

# Listeria monocytogenes Illness Outbreak Associated with Ready-to-Eat, Country-Cured Ham, 2017–2018

## After-Action Review Report 2018-16

May 13, 2020

### Overview

During April–November 2018, public health officials from Virginia, North Carolina, the Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA), and the Food Safety and Inspection Service (FSIS) investigated an outbreak of four reported *Listeria monocytogenes* illnesses linked to ready-to-eat country-cured ham manufactured at Establishment A. One death was reported from Virginia. This was the first reported multistate outbreak of listeriosis associated with an FSIS-regulated product since 2005; whole genome sequencing (WGS) was instrumental in detecting this outbreak and determining its source. Routine FSIS product and environmental sampling indicated the historical presence of *L. monocytogenes* in Establishment A. Three ham samples collected routinely by FSIS during 2016–2018 were positive for the outbreak strain of *L. monocytogenes*. An FSIS environmental assessment at Establishment A revealed the potential for cross-contamination and that the final cook-in-bag step may have been insufficient to address *L. monocytogenes* contamination for a product with a lower water activity. On October 3, 2018, Establishment A voluntarily recalled the implicated ham products. In response to this outbreak, FSIS plans to update Directive 10,240.4, Verification Activities for the *Listeria monocytogenes* Regulation and the Ready-to-Eat (RTE) Sampling Program. Additionally, FSIS added a related study to its Food Safety Research Priorities on the FSIS website and plans to update its “Appendix A” cooking guidance in 2020.

### Epidemiology

- Investigators used WGS to assess the relatedness of *L. monocytogenes* isolates and determine the outbreak strain.
- On April 23, 2018, FSIS noted that *L. monocytogenes* isolates from ham samples collected from Establishment A were genetically similar by WGS to *L. monocytogenes* isolated in July 2017 from an ill person.
- During June–August 2018, FSIS was notified of three additional ill people with the outbreak strain of *L. monocytogenes* (a total of four cases of illness; see Table 1 for epidemiologic details).
- Among the three ill people with exposure information, three (100%) reported consuming deli ham or other deli meat from a grocery store or restaurant.
  - The fourth ill person, who could not be interviewed, was a resident of an assisted living facility; the investigation revealed that ready-to-eat, country-cured ham was served at this facility.

**Table 1.** Case characteristics—*Listeria monocytogenes* illness outbreak associated with ready-to-eat, country-cured ham, 2017–2018.

Total number of cases and states of residence	4 cases from 2 states (see <a href="#">CDC map of reported cases</a> )
Date range for when <i>L. monocytogenes</i> was isolated from cases	July 8, 2017—August 11, 2018 (see <a href="#">CDC timeline of reported cases</a> )
Age range (median) in years	70-81 (76)
Percent female	50
Number of reported hospitalizations	4
Number of reported deaths	1 (Virginia resident)

### Traceback

- FSIS and North Carolina officials conducted a traceback investigation and determined that the common source of implicated ready-to-eat, country-cured ham products was Establishment A in North Carolina.

### Environmental Assessment

FSIS conducted food safety assessments at Establishment A in May 2018 and September 2018 and identified factors that may have contributed to the outbreak, including:

*L. monocytogenes* harborage

- Sampling results suggested the persistent presence of *L. monocytogenes* in Establishment A since 2002 (see **Product and Environmental Sampling**).

#### *Potential cross-contamination*

- The implicated product was considered to have not been exposed to the processing environment after undergoing an initial cook-in-bag lethality step to inactivate vegetative pathogens, including *L. monocytogenes*. However, the investigation revealed that the product was, in fact, exposed to the processing environment after cooking, which may have allowed the product to become contaminated with *L. monocytogenes*.
  - After an initial cooking step in a sealed bag, the ham was removed from the bag, drained of its juices, and placed into a second bag; during this process, the ham may have been cross-contaminated from the processing environment.
  - After being placed in the second bag, the ham and bag were placed into metal molds, the top of which was pressed down to form the ham, then re-cooked. In some instances, this process led to tears in the bag, which allowed the cooked ham to be exposed to the processing environment again. Products in bags in which tears were identified were removed from the torn bags, drained of any remaining juices, and placed into another bag for re-cooking.

#### *Possible insufficient lethality during cooking*

- Before being cooked multiple times, the ham was salt-cured and dried, thus lowering its water activity. Additionally, the draining of juices may have resulted in drier conditions during cooking. The establishment used FSIS cooking guidance (“Appendix A”) as scientific support that the cooking process achieved lethality of pathogens, including *L. monocytogenes*. However, Appendix A guidance was not intended for lower water activity products cooked under dry conditions or for products cooked multiple times. *L. monocytogenes* may survive cooking under these conditions. Hence, the process may not have been lethal to *L. monocytogenes*.

### **Product and Environmental Sampling**

- During 2002–2018, the following samples collected by FSIS during routine inspection activities were positive for *L. monocytogenes*, suggesting harborage at Establishment A:
  - Seven samples of ham produced by Establishment A; three of these, collected during May 2016–March 2018, were positive for the outbreak strain of *L. monocytogenes*.
  - Eight environmental samples from Establishment A. After an initial cooking step in a sealed bag, the ham was removed from the bag, drained of its juices, and placed into a second bag; during this process, the ham may have been cross-contaminated from the processing environment.

### **Industry, Public Health, and Regulatory Actions**

- During the investigation, Establishment A voluntarily ceased production of the ready-to-eat, country-cured ham products.
- Establishment A voluntarily recalled approximately 89,096 pounds of ready-to-eat ham products (produced during April 3, 2017–October 2, 2018) on October 3, 2018.
- As a result of this initial recall, there were four additional recalls of products that were made using the recalled ham products or that came into contact with equipment used to process the recalled ham products (one recall of FSIS-regulated products: October 5, 2018; three recalls of FDA-regulated products: October 4, 2018 , October 4, 2018 , and October 5, 2018 ).
- CDC published a Food Safety Alert about this outbreak on October 4, 2018 (final update December 18, 2018 ).

### **Lessons Learned and Related Policy Actions**

#### *WGS and outbreak surveillance*

- This was the first reported multistate outbreak of *L. monocytogenes* illnesses associated with FSIS-regulated product since 2005. With the advent of WGS, more *L. monocytogenes* illness outbreaks are being detected in recent years than in the past.

#### *Routine product and environmental sampling*

- The outbreak strain of *L. monocytogenes* was found in FSIS samples of ham produced by Establishment A that were collected routinely before the outbreak was recognized; this helped identify the source of the outbreak. Additionally, *L. monocytogenes* was found in other Establishment A product and environmental samples collected by FSIS before the outbreak investigation, which demonstrated *L. monocytogenes* harborage at Establishment A. These findings highlight the value of routine product and environmental sampling. This outbreak likely would not have been detected, nor its cause determined, without WGS.

#### *Traceback*

- When records are collected for a traceback investigation, considerations for the timeframe of records requested include workload burden imposed on businesses. During the initial traceback investigation at the assisted living facility where an ill person resided, the records obtained focused on

the most likely period of product receipt. These initial records indicated the facility had not received the product in question. Later, the scope of the records request was expanded to include additional records covering a longer timeframe. These additional records showed that the facility had, in fact, received the product in question. During traceback investigations, if the product is not identified in the initial focused records request, the scope should be expanded based upon product shelf life and pathogen incubation period.

#### *Preventing cross-contamination*

- Evidence from this outbreak investigation suggests that the ham may have become contaminated with *L. monocytogenes* from the processing environment at Establishment A. *L. monocytogenes* had been previously isolated from products produced by Establishment A and from its processing environment. *L. monocytogenes* harborage should be concerning even for products that are considered to not be exposed to the processing environment after undergoing a lethality step for *L. monocytogenes*. In response, FSIS plans to update [Directive 10,240.4, Verification Activities for the \*Listeria monocytogenes\* Regulation and the Ready-to-Eat \(RTE\) Sampling Program](#) to include additional instructions for its inspection program personnel regarding:
  - Verification of a product that is considered to not be exposed to the processing environment after undergoing a lethality step; and
  - Verification of an establishment's corrective actions in response to a finding of harborage.

#### *Proper cooking*

- The outbreak investigation indicated that the ham may not have received sufficient lethality treatment for *L. monocytogenes*. In response:
  - FSIS plans to update its cooking guidance in 2020 to clarify that [Appendix A](#) is not appropriate scientific support for lower water activity products cooked under dry conditions or for lower-water activity products cooked multiple times.
  - FSIS added a related study to its [Food Safety Research Priorities](#) on the FSIS website to promote needed research on this topic: "Determine whether sufficient lethality of *Listeria monocytogenes* and *Salmonella* is achieved for low water activity cured meat products such as country cured hams cooked using Appendix A time/temperature recommendations under high humidity conditions."

#### *Communication between partners*

- In general, partner agencies communicated well during this investigation, which facilitated the product recalls. Collaboration between FSIS and public health partners early in the investigation can assist with outbreak investigations. As described in the [Template for Including FSIS in Foodborne Illness Outbreak Response Procedures](#), when an outbreak associated with FSIS-regulated products occurs, FSIS encourages state agencies to include FSIS in the investigation by contacting the Office of Public Health Science (email: [FoodborneDiseaseReports@usda.gov](mailto:FoodborneDiseaseReports@usda.gov)) as well as local and [Regional contacts](#) in the Office of Investigation, Enforcement and Audit.
- When bacterial isolates from FSIS product or environmental samples are closely related by molecular subtyping (e.g., WGS) to isolates from ill people, it can be helpful for public health partners to know information about the establishment from which the sample was collected. Information about the establishment's product brands can be particularly helpful because brand information can increase the quality of exposure data collected via interviews of ill people and can speed identification of the suspect food vehicle. Through its established information-sharing process (FSIS [Directive 2620.5](#)), FSIS has decreased the time required to share information related to an outbreak investigation, including the number, name, and doing-business-as names of an establishment where a sample was collected and product brand information. However, barriers to sharing brand information remain and were encountered during this investigation. These barriers included commercial confidentiality concerns and the time required to gather brand names related to the samples, particularly when the sample was collected several years previously. FSIS should work to more rapidly share brand information, when possible, and public health partners should request such information as early as is feasible.
- After-action reviews shortly following the investigation are helpful for public health partners to understand the outcomes of the outbreak investigation and the purpose of the response work.

#### **Helpful Links**

- FSIS-regulated product recalls
  - [Recall 084-2018, October 3, 2018](#) (Establishment A)
  - [Recall 087-2018, October 5, 2018](#)
- FDA-regulated product recalls
  - [Recall, October 4, 2018](#)
  - [Recall, October 4, 2018](#)
  - [Recall, October 5, 2018](#)
- CDC Food Safety Alert, October 4, 2018 ([final update December 18, 2018](#) )
- [FSIS Directive 10,240.4, Verification Activities for the \*Listeria monocytogenes\* Regulation and the Ready-to-Eat \(RTE\) Sampling Program](#)
- [FSIS Food Safety Research Priorities](#)
- [FSIS \*Salmonella\* Compliance Guidelines for Small and Very Small Meat and Poultry Establishments that Produce Ready-to-Eat \(RTE\) Products and Revised Appendix A](#) (June 2017)
- [FSIS Directive 2620.5, Sharing Information with State or Local Agencies, Foreign Government Officials, and International Organizations](#)

