

***E. coli* O157:H7/Romaine Lettuce/Nov 2024**
Executive Incident Summary
CARA # [1280](#)
Date: 2/11/2025

Authors:

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EXECUTIVE SUMMARY

Initial Notification and Vehicle Identification

On 11/25/2024, CORE Signals was notified by CDC about an *E. coli* O157:H7 cluster (2411MOEXH-2). This cluster is genetically related to several historical clusters, including one 2021 outbreak cluster (2112MLEXH-1) that was closed with a confirmed vehicle of organic power greens by epidemiological and traceback evidence. Early in the investigation, 4 subclusters were identified, all with salad as the item of interest. On 11/25/2024, CDC identified leafy greens/iceberg lettuce as the leading hypothesis with 46 cases from 7 states: IL (6), IN (1), KS (1), MO (30), ND (1), OH (3), SD (1).

Epidemiology Overview & Genomic Analysis

On November 25, 2024, PulseNet coded an outbreak of *E. coli* O157:H7 2411MOEXH-2. At the time of closing, this investigation included 89 cases across 15 states: AR (2), CO (1), IL (7), IN (8), KS (1), KY (1), MO (50), MT (1), ND (2), NE (3), OH (8), PA (1), SD (1), TN (1), WI (2), all related within 0-4 alleles by cgMLST. Isolation dates ranged from November 7, 2024, to December 1, 2024. Reported onset dates (n=83) ranged from November 4, 2024, to November 30, 2024. Ages ranged from 4 to 90 years with a median age of 24. Sixty of 88 cases (68%) were female. Outcome information was available for 74 cases, of which 36 (49%) were hospitalized. There were 7 reported cases of HUS, and 1 death attributed to this outbreak.

A case in this investigation was defined as infection with *E. coli* O157:H7 with an isolate related to the outbreak strain within 0-4 alleles by cgMLST and isolation date ranging from November 7 to December 1, 2024.

This outbreak was coded following notification from colleagues in MO after they identified and investigated multiple illness linked to events catered by the same MO-based caterer. These events occurred between November 6 and November 8. All events included the same menu items with a few modifications. MO colleagues conducted a retrospective cohort study at 2 of the events and found that salads were the only statistically significant menu item across both events. Salads contained an iceberg/romaine lettuce blend, carrots, purple cabbage, onions, canned pimento, canned artichokes, parmesan cheese, and a house made salad dressing.

In total, 7 subclusters were identified across the multistate outbreak. These included (b)(4) MO catered events, an OH (b)(4) school, an IN restaurant, and IL restaurant, and an IL event catered by a different MO-based caterer. Salads were the common link across all 7 subclusters, and cases in all subclusters ate an iceberg/romaine lettuce blend. CDC deployed a focused questionnaire on November 26, 2024; 27 questionnaires were returned. Epi information was available for 65 cases, of which 60 (95%) reported consuming any type of leafy green prior to illness. Of 57 cases who could remember the exact type of leafy green consumed, 50 (88%) consumed romaine lettuce. This



is statistically significantly higher than the background rate of 49% from the FoodNet Population survey.

This outbreak was related to six historical investigations: 2302MLEXH-1, 2210MLEXH-3, 2210MLEXH-2, 2209MLEXH-1, 2112MLEXH-1, and 2106CAEXH-1. The only vehicle identified was for 2112MLEXH-1, which was closed with a confirmed vehicle of organic power greens. The NCBI tree for this strain included numerous nonclinical beef isolates.

Field Investigations & Findings

CORE issued nine assignments for traceback record collection to FDA Office of Inspections and Investigations (OII) Office of Human Food Inspectorate (OHFI) for this incident. There were no observations noted.

On 11/26/24, CORE issued eNSpect Assignment #257708 to OII OHFI 3E (Baltimore District Office) for traceback data collection from (b)(4) (b)(4) was identified as the supplier of lettuce blend to the distribution center.

On 11/27/24, CORE issued eNSpect Assignment #255727 to OII OHFI 4C (Kansas District Office) for traceback data collection from (b)(4) (b)(4) was identified as the supplier of lettuce mix to the distribution center.

On 11/27/24, CORE issued eNSpect Assignment #255729 to OII OHFI 2C (Cincinnati District Office) for traceback data collection from (b)(4) (b)(4) was identified as the supplier of shredded lettuce to the distribution center.

On 11/27/24, CORE issued eNSpect Assignment #255725 to OII OHFI 1C (Detroit District Office) for traceback data collection from (b)(4) (b)(4) was identified as a broker that supplied (b)(4) leafy green products.

On 11/29/24, CORE issued eNSpect Assignment #255828 to OII OHFI 2C (Cincinnati District Office) for traceback data collection from (b)(4) (b)(4) was identified as the supplier shredded lettuce to the distribution center.

On 12/3/24, CORE issued eNSpect Assignment #255996 OII OHFI 1W (San Francisco District Office) for traceback data collection from (b)(4) (b)(4) was identified as a common supplier of romaine lettuce.

On 12/9/24, CORE issued FACTS Assignment #12413245 to OII OHFI Produce Safety Branch for a farm inspection and sampling at (b)(4) (b)(4) of the ranches identified through traceback (b)(4) (b)(4) were investigated. The assignment was closed out with no observations.

On 12/11/24, CORE issued eNSpect Assignment #256346 to OII OHFI 1C (Detroit District Office) for traceback data collection from (b)(4) were identified as suppliers of romaine and iceberg lettuce.

On 12/12/24, CORE issued eNSpect Assignment #256441 to OII OHFI 5C (Dallas District Office) for traceback data collection from (b)(4) was identified as the processor/supplier of the spring mix.

Laboratory Sample Overview

While the outbreak strain was not detected in any inspectional samples collected during this response, 12 environmental and water samples were collected by FDA.

Traceback Abbreviated Summary

A traceback investigation was initiated in response to a *E. coli* O157 outbreak with leafy greens as the suspected vehicle. Each case included in the traceback investigation reported consumption of leafy greens prior to illness onset. Based on information available at the points of service (POS), the traceback focused on iceberg and romaine lettuce. The investigation consisted of three traceback legs representing twenty-eight cases and (b)(4) POS. The three traceback legs identified (b)(4) distribution centers, (b)(4) broker, (b)(4) processors, (b)(4) grower, and (b)(4) ranch. The traceback investigation determined that (b)(4), the sole processor, sourced romaine lettuce from (b)(4) grower, (b)(4). This romaine was available at all points of service during the specified timeframe of interest. Additionally, romaine lettuce supplied to (b)(4) POS was traced back to a common ranch and lot. Through analysis of records, (b)(4) lots of romaine lettuce were implicated, resulting in confirmation of romaine lettuce as the vehicle.

Product & Firm Actions

No product or firm actions were taken by FDA during this investigation. (b)(4) performed an inventory analysis to confirm there was no additional product available for consumption. Additionally, (b)(4) performed an internal investigation to review production and testing data as well as distribution patterns. The firm confirmed that both the raw material testing and finished product testing of the lot, (b)(4) (ranch), (b)(4) (lot), did not indicate the presence of *E. coli*. (b)(4) reported taking additional investigative steps, including an onsite review of the (b)(4) ranch.

Communications Overview

There were no public communications related to this outbreak. (b)(4) was not named during this outbreak because there was no product remaining in commerce.

Conclusions

Based on epidemiologic and traceback data, romaine lettuce was confirmed as the source of this outbreak. The traceback investigation determined that a sole processor sourced romaine lettuce

from (b)(4) grower that would have been available at all points of service during the timeframe of interest. Additionally, romaine lettuce supplied to (b)(4) POS was traced back to a common ranch and lot. While iceberg lettuce was also traced, there were no common growers identified. A farm investigation was performed at the identified grower to determine the route of contamination; however, there were no notable observations. At the conclusion of this response, this cluster included 89 cases across 15 states [AR (2), CO (1), IL (7), IN (8), KS (1), KY (1), MO (50), MT (1), ND (2), NE (3), OH (8), PA (1), SD (1), TN (1), WI (2)].

Acknowledgements

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IN	Epi
MN	RRT
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