pennsylvania DEPARTMENT OF HEALTH

PENNSYLVANIA DEPARTMENT OF HEALTH 2024— PAHAN –734-1-17-UPD

Update: Call for Cases of Elevated Lead Levels: Chromium Found in Recalled Applesauce Pouches - January 2024

DATE:	01/17/2024
TO:	Health Alert Network
FROM:	Debra L. Bogen, MD, FAAP, Acting Secretary of Health
SUBJECT:	Update: Call for Cases of Elevated Lead Levels: Chromium Found in Recalled Applesauce Pouches - January 2024
DISTRIBUTION:	Statewide
LOCATION:	Statewide
STREET ADDRESS:	n/a
COUNTY:	n/a
MUNICIPALITY:	n/a
ZIP CODE:	n/a
This transmission is a "Health Update" that provides updated information regarding an incident	

HOSPITALS: PLEASE SHARE WITH ALL MEDICAL, PEDIATRIC, INFECTION CONTROL, NURSING AND LABORATORY STAFF IN YOUR HOSPITAL EMS COUNCILS: PLEASE DISTRIBUTE AS APPROPRIATE; FQHCs: PLEASE DISTRIBUTE AS APPROPRIATE; LOCAL HEALTH JURISDICTIONS: PLEASE DISTRIBUTE AS APPROPRIATE; PROFESSIONAL ORGANIZATIONS: PLEASE DISTRIBUTE TO YOUR MEMBERSHIP

or situation; no immediate action necessary.

Summary

- This is a follow up to <u>PAHAN-730</u>.
- FDA product testing has identified high levels of chromium, in addition to lead, in cinnamon samples and recalled applesauce pouch products, including WanaBana, Schnucks, and Weis brands. Updates about the investigation can be found on the FDA website and the CDC website.
- Chromium is a naturally occurring element found throughout nature and can be found in several forms, most commonly as chromium (0), chromium (III), and chromium (VI). The form of chromium will determine the potential for toxicity, where chromium (III) is far less toxic than chromium (VI).
- While harm resulting from ingesting lead-contaminated food is relatively <u>well researched</u>, the health effects of eating food contaminated with chromium are not well understood.
- Due to limitations in available testing methods and samples, FDA was unable to definitively determine the form of chromium in the cinnamon or contaminated pouch products.
- Risk estimates of consuming 1 or 2 of the contaminated products every day for 15-365 days suggest there is a very low risk for non-cancerous adverse health effects. These estimates assume 100% of the detected chromium is chromium (VI), which is highly unlikely but is a "worst-case" scenario.
- If patients or clinicians are concerned or suspect chromium overexposure, a general clinical workup for anemia would be appropriate, since this is the health effect associated with the duration of exposure.
- Since chromium (III) is an essential nutrient and is naturally found in food, chromium will be detected in blood, urine, and hair. Concentrations of chromium in blood or urine cannot be used to predict health effects that might develop from chromium overexposure.
- More information on chromium can be found on the <u>ATSDR website</u>.
- Healthcare providers can refer to CDC's <u>COCA Now</u> announcement for information for additional guidance.
- For more information on childhood lead exposure in Pennsylvania, visit <u>Lead (pa.gov)</u> or contact PA DOH at 1-877-PA-HEALTH or by sending a secure email to <u>RA-DHBOE-RESPONSE@pa.gov</u> if you have any questions.

Background

Lead exposure can have serious consequences for children's and pregnant persons' health. Lead is ubiquitous in the environment; unfortunately, we cannot see, taste, or smell lead. Lead is much more harmful to children and pregnant persons because it can affect children's developing nervous systems and brains.

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.

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.

Chromium 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 (PbCrO4) (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.

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, and/or renal and hepatic dysfunction.

As of January 8, 2024, there have been 87 reports of adverse events potentially linked to recalled product submitted to <u>FDA</u>. To date, the age range of complainants is younger than 1 year to 53 years of age, and the median age is one year old.

The Centers for Disease Control and Prevention (CDC) is also providing <u>updates</u> on this investigation. As of January 5, 2024, CDC has received 321 reports from 38 states.

FDA's investigation is ongoing to determine the point of contamination and whether additional products are linked to illnesses.

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.

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

- Call an <u>FDA Consumer Complaint Coordinator</u> if you wish to speak directly to a person about vour problem.
- Complete an electronic Voluntary MedWatch form online.
- Complete a paper Voluntary MedWatch form that can be mailed to FDA.

Visit www.fda.gov/fcic for additional consumer and industry assistance.

Recommendations

For healthcare providers For Possible Lead Exposure:

- Review recall information, including pictures of the specific item being recalled. This information is available on the FDA website.
- Healthcare providers can refer to CDC's <u>COCA Now</u> announcement for information for additional guidance.
- Providers should raise awareness about the recalled products among patients or parents and recommend testing, as appropriate.
- Consider blood lead testing for individuals if they consumed these products or are exposed to other potential lead sources.
- The CDC is coordinating with state and local health departments to ascertain information from
 individuals with higher blood lead levels potentially associated with consuming recalled
 WanaBana, Schnucks, and Weis brand fruit purée products after November 2022. This is
 important to understand the scope and magnitude of the outbreak with respect to geography
 and time. Please refer to the CDC website for more information.
- Providers should report individuals with blood lead levels of 3.5 µg/dL or higher detected through venous, capillary or unspecified testing within 3 months after consuming a WanaBana, Schnucks, or Weis brand cinnamon applesauce or apple purée product containing cinnamon after November 2022 to PA DOH by securely emailing the following information to RA-DHBOE-RESPONSE@pa.gov or by fax: 717-772-6975.
- For additional information regarding the recall, providers can contact the PA DOH by securely sending an email to RA-DHBOE-RESPONSE@pa.gov.
- Laboratories and health care providers are required to report all blood lead test results, regardless of the lead level, for persons under 16 years of age to PA DOH through Pennsylvania's electronic disease surveillance system, PA-NEDSS. Individuals who need a PA-NEDSS account should complete a <u>Prime Contact Information Form</u> and send the completed form to <u>PA-NEDSS@pa.gov</u>.

For healthcare providers For Possible Chromium Exposure:

- Acute ingestion of chromium exceeding dietary recommendations may result in abdominal pain, nausea, vomiting, diarrhea, anemia, and/or renal and hepatic dysfunction.
- Medical treatment for chromium exposure is supportive as indicated from the clinical presentation. There is no specific antidote to treat chromium exposure, and there is no evidence to support the use of chelation therapy.
- Consider obtaining a urinalysis and comprehensive metabolic panel (CMP) including electrolytes, liver enzymes, and BUN/creatinine to assess for hepatic and renal injury. A complete blood count (CBC) can be used to assess for anemia and iron deficiency. These tests may be indicated at the discretion of the treating physician.
 - Consider tests for any patients who consumed recalled applesauce products and have concerning or persistent symptoms that cannot be readily explained, such as vomiting and diarrhea or signs of anemia.
 - Give priority to patients with higher blood lead levels (e.g. 10 µg/dL or higher).
- Clinicians may consider testing urine, blood, or serum chromium levels but results may be difficult to interpret and do not guide clinical management.

- Chromium levels in blood or urine reflect recent exposures and are not reflective of body burden. These lab tests are generally used to assess workers exposed to high levels in occupational settings via dermal or inhalational routes of exposure.
- Mean chromium levels in the general U.S. population are below limits of detection (LOD) in whole blood (LOD=0.41 μg/L) and urine (LOD=0.19 μg/L), as reported in the CDC National Report on Human Exposure to Environmental Chemicals. There is no international consensus on a normal or acceptable range of chromium levels and no established threshold at which toxicity occurs.
- Hair and nail samples are not reliable sample types to assess chromium exposure.
- Contact your local poison center (1-800-222-1222) for advice on diagnosing and managing lead and chromium toxicity.
- Consider consulting a <u>medical toxicology specialist</u> or a <u>Pediatric Environmental Health Specialty Unit (PEHSU)</u> expert for guidance regarding individual patients.

For parents and consumers:

- Encourage individuals to dispose of the recalled products immediately, consult a healthcare
 provider to see if testing is warranted if they or their child ate the product, and report previous
 consumption of the product to the provider if the individual has elevated blood lead levels.
- Consumers should not eat, sell, or serve these recalled products. Consumers should immediately stop using them and return them to the place of purchase for a full refund. Consumers with questions can contact WanaBana at support@wanabanafruits.com, or the Schnucks Customer Care team at 314-994-4400 or 1-800-264-4400, or the Weis Customer Service number at 866-999-9347.
- These products have a long shelf life. Consumers should check their homes and discard these products.
- 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.
- Contact your healthcare provider if you think you or your child may have symptoms of lead toxicity after eating recalled fruit pouches.

Additional resources on childhood lead exposure

- Lead Poisoning (pa.gov)
 - Elevated Blood Lead Level Resources (pa.gov)
 - Lead Poisoning FAQ (pa.gov)
- Childhood Lead Poisoning Prevention Program | CDC
- PA DOH lead information 1-800-440-LEAD

For questions, please call your local health department or PA DOH at 1-877-PA-HEALTH (877-724-3258).

Individuals interested in receiving future PA-HANs can register at https://ondemand.mir3.com/han-pa-gov/login/.

Categories of Health Alert messages:

Health Alert: conveys the highest level of importance; warrants immediate action or attention.

Health Advisory: provides important information for a specific incident or situation; may not require immediate action. **Health Update**: provides updated information regarding an incident or situation; unlikely to require immediate action.

This information is current as of January 17, 2024, but may be modified in the future.