

# E. coli O157:H7 Illness Outbreak Associated with Ground Beef, 2019

## After-Action Review Report 2020-04

July 21, 2020

### Overview

During November–December 2019, public health officials in Oregon and Washington states, the Centers for Disease Control and Prevention (CDC), and the Food Safety and Inspection Service (FSIS) investigated an outbreak of five confirmed *E. coli* O157:H7 illnesses associated with ground beef. The ill people reported consuming ground beef produced by three retailers (Retailers A, B, and C). The majority of the ill people reported consuming undercooked ground beef. There are minimal safety concerns with intact cuts (e.g., steaks that are not mechanically tenderized) externally contaminated with *E. coli* O157:H7 because normal consumer cooking to a rare or medium internal state will eliminate pathogens on the exterior. Ground beef and mechanically tenderized steaks, however, are higher-risk products because pathogens may move throughout the product and consumer cooking to a rare or medium internal state will not eliminate all *E. coli* O157:H7.

Retailers A and B produced raw, ground beef using whole cuts of beef that were intended for intact use without implementing additional measures to control *E. coli* O157:H7. This practice poses a food safety concern because beef-producing establishments typically apply more stringent methods to control *E. coli* O157:H7 in beef intended for non-intact use (e.g., ground beef and mechanically tenderized steaks) than in beef intended for intact use. Retailers A, B, and C produced ground beef using beef received from multiple establishments; however, one establishment (Establishment D) was a common supplier to all three retailers. Retailers A and B did not maintain complete and accurate grinding records in accordance with federal regulations, which prevented investigators from definitively determining the specific source material that had been used to produce the implicated ground beef and resulted in FSIS issuing Notices of Warning letters to the retailers. Three samples collected by Oregon officials of beef produced by Retailer A using material from Establishment D tested positive for the outbreak strain of *E. coli* O157:H7.

Retailer A voluntarily ceased selling retail-produced ground beef on November 8, 2019 and issued a [recall](#) on November 9, 2019. Oregon state public health officials issued press releases about this investigation on [November 10, 2019](#) and on [November 14, 2019](#). Prompt action by industry and public health officials likely prevented additional illnesses.

The findings of this outbreak investigation underscore that opportunities for enhancing food safety exist at multiple levels and highlight the need for continued illness-prevention efforts in three areas:

- [Retailer Requirements and Best Practices for Beef Grinding](#): Retailers and official establishments that grind beef are required to maintain complete and accurate grinding records ([9 CFR 320.1 \(b\)\(4\)](#)), and should follow best practices for grinding.
- [FSIS-Regulated Establishments and Retailers Addressing the Risk of \*E. coli\* O157:H7](#): Establishments that produce beef intended for non-intact use should address *E. coli* O157:H7 in their food safety systems, and establishments that produce beef for intact use should verify that the beef is being used as intended. Retailers can reduce the risk of *E. coli* O157:H7 adulteration by not using beef intended for intact use to produce ground beef or, alternatively, by implementing additional controls when grinding beef that was originally intended for intact use.
- [Consumer Education – Fully Cooking Ground Beef](#): Ground beef should be cooked to the recommended internal temperature of 160°F (71.1°C), as measured by a [food thermometer](#), before being consumed.

In response to this outbreak, both [FSIS](#) and the [Oregon Department of Agriculture \(ODA\)](#) submitted issues regarding retail beef grinding to the 2020 Conference for Food Protection (CFP), including a recommendation to update the CFP retail beef grinding guidelines. Updated guidelines will help increase awareness of record-keeping requirements and promote the adoption of best grinding practices among retailers.

### Epidemiology

- Investigators used whole genome sequencing (WGS) to assess the relatedness of *E. coli* O157:H7 isolates from illness cases and beef products and to determine the outbreak strain.
- On November 8, 2019, the Oregon Health Authority (OHA) notified FSIS of three confirmed cases of illness with the outbreak strain of *E. coli* O157:H7.
- Two additional confirmed cases with the outbreak strain were subsequently reported, for a total of five confirmed cases as of December 19, 2019. (See Table 1 and Figure 1 for epidemiologic details).
- All five (100%) cases reported consuming ground beef.

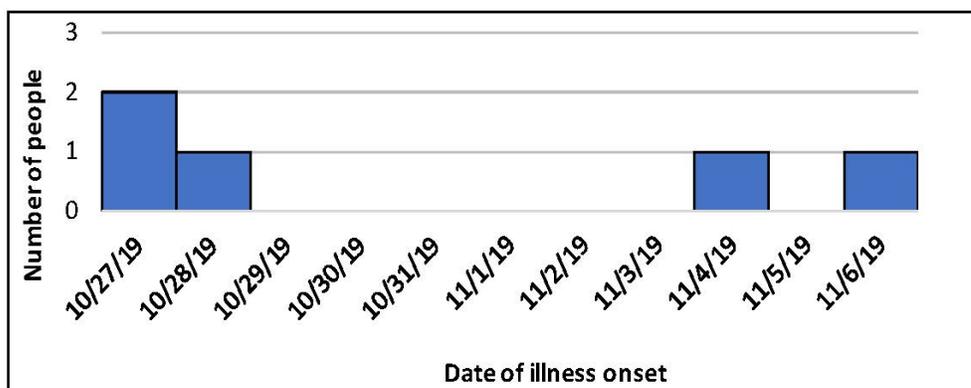
- o Four cases reported consuming ground beef purchased from Retailer A (three different locations).
- o One case reported consuming ground beef purchased from two different retailers, Retailer B (one location) and Retailer C (one location).
- o Four (80%) of the five confirmed cases reported consuming ground beef that had not been thoroughly cooked.
- By contacting customers of Retailer A, Oregon officials identified 59 additional presumptive (non-confirmed) cases based on their symptoms and link to Retailer A (per OHA [case definitions](#) ).

**Table 1.** Confirmed case characteristics—*E. coli* O157:H7 illness outbreak associated with ground beef, 2019.

Total number of cases and states of residence	5 confirmed cases from 2 states (4 in Oregon and 1 in Washington)*
Illness onset date range	October 27–November 6, 2019 (see Figure 1)
Age range (median) in years	8–90 (10)
Percent female	20
Number of reported hospitalizations	1
Number of reported deaths	0

\*59 additional [presumptive cases](#) were identified in Oregon.

**Figure 1.** Confirmed cases of illness with the outbreak strain of *E. coli* O157:H7 associated with ground beef, 2019, by illness onset date.



### Product Sampling

- Oregon officials collected and tested 20 samples of ground beef and beef trim from Retailer A that was produced using material from Establishments D, E, and F. Among these, 2 samples of beef (1 ground beef and 1 beef trim) produced by Retailer A using material from Establishment D were positive for the outbreak strain of *E. coli* O157:H7.
  - o Among 12 samples of ground beef, 1 tested positive for the outbreak strain.
  - o Among 8 samples of beef trim, 1 tested positive for the outbreak strain.
- Additionally, Oregon officials collected and tested 9 samples of beef products that customers had purchased from Retailer A and later returned after the recall was issued. Among these, 1 sample of ground beef that had been produced by Retailer A using material from Establishment D, was returned by a non-ill customer and tested positive for the outbreak strain of *E. coli* O157:H7.

### Environmental Assessment and Traceback Investigation

#### Traceback and Retail Grinding Assessment

- FSIS investigators visited multiple firms to conduct a traceback investigation and assess grinding practices, including Retailers A (three locations), B (one location), and C (one location). These retailers produced ground beef using beef received from multiple establishments, including one establishment (Establishment D) that supplied beef to all three retailers. Due to the lack of complete and accurate grinding records and the lack of microbiological independence between different beef sources at two of the retailers, investigators were not able to definitively determine the specific source material associated with illnesses or with the samples that tested positive for the outbreak strain.

### *Retailer A*

- The three locations of Retailer A produced raw, ground beef using beef intended for intact use supplied by two FSIS-regulated establishments (Establishments D and E) and one eligible importing foreign-country establishment (Establishment F) and did not implement additional controls for *E. coli* O157:H7. Retailer A was not aware of the intended use of the supplied beef; the bill of lading stating the intended use was not forwarded to the retailer from a distributor and this information was not otherwise relayed to the retailer.
- None of the three Retailer A locations maintained adequate grinding records nor maintained microbiological independence between the use of beef from different sources.

### *Retailer B*

- Retailer B produced raw, ground beef using beef intended for intact use supplied by Establishment D and other suppliers; Retailer B did not implement additional controls for *E. coli* O157:H7 and was not aware of the intended use of the supplied beef.
- Retailer B did not maintain adequate grinding records or maintain microbiological independence between the use of beef from different sources.

### *Retailer C*

- Retailer C produced raw, ground beef using non-intact (pre-ground) beef supplied by Establishment D and other suppliers.
- Retailer C maintained adequate grinding records and maintained microbiological independence between the use of beef from different sources.

### Assessment of Beef-Producing Establishments

- FSIS performed food safety assessments at Establishments D and E and did not identify evidence that would support FSIS taking regulatory control actions related to the outbreak.

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

- Based on epidemiologic evidence, Retailer A voluntarily ceased selling ground beef produced in-store on November 8, 2019. On November 9, 2019, Retailer A recalled all fresh, in-house ground beef and products made with fresh in-house ground beef with pack dates of October 19–23, 2019. Based on Oregon's sampling evidence, Retailer A subsequently expanded the recall on November 13, 2019 to include all fresh in-house ground beef products packed during October 19, 2019–November 8, 2019 and expanded the recall again on November 15, 2019 to include all fresh and frozen beef products with pack dates of October 19, 2019–November 15, 2019.
- Oregon officials issued press releases regarding the outbreak investigation on November 10, 2019 and on November 14, 2019.
- FSIS issued four Notices of Warning letters to Retailer A (three different locations) and Retailer B (one location) as a result of not maintaining grinding records in accordance with federal regulations.

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

#### Collaboration and Response

- Oregon public health officials rapidly notified Retailer A of the outbreak; prompt actions by Retailer A and Oregon public health officials, initially based upon epidemiologic evidence alone, likely prevented additional cases.
- Oregon public health officials quickly notified FSIS, which allowed FSIS to join the investigation early in the process.

#### Epidemiology

- Confirmed cases in an outbreak may comprise only a fraction of the actual number of outbreak-associated illnesses. In this outbreak investigation, by identifying additional presumptive cases through active case-finding, Oregon public health officials better defined the potential extent of the outbreak.

#### Retailer Requirements and Best Practices for Beef Grinding

- The lack of adequate retail grinding records prevented investigators from definitively determining the source material associated with illness. Retailers and other businesses that produce ground beef are required to maintain complete and accurate beef grinding records, including records of sanitation.

- Some retailers did not maintain microbiological independence between different sources used to produce the ground beef. Microbiological independence establishes the basis for which products are, or are not, implicated in response to positive results, recalls, outbreaks, etc. Production lots should be defined such that if an *E. coli* O157:H7–positive result is found for one production lot, product from another production lot would not be implicated. Two such production lots are referred to as “microbiologically independent.” Methods used to support microbiological independence may include, but are not limited to, robust sampling and testing data, application of antimicrobial interventions, and equipment sanitation. Establishing microbiological independence between lots can limit the scope of product affected by contamination and helps investigators determine the source material linked to illness.
- In collaboration with public health partners, FSIS is strengthening its outreach to encourage retailers to maintain complete and accurate beef grinding records and follow best practices for grinding.

#### Addressing the Risk of *E. coli* O157:H7

##### *Intended Use*

- In this outbreak investigation, investigators noted that retailers used beef that the producing establishment intended for intact use to produce raw ground beef, which most likely contributed to illness. FSIS is aware of five previous illness outbreaks in which using beef in a manner other than its intended use may have contributed to illness.
- The safety concerns associated with any raw beef product are based on how the product is intended to be consumed. There are minimal safety concerns with intact cuts (e.g., steaks that are not mechanically tenderized) externally contaminated with *E. coli* O157:H7 because normal consumer cooking to a rare or medium internal state will eliminate pathogens on the exterior. Ground beef and mechanically tenderized steaks, however, are higher-risk products because pathogens may move throughout the product and consumer cooking to a rare or medium internal state will not eliminate all *E. coli* O157:H7.
- Because of this difference, establishments often employ more rigorous controls to beef that will be consumed ground (or otherwise non-intact), when compared to intact beef. Therefore, a food safety concern can arise when a ground product is made from a product intended to be consumed intact.

##### *Establishments that Produce Beef*

- The findings of this investigation suggest that raw beef used to produce ground beef at retail was contaminated with *E. coli* O157:H7 when supplied to retailers. FSIS-regulated establishments that produce beef are required to address hazards, such as *E. coli* O157:H7, in their Hazard Analysis and Critical Control Point (HACCP) systems and to establish appropriate controls to prevent production of adulterated product. When using intended use to support decisions related to *E. coli* O157:H7, establishments that produce raw beef intended for intact use should have a system in place to ensure that customers and consumers are using the beef as intended. FSIS continues to consider how to best verify that FSIS-regulated establishments effectively address *E. coli* O157:H7.

##### *Distributors of Beef*

- Establishments and retailers cannot assume that intended use documentation will accompany the product as it goes through the distribution chain. Intermediate distributors of beef should ensure that all documentation regarding intended use continues to accompany the products throughout distribution.

##### *Retailers that Grind Beef*

- Retailers A and B were not aware of the beef’s intended use and the associated risk of the source materials used to make ground beef. As FSIS communicated in its 2020 CFP issue regarding intended use, based on 2019 data collected in conjunction with FSIS routine retail ground beef sampling, 83 percent of retailers used individually cryovaced packaged beef primals, sub-primals, or trim thereof (bench trim) to produce ground beef, while only 8 percent employed measures to mitigate *E. coli* O157:H7. Additionally, FSIS data suggest that a majority of retailers that produce ground beef are not aware of the source material’s intended use; therefore, they may be using beef intended for intact use only.
- In collaboration with public health partners, FSIS will continue educating retailers and regulated establishments on the risks of using beef intended for intact use to produce ground beef. Retailers can reduce the risk of *E. coli* O157:H7 adulteration by not using beef intended for intact use to produce ground beef without implementing additional controls when grinding beef intended for intact use.

##### *Conference for Food Protection (CFP)*

- In response to this outbreak and to support illness prevention efforts, [FSIS](#) and [ODA](#) each submitted issues to the 2020 CFP regarding retail beef grinding, including a recommendation to update the [CFP retail beef grinding guidelines](#). Also, FSIS previously submitted a related [issue](#) to the 2016 CFP.

### Consumer Education – Fully Cooking Ground Beef

- Cases reported consuming undercooked ground beef, which likely contributed to the outbreak. Undercooked ground beef is especially concerning because the grinding process may distribute pathogens existing on the surface of the meat throughout the product, and these pathogens can survive when ground beef is not thoroughly cooked. Public health agencies and food safety groups should continue to encourage consumers to cook ground beef until the internal temperature reaches 160°F (71.1°C), as measured by a food thermometer.

### **Helpful Links**

- [Recall](#) by Retailer A, November 9, 2019 (expanded November 13, 2019 and November 15, 2019)
- OHA Press Releases
  - [November 10, 2019](#)
  - [November 14, 2019](#)
- Conference for Food Protection
  - CFP [Guidance Document for the Production of Raw Ground Beef at Various Types of Retail Food Establishments](#)
  - Related CFP Issues:
    - FSIS: [2020 Council III-015](#) ; [2016 Council III-036](#)
    - ODA: [2020 Council III-016](#)
- *Federal Register* Notices
  - July 25, 1996: [Pathogen Reduction; Hazard Analysis and Critical Control Point \(HACCP\) Systems](#)
  - January 19, 1999: [Beef Products Contaminated with \*Escherichia coli\* O157:H7](#)
  - September 20, 2011: [Shiga Toxin–Producing \*Escherichia coli\*](#)
  - December 21, 2015: [Records to be Kept by Official Establishments and Retail Stores That Grind Raw Beef Products](#)
- FSIS Directives:
  - Directive 8010.1: [Methodology for Conducting In-Commerce Surveillance Activities](#)
  - Directive 10,010.1: [Sampling Verification Activities for Shiga Toxin–Producing \*Escherichia coli\* \(STEC\) in Raw Beef Products](#)
  - Directive 10,010.2: [Verification Activities for Shiga Toxin–Producing \*Escherichia coli\* \(STEC\) in Raw Beef Products](#)
- FSIS Guidance:
  - [FSIS Compliance Guideline for Minimizing the Risk of Shiga Toxin–Producing \*Escherichia coli\* \(STEC\) in Raw Beef \(including Veal\) Processing Operations – 2017 Compliance Guideline](#)
  - Fact sheet: [Ground Beef and Food Safety](#)
  - “askFSIS” Q&As:
    - [Adequate support for the intended use of beef primal and subprimal cuts](#)
    - [Supporting supply of raw beef intended for intact use](#)

*Last Modified Jul 21, 2020*