

Investigation Report:
Factors Potentially Contributing to the
Contamination of Packaged Leafy
Greens Implicated in the
Outbreak of *Salmonella* Typhimurium
During the Summer of 2021

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Reason for Investigation

In July and August of 2021, 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 packaged leafy greens produced at a Controlled Environment Agriculture (CEA) indoor hydroponic operation.¹

Total Illnesses: 31

Hospitalizations: 4

Deaths: 0

First illness onset: June 10, 2021

Last illness onset: August 18, 2021

States with Cases: IL (18), MI (1), PA (2) WI (10)

The outbreak response investigation found:

1. The outbreak was associated with the consumption of packaged leafy greens from the firm's CEA indoor hydroponic operation; 26 of 27 (96%) patients reported consuming any leafy greens prior to illness onset, with 20 of 24 cases reporting consumption of prepackaged salads. This firm's products were named specifically in 14 cases.
2. This outbreak was caused by *Salmonella* Typhimurium as determined by whole genome sequencing (WGS) analysis. The *Salmonella* Typhimurium isolates from ill consumers were closely related genetically; however, there were no product isolates for comparison.
3. Loyalty card data was received for nine cases. The information identified a common brand of packaged salads and the traceback investigation determined all of the points-of-service (POS) were supplied by the same hydroponic operation owned and operated by this firm. The firm's salad products purchased by ill consumers were confirmed to be produced at the firm's hydroponic operation.

FDA conducted an on-site produce safety investigation of the firm's CEA operation, as part of the outbreak investigation.

¹ Throughout this document the term "firm" is used to represent the business entity, while the term "operation" refers to the farm location.

Investigation Results

In July and August 2021, FDA investigators conducted an investigation of the CEA operation identified by FDA and CDC as the source of leafy greens associated with the *Salmonella* Typhimurium outbreak. The investigation² consisted of interviews with key personnel from the firm, direct observation of the firm’s operations, and the collection of samples for microbiological analysis, including samples of finished product, seeds, and growth media, water samples from locations on and around the grounds, as well as environmental swabs of surfaces throughout the operation.

This CEA operation produces leafy greens using common commercial high density hydroponic growing techniques with deep water culture and floating raft production methods. Firm personnel escorted FDA investigators through each stage of the operation, which includes seeding, growing, harvesting, packaging, and holding. Steps in the production process include the following:

- Leafy greens are grown on reusable polystyrene rafts that are filled with soilless growth media and seeds, sprayed with water from a municipal water supply, and placed in a climate-controlled room for seed germination prior to their transfer to numerous production ponds located within large scale greenhouses where they remain afloat throughout the growing process until removed sequentially for harvesting of the plants.
- Plastic-lined growing ponds are filled with water sourced from a municipal water supply that is further treated on-site through a four-stage sand filtration and UV system. The ponds typically receive additional water, as needed from one of two large cisterns situated above ground that hold the UV-treated water. Once in the growing ponds, the water is not routinely disinfected or otherwise treated.
- Leaf material harvested by cutting blades is deposited into reusable plastic containers that are placed in a commercial walk-in cooler. At the packing location, product is manually transferred from the reusable plastic containers into consumer size packages that are sealed and transferred to a cooler for cold holding until the time of shipment in refrigerated vehicles.

The FDA investigators’ observations and the analysis of approximately 300 product, water, and environmental subsamples collected during the investigation provide insights on how the pathogen may have first been introduced into the operation and factors that may have allowed the movement and growth of the pathogen within the establishment. The identified areas of concern regarding the firm’s ability to eliminate or minimize potential sources and routes of contamination of their product have been shared with the firm. Observations included:

² FDA initiated an investigation of the regulated CEA operation and received voluntary consent of the adjacent landowner, a non-FDA regulated entity, to collect samples from a stormwater retention basin located outside the CEA operation’s property. In this document, the term “investigation” is used to refer to both the on-site activities at the FDA regulated CEA and the permitted access to the adjacent property.

Protection of Raw Materials: The CEA operation stored its nutrient-rich growth media used in the production rafts in an outdoor location that was not adequately protected from potential sources of contamination such as animal intrusion, bird droppings, or water runoff. FDA's sampling of raw materials at the time of the investigation did not result in the recovery of any pathogens.

Growing Pond Water: A water sample collected by FDA from an active production pond yielded a positive result for *Salmonella* Liverpool, a strain not associated with the outbreak. The firm indicated the portions of the leafy greens that contact pond water during production and harvest are not intended to be retained for inclusion in final products. However, while on-site, FDA investigators observed that some lettuce leaves that contacted production pond water directly during raft removal from the ponds were not subsequently eliminated during harvest and post-harvest production practices. Production water contaminated with human pathogens and measures that do not adequately remove and discard leaves that were in direct contact with pond water could result in a contaminated finished product. The firm reported to investigators that water samples are collected weekly from each production pond and analyzed for generic *Escherichia coli*. The firm personnel indicated to investigators that ponds were treated with a hydrogen peroxide and peracetic acid solution when sampling revealed the presence of *E. coli* in the water; however, the firm did not have a procedure or systematic approach to ensure adequate pond water treatment. During the investigation the firm reported draining and cleaning two of their growing ponds. This involved draining the pond water, shoveling out all media that was deposited on the liner, and power washing and scrubbing the liner and the exteriors of circulation pipes with a commercial cleaning solution. The cleaned liner was then treated with a hydrogen peroxide and peracetic acid solution, and the pond was refilled with water and a hydrogen peroxide and peracetic acid solution. The firm reported that this process of draining and cleaning of a pond had not been completed prior to this occurrence.

Design and Maintenance of Operation: Investigators observed that the harvest blade on the harvest machine did not have positioning controls; there was no control to routinely and consistently exclude harvesting of leaves that may have come into contact with the pond water. Investigators also observed that condensate was accumulating on the exterior of overhead chiller water lines and dripping on product located near the growing ponds and on conveyors that move product from one location to another.

Cooling and Cold Holding of Post-harvest Product: The firm verbally reported to FDA investigators that the firm's product cooling procedures are designed to reduce product temperatures to 40°F prior to packaging. The firm reported that they monitor the air temperature within the cooler to ensure proper functioning. During the investigation, FDA did not verify whether the firm ensures that product is cooled to and maintained at the target temperature prior to final packaging.

Nearby Stormwater Retention Pond: FDA collected two water samples from a stormwater retention basin located outside of the CEA operation's property and approximately 25 feet from the CEA structure. A sample tested positive for the outbreak strain of *Salmonella* Typhimurium. Investigators did not observe specific routes of contamination to or from areas surrounding the CEA operation, such as infiltration of storm water runoff, infiltration by animals and pests, or

airborne transfer of contaminants to the growing environments from areas surrounding the operation.

Sanitary Pre- and Post-harvest Environments: The firm did not adequately document that cleaning and sanitizing of equipment, tools, and buildings used in growing operations is routinely conducted in accordance with the firm's procedures.

In what is believed to be FDA's first domestic investigation of a foodborne illness outbreak associated with leafy greens grown in a CEA operation, FDA's on-site investigation supported conclusions from its epidemiologic and traceback investigation that leafy greens grown hydroponically and packed on-site at a CEA operation were the vehicle for the *Salmonella* Typhimurium outbreak that sickened 31 individuals in 2021.

The investigation did not result in the identification of the specific source or route of contamination of the leafy greens. However, the agency identified certain conditions and practices that could result in contamination, including the presence of a different serotype of *Salmonella* in pond water used to grow the leafy greens, growth media storage practices, water management practices, and general sanitation practices at the CEA that were inadequate to prevent the introduction or spread of microorganisms of public health significance into the leafy greens. Aspects of the growing, harvesting, and packaging operations which could have resulted in *Salmonella* contamination and growth in the implicated packaged leafy greens include:

- FDA isolated the outbreak strain of *Salmonella* Typhimurium in a stormwater retention basin adjacent to the CEA farm. However, our investigation did not reveal if that stormwater retention basin was the source of the *Salmonella* that ultimately contaminated the leafy greens, or if instead, the bacterium was present at the CEA operation and then transferred by stormwater runoff or other means to the stormwater retention basin. This highlights the importance of assessing potential risks associated with adjacent and nearby land uses.
- FDA recovered *Salmonella* Liverpool (different than the serotype that caused the outbreak) from a water sample of an indoor production pond. This highlights the importance of minimizing sources of microbial contamination as well as operating and maintaining production ponds in a manner that does not result in the spread of pathogens to product.
- Growth media used in the hydroponic growing operations, which can support the growth of human pathogens when wetted, was not properly stored (such as within an enclosed container or structure) to protect it from contamination. If *Salmonella* was introduced into the growth media, it could be a source of direct contamination of plants during germination, lead to the contamination of pond water, or contribute to the contamination of food contact surfaces that may come into contact with edible portions of the leafy greens.
- Design and operation of the firm could be improved, including procedures for cleaning and sanitizing equipment, maintaining the production ponds, and preventing potential sources of contamination such as condensation from pipes above growing and packing operations.

The firm continues to cooperate with FDA and is voluntarily implementing improvements to the operation.

Requirements and Recommendations

CEA practices, such as those used in hydroponic greenhouse operations, differ in important ways from practices used in open field growing. However, many contamination risk factors are similar to those found in traditional agriculture. Other aspects of indoor CEA operations have more in common with food manufacturing operations and contamination risk factors in a controlled, indoor setting. The moist, warm environments in greenhouses and similar CEA operations can help support the growth of bacteria, including pathogens often implicated in foodborne illness outbreaks. Therefore, FDA highlights the following requirements and recommendations applicable to firms, such as the hydroponic operation implicated in this *S. Typhimurium* outbreak, engaged in CEA:

- Develop a keen understanding of potential sources and routes of contamination including the raw materials and inputs used, as well as possible sources of contamination throughout the operation.
- Implement effective sanitation procedures and sampling plans while also paying close attention to hygienic operations and equipment design, ensuring cleaning procedures do not contribute to the dispersion of microbial contaminants that may be present.
- Assess growing operations to ensure implementation of appropriate science- and risk-based preventive measures, including applicable required provisions of the FDA Food Safety Modernization Act (FSMA) Produce Safety Rule and good agricultural practices (GAPs).
- Implement procedures that are effective in rapidly cooling and cold holding harvested leafy greens after harvest and verify the effectiveness of the cooling and cold holding procedures, including the routine monitoring of processing and storage environments and product temperatures to prevent pathogen growth in harvested leafy greens.
- If employing tools such as pre-harvest and post-harvest sampling and testing of food, water, and the physical environment, seek to identify and inform sampling plans, limits of detection, and mitigation measures that control potential sources and routes of bacterial contamination in the growing and harvesting environment.
- Ensure that all growing pond water is safe and of adequate sanitary quality for its intended use, which includes implementing measures (such as water treatment) necessary to reduce the potential for contamination by known or reasonably foreseeable hazards.
- Perform a root cause analysis when a pathogen is identified in the growing environment, in raw agricultural inputs such as water, or in the agricultural commodity to determine how the contamination likely occurred and implement appropriate prevention and verification measures.
- Assess and mitigate risks associated with adjacent and nearby land uses that may impact CEA operations, in both rural and more urbanized settings.

The above is not an exhaustive list of requirements and recommendations that may help prevent the introduction of known or reasonably foreseeable biological hazards into or onto produce.

Glossary

Controlled Environment Agriculture (CEA): an advanced and intensive form of hydroponically based agriculture where plants grow within a controlled environment to optimize horticultural practices. CEA systems allow stable control of the plant environment including temperature, light, and carbon dioxide. (Source: [Cornell](#))

Deep water culture: a soilless hydroponic plant cultivation technique where plant roots are constantly submerged in a plant nutrient and oxygen-rich water solution.

Growth Media: in hydroponic plant cultivation systems, soilless materials which provide a substrate for seed germination, seedling growth, and mechanical support of plants.

Hydroponics: soilless plant production techniques used to grow plants using mineral nutrients dissolved in aqueous solutions.

Investigation: an information-gathering activity conducted for several reasons. The purpose of an investigation is to determine and document facts concerning an issue to inform the agency in making sound decisions.

Root cause analysis: a retrospective investigative method that can be applied to a wide range of events affecting food safety, especially problems of a recurring or unusual nature. This is an important step in helping industry modify practices to avoid identified risks and can provide more data that help detect potentially unsafe products.

Sample: a specific test for pathogens in a specific location or of specific materials, comprised of numerous sub-samples.

Stormwater retention basin: a control structure, such as a pond, with or without a structural form that provides retention of water runoff from impervious surfaces.

Relevant Links

[FDA Public Health Advisory: Outbreak Investigation of Salmonella Typhimurium: BrightFarms Packaged Salad Greens \(July 2021\)](#)

[CDC Food Safety Alert: Salmonella Outbreak Linked to BrightFarms Packaged Salad Greens](#)

[NCBI: Salmonella Typhimurium in Packaged Salad Greens](#)

[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](#)