ATTORNEYS GENERAL OF NEW YORK, COLORADO, CONNECTICUT, DELAWARE, HAWAII, ILLINOIS, MAINE, MARYLAND, MASSACHUSETTS, MICHIGAN, MINNESOTA, NEW JERSEY, NEW MEXICO, NEVADA, NORTH CAROLINA, OREGON, PENNSYLVANIA, VERMONT, WASHINGTON, AND WISCONSIN

Via Electronic Submission on Regulations.gov

February 14, 2024

Division of Dockets Management
Food and Drug Administration
Department of Health and Human Services, rm. 1-23
5630 Fishers Lane, rm. 1061
Rockville, MD 20852

Attn: Dr. Robert M. Califf, Commissioner
Attn: James Jones, Deputy Commissioner for Human Foods
Attn: Dr. Donald A. Prater, Acting Director of the Center for Food Safety and Applied Nutrition (CFSAN)
Attn: Dr. Conrad Choiniere, Director, CFSAN Office of Analytics and Outreach
Attn: Douglas Stearn, Acting Deputy Associate Commissioner for Regulatory Affairs

Request to Take Official Notice of Additional Relevant Information in Support of Citizen Petition and Petition for Reconsideration Requesting FDA Actions on Toxic Heavy Metals in Food Intended for Babies and Young Children
Docket Number FDA-2021-P-1144

Dear Dr. Califf, Mr. Jones, Dr. Prater, Dr. Choiniere and Mr. Stearn:

The offices of the undersigned Attorneys General request that the Food and Drug Administration (FDA) take official notice of three FDA documents relevant to our long-pending petition for reconsideration requesting that, among other things, FDA issue guidance to the baby food industry on finished product testing for lead and other toxic elements. The enclosed documents, which include FDA's series of public updates on its ongoing investigation of dozens of childhood lead poisoning cases nationwide linked with lead contamination of cinnamon applesauce products marketed to babies and young children, strongly reinforce the arguments of the Attorneys General in our reconsideration petition.

On June 1, 2022, the Attorneys General of New York, Colorado, Connecticut, Delaware, Hawaii, Illinois, Iowa, Maine, Maryland, Massachusetts, Michigan, Minnesota, New Jersey, New Mexico, Nevada, North Carolina, Oregon, Pennsylvania, Vermont, Washington, and Wisconsin submitted to FDA our request

for administrative reconsideration of FDA's May 2, 2022 denial of our citizen petition, filed October 21, 2021 (the "Reconsideration Petition"). In the 2021 petition, we urged the FDA to drive down the levels of toxic heavy metals in food intended for babies and young children, including by issuing FDA guidance on finished product testing.[1]

The three documents containing relevant facts warranting official notice in further support of our Reconsideration Petition are:

- FDA's January 2023 "Draft Guidance for Industry on Action Levels for Lead in Food Intended for Babies and Young Children" (Attachment A);
- FDA's series of public notices on its "Investigation of Elevated Lead & Chromium Levels: Cinnamon Applesauce Pouches," most recently dated February 13, 2024 (as of the date of this letter's submission) (Attachment B); and
- an FDA inspection report dated December 14, 2023 finding that the manufacturer of the recalled cinnamon applesauce products did not test the finished products for heavy metals prior to their distribution throughout the United States (Attachment C).

One of the key actions we requested in our original October 2021 petition is for FDA to issue guidance to industry that testing of finished baby food products for lead, inorganic arsenic, cadmium and mercury is a "preventive control" that should be performed by baby food manufacturers and distributors to help limit children's exposure to these toxic elements in their products. FDA regulations define a

[1] FDA regulations provide that "[t]he Commissioner shall *promptly* review a petition for reconsideration." 21 CFR § 10.33(d) (emphasis added). The Reconsideration Petition has been pending before FDA for over 20 months. This lengthy delay is especially concerning because of the lengthy and vague timelines that FDA set for itself to propose and finalize action levels for toxic elements in food for babies and young children as part of FDA's "Closer to Zero" plan, first announced in April 2021. Since then, as recently emphasized in a decision by the United States Court of Appeals for the Second Circuit, "FDA has abandoned these previously announced timelines" in its "Closer to Zero" plan, and FDA now provides "no timelines for when it expects to *finalize* action levels." *White et al. v. Beech-Nut Nutrition Co.*, 23-220-cv, 2024 WL 194699, at *10-11 (2d Cir. Jan. 18, 2024) (Summary Order) (emphasis in original) (reversing dismissal of putative class action lawsuit regarding heavy metals in baby food based on the Court's recognition of "indefinite delays" in progress on FDA's "Closer to Zero" plan for addressing toxic elements in baby food).

"preventive control" as "risk-based, reasonably appropriate procedures, practices, and processes" for "significantly minimiz[ing]" or "prevent[ing]" hazards, including chemical hazards, that are "consistent with the current scientific understanding of safe food manufacturing, processing, packing, or holding at the time of the analysis." 21 C.F.R. § 117.3. Following FDA's denial of our original petition in May 2022, our Reconsideration Petition responded to the points made in FDA's denial and clarified that finished product testing for lead and other toxic elements could properly be regarded as both a "verification" activity and a "preventive control," as those terms are defined and described at 21 C.F.R. §§ 117.165(a) and 117.3. We explained that "[n]othing in the regulatory definition of 'preventive control' prohibits the use of finished product testing as a preventive control for foods intended for babies and young children that are, or soon will be, covered by a proposed or final FDA action level for a toxic element." Reconsideration Petition, at 13.

The three attached FDA documents provide compelling additional support for our Reconsideration Petition urging FDA to expeditiously issue guidance to the baby food industry on finished product testing as a risk-based "preventive control" (as well as a "verification" activity).

(1) FDA's January 2023 *Draft* Guidance for Industry on Action Levels for Lead in Food Intended for Babies and Young Children

In January 2023, FDA issued draft guidance to industry on action levels for lead in processed food intended for babies and young children ("FDA Draft Lead Guidance"), as follows:

- 10 parts per billion (ppb) for fruits, vegetables (excluding single-ingredient root vegetables), mixtures (including grain and meat-based mixtures), yogurts, custards/puddings, and single-ingredient meats;
- 20 ppb for root vegetables (single ingredient); and
- 20 ppb for dry infant cereals.[2]

The FDA Draft Lead Guidance noted that it applies to "food packaged in jars, pouches, tubs, and boxes represented or purported to be specifically for babies and young children less than two years old."[3]

The undersigned Attorneys General (and others) submitted substantive comments to FDA acknowledging that its Draft Lead Guidance was "a welcome and important step that advances the goal for industry to 'reduce levels of lead in

[2] *See* Attachment A, at 3.
[3] *Id.* at 3 n.2.

products for babies and young children to as low as possible' and urging FDA to strengthen and expand its Lead Guidance in several meaningful ways.[4]

(2) FDA's series of public updates on its "Investigation of Elevated Lead & Chromium Levels: Cinnamon Applesauce Pouches"

On October 28, 2023, FDA issued the first of multiple public notices regarding an investigation of "WanaBana apple cinnamon fruit puree" pouches after learning that State of North Carolina public health authorities had "detect[ed] extremely high concentrations of lead" in those products. FDA's statement added that the agency had "reviewed and supports [the North Carolina Department of Health and Human Services'] analytical findings and found that analytical results at this level could result in acute toxicity."[5] On October 31, 2023, FDA publicized Wanabana LLC and Wanabana USA LLC's (together, "Wanabana") voluntary nationwide recall of its Apple Cinnamon Fruit Purée pouches.[6] On November 9, 2023, FDA publicized the voluntary recall of certain lots of two additional brands of cinnamon applesauce: Weis Cinnamon Apple Sauce, and Schnucks Apple Sauce with Cinnamon.[7]

FDA updates on its investigation dated November 16, 2023 and December 26, 2023 disclosed that the "level [of lead] detected in the FDA sample of WanaBana apple cinnamon puree is 2.18 parts per million (ppm), which, for context, is more than 200 times greater than the action level the FDA has proposed in draft guidance for fruit purees and similar products intended for babies and young children."[8] An FDA update from January 5, 2024 stated that "the cinnamon and recalled products also contained a high level of chromium" and that "the level of chromium detected in the reanalysis of FDA samples of the recalled WanaBana Cinnamon Apple Puree product yielded 0.590 and 0.566 ppm."[9] As of FDA's latest public update on its investigation, dated February 13, 2024, FDA discloses that it

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[4] *See* Letter to FDA from New York Attorney General et al. dated May 8, 2023, *available at* https://www.regulations.gov/comment/FDA-2022-D-0278-0067. All but one of the Attorneys General who signed the June 1, 2022 Reconsideration Petition pending before FDA were among the Attorneys Generals who submitted joint comments to FDA on its Draft Lead Guidance in May 2023. The Iowa Attorney General joined the Reconsideration Petition but did not join the May 2023 comment letter to FDA and does not join the present letter.
[5] *See* Attachment B.
[6] *Id.*
[7] *Id.*
[8] *Id.*
[9] *Id.*

"has received 90 reports of adverse events potentially linked to recalled product."[10] Of these cases identified by FDA, more than half are in the states of the undersigned Attorneys General. With respect to those cases reported directly to FDA, the agency states that "the median age is one year old."[11] Additionally, the latest FDA update states that "[a]s of February 9, [2024] CDC has received reports of 101 confirmed cases, 284 probable cases, and 37 suspected cases for a total of 422 cases from 44 different states through their [CDC] reporting structure."[12]

(3) FDA inspection report dated December 14, 2023

We recognize that investigation by FDA and its partners (including state partners) of the Wanabana/Weis/Schnucks lead contamination recall is ongoing, and that not all details about the practices of the companies involved in manufacturing and distributing these products are publicly known. However, one document that recently became public through a Freedom of Information Act request is the enclosed FDA Inspection Report (the "December 2023 FDA Inspection Report") dated December 14, 2023. The December 2023 FDA Inspection Report resulted from an eight-day FDA inspection of the facility in Ecuador where the recalled cinnamon applesauce products were manufactured by Austrofood S.A.S ("Austrofood") and thereafter distributed by Wanabana throughout the United States.[13] The December 2023 FDA Inspection Report states that Austrofood "did not sample and test the raw material or the finished product for heavy metals" and that subsequent "sampling conducted by FDA in the United States identified high level of lead in finished products distributed by Wanabana."[14]

As requested in the Reconsideration Petition, FDA should urgently issue guidance to industry on finished product testing for lead and other toxic elements in baby food.

The dramatic health harms to children in our states associated with the significant lead contamination in these recalled baby food products strongly reinforce our Reconsideration Petition, urging FDA, among other things, to expeditiously issue guidance to industry on finished product testing for lead and other toxic elements in foods intended for infants and young children. FDA has

[10] *Id.*
[11] *Id.*
[12] *Id.*
[13] *See* Attachment C.
[14] *See* Attachment C, page 1. The December 2023 FDA Inspection Report further states that "metal pieces" from a "conveyor" at the Austrofood facility "can break loose and become a sources of metal inclusion that could enter food during processing." *Id.* page 2.

confirmed that samples of the baby food products recalled in October and November 2023 contained more than 200 times the maximum acceptable concentration of lead under FDA's proposed action levels applicable to such baby food products.[15] And yet the December 2023 FDA Inspection Report found that no finished product testing for lead or other heavy metals was performed on these baby food products in the supply chain prior to Wanabana's nationwide recall—months after the products were distributed to consumers nationwide.[16]

The enclosed documents make it evident that some manufacturers and distributors of baby foods in the U.S. currently lack a clear understanding of the proper way to apply preventive controls to avoid adulteration of finished baby food products by lead or other toxic elements. Indeed, FDA has publicly supported, through its legislative proposals, a policy that would allow FDA to "require industry to conduct toxic element testing of final products marketed for consumption by infants and young children and maintain such records of these testing results for FDA inspection."[17]

We request that FDA take official notice of the FDA Draft Lead Guidance (Attachment A), the FDA Investigation of Elevated Lead & Chromium Levels: Cinnamon Applesauce Pouches (Attachment B), and the December 2023 FDA Inspection Report (Attachment C) without needing to re-open the administrative record. The doctrine of "official notice" permits an agency "to take notice of technical or scientific facts that are within the agency's area of expertise," even if those facts are "not included in the record." *Sykes v. Apfel*, 228 F.3d 259, 272 (3d Cir. 2000); *accord Union Elec. Co. v. FERC*, 890 F.2d 1193, 1202-03 (D.C. Cir. 1989); *see also* 21 C.F.R. § 12.95(a) (FDA regulation providing that "[o]fficial notice may be taken of such matters as might be judicially noticed by the courts of the United States or of any other matter peculiarly within the general knowledge of FDA as an expert agency"). Inasmuch as the enclosed documents are official publications of FDA and their reliability cannot seriously be disputed, FDA may take official notice of them as part of its review of the pending Reconsideration Petition.

We thank FDA for its attention to the Attorneys General Reconsideration Petition, and look forward to FDA's decision on it in the near future.

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[15] *See* Attachment B.
[16] *See* Attachment C, page 1.
[17] FDA, Summary of FY 2024 Legislative Proposals, at 3, https://www.fda.gov/media/166049/download?attachment#:~:text=The%20proposals%20include%20enhanced%20authorities,activities%20when%20inspections%20are%20not (last accessed Feb. 14, 2024).

Sincerely,

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Attorney General of New York

By: */s/ Max Shterngel*

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Enclosures: Attachment A (FDA Draft Guidance for Industry on Action Levels for Lead in Food Intended for Babies and Young Children); Attachment B (FDA Investigation of Elevated Lead & Chromium Levels: Cinnamon Applesauce Pouches); and Attachment C (December 2023 FDA Inspection Report of Austrofood S.A.S.)

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Action Levels for Lead in Food Intended for Babies and Young Children: Draft Guidance for Industry

Draft Guidance

This guidance is being distributed for comment purposes only.

Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that FDA considers your comment on this draft guidance before we begin work on the final version of the guidance, submit either electronic or written comments on the draft guidance within 60 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to http://www.regulations.gov. Submit written comments to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number FDA-2022-D-0278 listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this draft document contact the Center for Food Safety and Applied Nutrition (CFSAN) at 240-402-1700.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Food Safety and Applied Nutrition

January 2023

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Action Levels for Lead in Food Intended for Babies and Young Children: Draft Guidance for Industry[1]

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration's (FDA or we) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff responsible for this guidance at the phone number listed on the title page.

I. Introduction

FDA is committed to reducing lead in food. FDA's *Closer to Zero* action plan is a science-based, iterative approach to decreasing toxic elements, including lead, in foods over time, including by setting action levels. The purpose of this guidance is to provide information to industry on the action levels for lead in food intended for babies and young children. FDA considers the action levels described in this guidance to be achievable by industry when control measures are taken to minimize the presence of lead. Although action levels are levels at which FDA may regard a food as adulterated, our *Closer to Zero* action plan outlines other actions we will take to further reduce lead (as well as other toxic elements) in food and our expectation is that industry will strive for continual reductions over time.

Additionally, this document will present the background and rationale for FDA's action levels for lead in processed food intended for babies and young children:[2]

- 10 parts per billion (ppb) for fruits, vegetables (excluding single-ingredient root vegetables), mixtures (including grain and meat-based mixtures), yogurts, custards/puddings, and single-ingredient meats;
- 20 ppb for root vegetables (single ingredient); and
- 20 ppb for dry infant cereals.

[1] This guidance has been prepared by the Office of Food Safety, Division of Plant Products and Beverages in the Center for Food Safety and Applied Nutrition at the U.S. Food and Drug Administration.

[2] Processed food intended for babies and young children refers to food packaged in jars, pouches, tubs, and boxes represented or purported to be specifically for babies and young children less than two years old. It may include ready-to-eat foods (e.g., purees) as well as semi-prepared foods (i.e., dry infant cereals). It does not include raw agricultural commodities or homemade foods (e.g., fruit purees prepared at home). This guidance does not apply to infant formula, or any beverages, including toddler drinks. Lead in juices are addressed in a separate draft guidance, available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/draft-guidance-industry-action-levels-lead-juice.

Consistent with 21 CFR 109.6(d), these action levels reflect levels of lead at which FDA may regard the food as adulterated within the meaning of section 402(a)(1) of the Federal Food, Drug, and Cosmetic Act (FD&C Act). We intend to consider these action levels, in addition to other factors, such as our confidence in a measured analytical value, when considering whether to bring enforcement action in a particular case.

In general, FDA's guidance documents do not establish legally enforceable responsibilities. Instead, guidances describe FDA's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in FDA guidances means that something is suggested or recommended, but not required.

II. Background

Lead is toxic to humans and can affect people of any age or health status. Lead is especially harmful to vulnerable populations, including infants, young children, people who are pregnant and their fetuses, and others with chronic health conditions. Even low lead exposure can harm children's health and development, specifically the brain and nervous system. Neurological effects of lead exposure during early childhood include learning disabilities, behavior difficulties, and lowered IQ. Lead exposures also may be associated with immunological, cardiovascular, renal, and reproductive and/or developmental effects (Ref. 1). Because lead can accumulate in the body, even low-level chronic exposure can be hazardous over time (Ref. 2).

Lead is widely present in the environment due to both its natural occurrence and to human activities that have introduced it into the environment. Because lead may be present in environments where food crops used to make food intended for babies and young children are grown, various foods may contain small amounts of lead. Potential sources of lead in food include contaminated soil where crops are grown, contaminated water, atmospheric deposition from industrial activities, and old lead-containing equipment used to process food. As a result of the first three sources, agricultural crops (e.g., root vegetables) can take up lead from contaminated soil and contaminated soil may be deposited on plant surfaces (e.g., leafy vegetables and cereal grains). Studies suggest that manufacturers may be able to reduce lead levels in food by using practices such as thoroughly peeling root vegetables and thoroughly washing fruits and vegetables, particularly leafy vegetables (Refs. 3, 4, 5, 6). It is possible in some cases for manufacturers who have found elevated lead levels in sources of food intended for babies and young children to choose sources of food or food ingredients with lower lead levels or no detectable lead. Manufacturers could also consider increased testing of ingredients or finished products that are historically known to contain elevated lead levels; this is particularly important for ingredients or finished products intended for babies and young children. Additionally, manufacturers could consider examining their facilities, processes, and equipment to ensure that they are not contributing to lead in their products (Refs. 7, 8).

In 1999, the Joint World Health Organization (WHO)/Food and Agriculture Organization (FAO) Expert Committee on Food Additives (JECFA) released a toxicological assessment for lead,

which maintained the provisional tolerable weekly intake (PTWI) for lead of 25 micrograms per kilogram body weight (µg/kg bw) but noted that foods with high levels of lead remain in commerce (Ref. 9).

In 2011, JECFA reassessed the safety of lead and withdrew the PTWI for lead. JECFA further concluded that "it was not possible to establish a new PTWI [for lead] that would be considered to be health protective" (Ref. 7). JECFA concluded that in populations with prolonged dietary exposures to higher levels of lead, measures should be taken to identify major contributing sources and, if appropriate, to identify methods for reducing dietary exposure that are commensurate with the level of risk reduction (Ref. 9).

No safe level of lead exposure has been identified for protecting children's health. To help assess risk from lead, in 2018, FDA developed interim reference levels (IRLs) for dietary lead to replace FDA provisional tolerable total daily intakes (PTTDIs), which had been developed in the early 1990s. FDA updated the IRLs in 2022 (Ref. 2), using the Centers for Disease Control and Prevention's (CDC) updated blood level reference value (BLRV) of 3.5 µg/deciliter (dL) blood lead level and dietary conversion factors calculated by the Environmental Protection Agency to derive IRLs of 2.2 µg/day for children and 8.8 µg/day for women of child-bearing age (WOCBA), respectively. The IRL for WOCBA is protective against possible fetal lead exposure in women who are not yet aware that they are pregnant (Ref. 2).

The IRL is tied to a biological marker of exposure (blood lead levels) and represents the dietary lead needed to achieve a blood lead level 10 times lower than that associated with the CDC's BLRV. The CDC BLRV is a screening tool used to identify children who have higher levels of lead exposure and represents the level at which public health interventions should be initiated. The IRL represents the maximum daily dietary intake of lead from food that corresponds to the CDC's BLRV of 3.5 ug/dl, with an additional 10x safety factor applied. Even though no safe level of lead exposure has yet been identified for children's health, the IRL serves as a useful benchmark in evaluating the potential for adverse effects of dietary lead. In particular, FDA is focused on the potential for neurodevelopmental effects from lead exposure, as review of the scientific literature indicates that such adverse effects of lead consistently occur at a blood lead level associated with FDA's IRL for children.

In 2021, FDA initiated the *Closer to Zero* action plan that identifies actions we will take to reduce exposure to toxic elements, including lead, from foods eaten by babies and young children to as low as possible (Ref. 10). The plan outlines an iterative approach for achieving continual improvements over time, reducing children's exposure to lead and other toxic elements from food through activities such as setting action levels. We will identify IRLs for certain toxic elements as appropriate and may use the IRLs to help inform the development of action levels. The plan commits to consulting with stakeholders, including on the achievability of reducing toxic element levels in foods intended for babies and young children, and notes the importance of minimizing the potential for unintended consequences on the availability of nutritious foods for children. FDA intends to update the IRL and this guidance if, for example, CDC updates its BLRV or if other scientific information becomes available which could help us refine our IRL. Updates to the IRL will result in an evaluation of the lead action levels to determine whether the levels continue to be appropriate.

As the next step toward developing action levels under the *Closer to Zero* action plan, this guidance evaluates processed foods intended for babies and young children. In developing the action levels for these foods, we want to ensure that dietary exposure from the identified foods does not cause consumers to exceed the IRL. To do this, we consider intake of the food and the maximum level of lead that could be in the food without causing the IRL to be exceeded. We consider intake at the 90th percentile consumption level for the food/food category. By doing this, we account for consumers with high intake in our analysis of what the maximum lead level could be in the food without causing the consumer to be exposed to lead levels exceeding the IRL. Our proposed action levels also reflect the considerations discussed below.

III. Lead Levels Found in Food Intended for Babies and Young Children

A. Products and Data Included in the Evaluation of Lead in Food Intended for Babies and Young Children

FDA routinely monitors lead in food consumed by babies and young children through our Toxic Elements in Food and Foodware and Radionuclides in Food – Import and Domestic Compliance Program (the Toxic Elements Program or TEP),[3] special FDA surveys, and the Total Diet Study (TDS).[4] The TEP is a targeted monitoring program that monitors levels of certain toxic elements, including lead, in foods and foodware. Foods selected for analysis include those that are suspected of having elevated levels of toxic elements based on historical data or other information available to us. For lead analysis under the TEP, we place particular emphasis on foods consumed by babies and young children, who are especially sensitive to lead's adverse health effects because of their smaller body sizes and rapid development. We augment TEP collections by periodically conducting surveys to collect and analyze toxic elements in foods of interest, in this case, foods for babies and young children. The TDS is an ongoing market basket study representative of the U.S. diet that includes analysis of toxic elements such as lead.

As part of our evaluation, we examined the TEP data collected between fiscal years (FY) 2008 through 2021, FDA survey data collected in FY 2013-14 and FY 2021 (Tables 1 and 2), and TDS data collected between FY 2014-20 (Table 3) to determine current lead levels in foods intended for babies and young children. We then evaluated the ability of industry to achieve lower lead levels, using TEP data and FDA survey data. We also reviewed the TDS data as a complementary analysis.

B. Toxic Elements Program and FDA Survey Data

The 863 TEP (Ref. 11) and survey samples (Refs. 12, 13) include U.S. domestic and imported products, and consist of processed foods made specifically for babies and young children. To analyze these data for purposes of this guidance, we have separated these processed foods into

[3] https://www.fda.gov/Food/FoodborneIllnessContaminants/ChemicalContaminants/ucm2006907.htm.
[4] http://www.fda.gov/Food/FoodScienceResearch/TotalDietStudy/default.htm.

the following food categories for babies and young children: dry infant cereals (e.g., rice, wheat, and multi-grain cereals); fruits (single-ingredient or combination); vegetables (single ingredient or combination); mixtures (any combination of fruits, vegetables, grain, and meat); yogurts, custards/puddings, and single-ingredient meats (Table 1).

Table 2 shows the mean, standard deviation, and 90th and 95th percentiles of the data for each of the food categories for babies and young children. Lead concentrations varied among food categories for babies and young children. Fruits and mixtures had low lead levels, with means of 1.0 ppb and 3.0 ppb and 90th-95th percentiles of 2.4-3.7 ppb and 6.8-11.1 ppb, respectively. Yogurts, custards/puddings, and single-ingredient meats similarly had low lead levels, with a mean of 0.9 ppb and 90th-95th percentiles of 1.7-2.3 ppb. Vegetables had a mean lead level of 5.6 ppb and 90th-95th percentiles of 16.0-20.5 ppb. When single-ingredient root vegetables were placed in a separate category, the vegetables category had a lower mean and lower 90th-95th percentiles of 2.3 ppb and 6.6-10.2 ppb, respectively. Root vegetables had a mean of 8.5 ppb and 90th-95th percentiles of 20.2-25.7 ppb (Table 2, italics).

Dry infant cereals had higher lead concentrations than fruits, vegetables, mixtures, yogurts, custards/puddings, and single-ingredient meats, with a mean of 8.3 and 90th-95th percentiles of 20.1-23.0 ppb.

C. Total Diet Study Data

From FY 2014 to FY 2020, we collected and analyzed 686 samples of processed foods intended for babies and young children under the TDS program.[5] Most TDS samples are not samples of individual foods; they are composites ("averages") of three retail samples, all from different cities. Because the compositing provides an "average" result, and our achievability analysis is based on percentiles of lead concentrations in individual samples, we did not use the TDS data in the achievability analysis. The types of baby foods analyzed included dry infant cereals, fruits (single ingredient or combination), vegetables (single ingredient or combination), mixtures (any combination of fruits, vegetables, grains, and meat), and yogurts, custard/pudding, and single-ingredient meats.[6] All food categories had mean lead concentrations well below 10 ppb, with the exception of root vegetables, which had a mean concentration of 11.6 ppb. As with the TEP and FDA survey data, lower mean lead levels were observed for fruits, mixtures, yogurts, custards/puddings, and single-ingredient meats. However, dry infant cereal samples in the TDS had lower mean lead levels than samples from the TEP and FDA survey data.

[5] TDS results can be found online at: https://www.fda.gov/food/total-diet-study/analytical-results-total-diet-study.
[6] Infant formula and bottled water labeled for infants are also collected through the TDS program, but were not included in this analysis because they are composite samples (see section III.C). TDS infant formula data indicate that the majority of samples collected contain no lead (<limit of detection, which is 4.0 ppb). Grain-based snacks (e.g., arrowroot cookies, puffs, rusks, teething biscuits) also were analyzed; however, they are not addressed in this guidance. FDA is seeking additional information on this category of foods to inform whether an action level would be appropriate.

D. Summary of FDA Data

FDA's review of data indicates that different types of food intended for babies and young children exhibit different lead concentrations (Tables 2 and 3). In addition, for the TEP and survey data, 85 percent of samples had lead levels lower than 10 ppb, while for the TDS data 97 percent of samples had lead levels lower than 10 ppb. The mean lead levels for the categories of food intended for babies and young children were below 10 ppb (Tables 2 and 3) except for root vegetables (Table 3).

IV. FDA's Action Levels for Lead in Food Intended for Babies and Young Children

When evaluating possible action levels under 21 CFR 109.6 for lead in foods intended for babies and young children less than two years old, we took into account several considerations, including:

- the action level should minimize the likelihood that a consumer will be exposed to lead levels exceeding the IRL;
- as appropriate, there should be a limited number of unique action levels for simplicity;
- the action levels should result in a reduction in exposure to lead; and
- for those baby foods where lead levels are already relatively low, the action levels should be established where achievability is in the 90th-95th percentile range.[7]

Based on these considerations, the applicable criteria in 21 CFR 109.6, and analysis of the data, we identified the following action levels for lead in processed food intended for babies and young children:

- 10 ppb for fruits, vegetables (excluding single-ingredient root vegetables), mixtures, yogurts, custards/puddings, and single-ingredient meats;
- 20 ppb for root vegetables (single ingredient); and
- 20 ppb for dry infant cereals.

For fruits, vegetables (excluding single-ingredient root vegetables), mixtures, yogurts, custards/puddings, and single-ingredient meats, all of which have low lead levels, action levels can be established at 10 ppb.

Based on data used in this analysis, single-ingredient root vegetable products have higher lead levels than other vegetables (Table 2, italics). Root vegetables can absorb lead more readily

[7] This approach is consistent with the approach followed for setting international standards and the approach FDA has taken with respect to action levels for lead in other foods, as appropriate. The Codex Committee on Contaminants in Foods has used an achievability estimate of about 95% to recommend reductions in maximum levels (MLs) for lead in juices when more than 95% of the samples traded internationally had lead concentrations at or below proposed new MLs. FDA has used a similar approach in developing action levels for lead in juice, see https://www.fda.gov/food/chemical-metals-natural-toxins-pesticides-guidance-documents-regulations/draft-supporting-document-establishing-fdas-action-levels-lead-juice.

from the soil than other crops (Ref. 14). Moreover, at an action level of 10 ppb (the action level provided in this guidance for other vegetable products), root vegetable achievability was only 71%. For root vegetables, we expect that an action level of 20 ppb will help minimize the likelihood of significant exposure to lead, while also considering achievability. At the action level of 20 ppb, root vegetables have an achievability rate of 88%. Root vegetables are a source of several nutrients important in growth and development for babies and young children, and a lower action level could reduce the availability of single-ingredient root vegetable foods on the market intended for infants and young children. Therefore, we consider it appropriate to place single-ingredient root vegetables in their own category.

In evaluating data about the likelihood that a consumer will be exposed to lead levels exceeding the IRL, we also weighed certain product-specific considerations. For example, dry infant cereal is often the first food introduced to an infant population and may be the only solid food consumed for an extended period of time during a critical period of development. With these considerations in mind, we set an action level for dry infant cereal that is sufficiently health protective. At the action level of 20 ppb, dry infant cereals have an achievability rate of 90%.

We discuss the exposure assessment and achievability assessments used to support these action levels in more detail below.

A. Exposure Assessment

To examine the effect of the proposed action levels for food intended for babies and young children on lead exposure, we compared the estimated concentration of lead in these foods and dietary exposure to lead from these foods with and without the action levels. As shown in Table 4, the mean concentrations of lead and the 90th percentile (representing an upper bound) dietary exposures for babies and young children (0-23 months) in the absence of the action levels are as follows:

- fruits, vegetables (excluding single-ingredient root vegetables), mixtures, yogurts, custards/puddings, and single-ingredient meats (2.3 ppb, 0.81 µg/day);
- root vegetables (8.5 ppb, 0.89 µg/day); and
- dry infant cereals (8.3 ppb, 0.32 µg/day).

This upper bound percentile (90th percentile) was chosen as a health protective measure to account for babies and young children (0-23 months) who consume larger amounts of food and would therefore have higher exposures. As shown in Table 4, for Scenario A, the 90th percentile dietary exposures for babies and young children are below the IRL for lead of 2.2 µg/day for children. For scenario B, removing all samples with lead concentrations greater than the action level from the datasets results in a decrease in the estimated mean lead concentrations and the estimated dietary exposures from these foods. The estimated mean lead concentrations and 90th percentile dietary exposures are as follows:

- fruits, vegetables (excluding single-ingredient root vegetables), mixtures, yogurts, custards/puddings, and single-ingredient meats (1.7 ppb, 0.60 µg/day);
- root vegetables (6.2 ppb, 0.65 µg/day); and
- dry infant cereals (6.3 ppb, 0.25 µg/day).

The action levels for lead are estimated to result in the following reductions in lead exposure from consumption of these foods at the 90th percentile consumption level for babies and young children:

- fruits, vegetables (excluding single-ingredient root vegetables), mixtures, yogurts, custards/puddings, and single-ingredient meats (26%);
- root vegetables (27%); and
- dry infant cereals (24%).

B. Achievability Assessment

To assess achievability, or manufacturers' ability to achieve the action levels for lead, we determined the percentage of samples in each food category that fell at or below the proposed action levels. The achievability for each food category at the proposed action levels is in the 90 - 95% range identified in Section IV, with the exception of root vegetables, as shown below:

- 96% for fruits, vegetables (excluding single-ingredient root vegetables), mixtures, yogurts, custards/puddings, and single-ingredient meats, at 10 ppb;
- 88% for root vegetables, at 20 ppb; and
- 90% for dry infant cereals, at 20 ppb (Table 4).

In summary, for the combined category of fruits, vegetables (excluding single-ingredient root vegetables), mixtures, yogurts, custards/puddings, and single-ingredient meats, an action level of 10 ppb reduces dietary exposure to lead for babies and young children by 26% at the 90th percentile consumption level and has an achievability of 96%.

An action level of 20 ppb for single-ingredient root vegetables reduces dietary exposure to lead for babies and young children by 27% at the 90th percentile consumption level and has an achievability of 88%.

An action level of 20 ppb for dry infant cereals reduces dietary exposure to lead for babies and young children by 24% at the 90th percentile consumption level and has an achievability of 90%.

Based on our review of lead levels in foods intended for babies and young children that we collected from FY 2008 to FY 2021, in consideration of the IRL for lead of 2.2 µg/day for children (as shown in Table 4), and in accordance with 21 CFR 109.6, we are establishing the following action levels for lead:

- 10 ppb for fruits, vegetables (excluding single-ingredient root vegetables), mixtures, yogurts, custards/puddings, and single-ingredient meats;
- 20 ppb for root vegetables (single ingredient); and
- 20 ppb for dry infant cereals.

Though not binding, these action levels are intended to encourage manufacturers to maintain lead levels in food intended for babies and young children below the action levels, thus reducing risks associated with dietary lead exposures. The establishment of these action levels for lead in food intended for babies and young children in this guidance is consistent with FDA's longstanding policy of reducing consumers' lead exposure. The action is focused on certain foods intended for babies and young children, who are more sensitive than adults to the neurodevelopmental effects of lead exposure.

Consistent with 21 CFR 109.6(d), these action levels reflect levels of lead at which FDA may regard the food as adulterated within the meaning of section 402(a)(1) of the FD&C Act. We intend to consider these action levels, in addition to other factors, such as our confidence in a measured analytical value, when considering whether to bring enforcement action in a particular case.

We have consulted with the United States Department of Agriculture Food Safety Inspection Service (FSIS) on the inclusion of single-ingredient meats and mixtures that include meats as an ingredient in this guidance. FSIS supports the action levels developed by FDA and intends to consider these action levels, in addition to other factors, when considering appropriate FSIS actions in a particular case.

FDA recommends that the industry producing the foods in this guidance continue to work to lower the lead concentrations in these products to the greatest extent possible under current good manufacturing practices. As part of our *Closer to Zero* action plan, we intend to further engage with stakeholders on proposed action levels for other toxic elements in foods intended for babies and young children, including the achievability of such levels, and the feasibility of further reducing the presence of lead in food. We plan to monitor the levels of lead in food and children's exposure to lead from food to assess whether to adjust the action levels for the food intended for babies and children described in this guidance, or whether to add additional foods or food categories for babies and young children to this guidance as new information becomes available.

V. Conclusion

The action levels are part of our efforts under the *Closer to Zero* action plan to reduce exposure to toxic elements from foods eaten by babies and young children to the lowest possible levels. In our experience, action levels have been effective tools for encouraging manufacturers to lower the levels of contaminants in their products. We established these action levels in consideration of our IRLs for dietary lead, and the action levels are achievable by industry when control measures are taken to minimize the presence of lead.

We intend to consider the proposed action levels as an important source of information for determining whether a food for babies and young children is adulterated within the meaning of section 402(a)(1) of the FD&C Act. FDA considers on a case-by-case basis whether a food that contains a contaminant is adulterated. When considering whether to bring an enforcement action in a particular case, we will consider whether the lead causes a particular food to be adulterated under section 402(a)(1) of the FD&C Act.

VI. References

The following references marked with an asterisk (*) are on display at the Dockets Management Staff, Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. You may see them in person at this location between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at https://www.regulations.gov. References without asterisks are not on public display at https://www.regulations.gov because they have copyright restriction. Some may be available at the website address, if listed. References without asterisks are available for viewing only at the Dockets Management Staff. FDA has verified the website addresses, as of the date this document publishes in the *Federal Register*, but websites are subject to change over time.

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VII. Tables

Table 1. Summary of Data Used in Analysis of Lead in Foods for Babies and Young Children

Data Set	Fiscal Year	Number of Samples	Food Categories for Babies and Young Children
Toxic Element Program (TEP)	2008-2021[8]	356	dry infant cereals, fruits, mixtures, vegetables
FDA Survey 1	2013-14[9]	147	dry infant cereals, mixtures
FDA Survey 2	2021[10]	360	fruits, mixtures, vegetables, yogurts, custards/puddings, single-ingredient meats

Table 2. Analysis of Lead Data from the Toxic Element Program and FDA Surveys by Food Category

Food Category for Babies and Young Children	Number of Samples	Mean ± std. dev (ppb)	90th Percentile (ppb)	95th Percentile (ppb)
Fruits (single ingredient or combination)	110	1.0 ± 1.2	2.4	3.7
Mixtures	266	3.0 ± 5.0	6.8	11.1
Yogurts, custards/puddings, single-ingredient meats	33	0.9 ± 0.7	1.7	2.3
Vegetables (single ingredient or combination)	98	5.6 ± 7.3	16.0	20.5
Vegetables (single ingredient or combination excluding single-ingredient root vegetable products)	*47*	*2.3 ± 3.6*	*6.6*	*10.2*
Root vegetables	*51*	*8.5 ± 8.4*	*20.2*	*25.7*
Dry infant cereals	356	8.3 ± 8.8	20.1	23.0

[8] Available at https://www.fda.gov/media/164564/download.
[9] These FDA survey data are available at: https://www.fda.gov/food/metals-and-your-food/combination-metals-testing.
[10] Available at https://www.fda.gov/media/164565/download.

Table 3. Analysis of Lead Data from the Total Diet Study (FY2014-2020)[11] by Food Category for Babies and Young Children

Food Category for Babies and Young Children	Number of Samples	Mean ± std. dev (ppb)
Fruits (single type or combination)	231	0.17 ± 0.91
Mixtures	210	2.5 ± 3.9
Yogurts, custards/puddings, single-ingredient meats	83	0.49 ± 3.4
Vegetables (single type or combination)	139	4.9 ± 7.0
Vegetables (single type or combination excluding single-ingredient root vegetables products)	89	1.1 ± 2.3
Root vegetables	50	11.6 ± 7.6
Dry infant cereals	23	2.6 ± 2.9

[11] In 2018, the TDS sampling protocol was changed. See http://www.fda.gov/Food/FoodScienceResearch/TotalDietStudy/default.htm. In 2019, 241 samples of baby food were collected as part of a special TDS sampling assignment.

Table 4. Summary Data for Food Categories for Babies and Young Children: Action Levels, Achievability, and Mean Lead Concentrations/90th Percentile Lead Exposures from Food Consumption for Babies and Young Children (0-23 months) With and Without Action Levels

Food Category for Babies and Young Children	Action Level	Achiev - ability	90th Percentile 2-day Average Intake, Eaters Only, 0-23 mo[12]	Scenario A: No Action Level Estimated Mean Pb Concen- tration	Scenario A: No Action Level Estimated Pb Exposure from Baby Food at the 90th Percentile[13]	Scenario B: With Action Level Estimated Mean Pb Concentration[14]	Scenario B: With Action Level Estimated Pb Exposure from Baby Food at the 90th Percentile[13]	Reduction in Exposure at the 90th Percentile[15]
	ppb	%	g/day	ppb	µg/day	ppb	µg/day	%
Fruits, vegetables (excluding single-ingredient root vegetable products), mixtures, yogurts, custards/ puddings, single- ingredient meat	10	96	353	2.3	0.81	1.7	0.60	26
Root Vegetables	20	88	105	8.5	0.89	6.2	0.65	27
Dry infant cereals	20	90	39	8.3	0.32	6.3	0.25	24

[12] Concentration in sample (ug/kg) * 1 kg/1000 g conversion factor*upper-level consumption (g/day) = estimated total exposure (µg/day).

[13] Exposure estimates were calculated based on lead concentration data from the TEP and FDA survey data, and on baby food consumption data from What We Eat in America (WWEIA), the food consumption portion of the National Health and Nutrition Examination Survey (NHANES), 2003-2018. Estimates are for eaters only, 0-23 months. The 90th percentile lead exposures (representing an upper bound) from baby foods for NHANES/WWEIA respondents were calculated as products of the 90th percentile of the 2-day average consumption of each food category for babies and young children and the mean lead concentration in that food category. The term "eaters only" for the purposes of this data set means individuals from the survey that consumed this product to calculate intake. The 90th percentile dietary exposures for babies and young children are below the IRL for lead of 2.2 µg/day for children.

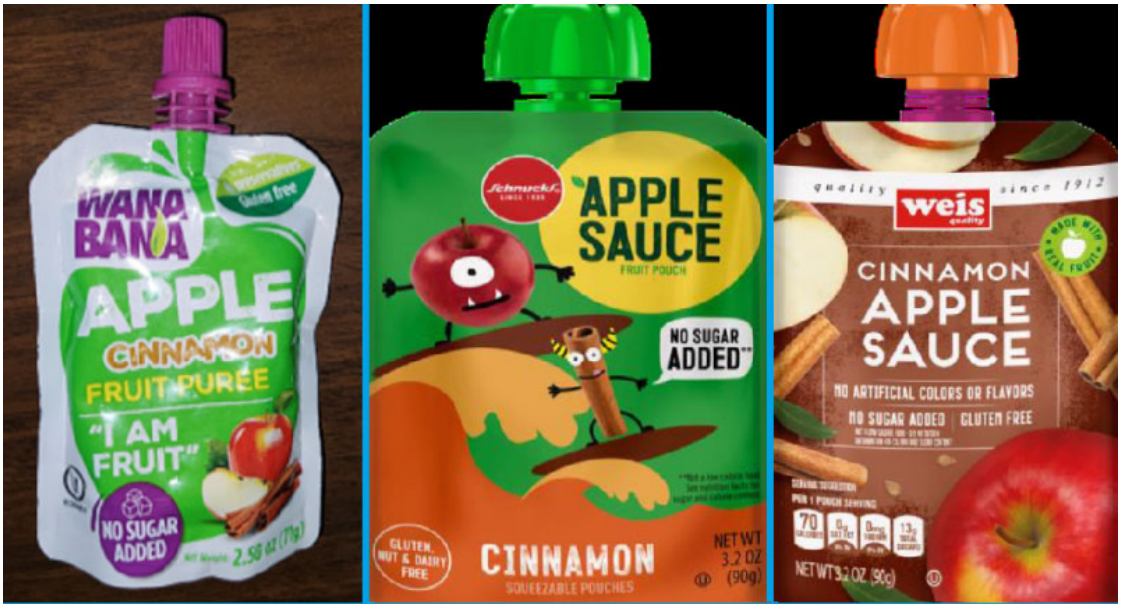
[14] Mean lead concentrations in Scenario B were calculated after removal of the TEP and FDA survey data for samples with concentrations above the action level.

[15] Calculated as ((lead exposure under Scenario A- lead exposure under Scenario B)/ lead exposure under Scenario A)*100. Calculations are based on unrounded data.

ATTACHMENT B

Investigation of Elevated Lead & Chromium Levels: Cinnamon Applesauce Pouches (November 2023)

Do not eat, sell, or serve multiple brands of recalled apple cinnamon fruit pouches. FDA's investigation is ongoing.



en español (Spanish) (/food/outbreaks-foodborne-illness/investigacion-sobre-los-niveles-elevados-de-plomo-y-cromo-en-las-bolsas-de-pure-de-manzana-y-canela)

Product

Recalled cinnamon apple puree and applesauce products. Information on lot codes and UPCs can be found in the firm's recall announcement (/safety/recalls-market-withdrawals-safety-alerts/wanabana-recalls-wanabana-weis-and-schnucks-apple-cinnamon-fruit-puree-pouches-cinnamon-apple-sauce).

- Recalled WanaBana apple cinnamon fruit puree pouches – including three packs
- Recalled Schnucks-brand cinnamon-flavored applesauce pouches and variety pack
- Recalled Weis-brand cinnamon applesauce pouches

At this time, the FDA does not have any evidence that this issue extends beyond the recalled products.

Symptoms of Lead Toxicity

Lead is toxic to humans and can affect people of any age or health status. Protecting children from exposure to lead is particularly important because they are more susceptible to lead toxicity. Most children have no obvious immediate symptoms. Parents and caretakers should consult a healthcare provider if you suspect a child may have been exposed to lead. Short term exposure to lead could result in the following symptoms: headache; abdominal pain/colic; vomiting; anemia. Longer term exposure could result in the following additional symptoms: irritability; lethargy; fatigue; muscle aches or muscle prickling/burning; constipation; difficulty concentrating/muscular weakness; tremor; weight loss.

Stores Affected

- WanaBana apple cinnamon fruit puree pouches are sold nationally and have been available through multiple retailers, including Amazon, Dollar Tree, Family Dollar/Dollar Tree combination stores, and other online outlets.
- Schnucks-brand cinnamon-flavored applesauce pouches and variety pack are sold at Schnucks and Eatwell Markets grocery stores.
- Weis-brand cinnamon applesauce pouches are sold at Weis grocery stores.

Status

Ongoing; updates to this advisory will be provided as they become available.

Recommendation

- Consumers should not eat, sell, or serve recalled WanaBana (/safety/recalls-market-withdrawals-safety-alerts/wanabana-recalls-wanabana-weis-and-schnucks-apple-cinnamon-fruit-puree-pouches-cinnamon-apple-sauce), Schnucks, or Weis-brand apple cinnamon pouches and should discard them.
- These products have a long shelf life. Consumers should check their homes and discard these products.
- To properly discard the product, consumers and retailers should carefully open the pouch and empty the content into a trash can before discarding the packaging to prevent others from salvaging recalled product from the trash. Clean up any spills after discarding the product then wash your hands.
- Contact your healthcare provider if you think you or your child may have symptoms of lead toxicity after eating recalled fruit pouches.
- Most children have no obvious immediate symptoms of lead exposure. If there's suspicion that a child may have been exposed to lead, **parents should talk to their child's healthcare provider about getting a blood test**.
- **For clinicians**, please refer to the Centers for Disease Control and Prevention's (CDC) Health Alert Network (https://emergency.cdc.gov/han/2023/han00500.asp) (HAN) and CDC's Clinician Outreach and Communication Activity (COCA Now) announcements (https://emergency.cdc.gov/newsletters/coca/2024/010524.html) for guidance on how to best care for patients who were potentially exposed to lead or chromium by consuming recalled products.
- If you or your child have symptoms or exposure to this product, you can also file a complaint or adverse event report (illness or serious allergic reaction).

Current Update

February 13, 2024

As of February 13, 2024, FDA has not received any additional confirmed complaints/reports of adverse events potentially linked to recalled product. To date, confirmed complainants, or people for whom a complaint or adverse event was submitted and met FDA's complainant definition, are between zero and 53 years of age and the median age is one year old.

CDC's National Center for Environmental Health is conducting case finding efforts in collaboration with state and local health departments. CDC's case definition for state partners includes a blood lead level of 3.5 µg/dL or higher measured within 3 months after consuming a recalled WanaBana, Schnucks, or Weis brand fruit puree product after November 2022. As of February 9, CDC has received reports of 101 confirmed cases, 284 probable cases, and 37 suspected cases for a total of 422 cases from 44 different states through their reporting structure. For more information, please visit CDC's page to review their case reporting methodology and findings.

CDC and FDA have different data sources, so the counts reported by each agency will not directly correspond. In addition, some people who were affected by the contaminated product might be reflected in both the numbers reported by the FDA and the numbers reported by CDC, so the numbers should not be added together.

FDA's investigation is ongoing to determine the point of contamination and whether additional products are linked to illnesses. FDA has no indication that this issue extends beyond these recalled products and does not have any confirmed reports of illnesses or elevated blood lead level adverse events reported for other cinnamon-containing products or cinnamon.

Previous updates not captured by the initial timeline below are in the Previous Updates section. FDA will update the advisory as information becomes available.

FDA Complaint/Adverse Event Report Overview

Total Complaint/Adverse Event Report: 90*
Report Date Ranges: October 17, 2023 – January 16, 2024
States with Complaint/Report: AL (1), AR (1), AZ (1), CA (1), CT (1),

Useful Links

- FDA Safety Alert (/food/alerts-advisories-safety-information/fda-advises-parents-and-caregivers-not-buy-or-feed-wanabana-apple-cinnamon-fruit-puree-pouches)

FL (1), GA (2), IA (1), IL (5), IN (1), KY (3), LA (4), MA (3), MD (7), MI (8), MO (3), NC (6), NE (2), NH (1), NJ (1), NM (1), NY (8), OH (3), OK (1), PA (2), SC (2), TN (3), TX (3), VA (2), WA (4), WI (2), WV (3), Unknown (3)
Product Distribution: Nationwide

**Estimate based on Consumer Complaint and CFSAN Adverse Event Reporting System (CAERS) reports received by the FDA.*

- CDC HAN Advisory - Lead (https://emergency.cdc.gov/han/2023/han00500.asp)
- CDC COCA Now Advisory - Chromium (https://emergency.cdc.gov/newsletters/coca/2024/010524.html)
- CDC Case Reports (https://www.cdc.gov/nceh/lead/news/lead-poisoning-outbreak-linked-to-cinnamon-applesauce-pouches.html)
- NCDHHS Health Alert (https://www.ncdhhs.gov/news/press-releases/2023/10/28/ncdhhs-urges-caution-after-reportable-lead-found-wanabana-brand-apple-cinnamon-puree)
- WanaBana Recall Announcement (/safety/recalls-market-withdrawals-safety-alerts/wanabana-issues-voluntary-recall-wanabana-apple-cinnamon-fruit-puree-pouches-due-elevated-lead)
- Expanded WanaBana Recall Announcement (/safety/recalls-market-withdrawals-safety-alerts/wanabana-recalls-wanabana-weis-and-schnucks-apple-cinnamon-fruit-puree-pouches-cinnamon-apple-sauce)
- FDA's Draft Guidance for Industry on Hazard Analysis and Risk-Based Preventive Controls for Human Food (/regulatory-information/search-fda-guidance-documents/draft-guidance-industry-hazard-analysis-and-risk-based-preventive-controls-human-food)
- Health Effects of Lead Exposure (https://www.cdc.gov/nceh/lead/prevention/health-effects.htm)
- Who to Contact

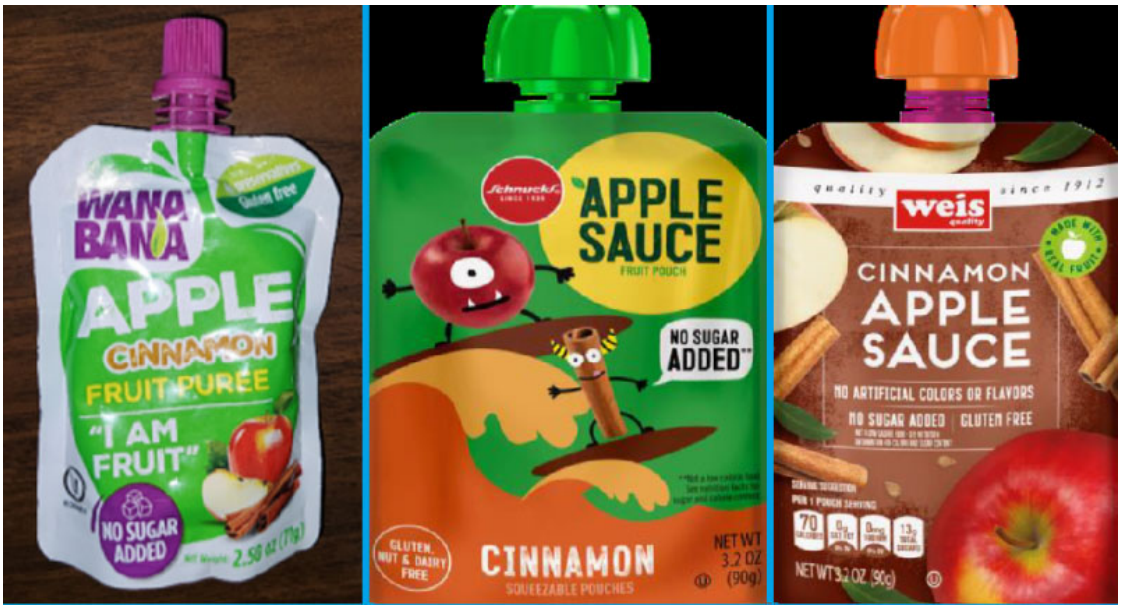
Initial Investigation Timeline

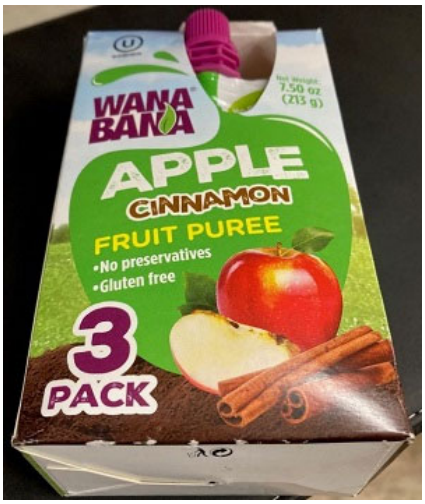
- On October 28, 2023, the FDA discussed the analytical findings with WanaBana LLC and issued a safety alert (https://www.fda.gov/food/alerts-advisories-safety-information/fda-advises-parents-and-caregivers-not-buy-or-feed-wanabana-apple-cinnamon-fruit-puree-pouches) warning consumers not to use WanaBana Apple Cinnamon Fruit Puree products. The same day, Wanabana LLC agreed to voluntarily recall the WanaBana Apple Cinnamon Fruit Puree products.
- On October 29, 2023, Wanabana LLC notified their customers about recall of the WanaBana Apple Cinnamon Fruit Puree products.
- On October 30, 2023, and through continued cooperation with the FDA, Wanabana LLC issued a press release regarding their voluntary recall (https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/wanabana-issues-voluntary-recall-wanabana-apple-cinnamon-fruit-puree-pouches-due-elevated-lead) of all WanaBana Apple Cinnamon Fruit Puree Pouches.
- On November 2, 2023, after reviewing records provided by the firm as part of their initial recall, the FDA learned that other products (i.e., certain Schnucks and Weis cinnamon applesauce pouches) were implicated in the recall and required additional public notice.
- On November 3, 2023, the FDA updated its safety alert to, among other things, include certain Schnucks and Weis cinnamon applesauce pouches.
- On November 5, 2023, the FDA held a call with the firm, Wanabana LLC. During the call, FDA staff discussed the investigation, requested additional information from the firm, and asked the firm to update their press release regarding their voluntary recall and to provide additional clarification regarding the scope of the recall of all apple cinnamon fruit puree products, which the firm verbally agreed to provide.
- On November 6, 2023, Apple Cinnamon Fruit Puree products from Austrofoods were added to Import Alert 99-42 (https://www.accessdata.fda.gov/cms_ia/importalert_1167.html).
- On November 9, 2023, Wanabana LLC issued their expanded recall announcement (https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/wanabana-recalls-wanabana-weis-and-schnucks-apple-cinnamon-fruit-puree-pouches-cinnamon-apple-

sauce) to include information on recalled Schnucks and Weis cinnamon applesauce pouches, which also impacts markets outside of the United States. Customer information provided by Wanabana LLC shows that product was also distributed to Cuba and the United Arab Emirates.

Additional FDA actions taken in response to this incident are captured in the previous updates below.

Product Images





Recalled Product

In response to this investigation, Wanabana has voluntarily recalled all WanaBana Apple Cinnamon Fruit Puree Pouches regardless of expiration date and lot code. Two additional brands of products are also subject to recall: certain Schnucks cinnamon-flavored applesauce pouches and variety pack and certain Weis cinnamon applesauce pouches.

International Distribution for Recalled Products

The recall impacts markets outside of the United States. Customer information provided by the firm shows that product was also distributed to Cuba and the United Arab Emirates.

About Chromium:

Chromium (https://www.atsdr.cdc.gov/toxfaqs/tfacts7.pdf) is a naturally occurring element. It is an essential trace nutrient important to the diet. Chromium exists predominantly in two forms, chromium (III) and chromium (VI). Chromium (III) is a nutritional form but can be toxic at elevated levels. Both forms of chromium are used in many industrial applications and may be a by-product of manufacturing processes. Chromium (VI), a more toxic form, may be used in these processes or produced as a by-product.

The FDA does recognize some accepted uses of various types of chromium as an ingredient in foods, including dietary supplements and for animal feed; however, chromium (VI) falls outside of these accepted types and exposure to elevated levels of this type of chromium in food is not well understood.

Previous Updates

February 6, 2024

Ecuadorian officials in Agencia Nacional de Regulación, Control y Vigilancia Sanitaria (ARCSA) have reported that Carlos Aguilera of Ecuador, the processor of the ground cinnamon supplied by Negasmart to Austrofoods and later used in recalled apple cinnamon products, is the likely source of contamination and is not in operation at this time. Additionally, according to ARCSA, the unprocessed cinnamon sticks used in recalled products were sourced from Sri Lanka and were sampled by ARCSA and found to have no lead contamination. ARCSA's investigation and legal proceedings to determine ultimate responsibility for the contamination are still ongoing.

The FDA has limited authority over foreign ingredient suppliers who do not directly ship product to the U.S. This is because their food undergoes further manufacturing/processing prior to export. Thus, the FDA cannot take direct action with Negasmart or Carlos Aguilera.

FDA has no indication that this issue extends beyond these recalled products and does not have any confirmed reports of illnesses or elevated blood lead level adverse events reported for other cinnamon-containing products or cinnamon.

As of February 5, 2024, FDA has not received any additional confirmed complaints/reports of adverse events potentially linked to recalled product. To date, confirmed complainants, or people for whom a complaint or adverse event was submitted and met FDA's complainant definition, are between zero and 53 years of age and the median age is one year old.

CDC's National Center for Environmental Health is conducting case finding efforts in collaboration with state and local health departments. CDC's case definition for state partners includes a blood lead level of 3.5 µg/dL or higher measured within 3 months after consuming a recalled WanaBana, Schnucks, or Weis brand fruit puree product after November 2022. As of February 2, CDC has received reports of 100 confirmed cases, 277 probable cases, and 36 suspected cases for a total of 413 cases from 43 different states through their reporting structure. For more information, please visit CDC's page (https://www.cdc.gov/nceh/lead/news/lead-poisoning-outbreak-linked-to-cinnamon-applesauce-pouches.html) to review their case reporting methodology and findings.

CDC and FDA have different data sources, so the counts reported by each agency will not directly correspond. In addition, some people who were affected by the contaminated product might be reflected in both the numbers reported by the FDA and the numbers reported by CDC, so the numbers should not be added together.

January 30, 2024

FDA has no indication that this issue extends beyond these recalled products and does not have any confirmed reports of illnesses or elevated blood lead level adverse events reported for other cinnamon-containing products or cinnamon.

As of January 29, 2024, FDA has not received any additional confirmed complaints/reports of adverse events potentially linked to recalled product. To date, confirmed complainants, or people for whom a complaint or adverse event was submitted and met FDA's complainant definition, are between zero and 53 years of age and the median age is one year old.

CDC's National Center for Environmental Health is conducting case finding efforts in collaboration with state and local health departments. CDC's case definition for state partners includes a blood lead level of 3.5 µg/dL or higher measured within 3 months after consuming a recalled WanaBana, Schnucks, or Weis brand fruit puree product after November 2022. As of January 26, CDC has received reports of 98 confirmed cases, 269 probable cases, and 37 suspected cases for a total of 404 cases from 43 different states through their reporting structure. For more information, please visit CDC's page (https://www.cdc.gov/nceh/lead/news/lead-poisoning-outbreak-linked-to-cinnamon-applesauce-pouches.html) to review their case reporting methodology and findings.

CDC and FDA have different data sources, so the counts reported by each agency will not directly correspond. In addition, some people who were affected by the contaminated product might be reflected in both the numbers reported by the FDA and the numbers reported by CDC, so the numbers should not be added together.

January 23, 2024

FDA has no indication that this issue extends beyond these recalled products and does not have any confirmed reports of illnesses or elevated blood lead level adverse events reported for other cinnamon-containing products or cinnamon.

As of January 22, 2024, FDA has received 90 confirmed complaints/reports of adverse events potentially linked to recalled product. To date, confirmed complainants, or people for whom a complaint or adverse event was submitted and met FDA's complainant definition, are between zero and 53 years of age and the median age is one year old.

CDC's National Center for Environmental Health is conducting case finding efforts in collaboration with state and local health departments. CDC's case definition for state partners includes a blood lead level of 3.5 µg/dL or higher measured within 3 months after consuming a recalled WanaBana, Schnucks, or Weis brand fruit puree product after November 2022. As of January 19, CDC has received reports of 97 confirmed cases, 253 probable cases, and 35 suspected cases for a total of 385 cases from 42 different states through their reporting structure. For more information, please visit CDC's page (https://www.cdc.gov/nceh/lead/news/lead-poisoning-outbreak-linked-to-cinnamon-applesauce-pouches.html) to review their case reporting methodology and findings.

CDC and FDA have different data sources, so the counts reported by each agency will not directly correspond. In addition, some people who were affected by the contaminated product might be reflected in both the numbers reported by the FDA and the numbers reported by CDC, so the numbers should not be added together.

January 16, 2024

As of January 16, 2024, FDA has received 89 confirmed complaints/reports of adverse events potentially linked to recalled product. To date, confirmed complainants, or people for whom a complaint or adverse event was submitted and met FDA's complainant definition, are between zero and 53 years of age and the median age is one year old.

CDC's National Center for Environmental Health is conducting case finding efforts in collaboration with state and local health departments. CDC's case definition for state partners includes a blood lead level of 3.5 µg/dL or higher measured within 3 months after consuming a recalled WanaBana, Schnucks, or Weis brand fruit puree product after November 2022. As of January 12, CDC has received reports of 93 confirmed cases, 233 probable cases, and 28 suspected cases for a total of 354 cases from 41 different states through their reporting structure. For more information, please visit CDC's page (https://www.cdc.gov/nceh/lead/news/lead-poisoning-outbreak-linked-to-cinnamon-applesauce-pouches.html) to review their case reporting methodology and findings.

CDC and FDA have different data sources, so the counts reported by each agency will not directly correspond. In addition, some people who were affected by the contaminated product might be reflected in both the numbers reported by the FDA and the numbers reported by CDC, so the numbers should not be added together.

January 9, 2024

As of January 8, 2024, FDA has received 87 confirmed complaints/reports of adverse events potentially linked to recalled product. To date, confirmed complainants, or people for whom a complaint or adverse event was submitted and met FDA's complainant definition, are between zero and 53 years of age and the median age is one year old.

CDC's National Center for Environmental Health is conducting case finding efforts in collaboration with state and local health departments. CDC's case definition for state partners includes a blood lead level of 3.5 µg/dL or higher measured within 3 months after consuming a recalled WanaBana, Schnucks, or Weis brand fruit puree product after November 2022. As of January 5, CDC has received reports of 86 confirmed cases, 209 probable cases, and 26 suspected cases for a total of 321 cases from 38 different states through their reporting structure. For more information, please visit CDC's page (https://www.cdc.gov/nceh/lead/news/lead-poisoning-outbreak-linked-to-cinnamon-applesauce-pouches.html) to review their case reporting methodology and findings.

CDC and FDA have different data sources, so the counts reported by each agency will not directly correspond. In addition, some people who were affected by the contaminated product might be reflected in both the numbers reported by the FDA and the numbers reported by CDC, so the numbers should not be added together.

January 5, 2024

In FDA's testing of the recalled products and the cinnamon collected from the Austrofoods facility, the agency has found chromium. People who ate recalled products, especially if they had elevated blood lead levels, may have been exposed to chromium and should inform their healthcare provider so they can monitor health and provide supportive care, as needed. Healthcare providers can refer to CDC's Clinician Outreach and Communication Activity (COCA Now) announcement (https://emergency.cdc.gov/newsletters/coca/2024/010524.html) for information for additional guidance.

Chromium (https://wwwn.cdc.gov/TSP/ToxFAQs/ToxFAQsDetails.aspx?faqid=61&toxid=17) is a naturally occurring element. It is an essential trace nutrient important to the diet that exists predominantly in two forms, chromium (III) and chromium (VI). Chromium (VI) is more toxic than chromium (III). Due to limitations in available testing methods, FDA was not able to definitively determine the form of chromium in the cinnamon apple puree sample (i.e., whether the chromium present is chromium (III) or chromium (VI)). The lead-to-chromium ratio in the cinnamon apple puree sample is consistent with that of lead chromate ($PbCrO_4$) (which contains chromium (VI)), but this is not a definitive indicator that lead chromate or chromium (VI) (the more toxic form of chromium) was present. Information on the health effects of eating food contaminated with chromium (VI) are limited. The chromium in lead chromate may also be converted to chromium (III) (the less toxic form of chromium) due to the acidity of the applesauce and the stomach.

Additional FDA Laboratory Results Indicate Chromium Contamination:

After additional analysis of both recalled cinnamon apple products and the cinnamon collected from the manufacturer in Ecuador, FDA has determined that, in addition to lead, the cinnamon and recalled products also contained a high level of chromium. The level of chromium detected in the two samples of cinnamon yielded 1201 and 531 parts per million (ppm). Because of the limited amount of cinnamon used in the finished product, the level of chromium detected in the reanalysis of FDA samples of the recalled WanaBana Cinnamon Apple Puree product yielded 0.590 and 0.566 ppm.

FDA also conducted testing for arsenic and cadmium, but those elements were not detected above trace levels in the cinnamon collected from the Austrofoods facility in Ecuador or in the recalled product. As part of this investigation, some state partners also conducted testing for toxic elements and only detected elevated levels of lead and chromium.

Health Implications & Recommendations:

The health effects of eating food contaminated with chromium (VI), as a constituent of lead chromate, are not well understood. Symptoms of chromium exposure from eating contaminated food may be nonspecific. Some people might not experience any symptoms. Symptoms for children are likely similar to those of adults. Acute ingestion of chromium exceeding dietary recommendations may result in abdominal pain, nausea, vomiting, diarrhea, anemia, renal and hepatic dysfunction.

Consumers should contact their healthcare providers if they are experiencing any symptoms following the consumption of recalled product. Consumers should also inform their healthcare provider that they may have been exposed to high levels of chromium and lead if recalled products were consumed so their provider can monitor and potentially address any adverse health effects.

Healthcare providers can refer to CDC's COCA Now announcement (https://emergency.cdc.gov/newsletters/coca/2024/010524.html) for information for additional guidance.

January 2, 2024

As of January 2, 2024, FDA has not received any new complaints/reports of adverse events potentially linked to recalled product. To date, confirmed complainants, or people for whom a complaint or adverse event was submitted and met FDA's complainant definition, are between zero and 53 years of age and the median age is one year old.

CDC's National Center for Environmental Health is conducting case finding efforts in collaboration with state and local health departments. CDC's case definition for state partners includes a blood lead level of 3.5 µg/dL or higher measured within 3 months after consuming a recalled WanaBana, Schnucks, or Weis brand fruit puree product after November 2022. As of December 29, 2023, CDC has received reports of 80 confirmed cases, 187 probable cases, and 20 suspected cases for a total of 287 cases from 37 different states through their reporting structure. For more information, please visit CDC's page (https://www.cdc.gov/nceh/lead/news/lead-poisoning-outbreak-linked-to-cinnamon-applesauce-pouches.html) to review their case reporting methodology and findings.

CDC and FDA have different data sources, so the counts reported by each agency will not directly correspond. In addition, some people who were affected by the contaminated product might be reflected in both the numbers reported by the FDA and the numbers reported by CDC, so the numbers should not be added together.

December 26, 2023

FDA is providing additional context about the amount of lead in testing results from cinnamon used as an ingredient in the recalled applesauce pouches and in testing results of the recalled pouches. As recently reported, FDA tested samples of the cinnamon collected from the Austrofoods manufacturing facility in Ecuador and used in the recalled applesauce pouches. The highest result was 5,110 parts per million (ppm), which was more than 2,000 times the level of 2.5 ppm being considered for bark spices (including cinnamon) by the international standard-setting body, Codex Alimentarius Commission (Codex) (https://www.fao.org/fao-who-codexalimentarius/en/) (http://www.fda.gov/about-fda/website-policies/website-disclaimer).

In addition, the testing results previously reported for the sample of recalled WanaBana cinnamon apple puree pouch collected from Dollar Tree had a lead concentration of 2.18 ppm which, for context, is more than 200 times greater than the action level of 0.01 ppm that the FDA has proposed in draft guidance (https://www.fda.gov/regulatory-information/search-fda-guidance-documents/draft-guidance-industry-action-levels-lead-food-intended-babies-and-young-children)for fruit purees and similar products intended for babies and young children.

Although there are proposed action levels for lead used for comparison, it is important to underscore that the FDA does not need an action level or guidance to take action when food contains a harmful substance, such as lead, that may render the food injurious to health.

As previously reported on December 18, 2023, the FDA has tested multiple products and, based on the current evidence, there are no further products being added to the recall at this time. Additionally, FDA and state partners have tested at least 136 samples of non-cinnamon containing products and all have been negative for elevated lead levels. Of those, 136 non-cinnamon containing samples, eleven are the Smoothie Mango Passionfruit Banana flavor of WanaBana purees, three of these samples are of the same lot that ARCSA originally reported as positive for lead, and FDA results were negative for elevated lead for all samples. In addition, FDA collected a sample of WanaBana Organic Mango Puree at import and sample results are negative for elevated levels of lead.

As of December 26, 2023, FDA has received 82 confirmed complaints/reports of adverse events potentially linked to recalled product. To date, confirmed complainants, or people for whom a complaint or adverse event was submitted and met FDA's complainant definition, are between zero and 53 years of age.

CDC's National Center for Environmental Health is conducting case finding efforts in collaboration with state and local health departments. CDC's case definition for state partners includes a blood lead level of 3.5 µg/dL or higher measured within 3 months after consuming a recalled WanaBana, Schnucks, or Weis brand fruit puree product after November 2022. As of December 22, CDC has received reports of 73 confirmed cases, 157 probable cases, and 21 suspected cases for a total of 251 cases from 34 different states through their reporting structure. For more information, please visit CDC's page (https://www.cdc.gov/nceh/lead/news/lead-poisoning-outbreak-linked-to-cinnamon-applesauce-pouches.html) to review their case reporting methodology and findings.

CDC and FDA have different data sources, so the counts reported by each agency will not directly correspond. In addition, some people who were affected by the contaminated product might be reflected in both the numbers reported by the FDA and the numbers reported by CDC, so the numbers should not be added together.

December 19, 2023

As of December 19, 2023, FDA has received 69 complaints/reports of adverse events potentially linked to recalled product. To date, confirmed complainants, or people for whom a complaint or adverse event was submitted, are under 6 years of age.

CDC's National Center for Environmental Health is conducting case finding efforts in collaboration with state and local health departments. CDC's case definition for state partners includes a blood lead level of 3.5 µg/dL or higher measured within 3 months after consuming a recalled WanaBana, Schnucks, or Weis brand fruit puree product after November 2022. As of December 15, CDC has received reports of 67 confirmed cases, 122 probable cases, and 16 suspected cases for a total of 205 cases from 33 different states through their reporting structure. For more information, please visit CDC's page (https://www.cdc.gov/nceh/lead/news/lead-poisoning-outbreak-linked-to-cinnamon-applesauce-pouches.html) to review their case reporting methodology and findings.

CDC and FDA have different data sources, so the counts reported by each agency will not directly correspond. In addition, some people who were affected by the contaminated product might be reflected in both the numbers reported by the FDA and the numbers reported by CDC, so the numbers should not be added together.

December 18, 2023

FDA's onsite inspection of the Austrofoods facility in Ecuador has ended. However, the FDA investigation of the elevated lead levels in recalled cinnamon applesauce pouches continues. During the inspection, investigators collected samples of cinnamon supplied by Negasmart to Austrofoods. These samples have undergone analysis and results show extremely high levels of lead contamination, 5110 parts per million (ppm) and 2270 ppm. For context, the international standard-setting body, Codex Alimentarius Commission (Codex) (https://www.fao.org/fao-who-codexalimentarius/en/) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) is considering adopting a maximum level of 2.5 ppm for lead in bark spices, including cinnamon, in 2024.

The FDA has tested multiple products and, based on the current evidence, there are no further products being added to the recall at this time. Additionally, FDA and state partners have tested at least 136 samples of non-cinnamon containing products and all have been negative for elevated lead levels. Of those, 136 non-cinnamon containing samples, eleven are the Smoothie Mango Passionfruit Banana flavor of WanaBana purees, three of these samples are of the same lot that the Agencia Nacional de Regulación, Control y Vigilancia Sanitaria (ARCSA) originally reported as positive for lead, and FDA results were negative for elevated lead for all samples. In addition, FDA collected samples of WanaBana Organic Mango Puree at import and sample results are negative for elevated levels of lead.

At this time, FDA is still relying on officials in Ecuador to support the investigation into Negasmart. To date, FDA has confirmed that Negasmart does not ship product directly to the U.S. and that, of Negasmart's direct customers, only Austrofoods ships product to the U.S.

Further, Ecuadorian officials from ARCSA report that Negasmart does not ship product outside Ecuador. ARCSA also reports that in their testing thus far, raw/unprocessed cinnamon from cinnamon importers in Ecuador do not appear to be contaminated with lead, whereas the ground or powdered cinnamon from Negasmart is contaminated. The Ecuadorian processor used by Negasmart is not currently operating.

While our information at this time indicates that in the U.S. the contaminated cinnamon is limited to only the applesauce products that have already been recalled, the FDA is still investigating whether the cinnamon in the recalled products was used in other products exported to the U.S. To date, increased screening for imported cinnamon from certain countries remains in place and FDA has no indication that this issue extends beyond these recalled products.

The FDA has limited authority over foreign ingredient suppliers who do not directly ship product to the U.S. This is because their food undergoes further manufacturing/processing prior to export. Thus, the FDA cannot take direct action with Negasmart. However, we are continuing to work closely with Ecuadorian officials, as they are conducting their own rapidly evolving investigations into the source of contamination. FDA is actively assessing information received, using all available resources to further protect public health.

In addition to coordinating with Ecuadorian officials, FDA also is continuing to take steps to make other countries aware of the ongoing investigation into elevated lead levels in cinnamon applesauce pouches manufactured by Austrofoods. As part of this effort, FDA sends updates of the FDA public health advisory to other countries through the World Health Organization (WHO) International Food Safety Authority Network (INFOSAN), which includes more than 200 partner countries.

Finally, we understand there is heightened awareness and interest in this incident, especially for families with small children. For that reason, in addition to continuing to provide timely updates on our investigation, FDA is also providing a timeline detailing the early stages of our investigation in an effort to be as transparent and forthcoming with information as possible.

December 12, 2023

FDA is conducting an onsite inspection at the Austrofoods facility located in Ecuador. Cinnamon samples collected from the lots used in recalled products will undergo laboratory analysis. FDA will update this advisory to share the sample results once the analysis is complete.

To date, the FDA has worked with Ecuadorian authorities to gather information about Negasmart, the supplier of cinnamon to Austrofoods, including whether the cinnamon in the recalled products was used in other products exported to the United States. Working together with Ecuadorian authorities, the FDA has confirmed that, of Negasmart's direct customers, only Austrofoods ships product to the US. In addition, the FDA has confirmed that Negasmart does not directly export products to the US.

As of December 11, 2023, FDA has received 65 reports of adverse events potentially linked to recalled product. To date, confirmed complainants, or people for whom an adverse event was submitted, are under 6 years of age.

CDC's National Center for Environmental Health is conducting case finding efforts in collaboration with state and local health departments. CDC's case definition for state partners includes a blood lead level of 3.5 µg/dL or higher measured within 3 months after consuming a recalled WanaBana, Schnucks, or Weis brand fruit puree product after November 2022. As of December 8, CDC has received reports of 46 confirmed cases, 68 probable cases, and 11 suspected cases for a total of 125 cases from 22 different states through their reporting structure. For more information, please visit CDC's page (https://www.cdc.gov/nceh/lead/news/lead-poisoning-outbreak-linked-to-cinnamon-applesauce-pouches.html) to review their case reporting methodology and findings.

CDC and FDA have different data sources, so the counts reported by each agency will not directly correspond. In addition, some people who were affected by the contaminated product might be reflected in both the numbers reported by the FDA and the numbers reported by CDC, so the numbers should not be added together.

FDA's investigation is ongoing to determine the point of contamination and whether additional products are linked to illnesses. FDA will update the advisory as information becomes available.

December 5, 2023

FDA has initiated an onsite inspection at the Austrofoods facility located in Ecuador. Ingredient sample collection is underway.

The FDA is continuing to coordinate with Ecuadorian authorities on the investigation of the source of elevated lead levels in cinnamon apple pouches. In addition, the Ecuadorian authorities report that Negasmart's cinnamon had higher levels of lead than allowed by Ecuador and that Negasmart, the supplier of cinnamon to Austrofoods, is currently under an Ecuadorian administrative sanctions process to determine the responsible party for the contamination.

As of December 5, 2023, FDA has received 64 reports of adverse events potentially linked to recalled product. To date, confirmed complainants, or people who an adverse event was submitted for, are under 6 years of age.

To date, the FDA has included adverse event reports submitted directly to the FDA that note blood lead levels at or above 3.5 micrograms of lead per deciliter of whole blood (µg /dL) within 3 months after consuming recalled product. The FDA is continuing to evaluate incoming adverse reports of illnesses. For background, the Centers for Disease Control and Prevention's (CDC) blood reference level of 3.5 µg /dL is the level at which the CDC recommends clinical monitoring of lead exposure in children.

CDC's National Center for Environmental Health is conducting case finding efforts in collaboration with state and local health departments. CDC's case definition for state partners includes a blood lead level of 3.5 µg/dL or higher measured within 3 months after consuming a recalled WanaBana, Schnucks, or Weis brand fruit puree product after November 2022. As of December 1, CDC has received reports of 18 confirmed cases, 30 probable cases, and 4 suspected cases from 13 different states through their reporting structure. For more information, please visit CDC's page to review their case reporting methodology and findings.

CDC and FDA have different data sources, so the counts reported by each agency will not directly correspond. In addition, some people who were affected by the contaminated product might be reflected in both the numbers reported by the FDA and the numbers reported by CDC, so the numbers should not be added together.

The FDA relies on self-reported information submitted by healthcare providers, consumers, and some state partners who submitted an adverse event report to FDA as an initial step in determining if a product is a potential shared source of exposure amongst complainants. Unlike outbreaks of foodborne illnesses that are genetically linked to pathogens, lead exposure in an individual can result from several sources. There is no established method to link lead exposure in an individual to a specific source, which can make establishing a causal relationship difficult.

While our total reports included in this advisory represent adverse event reports that have been submitted to FDA, we acknowledge that there are other avenues for reporting of lead exposure. However, we are working with our state partners and CDC to gather and evaluate as much data as possible, while recognizing there are different mechanisms being leveraged.

FDA's investigation is ongoing to determine the point of contamination and whether additional products are linked to illnesses. FDA will update the advisory as information becomes available.

November 30, 2023

On November 30, 2023, Austrofood, along with Wanabana USA, the distributor of WanaBana products in the United States, released a statement that reports that Wanabana has conducted a root cause investigation. Based on this investigation, the firm's leading hypothesis to date is that the cinnamon is the source of the elevated lead levels in the recalled products. The statement released today by Wanabana USA and Austrofood states that the cinnamon used to manufacture the recalled products was supplied by Negocios Asociados Mayoristas S.A., operating as Negasmart, a third-party distribution company located in Ecuador.

The FDA is continuing to work with Ecuadorian authorities to investigate the source of the contamination and to determine if the cinnamon in the recalled products was used in other products or distributed as a raw ingredient to other countries. FDA has confirmed that Negasmart does not import cinnamon directly into the U.S.

As of November 30, 2023, there have been 57 reports of adverse events potentially linked to recalled product submitted to FDA. To date, confirmed complainants are less than 1 to 5 years of age.

The FDA relies on self-reported information submitted by healthcare providers, consumers, and some state partners who submitted an adverse event report to FDA as an initial step in determining if a product is a potential shared source of exposure amongst complainants. Unlike outbreaks of foodborne illnesses that are genetically linked to pathogens, there is no method to link lead exposure to a specific source, which can make establishing a causal relationship complicated.

While our total reports included in this advisory represent complaints that have been reported to FDA, we recognize there are other avenues for reporting of elevated lead levels. For example, through case reporting from the state health departments to CDC which is routinely done for cases of childhood lead exposure. Because these different avenues for reporting represent two different mechanisms of collecting data, we are currently not including them in our advisory. However, we are working with our state partners and CDC to gather and evaluate as much data as possible, while recognizing there are different mechanisms being leveraged.

FDA's investigation is ongoing to determine the point of contamination and whether additional products are linked to illnesses. At this time, FDA has no indication that this issue extends beyond these recalled products, but to further protect public health, FDA is screening incoming shipments of cinnamon from multiple countries for lead contamination. As of November 30, 2023, there have been no screening results that have tested positive for higher levels of lead. Separately, Austrofood CIA LDA's apple cinnamon fruit puree pouch products exported to the U.S. were added to Import Alert 99-42 (https://www.accessdata.fda.gov/cms_ia/importalert_1167.html), detention without physical examination of foods due to heavy metal (toxic element) contamination.

FDA will update the advisory as information becomes available.

November 22, 2023

FDA, along with CDC and state and local partners, is investigating reports of elevated blood lead levels in individuals with reported exposure to Apple Cinnamon Fruit Puree pouches manufactured in Ecuador and sold under WanaBana, Weis, and Schnucks brands.

As of November 22, 2023, there have been 52 reports of adverse events potentially linked to recalled product submitted to FDA. To date, confirmed complainants are less than 1 to 4 years of age. FDA is continuing to evaluate incoming adverse event reports.

FDA is aware that recalled WanaBana Apple Cinnamon Puree is still on the shelves at several Dollar Tree stores in multiple states. FDA is working with the firm to ensure an effective recall. This product should not be available for sale and consumers should not purchase or consume this product as it is potentially contaminated with lead, which can be harmful to health, particularly for children.

To properly discard the product, consumers and retailers should carefully open the pouch and empty the content into a trash can before discarding the packaging to prevent others from salvaging recalled product from the trash. Clean up any spills after discarding the product then wash your hands.

FDA's investigation is ongoing to determine the point of contamination and whether additional products are linked to illnesses. At this time, the FDA is not aware of any other reports of illnesses or elevated blood lead level adverse events reported for other cinnamon-containing products or cinnamon.

FDA will update the advisory as information becomes available.

November 16, 2023

FDA, along with CDC and state and local partners, is investigating reports of elevated blood lead levels in individuals with reported exposure to Apple Cinnamon Fruit Puree pouches manufactured in Ecuador and sold under WanaBana, Weis, and Schnucks brands.

As of November 16, 2023, there have been 34 reports of illness potentially linked to recalled product submitted to FDA. FDA is continuing to evaluate incoming adverse reports of illnesses.

FDA and other state partners collected and analyzed additional product samples of fruit puree and applesauce pouches. FDA detected elevated levels of lead in one finished product sample of WanaBana Apple Cinnamon Puree collected from Dollar Tree. The level detected in the FDA sample of WanaBana apple cinnamon puree is 2.18 parts per million (ppm), which, for context, is more than 200 times greater than the action level the FDA has proposed in draft guidance (/media/164684/download?attachment) for fruit purees and similar products intended for babies and young children.

To date, sample analysis of WanaBana, Weis, and Schnucks fruit puree pouches that do not contain cinnamon and are not part of the recall, have not shown elevated levels of lead.

FDA's leading hypothesis is that cinnamon used in these recalled pouches is the likely source of contamination for these products; however, the FDA has not yet been able to collect and test samples of the cinnamon used in the recalled products. The FDA is continuing to work with Ecuadorian authorities to investigate the source of the cinnamon. At this time, FDA has no indication that this issue extends beyond these recalled products, but to further protect public health, FDA is screening incoming shipments of cinnamon from multiple countries for lead contamination.

In addition to determining the source of cinnamon, FDA's investigation is ongoing to determine the point of contamination and whether additional products are linked to illnesses. At this time, the FDA is not aware of any other reports of illnesses or elevated blood lead level adverse events reported for other cinnamon-containing products or cinnamon.

The FDA also reminds industry that it is the legal responsibility of companies distributing food products that are sold in the U.S., to comply with applicable requirements in the Federal Food, Drug, and Cosmetic Act (/regulatory-information/laws-enforced-fda/federal-food-drug-and-cosmetic-act-fdc-act) and FDA's regulations (https://www.ecfr.gov/current/title-21).

By law, food manufacturers have a responsibility to significantly minimize or prevent chemical hazards when needed. This includes putting in place any needed preventive controls to reduce or eliminate the presence of lead in their products. Most food manufacturers and processors are covered by the preventive control provisions of the Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food (https://www.ecfr.gov/current/title-21/chapter-I/subchapter-B/part-117) rule. The preventive control provisions require industry to implement controls to significantly minimize or prevent any identified chemical hazards, such as lead, requiring a control. In addition, some manufacturers may conduct verification activities like testing the final product.

For more information please see FDA's Draft Guidance for Industry on Hazard Analysis and Risk-Based Preventive Controls for Human Food (/regulatory-information/search-fda-guidance-documents/draft-guidance-industry-hazard-analysis-and-risk-based-preventive-controls-human-food).

FDA will update this advisory as information becomes available.

November 13, 2023

As reported in a safety alert (/food/alerts-advisories-safety-information/fda-advises-parents-and-caregivers-not-buy-or-feed-wanabana-apple-cinnamon-fruit-puree-pouches) issued by FDA on October 28, 2023, the FDA, along with the North Carolina Department of Health and Human Services (NCDHHS) and the North Carolina Department of Agriculture & Consumer Services (NCDA&CS) are investigating reports of four children with elevated blood lead levels, indicating potential acute lead toxicity. The NCDHHS investigation identified WanaBana Apple Cinnamon Fruit Puree pouches as a potential shared source of exposure. As part of their investigation, NCDHHS analyzed multiple lots of WanaBana Apple Cinnamon Fruit Puree, detecting extremely high concentrations of lead. The FDA has reviewed and supports NCDHHS's analytical findings and determined that levels of lead found in the analyzed pouches could result in acute lead toxicity.

As of November 13, 2023, there have been 22 reports of illness potentially linked to recalled product submitted to FDA. As part of this investigation, FDA and state partners are collecting and analyzing additional product samples of fruit puree and applesauce pouches. At this time, sample analyses have not shown elevated levels of lead in any non-recalled products.

On October 31, 2023, Wanabana LLC initiated a voluntary recall (/safety/recalls-market-withdrawals-safety-alerts/wanabana-issues-voluntary-recall-wanabana-apple-cinnamon-fruit-puree-pouches-due-elevated-lead) of all WanaBana Apple Cinnamon Fruit Puree Pouches. On November 9, 2023, Wanabana LLC expanded their recall announcement (/safety/recalls-market-withdrawals-safety-alerts/wanabana-recalls-wanabana-weis-and-schnucks-apple-cinnamon-fruit-puree-pouches-cinnamon-apple-sauce) to include information on recalled Schnucks and Weis cinnamon applesauce pouches.

The recall impacts markets outside of the United States. Customer information provided by the firm shows that product was also distributed to Cuba and the United Arab Emirates.

Since the first alert was issued this investigation has been transferred to FDA's Coordinated Outbreak Response & Evaluation (CORE) Network for additional follow up, in collaboration with the Centers for Disease Control and Prevention (CDC) and state and local partners. Two additional brands of products are also subject to recall: certain Schnucks cinnamon-flavored applesauce pouches and variety pack and certain Weis cinnamon applesauce pouches.

FDA is continuing to evaluate incoming reports of illnesses. FDA's investigation is ongoing to determine the source of lead contamination and whether additional products are linked to illnesses. FDA will update this advisory as information becomes available.

November 3, 2023

As reported in a safety alert issued by FDA on October 28, 2023, the FDA, along with the North Carolina Department of Health and Human Services (NCDHHS) and the North Carolina Department of Agriculture & Consumer Services (NCDA&CS) are investigating reports of four children with elevated blood lead levels, indicating potential acute lead toxicity. The NCDHHS investigation identified WanaBana Apple Cinnamon Fruit Puree pouches as a potential shared source of exposure. As part of their investigation, NCDHHS analyzed multiple lots of WanaBana Apple Cinnamon Fruit Puree, detecting extremely high concentrations of lead.

The FDA has reviewed and supports NCDHHS's analytical findings and found that analytical results at this level could result in acute toxicity. The FDA has shared the results with the firm and on October 31, 2023, Wanabana LLC initiated a voluntary recall of all WanaBana Apple Cinnamon Fruit Puree Pouches.

Since the first alert was issued this investigation has been transferred to FDA's Coordinated Outbreak Response & Evaluation (CORE) Network for additional follow up, in collaboration with the Centers for Disease Control and Prevention (CDC) and state and local partners. Two additional brands of products are also subject to recall: certain Schnucks cinnamon-flavored applesauce pouches and variety pack and certain Weis cinnamon applesauce pouches.

FDA has received additional reports of illnesses and is working to evaluate those complaints. FDA's investigation is ongoing to determine the source of lead contamination and whether additional products are linked to illnesses. FDA will update this advisory as information becomes available.

October 28, 2023

The FDA was recently made aware of a developing investigation by the North Carolina Department of Health and Human Services (NCDHHS) and the North Carolina Department of Agriculture & Consumer Services (NCDA&CS) regarding four children with elevated blood lead levels, indicating potential acute lead toxicity. The NCDHHS investigation identified WanaBana apple cinnamon fruit puree pouches as a potential shared source of exposure. As part of their investigation, NCDHHS analyzed multiple lots of WanaBana apple cinnamon fruit puree, detecting extremely high concentrations of lead. The FDA has reviewed and supports NCDHHS's analytical findings and found that analytical results at this level could result in acute toxicity. The FDA has shared the results with the firm whose representatives are cooperating with the FDA and have agreed to voluntarily recall all WanaBana apple cinnamon fruit puree pouches regardless of expiration.

The FDA is issuing this public health alert advising parents and caregivers not to purchase or feed WanaBana apple cinnamon fruit puree pouches to toddlers and young children because they may contain elevated levels of lead. The FDA is continuing to work with state officials and the firm, collecting additional information, and taking steps to remove all contaminated product from the market.

Who to Contact

Consumers who have symptoms should contact their health care provider to report their symptoms and receive care.

To report a **complaint** or **adverse event** (illness or serious allergic reaction), you can

- Call an FDA Consumer Complaint Coordinator (/safety/report-problem-fda/consumer-complaint-coordinators)if you wish to speak directly to a person about your problem.
- Complete an electronic Voluntary MedWatch form (https://www.accessdata.fda.gov/scripts/medwatch/medwatch-online.htm) online.
- Complete a paper Voluntary MedWatch form (/media/85598/download) that can be mailed to FDA.

Submit Questions/Get Assistance (https://www.fda.gov/fcic)

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Was this helpful? Yes No

ATTACHMENT C

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
12420 Parklawn Dr, Rm 2037 HFC-130 Rockville, MD 20857 FDA483responseinternational@fda.hhs.gov	12/4/2023-12/14/2023* FEI NUMBER 3013416401

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Francisco Pena, President

FIRM NAME	STREET ADDRESS
AUSTROFOOD S.A.S.	Av. General Enriquez , Tanicuchi Lote 8
CITY, STATE, ZIP CODE, COUNTRY Quito, Pichincha, 171104 Ecuador	TYPE ESTABLISHMENT INSPECTED Human Food Manufacturer

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

OBSERVATION 1

Your hazard analysis did not identify a hazard that required a preventive control.

Specifically, you conducted a hazard analysis on November 14, 2022, for all incoming raw materials, but did not identify any raw materials requiring a preventive control. In addition, cinnamon was not identified as a raw ingredient. On September 27, 2023, you conducted another hazard analysis for all raw materials ingredients including ground cinnamon. However, cinnamon was not considered a significant hazard requiring a preventive control for heavy metals including lead. In addition, you did not sample and test the raw material or the finished product for heavy metals. Furthermore, sampling conducted by FDA in the United States identified high level of lead in finished products distributed by Wanabana. FDA also conducted two sample collections of the ground cinnamon powder at Austrofood on December 05, 2023, and those samples also identified lead in the ground cinnamon.

OBSERVATION 2

Your written process preventive control and monitoring procedures were not appropriate to significantly minimize or prevent the hazard requiring a preventive control.

Specifically, your Food Safety Plan for "Fruit and Vegetable Pulp, Purees, and Compotes in Pouches M-ASC-004-C" (e.g., Appel Cinnamon Puree/Sauce) lists:

- a monitoring frequency of checking the temperatures for the (b) (4) pasteurizer ((b) (4))

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Brant M Schroeder, Investigator Israel Juarbe, Investigator Rowena Trevino-Solis, Non Reporting User	X Brant M Schroeder Investigator Signed By: Brant M. Schroeder -S Date Signed: 12-14-2023 09:40:51	12/14/2023

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
12420 Parklawn Dr, Rm 2037 HFC-130 Rockville, MD 20857 FDA483responseinternational@fda.hhs.gov	12/4/2023-12/14/2023* FEI NUMBER 3013416401

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Francisco Pena, President	
FIRM NAME	STREET ADDRESS
AUSTROFOOD S.A.S.	Av. General Enriquez , Tanicuchi Lote 8
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Quito, Pichincha, 171104 Ecuador	Human Food Manufacturer

and the (b) (4) pasteurizer "(b) (4) after the process starts" at the pasteurization steps. This frequency does not ensure compliance with the temperature critical limit at the pasteurization steps to control the pathogenic bacteria survival in the finished product.

- a monitoring procedure covering the temperature of the product at the (b) (4) pasteurization step; however, the monitoring procedures does not cover how the "(b) (4) " of processing time will be addressed. This procedure does not ensure compliance with the critical limit at the (b) (4) pasteurization step.

OBSERVATION 3

You did not identify a process preventive control for a hazard when one was needed.

Specifically, your Food Safety Plan for "Fruit and Vegetable Pulp, Purees, and Compotes in Pouches M-ASC-004-C" (e.g., Appel Cinnamon Puree/Sauce) does not identify the preventive control point that is necessary to control the physical hazard. There are numerous rough edges, chipped, and pitted areas on the stainless-steel (b) (4) conveyor that leads to the (b) (4) The metal pieces from the (b) (4) conveyor can break loose and become a sources of metal inclusion that could enter food during processing.

OBSERVATION 4

Your plant did not have adequate sanitary facilities and accommodations.

Specifically, there is no backflow protection to prevent or avert back siphonage on the water outlets with connecting hoses and threaded water faucet outlets throughout the plant.

*DATES OF INSPECTION

12/04/2023(Mon), 12/05/2023(Tue), 12/06/2023(Wed), 12/07/2023(Thu), 12/11/2023(Mon), 12/12/2023(Tue), 12/13/2023(Wed), 12/14/2023(Thu)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
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DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
12420 Parklawn Dr, Rm 2037 HFC-130 Rockville, MD 20857 FDA483responseinternational@fda.hhs.gov	12/4/2023-12/14/2023* FEI NUMBER 3013416401

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Francisco Pena, President

FIRM NAME	STREET ADDRESS
AUSTROFOOD S.A.S.	Av. General Enriquez , Tanicuchi Lote 8
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Quito, Pichincha, 171104 Ecuador	Human Food Manufacturer

X Israel Juarbe
Investigator
Signed By: Israel Juarbe Jr -S
Date Signed: 12-14-2023 09:41:23

X Rowena Trevino-Solis
Non Reporting User
Signed By: Rowena Trevino-solis -S
Date Signed: 12-14-2023 09:43:06

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EMPLOYEE(S) SIGNATURE
Brant M Schroeder, Investigator
Israel Juarbe, Investigator
Rowena Trevino-Solis, Non Reporting User

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Investigator
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Date Signed: 12-14-2023
09:40:51

DATE ISSUED
12/14/2023

The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."