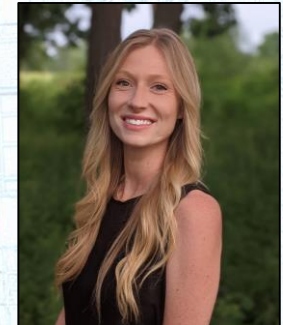


# ***FDA Update on Adjacent and Nearby Land Use (ANLU)***

***Karen Killinger, PhD  
Kurt Nolte, PhD  
Ali Strickland, PhD***



***FDA Center for Food Safety and Applied Nutrition  
Division of Produce Safety  
Fresh Produce Branch***

# Topics Covered

- 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



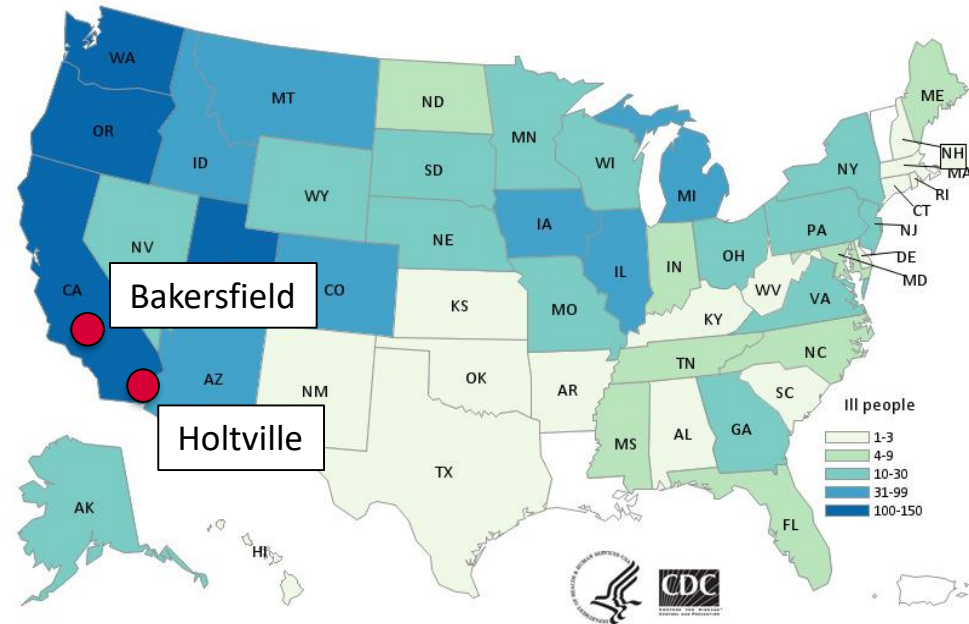
**Shiga Toxin-Producing *E. coli* (STEC) and *Salmonella* Outbreaks Linked to Adjacent and Nearby Land Use**

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

# 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



Modified from CDC, 2020

# 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 centered.

## 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>

# Red Onions

## *Salmonella* Newport 2020 Investigation

### Adjacent and Nearby Land Associations

- Several *Salmonella* positive environmental samples were collected on land adjacent to fields of interest
- Strains of *Salmonella* were recovered in:
  - adjacent canal sediments;
  - water used for irrigation;
  - drainage or tail water;
  - animal scat; and
  - on equipment.
- Cross connections between adjacent drainage water networks and irrigation delivery systems may be contributing factors
- Food contact surfaces were not inspected, maintained, or cleaned as necessary to protect against contamination

# **Peaches - *Salmonella* Enteritidis 2020 Outbreak**

- Outbreak timeframe: 06/29/2020 - 10/16/2020
- *Salmonella* Enteritidis infections in 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 producer associated with the 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>

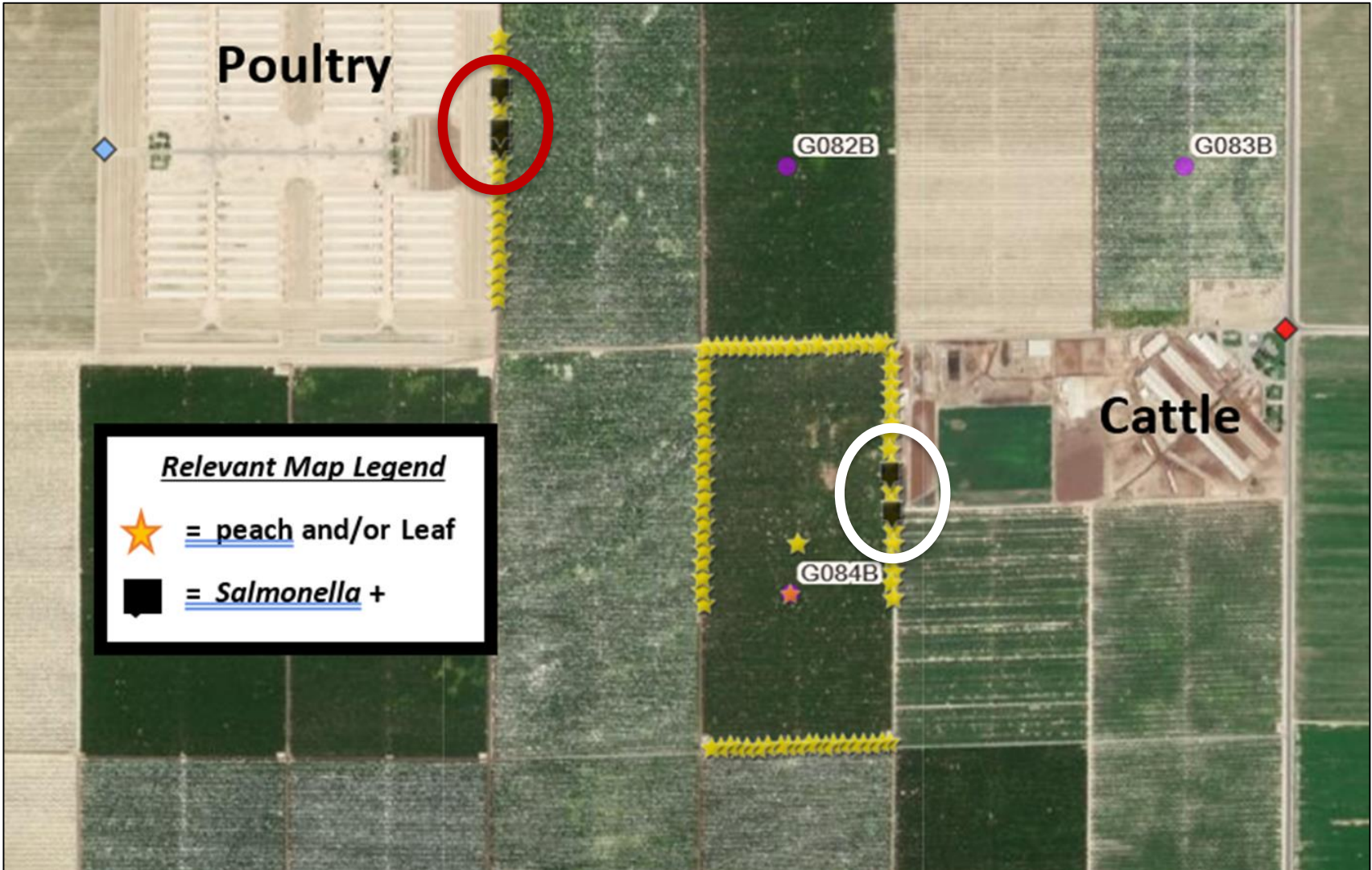


# Peaches

## *Salmonella* Enteritidis 2020 Investigation



### Adjacent and Nearby Land Associations



# Leafy Greens

## *E. coli* O157:H7

### 2018 – 2020 Investigations

- 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.

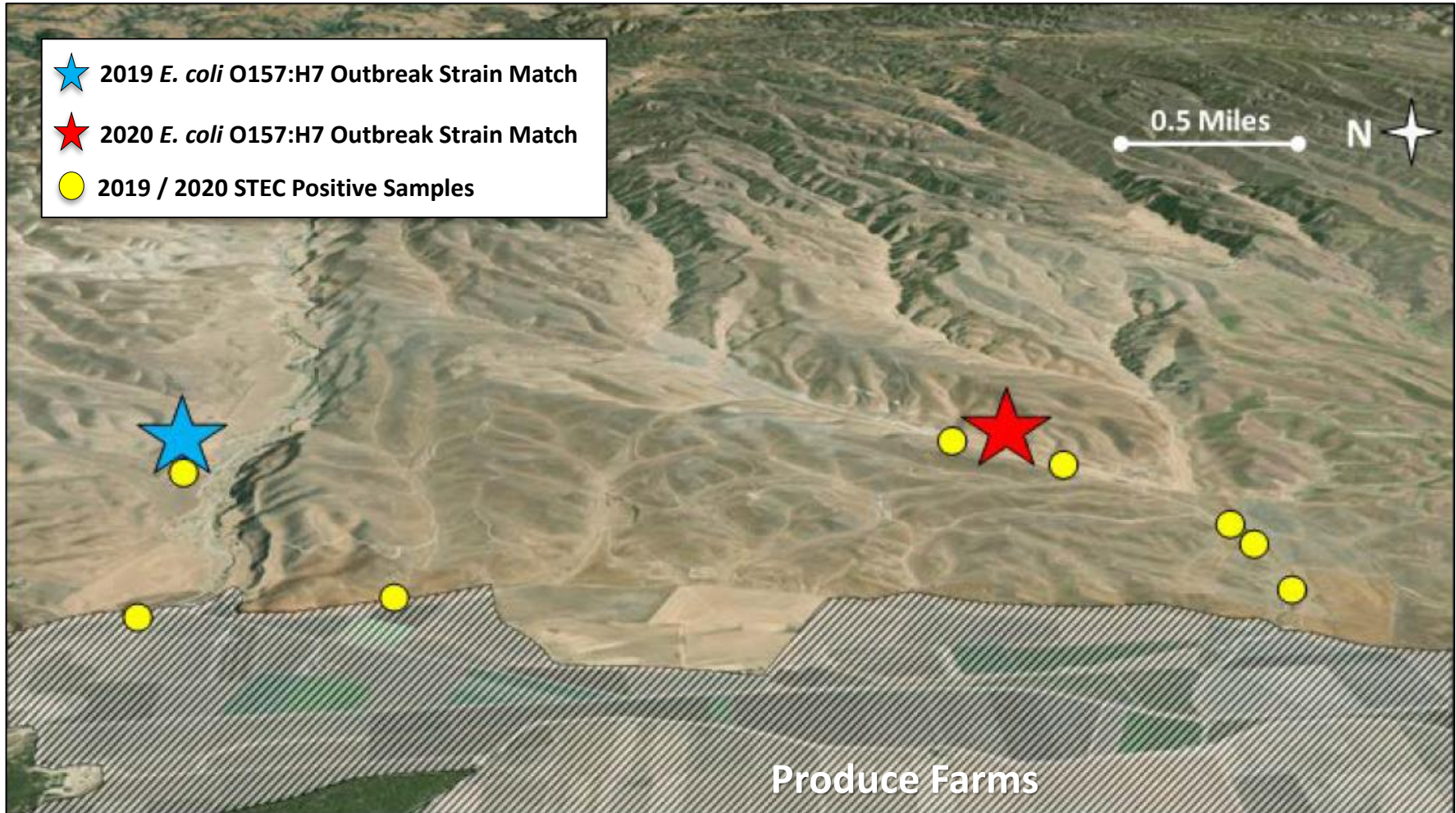
Isolates within this cluster of illnesses are part of a reoccurring strain of concern and are associated with outbreaks that have occurred in leafy greens each fall since 2017. The two most recent outbreaks associated with this strain were an outbreak in 2018 (linked to romaine lettuce from the Santa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

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

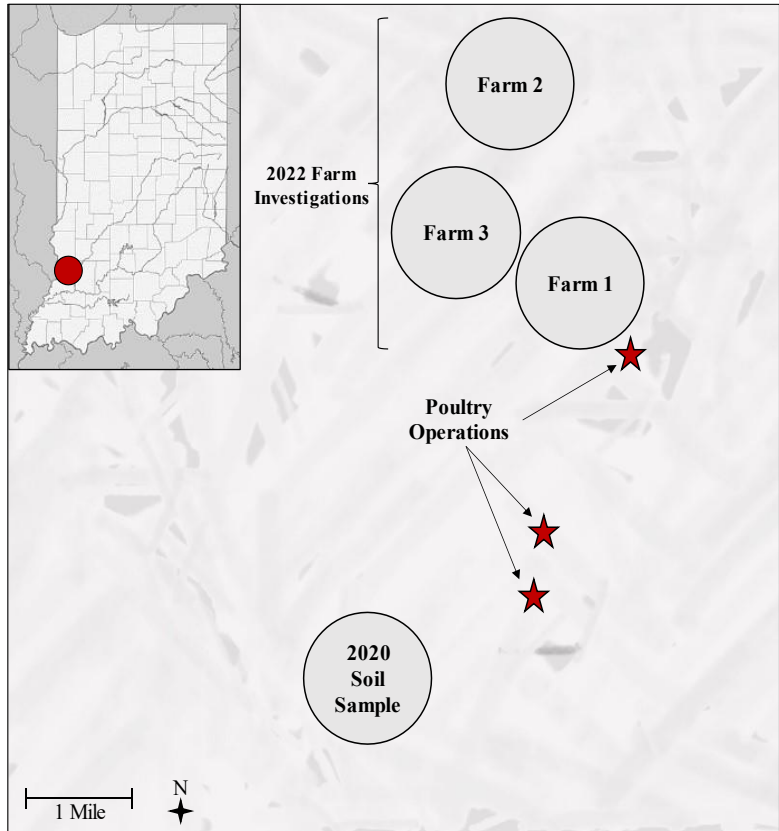
## Adjacent and Nearby Land Associations



# Cantaloupe *Salmonella* Typhimurium 2022 Investigation



- **Outbreak timeframe: July - September, 2022**
- ***Salmonella* Typhimurium infections in 11 states, associated with consumption of cantaloupe**
  - 88 cases, 32 hospitalizations, 0 deaths
- **FDA Traceback investigation**
  - 11 locations, 8 traced back to a common packinghouse
  - Three large, Southwest Indiana producers supplied the majority of implicated cantaloupe in 2022
- **Adjacent and Nearby Land Associations**
  - A *Salmonella* Typhimurium isolate from a soil sample in 2020 matched isolates recovered from farms in 2022 and the outbreak strain. Red stars indicate the relative proximities of the farms and poultry operations within the region.



# Factors Potentially Contributing to the Contamination of Cantaloupe Implicated in the Outbreak of *Salmonella* Typhimurium During the Summer of 2022

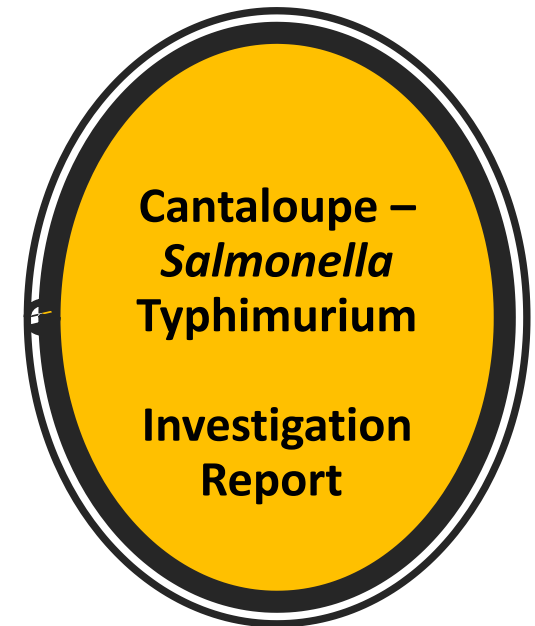


In August 2022, the U.S. Food and Drug Administration (FDA), Centers for Disease Control and Prevention (CDC), and state partners conducted an outbreak investigation into a multistate outbreak of *Salmonella* Typhimurium linked to cantaloupe.

- Total Illnesses: 87
- Hospitalizations: 32
- Deaths: 0
- Last Illness Onset: September 11, 2022
- States with Cases: GA (1), IL (5), IN (17), IA (38), KY (3), MI (3), MN (4), MO (2), OH (3), SC (1), WI (10)

The outbreak response investigation found:

1. In August 2022, CDC notified FDA about a multistate cluster of *Salmonella* Typhimurium illnesses with a potential signal for melon exposures. The cases were geographically distributed in the U.S. upper Midwest.
2. The isolates in this cluster of illnesses were within 7 alleles / 11 single-nucleotide polymorphisms (SNPs) of two FDA soil swab samples collected from a 2020 outbreak



<https://www.fda.gov/food/outbreaks-foodborne-illness/factors-potentially-contributing-contamination-cantaloupe-implicated-outbreak-salmonella-typhimurium>



# Cantaloupe – *Salmonella* Typhimurium

## Key Investigation Findings

- Contamination sources and *Salmonella* strains could be persistent in the growing environment
- All production fields were not under consistent management or control by cantaloupe growers
- Cleaning and sanitizing written SOPs were not consistent with daily practices and were not verified for effectiveness

# Topics Covered

- 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

Prevention

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Response

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Addressing Knowledge Gaps

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## 2023 Update

- FDA developed and released a fact sheet:  
*Adjacent and Nearby Land Use and its Impact on Produce Safety*
- Conducted over 10 technical assistance and outreach activities

# Leafy Greens STEC Action Plan



Prevention

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Response

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Addressing Knowledge Gaps

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- 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

# Adjacent and Nearby Land Use and Its Impact on Produce Safety

- Conditions and practices on adjacent and nearby land can impact all types of produce grown domestically or internationally
- Pathogens can be transferred from sources on adjacent and nearby lands to produce farms in several ways
- Understanding potential sources of pathogen and routes of contamination can help identify potential hazards for covered produce



Evaluating  
potential  
sources or  
routes of  
contamination  
from adjacent  
and nearby land

- Presence of domesticated animals, animal housing, animal waste
- Presence of wild animals, habitats or animal attractants
- Presence of waste or trash storage
- Practices for storage or application of soil amendments or manure
- Presence of recreational activities
- Proximity to toilet facilities, septic systems or wastewater treatment
- Equipment, vehicle and worker traffic patterns
- Land features and use
- Weather events



# 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
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- **Overview of Selected Produce Safety Rule Requirements**
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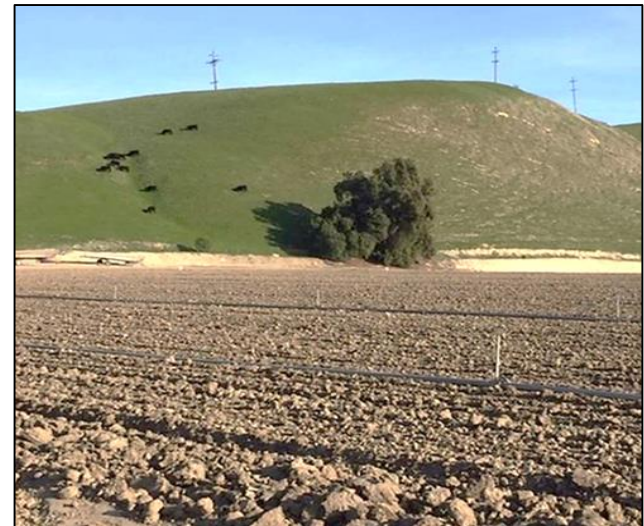
# Selected Produce Safety Rule Requirements: Domesticated and Wild Animals



## 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](http://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://www.fda.gov/food/foodborne-pathogens/leafy-greens-stec-action-plan>
- Adjacent and Nearby Land Use Factsheet:
  - <https://www.fda.gov/food/food-safety-modernization-act-fsma/adjacent-and-nearby-land-use-and-its-impact-produce-safety>

# Contact Information for International PSN

1) **Dr. Mauricio Castelo** ●  
International Produce Safety Network  
México, Centroamérica y el Caribe  
[Mauricio.Castelo@fda.hhs.gov](mailto:Mauricio.Castelo@fda.hhs.gov)

2) **Dr. Oscar Galagarza** ●  
International Produce Safety Network  
Sudamérica  
[Oscar.GalagarzaAngulo@fda.hhs.gov](mailto:Oscar.GalagarzaAngulo@fda.hhs.gov)



- PSN Directory: <https://www.fda.gov/media/105420/download>



# Produce Safety Network

- Produce Safety Network Mailbox in Spanish
  - [ProduceSafetyNetworkEnEspañol@fda.hhs.gov](mailto:ProduceSafetyNetworkEnEspañol@fda.hhs.gov)

Thank  
you!

Discussion and  
Questions?