The Integrated Consortium of Laboratory Networks Newsletter

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The Integrated Consortium of Laboratory Networks (ICLN) is a system of interconnected federal laboratory networks that can quickly respond to high-consequence incidents and give decision makers timely, credible, and interpretable data.

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FDA and FERN Laboratories Provide Quick Answers During WanaBana Cinnamon Applesauce Illness Investigations

The Food Emergency Response Network (FERN) is jointly organized and managed by HHS/FDA and USDA/FSIS. Using FERN labs, the FDA administers the Laboratory Flexible Funding Model (LFFM) which consists of cooperative agreements with state, territorial, tribal, and local laboratories for analytical work in chemical, microbiological, and radiological testing of food and feed. FERN is an integral part of the ICLN.

North Carolina Department of Health and Human Services (NC DHHS) was notified of elevated blood Lead (Pb) levels in young children. During their investigation of the Pb exposure, NC DHHS tested samples from the home/environment of the subject children. Laboratory testing discovered elevated Pb levels in WanaBana Cinnamon Apple Puree. In October 2023, NC DHHS notified FDA of these findings. Based on the NC DHHS findings, FDA issued a consumer advisory.

In November 2023, FDA leveraged LFFM state collection and analytical capacity to address an urgent need to test WanaBana/Weis/Schnucks products, which were all implicated early in the investigation. Initially, there were many unknowns. The LFFM laboratories were tasked with testing the related fruit purees to assist in determining the scope of the contamination in products produced by Austrofoods.

Within 6 calendar days (4 business days), LFFM labs and State Regulatory Partners (SRPs) collected 97 samples for toxic element analysis. 12 LFFM laboratories conducted testing as part of the priority testing effort. In addition, North Carolina Department of Agriculture (NCDA) tested the original samples collected by NC DHHS to confirm the elevated Pb levels. LFFM laboratories along with FDA laboratories effectively supported testing related to this complaint/illness investigation and demonstrated successful use of available surge capacity during a food safety emergency. LFFM and FDA labs tested both the fruit purees and packaging. Data generated confirmed that only the WanaBana Apple Cinnamon

Continued on next page

Continued from previous page

puree was implicated, and that only the WanaBana Apple Cinnamon puree produced in Ecuador was implicated. Cinnamon was determined to be the source of the contaminant.

Samples with elevated lead (Pb) levels were found by 4 states (MD, PA, NC, VA) and by FDA. These findings resulted in a data package submission for potential inclusion in pending FDA regulatory and compliance actions. These activities directly impacted public health, allowing isolation and removal of adulterated product in domestic and international commerce.

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

Vet-LIRN's Role in the Response to a Multi-State Outbreak of *Clostridium botulinum* in Horses

In December 2022, the Food and Drug Administration (FDA) Center for Veterinary Medicine (CVM) received an adverse event report describing neurologic illness in nine horses at a single farm in Louisiana. Eight horses died or were euthanized. All affected horses consumed the same brand of bagged commercial alfalfa cubes from a single lot and manufacturing site. Visual inspection of the cubes identified embedded animal tissue and fur. Given the clinical signs observed, rule out of other causes, and presence of the animal tissue, contamination of the cubes with *Clostridium botulinum* toxin was suspected as the cause of illness and death. Following the initial report, FDA-CVM received reports from four other states documenting similar complaints of neurologic illness and death in horses consuming the implicated cubes. FDA-CVM's Veterinary Laboratory Investigation and Response Network (Vet-LIRN) assisted with this multi-state outbreak investigation by reviewing animal medical records and conducting exposure interviews with animal owners. A Vet-LIRN laboratory identified the species of the embedded animal tissue, which aided in both root cause analysis and future mitigation efforts. Overall, FDA-CVM received reports of illness involving more than 97 horses, of which 57 died or were euthanized.

Equine botulism is a neurologic toxicosis in horses caused by exposure to potent neurotoxins produced by the bacteria *C. botulinum*. The neurotoxins, categorized as type A through G based on their antigenic differences, can cause neurologic symptoms such as flaccid paralysis, stumbling and uncoordinated movement, drooling, difficulty swallowing, muscle tremors, and respiratory paralysis. Equine botulism is typically caused by neurotoxin types A, B, and C, and is often fatal. Exposure to *C. botulinum* and its associated toxins occurs most commonly by consumption of spoiled or contaminated feed. Because of the embedded animal tissue and fur in the cubes and the consistent neurologic signs observed in the exposed horses, contamination of the feed with *C. botulinum* toxin leading to equine botulism was suspected.

C. botulinum type C toxin was identified in the alfalfa cubes. The FDA's Office of Regulatory Affairs (ORA) within the Office of Regulatory Science (ORS) tested the cubes using the mouse bioassay. Additionally, filth analysis was completed on the samples to try to identify the species of the animal tissue and fur imbedded in the cubes. To further identify the species of animal, Vet-LIRN worked with their network laboratory, the Animal Disease Diagnostic Laboratory at Purdue University (ADDL). Through previous Vet-LIRN grant funding, ADDL developed a method for meat speciation using a targeted next-generation sequencing panel for identification of animal species in pet foods. A subsample of mammalian tissue from the cubes was tested at ADDL using this panel. The results were a 100% match with domestic goat.

The coordinated effort to identify the tissue sample found in the implicated product highlights Vet-LIRN's mission of coordinating a network of laboratories with the goal of protecting human and animal health. Through cooperative agreements, network laboratories develop methods that can be used to support testing during adverse events affecting FDA-regulated products. Identification of animal species is a critical analytical tool for determining the type and origin of meat products. Understanding the cause of illness and source of the toxin can help support future mitigation efforts.