

ENVIRONMENTAL INVESTIGATION OF AN *ESCHERICHIA COLI*
O111:NM OUTBREAK IN OCTOBER 2015 ASSOCIATED WITH
UNPASTEURIZED APPLE CIDER

DECEMBER 2016

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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 Diseases Branch (IDB), Disease Investigations Section (DIS)

El Dorado County (EDC) Community Development Agency (CDA), Environmental Management Division (EMD)

DATES OF INVESTIGATION

10/19/15-8/9/16 including:

10/20/15-11/5/15 – Case Patient Sample Collection

10/21/15 – High Hill Ranch Environmental Assessment at Apple Pressing Facility

11/4/15 – High Hill Ranch Farm Investigation

11/30/15 – [REDACTED] Farm Investigation

12/3/15 – [REDACTED] Farm Investigation

8/9/16 – Follow-up at High Hill Ranch Apple Pressing Facility

EXECUTIVE SUMMARY

In October 2015, the California Department of Public Health (CDPH), Food and Drug Branch (FDB), Emergency Response Unit (ERU) investigated an outbreak of *E. coli* O111:NM. The epidemiologic investigation, completed by the CDPH, Division of Communicable Disease Control (DCDC), Infectious Diseases Branch (IDB), identified a total of fifteen cases in three California counties with illness onset dates ranging from 10/12/15 to 10/19/15. These clinical cases were all infected with Shiga toxin producing *Escherichia coli* (STEC) bacteria. Sacramento County Department of Health and Human Services staff completed food history interviews with three initial cases and determined these individuals had all visited Apple Hill between 10/9/15 and 10/12/15 and had consumed unpasteurized apple cider. Apple Hill is a region of El Dorado County in California that has many apple farms. Apple Hill is a seasonal destination popular with visitors in the autumn months.

As additional clinical cases emerged, local health departments questioned each patient about any visits to Apple Hill, specific ranches visited in Apple Hill, and what foods the patient consumed at each location. All clinical cases interviewed had either visited High Hill Ranch in the Apple Hill region and consumed unpasteurized apple cider; or had not visited Apple Hill, but consumed unpasteurized apple cider that had been purchased from High Hill Ranch.

Further laboratory analyses identified the STEC bacteria as *E. coli* O111:NM. Laboratory testing detected two rare Pulsed field gel electrophoresis (PFGE) patterns (XbaI EXDX01.0406/BlnI EXDA26.0103 and EXDX01.0109/BlnI EXDA26.010) in the clinical isolates.

ERU, along with staff from the El Dorado County, Community Development Agency, Environmental Management Division (EMD), initiated an investigation at High Hill Ranch (Placerville, CA). The team completed an environmental assessment of the apple cider processing facility and the firm's food handling practices. Additionally, the team collected environmental samples in the processing facility and product samples, including in-process and finished products. At a later date, the investigation team returned to assess the High Hill Ranch orchard and apple sorting area. During this inspection, the team observed evidence of animal intrusion and collected feces samples.

ERU staff collected and reviewed traceback documents in order to determine the sources for apples used to produce High Hill Ranch apple cider. This traceback investigation concluded that High Hill Ranch received and pressed apples from three apple suppliers during the period of time prior to the cases' exposures.

ERU conducted farm assessments at the farms that supplied apples used as ingredients for High Hill Ranch cider. These farms included High Hill Ranch, [REDACTED] and [REDACTED]. The teams observed evidence of animal intrusion at each of these farms and feces samples were collected from two of them.

Three confirmed case patients and a single unconfirmed case patient had leftover cider that they had consumed before they became ill. ERU staff collected these leftover samples. One of the cider samples (from a confirmed case patient) tested positive for *E. coli* O111:NM that had a PFGE pattern that was indistinguishable from one of the outbreak strains.

Investigators were not able to determine the exact cause of the outbreak, but observations were made of suspect conditions in the cider processing facility and at the apple farms. These included both animal intrusion and insanitary conditions. ERU and EMD worked together to provide recommendations to High Hill Ranch and the two other apple suppliers and assist the ranches with identifying and correcting these suspect conditions so any future illnesses from consuming High Hill Ranch unpasteurized apple cider could be prevented.

BACKGROUND

On 10/19/15, the California Department of Public Health (CDPH), Food and Drug Branch (FDB), Emergency Response Unit (ERU) was notified by the CDPH Division of Communicable Disease Control (DCDC), Infectious Diseases Branch (IDB), of an outbreak of Shiga-toxin producing *Escherichia coli* (STEC), that was epidemiologically linked to the consumption of unpasteurized apple cider. Initially, the investigation identified three geographically clustered cases with Shiga toxin positive testing results. Continued investigation identified two additional STEC cases in the next few days with all five cases stating they had visited Apple Hill between 10/9/15 and 10/12/15. In total, the investigation identified fifteen cases from Contra Costa, Sacramento, and Yolo Counties. All case patients associated with this outbreak reported consuming High Hill Ranch apple cider at either the ranch's self-serve, free sample station, or from retail containers purchased at High Hill Ranch. All of these patients reported purchasing the apple cider between 10/9/15 and 10/12/15. ERU and the El Dorado County Environmental Management Division initiated an onsite investigation at High Hill Ranch on 10/21/15, in response to epidemiological information supplied by IDB. The outbreak strain, *E. coli* O111:NM, was unknown until confirmed clinical laboratory testing results were reported on 10/29/15.

High Hill Ranch is located in the Apple Hill region of El Dorado County (See Figure 4) and is regulated by the El Dorado County (EDC) Community Development Agency (CDA), Environmental Management Division (EMD). This region contains many independently-owned apple orchards and draws thousands of visitors during each season.

EPIDEMIOLOGICAL SUMMARY

The final case count in this outbreak was fifteen confirmed cases from Contra Costa, Sacramento, and Yolo Counties with the majority of cases reported in Sacramento County. The illness onset dates ranged from 10/12/15 to 10/19/15. All interviewed case patients associated with this outbreak reported consuming apple cider from High Hill Ranch in Placerville, CA either from the self-serve, free sample station or from retail one-gallon or half-gallon containers. Out of the fifteen case patients reporting consumption of High Hill Ranch product, thirteen reported visiting High Hill Ranch prior to consuming the unpasteurized apple cider sold by this firm. Two additional case patients (siblings) did not visit High Hill Ranch, but did consume High Hill Ranch unpasteurized apple cider brought home by a relative who visited High Hill Ranch.

Laboratory testing of clinical samples from the case patients included in this outbreak detected *E. coli* O111:NM bacteria. These clinical samples were further analyzed using Pulsed field gel electrophoresis (PFGE). Laboratory testing detected two PFGE patterns (XbaI EXDX01.0406/BlnI EXDA26.0103 and EXDX01.0109/BlnI EXDA26.0103) in the clinical samples tested.

ENVIRONMENTAL ASSESSMENTS

HIGH HILL RANCH

On 10/21/15, ERU assisted EMD with an environmental assessment at High Hill Ranch, located at 2901 High Hill Road, Placerville, CA, in response to the STEC outbreak epidemiologically linked to apple cider produced at the facility. High Hill Ranch only sold foods at retail and was inspected and regulated by EMD. As a retail food facility, High Hill Ranch was not required to obtain a Processed Food Registration with FDB.

Ranch Owner, Jerry Visman, was the primary correspondent for High Hill Ranch throughout the investigation.

GENERAL FIRM AND FACILITY INFORMATION

High Hill Ranch was a producer of unpasteurized apple cider. The apple cider was sold under the High Hill Ranch brand name at their onsite retail store and in their onsite café. In addition to the unpasteurized cider, they sold several varieties of apples grown on their ranch and from other ranches in the Apple Hill region. They also sold pies and other apple-containing baked goods in High Hill Ranch's onsite bakery. In addition to apple products, High Hill Ranch had several booths with vendors selling craft items and a trout pond with catch-and-release fishing available to the public. High Hill Ranch was considered one of the busier apple farms in the Apple Hill area and potentially received thousands of visitors each weekend during apple season. High Hill Ranch was also a popular destination for school field trips. Several hundred children visited on school field trips during each week of apple season. The High Hill Ranch 2015 season ran approximately September through November.

High Hill Ranch consisted of four main buildings: (1) Apple Shed – contained apple sorting equipment and retail store; (2) Apple Cider Shed – contained the apple pressing operation and an area for cleaning the equipment; (3) Main Building – contained the pie shop, café, craft booths, and corporate offices; (4) Cold Storage Warehouse – used to store cider in retail packaging, apples, and supplies for the café.

COMMODITIES AND RAW MATERIALS

High Hill Ranch received apples from their own orchards as well as other orchards in the region. The firm sold many different varieties of apples in their retail store, however only a few select varieties were used to produce High Hill Ranch cider. High Hill Ranch employees hand sorted the incoming apples for visible defects, and then a rope sorter machine sorted the apples by size. These sorting procedures diverted the small, blemished, or otherwise undesirable apples away from the retail operation to the apple pressing operation. Apples destined for pressing proceeded down a wooden chute from the sorting area, bounced off a carpet bumper and landed in a wooden storage bin (Exhibit I). As needed, High Hill employees used a forklift to transport the storage bin containing the cider apples to the Apple Cider Shed for pressing (See Figure 1).

The firm did not maintain detailed source records for the apples used as ingredients in specific batches of cider.

The ranch had an onsite cold storage warehouse that was utilized for apples and other perishable items sold in their retail stores; however there was no refrigeration or other specialized storage for the apples used to make cider. Mr. Visman stated that, due to demand, most of the cider apples were pressed shortly after receipt.

According to traceback information obtained during the investigation, there were three suppliers of apples during the early part of the 2015 season, including October. They were High Hill Ranch [REDACTED] (Exhibit D).

High Hill Ranch typically produced cider on Wednesdays through Sundays, during usual business hours, as needed. Figure 1 summarizes the cider manufacturing process used by High Hill Ranch at the time of the outbreak.

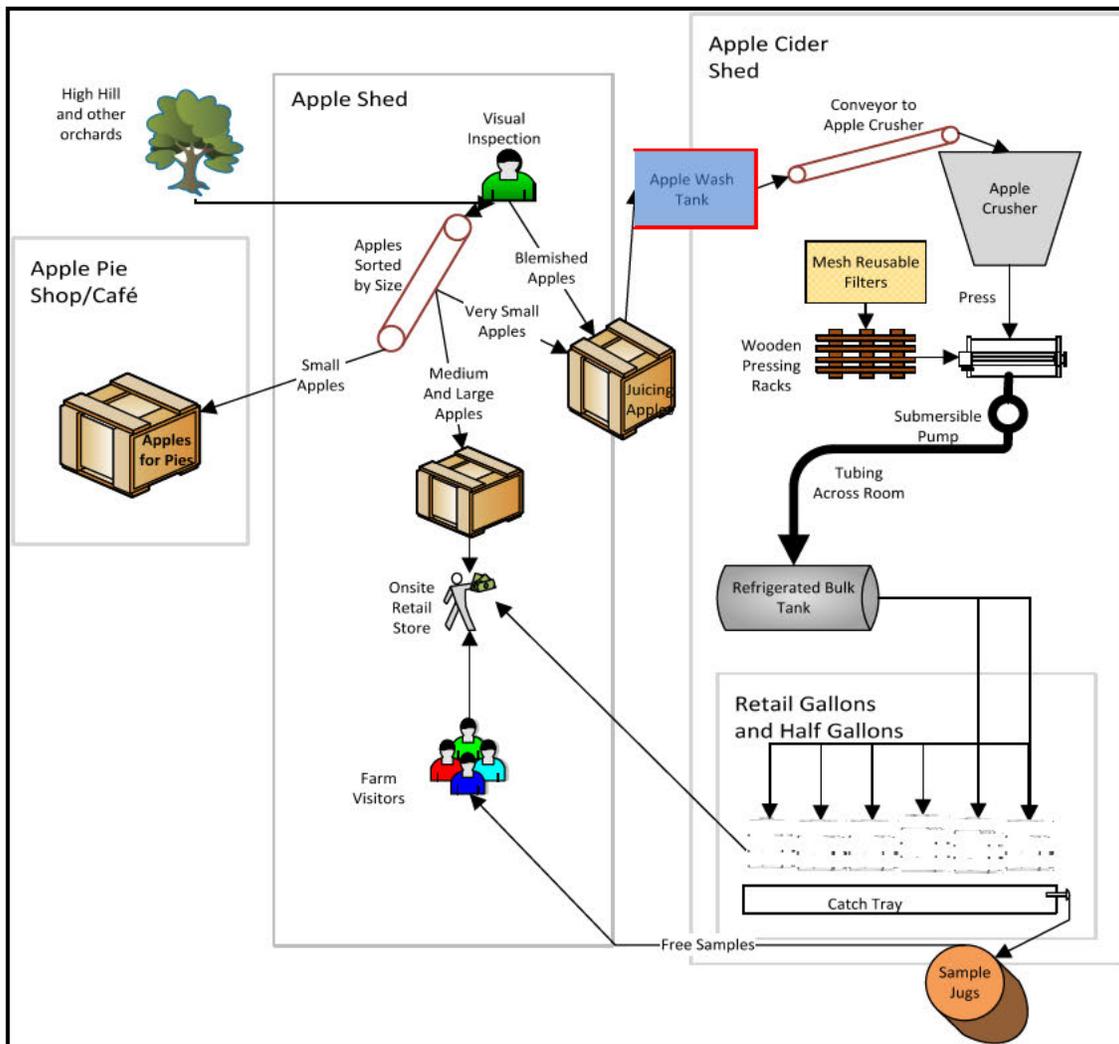


Figure 1 – High Hill Process Flow Diagram

The firm was not producing apple cider at the time of inspection. Mr. Visman described the process as follows:

1. High Hill Ranch employees sorted incoming apples in the Apple Shed.
2. A High Hill Ranch employee transported the cider apples in an unlined, wooden bin by forklift to an area just outside of the Apple Cider Shed.
3. As needed, an employee dumped the wooden bins of apples into the apple wash tank, which was located in an opening in the wall between the pressing area and the outside environment. The half of the tank that was outside the Apple Cider Shed was covered with a vinyl cover that was pulled back every time more apples were added, then the cover was placed back over the tank when through adding apples.
 - a. Wash water was sourced from El Dorado Irrigation District drinking water system.
 - b. At the time of inspection, Mr. Visman stated there was no sanitizer used in the wash water.
4. In the Apple Cider Shed, the apples were conveyed out of the wash tank on a conveyor apparatus which extended through the ceiling of the pressing room, and into the hopper at the top of the pressing machine.
5. The apples were dropped into a grinder that crushed the apples.
6. The crushed apples were gravity dispensed onto a reusable cloth, which covered a wooden tray.
7. After approximately [REDACTED] of apples had been dispensed, the cloth material was folded over on top of the apples, another wooden tray was stacked on top, and the new tray was covered in a reusable cloth
 - a. Approximately [REDACTED] layers of wooden trays were filled and stacked on one another before pressing.
8. A [REDACTED] press pressed down on the stacked trays of crushed apples causing the juice to run out the sides of the stack of trays. A stainless steel tank below the pressing machine collected the resulting juice.
9. A submersible pump in the stainless steel collection tank transported the juice into a stainless steel refrigerated storage tank.
10. As needed, High Hill Ranch employees dispensed the juice (also referred to as cider) into one-gallon or half-gallon plastic jugs for retail sale.
 - a. Typically, consumers purchased the packaged cider within one to two days of juicing.

As employees filled the retail containers, product would often spill over the outside of the container. A stainless steel catch tray below the filling area collected this overflow product and the filling employee transferred this overflow into an insulated jug for the dispensing of free samples to visitors.

According to Mr. Visman, High Hill's typical cider recipe was approximately [REDACTED] apples. [REDACTED] and various other apple varieties were also used, depending on availability.

PRODUCT PACKAGING

High Hill Ranch stored the empty jugs, used for the packaging of cider, in the attic area of the Apple Cider Shed. Mr. Visman stated that, prior to packaging a batch of cider, employees would first wipe the dust off the outer packaging before they removed the outer wrapping. After employees prepared the packaging for use, it was stored on tables along the wall nearest the bulk tank in the pressing room until the cider was packaged.

High Hill ranch packaged a majority of the cider into one-gallon and half-gallon jugs. Each jug had a single label on the front identifying the product, manufacturer, and the required legal statement regarding unpasteurized juice products. The product was labeled as High Hill Ranch Apple Cider (Figure 2). Each jug had a date sticker applied to the lid which was dated 14 days after bottling to reflect the 14 day shelf life of the product. The label included the following storage statements: "Keep Refrigerated" and "May Be Frozen Once". Mr. Visman stated that freezing the product would extend the shelf life past 14 days.



Figure 2 - High Hill Ranch Product Label

As needed, the High Hill Ranch staff emptied the catch tray into ten-gallon insulated jugs. The overflow cider was provided to customers for self-service free samples. The insulated jugs were unlabeled except for a sign, posted outside the Apple Cider Shed in the free samples area, indicating that the jugs contained free samples. Customers used paper cups provided by High Hill Ranch for self-service of the samples.

High Hill Ranch also filled a small percentage of their cider into bulk dispensers for sale in their onsite café. This juice was dispensed directly from the refrigerated bulk tank and into retail dispensers.

FINISHED PRODUCT STORAGE

After the product was packaged, the cider processing staff stored the finished products in a plastic bin containing ice and water, inside the Apple Cider Shed. At the time of inspection, ERU investigative staff observed a bin in the Apple Cider Shed containing multiple gallon jugs of cider half-submerged in an ice water mixture. The ice water temperature around the jugs was observed at 32°F. Then High Hill employees moved most of this finished product from the Apple Cider Shed directly to the retail store for sale to the public. If needed, the product may have been stored in the cold storage warehouse for one to two days.

The firm stored the insulated jugs containing the free samples at ambient temperature, usually outside, for convenient customer access. There was no further temperature control or monitoring once cider was placed into the insulated jugs. Once empty, the insulated jugs were either refilled with additional overflow product or with cider dispensed directly from the refrigerated bulk storage tank, depending if consumer demand exceeded the quantity of overflow product available.

PROCESS AND QUALITY CONTROLS

High Hill Ranch rinsed the apples in a tank containing municipal drinking water before pressing. Besides this rinse, the product had no other treatments before, during, or after processing.

There was no microbial or other testing conducted on the finished product or the raw ingredients.

SANITATION AND MAINTENANCE

The firm did not have any written sanitation procedures or cleaning logs available for review at the time of inspection, as the firm did not maintain these types of logs. Mr. Visman reported all details of the process verbally to the investigation team as follows:

Weekly:

- Employees emptied and cleaned the bulk product tank.
 - This included: (1) draining all cider from the tank, (2) rinsing the tank with municipal water and [REDACTED] (chlorine-based cleaner) to clean, and (3) rinsing with [REDACTED] (quaternary ammonia-based sanitizer).
 - The employees used the cleaning solutions along with nylon brushes to scrub the inside of the tank and remove and product residue until the tank was visually clean.
- High Hill Ranch employees emptied the tank of wash water for incoming apples.
 - High Hill Management instructed employees to empty the incoming wash tank more often if the tank had too much accumulation of leaves and dirt.
 - At the time of inspection, the tank had an accumulation of debris in the bottom of the wash tank and leaves floating in the top (Exhibit A, Photo 5). It was unclear when employees last emptied and cleaned the wash tank due to a lack of cleaning logs. Mr. Visman reported that it was the same water that was left over from the last time they had pressed apples, which he thought was about two days before the inspection.

Daily:

- Employees washed the cloths used for pressing.
 - High Hill employees washed the pressing cloths in a standard washing machine using [REDACTED] (chlorinated food-safe sanitizer).
 - Mr. Visman stated that one of the two washing machines onsite was designated for floor mats and the other was for the pressing cloths.
 - Employees dried all items by hanging them outside, in the open air, for several hours.

AREAS OF CONCERN

The apple processing area was not maintained in a sanitary condition at the time of inspection. There was a buildup of dust and dirt on top of the stacks of product packaging and there were exposed wood surfaces throughout the facility. Exposed wood surfaces are not easily cleanable and are not recommended for use in a food processing facility. Additionally, there was product buildup on and around the pressing equipment that Mr. Visman described as already cleaned (Exhibit A, Photo 1 & 2).

The firm also failed to maintain the food packaging storage area in a sanitary condition. The inspection team observed a buildup of dust and debris on top of the packaging being stored in the attic area and residue at the top of the apple crushing machine indicating a lack of adequate cleaning (Exhibit A, Photo 2 & 4). In addition to the accumulation of dirt, the attic had a pitched roof and one end of the roof had an open vent that lacked screening (Exhibit A, Photo 4). This created a potential for pests, dust, and other contaminants to enter the attic area. In the attic area, the top of the apple crushing machine was exposed and there were several open areas in the attic floor, directly above the processing equipment. Any contaminants or pests entering the attic area could fall through these open areas to the processing room below and could contaminate the production area, equipment, or the unpasteurized cider.

The firm failed to maintain the dispenser jugs used for samples in a sanitary condition. The inspection team observed that all of the jugs had a buildup of product residue inside the dispensing spout and around the lid seal. One jug that Mr. Visman specifically identified as already cleaned was observed with visible residue inside the dispensing spout (Exhibit A, Photo 3).

Additionally, during a subsequent inspection on 11/4/16, inspectional team members observed possible cat feces in the Apple Shed, near the area where High Hill Ranch sorted their incoming apples (Exhibit C) and rodent feces near the cold storage warehouse (Exhibit B, Photo 1 & 2). This presented an area of concern due to the possibility of contamination of the raw ingredients used to produce unpasteurized cider.

PERSONNEL TRAINING AND SUPERVISION

High Hill Ranch did not document any training of their employees and had no written procedures. Mr. Visman or a senior member of the team trained all employees on proper procedures prior to starting operations for the season in August each year. All ranch employees received annual retail food safety training as required to work in the onsite retail café.

FOOD WORKER HEALTH AND HYGIENE

According to Mr. Visman, while in the apple pressing room, workers wore rubber boots, jackets, hats, and reusable gloves over their usual clothes. High Hill Ranch washed these outer clothing items as needed. No employees were working at the time of inspection, so the inspection team could not verify practices and attire; however the team did observe these items hanging in various locations around the room.

PRODUCT DISTRIBUTION AND TRANSPORTATION

High Hill Ranch distributed their cider in three ways: (1) onsite retail sales, (2) purchased by individuals in the ranch's onsite café, and, (3) free samples available outside the Apple Cider Shed.

In addition to High Hill Ranch brand unpasteurized cider; the onsite store also sold [REDACTED]. [REDACTED] produced this pasteurized product at their neighboring processing facility. The [REDACTED] business was not related to High Hill Ranch in any way.

High Hill Ranch did not distribute unpasteurized cider to any wholesale customers or to any other offsite location.

COMPLAINTS

At the time of inspection, High Hill had not received any recent food safety related complaints. The firm did not have a system in place for recording any consumer complaints they received. However, Mr. Visman reported to the team that the ranch had received no complaints.

REGULATORY ACTIONS

FDB did not take any regulatory action during this inspection. The facility produced product solely for onsite, retail distribution, so they were not registered with FDB. Additionally, El Dorado County EMD inspectors were present at the time of inspection and documented similar observations to those noted above and issued their own inspectional report.

To determine likely apple suppliers, ERU conducted a traceback of apple cider products consumed by the case patients (Figure 3 & Attachment 1). ERU collected and analyzed documents showing the suppliers of apples to High Hill Ranch and the dates, varieties, and quantities supplied. Additionally, each supplier provided documents to determine the harvest dates for each of these apple shipments. The records collected indicated the apples pressed into apple cider available for purchase between 10/10/15 and 10/12/15 were likely from one of three farms: (1) High Hill Ranch, [REDACTED].

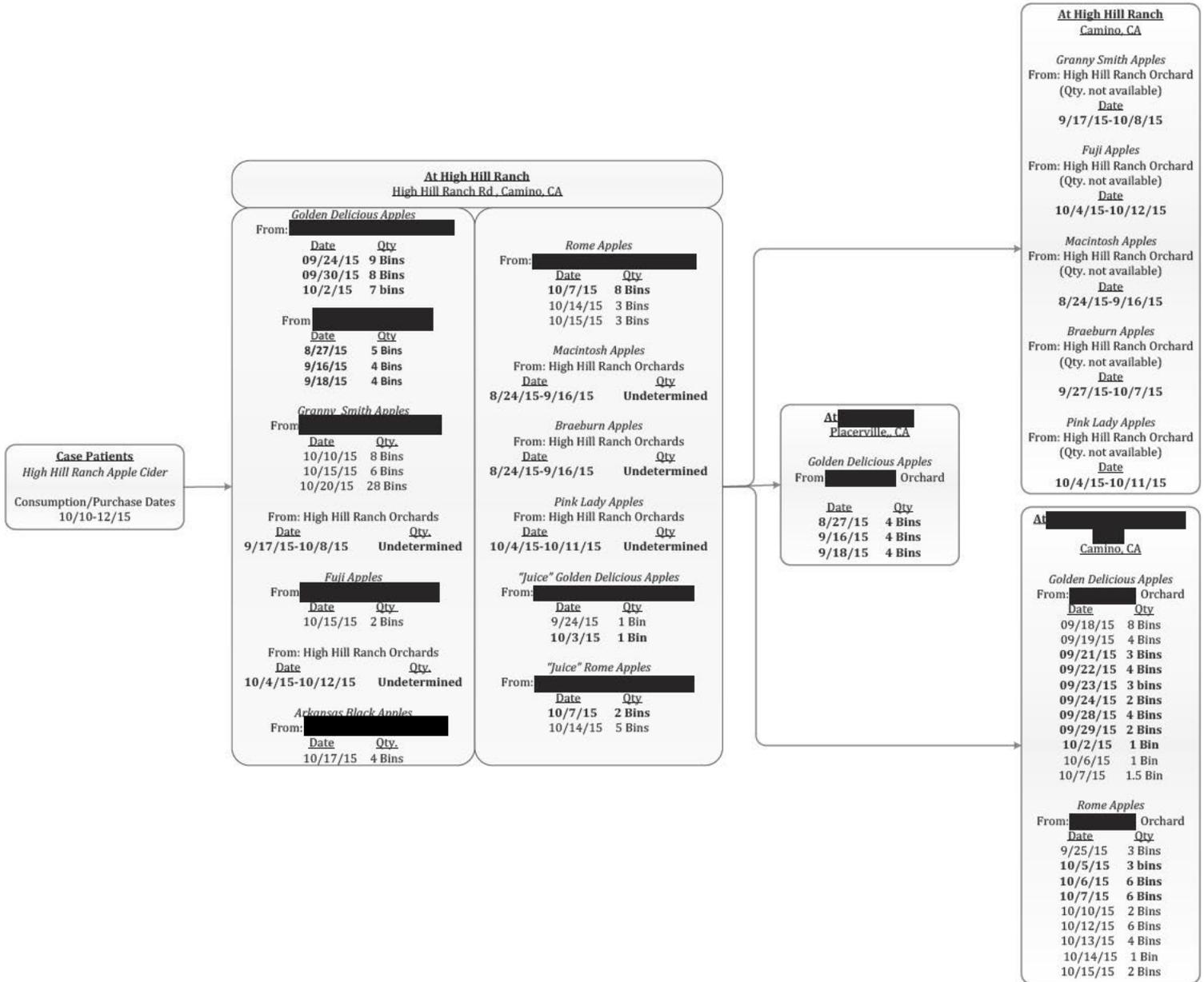


Figure 3 - High Hill Traceback Diagram

FARM INVESTIGATIONS

ERU staff collected information on each of the ranches of interest and produced maps for each ranch of interest which included the following information:

- Latitude and longitude of each ranch and their apple orchards
- Topographic data including elevation and slope
- Locations of Irrigation District infrastructure (canals, etc.)
- Locations of wells, septic tanks, and leech fields from county permit records
- Environmental sampling locations
- Orchard corners and other points of reference during onsite investigations



Figure 4 - High Hill Ranch, Suppliers and Surrounding Area

ERU deployed teams to the three farms identified in the traceback (Figure 3): [REDACTED] and High Hill Ranch. These ranches were of interest because they provided apples to High Hill Ranch who made cider from those apples in the period prior to the consumption/purchase dates of the case patients. The investigation teams completed a Farm Investigation Questionnaire at each farm, while making assessments regarding food safety. The teams also collected environmental samples of animal feces from each farm and GPS points to verify exact orchard locations.

HIGH HILL RANCH

On 11/4/15, a team consisting of ERU Investigators, ERU Environmental Scientists, and a representative from the El Dorado County EMD conducted a farm inspection at High Hill Ranch's orchard. The goal of this investigation was to assess any food safety concerns at the ranch since High Hill Ranch used their own orchards for most of the apples pressed into apple cider. Throughout the farm investigation, Jerry Visman, Owner, accompanied the team and provided information.

High Hill Ranch was located in the Apple Hill growing region of El Dorado County. The orchard was located adjacent to the Retail Shops and the Cold Storage Warehouse (Figure 5).

The ranch used municipal water provided by the El Dorado Irrigation District for all operations. High Hill Ranch did not further treat or test the municipal water provided by the water district. All waste water was disposed of in a county-approved septic system. The

High Hill Ranch employees harvested the apples from mid-September through early October, depending on variety. All varieties of apples were hand-picked from the trees using bare hands and then placed into reusable plastic totes. Apples were not harvested from the ground. As the harvester filled the tote, they emptied the apples into larger wooden bins for storage and transport.

The only animals used by the grower in the orchard were bees to pollinate the fruit, which do not present a significant food safety concern. The team observed customers visiting the ranch with domestic dogs at the time of inspection. Mr. Visman stated that dogs were not allowed in the orchard and the team did not see any evidence of dogs in the orchard. The team did observe a small flock of geese in the orchard during the inspection, as well as goose feces and tracks. Mr. Visman stated that the geese are migratory and only present seasonally, not during the growing or harvest season. Additionally, during the investigation, the team observed used baby diapers lying in the orchard. Mr. Visman stated that after harvest, the farm opens to the public and uses the orchards for parking. High Hill employees picked up trash in the orchard and around the property on a daily basis and there is no customer parking in the orchard when the apples have bloomed or are being harvested.

Attachment 2 contains more information regarding this farm assessment.

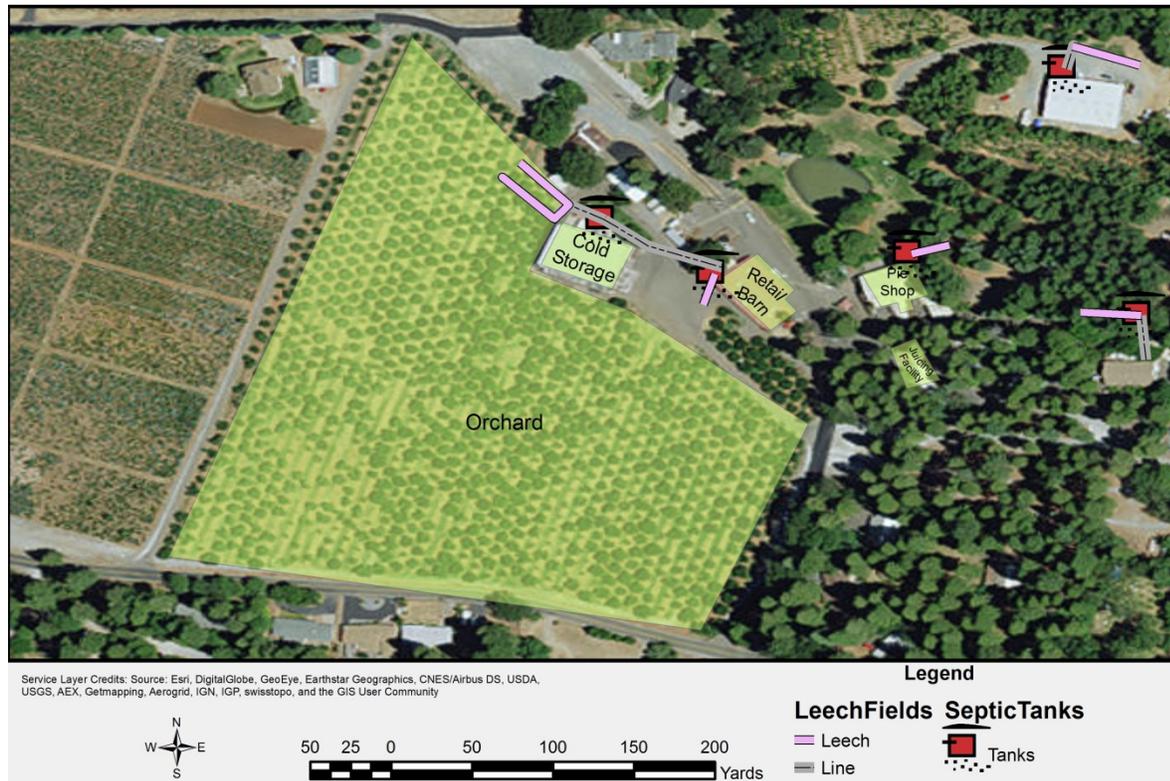


Figure 5 - High Hill Ranch Map

REGULATORY ACTIONS AT HIGH HILL RANCH

While conducting the farm investigation at High Hill Ranch, the team observed rodent feces in, on, and around open bags of popcorn stored behind the Cold Storage Warehouse (Exhibit B, Photo 1 & 2). A Notice of Violation (NOV) was issued to Mr. Visman on 11/4/15 informing him that the popcorn was not being stored in a manner that prevents contamination (Attachment 3). Mr. Visman chose to voluntarily destroy the affected product when the team lead notified him of the food safety concerns. He and another High Hill employee emptied the 9-50 pound bags of un-popped popcorn into a dumpster and poured bleach on top of it to denature the product (Attachment 4; Exhibit B, Photo 3).

Mr. Visman stated that this popcorn was stored inside a building during the season when it was in use. As a corrective action to this NOV, Mr. Visman informed the team he would retrain employees on proper food storage and inform his pest control company.

On 11/30/15, a team consisting of an ERU Scientist and a representative from the El Dorado County EMD conducted an investigation at [REDACTED] Ranch ([REDACTED]). The goal of this investigation was to assess any food safety concerns related to apples they supplied to High Hill Ranch for pressing into apple cider. Throughout the farm inspection, [REDACTED], Owner, accompanied the investigation team. Ranch Manager, [REDACTED], also provided additional information via e-mail and phone; however, [REDACTED] was not onsite at the time of inspection.

[REDACTED] Ranch was located in [REDACTED], CA, [REDACTED] of the Apple Hill growing Region of El Dorado County. Two homes, various fruit orchards, and pens containing cattle surrounded the apple growing orchard (Figure 6).

The ranch used municipal water, provided by the El Dorado Irrigation District, for all operations. The municipal water was not further treated or tested before use. All waste water was disposed of in a county-approved septic system. The septic leech field was not located in the orchard and there did not appear to be any septic leaks or overflow issues at the time of inspection.

[REDACTED], [REDACTED], and [REDACTED] were the harvest crew. They harvested the apples supplied to High Hill Ranch for the manufacturing cider between [REDACTED] and [REDACTED]. The apples were hand-picked from the trees and placed into reusable plastic totes. Apples were not picked up from the ground. As the harvester filled their tote, they emptied out the apples into larger bins for storage and transport. Bins containing apples were stored outside for up to a few days until distribution to wholesale customers. The bins used for the storage and transport of apples to High Hill Ranch were constructed of wood, as High Hill specifically requested wood bins to be used. All other customers' apples were stored and transported in plastic bins.

During the inspection, the team observed goose and deer feces in and around the orchard. Several lower tree branches were observed to have been chewed by an animal, most likely deer. An eight foot high deer fence surrounded the orchard area. The fence was complete except for one area that had an open gap. [REDACTED] stated that there were plans to build a gate and complete the fence before the 2016 apple season (Exhibit E)

In addition to the evidence of animals in the orchard, there was a pen containing two cows observed uphill from the orchard, towards the East. During the inspection, the team observed water leaking from a fresh water pipe inside the cow pen area and it was running downhill toward the orchard (Exhibit E).

Attachment 5 contains more information regarding this farm assessment.

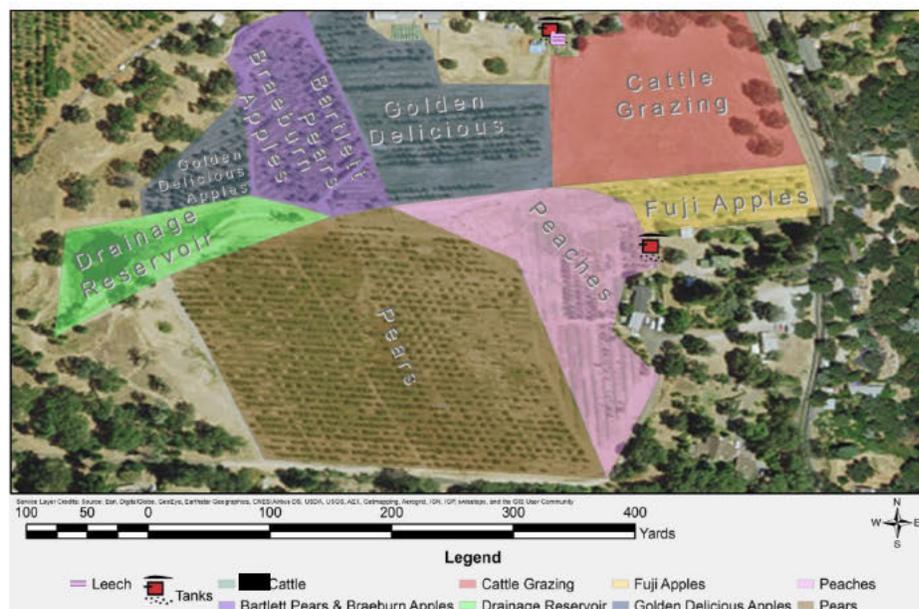


Figure 6 - [REDACTED] Ranch Map

[REDACTED]

On 12/3/15, a team consisting of an ERU Environmental Scientist, an ERU Investigator and a representative from the El Dorado County EMD conducted a farm investigation at [REDACTED] ([REDACTED]). The goal of this investigation was to assess any food safety concerns related to apples supplied by them to High Hill Ranch for pressing into apple cider. Throughout the farm inspection, [REDACTED], Owner, accompanied the investigation team.

[REDACTED] orchards were located in [REDACTED], CA, in the Apple Hill growing Region of El Dorado County. [REDACTED] consisted of a residence, orchards containing various types of apples, and a [REDACTED] (Figure 7; Exhibit D). The farm was located in a hilly area with a moderate slope running approximately east to west.

The ranch used municipal water, provided by the El Dorado Irrigation District, for all operations. The municipal water was not further treated or tested before use. All waste water was disposed of in a county approved septic system. The septic leech field was not located in the orchard and there did not appear to be any septic leaks or overflow issues at the time of inspection.

The ranch hired the same group of people every year on a temporary basis for harvest. This group harvested the apples between [REDACTED] as the product became ripe. The apples were hand-picked from the trees and placed into reusable plastic totes. Apples were not picked up from the ground. As each harvester filled their tote, they emptied the apples into a larger wooden or plastic bin for storage and transport.

The ranch did not use animals in the orchard for harvest or other uses. During the inspection, the team observed deer and deer feces in and around the orchard. The ranch had installed a deer fence around the orchard area, but often did not close the driveway gate, which allowed deer full access to the orchard (Exhibit J).

Attachment 6 contains more information regarding this farm assessment.

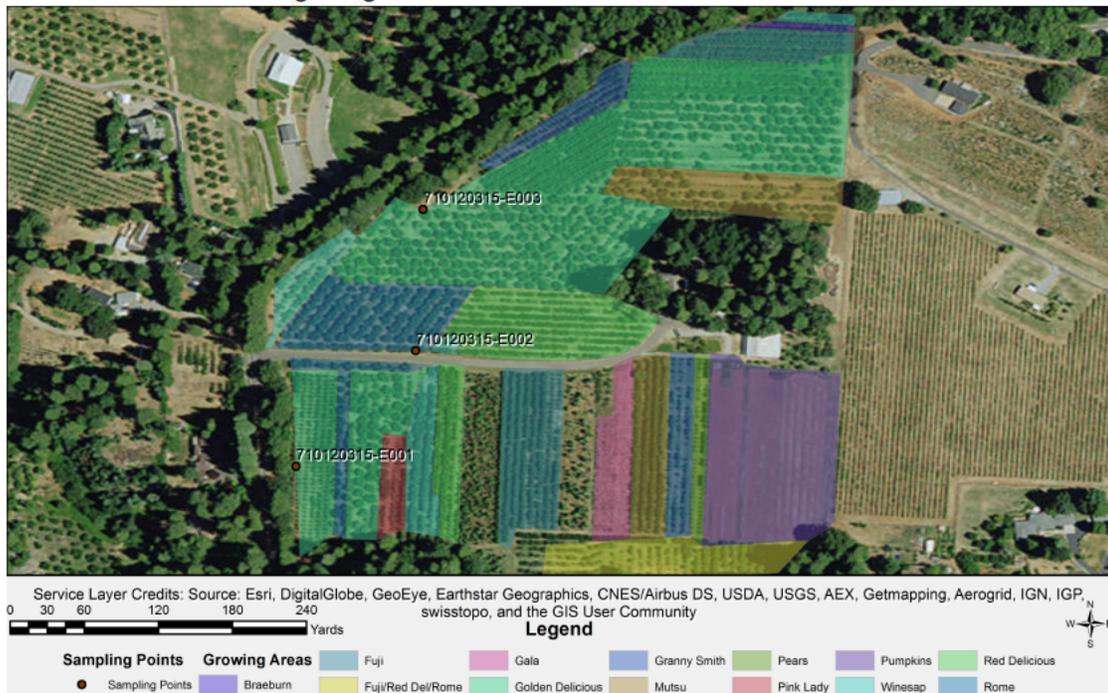


Figure 7 - [REDACTED] Map

SAMPLES COLLECTED

HIGH HILL RANCH APPLE CIDER SHED

On 10/21/15, ERU collected sixty environmental samples from food contact and non-food contact surfaces in the Apple Cider Shed (IS# 710102115) (Attachment 7 – Rows 3-47). The team collected these samples after High Hill Ranch employees had cleaned following the last round of juicing the previous day.

ERU also collected eleven samples of in-process and finished product at High Hill Ranch (IS # 710102115), including five samples from the bulk tank, two samples from the insulated jugs used for free samples and four samples of finished products (Attachment 7 – Row 48-58 and Attachment 12).

The samples were sealed in an ice chest with reusable ice packs according to ERU sample handling procedures. An ERU investigator submitted the sealed samples to the CDPH Food and Drug Laboratory Branch (FDLB) in Richmond, CA for Shiga-toxin producing *Escherichia coli* (STEC) testing on 10/22/15. FDLB did not detect STEC in these samples (Attachment 7 – Row 3-58, Column N).

HIGH HILL RANCH ORCHARD

On 11/4/15, ERU collected three fecal samples (IS# 710110415) from the ranch property (Attachment 7 – Row 71-73). One sample was possible cat feces found behind the rope sorter used for incoming apples, and two rodent feces samples were associated with the adulterated popcorn.

The investigative team placed the samples in an ice chest with reusable ice packs, according to ERU sample handling procedures. An ERU Environmental Scientist submitted the sealed samples to FDLB in Richmond, CA for STEC testing on 10/22/15.

FDLB did not detect STEC in any of these samples. (Attachment 7 – Row 70-72, Column N)

████████ RANCH ORCHARD

On 11/30/15, ERU collected ten fecal samples (IS# 710113015) from the orchard and surrounding area (Attachment 7 – Row 79-90). The samples consisted of two deer and three goose feces from within the orchard and five cow feces from the cow pen adjacent to and uphill from the orchard.

The investigative team placed the samples in an ice chest with reusable ice packs, according to ERU sample handling procedures. An ERU Investigator submitted the samples to FDLB in Richmond, CA for STEC analysis on 12/1/15.

FDLB detected STEC in two of the cow feces samples (Attachment 7– Row 83/84 & 87/88). The lab determined that the serotype in these samples was not *E. coli* O111, but was unable to determine the specific serotype. The PFGE pattern of the positive feces samples were EMSX01/EMSA26 and did not match the outbreak (*E. coli* O111:NM) pattern. The PFGE pattern, EMSX01/EMSA26, did not match any known CDC illness clusters (Attachment 9 – Row 83/84 & 87/88, Column V). ERU notified ██████████ of these results on 12/18/15 and discussed these findings with ranch management. See Corrective Actions – Farms – ██████████.

████████ ORCHARD

On 12/3/15, ERU collected three environmental samples (IS# 710110415) from the orchard and surrounding area (Attachment 7 – Row 94-97). The samples consisted of two deer feces found in the orchard and one sample of red delicious apples remaining on the tree after harvest, that were similar to those apples potentially used as ingredients in the suspect High Hill cider.

The investigative team placed the samples in an ice chest with reusable ice packs, according to ERU sample handling procedures. An ERU Investigator submitted the sealed samples to FDLB for STEC testing on 12/4/15.

FDLB did not detect STEC in any of these samples. (Attachment 7 – Row 94-97, Column N)

PRODUCT SAMPLES COLLECTED FROM CASE PATIENTS

SACRAMENTO CASE PATIENT

On 10/20/15, IDB notified ERU of a case patient associated with this outbreak who had an open container of High Hill Ranch Apple Cider with a small amount of product left in the container. The case patient had consumed cider from this container in the period just prior to the illness.

On 10/21/15, an ERU Investigator collected this sample (IS# 199102115-P001) from the case patient's home in Sacramento, CA (Attachment 8). The sample consisted of a single, one-gallon jug of High Hill Ranch Apple Cider containing approximately two inches of cider remaining in the container. The best by date on the lid was marked 10/20/15, indicating that the product was produced on 10/6/15, which was within the outbreak timeframe.

The Investigator placed the samples in an ice chest with reusable ice packs, according to ERU sample handling procedures. An ERU Investigator submitted the sealed samples to FDLB for STEC testing on 10/22/15.

FDLB detected Shiga toxin producing, *E. coli* O111:NM in this sample (Attachment 7 – Row 1, Column N). The PFGE pattern isolated from this sample (EXD01.0406/EXDA26.103) was indistinguishable from the strain associated with this outbreak (Attachment 7 – Row 1, Column V).

CITRUS HEIGHTS CASE PATIENT

On 10/26/15, IDB notified ERU of a second case patient associated with this outbreak that also had an open container of High Hill Ranch Apple Cider. The case patient had consumed cider from this container in the period just prior to her illness.

On 10/26/15, an ERU Investigator collected a sample of the leftover product (IS# 199102615-P001) from the case patient's home in Citrus Heights, CA (Attachment 9). The sample consisted of an opened one-gallon jug of High Hill Ranch Apple Cider. The best by date on the lid of the container was 10/20/15, indicating that the product was produced on 10/6/15, which was within the outbreak timeframe.

The Investigator placed the samples in an ice chest with reusable ice packs, according to ERU sample handling procedures. An ERU Environmental Scientist submitted the sealed samples to FDLB for STEC testing on 10/27/15

FDLB did not detect STEC in this sample (Attachment 7 – Row 67, Column N).

WOODLAND CASE PATIENT

On 10/28/15, IDB notified ERU of a third case patient associated with this outbreak who also had an opened container of High Hill Ranch Apple Cider. The case patient had consumed cider from this container in the period just prior to the patient's illness.

On 10/29/15, an ERU Environmental Scientist collected a sample of the leftover product (IS# 727102915-P001) from the case patient's home in Woodland, CA (Attachment 10). The container had approximately one-third of the gallon remaining. The ERU Environmental Scientist collected four 120mL samples of this product in sterile vials. Since the case patient requested to retain some of the original sample for possible independent testing, the remaining leftover product was not collected. The best by date on the lid of the apple cider container was 10/22/15, indicating that the product was produced on 10/8/15, within the timeframe of interest.

The Environmental Scientist placed the samples in an ice chest with reusable ice packs, according to ERU sample handling procedures. The Environmental Scientist then submitted the sealed samples to FDLB for STEC testing on 10/29/15.

FDLB did not detect STEC in this sample (Attachment 7 – Row 69, Column N). The case patient did not inform ERU if any independent testing was performed or not.

WEST SACRAMENTO CASE PATIENT SAMPLE

On 11/4/15, El Dorado County EMD notified ERU of a fourth case patient associated with this outbreak, who also had an open container of High Hill Ranch Apple Cider. The case patient had consumed cider from this container in the period just prior to her illness. During the preliminary epidemiologic interviews, the case patient reported that her sister, who also consumed cider from the same container, became mildly ill with diarrhea as well, but did not seek medical care.

On 11/5/15, an ERU Investigator collected a sample of the leftover product (IS# 194110515-P001) from the case patient's home in West Sacramento, CA (Attachment 11). The sample consisted of an opened one-gallon container of High Hill Ranch Apple Cider with approximately one inch of cider remaining in the container. The best by date on the container was 10/20/15, indicating that the product was produced on 10/6/15, which was within the outbreak timeframe.

The Investigator placed the sample in an ice chest with reusable ice packs, according to ERU sample handling procedures. An ERU Investigator submitted the sealed samples to FDLB for STEC testing on 11/6/15.

FDLB did not detect STEC in this sample (Attachment 7 – 76 & 77, Column N).

OVERALL SAMPLING SUMMARY

Sample Type	Total	Positive
Cider Processing Environmental Samples	60	0
Apple Farm Environmental Samples	9	2
Product Samples	11	0
Case Patient Product Samples	4	1

Table 1 - Overall Sampling Summary

Sampling Location	Sample Type	Results	PFGE
████████ Ranch	Cow Feces (2 samples)	STEC* (+)	EMSX01/EMSA26
Sacramento Case Patient	Open Container of Cider	<i>E. coli</i> O111:NM	EXD01.0406/EXDA26.103

PFGE Matches Outbreak

*STEC = Shiga Toxin Producing *E. coli*

Table 2 - Positive Sample Summary

In the course of this investigation, ERU collected 60 environmental samples from the High Hill processing area, nine environmental (fecal) samples from the ranches assessed, eleven finished and in-process product samples, and four case patient product samples. Two samples of cow feces from ██████████ Ranch tested positive for STEC; however it was not the same strain as the outbreak and did not have the same PFGE pattern as the outbreak strain. One High Hill cider sample obtained from a Sacramento case patient tested positive for *E. coli* O111:NM and the PFGE pattern of this sample was indistinguishable from the pattern associated with this outbreak.

RECALL ACTIVITIES AND PRESS

HIGH HILL RANCH RECALL

On 10/23/15, High Hill Ranch issued a press release indicating that illnesses in October may have been associated with visiting the ranch. The press release indicated that High Hill Ranch had discontinued providing free samples of apple cider to visitors (Exhibit F). The El Dorado County EMD Public Health Division also issued a press release (Exhibit G). The El Dorado County press release announced the voluntary recall of High Hill brand apple juice purchased on or after 10/6/15 and emphasized the risk of consuming unpasteurized apple cider from High Hill Ranch. Also, the press release also summarized the case counts to date and informed consumers of the signs of *E. coli* infection.

On 10/30/15, High Hill Ranch submitted samples of apple juice to an independent lab for testing. On 11/3/15, High Hill Ranch management stated publicly, including through their Facebook webpage that their juice samples were negative for *E. coli* and was safe to drink. Various media outlets noticed these assertions and began submitting inquiries to El Dorado County and FDB about the investigation and the link between High Hill's products and illnesses.

In response to the multiple media inquiries, the El Dorado County EMD issued a Fact Sheet on 11/5/15 (Exhibit H). The Fact Sheet outlined the status of the investigation with a focus on the samples collected and analyzed by FDLB and High Hill up to that date.

SUMMARY OF OUTBREAK INVESTIGATION FINDINGS

In conducting this investigation, CDPH-FDB and IDB determined that the unpasteurized apple cider produced by High Hill Ranch was the most likely source of the *E. coli* O111:NM that caused 15 illnesses in California. Environmental assessments completed at the apple cider facility and all three orchards showed areas of needed improvement in regards to food safety. ERU investigative team members collected High Hill Ranch apple cider from four ill individuals. A single sample of High Hill Ranch apple cider, collected from a case patient in Sacramento County, tested positive for *E. coli* O111:NM. The PFGE pattern of this sample was indistinguishable from one of the PFGE patterns found in case patients in this outbreak. This PFGE result, along with information obtained during the epidemiologic investigation, indicates that the unpasteurized cider produced by High Hill Ranch was the most likely source of the outbreak.

The environmental assessments conducted at the High Hill Ranch apple pressing facility identified several insanitary areas and the potential for contamination of the cider through multiple routes. These observations included the attic area situated over the production area with the vent open to pest intrusion, ceiling openings in the production room, feces found near High Hill Ranch's apple processing equipment and the use of soft carpet and other surfaces that were not easily cleanable in their apple sorting area. High Hill Ranch did not adequately clean and sanitize the equipment used for juicing as evidenced by a buildup of grime on the equipment, even though it was described as "clean" by firm management at the time of inspection. After the sorting and rinsing of the apples, High Hill Ranch pressed the fresh apples on inadequately cleaned equipment and sold the unpasteurized cider to consumers as well as gave away free samples to visitors. The cider did not receive any treatments to eliminate or reduce any pathogens that may have been in the product.

Evidence of animal intrusion was observed in all three of the orchards investigated. The most significant food safety concern at the orchards was at [REDACTED] Ranch, High Hill's largest supplier in 2015. The [REDACTED] Ranch orchard had cows immediately adjacent to and uphill from the orchard and two samples of feces from that pen tested positive for STEC. While the samples tested did not match the outbreak strains, pathogen transfer by animals or water to the apple orchard was possible. While all three orchards denied using apples that had fallen on the ground, the presence of animal feces in and around the orchards increased the risk of product contamination through employee practices, dust and other soil disturbances by equipment, and the potential contamination of the wooden crates storing the apples prior to pressing.

This outbreak centered on a small range of production dates and was likely the result of a single contamination event and not a sign of a harborage within High Hill Ranch's pressing equipment or a larger failure in their system. There were several areas that High Hill and the other growers could improve in their food handling practices to facilitate the prevention of future illnesses. These areas include sanitation of equipment, exclusion of animals in the processing facility, and the use of deer fences and other deterrents to keep wildlife out of the orchards.

CORRECTIVE ACTIONS

HIGH HILL RANCH CIDER MANUFACTURING

Upon notification of their association with this outbreak, High Hill Ranch voluntarily ceased cider production on 10/23/15. In coordination with El Dorado County EMD personnel, High Hill destroyed all of the cider in inventory on that date. This corresponded to their recall of all products manufactured on or after 10/6/15 (Recall Activities and Press - High Hill Ranch Recall). On 11/4/15, High Hill Ranch informed El Dorado County EMD that cider would not be produced for the rest of the 2015 season and they would focus on improving practices and sanitation for the 2016 season.

FARMS

Owners of all three orchards investigated were provided guidance on how they could improve their practices to increase food safety. The inspection team discussed these areas with orchards' owners and ranch managers during the onsite assessments. The owners all agreed that limiting animal intrusion would be beneficial and agreed to improve practices in that area.

████████ RANCH

████████ Ranch was the only orchard out of the three suppliers to High Hill Ranch to have an STEC isolate recovered from an environmental sample during this investigation. ERU had specific discussions with ██████████ and ██████████ regarding this finding. The discussion included the significance of potential pathogens located uphill from the orchard possibly contaminating the growing orchard via water run-off and the importance of completing the deer fence around the orchard to prevent animals tracking pathogens from other areas into the orchard. ██████████ stated she understood the significance and would be correcting the issue. ██████████ was also notified via e-mail of these results and also indicated he would be assisting with the necessary corrective actions in his role as Ranch Manager.

The Owner and Ranch Manager informed ERU that they would complete the deer fence around the orchard and repair the leaking water line in the cow pasture before the 2016 crop blooms. These actions could mitigate the potential movement of pathogens from the livestock into the orchard; therefore, preventing the contamination of apples.

FOLLOW-UP ACTIVITIES

On 8/9/16, an ERU Environmental Scientist accompanied El Dorado County EMD inspectors on an inspection of High Hill Ranch's cider operations prior to opening for the 2016 season. This inspection occurred before any cider was pressed for the season (Exhibit K). Most of the planned repairs had been completed as a result of the previous investigation. No employees were onsite at the time of inspection to verify revised procedures, however El Dorado County inspectors returned to the facility on High Hill's first day of processing for observation.

The corrective actions and upgrades undertaken by High Hill Ranch and observed by ERU investigative staff on 8/9/16 included (Exhibit K):

- Replacement of old, sanitizing agents with new, current supplies (Photo 2)
- The addition of a chlorinated rinse for all incoming apples after the wash tank (Photo 4)
- New, pressing racks and pressing cloths (Photo 1)
- Deep cleaning of all pressing equipment (Photo 3)
- Replacement of ceiling tiles with tiles that were more easily cleanable and replacement of missing tiles over the pressing area
 - This was in progress on the date of inspection.
 - County inspectors later verified that the ranch had completed this project before operation.

- Replacement of the pump used to move cider from the pressing equipment to the bulk tank with a new, more easily cleanable pump
 - At the time of inspection, firm management proposed using a pump that was not food-grade nor easily cleanable.
 - County inspectors verified that High Hill installed a food grade, easily cleanable pump prior to operation.
- High Hill Ranch owner proposed the installation of a system to treat the cider with ultraviolet light (UV) to reduce pathogens.
 - High Hill Ranch had not yet installed the system at the time of inspection.
 - ERU Scientists determined that the initially proposed system was suitable for drinking water, but did not appear suitable for unfiltered apple cider. ERU shared this information with the El Dorado County inspector for follow up.
 - The El Dorado County inspector verified that the system was not suitable and reported that they required High Hill Ranch to obtain approval from the county for any UV system or other equipment installed in the apple pressing area.
 - Firm management informed county inspectors they would not be using a UV system for the 2016 season.

ATTACHMENTS AND EXHIBITS

ATTACHMENTS

- Attachment 1 – Traceback Timeline
- Attachment 2 – High Hill Farm Investigation Questionnaire
- Attachment 3 – High Hill Notice of Violation
- Attachment 4 – High Hill Voluntary Condemnation and Destruction
- Attachment 5 – [REDACTED] Ranch Farm Investigation Questionnaire
- Attachment 6 – [REDACTED] Farm Investigation Questionnaire
- Attachment 7 – Investigation Sampling Summary
- Attachment 8 – Sacramento Case Patient Sample – Evidence Sample Receipt
- Attachment 9 – Citrus Heights Case Patient Sample – Evidence Sample Receipt
- Attachment 10 – Woodland Case Patient Sample – Evidence Sample Receipt
- Attachment 11 – West Sacramento Patient Sample – Evidence Sample Receipt
- Attachment 12 – High Hill Ranch Product Samples – Evidence Sample Receipt

EXHIBITS

- Exhibit A – Photos of High Hill Ranch Insanitary Conditions
- Exhibit B – Photos of High Hill Ranch Adulterated Product
- Exhibit C – Photos of High Hill Ranch Animal Intrusion
- Exhibit D – High Hill Ranch Suppliers
- Exhibit E – Photos of [REDACTED] Ranch
- Exhibit F – High Hill Ranch Press Release
- Exhibit G – El Dorado County Press Release Regarding High Hill Ranch Recall
- Exhibit H – El Dorado County Press Release – Fact Sheet
- Exhibit I – Photos of High Hill Ranch Apple Sorting Equipment
- Exhibit J – Photos from [REDACTED] Orchard
- Exhibit K – Photos from High Hill Ranch Pre-Season 2016 Inspection