

E.coli O121:H19/Romaine/Dec 2021
CARA 1050
Incident Summary Report

3/15/22

Authors:

CORE Signals & Surveillance Team: Brittany Carpenter, MPH CORE Response Team (3): Stranjae' Ivory, MPH

ABSTRACT

On 12/15/21, FDA CORE Signals received notification of a multistate cluster of E. coli O121:H19 from the Office of Regulatory Affairs (ORA) Human and Animal Food Operations (OHAFO) Division 6 West (Seattle District Office). The cluster included four cases from two states [MN (2) and WA (2)]. At the time of transfer, epidemiologic information identified romaine lettuce as the suspect vehicle. FDA's traceback investigation was initiated to identify the source of fresh romaine lettuce to two Chipotle Mexican Grill locations and two Panera Bread locations. CORE issued an assignment (eNSpect #217387) to ORA OHAFO Division 2 West (Kansas City District Office) for traceback record collection at Panera Bread headquarters (St. Louis, MO). ORA OHAFO Division 1 West (Minneapolis District Office) and Minnesota state partners aided in traceback record collection from Chipotle Mexican Grill (Rochester, MN) locations.) was identified as the common supplier of romaine lettuce to Chipotle Mexican Grill and Panera Bread locations. ORA OHAFO Division 5 West (San Francisco District Office) provided grower level information . Of the seven growers identified, (19) (4)) was the only common grower of fresh romaine lettuce for both Panera Bread and Chipotle Mexican Grill during our timeframe of interest. The vehicle for this outbreak was confirmed as romaine lettuce based on epidemiologic and traceback evidence. At the conclusion of the CORE Response phase, a total of four cases in two states [MN (2) and WA (2)] were associated with this outbreak.

SIGNALS AND SURVEILLANCE ACTIVITIES

On 12/15/21, Office of Regulatory Affairs Human and Animal Food Operations Division 6 West (Seattle District Office) notified CORE Signals of a multistate cluster of *E. coli* O121:H19 illnesses being investigated by Washington Department of Health. At the time of transfer, the cluster included four cases in two states: Minnesota (MN) - 2 and Washington (WA) - 2. Isolation dates ranged from 11/24/21-11/30/21. Cases ranged in age from 18-32 years (median=21), and 50% of cases were female. There were no hospitalizations, deaths, nor HUS reported. Centers for Disease Control and Prevention (CDC) assigned a pre-outbreak code instead of a defined outbreak code (POB2112MLEXK-1), due to PulseNet's tendency to reserve outbreak codes for enteric clusters with case counts greater than five.

Isolates were highly related within 1-2 SNPs (average: 2) by WGS in NCBI. Expanded analysis conducted by Center for Food Safety and Applied Nutrition Office of Analytics and Outreach found several clinical isolates related within 0-40 SNPs. Cluster isolates were also within 30 SNPs of a cluster of *E. coli* O121 illnesses from 2014 (PulseNet cluster code 1411MLEXK-1; EON-186948; CARA # 456). This incident was closed in the Signals stage with an unknown vehicle; however, leafy greens were an item of interest during the investigation.

Regarding cluster POB2112MLEXK-1, 4/4 cases reported consuming meals containing romaine lettuce prior to illness onset. Epidemiologic information from Washington Department of Health indicated WA cases consumed lunch from two different Panera Bread locations, one in Snohomish County and one in King County. MN state partners indicated MN cases consumed meals that included romaine lettuce from two different Chipotle Mexican Grill locations in Rochester, MN. Detailed exposure information is listed below.

			Meal Date(s) &		
ID	WGS ID	Location	Onset	Time	Meal(s)
MN_ H21-	PNUSAE091412	Chipotle Mexican	11/26/21	11/23/21,	11/23/21: Steak
16904		Grill #649		11/25/21	burrito w/Romaine
		1201 Broadway			lettuce
		Ave S, Rochester,			
		MN			11/25/21:
					Chicken/steak tacos
					w/Romaine lettuce
MN_ H21-	PNUSAE091113	Chipotle Mexican	11/26/21	11/20/21	Burrito bowl
16885		Grill#557			w/chicken, smoked
37		3780 Marketplace			brisket & Romaine
		Dr NW,			lettuce
		Rochester, MN			
WA_0697014	PNUSAE090854	Panera Bread	11/21/21	11/19/21,	Green Goddess
		Tacoma, WA		Lunch	Cobb Salad
					w/chicken, Green
					Passion smoothie
WA_0697354	PNUSAE091051	Panera Bread	11/23/21	11/19/21,	Caesar salad
		2107 S. 320th		Lunch	w/chicken,
		Federal Way			substituted with
		Federal Way,			(b) (4)
		WA			

by MN and WA state partners identified (4)) as the common supplier of romaine lettuce for Chipotle Mexican Grill and Panera Bread. Records indicated that both Chipotle Mexican Grill locations received romaine lettuce from a distributor, Records also indicated that (b) (4) sourced their , located in (b) (4)). Representatives at the MN Chipotle romaine product from Mexican Grill also stated they had a dedicated product that was packed specifically by (6) for Chipotle Mexican Grill. Traceback information obtained from Chipotle Mexican Grill identified in (b) (4), in addition to specific growers of romaine lettuce, including (1)] and **(b) (4)** both located in Traceback information obtained from Panera Bread identified) as a distributor of romaine lettuce, with product reportedly sourced from (b) (4)). Additional outreach to Panera Bread for further traceability and grower information had not yet occurred at the time of transfer. On 1/4/22, CDC identified romaine lettuce as the suspect vehicle based on epidemiologic and traceback information.

Rationale for Transfer:

CORE Signals transferred this incident to Response Team 3 on 1/5/22 based on the following rationale:

- This was a multistate outbreak with an FDA-regulated product, romaine lettuce identified as the leading hypothesis.
- Response coordination was needed to conclude the traceback investigation and identify the ranches of interest for the Panera leg.
- Shiga-toxin producing *E. coli* outbreaks linked to leafy greens continued to be of high interest because of the repeat nature of this pathogen/commodity pair. Obtaining more specific traceability information would allow for future prevention activities.

<u>RESPONSE</u>

Epidemiology

A case was defined as infection with *E. coli* O121:H7 whose isolate is indistinguishable to the outbreak strain (allele code EC1.0 - 18.1.14.38.16) by cgMLST with illness onset on or after November 21, 2021. This outbreak included four cases from two states. Isolation dates ranged from 11/24/21 to 11/30/21 and reported onset dates ranged from 11/21/21 to 11/26/21. Ages ranged from 18 to 32 years (median 21), and 50% of cases were female. No cases were hospitalized, developed HUS, or died. All isolates were indistinguishable from each other by cgMLST.

This outbreak was first reported to Centers for Disease Control and Prevention/Outbreak Response and Prevention Branch (ORPB) by Washington State Department of Health on 12/13/21 when they reported a trio of isolates with a matching allele code, two in WA, one in MN. On 12/15/21, a second MN case was identified. Both WA cases reported Panera Bread, one case had a Cobb Salad on 11/19/21 and onset of illness 11/21/21, and the second had a Caesar Salad on 11/19/21 and onset of illness 11/23/21. Both cases ate at different Panera Bread locations. Both MN cases reported Chipotle Mexican Grill. The first MN case reported a burrito bowl on 11/23/21 that had steak and chicken, lettuce, cheese and sour cream. The first MN also reported consuming tacos on 11/25/21 that had steak and chicken, lettuce, cheese and sour cream. This case's onset was 11/26/21. However, MN state partners confirmed that the reported Chipotle Mexican Grill location was closed on 11/25/21. The second MN case had Chipotle Mexican Grill on 11/20/21, and their meal was a chicken and brisket bowl, with rice, lettuce, cheese, salsa and sour cream. This case's onset was 11/26/21.

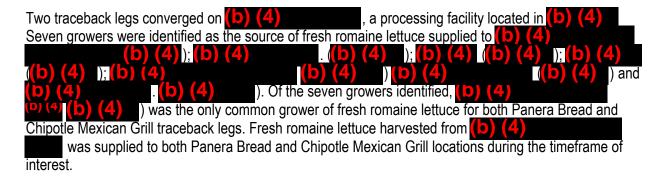
CDC has closed this investigation, as of 01/21/22, noting that romaine lettuce is the confirmed source of this outbreak. This outbreak has been reported to NORS, ID POB2112MLEXK-1.

The CDC linelist is available in CARA 1050.

Traceback

As of 1/21/22, four ill persons associated with this outbreak were reported from two states: MN (2) and WA (2). Reported illness onset dates ranged from 11/21/21 to 11/26/21. All four cases that were interviewed reported consuming meals containing fresh romaine lettuce in the week prior to illness onset.

A traceback investigation was initiated on 1/5/21 for fresh romaine lettuce as reported by four cases associated with four points of service (POS) in Minnesota and Washington. These individuals represented those with clinical isolates matched to the outbreak strain with reported exposure to fresh romaine lettuce in the week prior to their illness onset date. The timeframe of interest was 11/6/21 through 11/23/21 based on shelf life and turn-around time.



Office of Regulatory Affairs Human and Animal Food Operations Division 2 West (Kansas City District Office) and Office of Regulatory Affairs Human and Animal Food Operations Division 5 West (San Francisco District Office) shared grower information (as well as GPS coordinates) for Panera Bread and Chipotle Mexican Grill traceback legs. Office of Regulatory Affairs Human and Animal Food Operations Division 5 West (San Francisco District Office) followed up with (5) (4) to obtain GPS coordinates for the Chipotle Mexican Grill traceback leg. Office of Emergency Management Geographic Information Systems team provided a map of the traceback identified ranches associated with Panera Bread and Chipotle Mexican Grill traceback:

https://geoweb.fda.gov/portal/home/webmap/viewer.html?webmap=669161ce32b64a2c9f7561292b2135f5

The Traceback timeline, summary, and diagram are available in CARA 1050.

Establishment and Inspections

On 1/13/22, CORE issued an assignment (eNSpect Assignment #217387) for traceback data collection requesting traceback records from Panera Bread corporate headquarters (St. Louis, MO; FEI: 3006986852). On 1/18/22, Office of Regulatory Affairs Human and Animal Food Operations Division 2 West (Kansas City District Office) provided Panera Bread's grower information for suppliers to (19) (4). Office of Emergency Management Geographic Information Systems team mapped

growers' GPS coordinates. On 1/21/2022, the assignment was closed. Based on mapped coordinates, growers were located near the (b) (4)

Laboratory

There were no samples collected or analyzed during the response phase of this incident.

Product/Firm Action

There were no product/firm actions during the response phase of this incident.

COMMUNICATIONS

There were no public communications issued during the response phase of this incident.

CONCLUSION

As of 3/8/22, a total of four illnesses were reported from two states [MN (2) and WA (2)]. Both WA cases reported romaine lettuce containing meals from two Panera Bread locations. Both MN cases reported romaine lettuce containing meals from two Chipotle Mexican Grill locations. The traceback investigation identified (b) (4) as the common grower and ranch for fresh romaine lettuce supplied to a total of four POS. There were no product or firm actions. Based on epidemiologic and traceback evidence, romaine lettuce was confirmed as the vehicle for this *E.coli* O121:H19 outbreak.

ACKNOWLEDGEMENTS

CORE would like to acknowledge the work of Washington Department of Health and Minnesota State Partners for initiating the collection of epidemiologic and traceback information. Many thanks to Office of Regulatory Affairs Human and Animal Food Operations Division 1 West and Office of Regulatory Affairs Human and Animal Food Operations Division 2 West for accommodating our traceback requests from Chipotle Mexican Grill and Panera Bread. In addition, thank you to Office of Regulatory Affairs Human and Animal Food Operations Division 5 West and Office of Regulatory Affairs Human and Animal Food Operations Division 6 West for their efforts to collect traceback records and GPS coordinates. Your contributions to this outbreak investigation are appreciated.

INCIDENT COORDINATION GROUP

Incident Group List – E. coli O121:H19/Romaine/Dec 2021

Coordinated Outbreak Response and Evaluation Network

Signals & Surveillance: Brittany Carpenter

Response: Response Team 3

Lead Coordinator: Stranjae' IvoryOperations: Mardea Caulcrick-Grimes

• Planning: Dr. Adiam Tesfai

Outbreak Evaluation: Cerise Hardy

Outbreak Analytics

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Division II - BLT-DO (Baltimore District					
Office), NWJ-DO (New Jersey District					
Office)					
Division III ATL-DO (Atlanta District Office)					
District IV FLA-DO (Florida District Office)					
Division V – CIN-DO (Cincinnati District					
Office), NOL-DO (New Orleans District					
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FDA STEC Safety Council Work Group					
Office of the Center Director, International Affairs Staff	CAPT Teresa Fox, <u>IAS-Action@fda.hhs.gov</u>				
Office of the Commissioner					
Office of Chief Counsel	Heather Bennett				
Office of Global Policy and Strategy – Latin					
America Office					
Centers for Disease Control and Prevention	on				
Division of Foodborne, Waterborne, &	Zach McCormic				
Environmental Diseases – Outbreak	CDR Laura Gieraltowski				
Response and Prevention Branch (ORPB)	Thai-An Nguyen				
	Susan Lance (CDC Liaison)				
State Partners					
Minnesota	Minnesota Department of Agriculture				
WA					
CA					

SUPPORTING DOCUMENTS

- 1. CDC Line list
- 2. Traceback Diagrams (master and detailed)
- 3. Traceback Timeline
- 4. Traceback Summary
- 5. Observations and Recommendations

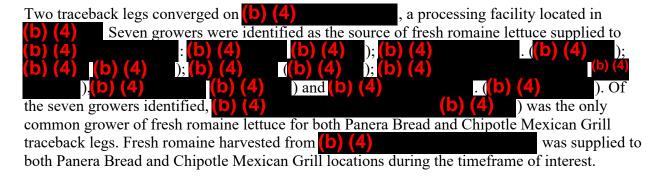
E. Coli O121:H19/Romaine Lettuce/Dec 2021 Traceback Investigation Summary CARA # 1050

For internal FDA use only. This summary contains confidential, commercial information and may not be released outside FDA without appropriate redaction.

Traceback Abstract

As of 1/21/2022, four ill persons associated with this outbreak have been reported from two states: MN (2) and WA (2). Reported illness onset dates ranged from 11/21/2021 to 11/26/2021. All four cases interviewed reported consuming meals containing fresh romaine lettuce in the week prior to illness onset.

A traceback investigation was initiated on 1/5/2021 for fresh romaine lettuce as reported by four cases associated with four points of service (POS) in Minnesota and Washington state. These individuals represented those with clinical isolates matched to the outbreak strain with reported exposure to fresh romaine lettuce in the week prior to their illness onset date. The timeframe of interest was 11/6/2021 through 11/23/2021 based on shelf life and turn-around time.



A master traceback diagram and detailed diagram illustrating the distribution of product is attached. Summaries of each traceback leg, including analysis and discussion follows:

TRACEBACK Leg 1 (Chipotle Mexican Grill Leg)

Points-of Service (POS): Chipotle Mexican Grill #649 and #557(Rochester, MN)



POS: Chipotle Mexican Grill #649 (Rochester, MN)

Chipotle Mexican Grill restaurant #649 is located at 1201 Broadway Ave S, Rochester, MN 55904. There was a single lab confirmed case associated with this POS. The case patient reports consuming a steak burrito with romaine lettuce on 11/23/2021 and had an onset date of 11/26/2021. This case patient also reported consuming chicken/steak tacos with romaine lettuce on 11/25/2021. However, Minnesota state partners confirmed this Chipotle Mexican Grill location was closed on 11/25/2021.

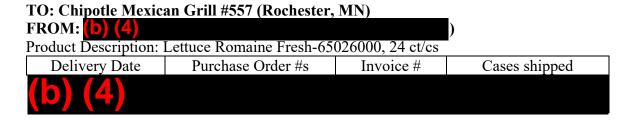
Minnesota State partners collected purchase order receiving reports, invoices, romaine lettuce grower level spreadsheet and shipping spreadsheet from Chipotle Mexican Grill. During the time frame of interest (11/9/2021-11/23/2021), this Chipotle Mexican Grill restaurant location received three shipments of fresh romaine lettuce from (b) (4) (b) (4) (c) Two (2) of the 3 were implicated due to the shelf life of the product and the ability to supply the exposure dates with a quick turn-around time.



POS: Chipotle Mexican Grill #557 (Rochester, MN)

This Chipotle restaurant is located at 3780 Marketplace Dr NW, Rochester, MN 55901. There was one lab confirmed case associated with this POS. This case reports a meal date on 11/20/2021, consuming a burrito bowl with chicken, smoked brisket with romaine lettuce. The case patient reported an onset of 11/26/2021.

Minnesota State partners collected purchase order receiving reports, invoices, romaine lettuce grower level spreadsheet and shipping spreadsheet from Chipotle Mexican Grill. During the time frame of interest (11/6/2021-11/20/2021), this Chipotle Mexican Grill received six shipments of fresh romaine lettuce from (b) (4) . Three (3) of the 6 shipments were implicated due to the shelf life of the product and the ability to supply the exposure dates with a quick turn-around time.





(b) (4)

(b) (4)

is a distributor located at (b) (4)

. During the time frame of interest, (b) (4) supplied fresh romaine lettuce to Chipotle Mexican Grill, Broadway and Marketplace locations.

Minnesota State partners collected purchase order receiving reports, invoices, romaine lettuce grower level spreadsheet and shipping spreadsheet from Chipotle Mexican Grill. (b) (4)

received shipments of fresh romaine lettuce from (b) (4)

during the timeframe of interest. From 11/6/2021 through 11/23/2021, (b) (4)

received five shipments of fresh romaine lettuce from (b) (4)

(b) (4)

Four of the five shipments were implicated because they were linked to (b) (4)

implicated outgoing shipments as well as the availability to supply the implicated lots at the POS and the shelf life of the product.

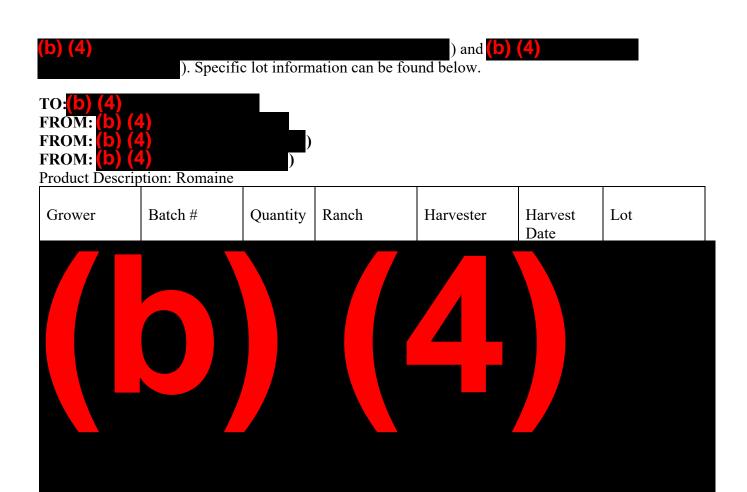
TO: (b) (4) (b) (4))
FROM: (b) (4) ((b) (4))

Product Description: Fresh Romaine Lettuce—CC1901, 24 ct

Received Date	Purchase Order #	SO#	Batch #	Quantity (cs)
(b		4		

(b) (4)

is located at (b) (4) . Minnesota state partners provider grower level spreadsheet data from Chipotle Mexican Grill for shipments of fresh romaine lettuce supplied to both Chipotle locations. Fresh romaine lettuce suppliers during the time frame of interest for the implicated shipments were: (b) (4) :



Grower level information was received from Chipotle POS. Additional follow-up was conducted by FDA Human and Animal Foods Division 5 West (SAN-DO) to obtain farm GPS coordinates from (b) (4)

TRACEBACK Leg 2 (b) (4)

Point-of Service: (b) (4)

Endpoints:



POS: (b) (4)

This **(b) (4)** is located at **(b) (4)**

There was a single lab confirmed case associated with this POS. The case patient reported a meal date of 11/19/2021 consuming a Caesar salad-substituted with Green Goddess mix with illness onset of 11/23/2021.

Washington State Department of Agriculture (WSDA) collected invoices, bills of lading and receiving logs from Panera Bread. FDA Human and Animal Foods Division 2 East (KAN-DO) collected additional invoices, bills of lading, receiving logs, cut sheet reports and harvest level spreadsheet data from Panera Bread's headquarters as part of eNSpect assignment #217387 for the period from 11/12/2021 through 11/19/2021.

During the time frame of interest (11/12-11/19/2021), this Panera Bread restaurant location received 8 shipments of romaine lettuce from the (b) (4). Six (6) of the 8 shipments were implicated due to the shelf life of the product and the ability to supply the exposure dates with a quick turn-around time. No invoices were provided for 11/18/2021. The (b) (4) advised CORE to refer to the paper logs provided for accurate shipment quantities and corresponding lot information as the ordering POS will occasionally make changes to orders after an invoice is created.



Product Description: Romaine Lettuce—Item # 1523431



POS: Panera Bread (Tacoma, WA)

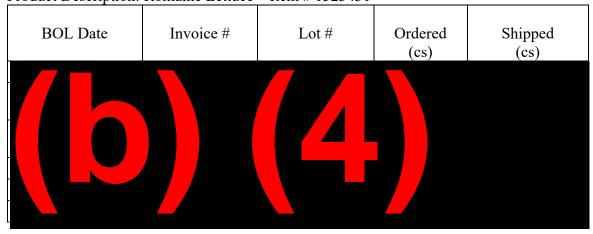
This Panera Bread restaurant is located at 4502 S. Steele St. Suite 125, Tacoma, WA 98409. There was one lab confirmed case associated with this POS. Case patient reports a meal date of 11/19/2021. Case reports consuming a Green Goddess Cobb salad with chicken and a green passion smoothie with illness onset date of 11/23/2021.

Washington State Department of Agriculture (WSDA) collected invoices, bills of lading and receiving logs from Panera Bread. FDA Human and Animal Foods Division 2 East (KAN-DO) collected additional invoices, bills of lading, receiving logs, cut sheet reports and harvest level spreadsheet data from Panera Bread's headquarters as part of eNSpect assignment #217387 for the period from 11/12/2021 through 11/19/2021.

During the time frame of interest (11/12-11/19/2021), this Panera Bread restaurant location received 6 shipments of romaine lettuce from the Panera Bread FDF. Five of the six shipments were implicated due to the shelf life of the product and the ability to supply the exposure dates with a quick turn-around time.

TO: Panera Bread (Tacoma, WA) FROM: (b) (4)

Product Description: Romaine Lettuce—Item # 1523431

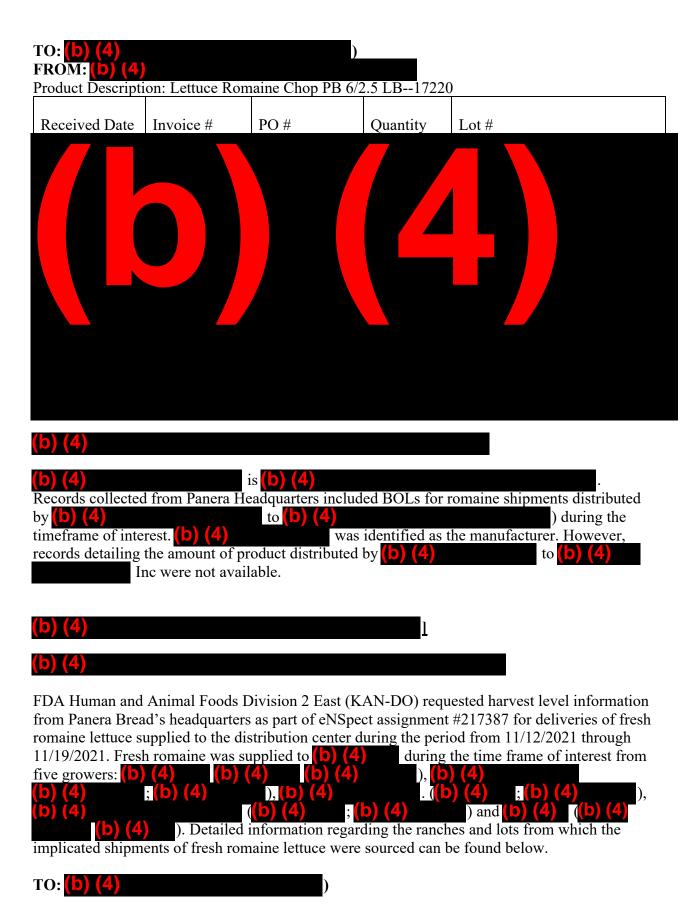


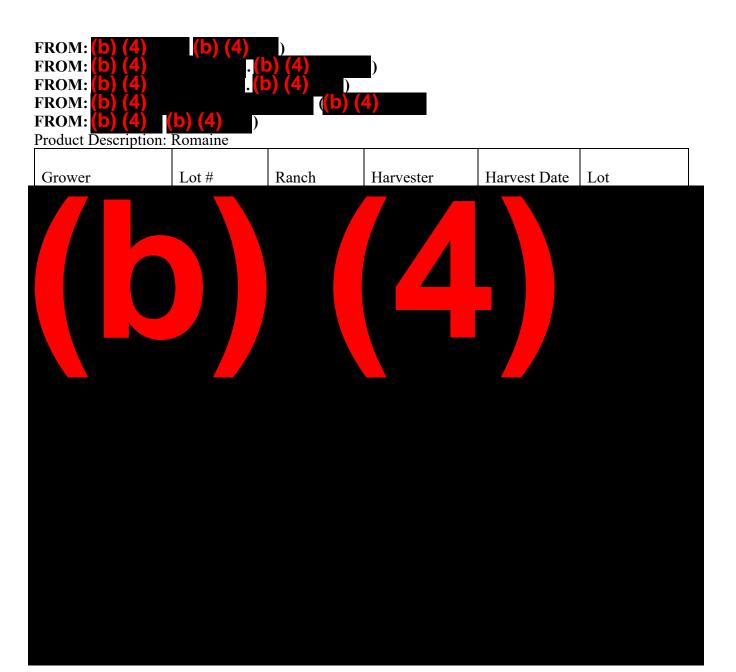
(b) (4)

During the time frame of interest (11/12/2021-11/19/2021), this distribution center supplied fresh chopped romaine lettuce to the Panera Bread Federal Way and Tacoma, WA locations.

Washington State Department of Agriculture (WSDA) collected invoices, bills of lading and receiving logs from Panera Bread. FDA Human and Animal Foods Division 2 East (KAN-DO) collected additional invoices, bills of lading, receiving logs, cut sheet reports and harvest level spreadsheet data from Panera Bread's headquarters as part of eNSpect assignment #217387 for the period from 11/12/2021 through 11/19/2021. During the time frame of interest, Panera Bread FDF received 7 shipments of fresh romaine lettuce from (b) (4)

(6) shipments, including one lot from 11/12/2021 were implicated due to their ability to supply the implicated lots at the POS. For shipment received on 11/12/2021, the distribution center confirmed there was no co-mingling of lots at any point in the supply chain. Occasionally pallets are received with multiple lot codes, however individual cases of product will always only contain a single lot of product. Products are not repacked or co-mingled at any point.





Given that grower level information and GPS coordinates was received from Panera Bread, no additional follow up was conducted with (b) (4)

Conclusion

A traceback investigation was initiated in response to an *E. coli* O121:H19 outbreak linked to fresh romaine lettuce. This investigation consisted of two traceback legs representing four cases who reported consuming romaine lettuce containing dishes at four different points of service in two states prior to their illness onset dates.

Following review of traceback records and information, two distributors were identified as the suppliers of fresh romaine lettuce to the points of services. Fresh romaine supplied to both

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distributors were sourced from (b) (4) , (b) (4) . Harvest level data provided by Panera Bread and Chipotle Mexican Grill was traced back to seven growers and nine ranches: (b) (4) (b) (4) ) associated with (b) (4) (b) (4)
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The traceback investigation converged on (b) (4) as the common grower for fresh romaine supplied to both the Panera Bread and Chipotle Mexican Grill legs.

Limitations

This traceback investigation was limited by the size of the illness clusters identified; there was only a single lab confirmed case associated with each POS. Additionally, the traceback was limited to only two distinct geographic regions. A combination of single cases within a limited geographical area could reduce the confidence in the traceback investigation.

Attachments

Master & Detailed Traceback Diagrams



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August 16, 2022

VIA PORTAL

Food and Drug Administration Division of Freedom of Information Office of the Executive Secretariat, OC 5630 Fishers Lane, Room 1035 Rockville, MD 20857

GENERAL OUTBREAK - FREEDOM OF INFORMATION ACT REQUEST

Dear CDC/ATSDR FOIA Officer:

An outbreak of E. coli O121 was investigated by the CDC, FDA, and state partners in November 2021. This outbreak has been linked to leafy greens supplied to Panera and Chipotle. There have been 2 cases in Washington and 2 cases in Minnesota. Reported onset dates range from 11/24/2021-11/26/2021. Marler Clark Law Firm represents clients who fell ill in this outbreak. We are writing to request copies of any records on file at the FDA, compiled between October 2021 and July 2022, regarding the investigation of this outbreak (CDC ID: POB2112MLEXK-1). We specifically request:

- all health department **summary reports (NORS reports)** of any investigations conducted for this outbreak;
- **complete linelists** of cases, lab specimen, and exposures pertaining to cases in the outbreak;
- results from any analytical studies done for this outbreak (such as case-control, case-case comparison studies, or binomial calculations); and
- traceback information into exposures and suspected sources identified for this outbreak;

In all instances, we understand that names and other identifying information for individuals must be redacted. We are willing to pay any reasonable fees associated with retrieving and copying this information. Please contact me at the above telephone number or electronic mail address if you need more information. Records should be released to my email (kdoherty@marlerclark.com), our FAX (206-346-1898), or to this address:

Marler Clark Law Firm Attn. Kiley Doherty 1012 First Avenue, Fifth Floor Seattle, WA 98104 Thank you very much for your assistance.

Sincerely,

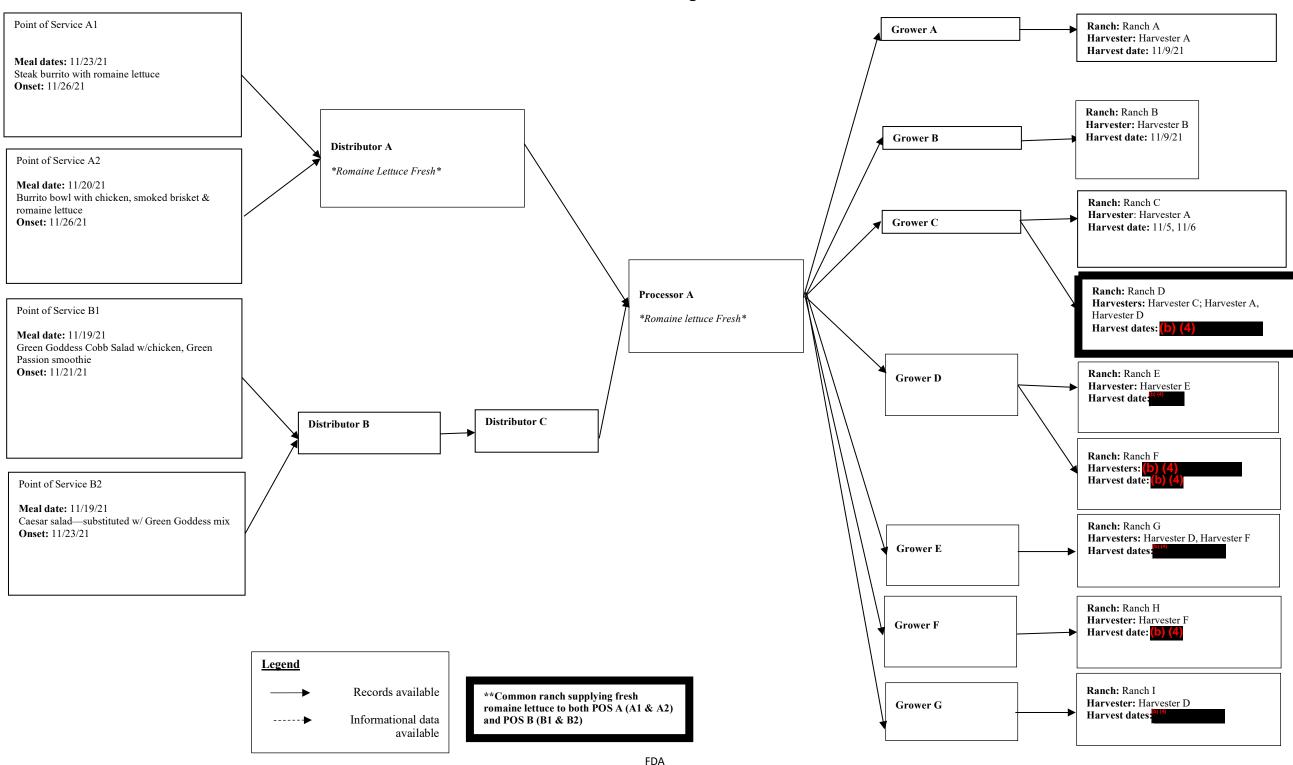
Kiley Doherty

Kiley Doherty, MPH

E. Coli O121:H19 – Romaine Lettuce

Multi-state Outbreak--Dec 2021

Traceback Diagram



Coordinated Outbreak Response and Evaluation [Date Created: 01/05/22; Date Updated: 3/31/22]