



E. coli O157:H7/Cheddar Cheese/Feb 2024

Executive Incident Summary Report

CARA #1215

Date: 04/29/2024

Authors:

CORE Signals & Surveillance Team: Tiffany Greenlee, MPH

CORE Response Team 3: Stranjae' Ivory, MPH

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EXECUTIVE SUMMARY

Notification

On 2/9/2024, CORE Signals was notified by CDC about an *E. coli* O157:H7 cluster (2402MLEXH-1) with an early signal for raw dairy products. At the time of notification, there were seven cases in three states: CA (4), CO (2), and TX (1).

Epidemiology Overview & WGS

As of 4/29/2024, there are 11 cases in five states [CA (4), CO (3), NJ (1), TX (1), and UT (2)]. Reported onset dates (n=11) ranged from 10/18/2023 to 2/5/2024. Ages ranged from 2 to 75 years (median: 25 years) and four of 11 cases (36%) were female. Of 11 patients with outcome information, five (45%) were hospitalized. Two patients developed HUS, and there were no reported deaths. Cases were defined as isolate highly related to the cluster clade by cgMLST with isolation dates from 10/19/2023 to 2/7/2024.

All isolates were related within 0-2 alleles by cgMLST with common allele code EC1.0 - 8.1.217.1. Isolates in this investigation were originally uploaded to the National Database where cgMLST analysis showed they were related to each other within 0-7 alleles. California state partner epidemiologists confirmed that one patient was a genetic and epidemiologic outlier. CDC agreed and adjusted the case definition to exclude the patient which narrowed the allele range among outbreak isolates to 0-2 allele differences.

Among cases with food exposure information, seven out of 10 cases (70%) reported consuming Raw Farm-brand Raw Cheddar cheese in the week before illness onset. This percent was higher than the 4.9% of people who said yes to consuming raw milk cheese on the FoodNet [Pop Survey](#), indicating Raw Farm-brand Raw Cheddar cheese as the source of the outbreak.

Field Investigations & Findings

CORE issued three assignments for traceback record collection. All assignments were conducted remotely and closed out with no FDA-Form 483 issued.

On 2/21/2024, CORE Response issued eNSpect assignment (#240258) to Office of Regulatory Affairs Human and Animal Food 4 West (DEN-DO) for traceback data collection at (b)(4)) for the six points of sale identified in the traceback investigation. Although (b)(4) does not maintain lot code information, receipts for direct deliveries from Raw Farm LLC did contain some lot code data. Estimated expiration dates were determined for the corresponding shipments of Raw Farm LLC cheese with available lot code information. Records did not contain shipments of Raw Farm LLC cheese to one

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of the reported (b)(4)) during the timeframe of interest. The eNSpect assignment #240258 closed on 3/5/2024.

On 2/21/2024, CORE Response issued eNSpect assignment (#240269) to Office of Regulatory Affairs Human and Animal Food 5 West (SAN-DO) for traceback data collection at (b)(4)) for the one point of sale identified in the traceback investigation. (b)(4) does not maintain lot code records. Therefore, lot code and expiration dates for Raw Farm-brand Raw Cheddar cheese from (b)(4) are missing from the traceback investigation. The eNSpect assignment #240269 closed on 2/26/2024.

On 3/6/2024, CORE Response issued eNSpect assignment (#240967) to Office of Regulatory Affairs Human and Animal Food 6 East (CHI-DO) for traceback data collection at (b)(4)) was identified as the distribution center for four non- (b)(4)) that were reported. Traceback records contained lot code and expiration dates for identified shipments of Raw Farm LLC cheese during the timeframe of interest. The eNSpect assignment #240967 closed on 3/21/2024.

A traceback data collection assignment was drafted for **Raw Farm LLC** (Fresno, CA; FEI: 3021306495) to document shipment and lot code information. However, the FDA Office of Chief Counsel advised against issuing the assignment due to ongoing litigation activities and communication challenges with the firm. Therefore, the assignment was not issued. CORE recommends assignment data requests be followed up on if the opportunity presents in future discussions with the firm to help inform root cause analyses as deemed appropriate.

Laboratory Sample Overview

The outbreak strain was not detected in any product samples collected during this outbreak investigation. 90 state samples were collected by California, Colorado, and Utah state partners. Due to chain of custody issues, seven of the samples were excluded for analysis. Of the remaining 83 samples, Office of Regulatory Affairs Office of Regulatory Science's Denver Laboratory (DENLHAF) analyzed one sample.

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Traceback Abbreviated Summary

Analysis of two traceback legs representing seven cases was initiated on 2/21/2024. All cases included in the traceback investigation reported exposure to Raw Farm-brand Raw Cheddar cheese prior to illness onset. Exposure/onset dates ranged from 10/2/2023 to 1/24/2024. The timeframe of interest for record collection was identified as 8/1/2023 through 1/24/2024. Raw Farm-brand Raw Cheddar cheese (block and shredded) was traced from seven points of sale. For shipments where lot code information was available, the traceback investigation identified dates of expiry for the Raw Farm-brand Raw Cheddar (shredded and block) cheese which is 4/22/2024 and 7/13/2024, respectively.

Product & Firm Actions

On 2/16/2024, Raw Farm LLC recalled certain lots of cheese produced up until or older than the following: Raw Cheddar Cheese – Pound Block (16oz) #20231113-1, Raw Cheddar Cheese – Half Pound Block (8oz) #20231113-1, Raw Cheddar Cheese – Half Pound Shred (8oz) #20240116. On 2/26/2024, Raw Farm LLC issued a Press Release and Notice to Consumers to withdraw and conclude their Voluntary Recall.

On 2/21/2024, ORA HAF 5 West (SAN-DO) informed CORE Response that (b)(4) pulled all of the Raw Farm-brand Raw Cheddar cheese in their possession at this point and halted the ability to order new product until following back up with FDA. On 3/1/2024, ORA HAF 4 West (DEN-DO) informed CORE Response that (b)(4) placed a block on the sale (since 2/16/2024) of all Raw Farm-brand Raw Cheddar cheese products.

Raw Farm LLC has a history of non-compliance resulting in an FDA Warning Letter and a Court Order of Permanent Injunction, which imposed restrictions from distributing in interstate commerce raw milk and raw kefir products for human consumption (injunction did not cover the aged raw cheese linked to this outbreak); at the time of this investigation additional legal proceedings and discussions were ongoing.

Communications Overview

On 2/16/2024, FDA released an [Outbreak Advisory](#) and CDC released a [Food Safety Alert](#) related to this incident. On 2/28/2024, FDA released an updated [Outbreak Advisory](#) and CDC released an updated [Food Safety Alert](#) related to this incident acknowledging the update to Raw Farm LLC's Press Release and recall withdrawal; FDA's consumer advice did not change. On 3/26/2024, FDA released an updated [Outbreak Advisory](#) and CDC released an updated/final [Food Safety Alert](#) related to this incident. In CDC's updated/final communication on 3/26/2024, CDC declared the conclusion of the outbreak investigation. This outbreak was reported to NORS with ID: 2402MLEXH-1.

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Conclusions

Epidemiologic and traceback evidence confirmed the vehicle as cheddar cheese (unpasteurized/raw milk cheddar cheese). Although we don't know how the contamination occurred, Raw Farm-brand Raw Cheddar cheese was determined to be the source of the outbreak. At the conclusion of this response, there are 11 cases from five states [CA (4), CO (3), NJ (1), TX (1), and UT (2)].

Acknowledgements

CORE would like to acknowledge the efforts of all our partners from this investigation. Special thanks to ORA HAF 4 West (DEN-DO), ORA HAF 5 West (SAN-DO), and ORA HAF 6 East (CHI-DO) for traceback data collection. Thanks to state partners (California Department of Public Health, California Department of Food and Agriculture, Colorado Department of Public Health and Environment, and Utah Department of Agriculture and Food) for sampling and inspectional activities. We also appreciate ORA ORS Denver Laboratory (DENLHAF) for analyzing the sample collected by Colorado Department of Public Health.

INCIDENT COORDINATION GROUP

CFSAN - Coordinated Outbreak Response and Evaluation Network

Signals & Surveillance: Tiffany Greenlee

Response: Response Team 3

- Lead Incident Coordinator: Stranjae' Ivory
- Operations Chief: Angela Fields
- Planning Chief: Bria Graham Glover

Outbreak Evaluation: Cerise Hardy

Outbreak Analytics

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Senior Leadership

FDA/CDC Liaison - Susan Lance

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Centers for Disease Control and Prevention	
Division of Foodborne, Waterborne, and Environmental Diseases	Michael Vasser Colin Schwensohn CDR Laura Gieraltowski CAPT Matthew Wise

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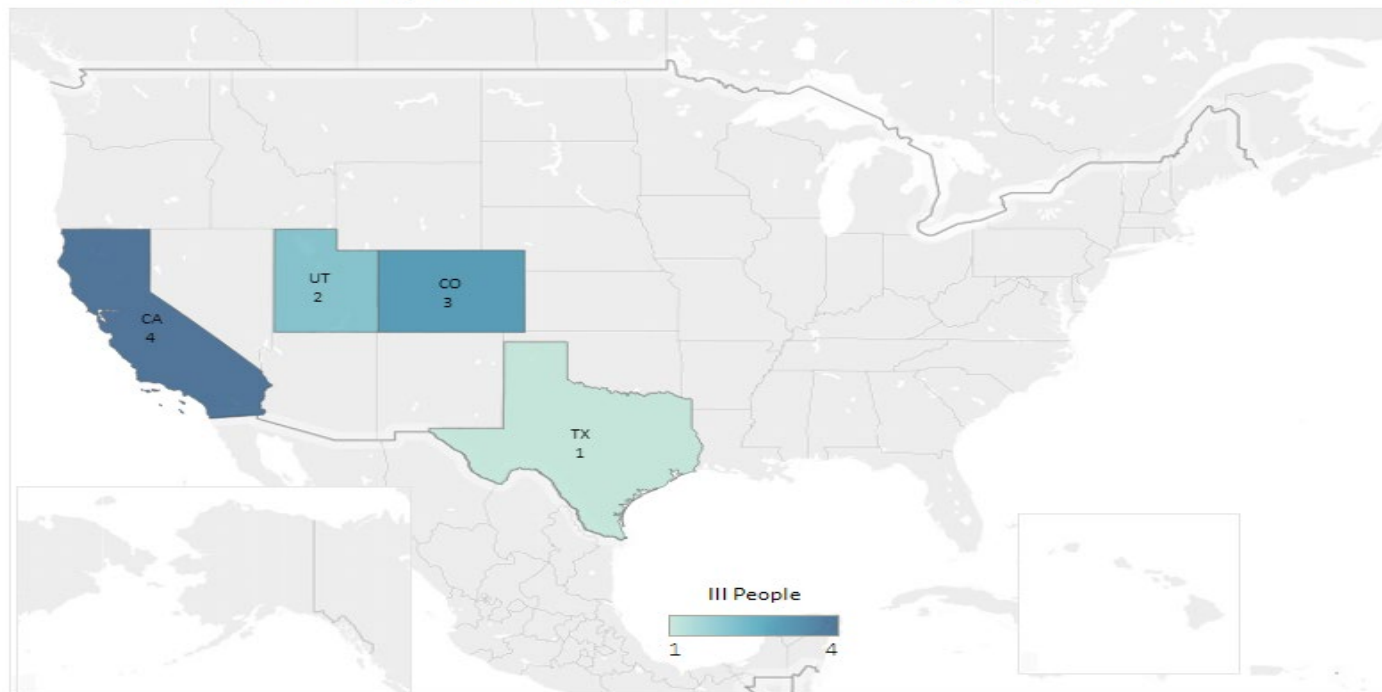
INCIDENT BRIEFING (ICS 201), Adapted for FDA

1. Incident Name: <u>E. coli O157 (2402MLEXH-1)/Raw Milk Cheese (Suspect)/Feb 2024</u>	2. CORE Incident Number: 1215	3. Date/Time Initiated: Date: 2/15/2024 Time: 2:30 PM
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4. Map/Sketch

Date: 2/15/2024

E. coli O157 (2402MLEXH-1)/Raw Milk Cheese (Suspect)/Feb 2024



6. Prepared by: Name: Tiffany Greenlee

Position/Title: Signals Team Member

Signature:

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Date/Time: 2/15/2024 2:30 PM EST

INCIDENT BRIEFING (ICS 201), Adapted for FDA

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5. Situation Summary and Health and Safety Briefing

On 2/9/2024, CORE Signals was notified by CDC of a new E. coli O157 (2402MLEXH-1) outbreak investigation. Currently there are 10 cases in 4 states: CA (4), CO (3), TX (1), and UT (2). Isolation dates range from 10/19/2023 to 2/1/2024. Reported onset dates among cases range from 10/18/2023 to 1/19/2024. Cases range in age from 2 to 58 years with a median of 21 years, and 30% are female. Currently 4 cases have been hospitalized, and at least 1 case has been diagnosed with HUS. No deaths have been reported.

Clinical isolates are related within 0-2 alleles by cgMLST and 0-2 SNPs (average: 1) in NCBI. There are no closely related non-clinical isolates in the NCBI tree. In an expanded analysis conducted by OAO, an overall CA signal was identified. Several isolates from CA including spinach, water, and bovine isolates were in the broader WGS tree, all over at least 50 SNPs away from the current cluster isolates. CDC PulseNet reported this cluster is genetically related within 0-7 alleles to 2 historical clusters including 2208MLEXH-2 (suspect fresh spinach) and 2308MLEXH-1 (unknown vehicle).

Among cases with available epidemiologic information, the following food items have been reported: ground beef (6; 2 from direct-to-consumer slaughtered cows), raw milk (3) and raw milk cheese (5). Among those with raw milk cheese exposure, 4 cases reported Raw Farm brand raw cheddar from Raw Farm (FEI: 3004054984, Fresno, CA). Three of these cases were from CA (2 purchased at (b)(4)). Other Raw Farm brand products were purchased by 1 CA case (CA M23F003882) including raw milk butter (purchased at (b)(4)) and raw milk kefir (purchased at (b)(4)). The 4th case with exposure to Raw Farm raw cheddar is from CO (CO 2401240279), who reported purchasing Raw Farm raw milk cheddar cheese, 16-ounce block at (b)(4), on 1/14/2024 through (b)(4). One UT case (UT 1923107) reported consuming raw milk from (b)(4). Another UT case (UT 1925419) reported consuming (b)(4) brand low-temp pasteurized non-homogenized milk purchased at (b)(4). This case also said maybe to consuming (b)(4) brand kefir, also low-temperature pasteurized, (b)(4) brand raw milk cheddar cheese, and Raw Farm brand cheddar block cheese, all purchased at (b)(4). No exposure information is available for the TX case. Top grocery stores reported by cases include (b)(4). Overall, cases in this cluster appear to shop at organic health food specialty stores.

Raw Farm LLC (FEI: 3004054984) is a manufacturer of raw milk, milk products, and raw kefir pet food located in CA. In 2021, the firm changed its name from Organic Pastures Dairy Company, LLC to Raw Farm, LLC. Raw Farm promotes a health-conscious philosophy and focus on food safety with a widespread presence on social media including several active social media accounts (e.g., Facebook, Twitter, Instagram, LinkedIn, TikTok) with thousands of followers.

The firm has a lengthy regulatory history with FDA and has been operating under permanent injunction since 2010 which enjoined the firm from distributing any raw milk products unless specifically authorized in writing by the FDA. The firm was distributing raw milk labeled as pet food in interstate commerce, with the intention of distributing raw milk products to humans. On July 27, 2023, a Consent Decree was filed against the firm due to violating the terms of the court order. During December 2023 and January 2024, FDA conducted inspections at the firm's creamery in Fowler, CA, their cheese production facility in Hanford, CA, and the dairy in Fresno, CA in follow-up to the injunction. Given the history of this firm and noted firm practices during inspections, OC is currently working on a legal strategy to enforce the terms of the consent decree which would include actions to prevent the release of additional, potentially contaminated raw milk cheese into commerce and recall of product already on the market.

Previous FDA inspections noted observations including issues with inadequate preventive controls, inadequate processes related to storing and producing food under conditions that protect against potential contamination, and inadequate written procedures for monitoring process controls and sanitation. The firm indicates that approximately 50% of cheddar cheese products are distributed in interstate commerce to customers, including but not limited to (b)(4). The firm also ships raw kefir pet food to out-of-state customers. According to the firm's website, they distribute two product lines nationwide: raw milk cheese (block and shredded) and raw pet food plain kefir. Other products including raw cream, raw butter, raw milk, and raw kefir are limited to the retail sale in CA.

Over the years, the firm has been linked to several outbreaks and has recalled products due to contamination with different pathogens. This firm is currently implicated in an ongoing outbreak investigation of Salmonella Typhimurium illnesses in CA with over 150 cases linked to raw milk (primarily in CA). The Salmonella outbreak strain was identified in raw milk and raw milk cheese products from testing conducted by CDPH. State officials believe one of the causes of the outbreak was related to infection and shedding associated with overcrowding of cows. In addition, information regarding their cheese making process as relayed by the firm appears to indicate that the firm uses potentially contaminated milk from cows that have tested preliminary positive for pathogens in their cheese production, essentially

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relying on the (b)(4)-day aging requirement for raw milk cheese as a (b)(4) step. In response to the E. coli O157 outbreak, CDPH initiated additional sampling activities targeting Raw Farm brand raw milk cheese and other products. On 2/12/2024 and 2/13/2024, CDPH collected 15 Raw Farm brand retail samples from different (b)(4) locations in CA including: 7 raw block cheddar, 2 raw shredded cheddar, 2 raw milk, 2 raw butter, and 2 raw kefir samples. Analysis for E. coli and Salmonella will be conducted with preliminary results expected early the week of 2/19/2024. On 2/14/2024 CDC reached out to CO and UT state partners about potential retail sampling of Raw Farm brand raw milk cheese. CO noted their lab does not have capacity for product sampling but can coordinate sample collection and transport of product to DENLHAF for testing. CORE Signals coordinated discussion with ORA/ORS to arrange for FDA analysis support. On 2/12/24, CDC held a multistate call to discuss the outbreak investigation. To collect more specific exposures of interest, CDC modified and deployed a focused questionnaire developed by CA focusing on raw milk, raw milk products, and beef exposures. State partners are in the process of reinterviewing cases and obtaining receipts and consumer purchase information if available. On 2/14/2024, CDC named raw milk cheese as the leading hypothesis in this investigation. Raw milk is a high-risk commodity for foodborne illness and has been associated with pathogens such as Listeria monocytogenes, Salmonella, Campylobacter, and E. coli. Since 2012, CORE Signals has investigated 15 incidents linked to raw milk or raw milk products, of which 6 were associated with E. coli. CORE Response was not activated for any of these incidents. Raw milk distribution tends to remain in intrastate commerce; therefore, investigations remain at the state level, and the burden of raw milk associated illnesses and outbreaks is likely underestimated. CORE Response has previously investigated 3 outbreaks of soft cheese made from raw milk. In addition, prior to the formation of CORE, FDA investigated an outbreak of (b)(4) locations in several western states. During that investigation, the question of whether (b)(4) days is adequate to eliminate pathogenic E. coli was raised. This incident is being transferred to CORE Response Team 3 based on the following rationale: An FDA-related product, raw milk cheese, has been identified as the leading hypothesis and the suspect vehicle for this ongoing outbreak of E. coli O157. Response coordination is needed for product sampling and other investigational activities. Products made from raw milk are well established as a potential vehicle for pathogens and have been implicated in past outbreaks. Additional preventative measures and consumer outreach may be needed to prevent additional illnesses and future outbreaks.		
Exposure Table		
No Exposure Table Available		

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6. Prepared by: Name: Tiffany Greenlee Position/Title: Signals Team Member Signature:		
ICS 201, Page 2		Date/Time: 2/15/2024 2:30 PM EST

Updated by FDA 2/2011

INCIDENT BRIEFING (ICS 201), Adapted for FDA

1. Incident Name: <u>E. coli O157 (2402MLEXH-1)/Raw Milk Cheese (Suspect)/Feb 2024</u>	2. CORE Incident Number: 1215	3. Date/Time Initiated: Date: 2/15/2024 Time: 2:30 PM
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7. Current and Planned Objectives:

(b)(5)

* Identify investigational POCs for CVM and FSIS partners.

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

Time: Actions:

6. Prepared by: Name: Tiffany Greenlee

Position/Title: Signals Team Member

Signature:

ICS 201, Page 3

Date/Time: 2/15/2024 2:30 PM EST

Updated by FDA 2/2011

INCIDENT BRIEFING (ICS 201), Adapted for FDA

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9. Current Organization (fill in additional organization as appropriate): Lead Coordinator: Stranjae Ivory Operations: Angela Fields Planning: Bria Graham-Glover		
6. Prepared by: Name: Tiffany Greenlee Position/Title: Signals Team Member Signature: _____		
ICS 201, Page 4		Date/Time: 2/15/2024 2:30 PM EST

INCIDENT BRIEFING (ICS 201), Adapted for FDA

1. Incident Name: <u>E. coli O157 (2402MLEXH-1)/Raw Milk Cheese (Suspect)/Feb 2024</u>		2. CORE Incident Number: 1215		3. Date/Time Initiated: Date: 2/15/2024 Time: 2:30 PM	
10. Resource Summary:					
Resource	Resource Identifier	Date/Time Ordered	ETA	Arrived	Notes (location/assignment/status)
Travis Hunt	Office of Human and Animal Food Operations - West (OHAFO-W)				
Susan Lance	Coordinated Outbreak Response and Evaluation Network (CORE)				CDC Liaison
Kristin Butler	Office of Food Safety				
Tennetta Hazard	Office of Food Safety				
Monica Metz	Office of Food Safety				
Cynthia Leonard	Office of Food Safety				
Nicole Yuen	Office of Human and Animal Food Operations - West (OHAFO-W)				
Steven Galvez	Office of Human and Animal Food Operations - West (OHAFO-W)				
Hermie Francisco	Office of Human and Animal Food				

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10. Resource Summary:						
	Operations - West (OHAFO-W)					
Matthew Kozler	Office of Human and Animal Foods Operations - West (OHAFO-W)					
Lori Holmquist Kim Livsey Holly Miller Nicole Vaught					ORA HAF Senior ERCs	
Darla Bracy Sergio Chavez Hermie Francisco Steven Galvez Nicole Yuen	Office of Human and Animal Foods Operations - West (OHAFO-W)				ORA HAF West5 ERC Group	
Clarice Ahn	Office of Human and Animal Foods Operations - West (OHAFO-W)					
Tim Muruvanda	Office of Analytics and Outreach					
Elizabeth Teter-Gossmann	Office of the Chief Counsel					
Robyn Jones	Office of Compliance					
Arthur Pightling	Office of Analytics and Outreach					
Nicole Clausen	Office of Human and Animal Foods Operations (OHAFO)					

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10. Resource Summary:						
Linda Stewart	Office of Human and Animal Foods Operations (OHAFO)					
Darlene Almogela	Office of Human and Animal Foods Operations - West (OHAFO-W)					
Stephen Walker	Office of Food Safety					
Edette Newby	Office of Compliance				RPRT	
Oliver Ou	Office of Compliance				RPRT	
Kerry Kurdilla	Office of Compliance				FAAB	
Sheena Phillips	Office of Compliance				FAAB	
Leslie Hintz	Office of Compliance				SME	
	Office of Compliance				OC distribution list	
Evelyn Ladines	Office of Regulatory Science					
Donna Williams Hill	Office of Regulatory Science					
Michael Vasser	National Center for Emerging and Zoonotic Infectious Diseases (NCEZID)					
Colin Schwensohn	National Center for Emerging and Zoonotic					

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10. Resource Summary:					
	Infectious Diseases (NCEZID)				
Laura Gieraltowski	National Center for Emerging and Zoonotic Infectious Diseases (NCEZID)				
6. Prepared by: Name: Tiffany Greenlee Position/Title: Signals Team Member Signature:					
ICS 201, Page 4		Date/Time: 2/15/2024 2:30 PM EST			

INCIDENT OBJECTIVES (ICS 202), Adapted for FDA

1. Incident Name:
E. coli O157:H7/Raw Milk Cheese/Feb 2024

2. Operational Period: Date From: 3/19/2024 Date To: 4/19/2024
Time From: 1500 EST Time To: 1500 EST

3. Objective(s):

(b)(5)

4. Operational Period Command Emphasis:

General Situational Awareness:

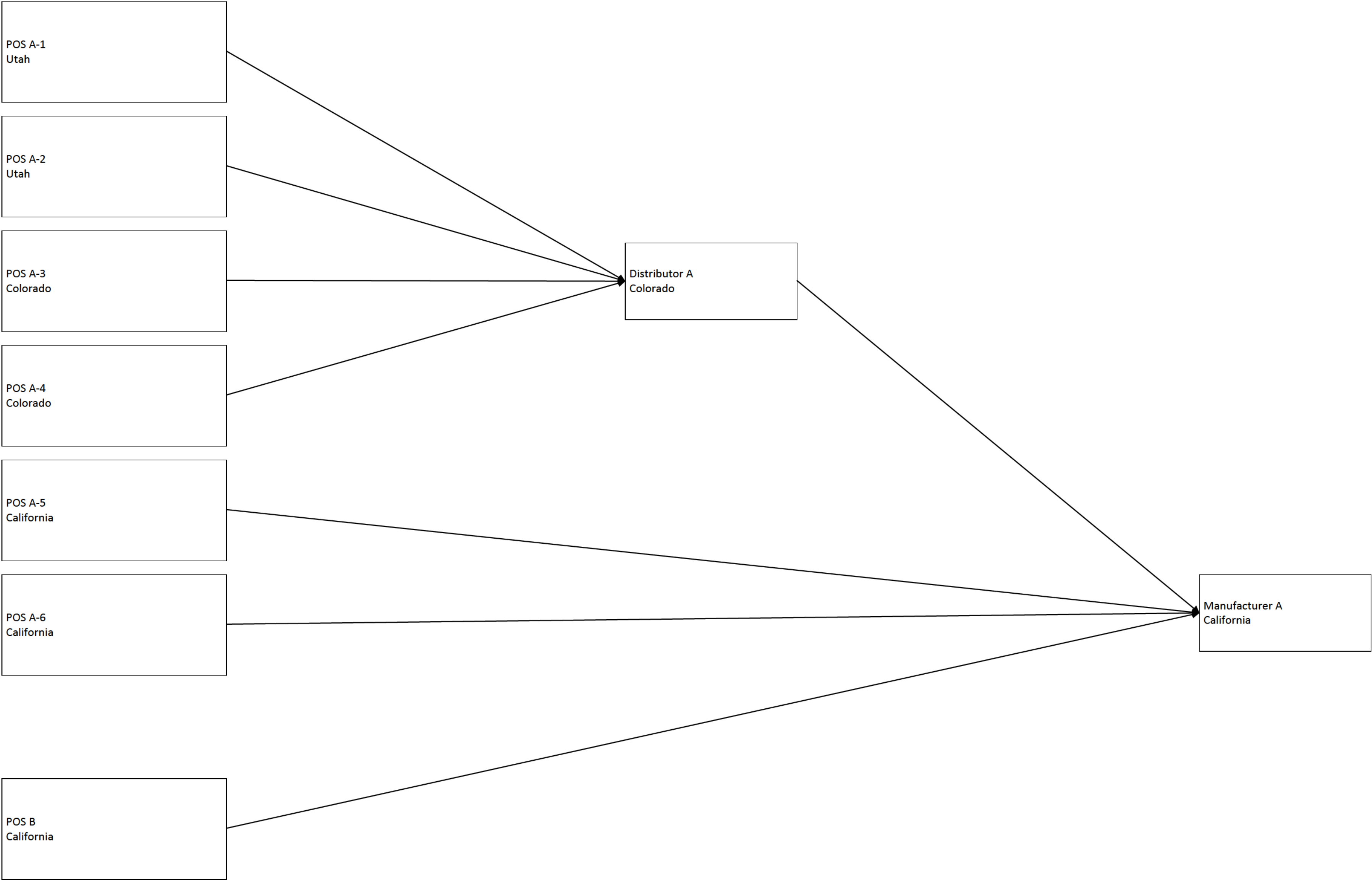
On 2/15/2024, CORE Signals transferred this incident to CORE Response Team 3. The strongest epi signal is Raw Farm, LLC branded products (ex: raw cheddar cheese). Raw Farm, LLC (FEI: 3004054984) is a manufacturer of raw milk, milk products, and raw kefir pet food located in Fresno, CA. In 2021, the firm changed its name from Organic Pastures Dairy Company, LLC to Raw Farm, LLC. On 2/12/2024 and 2/13/2024, California Department of Public Health (CDPH), collected 15 Raw Farm brand retail samples (7 raw block cheddar, 2 raw shredded cheddar, 2 raw milk, 2 raw butter, and 2 raw kefir) from (b)(4) sample results pending. On 2/15/2024, CDC informed CORE Response that the Utah Department of Agriculture and Food collected nine retail samples of Raw Farm brand products (3 raw kefir, 3 raw block cheddar, and 3 raw shredded cheddar) from a (b)(4) (b)(4). On 2/16/2024, ORA HAF 4W (DEN-DO) reported that all nine samples were negative for *E. coli* O157. On 2/16/2024, ORA HAF 4W (DEN-DO) reported that Colorado state partners collected one 16oz block of Raw Farm brand cheddar cheese which is being analyzed by ORA's DENLHAF (Denver Laboratory); sample results are pending. On 2/15/2024, CORE hosted a Special Purpose Tactics Call to discuss considerations for a Firm Call with Raw Farm, LLC and next steps. On 2/15/2024, CORE hosted Pre-Call for Firm Call #1 with Raw Farm, LLC as well as Firm Call #1 with Raw Farm, LLC. On 2/16/2024, Raw Farm, LLC agreed to recall all lots of cheese produced up until/older than the three lots of cheese named in their [Press Release](#): Raw Cheddar Cheese – Pound Block (16oz) #20231113-1, Raw Cheddar Cheese – Half Pound Block (8oz) #20231113-1, Raw Cheddar Cheese – Half Pound Shred (8oz) #20240116. As of 2/17/2024, ORA HAF 4W (DEN-DO) and 5W (SAN-DO) informed CORE Response that (b)(4) verbally agreed to pull Raw Farm brand product from their store shelves. On 2/16/2024, FDA released an [Outbreak Advisory](#) and CDC released a [Food Safety Alert](#) related to this incident.

Operational Period #1

On 2/20/2024, ORA HAF 5W (SAN-DO) informed CORE Response that CDPH collected 47 samples on 2/16/2024 of Raw Farm brand raw cheddar cheese (original flavor): 46 samples from several (b)(4) and one sample from a (b)(4). On 2/21/2024, ORA HAF 5W (SAN-DO) informed CORE Response that CDFE collected 18 samples (3 Raw Milk, 3 Heavy Whipping Cream, 3 Raw Milk Kefir, 3 Raw Cheddar Cheese, 3 Lightly Salted Raw Butter, 3 Cultured Raw Butter) of Raw Farm brand products on 2/20/2024 as part of routine pathogen surveillance. On 2/21/2024, ORA HAF 5W (SAN-DO) informed CORE Response that (b)(4) would pull all current inventory of Raw Farm's raw cheddar cheese in their possession at this point and halt the ability to order new product until following back up with FDA. On 2/21/2024, ORA ORS informed CORE Response the Raw Farm Raw Milk Cheddar Cheese (#783323), collected by Colorado state partners, is negative for *E. coli* O157:H7, *Listeria*, and *Salmonella*. On 2/21/2024, CORE Response issued eNSpect assignment (#240258) to ORA HAF 4W (DEN-DO) for traceback data collection at (b)(4) (b)(4). (b)(4) does not maintain lot code records of Raw Farm's products. (b)(4) is the distribution center for three non-CA (b)(4) that were reported. On 2/21/2024, CORE Response issued eNSpect assignment (#240269) to ORA HAF 5W (SAN-DO) for traceback data collection at (b)(4) (b)(4) does not maintain lot code records. There weren't any recorded shipments of Raw Farm brand cheese to the reported point of sale within two weeks of the case's reported purchase. Based on shipment data, the timeframe of interest expanded to three months. On 2/22/2024, ORA HAF 5W (SAN-DO) informed CORE Response that only 40 of the 47 collected samples collected by CDPH were suitable for analysis. The sample chain of custody for seven of the samples may have been compromised. The one sample collected from (b)(4) retail was not Raw Farm brand and was not included in the remaining 40 samples pending sample analysis by CDPH's FDLB. On 2/23/2023, ORA HAF 5W (SAN-DO) reported all 15 samples of Raw Farm brand products (7 Raw block Cheddar Cheese, 2 Raw shredded Cheddar Cheese, 2 Raw Milk, 2 Raw Butter, and 2 Raw Kefir) collected by CDPH were negative for *E. coli* (STEC) and *Salmonella*. On 2/26/2024, CDC hosted Multistate Call #2. On 2/26/2024, Raw Farm, LLC issued a Press Release and Notice to Consumers to withdraw and conclude their Voluntary Recall issued on 2/16/2024. On 2/27/2024, ORA HAF 4W (DEN-DO) provided the additional distribution information that was requested. On 2/28/2024, CORE Response followed up with ORA HAF 4W (DEN-DO) regarding previously

1. Incident Name: <i>E. coli</i> O157:H7/Raw Milk Cheese/Feb 2024	2. Operational Period: Date From: 3/19/2024 Date To: 4/19/2024 Time From: 1500 EST Time To: 1500 EST															
provided shipment and invoice data. On 2/28/2024, ORA HAF 5W (SAN-DO) informed CORE Response that CDPH's FDLB confirmed all 40 samples of Raw Farm brand Raw Cheddar cheese (16oz block) were negative for <i>E.coli</i>. On 2/28/2024, FDA released an updated Outbreak Advisory and CDC released an updated Food Safety Alert related to this incident acknowledging the update to Raw Farm's press release and recall withdrawal; FDA's consumer advice did not change. On 3/1/2024, ORA HAF 4W (DEN-DO) confirmed that (b)(4) placed a sale block (since 2/16/2024) of all Raw Farm's Cheddar Cheese products. On 3/5/2024, CDFA reported that all 18 samples of Raw Farm brand products are negative for <i>E.coli</i>, <i>Salmonella</i>, <i>Listeria</i>, and <i>Campylobacter</i>. Raw Farm's Raw Cheddar Cheese was not tested for <i>Campylobacter</i>.																
<u>Operational Period #2</u> On 3/6/2024, CORE Response issued eNSpect assignment #240967 to ORA HAF 6E (CHI-DO) for traceback data collection at (b)(4). On 3/11/2024, ORA HAF 6E (CHI-DO) provided CORE with traceability information from (b)(4) related to Raw Farm LLC brand cheddar cheese products sold at (b)(4) in Colorado and Utah. Based on the traceability data from (b)(4), the latest expiration dates for products available for ill persons were 7/9/2024 and 2/8/2024 for the Raw Farm LLC brand cheddar cheese (block) and Raw Farm LLC brand cheddar cheese (shredded); respectively.																
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): <table style="width: 100%; border: none;"> <tr> <td style="width: 33%;">☐ ICS 203</td> <td style="width: 33%;">☐ Map/Chart</td> <td style="width: 34%;"><u>Other Attachments:</u></td> </tr> <tr> <td>☐ ICS 204</td> <td>☐ Weather Forecast/Tides/Currents</td> <td>☐</td> </tr> <tr> <td>☐ ICS 205</td> <td></td> <td>☐</td> </tr> <tr> <td>☐ ICS 206</td> <td></td> <td>☐</td> </tr> <tr> <td>☐ ICS 208</td> <td></td> <td>☐</td> </tr> </table>		☐ ICS 203	☐ Map/Chart	<u>Other Attachments:</u>	☐ ICS 204	☐ Weather Forecast/Tides/Currents	☐	☐ ICS 205		☐	☐ ICS 206		☐	☐ ICS 208		☐
☐ ICS 203	☐ Map/Chart	<u>Other Attachments:</u>														
☐ ICS 204	☐ Weather Forecast/Tides/Currents	☐														
☐ ICS 205		☐														
☐ ICS 206		☐														
☐ ICS 208		☐														
7. Prepared by: Name: Bria Graham-Glover Position/Title: Planning Chief Signature: Bria Graham-Glover																
8. Approved by Incident Commander: Name: Angela Fields Signature: Angela Fields																
ICS 202	IAP Page _____															
Date/Time: 03/19/2024 15:00 EST																

E coli. O157:H7 – Multistate Outbreak Feb 2024
Master Traceback Diagram – Cheddar Cheese



Center for Drug Evaluation and Research Division of Applied Regulatory Science/Office of Clinical Pharmacology	
Center for Drug Evaluation and Research Division of Applied Regulatory Science/Office of Clinical Pharmacology	
Center of Veterinary Medicine	
Emergency Response Coordinators	David Rotstein Mark Glover
United States Department of Agriculture	
Food Safety and Inspection Service	Chen, Wu San - FSIS wusan.chen@usda.gov Andrea Cote
Animal and Plant Health Inspection Service	
State Partners	
California	California Department of Food and Agriculture California Department of Public Health
Colorado	Colorado Department of Public Health and Environment
Texas	Texas Department of State Health Services (DSHS)
Utah	Utah Department of Health & Human Services

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***E. coli* O157:H7/Cheddar Cheese/Feb 2024**
Abbreviated Traceback Investigation Summary
CARA #1215

For internal FDA use only. This summary contains confidential, commercial information and may not be released outside FDA with appropriate redaction.

SUMMARY

A traceback investigation was initiated on 2/21/2024 in response of *E. coli* O157:H7 infections with a vehicle of raw milk cheese. There were 11 cases from four states (CA (4), CO (3), NJ (1), TX (1), UT (2)). There were five hospitalizations and there were no reported deaths; two cases developed hemolytic uremic syndrome (HUS). Onset dates range from 10/18/2023 to 2/5/2024. Cluster isolates are related within 0-2 alleles by cgMLST, and 0-2 SNPs (average: 1) in NCBI. Based on whole genome sequencing analysis of *E. coli* isolates from ill people, the people affected by this outbreak were likely to share a common source of infection.

Interviews were conducted by state and local public health officials for ten patients of which seven (70%) reported consuming Raw Farm-brand Raw Cheddar cheese within the week prior to illness onset.

Analysis of two traceback legs representing seven cases was initiated on 2/21/2024. All cases included in the traceback investigation reported exposure to Raw Farm-brand Raw Cheddar cheese prior to illness onset. Exposure/onset dates ranged from 10/2/2023 to 1/24/2024. The timeframe of interest for record collection was identified as 8/1/2023 through 1/24/2024. Raw Farm-brand Raw Cheddar cheese (block and shredded) was traced from seven points of sale. For shipments where lot code information was available, the traceback investigation identified dates of expiry for the Raw Farm-brand Raw Cheddar (shredded and block) cheese of 4/22/2024 and 7/13/2024, respectively.

A flow diagram showing the distribution of product through the two traceback legs can be found in the traceback section of CARA.

Endpoint:	Address:	FEI:
Raw Farm LLC	7221 S Jameson Ave, Fresno, CA 93706	3021306495

Summary of Traceback Analysis:

(b)(4)

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(b)(4)

Six single cases of *E. coli* O157:H7 with known and potential exposure to Raw Farm-brand Raw Cheddar cheese that purchased product from six separate (b)(4) locations were identified. Each case met the following criteria for traceback: met the CDC case definition and had a purchase date or onset date associated with it. One case (CO) was able to provide verifiable consumer purchase information. Reported exposure or purchase dates ranged from 10/2/2023 to 1/24/2024. (b)(4)

(b)(4) provided receipts from Raw Farm LLC (Fresno, CA) for shipments to the store locations in CA. In addition to records provided by (b)(4), FDA also obtained records from the distributor (b)(4) for Raw Farm-brand Raw Cheddar cheese which traced back to Raw Farm LLC for the non-CA store locations. This leg did converge with the other leg that was traced.

Traceback Leg 2

(b)(4):
A single case of *E. coli* O157:H7 known exposure to Raw Farm-brand Raw Cheddar cheese that purchased at (b)(4) was identified. This case met the following criteria for traceback: met CDC case definition and had a purchase date associated with it. The exposure date for this case was 12/18/2023 with a purchase of 12/13/2023 or 12/15/2023. FDA was only able to obtain records provided by (b)(4). Records provided by (b)(4) identified Raw Farm LLC. This leg did converge with the other leg traced.

Traceback Conclusions

A traceback investigation was initiated in response to a *E. coli* O157:H7 outbreak with Cheddar Cheese (unpasteurized/raw milk cheddar cheese) as the vehicle. The investigation consisted of two traceback legs representing six cases reporting Raw Farm-brand Raw Cheddar cheese. Milk from sick cows was diverted to make raw milk cheddar cheese for both the shredded and block cheeses (due to the aging process). Given the production practices, both Raw Farm-brand Raw Cheddar cheeses (shredded and block) were traced. For shipments where lot code information was available, the traceback investigation identified dates of expiry for the Raw Farm-brand Raw Cheddar shredded and block cheddar cheese of 4/22/2024 and 7/13/2024, respectively.

Traceback Limitations

There were several limiting factors during the traceback investigation. Limited lot code information available at the points of sale (POS) included in the traceback investigation. Due to the ongoing compliance and legal actions against the firm, follow up with Raw Farm LLC was limited. No additional lot code information could be collected for the POS that received product directly from Raw Farm LLC. Additionally, because of the long shelf life of the traced product (240-day shelf life for block cheddar cheese and 90-day shelf life for shredded cheddar cheese), the timeframe of interest for record collection had to be expanded multiple times to capture shipments of the raw milk cheese.

CFSAN HEALTH HAZARD EVALUATION

HHE # 11121

RES # 94065

Section A. Incident Summary (to be completed by requesting CSO)

1. PRODUCT INFORMATION (Include relevant lot information if appropriate.)

Raw Farm brand Cheddar, blocks and shredded cheese products

2. FIRM INFORMATION (Include supplier information if appropriate and note if domestic or foreign.)

Raw Farm, LLC
Fresno, CA 93706

3. SOURCE OF PROBLEM

☐ Undeclared allergen:

☐ Presence of contaminant or impurities (specify):

☒ Microbial contamination (specify): *E. coli* O157:H7

☐ Presence of foreign bodies:

☐ Other:

4. NATURE OF PROBLEM (What happened to create the hazard/ problem? What is the extent of the problem and/or how was the problem identified? Include GMP, labeling errors, consumer complaints, etc.)

[Note: There's currently a multistate outbreak associated with Raw Farm LLC where the firm's Raw cheddar cheese has been implicated in an *E. coli* outbreak].

CORE Signals was notified by CDC of a new *E. coli* serotype O157:H7 (2402MLEXH-1) cluster with 7 cases in 3 states: CA (4), CO (2), and TX (1). All isolates are related by cgMLST and 0-1 SNPs (average: 0) in [NCBI](#). As of April 29, 2024, 11 confirmed infections had been reported from 5 states, including CA (4), CO (3), NJ (1), TX (1), and UT (2). Whole genome sequencing analysis of *E. coli* isolates from cases shows that all isolates are closely related. Dates of illness onset range from October 18, 2023 to February 5, 2024. Case ages range from 2 to 75 years (median 25) and 36% of cases are female. Five cases were hospitalized; two developed hemolytic uremic syndrome (HUS), a serious condition that can lead to kidney failure. No deaths have been reported.

5. Have any adverse reaction reports or other indication of injuries or diseases been reported relating to this problem?

☐ No

☒ Yes

6. PRECEDENT HHEs (Using the CFSAN HHE database, please summarize any related precedents. Please include reference numbers or copies of supporting precedent cases.)

<u>HHE #</u>	<u>Date Signed</u>	<u>Hazard Identified</u>
No similar HHEs could be determined.		

Section B. Health Effects Review (to be completed by HHEB member)

7. ADVERSE REACTION INFORMATION

What are anticipated health effects associated with this problem? (i.e., consumption of the product and/or specific ingredients) Include narrative and please describe severity. Explain and cite literature references when applicable.

From CDC memorandum to FDA, February 15, 2024:

“CDC has been collaborating with state and local partners to investigate a multistate outbreak of Shiga toxin- producing *E. coli* infections. As of February 14, 2024, a total of 10 confirmed infections have been reported from 4 states, including CA (4), CO (3), TX, and UT (2). Whole genome sequencing analysis of *E. coli* isolates from ill people shows that they are all closely related genetically to each other. This means that people in this outbreak are likely to share a common source of infection. Dates of illness onset range from October 18, 2023 to January 29, 2024. Ill people range in age from 2 to 58 years (median: 24) and 30% of ill people are female. Four patients have been hospitalized; one developed hemolytic uremic syndrome, a serious condition that can lead to kidney failure. No deaths have been reported.

State and local public health officials have interviewed people about the foods they ate in the week before they became ill. Of the 8 people interviewed, 7 (88%) reported consuming raw milk or cheese made from raw milk. Five (63%) ill people reported eating raw milk cheese. This percentage is significantly higher than the 4.9% of respondents who reported eating raw milk cheese in the 2018-2019 FoodNet Population Survey—a survey that helps estimate how often people eat various foods linked to diarrheal illness. This difference suggests that people in this outbreak got sick from eating raw milk cheese. Of the 5 people that remembered details of the raw milk cheese they ate, 5 specifically reported eating Raw Farm brand raw cheddar cheese. An additional ill person reported consuming Raw Farm brand raw milk and kefir products but not raw milk cheese.

In summary, epidemiologic evidence shows that raw milk cheddar cheese products and other raw milk products made by Raw Farm Inc. are the likely source of this outbreak.”

8. AT RISK POPULATION

Are there certain population(s) of consumers most likely to use and/or be most at risk from exposure to this problem or hazard? (Please list all that apply and provide additional explanation if necessary.)

☒ No – the general population is at risk

☐ Yes – check all that apply

☐ Infants

☐ Children

☐ Pregnant women, nursing women, or women of childbearing age

☐ Elderly consumers

☐ Individuals with allergy/intolerance to (food/product)

☐ Immunosuppressed individuals

☐ Medical conditions (e.g., diabetes, celiac disease)

☐ Other (please describe):

9. Is the problem easily identified by the user or are there other mitigating circumstances that lessen the probability that the product will be consumed?

☒ No

☐ Yes

10. What is the hazard associated with use of the product? (Select one. If more than one is selected, please explain.)

☒ Life-threatening (death has or could occur)

☒ Results in permanent impairment of a body function or permanent damage to a body structure

☒ Necessitates medical or surgical intervention (including hospitalization) to preclude or reverse permanent damage to a body structure or permanent impairment of a body function

☒ Temporary or reversible (without medical intervention)

☐ Limited (transient, minor impairment or complaints)

☐ No adverse health consequences

☐ Hazard cannot be assessed with the data currently available

11. What is the probability of each adverse event occurring, as specified in Item 10? (If more than one item is selected below, specify the corresponding health hazard.)

☒ Highly likely to occur (every time the product is used) **An outbreak has occurred**

☐ Likely to occur (reasonable probability of occurrence)

☐ Might occur (remote probability of occurrence)

☐ Unlikely to occur

☐ Unknown (please explain):

☐ Not applicable

Conclusion:

As the epidemiologic evidence clearly implicates only these products in the current outbreak, consumers exposed to these products are at high risk of developing *E. coli*-related illness, which could result in serious adverse health effects including death.

SIGNATURES

Requested By: Edette J. Newby -S
Edette Newby
Consumer Safety Officer

Digitally signed by
Edette J. Newby -S
Date: 2024.06.10
17:03:59 -04'00'

Date:

Karl C. Klontz -S
Karl C. Klontz, M.D., M.P.H.
Medical Officer
Health Hazard Evaluation Board Member

Digitally signed by Karl C. Klontz
-S
Date: 2024.06.10 16:22:14 -04'00'

Date:

Steven M. Grube -S
CAPT Steven M. Grube, MD
Chief Medical Officer
Center for Food Safety and Applied Nutrition
Food and Drug Administration

Digitally signed by Steven M.
Grube -S
Date: 2024.06.10 16:56:38 -04'00'

Date:

HUMAN FOODS PROGRAM HEALTH HAZARD EVALUATION

HHE # 11494

RES# 98703

Date Sent: 4/17/2026

Section A. Incident Summary (to be completed by requesting CSO)

1. PRODUCT INFORMATION (Include relevant lot information if appropriate.)

RAW FARM
ORIGINAL RAW CHEDDAR
80 OZ [BULK ITEM]

UPC: 835204001160

RAW FARM

RAW CHEDDAR Jalapeno
NEVER WARMED ABOVE 102F
(TRULY RAW)

MADE WITH WHOLE RAW MILK

MADE IN USA

KEEP REFRIGERATED

INGREDIENTS: whole raw milk, vegetable
rennet, cultures, kosher sea salt, 100%
organic chili powder jalapeno, air dried
green jalapeno peppers

Produced By:

RAW FARM, LLC

www.rawfarmusa.com

8 oz (227g)

UPC: 835204000330

16 oz (454g)

UPC: 835204000354

RAW FARM

RAW CHEDDAR Original

NEVER WARMED ABOVE 102F

(TRULY RAW)

MADE WITH WHOLE RAW MILK

MADE IN USA

KEEP REFRIGERATED

INGREDIENTS: whole raw milk, vegetable
rennet, cultures, kosher sea salt

Produced By:

RAW FARM, LLC

www.rawfarmusa.com

8 oz (227g)

UPC: 835204001177

16 oz (454g)

UPC: 835204000156

RAW FARM

RAW CHEDDAR SIMPLY SHREDDED
Original

MADE WITH: WHOLE RAW MILK

TRULY RAW - NEVER WARMED

ABOVE 102F

MADE IN THE USA

KEEP REFRIGERATED

INGREDIENTS: WHOLE RAW MILK,
VEGETABLE RENNET, CULTURES,
KOSHER SEA SALT

Produced By:

RAW FARM, LLC

www.rawfarmusa.com

8 oz (227g)

UPC: 835204001184

RAW FARM

SHREDDED RAW CHEDDAR

80 OZ [BULK ITEM]

UPC: 835204000194

2. FIRM INFORMATION (Include supplier information if appropriate and note if domestic or foreign.)

Raw Farm LLC
7221 S Jameson Ave
Fresno, CA 93706-9386

3. SOURCE OF PROBLEM

- ☐ Undeclared allergen:
- ☐ Presence of contaminant or impurities (specify):
- ☒ Microbial contamination (specify): E coli O157:H7
- ☐ Presence of foreign bodies:
- ☐ Other:

4. NATURE OF PROBLEM (What happened to create the hazard/ problem? What is the extent of the problem and/or how was the problem identified? Include GMP, labeling errors, consumer complaints, etc.)

RAW FARM-brand raw cheese/milk products linked to a multi-state outbreak of E. coli O157:H7.

3/13/26 - FDA/CORE and CDC held call with firm to notify them their raw cheese/milk products were linked to an ongoing outbreak. FDA requested the firm make a decision to voluntary recall cheese products within 24 hours.

3/14/26 - Firm declined to voluntary recall.

3/27/26 - FDA/CORE and CDC held call with firm to provide updated epidemiological data. FDA requested the firm reconsider a decision to voluntary recall cheese products within 24 hours. FDA recommended recall scope was for all cheese products sold or distributed after 12/15/25.

3/28/26 - Firm requested additional information prior to making a decision.

3/31/26 - (b)(5)

4/1/26 - Firm notified DRC of their decision to voluntary recall. Firm sent ^{(b)(5)} draft press releases for review, between 4/1-2/26.

4/2/26 - (b)(5)

4/3/26 - (b)(5)

4/4/26 - Firm submitted the updated draft press release of which (b)(5)

4/5/26 - (b)(5)

4/6/26 - Firm submitted an updated draft press release for review, which (b)(5)

4/7/26 - Firm issued "Updated" press release.

5. Have any adverse reaction reports or other indication of injuries or diseases been reported relating to this problem?

☐ No

☒ Yes (See Section 7)

6. PRECEDENT HHEs (Using the HFP HHE database, please summarize any related precedents. Please include reference numbers or copies of supporting precedent cases.)

<u>HHE #</u>	<u>Date Signed</u>	<u>Hazard Identified</u>
11197	11/08/2024	E coli O157:H7
11113	05/24/2024	E coli O157:H7

Section B. Health Effects Review (to be completed by HHEB member)

7. ADVERSE REACTION INFORMATION

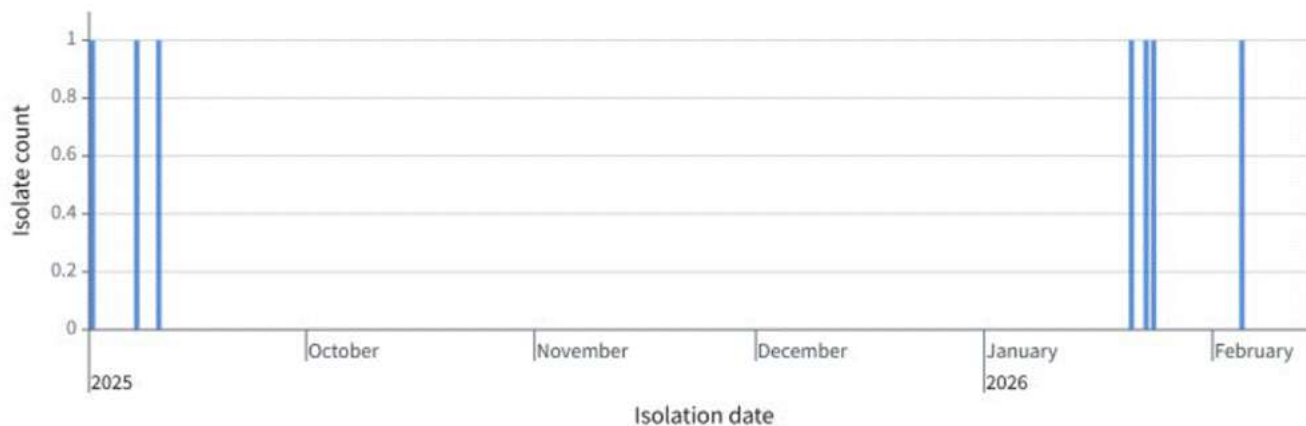
What are anticipated health effects associated with this problem? (i.e., consumption of the product and/or specific ingredients) Include narrative and please describe severity. Explain and cite literature references when applicable.

Epidemiologic findings have shown that human pathogens such as *Salmonella* and Shiga toxin-producing *E. coli* (STEC, including *E. coli* O157:H7) residing in RAW FARM, LLC (Raw Farm) fluid raw milk and Cheddar cheese made from raw milk aged for (b)(4) days have caused outbreaks of human illness. Contributing to these outbreaks is a policy followed by the firm wherein fluid raw milk found to

be contaminated with human pathogens is diverted to production of raw milk cheese aged for (b)(4) days without first undergoing (b)(4). Two recent outbreaks supported by epidemiologic findings which resulted from ingestion of Raw Farm raw milk and/or raw milk Cheddar cheese are presented below:

<u>Year</u>	<u>Pathogen</u>	<u>Number ill</u>	<u>Number states</u>	<u>Vehicle(s) of infection</u>
2024	<i>Salmonella</i> Typhimurium	151	3	Fluid raw milk
2024	<i>E. coli</i> O157:H7	10	4	Fluid raw milk Raw milk cheddar cheese

In March 2026, CDC, FDA, and state partners detected a multistate outbreak of *E. coli* O157:H7 infections. As of April, 2026, 9 people reported from 3 states have been infected with the outbreak strain. Illness onset dates range from September 1, 2025 to February 20, 2026. Ill people range in age from 1-28 years with a median age of 2 years; 44% are female. More than half of the illnesses have been in children under the age of 5 years, a group at elevated risk for severe outcomes of STEC infection. Of 8 ill people with outcome information available, 3 (33%) have been hospitalized. No deaths have been reported. One person developed hemolytic uremic syndrome (HUS). Over half of the illnesses involve children under the age of 5 years, a group at elevated risk for severe outcomes of STEC infection. Onset of illness dates known for eight persons are shown in the epidemic curve below. The nine individuals formed two groups, one consisting of three persons who fell sick in September of 2025 after drinking Raw Farm fluid raw milk and the other comprised of six individuals who became ill in January and February of 2026 after consuming Raw Farm cheddar cheese made from raw milk. The epidemic curve for eight of the ill individuals for whom onset of illness date is known is presented below.



Whole genome sequencing (WGS) analysis showed that bacteria isolated from ill people are very closely related genetically to one another (within 0-2 allele differences), suggesting ill people became ill from a common source. WGS indicates the outbreak strain produces the stx2 toxin but not the stx1 toxin, a toxin profile that has been associated with increased severity of STEC infections.

State and local public health officials are interviewing people or their caregivers about the foods they ate in the week before they got sick. Of the 9 people interviewed, 8 (88%) in this outbreak reported consuming or being served raw (unpasteurized) milk or cheese. This percentage was significantly

higher than the 6.4% of respondents who reported eating any raw or unpasteurized milk or cheese in the FoodNet Population Survey, a survey that helps estimate how often people eat various foods linked to diarrheal illness. This difference suggests that people in this outbreak got sick from eating raw dairy products. The one ill person who did not report consuming or being served raw milk or cheese did report having raw dairy products in the home but were unable to report if it was consumed prior to illness onset.

Of the 8 people that reported consuming or being served raw milk or cheese, 7 had brand information available. One person drank raw milk but didn't know the brand. Of the 7 people interviewed who knew a brand, 7 (100%) reported Raw Farm brand dairy products. In 2026, 5 people reported consuming or being served Raw Farm brand raw cheddar cheese. In 2025, 2 sick people reported consuming Raw Farm brand raw milk.

Summary. Factors which implicate RAW FARM, LLC as the source of *E. coli* O157:H7 infections
Four findings support a conclusion that fluid raw milk and cheddar cheese made from unpasteurized milk by Raw Farm caused the present outbreak of *E. coli* O157:H7 infections.

1. History. The occurrence of multiple recent outbreaks of human illnesses linked to ingestion of unpasteurized dairy products produced by Raw Farm demonstrates the firm's systematic potential to produce unsafe fluid raw milk and raw milk cheddar cheese marketed to the public.
2. Policy. The firm's diversion of fluid raw milk testing positive for one or more human pathogens to the production of cheddar cheese without an intervening (b)(4) step facilitates survival of pathogens in finished cheddar cheese product given that a (b)(4)-day aging process does not guarantee pathogen elimination.
3. Epidemiologic findings. The finding that 8/9 (88%) ill persons reported consuming or being served raw (unpasteurized) dairy products compared to a background rate of 4.6% of respondents from a national population survey (FoodNet) reporting consumption of unpasteurized dairy products suggests people in this outbreak became ill from eating raw dairy products. Moreover, of the 7 people interviewed who knew a brand, 7 (100%) reported Raw Farm brand dairy products.

The epidemic curve above supports the following chronologic events occurred in the present outbreak. The first three individuals who became ill with *E. coli* O157:H7 in September of 2025 acquired infection from fluid raw milk they ingested. Aliquots of the same fluid raw milk which produced the three illnesses was likely diverted to production of cheddar cheese without an intervening (b)(4) step. Following a (b)(4)-day aging process, the raw cheddar cheese was introduced to the public at which time five individuals became infected with the outbreak strain of *E. coli* O157:H7 because a (b)(4)-day aging process does not uniformly eradicate human pathogens. This series of events explains the bimodal nature of the epidemic curve – raw milk causing the first three cases in September 2025 and raw Cheddar cheese responsible for the five cases with onset of illness in January and February of 2026.

4. Whole genome sequencing. The tight clustering of whole genome sequencing (WGS) results of the nine human illnesses strongly supports a conclusion that illnesses resulted from exposure to the same products – in this case, ingestion of fluid raw milk or cheddar cheese made from raw milk. This finding combined with the observation described above pertaining to 8/8 ill persons

reporting consumption (or being served) raw (unpasteurized) dairy products compared to 4.6% of respondents from a national population survey reporting ingestion of raw (unpasteurized) dairy products makes it exceedingly unlikely that a food other than raw (unpasteurized) dairy products (e.g., lettuce or another leafy green product, etc.) was responsible for causing the illnesses. A sample of aged raw milk cheese collected by FDA yielded *E. coli* O157:H7 with a whole genome sequence that did not match the WGS pattern of the clinical cases constituting the present outbreak.

Shiga toxin-producing *Escherichia coli* (STEC) are bacteria that carry the genes producing Shiga toxins. These pathogens have the potential to cause diarrhea, which is often bloody, and can trigger a thrombotic microangiopathy (TMA) that leads to the hemolytic-uremic syndrome (HUS), which is defined as thrombocytopenia (platelet count <150,000 per cubic millimeter), nonimmune hemolytic anemia (hematocrit <30%), and azotemia (creatinine level higher than the normal range).^[i] Although a range of microbial pathogens can precipitate HUS, STEC are responsible for most cases in children worldwide. STEC of varying serotypes, including O157:H7, can produce toxins that are lethal to Vero cells (a widely used lineage of kidney epithelial cells derived from the African green monkey). These toxins, which are variably neutralized by antiserum to Shiga toxin produced by *Shigella dysenteriae* serotype 1, are thus referred to as Shiga toxins. Similarly, the bacteria that produce these toxins are referred to as STEC. STEC-expressing O antigens other than O157 are termed non-O157 STEC (e.g., O80, O104, O113, O121, and O145). The two Shiga toxin families, Shiga toxin 1 and Shiga toxin 2, have different clinical implications. Shiga toxin production is the cardinal virulence trait of STEC. Shiga toxin 2-producing serotypes are much more virulent than Shiga toxin 1-producing serotypes, which rarely lead to HUS unless they also produce Shiga toxin 2. Given their propensity to precipitate HUS on average 7 days after the onset of diarrhea, the subset of STEC that produce Shiga toxin 2 are referred to as “high risk.”

The incidence of STEC infection peaks during summer and fall and is greatest among children younger than 5 years of age, the group at highest risk for the development of HUS. Predominant STEC serogroups vary according to region. *E. coli* O157 is the most commonly identified serogroup in the stool of symptomatic persons worldwide. It is currently identified in 84% of HUS cases in the United States.ⁱ HUS develops in 15-20% of infected children with the greatest risk among those who are younger than 5 years of age. These findings are in keeping with results from a meta-analysis of 17 studies involving 1896 infected persons, 18% of whom had HUS.^[ii] Although HUS almost always manifests between days 5 and 14 of illness, microangiopathic changes are apparent by day 8 or 9. In illnesses that do not progress to the development of HUS, the platelet count often transiently decreases but remains within the normal range. Rapidly progressive thrombocytopenia is the sentinel and universal hematologic abnormality in patients in whom HUS develops and is often accompanied by hemoglobinuria.

[i] Freedman SB *et al.* Shiga Toxin-producing *Escherichia coli* and the hemolytic-uremic syndrome. *NEJM* 2023;389(15):1402-1414.

[ii] Freedman SB *et al.* Shiga toxin-producing *Escherichia coli* infection, antibiotics, and risk of developing hemolytic uremic syndrome: a meta-analysis. *Clin Infect Dis* 2016;62:1251-8.

8. AT RISK POPULATION

Are there certain population(s) of consumers most likely to use and/or be most at risk from exposure to this problem or hazard? (Please list all that apply and provide additional explanation if necessary.)

☒ No – the general population is at risk

☐ Yes – check all that apply

☐ Infants

☐ Children

☐ Pregnant women, nursing women, or women of childbearing age

☐ Elderly consumers

☐ Individuals with allergy/intolerance to (food/product)

☐ Immunosuppressed individuals

☐ Medical conditions (e.g., diabetes, celiac disease)

☐ Other (please describe):

9. **Is the problem easily identified by the user or are there other mitigating circumstances that lessen the probability that the product will be consumed?**

☒ No

☐ Yes

10. **What is the hazard associated with use of the product?** (Select one. If more than one is selected, please explain.)

☒ Life-threatening (death has or could occur) (hemolytic uremic syndrome)

☐ Results in permanent impairment of a body function or permanent damage to a body structure

☐ Necessitates medical or surgical intervention (including hospitalization) to preclude or reverse permanent damage to a body structure or permanent impairment of a body function

☐ Temporary or reversible (without medical intervention)

☐ Limited (transient, minor impairment or complaints)

☐ No adverse health consequences

☐ Hazard cannot be assessed with the data currently available

11. **What is the probability of each adverse event occurring, as specified in Item 10?** (If more than one item is selected below, specify the corresponding health hazard.)

☐ Highly likely to occur (every time the product is used)

☒ Likely to occur (reasonable probability of occurrence) (**death rate from HUS from *E. coli***

O157:H7 infection ~4.6% overall historically)

- ☐ Might occur (remote probability of occurrence)
- ☐ Unlikely to occur
- ☐ Unknown (please explain):
- ☐ Not applicable

Conclusion: Although a range of microbial pathogens can precipitate HUS, STEC such as *E. coli* O157:H7 are responsible for most cases in children worldwide. In addition to causing death, STEC-related manifestations may include kidney damage from hemolytic uremic syndrome and neurologic sequelae from thrombotic thrombocytopenic purpura. Whole genome sequencing indicates that, in the present situation, the outbreak strain produces the stx2 toxin but not the stx1 toxin, a toxin profile that has been associated with increased severity of STEC infections.

SIGNATURES

Requested By: 
Leonora Darlington
Consumer Safety Officer

Karl C. Klontz -S

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Karl C. Klontz, MD, MPH.
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Kathleen

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