

**Environmental Investigation of a *Campylobacter jejuni* Outbreak in 2012  
Associated with Claravale Farms Raw Whole Milk**

Final Report

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## **Agencies**

California Department of Public Health (CDPH), Food and Drug Branch (FDB), Emergency Response Unit (ERU)

California Department of Food and Agriculture (CDFA), Milk and Dairy Food Safety Branch

## **Dates of Investigation**

March 13–14, 2012 and April 23, 2012

## Executive Summary

In early February 2012, the California Department of Public Health (CDPH), Food and Drug Branch (FDB) was notified by the CDPH Infectious Diseases Branch (IDB) about a cluster of California residents with Campylobacteriosis. All cases had exposure to raw (unpasteurized) milk. IDB determined that the majority of case patients had consumed Claravale Farms brand raw milk products during the period preceding their illnesses. A total of 22 cases of *C. jejuni* were reported to IDB over the course of this investigation. The age range of case patients was one to 66 years. Illness onset dates ranged from January 29, 2012 to April 9, 2012. Five *Campylobacter* isolates collected from cases that had exposure to Claravale Farms raw milk were a genetic match using Pulsed field gel electrophoresis (PFGE). These isolates also matched the PFGE patterns from the Claravale Farms raw cream samples collected by FDB and the California Department of Food and Agriculture (pattern designation DBRS16.0024/DBRK02.1142).

Samples of Claravale Farms raw whole milk were collected from four case patients who still had remaining product. Samples were tested for *Campylobacter* and *Escherichia coli* O157:H7. *Campylobacter* was not detected in any of the raw milk samples, however, two unopened bottles of raw whole milk tested positive for *E. coli* O157:H7. FDB initiated an environmental investigation at the dairy based on the positive findings.

On March 13 and 14, 2012, FDB investigators collected a total of 170 samples at Claravale Farms: 22 product (whole raw cow milk, nonfat raw cow milk, raw cow cream, and raw goat milk), 62 sponge swabs, 11 soil, 17 water, and 58 feces. Of the 22 product samples, one (raw cow cream) was positive for *C. jejuni*, and two (one whole and one nonfat raw cow milk) were positive for non-O157:H7 *E. coli*. The California Department of Food and Agriculture (CDFA) also was on-site and collected product samples from the dairy which were tested for standard plate count, coliforms, *Campylobacter*, *Salmonella*, *E. coli* O157:H7, and *Listeria*. One sample, raw cow cream, was positive for *C. jejuni*. This finding prompted CDFA to issue a statewide recall and quarantine order to Claravale Farms on March 23, 2012. This order prevented the dairy from selling all raw milk products, and necessitated the removal of their raw cow milk, raw non-fat cow milk, raw cow cream, and raw goat milk from retail locations. Claravale Farms had already ceased distribution on March 19, 2012 due to their knowledge of CDFA's presumptive positive result of the raw cow cream sample. The firm ceased operations until the quarantine was lifted on March 29, 2012.

FDB and CDFA returned to Claravale Farms on April 23, 2012 due to additional Campylobacteriosis cases associated with raw milk from Claravale Farms subsequent to the CDFA quarantine release. Thirty one additional environmental samples were collected by FDB. *C. jejuni* was detected in one sample collected from a floor drain in the clean-in-place room. This sample did not match the outbreak strain.

CDPH's environmental and epidemiological investigation indicated that raw whole cow milk manufactured by Claravale Farms was likely contaminated with *C. jejuni* that led to illness. Operational deficiencies were reported which could have contributed to contamination of the raw milk.

## Background Information

In February 2012, a foodborne outbreak of *C. jejuni* (Pulsed Field Gel Electrophoresis, PFGE, pattern DBRS16.0024/DBRK02.1142) was epidemiologically linked to Claravale Farms in Paicines, California. The PFGE pattern combination DBRS16.0024/DBRK02.1142 was very uncommon and had not been previously uploaded in PulseNet. As of May 17, 2012, a total of 22 confirmed cases were reported to IDB. Nineteen of the 22 cases reported consumption of Claravale Farms raw (unpasteurized) milk, and the remaining three consumed raw milk, but could not recall the specific brand or had consumed both Claravale Farms raw milk and raw milk from another bottler.

A confirmed case was defined by IDB as “a person with culture-confirmed *Campylobacter* infection with a history of commercial raw dairy product consumption in the week before illness onset” (Attachment 1). The case patients who consumed Claravale Farms raw milk ranged from one to 66 years of age and lived in nine different counties in CA: Contra Costa (1), Los Angeles (1), Marin (4), Monterey (2), Orange (1), Nevada (1), Santa Cruz (6), San Francisco (3), and San Mateo (3) counties. The illness onset dates for the cases ranged from January 29, 2012 to April 9, 2012. Eleven of the 22 cases were children. Three adult patients were hospitalized due to Campylobacteriosis.

## Traceback of Claravale Farms Raw Milk Consumed by Four Case Patients

All 22 case patients associated with this investigation were interviewed to determine potential *Campylobacter* exposures. Nineteen cases reported consumption of Claravale Farms raw milk, and the remaining three cases had exposure to Claravale Farms raw milk and raw milk from another vendor. No other common exposures had been reported for all case patients. For the cases with Claravale Farms raw milk exposure, only four still had raw milk available for testing.

Product samples collected from the four cases were tested for *Campylobacter* and *E. coli* O157:H7 (Table 1). *Campylobacter* was not detected in any of the raw milk samples; however two unopened bottles of Claravale Farms raw whole milk were positive for *E. coli* O157:H7.

**Table 1 – Laboratory Results for Claravale Farms Product Samples Collected from Four Case Patients**

Case Number	County	Sample Number	Results	
			<i>Campylobacter</i>	<i>E. coli</i> O157:H7
6	Monterey	888021512–P001	Negative	Negative
		888021512–P002	Negative	Negative
7	Santa Cruz	888022712–P001	Negative	Positive
		888022712–P002	Negative	Positive
12	Marin	103031512A	Negative	Negative
17	Nevada	191040212–P001	Negative	Negative

IDB reported the locations where the case patients had purchased Claravale Farms raw whole milk. Deliveries of Claravale Farms raw whole milk by distributors to the reported retail locations were verified by invoices pertaining to the products purchased by the case patients. Periods of distribution were determined in consideration of the following points: (1) dates of illness onset, (2) estimated dates of consumption and/or purchase, (3) product sell-by dates (9 days), and estimated delivery schedules (1–2 day delivery period).

Specific case patient information is listed below:

Case patient #6 consumed Claravale Farms raw whole milk which was delivered to the home by a delivery service prior to the onset of illness reported as February 6, 2012. The patient recalled that the sell-by date of the consumed raw whole milk was February 7, 2012. The remaining product tested by the Food and Drug Laboratory Branch (FDLB) had a sell-by date of February 21, 2012 and had been purchased after the illness onset date. The name of the home delivery service and the actual date of the original purchase were unknown. The patient failed to respond to further requests for information.

Case patient #7 consumed Claravale Farms raw whole milk purchased on January 26, 2012 from New Leaf Market located at 1210 41<sup>st</sup> Avenue, Capitola, CA. The onset of illness was on January 29, 2012. The patient did not recall the expiration date of the product consumed before the onset of illness. The remaining product tested by FDLB had a sell-by date of February 7, 2012 and had been purchased after the illness onset date. Invoices showing deliveries of Claravale Farms raw milk to Dairy Delivery, and subsequently to New Leaf Market, before the onset date, were included as Attachments 2A and 2B. During the same

time period, New Leaf Market also received a shipment of raw milk directly from Claravale Farms. The invoices showing sales to New Leaf Market directly from Claravale Farms were included as Attachment 2C.

Case patient #12 consumed Claravale Farms raw whole milk purchased on February 29, 2012 from Three Stone Hearth located at 1581 University Avenue, Berkeley, CA. The onset of illness was on March 4, 2012. The patient did not recall the sell-by date of the milk consumed before the onset of illness. The remaining raw whole milk tested by FDLB had a sell-by date of March 14, 2012, and had been purchased after the illness onset date. Invoices showing deliveries of Claravale Farms raw milk to Real Food, and then to Three Stone Hearth, were included as Attachments 2D and 2E.

Case patient #17 consumed Claravale Farms raw whole milk purchased on March 16, 2012 from New Moon Natural Foods located at 11357 Donner Pass Road, #C, Truckee, CA. The onset of illness was March 19, 2012. The consumed raw whole milk had a sell-by date of March 24, 2012. The remaining product tested by FDLB also had a sell-by date of March 24, 2012. Invoices showing deliveries of Claravale Farms raw milk products to Dairy Delivery, to Veritable Vegetable, and then to New Moon Natural Foods were included as Attachments 2F, 2G, and 2H.

The extended time period between illness onset and diagnosis, coupled with the limited availability of raw milk samples retained by consumers, precluded FDB from identifying the particular sell-by date of Claravale Farms raw whole milk that was contaminated.

A traceback summary chart is provided below (Table 2), and a traceback diagram can be found in Attachment 3.

**Table 2 – Traceback Summary of Claravale Farms Raw Whole Milk Consumed by Four Case Patients**

Case Patient	Illness Onset Date	Location of Raw Whole Milk Purchase	Purchase Date	Product Tested Sell-by Date	Associated Invoices from Suppliers	Attachment Number
#6	2/6/12	Delivered to home in Monterey	Unknown	2/21/12 (1 opened bottle, 1 unopened bottle)	Unknown – Invoice unavailable	n/a
#7	1/29/12	New Leaf Market 1210 41 <sup>st</sup> Ave., Capitola, CA 95010	1/26/12	2/7/12 (2 unopened bottles)	Dairy Delivery - Invoice #100897 1/23/12 #101208 1/26/12  Claravale Farms – Invoice #06692 1/20/12 #06696 1/22/12 #06706 1/25/12	2B  2A, 2C
#12	3/4/12	Three Stone Hearth 1581 University Ave., Berkeley, CA 94703	2/29/12	3/14/12 (1 unopened bottle)	Real Food – Invoice #2041915 2/27/12  Claravale Farms – Invoice # 06800 2/27/12	2E  2D
#17	3/19/12	New Moon Natural Foods 11357 Donner Pass Rd., #C, Truckee, CA 96161	3/16/12	3/24/12 (1 unopened bottle)	Veritable Vegetable – Bill of Lading #27181 3/15/12  Dairy Delivery – Invoice #106149 3/15/12  Claravale Farms– Invoice # 06852 3/14/12	2H  2G  2F

## Environmental Investigation – Claravale Farms

### Claravale Farms

Ron Garthwaite, President  
33320 Panoche Road  
Paicines, CA 95043

FDB conducted two environmental investigations at Claravale Farms due to a *Campylobacter jejuni* outbreak associated with raw milk consumption. The 1<sup>st</sup> on-site investigation at Claravale Farms was on March 13–14, 2012, and the 2<sup>nd</sup> investigation was on April 23, 2012. Claravale Farms operated as a raw milk dairy that manufactured raw whole cow milk, raw non-fat cow milk, raw cow cream, and raw goat milk for wholesale distribution. Ron Garthwaite was the President of Claravale Farms.



Claravale Farms' milking (wet) herd consisted of approximately ■ Jersey cows and ■ goats. Non-milking (dry) cows and calves were also kept on the property. The Claravale Farms dairy consisted of five areas (processing, wet cow herd, dry cow herd, calf area, and goat herd). The processing area was built in 2007, and consisted of a milk bottling room, a bottle washing room, a milk storage cooler, and a milking barn.

FDB and CDFA performed inspections of the processing area, water system, food handling practices, and milking practices. Product samples including raw whole milk, raw non-fat milk, and raw cream were collected. FDB also conducted environmental sampling on equipment and other surfaces in the bottling room, bottle washing room, and the milking barn. Tap water was collected in the bottling room as well as feces, soil, and water samples in the wet herd, dry herd, calf, and goat areas. An inspection report from FDB's Food Safety Inspection Unit (FSIU) was included as Attachment 4.

Throughout this investigation, FDB investigators were accompanied at different times by Ron Garthwaite (President) and/or Collette Cassidy (Spouse).

### Calf and Cow Operations

The Claravale Farms property was situated on both sides of Panoche Road in Paicines, California. The processing, milking, wet herd, and goat areas were located on the north side and the calf and dry herd areas were located on the south side of Panoche Road.

Mr. Ron Garthwaite reported the following regarding Claravale Farms' herd management and milk production:

Lactating cows from the wet herd were bred to one of the ■ bulls located on-site. After breeding, the cows continued producing milk and remained in the wet herd until seven months pregnant. The pregnant cows were then transported to the dry herd area on the south side of Panoche Road for two months, until they were ready to give birth. At nine months gestation, the pregnant cows were placed in a birthing area adjacent to the dry herd pasture. These cows gave birth in the birthing area where they remained nursing their calves for at least four days. After approximately four days, the calves were carried by staff to the newborn calf barn. The mother cow was then integrated back into the wet herd.

The calf area consisted of a partially enclosed barn with stalls and three pastures. The wooden stalls in the calf barn were maintained in sanitary condition. The floors and walls of the calf barn appeared to be cleaned routinely. Each of the three pastures contained calves of a specific age range. These calves did not have direct contact with the wet herd cattle or goats. The calf areas were adjacent to the dry herd cow pasture but separated by wire fencing. Once separated from their mother, the calves were first placed in the calf barn until they were weaned at approximately two months of age. The calves were bottle fed line-loss milk or milk obtained from cows with mastitis. Line-loss milk was the milk drained out of the milking equipment lines after milking was finished and before cleaning of the lines took place.

The 0-2 month old calves in the calf barn area were also fed alfalfa hay and organic dairy pellet feed. Once the calves were weaned from milk, they were moved to the adjacent pasture until they were vaccinated at approximately 4-5 months of age. Once vaccinated, they were moved to another adjacent pasture until 8-13 months of age. The males were sold at auction and the females (heifers) were bred at approximately 13 months, with one of the [REDACTED] Claravale Farms bulls. The impregnated heifers were maintained in the dry herd until they were nine months pregnant – as described earlier. They were then moved into the birthing area to give birth. Once the calves were removed from the mothers, the mothers were integrated into the wet herd for the first time.

Claravale Farms dairy was located in a dry climate which normally received very little rain. For several weeks of the year, there were natural grasses available for the cows to graze on. During this time, the cows' diet was supplemented with alfalfa hay. Once the grasses dried up and the herd could no longer graze, the herds' main diet was alfalfa hay. Cows were only fed organic dairy pellets during milking.

Written Standard Operating Procedures (SOPs) regarding employee and equipment movement between the calf area, milking barn, and bottling facility were not maintained by Claravale Farms. Mr. Garthwaite stated that the employees were not required to remain in any specific area of the dairy. Employees were directed to spray off their footwear with water before entering the processing area. The employees were observed moving between milking, processing, and other areas freely and without spraying their footwear every time they entered processing areas.

#### Milking Operation – Milking Barn

The Milking Barn was part of a permanent structure on the north side of Panoche Road that was built in 2007. The structure had a roof and three open sides. It was attached to the building which contained the clean-in-place room (CIP), milk storage refrigeration unit, bottling room, and bottle washing room. Claravale Farms' wet herd (cow and goat) were milked twice daily, at approximately 0200 and 1400 hours. The goats were milked first and the cows milked second. At milking time, the goats entered the staging pen and waited for their turn to be milked at one of the four milking stations. Four goats at a time were admitted into the milking parlor where the milking stations were located. Each goat entered a milking station and climbed on top of a wooden stand. The wooden stand was used to lift the goats off the ground so they could reach the attached feeding trough. The goats were fed organic grain pellets while being milked. An employee prepared the teats for the milking process. For a detailed description of the goat teat preparation and milking process, refer to Attachment 4. The milking process for the goat herd took about four hours.

After the goats were milked, the firm performed a simplified clean-in-place (CIP) of the milk lines before milking the cows. The milk lines, including the milking apparatus, were first flushed with cold water, then with a solution of [REDACTED] (sanitizer – 12.5% sodium hypochlorite), followed by an in-line paper filter change.

The cows entered the staging pen at milking time. They were permitted to enter the milking salon one at a time until each of the four stalls was occupied. The cows extended their necks to the feeding trough and were fed organic grain pellets while an employee secured a bar to the side of the neck. The bar deterred the cows from backing out of the stalls prematurely. An employee cleaned the udders and teats. Before the milking apparatus was attached to the cows, their tails were manually draped over a horizontal bar which divided each milking stall. The tail was placed on the bar to prevent contamination of the cleaned teats, udders, and milking apparatus with feces that may be on the tail. It was common for cows to defecate during the milking process. The employees were observed responding to each fecal occurrence in a timely manner to maintain the cleanliness of the milking parlor as much as possible. For a detailed description of how the cows were cleaned and milked, refer to Attachment 4. The milking of the cows took 2-3 hours.

After the goat and cow herds were milked, firm employees performed a thorough CIP of the milk lines and milking apparatus. Refer to Attachment 4 for a complete description of the CIP process. The milking parlor was also cleaned and disinfected between the morning and evening milking sessions. The firm cleaned and sanitized the milking parlor floors with [REDACTED] Cleaner, Bleach, and [REDACTED] sanitizer, and then followed with a cold water rinse. After the CIP process and disinfection of the milking parlor, the equipment was ready to be used for the next milking session, which was approximately five hours later.

During the milking process of the goats and cows, an investigator observed the milking claw fall to the ground on two occasions. A firm employee picked up the milking claw and reapplied the apparatus to the goat or cow without any type of washing or sanitizing of the teat cups which contacted the floor. This was observed on two occasions, once during the goat milking and once during the cow milking. Also, several bird nests were observed in the eaves directly above the milking stations.

#### Processing Operation – Milk Bottling Room

**Goats' Milk:** The raw goat milk from the milking barn was transported via a closed piping system to the bottling room. The milk passed through an in-line paper filter on the way to the bottling room. The purpose of the filter was to prevent any large particles present in the milk from entering the bottling process. The goats' milk flowed from the closed system directly into a stainless steel milk can. Once the can was full, an employee poured the raw milk into the bottling machine reservoir.

The firm recently purchased a new manually operated bottling machine. The machine consisted of a single fill head; employees hand fed the bottles to the machine while filling was controlled by a foot pedal. The machine also had a capping mechanism for placing the plastic caps on the glass bottles. Once the bottles of goat milk were filled and capped, the milk was placed in plastic milk crates and stored in the walk-in refrigeration unit (less than [REDACTED] °F) adjacent to the bottling room.

**Cows' Milk:** After the goats' milk was bottled, the bottling machine was rinsed with water and [REDACTED] before the cows' milk bottling process began. The raw cow milk from the milking

barn was transported via a closed piping system to the bottling room, through a disposable paper filter, and into a milk tank located in the bottling room. The milk tank was maintained at approximately [REDACTED]°F. The temperature was monitored continuously using a recording chart. When it was time to bottle the cows' milk, an employee opened a valve on the tank to release enough milk to fill a stainless steel milk can. Once the can was full, an employee poured the milk into the bottling machine reservoir. The milk was filled into glass bottles and capped by the machine noted above. The filled bottles were placed in plastic crates and stored in the walk-in refrigeration unit.

**Cream and Non-Fat Milk:** The process for manufacturing and bottling cream and non-fat cows' milk was described by Mr. Garthwaite as follows, as the cream and non-fat milk processing operations were not observed:

A cream separator separated the cream and non-fat milk by centrifugation. Afterwards, the cream and non-fat milk were bottled individually using the automated bottling machine.

**Product Coding:** The milk (whole and non-fat) and cream products were stored in the walk-in refrigeration unit for 1-2 days after bottling. Immediately prior to shipping, each bottle was stamped on the cap with an expiration date. The milk that was sold to Northern California customers received a stamped date that was 9 days in the future. The milk that was sold to Southern California customers received a stamped date that was 12 days in the future. The difference in shelf life between Southern and Northern California was attributed to distribution patterns. The milk distributed to each area was handled in the same manner.

**Sanitation:** Sanitation procedures in the milk bottling room and the adjacent bottle washing room were described by Mr. Ron Garthwaite. The bottling machine and cream separator were partially disassembled and cleaned-in-place with [REDACTED] (chlorinated cleanser [REDACTED] [REDACTED] hot water, and [REDACTED] (acid-based cleanser [REDACTED] [REDACTED]. The disassembled parts were cleaned with hot water and [REDACTED] (iodine-based disinfectant [REDACTED]. The concrete floors were cleaned with [REDACTED] sodium hypochlorite, [REDACTED] (quaternary disinfectant [REDACTED] [REDACTED] and cold water. Bottling room sanitation was conducted by Claravale Farms employees, and took place after each batch of milk was processed.

The bottling room contained a refrigerated milk storage tank used to store cows milk. The storage tank was cleaned-in-place approximately three times per week using the same chemicals and process used for the bottling equipment.

The employees were observed wearing appropriate attire in the processing areas including disposable gloves, hair restraints, and aprons. Although the firm lacked signs instructing employees to wash their hands before they start work, after each absence from duty, and when their hands may have become soiled or contaminated, employees were observed washing their hands prior to bottling milk.

## Bottle Washing Operation – Returned Glass Bottles

Claravale Farms used glass bottles for the bottling of raw milk and cream. New glass bottles were sourced from [REDACTED]. The new glass bottles were stored indoors in cardboard boxes on wrapped pallets. The firm also accepted returns of used bottles from their customers. The returned glass bottles were stored outside until they were moved into the bottle washing room for washing and sanitizing. Before bottling, both new and returned bottles were cleaned and sanitized in the bottle washing room which was adjacent to the bottling room. The glass bottles were manually washed with [REDACTED] Cleaner with a mechanical rotating brush, rinsed with hot water, and then soaked in a warm solution of [REDACTED] disinfectant. The bottles were removed from the disinfectant and placed upside down in clean plastic crates to air dry. These plastic crates were only used for storing clean bottles. Other plastic crates were dedicated to shipping milk and receiving returned bottles. The firm sanitized all plastic crates with [REDACTED] after each use. If any caps were present on the returned glass bottles, the caps were discarded as they were disposable. New caps were obtained from the same supplier as the new glass bottles and were not treated prior to use. Stainless steel milk storage cans were washed with [REDACTED] cleaner and sanitized in a warm solution of [REDACTED] disinfectant.

The firm did not have a procedure to ensure that the disinfectant solutions were prepared to a specific concentration deemed to be effective for sanitizing the re-washed bottles. The employees were trained to add concentrated disinfectant to hot water until it reached a certain shade of orange. The firm did not have a testing kit to verify that the solution reached a concentration effective for sanitizing the glass bottles.

## Water

Hydro-geologic information for this location was limited. The California Department of Water Resources and the State Water Resources Control Board (SWRCB), Groundwater Ambient Monitoring and Assessment (GAMA) database lacked water quality data pertaining to this area.

Water was supplied to the property by a well that was built in approximately 1900. The wellhead was located on the south side of Panoche Road; the same side as the residence and calf/dry herd areas. Information was not available about the construction and specifications of the well, however, records obtained from San Benito County indicated a windmill was installed on the well in 1935. The well was outfitted with a three quarter horsepower submersible pump, with a [REDACTED] control panel, and a [REDACTED] submersible pump protector (Model SP-23).

The wellhead was visually inspected as part of the environmental investigation. The visible plumbing and check valves associated with the well equipment appeared appropriate for the application. There was a bolt on the coupling that appeared to have been retrofitted to the original casing to facilitate the placement of a sanitary seal and a rope was observed passing through an approximately 0.25 inch opening on the top of the sanitary seal. An aeromotor windmill shaft also entered through the sanitary seal. The integrity of the packing and gasket

of the windmill shaft was questionable due to the age and condition. The windmill was non-operational at the time of inspection.

A wooden water storage tank enclosure (well house), which contained an elevated tank, was located adjacent to the well head. The tank was a 1500 gallon translucent high-density polyethylene (HDPE) water storage tank that was fitted with a mechanical gauging system featuring a rope and pulley. An opening in the top of the tank with the rope passing through it could potentially contaminate water inside the storage tank. The environment inside the well house contained evidence that rodent and bird activity had taken place. Feathers and various feces were present in the enclosure and on top of the water storage tank. Algae growth was observed inside the tank and an accumulation of debris was observed at the bottom of the tank. An in-line one horsepower booster pump and pressure tank were also located in the well house. Claravale appeared to have facilitated water distribution to the south side of Panoche Road. Water flow to the property on north side of Panoche Road, where the dairy and wet herd/goat areas were located, was by gravity.

Additional water storage tanks were located on the north side of Panoche Road. Three black 5000 gallon HDPE tanks had been installed in-parallel, along with a one horsepower booster pump and pressure tank. All associated plumbing and fitting connections on the north side appeared to have been tight fitting and therefore protected from contamination through the fittings.

Water supplied to the dairy structure, on the north side of Panoche Road, was treated with a water softener prior to passing through an ultraviolet (UV) light disinfection system. The treatment system was installed in the summer of 2011 by [REDACTED]. The UV light system incorporated a [REDACTED], which was rated for a flow of up to 25 gallons per minute (gpm). The UV lamp system was designed to provide a minimum of 30 mJ/cm<sup>2</sup> dose of UV light. The system was maintained by [REDACTED] with annual replacement of both the UV lamp and quartz sleeve.

Elevated coliform levels, 23 colony forming unit (CFU)/100 mL, were detected in a routine sample of the dairy tap water on June 28, 2011 – before the installation of the UV disinfection system (Attachment 5). The routine sample had been collected and tested by CDFA, California Animal Health and Food Safety Laboratory. When the firm learned of the sample result, the well tank was manually dosed with a sodium hypochlorite solution and the UV disinfection system was installed in the summer of 2011. Subsequent water tests indicated that coliform levels of the water were within acceptable limits (Attachment 6).

## **Environmental Sampling and Results**

FDB investigators conducted an assessment of activities at Claravale Farms and collected both product and environmental samples in March and April of 2012. Product samples consisted of packaged raw whole cow milk, raw non-fat cow milk, raw cow cream, and raw goat milk. Environmental sampling focused on the milk bottling room, milking barn, wet and dry herd pastures, calf area, and goat area. Table 3 below is a summary of the 201 total samples collected during the course of this FDB investigation. All samples and controls were analyzed by CDPH-FDLB in Richmond, CA (Attachment 7).

**Table 3 – Types and Locations of Samples Collected by FDB at Claravale Farms**

Sampling Location	Type and Number of Samples					
	Product	Environmental Swab	Water	Feces	Soil	Total
Refrigeration Unit	27	2	---	---	---	<b>29</b>
Milk Bottling Room	---	34	2	---	---	<b>36</b>
Bottle Washing Room	---	9	---	---	---	<b>9</b>
CIP Room	---	4	---	---	---	<b>4</b>
Ice Machine	---	2	---	---	---	<b>2</b>
Restroom	---	1	---	---	---	<b>1</b>
Milking Barn	---	33	---	---	---	<b>33</b>
Cow Areas	---	---	6	30	6	<b>42</b>
Calf Area	---	3	7	20	4	<b>34</b>
Goat Area	---	---	2	8	1	<b>11</b>
<b>Total</b>	<b>27</b>	<b>88</b>	<b>17</b>	<b>58</b>	<b>11</b>	<b>201</b>

Samples were submitted to FDLB and tested for *Campylobacter* or shiga-toxin producing *E. coli* (STEC). In some cases, samples were tested for both *Campylobacter* and STEC (Table 4).

**Table 4** – Types of Samples Collected at Claravale Farms and Laboratory Analysis Conducted

Type of Samples Collected	Number of Samples Collected	Number of Samples Analyzed for <i>Campylobacter</i> Only	Number of Samples Analyzed for STEC Only	Number of Samples Analyzed for Both <i>Campylobacter</i> and STEC
Product	27	5	7	15
Environmental Swab	88	26	62	---
Water	17	---	15	2
Feces	58	---	50	8
Soil	11	---	11	---
<b>Total</b>	<b>201</b>	<b>31</b>	<b>145</b>	<b>25</b>

Of the 201 samples total collected in the course of this investigation, there were 174 (~87%) environmental samples. Of the 174 environmental samples (swabs, water, feces, and soil), 148 (85%) were tested for STEC. All 148 environmental samples were negative for STEC. Thirty six of 174 environmental samples were tested for *Campylobacter*. One environmental swab was positive for *C. jejuni* (IS# 191042312–E023). This sample was collected from a floor drain in the CIP Room (Table 5). The PFGE pattern of the *C. jejuni* (DBRS16.1348) found in the floor drain did not match the outbreak strain and did not match any other recent outbreak clusters.

**Table 5** – Summary of Positive *C. jejuni* Samples Collected at Claravale Farms

Sampling Location	Sample Type	Number of Positive Samples	Sample Number	Collected By	PFGE Pattern of <i>C. jejuni</i>	Match to Outbreak Strain
CIP Room	Floor Drain	1	191042312–E023	CDPH	DBRS16.1348	No
Refrigeration Unit	Raw Cream	1	CA–M12X01029	CDFA	DBRS16.0024/ DBRK02.1142	Yes
Cooler	Raw Cream	1	171031412–P001	CDPH	DBRS16.0024/ DBRK02.1142	Yes

Of the 201 samples total, 27 product samples were collected at Claravale Farms; 20 (74%) were tested for *Campylobacter*. One sample (5%) of raw cream was positive for *C. jejuni* (IS# 171031412–P001) and matched the outbreak strain (Table 5). Of the same 27 product



samples collected at Claravale Farms, 22 (82%) were tested for STEC. Two samples of raw cow milk were positive for non-O157:H7 *E. coli*. One raw whole milk sample contained *E. coli* O116:H12, Stx 1 (IS# 171031412-P007). The other raw non-fat milk sample contained *E. coli* O2:H27, Stx 2 (IS# 171031312-P006). Neither *E. coli* serotype detected had been associated with recent outbreaks (Table 6).

**Table 6** – Summary of Positive *E. coli* Samples Collected at Claravale Farms

Sampling Location	Sample Type	Sample Number	Serotype of <i>E. coli</i>	Shiga-like Toxin Type
Refrigeration Unit	Raw Whole Milk	171031412-P007	O116:H12	Stx 1
Refrigeration Unit	Raw Non-Fat Milk	171031312-P006	O2:H27	Stx 2

Samples of various raw milk products were also collected by CDFA on March 13, 2012 from Claravale Farms. The raw milk products were tested for standard plate count, coliform, *Campylobacter*, *Salmonella*, *E. coli* O157:H7, and *Listeria*. One Claravale Farms raw cow cream sample (CA\_M12X01029) collected by the CDFA was positive for *C. jejuni* and its PFGE matched the outbreak pattern (Table 5). This positive result prompted CDFA to issue a statewide recall and a quarantine order to Claravale Farms on March 23, 2012. The recall and quarantine order prevented Claravale Farms from selling all raw milk products, including raw goat milk. Claravale Farms had already ceased distribution on March 19, 2012 due to their knowledge of the presumptive positive result of the CDFA raw cream sample (CA\_M12X01029) before it was confirmed positive on March 23, 2012. The recall and quarantine order also necessitated the removal of their raw milk, raw non-fat milk, raw cream, and raw goat milk from retail locations. A recall was initiated by Claravale Farms on March 23, 2012. The firm ceased operations until the quarantine was lifted by CDFA on March 29, 2012 (Attachment 8).

Five case patient's clinical samples were selected by IDB for PFGE testing at the State Microbial Diseases Laboratory (MDL) (Table 7). Each of these case patients reported drinking Claravale Farms raw milk prior to onset of illness. Four of the 5 cases reported drinking Claravale Farms raw milk exclusively and one case reported drinking Claravale Farms raw milk and raw milk from another vendor. The PFGE patterns for the 5 clinical samples matched the PFGE pattern of the *C. jejuni* positive raw cream samples that were collected by FDB (171031412-P001) and CDFA (CA\_M12X01029) from Claravale Farms (Table 7).

**Table 7 – *C. jejuni* PFGE Patterns of Case Patients and Product Samples**

Case Number	Sample Type	County – Case Patients	Sample Number	PFGE Pattern of <i>C. jejuni</i>
6	Clinical specimen	Monterey	CA_M12X00546	DBRS16.0024/DBRK02.1142
17	Clinical specimen	Nevada	CA_M12X00969	DBRS16.0024/DBRK02.1142
28	Clinical specimen	Monterey	CA_M12X01152	DBRS16.0024/DBRK02.1142
29	Clinical Specimen	Santa Cruz	CA_M12X01416	DBRS16.0024/DBRK02.1142
31	Clinical Specimen	San Mateo	CA_M12X01264	DBRS16.0024/DBRK02.1142
N/A	Product: raw cream	N/A	CA_M12X01029	DBRS16.0024/DBRK02.1142
N/A	Product: raw cream	N/A	171031412-P001	DBRS16.0024/DBRK02.1142

## Summary of Findings

On March 13–14, 2012 and April 23, 2012, FDB investigators conducted environmental investigations at Claravale Farms and collected 27 product, 88 sponge swabs, 11 soil, 17 water, and 58 fecal samples. One raw cream sample was positive for *C. jejuni* and two raw milk samples were positive for non-O157:H7 *E. coli*. In addition to these findings, CDFA detected *C. jejuni* in a raw cream sample which prompted a quarantine order. The PFGE patterns from the FDB and CDFA raw cream samples matched each other and also matched the outbreak strain. One environmental swab, collected from a floor drain in the CIP Room, was positive for *C. jejuni*. The PFGE pattern from the sample collected from the drain did not match the outbreak strain.

An inspection of Claravale Farms' facility and operating procedures revealed deficiencies which could have contributed to contamination of the raw milk.

1. During the milking operation, the milking claw (attached to the animal by suction) fell onto the floor of the milking parlor on two occasions. The milking claw was then picked up by an employee and placed back onto the animal without washing and sanitizing the equipment.
2. The firm did not ensure that the concentration of the sanitizers were adequate for the conditions of use. Firm employees were unable to demonstrate that the strength of the sanitizers used on food contact surfaces was effective, either by measuring the recommended amount or by confirming the strength through testing.
3. Multiple bird nests were observed in the milking parlor ceiling above the milking area.

The PFGE pattern combination isolated from case patients and raw cream during this investigation (DBRS16.0024/DBRK02.1142) was very uncommon and had not been previously uploaded in PulseNet. Matching *C. jejuni* PFGE patterns between case patients who consumed Claravale Farms raw milk and sealed Claravale Farms raw cream samples indicated that raw milk contaminated with *C. jejuni* likely caused illness in California residents. Considering *C. jejuni* has historically been isolated in cow feces, it is likely that cross-contamination between feces containing *C. jejuni* and raw milk occurred at Claravale Farms during the outbreak period. Additional precautions to prevent this type of contamination, such

as segregating employees to specific areas of the plant, washing and sanitizing milking equipment once contaminated, were not observed at Claravale Farms.

The environmental and epidemiological investigation completed by CDPH indicated that raw whole milk manufactured by Claravale Farms was likely contaminated with *C. jejuni* that led to illness in at least 20 individuals in 9 counties throughout California.

## Attachments

1. CDPH Infectious Diseases Branch Investigative Summary
2. Traceback Invoices
  - A. Claravale Farms to Dairy Delivery
  - B. Dairy Delivery to New Leaf Market
  - C. Claravale Farms to New Leaf Market
  - D. Claravale Farms to Real Food
  - E. Real Food to Three Stone Hearth
  - F. Claravale Farms to Dairy Delivery
  - G. Dairy Delivery to Veritable Vegetable
  - H. Veritable Vegetable to New Moon Natural Foods
3. Traceback of Raw Whole Milk for *C. jejuni* Outbreak
4. CDPH Food Safety Inspection Unit Report – Claravale Farms
5. CDFA, California Animal Health and Food Safety Laboratory Report - Claravale Farms Water 6/28/2011
6. CDFA, California Animal Health and Food Safety Laboratory Report - Claravale Farms Water 8/11/2011, 12/6/2011, 3/23/2012
7. CDPH Food and Drug Branch Sample Summary
8. CDFA Release of Quarantine