



***E. coli* O157:H7/Walnuts/Mar 2024**
Executive Incident Summary
[CARA #1221](#)
Date: 07/11/2024

Authors:

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CORE Response Team 1: Brooke M. Whitney, PhD

EXECUTIVE SUMMARY

Notification

On 03/27/2024, CORE Signals was notified by CDC of a new Shiga Toxin producing *E. coli* (STEC) O157:H7 (2403MLEXH-2) cluster with a signal for walnuts and avocados with 7 cases. As of 4/12/2024, this outbreak included 8 cases in 2 states: CA (4) and WA (4).

Epidemiology Overview & WGS

As of 06/27/2024, a total of 13 cases were reported from 2 states: CA(7) and WA(6). Isolation dates ranged from 02/02/2024 to 04/07/2024. Reported onset dates (n=13) ranged from 02/01/2024 to 04/04/2024. Patients ranged in age from 6–84 years (median: 60); 8/13 (62%) were female. Among 13 people with outcome information, 7 (54%) were hospitalized, and no deaths were reported. All cases were related within 0–3 alleles by cgMLST with allele code, EC1.0 – 9.1.3.28x.

Early in the investigation, a signal for both walnut and avocados emerged. Eventually several patients were reinterviewed who reported walnut exposure in the week prior to illness and no avocado exposure. Among 11 patients interviewed with the focused questionnaire, 11/11 patients reported walnuts and 8/11 reported avocado. Among patients reporting walnut exposure, 10/11 reported getting their walnuts from a bulk, self-serve container in store and 1/11 reported a prepackaged bag of bulk walnuts. Organic halves and pieces of walnuts were reported by 11/11 patients.

CDC closed this investigation on 06/03/2024 after the number of uploads declined and environmental assessments concluded. This investigation will be reported to NORS as a foodborne outbreak, confirmed walnut under NORS ID: 2403MLEXH-2.

Laboratory Sample Overview

The outbreak strain was not isolated from any product or environmental samples collected during this response. FDA collected two product samples of walnuts and 11 environmental samples at the orchards and processing facility. State partners from CA and WA collected six product samples of walnuts. WA state partners tested an open, possibly co-mingled, sample collected from a patient home; the laboratory detected shiga toxin 2 via screening multiple times, but no isolate was recovered. FDA identified two subsamples of soil from (b) (4) that were initially reported Cannot Rule Out (CRO), but ultimately this sample was negative for STEC.

Traceback Abbreviated Summary

FDA initiated traceback at eight points of service (POS), six POSs were single case and two POSs were two case clusters. All cases traced reported purchasing walnuts from bulk bins at grocery/health food stores. Traceback records for 7/8 POSs converged on Gibson Farms, Inc. as the supplier of contaminated walnuts via (b) (4) distributors, (b) (4). For all the POS traced that received product from Gibson Farms, two expiry dates could explain the associated cases: 05/21/2025 and 06/07/2025. Both expiry dates were manufactured with walnuts from (b) (4) sourced the walnuts from multiple orchard locations. Near the end of the outbreak, new epidemiologic information indicated that an additional case purchased walnuts from (b) (4). Recall information indicated that this POS had received recalled walnuts from Gibson Farms via

(b) (4) with the expiry date 05/21/2025. One point of service (b) (4) received walnuts also through (b) (4) but reportedly from a different supplier (b) (4), which in turn received walnuts from (b) (4); however, there was a high degree of uncertainty surrounding the information obtained for this portion of the traceback investigation.

Field Investigations & Findings

FDA Offices of Regulatory Affairs (ORA) Produce Safety Network along with partners from California Department of Public Health and California Department of Food and Agriculture initiated two inspections at Gibson Farms Inc. and (b) (4), associated with this outbreak. For one inspection, at (b) (4), there were no observations noted; however, a FORM FDA 4056 was issued for Gibson Farms Inc with three observations. Additionally, FDA ORA Human and Animal Foods (HAF) divisions initiated four investigations for data collection at Gibson Farms Inc, (b) (4)

Product & Firm Actions

On 04/25/2024, Gibson Farms issued a recall of two lots of organic walnuts with expiry dates of 05/21/2025 and 06/07/2025. This recall was complicated due to customer purchasing through bulk bins, and the main distributor (b) (4), lacking lot-level traceability information.

Communications Overview

On 04/30/2024, public notices were released by both FDA and CDC. FDA outbreak notice is located at <https://www.fda.gov/food/outbreaks-foodborne-illness/outbreak-investigation-e-coli-o157h7-bulk-organic-walnuts-april-2024>, the FDA recall notice is located at <https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/gibson-farms-voluntarily-recalls-organic-light-halves-and-pieces-shelled-walnuts-because-possible>, and the CDC outbreak is located at <https://www.cdc.gov/ecoli/walnuts-04-24/index.html>.

Conclusions

Based on epidemiologic and traceback evidence, the vehicle for this outbreak was confirmed as walnuts. Challenges in this investigation included the time to collect epidemiologic information to narrow the leading hypothesis to a single vehicle and traceback challenges commonly encountered: shelf-stable product with long turn-around times at distribution, retail, and the consumer level, lot codes not tracked at the distributors between incoming shipments and outgoing shipments, co-mingled lots from different orchards, and bulk products with no lot coding available at the consumer level. As of 06/27/2024, a total of 13 cases were reported from 2 states: CA(7) and WA(6).

Acknowledgements

CORE would like to specifically acknowledge state partners in CA and WA on this investigation. FDA HAF divisions are also recognized for their efforts to collect traceback documents and execute the recall.

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INCIDENT OBJECTIVES (ICS 202), Adapted for FDA

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|---|--|
| 1. Incident Name: <i>E. coli</i> O157:H7 Walnuts/Mar 2024 | 2. Operational Period: Date From: 5/30/2024 Date To: 6/13/2024 Time From: 1600 Time To: 1300 |
| 3. Objective(s): <ul style="list-style-type: none"> Coordinate with federal, state, and local communications partners to ensure appropriate messaging is provided related to this investigation. <div style="background-color: #cccccc; padding: 10px; font-size: 2em; font-weight: bold; margin-top: 10px;">(b) (5)</div> | |
| 4. Operational Period Command Emphasis: | |
| <p>General Situational Awareness:</p> <p>Operational Period #1: On 3/27/2024, CORE Signals was notified by CDC of a new Shiga Toxin producing <i>E. coli</i> (STEC) O157:H7 (2403MLEXH-2) cluster with 7 cases. As of 4/16/2024, this outbreak includes 11 cases in 2 states: CA (6) and WA (5). Cases are highly related within 0-3 alleles by cgMLST and 0-4 (average: 2) SNPs in NCBI. Isolation dates range from 2/2/2024-4/5/2024. Ages range from 6-73 years (57% female). Nine cases were hospitalized, there are 2 reports of HUS and 0 deaths. CDC indicates that the reporting lag time for this outbreak is 34 days. As of 4/10/2024, exposure information is available for 7 case-patients: walnuts (6), avocado (6), and peanut butter (4, with 2 freshly ground). On 4/10/2024, CDC stated walnuts and avocados were their leading hypotheses, with walnuts being the item of greater interest. Of the six case-patients reporting walnuts, four reported organic, one reported conventional and one is unknown. All six case-patients report purchasing shelled walnuts (no shells) from a bulk bin, with four reporting halves and two reporting whole walnuts. There are no common stores among cases. Of the six case-patients reporting avocados, four report organic only, one reported non-organic, and one case reported both organic and not organic. Case-patients reported their avocado purchases at the same stores as their walnut purchases. The incident was transferred to CORE Response Team 1 on 4/12/2024. On 4/12/2024, HAF W5 provided CDPH's preliminary traceback for walnuts and avocados for two CA cases. Both points of service included were supplied walnuts by (b) (4). On 4/12/2024, CDC provided shopper card records provided by CA and WA state partners.</p> <p>Operational Period #2: As of 4/23/2024, there are 12 cases in two states: CA (6) and WA (6). On 4/17/2024, a CDC states call was held and consensus was reached to focus on walnuts as the suspect vehicle. On 4/17/2024, HAF W6 shared an additional shopper card record provided by WA DOH for a new WA case with walnut exposure. On 4/17/2024, HAF W5 shared invoices demonstrating incoming walnuts and avocados for (b) (4), a point-of-sale reported by a CA case; shelled walnuts were supplied by (b) (4). On 4/18/2024, HAF W5 shared additional traceback documents and an updated product flow diagram showing three points-of-sale where cases reported purchasing walnuts distributed from various (b) (4) locations. On 4/19/2024, WA DOH collected three samples of walnuts from two case homes. The walnuts collected may not be the same as consumed during exposure period due to turn-over. On 4/19/2024, ORA HAF W6 provided records related to (b) (4) a POS where a case reported purchasing bulk walnuts. All walnuts were distributed by (b) (4); the supplier of organic walnuts was Gibson Farms and the supplier of conventional walnuts was (b) (4). On 4/18/2024, CDPH collected two samples of walnuts from a case home. On 4/19/2024, CDPH collected a sample from a case home. On 4/22/2024, CORE issued eNSpect Assignment ID #242958 to HAF E1 to collect walnuts records and information from (b) (4). On 4/23/2024, CORE issued eNSpect Assignment ID #243071 to HAF W6 for traceback data collection at (b) (4). Information was later received confirming the source of organic walnuts as Gibson Farms.</p> <p>Operational Period #3: As of 4/30/2024, there are 12 cases in two states: CA (6) and WA (6). On 4/23/2024, HAF W6 provided additional traceback records demonstrating Gibson Farms as the supplier of organic walnuts to (b) (4), (b) (4) where two cases reported purchasing walnuts. On 4/23/2024, HAF E1 provided traceback information from (b) (4) stating their (b) (4) of organic walnuts to the stores of interest was Gibson Farms. Analysis of the expiration dates provided showed a single expiration date cannot explain all illnesses. On 4/23/2024, WA DOH reported to FDA and CDC that a sample of walnuts and unwashed jar collected from a case was CRO (cannot rule out) for shiga toxin 2. A separate, closed sample of a different, non-bulk, brand was negative. On 4/24/2024, HAF W6 provided additional information from WA DOH showing the purchase history for (b) (4) (where a single case purchased walnuts) from (b) (4). The organic walnuts supplied by (b) (4) were from (b) (4). On 4/24/2024, HAF E1 provided additional traceback information collected from (b) (4). On 4/24/2024, WA DOH confirmed to FDA that a sample of bulk walnuts collected from a case home was negative for STEC. On 4/24/2024, WA DOH reported to FDA and CDC that a re-interview with the case not associated with Gibson Farms occurred; this case reported they may have additionally purchased bulk walnuts from a different location than originally reported and</p> | |

1. Incident Name: *E. coli* O157:H7
Walnuts/Mar 2024

2. Operational Period: Date From: 5/30/2024 Date To: 6/13/2024
Time From: 1600 Time To: 1300

this purchase was confirmed. The distributor of bulk walnuts for this newly identified location was (b) (4). On 4/24/2024, the vehicle was confirmed as walnuts based on epidemiology and converging traceback. Additionally, an open state sample from a cases home is currently reported as CRO. On 4/24/2024, a firm call was held with Gibson Farms to inform them of the outbreak and discuss next steps; the firm agreed to move forward with product action to protect public health. On 4/25/2024, HAF E1 provided additional traceback information from (b) (4) confirming that the newly identified point-of-sale would have been supplied organic walnuts from Gibson Farms. On 4/25/2024, Gibson Farms provided a draft recall letter intending to recall the two lots identified with expiration dates of 5/21/2025 and 6/7/2025. On 4/26/2024, HAF W6 provided traceforward information from (b) (4) demonstrating where organic walnuts from Gibson Farms were distributed. (b) (4) supplied organic walnuts to (b) (4). On 4/26/2024, Gibson Farms, Inc. initiated a recall (RES 94521) of two lots of organic walnuts: lot 3325-043 and 3341-501 with expiration dates 5/21/2025 and 6/7/2025, respectively. Four customers received the product: (b) (4). On 4/26/2024, HAF E1 provided traceforward information from (b) (4) demonstrating where organic walnuts from Gibson Farms were distributed. Over (b) (4) unique account numbers (POS) received organic walnuts from sourced from Gibson Farms since October 2023. (b) (4) does not track lot code information for this product shipped to their customers. On 4/26/2024, HAF W5 provided additional traceback information collected by CDPH related to a case that shopped at (b) (4). The distribution center supplying organic walnuts to the (b) (4) location is a (b) (4) distribution center identified in the traceback; however, the documentation shows a different supplier for the organic walnut products. On 4/27/2024, HAF W5 provided information from (b) (4), a customer of Gibson Farms who received recalled product. All recalled product is currently under control at (b) (4) or their co-packer. On 4/29/2024, CDC coordinated a multistate call to discuss communication and recalls. On 4/29/2024, CDC coordinated a multistate call to discuss communication and recalls. On 4/30/2024, FDA posted press about the outbreak and recalled walnuts: <https://www.fda.gov/food/outbreaks-foodborne-illness/outbreak-investigation-e-coli-o157h7-bulk-organic-walnuts-april-2024>. On 4/30/2024, CDC posted press about the outbreak: <https://www.cdc.gov/ecoli/walnuts-04-24/index.html>. On 4/30/2024 HAF W5 reported walnuts samples collected by CDPH tested negative for EHEC.

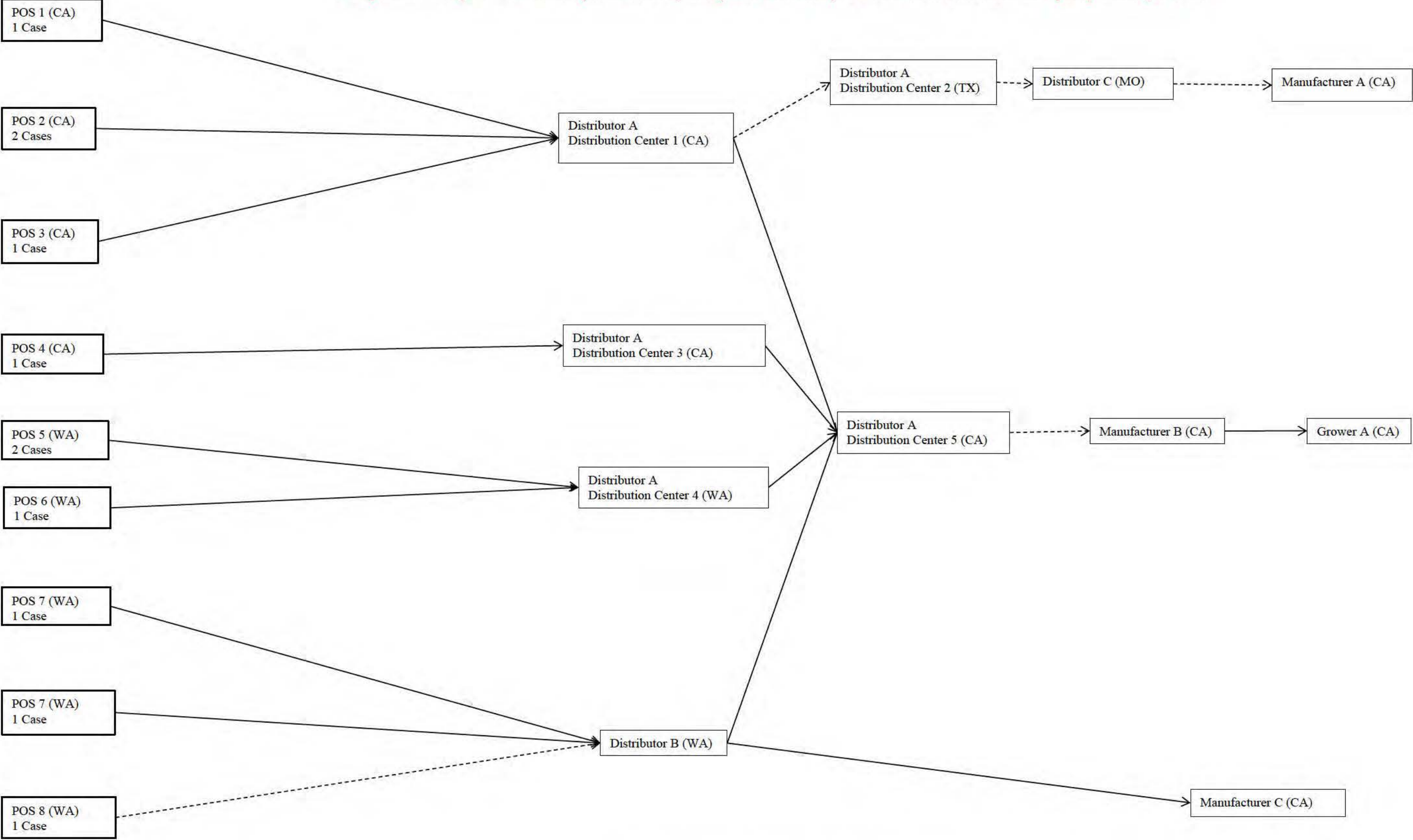
Operational Period #4: As of 4/30/2024, there are 12 cases in two states: CA (6) and WA (6). On 4/30/2024, CORE requested HAF E1 to gather additional information from (b) (4) related to a CA case who purchased walnuts at (b) (4). On 5/1/2024, HAF E1 provided traceback information from (b) (4) regarding the CA single case that purchased walnuts at (b) (4); the walnuts were sourced from (b) (4), (b) (4), (b) (4). CORE requested some follow-up about shipment timing and substitutions at the DC; the firm responded that substitutions were not allowed for private label products. On 5/1/2024, CORE issued an eNSpect Assignment ID # 243322 to HAF W5 for data collection from Gibson Farms (Hollister, CA). Gibson provided some information including farm certificates, equipment and huller cleaning records, and training records for (b) (4) however the requested trackback of recalled lots to the farm level was not provided. On 5/3/2024, CORE issued eNSpect Assignment ID # 243526 to HAF West 2 for traceback data collection from (b) (4).

Operational Period #5: As of 5/14/2024, there are 13 cases in two states: CA (7) and WA (6). On 5/9/2024, an additional case from CA was added to the outbreak cluster. This case did not provide a food history. On 5/10/2024, HAF W5 provided limited additional information from Gibson Farms; (b) (4) was specified as the common grower between the two recalled lots. On 5/10/2024, HAF W2 provided a response from (b) (4); the shipments of interest to (b) (4) via (b) (4) could have originated from (b) (4) different suppliers: (b) (4). Additional details regarding (b) (4) growers and hullers were supplied and none appear to be in common with those associated with Gibson Farms. On 5/14/2024, HAF W5 provided questions from Gibson Farms regarding traceback and epidemiologic information. The questions were shared with CDC for input. On 5/16/2024, CORE issued FACTS assignment #12366031 to ORA Produce Safety Network for a for cause inspection, data collection, and sample collection at (b) (4). On 5/16/2024, CORE issued FACTS assignment #12366017 to ORA Produce Safety Network for data collection, a Produce Safety Rule (PSR) inspection, and sample collection at Gibson Farms, Inc. (Hollister, CA). On 5/20/2024, ORA PSN, CDPH, and CDFA initiated a farm inspection at (b) (4). There was no activity in the orchards and there were no walnuts or hulls in the orchard or in the hulling operation. On 5/20/2024, ORA PSN collected six samples at orchards associated with (b) (4). These included both soil and water samples. On 5/21/2024, HAF W2 provided additional information from (b) (4). The walnuts to (b) (4) were sourced from (b) (4). On 5/22/2024, CORE received notification of Cannot Rule Out (CRO) for one sample collected on Monday, 5/20/2024. Sample # 1261314 is comprised of five subsamples of soil collected at (b) (4).

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| 1. Incident Name: <i>E. coli</i> O157:H7 Walnuts/Mar 2024 | 2. Operational Period: Date From: 5/30/2024 Date To: 6/13/2024 Time From: 1600 Time To: 1300 | | | | | | | | | | | | | | | |
| <p>(b) (4) Two of these subs are CRO. On 5/22/2024, ORA PSN closed out the inspection at (b) (4). A Form FDA 4056 was issued to with no observations. On 5/22/2024, ORA PSN initiate the inspection at Gibson Farms. Information related to the assignment questions was gathered and two samples of walnuts were collected. Sample #1261340 was collected from retained cases of lot 3325-043 and Sample #1261341 was collected from cases of walnuts comingled from different farms, including (b) (4).</p> <p>Operational Period #6: As of 5/30/2024, there are 13 cases in two states: CA (7) and WA (6). On 5/21/2024, ORA PSN collected four samples at two orchards and the hulling operation associated with (b) (4). These included soil, scat and sponges. On 5/21/2024, HAF W2 provided additional information from (b) (4). The walnuts to (b) (4) were sourced from (b) (4). On 5/22/2024, CORE received notification of Cannot Rule Out (CRO) for one sample collected on Monday, 5/20/2024. Sample # 1261314 is comprised of five subsamples of soil collected at (b) (4). Two of these subs are CRO. On 5/22/2024, ORA PSN closed out the inspection at (b) (4). A Form FDA 4056 was issued with no observations. On 5/22/2024, ORA PSN initiated the inspection at Gibson Farms. Information related to the assignment questions was gathered and two samples of walnuts were collected. Sample #1261340 was collected from retained cases of lot 3325-043 and Sample #1261341 was collected from cases of walnuts comingled from different farms, including (b) (4). On 5/24/2024, ORA PSN collected one dead end ultra filtration (DEUF) sample of untreated well water at Gibson Farms (Hollister, CA). On 5/24/2024, ORA PSN closed out their inspection at Gibson Farms (Hollister, CA) and issued a Form FDA 4056 with three observations related to untreated well water use and cleaning and sanitation. On 5/24/2024, HAF E1 (NWE) provided clarifying information from (b) (4) regarding ship dates and expiry dates for supplied by (b) (4) shipped from the (b) (4) to (b) (4). On 5/28/2024, ORA ORS notified CORE that the DEUF sample (#1261342) collected at Gibson Farms and the previously reported CRO of soil collected at (b) (4) (#1261314) are both negative for STEC.</p> | | | | | | | | | | | | | | | | |
| 5. Site Safety Plan Required? Yes <input type="checkbox"/> No <input type="checkbox"/> 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%;"><input type="checkbox"/> ICS 203</td> <td style="width: 33%;"><input type="checkbox"/> Map/Chart</td> <td style="width: 34%;"><u>Other Attachments:</u></td> </tr> <tr> <td><input type="checkbox"/> ICS 204</td> <td><input type="checkbox"/> Weather Forecast/Tides/Currents</td> <td><input type="checkbox"/> _____</td> </tr> <tr> <td><input type="checkbox"/> ICS 205</td> <td></td> <td><input type="checkbox"/> _____</td> </tr> <tr> <td><input type="checkbox"/> ICS 206</td> <td></td> <td><input type="checkbox"/> _____</td> </tr> <tr> <td><input type="checkbox"/> ICS 208</td> <td></td> <td><input type="checkbox"/> _____</td> </tr> </table> | | <input type="checkbox"/> ICS 203 | <input type="checkbox"/> Map/Chart | <u>Other Attachments:</u> | <input type="checkbox"/> ICS 204 | <input type="checkbox"/> Weather Forecast/Tides/Currents | <input type="checkbox"/> _____ | <input type="checkbox"/> ICS 205 | | <input type="checkbox"/> _____ | <input type="checkbox"/> ICS 206 | | <input type="checkbox"/> _____ | <input type="checkbox"/> ICS 208 | | <input type="checkbox"/> _____ |
| <input type="checkbox"/> ICS 203 | <input type="checkbox"/> Map/Chart | <u>Other Attachments:</u> | | | | | | | | | | | | | | |
| <input type="checkbox"/> ICS 204 | <input type="checkbox"/> Weather Forecast/Tides/Currents | <input type="checkbox"/> _____ | | | | | | | | | | | | | | |
| <input type="checkbox"/> ICS 205 | | <input type="checkbox"/> _____ | | | | | | | | | | | | | | |
| <input type="checkbox"/> ICS 206 | | <input type="checkbox"/> _____ | | | | | | | | | | | | | | |
| <input type="checkbox"/> ICS 208 | | <input type="checkbox"/> _____ | | | | | | | | | | | | | | |
| 7. Prepared by: Name: Johnson Nsubuga Position/Title: Planning Chief _____ Signature: Johnson Nsubuga _____ | | | | | | | | | | | | | | | | |
| 8. Approved by Incident Commander: Name: Brooke Whitney Signature: Brooke Whitney _____ | | | | | | | | | | | | | | | | |
| ICS 202 | IAP Page _____ | Date/Time: 5/30/2024 1300 | | | | | | | | | | | | | | |

TRACEBACK FLOW DIAGRAM

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***E. coli* O157:H7/Walnuts/Mar 2024**
Traceback Summary
CARA #1221
Date: 07/11/2024

Acronym Table

| <i>Acronym</i> | <i>Meaning</i> |
|-----------------------|---|
| CDPH | California Department of Public Health |
| DC | Distribution Center |
| HAF | Human and Animal Foods |
| ORA PSN | Office of Regulatory Affairs Produce Safety Network |
| PO | Purchase Order |
| POS | Point of service |
| WA DOH | Washington State Department of Health |

SUMMARY

The FDA initiated traceback at eight points of service (POS), six POSs were single case and two POSs were two case clusters. All cases traced reported purchasing walnuts from bulk bins at grocery/health food stores. Traceback records for 7/8 POSs converged on Gibson Farms, Inc as the supplier of contaminated walnuts via two distributors, (b) (4) [REDACTED]. For all the points of service traced that received product from Gibson Farms, two expiry dates could explain the cases: 5/21/2025 and 6/7/2025. Both expiry dates were manufactured with walnuts from (b) (4) [REDACTED]. Near the end of the outbreak, new epidemiologic information indicated that an additional case purchased walnuts from (b) (4) [REDACTED]. Recall information indicated that this POS had received recalled walnuts from Gibson Farms via (b) (4) [REDACTED] with the expiry date 5/21/2025. One point of service (b) (4) [REDACTED] received walnuts also through (b) (4) [REDACTED] but from a different supplier (b) (4) [REDACTED] which in turn received walnuts from (b) (4) [REDACTED].

TRACEBACK NARRATIVE

Traceback Criteria

Traceback was initiated on a case that reported the purchase of bulk walnuts. Cases were prioritized if there was a specific purchase date, ideally supported by shopper card records, were part of a sub-cluster, or reported a unique POS as deemed by participating state partners.

Traceback Leg 1

Point of Service 1: (b) (4)

| | |
|------------------|---|
| Point of Service | (b) (4) |
| Walnut Endpoint | Gibson Farms (1190 Buena Vista Rd. Hollister, CA) |

Two cases are associated with this POS. Both reported purchasing bulk organic walnuts. Table 1 below summarizes important data for the two cases.

Table 1: Epidemiologic parameters for cases who reported consuming organic walnuts from (b) (4).

| Case Number | Onset Date | Purchase Date |
|-------------|------------|---------------|
| (b) (6) | 3/6/2024 | unknown |
| (b) (6) | 3/22/2024 | 3/12/2024 |

Traceback documents from (b) (4) were collected by California Department of Public Health (CDPH) and sent to CORE via Human and Animal Foods (HAF) West (W) 5. These documents included invoices and a spreadsheet prepared by (b) (4) with the receiving history for walnuts and avocados called "Walnut and Avocado Receiving History." These documents indicated that the walnut supplier for bulk walnuts was (b) (4) (b) (4). According to the invoices, the bulk walnut product was (b) (4) sold in 25lb containers. Table 2 contains a summary of shipments from (b) (4) to (b) (4).

Table 2: Summary of deliveries of (b) (4)

| Delivery Date | Invoice Number | Qty (25 lb box) |
|---------------|----------------|-----------------|
|---------------|----------------|-----------------|

(b) (4)

An assignment was issued on 4/22/2024 to HAF East (E) 1 for traceback information from (b) (4) (eNSpect # 242958). As part of this assignment, specific questions were posed and spreadsheets and purchase orders were collected electronically via email. (b) (4) indicated that walnuts shipped to (b) (4) was shipped from the (b) (4). (b) (4) indicated that (b) (4) were supplied by Gibson Farms. (b) (4) also indicated they record an expiry date on incoming shipments but do not track lot numbers at their distribution centers so there is no way of confirming what lots were shipped to which POS from the DC. Table 3 below provides information supplied by (b) (4) showing shipments of walnuts from Gibson Farms to the (b) (4).

Table 3: Shipments of organic walnut halves and pieces from Gibson Farms to (b) (4)

| Purchase Order | Receive Date | Expiry Date |
|----------------|--------------|-------------|
| (b) (4) | (b) (4) | 6/7/2025 |
| | | 6/6/2025 |
| | | 5/21/2025 |
| | | 8/15/2025 |
| | | 7/30/2025 |

Given the known purchase date of 3/12/2024, this purchase was likely supplied by the shipment from (b) (4). This shipment was, given the shipment dates of product from Gibson Farms to (b) (4), most likely fulfilled with product with the expiry date 5/21/2025. The second case associated with this POS did not have a purchase date, but the reported onset date is 3/6/2024. This onset is before the (b) (4) delivery date, but the two previous shipments to (b) (4). These two shipment dates were likely supplied by the same shipment from Gibson Farms with an expiry date of 5/21/2025.

Conclusions and Limitations:

Though there are two cases associated with this POS, there is only one purchase date, meaning there is some uncertainty regarding (b) (6) since walnuts can kept for long periods of time. Case (b) (6) most likely consumed walnuts from Gibson Farms with an expiry date of 5/21/2025. Based on shipment schedules at (b) (4), these walnuts could have been supplied to (b) (4) shipments.

Another important traceback limitation is the paucity of lot code or expiry information from the (b) (4). Expiry date availability at the POS was estimated based on the timing of shipments to the (b) (4). Further, though (b) (4) did record expiry dates of incoming shipments, it only recorded one expiry date per shipment. If two lots with different expiry dates were received in one shipment, only one lot code was recorded.

Point of Service 2: (b) (4)

| | |
|------------------|---|
| Point of Service | (b) (4) |
| Walnut Endpoint | Gibson Farms (1190 Buena Vista Rd. Hollister, CA) |

One case, with an onset date of 2/1/2024, reported exposure to bulk organic walnuts from (b) (4). CDPH obtained shopper card and

traceback records from the POS. Shopper card records indicated a purchase date of 1/22/2024. According to account records, (b) (4) received organic shelled walnuts for the bulk bins from the (b) (4). On the statements, the product description is (b) (4). Table 4 summarizes the schedule of shipments from (b) (4) obtained from invoice statements collected by CDPH.

Table 4: Organic walnut shipments for (b) (4) from (b) (4)

| Invoice Date | Purchase Order # | Qty/Size |
|--------------|------------------|----------|
| (b) (4) | (b) (4) | 25 lb |
| | | 25 lb |
| | | 25 lb |
| | | 25 lb |

As outlined in the above section for POS 1, (b) (4) from (b) (4) were supplied by Gibson Farms and that (b) (4) does not track lot codes through their distribution centers. Table 3 shows shipments received from Gibson Farms to (b) (4). The most likely product that supplied the shipments to (b) (4) was from (b) (4) purchase order (PO) (b) (4) with an expiry date 6/7/2025.

Conclusions and Limitations:

The case most likely purchased Gibson Farms walnuts with expiry date 6/7/2025. An important traceback limitation is the paucity of lot code or expiry information from the (b) (4). Expiry date availability at the POS was estimated based on the timing of shipments to the (b) (4). Further, though (b) (4) did record expiry dates of incoming shipments, it only recorded one expiry date per shipment. If two lots with different expiry dates were received on one day, only one lot code was recorded.

Point of Service 3: (b) (4)

| | |
|------------------|---|
| Point of Service | (b) (4) |
| Walnut Endpoint | Gibson Farms (1190 Buena Vista Rd. Hollister, CA) |

One case (b) (6) reported consuming organic walnuts purchased in bulk from (b) (4). The onset date for this case was 2/15/2024, no purchase date was available. CDPH collected invoices from December 2023 to March 2024 from the POS. These invoices indicate that the POS receives organic bulk walnuts from (b) (4) with item description (b) (4). The last shipment received before the case's onset date was received on (b) (4) for invoice

(b) (4) 25lb boxes of organic shelled walnut halves and pieces.

An assignment was issued on 4/22/2024 to HAF East (E) 1 for traceback information from (b) (4) (eNSpect # 242958). (b) (4) indicated that walnuts shipped to this POS came from (b) (4) indicated that (b) (4) were supplied by Gibson Farms. (b) (4) also indicated they do not track lot numbers at their distribution centers so there is no way of confirming what lots were shipped to which POS from the DC. Table 5 shows the preceding two shipments to (b) (4) from Gibson Farms before product was shipped to the POS.

Table 5: Shipments from Gibson Farms to (b) (4)

| Purchase Order Number | Receive Date | Expiry date |
|-----------------------|--------------|-------------|
| (b) (4) | | 6/7/2025 |
| | | No Data |

Conclusions and Limitations:

It is more likely that the (b) (4) shipment used product from Gibson Farms that was received by (b) (4) on (b) (4) with an expiry date of 6/7/2025. But the product shipped to the (b) (4) on (b) (4) may have also been used (no expiry date available).

An important limitation in this part of the traceback is that the case associated with this POS lacks a purchase date. Since walnuts have a relatively long shelf life, there is a fair bit of uncertainty with this data. If we assume that the walnuts were purchased in the 6 weeks prior to illness, the most likely product available in the bulk bin for purchase came from Gibson Farms with a 6/7/2025 expiry date. Another important traceback limitation is the paucity of lot code or expiry information from the (b) (4). Expiry date availability at the POS was estimated based on the timing of shipments to the (b) (4). Further, though (b) (4) did record expiry dates of incoming shipments, it only recorded one expiry date per shipment. If two lots with different expiry dates were received in one shipment, only one lot code was recorded.

Point of Service 4: (b) (4)

| | |
|-------------------------|---|
| <i>Point of Service</i> | (b) (4) |
| <i>Walnut Endpoint</i> | Gibson Farms (1190 Buena Vista Rd. Hollister, CA) |

Two cases are associated with this point of service, both reported purchasing organic walnuts from a bulk bin at this POS. Table 6 contains relevant details about the two cases; Washington Department of Health (WDOH) collected shopper card records for these two cases.

Table 6: Case information including onset dates and purchase dates for two cases associated with (b) (4)

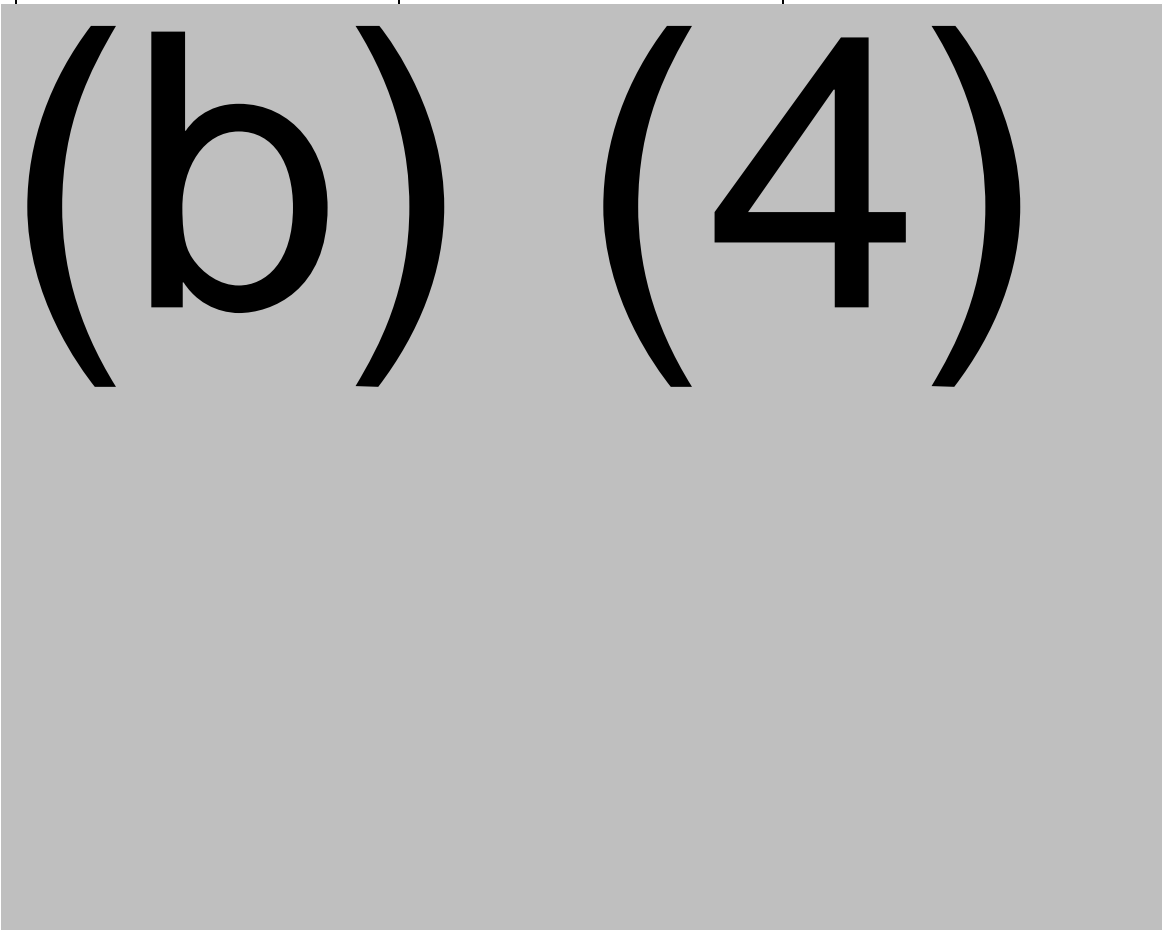
| Case # | Onset Date | Purchase Dates |
|---------|------------|----------------------|
| (b) (6) | 2/18/2024 | 1/19/2024, 1/31/2024 |
| (b) (6) | 4/4/2024 | 2/26/2024, 3/2/2024 |

WA DOH collected information and invoices from this POS which indicated that walnuts in the bulk bins came from (b) (4) with item description (b) (4)

WA DOH also stated that per the firm, during 1/1/2024 inventory there was 90 lbs. of walnuts on hand, indicating that the firm may potentially keep several boxes on hand. Table 7 below shows the deliveries to (b) (4) during the time period of interest. An assignment was issued on 4/22/2024 to HAF East (E) 1 for traceback information from (b) (4) (eNSpect # 242958). (b) (4) indicated in an email that walnuts shipped to this POS came from (b) (4)

Table 7: Shipments of walnuts for bulk distribution from (b) (4)

| Invoice Number | Delivery Date | Quantity |
|----------------|---------------|----------|
|----------------|---------------|----------|



| Invoice Number | Delivery Date | Quantity |
|----------------|---------------|----------|
| (b) (4) | | |

(b) (4) indicated that (b) (4) were supplied from Gibson Farms for the (b) (4) (b) (4) also indicated they do not track lot numbers at their distribution centers so there is no way of confirming what lots were shipped to which POS from the DC. Table 8 summarizes the shipments from Gibson Farms to (b) (4)

Table 8: Shipments of bulk organic walnuts from Gibson Farms to (b) (4)

| Purchase Order Number | Receive Date | Expiry Date |
|-----------------------|--------------|-----------------------|
| (b) (4) | | no exp date available |
| | | 6/7/2025 |
| | | 8/1/2025 |
| | | 5/8/2025 |

Conclusions and Limitations:

For case (b) (6) purchase date 1/19/2024 would have been supplied with Gibson Farms product that shipped to the (b) (4) on (b) (4) and no expiry date is available. The 1/31/2024 purchase could have been this same product or that delivered to the (b) (4) on (b) (4) with an expiry date of 6/7/2025. For (b) (6) purchase date 2/26/2024 could have been Gibson Farms product with a 6/7/2025 or 8/1/2025 expiry date. Finally, the 3/2/2024 purchase for this case was likely product with an expiry date of 8/1/2025 or 5/8/2025. The only potential overlap in product between these two cases is the 6/7/2025 expiry date, therefore this is the most likely product to have been contaminated for this POS.

Traceback limitations for this POS include that the (b) (4)) at times keeps several boxes on hand, which makes estimating usage patterns less precise. Further, both cases associated with this POS had multiple purchases.

Another important traceback limitation is the paucity of lot code or expiry information from the (b) (4). Expiry date availability at the POS was estimated based on the timing of shipments to the (b) (4). Further, though (b) (4) did record expiry dates of incoming shipments, it only recorded one expiry date per shipment. If two lots with different expiry dates were received in one shipment, only one lot code was recorded. Additionally, expiry dates were not available for all shipments.

Point of Service 5: (b) (4)

| Point of Service | (b) (4) |
|------------------|---------|
| | |

| | |
|-----------------|---|
| Walnut Endpoint | Gibson Farms (1190 Buena Vista Rd. Hollister, CA) |
|-----------------|---|

One case reported purchasing bulk organic walnuts from this POS, with an onset date of 3/6/2024. WA DOH obtained purchase records from the POS indicating that the case purchased walnuts on 2/26/2024. Traceback records obtained by WA DOH included invoices indicated that the shelled organic walnuts sold in bulk bins were supplied by (b) (4) and the item description is (b) (4). An assignment was issued on 4/22/2024 to HAF East (E) 1 for traceback information from (b) (4) (eNSpect # 242958). As part of this assignment, (b) (4) provided information, via email, that product to this POS was shipped from the (b) (4). Table 9 outlines walnut the deliveries to this POS from (b) (4) for the timeframe of interest based on stock rotation information from the POS.

Table 9: Shipments of shelled organic walnuts from (b) (4)

| Invoice Date | Invoice number | Qty |
|--------------|----------------|-----|
| (b) (4) | | |

These walnuts were supplied to (b) (4) by Gibson Farms; Table 8 outlines the schedule of shipments.

Conclusions and Limitations:

Given the timing of shipments to the POS and the DC, the product sent to the store (b) (4) likely had an expiry date of 6/7/2025 and the product sent to the store (b) (4) had an expiry date of either 6/7/2024 or 8/1/2024.

An important traceback limitation is the paucity of lot code or expiry information from the (b) (4). Expiry date availability at the POS was estimated based on the timing of shipments to the (b) (4). Further, though (b) (4) did record expiry dates of incoming shipments, it only recorded one expiry date per shipment. If two lots with different expiry dates were received in one shipment, only one lot code was recorded.

Traceback Leg 2

Point of Service 6: (b) (4)

| | |
|------------------|--|
| Point of Service | (b) (4) |
| Walnut Endpoints | Gibson Farms (1190 Buena Vista Rd. Hollister, CA) (b) (4) |

Case (b) (6) with an onset date of 2/6/2024, reported purchasing bulk walnuts from this POS. WA DOH collected shopper card records and invoices which indicated the case purchased walnut halves and pieces on 1/31/2024. The case reported purchasing organic walnuts but shopper card records did not indicate organic or conventional walnuts so both were traced. According to invoices from the POS, both conventional and organic bulk walnuts were supplied by (b) (4) (b) (4) (b) (4)). Table 10 summarizes the shipments from (b) (4) (b) (4).

Table 10: Bulk walnut products from (b) (4) (b) (4).

| Delivery Date | Product Description | Invoice # | Qty |
|-----------------|-------------------------|-----------------|------|
| (b) (4) (b) (4) | Walnuts organic Hlvs | (b) (4) (b) (4) | 251b |
| | Walnuts organic Hlvs | | 251b |
| | Walnuts halves & pieces | | 251b |

An assignment was issued to HAF W6 for records and information from (b) (4) (b) (4) on 4/24/2024. (b) (4) (b) (4) stated that conventional walnut halves and pieces were supplied by (b) (4) (b) (4) indicated walnuts that would have supplied the shipment to (b) (4) (b) (4) (b) (4) were from a shipment to (b) (4) (b) (4) and provided a copy of the invoice ((b) (4) (b) (4)). For organic walnut halves and pieces, (b) (4) (b) (4) stated that Gibson Farms supplied this product. The walnuts that supplied this POS were received by (b) (4) (b) (4). An invoice was provided for this shipment ((b) (4) (b) (4)) for (b) (4) (b) (4) lbs of (b) (4) (b) (4) (b) (4) with lot numbers 3321, 3325, and 2311-326. Receiving records from this shipment indicated an expiry date of 5/21/2025.

Conclusions and Limitations:

A limitation for this case is that the case reporting of organic walnuts conflicted with shopper card records indicating conventional walnuts. Given that all other cases reported organic walnuts and that Gibson Farms was the supplier for (b) (4) (b) (4) investigators considered the most likely source for this case to be product from Gibson Farms. (b) (4) (b) (4) did not record lot codes from the DC to the POS, but only one shipment was on hand during the time period of interest.

Point of Service 7: (b) (4) (b) (4)

| | |
|-------------------------|---|
| <i>Point of Service</i> | (b) (4) (b) (4) |
| <i>Walnut Endpoints</i> | Gibson Farms (1190 Buena Vista Rd. Hollister, CA) |

Case (b) (6) (b) (4), with an onset date of 4/2/2024, reported purchasing bulk organic walnuts from this POS. WA DOH collected shopper card records and invoices

from the POS. Shopper cards records demonstrated purchased of walnuts on 1/6/2024 and 1/21/2021. Invoices indicated this POS received product from (b) (4). Table 11 provides a summary of shipments information from the invoices collected by WA DOH.

Table 11: Summary of shipments from (b) (4)

| Invoice Date | Invoice # | Qty/sz |
|--------------|-----------|--------|
| (b) (4) | | 25lb |
| (b) (4) | | 25lb |

An assignment was issued to HAF W6 for records and information from (b) (4) on 4/24/2024. For organic walnut halves and pieces, (b) (4) stated that Gibson Farms supplied this product. The walnuts that supplied this POS were received by (b) (4). An invoice was provided for this shipment (b) (4) with lot numbers 3321, 3325, and 2311-326. Receiving records from this shipment indicated an expiry date of 5/21/2025.

Conclusions and Limitations:

This case purchased organic walnuts supplied by Gibson Farms with lot numbers 3321, 3325, or 2311-326. (b) (4) did not record lot codes from the DC to the POS, but only one shipment was on hand during the time period of interest.

Point of Service 8: (b) (4)

| | |
|-------------------------|---|
| <i>Point of Service</i> | (b) (4) |
| Walnut Endpoint | Gibson Farms (1190 Buena Vista Rd. Hollister, CA) |

One case (b) (6), with an onset date of 2/13/2024, reported purchasing bulk organic walnuts multiple times from (b) (4) during the exposure period. Case information was provided late in the investigation as the case did not reply initially to WA DOH outreach. No records were requested. As a result of the investigation at the two other (b) (4) POSs and the subsequent recall by Gibson Farms, it was known that this POS received recalled product from Gibson Farms that was sold as bulk organic walnut halves and pieces.

Conclusions and Limitations:

This case likely purchased organic walnuts supplied by Gibson Farms with lot numbers 3321, 3325, or 2311-326. (b) (4) did not record lot codes from the DC to the POS, but only one shipment was on hand during the time period of interest.

Overall Conclusions Across Legs 1 and 2

Looking across all POS that received product from Gibson Farms, all cases can be explained by exposure to two lots: 3341-501 (expiry date 6/7/2025) and 3325-043 (expiry date 5/21/2025).

Gibson Farms Suppliers

An assignment was issued to HAF W5 on 5/1/2024 for traceback information from Gibson Farms (FEI: 3002281309; 1190 Buena Vista Rd. Hollister, CA). Lot code or expiry date information was available inconsistently from DCs. Lot code, expiry date and grower information was requested for shipments during the time period of interest for all traceback legs associated with Gibson Farms. An assignment for an inspection was also issued to (b) (4)

(b) (4). As part of the inspection, Office of Regulatory Affairs Produce Safety Network (ORA PSN) collected firm information indicating businesses run by (b) (4)

Table 12 below, summarizes information provided by Gibson Farms via email to HAF W5 ERC on 5/10/2024 and information from (b) (4) provided during the inspection.

During the recall process, Gibson Farms provided shipping information which stated that all shipments from Gibson Farms to (b) (4) were sent to (b) (4). Shipments were specifically packaged and labeled for individual DCs such as (b) (4) but that shipping beyond (b) (4) was the responsibility of (b) (4)

Table 12: Summary of shipments from Gibson Farms to DCs during the timeframe of interest.

| Customer address | P.O. # | Delivery Date | Expiry Date/ Lot | Grower Name | Grower Address | Orchard (s) |
|------------------|--------|---------------|------------------|--------------|---------------------------------------|-------------|
| (b) (4) | | | 6/7/2025 | (b) (4) | (b) (4) | (b) (4) |
| | | | 3341-501 | | | |
| | | | 3340-328 | | | |
| | | | 6/6/2025 | | | |
| | | | unknown | | | |
| | | | | | | |
| | | | | | | |
| | | | 8/1/2025 | | | |
| | | | 4032-506 | | | |
| | | | 5/8/2025 | | | |
| | | | 3312-172 | Gibson Farms | 1190 Buena Vista Rd. Hollister, CA | (b) (4) |
| | | | 8/1/2025 | (b) (4) | (b) (4) | (b) (4) |
| | | | 4032-506 | | | |
| | | | 8/1/2025 | | | |
| | | | 4032-506: | | | |
| | | | 6/7/2025 | | | |
| | | | 3341-501 | | | |
| | | | 5/21/2025 | | | |
| | | | 3325-043 | | | |
| | | | 6/6/2025 | | | |
| | | | 3340-328 | | | |
| | | | 6/7/2025 | | | |
| | | | 3341-501 | | | |
| | | | 3311-367 | | | |
| | | | | | | |
| | | | 5/8/2025 | Gibson Farms | 1190 Buena Vista Rd. Hollister, CA | (b) (4) |
| | | | 3312-172 | | | |
| | | | 5/17/2025 | (b) (4) | (b) (4) | (b) (4) |
| | | | 3321-194 | | | |
| | | | 5/21/2025 | | | |
| | | | 3325-043 | | | |

Conclusions and Limitations:

In looking specifically across the two lots of interest 3341-501 (expiry date 6/7/2025) and 3325-043 (expiry date 5/21/2025), these two lots have a common grower and huller, (b) (4), but do not share any orchards in common. Harvest dates were collected but hulling dates were not collected. Information collected from ORA PSN during the inspection at (b) (4) indicated that product was hulled on (b) (4). Harvest dates are as follows for (b) (4):

Table 13: Harvest dates for (b) (4).

| |
|---------|
| (b) (4) |
|---------|

Traceback Leg 3

Point of Service 9: (b) (4)

| | |
|------------------|---------|
| Point of Service | (b) (4) |
| Walnuts Endpoint | (b) (4) |

A single case ((b) (6)) reported consuming walnuts purchased from the bulk bin from (b) (4). The purchase date was reported to be between 2/1/2024 and 3/1/2024 and the onset date was 3/28/2024. CDPH collected traceback information from (b) (4) for bulk walnuts. This information included a spreadsheet called (b) (4) from (b) (4), provided to the FDA via CDPH. This document indicated that bulk organic walnut halves and pieces, indicated in the spreadsheet as (b) (4) in 25lb packages were supplied by (b) (4) and (b) (4) received this product on (b) (4).

An assignment was issued on 4/22/2024 to HAF East (E) 1 for traceback information from (b) (4) (eNSpect # 242958). Under this assignment an additional shipment from (b) (4) on (b) (4) was identified as having supplied (b) (4) product during the time period of interest. According to information provided to the FDA by (b) (4) in an email to FDA HAF E1 ERC on 4/30/2024 and subsequently provided to CORE, this product was shipped from the (b) (4). According to the same communication, all these shipments were supplied by (b) (4). Further communication with (b) (4) provided by email on 5/17/2024 indicated that all three shipments of interest were

of product shipped from (b) (4). This same communication indicated that all three shipments of interest came from a single shipment of product from (b) (4), in purchase order (PO) (b) (4).

An assignment was issued to HAF West (W) 2 for traceback information from (b) (4) on 5/3/2024 (eNSpect # 243526). On 5/31/2024, HAF W2 received an email from the firm indicating that for (b) (4) PO (b) (4), the supplier of walnuts was (b) (4). The product was received by (b) (4) (b) (4), the product expiry date was 8/15/2024 and associated lot codes are (b) (4); the firm also indicated this product was (b) (4).

Conclusions and Limitations:

Limitations to the traceback are that the purchase of bulk walnuts was not documented and no specific purchase date was reported. The case simply reported purchasing bulk walnuts from (b) (4) in February 2024. This case was chosen for traceback despite lacking specific purchase information because the exposure indicated a (b) (4) (b) (4) that received product from a distribution center which had received Gibson Farms product. FDA inquired of (b) (4) about the possibility that Gibson Farms product may have been supplied either in error or as a substitution. (b) (4) indicated that the product for (b) (4) was a (b) (4) product and per company policy, cannot be substituted.

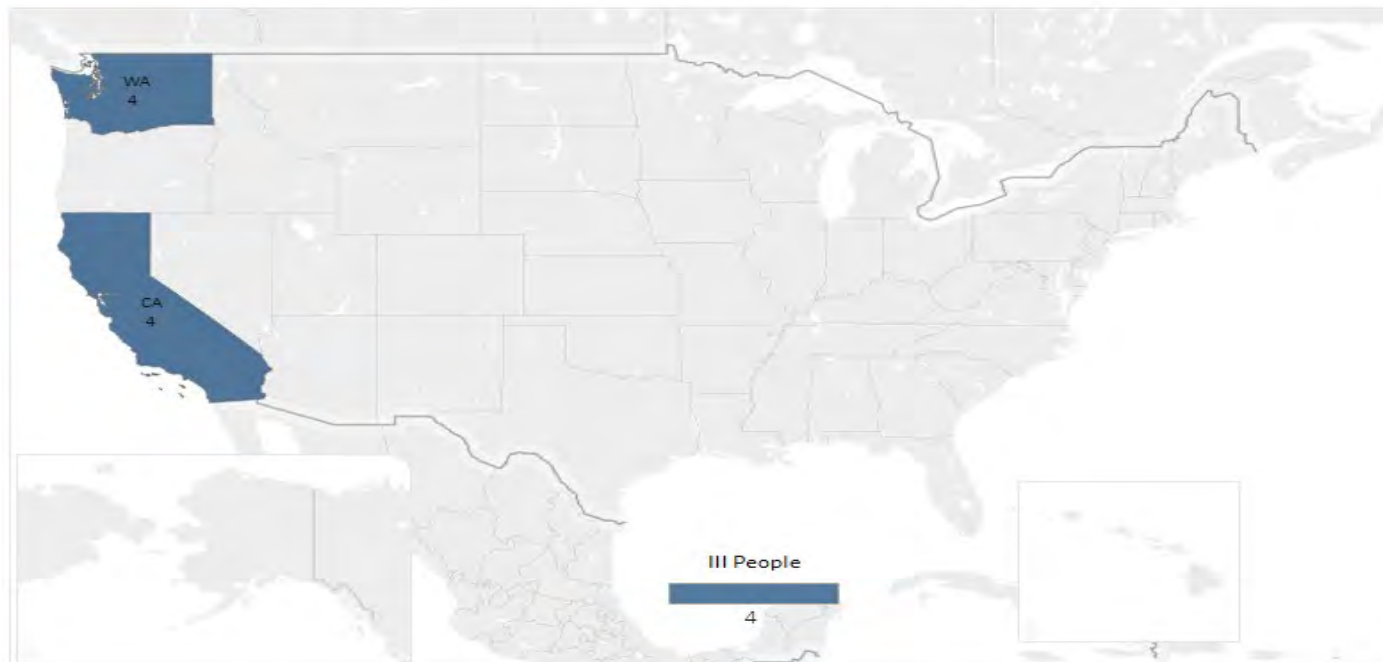
INCIDENT BRIEFING (ICS 201), Adapted for FDA

| | | |
|--|-------------------------------|---|
| 1. Incident Name: <u>E. coli O157:H7 (2403MLEXH-2)/Walnuts and Avocado (suspect)/Mar 2024</u> | 2. CORE Incident Number: 1221 | 3. Date/Time Initiated: Date: 4/12/2024 Time: 12:10 PM |
|--|-------------------------------|---|

4. Map/Sketch

Date: 4/11/2024

E. coli O157:H7 (2403MLEXH-2)/Walnuts and Avocado (suspect)/Mar 2024



https://www.ncbi.nlm.nih.gov/pathogens/tree#Escherichia_coli_Shigella/PDG000000004.4408/PDS000173794.26?key=XBLJ_7mdfOkrKUuFSkkTcC-RRiUw0JKpqtfavrvz4Lmi9uy2jPY

6. Prepared by: Name: Tracy Hawkins

Position/Title: Signals Team Member

Signature:

ICS 201, Page 1

Date/Time: 4/12/2024 12:10 PM EDT

| | | |
|--|-------------------------------|--|
| 1. Incident Name: <u>E. coli O157:H7 (2403MLEXH-2)/Walnuts and Avocado</u> <u>(suspect)/Mar 2024</u> | 2. CORE Incident Number: 1221 | 3. Date/Time Initiated: Date: 4/12/2024 Time: 12:10 PM |
|--|-------------------------------|--|

5. Situation Summary and Health and Safety Briefing

Background Summary:

On 03/27/2024, CORE Signals was notified by CDC of a new Shiga Toxin producing E. coli (STEC) O157:H7 (2403MLEXH-2) cluster with 7 cases. As of 4/12/2024, this outbreak includes 8 cases in 2 states: CA (4) and WA (4). Cases are highly related within 0-2 alleles by cgMLST and 0-4 (average: 2) SNPs in NCBI. Isolation dates range from 2/2/2024-3/9/2024. Ages range from 6-73 years (median: 47), and 5/8 (63%) are female. 4/6 (67%) are hospitalized, there are 2 reports of HUS and 0 deaths. CDC indicates that the reporting lag time for this outbreak is 34 days.

WA alerted CDC they do have two pending STEC cases that have similarities with this cluster. One case has a symptom onset date of 4/2/2024 and is a vegetarian who shops at (b) (4) (b) (4) who purchased walnuts. Their WGS is expected to be available Monday 4/15/2024. Their focused questionnaire is pending but they did share their (b) (4) membership and WA plans to request their purchase history. The other pending case had a symptom onset of 4/4/2024. This case shops at (b) (4), is mostly vegan, buys mostly organic and purchased walnuts. Culture is pending and WA requested this isolate to be prioritized for WGS once confirmed. WA asked the county to obtain (b) (4) purchase history for this case-patient.

This cluster is related via WGS to some historical clusters including: 2303MLEXH-1, (unknown vehicle, CARA 1148) and 1912VTEXH-1 (iceberg lettuce identified from Subway, CARA 939), and both are within 12 alleles and 40 SNPs of this cluster. The NCBI tree is quite large and there are bison/beef, manure samples, and CA environmental isolates in the broader sequencing tree. Outside the 40 SNPs, although within the same genetic SNP tree are clinical isolates from a recent local outbreak associated with the (b) (4). Guacamole was reported in the media as a possible outbreak source. County investigators did not determine how the guacamole could have been contaminated. LOS-DO has reached out to WA for information on that investigation.

Early in the investigation, a signal for healthy eaters was observed. Exposure information was available for 6/7 and patients were reporting avocado (5), kale (3), carrots (5), and bean sprouts (2) in their initial interviews but no suspect vehicle was identified. Freshly ground peanut butter was also of interest earlier in the investigation, with 4 cases reporting peanut butter and 2/4 reporting freshly ground peanut butter at the point of service (which was higher than expected according to CDC).

CDC hosted two multistate calls for states to provide updates on their cases and identify next steps. As of 4/10/2024, exposure information is available for 7 case-patients. The following exposures of interest were reported: walnuts (6), avocado (6), and peanut butter (4, with 2 freshly ground). Other reported exposures include: bananas (6), carrots (6), lemon (5), eggs (5), chicken (5), and other nuts (4: cashews, pecans). Grocery stores reported include: (b) (4)

On 4/10/2024, CDC stated walnuts and avocados were their leading hypotheses, with walnuts being the item of greater interest.

Of the 6 case-patients reporting walnuts, 4 report organic, 1 reports conventional and 1 is unknown. All 6 case-patients report purchasing shelled walnuts from a bulk bin, with 4 reporting halves and 2 reporting whole walnuts. There are no common stores among cases. Of the 6 case-patients reporting avocados, 4 report organic only, 1 reports non-organic, and 1 case reports both organic and not organic. Case-patients report their avocado purchases at the same stores as their walnut purchases (so again, no common stores for avocado exposures).

Shopper Card Records:

The WA Department of Health collected shopper card records for two cases, (b) (6) (b) (4) and (b) (6) (b) (4). WA did not share those records, but they did share their analysis comparing items of similarity including walnuts and avocados. CA reached out to the (b) (4) regarding case (b) (6) and was able to obtain shopper card records. The record shows several organic walnut and organic avocado purchases prior to symptom onset. CDC reached out to (b) (4) at the request of the CA Department of Public Health regarding case (b) (6) and the results showed only gas purchases. CDC plans to ask (b) (4) if there may be another card number associated with the same household. Additionally, CA has requested and is waiting for shopper purchase history from the (b) (4) (b) (4) for case (b) (6).

Commodity Summary:

The United States is the world's largest exporter of walnuts and California produces 99% of the nation's commercial English walnuts with almost all production taking place in the Sacramento and San Joaquin Valleys. Walnuts grown in

the US are distributed both domestically and internationally including Japan, Saudi Arabia, Israel, and Spain.

Most avocados available in the domestic market from January to April are supplied from Mexico. Southern CA and FL also supply a small fraction of product during this time as well.

Traceback Activities:

WA provided pictures of the walnuts that were available at the (b) (4) on 4/5/2024. The pictures are of Gibson's and (b) (4) walnuts. The Gibson's box has green writing. WA reached out to (b) (4) regarding organic walnut sourcing but found it unhelpful. They were told (b) (4) likely sources the walnuts from a combination of domestic and international suppliers that could include organic farms, cooperatives, and nut producers from different regions. WA is still looking for someone at (b) (4) who may have more information. (b) (4) distributed bulk walnuts to (b) (4). They also may have distributed shelled walnuts to (b) (4).

WA contacted the (b) (4) on 4/5/2024 regarding the source of their bulk bin walnuts sold in February and March of 2024. (b) (4) stated what was currently available was what would have also been available at the time period of interest. They had conventional walnuts halves and pieces distributed by (b) (4) and sourced from (b) (4) also had organic walnuts halves & pieces distributed by (b) (4) and sourced from Gibson's Farm. (b) (4) stated they reached out to (b) (4) to verify that was the supplier during the timeframe in question but have not heard a response yet. Finally, WA also contacted the (b) (4) (b) (4) store reported by a third case (b) (6) regarding the supplier of their bulk bin walnuts. (b) (4) reported (b) (4) as their supplier and WA is following up for that documentation. Note this 3rd WA case does not have a shopper record linked to it so the exposure is based on the interview report.

The CA Department of Public Health Food and Drug Branch contacted (b) (4) reported by case (b) (6) and the store stated (b) (4) is the supplier of their bulk walnuts. They only have organic, all "whole" (halves) not pieces and all shelled. The store manager is obtaining supplier information but did state the boxes have "green writing" and they have been ordering the same brand for years. CA also reached out to the (b) (4) and were able to collect invoices of walnuts from November 2023-January 2024. Their initial review of the records indicates the store received shelled walnuts from (b) (4) and in-shell walnuts from (b) (4).

At this time, avocado supplier information is only available for two points of service in CA. The CA Department of Public Health Food and Drug Branch reached out to (b) (4) who stated their avocados are all organic and received from (b) (4). CA also reached out to the (b) (4) and was able to obtain store invoices from November 2023 to January 2024. Their initial review of the invoices indicate the (b) (4) avocados were sourced from (b) (4). WA hopes to have source information for avocados soon.

Firm Summary:

(b) (4) is a processor of raw walnuts and was identified as a walnut supplier to (b) (4). This location performs the hulling (removing of the hull surrounding the nut shell), drying, shelling, and packaging of walnuts; it does not grow or harvest walnuts. The peak of the processing generally occurs between (b) (4). Between (b) (4) packing of products occurs although this is considered the "off season". Between (b) (4), limited activities occur at the facility, and this is considered "down time". Based on a 2012 FDA inspectional report, the firm sells its products (b) (4) wholesale, of which (b) (4) are sold in interstate commerce outside of CA and internationally, including (b) (4). All inspections of this firm have been classified as NAI.

Gibson's Farms was identified as a walnut supplier for (b) (4) stores in WA. This grower, harvester, and processor has two locations in Hollister, CA. The location on 7751 Fairview Rd (FEI: 2000047758) grows and harvests walnuts and apricots and processes apricots at this facility. Products are distributed both domestically and internationally. Their local domestic customer is (b) (4) and their foreign customer is (b) (4). Their last two inspections were classified as NAI.

The location on 1190 Buena Vista Rd (FEI: 3002281309) grows, harvests, and processes walnuts and apricots. Their last two inspections were classified as NAI. The firm sells their products domestically and internationally to customers located in (b) (4).

Historical outbreaks and recalls:

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| 1. Incident Name: <u>E. coli O157:H7 (2403MLEXH-2)/Walnuts and Avocado (suspect)/Mar 2024</u> | 2. CORE Incident Number: 1221 | 3. Date/Time Initiated: Date: 4/12/2024 Time: 12:10 PM |
| <p>Salmonella outbreaks have been associated with tree nuts including almond, Brazil nuts, cashew, coconut, hazelnut, pine nut, and pistachio and their processed products such as butters and vegan “cheese”. STEC outbreaks associated with nuts are less common; however, a Canadian outbreak linked to shelled walnuts occurred in 2011 (EON-65688). That outbreak resulted in 13 illnesses in Canada, and one genetic match to a WI case; cases were linked to raw shelled walnuts imported from the United States. The Canadian Food Inspection Agency (CFIA) together with Amira Enterprises, Inc. issued a warning to the public not to consume certain bulk and prepackaged raw shelled walnut products. Additionally, there was an unrelated recall in September 2011 of Johnvince Foods prepacked raw shelled walnuts that may have been contaminated with E. coli O157:H7 imported from the United States into Canada. Preliminary review has not identified common firm names between these two historical incidents in Canada and the current United States outbreak. Based on a public media search, there have been several recalls associated with E. coli and tree nuts including a 2018 recall of macadamia nuts (Mauna Loa Macadamia Nut Corp), and a 2011 outbreak and recall of hazelnuts (Defranco and Sons). That outbreak resulted in 8 cases of E. coli O157:H7 associated with bulk and consumer-packaged in-shell hazelnuts and mixed-nut products containing hazelnuts.</p> <p>Genetic Analysis:</p> <p>A genetic analysis performed by CFSAN’s OAO Bioinformaticians determined that the clinical isolates of cluster 2403MLEXH-2 were within 0-8 SNPs to 3 clinical isolates from MO(2) and MN(1). These clinical isolation dates are in September and October 2023. CDC reached out to these states for exposure information on these cases for possible inclusion into the cluster and MN responded their case did not fit the healthy eater profile. CDC did not include these 3 isolates in the cluster and plans to contact PulseNet International to inquire about isolates that may match this cluster.</p> <p>Rationale for Transfer:</p> <p>This incident is being transferred from CORE Signals to CORE Response Team 1 based on the following rationale:</p> <p>Two FDA-regulated products, avocados and walnuts, have been identified as leading hypotheses by CDC. Walnuts were prioritized as the item of most interest. Considering the long shelf life of walnuts, it is possible that contaminated product is still available for processing and sale.</p> <p>Response coordination is needed for traceback investigation and potential sampling activities to confirm a specific vehicle.</p> <p>Response coordination is also needed to coordinate any potential product actions and public communications.</p> <p>Two FDA-regulated products, avocados and walnuts, have been identified as leading hypotheses by CDC. Walnuts were prioritized as the item of most interest. Considering the long shelf life of walnuts, it is possible that contaminated product is still available for processing and sale.</p> <p>Response coordination is needed for traceback investigation and potential sampling activities to confirm a specific vehicle.</p> <p>Response coordination is also needed to coordinate any potential product actions and public communications.</p> | | |
| Exposure Table | | |

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|---|--------------------------------------|--|
| 1. Incident Name: <u>E. coli O157:H7 (2403MLEXH-2)/Walnuts and Avocado (suspect)/Mar 2024</u> | 2. CORE Incident Number: 1221 | 3. Date/Time Initiated: Date: 4/12/2024 Time: 12:10 PM |
| No Exposure Table Available | | |
| 6. Prepared by: Name: Tracy Hawkins Position/Title: Signals Team Member Signature: | | |
| ICS 201, Page 2 | | Date/Time: 4/12/2024 12:10 PM EDT |
| Updated by FDA 2/2011 | | |

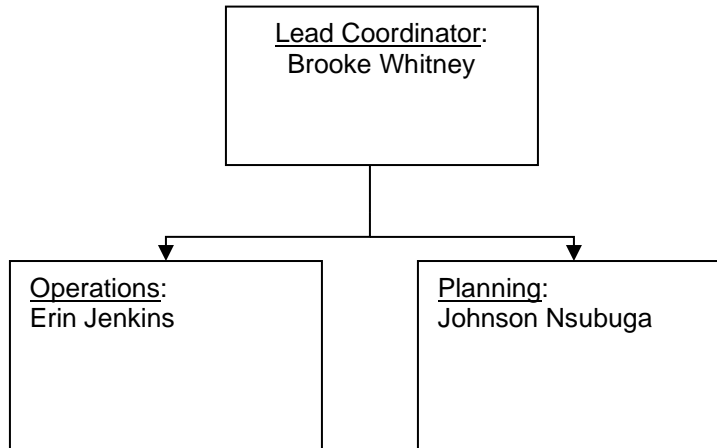
INCIDENT BRIEFING (ICS 201), Adapted for FDA

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| 1. Incident Name: <u>E. coli O157:H7 (2403MLEXH-2)/Walnuts and Avocado</u> <u>(suspect)/Mar 2024</u> | 2. CORE Incident Number: 1221 | 3. Date/Time Initiated: Date: 4/12/2024 Time: 12:10 PM |
| 7. Current and Planned Objectives: <div style="text-align: center; font-size: 100px; opacity: 0.5;">(b) (5)</div> | | |
| 8. Current and Planned Actions, Strategies, and Tactics: | | |
| Time: | Actions: | |
| 6. Prepared by: Name: Tracy Hawkins Position/Title: Signals Team Member Signature: | | |
| ICS 201, Page 3 | | Date/Time: 4/12/2024 12:10 PM EDT |
| Updated by FDA 2/2011 | | |

INCIDENT BRIEFING (ICS 201), Adapted for FDA

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



6. Prepared by: Name: Tracy Hawkins

Position/Title: Signals Team Member

Signature:

ICS 201, Page 4

Date/Time: 4/12/2024 12:10 PM EDT

INCIDENT BRIEFING (ICS 201), Adapted for FDA

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|---|--|--------------------------------------|-----|---|------------------------------------|
| 10. Resource Summary: | | | | | |
| Resource | Resource Identifier | Date/Time Ordered | ETA | Arrived | Notes (location/assignment/status) |
| Herminio Francisco | Office of Human and Animal Foods Operations - West (OHAFO-W) | | | | |
| Steven Galvez | Office of Human and Animal Foods Operations - West (OHAFO-W) | | | | |
| Nicole Yuen | Office of Human and Animal Foods Operations - West (OHAFO-W) | | | | |
| Kelsey Volkman | Office of Human and Animal Foods Operations - West (OHAFO-W) | | | | |
| | Office of Human and Animal Foods Operations (OHAFO) | | | | ORA HAF Senior ERCs |
| | Office of Human and Animal Foods Operations - West | | | | ORA SEA ERC |

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10. Resource Summary:

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|-----------------|---|--|--|--|--------------------------------------|
| | (OHAFO-W) | | | | |
| | Office of Human and Animal Food Operations - West (OHAFO-W) | | | | ORA HAF West5 ERC Group |
| Hsin Bai Yim | Office of Food Safety | | | | |
| Gordon Davidson | Office of Food Safety | | | | |
| Rhoma Johnson | Office of Food Safety | | | | |
| | Office of Food Safety | | | | DPS-ProcessedProduceBranch-Outbreaks |
| | Office of Food Safety | | | | DPS-Fresh Produce Branch-Outbreaks |
| Robert Literman | Office of Analytics and Outreach | | | | |
| Joel Merriman | Office of Compliance | | | | |
| Scott Izyk | Office of Compliance | | | | |
| Crystal McKenna | Office of Compliance | | | | |
| | Office of Compliance | | | | RCRT8 distribution list |
| Susan Lance | Coordinated Outbreak Response and Evaluation Network (CORE) | | | | FDA liaison to CDC |
| Angie Barrall | National Center for Emerging and Zoonotic | | | | |

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|--|--|-------------------------------------|--|--|---|--|
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| 10. Resource Summary: | | | | | | |
| | Infectious Diseases (NCEZID) | | | | | |
| Laura Gieraltowski | National Center for Emerging and Zoonotic Infectious Diseases (NCEZID) | | | | | |
| Susan Lance | National Center for Emerging and Zoonotic Infectious Diseases (NCEZID) | | | | | |
| Karen Neil | National Center for Emerging and Zoonotic Infectious Diseases (NCEZID) | | | | | |
| 6. Prepared by: Name: Tracy Hawkins | | Position/Title: Signals Team Member | | | Signature: | |
| ICS 201, Page 4 | | Date/Time: 4/12/2024 12:10 PM EDT | | | | |

CFSAN Biostatistics and Bioinformatics Staff 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_240327_Ec2403MLEXH-2_240328_NonPublic

Firm Name: 2403MLEXH-2

Pathogen: E. coli

Date Generated: 28 March, 2024

Sample or Facts IDs:

PNUSAE171324; PNUSAE172768; PNUSAE171809; PNUSAE170808; PNUSAE172875; PNUSAE170212; PNUSAE171280

WGS Discussion:

WGS analysis of 7 *E. coli* isolates associated with outbreak 2403MLEXH-2 revealed that they match three additional clinical isolates. Together, these isolates have an inconclusive relationship with 116 isolates including:

- 5 cattle/bison associated isolates
- 1 2023 CA manure isolate
- 110 clinical isolates, including isolates from 2303MLXH-1 and 1912VTEXH-1

Because the only non-clinical isolates in this cluster are beef-related, it suggests a potential beef signal.

Note: A group of West Seattle 2024 outbreak isolates classify into the same larger SNP tree, but they are not in the same subcluster as the isolates mentioned above which suggests that they are more distantly related.

Detailed Analysis

clust1 - PDS000173794.24

Based on SNP distance (0 - 8 SNPs), 2403MLEXH-2 isolates are a match to three clinical isolates from September - October 2023 from Minnesota and Missouri (PNUSAE156679; PNUSAE153311; PNUSAE152685). These isolates have an inconclusive relationship with 116 isolates in the larger cluster (0 - 40 SNPs, Mean SNP Distance: 16 SNPs).

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>.

clust1 - PDS000173794.24

