

INVESTIGATION OF LEAD IN APPLESAUCE POUCHES



DAVID NICHOLAS, MPH
 CHIEF EPIDEMIOLOGIST, OUTBREAK INVESTIGATION AND RESEARCH
 BUREAU OF COMMUNITY ENVIRONMENTAL HEALTH AND FOOD PROTECTION

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Background and Initial Steps

- October 17, 2023: North Carolina Department of Health and Human Services alerted U.S. Food and Drug Administration (FDA)
 - Four children with lead exposure potentially linked to consumption of cinnamon applesauce pouches
 - Blood lead levels $\geq 5 \mu\text{g}/\text{dL}$ identified through routine testing
 - Investigators identified a single brand of cinnamon applesauce as a potential shared source of exposure
 - Lab testing of products found lead concentrations 1.9-3 ppm (19 to 30 times higher than FDA's proposed action level)
- October 28, 2023: FDA issued public health alert
- October 30, 2023: Firm issued a voluntary recall
 - November 9, 2023: Firm expanded the recall to include two other brands produced by same manufacturer





Photos: FDA Source: Kual and Yeh, CDC 2024

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CDC Health Alert Network Advisory: 11/13/2023

High Blood Lead Levels in Children Consuming Recalled Cinnamon Applesauce Pouches



Distributed via the CDC Health Alert Network
 November 13, 2023, 2:00 PM ET
 CDC-HAN-02500

Distribution:

- Clinician Outreach and Communication Activity (COCA) listserv of ~64,000 self-subscribers and 100 organizations
- Public health officials at state, local, tribal, and territorial levels
- CDC's Emergency Preparedness & Response website
- Epi-X Network, ~6,000 public health professionals
- ~9,500 media and professional partners
- ~79,000 HAN self-subscribers

Source: Kual and Yeh, CDC 2024

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CDC National Call for Cases - 11/21/2023

Within 3 months of consuming a recalled product after November 2022: (date when product became available to retail consumers)

Suspect case:
 Blood lead level (BLL) $\geq 3.5 \mu\text{g}/\text{dL}$ through capillary or unspecified testing (not yet confirmed through venous blood testing)

Probable case:
 Venous BLL $\geq 3.5 \mu\text{g}/\text{dL}$, but

- Did not have a follow-up assessment to rule out other potential sources of lead exposure, or
- Did have a follow-up assessment completed, but the results indicated another source of lead exposure

Confirmed case:
 Venous BLL $\geq 3.5 \mu\text{g}/\text{dL}$, and follow-up assessment ruled out other sources as the likely cause of lead exposure

Source: Kual and Yeh, CDC 2024

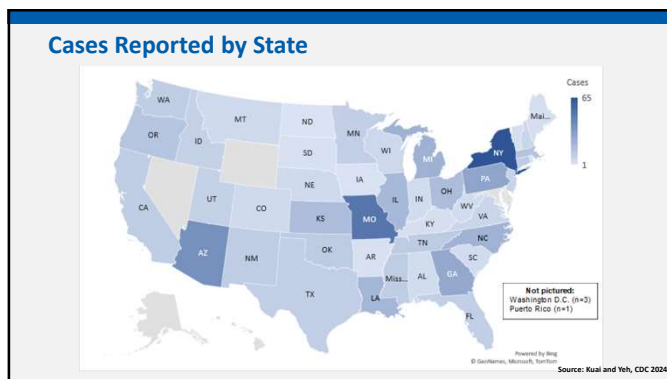
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CDC National Call for Cases: 11/21/2023 – 4/12/2024

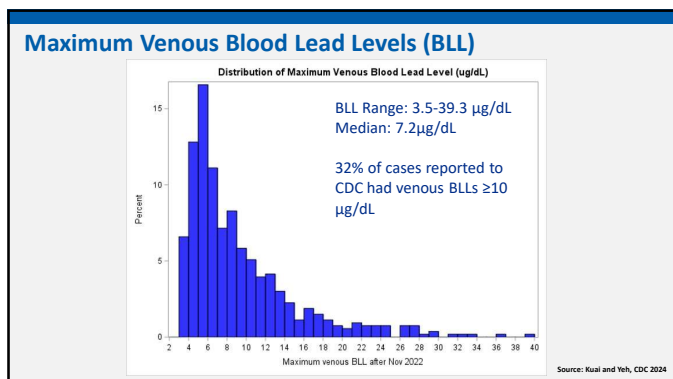
- 44 states, Washington D.C., and Puerto Rico submitted case data:** AL, AR, AZ, CA, CO, CT, FL, GA, IA, ID, IL, IN, KS, KY, LA, MA, ME, MI, MN, MO, MS, MT, NC, ND, NE, NH, NJ, NM, NY, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VA, VT, WA, WI, WV
- 566 total cases**
 - Suspect: 35 (6.2%)
 - Probable: 401 (70.8%)
 - Confirmed: 130 (23.0%)
- Maximum within-person venous blood lead level:**
 3.5–39.3 $\mu\text{g}/\text{dL}$ (median 7.2 $\mu\text{g}/\text{dL}$)

Source: Kual and Yeh, CDC 2024

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Symptoms Reported Among Cases

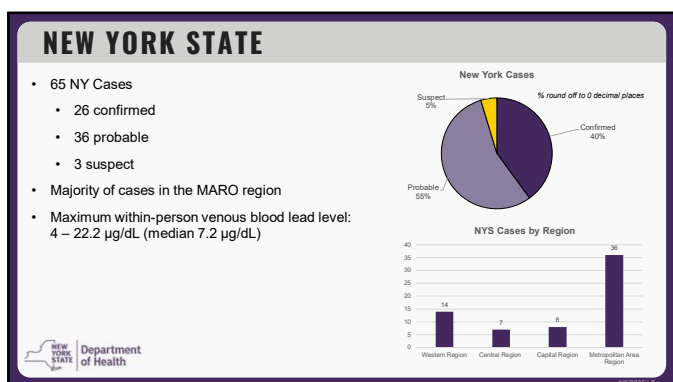
Among 405 of 566 persons with cases who had documented symptom data

Any symptoms	81 (20.0%)	Any developmental / behavioral symptoms	35 (8.6%)
Any GI symptoms	55 (13.6%)	Altered mood or behavior	23 (5.7%)
Abdominal pain	17 (4.2%)	Developmental symptoms	18 (4.4%)
Constipation	15 (3.7%)	Lethargy / fatigue	17 (4.2%)
Vomiting/nausea	16 (4.0%)	Headaches	10 (2.5%)
Diarrhea	10 (2.5%)	Other	22 (5.4%)
Other GI symptoms	21 (5.2%)		

Most individuals with cases were asymptomatic (324, 80%)

Source: Kval and Yeh, CDC 2024

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COCA Now

CDC Clinician Outreach and Communication Activity

January 5, 2024

Update on High Blood Lead Levels in Children Consuming Recalled Cinnamon Applesauce Pouches and Potential Chromium Exposure

- COCA Now Advisory published by CDC on January 5, 2024
- Targeted communication sent to physicians and other clinicians
- Included guidance on assessing for adverse effects of chromium in addition to lead exposure
- One-page fact sheet for lay audience in English and Spanish also published

Lead Exposure

The Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA), as well as state and local officials are investigating a link between blood lead levels (BLLs) ≥ 5 $\mu\text{g}/\text{dL}$ and children consuming certain apple puree and applesauce products containing cinnamon. Wanabana, Schrock's, and Weis brands have voluntarily recalled certain lots of the following products that were tested and found to contain high levels of lead:

- Wanabana brand apple cinnamon fruit puree pouches
- Schrock's brand cinnamon-flavored applesauce pouches
- Weis brand cinnamon applesauce pouches

CDC's National Center for Environmental Health (NCEH) and FDA's Coordinated Outbreak Response & Evaluation (CORE) Network continue investigations to identify individuals across the United States who may have consumed these products with high levels of lead. Updates about the investigation can be found on the FDA's website, [Investigation of Elevated Lead Levels, Cinnamon Applesauce Pouches \(November 2023\) | FDA](#). More details about case identification are available on CDC's website, [Lead Poisoning Outbreak Linked to Cinnamon Applesauce Pouches](#). Additional information for clinicians can be found in the CDC Health Advisory published November 13, 2023, [Health Alert Network \(HAN\) 00500 | High Blood Lead Levels in Children Consuming Recalled Cinnamon Applesauce Pouches](#).

Source: Kval and Yeh, CDC 2024

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- ### Limitations
- Cases were likely underreported
 - Required testing within 3 months of consuming the product
 - Younger children were more likely to be tested than older children, adolescents, and adults
 - Some retailers did not remove the product from their shelves, so ongoing exposure was possible
 - Limited information on symptoms and consumption patterns
 - Chromium exposure doses and valence forms were unknown, due to lab method limitations and potential conversion of chromium (VI) to chromium (III)
 - Uncertainty in some cases whether there were potential sources of lead exposure other than cinnamon applesauce
 - Differences among states:
 - Some states had more resources to conduct more thorough investigations
 - States have different childhood blood lead screening guidelines (e.g. universal vs. targeted)
- Source: Kval and Yeh, CDC 2024

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- ### Summary and Future Considerations
- Consumption of lead chromate-contaminated applesauce pouches resulted in at least several hundred cases of lead exposure in children nationwide
 - 32% of cases reported to CDC had venous BLLs ≥ 10 $\mu\text{g}/\text{dL}$
 - Long-term health effects of eating food contaminated with lead chromate are not well understood
 - Increased product testing, with an emphasis on foods intended for young children, may help identify and remove contaminated products
 - Secondary prevention with BLL testing and follow-up care as needed remains an essential tool for identifying children exposed to lead and sources of lead exposure
- Source: Kval and Yeh, CDC 2024

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THANK YOU! ANY QUESTIONS?



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