State of California—Health and Human Services Agency
California Department of Public Health

KAREN L. SMITH, MD, MPH
State Public Health Officer & Director

GAVIN NEWSOM
Governor

February 8, 2019

To: The Record

From: Emergency Response Unit

Re: **Environmental Investigation of an *E. coli* O157 Outbreak in August and September 2017 Associated with Leafy Greens**

The Food and Drug Branch is providing the following report of an investigation conducted by the Emergency Response Unit.

Brandon Adcock, Senior Environmental Scientist
Emergency Response Unit

Michael Needham, Chief
Emergency Response Unit

INVESTIGATION REPORT COVER SHEET

INVESTIGATION NAME: 17030_Jayleaf_LeafyGreens_EcoliO157_IDB_082917		**ASSIGNMENT DATE:** 8/29/17
ERU LEAD: Brandon Adcock		
FIRM NAME: JayLeaf		
ADDRESS: 3000 Ciennega Rd	**CITY:** Hollister	**ZIP CODE:** 95023
FIRM CONTACT: Jose Ornelas	**POSITION:** Chief Executive Officer (CEO)	**PHONE:** (831) 636-3900
E-MAIL ADDRESS: jose@jayleaf.com	**FAX:** n/a	**CELL PHONE:** N/A
REPORTING PERSON: Dr. Akiko Kimura	**AGENCY:** CDPH-IDB	**PHONE:** 213-620-2857

ACTIVITY: ☒ OUTBREAK INVESTIGATION ☐ PRODUCT CONTAMINATION INVESTIGATION ☐ PFR ENVIRONMENTAL ☐ RETAIL ENVIRONMENTAL ☒ TRACEBACK INVESTIGATION ☐ TAMPERING ☐ COMPLAINT ☒ SAMPLING ☐ TECHNICAL ASSISTANCE ☒ OTHER: Farm Investigation

ERU ELECTRONIC FILE LOCATION:
J:\ERU\Investigations\Investigations 2017\17030_Jayleaf_LeafyGreens_EcoliO157_IDB_082917\REPORTS\ERU\

ATTACHMENTS:

1) Cover Letter
2) Environmental Investigation Report
3) Attachments and Exhibits (as listed on page 19 of report)

ENFORCEMENT ACTIONS: ☐ NOV ISSUED ☐ EMBARGO ☐ VC & D ☐ REG. LETTER ☐ REFERRAL ☐ OTHER:

RECOMMENDATIONS: ☐ NAI ☒ VAI (MINOR VIOLATIONS / FIRM CORRECTING) ☐ OTHER:

COMMENTS / FOLLOW-UP ACTION: none

ERU LEAD SIGNATURE: Brandon Adcock #710 Brandon Adcock	**INV.#** 710	**REPORT DATE:** 2/7/2019
SUPERVISOR SIGNATURE: Michael Needham, Unit Chief		**DATE REVIEWED:** 2/8/2019

SUPERVISOR DISPOSITION:
No further actions indicated

Environmental Investigation of an *E. coli* O157 Outbreak in August and September 2017 Associated With Leafy Greens

Final Report

February 2019

Prepared by:

California Department of Public Health

Food and Drug Branch

Emergency Response Unit

California Department of Public Health

Food and Drug Branch

P.O. Box 997435, MS 7602

Sacramento, CA 95899-7435

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Agencies Involved

California Department of Public Health (CDPH)

- Food and Drug Branch (FDB), Emergency Response Unit (ERU).
- Food and Drug Laboratory Branch (FDLB)
- Division of Communicable Disease Control (DCDC), Infectious Diseases Branch, Disease Investigations Section (DIS)
- DCDC, Microbial Disease Laboratory (MDL)

United States Food and Drug Administration (FDA), San Francisco District Office (San-DO)

United States Centers for Disease Control and Prevention (CDC)

Dates of Investigation

8/29/17 – 6/5/18

Executive Summary

In the summer of 2017, The California Department of Public Health (CDPH), Food and Drug Branch (FDB), Emergency Response Unit (ERU) assisted with the investigation of an outbreak of Shiga toxin-producing *Escherichia coli* (STEC) O157 associated with leafy green exposure. The epidemiologic investigation identified 69 cases in this outbreak from eight states (62 cases from California). Of the interviewed case-patients, 52% indicated mixed greens, mesclun, and/or spring mix exposure outside the home prior to illness, which was significantly higher than the estimated background rate.

IDB referred fourteen cases with limited exposures and reliable food histories to ERU for traceback. In thirteen of these fourteen cases (93%), leafy green products consumed by the case -patient were processed at the Jayleaf facility in Hollister, CA. All thirteen of the cases with a confirmed or probable link to the Jayleaf processing facility had exposure to products grown on Cañada Ranch. A majority of these products were grown on a single lot on this ranch, Lot 3.

CalFERT teams conducted environmental assessments at the Jayleaf processing facility in Hollister, CA and at Cañada Ranch to determine if there were any ongoing food safety concerns or specific conditions that may have led to this outbreak. Through these assessments, the investigation team collected environmental swabs, wash water, and irrigation water samples. Additionally, the team collected product samples from Jayleaf's processing plant and from a retail location. The team submitted these samples to the CDPH, Food and Drug Laboratory Branch (FDLB) for *E. coli* testing. *E. coli* was not detected in any of these samples. The investigation team collected these samples approximately one month after illnesses. While the negative results provided evidence that there was not an ongoing food safety concern, they may not reflect conditions present when potentially contaminated product was harvested and processed.

The investigation conducted by ERU linked human illnesses to leafy green products grown on Cañada Ranch by [redacted] then processed and distributed by Jayleaf, LLC. While *E. coli* was not detected in the environmental or product samples, there was evidence that rented tractors may not have been cleaned and sanitized before use and significant areas of standing water was observed in multiple areas of the ranch. In addition, the practice of hand harvesting leafy greens and then re-harvesting from the same fields at a later date may result in contamination of the crops by employee practices.

On 9/11/17, ERU informed [redacted] and Jayleaf of the link between their products and illnesses, Jayleaf and [redacted] shared food safety consultant issued a letter to CDPH denying the link to illnesses. This letter cited laboratory evidence from their own testing and verification of the companies' sanitation and cleaning records. As the investigation continued, ERU management continued to inform Jayleaf and [redacted] of the strengthening link between Jayleaf product grown on Cañada Ranch and illnesses. On 10/10/17, [redacted] informed ERU that they would voluntarily destroy all remaining crops on Cañada Ranch, Lot 3 and would not grow any crops on this lot until spring, 2018.

On 6/5/18, an ERU team of investigators conducted a follow-up inspection at Cañada Ranch. Since the initial inspection, [redacted] transferred control of the ranch to a different, but related, company, [redacted] made several improvements to the ranch including: repairs and replacement of fencing and leaking sprinkler valves throughout the ranch; pre-harvest testing of all commodities harvested from the ranch; and re-grading the ranch to improve drainage. The follow up inspection in June 2018 verified these improvements and enhanced food safety procedures.

Epidemiological Summary

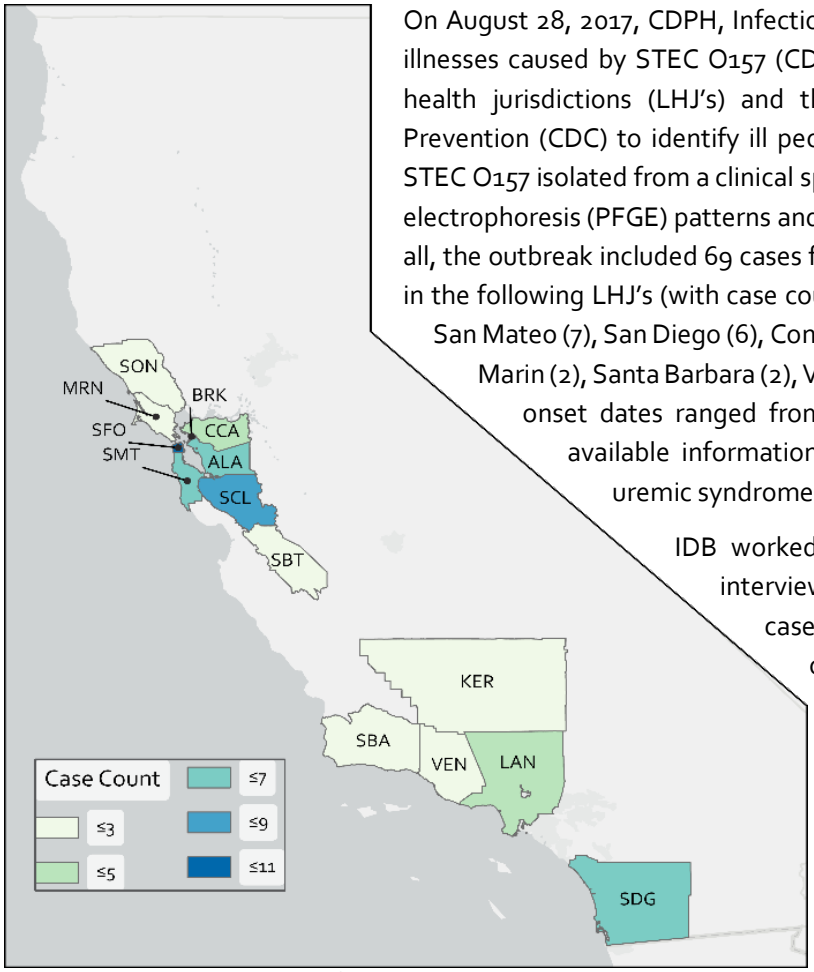

Figure 1 - California Case Counts by LHJ

On August 28, 2017, CDPH, Infectious Diseases Branch (IDB) began following a cluster of illnesses caused by STEC O157 (CDC cluster code 1709CAEXH-1). IDB worked with local health jurisdictions (LHJ's) and the United States Centers for Disease Control and Prevention (CDC) to identify ill people associated with this outbreak. Case-patients had STEC O157 isolated from a clinical specimen with one of five highly related pulsed-field gel electrophoresis (PFGE) patterns and had symptom onsets in August or September 2017. In all, the outbreak included 69 cases from eight states. California reported 62 of these cases in the following LHJ's (with case counts): San Francisco (11), Santa Clara (9), Alameda (7), San Mateo (7), San Diego (6), Contra Costa (4), Los Angeles (4), Berkeley (3), Sonoma (3), Marin (2), Santa Barbara (2), Ventura (2), Kern (1), and San Benito (1) (Figure 1). Illness onset dates ranged from 8/11-9/16/17. Eighteen (29%) of the 63 cases with available information were hospitalized and two of those had hemolytic uremic syndrome (HUS).

IDB worked with LHJ's to conduct food history and exposure interviews for 53 case-patients. Those interviews showed the cases were strongly associated with leafy green exposure outside the home (37/53 - 70%). Some of these cases (a total of 14) were referred to the CDPH Food and Drug Branch (FDB), Emergency Response Unit (ERU) for traceback (See Traceback section, below).

For more information on the epidemiologic investigation, see the full Investigative Summary titled CA EPI 18-04: Multistate Outbreak of Shiga Toxin-Producing Escherichia Coli (STEC) O157 Associated with Mixed Leafy Greens, Mizuna, and Arugula Produced by Company A, August–September 2017, available from CDPH-IDB.

Traceback

On September 7, 2017, IDB identified two case-patients who were good candidates for traceback. Both case-patients ate at a single location of a small restaurant chain in San Francisco, CA. ERU Inspectors contacted the restaurant and then distributors to determine the sources of the leafy green products consumed. Using the information gathered, ERU determined the shipments of interest for each step in the distribution chain using shipment patterns, and an expected shelf life of seven to ten days for these products in a restaurant setting. Over the next several weeks, ERU used the same process to investigate twelve additional case -patient exposures recommended by IDB. IDB selected all of these cases based on meeting the case definition for the outbreak, reliability of their food history and association with a restaurant sub-cluster or a single incident of leafy green consumption prior to illness onset.

In twelve of these fourteen cases (86%), leafy green products consumed by the case-patient were processed at the Jayleaf, LLC facility in Hollister, CA. Informational traceback linked an additional case to the same Jayleaf facility, but documents were not available to complete the traceback. This additional case resulted in a total of thirteen out of the fourteen case-patients (93%) being linked to Jayleaf products. The Jayleaf facility primarily produced products under the Jayleaf and [redacted] brands.

Although they often had a single leafy green exposure, these cases consumed multiple Jayleaf and [redacted] branded items. These items included single ingredient items such as mizuna or arugula, and multiple ingredient items such as spring mix products. Specific lot codes and production days were determined for each of the products consumed by the case-patients in the traceback. Jayleaf management provided traceback information to the ranch and lot level for each of the ingredients in these products. The information provided showed that individual products processed on a given day were often grown on multiple fields and each variety and lot of the mixed products consisted of multiple ingredients from multiple fields. Within all of that variability, all thirteen of the cases with a confirmed or likely link to the Jayleaf processing facility had exposure to products grown on Cañada Ranch by [redacted] Further analysis linked a majority of these case-patient exposures to a single area of that ranch (Lot 3).

Throughout the traceback investigation, ERU shared information and documents with the United States Health and Human Services Agency, Food and Drug Administration (FDA) through the California Food Emergency Response Team (CalFERT).

See Attachment 1 and Attachment 2 for a complete summary of the traceback portion of the investigation.

Environmental Investigation - Jayleaf Processing Plant

[redacted]

Figure 2 - Jayleaf Processing Facility and Surrounding Area

The strong traceback links to product processed by Jayleaf initiated further investigation of the facility and Jayleaf's food-handling practices. On September 20, 2017, a CalFERT investigative team consisting of ERU Inspectors, a FDA Consumer Safety Officer (CSO), and an IDB Epidemiologist inspected the Jayleaf processing facility in Hollister, CA. Jose Ornelas, CEO of Jayleaf, LLC and Frank Escobar, Quality and Compliance Administrator, accompanied the team and provided all information requested.

General Firm Information

The Jayleaf processing facility was located at 3000 Cienega Rd., Hollister, CA (Figure 2). The growing and harvest company, [redacted] the transport and sales company, [redacted] and the processing company, Jayleaf shared offices at this location. Different, but often overlapping, individuals owned each of these three companies. The Jayleaf processing facility had a valid Processed Food Registration and Organic Processed Product Registration with FDB (License # 52813) as well as a food facility registration with FDA (FEI # [redacted]).

The facility employed [redacted] full time, permanent employees. Jayleaf directly employed all employees, who worked year-around.

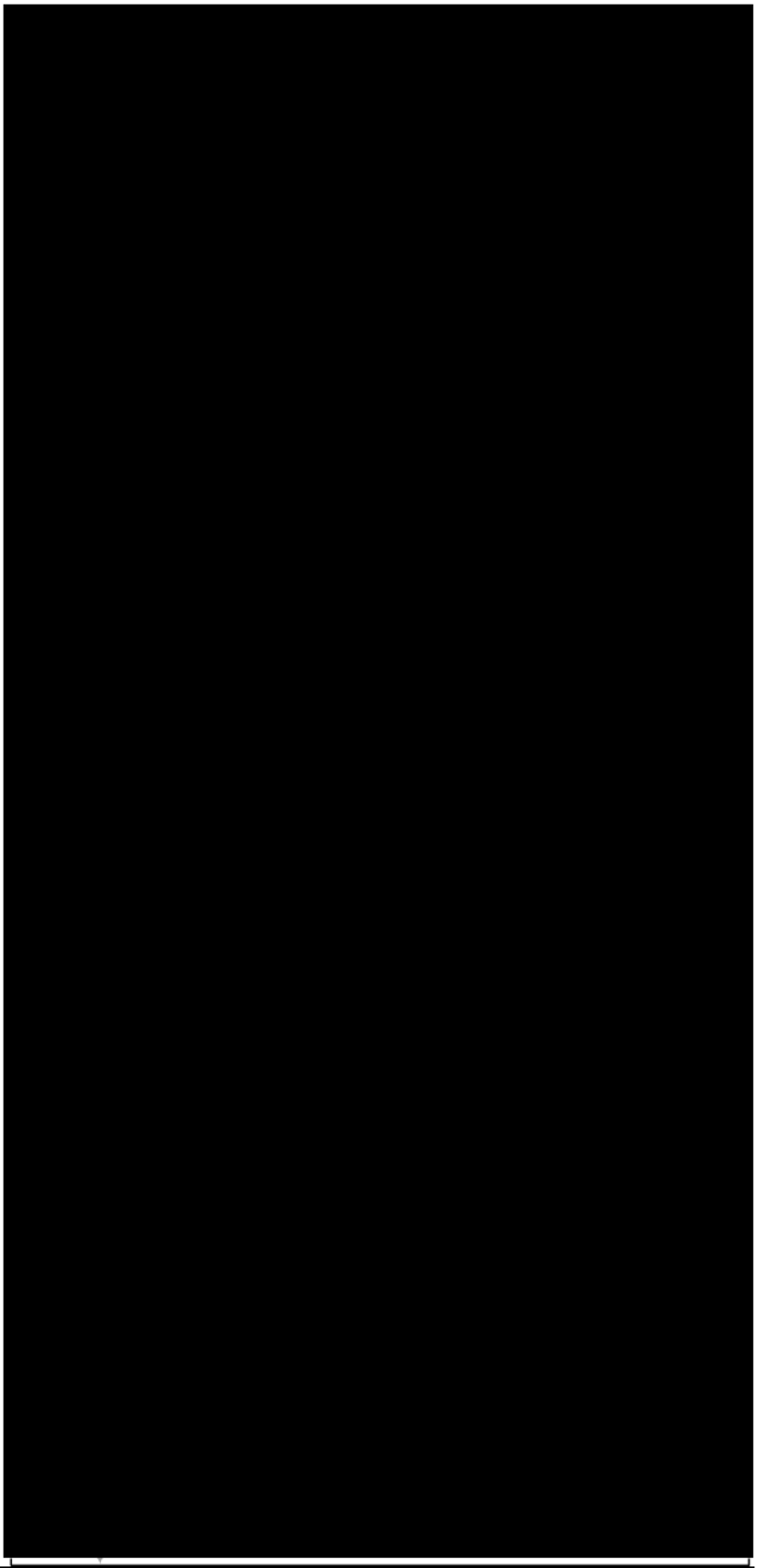

Figure 3 - Jayleaf Process Flow Diagram

Manufacturing Process

The team observed spring mix, spinach, and arugula production during the facility investigation.

Process Flow

During the time period around the outbreak, Jayleaf received and processed an average of [redacted] lbs. of ingredients per day (range [redacted]), six days per week (Monday through Saturday). The facility took in freshly harvested, individual, leafy greens (such as mizuna, chard, arugula, kale, or spinach) from their suppliers. They washed, chopped, and bagged these ingredients into multiple finished products. Primarily, this facility washed and combined the ingredients into various salad mixes (spring mix, Las Vegas, etc.). The proportions of primary ingredients defined the products. The composition of each lot was variable depending on availability of specific ingredients. In addition to these salad mixes, they also produced smaller quantities of custom blends and single-product items (radicchio, baby spinach, kale, etc.) for specific customers. Figure 3 outlines the Jayleaf processing plant product flow.

Incoming Ingredients

Jayleaf received ingredients from multiple farms. [redacted] grew and harvested most of the raw ingredients supplied to Jayleaf in the Hollister area. All of [redacted] produce was certified organic. Jayleaf used other growers, as needed, to maintain incoming ingredient levels. The leafy greens purchased from other growers were, primarily, conventionally grown (not organic).Trucks owned and operated by [redacted] brought the incoming ingredients to the facility on pallets in refrigerated trailers. The pallets contained the product in small, plastic totes. Employees visually inspected the incoming shipments and took the product by forklift into the processing room. Firm management reported that some products were vacuum cooled before processing, however none of the product of interest was cooled in this manner.

Jayleaf usually received and used Ingredients the same day. If needed, the ingredients were stored in a refrigerated room for [redacted] days.

Combining Ingredients and Quality Control

From the field totes, Jayleaf employees mixed the individual components together as they poured the products onto a conveyor. The mix then moved through an optical sorter, which rejected product that was not within specifications, before another employee visually inspected the product. The facility diverted all rejected product into their onsite compost for their adjacent growing operation.

Washing

After visual inspection, Jayleaf staff washed the product in three stages. In each stage a pump recirculated water within that stage. The system automatically added water as needed and employees completely emptied the water in the tanks at the end of the shift and when the water "appeared dirty." This complete emptying of the system happened about [redacted] to [redacted] times per day, according to management statements during the inspection.

Tank 1

The first wash step was a clean water wash. The product moved through a wash flume containing water from the onsite well and [redacted] ppm free chlorine. A chemical dispensing system added chlorine and QC personnel monitored the chlorine concentration using a handheld probe once every hour.

Tank 2

The next wash step was a wash by sprayers. The sprayers used chlorinated water from the onsite well. An automated system monitored Oxidation-Reduction Potential (ORP) and pH in the recirculating tank and used these numbers to determine appropriate chlorine additions. QC personnel verified the equipment was functioning properly [redacted] per shift through a digital readout on the equipment. Every [redacted] days, a QC employee verified the equipment's reading using a handheld probe and appropriate standards.

Tank 3

The final wash was in a flume of cooled, chlorinated well water. An adjacent water cooler maintained the water temperature around [redacted]°F. The automated system and QC personnel maintained and verified chlorine concentrations with the same parameters and methods described for Tank 2, above.

Drying

After washing, the equipment moved the product across a shaker table and employees loaded it into spin dry barrels. Employees loaded these barrels into one of [redacted] spin dryers.

Boxing and Labeling

After the spin-dry process, employees removed the barrels from the spin dryers and dumped them onto a conveyor for boxing. Jayleaf employees hand-filled the product into cases of 10-12 pounds, depending on product and customer specifications. Jayleaf purchased the boxes pre-printed with brand and product information. Production employees then sealed the cardboard cases and printed a lot code on the box indicating date and time of packaging.

Jayleaf diverted some of the product from the main packaging line into their small, custom packaging process. Instead of dumping the bin from the spin dryer onto the boxing conveyor, employees took product for these smaller orders from the spin dryers to the Small Item Room. If the product order was very small, leafy greens could be washed, cut, and dried in the packing room as well. These smaller orders were custom packs for specific customers and airfreight shipments.

Process and Quality Controls

Jayleaf processed products marketed as organic on the same line as products conventionally (not organically) grown. Physical process controls ensured a separation between organic and conventional products. Products to be sold as organic were

processed first, before conventional or a complete cleaning and sanitation was performed between processing conventional and organically marketed products.

To ensure the safety of incoming ingredients, Jayleaf suppliers were required to be LGMA certified or compliant and perform pre-harvest microbial testing on products.

PCR Wash Water Testing

Jayleaf Quality Control personnel collected [redacted] sample of wash water from each tank every [redacted] during production. Quality Control personnel tested [redacted] using a polymerase chain reaction (PCR) genetic screening process for generic *Coliform* and generic *E. coli* as a representative sample for the production run. QC personnel placed the samples from the rest of the day in a bag, which was stored frozen in a consumer-style freezer at [redacted]°C. During the inspection, the team reviewed records for the production dates linked to illnesses, 8/1/17-8/31/17, and these target organisms were not detected in any of the samples. According to Frank Escobar, Jayleaf's Quality and Compliance Administrator, the company's food safety consultant [redacted] designed a PCR screening protocol for the used wash water and they trained all employees on proper use of the laboratory equipment. Since this was an unusual screening method for a smaller leafy green processing facility, the team reviewed the testing protocol. To verify the execution of this procedure, the team asked Mr. Escobar and a QC Supervisor accompanying him to demonstrate the testing process. During the demonstration, the inspection team asked questions to clarify and verify the written procedure. The execution of the procedures and answers given by both Mr. Escobar and the QC Supervisor showed an apparent lack of training and knowledge with respect to both the PCR procedure and the specific equipment used. Specifically, firm employees were not calibrating the instrument or running positive and negative controls side by side with their samples daily, as required by their written protocol and laboratory best practices. When asked why they were not following the written protocol, Mr. Escobar stated they were executing the procedure as their consultant trained them. In addition to the improper use of the PCR instrument, the lab team, including the Laboratory Supervisor, demonstrated a lack of knowledge regarding the proper use of the other laboratory equipment. Specifically, there was confusion around the contrasting uses of a microcentrifuge and a vortex mixer. Laboratory staff also could not demonstrate how to reset the quantity on the micropipette.

In addition to the training and oversight deficiencies, an ERU Scientist looked into the specific equipment used. The instrument they were using to conduct the PCR tests, [redacted], had been discontinued by the manufacturer and, when it was produced, was designated for research use only (RUO), indicating it was not designed to accurately or reliably give the results Jayleaf management was expecting. Finally, the manufacturer of the reagents used for the test labeled the items for storage at -20° C. The team observed the reagents stored in a household freezer at [redacted]°C. Mr. Escobar verified that this was their usual storage conditions under the guidance of their food safety consultant.

These inconsistencies, lack of knowledge, and questionable practices indicated that the results obtained in the PCR process might not be valid. Despite training from their food safety consultant, evidenced by statements from management and certificates presented above the laboratory area, there was inadequate training of lab personnel and management. While they did not receive any actionable results, relying on this process and training to verify the firm's food safety standards was not adequate.

Additionally, the inspection team observed poor facility design in the laboratory area of building E2. The cement floor of the building was lower than the driveway outside the building with a sloped floor from the outside driveway into the building. Outside, Jayleaf employees were conducting routine cleaning and sanitizing activities while the lab demonstration was taking place. There was water flowing into the laboratory area and pooling under the laboratory table indicating a lack of sanitary environment and the potential for contamination of the samples processed.

Product Distribution

Product Packaging

Jayleaf packed all products into 10-12 lb. cases consisting of an outer, cardboard case and a plastic bag or bags inside containing product. Most of the product was inside a bag, which lined the inside of the cardboard case. Jayleaf also packaged a small number of items into 1-2lb sealed bags by customer request and for airfreight shipments. Regardless of bag size, Jayleaf packaged all products inside a pre-printed outer cardboard case that had the brand name and responsible firm pre-printed. Jayleaf packed items for airfreight and other items per customer request with ice packs inside the top of the case, outside the plastic bags. Jayleaf generally sent these iced shipments to customers using common carriers. They shipped all other products to customers in refrigerated trucks owned and operated by [redacted]

Lot Coding

Jayleaf printed a lot code on each outer case as it left the packaging area (Figure 4). The lot code varied by hour (straight underlined in Figure 3), but otherwise stayed the same for all products on a given day. The best by date was [redacted] days from date of production/packaging as indicated by the Julian date and day number in the lot code. The Julian date and the day number expressed the same information.

Jayleaf distributed product primarily under [redacted] brands, [redacted] (most of the product) and Jayleaf. Jayleaf was the sole supplier for [redacted] and Jayleaf branded product. Additionally, Jayleaf co-packed product under the [redacted] brand. They were not the sole supplier for this brand.

Jayleaf Lot Code Breakdown

[redacted]

Figure 4 - Lot Code Breakdown

Target Customer

All of the products produced at this facility were intended for general distribution. Jayleaf did not specifically designate their products for vulnerable populations, but their products were widely consumed by a variety of people including nursing home residents and school students as shown in the epidemiologic investigation and traceback.

Distribution Patterns

Jayleaf distributed year-around to wholesale customers only. While they did not package products in consumer packaging, some Jayleaf product was made directly available to consumers through loose, bulk purchases. Most of Jayleaf's direct sales were in the San Francisco Bay Area and Los Angeles Area (Figure 6). This sales pattern closely alligned with the case-patient counts reported by IDB and CDC (see Figure 1, Epidemiological Summary section, above).

All ingredients and products were sourced from the Hollister, California area. The company had limited interstate commerce with a single customer in four other states: Arizona, New York, South Carolina, and Hawaii (Figure 5).

Figure 6 - Jayleaf Distribution Pattern for 2017 – Coloring indicates relative numbers of cases sold

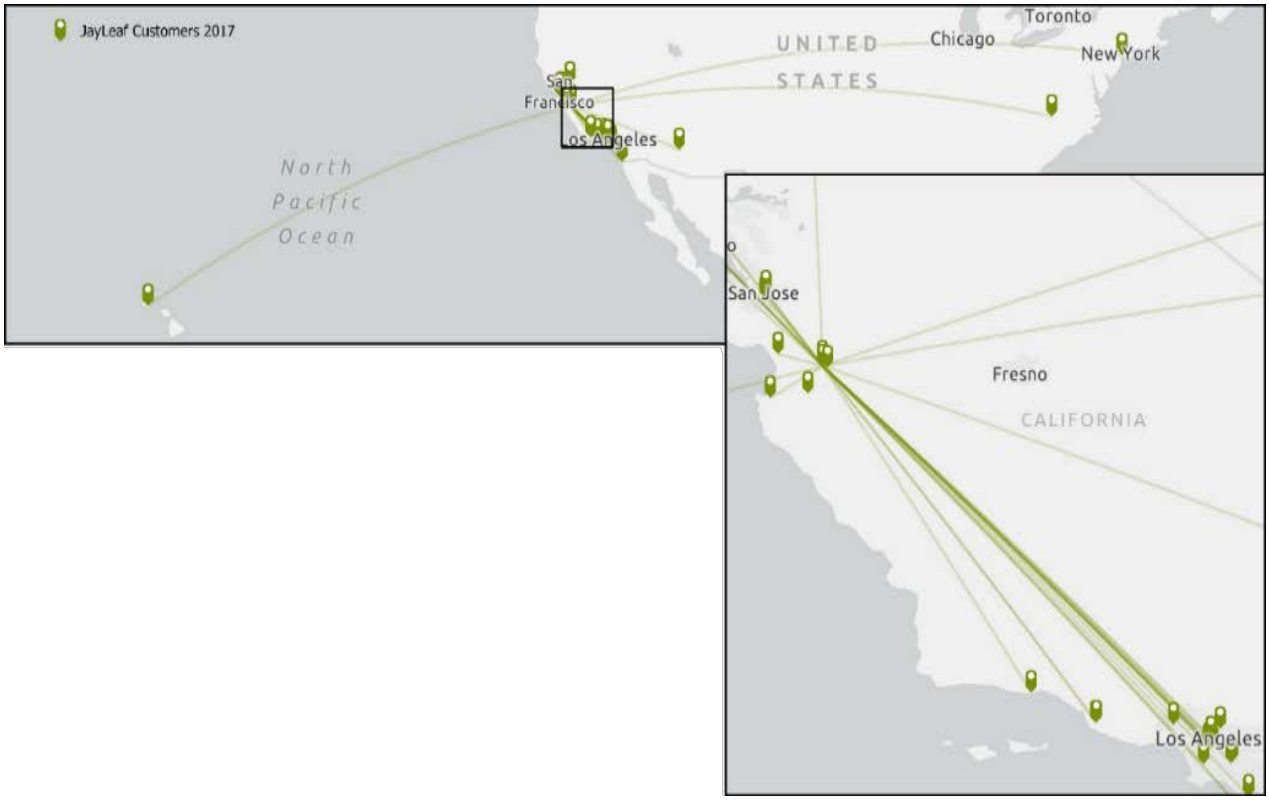

Figure 5 - Jayleaf Customers During 2017 – each green line represents one shipment, darker lines indicate more shipments

Facility Cleaning and Sanitation

Jayleaf completed routine sanitation on an ongoing basis throughout all areas with exposed food in the facility. The facility has [redacted] oxidizer foam dispensers at each entrance to limit bacteria carried in from the outside. Each entry door had a footbath with quaternary ammonia-based sanitizer. QA personnel ensured concentrations met the chemical manufacturer's instructions and verified the concentration every [redacted] hours.

At the end of each shift, Jayleaf employees cleaned and sanitized all surfaces in the production area. They first used pressurized water to remove the larger debris from the equipment. Employees then applied a detergent cleaning foam, which they left on the surfaces per the manufacturer's instructions. After the required time, they rinsed the foam off with pressurized water and applied a no-rinse quaternary ammonia-based sanitizer to all surfaces. Management verified cleaning and sanitation by a daily visual inspection and monthly swabs tested for aerobic plate count (APC).

The inspection team reviewed the logs for this sanitation and verification activity between 8/1/17 and the date of inspection to cover conditions during the outbreak period and at the time of inspection. The documents did not show any unusual occurrences. The records showed that the sanitation crew immediately re-cleaned any insufficiently cleaned areas and QC verified the area were clean before production.

Water and Plumbing

An on-site well (San Benito County Water District # [redacted]) was the sole source of water used on this property for all purposes including processing, cleaning, and irrigation of adjacent crops. Unless noted in a specific process (i.e. chlorination of the product wash tanks), Jayleaf did not treat the water physically or chemically before use. There was a backflow preventer attached to the main water line immediately after the well connection and the inspection team did not observe any improperly plumbed water outlets or drainage lines.

Monthly, Jayleaf tested the well water for total coliforms and *E. coli.* [redacted] collected samples from a sampling port near the well. They submitted the samples to [redacted] for testing. The inspection team reviewed several of the most recent testing results, including 7/13/17, which was the closest to the outbreak dates. The tests did not detect coliforms or *E. coli* in any of the samples.

Dedicated waste lines removed all processing wastewater from the facility. These lines deposited the wastewater into a settling tank to remove large solids. The system then routed the water out of the processing facility.

Toilets and sanitary facilities were self-contained and serviced by a portable toilet company on a regular basis. At the time of inspection, all toilets on site appeared clean, maintained, and did not appear to be leaking.

Pest Control

The facility had been using the same pest control company for over three years, as evidenced by the pest control records maintained onsite. Pest control company employees serviced the bait stations, traps and other control measures every two weeks. According to management and pest control records, mice were occasionally seen around the exterior of the processing facility. There were no mice seen or trapped inside the buildings, and the pest control company used tin cats and bait stations to control rodents in the exterior areas. The inspection team reviewed several months of pest inspection records and did not find any food safety concerns.

Personnel

Food Safety Training for Employees

The company had an on-boarding training list for all new employees and conducted ongoing food safety trainings at staff meetings and other times as needed. Employees appeared adequately trained to perform the food safety and sanitation tasks assigned.

Food Worker Health and Hygiene

Jayleaf provided clean outer garments (smocks, aprons, etc.) which designated employees washed and dried onsite. The inspection team observed employees properly washing hands before entering the production area after breaks. Additionally, employees appeared to have good hygiene and clean clothing during the inspection

Complaints

Outside of this investigation, the company had not received any food-safety related complaints.

Regulatory Actions

Though there were weaknesses in the firm's PCR screening process, the team did not note any significant concerns directly related to food safety during the processing facility investigation. Investigators discussed the weaknesses in the PCR screening process with firm management during the inspection. FDB took no regulatory action regarding findings at the processing facility.

Farm Investigation – Cañada Ranch

Due to a clear link between Cañada Ranch and illnesses, a CalFERT team initiated an investigation at this ranch on 10/5/17. The investigation covered the entire ranch with a focus on Lot 3, since that lot provided most of the relevant shipments in the traceback (see Traceback section, above). The team included ERU Inspectors, an FDA CSO, an IDB Epidemiologist, and a California Epidemiologic Investigation Service (Cal-EIS) Fellow.

A summary of the information gathered during the Cañada Ranch investigation is included below. A complete description of the information gathered during the investigation of Cañada Ranch is in the Farm Investigation Questionnaire (Attachment 3).

General Information

The Chief Operations Manager, Henry Catalan provided all information during this portion of the investigation. The ranch was located at [redacted] Hollister, CA. Jayleaf had owned and operated the ranch for three years prior to inspection. According to Mr. Catalan, the ranch had been fallow for eight years prior to Jayleaf's purchase and was used to grow food crops before that.

At the time of inspection, [redacted] operated the growing and harvesting activities on Cañada Ranch. This is a separate company from Jayleaf, but shares offices and some management with them. Mr. Catalan worked as Chief Operations Manager for both companies. [redacted] harvested various leafy green products from this ranch during the timeframe of interest (7/22-8/31/17) (Table 1). All crops grown on this ranch during the 2017 season were for Jayleaf. During the inspection, the team observed various crops growing including kale, chard, radicchio, and spinach. [redacted] irrigated the crops with sprinklers throughout growing cycle using water from an onsite well (see Water Sources, below).

Third Party Audits

Both the California Department of Food and Agriculture (for the California Leafy Green Products Handler Marketing Agreement, LGMA) and third-party auditing company [redacted] audited this ranch on a regular basis. Prior to this investigation, both of these audits last happened in the spring of 2017. The inspection team reviewed the audit reports and found no areas of concern (Attachment 4 & Attachment 5).

Product	Cañada Ranch Lot 1	2	3	Grand Total
Arugula	[redacted]			
Barbosa				
Chard				
Frisée				
Green Oak				
Green Romaine				
Kale				
Lettuces				
Lolla Rossa				
Mixed Greens				
Mizuna				
Mostasu				
Mustard				
Radicchio				
Red Chard				
Red Romaine				
Red Tatsoi				
Spinach				
Tatsoi				
Wild Arugula				
Grand Total				

Table 1 - Product Harvested from Cañada Ranch 7/22/17-8/31/17 (in lbs.)

Farm Layout

Exhibit A contains a map of Cañada Ranch and the surrounding area. Cañada Ranch consisted of approximately 83 acres. The neighboring land included multiple homes (on North and South), a ranch owned and controlled by another grower that was used to grow crops such as peppers and other crops for human consumption (West), and a berry farm (East – across street). The neighboring homes all used septic tanks for waste disposal. Records obtained by ERU Scientists showed the location of the wells and septic tanks in the area. According to that information, the closest septic field was approximately 125 feet from the growing area (Exhibit A, Brown polygons and yellow lines). There was no indication that sewage was a possible source of contamination at the time of inspection. The crops were grown on three lots, separated by farm roads consisting of soft dirt (Exhibit A).Each lot consisted of several [redacted]" beds separated by several inches for equipment wheels. The topography of Cañada Ranch was flat with very little slope. Due to the soft soil, and shallow slope, there were many areas of pooling water observed around the ranch; especially in areas being actively watered (Exhibit B, Photo 3). Besides drainage ditches and pooling water, there was no surface water on or near the ranch. Sanitary facilities onsite consisted of a single portable toilet with a collection tank – 100-200 feet from production fields and wellhead. Mr. Catalan verified that, as needed for harvest, [redacted] would

rent additional portable, self-contained toilets with hand wash sinks. A portable toilet company serviced all of these restrooms. The company removed waste from the toilet tanks in the yard area, away from production areas, and transported offsite for disposal. The toilets onsite at the time of inspection were clean, well maintained, and did not appear to be leaking.

Weather Information

There were no reports or rain, flooding, or other unusual weather conditions during the growing or harvesting timeframe.

Water Sources

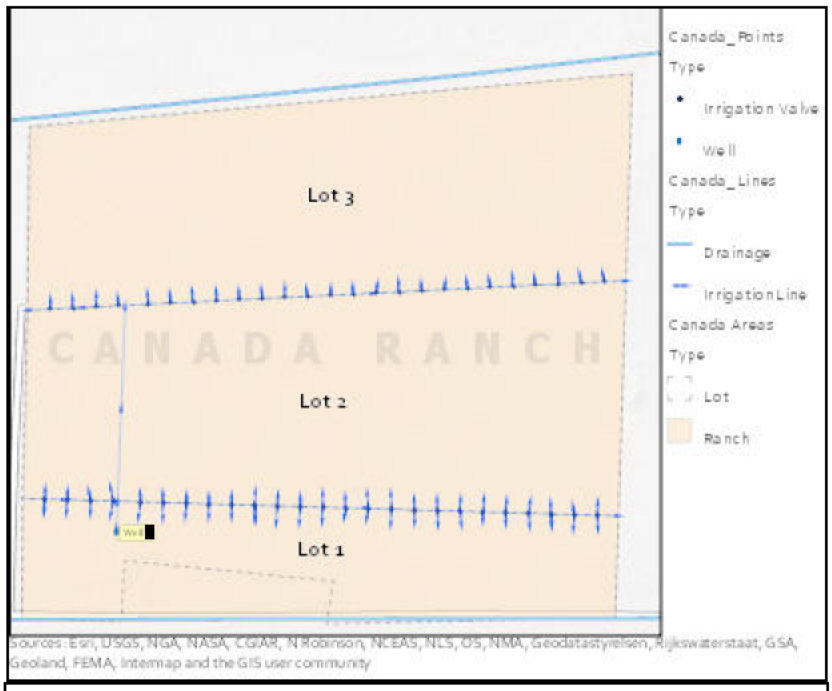

Figure 7 - Cañada Ranch Irrigation Diagram, 2017
(Note: Valve locations are for illustrative purposes only)

An onsite well (ID # [redacted]) (Exhibit B, Photo 1) was the sole source of water for the ranch. A pump moved the water from the well directly into a pressurized system for irrigation without any chemical or physical treatment. [redacted] used this water for sprinkler irrigation throughout the growing cycle as well as washing equipment in the onsite yard. The ranch did not use reservoirs, tail water, or other surface water. At the time of inspection, the wellhead appeared to be in good repair, above grade, and had no signs of contamination sources. There was no evidence that this water system connected to any neighboring properties or had any other sources of water besides the single well.

Irrigation water was distributed through a set of 8" sprinkler pipes with valves raised above the ground. All three of the valves were leaking at the time of inspection (Exhibit B, Photo 2). Mr. Catalan stated that ranch personnel repaired the valves in the off-season and they would repair them again after the 2017 growing season. Sprinklers connected to aboveground valves (Exhibit B, Photo 2) irrigated the ranch (Figure 7). Cañada Ranch personnel placed the sprinkler lines in the middle of the beds of product. As needed, they would move the sprinklers to other portions of the ranch.

To ensure microbial quality of the water, [redacted] employees collected well water monthly and submitted these samples to [redacted] for testing. [redacted] used LGMA and FDA Produce Safety Rule standards for water quality. The inspection team reviewed test results for the time of growing, harvest, and six months prior. All results were within specifications, and, specifically, the tests did not detect *E. coli* in any of the samples. During the July, 2017 [redacted] audit, water was collected from the valve immediately after the well and sprinklers being used to irrigate crops. The [redacted] audit also did not detect pathogens in these samples.

Equipment

[redacted] supplied, cleaned, and maintained all small harvest equipment (knives, gloves, etc.). Mr. Catalan provided Standard Operating Procedures (SOP's) and logs documenting equipment maintenance and cleaning during the time period of interest. The inspection team reviewed these records and the procedures and documentation appeared adequate to protect the product from contamination. At the time of inspection, no harvest activities were occurring, so the team could not verify the condition and sanitation of the harvest equipment.

[redacted] also owned a portion of the larger equipment (tractor, tilling blades, etc.) used for cultivation and growing. Ranch personnel did not use this larger equipment on any other ranches or for any other purposes. [redacted] stored, cleaned, and sanitized this larger equipment in an on-ranch cleaning area, adjacent to the fields. The cleaning area was sufficiently sloped and appeared to have sufficient drainage to prevent contamination of the crops. All water from the cleaning area drained into a nearby storm water drainage ditch. At the time of inspection, this equipment was onsite, but not in use. Mr. Catalan provided procedures and logs documenting equipment maintenance and cleaning during the time period of interest. The inspection team reviewed these records and the procedures and the processes appeared adequate.

[redacted] leased large equipment used during harvest (such as tractors, trailers, mowers, etc.) from [redacted] in [redacted] CA. Rental equipment was only used for harvest and firm management confirmed there was no rented equipment on site at the time of inspection. An ERU Inspector contacted [redacted] and spoke to a salesperson. He stated that all of the equipment leased to [redacted] was only used on ready to eat crops for human consumption and was not used on any feed crops or other areas where contaminated water or animal waste would be used. [redacted] hosed off the equipment using domestic water to remove large dirt buildup as needed, but did not conduct a thorough cleaning or sanitizing between rentals. The Inspector was unable to obtain the history of equipment specifically rented to [redacted]

Soil Amendments

Mr. Catalan stated that [redacted] did not use any soil amendments on this ranch. This included compost, organic fertilizers, and synthetic additives. The only soil amendment used on the ranch was tilling the leftover plant material back into the soil after harvest.

During the inspection, the inspection team observed many, cylindrical white pellets approximately 1" long and ½" in diameter along the farm road between Lots 1 & 2. The team attempted to sample these pellets for identification, however, ranch personnel had turned on sprinklers in the area, and the pellets had disintegrated before the team could sample them. When asked about these pellets, Mr. Catalan stated that these appeared to be fertilizer pellets and must have come off a rented tractor. This information indicates that ranch personnel were not sufficiently cleaning the rented tractors to remove sources of contamination. The inspection team discussed this concern with Mr. Catalan and he stated he would retrain the ranch employees on equipment cleaning.

Animal Management

According to ERU Geographic Information System (GIS) resources and onsite observations, there were no feedlots, concentrated animal feeding operations, or other commercial animal operations within one mile of Cañada Ranch (Exhibit A). The only domestic animals observed in or around the ranch were a small flock of five to six chickens on a neighboring property (Exhibit E, Photo 4). Due to land slope, ditches around the ranch, and the size of the flock, this flock of chickens did not pose a significant food safety concern. There were no open rangelands, wildlife areas, waste disposal sites, or other animal attractants observed near the ranch. [redacted] did not introduce any animals into crop production areas or use animals in ranch operations. There was a fence around the entire ranch. A woven mesh covered the north, south, and east sides of the fence to keep occasional, non-flying wildlife out of the growing area. There were several tears observed in the mesh, but no evidence that animals had entered the growing area. The wild animals observed during the inspection and in records reviewed were primarily birds. The records stated that birds were observed in small numbers and this was true at the time of inspection as well. The employees used flare guns and other annoyances as a deterrent. The harvest crew inspected the harvest area immediately prior to harvest for any evidence of animal intrusion. While the records did not state there was evidence of animals prior to any harvests, Mr. Catalan stated that [redacted] used LGMA guidelines to address potential food safety concerns if animal intrusion were found. Specifically, harvest personnel would create a buffer around the contaminated area and would not harvest that area.

Harvest

[redacted] harvested the crops grown on Cañada Ranch approximately [redacted] to [redacted] weeks after planting depending on demand and product growth rates. The company used a single crew of permanent employees to harvest all crops grown on Cañada Ranch. [redacted] utilized this crew on other [redacted] operated ranches as well. Harvest generally took place over the course of one week with the most desirable product picked each day, as needed to fill orders. After the initial harvest, [redacted] may have harvested the same plants a second or third time, depending on demand and product quality. These subsequent harvests were generally [redacted] to [redacted] weeks after the previous harvest. [redacted] harvested spinach, which was not the focus of this investigation, using a harvest machine with a reciprocating blade. The foci of this investigation, lettuce and other non-spinach products were hand harvested as follows:

1) Harvest personnel walked the harvest area for a final food safety assessment
2) The personnel then pulled the bulb up from ground using a gloved hand.
3) The crew then used a knife to cut the product off at the ground.
4) The crew then hand cut the leaves from the stem.
5) The product traveled along a conveyor to another member of the harvest crew who placed the item in a reusable plastic tote. The full totes were stacked on a pallet.
6) When full, the pallets were transferred to a truck for transport

- Note: these reusable plastic totes were stored and cleaned at the Jayleaf processing facility using well water, a food-safe detergent, and a quaternary-ammonia based sanitizer

Transportation

[redacted] transported all products from the field to Jayleaf for processing in cooled semi-trailer trucks owned and operated by [redacted] [redacted] only used these trucks to transport ready-to-eat leafy greens. Jayleaf personnel visually inspected and, if needed, washed the trucks in the yard of the Jayleaf processing facility. [redacted] used the same trucks to transport a large majority of final products to customers. During the inspection of the processing facility (above), the team inspected the trucks and they appeared generally clean and sanitary. The cooling unit was operating in two of the vehicles and both appeared to be working adequately.

Regulatory Actions

The team did not note any significant food safety concerns during the ranch investigation. Minor issues were noted with management during the inspection. FDB took no regulatory actions.

Sampling

Environmental Samples

Jayleaf Processing Plant

During the onsite investigation at the Jayleaf processing facility on 9/21/17, the team collected 22 environmental samples (20 swabs, 2 water samples) for *E. coli* testing. The team collected the environmental swabs from food contact and non-food contact surfaces throughout the facility and the two water samples from the processing wastewater settling tanks (Attachment 6, Lines 122-143). Due to Jayleaf's normal sanitation schedule and the timing of the inspection, the team collected these samples after sanitation crew had begun cleaning, but before sanitizing had taken place.

In addition to the environmental samples, the team collected 114 – 0.75mL samples of wash water (IS # 710092117-E023) covering all three tanks for production dated 8/10/17-8/31/17. Each sub-sample consisted of [redacted] mL of water in a microcentrifuge tube from each wash tank, [redacted], during production for a total of [redacted] per day depending on shift length (Attachment 6,

Lines 5-121). Jayleaf management requested that they be allowed to retain [redacted] ([redacted] mL) of each sample collected by the inspection team. Jayleaf had stored these samples frozen (approx. [redacted]° F) since they were collected. Jayleaf QA personnel and an ERU Inspector briefly thawed and divided the samples.

The environmental swabs, water, and wash water samples were assigned IS #710092117 and submitted to the Food and Drug Laboratory Branch (FDLB) in Richmond, CA on 9/22/17 using ERU's standard storage and transportation procedures. FDLB reported all environmental samples were non-detect for *E. coli* and composites of the wash water retains were PCR negative for *E. coli*.

Cañada Ranch

During the onsite investigation at Cañada Ranch on 10/5/17, the team collected 29 environmental samples (19 soil, 3 swabs, 7 irrigation water) for *E. coli* testing. The team collected the soil from active and recently harvested fields, environmental swabs from the outside of irrigation equipment, and water from sprinkler valves being used on product during the inspection (Attachment 6, Lines 146-174).

The environmental, and water samples were assigned IS # 710100517 and submitted to FDLB on 10/6/17 using ERU's standard storage and transportation procedures. FDLB reported all environmental samples were non-detect for *E. coli*.

Product Samples

Jayleaf Processing Plant

During the onsite investigation at the Jayleaf processing facility on 9/21/17, the team collected two – 1 lb. bags of finished product for *E. coli* testing (Attachment 6, Lines 144-145). These samples consisted of one bag of arugula (Lot 274701) and one bag of Spring Mix - Las Vegas Blend (Lot 12273730), which were being packaged in the Small Item Room during the inspection (Attachment 6 – Lines 144 & 145).

The product samples were assigned IS# 710092117 and submitted to FDLB on 10/6/17 using ERU's standard storage and transportation procedures. FDLB reported all product samples were non-detect for *E. coli*.

Retail Sampling

Portal Restaurant

On 9/19 and 9/20/17, Alameda County Department of Environmental Health impounded three cases of leafy green products at a case-patient exposure location, Portal Restaurant in Oakland, CA (1611 2nd Ave). According to their understanding of the traceback investigation to that point, Alameda County Environmental Health Inspectors determined this was product from the same suppliers as was available when the case-patients were exposed. An ERU Investigator collected 3-1 lb. bags on 9/20/17 for *E. coli* testing (Attachment 6, Lines 2-4). These three samples consisted of one of each of the following (Attachment 8):

- 4 lb. box of Wild Arugula – lot 269726– Jayleaf, LLC. Identified as responsible party
- 3 lb. box of Frisée – lot 1108 – Scarborough Farms identified as responsible party
- 4 lb. box of baby spinach – lot 267724 - Suprema, LLC. Identified as responsible party

These samples were assigned IS# 199092017 and submitted to FDLB on 9/21/17 using ERU's standard storage and transportation procedures. FDLB reported all product samples were non-detect for *E. coli*.

Case-patient Samples

No case-patient samples were collected for this investigation.

Recall Activities and Press

Jayleaf and CDPH did not initiate any recalls or issue any other public statements associated with this outbreak.

Summary of Outbreak Investigation Findings

In the summer of 2017, ERU investigated an outbreak of STEC O157 associated with leafy green exposure (CDC Cluster Code 1709CAEXH-1). In all, the epidemiologic investigation identified 69 cases as part of this outbreak from eight states (62 cases from California). Out of the 69 total cases, LHJ's and IDB interviewed 53 of them. Of those interviewed, 52% indicated mixed greens, mesclun, and/or spring mix exposure outside the home prior to illness.

IDB referred fourteen cases with limited exposures and reliable food histories to ERU for traceback. In 13 of these 14 cases (93%), leafy green products consumed by the case-patient were processed at the Jayleaf facility in Hollister, CA. ERU Inspectors traced back each ingredient in each of these products to the ranch and lot level. All thirteen of the cases with a confirmed or probable link to the Jayleaf processing facility had exposure to products grown on Cañada Ranch. [redacted] grew a majority of these products on a single portion of this ranch, Lot 3.

CalFERT teams conducted environmental assessments at the Jayleaf processing plant in Hollister, CA and at Cañada Ranch in Hollister, CA to find any underlying issues or concerns that may have led to this outbreak. Through these assessments, the investigation team collected environmental swabs, wash water, and irrigation water samples. Additionally, the team collected several product samples from Jayleaf's processing plant and from product in commerce. The team submitted these samples to FDLB for *E. coli* testing. *E. coli* was not detected in any of these samples. Due to the inherent lag in reporting and investigating outbreaks, the investigation team collected these samples approximately one month after case-patients reported illnesses. While these samples reflect the conditions present during the investigation, they may not accurately reflect the conditions when Jayleaf produced the suspect products.

Overall, the investigation conducted by CDPH determined that leafy green products grown on Cañada Ranch by [redacted] then processed and distributed by Jayleaf, LLC. were the most likely cause of this outbreak. The epidemiological and environmental health investigations all support this conclusion. While sampling did not detect *E. coli* in the implicated processing facility or the ranch, observations at Canada Ranch showed practices relatively unusual for the leafy green industry. These practices included hand harvesting of crops with multiple cuts over time; using sprinkler laid in the middle of the growing beds that had to be moved around the ranch, and excessive amounts of standing water. In addition, the team observed evidence that rented tractors were not inspected or cleaned between uses, including being used on other, unknown ranches.

Firm Responses

Initially, ERU notified Jayleaf & [redacted] food safety management about the link between their products and illnesses on 9/11/17 and continued requesting records and updating Jayleaf and [redacted] management as the investigation continued. On 10/1/17, Jayleaf management sent ERU a response to the investigation updates they were being provided. This response included a letter from Jayleaf and [redacted] shared food safety consultant, [redacted] (Exhibit G). Included with the letter was the results of the company's [redacted] sampling showing no pathogens detected in the wash water retains the company kept from the samples collected on 9/21/17 (Exhibit H). Additionally, [redacted] attached an article from the journal Genomic Research outlining the technical basis for their analytical approach (Exhibit I). According to their letter, the consultant's conclusion was "[neither Jayleaf nor [redacted]] could validly have been answerable for the CDPH accusation of a pathogenic outbreak." They based this conclusion on the tests they conducted and their review of both companies' procedures and records.

Corrective Actions

As the investigation continued, ERU updated [redacted] regarding the strengthening link between Cañada Ranch and illnesses. On 10/10/17, [redacted] President [redacted] sent CDPH a statement that they would voluntarily destroy all crops on Cañada Ranch, Lot 3.

Photos taken 10/11 and 10/12/17 by Mr. Catalan and provided to ERU Inspectors on 10/12/17 verified the crop destruction on Cañada Ranch, Lot 3 (Exhibit C, Exhibit F). Mr. Catalan stated that the destruction included approximately 160 beds of products including the following: red mustard, tatsoi, mizuna, kale, red chard, lollorosa, red romaine, green romaine, tango, and mixed lettuces. Additionally, [redacted] stated over the phone that [redacted] would not grow any crops on this lot until spring, 2018.

Cañada Ranch Follow Up Inspection

On 6/5/18, ERU staff conducted a follow-up inspection at Cañada Ranch. The purpose of this inspection was to observe any corrective actions and other changes in practices on Cañada Ranch since the last inspection on 10/5/17. After the end of the 2017 growing season, [redacted] started managing Cañada Ranch, including all growing and harvesting. The investigation team met with the current grower/harvester, [redacted] ([redacted]), represented by [redacted] All product grown on Cañada Ranch in the 2018 growing season was grown for Jayleaf, including spring mix varieties, spinach, arugula, kale, frisée, and radicchio.

Third Party Audits

LGMA performed the most current audit prior to this inspection on 5/1/18. The inspection team reviewed the LGMA Food Safety Audit Report and found no areas of concern (Attachment 9).

Farm Layout

ERU staff inspected the entire ranch, with a focus on the portion designated as Lot 3 in 2017. Since 2017, [redacted] changed the layout of the ranch, so the area formerly referred to as Lot 3 was now called Lot 5 (Exhibit D). The main reason for the change in layout was to prevent the waterlogged conditions that the CalFERT team observed during the last ranch assessment. In addition to the change in layout, [redacted] employees re-graded the entire ranch so that water would reliably flow to drainage ditches that bordered the ranch. To accommodate the new layout, [redacted] also moved farm roads and the lot lines were re-drawn. As part of the reconfiguration, [redacted] increased the size of the bed rows to [redacted] inches in order to accommodate a new sprinkler layout, which did not require crews to move sprinklers (Exhibit E – Photo 3).

Previously, [redacted] had minimal ongoing maintenance of the farm roads. At the time of reinspection, [redacted] employees scraped the new farm roads regularly to remove any loose dirt, which became mud in wet weather or with sprinkler overspray.

The newly designated Lot 5, on the north end of Cañada Ranch, was disked on 10/11/17 (see Corrective Actions, above) and remained fallow throughout the winter until [redacted] employees planted product on 1/19/18. At the time of inspection, chard was growing in Lot 5. Lot 4, adjacent to and south of Lot 5, was growing mizuna, red lettuce, green lettuce, spinach, and arugula (Exhibit E – Photo 4).

Water Sources

Well # [redacted] was still the sole source of water for the ranch. [redacted] employees replaced the distribution and sprinkler system during the ranch upgrades. All, previously leaking, 8-inch raised sprinkler valves were removed from the ranch. Ranch management laid new sprinkler pipes, without raised valves, in the furrows between every [redacted] beds (Exhibit E – Photos 5 & 3). The new sprinkler layout eliminated contact between the pipes and the growing produce and there was no longer a need for employees to move the sprinklers to other areas of the ranch.

Animal Management

[redacted] employees repaired many of the existing fences, animal deterrent barriers, and dust barriers. These repairs included the addition of animal deterrent and dust barriers to fences that did not have them before, including the fences on the west and east sides of the ranch. [redacted] employees also installed additional rodent traps along the fences.

The ERU team began the inspection at 4:00 am, before sunrise. The team observed the occasional bat flying overhead in the darkness and heard sounds of coyotes nearby. At sunrise, roosters crowed for about an hour from nearby properties. ERU surveyed the entire ranch in the daylight to look for evidence of animals on the ranch. The team observed several sets of raccoon tracks on the farm roads surrounding the outer edge of the ranch (Exhibit E – Photos 7 &8). A portion of the fence, on the Northwest corner of the ranch had an opening where a drainage ditch passed underneath with raccoon tracks leading from it and along the ranch roads (Exhibit E – Photo 9, center). The team notified [redacted] of these observations and he immediately initiated a fence repair in this area (Exhibit E – Photo 9, right). The team did not observe evidence of animals in the growing portions of the fields.

Harvest

At the time of re-inspection, [redacted] employees were collecting pre-harvest product samples of all commodities and sending them to a lab for *Salmonella* and *E. coli* testing. Previously, [redacted] only tested red and green lettuces, spinach, and arugula.

[redacted] harvest crews harvested all crops grown on Cañada Ranch. The crews received training every day in the form of tailgate meetings. The trainings included safe food handling practices and proper hygiene topics, including handwashing.

The Crew Foreman checked the field daily while the crop was growing and [redacted] minutes before the harvest, under floodlights. The Foreman looked for any weeds, animal intrusion, or other sources of contamination. If any plant or animal contamination was found, that portion of the field was marked off with a buffer and would not be harvested.

The inspection team observed a harvest crew harvesting chard and mizuna in Lot 4. There were two crew members walking in front of the harvest machine looking for adulterants (Exhibit E – Photo 1). A blower attached to the front of the harvesting machine blew off insects and other contaminants before using blades on the front of the harvest machine to cut the product off at the ground (Exhibit E – Photo 2). The machine conveyed the cut product up to the top of the machine where harvest crew members sorted through the product and placed acceptable product into reusable plastic bins. The workers sprayed the product in the bins with [redacted] ppm chlorinated water from an onboard water tank filled from the onsite well prior to harvest. When full, another set of harvest workers stacked the bins onto a flatbed trailer, which travelled alongside the harvesting machine in the field (Exhibit E – Photo 3). Jayleaf was responsible for the cleaning of the bins before returning to the field for reuse. Jayleaf delivered the clean bins in a refrigerated truck before harvest where they were stored until use.

A member of the harvest crew cleaned the harvest machine daily. In the on-ranch equipment yard, they rinsed the equipment with well water to remove the large dirt and plant material. Weekly, they performed a thorough cleaning and sanitizing. This included rinsing off large material, then scrubbing the equipment with [redacted] ounces of [redacted] solution mixed with water in a [redacted]-gallon bucket. The harvest crew then applied a [redacted]-ppm chlorine sanitizer, which they left on the equipment per the manufacturer's instructions.

Field Worker Sanitation

A portable toilet was parked on the farm road adjacent to the field being harvested. When the workers moved to the next field, they moved the trailer with them. [redacted] ([redacted] CA) maintained the toilet twice per week. During the inspection, the toilet appeared clean (Exhibit E – Photo 6, left) and the log on the door indicated that they had serviced the toilet for several months on schedule (Exhibit E – Photo 6, right). According to [redacted], a sanitation truck vacuumed the sewage out of the unit in the equipment yard (away from the growing area) and then transported the waste to an off-site sanitary dump facility for disposal.

A handwashing sink was located on the outside of the portable toilet unit and was adequately stocked with soap and paper towels. [redacted] employees restocked the paper towels and soap on an as-needed basis. Well #[redacted] supplied the handwashing water. The grey water from handwashing collected in a sealed tank on the portable toilet. The inspection team did not observe evidence of leaks from the portable toilet unit.

The team observed the workers wearing hair restraints, smocks over the clothes, and disposable gloves. The harvest crew appeared to have good hygiene and was observed washing hands after using the restroom.

No food safety concerns were observed during the harvest portion of the reinspection.

Summary of Follow-Up Findings

Due to the association with the outbreak in summer, 2017, [redacted] management made the following improvements to the ranch, which may result in enhanced food safety:

- Repaired fence and added additional mesh for the control of dust and small animals
- Removed all 8" sprinkler valves, resulting in less leaks and standing water.
- Installed permanent sprinkler system and increased bed size to [redacted]", so sprinkler pipes no longer touch growing product
- Regraded the ranch and ranch roads to improve drainage and reduce pooling water
- Pre-harvest testing of all commodities grown
- Single cut harvest, instead of multiple cuts
- Employees received additional training after the previous inspection and continue to receive training on a regular basis

ERU investigators did not observe any food safety concerns on the ranch, besides the raccoon paw prints on the farm road. The paw prints signaled that small mammals could potentially contact the growing produce and cause contamination.

Firm management immediately initiated a repair to the portion of the fence.

Recommendations for Further Follow Up

The follow up inspection in June 2018 indicated the ranch had undergone significant improvements for food safety. The team observed only minor food safety concerns and those seemed well controlled.

As of the date of this report, no further follow up for this investigation is indicated at this time.

Attachments and Exhibits

Attachments

Attachment 1 - Traceback Diagram
Attachment 2 - Traceback Timeline
Attachment 3 – Cañada Ranch Farm Investigation Questionnaire
Attachment 4 - 2017 Cañada Ranch LGMA Audit
Attachment 5 - 2017 Cañada Ranch [redacted] Audit - Testing Results
Attachment 6 - Sample Collection Log
Attachment 7 - Sample/Evidence Receipt for Sample 7100092117
Attachment 8 – Sample/Evidence Receipt for Sample 199092017
Attachment 9 - 2018 LGMA Audit

Exhibits

Exhibit A - Cañada Ranch and Surrounding Area – 2017 Layout
Exhibit B - Photos from Cañada Ranch – Collected 10/5/17
Exhibit C - Photos of Crop Destruction 10/12/17
Exhibit D - New vs Old Cañada Ranch Layouts
Exhibit E - Photos from Cañada Ranch Reinspeciton – Collected 6/5/18
Exhibit F - Crop Destruction Verification
Exhibit G - [redacted] Response to Initial Outbreak Notification
Exhibit H - [redacted] Testing Results
Exhibit I - Microbial Community Profiling Journal Article
Exhibit J - Jayleaf Response Letter