



KAREN SMITH, MD, MPH
Director & State Health Officer

State of California—Health and Human Services Agency
California Department of Public Health



EDMUND G. BROWN JR.
Governor

October 11, 2016

To: The Record

From: Emergency Response Unit

Re: **Environmental Investigation of the Escherichia coli O157 Outbreak in California Associated with Raw Whole Milk, January, 2016**

The Food and Drug Branch is providing the following report of an investigation conducted by the Emergency Response Unit.

Karl Birusingh, Investigator
Emergency Response Unit

Amber Barnes, Supervising Investigator
Emergency Response Unit

Michael Needham, Chief
Emergency Response Unit

**Environmental Investigation of the *Escherichia coli* O157 Outbreak in
California Associated with Raw Whole Milk, January 2016**

Report

May 2016

Prepared by:

California Department of Public Health
Food and Drug Branch
Emergency Response Unit
P.O Box 997435, MS 7602
Sacramento, CA 95899-7435

Table of Contents

Agencies.....	3
Dates of Investigation.....	3
Executive Summary.....	3
Background Information.....	5
Case Patient Information.....	6
Product Sampling.....	7
Recall.....	7
Environmental Investigation.....	7
Cow 149.....	8
Sampling Results.....	9
Summary of Findings.....	11
Attachments.....	12

Agencies

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

California Department of Food and Agriculture (CDFA), Animal Health and Food Safety
Services Division, Milk and Dairy Food Safety Branch

Fresno County Department of Public Health, Environmental Health Division, Milk and
Dairy Program

Date of Investigation

February 8, 2016

Executive Summary

Summary of Investigation as of March 29, 2016

In January 2016, 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 four California children with Shiga-toxin producing *E. coli* O157 infections who reported consuming a commercial brand of raw (unpasteurized) milk prior to illness onset. These children all had illness onsets in mid-January and reported consuming Organic Pastures Dairy Company (OPDC) brand raw cow milk before they became sick. Subsequent molecular strain typing of the *E. coli* O157 isolates from these four patients confirmed that they were closely related.

For the purposes of this investigation, a person was considered to be part of this outbreak if:

- 1) They had an onset of illness or specimen collection date on or after January 1, 2016;
- 2) Their clinical specimen yielded *E. coli* O157 with pulsed-field gel electrophoresis (PFGE) *Xba*I pattern EXHX01.6177 or EXHX01.6275, and *Bln*I pattern EXHA26.0628; and
- 3) The *E. coli* O157 isolate also had a closely related Multiple-Locus Variable Number Tandem Repeat Analysis (MLVA) pattern.

As of February 26, 2016, ten northern and central California residents infected with the outbreak strain of *E. coli* O157 and with illness onset in January had been identified. Nine case-patients had *E. coli* O157 with the predominant PFGE pattern combination EXHX01.6177/EXHA26.0628. One case-patient had a closely related PFGE pattern combination EXHX01.6275/EXHA26.0628. Both pattern combinations were given the Centers for Disease Control and Prevention (CDC) cluster code, 1602CAEXH-1. The patients were primarily children, with a median age of 8 years (range, 1 to 26 years). Onset dates of illness ranged from January 14 to January 28, 2016. Four were hospitalized, including two children with hemolytic uremic syndrome. Of these ten case-patients, nine were interviewed and one patient was lost to follow-up and was not interviewed. Of the nine that were interviewed, six (67%) reported consuming OPDC brand raw milk prior to illness onset and three denied raw milk exposure.

In response to the initial reports of illness, OPDC initiated a recall on February 5, 2016 of two lot codes of raw whole milk, with Use by dates of January 23, 2016 and January 26, 2016. This

recall affected over 100 retail locations in northern and central California. CDPH collected samples of OPDC brand raw milk products from a case patient in Fresno and from multiple retail locations throughout northern California. These samples of OPDC brand raw milk did not include the Use by dates recalled by the firm. *E. coli* O157:H7 was not detected in any of these samples of raw milk.

During recall discussions with FDB, OPDC management noted that *E. coli* O157:H7 had been detected by Polymerase Chain Reaction (PCR) in a bulk milk tank sample in early January 2016. Although this milk was not distributed to the public, this finding initiated further testing of the milking herd. One of the cows, Cow 149, was identified as having milk that was positive for *E. coli* O157:H7, and was removed from the milking herd. Four milk samples from Cow 149 were initially analyzed at a private lab and then sent for additional testing at UC Davis. FDB obtained the *E. coli* O157:H7 isolated from Cow 149 milk samples by UC Davis and delivered these isolates to the Food and Drug Laboratory Branch (FDLB) for PFGE testing. These four isolates, which had been isolated from milk collected from Cow 149 by OPDC, between January 9 and January 12, 2016, had PFGE combination EXHX01.6177/ EXHA26.0628, which was indistinguishable from the main outbreak pattern seen in the clinical isolates of the 1602CAEXH-1 cluster.

On February 8, 2016, FDB initiated an environmental investigation at OPDC. In the course of this investigation, FDB investigators collected a total of 97 environmental and product samples at OPDC, including 20 product samples (raw milk and cream), 56 cow feces, 18 soil, and 3 water. *E. coli* O157 was not detected in any of the product samples collected at OPDC. However, multiple environmental samples tested positive for *E. coli* O157:H7, including feces, soil, and water. These environmental samples were determined by FDLB to have 6 different PFGE patterns.

There were two PFGE pattern combinations that were predominate. Sixteen of the 22 positive samples had the same 2 patterns as seen in the case patients. These environmental sample isolates were also assigned the CDC cluster code, 1602CAEXH-1. The other 4 PFGE pattern combinations found in the remaining 6 isolates did not appear to be linked to any currently reported illnesses in PulseNet. In addition to these *E. coli* O157:H7 findings, five samples including soil and feces tested positive for non-O157 Shiga toxin-producing *E. coli*. These samples were further evaluated for PFGE and were determined to not be one of “the big 6” serotypes of *E. coli* shiga-toxin producers. All isolates of samples collected during the environmental investigation at OPDC were analyzed for Whole Genome Sequencing (WGS) and were highly related to the clinical isolates, within 0 to 4 single nucleotide polymorphisms (SNPs).

The epidemiologic, laboratory, and environmental investigation strongly indicates that raw milk distributed by OPDC in early January 2016 was contaminated with *E. coli* O157 and caused illness in at least six California consumers. The consumption of raw milk is not considered to be a common practice; however 67% of case-patients in this outbreak reported consuming OPDC raw milk. By comparison, only three percent of California residents interviewed for a national food exposures survey in 2006 reported drinking raw milk in the week prior to their interview.

In addition, the outbreak strain of *E. coli* O157 was very uncommon. The predominant PFGE pattern combination EXHX01.6177/ EXHA26.0628 had only been seen once in the national PulseNet database prior to January 2016, in a child with illness onset in October 2015 who did not drink raw milk, though her family frequently drank OPDC raw milk. The second pattern combination EXHX01.6275/ EXHA26.0628 was never identified in PulseNet prior to this

outbreak. Furthermore, all isolates in this outbreak had a closely related and uncommon MLVA pattern. WGS testing confirmed that the outbreak strains were highly related and most likely were from a single source.

Evidence collected to date, indicates that cattle in the OPDC milking herd were shedding *E. coli* O157:H7 that matched PFGE patterns associated with ten *E. coli* O157 illnesses in January 2016. In early January 2016, Cow 149 produced milk contaminated with *E. coli* O157:H7 which may have been bottled and shipped to the public. Feces, soil, and water collected from OPDC on February 8, 2016 tested positive for *E. coli* O157:H7 and matched the PFGE patterns associated with cluster. The collection of environmental samples from OPDC on February 8, 2016 focused on feces likely deposited on February 6, 7, and 8. It is unlikely that the positive findings from February 8, 2016 represent conditions linked to Cow 149. The isolation of *E. coli* O157:H7 and non-O157 Shiga toxin-producing *E. coli* from cattle used to produce raw milk for human consumption could result in additional illness to raw milk consumers in the future.

Background Information

In January 2016, CDPH was informed by CDPH-IDB about a foodborne illness outbreak of *E. coli* O157 that was epidemiologically linked to Organic Pastures Dairy Company (OPDC) in Fresno, CA. There was a cluster of four cases with Shiga-toxin producing *E. coli* O157 infections. FDB initiated an investigation as a result of this notification.

Previously, in 2011, CDPH-FDB had investigated a foodborne illness outbreak of *E. coli* O157:H7 that was also epidemiologically linked to OPDC. In this investigation, the *E. coli* O157:H7 outbreak strain was isolated from OPDC dairy cattle. The 2011 outbreak strain of *E. coli* O157:H7 was compared to that of the current, January 2016, outbreak strain. The two strains were found to be genetically different and the Pulsed Field Gel Electrophoresis (PFGE) pattern combination in the 2011 outbreak differed from the January 2016 outbreak.

As of January 2016, there were four California case patients (all children) with Shiga-toxin producing *E. coli* O157 infections who reported consuming a commercial brand of raw (unpasteurized) milk prior to illness onset. These children all had illness onsets in mid-January and reported consuming OPDC brand raw cow milk before they became sick. Subsequent molecular strain typing of the *E. coli* O157 isolates from these four patients confirmed that the isolates were closely related.

For the purposes of this investigation, a person was considered to be part of this outbreak if:

- 1) They had an onset of illness or specimen collection date on or after January 1, 2016;
- 2) Their clinical specimen yielded *E. coli* O157 with PFGE *Xba*I pattern EXHX01.6177 or EXHX01.6275, and *Bln*I pattern EXHA26.0628; and
- 3) The *E. coli* O157 isolate had a closely related Multiple-Locus Variable number tandem repeat Analysis (MLVA) pattern.

As of February 26, 2016, ten northern and central California residents were reported as infected with the outbreak strain of *E. coli* O157 and had illness onsets in January. Nine of the ten case-patients with *E. coli* O157, had the predominant PFGE pattern combination, EXHX01.6177/ EXHA26.0628. The remaining case-patient had a closely related PFGE pattern combination, EXHX01.6275/ EXHA26.0628. Both pattern combinations were given the Centers for Disease Control and Prevention (CDC) cluster code, 1602CAEXH-1.

As noted above, the case patients were primarily children, with a median age of 8 years (range, 1 to 26 years). Onset dates of illness ranged from January 14 to January 28, 2016. Four were hospitalized, including two children with hemolytic uremic syndrome. Of these ten case-patients, nine were interviewed and one patient was lost to follow-up and never interviewed. Of the nine that were interviewed, six (67%) reported consuming OPDC brand raw milk prior to illness onset and three denied known raw milk exposure.

Based on available information, FDB conducted an investigation at OPDC and collected both environmental and product samples during this process. Early on in the investigation, investigators also collected raw milk product samples from case patients.

Case Patient Information

Patients, and parents of case patients (due to the age of children with a median age of 8 years; range, 1 to 26 years), were interviewed by the local health department in the jurisdiction in which they lived, to determine potential *E. coli* O157:H7 exposures. The range of illness onset dates for the case patients was reported as January 14, 2016 to January 28, 2016.

Specific case patient information is listed below in Table 1 for confirmed case patients. :

Table 1 – Confirmed case patients

Case Patient	Age	Illness Onset	County of residence	Confirmed consumption of OPDC raw milk	Place of purchase
#1	3	1/16/2016	Sonoma	Yes	Oliver's
#2	13	1/18/2016	Santa Barbara	Yes	New Frontiers
#3	2	1/19/2016	Alameda	Yes	Alameda Natural Grocery
#4	2	1/25/2016	Fresno	Yes	Organic Pastures Dairy
#5	9	1/28/2016	Santa Clara	Yes	Piazza's
#6	1	1/20/2016	Fresno	Yes	Organic Pastures Dairy
#7	7	1/14/2016	San Luis Obispo	No	N/A
#8	18	1/15/2016	Humboldt	No	N/A
#9	26	1/21/2016	Kern	No	N/A
#10	10	1/19/2016	San Mateo	No	N/A

One of the confirmed case patients listed in Table 1 [REDACTED]

Prior to this outbreak, there was only one reported human isolate in the PulseNet national database matching the outbreak strain, PFGE pattern EXHX01.6177/ EXHA26.0628. This October 2015 sample was from a one year old child reported to have not consumed raw milk.

However, OPDC raw milk was consistently present in the home. [REDACTED]. Epidemiologists did not add the October 2015 patient to the present outbreak.

Product Sampling

On January 29, 2016, CDPH, FDB Emergency Response Unit (ERU) staff collected samples of OPDC brand raw whole milk from the Fresno County Public Health laboratory. FDB IS# 727012916-P002 sample of OPDC raw whole milk was collected by the Fresno County Department of Public Health from a case patient's home. FDB IS# 727012916-P003 was collected by Fresno County from OPDC directly during a routine sampling event. The samples were tested by FDLB in Richmond, California for the presence of *E. coli* O157:H7. All samples were negative for the pathogen.

On February 1 and 2, 2016, ERU staff collected retail samples of OPDC brand raw whole milk and raw skim milk. A total of 7 samples, 1 bottle raw skim milk and 6 bottles raw whole milk samples were collected from four retail locations. The FDB IS# 194020116-P001, 710020116-P001/P003 and 710020216-P001/P003 samples were tested by FDLB for the presence of *E. coli* O157. All samples were negative for the pathogen.

On February 3, 2016, ERU staff collected retail samples of OPDC brand raw kefir and raw whole milk. A total of 5 samples, one bottle raw kefir and four bottles raw whole milk were collected by Santa Clara County from one retail location. The FDB IS# 727020416-P001/P005 samples were tested by FDLB for the presence of *E. coli* O157. All samples were negative for the pathogen.

On February 8, 2016 ERU staff collected samples of OPDC brand products. A total of 20 samples, 12 bottles raw whole milk, 4 bottles raw cream and 4 bottles raw skim milk were collected from the OPDC facility in Fresno, CA. The FDB IS# 1920208-P001/P020 samples were tested by FDLB for the presence of *E. coli* O157. All samples were negative for the pathogen.

Recall

On February 5, 2016 Organic Pastures initiated a voluntary recall for two lots of OPDC brand raw whole milk. The recalled lots were coded 20160105-1 and 20160106-2 with Use by Dates of 1/23/16 and 1/26/16, respectively. The recalls were publicized via the OPDC Facebook page and the OPDC website, www.organicpastures.com.

On February 5, 2016, CDPH posted a California Food Recall Information Sheet to the CDPH website (Attachment 1).

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 cream, raw whole milk, raw skim milk, raw butter, and raw kefir.

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, and manufacturing rooms.

Investigators and inspectors from FDB, the California Department of Agriculture (CDFA) and Fresno County Department of Public Health met with [REDACTED] at OPDC on February 8, 2016. [REDACTED] was advised of the current foodborne illness outbreak epidemiologically linked to OPDC raw whole milk. [REDACTED] was advised that FDB ERU staff would be conducting environmental sampling in all outdoor areas of the farm. [REDACTED] was further advised buildings housing milking, bottling and manufacturing operations along with storage buildings would be excluded from sampling.

Throughout this investigation, FDB investigators were accompanied at different times by [REDACTED], COO; and/or [REDACTED], RAMP Auditor.

During the course of the investigation, FDB investigators collected a total of 97 environmental and product samples at OPDC, including 20 product samples (raw milk and cream), 56 cow feces, 18 soil, and 3 water. All collected samples were delivered to FDLB for microbiological analysis. Details on the findings can be found below in the “Environmental Sampling and Results” section of this report.

OPDC Cow 149

M. McAfee stated that on January 7, 2016, he had been notified by his contracted laboratory, Food Safety Net Services (FSNS) that milk samples had tested positive for *E. coli* O157. There were four isolates from the milk sample. The sample came from milk collected between January 9 and January 12, 2016. Although this milk was not distributed to the public, this finding initiated further testing of the milking herd. Further testing of the herd yielded a positive *E. coli* O157 result from milk cow #149.

After cow #149 was identified as having milk that was positive for *E. coli* O157, it was removed from the milking herd. M. McAfee theorized that *E. coli* O157 was present in cow #149's udder and the pathogen had been transferred to the bulk milk tanks 1 and 2 via normal milking routes. He further stated that a “false negative” testing result of tank 1 and 2 bulk milk had resulted in contaminated milk entering the marketplace. He further stated that milk present in bulk tanks 1 and 2 contained milk from cow 149. That milk was diverted to Triple T Dairies for pasteurization.

On February 4, 2016, OPDC sent a letter to CDFA and CDPH detailing the series of events that occurred leading up to the recall (Attachment 2).

During the February 8, 2016 discussion with the firm, the attending regulatory officials were told that cow 149 had been loaded and transported to [REDACTED] for slaughter.

According to [REDACTED], cow #149's movements were (Attachment 3):

12/22/15 149 came fresh
01/05/16 149 was moved to Pen 1
01/09/16 149 was quarantined
01/10/16 149 was moved to pen 8 (hospital pen)
02/08/16 149 left to be slaughtered

Four milk samples from Cow 149 were initially analyzed at the [REDACTED] private lab, and then sent for additional testing at the Western Center for Food Safety (WCFS) – University of California at Davis (UC Davis).

According to a February 23rd email from A. McAfee to M. Needham (Attachment 4), the sample number and collection dates were:

- 16-004666-004 – Milk – Cow 149 – 1/10/2016
- 16-004428-045 – Milk – Cow 149 – 1/9/2016
- 16-005490-004 – Milk – Cow 149 – 1/12/2016
- 16-004810-004 – Milk – Cow 149 – 1/11/2016

On February 11, 2016, Michael Needham, Unit Chief ERU received a telephone call from Dr. Michele Jay-Russell at WCFS (Attachment 5). Dr. Russell stated in summary that she been contacted by OPDC regarding shedding of *E. coli* O157 from cow 149's udder into milk. She had been provided four pure culture slant isolates from FSNS. The isolates were from cow 149 milk samples that OPDC had provided to FSNS. Dr. Russell determined the isolates were positive for stx1, stx2, hylA, and eaeA.

On February 12, 2016 FDB-ERU staff obtained the four *E. coli* O157 isolates from Cow 149 milk samples from the UC Davis laboratory (located at 1089 Vet Med Drive, Davis, CA). FDB delivered these isolates to FDLB for PFGE testing.

The FDB IS# 710021216-001 was assigned to the four isolates. FDLB separated the isolates and reassigned IS# 710021216-001A/D to the isolates as shown below.

- 16-004810-004 - 710021216-001A
- 16-004428-045 - 710021216-001B
- 16-004666-004 - 710021216-001C
- 16-005490-004 - 710021216-001D

FDLB determined the isolates yielded PFGE XbaI pattern EXHX01.6177 and *BlnI* pattern EXHA26.0628, which matched an outbreak strain. Details on the findings can be found below in the "Sampling Results" section of this report.

Sampling Results

During this investigation, a total of 111 samples were collected. This includes 34 raw milk or milk product and 77 environmental samples collected by FDB. Four additional isolates of *E. coli* O157 from OPDC raw milk samples initially analyzed by a private laboratory were collected and delivered to FDLB for molecular typing. This brings the grand total of samples collected by FDB to 115 covering the period of January 29, 2016 through February 8, 2016.

Of the 34 collected product samples, one was from a case patient in Fresno County, one was collected by Fresno County at OPDC, 12 were collected by FDB ERU at different retail

locations, and 20 (raw milk and cream) were collected by FDB ERU staff at the Organic Pastures dairy site.

As noted earlier, no *E. coli* O157 was detected in the collected product samples.

The environmental sampling portion of this investigation focused on the outdoor areas of the dairy (i.e., OPDC in Fresno, CA), and a total of 77 environmental samples were collected including 56 cow feces, 18 soil, and 3 water. Of the 77 samples, 22 (~29%) environmental samples tested positive for *E. coli* O157. Table 2 includes a listing of the 22 positive environmental samples.

Additional molecular testing was conducted on the isolates from the 22 environmental samples found positive for *E. coli* O157. This included PFGE and WGS. Table 2 summarizes the PFGE findings and provides information on sample description as well as relatedness to outbreak cluster code (1602CAEXH-1) set by CDC. Table 2 also includes details on the four *E. coli* O157 isolates from the OPDC raw milk *E. coli* O157 positive samples initially analyzed by FSNS. Table 2 has 26 entries because it includes the 22 *E. coli* O157 positive environmental samples collected by FDB as well as the four isolates from the four positive *E. coli* O157 raw milk samples OPDC sent for analysis to the private lab and eventually the WCFS – UC Davis.

It is evident from data in Table 2 that there were six unique PFGE-XbaI/PFGE-BlnI pattern combinations. Table 2 is color coded to allow for ease of identification of PFGE relatedness. Samples with the same color are closely related and are indistinguishable via PFGE.

Of the 22 positive *E. coli* O157:H7 environmental samples, 16 were indistinguishable from the outbreak strain (not including the four isolates received from WCFS – UC Davis).

Table 2 demonstrates that for samples with PFGE pattern combinations that were the same patterns assigned to the case patients, the sample isolates were also assigned CDC cluster code 1602CAEXH-1. Out of the six different PFGE pattern combinations, four combinations did not appear to be linked to any current foodborne illness outbreaks.

In addition to these *E. coli* O157 findings, five samples including soil and feces tested positive for non-O157 Shiga toxin-producing *E. coli*. These samples were further evaluated for PFGE and all samples underwent WGS analysis.

Table 2 – Positive *E. coli* O157 environmental samples collected at Organic Pastures Dairy Company.

Sample Number	Sample Description	PFGE XbaI Pattern	PFGE BlnI pattern
191020816-E001	Feces – pen 13	EXHX01.6177	EXHA26.0628
191020816-E003	Feces – pen 13	EXHX01.6275	EXHA26.0628
191020816-E011	Feces – pen 7	EXHX01.6275	EXHA26.0628
191020816-E013	Feces – pen 7	EXHX01.6275	EXHA26.0628
191020816-E014	Feces – pen 7	EXHX01.6275	EXHA26.0628
191020816-E015	Feces – pen 7	EXHX01.6275	EXHA26.0628
191020816-E016	Water – discharge from milking barn sump	EXHX01.6177	EXHA26.0628
191020816-E026	Soil – field north of milking barn	EXHX01.6177	EXHA26.0628
191020816-E035	Soil – field north of milking barn	EXHX01.6177	EXHA26.0628
191020816-E036	Soil – field north of milking barn	EXHX01.6177	EXHA26.0628

191020816-E037	Soil – west of feeding line	EXHX01.6275	EXHA26.0628
191020816-E038	Soil – west of feeding line	EXHX01.6177	EXHA26.0628
191020816-E039	Soil – west of feeding line	EXHX01.6177	EXHA26.0628
191020816-E040	Soil – west of feeding line	EXHX01.6177	EXHA26.0628
191020816-E047	Feces – pen 1	EXHX01.6177	EXHA26.0628
191020816-E052	Feces – pen 1	EXHX01.6177	EXHA26.0628
191020816-E012	Feces – pen 7	EXHX01.6280	EXHA26.1127
191020816-E017	Water – udder wash runoff	EXHX01.4541	EXHA26.4527
191020816-E043	Soil – west of feeding line	EXHX01.6177	EXHA26.2203
191020816-E045	Feces – pen 1	EXHX01.6284	EXHA26.4530
191020816-E049	Feces – pen 1	EXHX01.6284	EXHA26.4530
191020816-E054	Feces – pen 1	EXHX01.6284	EXHA26.4530

Working in collaboration with FDLB and IDB, FDB requested assistance from CDC in running comparison on these samples in order to determine how they are related to each other and the clinical isolates. CDC completed an expanded pairwise matrix analysis for this cluster (i.e., 1602CAEXH-1), including the clinical, environmental and food isolates collected in the investigation. It was determined that all sequences differ by 0 to 4 SNPs and appear highly related to each other. CDC also indicated that there were too few SNP differences to construct an hqSNP tree. These findings are in agreement and further support the outcome from the PFGE analysis.

Summary of Findings

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

The strain of *E. coli* O157 associated with this foodborne illness outbreak (CDC cluster code 1602CAEXH-1) is very uncommon. The predominant PFGE pattern combination EXHX01.6177/ EXHA26.0628 had only been seen once in the national PulseNet database prior to January 2016, in a child with illness onset in October 2015 who did not drink raw milk, though her family frequently drank OPDC raw milk. The second pattern combination EXHX01.6275/ EXHA26.0628 has never been identified prior to this outbreak.

The four isolates, which had been isolated from raw milk collected between January 9 and January 12, 2016, had PFGE combination EXHX01.6177/ EXHA26.0628 matching the PFGE combination from the clinical isolates. Based on the findings that these four isolates were genetically indistinguishable by PFGE from the main outbreak pattern seen in the clinical isolates, they were designated as part of the CDC outbreak cluster code 1602CAEXH-1.

The epidemiologic, laboratory, and environmental investigation strongly indicates that raw milk distributed by OPDC in early January 2016 was contaminated with *E. coli* O157:H7 and caused illness in at least six California consumers. The consumption of raw milk is not considered to be a common practice; however 67% of case-patients in this outbreak reported consuming OPDC raw milk. By comparison, only three percent of California residents interviewed for a national food exposures survey in 2006 reported drinking raw milk in the week prior to their interview.

All isolates in this outbreak have a closely related and uncommon MLVA pattern. Findings from WGS testing are in line with those from PFGE and MLVA analysis. WGS testing results support that the outbreak strains are from a single source.

Evidence collected to date, indicates that one or more cows in the OPDC milking herd were shedding *E. coli* O157:H7 that matched PFGE patterns associated with ten illnesses in January 2016. In early January 2016, Cow 149 produced milk contaminated with *E. coli* O157:H7, which may have been bottled and shipped to the public. Feces, soil, and water collected from OPDC on February 8, 2016 tested positive for *E. coli* O157:H7 and also matched the PFGE patterns associated with illness. The collection of environmental samples from OPDC on February 8, 2016 focused on feces likely deposited on February 6, 7, and 8. It is unlikely that the positive findings from February 8, 2016 represent conditions linked entirely to Cow 149.

The strain of *E. coli* O157:H7 isolated from the farm during this investigation and found to be indistinguishable from the outbreak strain was most likely present in the milking herd and transferred directly to the milk during the milking process. The isolation of *E. coli* O157:H7 and non-O157 Shiga toxin-producing *E. coli* from cattle used to produce raw milk for human consumption is concerning and could result in additional illness to raw milk consumers in the future.

Attachments

1. California Department of Public Health “California Food Recall Information” web page
2. Organic Pastures Dairy Company letter from Mark McAfee to the California Department of Agriculture and California Department of Public Health
3. OPDC letter detailing cow 149 movement
4. Email detailing summary of M. Needham/M. Jay-Russell phone conversation
5. Email thread between OPDC, M. Jay-Russell, and CDPH detailing information about the four cow 149 isolates