

**Environmental Investigation of the *Escherichia coli* O157:H7 Outbreak in
California Associated with Raw Whole Milk, Fall 2011**

Final Report

March 2012

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Agencies

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

Dates of Investigation

November 15 – 16, 2011 and December 13, 2011

Executive Summary

On November 9, 2011 the California Department of Public Health (CDPH), Food and Drug Branch (FDB) was contacted by CDPH Infectious Diseases Branch (IDB) regarding a cluster of five *Escherichia coli* O157:H7 cases. All the case patients were five years of age or younger and lived in Contra Costa (2), Kings (1), Sacramento (1), and San Diego (1) Counties. The illness onset dates for the five case patients ranged from August 25, 2011 to October 25, 2011. The Pulsed-Field Gel Electrophoresis (PFGE) pattern was reported as EXHX01.2294 / EXHA26.0071 with a Centers for Disease Control and Prevention (CDC) cluster code of 1111CAEXH-1. Three of the five children were hospitalized with hemolytic uremic syndrome (HUS).

Parents of the case patients were interviewed by public health staff regarding possible exposures to *E. coli*. Standard case report forms for all Shiga toxin producing *E. coli* cases in California indicated that all children had exposure to raw milk. The supplemental questionnaire verified that case patients consumed Organic Pastures Dairy Company (OPDC) raw whole milk or home-produced kefir made from OPDC raw whole milk prior to illness onset.

Based on the strength of epidemiological information, the data provided by CDC FoodNet, and other sources regarding *E. coli* infections and raw milk consumption, investigative and scientific staff from CDPH-FDB and inspectors with the California Department of Food and Agriculture (CDFA) initiated an environmental investigation at OPDC on November 15, 2011.

CDFA inspectors issued a “Notice of Required Action Pursuant to Quarantine” on November 15, 2011. This quarantine order prevented OPDC from selling, “All package sizes, flavors, types, and varieties of all raw milk and raw dairy products (except for cheese aged a minimum of 60 days), including but not limited to raw, whole milk; raw, skim milk; raw cream, raw butter, and all raw colostrum products and raw products labeled as Qephor”. The quarantine order also necessitated the removal of listed products from retail locations. A recall of all products documented in the “Notice of Required Action Pursuant to Quarantine” was initiated by OPDC on November 15, 2011.

During the course of this investigation, FDB Investigators collected a total of 172 samples consisting of 10 (1 pint) bottles of packaged colostrum, 5 soil, 14 water, 84

sponge swabs, and 59 feces (cow and calf). The packaged colostrum samples were analyzed for *E. coli* O157:H7 and *Campylobacter*. One sample of colostrum (IS#162111511P1) tested positive for pathogenic *E. coli* O8, O25:H28. All packaged colostrum samples were negative for *Campylobacter*. The soil, water, sponge swabs, and feces samples were analyzed for *E. coli* O157:H7. Ten samples from the calf area consisting of soil, water, a sponge swab, and calf feces were positive for *E. coli* O157:H7. Two of the ten samples, consisting of soil and calf feces, were determined to genetically match the outbreak strain of the case patients by two enzymes (*Xba*I and *Bln*I).

Background Information

In November 2011, a foodborne outbreak of *E. coli* O157:H7 was epidemiologically linked to OPDC in Fresno, CA. Five confirmed cases were reported by IDB. A confirmed case was defined by IDB as, "...laboratory-confirmed *E. coli* O157:H7 infection with cluster-strain PFGE pattern (*Xba*I EXHX01.2294/*Bln* EXHA26.0071) in a California resident with illness onset on or after July 1, 2011."

A previous *E. coli* outbreak investigation conducted by CDPH in 2006 isolated *E. coli* O157:H7 from OPDC dairy cattle. The PFGE pattern combination and the pattern isolated from cattle fecal samples for the 2006 outbreak differed from the current outbreak.

Traceback of Implicated Lots

Parents of case patients were interviewed (due to the age of children) to determine potential *E. coli* O157:H7 exposures. In each case, parents reported that their children drank OPDC raw whole milk or consumed home-produced kefir made from OPDC raw whole milk in the week prior to their illness onset dates. The range of illness onset dates for the case patients was reported as August 25, 2011 to October 25, 2011 (Attachment 1). Based on the information available, the range of exposure dates (i.e. 1 – 10 day window prior to the onset of illness) was determined for the five case patients.

IDB reported where each case patient (parent of case patient) had purchased OPDC raw whole milk. Invoices were collected by FDB verifying delivery of raw whole milk by OPDC to the reported retail locations. Periods of distribution were determined in consideration of the following points: (1) dates of illness onset, (2) estimated dates of consumption as reported by the parents of cases, (3) product shelf life (15 days), and (4) estimated delivery schedules (1 – 2 day delivery period).

Specific case patient information is listed below:

Case patient #1 consumed OPDC raw whole milk purchased between August 11, 2011 and August 25, 2011 from Henry's Farmers Market located at 1327 Encinitas Blvd., Encinitas, CA, or from "Jimbo's ...Naturally!" located at 12853 El Camino Real, San

Diego, CA or “Jimbo’s ...Naturally!” located at 10511 4-S Commons #155, San Diego, CA. The interviewed parent could not recall the product expiration date. Invoices showing OPDC product delivery of raw milk products to Henry’s Farmers Market and “Jimbo’s ...Naturally!” were included as Attachment 2A and 2B.

Case patient #2 consumed OPDC raw whole milk purchased on August 19, 2011 at Revive Café and Whole Farms Market located at 1807 Broadway, Fresno, CA. The interviewed parent could not recall the product expiration date and did not have a receipt. Invoices showing OPDC product delivery of raw milk products to Revive Café and Whole Farms Market were included as Attachment 2C.

Case patient #3 consumed OPDC raw whole milk purchased from Sprouts Farmers Market located at 8211 Laguna Blvd., Elk Grove, CA. The interviewed parent did not have a receipt, could not recall the date the product was purchased, and did not know the product expiration date. The illness onset date of September 14, 2011 was used by FDB to determine a probable purchase date of raw milk between August 20, 2011 and September 13, 2011. Invoices showing OPDC product delivery of raw milk products to Sprouts Farmers Market in Elk Grove were included as Attachment 2D.

Case patients #4 and #5 (siblings) consumed kefir products manufactured from OPDC raw whole milk purchased on September 28, 2011 at Lunardi’s located at 1600 Palos Verdes Mall, Walnut Creek, CA. The product expiration date was reported as October 12, 2011. Invoices showing OPDC product delivery of raw milk products to Lunardi’s were included as Attachment 2E.

The illness onset period and shelf-life of OPDC raw whole milk precluded FDB from identifying the contamination of OPDC raw whole milk to a particular lot code or expiration date. Based on available data, OPDC raw whole milk contaminated with *E. coli* O157:H7, was likely bottled and distributed at least three times to account for illness onset dates ranging from August 25, 2011 through October 25, 2011.

A traceback summary chart (Table 1) is provided below, and a traceback diagram can be found in Attachment 3.

Table 1 – Traceback summary of raw whole milk produced by Organic Pastures Dairy Company and linked to five *Escherichia coli* O157:H7 illnesses in California

Case Patient	Illness Onset	Location of OPDC Raw, Whole Milk Purchase	Purchase Date	Product Expiration Date	Associated Invoices from OPDC	Attachment Number
#1	8/24/2011	Henry's Farmers Market 1327 Encinitas Blvd., Encinitas (now known as Sprouts Farmers Market) or Jimbo's ...Naturally! 10511 4-S Commons #155, San Diego Jimbo's ...Naturally! 12853 El Camino Real, San Diego	8/11/2011 – 8/25/2011	Unknown	Henry's Farmers Market – Invoice #80401 8/2/2011 #80424 8/9/2011 #80460 8/16/2011 #80491 8/23/2011 Jimbo's ...Naturally! - Invoice #44639 8/18/2011 #44594 8/11/2011 #44544 8/4/2011 Jimbo's ...Naturally! – Invoice #80493 8/24/2011 #80463 8/16/2011 #80427 8/9/2011 #80404 8/2/2011	Attachment 2B – pages 2-5 Attachment 2A – pages 12-14 Attachment 2A – pages 24-27
#2	8/27/2011	Revive Café and Whole Farms Market 1807 Broadway, Fresno	8/19/2011	Unknown	Invoice #73805 8/17/2011 #63535441 8/12/2011	Attachment 2C – pages 10-11
#3	9/14/2011	Sprouts Farmers Market 8211 Laguna Blvd., Elk Grove	Unknown (determined to be 8/20/2011 to 9/13/2011 based on reported onset date)	Unknown	Invoice #23359 8/24/2011 #23404 8/31/2011 #23443 9/7/2011	Attachment 2D – pages 1-3
#4	10/25/2011	Lunardi's 1600 Palos Verdes Mall, Walnut Creek	9/28/2011	10/12/2011	Invoice #23559 9/27/2011	Attachment 2E – page 3
#5	10/29/2011	Lunardi's 1600 Palos Verdes Mall, Walnut Creek	9/28/2011	10/12/2011	Invoice #23559 9/27/2011	Attachment 2E – page 3

Environmental Investigation

Organic Pastures Dairy Company

Mark McAfee, CEO
7221 South Jameson Avenue
Fresno, CA 93706

FDB conducted an environmental investigation at OPDC, a Limited Liability Company with Mark McAfee listed as CEO. OPDC was a raw milk dairy that manufactured raw whole milk, raw skim milk, raw butter, raw cream, raw colostrum, raw Qephor (cultured colostrum), and cheese. The milk and colostrum were produced daily. Beef, almonds, and shell eggs were also sold by OPDC directly to consumers.

During this investigation, approximately [REDACTED] cattle were present on OPDC property with a milking herd of [REDACTED] cows and a dry herd (non-milking cows) of [REDACTED] cows. The OPDC property consisted of three areas including the calf area, mobile milking trailer, and main processing location adjacent to South Jameson Avenue. The main processing location consisted of general office space, a retail sales counter, milk silos, milk bottling room, milk storage room, Qephor (commonly spelled kefir) manufacturing room, and cheese manufacturing room. The majority of buildings located in this area were semitrailers that had been converted into non-moving processing facilities.

Investigators and inspectors from FDB and CDFA met with Mr. Mark McAfee at OPDC on November 15, 2011. Mr. McAfee was advised of the current foodborne illness outbreak epidemiologically linked to OPDC raw whole milk. CDFA inspectors issued a “Notice of Required Action Pursuant to Quarantine” (Attachment 4) which prevented OPDC from selling, “All package sizes, flavors, types, and varieties of all raw milk and raw dairy products (except for cheese aged a minimum of 60 days), including but not limited to raw, whole milk; raw, skim milk; raw cream, raw butter, and all raw colostrum products and raw products labeled as Qephor”. The quarantine order also necessitated the removal of listed products from retail locations. Mr. McAfee signed the quarantine order and indicated that the packaging and distribution of raw dairy products would cease immediately. Mr. McAfee also stated that he would initiate a recall of all products listed under the quarantine order (Attachment 5).

Dairy Operations

Throughout this investigation, FDB investigators were accompanied at different times by Mark McAfee, CEO; Aaron McAfee, COO; and/or Luis Hernandez, Creamery Manager.

Calf and Cow Operations

The calf area consisted of approximately one acre of fenced pasture (directly adjacent to South Jameson Avenue) and calf pens located between the office and calf-grazing area. Mr. Aaron McAfee reported the following regarding OPDC herd management and milk and colostrum production:

Newborn calves were removed from their mother after nursing for approximately 12 hours and transported by trailer to outdoor wood crates adjacent to the calf pasture. The calves were maintained in these crates from 0 – 3 months of age and were fed a mixture of colostrum and line loss milk. The line loss milk was collected daily directly from the milking equipment in the mobile milking facility prior to sanitation. Colostrum was collected from cows daily prior to milking the general herd. The wooden calf crates were routinely pressure washed, allowed to dry, and moved to dry ground in the calf area. Fresh bedding was added as needed. The wooden crates appeared to be maintained in sanitary condition. The floors and walls of the calf crates appeared to be cleaned routinely.

At four months of age, the calves were transferred from the wooden crates to the calf-grazing area. At approximately 12 months, the male calves were sold for slaughter. At approximately 14 months, the female calves were removed from the calf-grazing area and placed with the herd to be impregnated.

Mr. Aaron McAfee reported that prior to October 2011 all calves were being sold to a third-party for use in other dairies or to be slaughtered. After October 2011, male calves were sold for slaughter and female calves were raised by OPDC and integrated into the OPDC milking herd.

Heifers (young cows that had yet to produce a calf) were bred to bulls as early as 14 months of age and gave birth approximately nine months later. The impregnated heifers were maintained in the dry herd until they gave birth. After giving birth, the heifers produced colostrum for approximately seven days and then produced milk. Within approximately 24 hours of giving birth, heifers were marked with paint (to identify cows producing colostrum) and returned to the milking herd for daily milking.

Cows (mature females) were bred to bulls while still producing milk from a previous birth. These cows continued to produce milk from day one to day 210 of the pregnancy. At approximately day 210, the cow was moved from the milking herd to the dry herd and was not milked again until day 270. The cow gave birth in the dry herd around day 270.

Written Standard Operating Procedures (SOPs) regarding employee and equipment movement between the calf area, bottling facility, and mobile milking trailer were not maintained by OPDC. Employees from the mobile milking trailer transported the colostrum from the milk transport trailer to the cold storage room adjacent to the milk bottling room. These employees also transported colostrum and milk from the mobile milking trailer to the calves for daily feeding.

Mobile Milking Trailer – Milking Operation

The mobile milking trailer could be moved to multiple areas throughout the pastures owned by OPDC. The mobile milking trailer was pulled by a tractor and then positioned in a pit adjacent to a shade structure (Attachment 6). Twice daily, cows entered the

shade structure and waited for an open milking station. Guided by gates and fences, cows entered the milking area and were prepared for milking as follows:

- The cow teats were rinsed with water from a hose, wiped with a clean towel, and then an iodine-based sanitizer was applied.
- Milk was expressed from the cow teats onto the hand of the milking employee. The expressed milk was visually inspected and tasted. If the milk passed the sensory exams, the cow was ready to be milked.
- The milking claw was then attached to the cow teats and the automated milking process began.
- Milk was pulled from the teats of each cow using a vacuum system. The milk was then transferred by pump through a heat exchanger to lower the milk temperature and subsequently pumped to a milk transport trailer outside of the mobile milking trailer.
- After milking, the milk transport trailer was towed to the milk storage silo adjacent to the bottling room.

Mobile Milking Trailer – Colostrum Operation

In addition to raw milk, OPDC produced raw colostrum to feed calves and to be bottled for human consumption. Once calves were removed from their mothers (12 hours after birth), colostrum was collected from cows for approximately seven days. On day one, the milking cows produced almost entirely colostrum. Colostrum production decreased to approximately 50% colostrum and 50% milk by day three. On day seven the cow produced mostly milk with minimal colostrum. Approximately █% of all raw colostrum produced at OPDC was used to feed calves. The remaining █% of raw colostrum was bottled for human consumption. The colostrum was not pasteurized before packaging and distribution.

The collection of colostrum from cows was similar to the standard milking operation. Cows producing colostrum were milked before the milk producing cows. The colostrum was pumped to stainless steel collection containers in the mobile milking trailer. The covered containers of colostrum were then stored in the mobile milking trailer until the milking operation was completed. After collecting milk (approximately two hours), the colostrum was placed in plastic storage containers on the front of the milk transport trailer. The colostrum and milk (inside the milk transport trailer) were then towed by tractor to the milk storage silo area. An employee from the mobile milking trailer then transferred the colostrum from the milk transport trailer to the cold storage room adjacent to the milk bottling room. The colostrum was then filled and capped by machine before being stored for distribution.

The mobile milking trailer was observed in poor sanitary condition. The red hoses used for sanitation and to rinse cow udders were encrusted with black material. The iodine bucket used to hold the iodine application devices had an accumulation of brown material on the interior and exterior surfaces. The interior walls and floors of the milking trailer had an accumulation of rust and mud (Attachment 6 and 7).

Processing Location – Milk Bottling

The raw milk from the mobile milking trailer was transported to the silo storage area adjacent to South Jameson Avenue. The milk was then pumped from the trailer to refrigerated milk storage silos maintained at less than █ °F. The milk was pumped through a commercial filter to remove any large particles and transferred to the bottling room where it was filled into plastic bottles using an automated filler and capper. Once capped and labeled, the milk was stored in cold storage (less than █ °F) adjacent to the bottling room (Attachment 6).

Sanitation procedures in the milk bottling room were described by Mr. Aaron McAfee. Soap and hot water was used on all food contact surfaces. Standard dishwashing practices for all equipment that could be washed in a sink were used by OPDC. Chemical sanitizers were not used on any food contact surfaces in the bottling room. However, OPDC does utilize a clean-in-place (CIP) system using hot water (temperatures above █ °F) for the automated bottling equipment. Equipment sanitation took place at the end of the day and was conducted by OPDC employees.

Numerous deficiencies were noted within the milk bottling and milk storage rooms including the filler and capper operations. The six head filler had numerous areas of chipping paint and the capper had areas of flaking rust and chipping paint. Flying insects were noted in multiple areas of the milk bottling room including on food processing equipment. Rodent droppings were observed on the floor in the milk storage room and cleaned white buckets (used to store colostrum) were being stored on a piece of cardboard directly on the floor (Attachment 7).

Environmental Sampling and Results

FDB Investigators conducted an assessment of activities at OPDC and collected both product and environmental samples. Product samples consisted of packaged colostrum (intended for human consumption). Environmental sampling focused on the milk bottling room, mobile milking trailer, calf area, and cow pasture. Table 2 below provides a summary of the 172 samples collected during the course of this FDB investigation. All of the samples (product and environmental) were analyzed for *E. coli* O157:H7. Packaged colostrum samples were also tested for *Campylobacter*. All samples were analyzed and reported by the CDPH, Food and Drug Laboratory Branch (FDL) in Richmond, CA (Attachment 8).

Table 2 – Summary of All Samples Collected at Organic Pastures Dairy Company

Sampling Location	Type and Number of Samples per Location						Total
	Calf Feces	Cattle Feces	Colostrum (packaged)	Environmental Swab	Soil	Water	
Milk bottling room and milk silo room	---	---	---	29	---	---	29
Mobile milking trailer	---	---	---	47	---	7	54
Cow pasture / feeding area	---	43	---	3	---	5	51
Calf area	16	---	---	5	5	2	28
Cold storage	---	---	10	---	---	---	10
Total	16	43	10	84	5	14	172

Of the 172 total, ten (approx. 6%) product samples (packaged raw colostrum – unopened containers) were tested for both *E. coli* O157:H7 and *Campylobacter*. The ten raw colostrum samples were reported negative for *Campylobacter* by FDL. However, of these ten raw colostrum samples, one (IS# 162111511P1) was found positive for Shiga toxin-producing *E. coli*. Upon further testing, two isolates from this sample could not be serotyped by FDL and were subsequently sent to CDC for additional analysis. CDC determined that the two isolates collected from sample IS #162111511P1 were pathogenic *E. coli* O8, O25:H28 (Attachment 9).

All environmental samples collected in the milk bottling room, milk silo room, mobile milking trailer, and cow pasture/feeding area (n=134; approx. 78% of total samples collected) were negative for *E. coli* O157:H7. However, 10 of the 28 environmental samples collected in the calf area (approx. 36% for this area and 6% of total samples collected) were positive for *E. coli* O157:H7 (one sponge swab, three soil, one water, and five calf feces). Two of these ten (20%) environmental samples (IS# 185111611-101, calf feces and IS# 185111611-85, soil) genetically matched the outbreak strain of *E. coli* O157:H7. IDB reported the strain of *E. coli* O157:H7 that sickened the five case patients and matched the two samples collected from the calf area at OPDC was uncommon. This strain was only seen in California in three case patients in 2009, two case patients in 2010, and had yet to be identified in 2011 (Attachment 1). Table 3 provides a summary of all pathogenic *E. coli* positive samples collected at OPDC.

Table 3 – Summary of All Positive (n=11) Pathogenic *Escherichia coli* Samples Collected at Organic Pastures Dairy Company

Sampling Location	Sample Type	No. of Positive Samples	Serotype of Pathogenic <i>E. coli</i>	Match to Outbreak Strain
Cold Storage	Colostrum – finished product packaged for retail sales	1	O8, O25:H28	0
Calf area	Calf feces	5	O157:H7	1 out of 5
	Environmental swab	1	O157:H7	0
	Soil	3	O157:H7	1 out of 3
	Water	1	O157:H7	0

Note: The letter issued to Mark McAfee from FDB, dated January 17, 2012 (Attachment 7) indicated that one fecal sample and one water sample from the calf area tested positive for E. coli O157:H7 and matched the outbreak strain. This information was incorrect. The two samples that tested positive for the E. coli O157:H7 and matched the outbreak strain were feces and soil (IS# 185111611-101 - calf feces and IS# 185111611-85 - soil).

Additional product samples were collected by the Contra Costa County Environmental Health Services (CCCEHS) in late October 2011. CCCEHS collected the following products from the home of a case patient:

1. 64 fluid ounce – OPDC raw whole milk (lab #11BF00003) with an expiration date of October 12, 2011. This product was an open milk container collected from the refrigerator in a case patient’s home.
2. 64 fluid ounce – OPDC raw whole milk (lab #11BF00005) with an expiration date of November 09, 2011. This product was an unopened milk container collected at Lunardi’s Market located at 1600 Palos Verdes Mall in Walnut Creek, CA .
3. Pickles with kefir (open jar / lab #11BF00004) – This product was manufactured at the case patient’s home using OPDC raw whole milk as the base for the kefir.
4. Pickles with kefir (sealed jar / lab #11BF00002) – This product was manufactured at the case patient’s home using OPDC raw whole milk as the base for the kefir.

CCCEHS samples 11BF00002 – 11BF00005 were analyzed by the Contra Costa Public Health Laboratory (CCPHL) for *E. coli* O157 and *Shigella* species (Attachment 10). These samples were also analyzed by the United States Department of Agriculture (USDA) Laboratory (Western Regional Research Center) for *E. coli*, *E. coli* O157:H7, and Shiga toxin genes stx1 and stx2. All samples tested by CCPHL and USDA were negative (Attachment 10 and 11).

Summary of Findings

FDB determined that OPDC was operating under poor sanitary conditions at the time of the investigation. Numerous deficiencies were recorded regarding facility construction, equipment, and pest control. OPDC also failed to maintain SOPs related to the control of potential sources of contamination of raw milk from employees and equipment within and between the calf area, mobile milking trailer, and bottling room, which are critical to ensure the prevention of cross contamination of products produced at the facility. FDB determined that the potential for cross contamination existed between employees working in and around the mobile milking trailer that transported the colostrum from the milk transport trailer to the cold storage room adjacent to the milk bottling room. Additionally, employees working in and around the mobile milking trailer may have provided a direct route of cross-contamination from cows to the colostrum container and into the bottling plant.

FDB determined that *E. coli* O157:H7 was present in calf fecal material and in the environment where the calves were maintained. The calves were born on the property and remain on the property, therefore the only potential sources of exposure of the calves to *E. coli* O157:H7, were from (1) the milk and colostrum they received from the herd, (2) contact with workers whose hands or clothing were contaminated with fecal material from the herd, or (3) contact with fecal material or other contaminated materials brought to the calf area by workers who were working in and around the milking herd.

On December 13, 2011, FDB continued the investigation at OPDC. OPDC had completed a significant remodeling of the milk bottling room and milk storage room. Improvements to these areas included: the enlargement of the bottling room, installation of a new bottle filling and capping machine, and the installation of new floors, walls, and ceilings. The milk bottling and storage rooms were observed to be maintained in a sanitary condition.

Mr. Aaron McAfee reported that OPDC was in the process of developing “Calf Protocols.” These new procedures would: (1) eliminate “tours” to the calf area, (2) provide written standards for appropriate protective equipment to be worn in the calf area, (3) provide procedures for the transport of colostrum to the milk storage room to eliminate employees traveling from the mobile milking barn to the processing area, and (4) provide a new utility vehicle dedicated for use in the calf area that will eliminate the need for vehicles to travel to multiple areas of the milking and bottling operations.

On January 18, 2012, OPDC submitted a letter (Attachment 12) indicating all violative conditions had been corrected. OPDC also submitted a “Standard Sanitary Operating Procedure – Calf Raising Area Separation” document (Attachment 13). This document details procedures that will be used by OPDC, “...at all times for raising calves and maintaining proper isolation from the rest of the operation at OPDC.”

During this investigation FDB investigators collected a total of 172 samples (10 finished products and 162 environmental samples) from multiple locations at OPDC. Of the 172

samples, one (0.6%) product sample (packaged raw colostrum) tested positive for pathogenic *E. coli* O8, O25:H28. In addition, 10 samples from the calf area out of the 172 total samples collected (approx. 6%) were positive for *E. coli* O157:H7. Two of these ten (20%) environmental samples genetically matched the outbreak strain of *E. coli* O157:H7 identified as causing illness in five children within California.

The strain of *E. coli* O157:H7 isolated from the calf area during this investigation and found to be indistinguishable from the outbreak strain may have been present in the milking herd and transferred directly to the milk during the milking process.

Although *E. coli* O157:H7 was not isolated from raw milk products, pathogenic *E. coli* O8, O25:H28 was isolated from packaged colostrum collected at OPDC during this investigation. The quarantine order prevented this contaminated product from being delivered to retail locations and ultimately consumed by the public.

The environmental and epidemiological investigation completed by CDPH indicates that raw whole milk manufactured by OPDC was likely contaminated with *E. coli* O157:H7 that led to illness in five children in four counties throughout California.

Attachments

1. Letter from IDB to FDB regarding foodborne outbreak
2. Invoices from OPDC to retail locations
 - A. Jimbo's...Naturally! – San Diego area
 - B. Henry's Farmers Market – Encinitas, San Diego area
 - C. Revive Café and Whole Foods Market – Fresno
 - D. Sprouts Farmers Market – Elk Grove
 - E. Lunardi's – Walnut Creek
3. Traceback diagram
4. California Department of Food and Agriculture "Notice of Required Action Pursuant to Quarantine"
5. Organic Pastures Dairy Company recall notice
6. Photographs
 - A. Milk bottling room
 - B. Mobile milking trailer
 - C. Milking herd
 - D. Calf area
 - E. Facility improvements - Organic Pastures Dairy Company
7. Food and Drug Branch letter to Organic Pastures Dairy Company detailing violative conditions
8. Food and Drug Laboratory Branch – laboratory report
9. Centers for Disease Control and Prevention – laboratory report
10. Contra Costa Public Health laboratory report – raw whole milk / pickles
11. United States Department of Agriculture laboratory report – raw whole milk / pickles
12. Organic Pastures Dairy Company - corrective action response
13. Organic Pastures Dairy Company - Standard Sanitary Operating Procedures – Calf Raising Area Separation