

Establishment Inspection Report

Bravo Farms Cheese, LLC

Traver, CA 93673

FEI: 3003550969

EI Start: 11/04/2010

EI End: 12/01/2010

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SUMMARY

This comprehensive, compliance inspection of a cheese manufacturer was conducted under Compliance Program (CP) 7303.803 – Domestic Food Safety Program; CP 7303.037- Domestic & Imported Cheese and Cheese Products Program; CP 7321.005 – Domestic NLEA, Nutrient Sample Analysis and General Food Labeling Program; the Request for Inspections and Environmental Sampling for Listeria at Soft Cheese Firms-High Priority, DFIG No: 10-04, FACTS #1168701 and SAN-DO FY 2011 High Risk Work Plan, FACTS Assignment # 1240378, OP ID 5147790.

This inspection began at Bravo Farms Cheese, LLC on 11/4/10 as a response to an outbreak of a rare strain of *E.coli* 0157:H7 (Cluster 1011COEXH-1) reported in cheese samples offered for sale and consumed at Costco Wholesale stores during a cheese road show. The initial focus of this inspection concentrated on the 20 lb. wheels of Dutch Style Gouda cheese that Bravo Farms manufactured exclusively for Costco Wholesale stores. The 20 lb. wheels are cut into 1.5 lb. wedges for store sales.

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Gouda cheese not manufactured for Costco Wholesale is produced in a different shape hoop (or frame) used to form the cheese. There were thirty-seven confirmed illnesses linked to Bravo Farms Dutch Style Gouda cheese reported from five states; Arizona, California, Colorado, New Mexico and Nevada. Samples were collected and tested by multi-State agencies and FDA districts due to the widespread distribution of the cheese and reported incidences of illness. On 11/5/10, Bravo Farms initiated a recall of all of their Gouda cheese.

The current inspection covered a review of documents and records associated with the firm's manufacturing process, product storage and handling, sanitation procedures, shipment of products, traceability and measures the firm takes to ensure the safety of their products. The firm discontinued processing cheese after 11/5/10 which was the only opportunity the inspection team had to observe the operations associated with the cheese processing. This was the same day that we were conducting environmental sampling.

The Center for Food Safety and Applied Nutrition (CFSAN) requested that environmental swab samples be collected at the firm due to the high incidence of *Listeria* found in firms producing soft cheeses. On 11/5/10, thirty-nine environmental swab samples were collected in the milk room and packaging/processing area of the facility that resulted in one positive sub-sample for *Listeria monocytogenes* found in Zone 1 (See Samples Collection for more detail).

On 11/5/10, California Department of Food and Agriculture (known as CDFA for the remainder of this report), began their inspection of Bravo Farms Cheese and conducted their routine testing of the pasteurizer. On 11/9/10, a Notice of Violation was issued by CDFA to the firm to notify them of their inspectional findings (**Attachment #11**). A Notice of Violation was issued to the firm by CDFA on 11/10/10, which impounded all Gouda cheese, including Dutch Style and Tulare Cannonball varieties, indicating that no type of Gouda cheese should be sold or removed from the property without prior approval from CFDA (**Attachment #12**).

On 11/15/10, CDFA issued a Notice of Violation (**Attachment #13**) that impounded all cheeses at Bravo Farms Cheese due to possible contamination by *E. coli* 0157.H7 and/or *Listeria monocytogenes*. On 11/22/10, a joint conference call with CDFA and FDA was held with the firm that resulted in an issuance of a Quarantine Order (**Attachment #14**) and a recall of all cheeses manufactured by Bravo Farms Cheese, LLC was issued.

The previous inspection was conducted at the firm on 6/6/08. The firm was not processing cheese during that inspection and it was classified No Action Indicated (NAI). A Form FDA 483, Inspectional Observations was not issued but the following items were addressed with the firm.

The remarks in italics were observations made during the current inspection.

- Lack of control point to assure the addition of a non-irradiated spice ingredient, chipotle pepper, does not compromise the aged cheese product. Mr. Van Ryn said they boil the sage spice ingredient for ^{(b) (4)} minutes before adding it to the cheese vat, but not the chipotle pepper ingredient. The firm also does not require a COA for microbiological analysis from its

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supplier and was observed to be storing the scoop used to dispense the pepper spice in the spice's bag.

Mr. Boersma informed us that they boil the sage but do not receive any Certificate of Analysis (COA) on the Chipotle spice.

- Drain gutters in processing room (processing down w/processing equipment cleaned the week before) had moist dark colored debris w/pieces of observable cheese materials in them. *We did not see any dark colored debris. The firm was washing small pieces on the floor into the drain during the processing on 11/5/10.*
- Lack of running hot water in the employee restroom. *During the walk through on 11/4/10, the employee restroom and hand washing sinks in the processing area and milk room were checked. All stations had hot running water.*
- Rust on the over head metal vat equip observed over exposed cheese vats. *We did not observe any rust in this location*
- Missing screw observed over (b) (4) exposed cheese vats. The other (b) (4) vats had the respective screws in place. *We did not observe any missing screws.*
- Lack of system in place to assure the final product does not contain any extraneous materials. *We did not inquire about this but their CIP/COP records indicate a checkpoint inspection for the Pasteurizer & Screens. Mr. Boersma informed us this is the (b) (4) filter put one the end of the lines.*
- Pipe/ceiling junction area over Vat (b) (4) was observed to be crumbling and with loose ceiling pieces. *We did not observe this on our inspection.*

No consumer complaints were found in FACTS, and the firm informed us that they have not received any complaints. There is no prior history of recall or regulatory actions against this firm.

(b) (3) (A)

At the close of this current inspection, Form FDA 483, Inspectional Observations, was issued to Mr. William L. Boersma, Co-Owner on December 1, 2010 with the following nine summarized items (See OBJECTIONABLE CONDITIONS AND MANAGERMENTS RESPONSE heading of this report):

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.
2. Failure to manufacture foods under conditions and controls necessary to minimize the potential for growth of microorganisms.
3. All reasonable precautions are not taken to ensure that production procedures do not contribute contamination from any source
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.

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5. Employees in contact with food, food-contact surfaces, and food-packaging materials were not maintaining adequate personal cleanliness.
6. Suitable outer garments are not worn that protect against contamination of food, food contact surfaces, and food packaging materials.
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.
8. Failure to provide hand washing and hand sanitizing facilities at each location in the plant where needed.
9. Failure to wear beard covers where appropriate.

Present at the close-out discussion were William L. Boersma, Co-Owner; Jonathan A. Van Ryn, Co-Owner; Ryan L. Davis, Vice-President; (b) (6)

(b) (6); David L. Krall, CDFA, Dairy Program Coordinator, and Christina E. Asay, Dairy Food Specialist. We informed the firm during the reading of the FDA 483 that the observations listed on the FDA 483 were our observations of objectionable conditions found during the inspection and may not represent the final Agency determination regarding the firm's compliance with the Food, Drug, and Cosmetic Act (FD&C Act). We informed the firm's management that with the recovery of the *E. coli* 0157:H7 and *Listeria monocytogenes*, the cheese is considered to be an adulterated food under FD&C Act, 402(a)(4). In addition, we expressed our concern that they were processing their cheese under conditions that may be injurious to health and our concern with their ability to locate the source of the contamination. We also warned the firm's representatives that failure to correct the objectionable conditions may result in legal sanctions such as, seizure, injunction, and prosecution. Responses to each of the observations listed on Form FDA 483 were conveyed collectively by the firm's management and noted. Some of the items listed were already corrected or in the process of being corrected during our meeting. We inquired as to the final disposition of all of the cheese that is under quarantine by CDFA and Mr. Davis stated they are working on a plan with CDFA. Mr. Boersma also stated that they are working with consultants at (b) (4), the (b) (4) used by (b) (4).

At the close-out meeting, two Form FDA 463a, Affidavits were issued and signed by Jonathan A. Van Ryn, Co-Owner, to verify and document the interstate purchase and use of rennet and salt, used in all of the Bravo Farms cheeses. Mr. Van Ryn was then issued two Form FDA 484, Receipt for Samples. The samples documented environmental swabs and the finished product samples collected at the firm.

The firm's management was very cooperative and no refusals were made.

OUTBREAK EVENTS

(Written by Investigator Galvez)

- 37 confirmed cases of *E. coli* 0157:H7 (Cluster 1011COEXH-1) in five states, including 17 hospitalizations and 1 confirmed case of Hemolytic Uremic Syndrome (HUS). See

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Attachment #8, (b) (5)

(b) (5)

- Data implicated a variety of cheeses that were offered as samples during a Cheese Road Show at 10 Costco Wholesale store locations.
- Two states reported collecting samples from consumers that reported consuming Bravo Farms Cheese and becoming ill thereafter.
 - The State of Arizona reported that 3 samples of previously opened Gouda cheese collected from households tested positive for *E. coli* O157:H7, two of the samples matched the outbreak strain.
 - The State of New Mexico reported 1 sample that was collected was an intact, returned Gouda cheese product from the store that tested positive for *E. coli* O157:H7, this sample matched the outbreak strain.
- FDA collected 39 environmental samples at Bravo Farms Cheese, LLC, 1 sample on a food contact surface tested positive for *L. monocytogenes*.
- FDA collected 5 intact samples of Bravo Farms Gouda cheese from Costco Wholesale. One of the 5 samples tested positive for *E. coli* O157:H7.
- Between 11/9/10 and 11/15/10, CDFA collected 23 samples of various cheeses and lots at Bravo Farms in Traver, CA. Listed below are 16 of the 23 samples that tested positive for either *E. coli* O157:H7, *L. monocytogenes*, or *L. ivanovii*. (See **Attachment #9**)

Date of Manufacture	Lot Code	Cheese	Pathogen Found
5/12/10	(b) (4)	Tulare Cannon Ball	LM
6/3/10	(b) (4)	White Cheddar w/ Cabernet	LM
6/4/10	(b) (4)	Pepper Jack	LM
6/17/10	(b) (4)	Silver Mountain Cheddar	EC & LM
7/6/10	(b) (4)	White Cheddar	LM
7/29/10	(b) (4)	Tulare Cannon Ball	LM
7/29/10	(b) (4)	Pepper Jack	LM
8/13/10	(b) (4)	Tulare Cannon Ball	LM
8/13/10	(b) (4)	White Cheddar w/Sage, White Pepper & Onion	LI
8/24/10	(b) (4)	Dutch Style Gouda	LM
8/25/10	(b) (4)	Dutch Style Gouda(round)	LM
8/26/10	(b) (4)	Chipotle Cheddar	LM
9/2/10	(b) (4)	Dutch Style Gouda(round)	LM
9/3/10	(b) (4)	Dutch Style Gouda(round)	LM
9/7/10	(b) (4)	Pepper Jack	LM

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9/8/10	(b) (4)	Dutch Style Gouda(round)	LM
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*LM=*Listeria monocytogenes*, EC=*E. coli* 0157.H7, LI=*Listeria ivanovii*

ADMINISTRATIVE DATA

Inspected firm: Bravo Farms Cheese, LLC
 Location: 36005 Hwy 99
 Traver, CA 93673
 Phone: 559-897-4634
 FAX: 559-897-4635
 Mailing address: 36005 Hwy 99
 Traver, CA 93673
 jonathan@bravofarms.com

Dates of inspection: 11/4/2010, 11/5/2010, 11/8/2010, 11/9/2010, 11/10/2010, 11/15/2010,
 11/16/2010, 11/18/2010, 11/22/2010, 11/23/2010, 11/29/2010,
 12/1/2010

Days in the facility: 12

Participants: Joanne M. Fukuda, (Lead) Investigator (Present all days except 11/18/10)
 Steven M. Galvez, Investigator (Present all days except 11/4/10 & 11/8/10)
 Elva M. Centeno, Investigator (Present on 11/4/10, 11/5/10, 11/18/10 &
 12/1/10)

This was a team inspection conducted by Joanne M. Fukuda (lead), Steven M. Galvez and Elva M. Centeno. (I: Joanne M. Fukuda, We: Joanne M. Fukuda, Steven M. Galvez, Elva M. Centeno). All sections were written by Investigator Fukuda, in collaboration with team members, except in sections written by other members of the team, as noted. Due to the Veterans Day holiday on 11/11/10 and the Thanksgiving holiday on 11/24/10 until 11/29/10, there were a series of delays on visits and contact with the firm.

On 11/4/10, the first day of the inspection, Investigators Centeno and I, introduced ourselves, presented our FDA credentials and issued the FDA 482, Notice of Inspection to William (Bill) L. Boersma, Co-Owner who was identified as one of the most responsible persons at the facility. Mr. Jonathan A. Van Ryn, Co-Owner was also present on this day. They explained that they are equal partners. We informed Mr. Boersma and Mr. Van Ryn that we were at the firm to follow-up to an outbreak of *E. coli* that may be linked to Bravo Farms cheese that was sold to Costco Wholesale stores and that the source of the illness had not been established. The firm had completed production for the day and was conducting their clean-up of the facility so Mr. Boersma and Mr. Van Ryn led us on a walk through of the facility, explained the cheese processing and collectively answered our questions. Prior to leaving the firm, we were notified by James C. Henry, Supervisory Consumer Safety Officer that we should obtain documents for the Bravo Farms Dutch Style Gouda cheese sold to Costco Wholesale with the lot numbers of (b) (4) (June 1, 2010) through (b) (4) (July 23, 2010) that

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were identified by Costco Wholesale as the lot numbers of cheese provided at the cheese road show related to the illness outbreak. We were informed by Mr. Boersma and Mr. Van Ryn that the Dutch Style Gouda cheese manufactured in 20 lb. wheels, is only for Costco Wholesale and is aged for a minimum of 60 days, then cut into 1.5 lb wedges and then sent with a “sell by” date of 9 months to 12 months. The only other cheeses Bravo Farms sells to Costco Wholesale are packed and sold in gift packs. Mr. Van Ryn and Mr. Boersma informed us that they had been contacted by Costco Wholesale about the illnesses.

On the second day of the inspection, 11/5/10, Investigator Galvez joined Investigators Centeno and me to conduct environmental sampling at the firm. Our credentials were shown and a Form FDA 482, Notice of Inspection was issued to Mr. Boersma. Mr. Van Ryn inquired about our environmental sampling and we explained that we were conducting environmental sampling for *Listeria* and this was a standard practice at soft cheese manufacturers. Investigator Galvez collected environmental swab sample INV 636173 in the milk room and processing/packaging room, with Investigator Centeno assisting and taking photographs and I recorded and mapped swab locations and times. A Compact Disk containing photographs of swab locations (**Exhibit #35**) is attached to this report. In addition to the environmental samples, Investigator Galvez collected four aged, ready-to-eat cheese samples from the firm’s aging cellar under sample numbers INV 657180, INV 657181, INV 657182 and INV 636174. The firm did not accompany us or collect duplicate samples for the samples we collected.

Due to the lapse in time, Investigators Centeno and Galvez issued a new Form FDA 482, Notice of Inspection to Mr. Boersma on 11/18/10 to conduct a complete inventory count of all Bravo Farms cheese that was placed under an impound notice issued by CDFA on 11/15/10, under CDFA document number 76-094. On my return to the firm on 11/22/10, Investigator Galvez and I issued a new Form FDA 482, Notice of Inspection to Mr. Boersma.

FDA forms issued during the inspection included the Forms, FDA 482, FDA 483, FDA 484 and FDA 463(a) as follows:

Date	FDA Form Issued (Qty)	Presented to	Signed by
11/4/10	FDA 482	William L. Boersma	Investigators Centeno & Fukuda
11/5/10	FDA 482	William L. Boersma	Investigators Centeno, Galvez & Fukuda
11/18/10	FDA 482	Efrain G. Gutierrez	Investigators Centeno & Galvez
11/22/10	FDA 482	William L. Boersma	Investigators Fukuda & Galvez
12/1/10	FDA 483	William L Boersma	Investigators Centeno, Fukuda & Galvez
12/1/10	FDA 484 (2)	Jonathan A. Van Ryn	Investigator Galvez
12/1/10	FDA 463a (2)	Jonathan A. Van Ryn	Investigator Galvez

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An inspection and product sampling was also conducted by CDFA on 11/5/10. CDFA conducts routine audits and inspections of Bravo Farms Cheese, LLC. We introduced ourselves to Christina E. Asay, CDFA Dairy Food Specialist and Philip Fox, CDFA Dairy Food Specialist on this day. Our inspections and samplings were conducted separately from CDFA. FDA and CDFA shared inspectional findings and sampling results between agencies. For CDFA findings see, (**Attachment #10 to #14**). Many of the conference calls with the firm's management were conducted jointly.

I asked the firm if the United State Department of Agriculture (USDA) or any other regulatory agencies visit their facility. Mr. Boersma informed us that they would have to contact USDA if they were to export product but they are not exporting any of their cheese out of the country at this time.

HISTORY

William (Bill) L. Boersma began Bravo Farms Cheese at his dairy in 1995 in Visalia, California. In February 2006, Mr. Boersma began a partnership at the current location with Jonathan A. Van Ryn and is operating the business as Bravo Farms Cheese, LLC. This business is a 50/50 equal ownership between Mr. Boersma and Jonathan A. Van Ryn. William L. Boersma and Jonathan A. Van Ryn have other independent businesses but there are no other related businesses to this joint ownership. (b) (6)

The cheese manufacturing operation is adjacent to Bravo Farms store and restaurant. Jonathan A. Van Ryn's father, Jon A. Van Ryn is the owner of the property. Jon A. Van Ryn leases the store and restaurant out and has no involvement with these operations. William L. Boersma and Jonathan A. Van Ryn lease the property for the cheese making operation from Jon A. Van Ryn. Approximately two years ago, Jon A. Van Ryn incorporated a petting zoo on the premise that includes birds, donkeys, turkeys, chickens, and sheep. All of the animals are caged except we saw a rabbit and kitten roaming freely around the property. Approximately eight months ago, Mr. Jon A. Van Ryn also built a tree house in a huge tree located in the middle courtyard between the store, the restaurant and the cheese facility for children to climb for a fee. See (**Attachment #15**) for maps of the Bravo Farms property and facility.

There were a few changes from the previous inspection in 2008. The previous inspection noted that production is (b) (4) and cheese is cut and brined (b) (4) days with (b) (4) employees. Mr. Van Ryn provided the following information during this current inspection. The firm operates on about (b) (4) sq. feet. All of the cheese is manufactured from raw, unpasteurized milk and the only cheese that is pasteurized is their cheese curds. All of the processing of the cheese and packaging of aged, ready-to-eat cheese operations are within the same room. Cheese is manufactured (b) (4) on a (b) (4) from (b) (4). The firm has (b) (4) employees and (b) (4) employees.

I conducted a search in FDA FACTS and there were no consumer complaints found involving illness or injury related to Bravo Farms, LLC. Mr. Boersma informed me they have never received any consumer complaints on their cheese. Up to the time of the current inspection, the firm had not had

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any recalls on their product. (b) (3) (A)

All FDA correspondences should be addressed to:

Mr. William L. Boersma, Co-Owner & Mr. Jonathan A. Van Ryn, Co-Owner
c/o: Bravo Farms Cheese, LLC
36005 Highway 99
Traver, CA 93673

INTERSTATE COMMERCE

(Written by Investigator Galvez and Investigator Fukuda)

The firm manufactures approximately (b) (4) pounds of cheese annually under Interstate Milk Shipper's (IMS) plant identification number 06-827. Bravo Farms Cheese, LLC distributes about (b) (4) of their raw milk, aged ready-to-eat cheese out of state. The firm also manufacturer's pasteurized, ready-to-eat cheese curds that is sold exclusively at Bravo Farms store and restaurant.

Since the last inspection in 2008, Bravo Farms Cheese, LLC has increased their sales and distribution. All of the marketing and sales of Bravo Farms cheese is conducted by Mr. Boersma and Mr. Van Ryn. Mr. Boersma informed us that they promote their product at locations as, Farmer's Markets and their customer base consists of retail stores, restaurants and distributors. Mr. Boersma informed us that they have an internet site for sale of their cheese but sales on the internet are so small that they are considering removing this route of advertising. Mr. Davis informed us that any sales received through the internet would follow the same billing and shipping processing as their regular sales network. Mr. Van Ryn gave us the names of the following interstate and intrastate customers.

(b) (4) of the firm's randomly picked interstate customers are:

(b) (4)

The firm's intrastate customers include:

(b) (4)

Receipt of raw materials used at Bravo Farms Cheese, LLC:

All of the milk is purchased from a single dairy, (b) (4) located in (b) (4). This dairy is owned by (b) (4).

The firm purchases flavorings, culture and annatto from out of state suppliers. Some of flavors of cheese, such as garlic and horse radish, produced by Bravo Farms are made in limited quantities

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therefore these raw material components are minimal and may be purchased from (b) (4) (b) (4), as indicated by Mr. Boersma.

All cheeses produced by Bravo Farms Cheese, LLC contain salt and rennet as an ingredient. (See DOC 657185 and DOC 657186).

The salt has been ordered through (b) (4) since December 2009. Mr. Davis stated that prior to December 2009, Bravo Farms Cheese, LLC ordered salt from (b) (4) but he was unable to verify which division he ordered the salt from and for how long this practice took place. (b) (4) has a facility located at (b) (4). The (b) (4) facility transfers the salt it receives from (b) (4) at the (b) (4) facility to the facility in (b) (4). (b) (4) also received a shipment of salt from (b) (4) receives their salt from (b) (4) (DOC Sample 657186)

The rennet is also ordered through (b) (4). Mr. Davis stated that he does not believe Bravo Farms Cheese, LLC has ordered rennet from any other supplier. Records collected for the rennet show that Bravo Farms Cheese, LLC, has ordered rennet from (b) (4) since October 2007. (b) (4) receives rennet either directly from (b) (4) or through their (b) (4) facility who receives the rennet from (b) (4). (DOC Sample 657187)

Documentation for shipment of Dutch Style Gouda Cheese to Costco Wholesale Distribution:

Mr. Davis provided us copies of the documentation of shipments sent to Costco Wholesale stores distribution centers of the Dutch Style Gouda cheese implicated in the *E. coli* 0157.H7 outbreak. We collected the following documents for the shipments of cheese from 9/27/10 through 10/6/10. (Exhibit #1). Mr. Davis informed us that (b) (4) located in (b) (4) and (b) (4) in (b) (4) (Exhibit # 2) were used to haul these shipments to the Costco Wholesale distribution locations and he provided us the names and contact information of these trucking companies.

Date	Shipment Location	Invoice #	PO #	Copies of Documents Collected
9/27/10	(b) (4)	(b) (4)	(b) (4)	Invoice, Bill of Lading (BOL), signed BOL, P.O, Poundage sheet
9/30/10	(b) (4) *(b) (4) (b) (4)	(b) (4)	(b) (4)	Invoice, BOL, Signed BOL, P.O., Poundage sheet
10/6/10	(b) (4)	(b) (4)	(b) (4)	Invoice, BOL, Signed BOL, P.O., Poundage sheet.

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We also requested and received Bills of Lading and Invoices (**Exhibits #3**) for shipments sent to Costco Wholesale from 10/26/10, 10/28/10 and 11/1/10.

JURISDICTION

(This section was written collectively by Investigators Centeno, Galvez and Fukuda)

Bravo Farms Cheese, LLC manufactures various "raw milk" aged, ready-to-eat cheeses and pasteurized ready-to-eat cheese curds. These products include: Premium White Cheddar, Premium White Cheddar in Black Wax, Original Chipotle Cheddar, Western Sage Cheddar, Jalapeño Cheddar, Pepper Jack, Silver Mountain Clothbound Cheddar, Tulare Cannonball, and Dutch-Style Gouda. The firm informed us they only distribute cheese under the Bravo Farms label, see (**Exhibit #4**), Bravo Farms Labeling.

Bravo Farms will also add different flavors to these cheeses as; hot habanero, hickory smoke, garlic, cabernet, horse radish, and sage, white pepper, and onion. For example, one of the products is Dutch-Style Gouda with hickory flavoring. The Gouda cheese product will be labeled with the Dutch-Style Gouda label but the firm will add a small white sticker label with black printing which reads, "Hickory Smoked", to indicate the added flavoring, see (**Exhibit #5**), Bravo Farms Flavors added Labeling.

Bravo Farms Cheese, LLC sells product to various distributors and the firm may not be aware of the location of the final sale by the distributor. An example was the recall of Bravo Farms Cheese by Whole Foods. The firm did not sell their cheese directly to Whole Foods, a retail store therefore they were not aware of this sale and Mr. Davis informed us that he believes that Whole Foods purchased this from one of their distributors.

The firm sold cheese to Costco Wholesale, who further distributed these cheeses to their various locations in interstate commerce. These cheeses were linked to a multi-State cluster of illnesses. See (**Attachment #8**), (b) (5), (b) (5)

I asked for a promotional pamphlet of their cheese but Mr. Boersma informed me that he was currently out of them and when I asked for a list of all products manufactured by Bravo Farms Cheese, Mr. Davis provided me with a "Price List", (**Exhibit #6**). As Investigator Centeno & Galvez conducted an inventory of Bravo Farms cheeses, they found several cuts of cheese that were not listed on this Price list.

INDIVIDUAL RESPONSIBILITY AND PERSONS INTERVIEWED

The information for this inspection was provided by four individuals during direct personal interviews and requests.

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- William L. Boersma , Co-Owner
- Jonathan A. Van Ryn, Co-Owner
- Ryan L. Davis, Vice-President
- Efrain G. Gutierrez, Cheese Maker

Mr. Boersma and Mr. Van Ryn, both informed us that the operation is run as an equal partnership. They both make joint decisions on major issues, as the hiring and firing of personnel, major expenditures, and the final disposition of product but upon further discussion with them, it appeared there were some divisions of responsibilities based on their expertise. Mr. Boersma informed us that he shares responsibilities of sanitation and sales/marketing of Bravo Farms Cheese products with Jonathan A. Van Ryn. Mr. Boersma described himself as the "old" cheese maker and is primarily responsible for the cheese manufacturing and operation of the plant. He stated that his partnership with "young" Jonathan A. Van Ryn, with his degree in Dairy Science from Cal Poly, San Luis Obispo, California, makes them a good combination. Mr. Van Ryn's primary responsibilities lay with the written procedures, sales, quality assurance, testing and office duties. Mr. Van Ryn stated that many of his duties are being turned over to Ryan L. Davis, Vice-President. During this inspection, Mr. Boersma was available each day of our inspection, Jonathan Van Ryn was present on November 4, 5, 8, 22, 29, 30 and intermittently on some of the other days and Mr. Davis was available every day except on November 4th and 5th.

An organizational chart (**Exhibit #7**) was provided by Jonathan A. Van Ryn and it indicates Ryan L. Davis is the Plant Manager. Mr. Davis' current position is now Vice-President. Efrain G. Gutierrez is noted as Packaging Manager and David Steen as Cheese making Manager. Many of the production records, referred to as "Make Sheets", indicate "Efrain" as the Head Cheese maker. When we questioned Mr. Boersma about this discrepancy, he stated that both Efrain Gutierrez and David Steen are Cheese makers and Mr. Gutierrez makes most of the Gouda cheese so their duties may be interchanged. We witnessed Mr. Steen overseeing the cheese processing on 11/5/10 and both employees packaging aged, ready-to-eat cheese on different days that we were at the plant.

Jon A. Van Ryn, owner of the property is Jonathan Van Ryn's father who was not introduced as part of the management for Bravo Farms Cheese, LLC. (b) (6)

During a conference call on 11/22/10 that the firm had with CDFA and FDA involving the mandatory quarantine/recall, (b) (6)

Mr. Davis provided the majority of copies for the documents we received. Mr. Boersma provided copies of most of the production records "Make Sheets" and answered a majority of the questions. Mr. Van Ryn provided answers to questions and provided copies of records where stated in this report.

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William L. Boersma (Co-Owner):

All of the cheese formulations were developed by Mr. Boersma, who oversees the operation of the facility with Efrain G. Gutierrez. Any changes would be discussed with him in regards to cheese processing. Mr. Boersma informed us that he is not always at the plant and Mr. Gutierrez is the key person in charge of the processing. Mr. Gutierrez has been working with Mr. Boersma for about 20 years and started working for him at the dairy making cheese. Mr. Gutierrez reports directly to Mr. Boersma. He also stated that the rotation of the packaging of aged, ready-to-eat cheese is left to the packaging personnel. He stated that if there is a problem they will usually call him. We observed Mr. Boersma participating in the audit of the vat pasteurizer with CDFA on 11/5/10. He explained the processing and sanitation operation and was observed giving direction to many of the employees during our inspection. Mr. Boersma stated he is involved in equipment and plant maintenance but does not have any authority over the property.

Jonathan A. Van Ryn (Co-Owner):

Mr. Van Ryn is in charge of writing all the written procedures and documents, employee training, conducting recall audit checks, customer requirements, overseeing documentation for the firm, in-house testing of all incoming milk tankers for antibiotics, shipping, and most documentation for Bravo Farms Cheese. Mr. Boersma stated that Mr. Van Ryn is usually at the plant everyday and takes care of the office duties. We observed Mr. Van Ryn actively involved with the outside property clean-up operations on 11/9/10 (b) (6).

Ryan L. Davis (Vice-President):

Mr. Davis informed us that he is in charge of the day-to-day operations, the employees, scheduling, accounting (Accounts Receivable and Accounts Payable), ordering, suppliers and customers. He stated that he is in charge of the cheese making but was unable to answer specific questions in regards to sanitation. He provided copies to most of the documents received and answered a majority of the questions about the everyday activities. Mr. Davis was also observed talking to customers, requesting information from suppliers, and distributing checks to the employees. During the 11/22/10 conference call with CDFA and FDA, Mr. Davis did not identify himself as part of the firm on the roll call but addressed the majority of the questions and concerns for the firm. As stated he has taken over most of the duties previously conducted by Mr. Van Ryn.

FIRM'S TRAINING PROGRAM

(Written by Investigator Centeno and Investigator Fukuda)

On 11/4/10, Jonathan Van Ryn stated that he handles employee training at the firm and employees receive food safety training (b) (4). He provided us copies of Personal Hygiene and Proper Hand Wash Facilities (**Exhibit #8**), Cleaning Methods, Background, Cleaning and Sanitizing Program, and Cleaning Equipment and Facility (**Exhibit #9**), Plant and grounds GMP's and a sign posted on the entry door to the processing/packaging area near Vat (b)(4) (**Exhibit #10**). Mr. Efrain G. Gutierrez, Cheese Maker stated to Investigators Centeno and Galvez that he and David Steen currently train newly hired employees in-house on personal hygiene and GMP's.

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We received copies of the most current food safety training, held on (b) (4) (Exhibit #11) documenting that the employees were trained on (b) (4)

MANUFACTURING/DESIGN OPERATIONS

(This section was written collectively by Investigators Centeno, Galvez and Fukuda)

Bravo Farms has (b) (4) raw milk storage tank which has the capacity to hold (b) (4) gallons of milk. Mr. Boersma stated that they receive approximately (b) (4) gallons of milk per shipment. The milk storage tank is not enclosed within the facility. The only access to the inside of the milk storage tank is through the front portal door of the front of the milk storage tank, located in a separate room of the facility, referred to as the Milk Room. There is a temperature gauge on the tank and a separate temperature monitoring chart located on the east side of the tank. On 11/4/10, we noticed a temperature discrepancy between the two readings; the chart was reading warmer than the tank gauge. When asked, Mr. Van Ryn stated the temperature on the tank was correct and he would check into the variance.

Mr. Van Ryn informed us that raw milk is delivered to the firm on (b) (4) to manufacture cheese on (b) (4) and a (b) (4) tanker of milk is delivered on (b) (4) to manufacture cheese on (b) (4) but Mr. Boersma later stated that raw milk can be delivered any day and milk is ordered for production as needed. The raw milk is pumped from the milk tanker truck into the storage tanker. Mr. Boersma stated, they do not hold milk for more than (b) (4), as stated by the law.

The firm is currently processing approximately (b) (4) gallons of raw milk into cheese (b) (4) that yields about (b) (4) lbs. of cheese. Mr. Boersma stated that he manufactures his cheese from raw milk following the Code of Federal Regulations (CFR) and on several occasions cited the critical minimum 60 day hold time for aging and that the temperature must be kept at >35 degrees. The firm produces one product that requires the milk to be pasteurized, which is the cheese curd.

All of the cheese formulations were developed by William L. Boersma as well as some of the methods and ingredients. We obtained copies from Mr. Boersma and Mr. Van Ryn of their processing records, referred to as "Make Sheets". The majority of the Make Sheets obtained were from the production of the Dutch Style Gouda cheese produced for Costco Wholesale, between 6/1/10 and 9/1/10, (Exhibit #12). We reviewed these records and noted that the firm does not record flavorings (i.e. sage, garlic) or the lot numbers of the salt used in the milled cheese or the brining process.

Processing/Packaging Room:

All of the processing of young cheese (raw milk cheese prior to aging) and packaging of aged, ready-to-eat cheese are conducted within a single room that is approximately (b) (4) square feet. Mr. Van Ryn stated that the processing of young cheese and packaging of aged, ready-to-eat cheese can occur simultaneously in the same room. We observed employees using a garden hose with an

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adjustable, twist-type metal nozzle, spraying cheese into the drain running through the center of the processing area.

The firm uses (b) (4) vat pasteurizer to heat raw milk, water, or pasteurized milk for the production of cheese curds. This pasteurizer holds approximately (b) (4) gallons of milk at a time. (b) (4) cheese vats are used by the firm for the production of cheese. Cheese Vats (b) (4) gallons each and Vat (b) (4) gallons for processing. The firm uses (b) (4) centrifugal pumps for their operation; (b) (4) and the (b) (4).

There are two primary entry/exit doors leading into the processing room. Both doors had issues with gaps around the doors as discussed in Observation #4 in OBJECTIONABLE CONDITIONS AND MANAGEMENT'S RESPONSE section. A third double-door that leads directly outside was never opened and kept locked except on 11/9/10, when the doors were being repainted but during that time, a solid barrier was placed over the vacant spot. The primary door we observed employees' using was the double door located in the packaging area. This entrance is a heavy weight plastic double door that is very difficult to open and therefore personnel must use a lot of direct force with their hands or bodies to go through this entrance.

Aging Cellar and Aging Trailer:**Aging Cellar:**

The aging cellar is divided into two rooms and is located below the main facility that occupies a total space of about (b) (4) square feet. The aging cellar is accessed through a set of stairs or an elevator (**Exhibit #13**) that is about 6' X 3'. The elevator and stairway are located about 10 feet from the processing/packaging door, on the north side of the hallway leading from the processing/packaging room to the double doors leading outside. (**Exhibit #14**). The elevator is primarily used to transport the young and aged cheese to and from the processing/packaging room to the aging cellar. We observed two plastic carts used for these operational functions; a four-tiered cart (see photographs in Observation #3 in OBJECTIONABLE CONDITIONS AND MANAGEMENT RESPONSE) and a two layered cart. We observed the four-tiered cart transporting young and aged cheeses to and from the processing/packaging room. The two layered cart was seen primarily being used in the aging cellar but Investigator Centeno witnessed processing/packaging employees using this same cart to transport Tulare Cannonball cheese outside the facility on 11/4/10.

Mr. Boersma informed us that the temperature in the aging cellar is maintained, around (b) (4), using overhead fans. The firm has a combination (b) (4) designed to monitor the temperature and humidity in each room. Temperature recorders are located in each of the rooms (**Exhibit #15**) but they do not record the humidity. On 11/10/10, the East Aging room was reading (b) (4) RH and the West Aging Room was reading (b) (4) RH. There is a separate portable de-humidifier located in each room.

All of the young cheese stored for aging and the aged, ready-to-eat cheeses are stored side-by-side. (**Exhibit #16**). The firm's management informed us that they depend on their employees to monitor the proper packaging dates after the minimum 60 day requirement and do not have a rotational

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system to package the young cheese or their aged cheese. The cheeses are stored on shelves made out of wood, sitting on metal frames. The aging Tulare Cannonball cheese, Blú cheese, and the cheesecloth wrapped, Silver Mountain cheeses are not wrapped in (b) (4) for aging. The Blú cheese was only being stored on (b) (4) boards or plastic sheets (Exhibit #41), sitting on top of the wooden shelves. The Tulare Cannonball and the Silver Mountain Cheddar (Exhibit #42) cheeses that are placed on a plastic sheet on top of the wooden shelves. All of the other young cheeses were being aged in (b) (4) packaging and when we asked why these bulk young cheeses were aging in (b) (4) packaging, Mr. Boersma stated he did not know.

Mr. Boersma informed us that there is no scheduled cleaning in the cellar. There are no floor drains observed in the room and the only cleaner used to clean is apple vinegar and never chlorine.

Aging Trailer:

There is an elevated truck trailer located outside of the facility also used for aging with a non-railed handmade wooden stairway used to enter the trailer. Mr. Boersma informed us that the firm purchased and began using this trailer in 2006. There are plastic curtains immediately behind the roll-up door to the entry of the trailer. There is a refrigeration unit on the trailer and the only temperature monitoring device for this trailer was a hanging room thermometer. There was not any type of instrument to monitor the humidity or a recording device to record the temperature or humidity in the trailer. Mr. Boersma informed us that there used to be a temperature recording device on the north wall and was unaware that it was no longer being used in the trailer.

There were two rows of shelves holding young cheese that is tightly packed together in about (b) (4) square feet of space. The cheeses sit on wooden shelves. All of the cheeses in the aging trailer were packaged in (b) (4) packaging and sitting directly on the shelves. We did not observe any Tulare Cannonball cheese, Silver Mountain Cheddar or Blú cheese being aged in this trailer. As informed by management, there is no type of rotational system used to make certain cheese is removed and packaged on a first-in-first-out basis and they depend on their employees to make certain that cheese is properly rotated to meet the 60 day requirement. After the cheese has met the required aging period, the cheese must be transported back to the main facility on a cart to the packaging area to be cut and packaged. The packaged aged, ready-to-eat cheese is then transported on a cart back to the aging cellar for storage until shipment.

There was a padlock hanging on the trailer but we did not observe it being used to lock the trailer on the three days that we entered the trailer. Just below the trailer is an open sump pump that collects run off liquid/water debris from the plant. The firm is in the process of building covers for this pump but this will have to be approved by CDFA. Although we did not witness any off-odors coming from this area, the well was filled with cheese by-product residue and we were informed by CDFA that the odor gets very unpleasant when the weather gets hot.

Brining Room:

The wash curd cheeses are brined in a separate building. The formed wash curd cheese is transported outside, uncovered, across an open area to access the brining room. The brining process is conducted in food grade (b) (4) plastic cans designated as NSF for food grade. These have

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the same appearance and configuration as (b) (4) Gallon trash cans. Investigator Galvez and I also observed at least (b) (4) dirty NSF brining cans stacked directly on the ground next to broken cans and being used for outside clean-up. Mr. Boersma informed us that there is no way to differentiate between trash cans and brining cans but that the brining cans are cleaned before each use. Mr. Boersma informed us that formulations to make the brine solution cannot be calculated and that it is an art to make the proper (b) (4) salt solution needed. The measurements are taken with a hydrometer at (b) (4) and brining takes about (b) (4) hours per (b) (4) pounds of cheese. During our inspection, the firm did not have any cheese brining but Investigator Centeno observed uncovered Tulare Cannonballs being moved outside to the brining room.

Investigator Galvez and I saw a single brining can with residual brining solution in the room and there were several empty brining cans stacked in the storage trailer. This brining room is also used to hold cartons of product that were packaged and ready to be shipped. On 11/10/10, Investigator Galvez and I observed a pallet of miscellaneous boxes of cheese in the room. Mr. Boersma informed us that this was cheese that was to be destroyed. On 11/15/10, we observed Dutch Style Gouda cheese placed on a pallet that had been recalled and returned from the Bravo store. It was placed in the room and was not segregated from the other cheese prepared for shipping or labeled in a manner that differentiated from the cheese designated for shipment; i.e. Hold/Return tags, Quarantined. Investigator Galvez also observed a fiber drum with no identification that contained Jalapeño peppers in a salt solution that was not fully covered.

Storage Areas:**Facility Attic Area:**

The attic located over (b) (4) of the main facility, including over the processing/packaging area, is being used for storage. This area is divided into two separate rooms. Approximately 3/4 of the storage area in the attic was being used for retail merchandise, including packaged food items, to be sold by the Bravo Farms Store that operates separately from the cheese facility. The entire area was in disarray and filled with items to the edges of the attic. There were Cannonball hoops and metal hoops being stored in a plastic cart and on the floor in the midst of the retail items.

The entry door to the attic is in the middle of the firm's facility. The only way to access the attic door is through one of the entry doors to the firm's facility. We observed store employees entering and exiting both doors of the facility to obtain items from the attic or retrieving merchandise delivered for the store at the back receiving dock of the facility, where milk tankers are staged to unload milk deliveries. Pest control traps were observed around the inside perimeter of the attic. We did not observe any rodent activity but there were spider webs in many areas and on merchandise. I observed four, ~1/2" gaps in the southeast corner of the attic, directly over the processing area in which sunlight could be seen.

Storage Trailer:

The firm uses a truck trailer sitting directly on the ground that contains several miscellaneous items; e.g. the firm's packaging materials, brine cans, boards for gift packs. This included (b) (4) film

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that is used to (b) (4) the bare cheese. There were several items sitting directly on the floor of the trailer, stacked haphazardly, with the roll-up doors opened a majority of the time, (Exhibit #17). Investigator Galvez witnessed a rabbit with white paws coming out of the trailer on 11/9/10. This same rabbit was seen roaming in the donkey corral and in the common picnic area. Please see section on OBJECTIONABLE CONDITIONS AND MANAGEMENT'S RESPONSE for photographs. On 11/15/10, the firm was moving the trailer away from the building containing the brining room and as personnel were cleaning the area around the trailer with a hose, we observed several items getting wet within the trailer, as the uncovered boards used for Bravo Farms gift packs, (Exhibit #18).

There is no fenced area to prevent any public access into the trailer and the roll-up door was observed left open even when plant personnel were not present.

Chemical/Boiler Room:

There is a separate room that houses the boiler and chemicals, including drums of sanitizing solution used in the plant. Some of the drums of chemicals did not have a label or the print on the label had become unreadable. We observed miscellaneous items as cans of paint being stored on a metal rack in this room that was previously stored. The door to this room was left open even when plant personnel were not present allowing for possible public access.

Processing:

The firm discontinued processing cheese after 11/5/10. We only observed a part of the milling process and pressing process on 11/5/10, the day we conducted environmental sampling at the firm. On this day, (b) (4) vats (b) (4) were being used to manufacture Original Chipotle Cheddar and Vat (b) (4) being used for Dutch Style Gouda wheels of lot number 0309. The firm provided us a Product Flow Chart, (Exhibit #19).

The firm uses the following two methods to manufacture their cheese as explained to Investigators Centeno and Galvez by Mr. Boersma:

Washed Curd Process (Dutch Style Gouda, Tulare Cannonball, Jack, Colby):

(b) (4)

(b) (4)

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(b) (4)



Mill Curd Process (Cheddar, Silver Mountain Cheddar):

(b) (4)



(b) (4) Packaging

All of the (b) (4) packaging for the young cheese and aged, ready-to-eat cheese are purchased through (b) (4). The firm purchases the (b) (4) of bags in different sizes, but is of the same material and specification, **(Exhibit #20)**.

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(b) (4)

Sanitation

Bravo Farms has (b) (4) CIP (Clean In Place) (b) (4) and (b) (4) COP (Clean Out of Place) parts. We received copies of the firms CIP and COP procedure (**Exhibit #21**). Mr. Boersma stated that (b) (4) processing employees are responsible for conducting the CIP and COP cleaning.

After the delivery of each milk tanker, the line used to unload the milk is Cleaned In Place (CIP'ed). The firm does not keep records for a check of the line after CIP of the milk line.

The CIP line for the processing line includes the raw milk storage tank, the piping leading from the tank to the pasteurizer, the pasteurizer, and the piping leading from the pasteurizer to the cheese vats. He stated that CIP on this line is conducted (b) (4) but only on days that cheese is manufactured.

Employees conducting the sanitation operations are to follow the manufacture's instructions specified for the cleaning detergent and for the acid sanitizer. Mr. Boersma informed us that they work with the chemical company to determine what sanitizing solutions to use by checking the hardness of the water to determine the ratio of chemical to water but the firm does not keep any records to document the chemical mixing. When we asked Mr. Van Ryn about the checking of the water hardness and testing to determine the dilution ratio, he stated that since (b) (4) water is used, that water hardness should not be a factor. The solutions are mixed in-house and are not recorded on the Cleaning Log (CIP and COP).

All of the sanitation chemicals are purchased through (b) (4)

(b) (4) Mr. Davis provided us copies of a few of the invoices from chemicals purchased that includes (b) (4), which Mr. Boersma identified as the Acid Sanitizer. (**Exhibit #22**).

There is a sanitizing vat (bath) in the processing room used to sanitize COP parts (**Exhibit #23**). Examples of COP parts include the cheese cart and the cheese vats. Chlorine is used as the sanitizing solution. The firm's management informed us that this is changed by visual checks and by smell of the strength of chlorine in the vat. I asked if they used any type of tests to check the chlorine level but Mr. Boersma informed me that they tried using chlorine dip strips in the past but the employees had difficulty using them so they discontinued use. When I checked the chlorine level with a chlorine strip on 11/9/10, the level was >10ppm.

The firm also has two sanitizing foot baths located at both entries to the processing room. One foot bath is located at the door near Vat (b) (4) and the other at the double doors near the packaging area. Both foot baths were tested on 11/09/10, the test strips indicated that the Total Chlorine and Free Chlorine were at 0ppm at both locations.

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CIP/COP Documentation:

We received copies of the firm's Cleaning Log (CIP and COP) that documents their cleaning between 6/1/10 through 10/11/10 (**Exhibit #24**). This log records the date and time the CIP is done, along with the amount of water used, ounces of detergent, the temperature, duration of cleaning, and inspections conducted of the pasteurizer and screen and the COP parts. It appears from this log that the CIP and COP operations are conducted (b) (4) and during the (b) (4) hours of the production day. I asked Mr. Boersma about the degrees (°) symbol on the column listed as "Gal H2O" on the dates of 7-22-10 through 7-30-10 entered by David (**Exhibit #24**) and he informed me that this was probably just a mistake. The bottom of the CIP/COP document indicates that "only trained personnel including Jonathan Van Ryn, David Steen or (b) (6) are qualified for CIP". Mr. Boersma also clarified that the (b) (4) are screens at the end of the line that are checked after the system is cleaned. The COP log does not document the employee that cleaned/sanitized each COP part.

On 11/29/10, I asked the firm to explain the single entry for COP parts and what parts they are referencing, how the parts are inspected and if they are all cleaned on the day at the single time designated on the worksheet. We received the following replies from management. Mr. Boersma informed us that COP indicates any equipment that moves out of the room and CIP would be all other equipment. After Mr. Boersma left, Mr. Davis informed us, as directed by Mr. Van Ryn, that COP equipment is all equipment in the sanitizing vat. When we inquired about such things as tables and carts, he said he didn't know. He then went to ask Mr. Van Ryn to clarify our inquiry and (b) (6)

Our understanding from the above is that the COP parts range from utensils as knives to equipment as the mill curd. We did not observe a separate washing station in the packaging area therefore; all of the knives and utensils would have to be taken to and from the sinks located in the processing area of the room. All of the same packaging equipment is used for cutting cheese and to vacuum seal (b) (4) the young cheese and the aged ready-to-eat cheese. As management stated, since there is no log kept on the various COP parts, it would be difficult to determine if equipment used to cut young cheese could have been used on aged, ready-to-eat cheese prior to sanitizing.

The same sanitizing vat is used for all of the COP parts. This would include both parts used in the processing area and those used in the packaging area. The chlorine level in this vat is only maintained visually or by smell therefore there is no testing to verify that the levels are high enough to properly sanitize the parts.

The firm's management informed us that the employees interchange jobs throughout the process and packaging. We observed the same employees performing the different duties on different days. We observed the same personnel on 11/5/10, mixing the cheese in the vats and on a different day packaging aged, ready-to-eat cheese and transporting the cheese to the aging cellar on carts.

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Also, the COP log does not document which employee cleaned or sanitized each COP part. Since there are (b) (4) vats to process cheese, this may involve using the same equipment or part being used at different times and there would not be any documentation if proper cleaning was being conducted between uses.

Employee Practices

The division of responsibilities according to the organizational chart varies from the statements of management and varied from what was observed during the inspection as duties overlap and rotate. We observed and found documents of the same employees processing young cheese and packaging aged, ready-to-eat cheese.

There are two primary doors used by employees leading into the processing/packaging room. The door adjacent to the front entry is a single door and is further away from the materials and locations that the processing/packaging employees need to access. This single door is too narrow to transport and/or move raw materials, equipment, and carts to and from the processing/packaging room.

The primary door used by employees is the double door in the packaging area. Employees working in the processing area must pass through the packaging area to exit the room. We observed processing and packaging employees using this same double door in the packaging area a majority of the time to leave and return from breaks, transport young cheese and aged, ready-to-eat cheese, and bring equipment into the processing area. These double doors are made of heavy plastic and must be pushed with your hands or body to open the doors.

Since there is no hand washing station in the packaging area, the employees packaging cheese must use the hand washing sink in the processing area then cross back into the packaging area to return to work. The sanitizing bath that we observed employees using was also located in the processing area of the room.

All of the processing and packaging of young and aged, ready-to-eat cheese is done with employee's bare hands (**Exhibit #25**). During the cheddaring process, employees with observable hair on their forearms were observed mixing cheese with their bare hands, including their forearms in direct contact with the cheese curds. Mr. Boersma informed us that there is no practical way to use gloves during this process of mixing the curds.

The processing/packaging area is very small and as the firm's management stated, both processing and packaging may occur at the same time. After the cheese is processed, the processing employees would have to pass through the double doors in the packaging area to move the young cheese to the brining room or to the aging cellar or aging trailer. This may also involve passage through the packaging area while cheese is being packaged in order to transport raw materials or equipment involved with the processing step.

We observed employees, after the milling process in Vat (b) (4), move the mill into the packaging area. We collected an environmental sample from the mill after it was moved into the packaging area that tested positive for *Listeria monocytogenes*.

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The same packaging equipment and working area is used to cut young cheese for aging (slicer) and aged, ready-to-eat cheese for packaging. Since the firm does not document times that COP parts are cleaned and sanitized, there is no record to verify that there was actual sanitation that occurred between cutting the young cheese and aged cheese and by whom. Also, records indicate (Observation 3), that young cheese and aged cheese were packaged on the same day.

Employee training indicates that employees are not to wear their assigned aprons outside of the processing/packaging area. We were informed and observed employees wearing their protective aprons outside of the room as well as outside of the facility. This occurs as part of the work process, i.e., taking cheese to the brining room or cleaning equipment in outside areas or inadvertently not removed while taking breaks.

Testing on the foot baths indicated that the level of chlorine was zero and management stated that they do not check the chlorine levels. The employees wear the same shoes throughout the day walking through the processing and packaging areas as well as outside of the plant. Also, on 11/9/10, the foot bath was removed from the packaging area while employees were coming and going from the room and cheese was being transported out of the packaging area. Neither the employee's shoes nor the wheels of the cart used for transport were being sanitized.

There are only two carts used to transport young cheese and aged, ready-to-eat cheese. The firm's management could not verify when the carts are sanitized. The COP log does not document sanitation of the carts. Employees transporting aged cheese may not know if it had been used to transport young cheese just prior since there is no documentation. Also the carts are used to transport cheese to the outside brining room or aging trailer and then brought back into the facility without proper cleaning.

Mr. Gutierrez informed us that the firm provides uniforms to their employees. An outside laundry service delivers a new set of clean uniforms (b) (4). Employees change from street clothes when they arrive at work and back into street clothes before they leave for the day. Each employee has individually assigned plastic aprons that are marked with their name. We were told that they are not suppose to wear the aprons outside of the processing/packaging area but there may be times when an employee will get a raw material outside of the processing packaging room and forget to take off their apron. We observed employees washing trash receptacles at the outside sink and taking breaks while wearing their aprons.

Testing

A milk sample is collected from each tanker of milk delivered to Bravo Farms. The only test conducted on the incoming milk is an in-house test for antibiotics, which is conducted by Jonathan A. Van Ryn. Per (b) (4) requirements, the firm collects environmental samples for *Listeria* on a (b) (4) basis (Exhibit #26) and periodically collects finished product samples (Exhibit #27). The firm provided copies of environmental test results from April 2010 and July 2010 each of which consisted of three environmental samples. They also provided a copy of a finished product test result from December 2009 that consisted of one cheese sample. Mr. Van Ryn informed us that all samples are sent to (b) (4). The firm's management stated that they have not received a positive result to date.

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On 11/8/10, the firm stated that they have switched all of their testing from (b) (4) to (b) (4). Mr. Boersma stated that they had sent samples of all of their cheese to (b) (4) for testing but we were not informed of the results.

On 11/29/10, we inquired and Mr. Davis stated the firm is having their own tests conducted at (b) (4) that included testing on the animals for *E. coli* and all of the milk tankers of the transporter. We asked Mr. Davis if he would provide us with results of their testing, and he said he would but they had not received any of the firm's test results.

Mr. Boersma informed us that all water used at the firm is from (b) (4) water. Their water analysis for Total Coliform and *E. coli* is conducted by (b) (4). We were informed that the firm has not received any positive results for Coliform or *E. coli*. (Exhibit #28).

Mr. Boersma informed me that he conducts his own in-house calibrations of the firm's thermometers (b) (4) using a mercury thermometer but does not keep any records.

Inventory Control

Ryan L. Davis informed us that he takes a (b) (4), physical inventory by pounds of all of their cheese in stock. During the first recall involving Dutch Style Gouda cheese, we asked the firm to provide us with an inventory of all of the remaining stock of this cheese. Mr. Van Ryn converted the handwritten inventory taken by Mr. Davis onto a typed format and a copy was provided to us (Exhibit #29). On 11/5/10, we informed Mr. Boersma that we found several finished 8 oz. packages of aged, ready-to-eat cheese that did not have a lot number stamped on the finished packaged. On 11/18/10, Investigators Centeno and Galvez conducted a full inventory of all of the cheese at Bravo Farms Cheese in the Aging Cellar, Aging Trailer and the Brining Room (Attachment #16) which totaled to approximately (b) (4) lbs.

By-products from the plant

There are (b) (4) storage tanks located outside of the facility. (b) (4) are located next to the Aging trailer. Mr. Boersma explained the usage of each tank. (b) (4) tank is used to store the run-off whey from the plant. This liquid whey product is sent to (b) (4) to feed their dairy cows. (b) (4) Waste water from the plant. This is flushed through their septic system. The volume collected by the plant is only about (b) (4). Storage for water to be used in case of a fire.

Mr. Van Ryn and Mr. Boersma informed me that cheese is never reworked and any cheese that does not meet their specifications is destroyed (trashed). The primary reason for rejection is due to poor flavor (acidic or bitter).

Pest Control

The firm contracts their pest control with (b) (4). We received a copy of a map (Exhibit #30) from Mr. Van Ryn that shows the locations of the bait boxes and glue boards. (b) (4) visits the firm on a (b) (4) basis. Mr. Davis provided us a copy of an inspection report by (b) (4) (Exhibit #31). No rodent activity was observed during this inspection.

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When asked about the excessive fly activity observed on 11/4/10, Mr. Van Ryn replied that fly activity heightens during warmer weather and activity was much higher during August when the weather got very hot. There were no observations of any controls for fly activity. This is further discussed on the FDA 483, Inspectional Observations issued to the firm.

TRACEABILITY

At the onset of this inspection at Bravo Farms Cheese, LLC, we concentrated on lot numbers of Dutch Style Gouda cheese implicated in the Costco Wholesale, *E. coli* 0157:H7 illness outbreak. The lot number dates were provided to FDA from Costco Wholesale (**Attachment #18**). Costco Wholesale informed us that these lot numbers were provided by Bravo Farms. This list encompassed the lot numbers of (b) (4) (6/1/10) through (b) (4) (8/20/10).

The firm informed us that they only make 20 lb. "Big" Wheels of Dutch Style Gouda cheese for Costco Wholesale and that these wheels are cut down into 1.5 lb. wedges that are sent to Costco Wholesale distribution sites. The firm's management informed us that they were providing cheese for Costco Wholesale for the quarterly cheese road show.

On 11/5/10, Mr. Boersma stated, "There is no retail cutting prior to the 60 days" and provided all of the "Make Sheets" for the above mentioned lot numbers (**Exhibit #12**). Ryan Davis provided me with the Bills of Lading, Invoices and any other shipping documents for the shipments that went to Costco Wholesale during the time period indicated (**Exhibit #1**). We asked Bravo Farms to verify the lot numbers that went on each shipment. The firm's management then informed me that they do not record lot numbers on each invoice that is sent out. I referred to the list provided to FDA by Costco Wholesale of the lot numbers that Costco Wholesale received and said were provided to them from Bravo Farms. Mr. Boersma and Mr. Van Ryn stated that their Packaging Log would indicate the day that the aged, ready-to-eat cheese would have been packaged and these finished packages would have shipped within about a week of the packaging date specified on the Packaging Log. Mr. Davis provided me copies of the Packaging Log that dated from 5/28/10 through 11/01/10 (**Exhibit #32**).

A review of the Packaging Log revealed that there were several days in which young cheese had not met the required 60 day aging. Mr. Boersma stated on 11/9/10 that the firm "never cuts and wraps cheese prior to 60 days", to verify the discrepancy, I requested all Packaging Sheets from 10/13/10 through the last shipment day of 11/1/10. Concentrating on the Costco Wholesale Dutch Gouda cheese, there were 7 days between 8/30/10 and 11/1/10 that were packaged prior to the 60 day requirement (**Attachment #17**).

The Packaging Log also revealed that the aged, ready-to-eat cheese was not packaged in the order in which the cheese was manufactured. The firm's management informed us that they do not have a system that would track rotation of their stock to make certain the oldest cheese is packaged first; a first-in-first-out system. The Packaging Logs from 5/28/10 through 11/01/10 (**Exhibit #32**), indicated that aged, ready-to-eat cheese was packaged out of sequence for cheese manufactured from

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8/24/10 through 11/1/10, as shown on the copies of the breakdown of the Packaging Log to determine 60 day aging requirement (**Attachment #17**).

On the final day of inspection (11/29/10), I asked Mr. Davis how they provided the lot numbers to each shipment that was sent to Costco Wholesale (**Attachment #18**). Mr. Davis informed me that he went through the Packaging Log and backed out the lot numbers based on the (b) (4) and (b) (4).

MANUFACTURING CODES

(Written by Investigators Centeno and Investigator Galvez)

Bravo Farms Cheese, LLC is currently stamping a four digit lot code on their cheeses. They use the (b) (4). See (**Exhibit #33**), Bravo Farms Cheese, LLC lot code breakdown.

For example: (b) (4)



The firm manually stamps this code on each of their aged, ready-to-eat cheese product labels. We observed this code also being used on the Tulare Cannonball and Silver Mountain cheddar before they are placed into finished product packaging.

A "Sell By Date" is also used upon customer request. This is an adhesive sticker, label that is attached to the (b) (4) packaging prior to shipment. According to Mr. Davis, (b) (4) will request by email a "Sell By Date" ranging from 300 days-1 year.

If (b) (4) requested 300 days, this would require you to go back 300 days from the "Sell By Date" to find the final product packaging day for the cheese and it would be necessary to look at the Packaging log on that 300th day back to see what cheeses were packaged on that day.

For example: **November 5, 2010**

The 300th day back from November 5, 2010 would be January 5, 2010.

COMPLAINTS

(Written by Investigator Centeno)

Firm's management stated that they do not keep a complaint file. They further stated that they have not received any complaints.

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RECALL PROCEDURES

Jonathan A. Van Ryn conducts mock recalls (b) (4) a year that are performed in-house. The last (b) (4) mock recalls were conducted on (b) (4). Please see (Exhibit #34).

OBJECTIONABLE CONDITIONS AND MANAGEMENT'S RESPONSE**Observations listed on form FDA 483**

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.

Reference: 21 CFR 110.20(b)(2)

Supporting Evidence and Relevance:

- The diagram of the processing/packaging facility demonstrates the potential for cross contamination between processing of cheese and the packaging of aged, ready-to-eat cheese.

We were informed by management that the firm manufactures raw milk cheese at the same time that they package aged, ready-to-eat cheese. The processing employees were observed using the door near the packaging area to exit the processing/packaging room while cheese was being packaged. This double door is opened with bare hand contact by both processing and packaging employees due to its heavy weight.

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There is only a single hand washing station located in the processing area near the pasteurizer. Please see the diagram below.

(b) (4)



- The photograph below illustrates the areas, outside of the facility where employees must cross with uncovered cheese to access the brining room.

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(b) (4)



IMG_0490.jpg-Copy of photograph taken of storage trailer. Roll-up door observed open through-out the inspection

Exhibit #36, Photo #0490

Discussion with Management:

Mr. Van Ryn stated the brining operation has been moved from the outside room into 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:

Cheese Type	Package Date	Amount	Process Date Lot Code	60 Day Aging
(b) (4)	9/7/10	(b) (4)	(b) (4) (7/13/10)	(b) (4) (9/11/10)

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(b) (4) Gouda				
	9/7/10	(b) (4)	(b) (4) (7/14/10)	(b) (4) (9/12/10)
	9/8/10	(b) (4)	(b) (4) (7/14/10)	(b) (4) (9/12/10)
	9/8/10	(b) (4)	(b) (4) (7/21/10)	(b) (4) (9/19/10)
	9/9/10	(b) (4)	(b) (4) (7/16/10)	(b) (4) (9/14/10)
	10/5/10	(b) (4)	(b) (4) (8/17/10)	(b) (4) (10/16/10)
	10/5/10	(b) (4)	(b) (4) (8/18/10)	(b) (4) (10/17/10)
(b) (4) Jack	9/23/10	(b) (4)	(b) (4) (7/27/10)	(b) (4) (9/25/10)
	9/24/10	(b) (4)	(b) (4) (7/28/10)	(b) (4) (9/26/10)
	10/29/10	(b) (4)	(b) (4) (8/31/10)	(b) (4) (10/30/10)
(b) (4) White Cheddar	10/21/10	(b) (4)	(b) (4) (8/31/10)	(b) (4) (10/30/10)
	10/27/10	(b) (4)	(b) (4) (8/31/10)	(b) (4) (10/30/10)
(b) (4) Gouda	8/28/10	(b) (4)	(b) (4) (7/6/10)	(b) (4) (9/4/10)
(b) (4) Pepper Jack	9/6/10	(b) (4)	(b) (4) (7/15/10)	(b) (4) (9/13/10)
(b) (4) White Cheddar	10/28/10	(b) (4)	(b) (4) (8/31/10)	(b) (4) (10/30/10)

Reference: 21 CFR 110.80(b)(2)

Supporting Evidence and Relevance:

Review of the copies of the breakdown of the Packaging Log to determine 60 day aging requirement (**Attachment #17**) demonstrates the discrepancies indicated above.

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Discussion with Management:

Mr. Van Ryn stated that cheese will not be cut prior to the 60 days of aging and that the firm will implement a verification step. This will be implemented as of 12/1/10.

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.

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 (b) (4) hours prior to (b) (4) 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^{(b)(4)} 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^{(b)(4)}. 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^{(b)(4)} 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.

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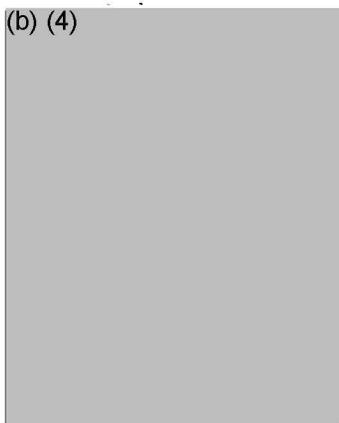
EI End: 12/01/2010

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.

Reference: 21 CFR 110.80

Supporting Evidence and Relevance:

- Below are the photographs of one of the carts used to transport young unpackaged cheese and aged, ready-to-eat cheese, in the hallway leading to the hallway packaging area.



IMG_0555.jpg-Copy of photograph taken of cart used to transport young cheese to the brining room, processing room, and aging rooms.

Exhibit 37, Photo #0555

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(b) (4)



IMG_525.jpg-Copy of photograph taken of cart used to transport young cheese to the brining room, processing room, and aging rooms.

Exhibit #37, Photo #525

- On 11/4/10, Investigator Centeno observed (b) (4) processing/packaging employees transporting young, unpackaged Tulare Cannonball cheese on a grey colored plastic, two-tiered cart to the brining room. This cart was then observed on 11/5/10, in the aging cellar where young and aged, ready-to-eat cheese is stored.
- Review of “Make Sheet” records and “Packaging Log” records 6/1/10 through 9/2/10 show you are packaging young cheese on the same day, in the same room, and using the same equipment as you are packaging aged, ready-to-eat cheese (**Exhibit #12 and #32**). Your “Make Sheets” dated 6/1/10, 6/8/10, 6/16/10, 7/7/10, 7/13/10, 7/20/10, 9/1/10 for Dutch Style Gouda show that you brine your cheese for (b) (4) hours and then package the cheese after the (b) (4) hours. Your “Packaging Log” shows that on 6/2/10, 6/9/10, 6/17/10, 7/8/10, 7/14/10, 7/21/10, 9/2/10 you are packaging aged, ready-to-eat cheese.
- Investigator Centeno observed condensation on the ceiling of the Processing room while product was being manufactured in uncovered Vat (b) (4)
- Photographs below illustrate the close proximity of the open public men’s restroom door which may be accessible to free roaming animals as shown by the cat in the photograph. The red door is an employee entry to the facility.

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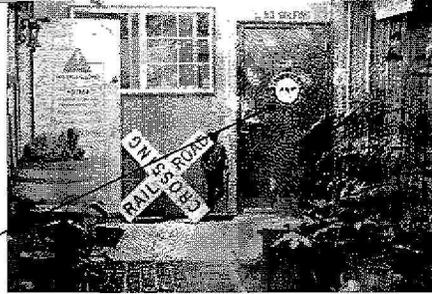
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(b) (4)

IMG_0586.jpg-Copy of Photograph taken of cat roaming freely near the processing facility.

IMG_2055.jpg-Copy of photograph of public men's restroom near the door to the processing facility. This restroom was regularly used by employees.



Employee door is kept unlocked.

Exhibit #37, Photo #0586

Exhibit #35, Photo #2055

- Investigator Fukuda tested the chlorine levels in the footbaths located at both entrances of the processing/packaging room with chlorine test strips.
- Investigator Galvez observed the relocated foot bath and watched employees moving the cart through the doorway.

Discussion with Management:

Mr. Van Ryn stated there will be a new COP list and a segregated cart for aged cheeses and unaged cheeses. He stated that he would start working on this as of 12/1/10. There were no responses to the other items within this observation.

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 ^{(b) (4)} 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

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room. One of the investigators observed a fly, fly out of Vat^{(b)(4)} that contained 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^{(b)(4)} 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 (b) (4) 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.

Reference: 21 CFR 110.35(c)

Supporting Evidence and Relevance:

- The photographs below illustrate the observable gaps on both entry doors. The third photograph is the fly observed during the environmental sampling.

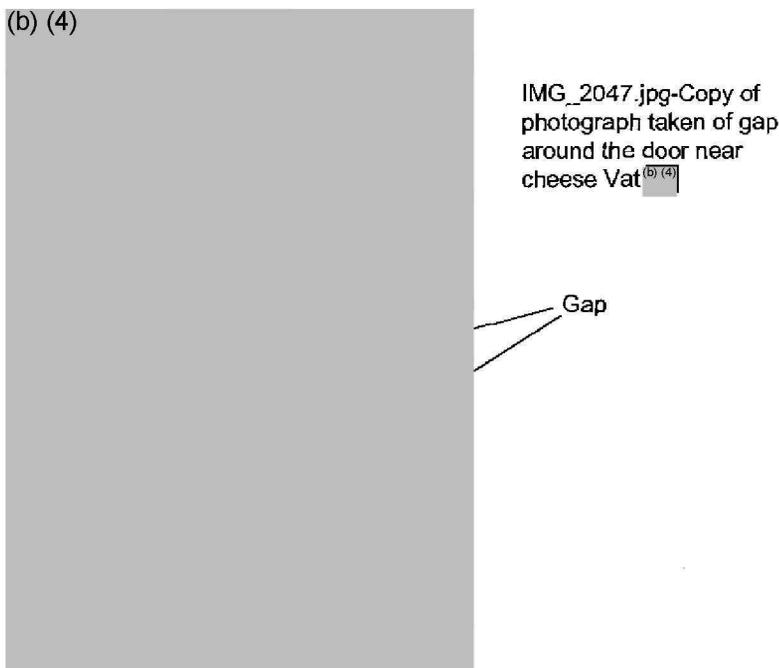


Exhibit #35, Photo #2047

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(b) (4)



IMG_2044.jpg-Copy of photograph taken of the gaps at the bottom hinges of the double door near the packaging area.

Gaps

Exhibit #35, Photo #2044

(b) (4)



IMG_2028.jpg-Copy of photograph of fly observed on Va^{(b) (4)} during cheese production on 11/05/10.

Exhibit #35, Photo #2028

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- The photograph below is the rabbit that Investigator Galvez witnessed coming out of the storage trailer.



IMG_0487.jpg-Copy of photograph taken of black rabbit roaming freely near the brining room and storage trailer.

Exhibit #36, Photo #0487

- The photographs below, taken on 11/10/10, is of the same rabbit seen coming out of the storage trailer.

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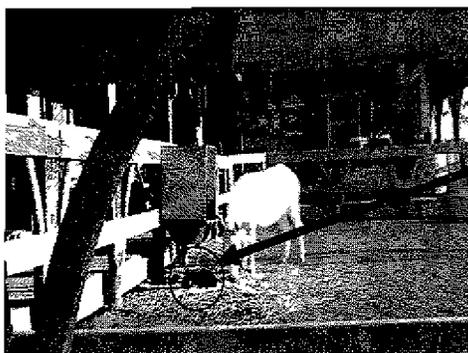
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IMG_0575.jpg-Copy of photograph taken of black rabbit roaming freely in the donkey pen

MG_0589.jpg-Copy of photograph taken of black rabbit roaming in the picnic area used by the public



Exhibit #37, Photo #0575

Exhibit #37, Photo #0589

Discussion with Management:

Mr. Boersma stated that both doors were currently being worked on. Mr. Davis informed us that this work would be completed by 12/3/10.

Mr. Boersma stated that the firm would contain the wildlife.

Mr. Davis stated it would be standard procedure to close the semi-trailer door. Mr. Van Ryn stated that as of 12/10/10, they would discontinue use of the semi-trailer for storage and the firm would move and store material in the facility's attic.

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

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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.

Reference: 21 CFR 110.10(b)(2)

Supporting Evidence and Relevance:

- Investigators Centeno and Galvez observed an employee improperly washing and sanitizing his apron.
- Employees stated to Investigators Fukuda and Galvez that aprons were not to be worn outside of the processing/packing area.

Discussion with Management:

Mr. Van Ryn and Mr. Davis stated that aprons are not allowed outside the packaging area. Mr. Van Ryn stated that he would renew and enhance the GMP training program by (b) (4). Mr. Van Ryn, Mr. Boersma and Mr. Davis stated that the FDA findings would be discussed with their employees.

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 (b)(4) 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.

Reference: 21 CFR 110.10(b)(1)

Supporting Evidence and Relevance:

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As per the firm's Personal Hygiene guideline #4 (**Exhibit #8**), employees are required to use a clean apron.

Discussion with Management:

Mr. Van Ryn stated that he would renew and enhance the GMP training program by (b) (4). Mr. Van Ryn, Mr. Boersma and Mr. Davis stated that the FDA findings would be discussed with their employees.

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 (b) (4).

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.

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.

Reference: 21 CFR 110.10(b)(3)

Supporting Evidence and Relevance:

As per the firm's Personal Hygiene guideline #1 (**Exhibit #8**), employees are required to always wash hands: After touching the face, hair (including a beard or moustache), or any unwashed body part; After smoking, eating, drinking, or taking any break; After any other activity that could potentially contaminate hands.

Discussion with Management:

Mr. Van Ryn stated that he would renew and enhance the GMP training program by (b) (4). Mr. Van Ryn, Mr. Boersma and Mr. Davis stated that the FDA findings would be discussed with their employees.

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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.

Reference: 21 CFR 110.37(e)(1)

Supporting Evidence and Relevance:

As per the firm's Personal Hygiene guideline #1 (**Exhibit #8**), employees are required to always wash hands: After any other activity that could potentially contaminate hands. Employees must use door handles to open doors when exiting the facility and entering the brining room.

Discussion with Management:

Mr. Van Ryn stated the brining operation has been moved from the outside room into the facility.

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.

Reference: 21 CFR 110.10(b)(6)

Supporting Evidence and Relevance:

As per the firm's Personal Hygiene guideline #5 (**Exhibit #8**), Keep hair neat and clean; use hair restraints (caps/hairnets). No loose, long hair. Beards and moustaches kept trimmed.

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Discussion with Management:

Mr. Van Ryn stated that he would renew and enhance the GMP training program by (b) (4). Mr. Van Ryn, Mr. Boersma and Mr. Davis stated that the FDA findings would be discussed with their employees.

REFUSALS

Firm's management was very cooperative and did not make any refusals.

GENERAL DISCUSSION WITH MANAGEMENT

(This section was written collectively by Investigators Centeno, Galvez and Fukuda)

At the close of the inspection on 12/1/10, we issued a Form FDA 483, Inspectional Observations to Mr. William L. Boersma, Co-Owner. The following individuals were present for the close out discussion:

William L. Boersma, Co-Owner
Jonathan A. Van Ryn, Co-Owner
Ryan L. Davis, Vice-President
David L. Krall, CDFA, Dairy Program Coordinator
Christina E. Asay, CDFA, Dairy Food Specialist
Joanne M. Fukuda, USFDA Investigator
Steven M. Galvez, USFDA Investigator
Elva M. Centeno, USFDA Investigator

(b) (6)



Prior to the discussion of the Form, FDA 483, Inspectional Observations, Investigator Galvez issued and obtained the signature on two Form, FDA 463a, Affidavits from Jonathan A. Van Ryn to document the purchase and use of the rennet and salt that is used in each type of cheese produced by Bravo Farms Cheese, LLC. Investigator Galvez also issued two Form FDA 484, Receipt for Samples for samples collected on 11/5/10 and 11/9/10 at the firm, consisting of environmental sample swabs and samples of Dutch-Style Gouda cheese and Premium White Cheddar with Garlic cheese.

Prior to reading and reviewing the Form, FDA 483, Inspectional Observations and non-reportable items, I explained the following points and emphasized the safety concerns with the cheeses produced by Bravo Farms Cheese and their operation.

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-
- Product with *E. coli* and *Listeria* are considered an Adulterated Food under the FD&C Act.
 - Concern by FDA and CDFA of the high recovery of *E. Coli* and *Listeria* in so many different types of Bravo Farms cheeses and varied lot/codes of cheeses
 - Unreported illnesses caused by Listeriosis due to delayed onset of symptoms.
 - *Listeria* has a high tolerance to salt and nitrite conditions
 - Great concern regarding the firm's inability to find the source of the *E. Coli* 0157:H7 and *Listeria monocytogenes* contaminating their cheese and that there is a high potential that these microorganisms still exist within their facility, equipment, environment, practices, etc. and safety concerns continue to exist and any cheese produced could be adulterated.

I informed the firm that this inspection was conducted to determine compliance with 21 CFR Part 110 and the observations made, were considered violations to 21 CFR Part 110, Current Good Manufacturing Practice in Manufacturing, Packing or Holding Human Food. We then issued Form, FDA 483, Inspectional Observations. (Please see section on OBJECTIONABLE CONDITIONS AND MANAGEMENT'S RESPONSE). During the reading of Form FDA 483, the firm chose not to comment but after we informed them that this would be public information, the firm stated that it would be in their best interest to include their response and their corrections to the Form FDA 483 observations so they would be included in the FDA inspection report. We then re-reviewed each observation with the firm and their comments were noted for each observation of the FDA 483.

Investigator Galvez stated that due to the 37 illnesses and numerous positive samples of *Listeria monocytogenes*, *E. coli*, and PFGE (pulsed field gel electrophoresis) matches of *E. coli* 0157:H7 to the outbreak strain that the agency believes that all cheeses produced at this firm are adulterated. He then stated that as an agency, we fully support CDFA's decision regarding the quarantine notice that has been issued to the firm. He then informed the firm that the FDA is here to protect public health and then warned them that the agency is prepared to use their regulatory tools such as; seizure, injunction, or prosecution, if appropriate.

We inquired about the final disposition of the cheese under quarantine. Mr. Davis stated that they are currently working on a plan to present to CDFA (California Department of Food and Agriculture) for the final disposition of the cheese under quarantine.

I again emphasized the importance of finding the source of the microorganism contamination, and if not found, there was the potential for more illnesses and possible deaths. We thanked the firm for their cooperation but warned them that they need to understand the seriousness of this problem. I quoted Jonathan A. Van Ryn's reason for the initial recall by Bravo Farms on the Dutch Style Gouda cheese as "Care for the Consumer" and explained that we (CDFA and FDA) also want to ensure the cheese is safe for all of their consumers.

ADDITIONAL INFORMATION

Copies of the following documents were given to the firm's management:

- Copy of FD&C Act for Adulterated Food – SEC. 402 [21 U.S.C. 342]
- Copy of 21CFR Part 110

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- Reportable Food Registry (RFR): At A Glance
- Guidance for Industry: Dairy Farms, Bulk Milk Transporters, Bulk Milk Transfer Stations and Fluid Milk Processors
- Guidance for Industry: Food Producers, Processors, and Transporters: Food Security Preventive Measures Guidance
- Guidance Draft: Control of *Listeria monocytogenes*
- Pamphlet: What You Need to Know About REGISTRATION of FOOD FACILITIES
- ALERT pamphlet and card

SAMPLES COLLECTED

Following are samples collected during the inspection at Bravo Farms Cheese.

Environmental Swab Samples:

A total of thirty-nine (39) sub-samples were collected by Investigator Galvez on 11/5/10 under sample number INV 636173. Nine sub-samples were collected in the Milk Room and thirty sub-samples were collected in the processing/packaging room. Of these, one sub-sample tested positive for *Listeria monocytogenes*.

Listed is the photo description of the sub-sample that resulted in the positive for *L. mono*.

Sample #	Sub #	Description	Location	Area
INV 636173	11	Movable cheese mill used to grind the large pieces of cheese curd to mix the salt/seasonings into the cheese pieces.	Packaging/ Processing Room	Rear guard of the mill
Route of Contamination: This is a direct food contact surface large, pieces of formed curd are fed to breakdown into small pieces back into a vat in order to add flavoring during the processing of the cheese. During our sampling, this equipment was being used in the processing area but was moved into the packaging area after use. The swab was taken after movement into the packaging area.				

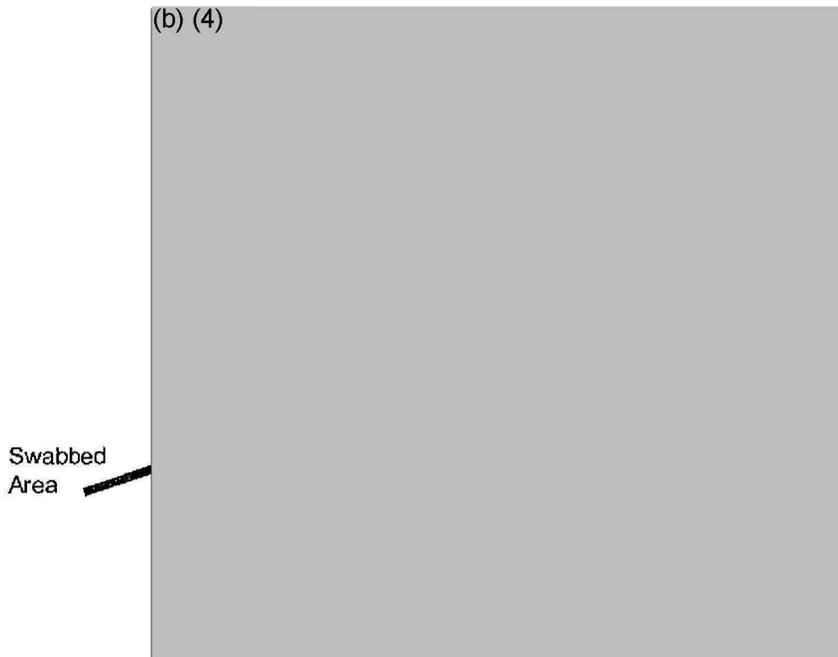


Exhibit #35, Photo #2012
Exhibit #35, Photo #2013

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Cheese samples collected:

A total of four cheese samples were collected on 11/5/10 and 11/9/10 as follows:

- INV 636174 Sample collected on 11/5/10 consists of 2 subs of approximately 10 lbs each of BRAVO FARMS DUTCH-STYLE GOUDA cheese from lot 7 16 10. Sample was submitted to SAN-Lab for E. coli testing. This sample tested negative.
- INV 657180 Sample collected on 11/5/10 consists of 10 subs of approximately 1 lb each of BRAVO FARMS DUTCH-STYLE GOUDA cheese from lot (b) (4). Sample was submitted to SAN-Lab for E. coli testing. This sample tested negative.
- INV 657181 Sample collected on 11/5/10 consists of 10 subs of approximately 1 lb each of BRAVO FARMS PREMIUM WHITE CHEDDAR WITH GARLIC cheese from lot (b) (4). Sample was submitted to SAN-Lab for E. coli testing. This sample tested negative.
- INV 657182 Sample collected on 11/5/10 consists of 10 subs of approximately 1 lb each of BRAVO FARMS DUTCH-STYLE GOUDA cheese from lot (b) (4). Sample was submitted to SAN-Lab for E. coli testing. This sample tested negative.
- INV 657183 Sample collected on 11/9/10 consists of 2 subs of approximately 10 lbs each of BRAVO FARMS DUTCH-STYLE GOUDA cheese from lot 9 8 10. Sample was submitted to SAN-Lab for E. coli testing. This sample tested negative.
- INV 657184 Sample collected on 11/9/10 consists of 2 subs of approximately 10 lbs each of BRAVO FARMS DUTCH-STYLE GOUDA cheese from lot 9 9 10. Sample was submitted to SAN-Lab for E. coli testing. This sample tested negative.

Documents samples collected:

- DOC 657185 Documentary sample documenting interstate commerce and showing the use of (b) (4) (rennet) by Bravo Farms Cheese, LLC. in all cheeses produced at the firm dating back to January 2008. The rennet is purchased from (b) (4)-
[REDACTED]
-
- DOC 657186 Documentary sample documenting interstate commerce and showing the use of salt by Bravo Farms Cheese, LLC. in all cheese produced at the firm dating

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back to December 2009. The salt is purchased from (b) (4) who transfers the salt from their facility in (b) (4) and who also purchases salt from (b) (4). orders their salt from (b) (4)

EXHIBITS COLLECTED

1. Copies of the documents for shipments of Dutch Style Gouda cheese sent to Costco Wholesale on 9/27/10, 9/30/10 and 10/6/10. (16 Pages)
2. Contact information for truck companies that hauled shipments to Costco Wholesale (1 Page)
3. Copies of Bill of Ladings and Invoices for shipment to Costco Wholesale from 10/26/10, 10/28/10 and 11/1/10 (6 Pages)
4. Copies of Bravo Farms Labeling. (2 Pages)
5. Copies of examples of Bravo Farms Flavors added Labeling. (4 Pages)
6. Copy of the Bravo Farms, Price List (2 Pages)
7. Copy of Bravo Farms Organizational Chart (1 Page)
8. Copies of Bravo Farms, Personal Hygiene and Proper Hand Wash Facilities. (2 Pages)
9. Copies of Bravo Farms Cleaning Methods, Sanitation, Background-Cleaning and Sanitizing Program, and Cleaning Equipment and Facility. (3 Pages)
10. Copies of Bravo Farms Plant and grounds GMP and a posted GMP sign. (2 Pages)
11. Copies of Food Safety Training conducted on (b) (4) (3 Pages)
12. Copies of production sheets (Make Sheets) for Costco Wholesale Dutch Style Gouda cheese wheels (6/1/10 through 9/1/10). (21 Pages)
13. Photograph of the inside of the elevator. (1 Page)
14. Photograph of the hallway from the processing/packaging to the back door. (1 Page)
15. Copy of examples of Temperature recording charts for Aging Cellars, East Room and West Room. (2 Pages)
16. Photographs of cheese in the Aging Cellar. (3 Pages)
17. Photograph of the inside of the Storage Trailer. (1 Page)
18. Photograph of the cleaning of the area around the Storage Trailer. (1 Page)
19. Copy of the Processing Flow Chart. (1 Page)
20. Copy of the (b) (4) Bag Specification (1 Page)
21. Copy of the CIP (Clean In Place) and COP (Clean Out of Place) Procedures. (1 Page)
22. Copies of the Invoices from (b) (4) chemical suppliers. (3 Pages)
23. Photograph of the COP Sanitizing Vat located in Processing Room (1 Page)
24. Copies of the Cleaning Log (CIP and COP) for 6/1/10 through 10/11/10. (3 Pages)
25. Photograph of employee handling cheese bare hands. (1 Page)
26. Copies of the results from (b) (4) for environmental sampling, 4/10/2010 and 7/8/2010. (2 Pages)
27. Copy of the result (b) (4) for finished product testing of Premium White Cheddar, dated 12/4/2009. (1 Page)
28. Copies of Bacteriological Water Analysis for water from (b) (4). (2 Pages)
29. Copy of Bravo Farms Inventory of Dutch Style Gouda cheese. (1 Page)

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30. Copy of map received from Bravo Farms of Bait Boxes & Glue Boards. (1 Page)
31. Copy of (b) (4) inspection. (1 Page)
32. Copies of the Packaging Log from 5/28/10 through 11/01/10. (26 Pages)
33. Copy of the Bravo Farms Manufacturing code. (1 Page)
34. Copy of Mock Recall conducted on (b) (4). (2 Pages)
35. Compact disk, Officially Sealed on 11/5/10, containing original photographs taken during environmental sampling by Investigator Centeno. (1 Page)
36. Compact disk, Officially Sealed on 11/9/10, containing original photographs taken by Investigator Galvez (1 Page)
37. Compact disk, Officially Sealed on 11/10/10, containing original photographs taken by Investigator Galvez (1 Page)
38. Compact disk, Officially Sealed on 11/15/10, containing original photographs taken by Investigator Galvez (1 Page)
39. Compact disk, Officially Sealed on 11/18/10, containing original photographs taken during inventory of Bravo Farms cheese by Investigator Centeno (1 Page)
40. Compact disk, Officially Sealed on 11/29/10, containing original photographs taken by Investigator Fukuda (1 Page)
41. Photograph of Bravo Farms Cheese, Blú cheese. (1 Page)
42. Photograph of Bravo Farms Cheese, Silver Mountain Cheddar. (1 Page)

ATTACHMENTS

1. Form FDA 482, Notice of Inspection issued to William L. Boersma (Co-Owner) on 11/4/10 (2 Pages)
2. Form FDA 482, Notice of Inspection issued to William L. Boersma (Co-Owner) on 11/05/10 (2 Pages)
3. Form FDA 482, Notice of Inspection issued to Efrain G. Gutierrez (Cheese Maker) on 11/18/10 (3 Pages)
4. Form FDA 482, Notice of Inspection issued William L. Boersma (Co-Owner) on 11/22/10 (3 Pages)
5. Form FDA 483, Inspectional Observations issued to William L. Boersma (Co-Owner) on 12/01/10
6. Form FDA 484, Receipt for Samples issued to Jonathan A. Van Ryn, dated 11/5/2010
7. Form FDA 484, Receipt for Samples issued to Jonathan A. Van Ryn, dated 11/9/2010
8. Copy of (b) (5) (b) (5) (12 Pages)
9. Copy of Summary Sheet received from CDFA of results from the 23 samples taken with accompanying lab analysis for each sample submitted (titled as California Animal Health & Food Safety Laboratory System) and copies of the State of California, Department of Food and Agriculture, Laboratory Analysis Request. One of the results listed is the result from the New Mexico Department of Health. (17 Pages)

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10. Copy of CDFA's sample of results from Cheddar Curds (titled as California Animal Health & Food Safety Laboratory System) and State of California, Department of Food and Agriculture, Laboratory Analysis Request (3 Pages)
11. Copy of State of California, Department of Food and Agriculture, Animal Health and Food Safety Services, Milk and Safety Branch, Notice of Violation, Form 72-094a, Permit No. 06-827, that are the results of the inspection conducted by CDFA at Bravo Farms on November 9, 2010 and the follow-up dated November 19, 2010. (7 Pages)
12. Copy of State of California, Department of Food and Agriculture, Animal Health and Food Safety Services, Milk and Safety Branch, Notice of Violation, Form 72-094a, Permit No. 06-827, dated November 10, 2010, 3:00 PM, releasing Tulare Cannonball Edam cheese from impound and a second Notice of Violation, dated November 10, 2010, 8:00 PM, impounding all of the Gouda cheese, including Dutch Style and Tulare Cannonball varieties. (2 Pages)
13. Copy of State of California, Department of Food and Agriculture, Animal Health and Food Safety Services, Milk and Safety Branch, Notice of Violation, Form 72-094, Permit No. 06-827, dated 11/15/2010, 3:15 PM, impounding all cheese at Bravo Farms. (1 Page)
14. Copy of CDFA, Notice of Required Action Pursuant to Quarantine, No 6037, dated 11/22/10 and a list of Distributors Address List received from CDFA on the same transmission. (4 Pages)
15. Copy of map of the Bravo Farms property and facility. (2 Pages)
16. Copy of the Bravo Farms cheese inventory taken on 11/18/10, labels and photographs of label, and maps. (35 Pages)
17. Copy of the breakdown of the Packaging Log to determine 60 day aging requirement. (8 Pages)
18. Copy of report with lot numbers of cheese received from Costco Wholesale that includes Dutch Style Gouda cheese. (5 Pages)

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Joanne M. Fukuda, Investigator



Steven M. Galvez, Investigator



Elva M. Centeno, Investigator