

Salmonella enterica serotype I 4,[5],12:i:- Illness Outbreaks Associated with Pork Products, 2015-2016

After-Action Review Report 2015-18/2016-13

October 26, 2017

Overview

During 2015-2016, the Washington State Department of Health (WADOH), the Centers for Disease Control and Prevention (CDC), and FSIS investigated two outbreaks of *Salmonella* I 4,[5],12:i:- infections linked to pork products produced by Establishment A, a federally inspected establishment. The first outbreak occurred during July through October 2015, resulting in a recall of whole hogs for barbeque and targeted FSIS sampling at the establishment. FSIS isolated *Salmonella* from carcass and pre-operational food contact swabs and cecal contents, with isolates characterized as the outbreak strain as defined by serotyping and pulsed-field gel electrophoresis (PFGE) analysis. As a result, additional whole hogs and fabricated pork products were recalled and FSIS issued a Notice of Intended Enforcement (NOIE) to the establishment. An NOIE informs an establishment that there is a basis for FSIS to withhold the marks of inspection or to suspend inspection and it can present corrective actions and planned preventive measures to achieve compliance to FSIS within three business days. The establishment voluntarily closed its operation in August 2015 in response to the outbreak investigation. The establishment resumed operations in June 2016 after FSIS held the NOIE in deferral in response to the establishment's proffered corrective actions and preventive measures to reduce the risk of contamination and achieve compliance. Shortly after the establishment reopened in June 2016, a second outbreak investigation linked illnesses among attendees at early July 2016 pig roast events to this establishment. In response to the second outbreak, pork products were recalled, Establishment A voluntarily suspended operations, and FSIS rescinded its grant of inspection in response to the establishment's request. As a result of these outbreak investigations, FSIS is collaborating with public health partners, researchers, and industry to enhance its understanding of this important pathogen. Additionally, FSIS and the Animal and Plant Health Inspection Service (APHIS) are continuing discussions to improve processes and procedures specific to pre-harvest investigations.

2015 Outbreak

The 2015 outbreak included 192 case-patients from 5 states (AK, CA, ID, OR, WA) with 96% (184/192) of case-patients from the state of Washington. Case-patient onset dates ranged from April 25, 2015 through October 6, 2015 (Figure 1); 49% (95/192) were male; the median age was 35 years (range: <1-90 years); and 17% (30/180) were hospitalized. Case-patients were infected with *Salmonella* I 4,[5],12:i:- with one of the following PFGE patterns: JPXX01.1314, JPXX01.2429, JPXX01.3161, JPXX01.2311, and JPXX01.3336; or *Salmonella* Infantis with PFGE pattern JFXX01.0046. Whole genome sequencing (WGS) was conducted and showed that isolates of all 5 *Salmonella* I 4,[5],12:i:- PFGE patterns were highly related to one another, and that all of the *Salmonella* Infantis isolates were highly related to one another. Antimicrobial susceptibility testing was conducted on 21 clinical isolates; 95% (20/21) were resistant to ampicillin, streptomycin, sulfisoxazole, and tetracycline (ASSuT resistance profile); 5% (1/20) had the ASSu resistance profile. 76% (94/123) of case-patients reported eating pork in the week before becoming ill; case-patients were exposed to pork at one of several different events, including sub-clusters associated with restaurants/caterers and at hog roasts (Table 1). CDC responded to a WADOH request for federal government assistance by joining state and local public health officials in Washington for the investigation as part of an Epi-Aid; an FSIS staff was invited to be part of the Epi-Aid.

Traceback

- Traceback by FSIS confirmed that 59% (55/94) of case-patients who consumed pork reported consuming pork produced by Establishment A.
 - Many of these case-patients consumed pork from whole hogs that were purchased raw from Establishment A and cooked at hog roasts.
 - Additional case-patients may have consumed pork from Establishment A, but this was not verified due to a lack of product purchase information.
- Multiple case-patients did not report consuming pork, but purchased other foods at locations that received pork products from Establishment A.
 - Seattle & King County Public Health inspected these locations and identified cross-contamination and other food handling violations, indicating that cross-contamination from pork to other products may have been the source of illness in these case-patients.

Sampling

- FSIS collected 16 environmental, 14 carcass swab, and 8 cecal samples from Establishment A.
 - 100% (14/14) of carcass swabs were *Salmonella* positive and 43% (6/14) were identified as the outbreak strain of *Salmonella* I 4,[5],12:i:- or Infantis.
 - 100% (8/8) of the cecal samples were *Salmonella* positive and all of them were identified as the outbreak strain of *Salmonella* I 4,[5],12:i:-.
 - 50% (8/16) of the environmental samples (including pre-operational food contact surface) were *Salmonella* positive, and 75% (6/8) were identified as the outbreak strain of *Salmonella* I 4,[5],12:i:- or Infantis.
 - 93% (14/15) of the *Salmonella* I 4,[5], 12:i:- outbreak strains exhibited the ASSuT resistance profile.

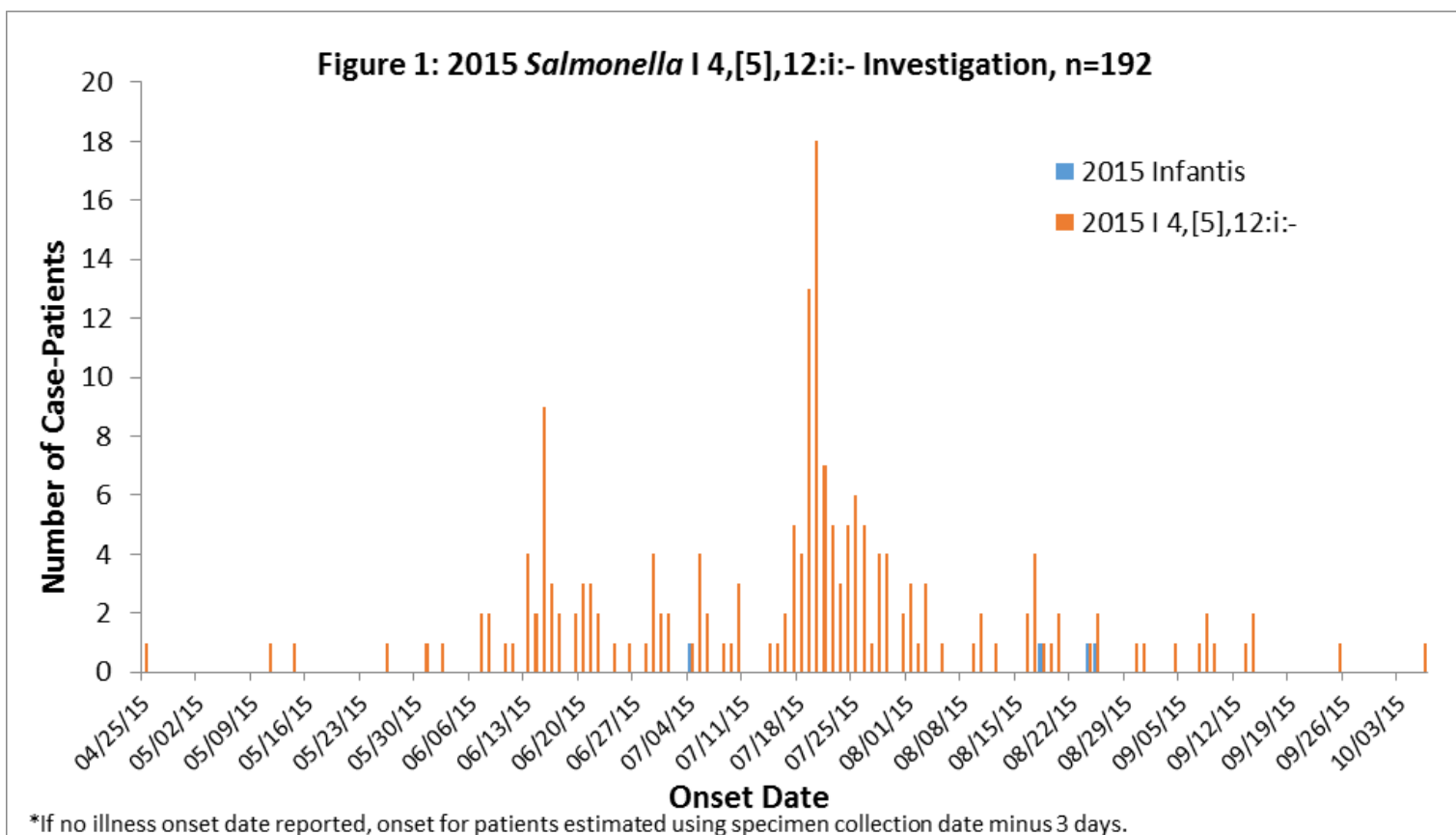
Regulatory Actions

- Following a Public Health Alert, the establishment initially recalled specific lots of whole hogs produced on various dates between April 18, 2015 and July 27, 2015 and later issued an expansion that included additional whole hogs and fabricated pork products produced on various dates between April 18, 2015 and August 26, 2015.
- FSIS issued an NOIE to Establishment A on August 11, 2015. The establishment remained under the NOIE until withdrawal from the grant of inspection.

Establishment Actions

- Establishment A voluntarily suspended operations on August 26, 2015 until June 13, 2016.
- The establishment hired a consultant and worked with FSIS field inspectors to assess procedures, ensure compliance with FSIS guidelines, and improve its slaughter processes. Actions taken by the establishment included:
 - Ensuring understanding of typical pre-evisceration and post-chill levels of *Salmonella*, based on the FSIS Market Hogs Survey.
 - Applying recommended sanitation best practices to scalding and singeing steps.
 - Antimicrobial intervention and verification sampling procedures to address *Salmonella*.
 - Chilling carcasses to a specific temperature within a defined time period and maintaining refrigeration throughout commerce
- Establishment A began producing roaster hogs again in June 2016.

Figure 1: 2015 *Salmonella* 14,[5],12:i:- Investigation, n=192



2016 Outbreak

The 2016 outbreak included 15 case-patients from Washington. Case-patient onset dates ranged from June 1, 2016 to August 10, 2016; 67% (10/15) were male; the median age was 26 years (range: 8-72); and none were hospitalized. Case-patients were infected with *Salmonella* 14,[5],12:i:- with PFGE pattern JPXX01.1314. Antimicrobial susceptibility testing was conducted on 3 clinical isolates and all had the ASSuT resistance profile. Among the case-patients with available information, 93% (13/14) reported pork exposure, with most case-patients (90%, 9/10) reported eating pork at hog roasts held on July 2, 2016 or July 3, 2016.

Traceback

- Traceback conducted by WADOH and FSIS identified Establishment A as the supplier for two hog roasts where case-patients were exposed to contaminated product.

Sampling

(Note: All samples were collected 7-10 days after the establishment had ceased operations)

- FSIS collected 40 environmental and 20 carcass swab samples from Establishment A.

- o 20% (4/20) of the carcass samples were *Salmonella* positive and 75% (3/4) were identified as the outbreak strain of *Salmonella* I 4,[5], 12:i:-, which exhibited the ASSuT resistance profile.
- o 3% (1/40) environmental sample was found to be positive, and it was also identified as an outbreak strain of *Salmonella* I 4,[5],12:i:-, which exhibited the ASSuT resistance profile (*Note: Environmental samples were held longer than typical for that type of sample prior to analysis, which may have affected recovery of Salmonella*).
- o WGS analyses performed by FSIS demonstrated that isolates from Establishment A were highly related to Washington case-patients from both 2015 and 2016 outbreaks.

Regulatory Actions

- o Following a [Public Health Alert](#), the establishment recalled approximately 11,658 pounds of pork products.

Establishment Actions

- o Establishment A voluntarily suspended operations and consulted with FSIS regarding additional improvements to their processes and decreasing contamination of their product.
- o The last day the establishment operated was on August 11, 2016.

Table 1: Summary of 2015 and 2016 Outbreak Investigations

| | 2015 | 2016 |
|-------------------------------------|--|-------------------|
| States | AK, CA, ID, OR, WA | WA |
| Case Counts | 192 | 15 |
| Illness Onset Dates | 4/25/15 to 10/6/15 | 6/1/16 to 8/10/16 |
| Hospitalization | 17% | 0% |
| Gender | 49% male | 67% male |
| Age Range (Median) | <1–90 (35) | 8-72 (26) |
| PFGE Pattern(s) | JPXX01.1314, JPXX01.2429, JPXX01.3161, JPXX01.2311, JPXX01.3336; JFXX01.0046 (<i>Salmonella</i> Infantis) | JPXX01.1314 |
| Antimicrobial Susceptibility | ASSuT | ASSuT |
| Pork Exposure | 76% | 93% |

Lessons Learned

- o CDC and Washington included FSIS in an Epi-Aid which promoted collaboration and data sharing, which alleviated some of the communication challenges encountered early on during the 2015 investigation; CDC plans to consider inviting FSIS participation for future Epi-Aids.
- o Early notification of outbreak from Washington in addition to availability of specific purchase and product information enabled FSIS to conduct timely traceback that shortened the time from outbreak notification to recall action in 2016.
- o Timely and frequent communications among FSIS program areas and with federal and state partners are essential for decision-making with clear understanding of roles and responsibilities to facilitate root cause analysis and eliminate the source of contamination.

Policy-Related and Follow-up

- o In [December 2016](#), FSIS published guidelines on safe transport, preparation, cooking, and packing leftovers regarding pig roasts.
 - o During 2015, and prior to the outbreak investigation, FSIS began national [exploratory sampling](#), which is intended to estimate the national prevalence of *Salmonella* in pork products that may be used to establish performance standards and provide industry guidance: Includes sampling of intact and non-intact whole muscle and comminuted pork products;
 - o Results were used to inform the development of a baseline study for these products to:
 - Determine prevalence of *Salmonella* and other bacterial organisms in pork products
 - Inform policy decisions which could include establishing a performance standard or other guidance for industry

- Phase 1 of this exploratory sampling project was completed in November 2015; phase II began on June 1, 2017. The agency has been conducting interim analyses for *Salmonella* between Phase 1 and the start of the baseline study (January 2016 through April 2017).
 - In FY2016, 12% (97/694) intact cuts of pork products tested positive for *Salmonella*; samples were collected from 188 establishments.
- In 2014, a Memorandum of Understanding (MOU) was signed between FSIS and APHIS to assess the root cause of foodborne outbreaks related to FSIS-regulated products.
 - FSIS and APHIS are continuing discussions to improve processes and procedures specific to pre-harvest investigations.
- Since January 2017, APHIS has been participating in FSIS' weekly meeting that discusses ongoing foodborne illness investigations.

Available Guidance for Industry

- Compliance Guideline for Controlling *Salmonella* in Market Hogs
- Notice 30-17, Raw Pork Products Sampling Program Phase II
- The Nationwide Microbiological Baseline Data Collection Program: Market Hogs Survey August 2010 – August 2011

Additional Information for Consumers

- Public Health Alert, July 31, 2015
- Public Health Alert, July 20, 2016
- Recall and Expansion
 - Recall 110-2015, August 13, 2015
 - Recall 110-2015 expansion, August 27, 2015
 - Recall 062-2016, July 21, 2016
- CDC final web posting for Multistate Outbreak of Multidrug-Resistant *Salmonella* I 4,[5],12:i:- and *Salmonella* Infantis Infections Linked to Pork, December 2, 2015
- Pig Roasting and Food Safety, December 21, 2016

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