

Listeria monocytogenes/(b)(5) (suspect)/Aug 2025

Executive Incident Summary

CARA#1334

Date: 12/05/2025

CORE Response Team 3

EXECUTIVE SUMMARY

Initial Notification and Vehicle Identification

On 8/21/2025, CDC notified CORE Signals about a *Listeria monocytogenes* cluster (PulseNet code (b)(5)). Early epidemiological information indicated a signal for (b)(5) including (b)(5). On 9/12/2025, CORE Signals and CDC named (b)(5) as the leading hypothesis for this outbreak based on preliminary epidemiologic data. Review of shopper card data for (b)(5) purchased from two (b)(4) grocery store locations, as well as the use of an online Global Trade Item Number (GTIN) lookup tool, indicated the (b)(5) were likely supplied by (b)(4). At the time of transfer on 9/16/2025, the cluster included 8 cases in states (b)(5).

Epidemiology Overview & Genomic Analysis

On 8/1/2025 PulseNet detected a cluster of 5 *Listeria monocytogenes* isolates and coded (b)(5). This outbreak included 8 cases from states (b)(5). All isolates were related at 0-9 alleles by wgMLST. Specimen collection dates ranged from 8/6/2024 to 8/11/2025. Ages ranged from 48 to 95 years (median: 78 years), and 38% of cases were female. Of 7 patients with outcome information, 7 (100%) were hospitalized. Of 6 patients with survival outcome information, there were 0 (0%) reported deaths.

A total of 8 LI forms were returned and analyzed. Among 5 patients with exposure information, 5 (100%) reported eating (n=4) or likely eating (n=1) (b)(5). Other reported (b)(5) included (b)(5). A common (b)(5) supplier was identified in traceback and FDA conducted swabbing and testing at the facility. (b)(5) were not available during the time of testing, but *L. monocytogenes* positive isolates that did not match the outbreak strain were identified in (b)(5) and in the facility environment. A voluntary recall of (b)(5) was initiated on 10/29/2025, due to results of the FDA inspection. There have been no new cases since 8/20/2025.

CDC closed this investigation on 11/3/2025 as an outbreak with (b)(5) as the suspect vehicle. This Outbreak will be reported to NORS, with ID: (b)(5).

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Field Investigations & Findings

On 9/18/2025, CORE issued eNSpect assignment #268566 to OII OHFI West Division 3 (SEA-DO) for traceback and record collection at (b)(4).

On 9/18/2025, CORE issued eNSpect assignment #268543 to OII OHFI West Division 3 (SEA-DO) for traceback and record collection at (b)(4).

_____ were supplied (b)(5) by (b)(4).

On 9/26/2025, CORE issued eNSpect assignment #269730 to OII Division of Produce Safety for traceback records and information collection, a Produce Safety Rule inspection, and sampling at (b)(4). FDA's investigation included information gathering, an on-site inspection, and sample collection. The inspection concluded on 10/9/2025 with the issuance of FDA Form 4056, Produce Farm Inspection Observations, citing concerns related to equipment and tools as well as inaccurate sanitation recordkeeping.

Laboratory Sample Overview

FDA collected seven product and environmental samples from (b)(4). Of these, three samples (one (b)(5), one environmental swab, and one water sample) tested positive for *Listeria monocytogenes*. One sample (water sample) tested positive for *Listeria innocua* and three samples were negative.

- Sample# (b)(4), consisting of 3 subs of holding (b)(4) water, *Listeria monocytogenes* detected in 2 subs and *L. innocua* detected in 1 sub.
- Sample # (b)(4), consisting of 10 subs of (b)(5), *Listeria monocytogenes* detected in 7 subs and *L. innocua* detected in all 10 subs.
- Sample # (b)(4) consisting of 80 environmental swabs, *Listeria monocytogenes* detected in 3 subs and *L. innocua* detected in 5 subs.
- Sample (b)(4), consisting of 1 sub of produce (b)(4) water reported as *Listeria innocua*.

Whole Genome Sequencing (WGS) results indicated that none of the positive samples matched the outbreak strain or any other isolates in the NCBI database.

Traceback Abbreviated Summary

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FDA initiated a traceback investigation on 9/16/2025 in response to the *Listeria monocytogenes* outbreak with (b)(5) identified as the suspected vehicle. Traceback was conducted for two cases, both of whom had purchased and consumed (b)(5) prior to illness onset. Both cases traced back to a single (b)(5) packer in (b)(5). However, traceback could not conclusively implicate the firm or any specific lot, variety, or growing field. Therefore, the outcome of the traceback investigation is inconclusive. Traceback activities concluded on 10/16/2025.

A complete Traceback summary and diagram is available in CARA.

Traceback limitation

The traceback investigation was limited due to lack of point of service subclusters and limited epidemiological data which included single cases with multiple exposures and several cases deemed lost to follow up. Additionally, although cases reported purchasing product from two different locations of the same retail chain, both stores were serviced by the same distribution center. This reduced the geographic diversity and supply-chain variability needed to fully evaluate potential distribution patterns. As a result, only two cases met inclusion criteria for traceback. One of these cases reported multiple (b)(5) purchases from both points of service during the timeframe of interest. Finally, commingling of different (b)(5) varieties at retail hindered efforts to isolate and implicate a specific variety, further limiting the resolution of the traceback.

Product & Firm Actions

Following FDA inspection at (b)(4) and finding of *Listeria monocytogenes* positive in the environment, on 10/27/2025, (b)(4) conducted an internal root cause analysis and identified pathogen harborage points associated with (b)(4) brushes. The firm reported that their investigation identified that (b)(4). (b)(4) also reported that they received presumptive positive results for *Listeria* species on these brushes.

On 10/29/2025, (b)(4) issued a [voluntary recall](#) of (b)(5)-grown conventional (b)(5). The recall was initiated based on the firm's internal root cause analysis conducted following FDA's inspection and *Listeria monocytogenes* finding. (b)(4) voluntary recall was bracketed based on the firm root cause analysis and extending back to the date the affected brush set was placed into service – i.e., September 14.

Communications Overview

There were no public communications related to this outbreak.

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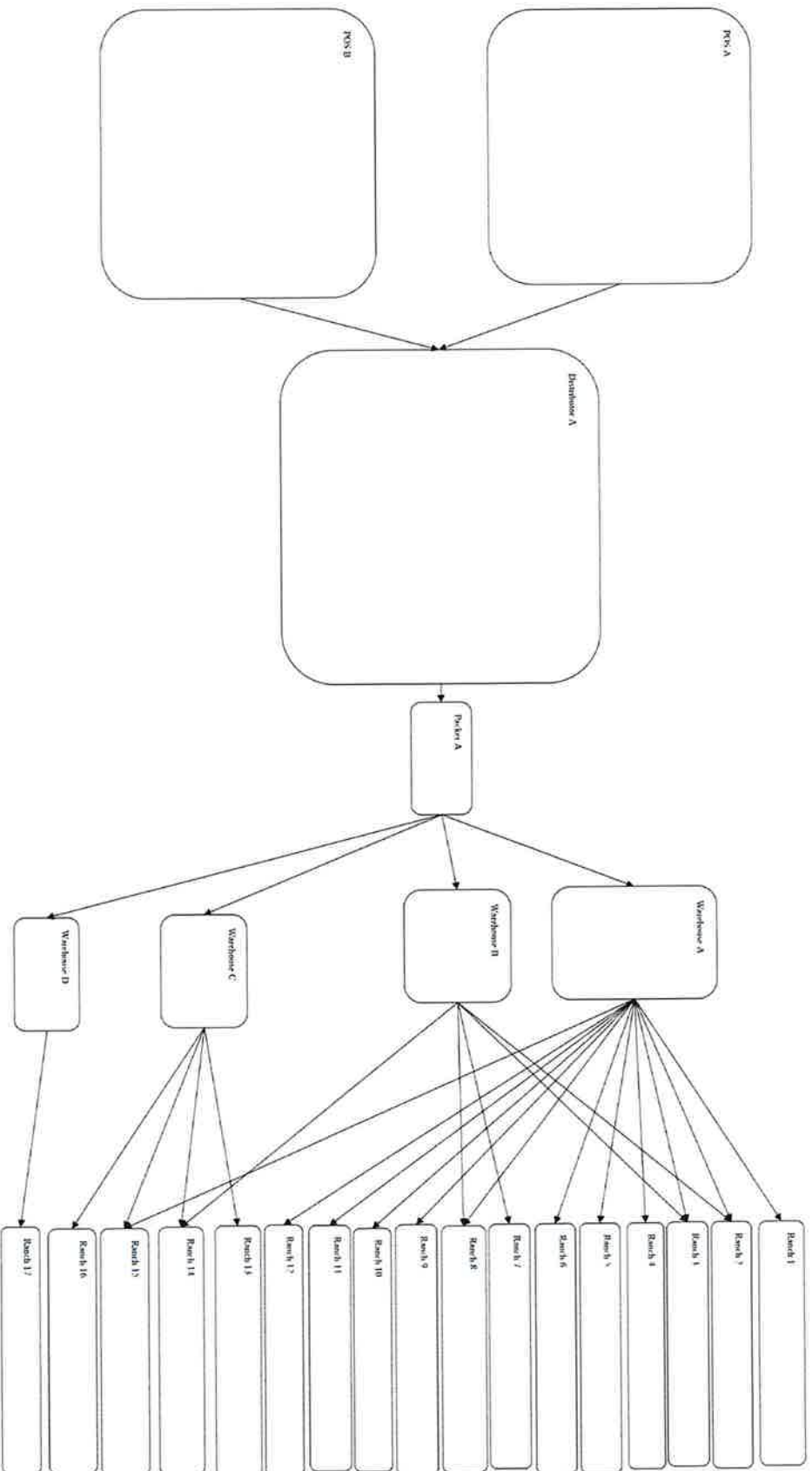
Conclusions

With the lack of sufficient traceback, or inspectional evidence, and limited laboratory evidence, (b)(5) remained the suspect vehicle for this outbreak investigation based on epidemiologic evidence alone. (b)(5) were supplied to the two points of services in our traceback by (b)(4) during the timeframe of interest for the cases. Through the analysis of the limited traceback information, a comprehensive inspection was performed at (b)(4). The inspection at (b)(4) resulted in the issuance of FDA Form 4056, Produce Farm Inspection Observations, citing concerns related to equipment and tools as well as inaccurate sanitation recordkeeping. Additionally, *Listeria monocytogenes* was identified from environmental and non-(b)(5) product samples during the inspection, but these samples did not match the outbreak strain. Other than the inspectional findings at (b)(4), there were no indicators to formulate a hypothesis as to source or route of contamination for this outbreak. At the conclusion of this response, this cluster included 8 cases in states (b)(5).

Acknowledgements

CORE would like to acknowledge the efforts of all our partners engaged in this investigation. Special thanks to OII Division of Produce Safety and state partners for their investigative efforts during the outbreak response.

Listeria monocytogenes – (b)(5) (suspect)
Multi-state Outbreak August 2025
TRACEBACK INVESTIGATION FLOW DIAGRAM
Master Traceback Diagram



Listeria monocytogenes Cluster (b)(5) Associated with (b)(5) (suspect) Consumption
Traceback Investigation Summary
CARA ID #1334

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SUMMARY

Traceback was completed at 2 points-of-service (POS) in response to a Listeria monocytogenes outbreak of 8 culture-confirmed illnesses with the same genetic fingerprint in (b)(5) states that were epidemiologically associated with (b)(5). An additional traceback leg was initiated but was later determined to be a secondary exposure and is not included on the final traceback diagram. As of 10/22/2025, ill persons with the outbreak strain have been reported from (b)(5). Reported onset dates have ranged from 8/5/2024 to 8/8/2025. There is a single case with an isolation date in 2024 (b)(5) and all other isolation dates span 6/23/2025 to 8/11/2025. Thirty eight percent of patients are female. For whom information is available, 6 cases were hospitalized and 0 died. CDC has received exposure information on 5 cases. Among these, 4/5 cases reported eating (b)(5) prior to illness onset. On 9/12/2025, CDC named (b)(5) as the leading hypothesis for this outbreak investigation. (b)(5) consumption ((b)(5) %) was significant based on a case-case analysis and was (b)(5) overall (b)(5) consumption ((b)(5) %) and summer seasonal consumption ((b)(5) %).

The outbreak strain is not genetically related to any other historical outbreak and within NCBI there are no non-clinical isolates highly related to the cluster.

A traceback investigation representing 2 cases was initiated beginning 9/16/2025 by FDA CORE Response Team 3. FDA consulted with CDC who provided updated case line listings with food history information. The "best cases" were identified as those that have reliable purchase information (shopper card records). One case purchased (b)(5) from a (b)(4). The other case purchased (b)(5) at a (b)(4). Although traceback efforts typically prioritize cases with a single exposure during the period of interest, this case was included due to the limited number of suitable candidates, and both sources of (b)(5) were traced initially. The exposure to (b)(5) purchased at (b)(4) was later

determined to be a secondary exposure and is not included in the final traceback diagram. An additional case was considered for traceback; however, reliable information on the date of purchase or exposure could not be confirmed.

One grower of (b)(5) is suspected, but traceback could not conclusively implicate the firm. A flow diagram (Exhibit 1) showing the distribution of product is attached.

Summary of the only traceback leg that was traced, including data analysis discussion, follows:

Traceback Leg 1

Point of Sale 1: (b)(5)

One case ((b)(5)), with known exposure to (b)(5) purchased at (b)(4) was identified. The illness onset date was 7/28/2025 and purchase dates of (b)(5) were 6/2/2025 and 6/20/2025, confirmed by shopper card records. This POS is supplied by the (b)(4). Relevant shipments from the DC to the POS occurred on 5/29/2025, 6/2/2025, 6/18/2025, and 6/19/2025 and are associated with the following purchase order numbers: (b)(4). Turnaround time for (b)(5) at the store is (b)(4).

Point of Sale 2: (b)(4)

A second case ((b)(5)), with known exposure to (b)(5) purchased at (b)(4) was identified. The illness onset date was 7/1/2025 and purchase dates of (b)(5) were 5/28/2025 and 6/11/2025, confirmed by shopper card records (customer purchase ID: (b)(4)). This case also purchased (b)(5) from (b)(4) on 6/21/2025. The exposure to (b)(5) from (b)(4) was determined to be a secondary exposure.

This (b)(4) POS is also supplied (b)(4) by the same (b)(4) distribution center in (b)(4). Relevant shipments from the DC to the POS occurred on 5/23/2025, 5/28/2025, 6/7/2025, and 6/11/2025 and are associated with the following purchase order numbers: (b)(4). Turnaround time for (b)(5) at the store is (b)(4).

Distribution Center: (b)(4))
(b)(4) DC is supplied (b)(5) from (b)(4) . The relevant purchase orders were received at the DC on 5/22/2025, 5/30/2025, and 6/7/2025. The turnaround time for (b)(5) at the DC is .

Grower: (b)(4)

FDA obtained records from (b)(4) These records allowed for traceback of lots of interest to 17 (b)(4) -owned ranches in (b)(5) listed below:

(b)(4)

Traceback Diagram for Listeria Monocytogenes Outbreak. These diagrams contain confidential information intended for FDA use in its law enforcement and/or regulatory activities. They may not be further distributed without the written consent of FDA Office of Emergency Operations. This diagram is updated as new information is received by FDA OEO.

Multiple varieties of (b)(4)

Traceback Limitations:

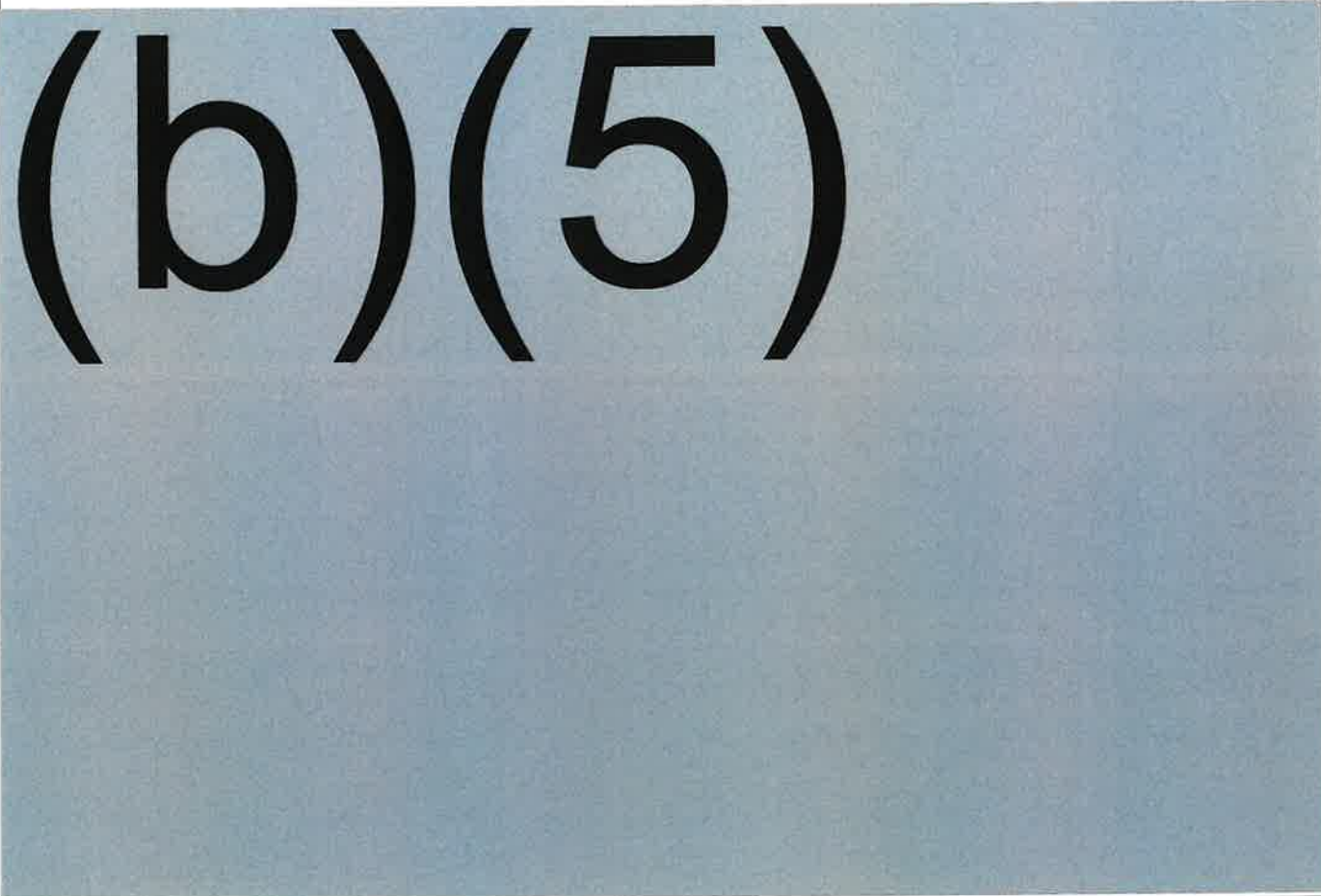
The traceback investigation was limited due to lack of point of service subclusters and limited epidemiological data which included single cases with multiple exposures and several cases deemed lost to follow up. Additionally, although cases reported purchasing product from two different locations of the same retail chain, both stores were serviced by the same distribution center. This reduced the geographic diversity and supply-chain variability needed to fully evaluate potential distribution patterns. As a result, only two cases met inclusion criteria for traceback. One of these cases reported multiple (b)(5) purchases from both points of service during the timeframe of interest. Finally, commingling of different (b)(5) varieties at retail hindered efforts to isolate and implicate a specific variety, further limiting the resolution of the traceback.

Traceback Conclusion:

Traceback was initiated for 3 points of sale where 2 cases purchased (b)(5). Although information was collected from (b)(4), the (b)(5) purchased from (b)(4) was later determined to be a secondary exposure. Both (b)(4) cases were supplied by the same distribution center, which was supplied by (b)(4). Given there was only one leg of traceback, no convergence was observed.

Final flow diagram attached.

INCIDENT BRIEFING (ICS 201), Adapted for FDA

1. Incident Name: Listeria monocytogenes (b)(5) (suspect)/Aug 2025	2. CORE Incident Number: 1334	3. Date/Time Initiated: Date: 9/16/2025 Time: 10:00 AM
4. Map/Sketch		
		
6. Prepared by: Name: Tyann Blessington		Position/Title: Signals Team Member
ICS 201, Page 1		Signature: _____ Date/Time: 9/16/2025 10:00 AM EDT

INCIDENT BRIEFING (ICS 201), Adapted for FDA

1. Incident Name: Listeria monocytogenes (b)(5) (suspect)/Aug 2025	2. CORE Incident Number: 1334	3. Date/Time Initiated: Date: 9/16/2025 Time: 10:00 AM
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5. Situation Summary and Health and Safety Briefing

On 8/21/2025, CORE Signals was notified by CDC about a new *Listeria monocytogenes* cluster (PulseNet code (b)(5)) and based on initial epidemiological information there was a signal for (b)(5), including (b)(5).

As of 9/16/2025, there are 8 cases in (b)(5) states (b)(5). Isolation dates span from 8/6/2024 to 8/11/2025. There is a single case with an isolation date in 2024 (b)(5) and all other illnesses span 6/23/2025 to 8/11/2025. Ages span from 48-95 years (median 78) and 38% are female. There are no pregnancy associated cases. Seven cases have outcome information, and all (7/7) were hospitalized and none (n=6) have died.

Isolates are genetically highly related and span 0-9 SNPs (average 4) by WGS and 0-9 alleles by wgMLST. This cluster is not genetically related to any other historical outbreak or any other non-outbreak isolates. Outside the range of nearby genetic proximity and approximately 100 SNPs away are several non-clinical isolates including (b)(5) and various environmental swabs from (b)(5). HFP Bioinformatics staff hypothesized that this indicated a broad signal for domestic agricultural commodities.

On 9/10/2025, CDC reported that (b)(5) identified a single clinical isolate, from October 2024, matching the outbreak strain. Epidemiological information is being sought.

On 9/9/2025, CDC hosted a multistate call for this investigation. Of the 8 *Listeria* Initiative questionnaires distributed, epidemiological information was collected for 5 cases, and the remaining cases were lost to follow up. All five cases (b)(5) report consuming (b)(5), 4/5 cases (b)(5) report (b)(5), 2/5 cases (b)(5) report (b)(5), and 2/5 cases (b)(5) report (b)(5) prior to illness onset. Shopper records have been collected from (b)(4) for the two (b)(5) cases. Both (b)(4) records indicate purchases of (b)(5) (b)(5) purchase date 5/28/2025, 6/11/2025; (b)(5) purchase date 6/2/2025, 6/20/2025), which appear to be loose. Based on a GTIN lookup tool, these (b)(5) are supplied by (b)(4) (b)(4) shopper records also indicated one (b)(5) case (b)(5) purchased (b)(5) on 6/21/2025 in a (b)(4). Based on (b)(4) item number database this product is sourced from either US or (b)(5). The supplier was not listed. (b)(5) partners are attempting to collect additional information, including shopper card information, for the single (b)(5) case (b)(5) who shopped at (b)(4) and reported purchasing (b)(5).

On 9/12/2025, CDC named (b)(5) as the leading hypothesis for this outbreak investigation. (b)(5) consumption (b)(4)% is significant based on a case-case analysis and is (b)(5) overall (b)(5) consumption (b)(4)% and summer seasonal consumption (b)(4)%. Other commonalities noted in the investigation included (b)(5) (5/5; 2 cases reported (b)(5) variety); however, this exposure was not considered significant in a case-case analysis. Three or less cases reported (b)(5).

(b)(4). Based on the most recent (b)(4) FDA inspection (2016) the firms scope includes (b)(4).

FDA has not collected microbiological samples at this firm. (b)(5) identified a different strain of *L. monocytogenes* on (b)(4) in 2019 (b)(4) in 2018. All samples were collected at retail in (b)(5).

CORE has coordinated several incidents involving *L. monocytogenes* and (b)(5). These include two 2020 sample-initiated retrospective investigations, one with (b)(5) as the suspected vehicles (b)(5) and one with (b)(5) as the confirmed vehicle (transferred to CORE Response in 2023; (b)(5) and an incident of interest in 2014 with (b)(5). In addition to these, there was also a *Salmonella* Enteritidis outbreak in 2020 with (b)(5) as the confirmed vehicle (b)(5).

This incident is being transferred from CORE Signals to CORE Response Team 3 based on the following rationale:

- * An FDA-regulated product, (b)(5), have been identified as the leading hypothesis for this outbreak investigation.
- * CORE Response coordination is needed to collaborate with state partners on traceback activities and with (b)(5).

1. Incident Name: Listeria monocytogenes (b)(5) (suspect)/Aug 2025	2. CORE Incident Number: 1334	3. Date/Time Initiated: Date: 9/16/2025 Time: 10:00 AM
partners on potential inspectional and sampling activities at (b)(4)		
Exposure Table		
No Exposure Table Available		
6. Prepared by: Name: Tyann Blessington	Position/Title: Signals Team Member	Signature:
ICS 201, Page 2	Date/Time: 9/16/2025 10:00 AM EDT	
Updated by FDA 2/2011		

INCIDENT BRIEFING (ICS 201), Adapted for FDA

1. Incident Name: Listeria monocytogenes (b)(5) (suspect)/Aug 2025	2. CORE Incident Number: 1334	3. Date/Time Initiated: Date: 9/16/2025 Time: 10:00 AM
7. Current and Planned Objectives:		

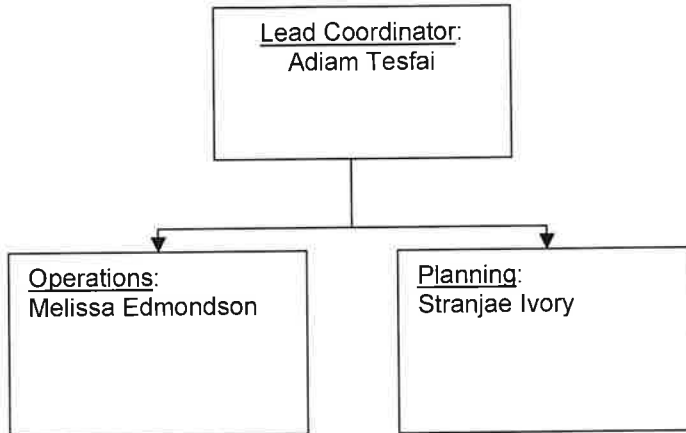
(b)(5)

8. Current and Planned Actions, Strategies, and Tactics:		
Time:	Actions:	
TBD	Tactics Call	
6. Prepared by: Name: Tyann Blessington		Position/Title: Signals Team Member
ICS 201, Page 3		Signature:
		Date/Time: 9/16/2025 10:00 AM EDT
Updated by FDA 2/2011		

INCIDENT BRIEFING (ICS 201), Adapted for FDA

1. Incident Name: Listeria monocytogenes (b)(5) (suspect)/Aug 2025	2. CORE Incident Number: 1334	3. Date/Time Initiated: Date: 9/16/2025 Time: 10:00 AM
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9. Current Organization (fill in additional organization as appropriate):



6. Prepared by: Name: Tyann Blessington	Position/Title: Signals Team Member	Signature:
ICS 201, Page 4	Date/Time: 9/16/2025 10:00 AM EDT	

INCIDENT BRIEFING (ICS 201), Adapted for FDA

1. Incident Name: Listeria monocytogenes (b)(5) (suspect)/Aug 2025		2. CORE Incident Number: 1334		3. Date/Time Initiated: Date: 9/16/2025 Time: 10:00 AM	
10. Resource Summary:					
Resource	Resource Identifier	Date/Time Ordered	ETA	Arrived	Notes (location/assignment/status)
	Office of Human Food Inspectorate				
OCE Email Distro List	Office of Compliance and Enforcement				
Kathy Tormey	Office of Compliance and Enforcement				
Katie Arnold	Office of Compliance and Enforcement				
Annemarie Buchholz	Office of Microbiological Food Safety				
Spencer Carran	Office of Coordinated Outbreak Response * Evaluation & Emergency Preparedness				OA POC-Training
Michael Bazaco	Office of Coordinated Outbreak Response * Evaluation & Emergency Preparedness				OA POC-Lead
Grace Tung	Office of Microbiological Food Safety				

1. Incident Name: Listeria monocytogenes (b)(5) (suspect)/Aug 2025		2. CORE Incident Number: 1334		3. Date/Time Initiated: Date: 9/16/2025 Time: 10:00 AM	
10. Resource Summary:					
	gical Food Safety				
	Office of Microbiological Food Safety				
	Office of Microbiological Food Safety				
Autumn Kraft	Office of Microbiological Food Safety				
	Office of Field Operations and Response				
Arthur Pightling	Office of Surveillance Strategy & Risk Prioritization				
Senior ERCs	Office of Field Operations and Response				
Byron Beerbower	Office of Human Food Inspectorate				
Nicole Clausen	Office of Human Food Inspectorate				
Kelsey Volkman					HFI West 3
Erin Dugan					HFI Central 5
Lindsay Bertling					HFI Central 2
Holly Smith					HFI Central 2
Herminio Francisco					HFI West 1

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10. Resource Summary:					
Steven Galvez					HFI West 2 (N. CA)
Nicole Yuen					HFI West 2 (N. CA)
Rochelle Medford	National Center for Emerging and Zoonotic Infectious Diseases (NCEZID)				
Amanda Conrad	National Center for Emerging and Zoonotic Infectious Diseases (NCEZID)				
6. Prepared by: Name: Tyann Blessington		Position/Title: Signals Team Member		Signature:	
ICS 201, Page 4		Date/Time: 9/16/2025 10:00 AM EDT			

INCIDENT OBJECTIVES (ICS 202), Adapted for FDA

1. Incident Name: <i>Listeria monocytogenes</i> (b)(5) (suspect)/Aug 2025		2. Operational Period #4 Date From: 10/23/2025 Time From: 1300 ET		Date To: 12/01/2025 Time To: 1500 ET
3. Objective(s): (b)(5)				
4. Operational Period Command Emphasis:				

INCIDENT OBJECTIVES (ICS 202), Adapted for FDA

1. Incident Name:

Listeria monocytogenes (b)(5) (suspect)/Aug 2025

2. Operational Period #4

Date From: 10/23/2025
Time From: 1300 ET

Date To: 12/01/2025
Time To: 1500 ET

General Situational Awareness

On 8/21/2025, CORE Signals was notified by CDC about a new *Listeria monocytogenes* cluster and based on initial epidemiological information there was a signal for (b)(5), including (b)(5). As of 9/23/2025, there are 8 cases in (b)(5) states (b)(5). Isolation dates span from 8/6/2024 to 8/11/2025. There is a single case with an isolation date in 2024 (b)(5), and all other illnesses span 6/23/2025 to 8/11/2025. Ages span from 48-95 years (median 78) and 38% are female. There is no pregnancy associated cases. Seven cases were hospitalized with no deaths reported. On 9/10/2025, CDC reported that (b)(5) identified a single clinical isolate, from October 2024, matching the outbreak strain. Epidemiological information is being sought. Isolates are genetically highly related and span 0-9 SNPs (average 4) by WGS and 0-9 alleles by wgMLST. This cluster is not genetically related to any other historical outbreak or any other non-outbreak isolates. Outside the range of nearby genetic proximity and approximately 100 SNPs away are several non-clinical isolates including (b)(5), and various environmental swabs from (b)(5).

Exposure information was collected for five cases and the remaining cases were lost to follow up. 5/5 cases (b)(5) report consuming (b)(5). 4/5 cases (b)(5) report (b)(5). 2/5 cases (b)(5) report (b)(5), and 2/5 cases (b)(5) report (b)(5) prior to illness onset. On 9/12/2025, CDC named (b)(5) as the leading hypothesis for this outbreak investigation. (b)(5) consumption (b)(5) was significant based on a case-case analysis and was (b)(5) overall (b)(5) consumption (b)(5) and summer seasonal consumption (b)(5). Other commonalities noted in the investigation included (b)(5) (5/5 cases) with two cases having reported the (b)(5) variety. However, this exposure was not considered significant in a case-case analysis. Three or less cases reported (b)(5).

Traceback information, shopper records have been collected from (b)(4) for the two (b)(5) cases. Both (b)(4) records indicate purchases of (b)(5) which appear to be loose. Based on a GTIN lookup tool, these (b)(5) are supplied by (b)(4). (b)(4) shopper records also indicated one (b)(5) case purchased (b)(5). The supplier was not listed but based on (b)(4) item number database this product was sourced from either the US or (b)(5). (b)(4) Based on the most recent FDA inspection (2016) the firm's products include (b)(4); however, as of September 2025, (b)(4).

On 9/16/2025, CDC reported that (b)(5) collected invoices from (b)(4) which is where the (b)(5) patient reported purchasing (b)(5). On 9/18/2025, CORE issued eNSpect assignments #268566 and #268543 to OII OHFI West Division 3 (SEA-DO) for traceback and record collection at (b)(4). On 9/19/2025, OII OHFI West Division 3 (SEA-DO) provided CORE with traceability information for eNSpect assignment #268566. (b)(4)

(b)(4)

On 9/19/2025, OII OHFI West

Division 3 (SEA-DO) provided CORE with traceability information for eNSpect assignment #268543. (b)(4)

Operational Period #1

On 9/26/2025, CORE issued eNSpect assignment #269730 to OII Division of Produce Safety for traceback records and information collection, a Produce Safety Rule inspection, and sampling at (b)(4). On 10/2/2025, OII Division of Produce Safety initiated eNSpect assignment #269730 at (b)(4).

Operational Period #2

On 10/2/2025, OII Division of Produce Safety initiated eNSpect assignment #269730 at (b)(4) and collected traceability information records. They also collected environmental (b)(4) and product (b)(4) samples. On 10/3/2025, Investigators collected additional documents including an environmental sampling plan, SSOPs for packing, and Sanitation Schedules. The investigation team collected water and sediment samples (Sample number (b)(4)). Traceability records indicate (b)(4).

On 10/9/2025, the inspection was closed with issuance of an FDA FORM 4056 PRODUCE FARM INSPECTION OBSERVATIONS citing concerns with equipment and tools and inaccurate sanitation recordkeeping.

Traceback records indicates that variety and traceability information is lost after product leaves (b)(4). (b)(4) records don't identify the Variety of the (b)(5) received. Traceback identified 9 ranches of greatest interest owned by (b)(4). These ranches supplied (b)(4). On 10/8/2025, Special

Purpose Tactics call was held to review traceability information and discuss inspectional observations at (b)(4).

On 10/5/2025, Office of Regulatory Testing and Surveillance reported that environmental (b)(4) and product (b)(4) samples are CRO. On 10/6/2025, OII Division of Produce Safety have collected additional water samples (b)(4) from (b)(4) and samples were shipped to SEA-LAB for analysis. On 10/6/2025, Office of Regulatory Testing and Surveillance reported that environmental samples (b)(4) are negative for *Listeria spp.*

On 10/11/2025, Office of Regulatory Testing and Surveillance provided sample analysis update for samples collected from (b)(4). Environmental samples (b)(4) reported negative for LM.

INCIDENT OBJECTIVES (ICS 202), Adapted for FDA

1. Incident Name: <i>Listeria monocytogenes</i> (b)(5) (suspect)/Aug 2025		2. Operational Period #4 Date From: 10/23/2025 Time From: 1300 ET		Date To: 12/01/2025 Time To: 1500 ET	
Sample # (b)(4) (One subsample of 1000mL recirculated produce wash water) reported as <i>Listeria innocua</i> (b)(4) (Two subsamples of 1000mL water from the farm's (b)(4) were reported as <i>Listeria monocytogenes</i> and one <i>Listeria innocua</i>. WGS analysis pending. For Sample (b)(4) (environmental Swabs) and Samples (b)(4) (b)(5) sample) confirmation analysis is pending. On 10/14/2025, Office of Emergency Response for <u>GIS mapping</u> for identified ranches of greatest interest and historical isolates most closely related to the current outbreak. Operational Period #3 On 10/20/2025, Office of Regulatory Testing and Surveillance provided sample analysis update for samples collected from (b)(4). For Sample (b)(4) (environmental swabs) three subsamples reported as <i>Listeria monocytogenes</i> and five subsamples reported as <i>Listeria innocua</i>. The three <i>Listeria monocytogenes</i> subsamples are from direct food contact surface, Zone 1 production environment. On 10/20/2025, Office of Compliance and Enforcement shared all sample results with (b)(4). (b)(4) plan on destroying all (b)(5) voluntary on hold associated with environmental sample #1285105. On 10/20/2025, (b)(4) provided firm corrective actions implemented after 10/02/2025, which was the day environmental and (b)(5) sample were collected. The firm resumed production/packing on 10/6/2025. On 10/22/2025, Division of Surveillance and Data Integration, Bioinformatics Staff provided WGS analysis result of <i>Listeria monocytogenes</i> positive samples (b)(4) (b)(5) Sample # (b)(4) (environmental swabs) and Sample# (b)(4) (water from the farm's (b)(4)). All three samples don't match the outbreak cluster and any other food, environmental, or clinical isolates currently in the database.					
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		c _____	
☐ ICS 205				c _____	
☐ ICS 206				c _____	
☐ ICS 208				c _____	
7. Prepared by: Name: Adiam Tesfai Position/Title: Planning Chief				Signature: <i>Adiam Tesfai</i>	
8. Approved by Incident Commander: Name: Adiam Tesfai				Signature: <i>Adiam Tesfai</i>	
ICS 202		IAP Page _____		Date/Time:	

Human Foods Program Signal Detection and Bioinformatics Branch

WGS Analysis Report

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Report Title: WGS-Report-(b)(4)

Firm Name: (b)(4)

Pathogen: *Listeria monocytogenes*

Date Generated: 22 October, 2025

Sample or Facts IDs:

(b)(4)

WGS Discussion:

Whole Genome Sequence Analysis of *Listeria monocytogenes* Isolates

Sample Overview

This analysis examined 18 *Listeria monocytogenes* isolates from three sample sources:

- 4 isolates from environmental sample (b)(4) subsamples
- 10 isolates from yellow peach sample (b)(4) subsamples
- 4 isolates from holding pond water sample (b)(4) subsamples

Key Findings

Strain Identification

The 18 isolates represent two strains (labelled clust1 and clust2):

- *Clust1* (b)(4) includes all of the isolates from the sample (b)(4) and sample (b)(4) subsamples (blue labels in phylogenetic tree below). Based on a mean SNP distance of 0.43 (range 0-2), these isolates match each other. They do not match other food, environmental, or clinical isolates currently in the database.
 - *Clust2* (b)(4) includes four of the isolates from the sample (b)(4) subsamples. Based on a mean SNP distance of 0 (range 0-0), these isolates match each other. They do not match other food, environmental, or clinical isolates currently in the database.
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CFSAN SNP Pipeline Version: v2.2.1.

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>.
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(b)(4)

(b)(7)(D)

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(b)(7)(C), (b)(7)(D)

— FDA 1281105-0000-000 2025-10-02 USA (b)(4)
— FDA 1281105-0000-000 2025-10-02 USA (b) environmental web springs

FOR 1285 106-5327-321 2025-10-02 USA (b)(4)

SNP range 0.2, mean 0.43