

Investigation Report:

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

## 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 2020 red onion outbreak were identified, including a leading hypothesis that contaminated irrigation water used in a growing field in Holtville, California may have led to contamination of the onions.

While our investigation did not occur during any harvesting activities, visual observations of the implicated red onion growing fields suggested several plausible opportunities for contamination including irrigation water, sheep grazing on adjacent land, as well as signs of animal intrusion, such as scat and large flocks of birds which may spread contamination. Similarly, the investigation did not occur while packing activities were ongoing. However, visual observations and records review of packing house practices confirmed numerous opportunities for spread of foodborne pathogens such as *Salmonella*, including signs of animal and pest intrusion as well as food contact surfaces which had not been inspected, maintained, cleaned, or sanitized as frequently as necessary to protect against the contamination of produce. Thomson International Inc. cooperated with FDA throughout the investigation and is continuing to engage with FDA on the agency's findings and recommendations.

Notably, *Salmonella* isolates from two sediment subsamples and two water subsamples collected during this investigation were found to be genetically related by WGS to clinical isolates from 2016 and 2018 foodborne illness outbreaks (*Salmonella* Muenchen and *Salmonella* Montevideo, respectively) associated with consumption of sprouts. This may be indicative of human pathogen persistence and distribution in this growing region (a concentrated area of seed for sprouting production), which could pose a risk of contamination for any produce commodity. FDA issued an assignment to follow-up at the associated firms. Sprouts are not a food vehicle of interest in the 2020 *Salmonella* Newport foodborne illness outbreak.

We urge growers to conduct risk assessments that include evaluation of hazards that may be associated with adjacent and nearby land uses—especially relating to the presence of livestock and wildlife and the potential for runoff into growing fields or water sources—and implement risk mitigation strategies where appropriate. FDA recognizes the interconnection between people, animals, plants, and their shared environment when it comes to public health outcomes, and we

encourage collaboration among various groups in the broader agricultural community (e.g., produce growers, those managing animal operations, state and federal government agencies, and academia) to address this issue.

This document provides an overview of the traceback investigation, subsequent on-site investigation, and factors that potentially contributed to the contamination of red onions with *Salmonella* Newport.

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## I. Outbreak Overview

Between June and October 2020, the U.S. Food and Drug Administration (FDA) and multiple state and federal partners were involved in an outbreak investigation of illnesses caused by *Salmonella* Newport and associated with the consumption of red (bulb) onions.

On July 31, 2020, FDA announced an investigation, conducted in conjunction with the U.S. Centers for Disease Control and Prevention (CDC), state partners, and Canadian officials (the Public Health Agency of Canada and the Canadian Food Inspection Agency), into an outbreak of *Salmonella* Newport infections in multiple U.S. states and Canadian provinces associated with the consumption of red onions. FDA's traceback investigation identified Thomson International Inc., headquartered in Bakersfield, California with additional operations in Holtville, California, as the likely source of contaminated red onions consumed in the United States.

On August 1, 2020, Thomson International Inc. recalled all red onions shipped from May 1, 2020 to August 1, 2020. The company also recalled yellow, white, and sweet yellow onions shipped from May 1, 2020 to August 1, 2020 due to concerns that they may have been cross-contaminated via food contact surfaces that were used to process red onions. As a result of the Thomson International Inc. recall, multiple firms initiated downstream recalls or posted notices of the Thomson International Inc. recall on their respective websites. By August 19, 2020, 14 companies that sold recalled onions under other labels or sold foods containing recalled onions, had issued additional product recalls.

In total, in the United States there were 1,127 reported illnesses across 48 states, making it the largest *Salmonella* outbreak in terms of illnesses in over a decade. The outbreak resulted in 167 hospitalizations. No associated deaths were reported. Illness onset ranged from June 19 through September 11, 2020. The outbreak was declared over in the United States by [CDC on October 8, 2020](#).

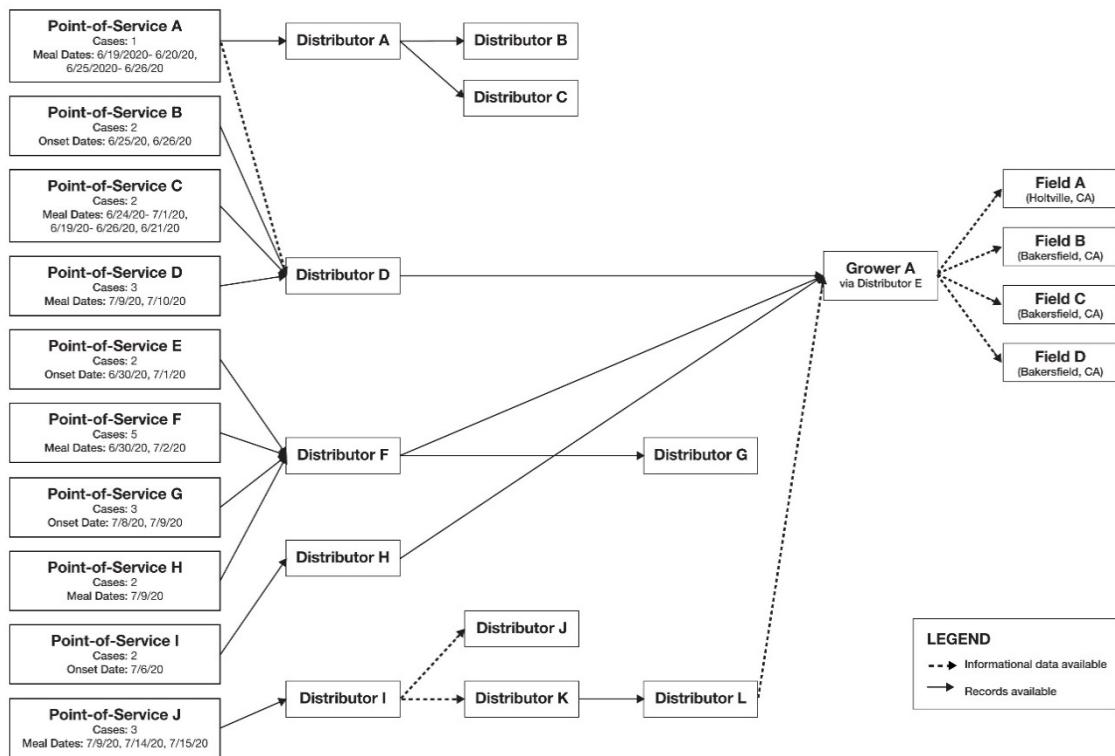
## II. Outbreak Response Activities and On-Farm Outbreak Investigations

The epidemiologic and traceback investigation conducted by FDA, CDC and state partners determined that red onions from Thomson International Inc. were the likely source of this outbreak in the United States. Ninety-one percent of ill persons interviewed (344/380) reported eating any type of onions or foods likely containing onions in the week before their illnesses started. This is notable in light of the 2006-2007 FoodNet population survey data, in which 71.3% of respondents reported eating white or yellow onions. Additionally, the proportion of cases reporting eating any type of onions in this outbreak is highly statistically significant ( $p < 0.001$ ) when compared to the population survey data. Of the 208 people who were asked what types of onions they ate, 137 (66%) reported eating red onions, 130 (63%) reported eating white onions, and 110 (53%) reported eating yellow onions. Most ill people reported eating more than one type of onion. The traceback investigation was further narrowed to red onions based on the findings of the Canadian outbreak investigation which identified red onions from Thomson International Inc. as the likely source of Canadian illnesses.

Food exposure information for ill consumers in the outbreak investigation was evaluated to determine points-of-service (POS) at which red onions may have been served or purchased. Based on this information, FDA, in collaboration with state and other government officials, initiated a traceback investigation of red onions associated with case exposures.

Tracebacks typically rely on only a subset of cases.<sup>1</sup> Cases were included in the traceback when there was more than one case at a single POS with exposure to red onions. There were 10 POS associated with 26 cases with known meal/exposure dates, which ranged from June 19, 2020 to July 15, 2020. Cases included in the traceback were those where there was sufficient epidemiological data in order to initiate the traceback. If cases could not remember or confirm their exposure to red onions, there was insufficient epidemiologic information to include them in the traceback investigation. Traceforward information was also obtained to identify manufacturers, distributors and retailers that potentially received recalled onions. The traceback investigation identified a grower that supplied red onions during the time period of interest, and the traceforward analysis of the implicated lots of red onions was consistent with the temporal and geographical distribution of cases.

**Figure 1. Redacted Traceback Diagram**



Notes: Solid lines represent record data; broken lines represent informational data. Red onions received by Distributors B, C, G, and J would not have been available at all POS, therefore additional follow-up was not conducted.

<sup>1</sup> For more details on the traceback methodology see Irvin, K., Viazis, S., Fields, A., Seelman, S., Blickenstaff, K., Gee, E., Wise, M., Marshall, K., Gieraltowski, L. and Harris, S., 2021. An Overview of Traceback Investigations and Three Case Studies of Recent Outbreaks of Escherichia coli O157: H7 Infections Linked to Romaine Lettuce Romaine Lettuce Traceback Investigations. *Journal of Food Protection*. <https://doi.org/10.4315/JFP-21-112>

The traceback investigation identified Thomson International Inc. as the source of the red onions served at ten POS based on convergence of four legs of the traceback investigation (See Figure 1). A tandem traceback investigation performed by the Canadian Food Inspection Agency also identified red onions from Thomson International Inc. as the likely source of the Canadian illnesses. Additionally, traceback investigations performed by state partners and an FDA traceforward investigation determined that yellow onions from Thomson International Inc. were potentially available at multiple POS identified by ill consumers.

The epidemiological and traceback evidence obtained during the outbreak investigation informed and helped prioritize four subsequent in-depth investigations of onion fields and packing and holding operations in the Southern San Joaquin Valley and Imperial Valley in California. The on-site investigations were conducted in collaboration with California state partners from August through October 2020. The scope and approach of these investigations focused on FDA-regulated entities, such as growers and farms, in the red onion supply chain that may have contributed to the outbreak.

Investigations were conducted by the FDA, the California Department of Food and Agriculture (CDFA), and the California Department of Public Health via the California Food Emergency Response Team (CalFERT). The multi-disciplinary teams had expertise in public health, produce safety, agriculture, veterinary medicine, epidemiology, microbiology, and environmental health. In addition to the extensive epidemiological and traceback analyses performed during the outbreak investigation, the investigation teams' actions and reports were informed by on-site observations, environmental sampling results, and responses to inquiries directed to responsible persons on-site at farm operations.

Potential sources and routes of *Salmonella* contamination of red onions were assessed on numerous onion fields and packing and holding lines at farms, located in the Southern San Joaquin Valley and Imperial Valley, that may have shipped red onions contaminated with the outbreak strain. Environmental sample types collected included animal scat, agricultural water, environmental swabs of food contact and non-food contact surfaces, soil samples, and sediment samples.<sup>2</sup> Product samples of bulk onions were also collected at one of the farms and at distribution centers, and tested for the presence of the outbreak strain. In addition, approximately 1,100 onion product subsamples were collected by investigators, from five distribution centers throughout the United States.<sup>3</sup> In total, nearly 2,000 subsamples were tested as a result of targeted sampling at distribution centers and the multiple field and packing house investigations.

The investigation teams conducted detailed interviews with farm personnel (management and non-management) during investigations at Thomson International Inc. locations identified by the traceback investigation. The investigation teams collected information regarding relevant food safety procedures, policies, and practices. However, the investigations were all conducted after the company's product recall and all harvesting, processing, and packing activities had ceased preventing direct observations of these processes. The investigations provided insights on several

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<sup>2</sup> Sample – a specific test for pathogens in a specific location or of specific materials, comprised of numerous sub-samples.

<sup>3</sup> Sub-sample – one single test for pathogens, many sub-samples may be taken out of one sample, as pathogens are not evenly distributed on soil, in water, or in fecal materials.

factors, which potentially contributed to the contamination of red onions grown in Holtville (Imperial Valley) and/or Bakersfield (Southern San Joaquin Valley). None of the samples taken matched the outbreak strain of *Salmonella* Newport. However, several subsamples tested positive for other strains of *Salmonella* Newport as well as other *Salmonella* serotypes. Thomson International Inc. cooperated with FDA throughout the investigation and is continuing to engage with FDA on the agency's findings and recommendations.

### Holtville, California, Farm Investigation

Numerous birds, ground squirrels, and bird scat were observed around the fields and equipment used in the onion operations. Adjacent farming land used for alfalfa production was observed with hundreds of sheep grazing, and sheep tracks and scat were observed directly adjacent to an onion field identified by the traceback investigation. Sheep on adjacent land, coupled with the large amount of bird and animal activity are potential sources of *Salmonella* in the onion field, impacts which can be heightened during irrigation or heavy rainfall events. In addition, while several cattle feeding operations are located within 3.5 miles of fields identified by the traceback, their association with this outbreak is unclear.

Multiple water samples collected from irrigation canals in the growing area were positive for *Salmonella*. Drainage and water seepage networks, managed by an outside entity, had various sites which cross-connect with irrigation water that is delivered to a field identified by the traceback investigation and others in the area. Two samples collected from drains in the drainage network were found to be positive for *Salmonella* strains, many of which were serotype Newport but did not match the outbreak strain. The cross-connection of irrigation canals and field drainage or seepage networks could serve as a route of broader contamination, particularly when these areas are habitats for wildlife. Irrigation water used to grow onions is not customarily treated before application to the field. The investigation results indicated that this operation's practices were generally consistent with industry-wide practices, including those pertaining to water use.

At the Holtville, California farm, which included growing fields, the investigation team observed field packing equipment with surfaces that were not smooth and cleanable. Such areas can accumulate extraneous material and moisture during cleaning and sanitizing operations, which may provide an opportunity for bacterial growth, including *Salmonella*.

From the Holtville, California location, twenty-two subsamples were reported positive for *Salmonella* including multiple isolates of *Salmonella* Newport. While none of the positive subsamples matched the whole genome sequence (WGS) of the outbreak strain of *Salmonella* Newport, a total of three different genotypical strains (unique WGS patterns) of *Salmonella* Newport were detected. Of the twenty-two positive subsamples for *Salmonella* in this region, four were from sediment samples, two were from animal scat, and sixteen were from water samples collected using high-volume dead-end ultrafiltration (See Table 1 & Figure 2).

Although unrelated to the *Salmonella* Newport onion outbreak strain, isolates of *Salmonella* from two sediment subsamples and two water subsamples were determined to be genetically related by



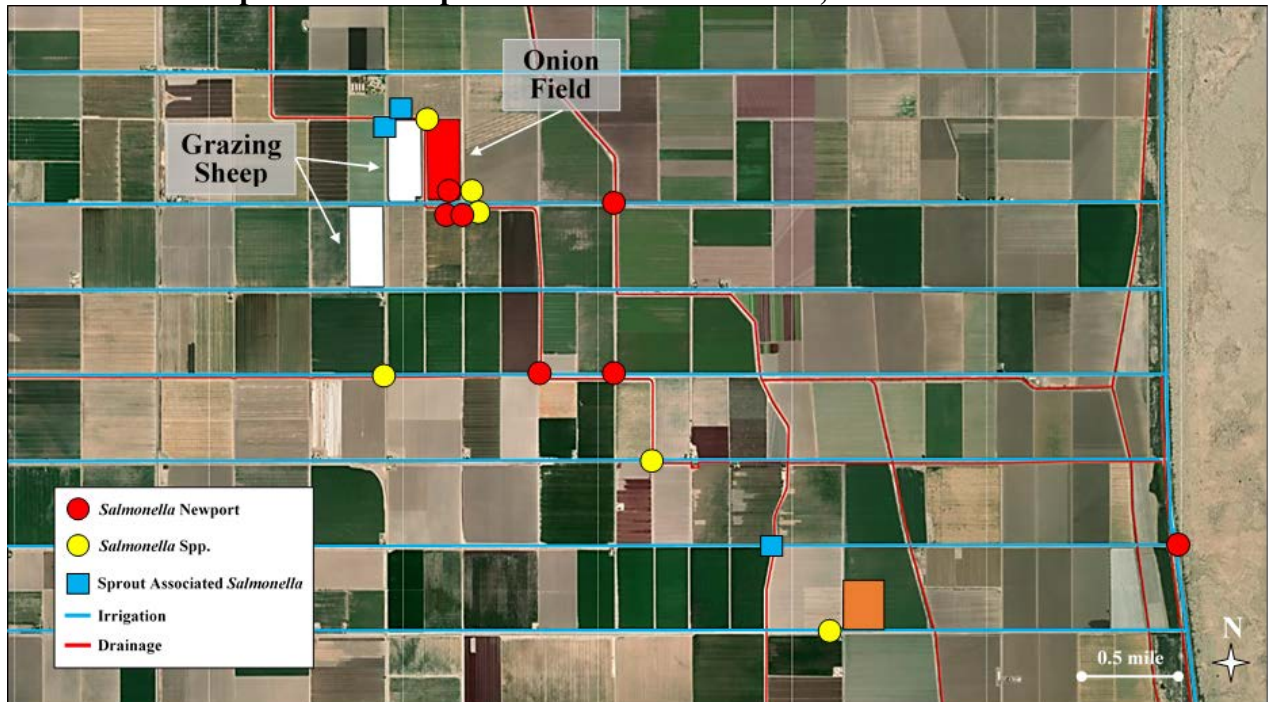
WGS to clinical isolates from 2016 and 2018 foodborne illness outbreaks (*Salmonella* Muenchen and *Salmonella* Montevideo, respectively) associated with consumption of sprouts. FDA issued an assignment to follow-up on these findings, which included additional environmental sampling and testing, assessment of production practices, and evaluation of seed supply chains.

**Table 1. Results from four, red onion outbreak investigations among two growing regions.**

| Result Distribution     |                     |                           |            |                       |                              |
|-------------------------|---------------------|---------------------------|------------|-----------------------|------------------------------|
| Location                | Site                | Subsample Type            | Subsamples | <i>Salmonella</i> (+) | <i>Salmonella</i> Newport(+) |
| Holtville, California   | Storage             | Environmental Swab        | 45         | --                    | --                           |
| Holtville, California   | Harvest Equipment   | Environmental Swab        | 15         | --                    | --                           |
| Holtville, California   | Production Field    | Environmental Swab        | 73         | --                    | --                           |
| Holtville, California   | Production Field    | Product (Residue)         | 3          | --                    | --                           |
| Holtville, California   | Production Field    | Soil                      | 1          | --                    | --                           |
| Holtville, California   | Production Field    | Water (Drainage)          | 2*         | --                    | --                           |
| Holtville, California   | Irrigation District | Water (Irrigation)        | 10         | 6                     | 3                            |
| Holtville, California   | Irrigation District | Water (Drainage, Seepage) | 10*        | 8                     | 6                            |
| Holtville, California   | Irrigation District | Sediment                  | 9          | 4                     | 1                            |
| Holtville, California   | Irrigation District | Scat                      | 2          | 1                     | --                           |
| Holtville, California   | Public Land         | Scat                      | 3          | 1                     | --                           |
| Holtville, California   | Public Land         | Miscellaneous             | 1          | --                    | --                           |
| Holtville, California   | Public Land         | Water                     | 2          | 2                     | 1                            |
| Bakersfield, California | Production Field    | Environmental Swab        | 59         | 1                     | --                           |
| Bakersfield, California | Production Field    | Product (Residue)         | 60         | --                    | --                           |
| Bakersfield, California | Production Field    | Sediment                  | 29         | 1                     | --                           |
| Bakersfield, California | Production Field    | Scat                      | 13         | --                    | --                           |
| Bakersfield, California | Production Field    | Soil                      | 33         | --                    | --                           |
| Bakersfield, California | Production Field    | Water (Irrigation)        | 10         | 1                     | --                           |
| Bakersfield, California | Production Field    | Water (Drainage)          | 1          | --                    | --                           |
| Bakersfield, California | Packinghouse        | Environmental Swab        | 279        | --                    | --                           |
| Bakersfield, California | Packinghouse        | Product (Raw)             | 154        | --                    | --                           |
| Bakersfield, California | Packinghouse        | Scat                      | 2          | --                    | --                           |
| Bakersfield, California | Public Land         | Miscellaneous             | 2          | --                    | --                           |
| Bakersfield, California | Packinghouse        | Scat                      | 12         | 2                     | --                           |
| Bakersfield, California | Packinghouse        | Soil                      | 1          | --                    | --                           |
| <b>Total</b>            |                     |                           | <b>831</b> | <b>26</b>             | <b>11</b>                    |

Notes: \* Includes 1-liter water grab samples. None of the positive subsamples were closely related by WGS to the outbreak strain of *Salmonella* Newport. In addition to the results in this table, 1,100 product subsamples were collected and analyzed from different points in the onion supply chain; all product subsamples were negative for the presence of *Salmonella*.

**Figure 2. A geographical subset and spatial distribution of positive *Salmonella* samples relative to the implicated onion production field in Holtville, California.**



Notes: Red circles indicate *Salmonella* Newport, yellow circles indicate other *Salmonella* spp., blue squares indicate locations of isolates that matched clinical isolates from sprout-associated outbreaks in 2016 and 2018. White and red rectangles indicate fields of onion production (red) and grazing sheep (white). Irrigation infrastructure is designated by blue lines, red lines indicate drainage and seepage networks, a concentrated animal feed operation (CAFO) is located at the orange square.

Sprouts were not a food vehicle of interest in the 2020 *Salmonella* Newport foodborne illness outbreak associated with red onion consumption. Nonetheless, the observed genetic association between pathogens found in the growing vicinity of the onions associated with this outbreak and clinical cases from earlier outbreaks associated with sprouts may be indicative of a persistence and distribution of human pathogens in this growing region (a concentrated area of seed for sprouting production) that could pose a risk of contamination for any produce commodity. Contaminated seed has historically been identified as the likely source of most sprout-related outbreaks and continues to be the most common source of contamination of sprouts.<sup>4</sup> This finding may suggest that *Salmonella* may persist in the broader agricultural environment over multiple growing seasons and/or be repeatedly introduced into the broader agricultural environment by human pathogen reservoirs such as animals. Growers should consider how human pathogen sources in the broader agricultural environment may lead to produce contamination, including seeds for sprouting intended for human consumption.

<sup>4</sup> See FDA Memorandum of Record: 2012 – 2020 Sprout-Related Outbreak Data, July 20, 2020, <https://www.regulations.gov/document/FDA-2014-N-0053-0096>

## Bakersfield, California, Farm Investigation

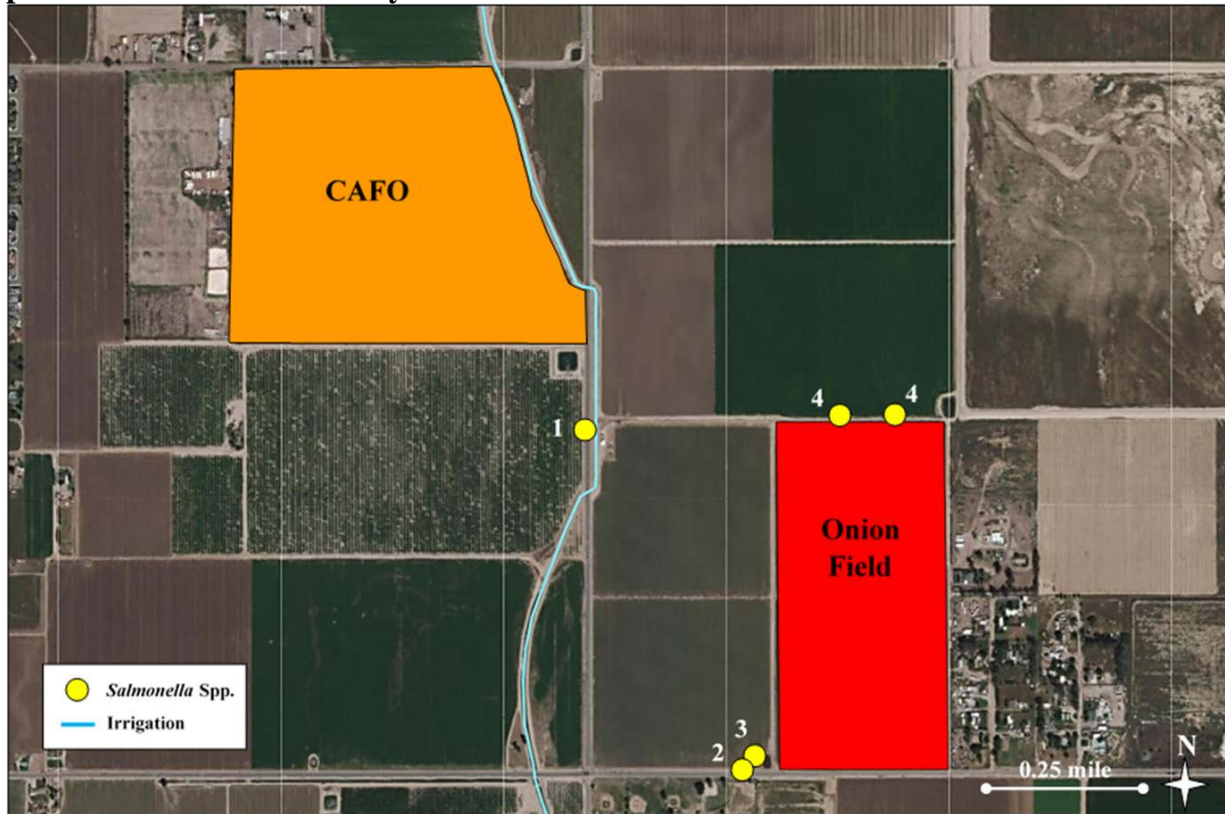
At the Bakersfield, California farm, which included a packing house and growing fields, the investigation teams noted that the firm did not take adequate measures to exclude pests from the fully enclosed buildings or prevent pests from becoming established in partially enclosed buildings. Birds, bird nests and cats were observed, along with animal scat, in and around buildings including evidence of pests on food contact surfaces. An environmental sample of irrigation water indicated the presence of *Salmonella*, and an environmental swab of a tailwater pump station and sediment collected at an on-farm tailwater collection basin also contained *Salmonella*. In addition, investigators noted frogs in water used to irrigate onion fields and bird activity in and around that water, each of which could serve as a source of contamination. However, irrigation water used to grow onions is not customarily treated before application to the field. The investigation results indicated that this operation's practices were consistent with the customary industry practice of using untreated irrigation water when growing onions. A concentrated animal feed operation (CAFO) was also identified less than a half mile from onion fields and immediately adjacent to an irrigation canal which supplied water to onion crops (See Figure 3).

Based on visual observation and records review at the packing house in Bakersfield, California, investigators noted that food contact surfaces were not inspected, maintained, cleaned, or sanitized as frequently as necessary to protect against the contamination of produce, and some equipment was not installed and maintained as to facilitate cleaning of the equipment and adjacent area. There were also shortcomings with recordkeeping and training procedures. Specifically, cleaning records did not provide the sufficient information to verify date and method of cleaning and sanitizing equipment, and training of persons who conduct harvest activities was found to be inadequate, as it did not include training on inspecting containers and equipment to ensure they are not a source of contamination or correcting and reporting problems with harvest equipment.

In this packing house, the onion packing lines were "dry operations," meaning cleaning and sanitation did not regularly involve the use of water. The lack of frequent wet cleanings prevented the firm from including a microbiological clean break between production lots. Because of this, the firm recalled all product that went through the two implicated packing lines due to the potential for cross-contamination.

From the Bakersfield, California locations, five subsamples were reported positive for *Salmonella*; however, none were identified as the *Salmonella* Newport serotype. Of the positive five subsamples, one was from sediment, two were from animal scat, one was from an environmental swab, and one was from an irrigation water sample collected using high-volume dead-end ultrafiltration (See Table 1 & Figure 3).

**Figure 3. Environmental recovery of *Salmonella* spp. in a Bakersfield, California onion production area identified by traceback.**



Notes: *Salmonella* was recovered within the onion growing environment in samples collected from an irrigation water source (1), tailwater collection basin sediment (2), a tailwater pumping station (3), and animal scat (4). A CAFO, identified in orange, is less than one half mile from the site of onion production.

### III. Factors Potentially Contributing to Contamination

The 2020 *Salmonella* Newport outbreak associated with red onions in the United States represents the largest *Salmonella* outbreak in more than a decade. Although 1,127 cases of illness were reported in the United States, this outbreak likely included tens of thousands of illnesses accounting for under-reporting and under-diagnosis.<sup>5</sup> The outbreak, linked to bulb onions—a commodity not previously associated with a reported foodborne illness outbreak—had serious public health consequences as well as ramifications for the produce industry. Although this is the first-time red onions have been implicated in an outbreak, other onion varieties have been identified as vehicles for transmission of foodborne disease.<sup>6</sup>

Although a conclusive root cause could not be identified, several potential contributing factors to the 2020 red onion outbreak were identified, including a leading hypothesis that contaminated irrigation water used in a growing field in Holtville, California may have led to contamination of

<sup>5</sup> Under-diagnosis and under-reporting multipliers of 29 for *Salmonella* spp. from Scallan, E., Hoekstra, R.M., Angulo, F.J., Tauxe, R.V., Widdowson, M.A., Roy, S.L., Jones, J.L. and Griffin, P.M., 2011. Foodborne illness acquired in the United States—major pathogens. *Emerging infectious diseases*, 17(1), p.7.

<sup>6</sup> See <https://www.cdc.gov/mmwr/preview/mmwrhtml/mm5247a5.htm>

the onions. This hypothesis is primarily based on the fact that all 6 subsample positives for *Salmonella* Newport were found in either water sources (5 of 6) or sediment (1 of 6) collected near the Holtville, California location (see Table 1). Additionally, all growers should be aware of adjacent and nearby land use practices, especially as it relates to the presence of livestock, and the potential for runoff to growing fields or water sources, to conduct appropriate assessments of risk and implement preventive measures where appropriate.

While our investigations did not occur while any harvesting activities were occurring, visual observations of the implicated red onion growing fields suggested several plausible opportunities for contamination, including sources of irrigation water, sheep grazing on adjacent land, as well as signs of animal intrusion, such as scat, and large flocks of birds which may spread contamination. Similarly, while the investigation did not occur while packing activities were ongoing, visual observation of packing house conditions and review of written procedures indicated numerous opportunities for spread of foodborne pathogens, such as *Salmonella*, including more signs of animal and pest intrusion as well as food contact surfaces that had not been inspected, maintained, or cleaned as frequently as necessary to protect against the contamination of produce.

Irrigation water used to grow onions is not customarily treated before application to the field, and the investigation results indicated that this operation's practices were consistent with this industry-wide practice. FDA has long emphasized that growers should assess irrigation water quality and apply measures, as appropriate, to minimize the risk of contamination.<sup>7</sup> FDA also continues to collaborate with the U.S. Environmental Protection Agency on outreach to stakeholders on a protocol for the development and registration of treatments targeting microorganisms of public health significance in pre-harvest agricultural water.

Although the investigation did not result in finding, by WGS, a highly related outbreak strain isolate in investigation samples, numerous *Salmonella* Newport isolates were found in water and sediment at different points in, and in proximity to, one of the onion farms implicated through FDA's traceback investigation. No *Salmonella* Newport isolates were found in the packing operation or at distribution centers despite numerous environmental and product samples taken.

Of interest, *Salmonella* isolates from two sediment subsamples and two water subsamples collected during this onion-associated outbreak investigation closely matched clinical isolates from sprout-associated outbreaks from 2016 and 2018 (*Salmonella* Muenchen and *Salmonella* Montevideo, respectively). This suggests that the growing region (a concentrated area of seed for sprouting production) and resident pathogens within that environment not specific to that commodity, may have some influence on contamination. Produce growers should consider this moving forward. Additionally, in light of these findings, the FDA is continuing with an ongoing assessment of this region to better understand the presence of microorganisms in the environment.

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<sup>7</sup> See <https://www.fda.gov/food/cfsan-constituent-updates/fda-finalizes-new-compliance-dates-agricultural-water-requirements> and <https://www.fda.gov/media/117408/download> for more detail.

## IV. Recommendations

In light of these findings, FDA encourages **all farms (including growers, harvesters, etc.)** to:

- Be cognizant of and assess risks that may be posed by adjacent and nearby land uses, especially as it relates to the presence of livestock and the interface between farmland, rangeland, irrigation water, and other agricultural areas.
- Assess growing operations to ensure that appropriate science- and risk-based preventive measures are in place, including applicable provisions of the FDA Food Safety Modernization Act (FSMA) Produce Safety Rule and good agricultural practices.
- Consider additional tools such as pre-harvest and/or post-harvest sampling and testing of products to help inform the risk assessment and clarify the need for specific prevention measures.
- When pathogens are identified through microbiological surveys, pre-harvest testing of produce, or post-harvest testing of produce implement industry-led root cause analyses to determine how the contamination likely occurred and then implement appropriate prevention and verification measures.
- Improve traceability through increased digitization, interoperability, and standardization of traceability records which would expedite traceback and help remove contaminated product from the marketplace more quickly, thereby preventing further illnesses. This is not only important for growers, but also critical for shippers, manufacturers, and retailers as well, to improve overall traceability throughout the supply chain.
- Growers (other than sprouts operations) should follow [good agricultural practices](#) to maintain and protect the quality of their water sources. FDA is engaging in a rulemaking to address concerns about the practical implementation of certain agricultural water provisions in the Produce Safety Rule for covered produce other than sprouts. Of note, compliance dates for agricultural water requirements for sprouts operations under the Produce Safety Rule already are in effect. As always, growers should take necessary action to ensure that their produce is not adulterated under the Federal Food, Drug and Cosmetic Act.

FDA recognizes the interconnection between people, animals, plants, and their shared environment when it comes to public health outcomes, and we encourage collaboration among various groups in the broader agricultural community (e.g., produce growers, those managing animal operations, state and federal government agencies, and academia) to address this issue.

FDA continues to leverage agency resources to expand the information available to growers on the capacity for foodborne pathogen survival, persistence, and movement in and through the agricultural environment. We will continue to support stakeholders' efforts to develop ways to better understand and mitigate the risk of contamination. Food safety is a shared responsibility that involves food producers, distributors, manufacturers, retailers, and regulators. FDA is committed to working with these stakeholders to advance this critical work.

## V. Relevant Links

[FDA Outbreak Investigation of Salmonella Newport: Red Onions \(July 2020\)](#)

[FDA Thomson International Inc. Conducts Voluntary Recall of Red, Yellow, White, and Sweet Yellow Onions Because of Possible Salmonella Risk](#)

[FDA 2020 Recalls of Food Products Associated with Onions from Thomson International, Inc. due to the Potential Risk of Salmonella](#)

[CDC Outbreak of Salmonella Newport Infections Linked to Onions](#)

[NCBI link to WGS information for a representative isolate](#)

[About the Produce Safety Network](#)

[About the CORE Network](#)

[About the Whole Genome Sequencing \(WGS\) Program](#)

[FSMA Produce Safety Rule](#)

[FSMA Preventive Controls for Human Foods Rule](#)

[FDA Bad Bug Book](#)