***E. coli* O157:H7/Onion (suspect)/Oct 2024**

Executive Incident Summary
CARA #1270
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Authors:
CORE Signals & Surveillance Team: Ashley Grant, MPH
CORE Response Team 4: Mardea Caulcrick-Grimes, MPH

EXECUTIVE SUMMARY

Initial Notification and Vehicle Identification

On 10/15/2024, CORE Signals and Surveillance Team was notified by the Centers for Disease Control and Prevention (CDC) and Colorado state partners about an increase in *E. coli* O157 cases in the Mountain West Region of the United States. That same day, PulseNet coded the cluster as cluster code 2410COEXH-1.

Based on the available epidemiologic data at the time, exposure to McDonald's quarter pounder hamburgers were identified as a significant item of interest and quickly began to define the outbreak. Upon notification of the outbreak, McDonald's HQ identified two ingredients - fresh, never frozen beef patties and raw sliced, yellow onions (slivered onions) – that are unique to the quarter pounder hamburger varieties compared to other hamburgers served at McDonald's.

On 10/20/2024, McDonald's HQ provided information from their review of the internal supply chain, and noted that the geographic distribution of illnesses, when compared to McDonald's restaurant locations mentioned by ill cases, was a near match to the distribution of onions as indicated by supplier level data. Distribution information in conjunction with epidemiological data indicated the raw sliced/silvered onions as a likely source of contamination, as compared to the fresh beef patties. Based on this information, on 10/20/2024, fresh sliced/slivered onions were identified as the leading hypothesis for the outbreak, however fresh beef patties could not be completely ruled out as an alternative hypothesis.

As a result, FDA and FSIS would conduct traceback of fresh raw onions and fresh ground beef patties, respectively. On 10/21/2024, this incident transferred to CORE Response Team 4 for further coordination related to onion traceback. At the time of transfer, there were 25 confirmed cases from 8 states: (CO (11), IA (1), MO (1), MT (1), NE (7), UT (2), OR (1) and WY (1).

Epidemiology Overview & Genomic Analysis

On October 15, 2024, PulseNet coded an outbreak of *E. coli* O157:H7 that were highly related to each other by whole genome sequencing. At the time of closing, this investigation included 104 cases across 14 states: CO (30), IA (1), KS (3), MI (2), MO (8), MY (19), NC (1), NE (13), NM (10), OR (1), UT (8), WA (1), WI (1), WY (6), all related within 0-3 alleles by cgMLST. Isolation dates ranged from October 2 to October 31, 2024. Reported onset dates (n=98) ranged from September 12 to October 21, 2024. Ages ranged from 1 year to 88 years, with a median age of 28. Forty-two of 104 cases (40%) were female. Outcome information was available for 98 cases, of which 34 (35%) were hospitalized due to their illness. There were 4 reports of cases with HUS, and there was one death attributed to the outbreak.

This outbreak was coded following notification from colleagues in CO after they detected a large, atypical increase of *E. coli* O157 infections across the state. Similar increases were observed in

neighboring Mountain West states. As WGS data became available, it was apparent the scope of this outbreak was much larger than first anticipated.

CDC deployed a focused questionnaire on October 16, 2024, slightly modifying a questionnaire deployed earlier by CO colleagues. In total, CDC received 72 focused questionnaires back. Epidemiological information was available for 81 cases in total. Eighty (80) of 81 cases (99%) reported a meal at a McDonald's location prior to becoming ill. This was statistically significantly higher than expected when compared to an internal CDC restaurant survey, which put the background rate for McDonald's at 22% ($p<.00001$). McDonald's locations were reported across the Mountain West of the US, and many cases outside that region reported traveling to or through the region prior to becoming ill.

Seventy-five cases were able to recall the exact menu item they consumed prior to becoming ill. Of the 75 cases, 63 (84%) consumed a menu item that contained fresh, slivered onions. Fifty-eight of 75 cases (77%) consumed a menu item that contained fresh ground beef. Fresh, slivered onions are a unique ingredient to 3 menu items: the Quarter Pounder (and its variants), the Steak Bagel, and the Daily Double. Fresh ground beef is also a unique menu item to the Quarter Pounder and its variants. Sixty cases reported consuming a Quarter Pounder or a variant. Two cases reported a Daily Double, and one case reported a Steak Bagel. Meal dates for those who reported McDonald's ranged from September 9 to October 19.

Following the end of the reporting lag period and a decline in new cases, CDC closed this investigation on December 6, 2024, as an outbreak linked to onions. This outbreak will be reported to NORS with NORS ID: 510963.

Field Investigations & Findings

There were three CORE issued assignments related to this outbreak investigation; one records collection and two associated with field investigations.

On 10/21/2024, CORE issued eNSpect Assignment #253286 to the Office of Inspections and Investigations (OII), Office of Human Food Inspectorate (OHFI) W4 (DEN) for traceback records and information collection at Taylor Farms Colorado Inc. (Colorado Springs, CO; FEI: 1783599). The Division initiated the assignment that same day and closed the assignment on 10/29/2024.

On 10/24/2024, CORE issued FACTS Assignment #12404946 to OII OHFI W4 (DEN) for a Full Scope Preventive Controls (PC) Inspection with environmental and finished product sampling and records collection at Taylor Farms Colorado Inc. (Colorado Springs, CO; FEI: 1783599). W4 (DEN) initiated the inspection at the firm on 10/28/2024. On 11/12/2024, W4 (DEN) inspectional team closed the assignment with issuance of an FDA Form-483. There were two discussion items noted on the final Form-483: one related to the firm's preventive controls record keeping requirements and the other related to their hazard analysis plan. Details regarding each of these

discussion items can be found in the Establishment Inspection Report (EIR) related to this inspection.

On 10/29/2024, CORE issued FACTS Assignment #12405863 to OII Division of Produce Safety (DPS) for a For-cause farm inspection with sampling and record collection at (b)(4) , WA; FEI: (b)(4)). On 10/30/2024, OII DPS accompanied by the Washington State Department of Agriculture (WSDA) initiated the inspection at the farm. On that same day, the inspectional team confirmed the farm location is the same location for the (b)(4)) and that the firms share the same management. Throughout the course of the investigation, the inspectional team met with management and production personnel from both firms ((b)(4)). On 11/4/2024, the team completed their investigation and in agreement with both firms, conducted a combined closeout with both firms. An FDA-4056 with written observations were issued to both firms. The FDA-4056 issued to (b)(4) noted 2 items-citing issues related to hygienic practices of personnel and issues related to cleaning and sanitizing of food contact surfaces. For the FDA-4056 issued to (b)(4) there were 4 noted items-issues related to animal intrusion, cleaning and sanitizing of food contact surfaces and two identified issues associated with inadequate record keeping as established by the Produce Safety Rule (PSR). Details regarding each of these noted observations can be found in the respective EIR for each firm.

Laboratory Sample Overview

FDA and state partners from Colorado and Michigan collected various samples/sample types (finished product, environmental, raw ingredient) from multiple establishments, however no sample collected and analyzed yielded the outbreak strain. Details regarding samples collected and analyzed by each agency can be found below.

State samples:

Colorado state partners:

On 10/19/2024, public health officials in Colorado embargoed (b)(4) lbs boxes of finished product Slivered Yellow Onions 3/16" 00028-246 (Lots: (b)(4)) and [redacted] boxes of 4:1 Pure Beef Hamburger Patties (fresh & frozen) from (b)(4) different McDonald's restaurant locations in (b)(4) [redacted]-McDonald's locations) (b)(4) ([redacted]-McDonald's location) for testing. On 10/21/2024, the embargoed products were transported to Colorado Department of Public Health and Environment (CDPHE) and Colorado Department of Agriculture (CDA). All beef products were delivered to CDA for analysis.

The (b)(4) lbs boxes of finished product onion samples were split into thirds by CDPHE, with CDPHE testing 1/3 of the sample, CDA testing another 1/3 and FDA testing the remaining 1/3.

CDPHE samples-On 10/29/2024, CORE was notified that all onions (1/3), analyzed by CDPHE screened negative for Stx2.

CDA samples-For their 1/3 onions, CDA reported on two different preliminary positives for *E. coli* O157:H7 via rt-PCR associated with sample #AA52696 (bag 1). The first preliminary positive was reported on 10/24/2024 and the second on 10/30/2024. Following multiple attempts at isolation, on 11/4/2024, CDA updated that they were unable to isolate *E. coli* O157:H7 from the sample and had completed analysis of all onions.

Beef analysis:
It is important to note, as it relates to the (b)(boxes of 4:1 Pure Beef Hamburger Patties; on 10/25/2024, USDA/FSIS and W4 (DEN) notified CORE that CDA completed analysis of all beef products (fresh and frozen) and all screened negative for *E. coli* O157:H7 via rt-PCR.

Michigan state partners:
On 10/31/2024, OII OHFI C1 (DET) notified CORE that Michigan Department of Agriculture and Rural Development (MDARD) and local health department collected open product samples of Yellow Slivered Onions (Lot (b)(4)) from a local McDonald's located in (b)(4), MI. On 11/1/2024, OII OHFI C1 (CHI) notified CORE that Michigan had completed their analysis and all samples resulted negative for *E. coli*. Of note, the samples were collected due to an influx of consumer complaints as there were no WGS confirmed case in the outbreak linked to this location. It is also important to note, that the Taylor Farms-Colorado Springs processing facility (facility of interest in this investigation) would not have supplied Yellow Slivered Onions to McDonald's retail locations in Michigan. Per information provided by McDonald's HQ, McDonald's retail locations in Michigan are serviced by the (b)(4).

FDA samples:
There were a total of 55 FDA samples collected from multiple firms/establishments during the Response phase of this outbreak response.

On 10/23/2024, OII OHFI W4 (DEN) collected five finished product samples (1273842, 1273843, 1273844, 1273845 & 1273846) of Slivered Onions from CDPHE (FDA's 1/3). On 10/25/2024, the Human Food Program (HFP), Office of Regulatory Testing and Surveillance (ORTS) reported all samples closed lab class LC1, negative for EHEC/STEC.

On 10/24/2024, OII OHFI W4 (DEN) collected two finished product samples (1264216 & 1264217) of Slivered Onions from McDonald's (b)(4), CO). On 10/25/2024, W4 (DEN) collected five additional samples (1264218, 1264219, 1264220, 1264221 & 1264222) of the Slivered Onions at this distro center. On 10/26/2024, 10/27/2024 & 10/30/2024 ORTS reported samples closed lab class LC1, negative for EHEC/STEC.

On 10/24/2024, OII OHFI W4 (DEN) collected three finished product samples (1278095, 1278096 & 1278097) of Slivered Onions from the McDonald's (b)(4), UT). On 10/28/2024, the Division collected two additional samples (1278098 & 1278099) of the Slivered Onions from this distribution center. On 10/26/2024, ORTS reported the

three initial samples collected on 10/24 as Cannot rule out (CRO) for stx2 on initial screening. Two subs (5 &10) associated with sample #1278095, all 10 subs associated with sample 1278096 and one sub (6) associated with sample 1278097 were the CROs. On 11/4/2024, ORTS reported samples (1278095 & 1278097) closed out lab class LC1, negative for EHEC/STEC. On 11/8/2024, ORTS closed sample #1278096 as lab class LC3 for the presence of Shigatoxic *E. coli* in 8 of the 10 subs (1-6, 9&10). WGS analysis revealed the eight isolates submitted to be STEC O168:H8 and were a match to each other, but not a match to clinical isolates associated with the outbreak cluster. Samples #1278098 and 1278099 were closed out lab class LC1, negative for EHEC/STEC on 10/31/2024 and 11/5/2024 respectively.

On 10/28/2024, OII OHFI C4 (KAN) collected five finished product samples (1265632, 1278293, 1278294, 1278295 & 1278296) of Slivered Onions from McDonald's (b)(4) , KS). On 10/29/2024, ORTS reported sample #1278295 as LC5 due to damage/leakage in transit. The remaining 4 samples were reported lab class LC1, negative for EHEC/STEC on 10/30/2024 and 11/1/2024.

OII OHFI W4 (DEN) collected a total of 13 (11-products, 2-environmental) samples at the Taylor Farms Colorado Springs processing facility as part of this outbreak response. Product samples consisted of McDonald's Slivered Onions (2), Whole peeled onion (1) and onions processed at the facility for non-McDonald's customers (8).
On 10/24/2024, W4 (DEN) collected two samples (1228886 & 1272852) of McDonald's Slivered Onions. On 10/26/2024, ORTS reported both samples closed out lab class LC1, negative for EHEC/STEC.
As part of the Full Scope PC Inspection, on 10/30/2024, OII OHFI W4 (DEN) collected five samples (1247260 & 1247261-(b)(4)), (1257881 &1257882-(b)(4) and one environmental sample (1278594). On 11/1/2024, ORTS reported sample #1247260 negative for EHEC/STEC. One sub each from samples 1247261 (#6), 1257881 (#7), 1257882 (#4) and 1278594 (#11) was reported CRO for stx2 on screening on 11/1/2024. On 11/2/2024, environmental sample (1278594) was closed lab class LC1, samples (1257882 & 1247261) were both closed lab class LC1 on 11/5/2024 and sample (1257881) was closed lab class LC1, negative for EHEC/STEC on 11/6/2024. On 10/31/2024, the investigational team collected six additional samples (1278595-environmental), (1273848-(b)(4)), (1278708 & 1278709-(b)(4)), (1278710-(b)(4) and (1278711-(b)(4)). On 11/4/2024, 11/5/2024 and 11/6/2024 ORTS reported samples closed lab class LC1, negative for EHEC/STEC.

During the onsite farm inspection at (b)(4) , OII DPS collected a total of 20 product and environmental samples (b)(4) -farm, (b) -packinghouse).
On 10/30/2024, OII DPS collected one environmental sample (1200105) from the packing line associated with (b)(4) lots of interest ((b)(4)). (b)(4) for the (b)(4) lots of interest. On 11/1/2024, ORTS reported three subs associated with the sample was CRO for *E. coli* O157:H7. On 11/2/2024, ORTS reported the sample closed out lab class LC1, negative for EHEC/STEC. On 10/31/2024, the investigational

team collected five whole onion samples (1176312, 1176313, 1176314, 1176315 & 1176316) at the (b)(4) . On 11/4/2024 ORTS reported sample (1176312) negative for EHEC/STEC. The four remaining samples were reported lab class LC1, negative for EHEC/STEC on 11/5/2024.
On 10/31/2024, OII DPS collected two environmental samples (1200106-swab from harvest equipment & 1200107-soil) and one residual onion sample (1176317) at grower (b)(4) . Samples (1176317 & 1200107) were reported negative for EHEC/STEC by ORTS on 11/4/2024 and 11/5/2024 respectively. On 11/5/2024, ORTS reported 2 subs (#6 & #15) associated with environmental sample (1200106) was CRO for STEC. On 11/8/2024, ORTS updated that eight isolates from sub (#15) was positive for stx2. On 11/12/2024, ORTS reported all eight isolates were identified as serotype O174:H21. On 11/20/2024, ORTS reported sample analysis was complete and the sample closed out lab class LC2 (Regulatory Action Not Indicated), Shigatoxic *E. coli* detected in one sub (15). WGS confirmed all eight isolates are a match to each other, but not a match to clinical isolates in this outbreak cluster.
On 11/1/2024, the investigational team collected seven environmental samples (1176319 &1176320-DEUF; 1176321-drag swab; 1200110, 1176318 & 1200111-sediments, & 1200109-soil). On 11/3/2024, 11/5/2024 and 11/6/2024, ORTS reported samples closed out lab class LC1, negative for EHEC/STEC.
On 11/4/2024, OII DPS investigational team collected four additional environmental samples (1200112, 1200113-soil; 1200108-DEUF & 1200114-scat). On 11/7/2024, ORTS reported samples (1200112, 1200108 & 1200114) closed out lab class LC1, negative for EHEC/STEC. Sample (1200113) was reported CRO for 5 subs (#1-5). On 11/19/2024, ORTS reported the sample closed out lab class LC1, negative for EHEC/STEC.

<u>FDA STEC Council Determination of Public Health Significance:</u>
FDA STEC Council provided their determination for the two non-O157:H7 samples identified during this investigation.

Sample (1278096)-O168:H8: On 11/5/2024, the STEC Council provided the following determination:

The STEC Council completed their review of isolates: FDA1278096-S001-005; FDA1278096-S002-018; FDA1278096-S002-029; FDA1278096-S003-034; FDA1278096-S004-054; FDA1278096-S006-091; FDA1278096-S009-136; FDA1278096-S009-137; FDA1278096-S009-142; FDA1278096-S009-147 and confirm these genetically indistinguishable isolates possess the stx2a gene and of serotype O168:H8.

It also appears that they have no close genetic matches to other strains (clinical or non-clinical) in the NCBI database. While the consensus is that these onion isolates of not of high-risk to human health, the Council could not reach consensus on the designation of moderate (Class II) or low (Class III) risk. The majority of members leaned towards a moderate risk due to the presence of stx2a and some historic reports of this serotype being isolated from patients previously.

Sample (1200106)-O174:H21: On 11/16/2024, the STEC Council provided the following determination:

The STEC Council completed their review of isolates: FDA1200106-S015-001; FDA1200106-S015-002; FDA1200106-S015-003; FDA1200106-S015-004; FDA1200106-S015-005; FDA1200106-S015-006; FDA1200106-S015-007; FDA1200106-S015-008 and confirm these genetically indistinguishable isolates possess the stx2d gene and of serotype O174:H21.

It also appears that they have no close genetic matches to other strains (clinical or non-clinical) in the NCBI database. While the consensus is that these environmental swab isolates of not of high-risk to human health, the Council could not reach consensus on the designation of moderate (Class II) or low (Class III) risk. The majority of members leaned towards a low (Class III) risk due to the lack of high-risk virulence genes and no historic reports of this serotype being isolated from patients previously.

For reference—guidelines used by STEC Council
Class I recall: *serious adverse health consequences or death*
Class II recall: *temporary or medically reversible adverse health consequences or low probability for serious adverse health consequences*
Class III recall: *not likely to cause adverse health consequences.*

Traceback Abbreviated Summary

A traceback investigation was initiated on 10/21/2024 in response to this multi-state *E. coli* O157:H7 outbreak with onions as the suspected vehicle.

The investigation consisted of 10 cases from 3 states (Colorado, Nebraska, and Utah), representing 10 points of sale (POS), but (b)(4) restaurant chain – McDonald's. There were three traceback legs, one leg representing (b)(different McDonald's restaurants located in Colorado. The second leg represented (b)(different McDonald's restaurants located in Nebraska. The final leg represented (b)(4) McDonald's location in Utah.

Based on the epidemiologic exposure data an initial signal for consumption of a Quarter Pounder at McDonalds restaurants. Case patients included in the traceback were laboratory confirmed *E. coli* O157:H7 infection with WGS matched to the outbreak strain, with the strongest exposure to fresh slivered onions on their Quarter Pounder prior to illness onset. The earliest exposure date reported on the cases associated with the traceback was 9/23/2024, last 10/6/2024, with illness onset dates for overall cases ranging from 9/12/2024 – 10/21/2024.

Following review of the traceback records and information received from McDonald's HQ, (b)(4) distributors were identified as the direct suppliers of the slivered onions to the POS during the time frame of interest. For the Colorado Leg, (b)(4) , CO) was identified as the sole supplier for slivered onions to all (b)(McDonald's restaurants included in the traceback during the time frame of interest. For the Nebraska leg, (b)(4) , KS) was identified as the sole supplier for slivered onions to all (b)(4) McDonald's restaurants included in the traceback during the time frame of interest. Finally, for the Utah leg, (b)(4) , UT) was identified as the sole supplier for slivered onions to the (b)(4) McDonald's restaurants included in the traceback during the time frame of interest.

All (b)(4) distribution centers received slivered onions from Taylor Farms Colorado, Inc. (Colorado Springs, CO). The onion traceback identified one sole grower – (b)(4) WA) and were packed by (b)(4) , WA) which supplied the whole onions that was subsequently processed at Taylor Farms Colorado, Inc. There were (b)(4) lots of interest – Lot (b)(4) from field (b)(4) , harvested on (b)(4) , and lot (b)(4) from field (b)(4)

(b)(4) harvested on (b)(4) . These lots were comingled to fulfill onion orders at Taylor Farms Colorado, Inc., (b)(4) .

Our traceback was limited due to there being only (b)(4) supply chain, but based on our limited traceback, records, and information collected and reviewed, onions was likely the source for this outbreak, but not confirmed.

Product & Firm Actions

Throughout the course of the investigation, FDA, CDC, and USDA/FSIS held numerous Firm Calls with the relevant firms of interest.

On 10/21/2024, FDA and CDC held a Firm Call with representatives from Taylor Farms Headquarters (HQ) (Salinas, CA) to update the firm on the outbreak, obtain traceability information regarding the product of interest and discuss public communications.

On 10/22/2024, Taylor Farms HQ (Salinas, CA) issued a voluntary recall and sent customer notification letters for all yellow onion products with an active best by dates processed and distributed out of the Taylor Farms Colorado Springs processing facility.

On 10/22/2024, FDA and CDC (hosted) held a Firm Call with McDonald's to discuss communications plans related to the incident. During that call, McDonald's updated on their action plans, including public messaging. The firm shared and provided written documentation indicating they took the following actions on 10/21/2024:

- Removed slivered onions distributed by (b)(4) supplier (Taylor Farms Colorado Springs) from restaurant menus in the affected states.
- Removed the Quarter Pounder beef patties and slivered onions from the affected restaurants.
- Issued a "Stop Sale" on all slivered onions coming out of the three identified distribution centers who received products from the Taylor Farms Colorado Springs processing facility.
- Out of an abundance of caution, placed a pause on sales of all beef patties used exclusively in the Quarter Pounder located in impacted states

On 10/24/2024, CDC, FDA and USDA/FSIS held a Firm Call with representatives from McDonald's to share information and provide updates related to the investigation.

On 10/25/2024, FDA and CDC held a Firm Call with representatives from Taylor Farms HQ to update the firm on investigational findings and address questions from the firm.

On 10/25/2024, FDA, CDC (hosted) and USDA held a Firm Call with representatives from McDonald's to discuss investigational findings and public communications due to an influx of media inquiries received by the firm.

On 10/30/2024, FDA and CDC held a Firm Call with representatives from Taylor Farms HQ to respond to and address questions from the firm.

Communications Overview

On 10/22/2024, CORE issued an Outbreak Advisory and CDC issued a Food Safety Alert related to this outbreak. Both outbreak notices were updated by the respective agencies on 10/25/2024, 10/30/2024, 11/13/2024 to reflect additional cases added to the outbreak cluster as well as investigational findings. On 12/3/2024, CDC and CORE issued the final updates to each web posting.

On 10/23/2024, the outbreak was added to the CORE Investigation Table (CIT) with "no vehicle identified." On 10/31/2024, the CIT was updated to list "Onion" as the likely vehicle. On 12/4/2024, the table was updated with a closure notice.

On 10/25/2024, Washington Department of Health issued public communications regarding the outbreak and the Taylor Farms recalled onions.

On 10/27/2024, Colorado Department of Agriculture issued a press release notifying the public that all beef patties tested by the agency resulted negative for *E. coli*.

Conclusions

On 10/20/2024, CDC named onions as the leading hypothesis for this *E. coli* O157:H7 outbreak based on the epidemiologic investigation which showed an early signal for exposure to McDonald's 13/14 (93%) within the week prior to illness onset. Interview of case patients regarding their McDonald's exposure indicated a signal for beef hamburger (13/13 or 100%), specifically Quarter Pounders (69%, 9/13). This was further supported with information provided by McDonald's HQ indicating fresh sliced raw onions and fresh beef patties are the two ingredients unique to the Quarter Pounder. Because fresh beef patties could not be ruled out, USDA/FSIS and FDA conducted traceback of the fresh beef patties and raw onions respectively.

FDA traceback of Slivered Onions supplied to (b)(4) McDonald's retail food establishments included in the traceback investigation identified (b)(4) manufacturing facility, Taylor Farms Colorado Inc. (Colorado Springs, CO) as the sole supplier of the processed Slivered Onions supplied to (b)(4) distribution centers that subsequently supplied the identified POS during the identified time frame of interest. (b)(4) grower, (b)(4) WA) was identified as the sole supplier of the raw ingredient, whole onions processed at the Colorado Springs processing facility during the time frame of interest. Although (b)(4) processor and grower were identified, the traceback investigation was limited to (b)(4) supply chain (McDonald's) and lacked variation in POS ideally sought to make comparisons and identified commonalties/convergence. A Full Scope PC Inspection was conducted at the Taylor Farms Colorado Springs processing facility to include environmental and product sampling. The inspection closed with issuance of an FDA Form 483, noting two discussion items. However, it is important to note that investigators were unable to observe production of the Slivered Onions as the firm ceased operations during the inspectional

period as of result of the investigation. In addition to the PC Inspection, an onsite farm inspection was conducted at the farm and associated packinghouse. The inspection closed with issuance of FDA Form 4056s to both firm with written observations.

FDA and state partners collected multiple types of samples from various types of retail establishments/firms for testing. One FDA sample of finished product recalled onion and one environment sample obtained from the grower of interest tested positive for serotype O168:H8 and O174:H21 respectively. No sample collected and analyzed yielded the outbreak strain.

Although the epidemiologic evidence strongly supports onions, due to a limited traceback, lack of microbiological and sufficient inspectional evidence, onion remained the suspect vehicle and likely source for this outbreak. On 12/6/2024, CDC closed the epidemiologic investigation with 104 cases from 14 states: CO (30), IA (1), KS (3), MI (2), MO (8), MT (19), NC (1), NE (13), NM (10), OR (1), UT (8), WA (1), WI (1), WY (6).

Acknowledgements

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INCIDENT COORDINATION GROUP

HFP Coordinated Outbreak Response and Evaluation (CORE) Network

Signals & Surveillance Team: Ashley Grant, Allison Wellman

Response: Response Team 4

- Team Lead: Katherine Kreil
- Lead Coordinator: Mardea Caulcrick-Grimes
- Operations Chief: Jamie Swann
- Planning Chief: Laura Kennedy

Outbreak Evaluation (OE) Team: Marie Armstrong, Tami Cloyd

Outbreak Analytics (OA) Team: CORE-Outbreak-Analytics-Team@fda.hhs.gov

Communications Team: Corinne Mowla, Anders Evenson

Senior Leadership Team: Stic Harris, Kari Irvin, Karen Blickenstaff, Alvin Crosby, Susan Lance

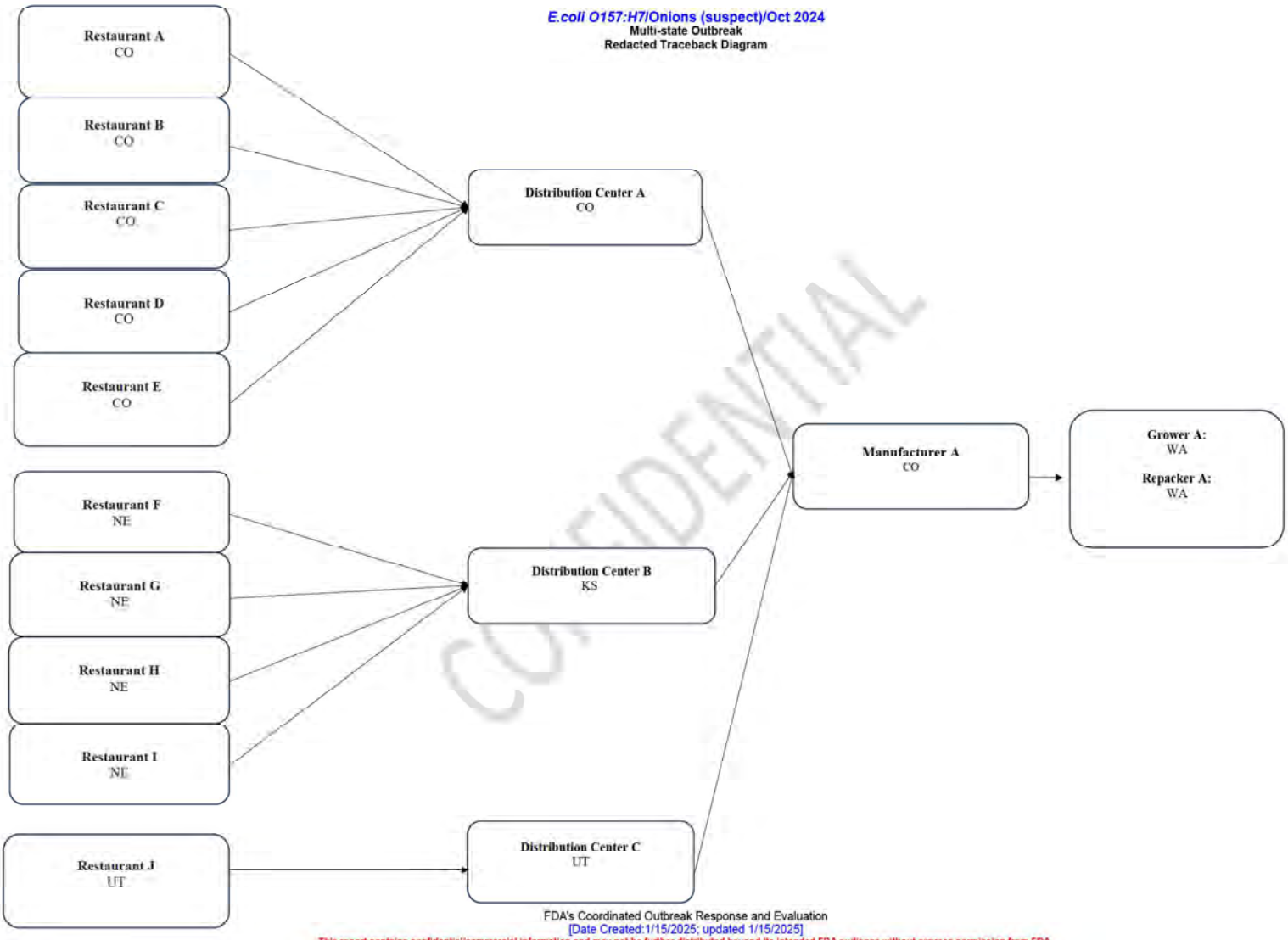
Office of Inspections and Investigations		
Office of Emergency Response (OER)– Division of Emergency Response – emergency.operations@fda.hhs.gov		
Director	Dominic Frasca	Dominic.Frasca@fda.hhs.gov

Supervisor West	Martin Guardia	Martin.Guardia@fda.hhs.gov
Supervisor East	Jamie Kamon	Jamie.Kamon@fda.hhs.gov
Office of Emergency Response – Division of Emergency Response – West & Central		
Field Emergency Response Coordinator, W2 (SAN)	Steven Galvez Nicole Yuen	Steven.Galvez@fda.hhs.gov Nicole.Yuen@fda.hhs.gov
Field Emergency Response Coordinator W4 (DEN)	Matthew Kozler	Matthew.Kozler@fda.hhs.gov
Field Emergency Response Coordinator, W3 (SEA)	Kelsey Volkman	Kelsey.Volkman@fda.hhs.gov
Field Emergency Response Coordinator, C5 (DAL)	Travis Hunt	Travis.Hunt@fda.hhs.gov
Field Emergency Response Coordinator, C1 (DET)	Marlon Turner	Marlon.Turner@fda.hhs.gov
Field Emergency Response Coordinator, C1 (CHI)	Joseph Cooper	Joseph.Cooper@fda.hhs.gov
Field Emergency Response Coordinator, C4 (KAN)	Erin Dugan	Erin.Dugan@fda.hhs.gov
Office of Inspections and Investigations (OII)		
Office of Inspections and Investigations – Program Operations Branch	Byron Beerbower Marty Rennells	oiiohfioutbreakresponse@fda.hhs.gov Byron.Beerbower@fda.hhs.gov William.Rennells@fda.hhs.gov
Office of Inspections and Investigations – Senior ERC	Holly Miller	Holly.Miller@fda.hhs.gov ; orahafseniorercs@fda.hhs.gov ;
Division **of Produce Safety**	Cullen Wilson Shane Rainey (mapper)	Cullen.Wilson@fda.hhs.gov Shane.Rainey@fda.hhs.gov
Office of Field Regulatory Operations, Division of Field Enforcement – Field Recall Effectiveness Branch	Pamela Ogonowski	Pamela.Ogonowski@fda.hhs.gov oiirecalls@fda.hhs.gov
Division of Field Enforcement	Jessica Kocian Winston Alejo	Jessica.Kocian@fda.hhs.gov Winston.Alejo@fda.hhs.gov
Office of the Commissioner		
Office of Chief Counsel	Claudia Ahiabor	Claudia.Ahiabor@fda.hhs.gov
Office of Emergency Management- Program Operations and Coordination Staff - GIS Branch	Dilip Bista	Dilip.Bista@fda.hhs.gov

Human Foods Program		
Office of Regulatory Testing and Surveillance	Zachary Miller Kimberly Spilman	Zachary.Miller@fda.hhs.gov Kimberly.spilman@fda.hhs.gov
Office of International Engagement	Rachel Bueide	Rachel.Bueide@fda.hhs.gov
Office of Microbiological Safety Senior Science Advisor	Tim Jackson	Timothy.Jackson@fda.hhs.gov
Office of Applied Microbiology and Technology	**Stephen Hughes**	Stephen.Hughes@fda.hhs.gov
Microbial Methods Development Branch	**Julie Kase**	Julie.Kase@fda.hhs.gov
Office of Microbiological Food Safety- Office of Produce Safety Division of fresh produce safety, Fresh Produce Policy Branch	Allie Strickland	DPS-FreshProduceBranch-Outbreaks@fda.hhs.gov
Office of Microbiological Food Safety - Office of Produce Safety Division of Processed Food and Beverages Safety Processed Produce Policy Branch	Adam Baker Grace Tung	DPS-ProcessedProduceBranch-Outbreaks@fda.hhs.gov
Office of Compliance and Enforcement, Office of Enforcement, Division of Produce and Import Enforcement, Produce Enforcement Branch -	RCRT 4	CFSANOCRCRT4@fda.hhs.gov
Office of compliance intervention & consultation, Division of Recalls and emerging issues.	Crystal McKenna Jinkee VilaBinayug Hanna Potter Martha Myrick Kathryn Nagy	crystal.mckenna@fda.hhs.gov Jinkee.VilaBinayug@fda.hhs.gov Hanna.Potter@fda.hhs.gov HFP-OCE-DREI-EIB-04@fda.hhs.gov OCIC-DREI-EIB@fda.hhs.gov Martha.Myrick@fda.hhs.gov Kathryn.Nagy@fda.hhs.gov

Office of Surveillance Strategy and Risk Prioritization – Division of Surveillance and Data Integration – Signal Detection & Bioinformatics Branch	Robert Literman	Robert.Literman@fda.hhs.gov
Centers for Disease Control and Prevention		
National Center for Emerging and Zoonotic Infectious Diseases (NCEZID)	Laura Gieraltowski Susan Lance (FDA Liaison) Thai-An Nguyen Colin Schwensohn Angelo Lodato (lead) Sarah Collier Lauren Gollarza Matthew Wise	lax2@cdc.gov sel0@cdc.gov; Susan.Lance@fda.hhs.gov ten9@cdc.gov hvq4@cdc.gov ekp1@cdc.gov sau9@cdc.gov knn0@cdc.gov cxx4@cdc.gov
Food Safety and Inspection Service (FSIS)		
Food Safety and Inspection Service	Jennifer Freiman Andrea Cote Bonnie Kissler	Jennifer.Freiman@usda.gov Andrea.Cote@usda.gov Bonnie.Kissler@usda.gov
State Partners		
Colorado	Rachel Jervis	rachel.jervis@state.co.us
Colorado	Daniel Mallal	daniel.mallal@state.co.us

E.coli O157:H7/Onions (suspect)/Oct 2024
Multi-state Outbreak
Redacted Traceback Diagram

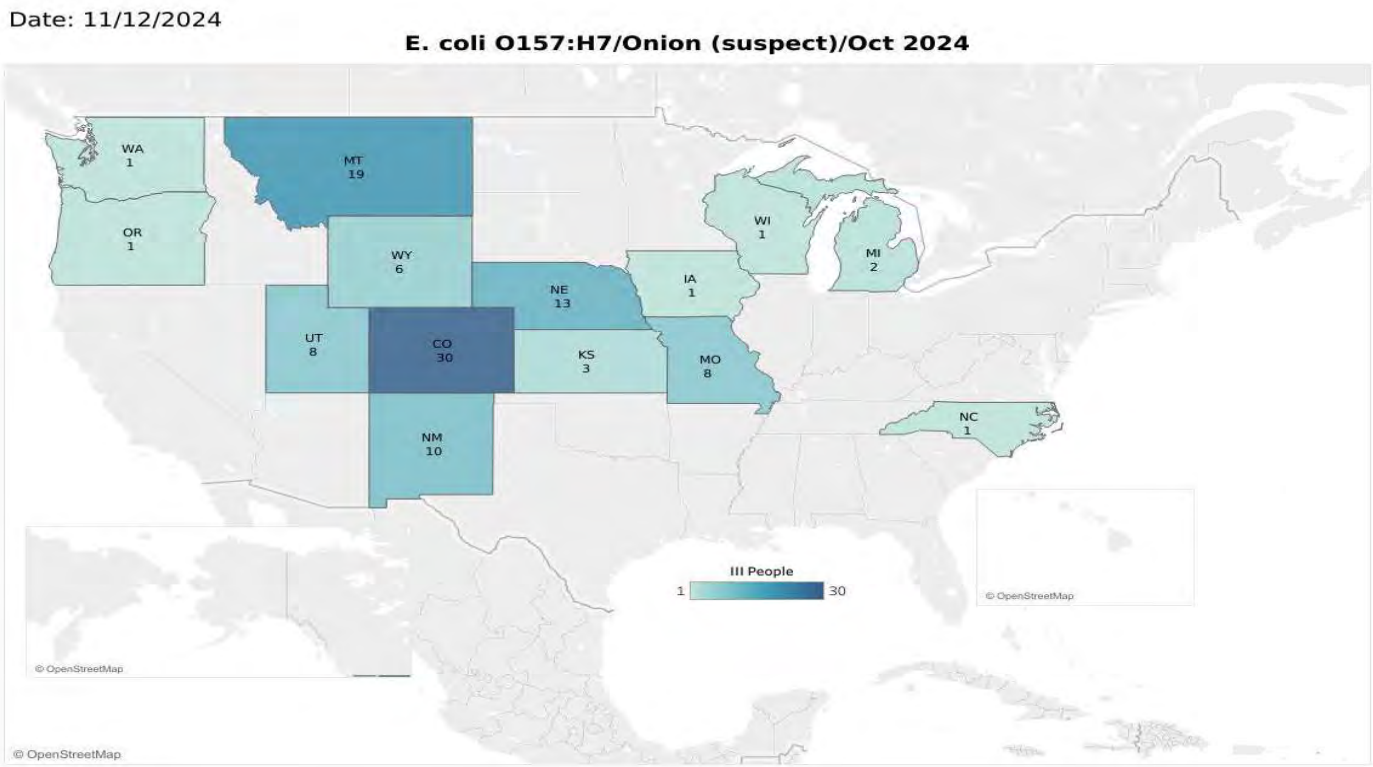


FDA's Coordinated Outbreak Response and Evaluation
[Date Created:1/15/2025; updated 1/15/2025]

INCIDENT BRIEFING (ICS 201), Adapted for FDA

1. Incident Name: E. coli O157:H7/Onion (suspect)/Oct 2024	2. CORE Incident Number: 1270	3. Date/Time Initiated: Date: 11/11/2024 Time: 10:09 PM

4. Map/Sketch



https://www.ncbi.nlm.nih.gov/pathogens/tree#Escherichia_coli_Shigella/PDG000000004.4886/PDS000181369.136?term=PNUSAE201185%20PNUSAE201106%20PNUSAE200336%20PNUSAE200328%20PNUSAE200673%20PNUSAE200329%20PNUSAE200661%20PNUSAE200338%20PNUSAE200321%20PNUSAE200664%20PNUSAE201438%20PNUSAE200706%20PNUSAE200865%20PNUSAE201105%20PNUSAE200660%20PNUSAE200669%20PNUSAE200687%20PNUSAE201255%20PNUSAE200671%20PNUSAE200657%20PNUSAE200672%20PNUSAE200334%20PNUSAE200666%20PNUSAE200339%20PNUSAE200674%20PNUSAE201107%20PNUSAE201527%20PNUSAE200654%20PNUSAE201032%20PNUSAE200547%20PNUSAE201481%20PNUSAE200704%20PNUSAE200882%20PNUSAE201037%20PNUSAE200959%20PNUSAE200707%20PNUSAE200519%20PNUSAE200314%20PNUSAE200518%20PNUSAE200698%20PNUSAE200697%20PNUSAE200517%20PNUSAE201036%20PNUSAE200962%20PNUSAE200703%20PNUSAE200699%20PNUSAE200709%20PNUSAE200840%20PNUSAE200590%20PNUSAE200806%20PNUSAE200418%20PNUSAE200516%20PNUSAE200751%20PNUSAE200992%20PNUSAE200712%20PNUSAE200340%20PNUSAE200327%20PNUSAE200303%20PNUSAE200964%20PNUSAE200333%20PNUSAE200749%20PNUSAE200757%20PNUSAE200909%20PNUSAE200753%20PNUSAE200841%20PNUSAE200857%20PNUSAE200977%20PNUSAE200332%20PNUSAE200665%20PNUSAE200658%20PNUSAE200880%20PNUSAE201029%20PNUSAE200616%20PNUSAE200702%20PNUSAE200615%20PNUSAE200371%20PNUSAE201417%20PNUSAE200668%20PNUSAE200670%20PNUSAE200323%20PNUSAE200667%20PNUSAE200642%20PNUSAE200906%20PNUSAE200631%20PNUSAE200304%20PNUSAE201211%20PNUSAE200705%20PNUSAE200961%20PNUSAE201390%20PNUSAE200708%20PNUSAE200963%20PNUSAE200758%20PNUSAE200609%20PNUSAE200313%20PNUSAE201016%20PNUSAE200558%20PNUSAE200612%20PNUSAE200624

6. Prepared by: Name: Ashley Grant Position/Title: Signals Team Member Signature:

ICS 201, Page 1 Date/Time: 11/11/2024 10:09 PM EST

INCIDENT BRIEFING (ICS 201), Adapted for FDA

1. Incident Name: E. coli O157:H7/Onion (suspect)/Oct 2024	2. CORE Incident Number: 1270	3. Date/Time Initiated: Date: 11/11/2024 Time: 10:09 PM

5. Situation Summary and Health and Safety Briefing

E. coli O157:H7 (2410COEXH-1)/Unknown/Oct 2024
Epidemiologic Investigation
On Tuesday, 10/15/2024, CORE Signals was notified by CDC and CO state partners about an uptick of E. coli O157 cases in the Mountain West region of the United States. On 10/15/2024, PulseNet coded this cluster with PulseNet code 2410COEXH-1.
As of 10/21/2024, there are 25 confirmed cases from 8 states: CO(11), IA(1), MO(1), MT(1), NE(7), UT(2), OR(1), and WY(1). Isolation dates range from 10/2/2024 to 10/9/2024, and onsets dates range 9/27/2024 to 10/7/2024. The reporting lag for this outbreak is 15 days. Currently, there are 13 isolates within the lag window. This outbreak is considered ongoing and is fast-moving. Cases range in age from 13 to 88 years old, with a median age of 23. 44% of cases are female; 41% of cases (9) have been hospitalized; no deaths have been reported; and one case of HUS has been reported in a case from NE.
On 10/18/2024, CDC hosted a state call with state partners, FDA, and USDA FSIS. During the call, several states noted numerous STEC clinical isolates pending sequencing, and they are expecting additional uploads/matching isolates to be added to the cluster during the week of 10/21/2024.
Isolates in this cluster are related by 0-3 alleles by cgMLST. Of note, none of the cluster isolates have been uploaded to NCBI, and a WGS relationship has not been determined. PulseNet identified three historical outbreaks related within 9 – 37 alleles to the current cluster. Historical outbreak 1811MLEXH-2, investigated in 2018, is related to the current cluster by 27 – 29 alleles and was closed with ground beef as the suspect vehicle. Historical outbreak 2205MLEXH-1, investigated in 2022, is related to the current cluster by 9-11 alleles and was closed with ground beef as the suspect vehicle. Historical outbreak 2208OHEXH-1 was also investigated in 2022 and is related to the current cluster within 32-37 alleles and was closed with romaine lettuce as the suspect vehicle. PulseNet also identified two non-clinical isolates related within 8 – 30 alleles to the current cluster: a 2022 FDA environmental isolate (air/cheese cloth) related within 8-10 alleles of the current outbreak and a 2022 USDA beef isolate related with 28-30 alleles of the current outbreak.
Epidemiologic information collected from cases indicates 93% (13/14) of cases report eating at McDonalds within the 7 days prior to illness onset. From a 2017 internal CDC restaurant survey, the background rate for respondents who reported eating at McDonald's was 22%, so this is a statistically significant exposure.
Common menu items reported by cases include beef hamburgers in general (100%; 13/13) and Quarter Pounder hamburgers specifically (69%; 9/13). Six cases either indicate 'yes' to onions on their Quarter Pounder or do not specifically say 'no' to onions. One case specifically notes 'no' to onions, and two other cases do not indicate one way or another if they had onions as a topping. Other menu items reported by cases include hamburgers, cheeseburgers, Big Macs, chicken nuggets, and French fries.
CDC organized information sharing calls with McDonald's HQ (McDonalds Corp. dba McDonalds; FEI 3008206122; Oak Brook, IL) on 10/16/2024, 10/18/2024 and 10/19/2024. According to McDonalds, the Quarter Pounder, Double Quarter Pounder, and Quarter Pounder Deluxe are the only hamburgers on the menu that are made with fresh, never frozen beef and are served with yellow, raw, sliced onions (referred to as "slivered" onions).
Epidemiologic information indicates that a significant driver of the outbreak is quarter pounder hamburgers at McDonald's. The two ingredients of most interest on these sandwiches were determined to be the fresh beef patties and the raw, sliced yellow onions, because these ingredients were distinct from the types of beef and onions used in other McDonalds sandwiches.
On 10/20/2024, McDonald's representatives provided the results of their internal ingredient supply chain review and noted that the geographic distribution of illnesses and McDonald's exposures overlaid with ingredient and supplier level data, suggesting the sliced onions were a more likely source than the fresh beef patties. Based on the traceability data provided by McDonalds, on 10/20/2024, onions were identified as the leading hypothesis for the outbreak vehicle (however, CDC has not conclusively ruled out the fresh beef patties as an alternative hypothesis, and FSIS is engaged in ongoing traceback activities related to this commodity).
On 10/19/2024, the Colorado Department of Public Health and Environment (CDPHE) notified CDC that they would be willing to collect and test samples of ground beef and raw onions, possibly embargoing some the products. CDPHE indicated they would sample over the weekend on 10/19 and 10/20/2024.

Menu & Ingredients
In 2018, McDonalds starting using fresh, rather than frozen beef for their Quarter Pounder hamburgers. Fresh patty hamburgers for the Quarter pounder, Double Quarter Pounder, and Quarter Pounder Deluxe are cooked to order. Toppings, including onions, cheese, and pickles (lettuce, tomatoes for the deluxe), are added to the patty and then wrapped/packaged for each order. Onions are not cooked and are served raw (sliced) on the patty.
McDonald's representatives stated that the slivered onions are only used on Quarter Pounder and Double Quarter Pounder hamburgers. The Big Macs and other hamburgers and cheeseburgers are made with (b)(4)).

Traceback Investigation

Slivered onions used by McDonald's for the Quarter Pounder hamburgers in the Mountain West region of the United States are sourced from Taylor Farms Colorado, Inc. (FEI 1783599; Colorado Springs, CO). Taylor Farms sources from specific growers and provides raw, whole onions to the Taylor Farms (TF) Colorado Springs processing facility. At the TF Colorado Springs processing facility, whole, raw onions are received and are processed (sliced), packed (pre portioned and bagged), and distributed to (b)(4) McDonald's distribution centers (DC) in the Mountain West region for further distribution. Onions processed by TF Colorado Springs for McDonalds Corp. are distributed to McDonalds restaurants within the Mountain West region. It was also noted that TF Colorado Springs processes onions for other firms, and that the onions, processing, packing, and distribution are not unique to McDonalds.

According to information provided by McDonalds HQ to CORE on 10/20/2024, (b)(4) were the onion suppliers for Taylor Farms Colorado during the time frame of interest (defined as the (b)(4) to the first confirmed meal date). Information provided by McDonalds indicates onions supplied by (b)(4) were (b)(4) grown. In addition, McDonalds also noted there were no changes in onion suppliers during the timeframe of interest and none of their restaurants required the use of a contingency plan for sourcing ingredients.

Taylor Farms Colorado Springs distributes to (b)(4) McDonalds DCs in the Mountain West Region: DC (b)(4), UT), DC (b)(4), MO), and DC (b)(4), CO). Collectively, these (b)(4) DCs distributed processed onions to McDonalds restaurants in CO, WY, KS, UT, NE, Western MO, Eastern NM, North Central ID, Eastern NV, and Southern MT.

Taylor Farms Colorado, Inc. (Colorado Springs, CO) is a manufacturer of fresh cut produce, including but not limited to diced tomatoes, diced onion, shredded lettuce, leafy greens, and cabbage for distribution via wholesale sale.

Taylor Farms Colorado Springs was last inspected in 8/2020 and rated NAI. A 483 was not issued, however three discussion items were addressed, including inadequate cleaning along the production line. The firm distributes approximately (b)(4) % of its finished products wholesale out of the state of Colorado and approximately (b)(4) % are sold in Colorado.

Per the firm, the main ingredient suppliers are Taylor Farms (Salinas, CA (lettuce)), (b)(4) .

The firm's top (b)(4) customers are (b)(4), CA), McDonalds (Chicago, IL), (b)(4), CT)

Taylor Farms Colorado Springs (b)(4) .

(b)(4) .

Firm Information

McDonald's Corporation, dba McDonald's, is an American multinational fast food chain. McDonalds has been headquartered in Chicago, IL, since June 2018. McDonald's is the world's largest fast food restaurant chain, serving over 69 million customers daily in over 100 countries. It is best known for its hamburgers, cheeseburgers, and French fries. McDonald's is the world's second-largest private employer with 1.7 million employees. As of 2022, McDonald's has the sixth-highest global brand valuation.

As noted by McDonalds HQ, each restaurant performs a daily food temperature check, testing both the temperature of raw food, cooked food, and cooking and storage equipment. McDonalds HQ also noted that both beef (frozen and raw) and produce are tested for STEC. There have been no recent positive findings.

Historical Outbreaks

Shortly after the emergence of STEC in 1982, there was a "hemorrhagic colitis" STEC outbreak among patrons of McDonald's restaurants in MI and OR. The outbreak was attributed to the hamburger patties.

In 2018, a multistate outbreak of Cyclospora was linked to the consumption of Fresh Express Salad Mix served at McDonald's.

In 2024, McDonald's McNugget Happy Meals in Ashland, AL, were implicated as the source of (b)(4) POS E. coli outbreak that occurred between March and April. An ongoing lawsuit states the Alabama Department of Public Health identified health violations at the restaurant, and cross-contamination was not ruled out.

1. Incident Name: E. coli O157:H7/Onion (suspect)/Oct 2024	2. CORE Incident Number: 1270	3. Date/Time Initiated: Date: 11/11/2024 Time: 10:09 PM

Pathogen/Commodity Pair
Currently, there are no historical outbreaks of STEC associated with bulb onions. If confirmed, this would be a novel pathogen/commodity pair.
In 2006, CDC identified an outbreak of E. coli O157 linked to (b)(4) of the United States. The epidemiologic investigation initially reported green onion as the likely source of the outbreak; however, during the course of the investigation, it was determined that shredded lettuce was the likely source of the outbreak. Following the outbreak, (b)(4) removed green onions from the menu. During the investigation yellow bulb onions collected from an open bin within a (b)(4) tested positive for a different strain of E. coli O157.
In 2015, CORE investigated an E. coli O157 outbreak (CARA ID: 526) linked to (b)(4) rotisserie chicken salad. A celery/onion blend ingredient processed by (b)(4) , CA) was an item of interest, but traceback did not converge on (b)(4) grower.
In 2021, spring onions (similar to green onions) were determined to be the source of an enteroinvasive E. coli (EIEC) outbreak in Denmark.

Rationale:
This incident is being transferred from CORE Signals to CORE Response Team 4 based on the following rationale:
- This is a rapidly expanding and severe multistate outbreak of E. coli O157:H7 illnesses with an FDA-regulated product, slivered onions served on McDonald's quarter pounders, identified as the suspect vehicle.
- Response coordination is needed for a traceback investigation, inspectional and sampling activities, potential product actions, and public communications.
- STEC outbreaks linked to onions is a novel pathogen/commodity pair.
- This incident has the potential to be high profile within FDA and in the public arena.

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- This is a rapidly expanding and severe multistate outbreak of E. coli O157:H7 illnesses with an FDA-regulated product, slivered onions served on McDonald's quarter pounders, identified as the suspect vehicle.
- Response coordination is needed for a traceback investigation, inspectional and sampling activities, potential product actions, and public communications.
- STEC outbreaks linked to onions is a novel pathogen/commodity pair.
- This incident has the potential to be high profile within FDA and in the public arena.

Exposure Table

No Exposure Table Available

6. Prepared by: Name: Ashley Grant	Position/Title: Signals Team Member	Signature:
ICS 201, Page 2	Date/Time: 11/11/2024 10:09 PM EST	

Updated by FDA 2/2011

INCIDENT BRIEFING (ICS 201), Adapted for FDA

1. Incident Name: E. coli O157:H7/Onion (suspect)/Oct 2024	2. CORE Incident Number: 1270	3. Date/Time Initiated: Date: 11/11/2024 Time: 10:09 PM

7. Current and Planned Objectives:

(b)(5)

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

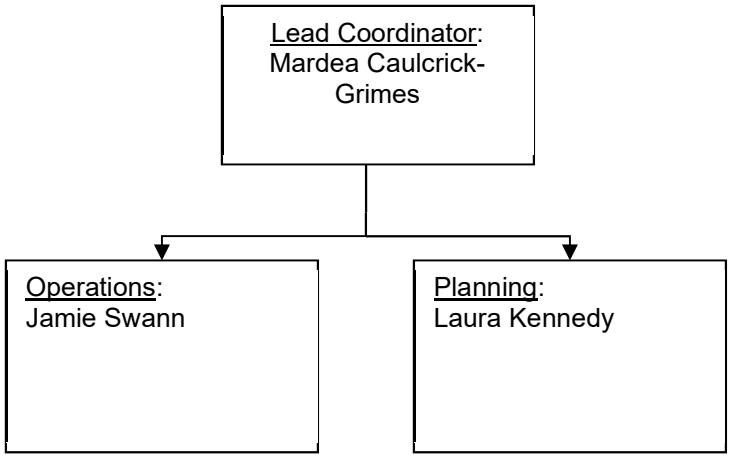
Time:	Actions:

6. Prepared by: Name: Ashley Grant Position/Title: Signals Team Member Signature:

INCIDENT BRIEFING (ICS 201), Adapted for FDA

1. Incident Name: E. coli O157:H7/Onion (suspect)/Oct 2024	2. CORE Incident Number: 1270	3. Date/Time Initiated: Date: 11/11/2024 Time: 10:09 PM

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



6. Prepared by: Name: Ashley Grant Position/Title: Signals Team Member Signature:

INCIDENT BRIEFING (ICS 201), Adapted for FDA

1. Incident Name: E. coli O157:H7/Onion (suspect)/Oct 2024	2. CORE Incident Number: 1270	3. Date/Time Initiated: Date: 11/11/2024 Time: 10:09 PM

10. Resource Summary:

Resource	Resource Identifier	Date/Time Ordered	ETA	Arrived	Notes (location/assignment/status)
Galvez, Steven					HFI West 2 (N. CA) HFI West 3
Clausen, Nicole					
Havranek, Jessica					
HFP-OCE-OCIC-DREI-EIB					
Literman, Robert					Office of Surveillance Strategy and Risk Prioritization (OSSRP); Division of Surveillance and Data Integration (DSDI); Signal Detection and Bioinformatics Branch (SDBB)
McKenna, Crystal A					Compliance-- SME
Vila Binayug, Jinkee M					Compliance-- Back-up CO
Potter, Hanna					Compliance-- Lead CO
RCRT4					Compliance
Baker, Adam					Office of Microbiological Food Safety--Processed Produce Branch
Grace Tung					Office of Microbiological Food Safety--Processed Produce Branch
Armstrong, Marie	Coordinated Outbreak Response and Evaluation Network (CORE)				
DPS-ProcessedProduceBranch-Outbreaks					Office of Microbiological Food Safety
Yuen, Nicole					HFI West 2 (N. CA) HFI West 3
Volkman, Kelsey					HFI West 3
Cooper, Joe					HFI Central 1

1. Incident Name: E. coli O157:H7/Onion (suspect)/Oct 2024	2. CORE Incident Number: 1270	3. Date/Time Initiated: Date: 11/11/2024 Time: 10:09 PM

10. Resource Summary:

Hunt, Travis					HFI Central 5
Kozler, Matthew					HFI West 4
Dugan, Erin					HFI Central 4
OII OHFI Outbreak Response					OII OHFI Outbreak Response
OII Senior ERCs					OII Senior ERCs
Miller, Holly					OII Senior ERCs
Frasca, Dominic					
DPS-FreshProduceBranch-Outbreaks					Office of Microbiological Food Safety
Lodato, Angelo R	National Center for Emerging and Zoonotic Infectious Diseases (NCEZID)				
Schwensohn, Colin A	National Center for Emerging and Zoonotic Infectious Diseases (NCEZID)				
Nguyen, Thai-An	National Center for Emerging and Zoonotic Infectious Diseases (NCEZID)				
Gieraltowski, Laura B	National Center for Emerging and Zoonotic Infectious Diseases (NCEZID)				
Collier, Sarah A	National Center for Emerging				

10. Resource Summary:

	and Zoonotic Infectious Diseases (NCEZID)				
Freiman, Jennifer	Food Safety and Inspection Service (FSIS)				
Cote, Andrea	Food Safety and Inspection Service (FSIS)				
Kissler, Bonnie	Food Safety and Inspection Service (FSIS)				

INCIDENT OBJECTIVES (ICS 202), Adapted for FDA

1. Incident Name: *E. coli* O157-H7/Onion (suspect)/Oct 2024	2. Operational Period #3: Date From: 11/8/2024 Date To: 11/14/2024 Time From: 1300EDT Time To:1300EDT

3. Objective(s):

(b)(5)

4. Operational Period Command Emphasis:

General Situational Awareness

As of 10/22/2024, there are 61 confirmed cases from 10 states: CO (27), IA (1), KS (1), MO (1), MT (12), NE (9), OR (1), UT (4), WI (1) and WY (4). Isolation dates range from 10/2/2024 to 10/14/2024, and onsets dates range 9/27/2024 to 10/07/2024. The reporting lag for this outbreak is 15 days. This outbreak is considered ongoing and is fast-moving. Cases range in age from 13 to 88 years old, with a median age of 23. 10 have been hospitalized; one death has been reported; and one case of HUS has been reported in a case from NE.

On 10/15/2024, CORE Signals was notified by CDC and CO state partners about an uptick of *E. coli* O157:H7 cases in the Mountain West region of the United States. On 10/15/2024, PulseNet coded this cluster with PulseNet code 2410COEXH-1.

On 10/18/2024, CDC hosted a state call with state partners, FDA, and USDA FSIS. During the call, several states noted numerous STEC clinical isolates are pending sequencing. Isolates in this cluster are related by 0-3 alleles by cgMLST.

Epidemiologic information collected from cases indicates 93% (13/14) of cases report eating at McDonalds within the 7 days prior to illness onset. From a 2017 internal CDC restaurant survey, the background rate for respondents who reported eating at McDonald's was 22%, so this is a statistically significant exposure. Common menu items reported by cases include beef hamburgers in general (100%; 13/13) and Quarter Pounder hamburgers specifically (69%; 9/13). Six cases either indicate 'yes' to onions on their Quarter Pounder or do not specifically say 'no' to onions. One case specifically notes 'no' to onions, and two other cases do not indicate one way or another if they had onions as a topping.

Epidemiologic information indicates that a significant driver of the outbreak is quarter pounder hamburgers at McDonald's. The two ingredients of most interest on these sandwiches were determined to be the fresh beef patties and the raw, sliced yellow onions, because these ingredients were distinct from the types of beef and onions used in other McDonalds sandwiches. On 10/20/2024, McDonald's representatives provided the results of their internal ingredient supply chain review and noted that the geographic distribution of illnesses and McDonald's exposures overlaid with ingredient and supplier level data, suggesting the sliced onions were a more likely source than the fresh beef patties. Based on the traceability data provided by McDonalds, on 10/20/2024, onions were identified as the leading hypothesis for the outbreak vehicle (however, CDC has not conclusively ruled out the fresh beef patties as an alternative hypothesis, and FSIS is engaged in ongoing traceback activities related to this commodity).

Slivered onions used by McDonald's for the Quarter Pounder hamburgers in the Mountain West region of the United States are sourced from Taylor Farms Colorado, Inc. (FEI 1783599; Colorado Springs, CO). Taylor Farms sources from specific growers and provides raw, whole onions to the Taylor Farms (TF) Colorado Springs processing facility. Taylor Farms Colorado Springs was last inspected in 8/2020 and rated NAI. An FDA- 483 was not issued, however three discussion items were addressed, including inadequate cleaning along the production line.

On 10/21/2024, CORE Signals and Surveillance Team transferred this incident to Response Team 4 for further coordination. On 10/21/2024, CORE issued eNSpect Assignment #253286 to Office of Inspection and Investigation Office of Human Food Inspectorate (OII OHFI) West 4 (DEN) for traceback records and information collection at Taylor Farms Colorado Inc. (Colorado Springs, CO; FEI: 1783599). On 10/21/2024, a Firm Call was held with representative from Taylor Farms HQ (Salinas, CA) to update and inform the firm about the outbreak investigation and obtain additional traceability information specific to growers and trace forward data. On 10/21/2024, OII OHFI W4 (DEN) provide records and information collected from Taylor Farms Colorado Inc. (Colorado Springs, CO) related to eNSpect Assignment #253286. On 10/22/2024, CDC and FDA held a firm call with McDonald's to discuss communications plans.

INCIDENT OBJECTIVES (ICS 202), Adapted for FDA

1. Incident Name: *E. coli* O157-H7/Onion (suspect)/Oct 2024	2. Operational Period #3: Date From: 11/8/2024 Date To: 11/14/2024 Time From: 1300EDT Time To:1300EDT

Operational Period 1 Accomplishments:

As of 10/29/2024, there are 85 confirmed cases from 13 states: CO (26), IA (1), KS (1), MI (2), MO (4), MT (17), NE (12), NM (5), OR (1), UT (7), WA (1), WI (1) and WY (5). Isolation dates range from 10/2/2024 to 10/18/2024, and onsets dates range 9/27/2024 to 10/16/2024. This outbreak is considered ongoing and is fast-moving. There has been 24 have been hospitalizations; one death has been reported; and two cases of HUS have been reported.

On 10/22/2024, CDC held Multi-state Call #2. The same day, CORE issued an Outbreak Advisory and CDC issued a Food Safety Alert related to this incident. On 10/22/2024, the Office of Emergency Response GIS specialist provided a map of the fields identified to date in the traceback investigation. On 10/22/2024, OII OHFI W2 (SAN) shared a map (provided by Taylor Farms HQ) depicting the distribution of onions produced at the Taylor Farms Colorado Springs processing facility which were distributed to non-McDonald's customers. These include onions sourced from the same raw material supplier and same production dates as the onions sold to McDonald's locations in this outbreak.

On 10/23/2024, OII OHFI W2 (SAN) shared a copy of Taylor Farm's customer notification letter with CORE. Then, CORE held Special Purpose Tactics Call (SPTC) #1 with HFP, OII SMEs and the relevant OHFI Divisions to discuss the logistics of a full scope Preventive Controls Inspection with environmental and product sampling at the Taylor Farms CO Springs processing facility and the potential for sampling processed slivered yellow onions removed from McDonald's restaurant locations. On the same day, OII OHFI C1 (CHI) informed CORE that McDonald's has confirmed all slivered onions are being held at (b)(4) distribution centers and are available for FDA sampling. On 10/23/204, OII OHFI W4 (DEN) updated that an investigator visited the Taylor Farms CO Springs processing facility and confirmed (b)(4) lots ((b)(4)) of the McDonald's slivered onion (b)(4) are on hold. Products are from the same grower ((b)(4)). OII OHFI W4 (DEN) collected 5 samples (#1273842, #1273843, #1273844, #1273845, #1273846) from the Colorado Department of Public & Environment (CDPHE) lab. Samples are a subset of (b)(4) lbs. boxes of slivered yellow onions collected by Colorado state partners from (b) different McDonald's restaurant locations in (b)(4) . Samples were sent to FDA Denver Laboratory for analysis. On 10/23/2024, CORE was notified by Michigan state partners via OII OHFI C1 (DET) of two Michigan case patients added to the outbreak cluster.

On 10/24/2024, CORE held Special Purpose Tactics Call (SPTC) #2 with HFP, OII SMEs and the relevant OHFI Divisions to discuss sampling and lab guidance at (b)(4) separate McDonald's Distribution Centers and the Taylor Farms CO Springs processing facility. CORE then issued Sampling Guidance to OII OHFI W4 (DEN) and OII OHFI C4 (KAN) for sample collection at the (b)(4) McDonald's DCs and the Taylor Farm CO Springs processing facility. On 10/24/2024, OII W2 (SAN) provided the Taylor Farms customer distribution list for the recalled Taylor Farms onions. That day, OII OHFI W4 (DEN) collected 3 samples (#1278095, 1278096 & 1278097) from (b)(4) , a McDonald's Distribution Center located in (b)(4) , Utah. The samples were shipped to FDA New York Lab for analysis. On 10/24/2024, OII OHFI W4 (DEN) collected 2 samples (1228886, 1272852) from the Taylor Farms CO Springs processing facility and 2 samples (1264216 & #1264217) from (b)(4) , a McDonald's Distribution Center located in (b)(4) . These samples were shipped to SAN Lab for analysis. On 10/24/2024, CDC, FDA and USDA/FSIS held a firm call with representatives from McDonald's to share information and provide updates related to the outbreak investigation.

On 10/24/2024, CORE issued FACTS Assignment #12404946 to OII OHFI W4 (DEN) for a Full Scope Preventive Controls Inspection with environmental and finished product sampling and record collection at Taylor Farms Colorado Inc. (Colorado Springs, CO; FEI: 1783599). On 10/24/2024, CORE was notified by Colorado state partner that the Colorado Department of Agriculture (CDA) sample #AA52696 (sliced raw onions) is preliminary positive for *E. coli* O157:H7 from rt-PCR screening. This sample was collected from (b)(4) McDonald's location at the (b)(4) . On 10/24/2024, Human Foods Program Office of Surveillance Strategy & Risk Prioritization, Division of Evaluation & Population Health Services, Signal Coordination & Triage Branch (HFP/SSRP/DEPHS/SCTB) notified CORE of 19 complaints potentially related to this outbreak investigation.

On 10/25/2024, HFP SSRP Division of Surveillance & Data Integration, Signal Detection and Bioinformatics Branch (DSDI/SDBB) provided the WGS report for 34 clinical isolates included in this cluster. The clinical isolates are a match but not a match to other isolates in the WGS tree. The closest FDA isolate (~17 SNPs away) is an Arizona soil isolate, collected in 2022 as part of a (b)(4) investigation. On 10/25/2024, HFP Office of Regulatory Testing and Surveillance (ORTS) Denver Lab reported sample analysis was completed for the 5 samples (#1273842, 1273843, 1273844, 1273845, 1273846) collected by OII OHFI W4 (DEN) from Colorado Department of Public Health and Environment (CDPHE) Laboratory. All samples closed out LC1, negative for *E. coli* O157:H7.

On 10/25/2024, OII OHFI W4 (DEN) collected 5 additional samples (#1264218, 1264219, 12644220, 1264221 & 1264222) from McDonald's (b)(4) , Colorado. These samples were delivered to Denver Lab for analysis. On 10/27/2027, HFP ORTS Denver Lab reported all 5 samples closed out LC1, negative for EHEC. On 10/25/2024, CDC and CORE updated their respective outbreak notices to reflect additional cases added to the outbreak cluster and updated investigational findings. On 10/25/2024, OII OHFI W3 (SEA) shared with CORE public communication issued by Washington Department of Health regarding this outbreak. On 10/25/2024, USDA/FSIS and OII OHFI W4 (DEN) notified CORE that CDA completed analysis of all beef products (fresh and frozen) collected from several McDonald's restaurant locations of interest and all screened negative for *E.coli* O157:H7 via

INCIDENT OBJECTIVES (ICS 202), Adapted for FDA

1. Incident Name: *E. coli* O157-H7/Onion (suspect)/Oct 2024	2. Operational Period #3: Date From: 11/8/2024 Date To: 11/14/2024 Time From: 1300EDT Time To:1300EDT

rt-PCR. On 10/25/2024, FDA and CDC held a firm call with representatives from Taylor Farms HQ (Salinas, CA) to update the firm on investigational findings and address questions from the firm.
On 10/26/2024, HFP ORTS New York Lab reported 2 subs (5 & 10) from sample #1278095, all 10 subs from sample #1278096 and 1 sub (6) from sample #1278097 are CRO for EHEC/STEC. These three samples were collected by OII OHFI W4 (DEN) from the McDonald's (b)(4) , UT). On 10/26/2024, HFP ORTS San Francisco Lab reported sample #1264217, collected from McDonald's (b)(4) , CO) closed LC1, negative for *E. coli* O157:H7 and samples #1272852 & 1228886, collected from the Taylor Farms Colorado Springs processing facility were negative for EHEC/STEC.
On 10/27/2024, Colorado Department of Agriculture (CDA) issued public communication notifying the public that all beef patties tested by the agency tested negative for *E. coli*.
On 10/28/2024, OII OHFI W4 (DEN) initiated the Full Scope PC Inspection with environmental and finished product sampling and records collection at Taylor Farms Colorado Inc. (Colorado Springs, CO; FEI: 1783599). On 10/28/2024, CORE held Special Purpose Tactics Call #3 to discuss the logistics of the on-site farm inspection at the grower of interest (b)(4) WA).
On 10/28/2024, OII OHFI W4 (DEN) collected 2 samples (#1278098 & 1278099) from McDonald's (b)(4) , Utah). These samples were shipped to New York Lab for analysis. On 10/28/2024, USDA/FSIS provided an update on the beef traceback investigation.
On 10/29/2024, CORE held Special Purpose Tactics Call #4 with FDA SMEs and OII OHFI W4 (DEN) investigational team to discuss the ongoing PC Inspection at Taylor Farms Colorado Inc. (Colorado Springs, CO) and possible environmental sampling activities to occur at the facility.

Operational Period 2 Accomplishments:

As of 11/8/2024, there are 103 confirmed cases from 14 states: CO (30), IA (1), KS (3), MI (2), MO (8), MT (19), NE (12), NC (1), NM (10), OR (1), UT (8), WA (1), WI (1) and WY (6). Isolation dates range from 10/2/2024 to 10/28/2024, and onsets dates range 9/24/2024 to 10/21/2024. There has been 34 have been hospitalizations; one death has been reported; and three cases of HUS have been reported.

On 10/28/2024, OII OHFI C4 (KAN) collected 5 samples (#1265632, 1278293, 1278294, 1278295 & 1278296) from McDonald's (b)(4) , KS). On 10/29/2024, Seattle Lab reported samples were received, however, sample #1278295 arrived damaged and leaking and will be classified as LC5. On 10/29/2024, CORE issued FACTS Assignment #12405863 to OII Division of Produce Safety for an on-site farm inspection with sampling and record collection at (b)(4) , WA; FEI: (b)(4)). On 10/29/2024, CORE was notified by CDPHE via OII OHFI W4 (DEN) that onion analysis was complete, and all samples screened negative for Stx2. On 10/29/2024, HFP Office of Compliance and Enforcement (OCE) informed CORE that Taylor Farms HQ (Salinas, CA) was notified of sample results, including "Cannot Rule Out" CRO.

On 10/30/2024, OII Division of Produce Safety (DPS) initiated FACTS Assignment #12405863, an onsite farm inspection with sampling and record collections at (b)(4) , WA). On 10/30/2024, CDC and CORE updated their respective outbreak notices to reflect additional cases added to the outbreak cluster as well as investigational findings. On 10/30/2024, CDC and FDA held a firm call with representatives from Taylor Farms HQ (Salinas, CA) to respond to and address questions from the firm. On 10/30/2024, OII OHFI W4 (DEN) collected 4 finished product samples (#1247260, 1247261, 1257881 & 1257882) and 1 environmental sample (#1278594) from Taylor Farms Colorado Inc. (Colorado Springs, CO) under eNSpect Assignment #12404946. The finished product samples represent a subset of non-McDonald's customer products the firm had on hold. Samples were shipped to New York Lab and delivered to Denver Lab for analysis. On 10/30/2024, ORTS San Francisco Lab reported sample #1264216, collected from (b)(4) , CO) closed lab class LC1, negative for *E. coli* O157:H7. On 10/30/2024, ORTS Seattle Lab reported samples #1265632 and #1278293 collected from (b)(4) , KS) closed lab class LC1, negative for *E. coli* O157:H7. On 10/30/2024, OII DPS collected one environmental sample (#1200105) from (b)(4) , Washington) under FACTS Assignment #12405863. The sample was shipped to Denver Lab for analysis. On 10/30/2024, OII OHFI W4 (DEN) notified CORE that CDA tested 5 additional subs from the AA52696 Bag 1 (same bag as the initial CRO) and is reporting another preliminary positive via rt-PCR. On 10/31/2024, OII OHFI C1 (DET) notified CORE that Michigan Department of Agriculture and Rural Development (MDARD) and local health department collected aseptic samples from open product associated with lot (b)(4) from a local McDonald's location ((b)(4) MI). On 10/31/2024, USDA/FSIS notified CORE and CDC that they plan to close their investigation

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1. Incident Name: *E. coli* O157-H7/Onion (suspect)/Oct 2024	2. Operational Period #3: Date From: 11/8/2024 Date To: 11/14/2024 Time From: 1300EDT Time To:1300EDT

related to this multistate outbreak of *E. coli* O157:H7. On 10/31/2024, OII OHFI W4 (DEN) collected 50 Environmental subs under sample #1278595 and 5 finished product samples (#1273848, 1278708, 1278709, 1278710 and 1278711) of sliced/diced/whole onions at Taylor Farms Colorado Inc. (Colorado Springs, CO; FEI: 1783599). On 10/31/2024, OII Division of Produce Safety (DPS) collected 5 samples (# 1176312, 1176313, 1176314, 1176315, 1176316) of onions from the (b)(4), WA. They collected 14 environmental subs under sample # 1200106 from harvest equipment used on fields at the (b)(4), WA. Additionally, they collected 5 subs of soil (sample #1200107) and 10 subs of residual onion samples (sample # 1176317) from field (b)(4).

On 11/1/2024, ORTS Denver Lab reported 1 sub (11) from environmental sample (#1278594) collected from Taylor Farms Colorado Inc. under eNSpect Assignment #12404946 is CRO for *E. coli* O157:H7. On 11/2/2024, Denver Lab reported the sample closed out lab class LC1, negative for *E. coli* O157:H7. On 11/1/2024, ORTS Denver Lab reported environmental sample (#1200105) collected from (b)(4) under FACTS Assignment #12405863 is CRO (3 subs) for *E. coli* O157:H7. On 11/2/2024, Denver Lab reported the sample closed lab class LC1, negative for *E. coli* O157:H7. On 11/1/2024, OII OHFI C1 (CHI) notified CORE that Michigan state partners have completed their analysis on the product samples collected from the (b)(4) McDonald's location. All samples resulted negative for *E.coli.* On 11/1/2024, ORTS Seattle Lab reported samples #1278294 & #1278296, collected from (b)(4) closed lab class LC1, negative for STEC. On 11/1/2024 ORTS New York Lab reported sample #1247260 (b)(4) diced onions), collected from Taylor Farms Colorado Inc. (Colorado Springs, CO) under eNSpect Assignment #12404946 was negative for EHEC/STEC. Samples #1247261 (sub 6), #1257881(sub 7) & #1257882 (sub 4) also collected at Taylor Farms Colorado Inc under eNSpect Assignment #12404946 were reported CRO (stx2 on screening). On 11/1/2024, HFP Office of Compliance and Enforcement (OCE) informed CORE that Taylor Farms HQ (Salinas, CA) was notified of additional sample results (all negatives), as well as sample #1278295 (collected from (b)(4) D/C), closed LC5 due to damage during transport. On 11/1/2024, OII DPS collected 7 samples at (b)(4) consisting of 2 DEUF (#1176319, 1176320), 1 drag environmental swab (1176321), 3 sediment (#1176318, 1200110, 1200111) and 1 soil (#1200109) under FACTS Assignment #12405863. Samples were shipped to Denver, Seattle, and Irvine labs for analysis.

On 11/3/2024, ORTS Denver Lab reported DEUF samples (#1176319, 1176320) and 1 environmental drag sample (#1176321) collected at (b)(4) under FACTS Assignment #12405863 closed lab class LC1, negative for *E. coli* O157:H7. On 11/4/2024, ORTS San Francisco and Seattle Labs reported samples #1176312(whole onion) collected at (b)(4)) and 1176317 (residual onion) collected at (b)(4) under FACTS Assignment #12405863 closed lab class LC1, negative. On 11/4/2024, OII W4 (DEN) updated that Colorado CDA has exhausted all efforts to isolate any *E. coli* O157:H7 from the onion sample #AA52696, collected from the (b)(4) McDonald's at (b)(4) and previously reported as CRO. All onions associated with the AA52696 bag has been analyzed. On 11/4/2024, HFP Signal Detection and Bioinformatics Branch notified CORE that WGS analysis of sample #1278096 (finished product) collected at the McDonald's (b)(4) reveals the isolates are a match to each other, but not a match to clinical isolates associated with this outbreak. The closest isolates are from a small cluster that contains only 2023 cattle feces isolates from California. On 11/4/2024, ORTS reported finished product samples #1278095 and #1278097, collected from (b)(4) and previously reported as CRO closed lab class LC1, negative for EHEC/STEC. On 11/4/2024, ORTS San Francisco Lab reported environmental sample #1278595, and finished product samples (#1278710, 1278708) collected at Taylor Farms Colorado Inc. under eNSpect Assignment #12404946 closed lab class LC1, negative for EHEC/STEC. On 11/4/2024, HFP Office of Compliance and Enforcement (OCE) informed CORE that Taylor Farms HQ (Salinas, CA) was notified of additional sample results (all negatives), including samples #1278095 & 1278097, collected from McDonald's (b)(4), and previously reported as CRO. On 11/4/2024, OII DPS collected 4 additional samples at (b)(4) consisting of 2 soil (#1200112 & 1200113), 1 DEUF (#1200108) and 1 scat (#1200114) under FACTS Assignment #12405863. On 11/4/2024, OII DPS closed FACTS Assignment #12405863, onsite farm inspection with sampling and record collections at (b)(4), WA).

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1. Incident Name: *E. coli* O157-H7/Onion (suspect)/Oct 2024	**2. Operational Period #3:** Date From: 11/8/2024 Date To: 11/14/2024 Time From: 1300EDT Time To:1300EDT

On 11/5/2024, New York Lab reported finished production samples (1257882, 1247261 (previously reported as CRO) & 1247260) collected from Taylor Farms Colorado Inc under eNSpect Assignment #12404946 closed lab class LC1, negative for EHEC/STEC. On 11/5/2024, ORTS New York Lab reported 2 subs (6 &15) from environmental sample #1200106 collected at (b)(4) under FACTS Assignment #12405863 is CRO for STEC. On 11/5/2024, ORTS reported samples (1176313, 1176314, 1176315 & 1176316) (whole onions) collected at (b)(4) and samples (1200107) (soil), (1200110) (sediment) collected at (b)(4) under FACTS Assignment #12405863 closed LC1, negative for EHEC/STEC. On 11/5/2024, ORTS San Francisco Lab reported finished product sample (1273848) collected at Taylor Farms Colorado Inc. under eNSpect Assignment #12404946 closed lab class LC1, negative for EHEC/STEC. On 11/5/2024, FDA STEC Council informed CORE they had completed their review of the 10 isolates associated with sample #1278096 (finished product sample collected from McDonald's (b)(4)) and provided their determination of public health significance. On 11/5/2024, ORTS closed out sample #1278099 (finished product) collected at McDonald's (b)(4) lab class LC1, negative for EHEC/STEC. On 11/5/2024, HFP Office of Compliance and Enforcement (OCE) informed CORE that Taylor Farms HQ (Salinas, CA) was notified of additional sample results (all negatives) for samples collected from McDonald's (b)(4) Taylor Farm Colorado Inc. (Colorado Springs, CO).

On 11/6/2024, ORTS Seattle Lab reported samples (#1176318 & 1200111) (sediments) collected at (b)(4) under FACTS Assignment #12405863 closed lab class LC1, negative for EHEC/STEC. On 11/6/2024, OII DPS shared with CORE copies of both FDA Form-4056s issued to (b)(4) under FACTS Assignment #12405863. On 11/6/2024, ORTS San Francisco Lab reported samples (1278709) (finished product) and (1278711) (whole peeled onions), collected at Taylor Farms Colorado Inc. under eNSpect Assignment #12404946 closed lab class LC1, negative for EHEC/STEC. On 11/6/2024, McDonald's informed CDC and FDA that they will be returning slivered onions to the menu at the impacted restaurants. The slivered onions for these restaurants will be sourced by another McDonald's supplier. On 11/6/2024, CORE held SPTC #5 with W4 (DEN) investigational team and SMEs to discuss the closeout of the Full Scope Preventive Controls Inspection (eNSpect #12404946) with environmental and finished product sampling and records collection at Taylor Farms Colorado Inc. (Colorado Springs, CO). On 11/6/2024, ORTS Irvine Lab closed out sample (1200109) (soil) collected at (b)(4) under FACTS Assignment #12405863 lab class LC1, negative for EHEC/STEC. On 11/6/2024, ORTS New York Lab closed out sample #1257881 (diced onion) collected from Taylor Farms Colorado Inc. under eNSpect Assignment #12404946 and previously reported CRO lab class LC1, negative for EHEC/STEC.

On 11/7/2024, ORTS New York and Seattle Labs reported samples (1200112) (soil), (1200108) (DEUF) and 1200114 (scat) collected at (b)(4) under FACTS Assignment #12405863 closed lab class LC1, negative for EHEC/STEC. Sample 1200113 (soil) also collected at (b)(4) under FACTS Assignment #12405863 is CRO (5 subs) for *E.coli* O157:H7. On 11/7/2024, HFP Office of Compliance and Enforcement (OCE) informed CORE that Taylor Farms HQ (Salinas, CA) was notified of the remaining sample results (all negatives) for samples collected from Taylor Farm Colorado Inc. (Colorado Springs, CO).

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)**:**

☐ ICS 203	☐ Map/Chart	Other Attachments:
☐ ICS 204	☐ Weather Forecast/Tides/Currents	☐ _____
☐ ICS 205		☐ _____
☐ ICS 206		☐ _____
☐ ICS 208		☐ _____

7. Prepared by: Laura Kennedy Position/Title: Planning Chief Signature: *Laura Kennedy*

INCIDENT OBJECTIVES (ICS 202), Adapted for FDA

1. Incident Name: *E. coli* O157-H7/Onion (suspect)/Oct 2024	**2. Operational Period #3:** Date From: 11/8/2024 Date To: 11/14/2024 Time From: 1300EDT Time To:1300EDT
8. Approved by Incident Commander: Name: Mardea Caulcrick-Grimes Signature: *Mardea Caulcrick Grimes*	
ICS 202 | **IAP Page _____**	Date/Time: 11/8/2024 1706 EST

Updated by FDA 2/2011

Human Foods Program Signal Detection and Bioinformatics Branch
WGS Analysis Report

This document may contain non-public information, including information for which public disclosure is prohibited by law, such as confidential commercial information (CCI). The information in this report must not be further disclosed without written permission by the FDA.

Report Title: WGS_Report_(b)(4)_241120_NonPublic

Firm Name: (b)(4)

Pathogen: E. coli

Date Generated: `20 November, 2024`

Sample or Facts IDs:

FDA1200106-S015-008; FDA1200106-S015-002; FDA1200106-S015-004; FDA1200106-S015-006; FDA1200106-S015-003; FDA1200106-S015-001; FDA1200106-S015-005; FDA1200106-S015-007

WGS Summary Table

Isolate	Collection Date	Location	Isolation Source	Match to Clinicals	NCBI Cluster
FDA1200106-S015-001	2024-10-31	USA:WA	environmental swab farm	No Match	PDS000206673.1
FDA1200106-S015-002	2024-10-31	USA:WA	environmental swab farm	No Match	PDS000206673.1
FDA1200106-S015-003	2024-10-31	USA:WA	environmental swab farm	No Match	PDS000206673.1
FDA1200106-S015-004	2024-10-31	USA:WA	environmental swab farm	No Match	PDS000206673.1
FDA1200106-S015-005	2024-10-31	USA:WA	environmental swab farm	No Match	PDS000206673.1
FDA1200106-S015-006	2024-10-31	USA:WA	environmental swab farm	No Match	PDS000206673.1
FDA1200106-S015-007	2024-10-31	USA:WA	environmental swab farm	No Match	PDS000206673.1
FDA1200106-S015-008	2024-10-31	USA:WA	environmental swab farm	No Match	PDS000206673.1

WGS Discussion:

WGS analysis of 8 *E. coli* isolates from FDA sample 1200106 revealed a single strain. The isolates matched each other and nothing else from the NCBI Pathogen Detection database.

Detailed Analysis

clust1 - PDS000206673.1

Based on SNP distance (0 - 1 SNPs; Mean: 0.25), the eight isolates from FDA sample 1200106 match each other and no other isolates from the NCBI Pathogen Detection database.

See below for phylogenetic clusters (if they were generated).

CFSAN SNP Pipeline Version: `v2.2.1`

Bioinformatician: `Robert L.`

References

- Information about the CFSAN SNP Pipeline can be found https://peerj.com/articles/cs-20/.
- Information on the interpretation of SNP distances and those clusters can be found https://www.frontiersin.org/articles/10.3389/fmicb.2018.01482/full.

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clust1 - PDS000206673.1

Human Foods Program Signal Detection and Bioinformatics Branch WGS Analysis Report

This document may contain non-public information, including information for which public disclosure is prohibited by law, such as confidential commercial information (CCI). The information in this report must not be further disclosed without written permission by the FDA.

Report Title: WGS_Report_TaylorFarms_241104_NonPublic

Firm Name: Taylor Farms

Pathogen: E. coli

Date Generated: `04 November, 2024`

Sample or Facts IDs:

FDA1278096-S001-005; FDA1278096-S002-018; FDA1278096-S002-029; FDA1278096-S003-034; FDA1278096-S004-054; FDA1278096-S006-091; FDA1278096-S009-136; FDA1278096-S009-137; FDA1278096-S009-142; FDA1278096-S009-147

WGS Discussion:

WGS analysis of 10 *E. coli* isolates from FDA sample 1278096 (unopened, 1 lb. bags of sliced onions) revealed a single strain. The isolates from FDA1278096 were a match to each other, and did not match any other isolates from the NCBI Pathogen Detection database. The closest NCBI PD isolates are derived from 2021 California cattle feces samples.

Detailed Analysis

clust1

Based on SNP distance (0 SNPs), the 10 *E. coli* isolates from FDA sample 1278096 are a match to each other. These isolates do not match any other isolates from NCBI PD. They are 39 - 42 SNPs from eight CA cattle feces isolates collected in 2021 (PDS000137951.3).

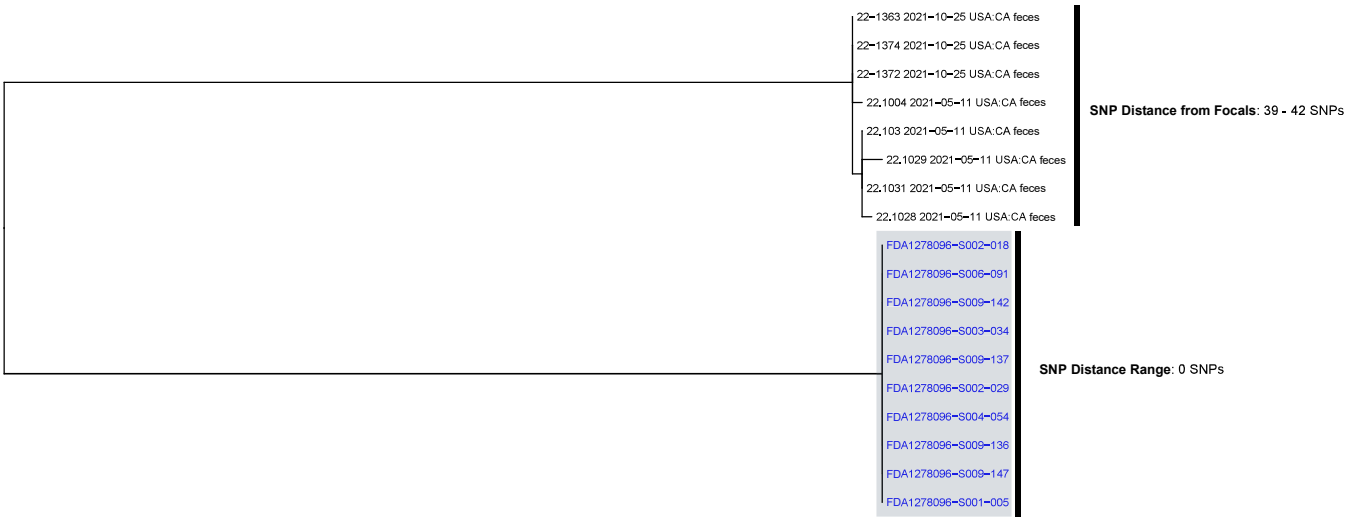
CFSAN SNP Pipeline Version: `v2.2.1`.

Bioinformatician: `Robert L.`

See below for phylogenetic clusters (if they were generated).

References

- Information about the CFSAN SNP Pipeline can be found https://peerj.com/articles/cs-20/.
- Information on the interpretation of SNP distances and those clusters can be found https://www.frontiersin.org/articles/10.3389/fmicb.2018.01482/full.


22-1363 2021-10-25 USA:CA feces
22-1374 2021-10-25 USA:CA feces
22-1372 2021-10-25 USA:CA feces
22.1004 2021-05-11 USA:CA feces
22.103 2021-05-11 USA:CA feces
22.1029 2021-05-11 USA:CA feces
22.1031 2021-05-11 USA:CA feces
22.1028 2021-05-11 USA:CA feces
SNP Distance from Focals: 39 - 42 SNPs
FDA1278096-S002-018
FDA1278096-S006-091
FDA1278096-S009-142
FDA1278096-S003-034
FDA1278096-S009-137
FDA1278096-S002-029
FDA1278096-S004-054
FDA1278096-S009-136
FDA1278096-S009-147
FDA1278096-S001-005
SNP Distance Range: 0 SNPs