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

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**Final Report**

September 2015

Prepared by:

California Department of Public Health, Food and Drug Branch

Emergency Response Unit - Food Safety Inspection Unit

California Department of Public Health

Food and Drug Branch

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### ERU ACTIVITY SUMMARY REPORT

<b>INVESTIGATION NAME:</b> 15020 Claravale RawGoatMilk Campy IDB 052715		<b>ASSIGNMENT DATE:</b> June 3, 2015										
<b>ERU LEAD:</b> Mario Velasquez												
<b>FIRM NAME:</b> Claravale Farm												
<b>ADDRESS:</b> 33320 Panoche Road		<b>CITY:</b> Paicines	<b>ZIP CODE:</b> 95043									
<b>FIRM CONTACT:</b> Ron Garthwaite		<b>PHONE:</b> [REDACTED]	<b>OTHER CONTACT INFO:</b> [REDACTED]									
<b>REPORTING PERSON/AGENCY:</b> Akiko C. Kimura, MD, CDPH-IDB		<b>PHONE:</b> 213-620-2857										
<p><b>ACTIVITY:</b></p> <table style="width: 100%; border: none;"> <tr> <td><input type="checkbox"/> PRODUCE INVESTIGATION</td> <td><input type="checkbox"/> PFR ENVIRONMENTAL</td> <td><input type="checkbox"/> RETAIL ENVIRONMENTAL</td> </tr> <tr> <td><input type="checkbox"/> TRACEBACK INVESTIGATION</td> <td><input type="checkbox"/> TAMPERING</td> <td><input type="checkbox"/> COMPLAINT <input checked="" type="checkbox"/> SAMPLING</td> </tr> <tr> <td><input type="checkbox"/> TECHNICAL ASSISTANCE</td> <td colspan="2"><input checked="" type="checkbox"/> OTHER: Outbreak Investigation</td> </tr> </table>				<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	
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<b>BACKGROUND:</b>												
<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 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 February and March 2015, CDPH investigated another outbreak of <i>C. jejuni</i> associated with raw cow milk produced by Claravale Farm. This outbreak affected seven California residents in multiple counties and led to an environmental investigation by FDB. Samples of raw cow milk products tested positive for <i>C. jejuni</i>. This investigation also led to a Quarantine Order being placed by CDFA. In response to this investigation and Quarantine Order, Claravale Farm ceased operations for over one month.</p> <p>This investigation report details a <i>C. jejuni</i> outbreak that began in late May 2015, when the CDPH, Infectious Diseases Branch (IDB) identified a patient with <i>C. jejuni</i> infection who reported consuming Claravale brand raw goat milk prior to their illness onset. IDB eventually identified a total of five case patients with <i>C. jejuni</i> infection [(Orange (3), Ventura (1), and Yolo (1)], who all reported consuming Claravale brand raw goat milk prior to their illness onsets. Although not culture-confirmed, an additional San Francisco resident reported gastrointestinal illness after consuming Claravale brand raw goat milk and was identified as a "suspected" case in this outbreak. The illness onset dates of all case patients in this outbreak were from May 18 to May 26, 2015. One case patient was hospitalized and no deaths were reported. <i>C. jejuni</i> isolates were collected from two case patients and analyzed by pulsed field gel electrophoresis (PFGE). Both <i>C. jejuni</i> isolates had the same primary enzyme PFGE pattern DBRS16.0067. One of these clinical isolates was tested by a secondary enzyme, and exhibited pattern DBRK02.1523. This indicated the bacteria isolated from these patients was genetically similar and likely shared a common source. All five case patients reported consumption of Claravale Farm brand raw goat milk during the period preceding their onset of campylobacteriosis. Given this food history, along with the PFGE data, it was determined that these cases likely shared Claravale Farm brand raw goat milk as a common route of exposure to <i>C. jejuni</i> (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 June 3, 2015, ERU collected 10 bottles of Claravale Farm raw milk (3 cow milk and 7 goat 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 the CDPH Food and Drug Laboratory Branch (FDLB) by a member of the FDB investigative team. FDLB analyzed these samples for *Campylobacter* (Attachment 2 and 3).

### **Onsite Investigation / Sample Collection**

On June 3, 2015, FDB collected raw milk product samples directly from Claravale Farm. Twenty one samples consisting of 10 quarts of raw goat milk, five quarts of raw whole cow milk, five pints of raw cow cream, and one quart of raw goat milk from the bulk tank were collected for microbiological testing. 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 FDB investigative team. FDLB analyzed these samples for *Campylobacter* (Attachment 4 and 5).

On June 9, 2015, ERU conducted an investigation and environmental sampling at Claravale Farm. The investigative team met with Claravale Farm owners, Ron Garthwaite and Collette Cassidy. Mr. Garthwaite accompanied the team throughout the inspection and sample collection. The layout of the facilities, water supply, general milking process, sanitation, and product distribution had not changed since the previous investigation in March 2015.

Multiple product and environmental samples were collected by the investigative team on June 9, 2015. The product samples included three bottles of raw cow cream that were packaged and ready for shipment. In addition three samples of raw goat milk were aseptically collected from the bulk tank in the bottling room using 100 ml sterile vials. Thirty three environmental samples were also collected, including: 30 goat fecal samples and three environmental swabs (from floor drains in the Milking Barn, Clean-in-Place (CIP) room, and the Milk Bottling Room). 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. FDLB analyzed the product and environmental samples for *Campylobacter* (Attachment 6 and 7).

### **Orange County Case Patient Sample**

On June 1, 2015, ERU was notified by IDB that an Orange County case patient (CA002) had a leftover container of homemade formula manufactured using Claravale Farm raw goat milk. This formula had been consumed by the case patient (approximately five months old) prior to illness onset. Orange County Health Care Agency (OCHCA) collected the leftover formula sample and two empty Claravale Farm raw goat milk bottles from the case patient's home. The left over formula sample and two empty bottles were transferred to ERU on June 3, 2015. The sample of formula 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 June 3, 2015. FDLB analyzed the sample for *Campylobacter* (Attachment 8 and 9).

### **San Francisco County Case Patient Sample**

On June 2, 2015, ERU was notified by CDFA of an illness complaint from a San Francisco County resident. This resident and her son (15 months old) both consumed Claravale Farm raw goat milk and reported becoming ill. Although this case patient and her son were never confirmed to be part of this outbreak, they were listed as "suspect" cases due to their food consumption history and reported illness. ERU collected an opened, 1 quart (1/4 full) bottle of Claravale brand raw goat milk from this suspect case patient's home on June 3, 2015. The suspected case patient purchased the Claravale Farm raw goat milk from Noriega Produce Market in San Francisco, CA on May 22, 2015. 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 for *Campylobacter* analysis (Attachment 10 and 11).

## FINDINGS AND CONCLUSIONS:

### Laboratory Results

IDB reported that two of the clinical samples collected from case patients that had been analyzed by PFGE were determined to have the same primary enzyme (SmaI) PFGE pattern DBRS16.0067. One of these clinical isolates was available for testing by a secondary enzyme. This case's secondary PFGE enzyme exhibited pattern DBRK02.1523. Results were reported on a line listing provided by IDB (Attachment 1).

Ten samples of Claravale Farm raw milk products (cow and goat) were collected from retail markets on June 3, 2015. One of these Claravale Farm raw goat milk samples (Investigator sample (IS) #191060315-P010/Sell-by June 01), that was collected at Mollie Stone's market in Greenbrae, California tested positive for *C. jejuni*. The PFGE pattern of this sample was DBRS16.0067/ DBRK02.1523. This PFGE pattern matched those identified by first and second enzyme in clinical cases, goat feces samples from Claravale Farm, and an additional sample of Claravale Farm raw goat milk collected from a suspect case patient in San Francisco County. An invoice and delivery records traceback confirmed delivery of Claravale farm raw milk products to Mollie Stone Market (Attachment 12).

Twenty one samples of Claravale Farm raw milk products (cow and goat) were collected from Claravale Farm on June 3, 2015. These samples tested negative for *C. jejuni*.

One sample of homemade formula manufactured using Claravale Farm raw goat milk was collected by OCHCA on June 1, 2015. The formula was submitted to FDLB for *Campylobacter* testing on June 3, 2015. This sample tested negative for *Campylobacter*.

One sample of a partially consumed bottle of Claravale Farm raw goat milk (1 quart, approximately ¼ full, Sell-by June 01) was collected from a suspect case patient's home in San Francisco County on June 3, 2015 (Attachment 10). This sample of milk tested positive for *C. jejuni* and was assigned PFGE pattern DBRS16.0067/ DBRK02.1523 (Table 1 and Attachment 11). This PFGE pattern matched those identified by first and second enzyme in clinical cases, goat feces samples from Claravale Farm, and the sample of Claravale Farm raw goat milk collected at Mollie Stone's in Greenbrae, California. An invoice and delivery records traceback confirmed delivery of Claravale farm raw milk products to Noriega Produce Market. (Attachment 13)

Three raw goat milk samples (bottled and ready for shipping) and three raw goat milk samples from the bulk tank were collected at Claravale Farm on June 9, 2015. These samples tested negative for *C. jejuni*.

Three environmental swabs were collected from Claravale Farm on June 9, 2015. These samples tested negative for *C. jejuni*.

Thirty goat feces samples were collected from Claravale Farm on June 9, 2015. These samples were submitted to FDLB and composited into 10 samples (3 goat feces per test run). One of the composited feces samples (IS #194060315E010-E012) tested positive for *C. jejuni*. Two isolates were collected from this composited positive sample and were assigned PFGE patterns DBRS16.0067/ DBRK02.1523 and DBRS16.2599/ DBRK02.1523. The first PFGE pattern (DBRS16.0067 / DBRK02.1523) matched those identified by first and second enzyme in clinical cases, Claravale Farm raw goat milk collected from a "suspect" case patient in San Francisco County, and Claravale Farm raw goat milk collected from Mollie Stone's in Greenbrae, California (See Table 1 below and Attachment 3, 7, and 11).

### Sampling Summary

In summary, 2 of 38 (5%) product samples collected tested positive for *C. jejuni*. These positive samples were PFGE matched to the two clinical case patients and fecal samples collected from goats at Claravale Farm. The PFGE matches between the product samples and clinical isolates, when combined with the reported food history, indicated that the case patients likely contracted the *C. jejuni* that caused their illness from consuming contaminated Claravale Farm goat milk. See Table 1 below, for a summary of positive samples collected during this investigation and the associated PFGE patterns. PFGE patterns matching the outbreak strain are shaded.

Table 1 – Samples found positive for *Campylobacter jejuni*.

Sample ID	Sample Type	Date Collected	Location Collected	Description	PFGE Pattern sMAI/ KPNI
194060315-P001	Product	6/3/15	Consumer Residence- San Francisco	Claravale Farm Grade A Raw Pure Goat Milk – June 01	DBRS16:0067/ DBRK02:1523
191060315-P010	Product	6/3/15	Mollie Stone, 270 Bon Air Center, Greenbrae	Claravale Farm Raw Goat Milk, Pure Goat Milk – June 01	DBRS16:0067/ DBRK02:1523
194060915-E010-E012	Feces	6/9/15	Claravale Farm Goat Area, Small Pen	Composited goat fecal sample	DBRS16:0067/ DBRK02:1523
194060915-E010-E012	Feces	6/9/15	Claravale Farm Goat Area, Small Pen	Composited goat fecal sample	DBRS16.2599/ DBRK02.1523

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

**Conclusions**

During this investigation, FDB determined that raw goat milk products produced by Claravale Farm were contaminated with *C. jejuni*. Potentially contaminated raw goat milk was distributed to retail locations throughout California and likely led to *Campylobacter* infections in at least five California residents. In addition to the raw goat milk samples, goat feces collected from the milking herd also tested positive for *Campylobacter*. One composited sample of goat feces matched the clinical cases by PFGE. All case patient isolates analyzed had a PFGE pattern matching those found in the finished raw goat milk collected at a retail location, from an open container of goat milk from a consumer, and from goat feces collected at Claravale Farm. This evidence indicated the same strain of bacteria was present in the case patients and finished raw goat milk from Claravale Farm.

In response to this investigation, Claravale Farm stopped bottling raw goat milk on June 3, 2015. Claravale Farm resumed bottling goat milk on June 18, 2015 after completing an internal investigation regarding goats infected with *Campylobacter*.

**SUPPORTING DOCUMENTATION:**

Attachments

- Attachment 01: Case patient line list
- Attachment 02: Evidence receipt for Claravale Farm retail milk samples collected June 3, 2015
- Attachment 03: Master laboratory reporting sheet – retail milk samples collected June 3, 2015
- Attachment 04: Evidence receipt for Claravale Farm milk samples collected June 3, 2015
- Attachment 05: Master laboratory reporting sheet - Claravale Farm milk samples collected June 3, 2015
- Attachment 06: Evidence receipt for Claravale Farm samples collected June 9, 2015
- Attachment 07: Master laboratory reporting sheet - Claravale Farm samples collected June 9, 2015
- Attachment 08: Evidence receipt for Orange County case patient goat milk samples received June 3, 2015
- Attachment 09: Master laboratory reporting sheet – Orange County goat milk sample received June 3, 2015
- Attachment 10: Evidence receipt for San Francisco suspected case patient goat milk sample
- Attachment 11: Master laboratory reporting sheet – San Francisco County goat milk sample
- Attachment 12: Traceback – invoice and delivery receipts of Claravale Farm goat milk to Mollie Stone Market
- Attachment 13: Traceback - invoice and delivery receipts of Claravale Farm goat milk to Noriega Market


**ERU ELECTRONIC FILE LOCATION:** J:\ERU\Investigations\Investigations 2015\15020\_Claravale\_RawGoatMilk\_Campy\_IDB\_052715\REPORTS\FINAL\

**ENFORCEMENT ACTIONS:**  NOV ISSUED  EMBARGO  VC&D  REG LETTER  REFERRAL

OTHER: N/A

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

**COMMENTS / FOLLOW-UP ACTION:**  
CDPH to continue to monitor for additional clusters of campylobacteriosis infections associated with the consumption of raw dairy products.

<b>ERU LEAD SIGNATURE:</b> Mario Velasquez 	<b>INV.#</b> 194	<b>REPORT DATE:</b> 9/9/15
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<b>SUPERVISOR SIGNATURE:</b> Amber Barnes #171 	<b>DATE REVIEWED:</b> 9/11/15
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**SUPERVISOR DISPOSITION:**  
Continue to work with IDB and monitor for new cases of *C. jejuni*.

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