
INVESTIGATION OF A *CAMPYLOBACTER JEJUNI* OUTBREAK IN 2015 ASSOCIATED WITH CLARAVALE FARM BRAND RAW COW MILK

Final Report

August 2015

Prepared by:

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Emergency Response Unit - Food Safety Inspection Unit

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ERU ACTIVITY SUMMARY REPORT

INVESTIGATION NAME: 15006 Claravale RawMilk Campy IDB 032015		ASSIGNMENT DATE: 03/05/2015	
ERU LEAD: Brandon Adcock #710			
FIRM NAME: Claravale Farm			
ADDRESS: 33320 Panoche Road		CITY: Paicines	ZIP CODE: 95043
FIRM CONTACT: Ron Garthwaite		PHONE: [REDACTED]	OTHER CONTACT INFO: [REDACTED]
REPORTING PERSON/AGENCY: Akiko Kimura, CDPH-DCDC-IDB		PHONE: 213-620-2857	
ACTIVITY: <input type="checkbox"/> PRODUCE INVESTIGATION <input type="checkbox"/> PFR ENVIRONMENTAL <input type="checkbox"/> RETAIL ENVIRONMENTAL <input type="checkbox"/> TRACEBACK INVESTIGATION <input type="checkbox"/> TAMPERING <input type="checkbox"/> COMPLAINT <input checked="" type="checkbox"/> SAMPLING <input type="checkbox"/> TECHNICAL ASSISTANCE <input checked="" type="checkbox"/> OTHER: Outbreak Investigation			
BACKGROUND:			
<p>Claravale Farm is a licensed raw milk dairy with the California Department of Food and Agriculture (CDFA). This firm bottles raw (unpasteurized) milk from cows and goats that has not been heat-treated to kill bacteria.</p> <p>In 2012, the California Department of Public Health (CDPH), Food and Drug Branch (FDB) investigated an outbreak of <i>Campylobacter jejuni</i> associated with raw cow milk and cream produced by Claravale Farm, located in Paicines, CA. This outbreak affected 22 California residents in multiple counties and led to an environmental investigation by Food and Drug Branch (FDB). Samples of raw milk products tested positive for <i>Escherichia coli</i> O157:H7, shiga toxin producing <i>E. coli</i> non-O157, and <i>C. jejuni</i>. This investigation led to a Quarantine Order being placed by CDFA. In response to the investigation and Quarantine Order, Claravale Farm ceased operations for approximately three weeks.</p> <p>In March of 2015, CDPH, Infectious Diseases Branch (IDB) identified three patients from Santa Cruz County with <i>C. jejuni</i> infection who all reported consuming Claravale brand raw cow milk prior to their illness onset. IDB eventually identified a total of seven case patients associated with this outbreak [Marin (1), Orange (1), and Santa Cruz (5)]. An additional Marin County patient with gastrointestinal illness and Claravale brand raw cow milk exposure was identified through polymerase chain reaction (PCR) testing only and was considered a probable case. Two of these patients were hospitalized and no deaths were associated with this outbreak.</p> <p>The illness onset dates of all case patients in this outbreak ranged from February 16 to March 25, 2015. <i>C. jejuni</i> isolates were collected from three case patients and analyzed by pulsed field gel electrophoresis (PFGE). These three <i>C. jejuni</i> isolates all had the same primary enzyme PFGE pattern (Smal pattern DBRS16.0068), indicating they were genetically similar and likely shared a common source.</p> <p>Given the consumption data, along with the PFGE results, it was determined that these cases likely shared Claravale Farm brand raw cow milk as a common route of exposure to <i>C. jejuni</i> (see Attachment 1).</p> <p>After being notified of these cases, the CDPH, FDB, Emergency Response Unit (ERU) initiated an investigation including environmental sampling, product sampling at both the retail and consumer level, and traceback of implicated product in connection with these illnesses.</p>			

SUMMARY OF ACTIVITY:

Retail Product Sampling

On March 4, 2015, FDB collected nine bottles of Claravale Farm raw milk from multiple retail locations in Northern California. All samples were properly labeled and sealed, packaged into an ice chest with gel ice packs, and delivered to Food and Drug Laboratory Branch (FDLB) by a member of the ERU investigative team on March 5, 2015. FDLB analyzed these samples for *E.coli* O157:H7 and *Campylobacter* (Attachments 2 and 3).

Onsite Investigation

On March 5, 2015, ERU conducted an environmental assessment and sampling at Claravale Farm. Frank Salsa, Dairy Foods Specialist from CDFA was also present for the beginning of the inspection. The investigative team met with Claravale Farm Owners, Ron Garthwaite and Collette Cassidy. Mr. Garthwaite accompanied the team throughout the inspection and sample collection.

Layout and Facilities

The Claravale Farm dairy is located at 33320 Panoche Road, Paicines, CA. The dairy property consisted of seven areas: milk processing barn, milking herd pen, dry herd pen, larger goat herd pen, smaller goat herd pen, young calf pen and older calf pen. The milk processing barn consisted of a milk bottling room, a bottle washing room, a milk storage cooler, and a milking barn (see Attachment 4). The Claravale Farm milking herds consisted of approximately [REDACTED] Jersey cows and [REDACTED] goats. Claravale Farm also maintained a non-milking (dry) herd which included cows that had just given birth, young calves, and older calves; none of whom were being used to produce milk for distribution at the time of the investigation.

Mr. Garthwaite stated that the farm used well water supplied by an onsite well for all domestic and production uses. The onsite well was located adjacent to the milking barn. Water was stored in two above ground tanks. The well water was treated by filtration for sediment and an ultraviolet light system prior to use.

Milking Process

Claravale Farm staff milked the cows and goats twice daily. The milking processes occurred daily at approximately 0200 and 1400 hours. The goat herd was milked first, followed by the cow herd. Upon the investigation team's arrival at the dairy, they were advised that the firm had just finished milking about 30 minutes prior to their arrival. The firm was about halfway through the Clean In Place (CIP) process of sanitizing the milk lines and stopped the CIP process at the team's request to allow for environmental sampling.

The overall milking process was described by a Claravale employee as follows:

- 1) Goats were led into a receiving chute at one end of the milking barn.
- 2) Goats were led one at a time into a milking chute for milking.
- 3) Teats on the goat were dipped in an iodine solution in a blue bottle designated for pre-milking teat dip.
- 4) The teats were wiped off with a paper towel (single use) and the goat was connected to a milking machine.
- 5) After milking, the goat was disconnected from the milking equipment and its teats were dipped in a different, green bottle of the same iodine solution designated for post-milking teat dip
- 6) The teats were wiped with a paper towel.
- 7) The goat was then led out an exit chute to a second holding pen until all the goats were milked at which time they were all released to the grazing area.
- 8) Once all goats were milked, the milking system equipment was cleaned using a CIP system.
 - The CIP process on the milk lines consisted of using [REDACTED] sanitizer circulated in the system for [REDACTED].
- 9) The cows were milked in a similar manner as described above.

Sanitation

The CIP sanitation process, performed after the morning and afternoon milking sessions, was described by the employee as follows:

- 1) [REDACTED] were mixed with 10 to 12 gallons of water.
- 2) The solution was circulated through the milk pipelines for [REDACTED]

degrees Fahrenheit.

3) The system was washed with a strong acid solution.

Mr. Garthwaite provided Exhibit A outlining the CIP process. Since the CIP procedure was written in Spanish, a member of the ERU investigative team translated it with the assistance of Google Translate. The verbal description provided to the investigative team by the employee performing the operation was consistent with the written procedure provided. Mr. Garthwaite advised that, although they did not keep written records for sanitation, Claravale Farms employees washed and sanitized the milking system after each milking.

Distribution

During the investigation, management provided a list of all sales in the two months leading up to the onsite investigation (Exhibits B and C). This list showed distribution to various retailers in Northern and Southern California.

At the time of inspection a sign was observed on the street side of the milking barn indicating individual bottles of milk and raw milk cheese were available for walk-up purchase. Mr. Garthwaite stated that the firm no longer sold products to individual customers in any way and no longer sold to walk-up customers. Mr. Garthwaite stated that the cheese was made at a facility down the road; however, the firm had not sold any cheese products for "a couple years" prior to the inspection. At the time of the investigation, Claravale Farm only distributed their milk products through third party wholesale distributors.

During the inspection, the team observed a distributor receiving a shipment of milk for distribution. Crates of empty, used bottles were unloaded from a van with an apparent refrigeration unit on top and taken into the washing room in the milking barn. After unloading, crates containing filled bottles of milk were loaded from the milk storage cooler into the van. Mr. Garthwaite stated that the van observed at the time of inspection belonged to the distributor and contained products being distributed to locations in Southern California.

Samples Collected

Multiple product samples and environmental samples were collected by the investigative team. The product samples consisted of 11 raw milk product samples that were packaged in consumer bottles and were ready for shipment. These product samples included two bottles of raw cream (cow), four bottles of raw whole cow milk, three bottles of nonfat raw cow milk, and two bottles of raw goat milk. The sell by date on these product samples were March 14, 2015 and March 17, 2015 (Attachment 5 and Table 1).

A total of 106 environmental samples were also collected, including: 40 fecal samples (10 from the goat herd, 10 from the milking cow herd, and 20 from the dry cow herd and calf pens), one water sample (from the drinking water trough in the calf pen), and 65 environmental swabs from locations in and around the milking barn (Attachment 6). All samples were properly labeled and sealed, packaged into an ice chest with gel ice packs, and delivered to FDLB by a member of the ERU investigative team on March 6, 2015. FDLB analyzed the environmental samples collected for *Campylobacter* and the product samples for *Campylobacter* and *E.coli* O157:H7.

Marin County Case Patient Samples

On March 18, 2015, IDB notified ERU that a Marin County case patient (CA007) had multiple leftover raw milk samples, from the period preceding their illness onset. This case was an infant of approximately six months of age and was a probable case in this outbreak due to the causative agent being identified by PCR analysis only. The infant had been fed formula made with Claravale Farm raw milk during the period preceding the onset of illness. ERU collected the leftover raw milk samples from the case patient's home on March 19, 2015. The samples collected consisted of one closed bottle of Claravale raw whole cow milk (sell by 3/16/15), one open bottle of Claravale whole cow milk (sell by 3/16/15) and 250 mL of homemade baby formula (Attachment 7 and 8). The father of the case patient stated the formula had been made from the opened bottle of Claravale raw milk. The recipe for this baby formula was provided to the Investigator by the family, along with a photo copy of the cover of the book where the formula recipe was published (see Exhibit D). All samples were properly labeled and sealed, packaged into an ice chest with gel ice packs, and delivered to FDLB by a member of the ERU investigative team on March 19, 2015. FDLB analyzed the samples for *Campylobacter*.

Orange County Case Patient Sample

On March 30, 2015, ERU was notified by CDPH-IDB of an additional case patient in Orange County (CA009) who was associated with this outbreak. The patient reported consuming Claravale brand raw milk products daily and was later confirmed with a matching PFGE pattern to the other cases in this outbreak. Orange County Health Care Agency (OCHCA) collected an opened, one quart (1/3 full) bottle of Claravale brand raw cow milk from the home of case patient CA009 on March 30, 2015 (Attachment 9). The case patient informed OCHCA that the product was most likely purchased at Mother's Market (5759 E. Santa Ana Canyon Rd., Anaheim, CA 92807) on March 21, 2015. The sample was shipped from the OCHCA public health lab to ERU in a cooler containing gel icepacks. The sample was received on April 2, 2015, by ERU staff and the temperature was checked to confirm the sample was below 45°F. This sample was properly labeled and sealed, packaged into an ice chest with gel ice packs, and delivered to FDLB by a member of the ERU investigative team on March 21, 2015 for *Campylobacter* analysis (Attachment 10).

FINDINGS AND CONCLUSIONS:

Laboratory Results

IDB reported that all three of the clinical samples collected from case patients had matching primary enzyme PFGE pattern DBRS16.0068 (Attachment 1).

Of the 11 product samples collected at Claravale Farm on March 5, 2015, three raw cow milk samples (all sell by March 14, 2015) and one cream (cow) sample (sell by March 14, 2015) were positive for *C. jejuni*. None of the samples tested were positive for pathogenic *E. coli*. The product samples which tested positive for *C. jejuni* were also determined to have PFGE pattern DBRS16.0068 (Table 1 and Attachment 6).

Two of the 65 environmental swabs collected in the Claravale Farm Milking Barn were positive for *C. jejuni*. One of these positive samples was collected from a drain in the milking area and the other from the floor of one of the milking chutes. When analyzed by PFGE, the samples were determined to be pattern DBRS16.0014 (drain) and DBRS16.0146 (chute) as shown in Table 1 and Attachment 6. While neither of these PFGE patterns matched the clinical cases, the presence of *C. jejuni* in the milking area indicates that a pathogen was present at the time of inspection and could potentially contaminate any milk products bottled at the facility.

Eight of the 40 fecal samples collected on March 5, 2015 tested positive for *C. jejuni*. These samples were analyzed by PFGE and had multiple patterns (see Table 1 and Attachment 3). As with the environmental swab samples, these did not match the outbreak strain, but the data showed the presence of *Campylobacter* in the milking and non-milking cattle herds at the time of inspection.

All of the retail product samples collected on March 4, 2015 were negative for *Campylobacter* and *E. coli* O157:H7. The consumer samples collected March 19 and 30, 2015 were also negative for *Campylobacter*. (Attachment 2 and 3). The sell by dates of the products sampled were between March 9 and 31, 2015. These sell by dates indicated that the samples were produced after the illness onset of a majority of the cases associated with this outbreak. The case patients with illness onsets within the sell by date range of the sampled products reported daily consumption of Claravale milk; therefore, these cases were most likely exposed to earlier sell by dates of the products as well as the later dated products.

Sampling Summary

Table 1 below provides a summary of positive samples collected during this investigation and the resulting PFGE findings. Matching PFGE patterns to the outbreak strain are shaded in grey.

In summary, four (18%) of the product samples collected were positive for *C. jejuni*. All four of the product positive samples were determined to be a genetic match by PFGE to the isolates from the three case patients. Additionally, two samples out of the 65 environmental swabs (3%) and eight out of the 40 feces samples (20%) tested positive for *C. jejuni*, however, PFGE results indicate that these positive samples were not a genetic match to the outbreak strain.

Table 1 – Product and environmental samples found positive for *Campylobacter jejuni*.

Sample ID	Sample Type	Date Collected	Location Collected	Description	PFGE Pattern
710030515-F011	Feces	3/5/15	Claravale Farm – Milking Cow Pen	East side, near water trough	DBRS16.0035
710030515-F012	Feces	3/5/15	Claravale Farm – Milking Cow Pen	Cow 3612, East side, near water trough	DBRS16.0146/ DBRK02.1412
710030515-F016	Feces	3/5/15	Claravale Farm – Milking Cow Pen	West side, near hay bales	DBRS16.0085
710030515-F020	Feces	3/5/15	Claravale Farm – Milking Cow Pen	Cow # 333, East side, near hay bales	DBRS16.0008/ DBRK02.0028
710030515-F021	Feces	3/5/15	Claravale Farm – Dry Cow Herd Pen	Near entrance	DBRS16.0146/ DBRK02.1412
710030515-F022	Feces	3/5/15	Claravale Farm – Dry Cow Herd Pen	Near South end of small pen	DBRS16.0146/ DBRK02.1412
710030515-F023	Feces	3/5/15	Claravale Farm – Dry Cow Herd Pen	Middle of pen; North side	DBRS16.0146/ DBRK02.1412
710030515-F024	Feces	3/5/15	Claravale Farm – Dry Cow Herd Pen	Cow # 377 middle of pen; North side	DBRS16.0014
710030515-E003	Environmental Swab	3/5/15	Claravale Farm – Milking Area	Drain canal	DBRS16.2765
710030515-E008	Environmental Swab	3/5/15	Claravale Farm – Milking Area	Floor area of chute 3	DBRS16.0146/ DBRK02.1412
710030515-P002	Product	3/5/15	Claravale Farm	Raw cream (cow) – Sell By 3/14/15	DBRS16.0068*
710030515-P004	Product	3/3/15	Claravale Farm	Raw whole milk (cow) – Sell By 3/14/15	DBRS16.0068
710030515-P005	Product	3/5/15	Claravale Farm	Raw whole milk (cow) – Sell By 3/17/15	DBRS16.0068
710030515-P006	Product	3/5/15	Claravale Farm	Raw whole milk (cow) – Sell By 3/17/15	DBRS16.0068

* Pulsed Field Gel Electrophoresis (PFGE) pattern matching clinical isolates.

Conclusions

During this investigation, FDB determined that raw milk products produced by Claravale Farm were contaminated with *C. jejuni*. Potentially contaminated raw milk was distributed to retail locations throughout California and likely led to *Campylobacter* infections in at least seven California residents. In addition to the raw cow milk and cream samples; cow feces collected from the milking herd and non-milking herd, as well as environmental swab samples collected in the milking area, tested positive for *Campylobacter*. While these environmental samples did not match clinical cases by PFGE, the presence of the pathogen in the milking area and cow herd feces indicated that the product could potentially become contaminated and persist in the finished product due to a lack of pasteurization or other treatment to reduce pathogens. All case patient isolates analyzed had a PFGE pattern matching those found in the finished raw milk products collected at Claravale Farm. This evidence indicated the same strain of bacteria was present in the case patients and finished raw milk from Claravale Farm.

In response to FDB's finding of *C. jejuni* in Claravale raw milk products, CDFA issued Claravale Farm a Quarantine Order on March 21, 2015. The Quarantine Order resulted in a recall of all raw milk produced by Claravale Farm and the temporary cessation of production at the dairy.

In response to this recall, the ERU recall team contacted nine distributors and obtained distribution lists including 156 retail locations that sold the recalled product in California. The ERU recall team compiled a list of retail customers (Attachment 11) and published the list to the California Food Recall webpage, along with a California Recall Information Sheet (Attachment 12).

As a result of FDB's investigational findings, the firm conducted additional fecal testing of the cows and removed any *Campylobacter* infected cows. The farm staff was also re-trained on cleaning and sanitizing procedures. After correcting conditions to the satisfaction of CDFA regulators and providing three consecutive negative milk samples to CDFA, Claravale Farm was permitted to resume the distribution of raw milk on April 27, 2015.

SUPPORTING DOCUMENTATION:

Attachments

- Attachment 1: Case Patient Line List
- Attachment 2: Evidence Receipts - Retail Sampling
- Attachment 3: Master Laboratory Reporting Sheet – Retail Samples
- Attachment 4: Claravale Farm Facility Map and Sampling Locations
- Attachment 5: Evidence Receipt - Claravale Samples
- Attachment 6: Master Laboratory Reporting Sheet – Claravale
- Attachment 7: Master Laboratory Reporting Sheet – Marin County Samples
- Attachment 8: Evidence Receipt - Marin County Case Patient Sample
- Attachment 9: Evidence Receipt - Orange County Case Patient Sample
- Attachment 10: Master Laboratory reporting Sheet – Orange County Sample
- Attachment 11: California Retail Distribution List for Recall
- Attachment 12: California Recall Information Sheet

Exhibits

- Exhibit A: Claravale CIP Process with translation
- Exhibit B: Claravale Distribution Records for February, 2015
- Exhibit C: Claravale Distribution Records for March, 2015
- Exhibit D: Raw Milk Baby Formula Recipe

ERU ELECTRONIC FILE LOCATION:

J:\ERU\Investigations\Investigations 2015\15006_Claravale_RawMilk_campy_IDB_030215\REPORTS

ENFORCEMENT ACTIONS: NOV ISSUED EMBARGO VC&D REG LETTER REFERRAL
 OTHER: CDFA Dairy Quarantine

RECOMMENDATIONS: NAI MINOR VIOLATIONS / FIRM CORRECTING
 OTHER: Monitor for additional *C. jejuni* illnesses.

COMMENTS / FOLLOW-UP ACTION:

CDPH to continue monitoring for additional clusters of campylobacterosis or *E. coli* infections associated with the consumption of raw dairy products.

ERU LEAD SIGNATURE:
Brandon Adcock

INV.#
710

REPORT DATE:
8/14/15

SUPERVISOR SIGNATURE:
Amber Barnes #171

DATE REVIEWED:
8/14/15

SUPERVISOR DISPOSITION:

Continue to work with IDB and monitor for new cases of C. jejuni.

(8/28/08- ERU ACTIVITY SUMMARY FORM)