

Environmental Investigation of an *E. coli* O157 Outbreak in 2016 Associated with Organic Pastures Dairy Company Raw Milk

Summary of Investigation as of March 3, 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 have 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 are 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.

In response to the initial reports of illness, OPDC initiated a recall on February 5, 2016 of two lot codes of raw milk (Use by January 23, 2016 and January 26, 2016). This recall affected over 100 retail locations in northern and central California. Samples of OPDC brand raw milk products were collected 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 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 resulted in further testing of the milking herd. One of the cows, Cow 149, was identified as having milk that was positive for *E. coli* O157, 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 isolated from Cow 149 milk samples from 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 between January 9 and January 12, 2016, had PFGE combination EXHX01.6177 / EXHA26.0628, which were indistinguishable from the main outbreak pattern seen in the clinical isolates and were designated as part of cluster code 1602CAEXH-1.

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 the following PFGE patterns.

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-E043	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-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

The two highlighted PFGE pattern combinations were the same patterns as those associated with isolates from the case patients. These environmental sample isolates were also assigned CDC cluster code 1602CAEXH-1. The third PFGE pattern combination EXHX01.6284 / EXHA26.4530 did not appear to be linked to any case patients and was new to the national PulseNet database. 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 are being further evaluated by PFGE. All isolates of samples collected during the environmental investigation at OPDC are currently being analyzed for Whole Genome Sequencing (WGS).

The epidemiologic, laboratory, and environmental investigation strongly indicates that raw milk produced 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 identified in this cluster 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 reported that they frequently drank OPDC raw milk. The second pattern combination EXHX01.6275 / EXHA26.0628 has never been identified prior to this outbreak. Furthermore, all isolates in this outbreak have a closely related and uncommon MLVA pattern. Although confirmatory WGS testing is in progress, the laboratory findings to date support that the outbreak strains are from a single source.

Evidence collected to date, indicates that cattle in the OPDC milking herd were shedding *E. coli* O157 that matched PFGE patterns associated with ten illnesses in January 2016. In early January 2016, Cow 149 produced milk contaminated with *E. coli* O157 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 PFGE patterns for those isolates also matched those patterns associated with the illnesses. 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 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 if not addressed at the dairy.