbox"/> 371 Truth in Lending <input type="checkbox"/> 380 Other Personal Property Damage <input type="checkbox"/> 385 Property Damage Product Liability | <input type="checkbox"/> 625 Drug Related Seizure of Property 21 USC 881 <input type="checkbox"/> 690 Other LABOR <input type="checkbox"/> 710 Fair Labor Standards Act <input type="checkbox"/> 720 Labor/Management Relations <input type="checkbox"/> 740 Railway Labor Act <input type="checkbox"/> 751 Family and Medical Leave Act <input type="checkbox"/> 790 Other Labor Litigation <input type="checkbox"/> 791 Employee Retirement Income Security Act IMMIGRATION <input type="checkbox"/> 462 Naturalization Application <input type="checkbox"/> 465 Other Immigration Actions | <input type="checkbox"/> 422 Appeal 28 USC 158 <input type="checkbox"/> 423 Withdrawal 28 USC 157 PROPERTY RIGHTS <input type="checkbox"/> 820 Copyrights <input type="checkbox"/> 830 Patent <input type="checkbox"/> 835 Patent - Abbreviated New Drug Application <input type="checkbox"/> 840 Trademark <input type="checkbox"/> 880 Defend Trade Secrets Act of 2016 SOCIAL SECURITY <input type="checkbox"/> 861 HIA (1395ff) <input type="checkbox"/> 862 Black Lung (923) <input type="checkbox"/> 863 DIWC/DIWW (405(g)) <input type="checkbox"/> 864 SSID Title XVI <input type="checkbox"/> 865 RSI (405(g)) FEDERAL TAX SUITS <input type="checkbox"/> 870 Taxes (U.S. Plaintiff or Defendant) <input type="checkbox"/> 871 IRS—Third Party 26 USC 7609 | <input type="checkbox"/> 375 False Claims Act <input type="checkbox"/> 376 Qui Tam (31 USC 3729(a)) <input type="checkbox"/> 400 State Reapportionment <input type="checkbox"/> 410 Antitrust <input type="checkbox"/> 430 Banks and Banking <input type="checkbox"/> 450 Commerce <input type="checkbox"/> 460 Deportation <input type="checkbox"/> 470 Racketeer Influenced and Corrupt Organizations <input type="checkbox"/> 480 Consumer Credit (15 USC 1681 or 1692) <input type="checkbox"/> 485 Telephone Consumer Protection Act <input type="checkbox"/> 490 Cable/Sat TV <input type="checkbox"/> 850 Securities/Commodities/Exchange <input type="checkbox"/> 890 Other Statutory Actions <input type="checkbox"/> 891 Agricultural Acts <input type="checkbox"/> 893 Environmental Matters <input type="checkbox"/> 895 Freedom of Information Act <input type="checkbox"/> 896 Arbitration <input type="checkbox"/> 899 Administrative Procedure Act/Review or Appeal of Agency Decision <input type="checkbox"/> 950 Constitutionality of State Statutes |
| REAL PROPERTY | CIVIL RIGHTS | PRISONER PETITIONS | | | |
| <input type="checkbox"/> 210 Land Condemnation <input type="checkbox"/> 220 Foreclosure <input type="checkbox"/> 230 Rent Lease & Ejectment <input type="checkbox"/> 240 Torts to Land <input type="checkbox"/> 245 Tort Product Liability <input type="checkbox"/> 290 All Other Real Property | <input type="checkbox"/> 440 Other Civil Rights <input type="checkbox"/> 441 Voting <input type="checkbox"/> 442 Employment <input type="checkbox"/> 443 Housing/Accommodations <input type="checkbox"/> 445 Amer. w/Disabilities - Employment <input type="checkbox"/> 446 Amer. w/Disabilities - Other <input type="checkbox"/> 448 Education | Habeas Corpus: <input type="checkbox"/> 463 Alien Detainee <input type="checkbox"/> 510 Motions to Vacate Sentence <input type="checkbox"/> 530 General <input type="checkbox"/> 535 Death Penalty Other: <input type="checkbox"/> 540 Mandamus & Other <input type="checkbox"/> 550 Civil Rights <input type="checkbox"/> 555 Prison Condition <input type="checkbox"/> 560 Civil Detainee - Conditions of Confinement | | | |

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

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

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing (Do not cite jurisdictional statutes unless diversity):
28 U. S. C. § 1332(d)(2)

Brief description of cause:
Neg. & Int., Unjust Enrichment

VII. REQUESTED IN COMPLAINT:

CHECK IF THIS IS A CLASS ACTION UNDER RULE 23, F.R.Cv.P.

DEMAND \$
5,000,000.00

CHECK YES only if demanded in complaint:
JURY DEMAND: Yes No

VIII. RELATED CASE(S) IF ANY

(See instructions):

JUDGE _____

DOCKET NUMBER _____

DATE

SIGNATURE OF ATTORNEY OF RECORD

2/22/2021

FOR OFFICE USE ONLY

RECEIPT # _____

AMOUNT _____

APPLYING IEP _____

JUDGE _____

MAG. JUDGE _____

CERTIFICATION OF ARBITRATION ELIGIBILITY

Local Arbitration Rule 83.7 provides that with certain exceptions, actions seeking money damages only in an amount not in excess of \$150,000, exclusive of interest and costs, are eligible for compulsory arbitration. The amount of damages is presumed to be below the threshold amount unless a certification to the contrary is filed.

Case is Eligible for Arbitration

I, _____, counsel for _____, do hereby certify that the above captioned civil action is ineligible for compulsory arbitration for the following reason(s):

- monetary damages sought are in excess of \$150,000, exclusive of interest and costs,
- the complaint seeks injunctive relief,
- the matter is otherwise ineligible for the following reason

DISCLOSURE STATEMENT - FEDERAL RULES CIVIL PROCEDURE 7.1

Identify any parent corporation and any publicly held corporation that owns 10% or more of its stocks:

RELATED CASE STATEMENT (Section VIII on the Front of this Form)

Please list all cases that are arguably related pursuant to Division of Business Rule 50.3.1 in Section VIII on the front of this form. Rule 50.3.1 (a) provides that "A civil case is "related" to another civil case for purposes of this guideline when, because of the similarity of facts and legal issues or because the cases arise from the same transactions or events, a substantial saving of judicial resources is likely to result from assigning both cases to the same judge and magistrate judge." Rule 50.3.1 (b) provides that " A civil case shall not be deemed "related" to another civil case merely because the civil case: (A) involves identical legal issues, or (B) involves the same parties." Rule 50.3.1 (c) further provides that "Presumptively, and subject to the power of a judge to determine otherwise pursuant to paragraph (d), civil cases shall not be deemed to be "related" unless both cases are still pending before the court."

NY-E DIVISION OF BUSINESS RULE 50.1(d)(2)

- 1.) Is the civil action being filed in the Eastern District removed from a New York State Court located in Nassau or Suffolk County? Yes No
- 2.) If you answered "no" above:
 - a) Did the events or omissions giving rise to the claim or claims, or a substantial part thereof, occur in Nassau or Suffolk County? Yes No
 - b) Did the events or omissions giving rise to the claim or claims, or a substantial part thereof, occur in the Eastern District? Yes No
 - c) If this is a Fair Debt Collection Practice Act case, specify the County in which the offending communication was received:

If your answer to question 2 (b) is "No," does the defendant (or a majority of the defendants, if there is more than one) reside in Nassau or Suffolk County, or, in an interpleader action, does the claimant (or a majority of the claimants, if there is more than one) reside in Nassau or Suffolk County? Yes No

(Note: A corporation shall be considered a resident of the County in which it has the most significant contacts).

BAR ADMISSION

I am currently admitted in the Eastern District of New York and currently a member in good standing of the bar of this court.

Yes No

Are you currently the subject of any disciplinary action (s) in this or any other state or federal court?

Yes (If yes, please explain) No

I certify the accuracy of all information provided above.

Signature: _____

AO 440 (Rev. 06/12) Summons in a Civil Action (Page 2)

Civil Action No. _____

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))

This summons for *(name of individual and title, if any)* _____
was received by me on *(date)* _____.

I personally served the summons on the individual at *(place)* _____
_____ on *(date)* _____; or

I left the summons at the individual's residence or usual place of abode with *(name)* _____
_____, a person of suitable age and discretion who resides there,
on *(date)* _____, and mailed a copy to the individual's last known address; or

I served the summons on *(name of individual)* _____, who is
designated by law to accept service of process on behalf of *(name of organization)* _____
_____ on *(date)* _____; or

I returned the summons unexecuted because _____; or

Other *(specify)*:

My fees are \$ _____ for travel and \$ _____ for services, for a total of \$ _____ 0.00.

I declare under penalty of perjury that this information is true.

Date: _____

Server's signature

Printed name and title

Server's address

Additional information regarding attempted service, etc:

ClassAction.org

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