FDA CORE NETWORK | COORDINATED OUTBREAK RESPONSE & EVALUATION

Listeria monocytogenes/Unknown/Oct 2019

CARA #918

EON # 405644

Incident Summary Report

April 25, 2023

Authors:

CORE Signals & Surveillance Team: Allison Wellman

CORE Response Team 1: Brooke M. Whitney, Ph.D.

ABSTRACT

In 2017, Pulsenet initially identified this cluster. Two previous CORE outbreak responses were initiated in 2017 and 2018, respectively. The epidemiologic information regarding a potential vehicle remains unclear, but ice cream, frozen foods, and potato-containing items have been of interest. SENASICA has tested multiple raw potatoes for *Listeria monocytogenes* and submitted the resulting sequences to NCBI; as of March 2023, the NCBI cluster includes 32 isolates from SENASICA labeled as originating from potato. Previous response traceback has focused on the initial SENASICA potato isolates and appear to converge to (b)(4) CO. Specifically, a large supplier named (b)(4) . Potential relationships between this supplier and the exposures noted by cases have been considered, but with no conclusions. CORE held an information-sharing call with (b)(4) , but no specific regulatory ask was made. Additionally, there were no other regulatory activities or communications related to this outbreak investigation. The vehicle remains unknown. As of 3/3/2023, the REP strain included 81 ill people from 23 states: AL (8), AR (6), AZ (2), CA, CO (2), FL (5), GA (9), IL, IN, KS, KY, LA (2), MI, MO (8), NC, NE, NM (3), OH, OK (7), PA (3), TX (15), VA, and WV.

SIGNALS AND SURVEILLANCE ACTIVITIES

1st CORE Response (2017)

This cluster was initially identified by PulseNet in 2017, and the earliest epidemiologic information indicated ice cream as a suspect vehicle. CDC and FDA investigated the ice cream exposures reported by cases and inspected several ice cream facilities; however, the outbreak strain was never found in any facility or product and traceback did not converge on a single brand. As a result, the investigation was not able to confirm ice cream as the vehicle and it was eventually closed by FDA and CDC in September of 2017 with a total of 11 cases included in the cluster. Although that investigation closed, additional illnesses matching the outbreak strain continued to occur and CDC continued to follow-up with new cases using open-ended interviews. Based on subsequent exposure information that was collected during these interviews, processed frozen meals and frozen snack foods emerged as items of interest; however, no common brands or manufacturing firms were identified. Further information for the response activities can be found in EON-315180 (CARA ID 656).

2nd CORE Response (2018)

In mid-2018, this strain was identified in NCBI from raw potatoes of U.S. origin but tested by the Mexican agency SENASICA upon export from the U.S.; these potato samples had collection dates between 2015 and 2017. At this point, FDA and CDC re-opened an outbreak investigation and Response Team 3 conducted informational traceback and traceforward for these matching potato samples to ascertain whether a connection could be made between potatoes and the frozen food exposures, which sometimes included potato as an ingredient. (b)(4) CO region was a commonality among farms identified as possible suppliers for the positive products, and numerous customers were identified for (b)(4), one of the common brokers supplying potatoes from the region. The traceforward was not exhaustive due to resource constrains, nor were any facilities inspected as a result of the traceforward. The investigation was unable to identify any connection between the cases' frozen food exposures and the potatoes that would explain the relatedness by WGS. No vehicle was confirmed, and no product manufacturer was implicated during this 2018 outbreak response. Further information for the response activities can be found in EON-366555 (CARA ID 775)

Activities beginning in 2019

Thirteen additional cases were reported after the 2018 outbreak investigation closed in April 2019. At the time of the third transfer to Response Team 1 on 11/7/2019, the cluster included 54 cases from 19 states: AL (6), AR (3), AZ, CO, FL (3), GA (7), IN, KS, KY, LA (2), MO (3), NC, NE, NM, OH, OK (4), PA, TX (15), and WV (1), with isolation dates from 9/16/2011 to 9/4/2019. Cases ranged in age from 0 – 104 years (median = 62 years), and 57% of cases were female. At the time, there had been 47 hospitalizations (87%), 5 deaths reported, 14 pregnancy-associated cases, and 4 fetal losses.

Case-patients had been interviewed by state partners and CDC using several approaches including the *Listeria* Initiative questionnaire, open-ended interviews, and two different supplemental questionnaires including questions about processed frozen foods and potato products. Many cases had reported consuming lower-cost foods and frozen foods, including a variety of frozen meals and frozen snack foods, as well as fresh, frozen, and refrigerated potato products, although no specific brand or type of

frozen/processed food items or potato products stood out in common amongst cases. A majority of cases [26/40 (65%)] with grocery store information available reported shopping at (b)(4) . Only 7 patients shopped at a single grocery store; of those, three were exclusive (b)(4) shoppers. Other stores commonly reported include (b)(4) [8/40 (20%)] and (b)(4) [6/40 (15%)]. No single suspect food vehicle had been identified based on the information gathered at the time of transfer in 2019.

On 10/24/2019, CORE and CDC held a call to generate ideas for next steps to respond to this persistent strain and the continuing illnesses. The discussion included hypotheses that contaminated potato products were potentially introduced into processing facilities where the strain became resident in the manufacturing environment. This scenario would result in the potential for a variety of processed frozen foods being contaminated with the outbreak strain and could explain why the epidemiologic investigation has failed to identify a single suspect vehicle. Potential action items identified for follow-up during this call included:

1) An informational conference call with the corporate office of the primary retailer reported by cases (b)(4)).
2) Industry consultation-type discussions with trade organizations (processed frozen food industry and/or the potato industry).
3) Research lab studies, including potential CDC collaboration with academia to test raw potatoes and/or frozen/refrigerated processed foods, and a FDA research project to study *L. monocytogenes* in non-RTE processed/frozen foods and variations in cooking and handling processes. During previous investigations, CFSAN SMEs have indicated that sampling of raw potatoes is not conducted in the U.S. due to the designation as a raw agricultural commodity.
4) CDC offered to re-evaluate their questionnaire and approach to obtaining exposure information to determine whether additional questions on frozen food exposures should be added and to see if they could improve the compliance rate with the focused questionnaire.
5) Additionally, CDC offered to perform a molecular epi analysis of the WGS data to evaluate any potential subclustering by sequencing, and the characteristics within any subclusters.

This incident transferred to Response Team 1 on 11/7/2019. The rationale for transfer of the *Listeria monocytogenes* (1702MLGX6-1)/Unknown/ML/Oct 2019 incident is as follows:

- This is an ongoing outbreak of *Listeria monocytogenes* that has been previously investigated by CDC, states and FDA in 2017 and 2018, but for which no vehicle was identified. Items of interest include FDA-regulated foods such as variety of frozen meals and frozen snack foods, as well as frozen and refrigerated potato products and foods containing potatoes as an ingredient.
- Industry consultation calls are (b)(5)
- Coordination of further discussion of proposed research initiatives with subject matter experts is needed.
- Firm inspections may be needed to further assess potential sources of this outbreak, including firms previously identified during the potato traceforward, as well as other firms identified through discussion with (b) (4) or other industry consultation discussions that may occur.

EPIDEMIOLOGY

One of the limitations for the epidemiology is the broad timeframe of illnesses and the fact that case-patients have been interviewed using several approaches including the *Listeria* Initiative questionnaire, open-ended interviews, and two different supplemental questionnaires including questions about processed frozen foods and potato products.

In November 2019, CORE Response Team 1 had a close look at the ingredients for specific food items that had been reported. With potatoes as a known contaminated product with this strain, the team noted that many of the frozen food items also contained some type of food starch, which may be derived from potatoes. Further, this starch may be used as an anti-caking agent in shredded cheese. CDC considered shredded cheese without running a full case-case analysis, which showed this specific exposure as not quite significant.

One epi link of interest that was not thoroughly explored by FDA was mention of two cases who were tightly related by WGS and both mentioned (b)(4) pot pies. This is a frozen item that contained potatoes, but also meat, and therefore are USDA-regulated products. FDA did not pursue information related to the manufacturing firm or product sampling because of the regulatory status.

On 6/9/2021, CDC assigned this outbreak cluster to a REP code (reoccurring, emerging, and persisting strains) and informed state partners of this status. The REP code assigned was REPGX601 and was based on the persistence of this strain.

As of 3/3/2023, the REP strain included 81 ill people from 23 states: AL (8), AR (6), AZ (2), CA, CO (2), FL (5), GA (9), IL, IN, KS, KY, LA (2), MI, MO (8), NC, NE, NM (3), OH, OK (7), PA (3), TX (15), VA, and WV. Isolation dates range from September 16, 2011 through December 26, 2022. All isolates are related within 0-36 alleles and a median of six. Ages range from less than one through 104 years with a median of 63 years and 46 (57%) are female. Of the 71 patients we have information for, 64 (90%) have been hospitalized and there are 11 reported deaths. Seventeen cases are pregnancy-associated with five resulting in fetal loss. Of the 25 patients where we have information either from supplemental questionnaires or shopper card records, 25/25 (100%) reported exposure to fresh or frozen potato products from a variety of stores, brands, and restaurants.

LABORATORY

Three FDA samples were collected and 45 potato-containing product samples were collected by Michigan Department of Agriculture and Rural Development (MDARD) as a result of this outbreak investigation. None were positive for *Listeria monocytogenes*.

FDA Samples

(b)(4)) issued an RFR for shredded cheese on 11/26/2019 based on a customer report of positive *Listeria monocytogenes* sample (EON-407964). Because of the potato starch used in shredded cheese hypothesis, CORE Response Team 1 requested HAF 2E (PHI-DO) collect a sample of the potato starch and determine if the third-party positive isolates are available for sequencing. On 12/2/2019, HAF E2 collected FDA sample 1117864 of potato starch at

(b)(4) . The manufacturer was listed as (b)(4)). ON 12/9/2019, this sample was reported negative for *L. monocytogenes*.

Additional samples not directly related to the outbreak investigation were also collected. The customer who found the initial positives sent the isolates to FDA for characterization under sample 652122. (b)(4)) had a positive shredded cheese positive sample (FDA sample 1115197) and positive environmental swabs in 2019 (FDA sample 1109687) and then again in 2020 (FDA sample 1132284). These isolates cluster with each other, but do not match the outbreak strain or other clinical isolates by WGS.

On 3/11/2021, CDC alerted CORE of an additional case with an isolation date of 1/27/2021. Colorado Department of Public Health and Environment (CDPHE) collected relevant products, which were reportedly the same brand available prior to illness, although not necessarily the exact product consumed before illness. On 3/23/2021, HAF W4 received the samples collected by CDPHE and the samples were analyzed by FDA's Denver Laboratory for *Listeria monocytogenes*. Sample #1156235 consisted of opened frozen French fries and Sample #1156236 was of whole raw potatoes. On 03/26/2021, both of these samples were finalized with no *Listeria monocytogenes* found.

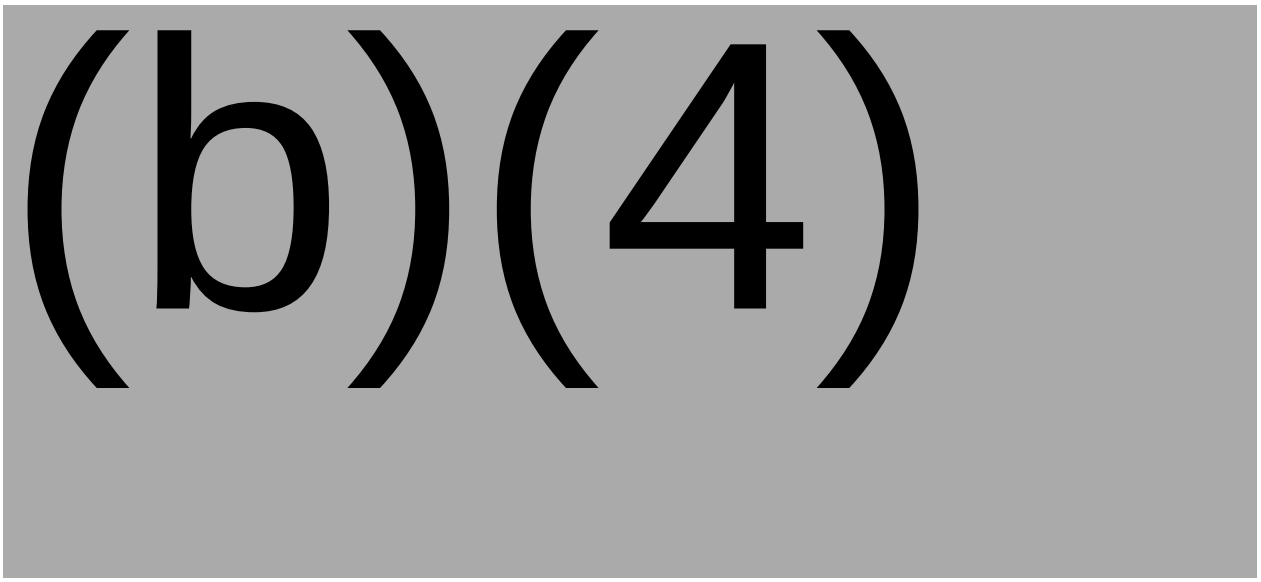
State Samples

Michigan

In July 2021, in response to a MI case newly included in the cluster, MDARD collected 45 frozen potato/potato starch related samples, summarized in the table below:

(b)(4)

On 7/16/2021, HAF E6 reported three of the (b)(4) meals tested were CRO. It should be noted that those meals are FSIS-regulated. The organism recovered from each of these samples was *Listeria innocua*. Details of the products with *L. innocua* include:



Each of these products are regulated by FSIS, but all contain mashed potatoes as a component. According to FDA records, the code 5009 is for the (b)(4) manufacturing location in (b)(4) and (b)(4) is the establishment number for USDA-regulated products for the same location.

Whole Genome Sequencing

On 11/14/2019, OAO/Biostatistics & Bioinformatics Branch provided an updated WGS (SNP) analysis showing that the seven SENASICA potato isolates are genetically identical to 57 clinical isolates in the database at 0-20 SNPs with a median of 5 SNPs. At the time, all isolates in the cluster were highly related by WGS (within 0-24 alleles, median 5 alleles). By SNP analysis this is 0-20 SNPs with a median of 5, including clinical isolates as well as several U.S. potato isolates tested by SENASICA in 2015 and 2016 and uploaded to NCBI in 2018, which was a focus of the 2018 investigation. The relatedness of this cluster is on the upper end of what FDA considers genetically identical. It should also be noted that the potato isolates from SENASICA do not necessarily tightly cluster near each other; rather, they are spread out among the WGS tree.

In August 2020, CORE Signals flagged for CORE Response Team 1 that 16 additional isolates from SENASICA had been added to the cluster. Additionally, two other WGS clusters had uploads from SENASICA with potato isolates included. Information for the metadata associated with these isolates was requested from SENASICA and the supplier information for 16 potato isolates was returned. (b)(4) different US-based exporters to Mexico were named. (b)(4) suppliers were also identified when CORE Response Team 3 conducted their traceback that converged on (b)(4). The isolation dates for these isolates were May – August, 2018. As of March 2023, SENASICA had uploaded 32 isolates to NCBI with a descriptor of “potato” and one isolate labeled “apple,” all within the cluster where the REP strains fall.

Potential Sampling Strategy

At the end of Jan 2020, the best approach was determined to be collecting product samples of specific products case patients had purchased. CORE worked with CDC to develop a prioritized list of samples to be collected. Following development of the priority samples, FDA intended to use a pilot program to have a third-party contractor collect the samples. The sampling plan conceived was to provide the contractor a general geographic area, specific retail chains to target, and specific products that are relatively easy to find for collection. The products of interest that were not FSIS-regulated generally included frozen French fries and other frozen potato products and potentially cheese pizza or pizza rolls without meat. The prioritized list from CDC included:

(b)(4)

On 2/5/2020, CORE provided the following sampling strategy to the Deputy Director for Scientific Operations of CFSAN for consideration:

Geographic areas to sample:

- (b)(4) OK
- (b)(4) TX ((b)(4))
- (b)(4) AL

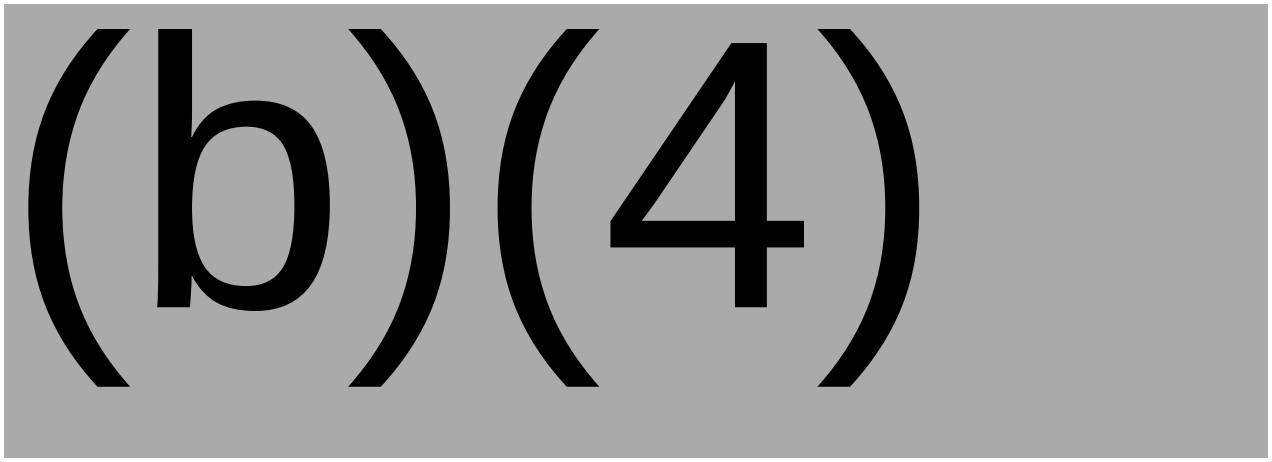
Rationale: Case distribution (19 states): AL (6), AR (3), AZ, CO, FL (3), GA (8), IN, KS, KY, LA (2), MO (3), NC, NE, NM, OH, OK (5), PA, TX (15), WV. While the case distribution has a relatively broad range across the southern/southwestern states, these specific counties are associated with the highest concentration of cases. Additional areas with concentrations of cases could be provided if this plan proceeds.

Retail Locations to sample:

(b)(4)

Rationale: (b)(4) were the (b)(4) retailers mentioned most by case patients. One of the most recent cases was a (b)(4) shopper and (b)(4) was mentioned by cases and we know distributes frozen potato products manufactured by (b)(4) under their store brand.

Products:



Rationale: (b)(4) is a manufacturer that we know uses potatoes from (b)(4). They manufacture under many different brands, but also their own brand. *The other priority starred products are specific products that were mentioned by case patients when asked about potato products.

Ultimately, a number of complicating factors hindered executing the sampling, including COVID-19 and its impacts on in-person work, concern regarding retail sampling, and compliance complications with sampling non-RTE products. One approach to address this may be to conduct the study via a contractor.

Laboratory Conclusions

Three FDA samples were collected and 45 potato-containing product samples were collected by Michigan Department of Agriculture and Rural Development (MDARD) as a result of this outbreak investigation. None were positive for *Listeria monocytogenes*, but MDARD did identify *L. innocua* in (b)(4) (b)(4) potato-containing products. A sampling strategy was developed, but not implemented.

TRACEBACK

Potato Traceback/Traceforward

As previously mentioned and determined by CORE Response Team 3, the SENASICA potato isolates appear to converge via traceback to (b)(4), CO. Specifically, a supplier named (b)(4). An investigation did occur at (b)(4) in 2018. According to that investigation, potatoes may be stored up to 11 months and typically temperature and humidity is controlled under these storage conditions. At this point in the process, potatoes are considered raw agricultural commodity.

Previously, a traceforward from (b)(4) was conducted in 2018. While many firms were identified, some firms were flagged for further exploration based on historical interest as well as geography:

- (b)(4), OK) previously received potatoes from (b)(4), but at the time of consideration in 2019 was out of business, with some of the equipment moved to (b)(4). At the time, (b)(4) occupied the location with one FDA-regulated line.

- (b)(4) MO) received potatoes from (b)(4) and in 2009 had a positive product for *Listeria monocytogenes*. The more recent environmental samples collected in 2017 were negative for *Listeria monocytogenes*. This firm mainly manufactures potato products and makes 17 brand names, including some store brands. It should be noted that the epidemiology does not strongly point to the frozen potato products manufactured here.
- (b)(4) , KS) at the time had a recent inspection that was unrelated to this outbreak. The environmental samples collected were negative for *Listeria monocytogenes*. During the contemporary inspection unrelated to this outbreak, environmental samples collected were negative for *Listeria monocytogenes*.
- (b)(4) , OK) is in the right geography of the cases, but handling and distribution from this firm was not investigated further.
- (b)(4) received potatoes from (b)(4) and during the first tactics call, CORE Response Team 3 mentioned they receive B grade potatoes.

Establishment Inspections and Investigations

Following the 2018 response activities by Response Team 3, a workplan request was submitted by CORE in April 2019 for the listed firms below for the RTE foods environmental sampling plan. Ultimately due to resource constraint and the fact that some of these manufacturers did not make RTE foods, the request was not directly fulfilled.

Firms that were listed the workplan request:

(b)(4)

District Office

(b)(4) , CO; FEI: (b)(4))

As a result of the SENASICA isolates and CORE Response Team 3's traceback, an inspection occurred in 2018 at (b)(4) . Full details of this inspection can be found elsewhere. Farmers provide transportation to the facility. Employees (b)(4) . (b)(4) . The general process is: (b)(4)

In November 2019, CORE Response Team 1 posed some follow-up questions, including about the processing facility that potatoes are sent to after sorting – the referenced processor is a facility that (b) (4) , but no additional information was collected on this at the time.

(b)(4) CO; FEI: (b)(4))

Division review of FDA inventory showed (b)(4) potato manufacturer in Colorado ((b)(4) ') is (b)(4) . Per their last EI they (b)(4) Colorado state partners believe this is where (b)(4)

(b)(4) is in (b)(4) (I think it's called (b)(4) in Colorado (b)(4) .

(b)(4) , MO; FEI: (b)(4))

CORE reviewed FDA information regarding (b)(4) since they have been noted as a customer of (b)(4) and their products may fit the distribution pattern noted for cases. This firm manufactures many different brands, but of note, none are (b)(4) . However, (b)(4) itself may be sold at (b)(4) according to internet research. Also, there is no indication that (b)(4) manufactures for national potato brands, such as (b)(4) . They have had a previous detections of *Listeria monocytogenes* in retail package of (b)(4) Shredded Hashbrowns, tested by Minnesota in 2009 and positive FDA swabs at the facility in 2010. As of 1/12/2023, these isolates make up unique cluster in NCBI which does not contain any clinical isolates. In addition to retail products, the firm manufactures product such as potato shreds and dices in bulk; it's plausible these products may be used as an ingredient in other products, such as frozen pot pies.

State

(b)(4) , KS; FEI: (b)(4))

This firm was noted as a customer of (b)(4) On 11/4/2019, Kansas Department of Agriculture initiated a PC inspection at (b)(4) accompanied by FDA. This inspection was not conducted as a direct result of the outbreak investigation or at the direct request of CORE. At the time of inspection, the firm generally manufactured ready-to-eat baked items, including potato-containing items such as baked scalloped potatoes, hash brown casserole, and tricolored roasted potatoes. FDA collected sample #1126053, comprised of 83 swabs, which were negative for *Listeria monocytogenes*. An FDA 483 was not issued, but there were several observations noted, and the inspection classified as Voluntary Action Indicated.

Product/Firm Actions/Firm Events

On 11/8/2019, CDC hosted a call with (b)(4) to discuss the epidemiologic information gathered. At the time, of 40 patients with good case/interview information, 26 were (b)(4) customers. CORE participated in the call, but no specific ask or information request was made. Specific cases information related to the (b)(4) shoppers was provided to (b)(4) for their consideration. On 11/21/2019, HAF W3 provided a response from (b)(4) that the exposure data

provided to them by CDC did not provide a clear indication of what raw potato supplier or manufacturer of potato-containing frozen products may be in common among the cases.

On 11/22/2019, CORE requested that HAF W3 reach out to (b)(4) for manufacturer information for specific products purchased at (b)(4) as reported by case patients. On 1/29/2020, HAF W3 provided (b)(4) response, but only included the distribution center location without any of the manufacturing firm locations as requested. The rationale provided was, "Regarding the manufacturing information, at this time there is not enough information for us to query information. For many of the products, a manufacturer may produce different varieties at different plants. For example all cheese and veggie pizzas may be produced at Plant A while all meat pizzas are produced at Plant B. Additionally, some suppliers produce the same product at multiple locations and may fulfill orders to (b)(4) based on inventory – so we may not even be able to obtain that information even if involving the supplier unless we had lot code information. The best we could do would be providing the supplier information – which likely isn't that helpful as the items are national branded and could be found doing a simple google search."

COMMUNICATIONS

No public communications were issued as a result of this outbreak investigation.

CONCLUSION

The vehicle for this outbreak remains unknown. The most promising clue gathered includes the identification of matching strains of *Listeria monocytogenes* from raw potatoes sourced from (b)(4) CO. Some hypotheses which were considered include: a variety of non-RTE frozen potato products that were reported by cases and the possibility of potato starch serving as a common contaminant, possibly for shredded cheese. However, a common point of contamination or direct link to potatoes from (b)(4), CO was not made. Given the genetic diversity, it is unlikely these illnesses arose from a point source contamination. Rather, it is likely there are multiple specific vehicles involved in this outbreak, and possibly multiple manufacturing facilities. This is supported not only by the genetic diversity within the cluster, including the potato isolates, but also by the lack of a specific vehicle identified via epidemiologic evidence.

If this issue is to be revisited in the future, CORE could consider looking most closely at cases whose clinical isolates are the most highly related and commonalities among those cases, potentially as individual outbreaks, as determined by colleagues at CDC. Use this analysis to guide sample collection or facility investigations. Also consider retrieving the details of the SENASICA isolates uploaded in 2020 to the multiple WGS clusters. Another consideration is to swab or collect finished product samples from the (b)(4) location in (b)(4), MO ((b)(4)). According to FDA records, this facility manufactured the (b)(4) products that tested positive for *Listeria innocua* and this location manufactured (b)(4) pot pies, one item of most interest from CDC early evaluation, but not an FDA-regulated product. Lastly, the sampling plan outlined in the Laboratory Conclusion section should be reconsidered.

ACKOWLEDGEMENTS

CORE would like to thank all the partners, including federal, state, and local, involved in this investigation. In particular, the *Listeria* group at CDC who continue to gather information that may one day solve this outbreak. CORE also wishes to express sincere appreciation to those engaged in this outbreak who were willing to provide ideas and brainstorm with the incident group on this unusual outbreak investigation.

INCIDENT COORDINATION GROUP

Incident group developed in 2019. Please note some partners listed below may not currently hold the listed positions or affiliations.

Office of Regulatory Affairs	
Human and Animal Food	
HAF 2E (Philadelphia) (Baltimore)	Judy Paterson Valeria Moore
HAF 3E (Atlanta)	Wilbur Huggins
HAF 4E (Florida) (San Juan)	Nelson Venerio Marianela Aponte Cruz
HAF 5E (Cincinnati) (New Orleans)	Brenda Zimmer Lindsey Bertling
HAF 6E (Detroit)	Lisa Joseph
HAF 2W (Kansas City)	Erin Dugan
HAF 3W (Dallas)	Jane Broussard
HAF 4W (Denver) (Los Angeles)	Holly Miller Hermie Francisco
Headquarters	
Domestic Human and Animal Foods Operations Branch	ORA/OHAFO/OHAFOW/DDHAFO/DHAFOB Linda Stewart Lourdes Andujar (back up), Brian Ravitch and Larry Stringer
Office of Human and Animal Food Operations -Immediate Office	Bruce Ross
Office of Human and Animal Food Operations – Senior ERC	Chris Yee Kim Livsey
Office of Regulatory Science	Terri McConnell Gina Hall
Office of Enforcement and Import Operations – Division of Import Operations	Jeffery O Hilgendorf

ORA Office of Strategic Planning and Operations Policy/ Recall Operations Branch	ORA OSPOP ENFORCEMENT Recall Operations Branch
Office of the Commissioner	
Office of Chief Counsel	Ashley Zborowsky, Carrie James
Office of International Programs, Latin America Office	Ken Nieves, Jason Cornell
Center for Food Safety and Applied Nutrition	
Senior Science Advisory Staff	Mickey Parish Les Smoot Jenny Scott
International Affairs Staff	Teresa Fox Jeff Read
CFSAN/OFS/Division of Plant Products and Beverages	Donald Kautter
OFS/Division of Produce Safety	Cecilia (Maria) Crowley
OFS/Multi-Commodity Foods (Refrigerated and Frozen Food)	Andreas Keller Lisa Ross
Office of Regulatory Science/Division of Microbiology	Dumitru Macarisin
Office of Compliance	CFSANOCRCRT21@fda.hhs.gov Robyn Jones (OC Supervisor) Kristen Jackson Lisa Thursam Reeba Roy (Recalls) Edette Newby (Recalls back-up) Leslie Hintz (SME)
Office of Analytics and Outreach (Biostatistics and Bioinformatics Staff)	Arthur Pightling
Centers for Disease Control and Prevention	
Division of Foodborne, Waterborne, and Environmental Diseases	Amanda Conrad Matt Wise Laura Gieraltowski Michael Vasser
State Partners	
AK	
MO	
TX	
KS	
Office of Coordinated Outbreak Response and Evaluation	

Senior Leadership	Stic Harris Kari Irvin Karen Blickenstaff Susan Lance Doug Karas
Signals	Alison Wellman
Post Response	Cerise Hardy
Communications	Lindsay Dashefsky / Doug Karas
CORE Response Team 1	Alvin Crosby (Team Lead) Brooke Whitney (Lead Coordinator) Monica McClure (Operations Chief) Erin Jenkins (Planning Chief) Kate Kreil Johnson Nsubuga Sharon Seelman

INCIDENT OBJECTIVES (ICS 202), Adapted for FDA

1. Incident Name: *Listeria monocytogenes* (1702MLGX6-1)/Unknown/Oct 2019 EON-405644	2. Operational Period: Date From: 12/3/2019 Time From: 1400 ET	Date To: 12/17/2019 Time To: 1300 ET

3. Objective(s):

(b)(5)

4. Operational Period Command Emphasis:

General Situational Awareness:

Operational Period #1: CORE and CDC are continuing to evaluate the persistent strain of *Listeria monocytogenes* associated with cluster 1702MLGX6-1, and on 11/7/2019 the incident was transferred to CORE Response Team 1. As of 11/14/2019, there are 55 reported cases in this cluster from 19 states: AL (6), AR (3), AZ, CO, FL (3), GA (7), IN, KS, KY, LA (2), MO (3), NC, NE, NM, OH, OK (5), PA, TX (15), WV (1). Patients range in age from 0-104 years (median 61); 31 (57%) patients are female. Forty-eight patients have been hospitalized and there are five reported deaths. Fourteen illnesses are pregnancy-associated and four resulted in fetal loss. This cluster was previously investigated in 2017 and 2018, but no vehicle was confirmed during the outbreak response. CDC closed the cluster investigation in early 2019 and since then, 14 new clinical matches with this strain have been identified. Isolation dates range from 9/16/2011 - 9/4/2019. All isolates in the cluster are highly related by WGS (within 0-24 alleles, median 5 alleles), including clinical isolates as well as several U.S. potato isolates tested by SENASICA in 2015-2016 and uploaded to NCBI in 2018, which was a focus of last year's investigation. Currently, no suspect vehicle has been identified. Case-patients have been interviewed using several approaches including the *Listeria* Initiative questionnaire, open-ended interviews, and two different supplemental questionnaires including questions about processed frozen foods and potato products. Many cases have reported lower-cost foods and frozen foods, including frozen meals and frozen snack foods, as well as fresh, frozen, and refrigerated potato products, although no specific brand or food item is standing out. A majority of cases [26/40 (65%)] with grocery store information available have reported (b)(4) or (b)(4) in common. On 11/8/2019, CDC hosted a call with (b)(4) to discuss the epidemiologic information gathered thus far. CORE participated in the call, but no specific ask or information request was made. On 11/12/2019, CDC formally re-opened the investigation for this cluster (1702MLGX6-1).

INCIDENT OBJECTIVES (ICS 202), Adapted for FDA

1. Incident Name: *Listeria monocytogenes* (1702MLGX6-1)/Unknown/Oct 2019 EON-405644	2. Operational Period: Date From: 12/3/2019 Time From: 1400 ET Date To: 12/17/2019 Time To: 1300 ET

Operational Period #2: **As of 11/14/2019, there are 55 reported cases in this cluster from 19 states: AL (6), AR (3), AZ, CO, FL (3), GA (7), IN, KS, KY, LA (2), MO (3), NC, NE, NM, OH, OK (5), PA, TX (15), WV (1). On 11/14/2019, OAO/Biostatistics & Bioinformatics Branch provided an updated WGS (SNP) analysis showing that the seven SENASICA potato isolates are genetically identical to 57 clinical isolates in the database at 0-20 SNPs with a median of 5 SNPs; two of these clinical isolates are likely duplicates. On 11/18/2019, HAF 2W provided additional details regarding the state investigation that occurred at (b)(4)) starting 11/04/2019. On 11/21/2019, HAF 3W provided a response from (b)(4) that the exposure data provided to them by CDC did not provide a clear indication of what potato supplier or manufacturer of potato-containing frozen products may be in common among the cases. On 11/22/2019, CORE requested that HAF 3W reach out to (b)(4) for manufacturer information for specific products purchased at (b)(4) as reported by case patients. On 11/27/2019, CORE provided an update and list of potential actions to the incident group for review which were: follow-up with (b)(4) regarding manufacturer information, follow-up with (b)(4) and associated firms in (b)(4), CO, and pursue a possible hypothesis that potato starch used in frozen foods and shredded cheese may be the source of *L. monocytogenes*. Also on 11/27/2019, CORE requested sampling of potato starch at (b)(4)) in conjunction with an already scheduled inspection in response to an RFR indicating *L. monocytogenes* was recovered from the company's shredded cheese; at this time there is no indication that this event is linked to the current outbreak investigation. On 12/2/2019 HAF 2E (PHI) reported collecting potato starch from (b)(4) for *L. monocytogenes* testing at Southeast Food and Feed Lab. Additionally, the original isolate leading to this RFR was sent to the FDA Arkansas Lab for whole genome sequencing.**

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: Erin Jenkins Position/Title: Planning Chief Signature: Erin Jenkins

8. Approved by Incident Commander: Name: Brooke Whitney Signature: Brooke Whitney

ICS 202	IAP Page _____	Date/Time: 12/3/2019 Eastern Time: 3:30

Updated by FDA 2/2011

INCIDENT OBJECTIVES (ICS 202), Adapted for FDA

1. Incident Name: *Listeria monocytogenes* (1702MLGX6-1)/Unknown/Oct 2019 EON-405644	2. Operational Period: Date From: 11/14/2019 Time From: 1400 ET Date To: 12/03/2019 Time To: 1400 ET

3. Objective(s):

(b)(5)

4. Operational Period Command Emphasis:

General Situational Awareness:

Operational Period #1: CORE and CDC are continuing to evaluate the persistent strain of *Listeria monocytogenes* associated with cluster 1702MLGX6-1, and on 11/7/2019 the incident was transferred to CORE Response Team 1. As of 11/14/2019, there are 55 reported cases in this cluster from 19 states: AL (6), AR (3), AZ, CO, FL (3), GA (7), IN, KS, KY, LA (2), MO (3), NC, NE, NM, OH, OK (5), PA, TX (15), WV (1). Patients range in age from 0-104 years (median 61); 31 (57%) patients are female. Forty-eight patients have been hospitalized and there are five reported deaths. Fourteen illnesses are pregnancy-associated and four resulted in fetal loss. This cluster was previously investigated in 2017 and 2018, but no vehicle was confirmed during the outbreak response. CDC closed the cluster investigation in early 2019 and since then, 14 new clinical matches with this strain have been identified. Isolation dates range from 9/16/2011 - 9/4/2019. All isolates in the cluster are highly related by WGS (within 0-24 alleles, median 5 alleles), including clinical isolates as well as several U.S. potato isolates tested by SENASICA in 2015-2016 and uploaded to NCBI in 2018, which was a focus of last year's investigation. Currently, no suspect vehicle has been identified. Case-patients have been interviewed using several approaches including the *Listeria* Initiative questionnaire, open-ended interviews, and two different supplemental questionnaires including questions about processed frozen foods and potato products. Many cases have reported lower-cost foods and frozen foods, including frozen meals and frozen snack foods, as well as fresh, frozen, and refrigerated potato products, although no specific brand or food item is standing out. A majority of cases [26/40 (65%)] with grocery store information available have reported (b)(4) or (b)(4) in common. On 11/8/2019, CDC hosted a call with (b)(4) to discuss the epidemiologic information gathered thus far. CORE participated in the call, but no specific ask or information request was made. On 11/12/2019, CDC formally re-opened the investigation for this cluster (1702MLGX6-1).

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: Erin Jenkins Position/Title: Planning Chief Signature: _

8. Approved by Incident Commander: Name: Brooke Whitney Signature:

ICS 202	IAP Page _____	Date/Time: Eastern Time: 11/15/2019; 1445 ET