

Investigation Summary: Factors Potentially Contributing to the Contamination of Romaine Lettuce Implicated in the Fall 2018 Multi-State Outbreak of *E. coli* O157:H7

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This document provides an overview of the investigation approach and factors that potentially contributed to the contamination of romaine lettuce with *E. coli* O157:H7 in a multi-state foodborne illness outbreak in the Fall of 2018.

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I. Background

On November 1, 2018, the U.S. Food and Drug Administration (FDA), in conjunction with the U.S. Centers for Disease Control and Prevention (CDC), state partners and Canadian Officials (Public Health Agency of Canada and Canadian Food Inspection Agency) began to investigate an outbreak of *E. coli* O157:H7 infections in multiple U.S. states and Canadian provinces. This outbreak was declared over in the U.S. by the [CDC on January 9, 2019](#). In total, there were 62 reported illnesses in 16 states and the District of Columbia, resulting in 25 hospitalizations and two cases of hemolytic uremic syndrome (HUS). There were no deaths.

The investigation conducted by FDA, CDC and state partners determined that consumption of contaminated romaine lettuce was the cause of the outbreak in the U.S. Thirty (83%) of 36 ill consumers interviewed reported eating romaine lettuce the week before illness onset. This percentage was significantly higher than results from a survey of healthy people in which 46% reported eating romaine lettuce in the week before they were interviewed. All *E. coli* O157:H7 isolates from ill consumers had a rare genetic fingerprint, as determined by whole genome sequencing, that was closely related to one previously seen in ill consumers in the U.S. and Canada in the Fall of 2016 and the Fall of 2017. While no food vehicle was conclusively identified in the U.S. during the Fall

2016 and 2017 *E. coli* O157:H7 outbreaks, leafy greens – and romaine lettuce in particular – was the suspect food vehicle in 2017 based on epidemiological and traceback information, as well as investigation results from Canadian public health officials. Canadian public health officials were able to identify romaine lettuce as a suspect food vehicle in 2017 because a majority of ill consumers in Canada reported consuming romaine. In the U.S., individuals who fell ill reported consuming various types of leafy greens, but there was not the same level of specificity in reporting romaine consumption that would allow for identifying romaine as a suspect food.

As the 2018 investigation continued, FDA determined that there was an imminent threat to public health and safety based on the epidemiological evidence and historical information. Due to this determination, FDA issued a [public health advisory on November 20, 2018](#). Because the exact growing locations and dates of harvest were uncertain in available traceback records, and the outbreak appeared to be ongoing, FDA recommended that consumers not eat any romaine lettuce until further notice. FDA also requested that industry voluntarily withdraw product from the market and withhold distribution of romaine lettuce until FDA could either identify the specific source of contaminated romaine lettuce and take appropriate action; or determine that the outbreak was over.

Food exposure information for ill consumers was evaluated to determine points of service at which contaminated romaine lettuce may have been served. FDA, in collaboration with state officials, initiated tracebacks from six points of service that identified 14 distributors, 17 farms and 15 ranches (i.e. specific fields) in multiple California counties as potentially supplying romaine lettuce that was contaminated and consumed during this outbreak. FDA, California health and agriculture authorities, and the CDC conducted on-site investigations of farms and lettuce cooling facilities in California that were identified by the FDA and state tracebacks. Tracebacks done by Canadian authorities also informed these investigations.

By [November 26, 2018](#), tracebacks identified a specific California growing region where romaine lettuce contaminated with the outbreak strain likely originated and this information was communicated to the public. Finally, on [December 13, 2018](#), the traceback resulted in a narrowing of the geographic origin identified to three specific California counties, and this information was also communicated to the public.

The historical, epidemiological and traceback analyses from the 2016 and 2017 outbreaks, as well as new epidemiological and traceback information performed during this outbreak, informed and helped prioritize subsequent in-depth investigations of romaine lettuce farms. The on-farm investigations were conducted in collaboration with CDC and state partners from November through December 2018.

A sediment sample taken from an on-farm water reservoir in Santa Maria in Santa Barbara County, California tested positive for the outbreak strain of *E. coli* O157:H7. This farm, identified in multiple legs of the Fall 2018 U.S. and Canadian traceback investigations, was also identified as one of the potential suppliers of leafy greens or romaine lettuce in the 2017 U.S. and Canadian traceback investigations. While there is insufficient evidence to conclude that this farm was the sole source of the outbreak, the outbreak strain of *E. coli* O157:H7 was not detected in more than 150 other samples collected during this investigation.

II. On-Farm Foodborne Illness Outbreak Investigations

The FDA uses a spectrum of procedures that includes facility and on-farm inspections, investigations and environmental assessments to identify the business entity or entities responsible for an outbreak and gathering information about potential contributing factors. This information informs agency decision-making regarding potential regulatory actions and policy.

In this case, the investigation was conducted by the FDA's [Produce Safety Network](#), CDC, the California Department of Food and Agriculture (CDFA), and the California Department of Public Health (CDPH). The multi-disciplinary teams had expertise in public health, including produce safety, agriculture, veterinary medicine, epidemiology, microbiology, and environmental health. Besides the extensive epidemiological and traceback analyses performed during the outbreak investigation, the investigation team's actions and reports were informed by on-farm observations, environmental sampling and inquiries directed to responsible persons onsite at farm operations.

The scope and approach of this investigation was focused on FDA-regulated entities to identify farms and firms in the romaine lettuce supply chain that may have contributed to the outbreak. The information collected from this investigation can and should be used to reduce the potential for another outbreak associated with leafy greens or other fresh produce commodities.

The investigation teams used the FDA Food Safety Modernization Act (FSMA) [Produce Safety Rule](#) and Good Agricultural Practices (GAPs) as the basis for assessing potential contributing factors that could have led to contamination of romaine lettuce on farms identified in the traceback. Areas of focus on these farms included but were not limited to:

- agricultural water;
- equipment, tools, and sanitation
- soil amendments;
- growing and harvesting practices;
- animal intrusion;
- adjacent land use; and

- employee health and hygiene practices.

The romaine lettuce that made people sick was likely harvested between late September and mid-November 2018, a conclusion based on: known production practices; the anticipated shelf-life of romaine lettuce; and the fact that reported illness-onset dates occurred from October 7 through December 4, 2018.

The traceback indicates that the contaminated lettuce may have been grown on multiple farms as not all traceback legs led to the farm on which sediment from a water reservoir tested positive for the *E. coli* O157:H7 outbreak strain. An alternative explanation for this lack of traceback convergence to a single farm may be due to ill consumers having multiple romaine lettuce exposures and limited recollection of exposures and brands they ate.

Additionally, only a few relatively small clusters of people (individuals with the outbreak strain who reported eating a food from the same restaurant or purchasing from the same retail store) were identified during this outbreak. Larger clusters (e.g., more sick persons per cluster) or more total clusters of ill individuals would have increased the fidelity and power of the traceback investigation findings. It is also possible that additional unidentified food vehicles, including additional fresh produce items, may have contributed to this outbreak.

Potential sources and routes of *E. coli* O157:H7 were assessed on leafy greens farms in the various California growing areas that potentially shipped romaine lettuce contaminated with the outbreak strain. Sample types collected included soil, animal excreta, biological soil amendments of animal origin, and agricultural water (including subsurface water, surface water, and reservoir sediment).

The investigation teams conducted in-depth interviews with produce farm personnel and postharvest cooling and storage operation personnel during on-site visits to farms identified and prioritized by the traceback investigation. The investigation teams collected information regarding relevant food safety procedures, policies, and practices.

As discussed in the [Environmental Assessment of Factors Potentially Contributing to the Contamination of Romaine Lettuce Implicated in a Multi-State Outbreak of *E. coli* O157:H7](#), which details the findings of an unrelated 2018 investigation into contamination that originated in the Yuma growing region, food safety problems related leafy greens are a longstanding issue. FDA and CDC identified 28 foodborne illness outbreaks of Shiga-toxin producing *E. coli* (STEC) with a confirmed or suspected link to leafy greens in the United States between 2009 and 2017. STEC contamination of leafy greens has been identified by past investigations, traceback, observation, and sample collection results as most likely to occur in the farm environment.

The intestinal tracts of many animals are well-established reservoirs for *E. coli* O157:H7, and in particular, ruminant animals (e.g. cattle, goats, deer) that are colonized with STEC and shed the organism in feces. Various fresh water sources, including municipal well and recreational water, have been the source of *E. coli* O157:H7 infections in people, as has contact with colonized animals at farms or petting zoos. However, most *E. coli* O157:H7 infections in humans occur from consuming contaminated food.

III. Factors Potentially Contributing to the Introduction and Spread of Pathogenic *E. coli* O157:H7

The investigation teams made numerous visits to leafy greens farms in various counties and growing regions of California. During these visits, the teams collected environmental samples, including soil, water, and animal excreta. As described above, one of these samples was found to contain *E. coli* O157:H7 with the same rare genetic fingerprint (detected by whole genome sequencing) as the outbreak strain. This sample was collected on November 26, 2018 from the sediment of an on-farm water reservoir that was used by the aforementioned farm in Santa Maria in Santa Barbara County identified in the traceback as a supplier of romaine lettuce consumed by ill persons prior to illness onset.

As previously noted, the outbreak strain was identified in one sample of sediment from an on-farm water reservoir in Santa Maria in Santa Barbara County, California. This finding indicates that the outbreak strain was present in the water of this on-farm reservoir at some point in time.

On December 17, 2018 the farm [recalled](#) red leaf lettuce, green leaf lettuce and cauliflower that may have been contaminated due to use of agricultural water from the on-farm reservoir. FDA is also following up on this investigation and has offered to review the farm's mitigation plans going forward.

Bacteria, such as *E. coli* O157:H7 can float freely in water but because they have a charged surface, they are predominantly associated with fine particulate matter, such as sediment in bodies of water, where they can persist for extended periods of time. The sediment in the bottom of reservoirs where *E. coli* O157:H7 can persist is likely to be stirred up into the water when pumps are used to convey water out of a reservoir. The investigation team was not able to determine how this on-farm water reservoir became contaminated with the outbreak strain.

FDA considers that the most likely way romaine lettuce on a specific ranch on this farm became contaminated was from the use of water from this reservoir as agricultural water (i.e., came into contact with the harvestable portion of the romaine lettuce), since the outbreak strain of *E. coli* O157:H7 was found in sediment from the reservoir and in

no other sampled locations. This reservoir was not interconnected to other water sources or distribution systems in the growing region. Traceback investigation analysis indicated that other ranches owned by the same farm as well as other farms may have introduced into commerce contaminated romaine lettuce or other produce items. These other farms did not use water from the water reservoir where the outbreak strain of *E. coli* O157:H7 was found and FDA was not able to identify a potential source of contamination.

In the case of the Santa Maria farm, the precise route of contamination is uncertain. However, based on interviews with the grower, there are several plausible ways in which water from the on-farm water reservoir may have come into contact with the implicated romaine lettuce, including direct harvest/postharvest application to the crop and/or use of reservoir agricultural water on harvest equipment food contact surfaces. The use of agricultural water from a reservoir open to the environment has higher food safety risk as compared to that associated with use of ground water, because of the increased potential for human pathogens to contaminate surface water.

In this case, the farm did have a procedure in place to collect and test reservoir agricultural water for generic *E. coli* and treat the agricultural water with a sanitizer before use. However, the investigation team noted that verification procedure records did not document that the water sanitizer was present at levels that would assure that the water used to contact romaine lettuce at harvest, during postharvest handling, and to wash/rinse harvest equipment food contact surfaces was not contaminated with pathogenic bacteria.

Inspection of water tank sanitizer treatment systems used in harvest/postharvest handling revealed that some units had undissolved sanitizer cakes and that some tank systems were constructed in a manner that likely did not allow for optimal sanitizer treatment of the agricultural water before use. Additionally, untreated water from the contaminated reservoir was used to fill tank trucks which broadly sprayed water on roads for dust abatement and these roads were traveled on by harvest equipment prior to commencing harvest operations. FDA cannot rule out that there are other sources or means of romaine lettuce contamination that were not identified during these investigations.

Information collected by the investigation team indicates that the farm only directly applied agricultural water from the reservoir to their romaine lettuce crop during germination and then irrigated by above-ground drip irrigation tape. Water from the contaminated on-farm water reservoir was reported not to have been used for dilution of ground-based spraying of crop protection chemicals during the growing season.

It is uncertain how the outbreak strain of *E. coli* O157:H7 was introduced into this on-farm water reservoir. The first illnesses in this outbreak occurred in early October 2018,

and therefore the outbreak strain may have been present in the on-farm water reservoir for some months or even years before the investigation team collected the positive sample, or the outbreak strain may have been repeatedly introduced into the reservoir from an unknown source. Generic *E. coli* has been demonstrated to survive in sediments much longer than in the overlying water. The investigation team did not identify any obvious route for contamination of the on-farm water reservoir.

However, evidence of extensive wild animal activity, including waterfowl, rodents, coyotes, etc., and animal burrows near the contaminated reservoir sediment was noted by the investigation team and likely warrants consideration as a possible source(s) of the human pathogen found in the on-farm water reservoir. Additionally, adjacent land use including the use of soil amendments, or for animal grazing on nearby land by cattle and horses, may have had the potential to be reservoirs of *E. coli* O157:H7.

Explanations other than the ones offered above as to how the on-farm water reservoir became contaminated are also possible.

IV. Summary

FDA has identified the following factors and findings as those that most likely contributed to the contamination of romaine lettuce from one farm in Santa Maria in Santa Barbara County, California, that was linked to some illnesses during this outbreak.

- The outbreak strain of *E. coli* O157:H7 was found in the sediment of an on-farm water reservoir in Santa Maria in Santa Barbara County, California.
- The outbreak strain was not found anywhere else in sampling done during the investigation in various California leafy greens growing areas and counties.
- FDA has concluded that the water from the on-farm water reservoir where the outbreak strain was found most likely led to contamination of some romaine lettuce consumed during this outbreak.
- Traceback investigation analysis indicated that other ranches owned by the same farm as well as other farms may have introduced into commerce contaminated romaine lettuce or other produce items. These other farms did not use water from the water reservoir where the outbreak strain of *E. coli* O157:H7 was found and FDA was unable to identify a potential source of contamination.
- FDA has concluded that the water from the on-farm water reservoir where the outbreak strain was found was most likely not effectively treated with a sanitizer and this may have led to contaminated water directly contacting romaine lettuce after harvest or by the washing/rinsing harvest equipment food contact surfaces.
- There are several ways in which water from the on-farm water reservoir may have come into contact with the implicated romaine lettuce, including direct

harvest/postharvest application to the crop and/or use of reservoir agricultural water on harvest equipment food contact surfaces.

- FDA does not know how and when the on-farm water reservoir became contaminated with the outbreak strain. No evidence was found to identify and confirm an obvious route for on-farm contamination, or from adjacent land, to the on-farm water reservoir. Other explanations regarding how the on-farm water reservoir was contaminated with the *E. coli* O157:H7 outbreak strain aside from the potential contributing factors identified in this report are possible.
- Foodborne illness outbreaks caused by this specific strain of *E. coli* O157:H7 occurred in 2016, 2017, and 2018, indicating that the outbreak strain may have either persisted in the environment or may have been repeatedly introduced into the environment from an unknown source. Public health officials in the U.S. and Canada were unable to definitively confirm the food vehicle and ultimate source(s) of the 2016 and 2017 illnesses.
- FDA cannot rule out that other sources or means of romaine lettuce contamination with the outbreak strain of *E. coli* O157:H7 may have occurred.

V. Recommendations for Prevention of Pathogenic *E. coli* O157:H7 Contamination Based on these Findings

This is the second multi-state STEC outbreak associated with romaine lettuce in the United States in 2018. This outbreak has had serious public health consequences as well as ramifications for the produce industry. Implementation of appropriate science- and risk-based preventive measures to reduce the potential for contamination of leafy greens from farm to fork is the most effective and practicable means to assure the safety of produce.

The circumstances which lead to produce contamination and foodborne illness outbreak are often situation specific but involve previously identified hazards and routes of contamination. In this case use of agricultural water contaminated with the outbreak strain of *E. coli* O157:H7 was the most likely cause of the outbreak. While the hazard and route of contamination are similar to the *E. coli* O157:H7 outbreak associated with romaine lettuce consumption that occurred in the Spring of 2018, it differs in a number of ways. The water reservoir associated with this outbreak was not interconnected to other water sources or distribution systems in the growing region. Additionally, a closely related rare genetic fingerprint of the outbreak strain as determined by whole genome sequencing, had been seen previously in ill consumers in the U.S. and Canada in the Fall of 2016 and the Fall of 2017.

The FDA recommendations as a result of this investigation are similar to and reinforce the changes recommended in the [Environmental Assessment associated with the Spring of 2018 STEC outbreak associated with romaine lettuce from the Yuma growing region](#).

FDA, state regulatory partners, and the produce industry all have critical responsibilities for ensuring the safety of produce. FDA sets standards for the safe growing, harvesting, packing, processing and holding of produce¹, and works in collaboration with our state counterparts to ensure compliance with these standards. FDA also works with a number of stakeholders to provide training and technical assistance on safe practices and conducts various forms of research to better understand how contamination events occur. At the same time, industry has the responsibility for ensuring that the foods they bring to market are safe for consumers to eat. All segments of the leafy greens industry should thoroughly review current operations, procedures, policies and practices taking into consideration the findings of this investigation report, the [FSMA Produce Safety Rule](#), the [FSMA Preventive Controls for Human Foods Rule](#) and other relevant FSMA regulations.

[FDA FSMA Produce Safety Rule](#) specifically requires that growers, including leafy greens growers, assess their growing operations to minimize the risk of serious adverse health consequences or death from the use of, or exposure to, covered produce, including those measures reasonably necessary to prevent the introduction of known or reasonably foreseeable hazards into covered produce, and to provide reasonable assurances that the produce is not adulterated under the Federal Food, Drug, and Cosmetic Act.

Other science-based information relevant to the reduction or elimination of human pathogens on leafy greens should also be considered. Necessary modifications should be made to operations, procedures, policies and practices to ensure safe products for consumers and minimize the likelihood of similar outbreaks in the future. In the case of the California farm linked to this outbreak, FDA has offered to review any mitigation plans the firm may choose to submit to the agency.

Outbreaks involving leafy greens are challenging to investigate because of the short shelf-life of the product leading to lack of available identifying packaging at the time of the investigation, the wide distribution and consumption of leafy greens, the complex supply chain between the farm and the end user and traceability records and product labeling that often lack key data elements (e.g. where leafy greens are specifically grown). These factors further demonstrate the importance of implementation of applicable provisions of the [FSMA Produce Safety Rule](#) and Good Agricultural Practices (GAPs) on all produce farms.

These provisions are designed to prevent food contamination, foodborne illness, and foodborne outbreaks rather than reacting to them once they've already occurred.

FDA recommends that growers of leafy greens assess their growing operations for compliance with applicable requirements of the FSMA Produce Safety Rule and GAPs, including:

- assure that all agricultural water (water that directly contacts the harvestable portion of the crop and/or food contact surfaces and harvest equipment) used by growers is safe and of adequate sanitary quality for its intended use¹. This may include the development and use of validated and verified treatment of agricultural water, when growers choose to use agricultural water treatment as a preventive measure (any agricultural water treatment must also adhere to any other Federal, State, Local, or other regulations on implementation);
 - assess and mitigate risks related to wild animal intrusion that may contaminate agricultural water;
 - assess and mitigate risks related to land uses near or adjacent to agricultural water sources that may contaminate agricultural water; and
- perform a root cause analysis when a foodborne pathogen is identified in the growing environment, in agricultural inputs (e.g., agricultural water or soil amendments), in raw agricultural commodities or in fresh-cut ready-to-eat produce. The goal of a root cause analysis is to determine the likely source of the contamination, if prevention measures have failed, and whether additional measures are needed to prevent a reoccurrence.

Other FDA recommendations have a broader target audience.

- FDA urges other government and non-government entities, produce growers and trade associations both domestically and internationally to develop real time procedures to quickly explore the possible scope, source(s) and route(s) of contamination when human pathogens of public health significance are detected by routine pre-harvest or finished product verification testing. Local in-depth knowledge and actions are critical in helping determine likely potential routes of contamination of leafy greens in the regions in which they are grown. This information is critical to developing and implementing appropriate science and risk based preventive measures to reduce the potential for another outbreak associated with leafy greens or other fresh produce commodities. Widespread sharing of such findings among the leafy greens and produce industry would also be helpful to increase awareness of potential routes of contamination and preventive measures. FDA has provided and is committed to providing technical assistance to state regulatory partners and the produce industry to enhance produce safety.
- FDA continues to recommend that leafy green growers, buyer/shippers, and retailers be able to trace product back to the specific source in real time and make information about the source, such as harvest date and standardized

growing regions, readily available for consumers on either packaging, point of sale signs, or by other means. In response to this outbreak FDA requested, and the leafy greens industry agreed to provide, voluntary labeling of romaine lettuce products to provide consumers with information on where their romaine lettuce is grown and the date on which it was harvested. The purpose of this new voluntary labeling was to help consumers discern, in the event of an outbreak, whether romaine lettuce products available for purchase at retail stores or restaurants were harvested after the outbreak or not grown in an implicated growing region. The voluntary labeling also provides for improved romaine lettuce traceability and, if need be, provides FDA with the ability to focus future public health communications about the safety of romaine lettuce from a particular growing region or harvest date.

- FDA strongly encourages the entire leafy greens supply chain to adopt traceability best practices and state-of-the-art technology to assure quick, accurate and easy access to key data elements from farm to fork when leafy greens are involved in a potential recall or outbreak. Fresh produce, including leafy greens, are a highly perishable commodity, and traceability information should facilitate the rapid tracking of implicated product throughout the entire supply chain to expedite its removal from commerce, prevent additional consumer exposures, and properly focus any recall actions. A key element that would assist tracing efforts during an outbreak is the ability to identify specific farms or ranches and dates of harvest for product that contribute to production lots if product has been commingled. While it is important to understand where the product was grown and not simply the location of the business entity that shipped or processed it, it is equally important to be able to determine which farm(s) and growing region(s) are responsible for supplying the contaminated product, and the time frame when product was supplied.
- This information is crucial to the development of accurate public health messages to protect the public and empower retail establishments and consumers to take appropriate actions to prevent exposure. Without the ability to identify the growing region or specific suppliers of suspected shipments, public messaging by FDA and other public health partners during outbreaks or recalls will continue to be broad out of necessity, likely including farms and growing regions that are not responsible for the contamination. If supplier data are maintained when the product is co-mingled and consumers can differentiate where and when product was harvested, it is easier to narrow the number of suspected shipments and suppliers of the contaminated product once it is processed.

Footnote:

¹ The FDA has [proposed](#) [Docket No. FDA–2011–N–0921 Federal Register Vol 82: No. 176 Wednesday, September 13, 2017] to extend, for covered produce other than sprouts, the dates for compliance with the agricultural water provisions in the Produce Safety Rule. The agency is proposing to extend the compliance dates to address questions about the practical implementation of compliance with certain provisions and to consider how we might further reduce the regulatory burden or increase flexibility while continuing to achieve our regulatory objectives, in keeping with the Administration’s policies. In the interim FDA is providing technical assistance to the produce industry as it considers the most effective and feasible ways to prevent adulteration of fresh produce from agricultural water.

VI. Relevant Links

- Statement from FDA Commissioner Scott Gottlieb, M.D.
- [FDA Investigating Multistate Outbreak of *E.coli* O157:H7 Infections Linked To Romaine Lettuce](#) (FDA posting for this outbreak)
- [CDC Multistate Outbreak of *E.coli* O157:H7 Infections Linked to Romaine Lettuce \(Final Update\)](#) (CDC posting for this outbreak)
- [Canada Public Health Notice - Outbreak of *E. coli* Infections Linked to Romaine Lettuce](#) (Canadian posting for this outbreak)
- [NCBI link to the WGS information related to this outbreak](#)
- [About the Produce Safety Network](#)
- [About the CORE Network](#)
- [FSMA Produce Safety Rule](#)
- [FSMA Preventive Controls for Human Foods Rule](#)
- [FDA Bad Bug Book](#)