Lead and Chromium/Fruit Puree Pouches/Nov 2023

Executive Incident Summary

CARA#1198

Date: 2/13/2024

Authors:

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EXECUTIVE SUMMARY

Notification

On 11/01/2023 CORE Signals was notified by CFSAN Office of Compliance (OC) of an adverse event investigation with reports of elevated blood lead levels in children who consumed WanaBana apple cinnamon fruit puree. Product sampling was conducted by NC partners and results indicated the apple cinnamon fruit puree product contained extremely high levels of lead. A request was made from OC for CORE's assistance with coordination of the rapidly evolving investigation. At the time of initial notification, there were 4 children from NC with elevated lead levels and further investigational activities being conducted by NC state partners.

Epidemiology Overview & Clinical WGS

The epidemiology for this investigation into lead and chromium in fruit puree pouches was maintained by both FDA and CDC separately. FDA's confirmed complainant definition for this incident was "elevated blood lead levels of 3.5 µg/dL or higher, detected through laboratory testing in a person within three months after consuming apple cinnamon puree pouch manufactured by Austrofood (Sangolqui, Ecuador) after November 2022". There were 131 adverse events reported through Consumer Complaints and CFSAN Adverse Events Reporting System (CAERS) reports which were reviewed between 11/02/2023 - 01/18/2024. FDA's count of confirmed complainants includes 90 complainants from 32 states and three from an unknown state(s): AL (1), AR (1), AZ (1), CA (1), CT (1), 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), UNK (3). Ages range from <1 to 53 years (median: 1), 44% are female, one was hospitalized, and no deaths were reported. Complainant report dates range from 10/17/2023 to 01/16/2024. Symptoms reported by complainants included lethargy, loss of appetite, behavioral issues, gastrointestinal distress, weight loss, headaches, joint aches, sleep disruption, and developmental delays. Blood Lead Levels (BLLs) reported were between 3.5 µg/dL and 28.8 µg/dL.

States were asked by CDC to report cases of blood lead levels ≥3.5 µg/dL among people who consumed one of the recalled products within three months prior to the blood lead test. Cases were classified as either confirmed, probable, or suspected based on the result and type of blood lead level testing and environmental assessment of other possible sources of lead exposure. Case classifications assigned by states were accepted by CDC.CDC will continue to solicit case reports through early April 2024, but as of 2/2/2024, 413 cases had been reported by states to CDC (100 confirmed, 277 probable and 36 suspect), from 43 states (AL, AR, AZ, CA, CO, CT, FL, GA, IA, ID, IL, IN, KS, KY, LA, MA, ME, MI, MN, MO, MS, MT, NC, ND, NE, NH, NJ, NM, NY, OH, OK, OR, PA, RI, SC, TN, TX, UT, VA, VT, WA, WI, and WV). Ages ranged from 6 months to 53 years (median 1.7 years). The median of the within-person maximum reported venous blood lead levels was 8.1 µg/dL (25^{th}–75^{th} percentiles: 5.4–12.3 µg/dL). Of the 312 people for whom information about hospitalization was available, one was hospitalized. According to the state that reported the hospitalized case, the hospitalization was not considered to be related to the exposure.

Field Investigations & Findings

During the investigation, it was reported that Austrofood (manufacturer) and WanaBana (importer) are owned and operated by the same individual. FDA ORA Division of Foreign Human and Animal Food Operations conducted an inspection at Austrofood's manufacturing facility in Ecuador between 12/04/2023 and 12/14/2023. The FDA foreign inspection team was accompanied by representatives from Agnecia Nacional de Reulacion (ARCSA; Ecuadorian authority that regulates finished food product) and Agrocalidad (Ecuadorian authorities that cover raw materials). The firm was not processing any food products during the inspection; however, a walk-through of the facility was conducted, an ingredient and hazard analysis for processing of apple cinnamon puree/sauce was completed, and preventive controls and procedural updates were discussed.

A four-item FDA-483 was issued to Austrofood following the inspection. Findings included the following:

1. The firm's hazard analysis did not identify a hazard that required a preventive control. This referred to ground cinnamon, as a raw ingredient, being considered a significant hazard requiring a preventive control for heavy metals including lead. In addition, the raw material nor the finished product was sampled/tested for heavy metals.
2. The firm's written process preventive control and monitoring procedures were not appropriate to significantly minimize or prevent the hazard requiring a preventive control. Referred to monitoring temperature to ensure compliance with the critical limit at the (b)(4) .
3. The firm did not identify a process preventive control for a hazard when one was needed. There are numerous rough edges, chipped, and pitted areas on the (b)(4) . The metal pieces from the (b)(4) can break loose and become a sources of metal inclusion that could enter food during processing.
4. The 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.

Laboratory Sample Overview

A total of 55 FDA collected samples were analyzed for lead. If elevated levels of lead were found, samples were also analyzed for chromium. Nine FDA, which included two WanaBana apple cinnamon fruit purees product of Ecuador, 5 WanaBana non-cinnamon containing fruit purees product of Ecuador, and two Weis cinnamon applesauce pouches product of USA. Forty-four samples were collected at import, which included 18 cinnamon powder and bark samples with a country of origin listed as Sri Lanka and 26 non-cinnamon containing products manufactured by Austrofood. Finally, 2 samples of cinnamon powder were collected during the firm inspection at Austrofood. Elevated levels of lead and chromium were detected in four samples of the 55 samples; 2 WanaBana apple cinnamon fruit purees collected from retail and 2 cinnamon powder collected at Austrofood (See Table 1).

Table 1. FDA Samples with Elevated Lead and Chromium Levels

Sample #	Product	Pb ppm	Cr ppm	Molar Ratio
1234871	Wanabana Apple Cinnamon Fruit Puree	2.180	0.590	~1:1
1234177	Wanabana Apple Cinnamon Fruit Puree	2.220	0.566	~1:1
1085090	Austrofoods/Negasmart Ground Cinnamon	5112	1201	~1:1
1085091	Austrofoods/Negasmart Ground Cinnamon	2273	531.1	~1:1

A total of 141 samples were collected and analyzed by LFFM and state partners for elevated levels of lead. One-hundred and nine samples were collected domestically from retail and 32 samples were

collected from complainants' homes. Samples included 26 WanaBana apple cinnamon fruit purees (product of Ecuador), 71 WanaBana non-cinnamon containing fruit purees (product of Ecuador), 25 of various Weis applesauce (product of USA), one Weis cinnamon applesauce (product of Ecuador), 5 Schnuck's non-cinnamon containing applesauce (product of Ecuador), and 13 samples from various brands not implicated in this incident (b)(4) . Lead was detected at high levels in 27 product samples (See Table 2). All products with elevated levels of lead were included in the recall. Only 2 states, Virginia and Maryland, were able to be tested for chromium. Both samples contained elevated levels of chromium.

Table 2. LFFM State Samples with Elevated Levels of Lead and Chromium

State Collection	Sample Number	Product Description	Pb ppm	Cr ppm[1]	Molar Ratio[2]
Virginia Department of Health	WB11212023-01	Wanabana Apple Cinnamon Fruit Puree	2.403	0.6404	0.94
Virginia Department of Health	E231101054	Wanabana Apple Cinnamon Fruit Puree	3.293	0.8097	1.02
Maryland State Department of Health	FC2400005312 (FACTS: 1243289)	Wanabana Apple Cinnamon Fruit Puree	6.354	1.707	0.93
Maryland State Department of Health	FC2400005311 (FACTS: 1243288)	Wanabana Apple Cinnamon Fruit Puree	6.122	1.567	0.98
Maryland State Department of Health	FC2400005313 (FACTS: 1243290)	Wanabana Apple Cinnamon Fruit Puree	6.011	1.529	0.99
Maryland State Department of Health	FC2400004901 (FACTS: 1242096)	Wanabana Apple Cinnamon Fruit Puree	6.305	1.477	1.07
North Carolina Department of Agriculture	FDC0222756	Wanabana Apple Cinnamon Fruit Puree	2.16	N/T	N/A
North Carolina Department of Agriculture	FDC0222760	Wanabana Apple Cinnamon Fruit Puree	2.41	N/T	N/A
North Carolina Department of Agriculture	FDC0222758	Wanabana Apple Cinnamon Fruit Puree	2.45	N/T	N/A
North Carolina Department of Agriculture	FDC0222755	Wanabana Apple Cinnamon Fruit Puree	2.49	N/T	N/A
North Carolina Department of Agriculture	FDC0222757	Wanabana Apple Cinnamon Fruit Puree	2.53	N/T	N/A
North Carolina Department of Agriculture	FDC0222759	Wanabana Apple Cinnamon Fruit Puree	3.19	N/T	N/A
North Carolina Department of Health	ES230821-0001-001	Wanabana Apple Cinnamon Fruit Puree	1.87	N/T	N/A
North Carolina Department of Health	ES231027-0014-002	Wanabana Apple Cinnamon Fruit Puree	1.9	N/T	N/A
North Carolina Department of Health	ES230817-0129-001	Wanabana Apple Cinnamon Fruit Puree	2.3	N/T	N/A
North Carolina Department of Health	ES231020-0007-003	Wanabana Apple Cinnamon Fruit Puree	2.45	N/T	N/A
North Carolina Department of Health	ES231020-0007-007	Wanabana Apple Cinnamon Fruit Puree	2.88	N/T	N/A
North Carolina Department of Health	ES231020-0007-008	Wanabana Apple Cinnamon Fruit Puree	3	N/T	N/A

North Carolina Department of Health	ES231027-0014-001	Wanabana Apple Cinnamon Fruit Puree	3.1	N/T	N/A
North Carolina Department of Health	ES231027-0014-003	Wanabana Apple Cinnamon Fruit Puree	5.2	N/T	N/A
North Carolina Department of Health	ES231027-0014-004	Wanabana Apple Cinnamon Fruit Puree	5.2	N/T	N/A
South Carolina Department of Health	Unknown	Wanabana Apple Cinnamon Fruit Puree	11	N/T	N/A
Southern Nevada Health District	23111073-03	Wanabana Apple Cinnamon Fruit Puree	11.4	N/T	N/A
Southern Nevada Health District	23111073-05	Wanabana Apple Cinnamon Fruit Puree	11.5	N/T	N/A
Southern Nevada Health District	23111073-02	Wanabana Apple Cinnamon Fruit Puree	12.3	N/T	N/A
Southern Nevada Health District	23111073-06	Wanabana Apple Cinnamon Fruit Puree	15.1	N/T	N/A
Pennsylvania Department of Agriculture	F2300877-1	Weis Cinnamon Applesauce Pouches	1.4422	N/T	N/A

[1]NT stands for "Not Tested"
[2]N/A stands for "Not Applicable"

All samples that were analyzed for lead and chromium have consistently yielded an ~1:1 Pb:Cr molar ratio. This ratio is consistent with that of lead chromate (PbCrO4), which contains hexavalent chromium (VI; a toxic form of chromium), but this is not a definitive indicator that lead chromate or chromium (VI) was present. Due to limitations in available testing methods, FDA is not able to definitively determine the form of chromium in the cinnamon or apple puree samples. However, testing completed by FDA's Forensic Chemistry Center on the raw cinnamon powder using Raman spectroscopy, an internally validated laboratory method, showed that multiple conglomerate particles isolated from each sample were determined to contain lead (II) chromate. Unfortunately, this method of testing was not appropriate to conduct on finished product due to low concentration of lead (II) chromate.

Traceback Abbreviated Summary

FDA performed a traceback investigation for fruit puree pouches after receiving a complaint from North Carolina Department of Health and Human Services (NCDHHS) identifying WanaBana apple cinnamon fruit puree pouches as a potential shared source of lead exposure in four children. Multiple lots of this product were tested by NCDHHS, and extremely high levels of lead were detected, between 1.87 µg/dL - 5.2 µg/dL

The apple cinnamon fruit puree pouches were manufactured by Austrofoods CIA LDA (Sangolquí, Ecuador) and imported to the United States under three different brand names: WanaBana, Weis, and Schnucks. During the investigation, traceback was narrowed to cinnamon, supplied by Negasmart (Quito, Ecuador), used to manufacture the fruit puree pouches. Review of information collected by FDA from Negasmart, showed (b)(4) different Ecuadorian ground cinnamon suppliers. Of these (b)(4) suppliers, two (Aguilera Gonzalez Carlos Alberto (b)(4)), were noted to have supplied all cinnamon during the timeframe of interest (November 2022 – October 2023). Notably, (b)(4) used Aguilera Gonzalez Carlos Alberto to grind cinnamon sticks to powder which was later supplied to Negasmart. The traceback investigation showed convergence at Aguilera Gonzalez Carlos Alberto, a cinnamon supplier and grinder.

Furthermore, ARCSA, revealed Aguilera Gonzales Carlos Alberto did not have good sanitary practices, was not registered, or permitted, and as a result the firm was temporarily shut down pending an investigation.

Through rigorous product testing, apple cinnamon fruit puree pouches manufactured by Austrofoods were implicated and recalled during this incident. Further testing also supported cinnamon as the contaminated ingredient. Lead was hypothesized to have been introduced into the cinnamon during the grinding process. FDA has no evidence to suggest contamination extends beyond these three products/brands.

Product & Firm Actions

On 10/29/2023 WanaBana issued a voluntary recall of all Austrofood manufactured apple cinnamon puree pouches. This recall included 2,998,088 units including Weis, Schnucks, and WanaBana brand apple cinnamon puree pouches distributed between November 2022 and October 2023 to the United States, Cuba, and United Arab Emirates. Of note, product was noted to have been sent to the United Arab Emirates, but the recall was initiated before it was received, so product was returned before distribution to stores. On 11/06/2023, Austrofood apple cinnamon puree was added to Import Alert 99-42 for detention without physical examination of foods due to heavy metal contamination. Import screening was put in place for colored spices from Ecuador, products containing cinnamon from Ecuador, cinnamon from Sri Lanka, and firms identified in traceback and traceforward.

Communications Overview

CDC issued an investigation notice on 11/13/2023 (Lead and Chromium Poisoning Outbreak Linked to Cinnamon Applesauce Pouches | Lead | CDC), a Health Advisory Network email on 11/13/2023 (Health Alert Network (HAN) - 00500 | High Blood Lead Levels in Children Consuming Recalled Cinnamon Applesauce Pouches (cdc.gov), a Clinical Outreach and Communication Activity on 01/05/2024 (COCA Now), and an initial Epi-X on 11/13/2023 with updates as warranted. FDA issued an initial webpost on 10/28/2023 (Investigation of Elevated Lead & Chromium Levels: Cinnamon Applesauce Pouches (November 2023) | FDA) and a recall notice on 11/09/2023 (WanaBana Recalls WanaBana, Weis, and Schnucks Apple Cinnamon Fruit Purée Pouches & Cinnamon Apple Sauce Due to Elevated Lead Levels | FDA with updates as warranted. INFOSAN issued a notice to international partners concerning FDA's investigation on WanaBana on 11/09/2023.

Conclusions

For this adverse illness event investigation, apple cinnamon puree pouches manufactured by Austrofood in Ecuador were confirmed as the vehicle for illness, with cinnamon as the likely source of lead and chromium contamination based on adverse event, laboratory, and traceback data. While cinnamon distributers and a cinnamon powder manufacturer were identified, these firms were under Ecuadorian authority and limited records and sampling information was available to FDA. Lead chromate was most likely added to cinnamon powder, not bark, and all cinnamon powder was distributed and manufactured in Ecuador.

INCIDENT COORDINATION GROUP

CFSAN - Coordinated Outbreak Response and Evaluation Network

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- Lead Coordinator: Natalie Cataldo
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AL, AR, CA, CT, FL, GA, IL, IN, IA, KY, LA, MD, MA, MI, MO, NE, NH, NJ, NM, NY, NC, OH, OK, PA, SC, TN, TX, VA, WA, WV, WI	

INCIDENT OBJECTIVES (ICS 202), Adapted for FDA

1. Incident Name: Lead and Chromium/Fruit Puree Pouches/Nov 2023	2. Operational Period: #8 Extension #1 Date From: 1/16/2024 @ 1300 EST Date To: 2/13/2024 @ 1300 EST

3. Objective(s):

(b)(5)

4. Operational Period Command Emphasis:

General Situational Awareness: On 10/31/2023, OC requested coordination assistance from CORE for an evolving investigation into elevated lead levels in apple cinnamon puree pouches. This product has been linked to 4 cases in children from NC who developed elevated blood lead levels after consuming the product. North Carolina Department of Health and Human Services (NCDHHS) conducted an investigation and identified WanaBana apple cinnamon fruit puree pouches as a potential shared source of exposure in the four children. OC is currently monitoring these NC illness investigations. There may possibly be a 5th case from MD linked to this product. On 10/30/2023, ORA received a consumer complaint for a child with high blood lead levels who consumed WanaBana applesauce pouches multiple times per day. This complaint review and ORA investigation are ongoing.

The apple sauce pouch product is manufactured by Austrofood CIA LDA (FEI: 3013416401) in Ecuador and imported by Wanabana, LLC/Wanabana (FEI: 3015811985) located Jacksonville, FL. Multiple lots of this product were tested by NCDHHS. Extremely high levels of lead were detected. In response to these results, and link to elevated blood levels in children, FDA issued a consumer safety advisory on 10/30/2023. Office of Compliance conducted an import analysis and found that other brands may have used products from Austrofood CIA LDA.

On 10/28/2023, results of the testing were shared with Austrofood CIA LDA, whose representatives agreed to voluntarily recall all WanaBana apple cinnamon fruit puree pouches regardless of expiration. The firm has began notifying their direct customers and on 10/29/2023 submitted a draft press release to OPCE ROB. Of note, CFSAN collected and tested an apple sauce pouch that was recalled. Results at the CFSAN lab also detected elevated lead consistent with NCDHHS findings. On 10/29/2023, DIO issued increased screening for apple products from 2 FEIs for Austrofood CIA LDA.

On 11/1/2023, OC issued a sampling assignment to ORA Divisions (HAF1E NWE-DO, NWY-DO; HAF2E PHI-DO, NWJ-DO, BLT-DO; HAF5E CIN-DO; HAF6E CHI-DO, DET-DO; HAF1W MIN-DO; HAF2W KAN-DO) for Weis and Shnucks products based on indications from imports that Austrofoods CIA LDA also supplied those brands and a sampling request to LFFM for WanaBana products containing cinnamon. On 11/1/2023, OC submitted a request to broaden the increased screening on Austrofoods CIA LDA to include all FEIs and all products exported. On 11/1/2023, this incident transferred to CORE Response Team 2 for further coordination.

On 11/2/2023, ORA shared that the cinnamon supplier for the recalled product was Negasmart SA (FEI: N/A, Ecuador) and that Austrofoods CIA LDA (Ecuador) is a processing facility owned by the same partners as WanaBana USA LLC (Jacksonville, FL). On 11/2/2023, ORA and LAO coordinated an inspection at Austrofoods CIA LTA (Ecuador) to occur in December 2023 or January 2024; CORE will assist on any potential additional assignment questions. On 11/2/2023, DIO and ORA collaborated to merge the multiple FEIs for Austrofood CIA LDA. On 11/2/2023, ORA sent a list of questions that will help determine suppliers, customers, and manufacturing processes for fruit puree products drafted by CORE and OC to Austrofood CIA LDA. Responses are expected within 24 hours. On 11/2/2023, CORE received 11 Consumer Complaints from 10/18-31/2023 and 2 CAERS from 11/2/2023; these are currently under review.

As of 11/3/2023, this incident includes 4 cases from NC from ages 1-3 years and 1 potential case from MD.

Operational Period #1 Accomplishments: On 11/2/2023, HAFE1 and HAFE2 collected Weis brand cinnamon applesauce (both samples were a product of USA not Ecuador). On 11/3/2023, HAFW1 collected WanaBana brand Apple Puree Pouches (without cinnamon). From 11/3-6/2023, ORS reported the Weis brand cinnamon applesauce (product of USA) collected by HAE1 and HAFE2, were below the limit of detection for lead and the Arizona Department of Health and Human Services reported 10

INCIDENT OBJECTIVES (ICS 202), Adapted for FDA

WanaBana fruit pouches (non-cinnamon) and the packaging were also non-detect for lead. On 11/3/2023, HAFE3 state liaison preliminarily reported that 7 samples collect by North Carolina Department of Agriculture (NCDA) were found to have lead levels between 1900-2400ppb; ORA/ORS will conduct technical reviews to corroborate findings. On 11/3/2023, the following adverse illness definition was established by FDA and CDC for the current incident: "Elevated blood lead levels of 3.5 ug/dL or higher, with no other known explanation or source of exposure, detected through laboratory testing in a person within 3 months after consuming a WanaBana apple cinnamon puree pouch product". On 11/3/2023, Schnuck Markets issued a recall for Schnuck-brand cinnamon applesauce pouches. On 11/3/2023, ORAE4 recalls provided information from WanaBana/Austrofoods including a consignee list and recall information. On 11/3/2023, an Epi-X communication was issued reporting FDA's advisory warning customers not to sell, eat, or serve WanaBana Apple Cinnamon Fruit Puree Pouches. On 11/3/2023, FDA updated their safety alert to include recall information for Schnuck and Weiss brand cinnamon applesauce. On 11/4/2023, LAO reported that the cinnamon used by the supplier Negasmart (Ecuador) is from Sri Lanka. On 11/4/2023, Minnesota Department of Health issued a press release urging people not to eat WanaBana apple cinnamon fruit pouches. On 11/5/2023, a firm call was held with Austrofoods (Ecudaor) to discuss future communications and questions regarding distribution, suppliers, and manufacturing processes. On 11/5/2023, Puerto Rico issued communications relaying FDAs safety alert for high lead levels in WanaBana applesauce with cinnamon. On 11/5/2023, OC submitted a request for increased screening (100% screening) for all cinnamon imported from Sri Lanka. From 11/3-5/2023, FDA received 8 consumer complaints and 5 CAERS. On 11/6/2023, LAO reported that NEGASMART (Ecuador), the cinnamon supplier for Austrofoods (Ecuador), is supplied cinnamon from [redacted] firms, (b)(4) [redacted]. On 11/6/2023, Weis Markets added Weis Quality Cinnamon Apple Sauce Pouches as a recalled product on their current recalls webpage.

As of 11/7/2023 this incident includes 11 complainants from AR (1), LA (1), MD (1), MO (1) NC (2), NM (1), OH (1), PA (1), WA (1), UNK (1). Ages range from 1-3.

Operational Period #2 Accomplishments: On 11/7/2023, 1 CAERS event and 1 CC event was reported to CORE. On 11/7/2023, sample F2300877-1, collected by Pennsylvania Department of Agriculture, was preliminarily reported by ORA to contain elevated levels of lead, 1418 ug/kg. This sample is Weis brand cinnamon applesauce COO Ecuador. ORA to review data package for final reporting. On 11/8/2023, sample FC2400004901, collected by Maryland State Department of Health, was preliminarily reported by ORA to contain elevated levels of lead, 6430 ug/kg. This sample is WanaBana brand apple cinnamon fruit puree COO Ecuador. ORA to review data package for final reporting. On 11/9/2023, a 50 states notification was sent requesting additional targeted Recall Audit Checks for the WanaBana voluntary recall of apple cinnamon fruit pouches. On 11/9/2023, ORA reported that FDA sample 1234871 collected by HAFW1 was above the referral level for lead, 2.18 ppm. This sample is WanaBana brand apple cinnamon puree (COO Ecuador). From 11/9-11/13/2023, 12 CAERS events and 10 CC events were reported to CORE.

As of 11/14/2023 this incident includes 29 complainants from AL (1), AR (1),CT(1), IL (1), LA (3), MD (1), MO (1), NE (1), NC (5), NM (1), NY (4), OH (1), PA (1), SC (2), TN (1), TX (1),VA(1), WA (1), UNK (1). Ages range from 0-3.

Operational Period #3 Accomplishments: Between 11/13-11/20/2023, 25 CAERS events and 26 CC events were reported to CORE. On 11/15/2023, a cinnamon sample was collected by the Division of Northeast Imports. This is FDA sample #1243159 produced by (b) (4) of Sri Lanka. On 11/15/2023, samples #1243217, #1243219, #1243222 of Mango, Passion Fruit and Banana Beverage (one sample) and Banana, Strawberry and Beet Beverage (two samples) from Austrofoods (COO Ecuador) were collected by the Division of Southeast Imports. On 11/21/2023, 3 Maryland LFFM samples were preliminarily reported by ORS to have elevated levels of lead. All 3 samples were WanaBana brand apple cinnamon fruit puree COO Ecuador with lead levels of 5930 ug/kg, 5850 ug/kg, and 6150 ug/kg. On 11/22/2023, a second call with Ecuadorian competent authorities for information sharing will be held.

As of 11/21/2023 this incident includes 48 complainants from AL (1), AR (1), CA (1), CT (1), FL (1), GA(1), IA (1), IL (2), KY (2), LA (4), MA (2), MD (2), MI (2), MO (1), NC (5), NE (1), NH (1), NM (1), NY (7), OH (2), SC (2), TN (1), TX (2), VA(1), WA (2), UNK (1). Ages range from 0-4.

Operational Period #4 Accomplishments: Between 11/21-11/28/2023, 10 CAERS events and 9 CC events were reported to CORE. On 11/21/2023, an Epi-X was sent by CDC to states asking them to identify possible cases, using their stratified case definition, and reporting those cases to CDC. On 11/22/2023, a firm call with Dollar Tree HQ occurred to discuss upcoming public communications and recall effectiveness. On 11/22/2023, FDA updated the web page to warn consumers not to purchase recalled product that is still available on shelves at Dollar Tree stores. On 11/22/2023, LOA provided the ARCSA (Ecuadorian sanitation authority) laboratory results for their samples of apple cinnamon puree, smooth mango passion fruit banana puree, and cinnamon collected. On 11/27/2023, DIO updated import screenings for cinnamon from Sri Lanka and Ecuador to only include ground cinnamon.

INCIDENT OBJECTIVES (ICS 202), Adapted for FDA

As of 11/28/2023 this incident includes 56 complainants from AL (1), AR (1), CA (1), CT (1), FL (1), GA (2), IA (1), IL (2), KY (3), LA (4), MA (3), MD (3), MI (3), MO (1), NC (5), NE (1), NH (1), NM (1), NY (8), OH (2), PA (1), SC (2), TN (1), TX(3), VA(1), WA (3). Age range is <1-5 years.

Operational Period #5 Accomplishments: Between 11/28-12/12/2023, 4 CAERS events and 1 CC events were reported to CORE. On 11/28/2023, HAFE4 provided additional laboratory method reports from Austrofoods for their 3 cinnamon samples. On 11/28/2023, CORE coordinated an SPTC for the foreign inspection team to review assignment questions related to the upcoming foreign inspection at Austrofoods (Ecuador). On 11/30/2023, samples #1244318, #1244320, #1244321, #1244468 of WanaBana brand mango passion fruit and banana beverage (COO Ecuador), Soursop Juice (COO Ecuador) manufactured by Austrofoods, WanaBana brand banana strawberry orange and beet beverage (COO Ecuador), and (b) (4) (COO Sri Lanka) were collected by the Division of Southeast Imports. On 12/1/2023, ORA/ORS reported that samples #1243935, #1244048, #1244053, and #1244057 were negative for elevated lead. On 12/1/2023, a 50-state notice was issued by FDA requesting state partner assistance to ensure removal of recalled WanaBana product from US Dollar Tree stores. On 12/4/2023, a 50-state conference call was held to discuss the FDA request for State assistance and what is needed to effectuate the WanaBana recall. On 12/4/2023, ORA/ORS reported that imported finished product samples #1244318, #1244320, #1244321 were negative for elevated lead levels. On 12/4/2023, import samples #1244698, #1244706, #1244712 of banana strawberry smoothie, strawberry raspberry blackberry smoothie, and mango apple passionfruit smoothie manufactured by Austrofoods were collected by the Division of Southeast Imports. On 12/5/2023, ORA Foreign Inspection Branch reported that they collected two cinnamon powder samples, #1085090 and #1085091, representing two different lots that were previously used in the production of recalled apple cinnamon puree. On 12/5/2023, samples #1244806, #1244808, #1244778, #1244811, #1244812, #1244813, #1244814, #1244816, #1244819 of banana strawberry beet smoothie, tropical blend smoothie, mango passionfruit banana smoothie, banana strawberry puree, soursop organic pouch, kale spinach mango puree, apple beet broccoli banana puree, and mango puree banana passionfruit puree manufactured by Austrofoods (Ecuador) were collected by the Division of Southeast Imports. On 12/5/2023, sample #1244914 of whole cinnamon (COO Sri Lanka) manufactured by (b)(4) was collected by the Division of Northeast Imports. On 12/6/2023, ORA/ORS reported that sample #1244468 (b) (4) (COO Sri Lanka) manufactured by (b)(4) was negative for elevated lead. On 12/11/2023, ORA/ORS reported that import samples #1244806, #1244808, #1244778, #1244811, #1244812, #1244813, #1244814, #1244816, #1244819, #1244698, #1244706, and #1244712 of banana strawberry beet smoothie, tropical blend smoothie, mango passionfruit banana smoothie, banana strawberry puree, soursop organic pouch, kale spinach mango puree, apple beet broccoli banana puree, mango puree, banana passionfruit puree, banana strawberry smoothie, strawberry raspberry blackberry smoothie, and mango apple passionfruit smoothie manufactured by Austrofoods were negative for elevated lead.

As of 12/12/2023 this incident includes 65 complainants from Adverse Events Distribution: AL (1), AR (1), CA (1), CT (1), FL (1), GA (2), IA (1), IL (3), KY (3), LA (4), MA (3), MD (6), MI (3), MO (1), NC (5), NE (2), NH (1), NM (1), NY (8), OH (3), PA (1), SC (2), TN (1), TX(3), VA(2), WA (3), WI (1), UNK (1). Age range is <1-5 years.

Operational Period #6 Accomplishments: Between 12/12/2023-01/02/2024, 14 CAERS events and 9 CC event were reported to CORE. On 12/11/2023, ORA/ORS reported that samples #1244806, #1244808, #1244778, #1244811, #1244812, #1244813, #1244814, #1244816, #1244819, #1244698, #1244706, and #1244712 of banana strawberry beet smoothie, tropical blend smoothie, mango passionfruit banana smoothie, banana strawberry puree, soursop organic pouch, kale spinach mango puree, apple beet broccoli banana puree, mango puree, banana passionfruit puree, banana strawberry smoothie, strawberry raspberry blackberry smoothie, and mango apple passionfruit smoothie manufactured by Austrofoods were negative for elevated lead. On 12/12/2023, sample #1245451 of cinnamon bark (COO Sri Lanka) produced by (b)(4) was collected by the Division of Northern Border Imports. On 12/13/2023, ORA/ORS reported that samples #1085090 and #1085091 collected by ORA foreign inspection branch, were found to have elevated lead levels of 5112 ppm and 2773 ppm. On 12/13/2023, ORA HAFW5 reported that 4 samples of WanaBana Apple Cinnamon puree pouches collected by Southern Nevada Health District were found to have elevated lead levels of 12,300 ppb, 11,400 ppb, 11,500 ppb, and 15,100 ppb. On 12/13/2023, sample #1245779 of whole cinnamon (COO Sri Lanka) manufactured by (b)(4) was collected by the Division of West Coast Imports. On 12/14/2023, CDC held a 50-states call. On 12/14/2023, ORA foreign inspection branch closed out their inspection at Austrofoods (Ecuador), issued a 4-item FDA-483, and 1551s were provided to the firm for the 2 cinnamon samples collected during the inspection. On 12/15/2023, ORA/ORS reported that import samples #1244914 and #1245451 of whole cinnamon (COO Sri Lanka) manufactured by (b)(4) and cinnamon bark (COO Sri Lanka) manufactured by (b)(4) were negative for elevated lead. On 12/15/2023, ORA Recalls Operations Branch issued a Recall Audit Check assignment request to all HAF divisions for 51 Family Dollar/Dollar Tree Combination Stores. On 12/19/2023, a call with ARCSA, Ecuador's competent authority, will be held to discuss traceback and traceforward information and sample results collected. On 12/15/2023, samples #1246195, #1246230, # 1246144, #1246146, #1246182, #1246184 of cinnamon sticks (COO Sri Lanka) were collected by the Division of West Coast Imports. On 12/20/2023, DIO requested the removal of cinnamon from Sri Lanka from import screening.

INCIDENT OBJECTIVES (ICS 202), Adapted for FDA

On 12/20/2023, ORA/ORS reported that import sample #1245779 of Cinnamon (b)(4) " manufactured by (b) (4) (COO Sri Lanka) was negative for elevated lead. On 12/20/2023, data packages for four samples # 23111073-02, #23111073-03, #23111073-05, #23111073-06 of Wanabana Apple Cinnamon Fruit Puree pouches were requested from Southern Nevada Department of Health for ORA/ORS review. On 12/21/2023, LAO provided requested documents from ARCSA describing their investigative findings into Austrofoods and Negasmart. On 12/20/2023, sample #1246503 of cinnamon sticks (COO Sri Lanka) manufactured by (b)(4) was collected by the Division of West Coast Imports. On 12/21/2023, sample #1246499 of cinnamon powder (COO Sri Lanka) manufactured by (b)(4) was collected by the Division of Northeast Imports. On 12/22/2023, FCC analyzed ground cinnamon samples #1085090 and #1085091 using an alternate light source (ALS) and found that the samples were not consistent with 2 locally purchased ground cinnamon powders purchased as controls. Additional analyses are ongoing to further characterize these samples. On 12/23/2023, sample #1234871 of apple cinnamon puree was reanalyzed by ORA/ORS and found to have .590 ppm of chromium, as well as the 2.231ppm of lead previously reported. On 12/26/2023, ORA/ORS reported that import samples #1246195, #1246230, #1246144, #1246146, #1246182, and #1246184 of whole and broken cinnamon (COO Sri Lanka) were negative for elevated lead. On 12/26/2023, 1 CAERS event was reported to CORE. On 12/27/2023, OAO provided an updated Human Health Assessment using the Austrofoods apple cinnamon puree recipe and lead/chromium levels found in FDA's sample #1234871. On 12/27/2023, HAFW5 collected and shipped one previously analyzed Nevada sample to FDA, sample #1234177, for reanalysis for lead and chromium. On 12/28/2023, ORA/ORS reported chromium levels of .809 ppm and .640 ppm for Virginia LFFM samples and 1.477 ppm, 1.567 ppm, 1.707 ppm, and 1.529 ppm for Maryland LFFM samples. On 12/28/2023, sample #1246940 of cinnamon powder (COO Sri Lanka) manufactured by (b) (4) was collected by the Division of West Coast Imports. On 12/28/2023, import samples #1246881, #1246883, #1246885, and #1246881 of frozen blackberry pulp, frozen lulo pulp, frozen mango pulp, and frozen pineapple chunks manufactured by Austrofoods (Ecuador) were collected by the Division of Northeast Imports. On 12/29/2023 ORA/ORS reported that sample #1234177 of WanaBana brand Apple Cinnamon Puree collected by Southern Nevada Health District was positive for elevated lead and chromium at 2.22 ppm and .556 ppm. On 12/29/2023, ORA/ORS reported that import samples #1246503 of cinnamon sticks (COO Sri Lanka) manufactured by (b)(4) and #1246499 of cinnamon powder (COO Sri Lanka) manufactured by (b)(4) were negative for elevated lead.

As of 1/02/2024 this incident includes 82 complainants from Adverse Events Distribution: AL (1), AR (1), CA (1), CT (1), FL (1), GA (2), IA (1), IL (5), IN (1), KY (3), LA (4), MA (3), MD (6), MI (7), MO (2), NC (5), NE (2), NH (1), NJ (1), NM (1), NY (8), OH (3), PA (2), SC (2), TN (3), TX(3), VA(2), WA (4), WI (2), WV (1), UNK (3).Age range is <1-53 years with 1 hospitalization.

Operational Period 7 Accomplishments: On 1/2/2024, sample #1247247 of cinnamon sticks (COO Sri Lanka) manufactured by (b)(4) was collected by the Division of West Coast Imports. On 1/3/2024, LAO provided responses from Negasmart (Ecuador) for questions posed regarding suppliers and cinnamon processing. On 1/4/2024, sample #1247311 of non-cinnamon containing fruit puree variety pack manufactured by Austrofoods was collected by the Division of Southeast Imports. On 1/5/2024, HAFE3 reported that South Carolina Department of Health and Environmental Control analyzed 1 sample of WanaBana apple cinnamon puree pouch with lead levels of 11ppm. FDA has requested a sample from the same pack is shipped to an FDA laboratory for analysis. On 1/5/2024, FDA updated their webpage to include information on chromium found in FDA samples of cinnamon powder and recalled apple puree products. On 1/5/2024, sample #1247722 of cinnamon powder (COO Sri Lanka) manufactured by (b)(4) was collected by the Division of West Coast Imports. On 1/5/2024, sample #1247722 of cinnamon powder (COO Sri Lanka) manufactured by (b)(4) was collected by the Division of West Coast Imports. On 1/7/2024, LAO provided responses from Negasmart to our questions and sample results for cinnamon from suppliers (b) (4) On 1/9/2024, ORA/ORS reported that import samples #1246940, #1246881, #1246883, #1246885, #1246881, #1247247, and #1247311 of cinnamon powder (COO Sri Lanka), frozen blackberry pulp (Austrofoods), frozen lulo pulp (Austrofoods), frozen mango pulp (Austrofoods), frozen pineapple chunks (Austrofoods), cinnamon sticks (COO Sri Lanka), and non-cinnamon containing fruit puree variety packs (Austrofoods) were negative for elevated lead. On 1/19/2024, ORA/ORS reported that import sample #1247722 of cinnamon powder (COO Sri Lanka) was negative for elevated lead. On 1/21/2024, LAO sent a laboratory certificate for lab samples conducted on behalf of Negasmart (Ecuador). On 1/22/2024, ORA Foreign Office reported that Austrofoods has begun manufacturing apple cinnamon puree for a new customer, (b)(4) , using a new cinnamon supplier, (b)(4) , a U.S. based company. They have requested information from DIO on how to begin importation into the United States. On 1/24/2024, FDA's Forensic Chemistry Center (FCC) reported cinnamon samples collected from Austrofoods were preliminarily determined to contain lead chromate by Ramon spectrometry.

As of 2/6/2024 this incident includes 90 complainants from Adverse Events Distribution: AL (1), AR (1), AZ (1), CA (1), CT (1), FL (1), GA (2), IL (5), IN (1), IA (1), KY (3), LA (4), MD (7), MA (3), MI (8), MO (3), NE (2), NH (1), NJ (1), NM (1), NY (8), NC (6), OH (3), OK (1), PA (2), SC (2), TN (3), TX (3), VA (2), WA (4), WV (3), WI (2), UNK (3). Age range is <1-53 years with 1 hospitalization.

INCIDENT OBJECTIVES (ICS 202), Adapted for FDA

5. Site Safety Plan Required? Yes ☐ No ☒
Approved Site Safety Plan(s) Located at:

6. Incident Action Plan (the items checked below are included in this Incident Action Plan)**:**

☐ICS 203☐ Map/Chart Other Attachments:
☐ICS 204☐ Weather Forecast/Tides/Currents☐
☐ICS 205☐
☐ICS 206☐
☐ICS 208☐

7. Prepared by: Margaret Kirchner Position/Title: Planning Chief Signature: *Margaret Kirchner*

8. Approved by Incident Commander: Name: Natalie Cataldo Signature: *Natalie Cataldo*

ICS 202	**IAP Page _____**	Date/Time: 2/6/2023 1400 EST

Updated by FDA 2/2011

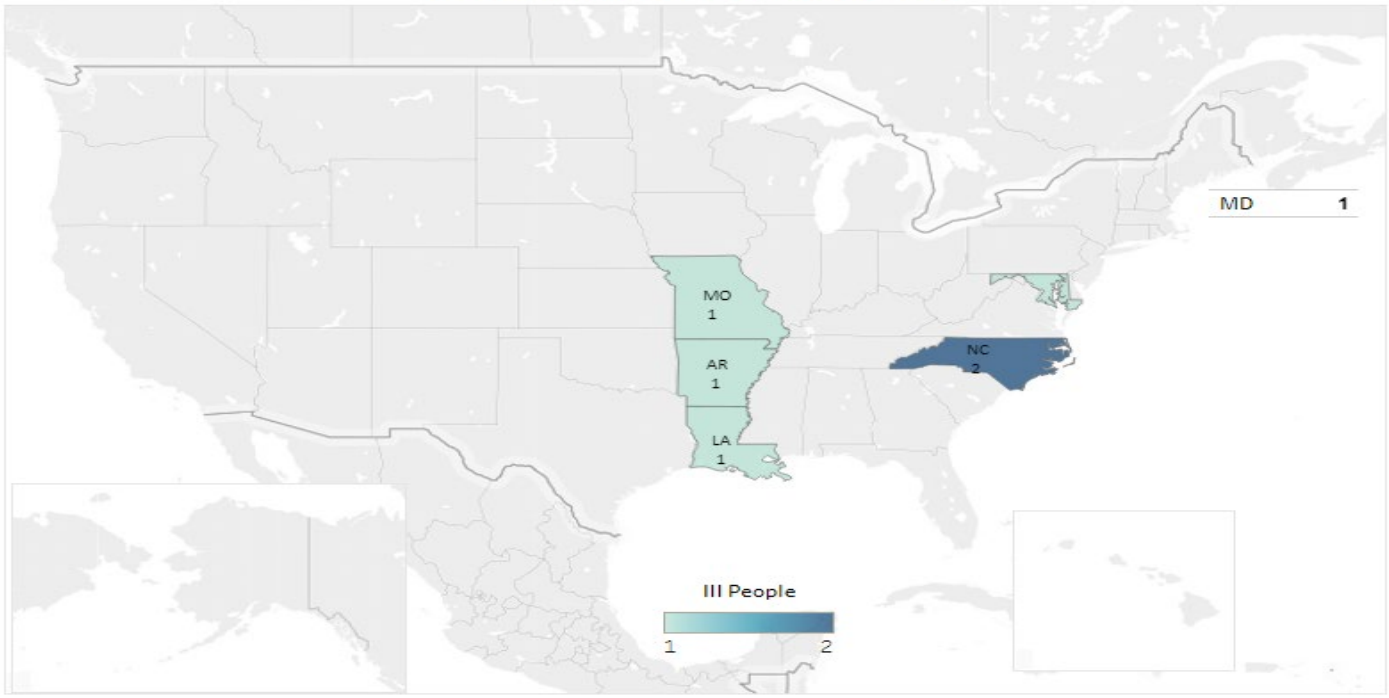
INCIDENT BRIEFING (ICS 201), Adapted for FDA

1. Incident Name: Lead/Fruit Puree Pouches/Nov 2023	2. CORE Incident Number: 1198	3. Date/Time Initiated: Date: 11/1/2023 Time: 4:00 PM

4. Map/Sketch

Date: 11/6/2023

Lead/Fruit Puree Pouches/Nov 2023



6. Prepared by: Name: Tiffany Greenlee Position/Title: Signals Team Member Signature:

ICS 201, Page 1 Date/Time: 11/1/2023 4:00 PM EDT

Updated by FDA 2/2011

INCIDENT BRIEFING (ICS 201), Adapted for FDA

1. Incident Name: Lead/Fruit Puree Pouches/Nov 2023	2. CORE Incident Number: 1198	3. Date/Time Initiated: Date: 11/1/2023 Time: 4:00 PM

5. Situation Summary and Health and Safety Briefing

On 10/31/2023, OC requested coordination assistance from CORE for an evolving investigation into elevated lead levels in apple cinnamon puree pouches. This product has been linked to 4 cases in children from NC who were reported to have developed elevated blood lead levels after consuming the product.

North Carolina Department of Health and Human Services (NCDHHS) conducted an investigation and identified WanaBana apple cinnamon fruit puree pouches as a potential shared source of exposure in the four children. OC is currently monitoring these NC illness investigations. There may possibly be a 5th case from MD linked to this product. On 10/30/2023, ORA received a consumer complaint for a child with high blood lead levels who consumed WanaBana applesauce pouches multiple times per day. This complaint review and ORA investigation are ongoing.

The apple sauce pouch product is manufactured by Austrofood CIA LDA (FEI: 3013416401) in Ecuador and imported by Wanabana LLC (FEI: 3015811985) located Jacksonville, FL. Wanabana LLC is a partner of Wanabana USA LLC. There is a relationship between the importing company and manufacturer in Ecuador, Austrofood is owned by the same partners as Wanabana USA LLC. In addition to Wanabana branded products, Austrofood also produces private label products for Weis and Schnucks. These are distributed under the private label (b)(4) . The Wanabana apple cinnamon fruit puree product contains a limited number of ingredients including apple puree, cinnamon powder, and citric acid. The cinnamon is sourced from Negasmart S. A. in Quito Ecuador.

Multiple lots of this product were tested by NCDHHS as part of 3 different lead investigations linked to children with lead poisoning. All samples were collected on 10/18/2023 from Dollar Tree ((b)(4) , NC). Extremely high levels of lead were detected on 10/24/2023 ranging from 2.5 mg/kg – 3.0 mg/kg. FDA review of lab results for two additional samples collected by NC county partners in August is pending. In response to these results, and link to elevated blood levels in children, FDA issued a consumer safety advisory on 10/30/2023.

On 10/28/2023, results of the testing were shared with Austrofood CIA LDA, whose representatives agreed to voluntarily recall all WanaBana apple cinnamon fruit puree pouches regardless of expiration. The firm has began notifying their direct customers and on 10/29/2023 submitted a draft press release to OPCE ROB. Of note, CFSAN collected and tested an apple sauce pouch that was recalled. Results at the CFSAN lab also detected elevated lead consistent with NCDHHS findings.

Additional product testing activities are underway to determine the scope of potential contamination among products produced by Astrofood. A testing request from ORA ORS was sent on 11/1/2023 to applicable state LFFM laboratories asking states to collect samples of Wanabana, Weis, and Shnucks brand pureed snack pouches, particularly focusing on any products that contain cinnamon. FDA product sampling activities for the apple cinnamon products are currently being conducted.

This incident will be transferred to RT2 based on the following rationale:
CORE coordination and support for an evolving incident involving illnesses linked to elevated lead levels in Apple Cinnamon Puree Pouches has been requested by CFSAN Office of Compliance. This product is consumed by children, a vulnerable population at risk for significant adverse outcomes from lead exposure, and the scope of the incident is rapidly expanding. CORE Response coordination is needed to support activities related to traceback, potential inspection and sampling activities, product actions, case finding, and public communications.

1. Incident Name: Lead/Fruit Puree Pouches/Nov 2023	2. CORE Incident Number: 1198	3. Date/Time Initiated: Date: 11/1/2023 Time: 4:00 PM

Exposure Table

No Exposure Table Available

6. Prepared by: Name: Tiffany Greenlee	Position/Title: Signals Team Member	Signature:
ICS 201, Page 2	Date/Time: 11/1/2023 4:00 PM EDT	

Updated by FDA 2/2011

INCIDENT BRIEFING (ICS 201), Adapted for FDA

1. Incident Name: Lead/Fruit Puree Pouches/Nov 2023	2. CORE Incident Number: 1198	3. Date/Time Initiated: Date: 11/1/2023 Time: 4:00 PM

7. Current and Planned Objectives:

(b)(5)

8. Current and Planned Actions, Strategies, and Tactics:

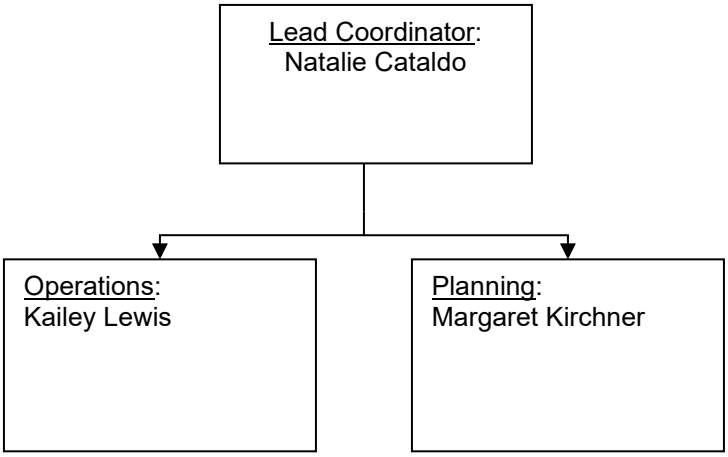
Time:	Actions:

6. Prepared by: Name: Tiffany Greenlee Position/Title: Signals Team Member Signature:

INCIDENT BRIEFING (ICS 201), Adapted for FDA

1. Incident Name: Lead/Fruit Puree Pouches/Nov 2023	2. CORE Incident Number: 1198	3. Date/Time Initiated: Date: 11/1/2023 Time: 4:00 PM

9. Current Organization (fill in additional organization as appropriate)**:**



6. Prepared by: Name: Tiffany Greenlee Position/Title: Signals Team Member Signature:

INCIDENT BRIEFING (ICS 201), Adapted for FDA

1. Incident Name: Lead/Fruit Puree Pouches/Nov 2023	2. CORE Incident Number: 1198	3. Date/Time Initiated: Date: 11/1/2023 Time: 4:00 PM

10. Resource Summary:

Resource	Resource Identifier	Date/Time Ordered	ETA	Arrived	Notes (location/assignment/status)
Maria Knirk	Office of Compliance				
Michael A McLaughlin	Office of Regulatory Science				
Lauren V Yeung	Office of Regulatory Science				
Katherine Arnold	Office of Compliance				
Scott MacIntire	Office of Human and Animal Foods Operations - West (OHAFO-W)				
Vinetta Howard King	Office of Human and Animal Foods Operations - East (OHAFO-E)				
Amy Barringer	Office of Compliance				
Erik Mettler					
Ann Oxenham	Office of Compliance				
Kristen C Jackson	Office of Compliance				
Reeba Roy	Office of Compliance				
Thomas Kuntz	Office of Compliance				
Katherine Arnold	Office of Compliance				

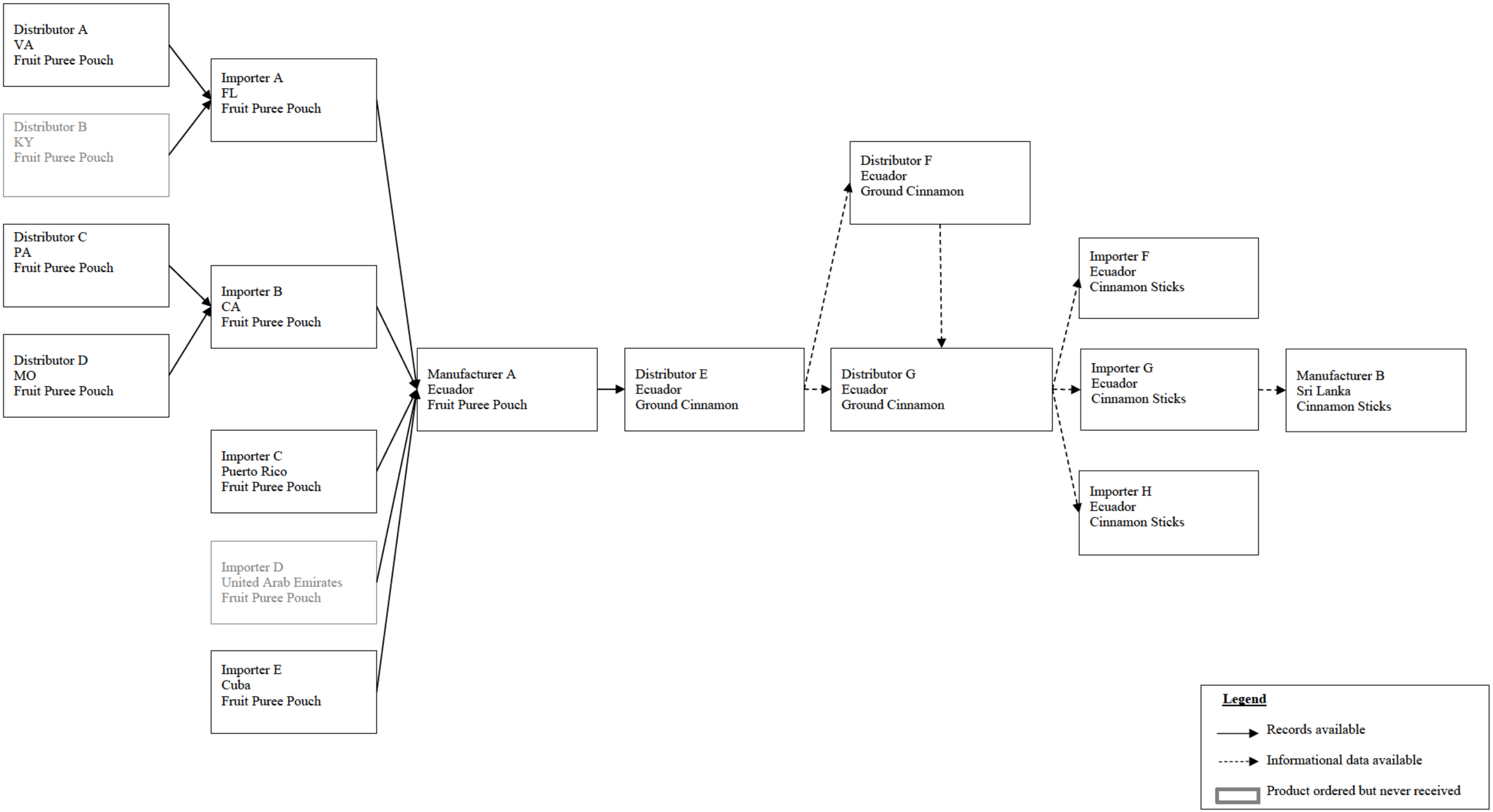
6. Prepared by: Name: Tiffany Greenlee Position/Title: Signals Team Member Signature:

1. Incident Name: Lead/Fruit Puree Pouches/Nov 2023	2. CORE Incident Number: 1198	3. Date/Time Initiated: Date: 11/1/2023 Time: 4:00 PM
10. Resource Summary:		
ICS 201, Page 4	Date/Time: 11/1/2023 4:00 PM EDT	

Updated by FDA 2/2011

Lead and Chromium/Fruit Puree Pouches/Nov2023

Traceback Flow Diagram



FDA

Coordinated Outbreak Response and Evaluation Network

[Date Created: 11/03/23, updated 02/06/24]

U.S. FOOD & DRUG ADMINISTRATION

Memorandum

Date: January 23rd, 2024

From: Supervisory Research Chemist, Chemical Contaminants Branch, HFS-716
CFSAN/ORS/DBC/CHCB

To: Katherine Arnold, Consumer Safety Officer
Division of Enforcement/Office of Compliance

Subject: Analytical Worksheet Review – Apple Cinnamon Fruit Purée
Work 543298
Task 721848
Sample FC2400004901

The analytical package from Maryland Department of Health supports the findings of 5.55 mg/kg lead (Pb) and 1.41 mg/kg chromium (Cr) in sample FC2400004901 - Wanabana Apple Cinnamon Fruit Purée in a pouch. This result is the average concentration from analyses of duplicate analytical portions taken from a composite. The composite was made from equal portions of 4 retail boxes of 3 pouches each, for a total of 12 subsamples. The sample was previously analyzed for Pb and those results were supported, and agree to the reanalysis within the expanded uncertainty. Using an average atomic mass of 207.2 amu for Pb, and 51.996 amu for Cr, the molar ratio of Pb to Cr was calculated to be 0.99.

The analysis method (**Modified** EAM 4.7 v1.2: Inductively Coupled Plasma-Mass Spectrometric Determination of Arsenic, Cadmium, Chromium, Lead, Mercury, and Other Elements in Food Using Microwave Assisted Digestion) was appropriate. The Cr results calculated in this memo differ slightly from those reported by MD Dept of Health. MD reported results using ^{52}Cr. However, ^{53}Cr has a lower polyatomic interference and better signal to background at m/z 53. In the analytical worksheet packages, the background equivalent concentration (false positive) was calculated as 2.4 ppb at m/z 52, and 0.25 at m/z 53. Therefore, due to the lower background, and better signal to background ratio, ^{53}Cr was used as the reporting isotope for chromium. Proper

method performance was demonstrated by quality control samples including blanks, a reference material, a fortified (spike) portion, and other quality controls. No problems or issues were identified with the analysis.

Patrick J. Gray -S

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Date: 2024.01.23 23:36:27 -05'00'

Patrick J. Gray, Ph.D.

U.S. FOOD & DRUG ADMINISTRATION

Memorandum

Date: November 22nd, 2023

From: Supervisory Research Chemist, Chemical Contaminants Branch, HFS-716
CFSAN/ORS/DBC/CHCB

To: Katherine Arnold, Consumer Safety Officer
Division of Enforcement/Office of Compliance

Subject: Analytical Worksheet Review – Apple Cinnamon Fruit Purée
Work 543298
Task 716125
Sample FC2400004901

The analytical package from Maryland Department of Health supports the findings of 6.43 mg/kg lead (Pb) in sample FC2400004901 - Wanabana Apple Cinnamon Fruit Purée in a pouch. This result is the average concentration from analyses of duplicate analytical portions taken from a composite. The composite was made from equal portions of 4 retail boxes of 3 pouches each, for a total of 12 subsamples.

The analysis method (Modified EAM 4.7 v1.2: Inductively Coupled Plasma-Mass Spectrometric Determination of Arsenic, Cadmium, Chromium, Lead, Mercury, and Other Elements in Food Using Microwave Assisted Digestion) was appropriate. Proper method performance was demonstrated by quality control samples including blanks, reference materials, a fortified (spike) portion of a similar sample, and other quality controls. No problems or issues were identified with the analysis. The reported limit of quantification was 0.028 mg/kg Pb.

Patrick J. Gray -S
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Date: 2023.11.22 09:42:24 -05'00'

Patrick J. Gray, Ph.D.

U.S. FOOD & DRUG ADMINISTRATION

Memorandum

Date: November 29th, 2023

From: Supervisory Research Chemist, Chemical Contaminants Branch, HFS-716
CFSAN/ORS/DBC/CHCB

To: Kristen Jackson, Regulatory Officer
Division of Enforcement/Office of Compliance

Subject: Analytical Worksheet Review – Apple Cinnamon Fruit Purée

Work	540580	
Task	716907	
Samples	ES230817-0129-001	2.3 mg/kg Pb
	ES230821-0001-001	1.9 mg/kg Pb

The North Carolina Department of Health and Human Services (NC DHHS) state analytical package supports the **semi-quantitative** findings of 2.3 mg/kg lead (Pb) in sample ES230817-0129-001, and 1.9 mg/kg lead (Pb) in sample ES230821-0001-001. Both samples were of the same product but were different lot numbers: Wanabana Apple Cinnamon Fruit Purée in a pouch. The analytical package did not include information on how the sample was homogenized, composited, or the number of subsamples.

Email communications with NC DHHS stated that the sample preparation method was EPA method 3050b – Acid Digestion of Sediments, Sludges, and Soils (modified) which included a nitric acid matrix decomposition by hot block at 95°C for two hours. Modifications include the use of 2 mL of concentrated HNO_3 and 2 mL of H_2O_2 instead of the continuous HNO_3 addition, and dilution to 50 mL instead of 100 mL. The NC DHHS hot block digestion procedure is less robust than the typical FDA closed vessel microwave digestion procedure at 200-250°C, may incompletely recover Pb, and consequently underestimate the concentration of Pb in foods. The levels reported should be treated as semi-quantitative lower estimates.

The analysis was done by Inductively Coupled Plasma Mass Spectrometry according to EPA 6020b with some minor modifications. There was no instrument tuning or performance report included to establish that the ICP-MS met the manufacturer specifications on the day of analysis but review of the instrument data indicate that the instrument was functioning properly. The lab did not include a spectral interference check solution, but it is unlikely that spectral interferences would overlap Pb isotopes at m/z 206, 207, or 208. Proper method performance was demonstrated by quality control samples including method blanks, a matrix blank, duplicate matrix spikes, independent calibration verification solution, and continuing calibration blank and continuing calibration verification solutions. These quality controls displayed acceptable recoveries. The lab also analyzed a laboratory control sample and indicated that its recovery was acceptable according to the laboratory SOP. The laboratory only analyzed a single analytical portion of the food, so it is not possible to calculate the average concentration from multiple portions.

The lab did not provide information to their limits of detection and quantification. A re-sampling of this food, analyzed using FDA EAM 4.7 or a similarly validated method, would provide increased confidence and a fully quantitative concentration of Pb.

Patrick J. Gray -S

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Date: 2023.11.29 12:21:40 -05'00'

Patrick J. Gray, Ph.D.

U.S. FOOD & DRUG ADMINISTRATION

Memorandum

Date: October 27th, 2023

From: Supervisory Research Chemist, Chemical Contaminants Branch, HFS-716
CFSAN/ORS/DBC/CHCB

To: Katherine Arnold, Consumer Safety Officer
Division of Enforcement/Office of Compliance

Subject: Analytical Worksheet Review – Apple Cinnamon Fruit Purée
Case 540580
Task 714174
Samples ES231020-0007-003
ES231020-0007-007
ES231020-0007-008

The North Carolina Department of Health and Human Services (NC DHHS) state analytical package supports the findings of 2.5 mg/kg lead (Pb) in sample ES231020-0007-003, 2.9 mg/kg lead (Pb) in sample ES231020-0007-007, and 3.0 mg/kg lead (Pb) in sample ES231020-0007-008. All three samples were of the same product: Wanabana Apple Cinnamon Fruit Purée in a pouch. The analytical package did not include information on how the sample was homogenized or composited or the number of subsamples.

The sample preparation method was EPA method 3050b – Acid Digestion of Sediments, Sludges, and Soils (modified) which included a nitric acid matrix decomposition by hot block at 95°C for two hours. Modifications include the use of 2 mL of concentrated HNO_3 and 2 mL of H_2O_2 instead of the continuous HNO_3 addition, and dilution to 50 mL instead of 100 mL. The NC DHHS hot block digestion procedure is less robust than the typical FDA closed vessel microwave digestion procedure at 200-250°C, may incompletely recover Pb, and consequently underestimate the concentration of Pb in foods. The levels reported should be treated as semi-quantitative lower estimates.

The analysis was done by Inductively Coupled Plasma Mass Spectrometry according to EPA 6020b with some minor modifications. There was no instrument tuning or performance report included to establish that the ICP-MS met the manufacturer specifications on the day of analysis but review of the instrument data indicate that the instrument was functioning properly. The lab did not include a spectral interference check solution, but it is unlikely that spectral interferences would overlap Pb isotopes at m/z 206, 207, or 208. Proper method performance was demonstrated by quality control samples including method blanks, a matrix blank, duplicate matrix spikes, independent calibration verification solution, and continuing calibration blank and continuing calibration verification solutions. These quality controls displayed acceptable recoveries. The lab also analyzed NIST 3299 Ground Turmeric (Curcuma longa L.) Rhizome standard reference material with a 76% recovery. This recovery was acceptable according to the laboratory SOP. However, it is indictive of an incomplete Pb recovery from the food sample, further supporting the concentrations measured as lower estimates of the true Pb concentration in the samples. The laboratory only analyzed a single analytical portion of the food so it is not possible to calculate the average concentration from multiple portions.

The lab did not provide information to their limits of detection and quantification. However, the signal intensity measured in the method and matrix blanks were three orders of magnitude less than the sample signal intensity and it can be concluded that the concentrations in the food samples were far above the laboratory limits of detection and quantification. A re-sampling of this food, analyzed using FDA EAM 4.7 or a similarly validated method, would provide increased confidence and a fully quantitative concentration of Pb.

Patrick J. Gray -S

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Date: 2023.10.27 14:15:59 -04'00'

Patrick J. Gray, Ph.D.

U.S. FOOD & DRUG ADMINISTRATION

Memorandum

Date: November 9th, 2023

From: Supervisory Research Chemist, Chemical Contaminants Branch, HFS-716
CFSAN/ORS/DBC/CHCB

To: Kristen Jackson, Regulatory Officer
Division of Enforcement/Office of Compliance

Subject: Analytical Worksheet Review – Apple Cinnamon Fruit Purée

Case	542482	
Task	715558	
Samples	FDC0222755	2.49 mg/kg Pb
	FDC0222756	2.16 mg/kg Pb
	FDC0222757	2.53 mg/kg Pb
	FDC0222758	2.45 mg/kg Pb
	FDC0222759	3.19 mg/kg Pb
	FDC0222760	2.41 mg/kg Pb

The analytical package from North Carolina Department of Agriculture and Consumer Services Food and Drug Protection Division Laboratory supports the findings of 2.49 mg/kg lead (Pb) in sample FDC 0222755, 2.16 mg/kg lead (Pb) in sample FDC 0222756, 2.53 mg/kg lead (Pb) in sample FDC 0222757, 2.45 mg/kg lead (Pb) in sample FDC 0222758, 3.19 mg/kg lead (Pb) in sample FDC 0222759, and 2.41 mg/kg lead (Pb) in sample FDC 0222760. All six samples were of the same product but were different lot numbers: Wanabana Apple Cinnamon Fruit Purée in a pouch. These results are the average concentrations from analyses of duplicate analytical portions taken from a composite. Samples FDC 0222755, FDC 0222756, FDC 0222757, FDC 0222759 and FDC 0222760 composites were made from equal portions of 7 subsamples. Sample FDC 0222758 composite was made from equal portions of 4 subsamples.

The analysis method (FDPD-TM.1042, Analysis of Total Elements in Food Products by ICP-MS) was appropriate. This method is based on FDA Elemental Analytical Manual Method 4.7, Inductively Coupled Plasma-Mass Spectrometric Determination of Arsenic, Cadmium,

Chromium, Lead, Mercury, and Other Elements in Food Using Microwave Assisted Digestion, versions 1.0 (2013). 1.1 (2015), and 1.2 (2020). Proper method performance was demonstrated by quality control samples including blanks, reference materials, a fortified (spike) portion, and other quality controls. No problems or issues were identified.

Patrick J. Gray -S

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Date: 2023.11.09 15:04:11 -05'00'

Patrick J. Gray, Ph.D.

U.S. FOOD & DRUG ADMINISTRATION

Memorandum

Date: November 8th, 2023

From: Supervisory Research Chemist, Chemical Contaminants Branch, HFS-716
CFSAN/ORS/DBC/CHCB

To: Kristen Jackson, Regulatory Officer
Division of Enforcement/Office of Compliance

Subject: Analytical Worksheet Review – Apple Cinnamon Fruit Purée

Case	542585	
Task	715397	
Samples	ES231027-0014-001	3.1 mg/kg Pb
	ES231027-0014-002	1.9 mg/kg Pb
	ES231027-0014-003	5.2 mg/kg Pb
	ES231027-0014-004	5.2 mg/kg Pb

The North Carolina Department of Health and Human Services (NC DHHS) state analytical package supports the **semi-quantitative** findings of 3.1 mg/kg lead (Pb) in sample ES231027-0014-001, 1.9 mg/kg lead (Pb) in sample ES231027-0014-002, 5.2 mg/kg lead (Pb) in sample ES231027-0014-003, and 5.2 mg/kg lead (Pb) in sample ES231027-0014-003. All four samples were of the same product but were different lot numbers: Wanabana Apple Cinnamon Fruit Purée in a pouch. The analytical package did not include information on how the sample was homogenized, composited, or the number of subsamples. The NC State Laboratory of Public Health certificate of analysis was written for environmental dust wipes and was inappropriate for food samples. However, the sample preparation and instrumental data worksheets indicated that the analysis was appropriate for food samples.

Email communications with NC DHHS stated that the sample preparation method was EPA method 3050b – Acid Digestion of Sediments, Sludges, and Soils (modified) which included a nitric acid matrix decomposition by hot block at 95°C for two hours. Modifications include the use of 2 mL of concentrated HNO_3 and 2 mL of H_2O_2 instead of the continuous HNO_3 addition, and

dilution to 50 mL instead of 100 mL. The NC DHHS hot block digestion procedure is less robust than the typical FDA closed vessel microwave digestion procedure at 200-250°C, may incompletely recover Pb, and consequently underestimate the concentration of Pb in foods. The levels reported should be treated as semi-quantitative lower estimates.

The analysis was done by Inductively Coupled Plasma Mass Spectrometry according to EPA 6020b with some minor modifications. There was no instrument tuning or performance report included to establish that the ICP-MS met the manufacturer specifications on the day of analysis but review of the instrument data indicate that the instrument was functioning properly. The lab did not include a spectral interference check solution, but it is unlikely that spectral interferences would overlap Pb isotopes at m/z 206, 207, or 208. Proper method performance was demonstrated by quality control samples including method blanks, a matrix blank, duplicate matrix spikes, independent calibration verification solution, and continuing calibration blank and continuing calibration verification solutions. These quality controls displayed acceptable recoveries. The lab also analyzed NIST 3299 Ground Turmeric (Curcuma longa L.) Rhizome standard reference material with a 79% recovery. This recovery was acceptable according to the laboratory SOP. However, it is indictive of an incomplete Pb recovery from the food sample, further supporting the concentrations measured as lower estimates of the true Pb concentration in the samples. The laboratory only analyzed a single analytical portion of the food, so it is not possible to calculate the average concentration from multiple portions.

The lab did not provide information to their limits of detection and quantification. However, the signal intensity measured in the method and matrix blanks were three orders of magnitude less than the sample signal intensity and it can be concluded that the concentrations in the food samples were far above the laboratory limits of detection and quantification. A re-sampling of this food, analyzed using FDA EAM 4.7 or a similarly validated method, would provide increased confidence and a fully quantitative concentration of Pb.

Patrick J. Gray -S

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Date: 2023.11.08 15:57:36 -05'00'

Patrick J. Gray, Ph.D.

U.S. FOOD & DRUG ADMINISTRATION

Memorandum

Date: November 27th, 2023

From: Supervisory Research Chemist, Chemical Contaminants Branch, HFS-716
CFSAN/ORS/DBC/CHCB

To: Katherine Arnold, Consumer Safety Officer
Division of Enforcement/Office of Compliance

Subject: Analytical Worksheet Review – Apple Cinnamon Fruit Purée
Work 544354
Task 716883
Sample ES231101054

The Virginia Division of Consolidated Laboratory Services state analytical package requires reanalysis before it can be supported. The laboratory finding of 3.36 mg/kg lead (Pb) in sample ES231101054 - Wanabana Apple Cinnamon Fruit Purée in a pouch fell outside the calibration range and cannot be supported with the current analytical worksheet packet. Only one sample was submitted to the lab so there was no composite.

The lab analyzed sample ES231101054 with duplicate dilution factors. The initial digestion resulted in a test solution above the calibration range, and the second 1000x further dilution resulted in a test solution with concentration less than the lab's analytical solution quantification limit (ASQL). The laboratory should prepare new duplicate analytical portions so that analytical test solution concentrations fall within the calibration range.

Patrick J. Gray -S

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Date: 2023.11.27 15:45:56 -05'00'

Patrick J. Gray, Ph.D.

U.S. FOOD & DRUG ADMINISTRATION

Memorandum

Date: December 27th, 2023

From: Supervisory Research Chemist, Chemical Contaminants Branch, HFS-716
CFSAN/ORS/DBC/CHCB

To: Katherine Arnold, Consumer Safety Officer
Division of Enforcement/Office of Compliance

Subject: Analytical Worksheet Review – Apple Cinnamon Fruit Purée
Sample 1234871 reanalysis to include chromium

The analytical package from Kansas City Laboratory supports the findings of 2.23 mg/kg lead (Pb), and 0.590 mg/kg chromium (Cr) in sample 1234871: Wanabana Apple Cinnamon Fruit Purée in a pouch. This concentration is the average from analyses of duplicate analytical portions. Each analytical portion was taken from a composite made from equal portions of 16 subsamples. The sample composite was previously analyzed for Pb only and that analytical package supported 2.18 mg/kg Pb. The two results agree within 3%.

The analysis method (EAM 4.7 v1.2: Inductively Coupled Plasma-Mass Spectrometric Determination of Arsenic, Cadmium, Chromium, Lead, Mercury, and Other Elements in Food Using Microwave Assisted Digestion) was appropriate. Proper method performance was demonstrated by quality control samples including blanks, reference materials, a fortified (spike) portion, and other quality controls. No problems or issues were identified with the analysis.

Patrick J. Gray -S

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Date: 2023.12.27 10:55:17 -05'00'

Patrick J. Gray, Ph.D.

U.S. FOOD & DRUG ADMINISTRATION

Memorandum

Date: November 15th, 2023

From: Supervisory Research Chemist, Chemical Contaminants Branch, HFS-716
CFSAN/ORS/DBC/CHCB

To: Katherine Arnold, Consumer Safety Officer
Division of Enforcement/Office of Compliance

Subject: Analytical Worksheet Review – Apple Cinnamon Fruit Purée
Sample 1234871

The analytical package from Kansas City Laboratory supports the findings of 2.18 mg/kg lead (Pb) in sample 1234871: Wanabana Apple Cinnamon Fruit Purée in a pouch. This concentration is the average from analyses of duplicate analytical portions. Each analytical portion was taken from a composite made from equal portions of 16 subsamples.

The analysis method (EAM 4.7 v1.2: Inductively Coupled Plasma-Mass Spectrometric Determination of Arsenic, Cadmium, Chromium, Lead, Mercury, and Other Elements in Food Using Microwave Assisted Digestion) was appropriate. Proper method performance was demonstrated by quality control samples including blanks, reference materials, a fortified (spike) portion of a similar sample, and other quality controls. No problems or issues were identified with the analysis.

Patrick J. Gray -S
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Date: 2023.11.15 21:48:59 -05'00'

Patrick J. Gray, Ph.D.

U.S. FOOD & DRUG ADMINISTRATION

Memorandum

Date: February 15th, 2024

From: Supervisory Research Chemist, Chemical Contaminants Branch, HFS-716
CFSAN/ORS/DBC/CHCB

To: Katherine Arnold, Consumer Safety Officer
Division of Enforcement/Office of Compliance

Subject: Analytical Worksheet Review – Ground Cinnamon
Samples 1085090 and 1085091

Samples 1085090 and 1085091 were previously analyzed at the FDA Kansas City Laboratory. The KCL analytical worksheet package supported the findings of 5110 mg/kg lead (Pb) and 1200 mg/kg chromium (Cr) in sample 1085090: Negasmart ground cinnamon. The analytical package also supported the findings of 2270 mg/kg lead (Pb) and 531 mg/kg chromium (Cr) in sample 1085091: Negasmart ground cinnamon. These concentrations were the averages from analyses of duplicate analytical portions of each sample. Each analytical portion was taken from a composite made from equal portions of 12 subsamples.

The analytical packages from the Cincinnati Forensic Chemistry Center (FCC) support the findings of a lead-to-chromium (Pb:Cr) molar ratio of 1.03 ± 0.064 in sample 1085090-1 and a Pb:Cr molar ratio of 0.978 ± 0.061 in sample 1085091-1. The test portions (lab samples) that were analyzed by Raman spectroscopy were also used to measure the molar ratio of Pb:Cr by inductively coupled plasma mass spectrometry (ICP-MS). The expected molar ratio of $PbCrO_4$ is 1.00. FCC also analyzed 3 different $PbCrO_4$ control materials and reported Pb:Cr ratios of 0.979 ± 0.061, 0.994 ± 0.062, and 1.00 ± 0.062.

The FCC analysis method was modified from EAM 4.7 v1.2: Inductively Coupled Plasma-Mass Spectrometric Determination of Arsenic, Cadmium, Chromium, Lead, Mercury, and Other

Elements in Food Using Microwave Assisted Digestion.[1] The following method deviations were noted by FCC:

1. Samples were not digested using a microwave digestion system; rather, samples were dissolved using HNO_3 and heated to 50 °C while sonicating overnight.
2. A smaller sample mass was used than recommended (~0.2 mg versus 250 mg)
3. Standards and second dilutions of samples were prepared in 5% HNO3.
4. Internal standard was only ^{103}Rh in 5% HNO_3, no HCl or isopropyl alcohol was included in the internal standard to reduce $^{40}Ar^{12}C$ interference on ^{52}Cr.
5. Only Pb and Cr were reported as they were the target analytes.
6. Due to sample preparation related to Raman analysis, the reconciliation of the sample mass was not possible, therefore the quantitated results only related to the solutions analyzed and should not be used to determine the concentrations of Pb and Cr in samples 1085090-1 and 1085091-1 as received.
7. Quality Assurance measures such as reproducibility (only one preparation for each sample was deemed necessary), FAP, and FAS were not included due to the goals of this analysis.
8. A standard reference material, NIST SRM 1643f: Trace Elements in Water was used to verify calibration curve accuracy.

The analytical worksheet package supports the Pb:Cr molar ratio in the same material used for Raman spectroscopy. The method modifications were appropriate. All samples, blanks, and control samples were processed using identical method modifications. Proper method performance was demonstrated by control samples including blanks and reference materials. No problems or issues were identified with the analysis.

Patrick J. Gray -S

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Patrick J. Gray, Ph.D.

1. Gray, et. al., Inductively Coupled Plasma Collision Cell Quadrupole Mass Spectrometric Determination of Extractible Arsenic, Cadmium, Chromium, Lead, Mercury, and Other Elements in Food Using Microwave-Assisted Digestion: Results from an FDA Interlaboratory Study, *Journal of AOAC INTERNATIONAL*, Volume 102, Issue 2, 1 March 2019, Pages 590–604, https://doi.org/10.5740/jaoacint.18-0129

U.S. FOOD & DRUG ADMINISTRATION

Memorandum

Date: December 13th, 2023

From: Supervisory Research Chemist, Chemical Contaminants Branch, HFS-716
CFSAN/ORS/DBC/CHCB

To: Katherine Arnold, Consumer Safety Officer
Division of Enforcement/Office of Compliance

Subject: Analytical Worksheet Review – Ground Cinnamon
Samples 1085090 and 1085091

The analytical package from Kansas City Laboratory supports the findings of 5110 mg/kg lead (Pb) and 1200 mg/kg chromium (Cr) in sample 1085090: Negasmart ground cinnamon. The analytical package also supports the findings of 2270 mg/kg lead (Pb) and 531 mg/kg chromium (Cr) in sample 1085091: Negasmart ground cinnamon. These concentrations are the averages from analyses of duplicate analytical portions of each sample. Each analytical portion was taken from a composite made from equal portions of 12 subsamples.

The analysis method (EAM 4.7 v1.2: Inductively Coupled Plasma-Mass Spectrometric Determination of Arsenic, Cadmium, Chromium, Lead, Mercury, and Other Elements in Food Using Microwave Assisted Digestion) was appropriate. Proper method performance was demonstrated by quality control samples including blanks, reference materials, a fortified (spike) portion of a similar sample, and other quality controls. No problems or issues were identified with the analysis.

Patrick J. Gray -S
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Date: 2023.12.13 22:52:02 -05'00'

Patrick J. Gray, Ph.D.

U.S. FOOD & DRUG ADMINISTRATION

Memorandum

Date: November 21st, 2023

From: Supervisory Research Chemist, Chemical Contaminants Branch, HFS-716
CFSAN/ORS/DBC/CHCB

To: Katherine Arnold, Consumer Safety Officer
Division of Enforcement/Office of Compliance

Subject: Analytical Worksheet Review – Apple Cinnamon Fruit Purée
Sample F2300877-1

The analytical package from the Pennsylvania Department of Agriculture requires further information before it can be supported. The worksheets included the sample preparation and digestion information, but there were no instrumental data printed from the software. The data in unlocked excel sheets should be printed directly from the (b)(4) software before it can be supported. Please ask the PA Dept. of Ag. to submit the instrumental raw data and then reissue a task to CFSAN/ORS.

Patrick J. Gray -S
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Date: 2023.11.21 14:00:08 -05'00'

Patrick J. Gray, Ph.D.

U.S. FOOD & DRUG ADMINISTRATION

Memorandum

Date: December 3rd, 2023

From: Supervisory Research Chemist, Chemical Contaminants Branch, HFS-716
CFSAN/ORS/DBC/CHCB

To: Katherine Arnold, Consumer Safety Officer
Division of Enforcement/Office of Compliance

Subject: Analytical Worksheet Review – Apple Cinnamon Fruit Purée **revised December 3rd, 2023**
Sample F2300877-1

The analytical package supports the findings of 1.44 mg/kg lead (Pb) in sample F2300877-1: Wanabana Apple Cinnamon Fruit Purée in a pouch. This concentration is the average from analyses of duplicate analytical portions. Email communication with the Pennsylvania State Department of Agriculture laboratory confirmed that the Pb isotope correction equation was used, and this memo is an update to a previous memo dated November 28th.

The analysis method (EAM 4.7 v1.2: Inductively Coupled Plasma-Mass Spectrometric Determination of Arsenic, Cadmium, Chromium, Lead, Mercury, and Other Elements in Food Using Microwave Assisted Digestion) was appropriate. Proper method performance was demonstrated by quality control samples including blanks, reference materials, a fortified (spike) portion of a similar sample, and other quality controls.

Patrick J. Gray -S

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Date: 2023.12.03 13:52:24 -05'00'

Patrick J. Gray, Ph.D.

U.S. FOOD & DRUG ADMINISTRATION

Memorandum

Date: November 28th, 2023

From: Supervisory Research Chemist, Chemical Contaminants Branch, HFS-716
CFSAN/ORS/DBC/CHCB

To: Katherine Arnold, Consumer Safety Officer
Division of Enforcement/Office of Compliance

Subject: Analytical Worksheet Review – Apple Cinnamon Fruit Purée
Sample F2300877-1

The analytical data package supports the **semi-quantitative** result of 1.44 mg/kg Pb in sample F2300877-1: Apple Cinnamon Fruit Purée. The analysis method (EAM 4.7 v1.2: Inductively Coupled Plasma-Mass Spectrometric Determination of Arsenic, Cadmium, Chromium, Lead, Mercury, and Other Elements in Food Using Microwave Assisted Digestion) was appropriate. Method performance was demonstrated by quality control samples including blanks, a reference material, a fortified (spike) portion of a similar sample, and other quality controls.

The Pennsylvania Department of Agriculture analytical package requires further information before it can be **quantitively** supported. The lab analyzed only ^{208}Pb. Lead isotope abundances vary by geographic location and the isotopic abundance of Pb in the calibration standards may be different than the area where the food was grown. The acceptable procedure to account for geographic variation of Pb isotopes is to sum the measured intensities of ^{206}Pb, ^{207}Pb, and ^{208}Pb. FDA EAM method 4.7 accounts for this correction in section 4.7.7: Instrument Setup. If other isotopes were measured and the isotope sum correction equation was used, those data were not shown in either the instrument raw data, or in the excel data calculation sheets. The missing isotope correction equation does not mean that the apple cinnamon fruit purée was without Pb contamination/adulteration. However, the missing correction equation prevents CFSAN/ORS from supporting these **quantitative** results and conclusion.

Patrick J. Gray -S

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Patrick J. Gray, Ph.D.