



RON CHAPMAN, MD, MPH
Director & State Health Officer

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



EDMUND G. BROWN JR.
Governor

January 17, 2012

Mark McAfee, CEO
Organic Pastures Dairy LLC
7221 So. Jameson
Fresno, CA 93706

Dear Mr. McAfee:

On November 15 and 16, 2011, the California Department of Public Health, Food and Drug Branch (FDB) conducted an environmental investigation at Organic Pastures Dairy Company (OPDC), in Fresno, CA. This investigation was conducted pursuant to the authority granted to the Department under California Health and Safety Code sections 131100, 100325 and 110140. The investigation was initiated because of a cluster of illnesses in five children from four counties throughout California infected with *E. coli* O157:H7 having an identical, uncommon pulsed-field gel electrophoresis (PFGE) pattern. Illness dates for these cases extends from August 25 through October 25, 2011. The median age of case-patients is 4 years (range 1-5 years). Three case-patients developed hemolytic uremic syndrome (HUS) and were hospitalized. There have been no deaths. Epidemiological information indicated that the only common exposure all five had prior to illness onset was consumption of OPDC raw milk. Data from the CDC FoodNet 2006-2007 population survey estimates that only 3% of the California population interviewed had consumed raw milk in the week prior to interview. The finding that all five cases had exposure to a food item that is consumed by only 3% of the population and no other exposure in common, indicates a strong epidemiologic link between the raw milk exposure and illness.

During the investigation at OPDC, FDB collected a significant number of samples that included; manure, colostrum, water, soil, and environmental swabs of food and non-food contact surfaces. Ten of the samples collected from the calf area were positive for *E. coli* O157:H7 (1 swab, 3 soil, 1 water, and 5 fecal), of which two of the isolates (1 fecal and 1 water) had a PFGE pattern indistinguishable from the outbreak strain. FDB believes that the *E. coli* O157:H7 contamination found in the calving area originated from maternal cows and subsequently passed to calves, either directly through feeding, indirectly through fecal-oral transmission, or by translocation through movement of personnel and equipment used on the farm. While one or several of these transmission pathways might have contributed to the contamination in the calving area, the fact that *E. coli* O157:H7 identical to the outbreak strain was recovered from OPDC environment

supports the probability that the OPDC raw milk that the case patients consumed was similarly contaminated leading to their illnesses.

Additionally, FDB analyzed samples of packaged Colostrum collected from your facility and isolated shiga-toxin producing pathogens. The pathogen is very rare and we were unable to serotype it at our laboratory. The isolate has been sent to the U.S. Centers for Disease Control and Prevention for further evaluation. The presence of any pathogen in Colostrum constitutes the product being adulterated as defined by California Health and Safety Code section 110545 and 110560.

In addition to obtaining samples, FDB conducted an inspection of OPDC production areas. During the inspection, sanitary deficiencies were noted in the Milk Bottling Room, Milk Storage Rooms, Labeling Room, "Kefir" Room and common areas. The following deficiencies were identified:

Milk Bottling Room:

1. The firm failed to maintain equipment in good repair and in sanitary conditions so as to protect products from potential contamination. The following conditions were observed:
 - a. Paint was observed chipping off of the bottle feeders on the bottle filling machine.
 - b. Small hardware on the capper machine (spring and nuts) was rusted and pieces of rust were observed to be falling off. The hardware was located directly above the bottle conveyor.
 - c. Pieces of aluminum were falling off of the cap dispenser line. The cap dispenser was located directly above the bottle conveyor.
2. The firm failed to maintain facility in good repair so as to protect products from potential contamination. The following conditions were observed:
 - a. A small window on the south wall of the bottling room (located near the bottle feeder) was sealed using uneven layers of a sealer foam. Foam layers were not easily cleanable. Mold/mildew was observed growing on the foam.

Milk Storage Rooms:

1. The firm failed to effectively exclude pests so as to protect products from potential contamination. The following condition was observed:
 - a. Rodent droppings were observed on the floors of Milk Storage Room 2 (South trailer).
2. The firm failed to maintain milk storage areas in good repair and in sanitary conditions so as to protect products from potential contamination. The following conditions were observed:
 - a. Storage room floors were observed in a state of disrepair. Uneven floors surfaces were observed in Milk Storage Room 2.

- b. Milk Storage Room 1 (north trailer) was not maintained in a clean and sanitary condition. Spilled milk on the floors of room 1 had not been cleaned up.
3. The firm failed to store product handling containers in a manner that would protect them from potential contamination. The following condition was observed:
 - a. White plastic buckets used to handle/store colostrum were being stored inverted on a piece of cardboard lying directly on the floor.

Bottle Labeler Room:

1. The firm failed to protect empty milk containers from potential glass contamination. The following condition was observed:
 - a. The lighting fixtures located directly above the labeling machine lacked shatter proof covers.

Kefir Room:

1. The firm failed to maintain facilities in good repair and in sanitary conditions so as to protect products from potential contamination. The following conditions were observed:
 - a. Paint was chipping off of the walls and ceilings of the Kefir Processing Room.
 - b. Parts of the ceilings were observed in a state of disrepair and were not clean.
 - c. An accumulation of mold/mildew was observed on the ceilings of the Kefir room.
2. The firm failed to protect products from potential glass contamination. The following condition was observed:
 - a. The lighting fixtures located on the south side of the "Kefir" Room lacked shatter proof covers.

Common Areas including Milk Storage Silos:

1. The firm failed to protect products (Colostrum) from potential contamination in that the following condition was observed:
 - a. Black bins that were used to transport Colostrum containers were not maintained in a clean and sanitary condition. Used, soiled cloth towels along with an accumulation of dirty liquid was observed in the bottom of the bins.
2. The firm failed to maintain grounds in sanitary conditions and in good repair so as to protect products from potential contamination. The following conditions were observed:
 - a. Milk from the bottling and storage trailers was observed dripping and accumulating on the concrete pad below the trailers.

Mark McAfee
January 17, 2012
Page 4

- b. Main drain on the southwest corner of the facility was uncovered with an accumulation of standing sewage water. A large number of flies were observed flying over and around the uncovered drain.

During a follow-up inspection conducted on December 13, 2011, FDB noted that some equipment and operational changes had been made to dairy operations. Specifically, facility renovations had occurred in the capper/filler room and that new capper/filler equipment had been installed. In addition, staff discussed operational protocols that had been instituted for the calving area, pre-milking procedures, and requirements that restrict employee movement within the facility and require personal protective equipment.

FDB requests that you provide adequate documentation that the deficiencies noted during the inspection have been mitigated and systemic procedures have been implemented to prevent their reoccurrence. FDB will continue to work with OPDC to assure that operational and sanitary operations reduce the risk of contamination of raw milk dairy products produced by the firm.

If you have any additional questions or concerns, please call me at (916) 650-6500.

Sincerely,



Patrick Kennelly, Chief
Food Safety Section
Food and Drug Branch

cc: Steve Beam, Branch Chief
California Department of Food and Agriculture
Milk and Dairy Foods Safety Branch

Barbara Cassens, District Director
US Food and Drug Administration
San Francisco District