U.S. FOOD & DRUG ADMINISTRATION

Outbreak Investigation Report:

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

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Reason for Field Investigation

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 investigation in Indiana. As a part of the 2022 investigation, FDA and state partners collected multiple samples, but none of the resulting isolates were a definitive match to the 2022 outbreak strain.
3) FDA's 2022 traceback investigation identified 11 points of service, of which 8 traced back to a common packinghouse. Although a common packinghouse was identified, there was no convergence to a single shipment of products, and therefore three farms that supplied the common packinghouse were identified as potential sources of cantaloupe.

As a result of the traceback, FDA conducted investigations in Indiana at all three farms, their common packinghouse and nearby public lands. *Salmonella* positive environmental samples were found at each location, but none of the resulting *Salmonella* isolates conclusively matched the outbreak strain by whole genome sequencing (WGS). No cantaloupes were recalled and no public warning was issued due to the implicated products no longer being on the market.

Investigation Results

In August 2022, FDA investigators conducted several investigations of the farms identified through the traceback investigation.

Investigation limitations. In August 2022, FDA investigation teams conducted detailed interviews with owners at the three farm locations and their common packinghouse identified by the outbreak traceback investigation. The investigation resulted in the collection of information regarding relevant food safety, growing, harvesting, and post-harvest handling procedures, policies, and practices. However, all investigations were conducted after growing, harvesting, and post-harvest activities had ceased, limiting direct observations of these processes. Investigation outcomes provided insights on several factors, which potentially contributed to the contamination of melons grown in the SW Indiana region.

Brief synopsis of farming operations and agricultural region. General cropping patterns in the region included grain, oilseed, and beans, interspersed with various vegetable crops, including melons. While locations of several poultry feeding operations were identified in the region during the investigation, their potential contributions to this outbreak investigation were not specifically determined.

Weather related events during spring and summer, 2022. Widespread precipitation during spring, 2022 prompted the Indiana Department of Environmental Management, Confined Feeding Operations Program to provide assistance to confined animal feeding operations and concentrated animal feeding operations with appropriate guidance for storage or land application of manure. Media outlets reported heavy rains between July 23, 2022, and July 29, 2022, which resulted in power outages, road and bridge damage, road closures, and flooding in the growing area.

Whole genome sequencing analysis summary. FDA routinely sequences the genomes of *Salmonella* isolates and uploads the whole genome sequence (WGS) data to the National Center for Biotechnology Information (NCBI) Pathogen Detection database. That database currently hosts WGS data for over 500,000 *Salmonella* isolates collected over decades from locations around the world. For a set of *Salmonella* isolates, FDA performs high-resolution WGS analysis to determine how likely it is that they came from the same source. *Salmonella* isolates that have very similar genomes are called a 'match'; those with substantially different genomes are deemed 'not a match' and are often referred to as different 'strains'; and those with an intermediate level of differences in genomes are referred to as 'genetically related'. The relationships between the isolates collected in this investigation and isolates from the NCBI Pathogen Database are shown in Figure 1, and a general spatial distribution of farm investigation locations is shown in Figure 2.

Isolates collected from Farm 1 were classified into an NCBI *S.* Typhimurium grouping (Fig. 1A). These isolates represent a single strain that matches three human clinical cases collected between 2016 – 2018 indicating that this strain has caused disease. The isolates recovered from Farm 1 were genetically related to the 2022 multistate *S.* Typhimurium outbreak (Fig. 1A), as well as isolates sampled from a cantaloupe in 2013, isolates collected from Indiana ground turkey in 2016, and isolates from a 2020 Indiana soil subsample (Fig. 1A).

Isolates from Farm 2, Farm 3, and the packinghouse were classified into two strains that fall into a single NCBI *S.* Newport grouping (Fig. 1B): The first strain included all isolates collected from Farm 3 and the packinghouse, along with some of the isolates collected from Farm 2 (Fig. 1B; Strain 1). These isolates were a match to 23 clinical cases spanning 2017 - 2022 (Fig. 1B; Strain 1). The second strain contained the remaining isolates collected from Farm 2, and these were a match to three clinical cases collected between 2016 – 2021 (Fig. 1B; Strain 2), indicating that both these *S.* Newport strains have caused disease. The isolates recovered from Farm 2, Farm 3, and the packinghouse were genetically related to a 2020 multistate *S.* Newport outbreak, as well as isolates collected as part of a Missouri poultry investigation in 2016 (Fig. 1B).

Sampling on public land at off-farm locations resulted in the collection of other strains of *Salmonella*, with one isolate collected by water filtration matching a 2020 human clinical isolate. Additionally, water filtration samples collected from different water drainage systems separated by approximately 4.5 miles contained isolates that matched one another. Taken together, these results suggest that *Salmonella* presence is a reoccurring issue which may impact the safety of melons grown in this region.

Individual Farm Operational and Sampling Summaries

Farm 1:

Disposition of field in question. Farm 1 leased approximately 60 acres of farmland used to grow cantaloupes associated with this outbreak. Specific terms of use land agreements that outline parameters when land is not used for cantaloupe production were not reviewed during the time of inspection. While field investigators did not observe potential sources or routes of water runoff from adjacent fields, a drainage ditch was observed on the southeast border of the field in question. Flooding impacts from heavy rain events are monitored, but not documented, and no evidence of flooding was observed on the farm during the inspection. The grower also stated that flooding did not impact ground preparation and spring planting of cantaloupe nor the growth and harvest of the crop. Several turkey feeding operations were observed in the immediate area, the nearest is located within one mile of the field in question. Crops being cultivated during the time of inspection on lands adjacent to the field of interest included field corn and soybeans.

Cantaloupe growing and management practices. The previous crop rotation for this field included double-cropped soybeans behind wheat, which was grown and managed by Farm 1. Cantaloupe preplant practices were comprised of a fall (2021) deep tillage operation followed by field cultivation and raised planting bed establishment during spring, 2022. Prior to cantaloupe transplanting, plastic mulch was applied to the surface of raised beds equipped with drip irrigation. Cantaloupe (cultivar 'Aphrodite') transplanting occurred in fields managed by Farm 1 between May 1 through the first week of June using a water wheel transplanter to manually transplant cantaloupe seedlings through plastic mulch into soil. Cantaloupe transplants were sourced from an Indiana supplier. Water used during the process of transplanting cantaloupe seedlings was not reviewed for microbial quality at the time of inspection. The crop was grown and managed using conventional production practices.

Agricultural water. Well water, pumped from a dedicated well at a depth of approximately 60 feet, was applied directly to plant roots via a drip irrigation system and was assessed for generic *Escherichia coli* and generic coliforms 2 to 5 times during the growth cycle of the crop (May – July). No water treatments were used by this operation. Water sourced from wells was used to irrigate the crop and in the preparation of pesticide mixtures for insect control. While water quality records were not reviewed by investigators, the grower verbally stated that well water was within water quality standards of the operation (no detectable generic *Escherichia coli*).

Animal management and Biological Soil Amendments of Animal Origin (BSAAO) use. A field drainage ditch, adjacent to the field in question, is lined with trees and small shrubs which could serve as a potential animal harborage site. The farm visually monitors animal activity in growing areas but does not document it. No mammalian activity was observed during the inspection. The grower stated that BSAAO were not used during the growing and harvesting of the cantaloupe crop nor in the production of rotation crops grown on the same field in question. Use of BSAAO in adjacent farmland growing field crops was not known by the farm.

Harvest tools and equipment. Third party contracted field crews bulk harvested cantaloupes manually into vinyl-lined trailers used to transport the fruit to an off-site sorting, washing, and packing operation. Cantaloupes were harvested multiple times based on crop maturity. The Farm 1 representative stated that while harvest trailers are owned by the farm, they are cleaned after each use by the packing operation. Cleaning and sanitizing procedures and records were not available for review during the time of

inspection. Equipment used in the harvest of cantaloupe are cleaned as needed by the farm. Documentation and records were not reviewed at the time of inspection.

Environmental sampling and Whole-Genome Sequencing. At Farm 1, FDA investigators collected 5 soil scoop subsamples from discrete sample locations and 12 soil drag swab subsamples from cantaloupe growing fields. No *Salmonella* isolates were recovered in soil scoop subsamples, but one soil surface drag swab resulted in the recovery of 12 *S*. Typhimurium isolates. WGS analysis found that these isolates represent a single strain that matches human clinical isolates from 2016, 2017, and 2018 indicating that this strain has caused illnesses.

Farm 2:

Disposition of field in question. Cantaloupes were grown on 45 acres of leased farmland which, when not planted in cantaloupe, is subleased to other farmers that grow non-produce crops. Terms of lease agreements were not evaluated during this investigation. The grower stated that extreme weather events in 2022 did not impact field preparation and planting activities nor the production of cantaloupes during growing and harvest periods. At the time of inspection, crops being grown on land adjacent and near the field of interest consisted of field corn, soybeans, and alfalfa.

Cantaloupe growing and management practices. Historical crop rotation practices for the field in question involved growing cantaloupe every 3 to 5 years in succession with field corn, soybeans, winter wheat and other agronomic crops during non-cantaloupe seasons. To prepare the cantaloupe field for planting, a fall (2021) soil tillage operation was followed by field cultivation and planting bed establishment during spring, 2022. The cropping system used to grow the crop consisted of using a plasticulture-based system which involved layering plastic mulch on raised planting bed surfaces and the installation of subsurface drip irrigation tape, pressurized by a dedicated well and booster pump. The grower indicated that cantaloupe melons grown at Farm 2 used chemical fertilization practices, and did not require pesticide, fungicide, or herbicide applications.

Agricultural water. A dedicated well, located within the field in question, provided water utilized solely for irrigation purposes. At the time of inspection, the well was capped and not accessible for water sampling. The grower indicated that water quality testing of the well is conducted during the growing season (May – July). An analytical record provided for review (May 2022) suggested that water used to grow cantaloupes met state, local, and regional water quality standards for agricultural water (no detection of generic *Escherichia coli* and generic coliforms). Subsequent agricultural water records were not reviewed during the time of inspection.

Animal management and BSAAO use. Indications of wild animal activity, such as animal tracks and bird activity, were observed at Farm 2 by investigators during the time of inspection. While evidence of on-farm animal activity was monitored and corrective actions were implemented by employees during the growth and harvest of the crop, specific documentation of these actions was not reviewed by inspectors. The grower indicated that no known BSAAO were utilized during the production of the cantaloupe crop in question and verbal agreements were used between the lessor and lessee to determine the use of BSAAO during non-cantaloupe cropping years.

Harvest tools and equipment. A third-party harvest company was contracted by Farm 2 during the period of cantaloupe harvest (July – August). Based on crop maturity, field crews hand harvested cantaloupes multiple times during the season and did not utilize hand tools during harvest. Harvested fruit was transferred into trailers and transported to the packing operation for washing, sorting, sizing, and

packing prior to shipment and consumption by consumers. While trailers used to transport the crop were not observed during the inspection, the grower stated that harvest trailers were cleaned prior to use, although specific protocols and records were not reviewed by the inspection team.

Environmental sampling and Whole Genome Sequencing. At Farm 2, FDA investigators collected 12 soil surface drag swabs from field surfaces and 6 soil scoop subsamples. Three of the twelve drag swabs yielded 30 *S.* Newport isolates, and soil scoops from Farm 2 yielded no *Salmonella* spp. isolates. The 30 isolates represent two separate strains. Isolates from 2/3 *Salmonella*-positive drag swabs matched (1) *S.* Newport isolates recovered from Farm 3, (2) isolates recovered from the post-harvest handling and packing entity associated with this outbreak, and with (3) 23 human clinical isolates collected between 2017 – 2022, indicating that this strain has caused illnesses. Isolates derived from the third drag swab were a match to 3 human illness clinical isolates recovered in 2016, 2019, and 2021, indicating that this strain has also caused illnesses.

Farm 3

Disposition of field in question. Approximately 140 acres of leased agricultural land was used to grow cantaloupes on Farm 3. Historical crop rotation records were not available for review by investigators, and firm management was not fully aware of specific crop rotation cycles or growing practices used by other land lessees during non-cantaloupe production seasons. Investigators did not review land use lease agreements associated with Farm 3 to determine the nature of land use during non-cantaloupe production seasons. A turkey feeding operation is positioned within a 2-mile radius of the field in question. While heavy rains in the growing area were noted during the growth or harvest of the crop by investigators, the Farm 3 representative indicated that these extreme weather events did not negatively affect the growth or management of the crop. Field maps showing water drainage flow patterns were not reviewed at the time of the investigation. Investigators did not evaluate the impacts of adjacent and nearby lands on the production of cantaloupes at Farm 3. The representative of Farm 3 stated that the farm was audited by a third-party program and inspected by the state without objectionable conditions.

Cantaloupe growing and management practices. FDA was unable to determine the cultural practices used to grow and manage cantaloupes produced on Farm 3.

Agricultural water. Irrigation water, delivered to plant roots via subsurface drip irrigation methods, was sourced from a dedicated well, approximate 80 to 100 feet deep, located adjacent to the field of interest. Well water microbial analysis was performed by Farm 3, two to three times during the cantaloupe growing season. Farm 3 verbally indicated that all water tests were negative for generic *Escherichia coli* and generic coliforms. The well pump was shut off for the season and therefore the well water was not accessible for sampling by the investigation team during the time of the investigation. Laboratory monitoring records and farm water quality standards were not reviewed during the time of the investigation. Water used to prepare pesticide and fungicide crop protection mixtures was not assessed during this investigation.

Animal management and BSAAO Use. When field-level, animal intrusion events occur, farm personnel are instructed to deter or exclude animals from farm fields and alert management and harvest supervisors of potential contamination. It is unknown if animal intrusion events occurred at Farm 3, evidence of animal activities in the field during the growth and harvest of the crop was not observed at the time of the investigation. The Farm 3 representative indicated to investigators that applications of

untreated turkey manure are conducted within a 2-to-2.5-year cycle, during non-cantaloupe growing seasons when the field of interest is under the control of different management. Investigators determined that untreated turkey manure was provided by a third-party supplier who also transported and managed broadcast applications to fields, however, specific details regarding application timing, staging or storage locations, rates, and manure related documentation was not collected. Investigators requested a turkey manure Certificate of Analysis for review, but it was not collected during the investigation.

Harvest tools and equipment. Depending on maturity, cantaloupe melons were harvested manually by a contracted, third-party harvest firm multiple times at Farm 3 without the use of hand tools. Harvest crews transferred melons into either bulk harvest trailers or modified buses for transport to subsequent off-site, post-harvest packing operations. The Farm 3 representative stated that while standardized harvest and transport equipment cleaning and sanitizing procedures are utilized with no compliance deficiencies noted, documentation and records outlining these activities were not reviewed by investigators.

Environmental sampling and Whole-Genome Sequencing. At Farm 3, FDA investigators collected 5 soil scoop subsamples from discrete field locations and 12 soil drag swabs from field surfaces. All soil scoop subsamples were negative for *Salmonella* spp., but one drag swab resulted in the collection of 5 *S.* Newport isolates which were determined by WGS analysis to represent a single strain. These isolates were a match to (1) *S.* Newport isolates recovered from Farm 2, (2) isolates recovered from the post-harvest handling and packing entity associated with this outbreak, along with (3) 23 human clinical isolates collected between 2017 – 2022, indicating that this strain has caused illnesses.

Packinghouse

Overview of the Packinghouse and Product Flow. Cantaloupes were transported via bulk trailer from the field to the unloading door of the packinghouse. Melons were placed on an unloading ramp and conveyed by belt to incline rollers and passed through a washing spray station. Melons were washed by being passed through brush rollers with overhead spray nozzles using single-use municipal water containing an antimicrobial solution. After washing, cantaloupes were moved to grading rollers, and culled melons were removed from the line by diverting them outside to the northern side of the packinghouse. Once graded, melons moved to size rollers, after which employees hand-packed cantaloupe into single use corrugated boxes. Boxed melons were either loaded onto transport trailers that were maintained at 38°F or held for up to 48 to 72 hours at ambient temperatures in the packinghouse. If held at ambient temperature for more than 72 hours, product was repacked to verify quality standards. The investigation revealed that cantaloupes were usually shipped out the same day that they were packed. The entity conducts routine monitoring for pests and has pest control measures in place through a third-party. Personnel training records are established and kept.

Overview of Post-Harvest Practices. Cleaning and sanitation procedures were performed at the end of the production day as well as between different lots. Cleaning and sanitation records did not show any instance in which different lots were packed on the same day. The firm's daily procedures consisted of cleaning and removing physical debris from equipment surfaces, rinsing equipment, including interior areas, water trapping areas, and under equipment, with municipal water. Surfaces were then soaped from bottom to top with a foamer, after which the foam detergent was rinsed with municipal water and visually inspected. If visibly clean, ATP tests were then performed to determine cleaning efficacy. If surfaces were passed as clean as per the ATP test, a cleaning product was diluted and applied to the equipment with a handheld pump sprayer, and air dried with no rinse. The standard operation procedures (SOP)

stated that a quaternary ammonium-based sanitizer was used during this final cleaning and sanitation step, although investigational findings found that a product intended to assist in fruit and vegetable washing was applied to equipment surfaces. As such, the cleaning product that was used as a final step was inconsistent with the SOP provided by the firm. The entity reported conducting microbial water testing annually for water used during post-harvest activities by testing for generic *E. coli* and total coliforms (microbial criteria: non-detect per 100 mL of water). An EPA-registered sodium chlorite antimicrobial was added to municipal water to generate chlorine dioxide at a target concentration of 5 ppm, which was applied in an overhead spray in conjunction with brush rolling to wash cantaloupes prior to grading. The packinghouse provided a monitoring template that stated chlorine dioxide levels were monitored hourly via test strips. A single measurement of 5 ppm chlorine dioxide was recorded, per day, on a separate record sheet that also documented equipment cleaning procedures. The single-use water from the overhead spray was collected in a drain system and emptied into a leach field that is not used to grow produce.

Sampling and Investigational Findings in Packinghouse. Three samples were collected during the packinghouse inspection. Two samples consisting of (1) 20 environmental sponge swabs collected from equipment dedicated to packing cantaloupes and (2) 33 environmental sponge swabs collected from transport trailers dedicated to transporting cantaloupes were all negative. The third sample, which consisted of 55 environmental sponge swabs collected from equipment dedicated to packing cantaloupes, resulted in a positive test for *S.* Newport in a subsample collected from the brush roller used for washing cantaloupes; it was not in use during the time of the investigation as the packing season was complete. WGS analysis revealed that these isolates were a match to isolates recovered from Farms 2 + 3, along with 23 human clinical isolates collected between 2017 – 2022 indicating that this strain has caused illnesses.

Off-farm, Public Land Samples

Past glacial outwash, and more recent erosion activities, resulted in the deposition of coarse textured medium and fine sands which served as primary parent materials for the formation of agricultural soils in the region. The resulting undulating topography with soils predominantly consisting of loamy sand or sandy loam textures are considered very well drained with high water infiltration rates and low runoff potential. Because bedrock is found in some areas as close as five feet from the soil surface, water tables are generally high in this area and are augmented by several dredged drainage ditches to assist in managing subsurface water accumulation.

Three additional samples were collected at public access sites along two of these water drainage ditches to assess potential human pathogen presence, movement, and persistence in the environment. All drainage ditch samples were collected within the general vicinity (see Figure 2) of the farming and packing operations associated with this outbreak. None of the off-farm isolates recovered were genetically related to isolates recovered from Farms 1, 2, 3, or the cantaloupe packing entity, but one water filtration sample resulted in the recovery of 4 *Salmonella* isolates that genetically matched a 2020 Indiana human clinical isolate. Taken together, the drainage water samples resulted in the recovery of multiple *Salmonella* strains, and a soil sample collected at a drainage ditch embankment location resulted in the recovery of 18 *S.* Newport isolates that matched no *Salmonella* DNA sequences in the National Center for Biotechnology Information Pathogen Database.

Requirements and Recommendations

The investigation did not result in the identification of a specific microbial source or route that resulted in the contamination of cantaloupes associated with this outbreak. However, the agency identified *Salmonella* spp. in on-farm, post-harvest, and off-farm environments. Aspects of the growing, harvesting, and packing operations which could have resulted in *Salmonella* contamination associated with the implicated cantaloupe melons include:

- Common Contamination Sources of *Salmonella*. Matching *S.* Newport isolates were recovered from Farm 2, Farm 3, and the melons post-harvest packing entity in this investigation, and these isolates were genetically related to clinical samples associated with a 2020 outbreak. The genetic relatedness between the 2020 outbreak isolates and those collected here provide evidence that common contamination sources and *Salmonella* strains could be persistent within this growing environment.
- Off-Season Land Use. As all farmland associated with this outbreak was not under consistent management or control by cantaloupe growers, investigators were unable to completely determine and evaluate a complete profile of land use hazards. However, evidence suggests that cantaloupe farms did not routinely monitor for potential food safety hazards during non-cantaloupe growing seasons, such as in the applications of untreated turkey manure to land used for the production of cantaloupe. Of note, WGS analysis revealed that *Salmonella* isolates collected from all farms and the associated packinghouse were genetically related both to multistate outbreaks of salmonellosis associated with melons as well as poultry-related isolates, supporting the hypothesis that the outputs from poultry operations may have contributed to these human illness outbreaks of salmonellosis.
- Human Pathogen Reservoirs. The recovery of multiple *Salmonella* strains with clear association with human illness distributed widely within the growing environment may be indicative of robust human pathogen reservoirs which persist and circulate within this growing region. Considering these findings, the FDA is continuing an ongoing assessment of this region to better understand the presence of pathogens in the growing environment.
- Post-Harvest Environments. Written SOPs for cleaning and sanitation were inconsistent with the practices reported by responsible individuals at the packinghouse to the investigator, and the effectiveness of cleaning practices was not verified. Additionally, investigational findings revealed that a final step involved the use of a cleaner labeled for aiding the washing of fresh produce, with or without an antimicrobial, was used on food contact surfaces, contrary to the instructions on the label. Following proper cleaning procedures, sanitizer use on packinghouse food contact surfaces is needed to protect against the contamination of melons. Implementing the appropriate verification procedures for cleaning and sanitization practices is essential to protect against the contamination of melons in packinghouses.
- Pathogen Population Diversity. The recovery of multiple and diverse strains of *Salmonella* within the immediate growing and non-growing environments suggests that the region may contain multiple reservoirs for *Salmonella* spp. In addition, the recovery of *Salmonella* spp. in the broader agricultural environment, as demonstrated by the same *Salmonella* Newport strain being found at Farms 2 and 3 and the packinghouse, exemplifies the complex environmental survival, proliferation, and dispersal mechanisms which can challenge food safety mitigation practices.

In light of these investigation findings, FDA highlights the following recommendations and requirements applicable to firms, such as growers of melons and similar produce:

- Review current conditions and practices to determine whether they are adequate or if additional prevention measures are warranted.

- Understanding previous land use can help farms identify and address potential sources of pathogens that may affect their farming operations.

- 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, including poultry, and the interface between farmland, and other agricultural areas.

- Consider additional tools such as pre-harvest and/or post-harvest sampling and testing of products to help inform the need for specific prevention measures.

- Poultry manure, while valued for its fertilizer value, is a known reservoir for *Salmonella* spp. Proper application of a manure that has been treated with a validated and verified process to reduce pathogens (e.g. composting with time and temperature measurements) can significantly reduce the potential for the integration of *Salmonella* or other human pathogens into soils (as compared to the use of raw manures).

- Inspect, maintain, and clean and, when necessary and appropriate, sanitize all food contact surfaces of equipment and tools used as frequently as reasonably necessary to protect against contamination.

- When appropriate, use EPA-approved products according to the label for cleaning and sanitizing.

- Inconsistent adherence to or deviation from existing SOPs for cleaning and sanitizing by farms can affect produce safety. Effective communication on farms about SOPs and any changes to those SOPs can help ensure that food safety practices are being followed.

- Root cause analyses may be useful in identifying for growers how human pathogen sources in the broader agricultural environment may contribute to contamination.

- 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, manufactures, and retailers as well, to improve overall traceability throughout the supply chain.

FDA recognizes the interconnection between people, animals, plants, and their shared environment (One Health) 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. Growers also have the opportunity to request on farm readiness reviews to better understand the PSR regulatory requirements.

Local in-depth knowledge and actions are critical in helping resolve potential routes of contamination of cantaloupe melons in the Southwest Indiana growing region associated with this foodborne illness outbreak, including Knox and Gibson Counties of Indiana moving forward. FDA urges other government and non-government entities, produce growers and trade associations to further explore possible source(s) and route(s) of contamination associated with the outbreak pathogen and with other foodborne pathogens of public health significance. This information is critical to developing and implementing short- and long-term remediation measures to reduce the potential for another outbreak associated with cantaloupes or other fresh produce commodities.

FDA will work in conjunction with the Indiana State Department of Health to increase awareness amongst the melon growing industry of pathogenic environmental strains in the region to develop and promote risk reduction strategies related to melon growing and harvesting to minimize the impact of these strains.

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.

Glossary

FDA is providing these definitions to assist in understanding these terms as they are used in this report.

Field: a contiguous set of land devoted to the growing and/or harvesting of crops.

Human pathogen reservoir: the habitat in which the agent (e.g., *Salmonella*) normally lives, grows, and multiplies.

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.

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

Strain: A strain represents a lineage whose high genetic similarity suggests they share a recent, common origin

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.

Relevant Links

Food Safety Tips for Consumers & Retailers During an Outbreak

About the CORE Network

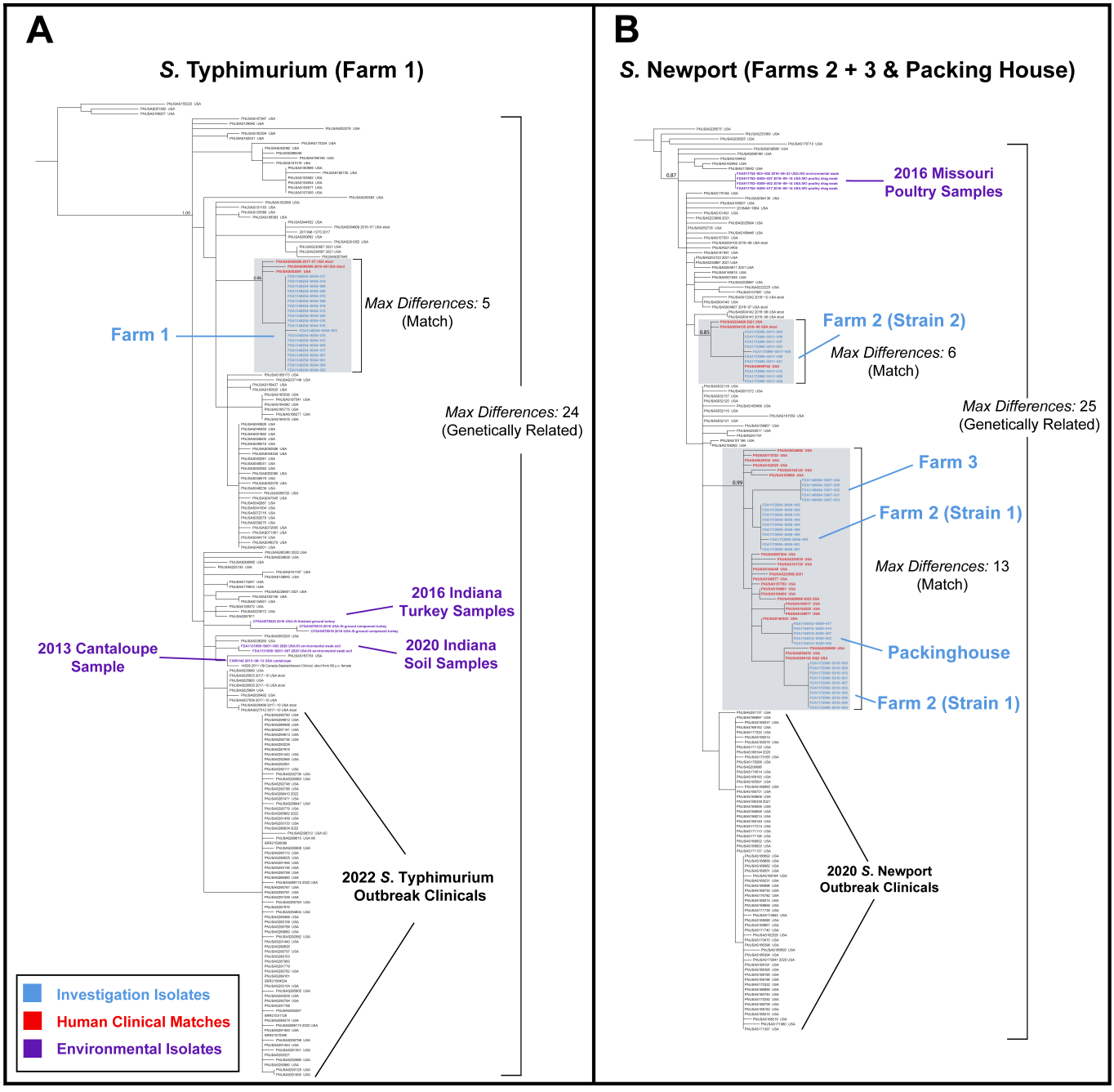
About the Whole Genome Sequencing (WGS) Program

FSMA Final Rule on Produce Safety

FDA Bad Bug Book

Technical Appendix

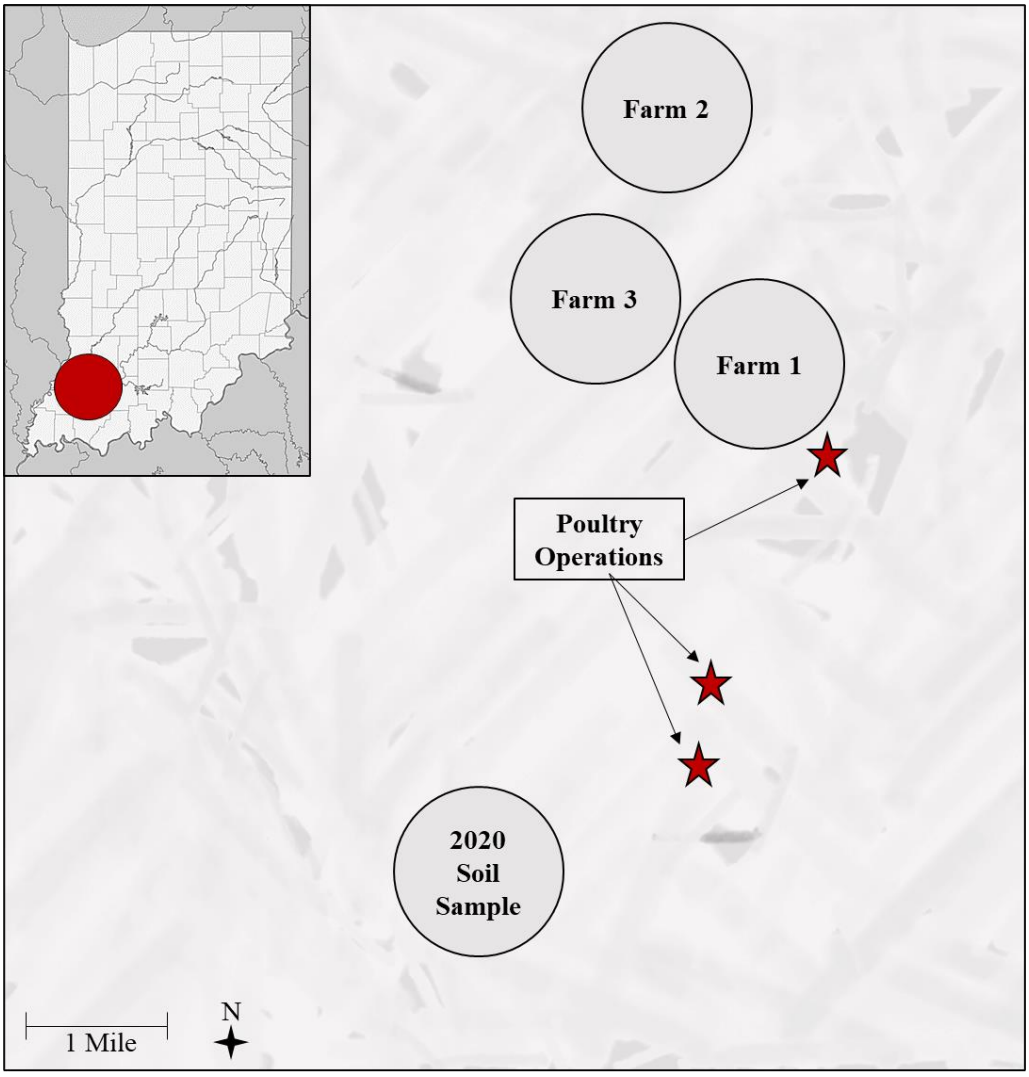
Figure 1: Relationships between *Salmonella* isolates collected as part of this investigation (blue) and isolates from the NCBI Pathogen database



Note: Isolates designated as a 'match' to the investigation isolates are outlined in the gray boxes. Matching human clinical cases are noted with red text. Environmental samples (i.e., isolates derived from facilities, goods, or natural areas collected independently from this investigation) found to be genetically

related to the investigation isolates are noted with purple text. (A) Isolates from Farm 1 match three human clinical cases and are genetically related to the focal *S.* Typhimurium multistate outbreak, along with Indiana soil from 2020, a 2013 cantaloupe sample, and 2016 isolates sampled from Indiana ground turkey. (B) Isolates from Farm 2 represent two *S.* Newport strains. The isolates from Farm 3 and the Packinghouse match one of the strains found on Farm 2 (Strain 1), along with 29 clinical cases, and the other strain detected at Farm 2 (Strain 2) matches three human clinical cases. Like the *S.* Typhimurium grouping, these *S.* Newport isolates are also genetically related to a 2020 multistate outbreak as well isolates derived from a 2016 poultry investigation in Missouri.

Figure 2. A spatial distribution of cantaloupe farm locations in southwest Indiana during for-cause inspections in 2023 (Farms 1 – 3)



Note: The location of a 2020, for-cause cantaloupe inspection resulted in the recovery of a *Salmonella* Typhimurium isolate from a soil subsample genetically related to isolates recovered in 2022 at Farm 1. Red stars indicate the relative proximities of poultry operations within the region.