

Memorandum

To: Gerald Bromley, Director, Division of Domestic Human and Animal Food Operations

From: Kevin Gerrity, Consumer Safety Officer

Date: October 24, 2018

Subject: Memorandum to the File on the Environmental Assessment; Yuma 2018 *E. coli* O157:H7 Outbreak Associated with Romaine Lettuce

SUMMARY

This Environmental Assessment (EA) was conducted as a multi-agency mission led by the FDA Office of Regulatory Affairs (ORA) Human and Animal Food Operations – West (HAFO-W) and the Centers for Disease Control and Prevention (CDC), at the request and with the assistance of the FDA Center for Food Safety and Applied Nutrition (CFSAN)/Coordinated Outbreak Response Evaluation (CORE) team, in response to an *E. coli* O157:H7 outbreak associated with the consumption of romaine lettuce sourced from the winter growing areas in and around Yuma County, Arizona, and Imperial County, California (referred to in this report as the Yuma growing region). The EA was conducted to identify factors that potentially contributed to the introduction and spread of the outbreak strain of *E. coli* O157:H7 that contaminated the romaine lettuce associated with this outbreak.

During this EA, three samples of irrigation canal water collected by the team were found to contain *E. coli* O157:H7 with the same rare molecular fingerprint (using whole genome sequencing (WGS)) as the strain that produced human illnesses (the outbreak strain). These samples were collected from an approximate 3.5-mile stretch of an irrigation canal in the Wellton area of Yuma County that delivers water to several of the farms identified in the traceback investigation as shipping romaine lettuce that was potentially contaminated with the outbreak strain. The outbreak strain was not identified in any of the other samples collected during this EA, although other pathogens of public health significance were detected.

ENDORSEMENT

Date: October 24, 2018

From: Gerald Bromley, Director, Division of Domestic Human and Animal Food Operations

To: DEN-DO Files

The memo of this Environmental Assessment regarding the *E. coli* O157:H7 multistate outbreak is completed and forwarded to the Denver District Files.

ORIG: To DEN-DO Files (FEI: Not Applicable)

Gerald D.
Bromley Jr -S

Digitally signed by Gerald D. Bromley Jr
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DN: c=US, o=U.S. Government, ou=HHS,
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10/24/2018

**Gerald Bromley
Director
Division of Domestic Human
and Animal Food Operations**

Date

ENVIRONMENTAL ASSESSMENT COMPLETE NARRATIVE REPORT

INTRODUCTION

This Environmental Assessment (EA) was conducted as a multi-agency effort led by the FDA Office of Regulatory Affairs (ORA) Human and Animal Food Operations – West (HAFO-W) and the Centers for Disease Control and Prevention (CDC), at the request and with the assistance of the FDA Center for Food Safety and Applied Nutrition (CFSAN)/Coordinated Outbreak Response Evaluation (CORE) team. The EA was conducted in response to an *E. coli* O157:H7 outbreak associated with the consumption of romaine lettuce sourced from the winter growing areas in and around Yuma County, Arizona, and Imperial County, California (referred to in this report as the Yuma growing region) in order to identify factors that potentially contributed to the introduction and spread of the outbreak strain.

The traceback investigation identified a total of 36 growing fields on 23 farms in Arizona and California as potential sources of contaminated lettuce consumed during the outbreak. (See Attachment A.) A total of seven intermediate shippers received the romaine lettuce from these 23 farms, and all but one of these intermediate shippers commingled romaine lettuce from multiple farms upon receipt. The exception was an intermediate shipper that received romaine lettuce associated with the outbreak from only one farm. Whole-head romaine lettuce was traced from this one farm through the intermediate shipper to a correctional facility in Alaska where exposed inmates became infected with the outbreak strain.

Based on the period when the outbreak occurred, the romaine lettuce consumed by ill individuals was likely harvested from early March through mid-April 2018. The EA team conducted its initial on-site activities from June 4-7, 2018. At the time of the EA, no romaine lettuce was being grown, harvested, packed or held from the Yuma growing region.

During site visits by the EA team, mobile task force teams were deployed daily in the Yuma growing region to conduct various environmental assessment tasks. Activities focused on potential sources of *E. coli* O157:H7 in the environment that could have led to contamination of the romaine lettuce, including water and wild and domesticated ruminant animals. The EA team assessed the Colorado River, Yuma growing region irrigation canals, wildlife corridors, and concentrated animal feeding operations (CAFOs) in areas around farms identified in the traceback. The team interviewed growers representing 21 of the 23 traceback-related farms, gathering information on romaine lettuce growing practices and conditions, including:

- agricultural water;
- agricultural chemical spray applications;
- soil amendments;
- harvesting;
- animal intrusion;
- adjacent land use; and
- employee health and hygiene practices.

The EA team collected a variety of environmental samples. Because the Yuma region’s growing season had concluded weeks before the EA started, no leafy greens were available for sampling and testing by the team.

The EA team also assessed aerial spraying operations since the pesticides they use are diluted with water that comes in contact with crops. From July 10-13, 2018, team members returned to the Yuma region to collect ground water samples from two Wellton-area Arizona Department of Agriculture (AZDA) groundwater pesticide monitoring wells and from a section of salt water drain canal downstream of the Wellton-Mohawk Irrigation and Drainage District (WMIDD) area of responsibility.

During the week of August 6, 2018, additional environmental samples were collected by EA team members in cooperation with the WMIDD, AZDA, and the Arizona Department of Environmental Quality (ADEQ), including ground water and WMIDD irrigation canal water samples.

ENVIRONMENTAL ASSESSMENT TEAM

The Lead Investigator for the EA was Kevin Gerrity, FDA National Food Expert from the Office of Regulatory Affairs, Office of Human and Animal Food Operations—West.

The other EA team members were as follows:

Travis Brown, ORISE Fellow
CDC

Diane Ducharme, Staff Fellow
FDA/CFSAN

Angela Fields, Consumer Safety Officer
FDA/CFSAN

Daniel Gorski, Consumer Safety Officer
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Vince Hill, Environmental Engineer
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Erin Holliman, Consumer Safety Officer
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Amy Kahler, Microbiologist
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Michael Kawalek, Microbiologist
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Theresa Klamann, Consumer Safety Officer
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Kurt Nolte, Staff Fellow
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Garrad Poole, Consumer Safety Officer
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Jacob Reynolds, Consumer Safety Officer
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Linda Stewart, Consumer Safety Officer
FDA/ORA

Socrates Trujillo, Consumer Safety Officer
FDA/CFSAN

Daniel Velasquez, Microbiologist
FDA/ORA

J. Christopher Yee, Program Manager
FDA/ORA

Two AZDA representatives also attended multiple EA team field operations as observers.

IRRIGATION CANAL WATER FINDING

Through ultrafiltration sampling of irrigation water conducted during the initial site visit in June, *E. coli* O157:H7 was detected in three places along a 3.5-mile section of the Wellton irrigation canal that is operated by the WMIDD. The locations of the three samples were approximately one mile upstream of a CAFO, adjacent to the CAFO, and approximately one mile downstream of the CAFO (Figure 1). Genetic analyses of these isolates using pulsed field gel electrophoresis (PFGE) and WGS determined that the *E. coli* O157:H7 found in these three Wellton irrigation canal water samples is the same strain that caused the outbreak. Some of the EA activities described in this report were conducted throughout the Yuma growing region before the EA team was aware of this significant finding. Once the EA team became aware of the positive findings, certain activities were focused on areas around the section of the irrigation canal where these positive water samples were obtained.



Figure 1. Wellton Irrigation Canal. This Google Earth view depicts a section of the Wellton main canal adjacent to a CAFO and locations of three outbreak-pathogen-positive irrigation water samples. The sample locations are upstream, adjacent to, and downstream of the Wellton-area CAFO. Also noted are unlined irrigation canal sections and a CAFO retention pond. Water in the canal flows from west (left) to east (right) in the figure above. The CAFO at the bottom center of Figure 1. See Figure 2 for an enlarged image of the CAFO.

GROWER INTERVIEWS

On its initial visit, the EA team gathered information on 21 of the 23 farms, covering 34 of the 36 growing fields identified by the traceback. The team conducted interviews, using a standardized questionnaire, with 13 growers who operated a total of 19 farms, and used information from the initial outbreak investigation for one grower who operated two farms identified by traceback. The EA team made several unsuccessful attempts to contact the grower(s) for the two farms for which interviews were not performed.

The interviewed growers reported that their irrigation water was delivered by one of four irrigation districts:

1. Imperial Irrigation District (IID), which includes the Vail, Spruce, Moorehead, and Ash, and Highline canals;
2. Yuma County Water Users Association (YCWUA);
3. Yuma Irrigation District (YID); and
4. WMIDD, which includes the Wellton, Mohawk, and Texas Hill canals.

The growers reported the following common elements:

- The romaine lettuce crops that were identified in the traceback as possibly being contaminated with the outbreak strain were grown under conventional agricultural practices. No organic crops were grown on farms identified by the traceback.
- For most of the growing fields, no biological soil amendments of animal origin were used. Only two of the 34 growing fields were pre-treated with composted manure as a soil amendment.
- Colorado River water, delivered via open irrigation canal, was used to irrigate romaine lettuce on all 21 of the reporting farms. One farm reporting using well water in addition to canal water to irrigate crops.
- Overhead sprinkler irrigation was used during the germination of romaine lettuce on all 21 of the reporting farms, with germination periods ranging from 5 to 12 days.
- Furrow irrigation was used after germination on 19 of the 21 reporting farms. Two farms in Imperial County used overhead sprinkler irrigation throughout the growing season.
- Irrigation canal water was used to dilute agricultural chemicals that were applied directly onto romaine lettuce crops on 17 of the 21 reporting farms in Arizona and California.

Table 1. Summary of Grower Information

Traceback Shipper Leg	Grower ID # of Farms	Growing Fields: <i>Previous Crops / Adjacent Crops</i>	Irrigation Water Source/ <u>Method</u> (Post Germination)	Primary Water Source for Chemical App.	Chemical Application Post 2-21 freeze (Y or N)	Biological Soil Amendments (Y or N)	Animal Intrusion (Y or N)	Weather Events (Y or N)
Shipper A	Grower 1 3 Farms	<i>Sudan grass</i> <u>Unknown</u>	<i>IID</i> <u>Canals:</u> (b) (4), (b) (6) <u>Post-Germination:</u> • Furrow	Canal	N	N	N	N
Shipper B	Grower 2 3 Farms	<i>Sudan grass, Wheat, Cotton</i> <u>Romaine</u>	<i>WMIDD</i> <u>Canals:</u> (b) (4), (b) (6) <u>Post-Germination:</u> • Furrow	Well	N	N	Y Birds, coyotes, deer	N
Shipper B	Grower 3 2 Farms	<i>Sudan grass, Wheat, Cotton</i> <u>Iceberg, Onion Seed, Spinach, Date Palms</u>	<i>WMIDD</i> <u>Canals:</u> (b) (4), (b) (6) <u>Post-Germination:</u> • Furrow	Well	N	Y Composted manure	N	N
Shipper B	Grower 4 1 Farm	<i>Wheat</i> <u>Fennel, Romaine</u>	<i>YCWUA</i> <u>Canal:</u> (b) (4), (b) (6) <u>Post-Germination:</u> • Furrow	Well and Canal	N	N	N	Y Frost late Feb.-early Mar.

Traceback Shipper Leg	Grower ID # of Farms	Growing Fields: <i>Previous Crops / Adjacent Crops</i>	Irrigation Water Source/ <u>Method (Post Germination)</u>	Primary Water Source for Chemical App.	Chemical Application Post 2-21 freeze (Y or N)	Biological Soil Amendments (Y or N)	Animal Intrusion (Y or N)	Weather Events (Y or N)
Shipper B	Grower 5 2 Farms	<i>Wheat, Cotton</i> <u>Onion, Mustard, Radish</u>	<i>WMIDD</i> <u>Canal:</u> (b) (4), (b) (6) <u>Post-Germination:</u> • Furrow	Canal	Y 2 fields	N	N	N
Shippers C & D	Grower 6 2 Farms	<i>Wheat, Cotton</i> <u>Iceberg, Romaine</u>	<i>WMIDD</i> <u>Canals:</u> (b) (4), (b) (6) <u>Post-Germination:</u> • Furrow	Canal	Y	N	N	Y 30 MPH winds in Feb.
Shipper E	Grower 7 1 Farm	<i>Cantaloupe</i> <u>Iceberg, Spinach</u>	<i>WMIDD</i> <u>Canal:</u> (b) (4), (b) (6) <u>Post-Germination:</u> • Furrow	Well and Canal	Y	N	Y Coyote	N
Shipper F	Grower 8 1 Farm	<i>Sudan grass</i> <u>Unknown</u>	<i>IID</i> <u>Canal:</u> (b) (4), (b) (6) <u>Post-Germination:</u> • Sprinkler	Canal	N	N	N	N
Shipper F	Grower 9 1 Farm	<i>Sudan grass</i> <u>Celery, Iceberg</u>	<i>IID</i> <u>Canal:</u> (b) (4), (b) (6) <u>Post-Germination:</u> • Furrow	Canal	N	N	N	N

Traceback Shipper Leg	Grower ID # of Farms	Growing Fields: <i>Previous Crops / Adjacent Crops</i>	Irrigation Water Source/ <u>Method (Post Germination)</u>	Primary Water Source for Chemical App.	Chemical Application Post 2-21 freeze (Y or N)	Biological Soil Amendments (Y or N)	Animal Intrusion (Y or N)	Weather Events (Y or N)
Shipper F	Grower 10 1 Farm	<i>Sudan grass</i> <u>Iceberg, Sunflower, Alfalfa</u>	<i>IID</i> Canal: (b) (4), (b) (6) Post Germination: Sprinkler	Canal	N	N	Y Burrowing Owls	Y ~2/20 freeze caused blistering
Shipper G	Grower 11 1 Farm	<i>Unknown</i> <u>Iceberg, Red Cabbage</u>	<i>WMIDD</i> Canal: (b) (4), (b) (6) Post-Germination: • Furrow	Canal	Y	Y Composted Manure pre-season	N	Y Mid-Feb. freeze caused leaf peeling; high winds followed
Shipper G	Grower 12 1 Farm	<i>Wheat</i> <u>Iceberg, Broccoli seed</u>	<i>WMIDD</i> Canal: (b) (4), (b) (6) Post-Germination: • Furrow	Well	N	N	N	N
Shipper G	Grower 13 1 Farm	<i>Wheat</i> <u>Romaine</u>	<i>WMIDD</i> Canal: (b) (4), (b) (6) Post-Germination: • Furrow	Canal	Y	N	N	N

Traceback Shipper Leg	Grower ID # of Farms	Growing Fields: <i>Previous Crops / Adjacent Crops</i>	Irrigation Water Source/ <u>Method (Post Germination)</u>	Primary Water Source for Chemical App.	Chemical Application Post 2-21 freeze (Y or N)	Biological Soil Amendments (Y or N)	Animal Intrusion (Y or N)	Weather Events (Y or N)
Shipper G	Grower 14 1 Farm	<i>Fallow</i> <u>Spinach,</u> <u>Cabbage,</u> <u>Romaine</u>	<i>YID</i> Canal: (b) (4), (b) (6) Post-Germination: • Furrow	Well and Canal	N	N	N	N

IID = Imperial Irrigation District
WMIDD = Wellton-Mohawk Irrigation and Drainage District
YCWUA = Yuma County Water Users Association
YID = Yuma Irrigation District
Y or N = Yes or No

Note: Table 1 is organized by shipper and contains data from the 13 interviewed growers. One grower operated multiple farms and sold product to two shippers; thus, the grower appears in two rows of Table 1, each with its own grower number due to differences in information.

AGRICULTURAL CHEMICAL APPLICATIONS

Because many growers reported the use of irrigation canal water to dilute agricultural chemicals that came into direct contact with the crop, the EA team assessed the sources of water used for this purpose. For example, the EA team received agricultural chemical spray information from grower interviews and through mandatory reports of pesticide applications filed with the AZDA by two licensed chemical applicators who serve farms irrigated by the WMIDD. The WMIDD irrigation canal system was cited as the sole source of agricultural chemical dilution water for either ground-based or aerial applications on six of the 13 reporting farms. Well water was reportedly the sole source of water for agricultural chemical dilution on six other farms irrigated by the WMIDD irrigation canal system. On one of the 13 farms, both WMIDD irrigation canal water and well water were cited as agricultural chemical dilution water sources.

Growers served by the WMIDD reported chemical spray applications ranging from one ground application combined with three aerial applications over the entire growing season to three ground applications combined with four aerial applications over the entire growing season. For six of the farms that reported using WMIDD irrigation canal water (solely or partially) to dilute agricultural chemicals, growers indicated that agricultural chemicals were applied to romaine lettuce crops after a freeze event

on February 21, 2018. This freeze event likely led to damage of some portion of the romaine lettuce crop, which may have rendered it more susceptible to microbial contamination.

The EA team met with both chemical applicators and reviewed records provided by one applicator.

Chemical Applicator A: This applicator primarily uses (b) (4), (b) (6) wells for chemical dilution water; (b) (4), (b) (6) is at the firm's primary business location on a (b) (4), (b) (6) and the (b) (4), (b) (6) located at a Wellton Valley growing area (b) (4), (b) (6). The firm's wells (b) (4), (b) (6) feet deep. Applicator A reported that his (b) (4), (b) (6) can use irrigation canal water to dilute chemicals but indicated that this not a normal practice. Applicator A further reported that the firm's (b) (4), (b) (6)

Applicator A reported that the firm's aerial spray tanks are (b) (4), (b) (6) is used in the spray tanks as an oxidizer to ensure that no chemical residues remain in the spray tanks. The applicator offered the EA team spray records for review. Applicator A also allowed the team to sample its (b) (4), (b) (6) well; neither generic E. coli nor E. coli O157:H7 were detected in this water sample. Grower information and AZDA records identify Applicator A as the contract sprayer for six of the 13 reporting farms served by the WMIDD.

Chemical Applicator B: This applicator primarily uses WMIDD irrigation canal water to dilute chemicals for aerial applications made in the Wellton area. During an initial discussion, Applicator B stated that the firm's aircraft generally obtain chemical dilution water from the WMIDD irrigation canal nearest to the field to be sprayed, or from the firm's Wellton Valley growing area (b) (4), (b) (6) water tank, which is sourced with WMIDD canal water. Grower information and AZDA records identify Applicator B as the contract sprayer for five of the 13 reporting farms irrigated by the WMIDD.

Of the remainder, one farm reported using both Chemical Applicators A and B, and one farm did not report any aerial spraying of romaine lettuce crops.

GROWING SEASON WEATHER EVENTS

The EA team assessed weather events as potential contributing factors, such as contamination occurring through windborne transmission of contaminated dust to romaine lettuce crops. The team also considered the potential for leaf damage from a freeze and for the condensation of atmospheric moisture on the romaine leaves to create conditions favorable for windborne pathogen capture and survival.

The EA team contacted the University of Arizona Extension Service Biometeorology Specialists, who provided an analysis of weather data from a Roll, AZ, monitoring station that showed that on February 21, 2018, area crops were subjected to approximately 7.25 hours of temperatures below freezing.

After the freeze event, the Roll, AZ, monitoring station recorded wind speeds exceeding 10 miles per hour (MPH) on three days:

02/23/2018: 16 MPH winds from the west-northwest.

03/04/2018: 11.2 MPH winds from the northwest.

03/14/2018: 13 MPH winds from the west.

CAFO ASSESSMENTS

In the initial site visit by the EA team in June, CAFOs in Yuma and Imperial Counties were assessed as potential sources for the outbreak strain. There are three animal feedlots in Yuma County, including one that is adjacent to the 3.5-mile stretch of the Wellton irrigation canal where the outbreak strain of *E. coli* O157:H7 was found. The other Yuma County CAFOs are in other parts of the county.

Wellton-Area CAFO

CAFO Operations

The Wellton-area CAFO (Figure 2) is a large operation, with a permitted capacity of (b) (4), (b) (6) head of cattle. Approximately (b) (4), (b) (6) head of steer were present during on-site EA activities.

Steers (mostly Holsteins) are typically brought into the operation before they reach maturity and are sold after several months of growth at the CAFO. The steer pen flooring material comprises native sand and organic material (manure) that has been compacted over time. There has been no change in the type of material used for, or operation of, the pen flooring material over the decades that the CAFO has been in operation. The managers of this facility told the EA team that the potential for nutrient permeability (as well as microbiological pathogen transport) down through the pen flooring to the ground under the pen and into groundwater is very low. In September 2018, the CAFO managers provided soil permeability analyses for soil samples collected from cattle pens in that month to support that assertion. The groundwater depth under the CAFO was estimated to be approximately 70 feet as of January 2018, according to a U.S. Department of Interior Bureau of Reclamation map.

Each pen on the CAFO is cleaned out via mechanical scraping at least (b) (4), (b) (6) per year using front-end loaders (dedicated for this purpose), which push/scrape the manure into central collection corridors. (b) (4), (b) (6) pens are cleaned out/scraped (b) (4), (b) (6). Each pen yields approximately (b) (4), (b) (6) loads of manure, depending on the size of the steers.

When critical mass is achieved in the central collection corridors, the manure is loaded into side-dump trucks (dedicated for this purpose) for transport to one of two composting facilities (one to the north, and

the other to the west) that are owned and operated by the CAFO. Animal carcasses are separately taken to a regional landfill.

The EA team observed operations to move the manure from the CAFO to the north composting facility. During the on-site activities, the EA team observed dump trucks operating approximately every (b) (4), (b) (6) minutes between the CAFO and the north composting facility. The trucks use a different route when hauling manure to the west composting facility.

The CAFO has several wells, an irrigation canal, and two cattle pen drainage retention ponds to use as water sources. The two retention ponds are designed to contain runoff from the feedlot during rain events, where excess water from the feedlot is directed into dedicated channels along the pens and gravity-transported through dedicated conveyance piping into each retention pond to mitigate the risk of contaminating either ground water or the irrigation canal. The CAFO is licensed to pump the retention pond water for designated uses--such as application to agronomic crops--and may also use this water for dust abatement purposes. During on-site activities, the EA team observed that the water level in the west retention pond was very low (approximately 6 inches deep), due to the lack of recent rain. Both retention ponds contain (b) (4), (b) (6) liner to reduce the potential for contamination of the groundwater due to leakage.

The feedlot's operation is permitted by ADEQ under the Arizona Pollutant Discharge Elimination System program, which regulates the discharge of pollutants under the Clean Water Act and includes requirements for capacity and seepage. Measures implemented to prevent contamination of the irrigation canal from the feedlot include the construction of diversion ditches and soil berms adjacent to the CAFO and uphill from the canal, as well as levelling the topography of the feedlot pens to prevent any potential runoff during storm events from entering the irrigation canal. The EA team observed some soil erosion in the soil berms adjacent to the feedlot, but the intact berms coupled with surface topography and drainage system suggest runoff would be prevented from entering the canal. Well water is used for animal watering (both drinking and cooling when necessary via convection spray and sprinklers). The pens all contained sun shielding (heavy mesh tarp) that ran along the top of the pens to help protect the steers from UV exposure and heat.

As noted above, water from the retention ponds may be used for dust abatement purposes. The irrigation canal water is also available for use as dust abatement and is typically used for the composting operations.

CAFO Composting

Raw manure is transported directly from central collection corridors, adjacent to animal pens, to the composting pad in dedicated side-dump trucks. The EA team noted raw manure dropped from a truck during transport to the north composting facility. The team collected samples of the dropped manure. These samples were negative for *E. coli* O157:H7.

At the north and west composting facilities, the manure is dumped in the formation of windrows. It takes about ^{(b) (4), (b) (5)} dump truck loads of manure to make a single windrow. The EA team estimated that each row is approximately 750 feet long by 20 feet wide, using toolset analysis on GeoWeb.

The records the CAFO managers provided to the EA team for a lot of stabilized compost indicated that the facility has a scientifically-validated treatment process for biological soil amendments of animal origin that meets an appropriate microbiological standard.

Growers operating under the Arizona Leafy Greens Marketing Agreement (AZ LGMA) and the California Leafy Greens Marketing Agreement (CA LGMA) are required to have their compost tested for pathogens. Therefore, the CAFO sends samples of each lot of stabilized compost to an independent laboratory for pathogen testing and chemical/metal composition analysis, for stabilized compost sold to these growers. The compost can be transported from the compost facility only after the analytical results are received and the facility confirms that the compost meets all requirements of the growers. The CAFO provides all of the analytical information to the grower that receives the compost.

The EA team was provided with redacted copies of the types of records that the growers require for Good Agricultural Practices (GAP) or LGMA purposes, including time/temperature, pathogen testing and chemical/metal composition. The managers also provided records for the compost that the EA team sampled.

All finished (treated and documented) compost that is sold to growers is loaded and transported by a single trucking company that specializes in hauling fertilizer. This trucking company is under contract with the CAFO and uses its own front-loaders at the composting operation, loading its trucks directly from the compost pad. The windrows stay in place – from start to finish – during the entire composting process, until sold and removed by the trucking company. The trucking company transports the compost directly to the growers.

The EA team found no obvious potential for cross-contamination between raw manure and finished compost, as the trucks used to transport finished compost are dedicated for this purpose and use different roads than the dump trucks dedicated to hauling raw manure to the composting facilities.

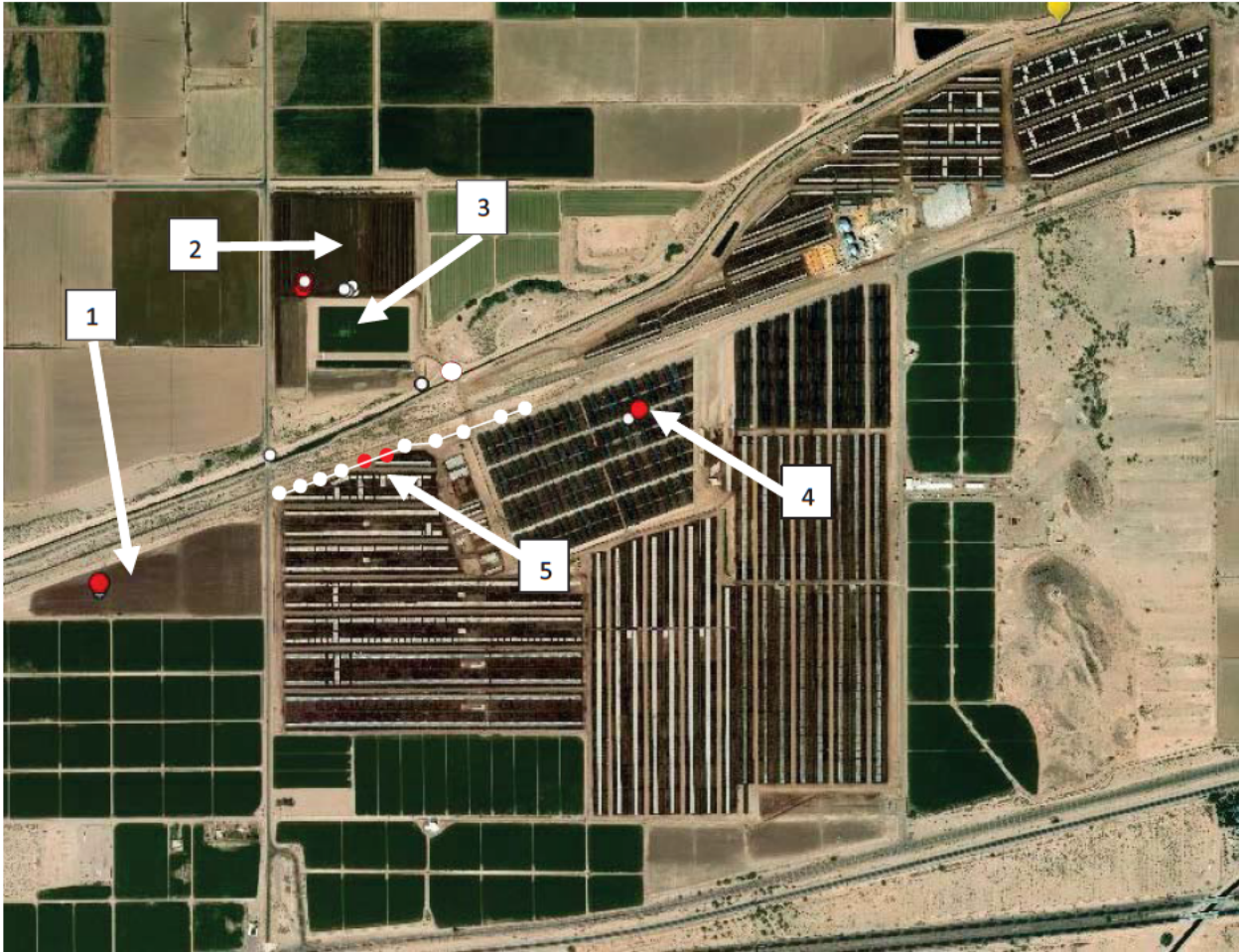


Figure 2. Overview of Wellton area CAFO and adjacent canal property, including West (1) and North (2) Composting Facilities, North retention pond (3), fresh manure sampling location of steer feeding pens (4), Drag Swabs and soil samples along feedlot perimeter fence-line (5). Circles represent EA team sampling locations (compost and manure). Red circles indicate samples that were positive for STECs. No samples were positive for the outbreak strain.

The EA team collected a total of six samples from the Wellton-area CAFO, consisting of composted manure, dry manure, fresh manure, spilled fresh manure, well water, and feedlot drainage water from the north retention pond. The outbreak strain was not detected in any of these samples. However, the Wellton-area CAFO is a very large facility with a high turnover of steers. This limited sampling was performed after the outbreak had occurred and before the results of the irrigation canal testing were known. Since the sampling was limited, it is not possible to draw statistically valid conclusions regarding the presence or absence of the outbreak strain on this facility based on the number of samples collected and when they were collected relative to the outbreak.

Imperial County CAFOs

The EA team also collected composting manure from a CAFO located near Imperial County farms identified by traceback. The outbreak strain was not detected, although a non-O157 STEC was found in the in-process compost from the Imperial Valley CAFO.

The EA team collected samples of surface water from a public pond immediately adjacent to another Imperial County CAFO near the farms identified in the traceback. The team also sampled three canals located near additional CAFOs that provide water to these farms. The outbreak strain was not detected in any samples of surface water or irrigation water from Imperial County.

The EA team interviewed the management of an Imperial County CAFO to determine whether there is a source of animals in common with the Wellton-area CAFO and found that these operations source their steers from different states.

WILDLIFE/ANIMAL INTRUSION ASSESSMENT

The 2017-2018 winter desert season in the region was dry. Monthly rainfall totals (in inches) include October (0.00), November (0.05), December (0.00), January (0.07), February (0.01), March (0.01) and April (0.00). With little rain and an abnormally warm fall and winter, desert habitats were exceptionally dry likely resulting in less natural vegetation and water to support native animal species. The EA team assessed wild animal activities, through collection of scat in and around the Gila River corridor in Yuma County, along irrigation canal banks and production fields, from various areas of the Colorado River environmental assessment area, and through interviews with growers.

The EA team noted that the area surrounding several fields in and around the Gila River wildlife corridor experienced a wildfire during the growing season (March 19 – 21, 2018). The fire was extinguished by the WMIDD using fire breaks; no chemical or water applications were used in fighting the fire. None of the farms noted any significant increase in wildlife activity resulting from the wildfire. In addition, *E. coli* O157:H7 illnesses confirmed to be part of the outbreak occurred before this date, meaning contamination likely preceded the occurrence of the wildfire. The EA team collected scat samples from within areas of the Gila River bed and associated fields which did not yield the outbreak strain; however, sampling was limited so it is not possible to draw statistically valid conclusions regarding the presence or absence of the outbreak strain in Yuma County wildlife.

No wildlife corridors were identified adjacent to any of the Imperial County farms identified in the traceback.

COLORADO RIVER WATER ASSESSMENT

The 23 farms identified by traceback share a common source of irrigation water in the Colorado River. Because of this commonality, the EA team assessed Colorado River water as a potential source for the outbreak pathogen.

Colorado River water is delivered to farms in the Yuma growing region via managed canal systems that take Colorado River water at the Imperial Dam. Therefore, the EA team identified the Imperial Dam and upstream areas north of the dam as the area of interest in the Colorado River assessment.

The Palo Verde Valley growing area is located approximately 95 river miles upstream of the Imperial Dam, near Blythe, California. Winter crops in the Palo Verde Valley include romaine lettuce. No romaine lettuce or other crops from the Palo Verde Valley growing region were associated with this outbreak. Therefore, the EA team identified the Colorado River take-out for the Palo Verde Valley irrigation canal system at the Palo Verde Dam as the northern endpoint of the area of interest in the Colorado River assessment.

The approximate 95-mile stretch of the Colorado River between the Imperial Dam and the Palo Verde Dam is sparsely populated. This section of the river contains approximately 12 isolated seasonal resort communities, two wildlife preserves, and concentrated agricultural use in the Palo Verde Valley area. The California Army National Guard provided the EA team with helicopter support to scout this section of the Colorado River for potential outbreak strain sources. The helicopter scouting mission covered the Colorado River from the Imperial dam north to the Palo Verde dam, and included portions of the Palo Verde valley growing area on the southbound return trip. No potential sources for the outbreak strain were observed along the Colorado River or within the Palo Verde valley growing area.

The EA team collected water samples from the Palo Verde take-out at the Palo Verde Dam, the Palo Verde outfall canal, the California and Arizona take-outs at the Imperial Dam, the All-American Canal (California) de-silting ponds, and the Arizona side canal adjacent to a dam-front resort community.

E. coli O157:H7 was not detected in any sample of Colorado River water.

WMIDD GROUND WATER ASSESSMENT

WMIDD operates two canal systems: an irrigation water canal system that delivers water from the Colorado River Imperial dam to Wellton-area farms, and a salt water canal system that is utilized to discharge saline ground water from the Wellton valley to the Colorado River. Multiple shallow-well pumps operated by the WMIDD draw saline ground water to depths below the root zone so that Wellton valley land can be used for growing produce. This saline ground water is delivered to the Colorado River at a point downstream of the Imperial Dam. The EA team found that shallow ground water is directly pumped into WMIDD irrigation canals at two locations. The outbreak strain was detected in a WMIDD irrigation canal sample that was collected immediately downstream of one of these shallow

ground water discharges into the Wellton irrigation canal. The team also found an area where ground water may be seeping directly into unlined sections of the Wellton irrigation canal; this potential ground water seepage area is within the approximate 3.5-mile section of the Wellton irrigation canal where the outbreak strain was detected.

The EA team identified two potential routes of contamination of ground water from the Wellton-area CAFO. Contamination could occur via direct percolation through the sandy soil of the CAFO feedlot into the shallow ground water. However, as noted previously, CAFO management provided soil permeability analysis results for soil samples collected from cattle pens which demonstrate very low permeability and thus low likelihood of pathogen transport through the pen flooring and into the ground under the pens. The second potential route may be groundwater contamination through one or more of (b) (4), (b) (6) and possibly (b) (4), (b) (6) onsite wells at the CAFO. (b) (4), (b) (6) wells are listed for this CAFO in publicly available information on the Arizona Department of Water Resources (ADWR) website. (b) (4), (b) (6) active wells are listed under the current CAFO operator’s name, and (b) (4), (b) (6) wells are registered under the (b) (4), (b) (6). The ADWR provided the EA team with copies of registrations for (b) (4), (b) (6) wells on the CAFO property, including a farm well that was constructed in (b) (4), (b) (6) for which the current status is unknown:

(b) (4), (b) (6)

(b) (4), (b) (6)

(b) (4), (b) (6)

Based upon Bureau of Reclamation hydrologic data, including a Bureau of Reclamation Wellton Area Groundwater Map, the EA team determined that ground water under the Wellton-area CAFO most likely flows from the southeast towards the northwest. This roughly aligns with groundwater flowing from the CAFO area towards the unlined sections of the Wellton irrigation canal that are upstream of the CAFO in terms of irrigation canal flow. (See Figure 1.) The Bureau of Reclamation indicated that these sections of the Wellton irrigation canal are currently unlined because ground water upwelling damaged the previous cement lining.

WATER SAMPLING

Yuma County

As noted previously, *E. coli* O157:H7 was detected in three places along an approximate 3.5-mile section of the WMIDD Wellton irrigation canal. The locations of the three samples were approximately one mile upstream of a CAFO, adjacent to a CAFO, and approximately one mile downstream of the CAFO (Figure 1). Genetic analyses of these isolates using PFGE and WGS determined that the *E. coli* O157:H7 found in the Wellton irrigation canal water in all three locations was the same strain that caused the outbreak. In June, water samples were also collected from one CAFO well serving the feedlot (approx. 150 ft. deep) and retention pond located on the feedlot property. The well sample was collected after the water passed through a plumbed sand filtration system that was not feasible to bypass for sampling. *E. coli* O157:H7 was not detected in either sample.

In July, water samples were collected from two State of Arizona pesticide ground water monitoring wells (Figure 3), as well as from the salt drainage canal downstream of the WMIDD area of responsibility (Figure 4). *E. coli* O157:H7 was not detected in either the ground water monitoring wells or the salt drainage canal.



Figure 3. Map of July water sampling locations from State of Arizona ground water pesticide monitoring wells.



Figure 4. Map of July sampling location in salt water drain canal downstream of the WMIDD area of responsibility.

In August 2018 additional ground and irrigation canal water samples were collected in Yuma County. The sampling sites included the three Wellton irrigation canal sites that tested positive in June 2018 sampling, the irrigation canal before the Wellton-Mohawk canal split, within the Mohawk canal, the termination point of both the Wellton and Mohawk irrigation canals, and the Wellton-Mohawk drainage canal; none of the samples collected in August were positive for the outbreak pathogen.

Colorado River

Water samples were collected from the Palo Verde (PV) valley and Imperial Dam area (Figures 5 & 6).



Figure 5. Map of June sampling locations at PV Dam and PV Irrigation Canal discharge into the river.



Figure 6. Map of June sampling locations at Imperial Dam and All American and AZ irrigation canals.

Imperial County

In June, the EA team collected samples of surface water from a public pond (Figure 7) immediately adjacent to an Imperial County CAFO near Imperial County farms identified by traceback and from irrigation canal drainage into the Salton Sea (Figure 8). The outbreak strain was not detected.



Figure 7. Map of June water sampling location in Imperial Valley at Ramer Lake adjacent to cattle feedlot

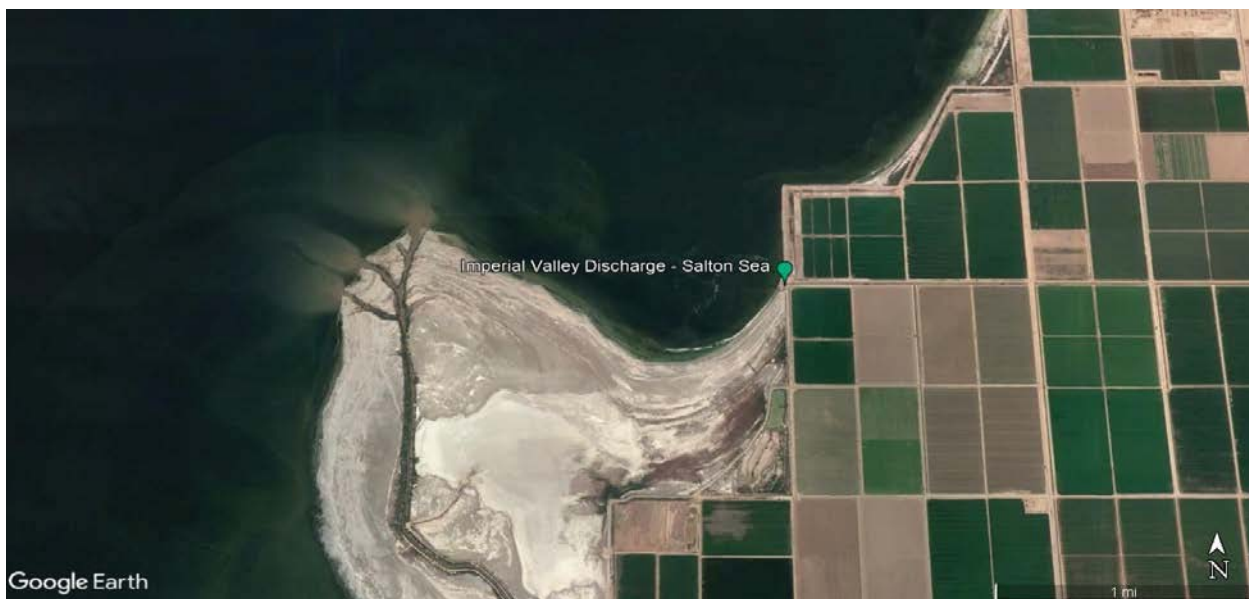


Figure 8. Map of June water sampling location at Imperial Valley drainage canal discharge into Salton Sea.

In July, the team also collected irrigation water from three Imperial County irrigation canals that provide water to Imperial County farms identified by traceback (Figure 9); all three of these irrigation canals have CAFOs near them. Six strains of *E. coli* O157:H7, each genetically distinct from each other, were detected at one canal water site (Spruce Main Delivery 49/50) in Imperial Valley, although none match the outbreak strain. (See Table 3.)

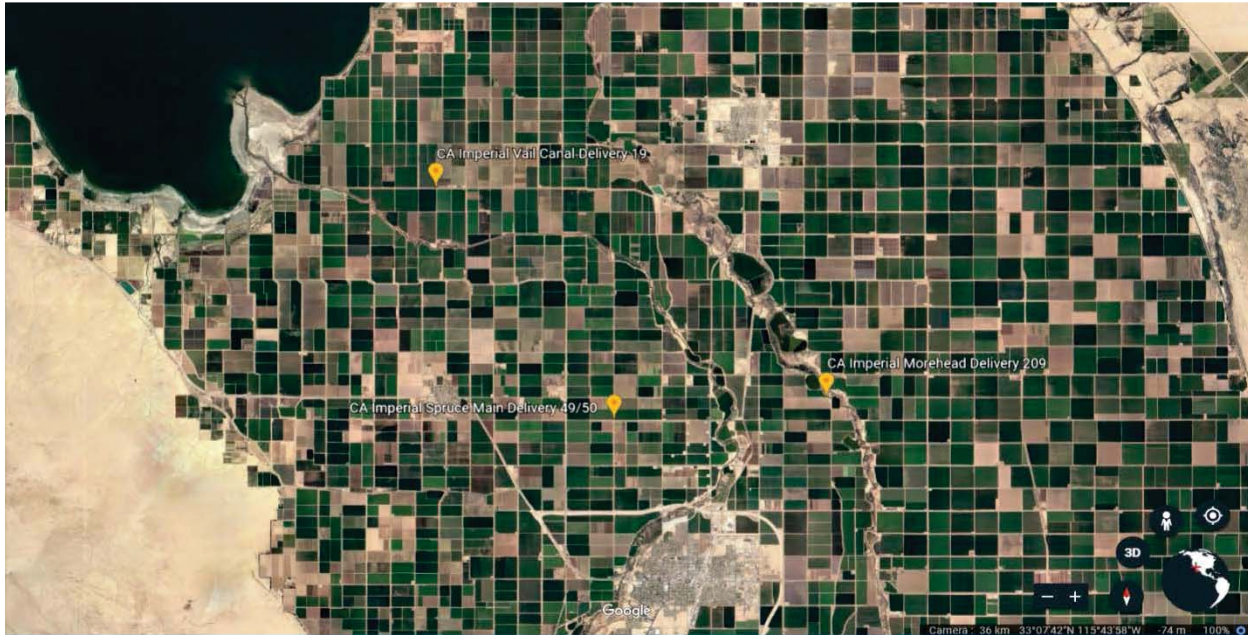


Figure 9. Map of July water sampling locations in CA Imperial Drainage District canals.

Table 2. Results of June Water Sampling

Site Description	Physical Water Quality Parameters ¹	Total coliforms (MPN/100 mL)	<i>E. coli</i> (MPN/100 mL)	Enterococci (MPN/100 mL)	Results: <i>E. coli</i> O157:H7, Other STECs, <i>Salmonella spp.</i>
Palo Verde Outfall	Temp: 24.5 pH: 7.96 Turbidity: 15.6 Conductivity: 1604 TDS: 926 Salinity: 688	>2419.6	71.7	866.4	Not detected
Palo Verde Dam Intake	Temp: 25.1 pH: 8.28 Turbidity: 1.59 Conductivity: 922 TDS: 665 Salinity: 446	1553.1	16.8	24.3	Not detected
Ag. Chemical Applicator's Well	Temp: NT ² pH: NT Turbidity: 0.17 Conductivity: NT TDS: NT Salinity: NT	71.7	<1	1	Not detected
(b) (6) – Imperial Dam	Temp: 27.4 pH: 8.26 Turbidity: 4.03 Conductivity: 1014 TDS: 718 Salinity: 499	>2419.6	11.0	33.2	Not detected
Hidden Shores Beach	Temp: 27.8 pH: 8.29 Turbidity: 7.15 Conductivity: 1010 TDS: 719 Salinity: 499	>2419.6	24.3	62.7	Not detected
Wellton Irrigation Canal Downstream of CAFO	Temp: 26.6 pH: 8.26 Turbidity: 1.79 Conductivity: 1365 TDS: 966 Salinity: 536	>2419.6	83.9	48.2	Detected ³
Wellton Irrigation Canal Adjacent to CAFO	Temp: 26.9 pH: 8.44 Turbidity: 2.9 Conductivity: 1179 TDS: 836 Salinity: 583	>2419.6	84.2	35.5	Detected ³
Wellton Irrigation Canal Upstream of CAFO	Temp: 27.5 pH: 8.33 Turbidity: 1.65 Conductivity: 1125 TDS: 794 Salinity: 534	>2419.6	4.1	9.5	Detected ⁴

Site Description	Physical Water Quality Parameters ¹	Total coliforms (MPN/100 mL)	<i>E. coli</i> (MPN/100 mL)	Enterococci (MPN/100 mL)	Results: <i>E. coli</i> O157:H7, Other STECs, <i>Salmonella spp.</i>
CAFO Well #1	Temp: 25.4 pH: 7.08 Turbidity: 0.12 Conductivity: 2490 TDS: 1790 Salinity: 1270	<1	<1	<1	Not detected
CAFO Drain Ditch	Temp: 31.4 pH: 9.12 Turbidity: 413 Conductivity: OR ⁵ TDS: OR Salinity: OR	163000	<1	<1000	Not detected
All American Canal Intake	Temp: 25.9 pH: 8.26 Turbidity: 4.24 Conductivity: 1025 TDS: 727 Salinity: 506	>2419.6	13.4	26.9	Not detected
Ramer Lake Boat Ramp	Temp: 30.4 pH: 8.73 Turbidity: 62.0 Conductivity: 3580 TDS: 2530 Salinity: 1880	>2419.6	25.9	16.0	Not detected
Imperial Valley Discharge – Salton Sea	Temp: 31.8 pH: 8.12 Turbidity: 49.0 Conductivity: 5540 TDS: 3910 Salinity: 2980	8664000	110	1000	Not detected
CA Sediment Imperial Discharge	Temp: 25.8 pH: 8.38 Turbidity: 11.7 Conductivity: 1013 TDS: 722 Salinity: 506	>2419.6	14.8	41.9	Not detected

¹ Water temperature (°C), Turbidity (NTU), Conductivity (µS/cm), Total dissolved solids (TDS, ppm), Salinity (ppm)

² Not tested

³ Two unique *E. coli* O157:H7 strains detected matching the outbreak

⁴ One *E. coli* O157:H7 strain detected matching the outbreak

⁵ Over range

Table 3. Results of July Water Sampling

Site Description	Physical Water Quality Parameters ¹	Total coliforms (MPN/100 mL)	<i>E. coli</i> (MPN/100 mL)	Enterococci (MPN/100 mL)	Results: <i>E. coli</i> O157:H7, Other STECs, <i>Salmonella</i> spp.
Salt Canal Y Discharge	Temp: 30.7 pH: 8.09 Turbidity: 32.4 Conductivity: 3500 TDS: 2500 Salinity: 1850	>2419.6	161.6	1203.3	Not detected
AZ Groundwater Well near CAFO	Temp: 27.2 pH: 7.41 Turbidity: 41.5 Conductivity: 2500 TDS: 1760 Salinity: 1270	2.0	<1	<1	Not detected
CA Imperial Moorehead Delivery 209 Irrigation Canal	Temp: 29 pH: 8.3 Turbidity: 7.45 Conductivity: 1083 TDS: 778 Salinity: 536	>2419.6	59.1	227.9	Not detected: O157:H7 Detected: O178:H19
CA Imperial Spruce Main Deliver 49/50 #1 Irrigation Canal	Temp: 30.5 pH 8.45 Turbidity 56.5 Conductivity: 1111 TDS: 787 Salinity: 549	>2419.6	313	>2419.6	Detected: ² O157:H7, O6:H34, O181:H49, O153:H25; non-STEC O175:H16; <i>Salmonella Agona</i>
CA Imperial Vail Canal Delivery 19 Irrigation	Temp: 31.5 pH: 8.35 Turbidity: 82.5 Conductivity: 1077 TDS: 762 Salinity: 536	>2419.6	90.9	1413.6	Not detected: O157:H7 Detected: <i>Salmonella Synhymenium</i> ; non-STEC O175:H16
AZDA Pesticide Monitoring Well #3	Temp: 27.1 pH: 7.51 Turbidity: 34.6 Conductivity: 2970 TDS: 2120 Salinity: 1510	4.1	<1	15.6	Not detected

¹ Water temperature (°C), Turbidity (NTU), Conductivity (µS/cm), Total dissolved solids (TDS, ppm), Salinity (ppm)

² Six unique *E. coli* O157:H7 strains detected, none matched outbreak strain.

Table 4. Results of August Water Sampling

Site Description	Physical Water Quality Parameters ¹	Total coliforms (MPN/100 mL)	<i>E. coli</i> (MPN/100 mL)	Enterococci (MPN/100 mL)	Results: <i>E. coli</i> O157:H7, Other STECs, <i>Salmonella</i> spp.
Wellton Canal downstream of CAFO	Temp: 31.8 pH: 7.07 Turbidity: 1.64 Conductivity: 1080 TDS: No data Salinity: No data	>2419.6	151.5	69.5	Not detected
Wellton Canal downstream of CAFO; Well Head	Temp: 26.5 pH: 6.85 Turbidity: 0.41 Conductivity: 2640 TDS: No data Salinity: No data	<1	<1	<1	Not detected
Wellton Canal next to CAFO	Temp: 32.7 pH: 8.04 Turbidity: 1.47 Conductivity: 1109 TDS: No data Salinity: No data	>2419.6	78.9	21.1	Not detected
Well Head (b) (4), (b) (6)	Temp: 27.1 pH: 6.97 Turbidity: 0.18 Conductivity: 2500 TDS: No data Salinity: No data	3.1	<1	<1	Not detected
Mohawk Canal terminus	Temp: 29.7 pH: 8.45 Turbidity: 4.50 Conductivity: 1093 TDS: 775 Salinity: 538	>2419.6	12.2	26.6	Not detected
Wellton Canal terminus	Temp: 31.4 pH: 8.21 Turbidity: 0.94 Conductivity: 1118 TDS: 792 Salinity: 550	>2419.6	40.8	40	Detected: O157:H45
Drainage Well-GW Input	Temp: 27 pH: 7.52 Turbidity: 0.22 Conductivity: 3340 TDS: 2340 Salinity: 1720	7.5	<1	2	Not detected
Drainage Well-downstream of GW Input	Temp: 31.1 pH: 7.82 Turbidity: 1.56 Conductivity: 4000 TDS: 2780 Salinity: 1970	>2419.6	365.4	980.4	Not detected

Site Description	Physical Water Quality Parameters ¹	Total coliforms (MPN/100 mL)	<i>E. coli</i> (MPN/100 mL)	Enterococci (MPN/100 mL)	Results: <i>E. coli</i> O157:H7, Other STECs, <i>Salmonella spp.</i>
Mohawk Canal south of CAFO	Temp: 30.2 pH: 7.95 Turbidity: 28.7 Conductivity: 1110 TDS: No data Salinity: No data	>2419.6	3.1	14.4	Not detected
Wellton Canal upstream of CAFO	Temp: 30.8 pH: 7.8 Turbidity: 6.17 Conductivity: 1091 TDS: No data Salinity: No data	>2419.6	2	18.1	Not detected
Well Head by CAFO	Temp: 28.7 pH: 6.8 Turbidity: 0.08 Conductivity: 2530 TDS: No data Salinity: No data	<1	<1	<1	Not detected
Wellton Canal	Temp: 30.3 pH: 8.15 Turbidity: 7.23 Conductivity: 1138 TDS: 792 Salinity: 558	>2419.6	4.1	20.9	Not detected
Wellton Canal—Head	Temp: 32 pH: 8.13 Turbidity: 21.1 Conductivity: 1098 TDS: 763 Salinity: 533	>2419.6	2	12.4	Not detected

¹ Water temperature (°C), Turbidity (NTU), Conductivity (µS/cm), Total dissolved solids (TDS, ppm), Salinity (ppm)

Other Potential Pathogen Findings

Some of the EA samples were tested for pathogens other than *E. coli* O157:H7. Table 6 below provides details regarding EA sample results that were found to be positive for *Salmonella* spp. and other STECs.

Table 6. Soil, Compost, Manure, and Scat Sampling—Positive Results

Site Description	STECs	<i>Salmonella</i>
Wellton CAFO -West Composting Facility – Finished Compost	O103:H11 STEC (stx1a/eae positive)	Negative
Wellton CAFO - Dried Manure – approx. 6-month-old – Collected from North Composting Facility	O unknown:H2 STEC (stx1a positive/eae negative)	Negative
	O171:H2 STEC (stx1a positive/eae negative)	
Wellton CAFO - Fresh Manure from 15-16-month-old Steer / (b) (4), (b) (6)	O130:H9 (stx1a positive/eae negative)	Negative
	O unknown:H12 (stx1c positive/eae negative)	
Wellton CAFO - Drag Swab along Feedlot Perimeter Fence-line	O3:H12 (stx1a positive/eae negative)	Negative
Wellton CAFO - Soil Samples along Feedlot Perimeter Fence-line	O103:H11 STEC (stx1a positive/eae positive)	Negative
	O3:H12 (stx1a positive/eae negative)	
Water/Sediment on farm	Stx2 positive/eae negative– No Serotyping	
Coyote Scat	Stx1 Positive/eae negative – No Serotyping	
Slime/Sediment	O132:H18 stx2 positive/eae negative	
Scat	O9:H9 (stx1a positive/eae negative)	
	O23:H16 (stx1a positive/eae negative)	
Canal swab downstream of ground water discharge pipe	Unknown Serotype (stx2d positive/eae negative)	
In-Process Compost	O160:H12 (stx1c positive/eae negative)	
CA Imperial Moorehead Delivery 209 Irrigation Canal	O178:H19	
CA Imperial Spruce Main Delivery 49/50 #1 Irrigation Canal	O157:H7; ¹ O6:H34, O181:H49, O153:H25; non-STECS O175:H16	<i>Salmonella Agona</i>
CA Imperial Vail Canal Delivery 19 Irrigation	Negative	<i>Salmonella Typhimurium</i>

¹ Not the outbreak strain of *E. coli* O157:H7.

Whole genome sequencing of STEC isolates was used to identify the presence of virulence factors associated with pathogenicity, including Shiga toxins and intestinal adherence factor (eae).

E. coli O130:H11 was found in finished compost on the Wellton-area CAFO and in soil from the CAFO perimeter; these strains were determined by WGS to be a match to each other.

Some STEC isolates are reported above as O unknown because they were too complex to be typed into one of the approximately 180 O types; other STEC isolates could not be serotyped and are reported as unknown. All of these O unknowns and unknown serotypes were eae negative, meaning they lack the attachment factor which is associated with more severe human infections.

CONCLUSION

This memo of investigation summarizes the activities of the Environmental Assessment team along with the environmental and laboratory findings. The interpretation of these findings and recommendations arising from the investigation are contained in a separate Environmental Assessment document.

Kevin T.
Gerrity -S

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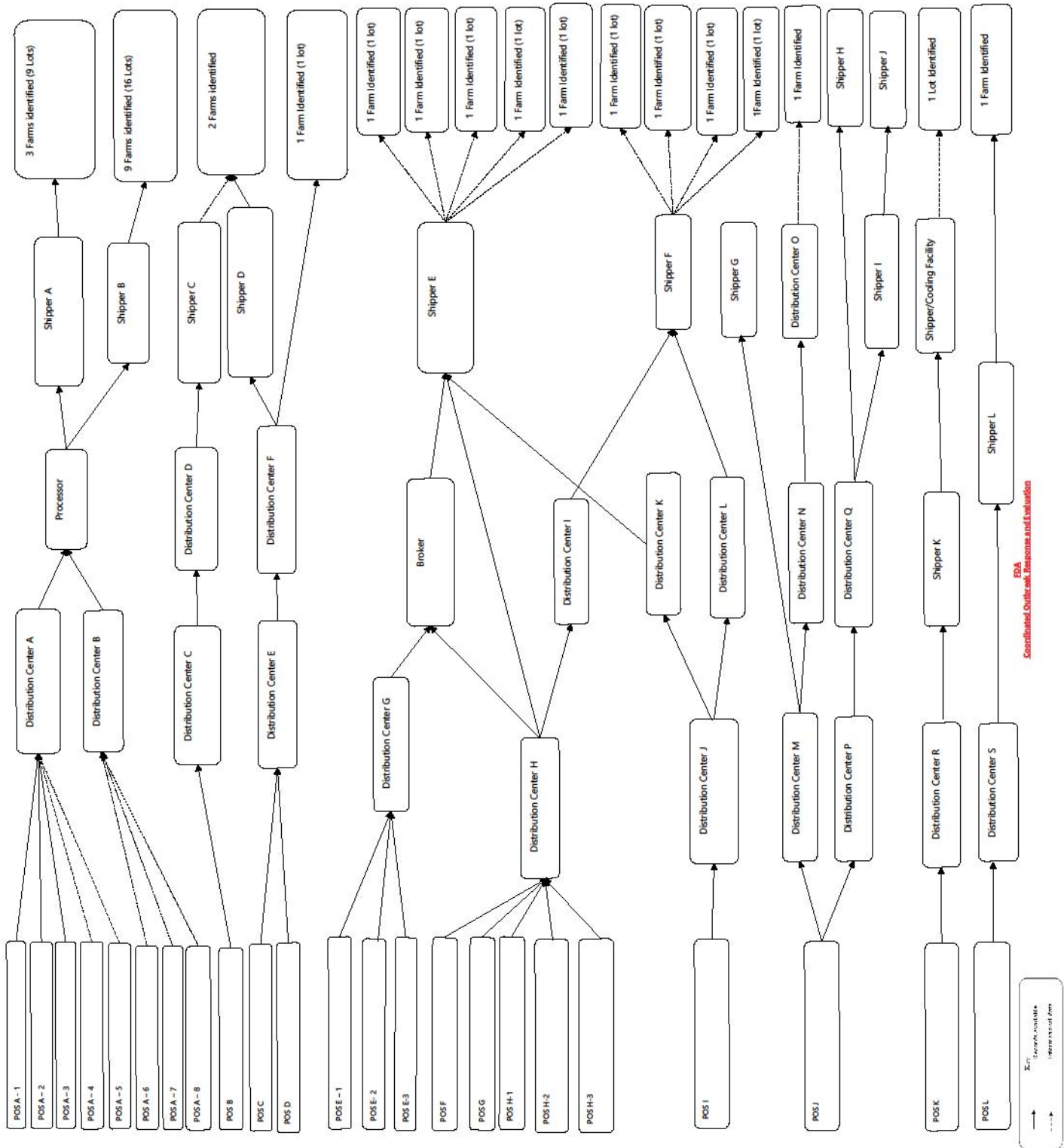
10/24/2018

Kevin Gerrity
Consumer Safety Officer
National Food Expert

Date

ATTACHMENT A – MASTER TRACEBACK DIAGRAM

E. coli O157:H7 – Remain
Multi-state Outbreak April 2018
Master Redacted Traceback Diagram
This report should not be further distributed beyond its intended FDA audience without express permission from FDA



FDA
Coordinated Outbreak Response and Evaluation