

***E. coli* O157:H7/Romaine Lettuce/Nov 2024**
Traceback Investigation Summary
CARA# 1280

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SUMMARY

A traceback investigation was initiated on 11/26/2024 at (b)(4) points-of-service (POS) in response to a *E. coli* O157 outbreak. As of 1/7/2024, 89 ill persons with the outbreak strain have been reported from 15 states; AR (2), CO (1), IL (7), IN (8), KS (1), KY (1), MO (50), MT (1), NE (3), ND (2), OH (8), PA (1), SD (1), TN (1), WI (2). Reported illness onset dates ranged from 11/4/2024 – 11/30/2024. Ages ranged from 4 to 90 years with a median age of 24. Sixty of 88 cases (68%) were female. There were seven reported cases of HUS, thirty-six hospitalizations and one death.

In total, seven subclusters were identified across the multistate outbreak. These included three 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 commonly reported across all seven subclusters; cases reporting consuming an iceberg/romaine lettuce blend. CDC deployed a focused questionnaire on November 26, 2024; 27 questionnaires were returned. Epidemiological 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.

Factors used in identifying the best available cases were individuals with a WGS match to the outbreak, confirmed cases with known onset dates and exposure/purchase dates associated with a particular point of service/sale location, documented food exposures for leafy greens, and limited food exposures to leafy greens.

The timeframe of interest for record collection was two weeks prior to illness onset.

A master traceback diagram is available in CARA. Summaries of each traceback leg, including data analysis discussion, follow.

Traceback Analysis

Invoices were collected for five points of sale representing twenty-eight cases. During the timeframe of illness, (b)(4) implicated shipments of romaine were supplied to (b)(4) of the five points of service.

One processor, Taylor Farms of Salinas, CA supplied all the romaine lettuce that would have been available at all points of sale during the timeframe of interest through seven distribution centers. The romaine lettuce supplied by Taylor Farms of Salinas, CA was grown by Anthony Costa and Son's LLC (Soledad CA).

Traceback Leg 1: (b)(4) School (b)(4), OH

Point of Service (POS):

(b)(4)

Endpoints:

1. Anthony Costa and Son's LLC; 36817 Foothill Rd Soledad CA 93960-9656

(b)(4) School

This school is located at (b)(4).

There were three cases (OH__24GM002814, OH__24GM002833, OH__24GM002850) associated with this POS with onset dates of 11/6/24, 11/9/24, and 11/10/24.

Ohio state partners provided CORE with invoices from (b)(4) School. The invoices identified (b)(4) as the sole supplier of Ready Set Serve By (b)(4), Lettuce Blend Iceberg/ROMN, Ready Set Serve By (b)(4) Lettuce Salad MXD, and Ready Set Serve By (b)(4) Chopped Romaine to the point of service during the timeframe of interest of 10/23/2024 – 11/10/2024. (b)(4) shipment was implicated.

AT: (b)(4) School

FROM: (b)(4)

Product Description: Lettuce Blend Iceberg/ROMN, Lettuce Salad MXD, Ready Set Serve By (b)(4) LETTUCE ROMAINE CHOP

Invoice Date	Invoice #	Item #	QTY:
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(b)(4)

(b)(4)

Final – Traceback Diagram for Salmonella Thompson Outbreak. These diagrams contain confidential commercial information intended for FDA use in its law enforcement and/or regulatory activities. They may not be further distributed without the written consent of FDA.

Revised: 10 Apr 08

(b)(4), OH) is located at (b)(4). (b)(4) was identified as the distributor of romaine to (b)(4) School. Under CORE assignment #255725, OII OHFI Central Division 1 (Detroit District Office) collected traceability information from (b)(4).

(b)(4), OH) received four shipments. This included one shipment of 6x2 LB LETTUCE ROMAINE CHOP, two shipments of 4x5 LB LETTUCE BLND ICEBERG/ROMN, and one shipment of 4x5 LB LETTUCE SALAD MXD from Taylor Farms of California (Salinas, California) (through (b)(4)). The firm uses the (b)(4).

The firm's traceability program (b)(4). (b)(4) shipment was implicated because the shipment would have been available at the POS during the timeframe of interest.

AT: (b)(4)
FROM: (b)(4)
Product Description: Ready Set Serve By (b)(4) LETTUCE ROMAINE CHOP & Ready Set Serve By (b)(4) Lettuce Blend Iceberg/ROMN 50/50, Ready Set Serve By (b)(4) Lettuce Salad MXD

Delivery Date	Invoice	Item Description	Item Code	Brand	PO Number
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(b)(4)

(b)(4) (b)(4)
(b)(4) is located at (b)(4). (b)(4)
is comprised of (b)(4) members to include: (b)(4)

(b)(4) served as the broker for sales between (b)(4) and Taylor Farms of California (Salinas, CA). (b)(4) does not take physical possession of the product or manipulate it. Traceability information, including bills of lading, were collected from (b)(4)) by OHFI Central Division 1 (Detroit District Office) under eNSpect assignment #255725.

Taylor Farms of California (Salinas, CA; FEI: 3012342127)

Taylor Farms of California is located at 1085 Abbott St Salinas CA 93901. Taylor Farms of California served as the processor of leafy greens. Leafy greens blends were run on blend lines while single varieties of leafy green (i.e. chop romaine or shredded lettuce) were ran on single commodity lines. According to Taylor Farms of California, there was a 16-day shelf life for the leafy green products. During the timeframe of interest, Taylor Farms of California (Salinas, CA) supplied thirteen shipments of leafy greens. This included seven shipments of MARKON BLEND LETT/ROM UPC 50/50 4/5#, three shipments of Markon UPC ROMAINE CHOP 6/2#, and three shipments of MARKON LETTUCE UPC SALAD MIX 4/5#.

Taylor Farms of California's traceability program was able to link incoming shipments with outgoing shipments based on raw lot numbers linked to the finished lot codes. One shipment was implicated because the shipment would have been available at the POS during the timeframe of interest. Traceability information, including bills of lading, was collected from Taylor Farms of California by OII OHFI West Division 1 (San Francisco District Office) under eNSpect assignment #255996.

AT: (b)(4)
FROM: Taylor Farms of California (Salinas, CA)

Ship Date	Buyer PO	Item #	Description	TF Lot Number	TF Order Number	QTY:
10/13/24	T878330P01 / 4 511950611	1060019	MARKON UPC ROMAINE CHOP 6/2#	WO2024285 & WO2024286	SO-1851 827	144
10/16/24	T881310P01/4511956239	1060019	MARKON UPC ROMAINE CHOP 6/2#	WO2024289	SO- 1852264	144
10/17/24	T884600P0 1/451 1962400	1060019	Markon UPC ROMAINE CHOP 6/2#	WO2024290	SO- 1852776	72
10/19/24	T891190P02/4511974132	1070034	MARKON BLEND LETT/ROM UPC 50/50 4/5#	WO2024293	SO- 1853586	120

10/24/24	T900120P 02/4511991481	1070034	MARKON BLEND LETT/ROM UPC 50/50 4/5#	WO2024297	SO- 1854908	40
10/25/24	T904310P01/4511998204	1070034	MARKON BLEND LETT/ROM UPC 50/50 4/5#	WO2024299	SO- 1 855396	120
10/26/24	T906770P01/4512004017	1070034	MARKON BLEND LETT/ROM UPC 50/50 4/5#	WO2024300	SO- 1855854	80
10/26/24	T906770P01/4512004017	1050046	MARKON LETTUCE UPC SALAD MIX 4/5#	WO2024299 WO2024300	SO- 1855854	280
10/30/24	T9I3040P01/4512014994	1070034	MARKON BLEND LETT/ROM UPC 50/50 4/5#	WO202 4303	SO- 1856796	80
10/30/24	T9I3040P01/4512014994	1050046	MARKON LETTUCE UPC SALAD MIX 4/5#	WO2024304	SO- 185 6796	350
10/31/24	U100470P01/4512021237	1070034	MARKON BLEND LETT/ROM UPC 50/50 4/5#	WO2024303	SO- 1857313	40
10/31/24	U100470P01/4512021237	10500146	MARKON LETTUCE UPC SALAD MIX 4/5#	WO2024304, WO2024305	SO- 185313	420
11/1/24	U104520P02/4512028307	1070034	MARKON BLEND LETT/ROM UPC 50/50 4/5#	WO2024305	SO- 185785'9	200

Anthony Costa and Sons (Soledad CA; FEI: 3005964451)

Anthony Costa & Sons LLC is at located 36817 Foothill Rd Soledad CA 93960-9656. Anthony Costa & Sons LLC is a sister company and parallel to Costa Farms Inc. Both entities own different fields but have the same ownership and same management. The fields of interest, Ernie Binsacca Ranch and Silliman Ranch are both owned by Anthony Costa & Sons LLC. According to the grower,

Final – Traceback Diagram for Salmonella Thompson Outbreak. These diagrams contain confidential commercial information intended for FDA use in its law enforcement and/or regulatory activities. They may not be further distributed without the written consent of FDA.

Revised: 10 Apr 08

they are exclusively a grower and own the product until a shipper takes over the product to commence harvesting. According to the farm, they do not have a say in what crop will be planted, nor when harvest begins, nor provide any harvest equipment, or harvest employees. Both lots were fallow at the time of the inspection. Traceability information was collected by ORA Produce Safety Network from Anthony Costa & Sons LLC (Soledad, CA) under FACTS assignment #12413245.

AT: Taylor Farms of California (Salinas, CA)
FROM: Anthony Costa and Sons (Soledad CA)
Product: Romaine Lettuce

Harvest/ Ship Date:	Customer PO	QTY:
10/19/2024	T891190P02/4511974132	120

Traceback Leg 2: (b)(4)

Point of Service (POS):

(b)(4)

2. Andre's Banquet- South; 4254 Telegraph Rd ST Louis, MO 63129

(b)(4)

Endpoints:

1. Anthony Costa and Son's LLC; 36817 Foothill Rd Soledad CA 93960-9656

(b)(4)

This restaurant is located at (b)(4). There were two cases (MO__1132848 and MO__1131716) associated with this POS with a meal date of 11/6/24 and onset dates of 11/12/24 and 11/9/24 respectively. These cases confirmed consumption of salads. The timeframe of interest for record collection was 10/23/2024 – 11/6/2024.

Missouri state partners provided CORE with invoices from (b)(4)

(b)(4). The invoices identified (b)(4) as the sole supplier of (b)(4) shipment of Lettuce Blend 80/20 w/ SEP to the point of service during the timeframe of interest.

AT: (b)(4)

FROM: (b)(4)

Product Description: Lettuce Blend 80/20 w/ SEP

Delivery Date	Invoice #	Item #	QTY:
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(b)(4)

Andre's Banquet- South

This banquet hall/ caterer is located at 4254 Telegraph Road St Louis, MO 63129. There were twenty-two cases associated with this POS with meal dates ranging 11/6/2024- 11/8/2024. The cases were served Lettuce Blend 80/20 w/ SEP during three separate events. The timeframe of interest for record collection was 10/23/2024 – 11/6/2024.

Missouri state partners provided CORE with invoices from (b)(4). The invoices identified (b)(4) as the sole supplier of (b)(4) shipment of Lettuce Blend 80/20 w/ SEP to the point of service during the timeframe of interest.

AT: Andre's Banquet- South
FROM: Performance FoodService Middendorf
Product Description: Lettuce Blend 80/20 w/ SEP

Delivery Date	Invoice #	Item #	QTY:
11/5/2024	4883028	872631	6 CS

(b)(4)
This (b)(4) (b)(4). There were two cases (IL2 __S240044146 and MO __1132846) associated with this POS with onset dates of 11/12/2024 and 11/13/2024. The cases confirmed consumption of salads. The point of sale confirmed that Lettuce Blend 80/20 w/ SEP is used for all salads. The timeframe of interest for record collection was 10/23/2024 – 11/8/2024.

Illinois state partners provided CORE with invoices from (b)(4). The invoices identified (b)(4) as the suppliers of Lettuce Blend 80/20 w/ SEP to the point of service during the timeframe of interest. (b)(4) supplied (b)(4) shipment of Lettuce Blend 80/20 w/ SEP to the point of service during the timeframe of interest. (b)(4) supplied (b)(4) shipments of Lettuce Blend 80/20 w/ SEP to the point of service during the timeframe of interest. (b)(4) shipment from (b)(4)

(b)(4) and (b)(4) shipment from (b)(4) were implicated.

AT: (b)(4)
FROM: (b)(4)
Product Description: Lettuce Blend 80/20 w/ SEP

Delivery Date	Invoice #	Item #	QTY:
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(b)(4)

AT: (b)(4)
FROM: (b)(4)
Product Description: (b)(4) Lettuce Mix 80/20 SEP Bags

Delivery Date	Invoice #	Item #	PO #	QTY:
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(b)(4)

(b)(4)
(b)(4) is located at (b)(4).
(b)(4) was (b)(4) of the distributors for (b)(4). This distributor supplied (b)(4) Lettuce Mix 80/20 SEP Bag to (b)(4). Under CORE assignment #255727, OHFI Central Division 4 (Kansas District Office) collected traceability information from (b)(4).

(b)(4) received three shipments of IMPFRSH Lettuce Mix 80/20 SEP Bags from Taylor Farms of California. The firm uses the (b)(4). Three shipments received by the distributor from Taylor Farms of California (Salinas, CA) were implicated because the shipments would have been available at the POS during the timeframe of interest.

AT: (b)(4)
FROM: Taylor Farms of California
Product Description: IMPFRSH Lettuce Mix 80/20 SEP Bags

<u>Received Date</u>	<u>PO Reference Number</u>	<u>Item Code</u>	<u>QTY</u>
10/22/2024	14531050	170003	30
10/29/2024	14548090	170003	20
11/2/2024	14555380	170003	70

(b)(4)

(b)(4) is located at (b)(4). (b)(4) was (b)(4) of the distributors for (b)(4). This distributor supplied Lettuce Blend 80/20 w/ SEP to (b)(4). Under CORE assignment #255727, OHFI Central Division 4 (Kansas District Office) collected traceability information from (b)(4).

(b)(4) received two shipments of Lettuce Blend 80/20 w/ SEP from Taylor Farms of California. The firm uses the (b)(4).

The firm's traceability program (b)(4). (b)(4) shipment was implicated because the shipment would have been available at the POS during the timeframe of interest.

AT: (b)(4)
FROM: Taylor Farms of California (Salinas, CA)
Product Description: Lettuce Blend 80/20 w/ SEP

Received Date	Invoice #	Traceability Lot Code	Product Description	QTY:
11/1/2024	1089878	Pack Julian Date: 298; Best By: 11/09/2024	872631 Lettuce Blend 80/20 w/ SEP	50
10/29/2024	1089399	Pack Julian Date: 297; Best By: 11/08/2024	872631 Lettuce Blend 80/20 w/ SEP	60

Taylor Farms of California (Salinas, CA; FEI: 3012342127)

Taylor Farms of California is located at 1085 Abbott St Salinas CA 93901. Taylor Farms of California served as the processor of leafy greens. Leafy greens blends were run on blend lines while single varieties of leafy green (i.e. chop romaine or shredded lettuce) were ran on single commodity lines. According to Taylor Farms of California, there was a 16-day shelf life for the leafy green products. During the timeframe of interest, Taylor Farms of California (Salinas, CA) supplied two shipments of Lettuce Blend 80/20 w/ SEP.

Taylor Farms of California's traceability program was able to link incoming shipments with outgoing shipments based on raw lot numbers linked to the finished lot codes. One shipment to (b)(4) and one shipment to (b)(4) were implicated because the shipments would have been available at the POS during the timeframe of interest. Traceability information, including bills of lading, was collected from

Taylor Farms of California by OII OHFI West Division 1 (San Francisco District Office) under eNSpect assignment #255996.

TO: (b)(4)

FROM: Taylor Farms of California (Salinas, CA)

Product Description: Lettuce Blend 80/20 w/ SEP

Harvest Date	Invoice #	Lot # PO	Traceability Lot Code	Product Description	QTY:
10/23/2024 10/24/2024	1089878	STF298A05/04	Pack Julian Date: 298; Best By: 11/09/2024	872631 Lettuce Blend 80/20 w/ SEP	50
10/19/2024	1089399	STF297A05	Pack Julian Date: 297; Best By: 11/08/2024	872631 Lettuce Blend 80/20 w/ SEP	60

TO: (b)(4)

FROM: Taylor Farms of California (Salinas, CA)

Product Description: IMPFRSH Lettuce Mix 80/20 SEP Bag

Harvest Date	PO Reference Number	Lot PO	Item Code	QTY
10/18/2024	14531050	STF293A05	170003	30
10/28/2024	14548090	STF302A04	170003	20
10/31/2024	14555380	STF305A05	170003	70

Anthony Costa and Sons (Soledad CA; FEI: 3005964451)

Anthony Costa & Sons LLC is located at 36817 Foothill Rd Soledad CA 93960-9656. Anthony Costa & Sons LLC is a sister company and parallel to Costa Farms Inc. Both entities own different fields but have the same ownership and same management. The fields of interest, Ernie Binsacca Ranch and Silliman Ranch are both owned by Anthony Costa & Sons LLC. According to the grower,

they are exclusively a grower and own the product until a shipper takes over the product to commence harvesting. According to the farm, they do not have a say in what crop will be planted, nor when harvest begins, nor provide any harvest equipment, or harvest employees. Both lots were fallow at the time of the inspection. Traceability information was collected by ORA Produce Safety Network from Anthony Costa & Sons LLC (Soledad, CA) under FACTS assignment #12413245.

Traceback Leg 3: (b)(4)

Point of Service (POS):

(b)(4)

Endpoints:

1. Anthony Costa and Son's LLC; 36817 Foothill Rd Soledad CA 93960-9656

(b)(4)

(b)(4)

This point of service is located at (b)(4). There were two cases (IN__C24059078 and IN__C24059350) associated with this point of service with meal dates of 11/4/24 and 11/7/2024. These cases reported consumption of salads (crab cake and cobb salad). According to state officials, during the 11/27/2024 inspection, the head chef confirmed the restaurant (b)(4)

(b)(4)

. The timeframe of interest for record collection was 10/21/2024– 11/7/2024.

Indiana state partners provided CORE with invoices from (b)(4)

. The invoices identified (b)(4) as the supplier of Lettuce Romaine Blend 50/50 to this POS during the timeframe of interest.

From: (b)(4)

Product Description: Lettuce Romaine Blend 50/50

Delivery Date	Invoice #	Item #	Product Description	QTY:
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(b)(4)

(b)(4)

(b)(4)
(b)(4) is located (b)(4)
(b)(4) was identified as
the sole distributor of romaine lettuce to (b)(4)
(b)(4). Under CORE assignment #256346, OHFI Central Division 1 (Detroit
District Office) collected traceability information from (b)(4)
(b)(4).

(b)(4) received six shipments of
Lettuce Romaine Blend 50/50 from Taylor Farms of California. The firm (b)(4)
(b)(4) utilizes
(b)(4). At receiving, the shelf life for processed leaf lettuce is (b)(4) days and (b)(4)
days for whole head lettuce.

The firm's traceability program (b)(4)
(b)(4) shipment was implicated because the
shipment would have been available at the POS during the timeframe of interest.

AT: (b)(4)
FROM: Taylor Farms of California (Salinas, CA)
Product Description: Lettuce Romaine Blend 50/50

DELIVERY DATE	INVOICE #	ITEM #	Internal Lot Code	Vendor SO	PROCESSOR LOT	QTY
10/21/2024	17338463	9202	72411306	3361103	STF281A06	1 CS
10/30/2024	17357975	9202	72648407	3365381	STF297A05	1 CS
10/30/2024	17357975	9202	72648407	3365381	STF298A05	1 CS
11/1/2024	17363335	9202	72648407	3365381	STF298A05	2 CS

10/30/2024	17363335	9202	72648407	3365381	STF298A05	1 CS
11/4/2024	17368379	9202	72722205	3366857	STF303A05	1 CS

Taylor Farms of California (Salinas, CA; FEI: 3012342127)

Taylor Farms of California is located at 1085 Abbott St Salinas CA 93901. Taylor Farms of California served as the processor of leafy greens. Leafy greens blends were run on blend lines while single varieties of leafy green (i.e. chop romaine or shredded lettuce) were ran on single commodity lines. According to Taylor Farms of California, there was a 16-day shelf life for the leafy green products. During the timeframe of interest, Taylor Farms of California (Salinas, CA) supplied two shipments of LETTUCE ROM BLND 50/50 NO COLO.

Taylor Farms of California's traceability program was able to link incoming shipments with outgoing shipments based on raw lot numbers linked to the finished lot codes. All shipments were implicated because the shipments would have been available at the POS during the timeframe of interest. Traceability information, including bills of lading, was collected from Taylor Farms of California by OII OHFI West Division 1 (San Francisco District Office) under eNSpect assignment #255996.

Product Description: LETTUCE ROM BLND 50/50 NO COLO

TO: Taylor Farms

FROM: Anthony Costa and Son's LLC

Processor Lot	Harvest Date	Ranch	Lot
STF297A05	10/23/2024	Silliman	S-3B-TF86
STF297A05	10/23/2024	Silliman	S-3B-TF86

(b)(4)
(b)(4) is located at (b)(4). This firm was identified as a processor of leafy green. (b)(4) supplied (b)(4) shipments of LETTUCE ROM BLND 50/50 NO COLO and (b)(4) shipment of LETTUCE ROM BLND70/30 NO COLO to (b)(4). CORE did not issue an assignment to this firm, therefore additional traceability or grower level information was obtained.

TO: (b)(4)

FROM: (b)(4)

Product Description: LETTUCE ROM BLND 70/30 NO COLO, LETTUCE SHRED 1/8", LETTUCE ROM BLND 50/50 NO COLO

DELIVERY DATE	INVOICE #	ITEM #	PRODUCT DESCRIPTION	Internal Lot Code	Vendor SO	PROCESSOR LOT	QTY
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(b)(4)

Anthony Costa and Sons (Soledad CA; FEI:3005964451)

Anthony Costa & Sons LLC is located at 36817 Foothill Rd Soledad CA 93960-9656. Anthony Costa & Sons LLC is a sister company and parallel to Costa Farms Inc. Both entities own different fields but have the same ownership and same management. The fields of interest, Ernie Binsacca Ranch and Silliman Ranch are both owned by Anthony Costa & Sons LLC. According to the grower, they are exclusively a grower and own the product until a shipper takes over the product to commence harvesting. According to the farm, they do not have a say in what crop will be planted, nor when harvest begins, nor provide any harvest equipment, or harvest employees. Both lots were fallow at the time of the inspection. Traceability information was collected by ORA Produce Safety Network from Anthony Costa & Sons LLC (Soledad, CA) under FACTS assignment #12413245.

Traceback Conclusions

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 five POS. The three traceback legs identified four distribution centers, one broker, two processors, one grower, and one ranch. The traceback investigation determined that Taylor Farms of California, the sole processor, sourced romaine lettuce from a single grower, Anthony Costa and Sons. This romaine was available at all points of service during the specified timeframe of interest. Additionally, romaine lettuce supplied

to (b)(4) of the five POS was traced back to a common ranch and lot. Through analysis of records, (b)(4) lot of romaine lettuce were implicated, resulting in confirmation of romaine lettuce as the vehicle.

Traceback Limitations

One limitation encountered during the response process was the timing of the incident transfer. The incident transferred to response one day ahead of a major federal holiday and an extended weekend. Despite successfully issuing four assignments prior to the official holiday, scheduled time off and the holiday itself contributed to delays in receiving traceability records. The factors affected the timely retrieval of records and contributed to delays in the overall response process.

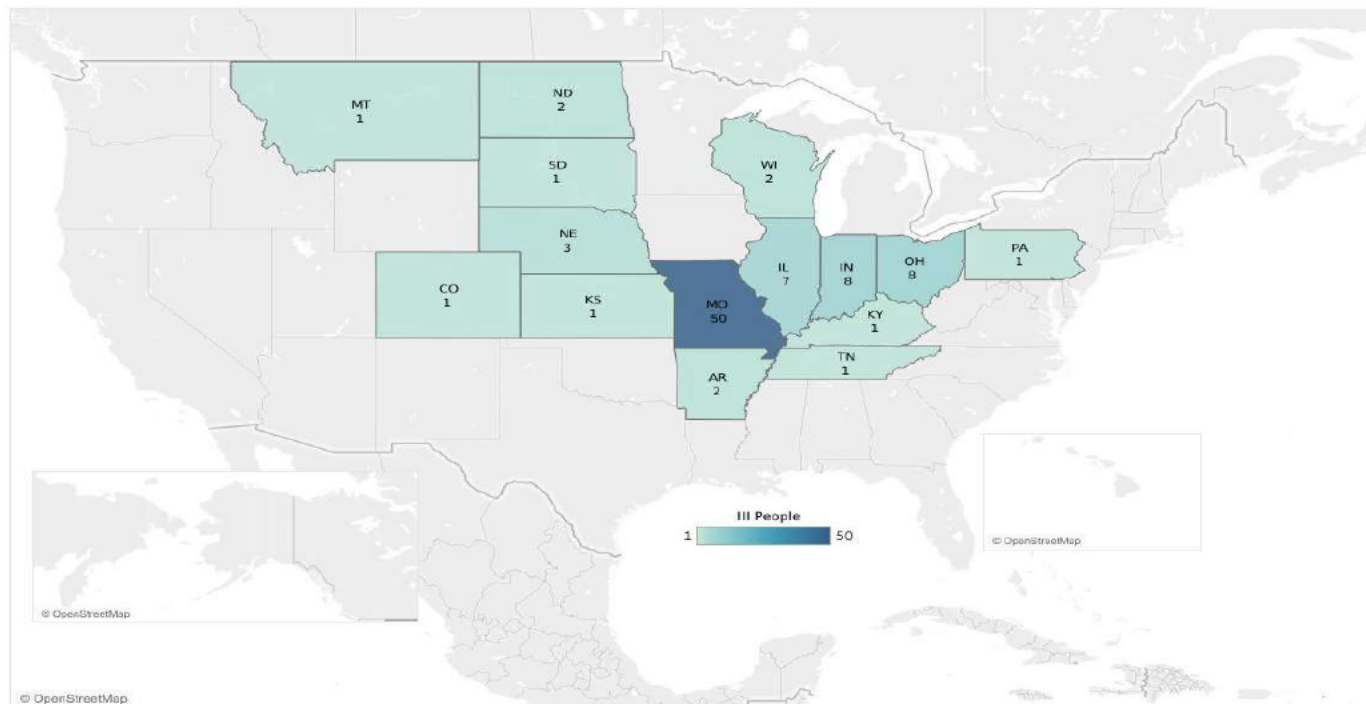
INCIDENT BRIEFING (ICS 201), Adapted for FDA

1. Incident Name: <u>E. coli O157:H7/Romaine Lettuce/Nov 2024</u>	2. CORE Incident Number: 1280	3. Date/Time Initiated: Date: 1/8/2025 Time: 8:24 AM
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4. Map/Sketch

Date: 1/8/2025

E. coli O157:H7/Romaine Lettuce/Nov 2024



https://www.ncbi.nlm.nih.gov/pathogens/tree#Escherichia_coli_Shigella/PDG000000004.4996/PDS000181369.184?term=PNUSAE202376%20PNUSAE202606%20PNUSAE202415%20PNUSAE202610%20PNUSAE202411%20PNUSAE202390%20PNUSAE202406%20PNUSAE202407%20PNUSAE202388%20PNUSAE202443%20PNUSAE202982%20PNUSAE203069%20PNUSAE202003%20PNUSAE202462%20PNUSAE202891%20PNUSAE202714%20PNUSAE202382%20PNUSAE202675%20PNUSAE202410%20PNUSAE202611%20PNUSAE202377%20PNUSAE202603%20PNUSAE202416%20PNUSAE202380%20PNUSAE202677%20PNUSAE202395%20PNUSAE202409%20PNUSAE202412%20PNUSAE202460%20PNUSAE202405%20PNUSAE202463%20PNUSAE202829%20PNUSAE202853%20PNUSAE202850%20PNUSAE202595%20PNUSAE202396%20PNUSAE202397%20PNUSAE203160%20PNUSAE202378%20PNUSAE202612%20PNUSAE202394%20PNUSAE202604%20PNUSAE202381%20PNUSAE202385%20PNUSAE202392%20PNUSAE202601%20PNUSAE202393%20PNUSAE202389%20PNUSAE202185%20PNUSAE202608%20PNUSAE202609%20PNUSAE202676%20PNUSAE202384%20PNUSAE202674%20PNUSAE202605%20PNUSAE202413%20PNUSAE203076%20PNUSAE202672%20PNUSAE202695%20PNUSAE202553%20PNUSAE202663%20PNUSAE202662%20PNUSAE202963%20PNUSAE202961%20PNUSAE202453%20PNUSAE202987%20PNUSAE202854%20PNUSAE202458%20PNUSAE202408%20PNUSAE202391%20PNUSAE203074%20PNUSAE203158%20PNUSAE202383%20PNUSAE202386%20PNUSAE202414%20PNUSAE202442%20PNUSAE203048%20PNUSAE202340%20PNUSAE202455%20PNUSAE202112%20PNUSAE202602%20PNUSAE202379%20PNUSAE202387%20PNUSAE203354%20PNUSAE202900%20PNUSAE203475%20PNUSAE202960%20PNUSAE202555

6. Prepared by: Name: Tracy Hawkins

Position/Title: Signals Team Member

Signature:

ICS 201, Page 1

Date/Time: 1/8/2025 8:24 AM EST

INCIDENT BRIEFING (ICS 201), Adapted for FDA

1. Incident Name: <u>E. coli O157:H7/Romaine</u> <u>Lettuce/Nov 2024</u>	2. CORE Incident Number: 1280	3. Date/Time Initiated: Date: 1/8/2025 Time: 8:24 AM
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5. Situation Summary and Health and Safety Briefing

On 11/25/2024, CDC notified CORE Signals of a newly coded E. coli O157:H7 cluster (PulseNet ID: 2411MOEXH-2). As of 11/26/2024, there are 46 cases from 7 states: IL (6), IN (1), KS (1), MO (30), ND (1), OH (3), SD (1). Isolation dates range from 11/7/2024 to 11/16/2024, and symptom onset dates range from 11/4/2024 to 11/13/2024. Cases range in age from 7 to 78 years (median:17) and 65% of cases are female. There are 18 hospitalizations, 3 cases of HUS, and 0 deaths.

Cluster isolates are highly related within 0-1 alleles by cgMLST and 0-2 (average: 0) SNPs in NCBI. This cluster is related to 6 historical clusters including: 2302MLEXH-1, 2210MLEXH-3, 2210MLEXH-2, 2209MLEXH-1, 2112MLEXH-1, 2106CAEXH-1. Only one of these historical clusters had a vehicle identified, 2112MLEXH-1 (CARA ID: 1052), and was closed with a confirmed vehicle of organic power greens by epidemiological and traceback evidence. Clinical isolates in the 2112MLEXH-1 and the 2411MOEXH-2 clusters are 0-23 (average: 9) SNPs apart in NCBI. This cluster is NOT part of a REP strain, however is "REP-adjacent" to the persisting REPEXH01. This REP strain is diverse and has been associated with leafy greens, ground beef, and environmental exposures.

On 11/25/2024, CDC stated leafy greens/iceberg lettuce are considered a leading hypothesis for this investigation.

There are currently 4 subclusters under investigation, and all have salad as an item of interest. According to media, one subcluster in MO involves 5 separate events associated with one caterer (Andre's Banquets and Catering; St. Louis, MO). One event involves a Marching Band school banquet at the Rockwood Summit High School in St. Louis, MO on 11/7/2024; there are currently 19 confirmed cases and reportedly about 100 illnesses associated with this event. The LHD disseminated a survey and narrowed their focus to an iceberg lettuce salad based on 278 survey responses; the salad was prepared by Andre's Banquets and Catering (St. Louis, MO). Salad ingredients include lettuce mix (iceberg lettuce, julienned carrots, cabbage), canned pimientos, parmesan cheese, and salad dressing prepared by the caterer. MO was able to collect an unopened bag of iceberg mix, which contained smaller bags of carrots and cabbage, from the same delivery order to the caterer as the suspected meal. This lettuce mix, containing iceberg/romaine, carrots, and cabbage, tested negative for STEC O157. MO reportedly collected invoices from the caterer, which indicated Performance Foodservice as the supplier. The lettuce mix was listed as "Peak *Lettuce Blend 80/20 W/sep" on the invoices, per MO.

Two subclusters involve (b)(4) in the midwest: (b)(4). Overall, there are 8 illnesses and 6 hospitalizations associated with these (b)(4) POS, of which 4 cases are confirmed. Five illnesses report exposure at a catered lunch on 11/6/24, prepared by (b)(4). All report consuming salad at the catered lunch. Their symptom onset dates range from 11/9/2024-11/16/2024. 2 WGS confirmed cases are associated with (b)(4). Meal dates range from 11/8/2024-11/9/2024. Their symptom onset dates range from 11/12/2024-11/14/2024. All cases report consuming salad at this establishment. Specific ingredients have not yet been identified; invoices have been received.

A fourth subcluster involves a (b)(4) school in OH. According to OH partners, there are 3 WGS confirmed cases and 1 suspect case in this cluster. CDC stated all 4 students report consuming salads at the salad bar in the school cafeteria. In SEDRIC, 2 of the WGS confirmed cases also noted they often eat at the salad bar. Invoices have been received.

Records have been received for the Andre's Banquet and Catering associated with the Oakville High School Band Banquet (1 MO case (MO-1131715)) on 11/6/2024, the Rockwood Summit High School Marching Band Banquet on 11/7/2024, and the Rockwood Summit High School Veteran's Day Luncheon on 11/8/2024. Records have also been received for the (b)(4) (b)(4) and the OH (b)(4) school. Records are pending on the MO case (MO_1131833) who reported a banquet event on 11/8/2024.

Leafy greens and STEC are a well-established pathogen pair, with over 30 outbreaks investigated by CORE where a variety of leafy green types were named the confirmed or suspect vehicle. US and Mexico are the predominant countries of origin for leafy greens identified as the source of the outbreaks. Among these, iceberg lettuce was the suspect source for four outbreaks. There are also several historically related outbreaks by WGS to the current cluster, and, as noted above, outbreak 2112MLEXH-1 (CARA ID: 1052), is most closely related and was the only outbreak with a confirmed vehicle. The traceback investigation concluded that Taylor Farms Retail (Salinas, CA) was the common processor and supplier of the Power Greens packaged salads. (b)(4) ranches of interest were identified during the investigation, (b)(4).

Historically, several outbreaks have been investigated in late fall during the transition time between leafy green production in United States growing regions. During the fall months (typically October/November), leafy green

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production generally ends in Salinas and transitions to Yuma, AZ. Past outbreaks have often occurred during this transition period and have involved the last few leafy greens crops produced in Salinas. During this time, (b)(4) (b)(4) This year, due to hotter temperatures than normal, harvesting of fall/winter whole head iceberg in Yuma, AZ, began in (b)(4), with the (b)(4) shipment starting on (b)(5). The (b)(4) shipment from Yuma occurred on (b)(5). Of note, SMEs shared that (b)(4) shipments of leafy greens could be partial loads containing lettuce grown in CA and AZ. CORE Signals is transferring this incident to CORE Response Team 3 based on the following rationale: This is a rapidly growing multistate outbreak with a suspected FDA-regulated product, leafy greens/iceberg lettuce, identified as a leading hypothesis. Early response coordination is needed to conduct traceback, potential product and firm actions, and potential firm/facility and growing location investigations, especially given the short shelf life of leafy green products. This is a repeat hazard/commodity pair of great interest to FDA and stakeholders. Leafy greens are well established as a potential vehicle for E. coli O157:H7. Additional preventive measures and consumer outreach may be needed to prevent additional illnesses and future outbreaks. -- This is a rapidly growing multistate outbreak with a suspected FDA-regulated product, leafy greens/iceberg lettuce, identified as a leading hypothesis. -- Early response coordination is needed to conduct traceback, potential product and firm actions, and potential firm/facility and growing location investigations, especially given the short shelf life of leafy green products. -- This is a repeat hazard/commodity pair of great interest to FDA and stakeholders. Leafy greens are well established as a potential vehicle for E. coli O157:H7. Additional preventive measures and consumer outreach may be needed to prevent additional illnesses and future outbreaks.								
Exposure Table No Exposure Table Available								
<table border="0" style="width: 100%;"> <tr> <td data-bbox="94 1619 764 1671">6. Prepared by: Name: Tracy Hawkins</td> <td data-bbox="764 1619 1279 1671">Position/Title: Signals Team Member</td> <td data-bbox="1279 1619 1526 1671">Signature:</td> </tr> <tr> <td data-bbox="94 1671 764 1713">ICS 201, Page 2</td> <td colspan="2" data-bbox="764 1671 1526 1713">Date/Time: 1/8/2025 8:24 AM EST</td> </tr> </table>			6. Prepared by: Name: Tracy Hawkins	Position/Title: Signals Team Member	Signature:	ICS 201, Page 2	Date/Time: 1/8/2025 8:24 AM EST	
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Updated by FDA 2/2011								

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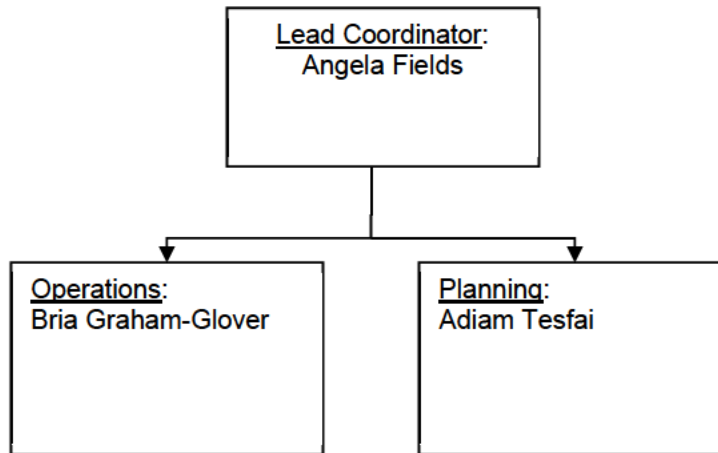
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7. Current and Planned Objectives:		
(b)(5)		
8. Current and Planned Actions, Strategies, and Tactics:		
Time:	Actions:	
TBD	Tactics Call #1	
6. Prepared by: Name: Tracy Hawkins Position/Title: Signals Team Member Signature:		

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9. Current Organization (fill in additional organization as appropriate):



6. Prepared by: Name: Tracy Hawkins

Position/Title: Signals Team Member

Signature:

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10. Resource Summary:					
Resource	Resource Identifier	Date/Time Ordered	ETA	Arrived	Notes (location/assignment/status)
Joseph Cooper					HFI Central 1
Erin Dugan					HFI Central 4
Sana Elassar					HFI Central 3
Holly Smith					HFI Central 2
OII Senior ERCs					OII/OHRI- OII Senior ERCs
Tim Muruvanda					Office of Surveillance Strategy and Risk Prioritization (OSSRP); Signal Detection and Bioinformatics Branch (SDBB)
DPS-ProcessedProduceBranch-Outbreaks					Office of Microbiological Food Safety- Processed Produce
DPS-FreshProduceBranch-Outbreaks					Office of Microbiological Food Safety- Fresh Produce
Kurt Nolte					Office of Microbiological Food Safety- Fresh Produce
Kathy Tormey					HFP OCE (Lead)
Crystal McKenna					HFP OCE (SME)
Distro list for OCE EIB					HFP OCE
Katie Arnold					HFP OCE
Kristen Jackson					HFP OCE
Marlon Turner					HFI Central 1
Angelo Lodato	National Center for Emerging and Zoonotic Infectious Diseases (NCEZID)				
Laura Gieraltowski	National Center for Emerging				

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10. Resource Summary:					
	and Zoonotic Infectious Diseases (NCEZID)				
Zach McCormic	National Center for Emerging and Zoonotic Infectious Diseases (NCEZID)				
Matt Wise	National Center for Emerging and Zoonotic Infectious Diseases (NCEZID)				
6. Prepared by: Name: Tracy Hawkins		Position/Title: Signals Team Member		Signature:	
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INCIDENT OBJECTIVES (ICS 202), Adapted for FDA

1. Incident Name:

E. coli O157:H7/Romaine Lettuce /Nov 2024

2. Operational Period: Date From: 12/19/2024 Date To: 1/19/2025
Time From: 1500 EST Time To: 1500 EST

3. Objective(s):

(b) (5)

4. Operational Period Command Emphasis:

General Situational Awareness:

On 11/25/2024, CDC notified CORE Signals of a newly coded *E. coli* O157:H7 cluster (PulseNet ID: 2411MOEXH-2). As of 12/2/2024, there were 62 cases from nine states: IL (7), IN (4), KS (1), KY (1), MO (40), ND (1), OH (5), SD (1), WI (2). Isolation dates range from 11/7/2024 to 11/17/2024, and symptom onset dates range from 11/4/2024 to 11/14/2024. Cases range in age from 6 to 82 years (median:19) and 65% of cases are female. There are 22 hospitalizations, 5 cases of HUS, and 0 deaths. Clinical isolates are highly related within 0-1 alleles by cgMLST and 0-2 (average: 0) SNPs in NCBI. This cluster is related to six historical clusters spanning from 2021 to 2023, one of which closed with a confirmed vehicle of organic power greens by epidemiological and traceback evidence (2021). Clinical isolates in the current cluster and the historical cluster are 0-23 (average: 9) SNPs apart in NCBI. On 11/25/2024, CDC stated leafy greens/iceberg lettuce are considered a leading hypothesis for this investigation.

Historically, several outbreaks have been investigated in late fall during the transition time between leafy green production in United States growing regions. During the fall months (typically October/November), leafy green production has generally ended in Salinas and transitioned to Yuma, AZ. This year, due to hotter temperatures than normal, harvesting of fall/winter whole head iceberg in Yuma, AZ, began in late October, with the first partial shipment starting on (b)(4). The first full shipment from Yuma occurred on 11/6/2024. Of note, SMEs shared that early shipments of leafy greens could be partial loads containing lettuce grown in CA and AZ.

Of the four traceback subclusters under investigation, all cases reported salad as an item of interest. There was a subcluster in MO representing of multiple catered events supplied by (b)(4) caterer, two additional subclusters involving (b)(4) in the Midwest located in IL and MO and a fourth subcluster involving a (b)(4) school in OH.

On 11/26/2024, CORE issued eNSpect #257708 to Office of Human Food Inspectorate (OHFI) East Division 3 (BLT) for traceback data collection at (b)(4). On 11/27/2024, CORE issued three additional traceback assignments for traceback record collection: eNSpect #255725 to OHFI Central Division 1 (DET) at (b)(4), eNSpect #255729 to OHFI Central Division 2 (CIN) at (b)(4), and eNSpect #255727 to OHFI Central Division 4 (KAN) at (b)(4). On 11/29/2024, (b)(4) identified Taylor Farms (Salinas, CA) as the processor of leafy greens via a broker, (b)(4). In response to eNSpect assignment #255729, on 11/29/2024, CORE issued eNSpect #255828 to OHFI Central Division 2 (CIN) for traceback data collection at (b)(4). On 12/2/2024, OHFI East Division 3 (BLT) provided traceback data collection from (b)(4) identifying Taylor Farms (Salinas, CA) as the supplier for their PEAK Lettuce Blend 80/20.

On 12/3/2024, OHFI Central Division 2 (CIN) provided traceback data from (b)(4) identifying (b)(4) as the processor for their leafy greens.

On 12/3/2024, OHFI Central Division 4 (KAN) provided traceback data from (b)(4) identifying Taylor Farms (Salinas, CA) as one of the suppliers of lettuce. On 12/3/24, CORE issued eNSpect assignment #255996 to OHFI West Division 2 (SAN) for traceability data collection from Taylor Farms (Salinas, CA). On 12/3/2024, Firm Call was held with representatives from Taylor Farms (Salinas, CA). As of 12/04/2024, 69 cases in 10 states IL (7), IN (4), KS (1), KY (1), MO (45), MT (1), ND (2), OH (5), SD (1), WI (2).

Operational Period # 1

On 12/5/2024, a second firm Call was held with CDC and representatives from Taylor Farms (Salinas, CA) to discuss investigational updates and to address questions provided by Taylor Farms prior to the call. Taylor Farms shared their internal traceability data and analysis and determined there were no commonalities identified. FDA shared our traceback findings identifying the single grower and ranch for romaine lettuce. On 12/6/2024, CORE held Special Purpose Tactics #1 to discuss a farm investigation and potential sampling at

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Anthony Costa & Son's LLC (Soledad, CA; FEI: 3003749399), the single grower and ranch that was identified through traceback. On 12/9/2024, CORE issued FACTS # 12413245 to OII Produce Safety Network for a farm and sampling assignment at Anthony Costa & Son's LLC (Soledad, CA; FEI: 3003749399). On 12/9/2024, Taylor Farms provided an update on their internal investigation stating there were no concerns regarding their internal farm investigation of Anthony Costa & Son's LLC. On 12/10/2024, OII Produce Safety Network initiated the farm and sampling assignment at Anthony Costa & Son's LLC (Soledad, CA; FEI: 3003749399). Ten samples (INV1199683 and INV1199685 [Sediment], INV1199684 [Scat], INV1199686 and INV1199687 [DEUF Water], INV1204247, INV1204248, INV1204250 & INV1199688 [Soil], and INV1204249 [Environmental]) were collected. On 12/11/24, CORE issued eNSpect assignment #256441 to OHFI Central Division 5 (DAL) for traceability data collection from (b)(4) . Both assignments were related to a newly identified subcluster in Indiana where one of the cases died. On 12/11/2024, OII Produce Safety Branch continued the for-cause inspection at Anthony Costa & Son's LLC (Soledad, CA; FEI: 3003749399) collecting two samples (INV1282822 [Sediment], and INV1199689 [Environmental]). Inspectors were unable to collect water samples as the catch pond had been drained. As of 12/12/2024, 84 cases in 14 states AR (2), CO (1), IL (7), IN (8), KS (1), KY (1), MO (47), MT (1), NE (2), ND (2), OH (8), PA (1), SD (1), WI (2). <u>Operational Period #2</u> On 12/12/2024, the OII DPS Investigational Team closed out the farm inspection with Anthony Costa & Sons LLC (Soledad, CA). There were no written observations. On 12/13/24, OHFI Central Division 5 (DAL) provided traceability data from (b)(4)) under assignment #256441. The organic spring mix was supplied through (b)(4)) and processed by (b)(4)). On 12/13/2024 and 12/14/2024, all samples collected during the farm inspection were reported negative. On 12/16/2024, OHFI Central Division 1 (DET) provided all traceability data requested from (b)(4) . Taylor Farms (Salinas, CA) was identified as a supplier of their romaine lettuce blend. Based on the traceability data provided, Anthony Costa was identified as one of the growers of romaine from the Silliman Ranch. The Silliman Ranch was included in the recent farm inspection under assignment #12413245. On 12/17/2024, FDA and CDC provided further explanation to Taylor Farms (Salinas, CA) about the epidemiologic and traceback investigations for this outbreak response. FDA has concluded the traceback investigation. On 12/18/2024, the incident title was updated to reflect a change from a confirmed vehicle of leafy greens to a confirmed vehicle of Romaine Lettuce due to the traceback findings. As of 12/19/2024, 88 cases in 14 states: AR (2), CO (1), IL (7), IN (8), KS (1), KY (1), MO (50), MT (1), NE (2), ND (2), OH (8), PA (1), SD (1), WI (2)																
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		☐
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☐ ICS 208		☐														
7. Prepared by: Name: Eric Holm Position/Title: Planning Chief Signature: <i>Eric Holm</i>																
8. Approved by Incident Commander: Name: Angla Fields Signature:																
ICS 202	IAP Page _____	Date/Time: 12/19/2024 12:00														