FDA CORE NETWORK | COORDINATED OUTBREAK RESPONSE & EVALUATION

***Listeria monocytogenes* (1702MLGX6-1)/Unknown/May 2018**
EON-366555

Incident Summary
Final Report
February 8, 2019

Authors:
CORE Signals & Surveillance Team: Allison Wellman
CORE Response Team 3: Adiam Tesfai

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Abstract
CORE Signals began evaluating a multistate cluster of *Listeria monocytogenes* illnesses in May 2018 after learning of imported potato samples collected in Mexico by SENASICA matching clinical isolates of *Listeria monocytogenes* (1702MLGX6-1) cluster by Whole Genome Sequence (WGS) analysis. FDA initiated informational traceback based on the WGS information. FDA Office of Regulatory Affairs Division of Human and Animal Food (ORA HAF) 2 West initiated inspection and record collection at the (b)(4) TX) identified as exporter of SENASICA *Listeria monocytogenes* positive potato samples. Additionally, CORE requested record collection from ORA HAF 1W at (b)(4) , WI), ORA HAF 6W at (b)(4) , ID) and from ORA HAF 4W at (b)(4) , CO). The outbreak strain of *Listeria monocytogenes* was not recovered from any consumer product samples collected by states and informational traceback was inconclusive. Due to the lack of positive product samples, additional epidemiological information and traceback convergence, no vehicle was confirmed, and no product manufacturer was implicated during this outbreak response. A total of 39 cases (with 33 hospitalizations including four deaths attributed to listeriosis) in 19 states were associated with this outbreak.

Signals and Surveillance Activities

During 2017 and 2018, CORE collaborated with CDC on the ongoing investigation of *Listeria monocytogenes* cluster 1702MLGX6-1. At the time of transfer on 9/25/18, this cluster of illnesses included cases from 2015 to August 2018. This cluster was previously identified in 2017 and investigated by FDA, CDC, and states with a suspect vehicle of ice cream. The previous investigation was not able to confirm the vehicle and was eventually closed in September of 2017. After the investigation closed, additional illnesses matching the outbreak strain continued to occur. CDC continued to follow-up with new cases using open-ended interviews and processed frozen meals and frozen snack foods emerged as items of interest. In late May 2018, CORE Signals learned of WGS data recently uploaded to NCBI by the Mexican agency SENASICA for a *Listeria monocytogenes* isolate (SENASICA_Li_U95) from a 2017 imported potato sample matching clinical isolates from cluster 1702MLGX6-1. CORE Signals reached out to the FDA Latin America Office/Mexico City Office to request additional information from SENASICA about the potato sample. SENASICA reported that the Lm isolate was from a fresh potato sample collected by Mexican authorities on 7/24/17 and was a product of U.S. origin exported by (b)(4) , TX) to MX. Mexican officials indicated that the sample was collected as part of a contaminant monitoring program for imported vegetables. As of 9/24/18, WGS analysis had identified seven potato isolates from multiple U.S. suppliers that were genetically identical to each other and to 36 clinical isolates (within 0-17 SNPs, median 4 SNPs).
https://www.ncbi.nlm.nih.gov/Structure/tree/#!/tree/Listeria/PDG000000001.988/PDS000003225.47
On 9/24/18, CDC provided an updated epi summary: Cluster 1702MLGX6-1 included 33 listeriosis illnesses from 16 states [AL (4), AR (2), AZ, CO, FL, GA (5), KS, KY, MO, NC, NE, NM, OH, OK (3), PA, and TX (7)] with isolation dates ranging from 10/24/2015 - 8/14/2018. Patients ranged in age from <1-104 years (median 61); 17 (51%) patients are female. Listeria Initiative (LI) data was available for 30 patients. Among those, 26 patients had been hospitalized and there were four reported deaths. Ten illnesses were pregnancy-associated and three resulted in a fetal loss. Two additional cases not included in the case count above were ill in 2011 (GA and MO) but were included in the line list and WGS tree (these were being considered suspect cases). This cluster had been under investigation since February 2017 and early on a supplemental questionnaire was deployed to get more information about foods not listed

on the LI form. From the supplemental forms that were received, there was a signal for lower cost foods and frozen foods, specifically store-brand Neapolitan ice creams. FDA and states performed traceback and sampling, but the outbreak strain was not isolated from any products or facilities. CDC decided to perform open-ended interviews on ill people, beginning in early 2018, when ice cream was not able to be confirmed as the vehicle, and new illnesses matching the outbreak strain continued to occur. At the time of transfer, six open-ended interviews had been completed and had again confirmed a signal for frozen foods (not limited to ice cream). Since identifying potato isolates uploaded to NCBI, CDC began collecting specific information on potato exposures during the open-ended interviews and compared frozen foods reported by cases to try to find a common food item or brand. CDC indicated that potato salad was the only question on potato exposure included on the Listeria Initiative(LI) form, so CDC reviewed all data sources (i.e., LI form, supplemental questionnaire, open-ended interviews) to compile information on potato exposures. Twelve patients reported any type of potato product (this would include chips and fresh potatoes). Eight had exposure information that potentially indicated potato products in frozen or refrigerated items, including pot pies, perogies, and other frozen meals.

At the time of transfer, a total of seven SENASICA Lm isolates from fresh potatoes sourced from the U.S. suppliers had been identified in NCBI that were highly related by WGS to the clinical cluster (See WGS Report. Potato sample collection dates ranged from 7/7/2015 to 7/24/2017, and SENASICA reported that product was sourced from (b)(4) . exporters: including (b)(4) from (b)(4) , TX), (b)(4) from (b)(4) ., and (b)(4) from (b)(4) , ID). Supplier information was unknown for one SENASICA potato sample. On 9/18/18, FDA and CDC held a Firm Call with (b)(4) . to discuss the sample results and request additional information regarding (b)(4) supply chain and distribution of raw potatoes. (b)(4) provided the names of their brokers for fresh potatoes: (b)(4) . During the call, (b)(4) indicated they received potatoes from CO, ID, and WA, and from May through September potatoes mainly came from CO. After harvesting, (b)(4) . (b)(4) only exported product to (b)(4) firms in (b)(4) Mexico for retail at a regional Mexican (b)(4) chain in (b)(4) Mexico. (b)(4) described that additional supplier information for raw potatoes exported to Mexico was available on the USDA-APHIS phytosanitary certificates. During the firm call, (b)(4) , a potato supplier to (b)(4), participated in the call along with (b)(4) representatives.

CFSAN SMEs indicated that sampling of raw potatoes is not conducted in the U.S. due to the designation as a raw agricultural commodity.

Given the new sequencing information for potato isolates matching the clinical cluster, and those cases in this cluster continued to occur with no suspect vehicle identified, a traceback and trace forward investigation was needed to identify potentially associated manufacturers of processed or frozen products to help inform the epidemiologic investigation.

CORE Signals transferred this incident to CORE Response Team 3 on 9/25/18. The rationale for transfer was as follows:

1) This was an ongoing outbreak of Listeria monocytogenes, which had been investigated by CDC, states and FDA previously but for which no vehicle was identified.
2) Whole genome sequencing analysis had identified multiple potato isolates that were highly related to the clinical illnesses in this cluster. These potato isolates were uploaded by SENASICA

(Mexico), but represented raw potatoes collected from at least (b)(different US exporters and originating in the US.

3) Extensive open-ended interviewing by CDC yielded a signal for various types of frozen food items. Some of these items (including pot pies, pierogies, and other frozen meals) may include potatoes as ingredients. There had not been a signal for raw potatoes.
4) Documenting the potato supply chain (traceback of the raw potatoes to their source(s) and trace forward of these potatoes to other consignees, including potential frozen food manufacturers) was critical to thoroughly evaluating the signals provided by the WGS (potatoes involved in some way) and epidemiology (frozen foods, perhaps incorporating potatoes as an ingredient).
5) Additional firm calls to exporters, brokers, or growers/suppliers may have been (b)(5) .
6) Coordination with LAO to request additional sample and firm information from SENASICA may have been needed.
7) Based on evidence obtained through the traceback and trace forward investigations, (b)(5) .

Epidemiology

A confirmed case was defined as an infection with *Listeria monocytogenes* and clinical isolates matching PFGE AscI/ApaI pattern combination GX6A16.0140\GX6A12.2167 and closely related by whole genome sequencing. The cluster includes 39 listeriosis illnesses from 19 states [AL (5), AR (3), AZ, CO, FL, GA (5), IN, KS, KY, LA, MO, NC, NE, NM, OH, OK (4), PA, TX (8), and WV] with isolation dates ranging from 10/24/2015-1/1/2019. Patients range in age from <1-104 years (median 63); 21 (53%) patients are female. Listeria Initiative (LI) data is available for 38 patients. Among those, 33 patients have been hospitalized and there are four reported deaths. Eleven illnesses are pregnancy-associated and 3 resulted in a fetal loss.

The CDC line list is available in the attachments section in EON-366555.

Laboratory

FDA Samples

There were no FDA samples collected in association with this outbreak.

State Samples

Louisiana State partners collected russet and sweet potatoes from consumer home. All samples collected by state partners were negative for *Listeria monocytogenes*.

WGS analysis

As of 2/7/18, WGS analysis had identified six potato isolates from multiple U.S. suppliers that were genetically identical to each other and to 36 clinical isolates (within 0-17 SNPs, median 4 SNPs).

WGS analysis report is available in the attachments section in EON-366555.

Traceback

Potatoes from seven positive SENASICA samples from 7/7/2015-7/24/2017 were traced back to the farm level. Traceback identified (b)(4) brokers, (b)(4) farms, and (b)(4) consignees. The farms identified on traceback were all in the (b)(4), CO area. All potatoes associated with the specific USDA Animal and Plant Health Inspection Service (APHIS) phytosanitary certificates were only exported to Mexico.

Traceforward was conducted on one of the brokers supplying potatoes to (b)(4) ; the broker is identified as (b)(4) . (b)(4) customer list was obtained for all potatoes that were sent to export or for further processing for the timeframe of 9/1/2015-7/31/2016. Thirteen customers were identified on the customer list from (b)(4) , none of which were manufacturing frozen foods of interest. No follow up was performed at the identified customers.

Due to the lack of: lot information at the consumer level, point of service clusters, and exposure dates, and the scope of the informational traceback could not be narrowed. Therefore, no regulatory traceback was conducted.

A product flow diagram is available in the attachments section in EON-366555.

Establishment Inspections and Investigations

On 10/1/18, CORE issued assignment #106653 to ORA HAF 3W for record collection at (b)(4) , TX) identified as the exporter of record for the SENASICA *Listeria monocytogenes* positive potato samples. Of these seven positive samples, four were exported to Mexico by (b)(4). The firm provided its traceback and product handing information. The investigation was closed on 10/1/18; no significant observations were documented.

CORE requested record collection from ORA HAF 1W at (b)(4) , WI), Wisconsin Department of Agriculture, Trade and Consumer Protection collected information about where the potatoes associated with Phytosanitary Certificate (b)(4) were sourced and where those potatoes were sold.

CORE requested record collection from ORA HAF 6W at (b)(4) , ID) and from ORA HAF 4W at (b)(4) , CO) which provided potato traceback records and customer lists for potatoes sold internationally and for further processing.

Regulatory/Product Actions

No regulatory or product actions were taken during this incident response.

Communications

There was no public communication during this outbreak response.

Acknowledgements

CORE would like to acknowledge the work of the Office of Regulatory Affairs Human and Animal Food Division 1W, 3W, 4W, 6W during the outbreak. Acknowledgements are extended to all FDA, CDC, USDA and state partners that provided assistance and expertise throughout this investigation.

Conclusion

As of 2/4/19, a total of 39 confirmed cases of listeriosis illnesses were identified from 19 states [AL (5), AR (3), AZ, CO, FL, GA (5), IN, KS, KY, LA, MO, NC, NE, NM, OH, OK (4), PA, TX (8), and WV] including 33 hospitalizations and four deaths with isolation dates that ranged from 10/24/2015-1/1/2019. Informational Traceback identified five different farms in Colorado that may have supplied the seven positive potato samples collected by SENASICA. In the absence of any additional laboratory or epidemiology information; no vehicle was identified in this outbreak response.

Incident Coordination Group List

Coordinated Outbreak Response and Evaluation Network
Signals & Surveillance: Allison Wellman
Response: Response Team 3

- Lead Coordinator: Adiam Tesfai
- Operations: LT Mark Otto
- Planning: Angela Fields

Post Response: Cerise Hardy, CAPT Sheila Merriweather, Marianne Fatica
Communications
Senior Leadership

Office of Regulatory Affairs	
Human and Animal Food East	
Division II - PHI-DO	Judy Paterson
Division III – ATL-DO	Wilbur Huggins
Division IV – FLA-DO	Nelson Venerio
Division V – CIN-DO	Brenda Zimmer
Human and Animal Food West	
Division I – MIN-DO	Heidi DeBeck
Division II – KAN-DO	Lisa Flores, Erin Dugan
Division III – DAL-DO	Jane Broussard
Division IV – DEN-DO, LOS-DO	ORA DEN ERC, ORA HAF WEST4 Food Events <orahafwest4foodevents@fda.hhs.gov>, Hermie Francisco
Division VI – SEA-DO	ORA SEA ERC
Headquarters	

Office of Human and Animal Food Operations – Senior ERC	ORA HAF SERCs
Division of Domestic Human and Animal Foods Operations	Brian Ravitch ORA HAF ERCG <ORAHAFECRG@fda.hhs.gov>
ORA Produce Safety Network	
Office of Regulatory Science	Peggy Carter
Division of Import Operations	Jeffery Hilgendorf, Ashley Abraham Lorie Hannappel – FSVP
Office of Enforcement & Import Operations	
Office of Partnerships	Bruce Ross ORA OP DI International and Federal Group oraopdiintlandfederalgroup@fda.hhs.gov Ana Lilia Sandoval, Michelle Rodriguez OC-OIP-LAO-Mexico <OC-OIP-LAO-Mexico@fda.hhs.gov>
Center for Food Safety and Applied Nutrition	
Office of Compliance	Arma White, Asha Dwarka, Leslie Hintz Recalls – Vickery Brewer, Edette Newby CFSAN OC RCRT1 <CFSANOCRCRT1@fda.hhs.gov>
Office of Food Safety	Don Kautter, Mickey Parish, Jim Gorny
Division of Produce Safety	Joy Johanson, Ceilia Crowley
Produce Safety Network	
International Affairs Staff	Teresa Fox IAS-ACTION <IAS-ACTION@fda.hhs.gov>
Office of Analytics and Outreach	Arthur Pightling, Errol Strain CFSANRegGenTeam <CFSANRegGenTeam@fda.hhs.gov>
Office of the Commissioner	
Office of Chief Counsel	Heather Bennett
Office of Emergency Management	
Office of Food & Veterinary Medicine	
Centers for Disease Control and Prevention	
Division of Foodborne, Waterborne, and Environmental Diseases; Outbreak Response and Prevention Branch	Amanda Conrad, Jessie Marus, LCDR Laura Gieraltowski, CDR Matt Wise
US Department of Agriculture	
Animal and Plant Health Inspection Service	Sterling, Joyce J - APHIS <Joyce.J.Sterling@aphis.usda.gov>; Bishop, Bob M - APHIS <Robert.M.Bishop@aphis.usda.gov>;

	Campbell, Laney - APHIS <Laney.E.Campbell@aphis.usda.gov>; Wells, Terrance D - APHIS <Terrance.D.Wells@aphis.usda.gov>; Hardy, Brannen - APHIS <Brannen.V.Hardy@aphis.usda.gov>
State Partners	
AR, CO, GA, KY, NM, OH, LA	

INCIDENT OBJECTIVES (ICS 202), Adapted for FDA

1. Incident Name: *Listeria monocytogenes*/Unknown/May 2018	2. Operational Period: Date From: 11/01/18 Date To: 11/08/18 Time From: 1700EST Time To: 1700EST

3. Objective(s):

(b)(5)

4. Operational Period Command Emphasis:

1. Incident Name: *Listeria monocytogenes*/Unknown/May 2018	2. Operational Period: Date From: 10/18/18 Time From: 1700EST	Date To: 11/1/18 Time To: 1700EST

General Situational Awareness:

On 9/24/18, CDC provided an updated epi summary: Cluster 1702MLGX6-1 includes 34 listeriosis illnesses from 16 states [AL (5), AR (2), AZ, CO, FL, GA (5), KS, KY, MO, NC, NE, NM, OH, OK (3), PA, and TX (7)] with isolation dates ranging from 10/24/15-8/14/18. Patients range in age from <1-104 years (median 62); 17 (50%) patients are female. *Listeria* Initiative (LI) data is available for 31 patients. Among those, 26 patients have been hospitalized and there are 4 reported deaths. Ten illnesses are pregnancy-associated and three resulted in a fetal loss. Two additional cases not included in the case count above were ill in 2011 (GA and MO), but are included in the line list and WGS tree, these are currently being considered suspect cases. This cluster has been under investigation since February 2017 and early on a supplemental questionnaire was deployed to get more information about foods not listed on the LI form. CDC decided to perform open-ended interviews on ill people, beginning in early 2018, when ice cream was not able to be confirmed as the vehicle, and new illnesses matching the outbreak strain continued to occur. Six open-ended interviews have been completed so far and have again confirmed a signal for frozen foods (not limited to ice cream). Eight cases have reported exposure information that potentially indicates potato products in frozen or refrigerated items, including pot pies, perogies, and other frozen meals. In late May 2018, CORE Signals learned of WGS data uploaded to NCBI by SENASICA for a *Listeria monocytogenes* isolate (SENASICA_Li_U95) from a 2017 imported potato sample matching clinical isolates from cluster 1702MLGX6-1. CORE Signals reached out to the FDA LAO-Mexico City Office to request additional information from SENASICA about the potato sample. As of 9/24/18, WGS analysis had identified seven potato isolates from multiple U.S. suppliers that are genetically identical to each other and the clinical isolates (within 0-17 SNPs, median 4 SNPs). Potato sample collection dates range from 7/7/15 to 7/24/17.

Operational Period 1: On 9/31/18, USDA APHIS shared phytosanitary certificates for the seven LM positive potato samples; potato origin is identified as Colorado ((b)(4)). On 10/1/18, CORE issued assignment #106653 to ORA HAF 3W for record collection at (b)(4) , TX); and requested record collection from ORA HAF 1W at (b)(4) , WI) and ORA HAF 6W at (b)(4) , ID). On 10/2/18, CORE requested record collection from ORA HAF 4W at (b)(4) , CO). On 10/3/18, CORE received supplier information regarding the one additional potato sample from SENISICA. On 10/11/18, a Special Tactics Call was held to discuss sharing of information provided by MX with incident stakeholders (Commissioned Officials, 20.88 agreements, and MOUs).

On 10/26/18, ORA HAF 4W provided additional information regarding traceback information of diverted potatoes that do not meet export quality standards form (b)(4) , CO). On 10/26/18, CFSAN Office of Food Safety, Office of Compliance and CORE held a meeting with National Potato Council (NPC) and answered questions from the NPC regarding potato sampling by Mexico. On 10/31/2018, CORE and CDC held a meeting to discuss ongoing epi investigation and traceback challenges and limitations. On 10/31/18, ORA HAF 1W provided traceback records associated with (b)(4) , WI). Review of traceback/trace forward documents is ongoing.

5. Site Safety Plan Required? Yes ☐ No ☐

Approved Site Safety Plan(s) Located at:

6. Incident Action Plan (the items checked below are included in this Incident Action Plan):

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

7. Prepared by: Name: Adiam Tesfai Position/Title: Signature: _____

8. Approved by Incident Commander: Name: Adiam Tesfai Signature: *Adiam Tesfai*

ICS 202	IAP Page _____	Date/Time: 11/1/18 1500 EST