ENVIRONMENTAL INVESTIGATION OF AN *ESCHERICHIA COLI* O157:H7 OUTBREAK IN OCTOBER 2013 ASSOCIATED WITH PRE-PACKAGED SALADS

Final Report

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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)

CDPH, Food and Drug Laboratory Branch (FDLB)

CDPH Division of Communicable Disease Control (DCDC), Infectious Disease Branch, Disease Investigations Section (DIS)

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

United States Centers for Disease Control (CDC)

United States Department of Agriculture (USDA) Food Safety and Inspection Service (FSIS)

DATES OF INVESTIGATION

October 30, 2013 – January 27, 2014

EXECUTIVE SUMMARY

California Department of Public Health (CDPH), Food and Drug Branch (FDB), Emergency Response Unit (ERU) investigated a multi-state foodborne illness outbreak of *Escherichia coli* O157:H7 (PulseNet Cluster ID 1310CAEXH-1) linked to the consumption of pre-packaged salads purchased in October 2013 at multiple retail locations. The outbreak included a total of 33 ill persons in 4 states; Arizona (1), California (28), Texas (1), and Washington (3). The illness onset dates ranged from October 5, 2013 to November 1, 2013. The case patients had a single matching strain of *E. coli* O157:H7 (*Xba*I EXHX01.0589 and *Bln*I EXHA26.3182).

Initially, two varieties of Trader Joe's salads were suspected food vehicles in this outbreak. These Trader Joe's salads were produced by the same manufacturer, Atherstone Foods Inc. in Richmond, CA. As the epidemiological investigation progressed, two additional salads were identified as possibly causing illness. One of these salads was manufactured by [redacted] in Oakland, CA, while the other salad was also manufactured by Atherstone Foods Inc., for the Walgreens chain of drug stores. Analysis of the common ingredients among all four salads revealed that romaine lettuce was the only common component. FDB narrowed the traceback to romaine lettuce and determined that a single field of romaine lettuce in Modesto, CA, grown by Ratto Bros. could have been used in the production of all four salads.

FDB and the United States Food and Drug Administration (FDA) conducted an environmental investigation at Atherstone Foods, Inc. (DBA: Glass Onion Catering), in Richmond, CA. Seven retain product samples (consisting of the two implicated Trader Joe's salads) were collected by FDB and tested by the Food and Drug Laboratory Branch (FDLB) in Richmond, CA. These samples were negative for *E. coli* O157:H7. The inspection at Atherstone Foods, Inc. did not result in any food safety violations or potential areas of cross-contamination.

FDB and FDA continued the outbreak investigation at the grower of the suspected romaine. Investigators inspected Ratto Bros. procedures related to growing, handling and transport of the suspect romaine lettuce. Distribution documents, farm conditions, and water systems used by Ratto Bros. were reviewed in detail. Five of 44 environmental samples collected from areas around the implicated ranch were positive for *E. coli* O157:H7. One of these samples was obtained from a private road while the other four samples were collected on public roads near the implicated field. The positive samples were not a genetic match to the outbreak strain.

FDB could not determine the root cause of contamination to the salads implicated in this outbreak. Investigators identified factors during the investigation at the implicated field that could have contributed to contamination of romaine in a farm environment. These potential factors were wind transferring pathogens from contaminated areas to growing fields and farm equipment contaminating crops after using public roads shared with neighboring cattle operations. Ratto Bros. management responded to the Department's findings by enhancing their current procedures and adopting new procedures in an effort to prevent potential contamination events in the future.

Background

On 10/30/2013, the California Department of Public Health (CDPH), Food and Drug Branch (FDB), Emergency Response Unit (ERU) was notified of a multi-state foodborne outbreak of *Escherichia coli* O157:H7 (PulseNet Cluster ID 1310CAEXH-1) that was epidemiologically linked to the consumption of pre-packaged salads purchased at multiple Trader Joe's stores. Out of five California cases initially interviewed, four indicated shopping at Trader Joe's and consumed pre-packaged Trader Joe's salads. As the outbreak case count increased, the majority of California cases were from the extended San Francisco Bay Area with a few cases in Los Angeles County. Additionally, there were other cases in Washington, Arizona, and Texas that had mentioned consuming specific Trader Joe's salads. It was determined that most case patients had exposure to one or both of the following salad varieties, Trader Jose's Mexicali Salad with Chili Lime Chicken and Trader Joe's Field Fresh Chopped Salad with Grilled Chicken. Upon initial investigation into Trader Joe's distribution patterns, it was determined that one processor, Atherstone Foods Inc., was the sole supplier of these salads in the regions where illnesses were being reported. This information prompted ERU staff to trace back the common ingredients in Trader Jose's Mexicali Salad with Chili Lime Chicken and Trader Joe's Field Fresh Chopped Salad with Grilled Chicken.

Epidemiological Summary

A total of 33 ill persons in the following 4 states were infected with the outbreak strain of Shiga toxin-producing *E. coli* O157:H7; Arizona (1), California (28), Texas (1), and Washington (3). The illness onset dates ranged from October 5, 2013 to November 1, 2013. The CDC designated cluster code for this outbreak was 1310CAEXH-1. Ill persons ranged in age from 2 years to 78 years, with a median age of 29 years. Sixty four percent of cases were female, nine were hospitalized, and two cases developed hemolytic uremic syndrome (HUS). No deaths were reported.

CDC reported that public health laboratories performed pulsed-field gel electrophoresis (PFGE) diagnostic testing with samples obtained from case patients and compared the patients' patterns to the data maintained in PulseNet, a national microbiological subtyping network that performs molecular surveillance of foodborne infections. The cases identified in this outbreak shared a single matching strain of *E. coli* O157:H7 with the following combination of PFGE patterns, *Xba*I EXHX01.0589 and *Bln*I EXHA26.3182.

Traceback

At the beginning of the traceback investigation, ERU compared the ingredients between the two Trader Joe's salads initially identified by CDPH, Division of Communicable Disease Control (DCDC). The two salads had seven common ingredients: romaine lettuce, red cabbage, red bell pepper, shredded Asiago cheese, corn, chicken, and lemon juice. ERU initiated traceback of three of the seven common ingredients: romaine lettuce, red cabbage, and red bell pepper. The remaining four common ingredients were not initially traced back, due to having undergone certain processing steps or because historically these products had not been associated with *E. coli* illnesses. The cut corn was received frozen from the supplier. Frozen corn has not been linked to *E. coli* illnesses in the recent past. Asiago cheese was a type of hard, dry cheese that is aged for an extended period of time to achieve the attributes desired in Asiago cheese. The aging process and low water activity

lessens the chance that *E. coli* remained in the cheese. The pH of lemon juice was too low to sustain *E. coli*, so lemon juice was not considered. Chicken was not traced back initially because it was a pre-cooked product. When compared to raw produce, cooked chicken was considered less of an *E. coli* risk than the three ingredients that were chosen for the traceback.

Additional epidemiological information was received during the course of the traceback, so two additional traceback legs were added. One of the added traceback legs consisted of a case patient that consumed a [redacted] purchased from [redacted], an eatery on the University of [redacted] campus. This salad was manufactured by [redacted] in Oakland, CA. The second added traceback leg consisted of one case that consumed both a [redacted] and Good & Delish California Style Grilled Chicken Salad. Both salads were purchased at a Walgreens in San Francisco. The [redacted] was manufactured by [redacted] in Sacramento, CA. The Good and Delish California Style Grilled Chicken Salad was manufactured by Atherstone Foods Inc. in Richmond, CA. After having compared the common ingredients in the three newly implicated salads to the two previously implicated salads, it was determined that there was only one ingredient common in all five of the salads, romaine lettuce. Therefore, the remainder of the traceback investigation concentrated on romaine lettuce only.

Eventually, the traceback investigation consisted of three traceback legs. The three traceback legs were designated as the Trader Joe's leg, the University leg, and the Walgreens leg. Cases chosen for the traceback investigation consisted of those that had good recall of their food history, had clinical samples that matched the PFGE pattern of the outbreak strain, and had reported specific purchase dates or a range of purchase dates.

Invoices, bills of lading, and production records were obtained from all points in the distribution of the implicated salads. ERU reviewed the documents to narrow the shipments that took place during the time period of interest to only the shipments that could feasibly be available at retail on the specified purchase dates. Shelf life of the salads was also considered during the process of narrowing the suspect shipments. Investigators obtained the shelf life information from each salad producer in the traceback. All of the salads in the traceback had an eight day shelf life, except the [redacted], which had a six day shelf life. A traceback diagram for romaine lettuce was created with the traceback data obtained (Attachment 1). Five salads were traced back in the diagram (see Table 1 below). Atherstone Foods, Inc. (DBA: Glass Onion Catering) was a common processor for three salads, [redacted]. was the processor for one salad, and [redacted] was processor for one salad. The diagram showed convergence at the romaine supplier used by the Atherstone Foods Inc. and [redacted] used romaine lettuce that was supplied by a different grower when compared to Atherstone Foods Inc. and [redacted] In addition, the case patient who consumed the salad from [redacted] also consumed a salad produced by Atherstone Foods Inc. during the time period of interest.

Table 1: Processors of Traced Back Salads

Salad Name	Processor
Trader Jose's Mexicali Salad with Chili Lime Chicken	Atherstone Foods Inc.
Trader Joe's Field Fresh Chopped Salad with Grilled Chicken	Atherstone Foods Inc.
Good & Delish California Style Grilled Chicken Salad	Atherstone Foods Inc.
[redacted]	[redacted]
[redacted]	[redacted]

ERU was able to determine that a single grower and field could have been the source of romaine lettuce for all three of the traceback legs. The field implicated by epidemiological traceback was Ranch 9, Field 1, Valve 11 (R9F1V11) owned by Lake Bottom LLC with all growing and harvesting operations conducted by Ratto Bros.

Environmental Investigation at Atherstone Foods Inc.

On November 8, 2013, FDB and FDA investigators initiated an inspection at Atherstone Foods Inc. in response to the *E. coli* O157:H7 outbreak epidemiologically linked to ready-to-eat (RTE) salads purchased at Trader Joe's locations in the extended San Francisco bay area. Atherstone Foods Inc. was located at 200 W. Ohio Ave., Richmond, CA 94804. Atherstone Foods Inc. manufactured various refrigerated RTE salads, wraps, and baked goods under their brand name and also co-packed for customers such as Trader Joe's, Walgreens, [redacted]. The firm also manufactured products containing meat which were regulated by the United States Department of Agriculture, Food Safety and Inspection Service (USDA-FSIS). Thomas E. Atherstone (owner) and [redacted] (plant manager) were interviewed regarding all aspects of facility operations relating to food receiving, handling, holding, packing, and distribution practices. The Atherstone Foods Inc. inspection report and associated attachments, including sanitation logs, internal testing results, pest control records, and FDB regulatory documents can be found in Attachment 2.

As a result of epidemiological work conducted by DCDC and preliminary investigative work conducted by FDB, the following two Trader Joe's salads were the focus of this inspection: Trader Jose's Mexicali Salad with Chili Lime Chicken and Trader Joe's Field Fresh Chopped Salad with Grilled Chicken. The last production date for these salads was November 6, 2013. The quantity last produced was 1,988 retail packages of the Field Fresh Chopped Salad and 2,800 retail packages of the Mexicali Salad, with a USE BY date of 111413. Since the salads were not being produced on the day of inspection, the manufacturing process was observed for a low calorie Greek wrap and an Asian style chicken wrap. The firm's process for manufacturing wraps was similar to the production processes used to manufacture salads.

Process Flow

Atherstone Foods Inc. took several steps to ensure the quality and safety of their incoming ingredients. Raw material receiving practices included the following: employees documented the temperature of all incoming

trucks; food product packaging materials were inspected for damage and pest activity; food products were logged onto a receiving sheet; a receiving date was applied to all food products exterior packaging; and food products were stored in the receiving walk-in cooler (35°F) until needed. The firm used first-in, first-out (FIFO) product rotation practices. Prepared fresh ingredients were usually used within two to three days of preparation. Other ingredients, such as cheese, were used within five days.

The first part of the processing procedure took place in the refrigerated Preparation room, which was observed to be maintained at 45°F. First, all produce was rinsed with a [redacted] additive which was an Environmental Protection Agency (EPA) registered antimicrobial water additive for pathogen reduction in fruit and vegetable processing water. The [redacted] system was connected to two sinks and an automated produce wash system. The two sinks were used for smaller batches of produce while the produce wash system was primarily used to wash larger amounts of chopped romaine lettuce. Romaine lettuce was one of the main ingredients for many of the firm's RTE products such as salads and wraps. Produce was exposed to the [redacted] wash for approximately [redacted] seconds, excess water was removed using spinners, placed in plastic containers with lids, labeled with a preparation date with the name of the person who prepared the ingredient, and was placed in the In-process Hold Room ([redacted]°F) until needed. Employees measured the concentration of [redacted] in the wash system at every product change over. The target concentration range was between [redacted] parts per million (ppm). Production records from September 1, 2013 through November 8, 2013 indicated that all processing water was maintained at the target concentration levels.

In addition to the preparation of chopped vegetables, salad dressings were prepared in the same room. The salad dressing ingredients were measured and poured into an approximately 5 gallon plastic container then blended using a [redacted] blender. After being poured into an approximately 20 to 30 gallon container, the containers were labeled with a preparation date, name of the person who prepared the ingredient, an allergen label if required, and placed in a temperature controlled storage room until further use or immediately transferred to a filler machine, which was about 10 feet from the blender area. The dressing was automatically dispensed into 1.5 oz. or 2 oz. plastic containers and heat sealed. If 3 oz. dressing containers were being used, they were [redacted] filled and [redacted] capped. The dressings were placed into an empty, individual serving container before being moved to the Assembly Room, where the finished wrap or salad was put in the container.

The assembly of the wraps took place in the refrigerated Assembly Room ([redacted]°F). Tortillas were placed individually on a conveyor belt. As the tortillas traveled down the conveyor belt, employees manually added lettuce, peppers, cheese, carrots, green onions, and chicken. The chicken was received pre-cooked and frozen from their supplier. The wraps were assembled by hand, weighed, and then placed into an individual serving container containing the packaged dressing. The salad container was transferred to a packaging table where the wrap was weighed once again, cut in half, packaged in a plastic bag, and placed in the serving container with salad dressing alongside, and manually closed. All finished product containers were labeled with a "Perishable Keep Refrigerated" statement along with a six (6) digit "USE BY" date. (i.e. "USE BY 111413") and had either a 7 day or 8 day shelf life, depending on the product. Finished products were placed into a larger plastic tote and stored in the finished product warehouse room (36°F) until distributed.

The firm collected retain samples from each lot. The firm's protocol for collecting retains was to collect one finished product (wrap or salad) for each production day. The retain samples were stored under refrigerated conditions and destroyed once the expiration date was reached.

On a random basis USDA-FSIS analyzed finished, meat-containing products for *Salmonella* and *Listeria monocytogenes*. Records indicated that finished products, collected from 2/19/13 to 9/11/13, tested negative for these pathogens.

WATER

The firm used municipal water for the washing of produce, cleaning of facility and equipment, and hygiene of employees. Water was analyzed on a yearly basis for coliforms. The latest coliform testing date, from March 6, 2013, indicated negative coliform findings. The analysis was conducted by [redacted]

The firm did not use any type of water filtration system.

PEST CONTROL

The firm contracted pest control with [redacted] on a bimonthly basis. [redacted] Company was located at [redacted]. The pest control company inspected exterior bait stations, interior rodent traps, and insect attractant lights. No significant pest activity was noted in pest records between 6/6/2013 and 11/4/2013. No pests or evidence of pest activity were observed during the inspection.

EMPLOYEE TRAINING AND PRACTICES

The firms' employees received in-house training on general Good Manufacturing Practices (GMPs) and employee hygiene, such as hand washing and not working when ill. No violations of GMPs or employee hygienic practices were observed during the course of the inspection.

FACILITY CLEANING AND SANITATION

Tables and conveyors were cleaned and sanitized with a quaternary ammonium based cleaner prior to starting a new product. A "Sanitation Control" form was filled out and checked by staff members prior to starting each production.

The firm had an automated system to dispense detergents and sanitizers. The quaternary ammonium sanitizer in the Preparation room was observed to be maintained between [redacted] ppm. The sanitizer concentrations were checked three times a day for accuracy, in the morning, during production, and during sanitation.

All utensils used in the preparation and assembly rooms such as cutting boards, knives, and buckets were used once, then transferred to the cleaning and sanitizing room to be washed, rinsed, and sanitized. Once clean, utensils were stored in a separate room, inside the cleaning and sanitizing room. Clean utensils were observed stored in racks and in adequate sanitary conditions.

On a yearly basis, the firm checked processing areas for allergen residue. Review of records from 4/16/13 through 6/7/13 revealed negative findings.

Product Distribution

Finished products were primarily distributed to retail establishments. The purchasing customers arranged for the delivery of products from Atherstone Foods Inc. to locations in California and other states across the United States. Large customers contracted with trucking companies for the transportation of the purchased products from Atherstone to various distribution centers. The distribution centers supplied the products to retail locations. Smaller companies sometimes picked-up the finished products using their own delivery vehicles.

Samples Collected

Product Samples

FDB collected seven retained Trader Jose's Mexicali Salad with Chili Lime Chicken (4 count) and Trader Joe's Field Fresh Chopped Salad with Grilled Chicken (3 count) samples from Atherstone Foods Inc. for *E. coli* O157:H7 testing. The CDPH, Food and Drug Laboratory Branch (FDLB) performed the analysis of the samples. See Table 2 and Table 3 which detail the salads collected and their associated Use By Dates below.

Table 2: Collected Retained Samples of Trader Jose's Mexicali Salad with Chili Lime Chicken (11 oz.)

Sample Number (I.S.)	Use By Date
710110713-P001	110813
710110713-P002	110713
710110713-P003	110613
710110713-P006	111413

Table 3: Collected Retained Samples of Trader Joe's Field Fresh Chopped Salad with Grilled Chicken (10.7 oz.)

Sample Number (I.S.)	Use By Date
710110713-P004	110613
710110713-P005	110713
710111413-P007	111413

The retain salad samples collected were not from the period of interest, but were the oldest retained samples available. There were no retained salads left from the period of interest, as the firm discarded the salads once they reached their expiration date.

All product samples collected by FDB were reported negative by FDLB for *E. coli* O157:H7.

Environmental swabs were not collected at the facility due to the length of time between the period when the suspect salads would have been produced and the time of the inspection.

Regulatory Actions at Atherstone Foods Inc.

Based on the epidemiological and traceback information known at the time of inspection, FDB placed 1,985 containers of Trader Joe's Field Fresh Chopped Salad with Grilled Chicken and 2,797 containers of Trader Jose's Mexicali Salad with Chili Lime Chicken under embargo on November 8, 2013. A Notice of Violation (NOV) was issued to the firm because the salads may have been produced, prepared, packed, or held under insanitary conditions, whereby they may have become injurious to health, as indicated by the epidemiological and traceback data. On November 15, 2013, FDB removed the embargo to allow the firm to voluntarily destroy the previously embargoed salads because they were at the end of their shelf life. An FDB investigator witnessed the destruction of the salads on the same day.

Corrective Actions

Atherstone Foods Inc. ceased the manufacture of Trader Joe's RTE salads on November 7, 2013 after receiving notification regarding the likely association of the salads with an outbreak. Atherstone Foods Inc. resumed production of RTE salads for Trader Joe's on November 9, 2013. The firm voluntarily completed an internal audit of operations on November 19, 2013 and November 20, 2013. As a result of their internal audit, firm management ultimately decided to modify some of their Standard Operating Procedures (SOPs) relating to their [redacted] system. One change that was implemented in the [redacted] system was the length of time that the vegetables were submerged in the sanitizer, which was increased from [redacted] seconds to [redacted] minutes. Also, the target concentration of [redacted] sanitizer in the vegetable wash water was increased to [redacted] ppm from the previous range of [redacted] ppm. The new procedures were implemented on December 23, 2013.

Environmental Investigation at Lake Bottom LLC

On November 21, 2013, FDB and FDA investigators initiated an inspection at Lake Bottom LLC in response to the *E. coli* O157:H7 outbreak epidemiologically linked to RTE salads purchased at multiple retail locations in multiple states. The salads were manufactured by Atherstone Foods Inc. and had used romaine lettuce grown and harvested by Ratto Bros. on property owned by Lake Bottom LLC.

Ratto Bros. was an incorporated company located at 6312 Beckwith Road in Modesto, CA. This location included office space, a hydro-cooler, repacking, and cold storage. Ratto Bros. was a grower of a variety of produce commodities, such as lettuce, cilantro, mustard, kale, spinach, and beets. The focus of the field inspection was on Ranch 9. As part of the investigation at Lake Bottom LLC, a FDB Farm Questionnaire was administered to Ronald Ratto (President of Ratto Bros.), and [redacted] (Food Safety Manager). The completed FDB Farm Questionnaire can be found in Attachment 3. The answers to the FDB Farm Questionnaire were provided to investigators verbally, along with written documentation and records.

Crop Information

The field of interest, determined by the traceback investigation, was Ranch 9, Field 1, Valve 11 (R9F1V11). See photo below for map of Ranch 9, including R9F1V11. The product implicated by traceback and harvested from R9F1V11 was referred to as Block #33953 on some Ratto Bros. documents provided to investigators.

The address of the field was [redacted]. Field R9F1V11 was approximately [redacted] acres in size. The implicated romaine lettuce, [redacted] variety, was supplied to Atherstone Foods Inc. by

Ratto Bros. It was planted on August 10, 2013 and harvested on October 2, 3, and 4, 2013. A total of 1,067, 24-count cardboard cases of romaine lettuce were harvested from R9F1V11 over the course of the harvesting period. There were also 739, 15-count reusable plastic containers (RPCs) of romaine harvested from this field on October 3 and 4, 2013. The romaine shipped by Ratto Bros. to the distributors in the traceback was all packaged in cardboard cases, not RPCs. The romaine packaged in RPCs was sent to other customers, unrelated to this outbreak investigation.

During the growing period of the romaine lettuce (8/10/13 – 10/4/13), a portion of field R9F1V11 was being used to grow red leaf lettuce. The crop grown on R9F1V11, previous to the suspect romaine, was cilantro. At the time of inspection, Chinese mustard which had been planted on October 25, 2013, was observed growing on R9F1V11. Parsley, bok choy, and mustard were grown on the adjacent fields; R9F1V12 to the East and R9F1V10 to the West. The field directly to the South of R9F1V11 was separated by a farm road and belonged to a different owner. This land was not part of Ranch 9, and was fallow at the time of inspection. A field directly across [redacted], approximately 75 feet North of R9F1V11, was part of a Concentrated Animal (cattle) Feeding Operation (CAFO), not owned by Lake Bottom LLC. During the inspection of Ranch 9, investigators observed remains of a corn silage crop in this CAFO-owned field to the North. It had already been harvested. The cattle contained in the CAFO to the Northwest were housed approximately 0.2 miles away from R9F1V11. To the West of Ranch 9, approximately 450 feet from R9F1V11, was an almond orchard not owned by Lake Bottom LLC. The almond orchard was separated from the Lake Bottom LLC fields (closest

field was R9F1V12) by a dirt farm road and a ditch that was alongside R9F1V12. There was another CAFO approximately one-half mile to the Southwest of R9F1V11.

AUDIT HISTORY

Ratto Bros. was a member of the California Leafy Green Products Handler Marketing Agreement (LGMA), a group formed by farmers for the purpose of protecting public health by reducing potential sources of contamination in leafy greens produce. LGMA members are required to follow certain food safety protocols developed by university and industry scientists, food safety experts, farmers, shippers, and processors. As a member of LGMA, Ratto Bros. underwent regular audits by California Department of Food and Agriculture (CDFA) inspectors, contracted to perform LGMA audits. The most current LGMA audit performed on Ranch 9, previous to the romaine harvest, was on July 11, 2013. There was only one infraction noted on the audit report. The infraction was classified by the CDFA inspector as minor. The minor infraction consisted of several items. These items were a clogged harvest sanitation sink, lack of hand soap in the soap dispenser, the fresh water (for hand washing) tank cap was missing, and the lack of a sign instructing workers to wash their hands. The infraction was immediately corrected by the removal of the sanitation unit from the area and replacement with another unit. (Exhibit A)

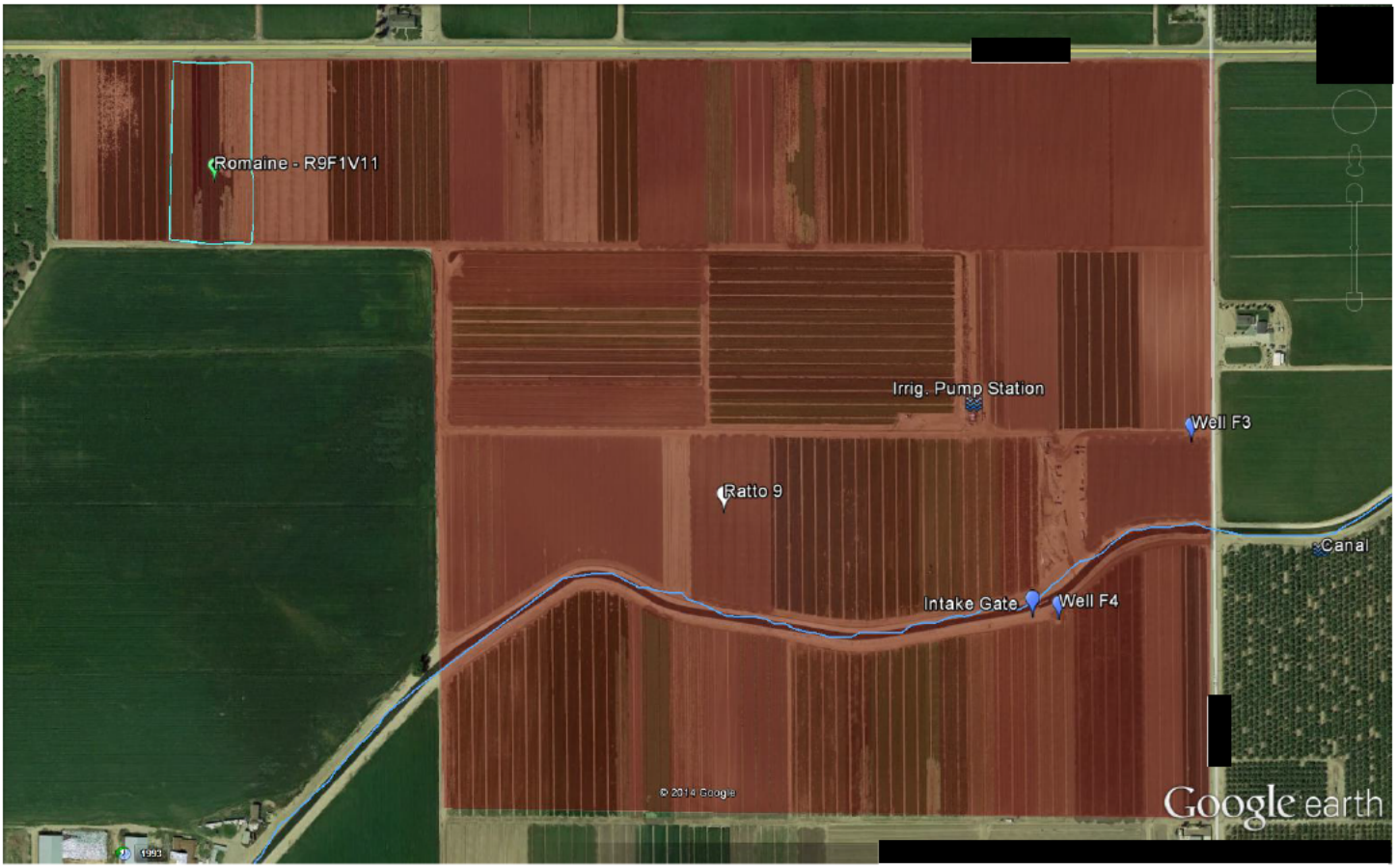
Ratto Bros. also underwent routine audits from a third party, [redacted]. The most recent [redacted] audit before the implicated romaine harvest was on August 8, 2013 (Exhibit B). The audit was performed on Ranch 6, 9, and 10 and the audit evaluated two areas, food safety management system requirements and good agricultural practices requirements. The firm had received a total score (before corrections) of 95.91% out of a possible 100%. The area where Ratto Bros. lost points in the audit was in good agricultural practices. They were marked down because there was animal activity (birds) on Ranch 6 during the audit, there were three dogs observed on land adjacent to Ranch 6, a water source was accessible to animals, and a water source was not free from a contamination issue (vegetation). The final [redacted] audit score was recalculated after corrective actions were performed by Ratto Bros. The final score was 99.32% out of 100% due to the fact that not all of the firm's corrective actions were accepted by the [redacted] auditor. The corrective action that was not accepted by the [redacted] auditor was the non-conformance related to animals having access to the water source (open canal). The firm had taken measures to ensure that water used for irrigation, washing of equipment, and mixing of pesticides remained free of contaminants by filtering the water from an open source, chlorinating, testing regularly, maintaining equipment to ensure that it was not a source of contamination to the water source, and employing personnel and a security company to patrol the ranches. The aforementioned measures were not accepted by the [redacted] auditor, thus not allowing the full score of 100% to be reached. (Exhibit C)

Ratto Bros. also performed internal audits which were based on LGMA metrics: environmental assessments of adjacent land use, pre-season assessments, and pre-harvest food safety environmental field inspections. Internal audit records related to the romaine grown on R9F1V11 were reviewed by investigators and no violative conditions were noted. Although no violations of LGMA metrics were noted in the audits, the presence of a CAFO was noted as being located 300 feet away from a growing field and a house with a septic leach field was noted as being 100 feet away. The LGMA metrics required that a CAFO be located at least 400 feet away, if no mitigating steps were taken. However, Ratto Bros. listed the presence of a dairy fence as a

mitigating step. Relative to the distance of the house with the septic leach field from a field, the LGMA metrics only required a 30 foot buffer, so the house being 100 feet away was not considered an area of concern according to LGMA metrics.

WATER

Ratto Bros. had a written policy for the management of water on the farm. The policy dictated how water was to be used and summarized any preventative controls and procedures in relation to water use. The romaine lettuce on R9F1V11 was irrigated by sprinklers with a combination of water from two fully contained wells and a Modesto Irrigation District owned canal. The wells were both located on Ranch 9. One was called "Field 3 Well" and the other was "Field 4 Well." The canal, called "[redacted] was a concrete lined, open canal and it flowed through Ranch 9, from East to West (Attachment 4). The canal was used as the primary irrigation source on Ranch 9, unless the water pressure dropped too low. When a drop in water pressure was detected by automatic water pressure monitoring equipment, water from either Field 3 Well or Field 4 Well was automatically added. All three water sources were routed through a filter and a treatment station prior to irrigation. The canal water was drawn through an intake gate, across a metal mesh screen to filter out large debris, and then pumped into a system of sand filters. The water was automatically injected with calcium hypochlorite before coming together with well water, and then pumped out through the sprinkler system to the field. The firm's target range for the residual concentration of calcium hypochlorite was between [redacted] ppm to [redacted] ppm at the sprinkler head. The residual chlorine concentration in the water was tested on a weekly basis. Ranch 6, 9, and 10 shared the same water sources, and water filtering and treatment station. These water sources were also utilized for other uses besides irrigation of the fields such as for the mixing or application of fertilizers or pesticides, or for rinsing off farm equipment. Refer to the map below for the water source locations. The firm did not use water from other open sources, such as creeks, reservoirs, tail water, or ponds. They also did not use recycled, reclaimed, or grey water.



The wells appeared to be in good condition with no visible leaks in the plumbing, gaps around the seal, standing water, or evidence of vermin or burrows. Irrigation water from the Modesto Irrigation District was not in the canal at the time of inspection and was not being applied to current crops. Since mid-October 2013, the irrigation district had stopped supplying water to the canal due to planned maintenance events. Although the irrigation district had stopped supplying water in the canal, investigators observed pooling water in the canal due to the recent heavy rains that occurred prior to the inspection. Firm management stated that they had not used the water from the canal since the canal closed for maintenance. The condition of the canal and the surrounding areas appeared well maintained. There was no vegetation, trash, or evidence of animals, such as animal droppings, tracks, burrows, or other sources of contamination observed near the canal.

Ratto Bros. tested irrigation water for *E. coli* on a monthly basis. The samples were collected by members of their staff following a written water sampling procedure. The water samples were sent to [redacted] for analysis. There were no elevated levels of *E. coli* reported in the period just prior to and during the growing of the romaine lettuce.

The firm also performed Irrigation Sanitary Assessments on pump stations, wells, canals, pipes, and filters. The firm supplied investigators with documentation of the two Irrigation Sanitary Assessments performed during the growing period. The Irrigation Sanitary Assessment consisted of a check sheet that the employee was to complete as they made observations by checking off yes or no, then recording comments if something unusual was observed. The check sheet listed questions about animal intrusion, condition of water systems

and surrounding areas, vegetation intrusion, poor drainage in piping, and other potential conditions that could contribute to water contamination. Investigators reviewed the records provided and no unusual conditions were noted on the firm's Irrigation Sanitary Assessments.

Field R9F1V11 was irrigated by sprinklers "every few days" during the growing period, up to approximately three days before harvest. The firm did not keep records of precisely which days the field was watered.

Investigators inspected the wells, canal, and filter/treatment station for deficiencies that could cause contamination of water. Other than the firm using irrigation water sourced from an open canal, investigators did not see any conditions in the water system that would have caused a contamination event in the romaine due to irrigation water. Taking into account the water testing results provided to FDB and the investigators observations of the water system, the firm's water treatment and system maintenance procedures appear to have been adequate.

Weather Conditions

The farm investigation took place following a heavy rainstorm. Historical weather data obtained from National Oceanic and Atmospheric Administration's (NOAA) National Climatic Data Center (NCDC) records indicated that 1.1 inches of rainfall was received in Modesto during the rainstorm that preceded the inspection (Attachment 5). Although the rain had stopped the night before, there were still puddles of water remaining on the surrounding public roads and private farm roads at the time of inspection. No rain puddles were observed in Ranch 9 Field 1, Valves 9-12. The ground beneath the almond trees in the adjacent orchard, to the West of Ranch 9 Field 1, appeared dry. The drainage ditch on the West end of Ranch 9 Field 1 did not have any water collected in it. Investigators did not observe any areas, indicated by erosion or ruts, that appeared to have been flooded or had experienced run-off during the storm. Ranch 9 Field 1 was relatively level with the farm road to the West and was separated by a drainage ditch from the farm road. Field 1 was slightly lower compared to the level of the public road to the North, [redacted]. Although Field 1 was slightly lower, there was a strip of land, approximately 20 feet in width that acted as a buffer between [redacted] and the edge of the field. There was no evidence, such as erosion or ruts in the soil, observed on the strip of land that was indicative of water run-off having travelled into the field.

Firm management reported that there was no significant weather conditions, such as flooding or drainage from rain, that occurred on Ranch 9 during the growing period of the suspect romaine crop (8/1/13 – 10/4/13). According to historical weather data obtained by FDB from NOAA-NCDC, there was no significant rainfall recorded during the growing period (Attachment 5). On September 21, 2013, there was one occurrence of rain of only 0.13 inches recorded in the area.

Investigators observed breezy conditions accompanied by wind gusts during the farm inspection. The wind direction did not always come from the same direction and continually changed direction. NOAA-NCDC historical weather records indicated that a range of wind speeds between 7 MPH and 10 MPH was common on most days during the growing period (Attachment 5). FDB considered wind a possible route of contamination to consider, as it could have carried contaminated particles into the growing field where they could have landed on produce causing contamination.

Investigators observed two CAFOs within one-half mile of R9F1V11. Since these CAFOs housed cattle (known reservoirs of pathogenic *E. coli*), it may have been possible for pathogenic *E. coli* to be carried via wind or other means (e.g., flies acting as vectors) to the product growing in R9F1V11.

Investigators observed an almond orchard approximately 140 yards to the west of R9F1V11. The orchard was not part of Lake Bottom LLC property and was owned by another party. Ratto Bros. management stated that dairy effluent was likely used to irrigate the trees in the almond orchard. Applying dairy effluent to almond orchards is one approach for farmers to irrigate almond trees. If dairy effluent was applied in the orchard, it may have been possible that wind could carry contaminants from the dairy effluent and deposit them on the romaine that grew in R9F1V11.

Animal Management

Ratto Bros. animal prevention procedures include discouragement tactics such as, bird guns, gopher traps, and regular monitoring of animal activity by employees. The firm was not aware of any issues with wild or domestic animal intrusion on Ranch 9, although sightings of birds flying overhead and the occasional rodent were considered normal in this area. The firm did not witness any potentially hazardous conditions arising from the occasional birds or rodents that they have observed before. There were dogs located on a neighboring property to Ranch 9, although not adjacent to R9F1V11. Ratto Bros. staff had not observed the neighboring dogs running loose, as they were contained in the neighbor's yard by fencing. There were no farm animals housed or grazed on Ranch 9 and there was no grazing observed nearby. However, there were two CAFOs containing cattle located close to Ranch 9. The CAFO to the Northwest was approximately one-quarter mile away from R9F1V11 and the CAFO to the Southwest was approximately one-half mile from R9F1V11. Refer to photo below for locations of CAFOs relative to Ranch 9. The proximity of the cattle to R9F1V11 could present possible risks of contamination of the crop via shared roads, contaminants from the CAFOs being carried in the wind to the growing field, flying vectors carrying fecal matter onto growing product, or contamination from irrigation activities via the spraying of dairy effluent on the CAFO's corn silage crop within 25 yards of R9F1V11. The geography, barriers (ditches), and slope of the land observed, indicated that direct water drainage from the CAFO property to Ranch 9 was unlikely during the growing period.

Investigators found no evidence of animal intrusion, such as feces, burrows, nests, tracks, or disturbed vegetation during the farm inspection of Ranch 9.

Farm Equipment

The farm vehicles and cultivation equipment used during the growing and harvest of the romaine lettuce were owned and maintained by Ratto Bros. Ratto Bros. did not share equipment with other growers or harvesters. The firm did not have written procedures for the cleaning of the cultivation equipment or farm vehicles. Ratto Bros. indicated that farm tractors were usually rinsed with potable water on a cement wash pad to remove excess mud and debris before leaving each ranch. Occasionally, a specially equipped washing truck with a high pressure washer spent a full or partial day cleaning the tractors. The tractor and vehicle cleanings were performed at the discretion of the operators and the firm did not keep records of these cleanings.

The equipment and vehicles travelled between fields on shared public roads in Modesto and the private farm roads on Lake Bottom LLC land. Access for some of the farm roads was shared with users from adjacent properties. Since the Ratto Bros. tractors and vehicles shared the roads with the public and other surrounding farms and dairies, there was the potential for transfer of contamination from the roads to the farm vehicles and tractors after they had already been rinsed or cleaned. The tractors and vehicles were not re-cleaned or sanitized upon entering Ranch 9 after driving on the roads.

Fertilizer, Pesticide, and Fungicide Treatments

The romaine lettuce from field R9F1V11 was grown conventionally with the use of both synthetic and non-synthetic agents and soil amendments. Investigators reviewed the fertilizer, pesticide, and fungicide application records that Ratto provided relating to the Block #33953 romaine from R9F1V11 and adjacent

fields. The records indicated that Ratto Bros. did not use any animal or manure based products on the suspect field or adjacent fields. The water used for the application of the treatments was the same water that was used for irrigation. FDB did not find (based on review of records) any deficiencies relating to the fertilizer, pesticide or fungicide treatments that were applied on R9F1V11 or adjacent fields.

Compost Management

Documents obtained from Ratto Bros. indicated that compost was not used on R9F1V11 or any other part of Ranch 9 for at least seven months before the planting of Block #33953. However, compost was used on other Ratto Bros. crops in the area. Ratto Bros. produced the compost in-house from Ratto Bros. sourced plant waste and green waste supplied by [redacted] in Modesto, CA. [redacted] certified that the green waste was manure free and was tested for *E. coli* and *Salmonella*. Additionally, Ratto Bros. had tested their compost for *E. coli* at various stages of production. The compost was produced in a compost yard on Ranch 7. See location on photo below. Firm management explained that the compost ingredients were arranged in uncovered windrows and turned on a regular basis. According to the firm, the compost production and spreading equipment were only used for compost. The firm had written procedures for the production of compost and maintained compost production logs which included the addition of water, temperature monitoring, and the turning over.

Ratto Bros. had ceased their production of compost in mid-September 2013, as it was no longer economically feasible. At the time of inspection, the compost yard on Ranch 7 was barren and there was no remaining compost.

HARVEST PRACTICES

Ratto Bros. performed both the growing and harvesting of the implicated romaine lettuce. There were no harvesting activities observed during inspection, so investigators reviewed the firm's records and interviewed Ratto Bros. management and staff to obtain information. The harvest crews used for harvesting Block #33953 were Crews #2 and #3. Harvest Crew #2 harvested the romaine lettuce on 10/2/2013 and 10/3/2013. Harvest Crew #3 harvested romaine on 10/4/2013. The suspect lettuce was hand harvested by workers with gloved hands and knives. The workers cut the romaine from the stem, inspected the head for quality and visible contamination, removed the outer leaves, and placed the head directly into single-use cardboard boxes, 24 heads per box. Each box was then placed on a flatbed trailer which was attached to either a truck or tractor and was parked in the field alongside the harvest workers.

The firm had procedures for cleaning the trucks, tractors and trailers used for harvest. The vehicle operators were responsible for ensuring that the trucks or tractors were cleaned with potable water and detergent at least once weekly or more if needed. They were also responsible for cleaning the flatbed trailers each morning with potable water and detergent. The truck, tractor, and trailer washing activities did not take place near the field. The firm maintained logs of the truck/tractor and trailer cleanings when used for harvest. Although the harvest crew buses were on the same cleaning schedule as the trucks, the firm did not keep cleaning logs of the buses.

Each harvest event was supervised by a Harvest Supervisor. The Harvest Supervisor ensured that the workers looked healthy, abided by firm procedures, and followed good agricultural practices. They also ensured that the disinfectant solutions used for glove dips and knife dips were maintained at proper concentrations and pH levels. The target concentration range for the chlorine solution was [redacted] ppm and the target range for the pH was [redacted]. The firm maintained sanitation logs for the glove and knife dips. There were no deviations noted on the logs reviewed by investigators.

Employee Practices and Training

All employees were trained before starting work for the first time. Trainings were also provided to workers on an ongoing rotational basis. Trainings included food security, food safety, product handling, and how product becomes contaminated with *E. coli*.

Harvest workers were asked if they had any illness and were visually screened for illness symptoms by the Harvest Supervisor before starting work. The Supervisor observed the employees participate in a short session of physical exercises and yoga before starting the harvest. If any worker looked fatigued or showed signs of illness they were further screened or prohibited from working that day. All employee illness observations and reports were recorded in a monthly sick log. The sick logs for October 2013 were reviewed by investigators and there was one employee illness reported before the implicated harvests. On October 1, 2013, this employee had exhibited red eyes and sneezing symptoms. The Supervisor prohibited the employee from working on that day.

Harvest workers wore disposable gloves, hairnets, and aprons when harvesting produce. Disposable gloves were discarded when soiled and when employees went on breaks. The knives were stored in the knife dips containing chlorine sanitizer solution when not in use. Employees were also instructed to take their aprons off and hang them on hooks in a specified area before taking breaks. Employees were instructed to wash their hands with soap and water before commencing work and upon returning to work after breaks. The Supervisors monitored the activities of the employees to ensure that they were following the approved procedures at all times.

Restroom Facilities

The workers were provided portable restrooms when working in the fields. There were no portable restrooms available for observation at the time of the field inspection. Mr. Ratto explained that the restroom units were parked on trailers on roads alongside the fields when workers were present. The restroom units were equipped with hand washing sinks, clean water, and soap. The portable restrooms were owned by [redacted] and maintained by them on an every other day basis or more often, if needed. The Harvest Supervisor checked each unit daily to make sure that it was adequately stocked and its tanks were not leaking. If there was a problem with the unit, it was replaced immediately.

Cooling Facility

Ratto Bros. cooling facility was located at 6312 Beckwith Road, Modesto, CA; the same location as the Ratto Bros. offices. It was the firm's usual practice to cool freshly harvested romaine in a hydro-cooler or hydro-vac machine within 1-2 hours after harvest. Upon arrival at the cooling facility, each trailer load was assigned a lot number and each pallet of boxes on the trailer load was assigned a pallet number for traceability purposes. A

tag containing the lot number and other product information, such as product name, pack date, and container type, was applied to each box of romaine.

The water used in the hydro-cooler and hydro-vac systems was sourced from a domestic well located on-site and had been tested monthly. The water in both coolers was sanitized with [redacted] (Calcium Hypochlorite). The coolers were outfitted with an automatic chlorine monitoring and injection system that was also monitored by employees. Ratto Bros. policy stated that the acceptable concentration of free chlorine in cooler water should be above [redacted] ppm and the pH should range between [redacted] while in operation. Cooler operating employees monitored the free chlorine and pH hourly and only added more sanitizer to the cooler water if needed. Theoretically, firm employees should not have to add sanitizer manually if the automatic monitoring and injection system was working properly. Records indicated that no additional sanitizer had been added by the employees during the cooling of the implicated romaine. The records reflected that the cooler water was measured between [redacted] ppm free chlorine and the pH was between [redacted] while in operation.

The water in the hydro-cooler was recirculated and the water in the hydro-vac system was not recirculated. The recirculated water in the hydro-cooler was kept clean with sanitizer and with the use of a [redacted] filtering system that removed solids from the water, such as sediment and plant debris, through use of a sediment tank. Any water that was ejected from the system was continuously replenished with fresh water. The discarded water containing sediment was routed to an evaporation pond on-site.

The firm had written procedures for the cleaning of the coolers. They used a chlorinated, foaming detergent called [redacted] and [redacted] sanitizer to clean and sanitize the inside of the coolers on a daily basis. The firm's records indicate that the cleanings were performed at the end of each day. No deviations were noted in the cooler sanitation and monitoring records that were reviewed by the investigators.

After cooling, the product was either loaded on a waiting delivery truck for transport to the customer or was stored in a refrigerated room in the Ratto Bros. warehouse prior to shipping.

TRANSPORTATION

Each load of boxed romaine on pallets was transported by open flatbed trailer directly from the field to the cooler. The trailers were pulled by either trucks or tractors. The harvest vehicles and trailers were owned and maintained by Ratto Bros. The firm had records of which trailer was used to haul each load of romaine from the field to the cooler. The truck or tractor operator was responsible for cleaning the vehicles and trailers every day before use.

Once the customer orders were ready to ship, the cooled product was loaded into refrigerated trucks, which were not owned by Ratto Bros. Transportation of the product was arranged and contracted by Ratto Bros. customers.

SAMPLES COLLECTED

ENVIRONMENTAL SAMPLES

A total of 44 environmental samples were collected at Lake Bottom LLC ranches during the course of the entire investigation (Attachment 6). On 11/21/2013, investigators collected 9 samples of wet soil, sediment, and standing water from areas adjacent to and surrounding Ranch 9 and near Ranch 7. This was in addition to one sample of water collected from the [redacted] canal on Ranch 9; yielding 10 samples total. The 10 samples collected on 11/21/2013 were tested for *E. coli* O157:H7 and non-O157 Shiga-toxin producing *E. coli* (STEC) by FDLB. The lab reported that five samples collected from a private road and two public roads were positive for *E. coli* O157:H7. All samples were negative for non-O157 STEC. Locations for all samples collected on 11/21/2013 can be seen in the map below. Red markers indicate positive findings. Photos of the locations where the positive samples were collected can be found in Exhibit D.

The five *E. coli* O157:H7 positive samples detected by FDLB were not a genetic match to the outbreak strain (EXHX01.0589 /EXHA26.3182) using pulsed field gel electrophoresis (PFGE). However, the PFGE patterns of three of the five samples matched each other. See Table 4 below. FDLB reported that PulseNet research indicated that the five positive samples were not related to any current outbreaks and were considered "rare" or new to PulseNet.

Table 4: PFGE Results of the *E. coli* O157:H7 Positive Samples Collected on November 21, 2013

Sample Number (I.S.)	Sample Type	Location	PFGE-*Xba*I Pattern	PFGE-*Bln*I Pattern
171112113-004	Water	Private dirt road between almond orchard and R9 (Lake Bottom, LLC.)	EXHX01.1792	EXHA26.0892
171112113-007	Soil/Water	[redacted] (Public)	EXHX01.1792	EXHA26.0892
171112113-009	Water	[redacted] (Public)	EXHX01.1792	EXHA26.0892
171112113-006	Soil	[redacted] (Public)	EXHX01.0078	EXHA26.1680
171112113-008	Soil	[redacted] (Public)	EXHX01.4959	EXHA26.0892

On 12/11/2013, FDB and FDA Investigators returned to Lake Bottom LLC to collect (1) soil samples from the perimeters of Ranch 9 Field 1 and Ranch 7 Field 5, (2) soil from the compost yard on Ranch 7 where compost was previously stored, and (3) pre- and post-chlorinated irrigation (well) water. This sampling activity was led by FDA with assistance from FDB. A total of 23 soil samples and two irrigation water samples were collected. The scope of the sampling completed on this day was expanded to include Ranch 7, due to the close proximity of the *E. coli* O157:H7 positive samples that were collected from [redacted] on 11/21/2013, directly in front of Ranch 7. The samples were analyzed by the FDA San Francisco District Laboratory (SAN-Lab) in Alameda, CA. All samples were negative for *E. coli* O157:H7 and non-O157 STEC.

On 1/9/2014, FDB returned to Lake Bottom LLC to collect air samples from areas around R9F1V11, and the areas of [redacted] and [redacted] where positive *E. coli* O157:H7 samples were collected on 11/21/2013 (Attachment 7). Nine air samples were collected using a Sartorius AirPort MD8 air sampling machine. The samples were transported to FDLB in Richmond, CA for *E. coli* O157:H7 and non-O157 STEC analysis. All 9 samples were negative for *E. coli* O157:H7 and non-O157 STEC.

Product Samples

Product samples were not available for collection at Ratto Bros., as the firm did not have product retained from the romaine harvest of interest.

Corrective Actions

After receiving notification regarding the positive *E. coli* O157:H7 samples that were collected around Lake Bottom LLC Ranches 9 and 7, Ratto Bros. management took internal action to not harvest or ship any products that were grown in the vicinity of the positive environmental samples. These areas included the following fields: R9F1V9, R9F1V10, R9F1V11, R9F1V12, R7F1V1, R7F3V1, and R7F5V1.

In a conference call with Ratto Bros. management on 4/10/2014, Ronald Ratto summarized the corrective actions that the company had implemented or were in the process of implementing. Ratto Bros. had retained

a food safety consultant to assist the firm in conducting a root cause investigation. The corrective actions included the following:

1. Start a pre-harvest *E. coli* testing program for raw product.
2. Restrict road access by Ratto Bros. farm vehicles and equipment by avoiding high-risk sections of public roads and starting a Road Monitoring Program.
3. Build a ditch alongside the public roads and perform modifications to existing Lake Bottom LLC roads in order to prevent potential run-off from entering nearby fields.
4. Evaluate buffer distances to surrounding properties. Increase the buffer distance to [redacted] feet for any areas of risk. Evaluate changing the types of crops grown in identified areas of risk.
5. Increase communication with neighbors to establish foundation for the monitoring of potential high-risk activities taking place on adjacent properties, such as manure spraying.
6. Enhance employee education including the following topics; how to identify risk scenarios, monitoring activities on adjacent property, and animal intrusion training (LGMA and in-house).
7. Increase frequency of pathogen testing in irrigation water.
8. Improve the farm equipment cleaning program. This may include increased cleaning frequencies, increased cleaning intensity, adding additional equipment to the cleaning program, and allocating more employees to cleaning responsibilities.

Recall Activities and Press

Atherstone Foods Inc. Recalls

On 11/9/2013, Atherstone Foods, Inc. (DBA: Glass Onion Catering) of Richmond, CA recalled RTE salads and wraps with "Best Buy" dates of 9/23/13 through 11/14/13 because they may have been contaminated with the pathogen *E. coli* O157:H7 (Attachment 8).

On 11/10/2013, USDA-FSIS announced that Glass Onion Catering was recalling approximately 181,620 pounds of RTE salads and sandwich wrap products with fully-cooked chicken and ham because some of these products have been linked to the illnesses through the epidemiological and traceback investigation (Attachment 9).

No other firms issued recalls as a result of this outbreak.

Summary of Outbreak Investigation Findings

In conducting this investigation, FDB determined that romaine lettuce from Lake Bottom LLC in Modesto, CA was a potential source of *E. coli* O157:H7 that caused illness in Arizona, California, Texas, and Washington due to the consumption of contaminated, pre-packaged salads. An investigation at Atherstone Foods Inc. did not identify insanitary conditions or potential cross-contamination events at the salad manufacturing plant. The traceback investigation conducted by FDB showed convergence, as Ratto Bros. was the only supplier of the romaine used in the four suspect salads included in the traceback. The investigation identified two cattle operations located approximately one-quarter mile and one-half mile away from the suspect field. Additionally, it was reported that dairy effluent was regularly applied to a corn silage field and an almond orchard nearby, approximately 25 yards and 140 yards away from the suspect field. The proximity of the two

CAFOs, along with typical activities associated with cattle operations, indicated that pathogen transfer routes in the environment needed to be considered.

Multiple air samples conducted by FDB on Lake Bottom LLC Ranch 9 did not isolate *E. coli* in the air. These results only represent the findings on the particular sampling day. The exact conditions near the harvesting dates of the implicated romaine, including the activities on adjacent property, are unknown. Samples of soil and water collected from Lake Bottom LLC ranches were negative for *E. coli* O157. Multiple samples of soil and water collected from an adjacent private road and two public roads resulted in five samples testing positive for *E. coli* O157:H7. The five positive samples were in the vicinity of the suspect field (Ranch 9) and Ranch 7; however, the PFGE patterns of the positive samples did not match the outbreak strain. Although the matching strain was not found, the presence of *E. coli* O157:H7 in the environment adjacent to Lake Bottom LLC Ranch 9 was evident. The positive samples were found on roads shared by Ratto Bros.'s farm equipment, general public vehicles, and vehicles from surrounding farms. Area roads provided a possible route of cross-contamination from these other users to the farm and fields harvested by Ratto Bros.

The close proximity of the field of interest to active cattle operations, when combined with the possibility of windborne cross-contamination and the sharing of roads between cattle operations, farm equipment used for RTE crops, and the public, may have contributed to the contamination of the implicated romaine crop. However, the direct route of contamination that led to this outbreak was not able to be determined.

ATTACHMENTS

Attachment 1 - Romaine Lettuce Traceback Diagram

Attachment 2 - Atherstone Foods Inc. Inspection Report with Attachments and Exhibits

Attachment 3 – Food and Drug Branch (FDB) General Farm Questionnaire

Attachment 4 - Modesto Irrigation District Canal System Map

Attachment 5 - Modesto Weather Data (Aug. 2013 – Nov. 2013) from NOAA-NCDC

Attachment 6 – Food and Drug Laboratory Branch Analytical Packet for All Ratto Bros. Samples

Attachment 7 - Ratto Bros. Air Sampling Activity Report with Attachments

Attachment 8 - Glass Onion Catering Press Release

Attachment 9 – Food Safety Inspection Services (FSIS) Press Release

EXHIBITS

Exhibit A - Ratto Bros. Leafy Greens Marketing Agreement (LGMA) Audit

Exhibit B - Ratto Bros [redacted] Audit

Exhibit C- Ratto Bros. [redacted] Corrective Actions

Exhibit D - Photos of Positive Sample Locations (Ratto Bros.)