

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION**

DISTRICT ADDRESS AND PHONE NUMBER 1431 Harbor Bay Parkway Alameda, CA 94502-7070 (510) 337-6700 Fax: (510) 337-6702 Industry Information: www.fda.gov/oc/industry		DATE(S) OF INSPECTION 11/04/2010 - 12/01/2010*
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED TO: William L. Boersma, Co-Owner		FEI NUMBER 3003550969
FIRM NAME Bravo Farms Cheese, LLC	STREET ADDRESS 36005 Hwy 99	
CITY, STATE, ZIP CODE, COUNTRY Traver, CA 93673	TYPE ESTABLISHMENT INSPECTED Cheese Manufacturer	

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

OBSERVATION 1

Proper precautions to protect food, food-contact surfaces, and food-packaging materials from contamination with microorganisms, filth, and extraneous material cannot be taken because of deficiencies in plant design.

Specifically, your facility is designed such that employees processing young cheeses (raw milk cheese prior to aging) must pass through the packaging area where aged, ready-to-eat cheese is packaged to access the aging cellar, the brining room, truck trailer used for aging cheese, and to obtain raw materials used in processing. In addition, there is no hand washing station located in the packaging area. Employees working in the packaging area must cross into the cheese processing area to access the nearest hand washing station.

Your washed curd process requires the employees to exit the facility to the outside environment to access the brining room to brine young cheeses. This requires your employees to exit the facility and cross the raw milk unloading dock and shipping/receiving dock. There is approximately 10 feet of uncovered open air space before reaching the brining room. Cheese is delivered to the brining room in an uncovered push cart. On 11/4/10, employees were observed using the cart to transport unwrapped, young Tulare Cannonball cheese outside of the facility.

OBSERVATION 2

Failure to manufacture foods under conditions and controls necessary to minimize the potential for growth of microorganisms.

Specifically, your firm's management informed us that you do not package young cheese until it meets the 60 days necessary to meet the requirements of non-pasteurized cheeses. In addition, your firm's management also stated that it is normal procedure to ship product within, approximately a week of packaging ready-to-eat cheese. Upon evaluation of your Packaging Log used to document your packaging of aged cheese from 8/24/10 through 11/1/10, we found several days and different types of cheeses that were packed prior to the 60 day requirement. Following are the noted discrepancies:

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Joanne M. Fukuda, Investigator <i>Joanne M. Fukuda</i> Steven M. Galvez, Investigator <i>SG</i> Elva M. Centeno, Investigator <i>Elva M. Centeno</i>	12/01/2010

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Cheese Type	Package Date	Amount	Process Date Lot Code	60 Day Aging
(b) (4) Gouda	9/7/10	(b) (4)	0194 (7/13/10)	0254 (9/11/10)
	9/7/10	(b) (4)	0195 (7/14/10)	0255 (9/12/10)
	9/8/10	(b) (4)	0195 (7/14/10)	0255 (9/12/10)
	9/8/10	(b) (4)	0202 (7/21/10)	0262 (9/19/10)
	9/9/10	(b) (4)	0197 (7/16/10)	0257 (9/14/10)
	10/5/10	(b) (4)	0229 (8/17/10)	0289 (10/16/10)
(b) (4) Jack	10/5/10	(b) (4)	0230 (8/18/10)	0290 (10/17/10)
	9/23/10	(b) (4)	0208 (7/27/10)	0268 (9/25/10)
	9/24/10	(b) (4)	0209 (7/28/10)	0269 (9/26/10)
(b) (4) White Cheddar	10/29/10	(b) (4)	0243 (8/31/10)	0303 (10/30/10)
	10/21/10	(b) (4)	0243 (8/31/10)	0303 (10/30/10)
(b) (4) Gouda	10/27/10	(b) (4)	0243 (8/31/10)	0303 (10/30/10)
	8/28/10	(b) (4)	0187 (7/6/10)	0247 (9/4/10)
(b) (4) Pepper Jack	9/6/10	(b) (4)	0196 (7/15/10)	0256 (9/13/10)
(b) (4) White Cheddar	10/28/10	(b) (4)	0243 (8/31/10)	0303 (10/30/10)

OBSERVATION 3

All reasonable precautions are not taken to ensure that production procedures do not contribute contamination from any source.

Specifically, your employees use a cart for transporting young, unpackaged cheese to the brining room for further processing; this cheese is then loaded back onto the same cart after brining and transported back into the processing facility to package for aging. The same cart is then used to transport the packaged young cheese to the aging cellar. This cart is used to transport the aged, ready-to-eat cheese from the aging cellar to the packaging/processing area for cutting and finished product packaging/labeling. The packaged, aged, ready-to-eat cheese is transported on the same cart back to the aging cellar. You were unable to identify a cleaning and sanitizing schedule for your COP (Clean Out of Place) equipment, which includes the cart.

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	Joanne M. Fukuda, Investigator <i>JMF</i> Steven M. Galvez, Investigator <i>SG</i> Elva M. Centeno, Investigator <i>EMC</i>	12/01/2010

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In addition, you're packaging young cheese and aged, ready-to-eat cheese on the same packaging equipment. According to your records, your young, Dutch Style Gouda cheese is brined for twenty-four hours prior to Cryovac packaging for aging. A review of your "Make Sheet" records for your young Dutch Style Gouda cheese and your "Packaging Log" for your aged, ready-to-eat cheese from 6/1/10 to 9/2/10 indicates you would have (b) (4) packaged the brined, young cheese on the same day as aged, ready-to-eat cheese. You were unable to identify a cleaning and sanitizing schedule for your COP (Clean Out of Place) packaging equipment.

On 11/5/10, condensation was observed on the processing/packaging room ceiling. Original Chipotle Cheddar Cheese was being processed in open Vat #1 directly under the ceiling with observable condensate.

On 11/4/10, an employee from the cheese processing area was observed leaving the public men's restroom, outside of the facility, and returning directly to the Processing area using the door located near Vat #1. The public restroom door is propped open during business hours; we observed a cat and a rabbit roaming free in the direct vicinity of this restroom. In addition we observed numerous people not associated with cheese processing using the same entrances and exits to the facility.

On 11/9/10, the Chlorine levels of the foot bath located at the door near Vat #1 and the foot bath located at the door near the Packaging area were tested. The test strips indicated that the Total Chlorine and Free Chlorine were at 0 ppm at both locations. We observed your employees wearing the same footwear both inside and outside of the packaging/processing facility.

On 11/10/10, the foot bath located at the door near the Packaging area was moved away from the entrance. Shortly thereafter, employees were observed entering and exiting the Packaging area moving aged, ready-to-eat cheese on a cart without using the foot bath.

OBSERVATION 4

Effective measures are not being taken to exclude pests from the processing areas and protect against the contamination of food on the premises by pests.

Specifically, we observed your single, swinging door located near Vat #1, has ~1" continuous gap around the door and your double-doors located near the packaging area have ~1" gaps located around the two bottom hinges. On 11/4/10, we observed at least 50 flies in the processing/packaging room. One of the investigators observed a fly, fly out of Vat #3 that contained

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hoops of Cannonball cheese. On 11/5/10, two flies were observed in the processing/packaging room. We observed one fly on the ledge of Vat #1 filled with Chipotle Cheddar Cheese.

On 11/9/10, a black rabbit with white paws was observed coming out of the semi-truck trailer, used for storage which includes: (b) (4) packaging bags, brining Rubbermaid cans, finished packaging fiber boxes. This trailer is sitting flush on the ground near the brining room. The roll-up door for this trailer is left open during the hours of operation.

OBSERVATION 5

Employees in contact with food, food-contact surfaces, and food-packaging materials were not maintaining adequate personal cleanliness.

Specifically, on 11/5/10, we observed an employee using his hands to splash water from the utensil sanitizing bath onto his apron, he then returned to mixing cheese with his bare hands.

On 11/9/10, we observed an employee walking outside the processing/packaging area without removing his apron, and then he returned to packaging aged, ready-to-eat cheese without properly sanitizing his apron.

OBSERVATION 6

Suitable outer garments are not worn that protect against contamination of food, food contact surfaces, and food packaging materials.

Specifically, your employees were regularly observed taking breaks outside of the facility in their production uniforms.

On 11/5/10, we observed an employee in your processing/packaging area mixing young cheese in Vat #1 without wearing an apron.

On 11/9/10, we observed an employee in the processing/packaging area packaging aged, ready-to-eat cheese, who was not wearing an apron.

OBSERVATION 7

Employees did not wash and sanitize hands thoroughly in an adequate hand-washing facility at any time their hands may have become soiled or contaminated.

Specifically, on 11/5/10, we observed an employee scratching his chin underneath his beard net during hand mixing of the milled cheese located in Vat #1.

On 11/9/10, we observed an employee returning to package aged, ready-to-eat cheese after taking a break without washing his hands; employee dipped his hands in the vat used to sanitize utensils.

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Cheese Manufacturer

On 11/15/10, we observed an employee scratch his apron while packaging aged, ready-to-eat cheese with his bare hands. This employee was observed leaving the packaging/processing room with his apron on and not sanitizing the apron upon his return to packaging aged, ready-to-eat cheese.

OBSERVATION 8

Failure to provide hand washing and hand sanitizing facilities at each location in the plant where needed.

Specifically, your brining room, located outside of your facility, does not have a hand washing or sanitizing station. Your employees who transport young cheese must handle the cheese with their bare hands in order to place the cheese into the brining solution.

OBSERVATION 9

Failure to wear beard covers where appropriate.

Specifically, on 11/9/10, we observed an employee with facial hair not wearing a beard cover while packaging aged, ready-to-eat cheese.

*** DATES OF INSPECTION:**

11/04/2010(Thu), 11/05/2010(Fri), 11/08/2010(Mon), 11/09/2010(Tue), 11/10/2010(Wed), 11/15/2010(Mon), 11/16/2010(Tue), 11/18/2010(Thu), 11/22/2010(Mon), 11/23/2010(Tue), 11/29/2010(Mon), 12/01/2010(Wed)

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OF THIS PAGE**

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Joanne M. Fukuda, Investigator *Joanne M. Fukuda*
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DATE ISSUED

12/01/2010