

FDA Update on Adjacent and Nearby Land Use (ANLU)

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Topics Covered

- 2020 Salmonella and Shiga Toxin-Producing *E. coli* (STEC) Outbreaks & Investigation Reports
 - Findings related to adjacent and nearby land use
- Leafy Greens STEC Action Plan
 - Adjacent and nearby land use efforts
- Overview of Selected Produce Safety Rule Requirements
- Summary and Resources



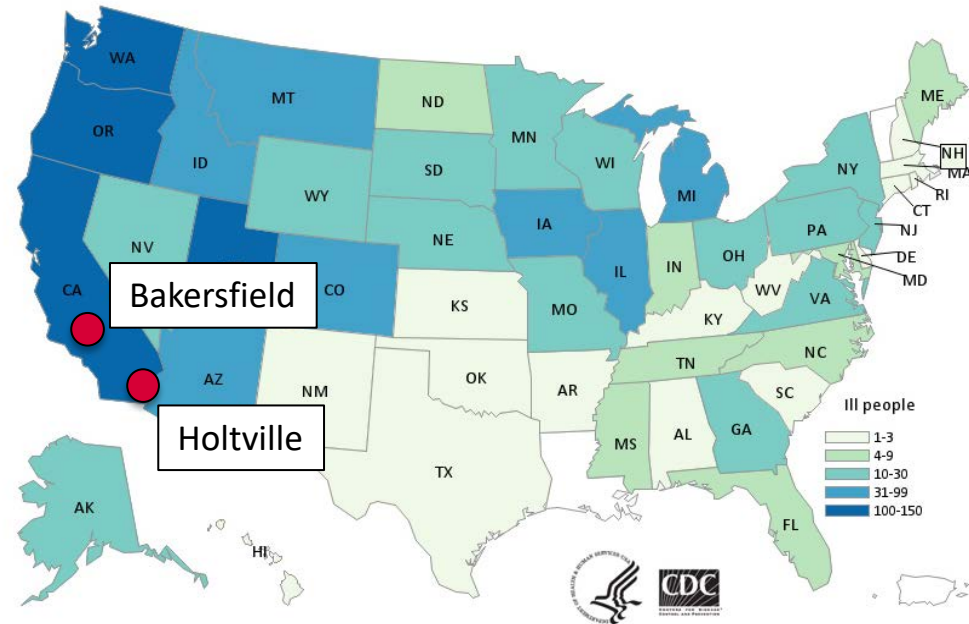
Shiga Toxin-Producing *E. coli* (STEC) and *Salmonella* Outbreaks

- Red (Bulb) Onions**
- Peaches**
- Leafy Greens**

Red Onions – *Salmonella* 2020 Newport Outbreak

- Outbreak timeframe:
6/19/2020 - 10/8/2020
- *Salmonella* Newport infections across 48 U.S. states, associated with consumption of red onions
 - 1127 cases, 167 hospitalizations, 0 deaths
 - 515 additional cases identified in Canada
- FDA traceback investigation
 - Thomson International, Inc. headquartered in Bakersfield, CA

People infected with the outbreak strain of *Salmonella* Newport by state of residence



Factors Potentially Contributing to the Contamination of Red Onions Implicated in the Summer 2020 Outbreak of Salmonella Newport

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A red oval graphic with a black border and a white inner border. The text inside is white and reads: "Red Onions - Salmonella Newport Investigation Report".

Red Onions - *Salmonella* Newport Investigation Report

Executive Summary

Between June and October 2020, federal and state agencies investigated a *Salmonella* Newport foodborne illness outbreak associated with consumption of red onions from the Southern San Joaquin Valley and Imperial Valley in California. The outbreak, which caused 1,127 reported domestic illnesses and 515 reported Canadian cases, is the largest *Salmonella* outbreak in over a decade. This outbreak is also remarkable because the food vehicle, whole red onions, is a raw agricultural commodity that had not been previously associated with a foodborne illness outbreak.

The U.S. Food and Drug Administration (FDA), alongside state and federal partners, investigated the outbreak to identify potential contributing factors that may have led to red onion contamination with *Salmonella* Newport. While the *Salmonella* Newport outbreak strain (specific whole genome sequence [WGS]) was not identified in any of the nearly 2,000 subsamples tested, a total of 11 subsamples (10 water and 1 sediment) collected near one of the growing fields identified in the traceback were positive for *Salmonella* Newport, representing a total of three different genotypical strains (unique WGS patterns). Although a conclusive root cause could not be identified, several potential contributing factors to the

<https://www.fda.gov/food/outbreaks-foodborne-illness/factors-potentially-contributing-contamination-red-onions-implicated-summer-2020-outbreak-salmonella>

Investigation General Observations and Findings

- Several environmental samples collected on land adjacent to the fields of interest were positive for *Salmonella* serovars (none closely related to outbreak strain)
- Strains of *Salmonella* recovered in adjacent canal sediments, water used for irrigation, drainage/tail water, in animal scat and on equipment
- Cross connections between adjacent drainage or seepage water networks and irrigation delivery systems may be contributing factors.
- Food contact surfaces had not been inspected, maintained, or cleaned as frequently as necessary to protect against the contamination of produce
- Leading hypothesis - contaminated irrigation water led to outbreak

Peaches - *Salmonella* Enteritidis 2020 Outbreak

- Outbreak timeframe:
06/29/2020- 10/16/2020
- *Salmonella* Enteritidis infections across 17 states, associated with consumption of peaches
 - 101 cases, 28 hospitalizations, 0 deaths
 - Additional illnesses in Canada
- FDA Traceback investigation
 - No single point source
 - One large grower/producer = majority of implicated peaches



Factors Potentially Contributing to the Contamination of Peaches Implicated in the Summer 2020 Outbreak of Salmonella Enteritidis



Executive Summary

Between August and October 2020, the U.S. Food and Drug Administration (FDA) and multiple state and federal partners investigated an outbreak of *Salmonella* Enteritidis infections linked to peaches packed or supplied by a large grower/producer. In total, in the U.S. there were 101 reported illnesses across 17 states. Based on the historical outbreak data, this multistate outbreak appears to represent a novel commodity/pathogen pair. The epidemiological and traceback investigation identified the large grower/producer's packinghouses, cooling facilities and/or orchards as a potential source of the peaches and helped prioritize investigational activities.

The investigation did not result in finding the outbreak strain (via whole genome sequencing (WGS)) in investigation samples, however, numerous *Salmonella* isolates were found in samples collected from the peach orchards. Multiple *Salmonella* isolates from product (peach) and peach tree leaf sampling activities conducted during this investigation genetically resembled historical chicken and cattle isolates not associated with this outbreak or any known foodborne illnesses. Geospatial analyses of the orchards that supplied fresh peaches during the period of interest, coupled with WGS analysis that showed closely related *Salmonella* isolates from peach/leaf and historical animal samples



<https://www.fda.gov/food/cfsan-constituent-updates/fda-releases-investigation-findings-following-summer-2020-outbreak-linked-peaches>



Peaches - *Salmonella* Enteritidis Investigation

FDA

Investigation General Observations and Findings

- Environmental and product samples:
 - All raw product samples negative for *Salmonella* spp.
 - Collected peach leaves and fruit from orchard located directly adjacent to poultry CAFO
 - *Salmonella* Alachua isolates recovered from fruit and leaves. Not related to outbreak strain
 - WGS matched to chicken isolates
 - Prompted voluntary recall by firm, preventing contaminated product from reaching market
- Peach leaf sampling from 5 additional orchards
 - *Salmonella* Montevideo isolates recovered from leaves, not closely related to outbreak strain
 - WGS matched to cattle isolates

2018 – 2020 Leafy Greens – *E. coli* O157:H7 Outbreaks

- **Spring, 2018 (Yuma, AZ)**
 - 210 Illnesses
 - 96 Hospitalizations
 - 27 HUS
 - 5 Deaths
- **Fall, 2018 (Santa Maria, CA)**
 - 62 Illnesses
 - 25 Hospitalizations
 - 2 HUS
- **Fall, 2019 (Salinas Valley, CA)**
 - 167 Illnesses
 - 85 Hospitalizations
 - 15 HUS
- **Fall, 2020 (Salinas Valley, CA)**
 - 40 illnesses
 - 20 hospitalizations
 - 4 HUS



Factors Potentially Contributing to the Contamination of Leafy Greens Implicated in the Fall 2020 Outbreak of *E. coli* O157:H7



Executive Summary

Between August and December 2020, the U.S. Food and Drug Administration (FDA) and multiple state and federal partners were involved in an outbreak investigation related to *E. coli* O157:H7 illnesses and the consumption of leafy greens. The outbreak, which caused 40 reported domestic illnesses, was linked via whole genome sequencing (WGS) and geography to outbreaks traced back to the California growing region associated with the consumption of leafy greens in 2019 and 2018. FDA, alongside state and federal partners, investigated the outbreak to identify potential contributing factors that may have led to leafy green contamination with *E. coli* O157:H7. The *E. coli* O157:H7 outbreak strain was identified in a cattle feces composite sample taken alongside a road approximately 1.3 miles upslope from a produce farm with multiple fields tied to the outbreaks by the traceback investigations. In addition, several potential contributing factors to the 2020 leafy greens outbreak were identified.

Isolates within this cluster of illnesses are part of a reoccurring strain of concern and are associated with outbreaks that have occurred in leafy greens each fall since 2017. The two most recent outbreaks associated with this strain were an outbreak in 2018 (linked to romaine lettuce from the Santa Maria growing region of California) and an outbreak in

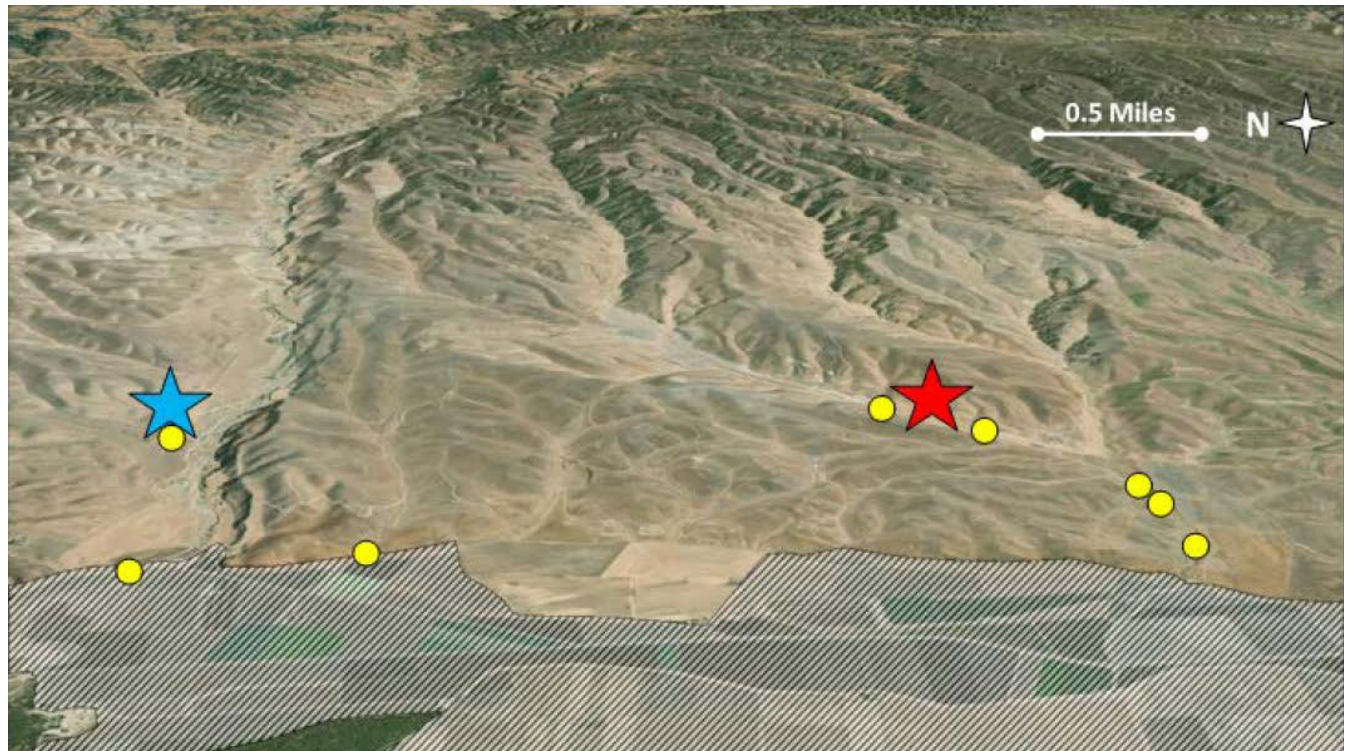


<https://www.fda.gov/food/outbreaks-foodborne-illness/factors-potentially-contributing-contamination-leafy-greens-implicated-fall-2020-outbreak-e-coli>

2020 Leafy Greens - *E. coli* O157:H7 Investigation

An Example of Adjacent and Nearby Land Associations

- *E. Coli* outbreak strain identified in cattle feces 1.3 mi upslope from farm
 - This sample collected ~3 miles from positive sample of 2019 *E. coli* outbreak strain
- 36 out of 38 *E. coli* positive samples were STEC *E. coli*
- No direct source or route of contamination, ANLU definitely a factor
- Previous *E. coli* outbreaks of related strains have occurred in this growing region with similar possible causes



Topics Covered

- 2020 Salmonella and Shiga Toxin-Producing *E. coli* (STEC) Outbreaks & Investigation Reports
 - Findings related to adjacent and nearby land use
- **Leafy Greens STEC Action Plan**
 - Adjacent and nearby land use efforts
- Overview of Selected Produce Safety Rule Requirements
- Summary and Resources

Leafy Greens STEC Action Plan

Prevention

1. Advance Agricultural Water Safety
2. Enhance Inspections, Audits and Certification Programs
3. Buyer Specifications
4. Leafy Greens Data Trust
5. Microbiological Surveys for STEC Detection and Enhanced Sampling Protocols
6. Increase Awareness and Address Concerns Around Adjacent and Nearby Land
7. Establish and Strengthen Regular Outreach and Communication Programs for Stakeholders in Growing Regions

Response

8. Investigation Reports
9. Conduct Follow-Up Surveillance During the Fall 2020 California Growing/ Harvest Season
10. Promote Tech-Enabled Traceability
11. Improve Utilization of Shopper Card Data
12. Accelerate Whole Genome Sequencing Data Submissions by States
13. Advance Root Cause Analysis Activities
14. Enhance Outbreak and Recall Communications

Addressing Knowledge Gaps

15. Longitudinal Studies
16. Data Mining and Analytics on Previous Outbreaks
17. Adjacent and Nearby Land Use
18. Compost Sampling Assignment with California



- Adjacent and nearby land use addressed in each part of the plan

Leafy Greens STEC Action Plan



Prevention

Response

Addressing Knowledge Gaps



2022 Update

- Communicated with federal agencies and industry groups to evaluate opportunities and barriers which led to technical assistance and outreach activities
- FDA participated in Leafy Greens Marketing Agreement (LGMA) and Western Growers Association (WGA) meetings, offering technical assistance on the LGMA's metrics review
- Provided technical assistance to the California Agricultural Neighbors (CAN) workgroup led by CDFA and Monterey County Farm Bureau

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Selected Produce Safety Rule Requirements: Domesticated and Wild Animals



Subpart I—Domesticated and Wild Animals

§ 112.83 What requirements apply regarding grazing animals, working animals, and animal intrusion?

- (a) You must take the steps set forth in paragraph (b) of this section if under the circumstances there is a reasonable probability that grazing animals, working animals, or animal intrusion will contaminate covered produce.
- (b) You must:
 - (1) Assess the relevant areas used for a covered activity for evidence of potential contamination of covered produce as needed during the growing season (based on your covered produce; your practices and conditions; and your observations and experience); and
 - (2) If significant evidence of potential contamination is found (such as observation of animals, animal excreta or crop destruction), you must evaluate whether the covered produce can be harvested in accordance with the requirements of § 112.112 and take measures reasonably necessary during growing to assist you later during harvest when you must identify, and not harvest, covered produce that is reasonably likely to be contaminated with a known or reasonably foreseeable hazard.



Selected Produce Safety Rule Requirements: Growing, Harvesting, Packing and Holding

Subpart K—Growing, Harvesting, Packing, and Holding Activities

§ 112.112 What measures must I take immediately prior to and during harvest activities?



You must take all measures reasonably necessary to identify, and not harvest, covered produce that is reasonably likely to be contaminated with a known or reasonably foreseeable hazard, including steps to identify and not harvest covered produce that is visibly contaminated with animal excreta. At a minimum, identifying and not harvesting covered produce that is reasonably likely to be contaminated with animal excreta or that is visibly contaminated with animal excreta requires a visual assessment of the growing area and all covered produce to be harvested, regardless of the harvest method used.

§ 112.113 How must I handle harvested covered produce during covered activities?

You must handle harvested covered produce during covered activities in a manner that protects against contamination with known or reasonably foreseeable hazards—for example, by avoiding, to the degree practicable, contact of cut surfaces of harvested produce with soil.

Selected Produce Safety Rule Requirements: Equipment, Tools, Buildings and Sanitation

Subpart L—Equipment, Tools, Buildings, and Sanitation

§ 112.123 What general requirements apply regarding equipment and tools subject to this subpart?

(d)(1) You must inspect, maintain, and clean and, when necessary and appropriate, sanitize all food contact surfaces of equipment and tools used in covered activities as frequently as reasonably necessary to protect against contamination of covered produce.

§ 112.128 What requirements apply regarding pest control in buildings?

(a) You must take those measures reasonably necessary to protect covered produce, food contact surfaces, and food-packing materials from contamination by pests in buildings, including routine monitoring for pests as necessary and appropriate.





Summary

Additional Resources

- FDA Produce Safety Draft Guidance Webpage:
 - <https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm606284.htm>
- Guidance for Industry: Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables:
 - <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-guide-minimize-microbial-food-safety-hazards-fresh-fruits-and-vegetables>
- Technical Assistance Network (TAN):
 - Visit www.fda.gov/fsma and go to “[Contact Us](#)”
- Produce Safety Network:
 - <https://www.fda.gov/food/food-safety-modernization-act-fsma/produce-safety-network>
- CDC Outbreak Map:
 - <https://wwwn.cdc.gov/norsdashboard/>
- Leafy Greens STEC Action Plan:
 - <https://wwwn.cdc.gov/norsdashboard/>



Produce Safety Network

- Produce Safety Network Mailbox in Spanish
 - ProduceSafetyNetworkEnEspañol@fda.hhs.gov

Thank
you!

Discussion and
Questions?