



DEPARTMENT OF HEALTH AND HUMAN SERVICE

Southwest Region

Food and Drug Administration
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REFERENCED FIRM:
Jensen Farms
31 N. Cline Street
Granada, CO 81041
FEI: 3008442043

January 6, 2012

To Whom It May Concern,

This cover letter is written to provide information about the document entitled "Establishment Inspection Report" (EIR) for the Environmental Assessment (EA) conducted at Jensen Farms (FEI: 3008442043) on September 22-23, 2011. This document was created as an EIR at my direction, which was an error. The EA was performed as an investigation and not as part of an inspection under the authority of Section 704 of the Federal Food, Drug, and Cosmetic Act. Subsequently, corrections were made to the document, including removal of the description as an "Establishment Inspection Report." The corrected document, dated December 15, 2011, is now a memorandum to the file of the EA conducted at Jensen Farms at Granada, Colorado.

Respectfully,

A handwritten signature in blue ink, appearing to read "D. Miser", with a long horizontal flourish extending to the right.

David L. Miser, Acting Director of Investigations Branch
Denver District



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Memorandum

Date December 15, 2011
From Kathryn M. Mogen, CSO
Subject Memorandum to the File on the Environmental Assessment
To LaTonya M. Mitchell, District Director *ym*
Via David Miser, Acting DIB and via Bryan J. Love, SCSO

REFERENCED FIRM:
Jensen Farms
31 N. Cline St.
Granada, CO 81041
FEI: 3008442043

SUMMARY

This environmental assessment was conducted per direction of CFSAN's Coordinated Outbreak Response Evaluation (CORE) team, DEN-DO Investigations Branch (IB) and Compliance Branch (CB) in response to an on-going listeria outbreak. The purpose of the environmental assessment was to conduct a root cause analysis and determine any possible routes of contamination that could lead to a listeria outbreak in whole cantaloupes at the farm. The environmental assessment was conducted with the cooperation of the farm on a voluntary basis. The farm is co-owned by brothers Eric S. Jensen and Ryan D. Jensen. Both owners agreed to participate in the environmental assessment with promises of certain conditions made including sharing information collected, sharing sample results and involving the firm in any conference calls regarding the assessment after the conclusion of the on-site evaluation.

The previous inspection was conducted on 9/10/11 by a joint FDA/ Colorado Department of Public Health and Environment (CDPHE) team. During this environmental assessment a sample of raw, whole cantaloupe was collected from the firm's walk-in cooler and five out of ten cantaloupe tested were positive for *Listeria monocytogenes* with PFGE matches to the current outbreak's strain known as cluster two. Thirteen of thirty-nine environmental swabs that were collected from the firm's cantaloupe processing equipment and surrounding areas were also found to be positive for *Listeria monocytogenes* with PFGE matches to the current outbreak's strains known as clusters two, three and four. The inspection was classified OAI due to the high number of positive sample results. No FDA 483, Inspectional Observations was issued. A few GMP observations were verbally discussed with management including the following: **b(4)** rollers had an accumulation of dirt and needed to be cleaned, the poles used to push cantaloupes on the packing table had balls of **b(4)** on the ends that are not cleanable, and an employee wearing gloves was seen touching her face and then touching the cantaloupes. Mr. Ryan Jensen, Co-owner, promised correction to all observations.

Continued, Page Two

ENDORSEMENT

Date January 4, 2012
From Kathryn M. Mogen, CSO
To DEN-DO Files / Thru: David L. Miser, Acting DIB *DLM*

The memo of this Environmental Assessment follow-up at Jensen Farms regarding the *Listeria monocytogenes* multistate outbreak is complete and forwarded to DEN-DO Files for Jensen Farms / Granada, CO.

ORIG: To DEN-DO Files (FEI: 3008442043)

SUBJECT: Memorandum to the File on the Environmental Assessment

The current environmental assessment was conducted on 9/22/11-9/23/11 by a team of FDA, Colorado Department of Agriculture, and CDPHE personnel. The team met in the evening on 9/20/11 and all day 9/21/11 to discuss possible routes of contamination and plan for the assessment. On 9/22/11 the team divided into three groups in order to accomplish all the necessary tasks. One group met with Mr. Ryan Jensen to interview him about on-farm practices and pack-house processes. Mr. Ryan Jensen also accompanied the interview group to the packing house where 19 environmental samples were collected from the cantaloupe processing line and surrounding area. Ten (10) cantaloupes were collected from the firm's walk-in cooler as well. Two other groups collected environmental samples at the Carlton Field in Carlton, CO including the following: 20 cantaloupes, 6-100 ml water samples, 14 drag swabs, 8-1 quart soil samples and 3 animal feces samples.

On 9/23/11 the teams collected 20 cantaloupes from the New Field and conducted an environmental assessment of the field. At the close of the assessment, the team informed Mr. Eric Jensen that sample results would be shared with the farm as soon as possible and that they would be informed shortly of any findings. We also discussed the observations made at the packing house at the time they were made as well as at the conclusion of the assessment including the following:

- The condensate drain line from the old cooler that drains onto the floor near the cantaloupe processing line and continues to run under the processing line to the gravel parking lot.
- Some areas on the equipment used to wash and dry the cantaloupes do not appear to be constructed in a manner that is cleanable. The **b(4)** rollers are attached to the metal roll bars with **b(4)**. There were deep crevices on the roller bar assemblies.

ADMINISTRATIVE DATA

Inspected firm: Jensen Farms
 Location: 31 N. Cline
 Granada, CO 81041
 Phone: 719-537-0107
 FAX:
 Mailing address: 28948 County Rd. 30.5
 Holly, CO 81047

Dates of field work: 9/22/2011, 9/23/2011
 Days in the facility: 2
 Participants: Kathryn M. Mogen, Investigator
 Edith M. Gonzalez, Investigator
 Felix J. Marrero, Investigator

Due to the voluntary nature of this environmental assessment, most FDA credentials were not displayed and an FDA 482, Notice of Inspection was not issued. Form FDA 484, Receipt for Samples, was issued to Mr. Eric S. Jensen, Co-owner at the conclusion of the assessment. This was a joint FDA/State environmental assessment and the following individuals participated in the environmental assessment and sample collections:

Name	Agency	Title
Kathryn M. Mogen	FDA DEN-DO	CSO, Lead Investigator
Felix J. Marrero	FDA DEN-DO	CSO
Edith M. Gonzalez	FDA DEN-DO	CSO
Tracy S. DuVernoy	FDA CFSAN	Veterinary Medical Officer
Sheila P. Merriweather	FDA CFSAN	Epidemiologist
James R. Gorny	FDA CFSAN	Sr. Advisor for Produce
Norman Fogg, Jr.	FDA DDFI	CSO
Jeffrey T. McCollum	CDPHE	Epidemiologist
Meredith Bradbury	CDPHE	Epidemiologist

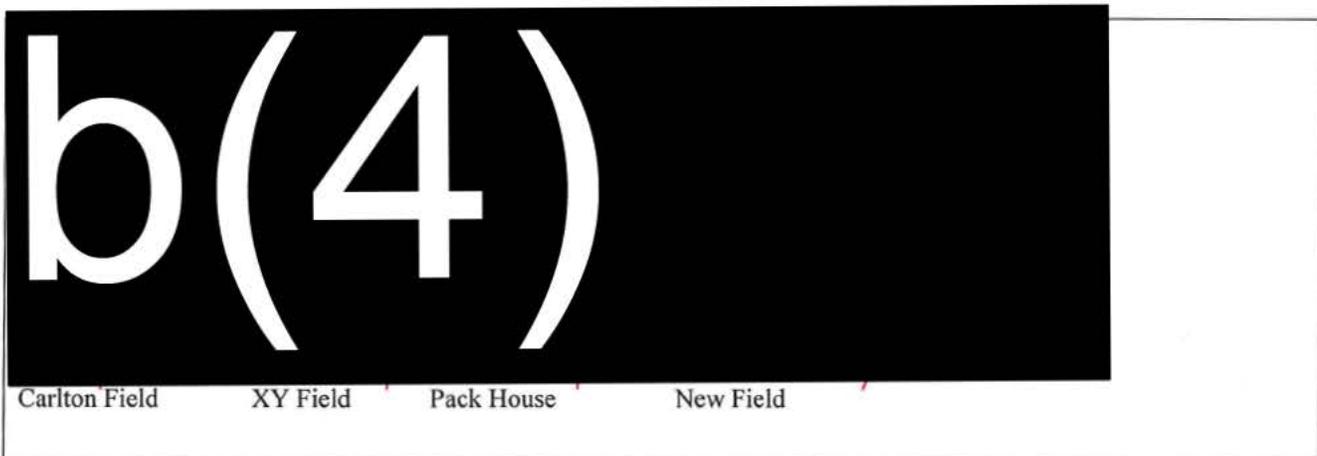
Clark Wilson	CDPHE	Environmental Protection Specialist
Mitch Yergert	CO Dept. of Agriculture	Director, Division of Plant Industries
Ken Newens	CO Dept. of Agriculture	Field Veterinarian

Keith Siemens, Sanitarian for the Prowers County Health arrived at the start of the environmental assessment on 9/22/11 and accompanied the sampling group in the morning. He also provided information regarding local weather patterns and biosolids applications to the group. Edith Gonzalez, Mitch Yergert and Ken Newens were not present on 9/23/11. The entire team was present throughout the rest of the environmental assessment. Kathryn M. Mogen was lead investigator and wrote this report in its entirety. In this report, "I" refers to Kathryn M. Mogen.

This environmental assessment was conducted with the purpose of determining a potential root cause analysis of the on-going listeria outbreak associated with cantaloupes at Jensen Farms. More general firm information is included in the report from the FDA inspection conducted on 9/10/11.

FARM LOCATION INFORMATION

Jensen Farms grew cantaloupes on three leased fields in 2011 referred to by the farm as New Field, Carlton Field and XY Field. Following is a map identifying the approximate locations of the fields. The Carlton Field had **b(4)** acres of cantaloupes this year, New Field had **b(4)** acres, and XY Field and **b(4)** acres. The Environmental Assessment team visited all three fields during the investigation. Refer to the following aerial diagram for locations of these fields:



ORDER OF EVENTS

Pre-Assessment Activities

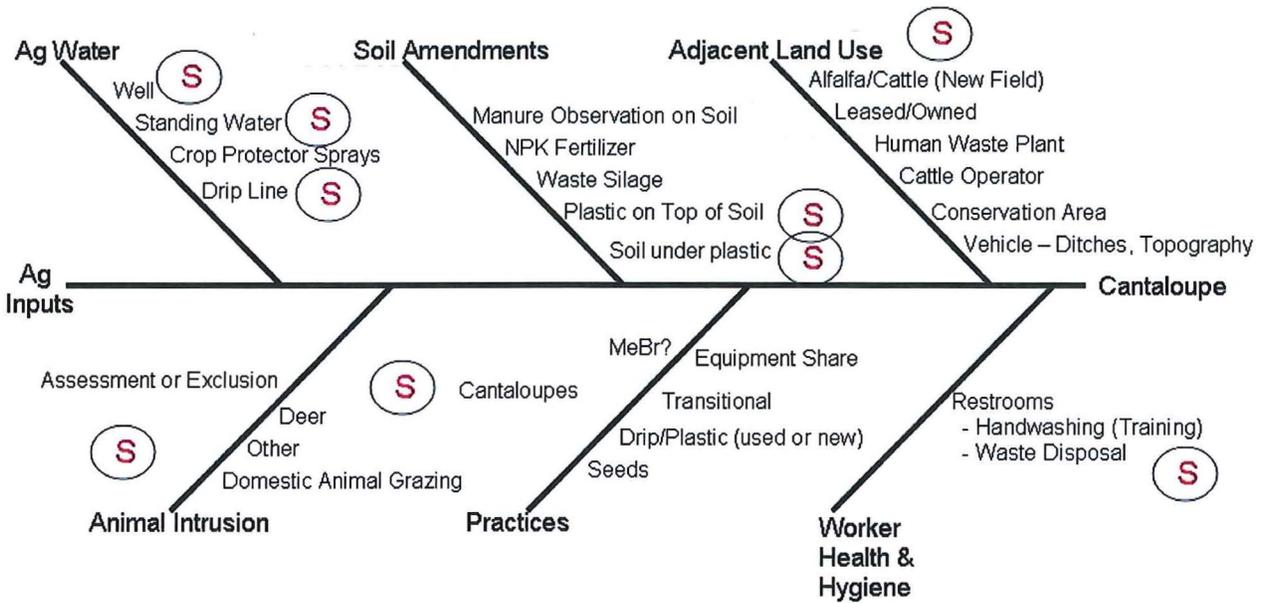
The team assembled on 9/20/11 at 6:30 PM at the conference room in the Holiday Inn Express in Lamar, CO. Each team member introduced his/her self and the team discussed the plan for the following day. Originally the environmental assessment had been planned to occur on 9/21/11, but the Jensen's requested a change of date at the last minute due to meetings that would take place with their insurance company.

On 9/21/11 the team assembled at 8:00 AM at the same conference room in the Holiday Inn Express in Lamar, CO. Jim Gorny lead the team in a brainstorming session to determine potential routes of contamination and decide on a field sampling strategy. Information from the previous FDA/State inspection was shared with the group by those who participated in the last inspection (Clark Wilson, Jeff McCollum and myself). Information regarding local field practices, animal populations and weather patterns was relayed to the group by the Colorado Department of Agriculture representatives. The following diagrams were created as a result of this brainstorming session:

Root Cause Analysis: Agricultural Production Operations

Lim Sources:

- Ruminant Animals
- Decaying Vegetation (e.g. silage)



Potential Environmental Contributing Factors:

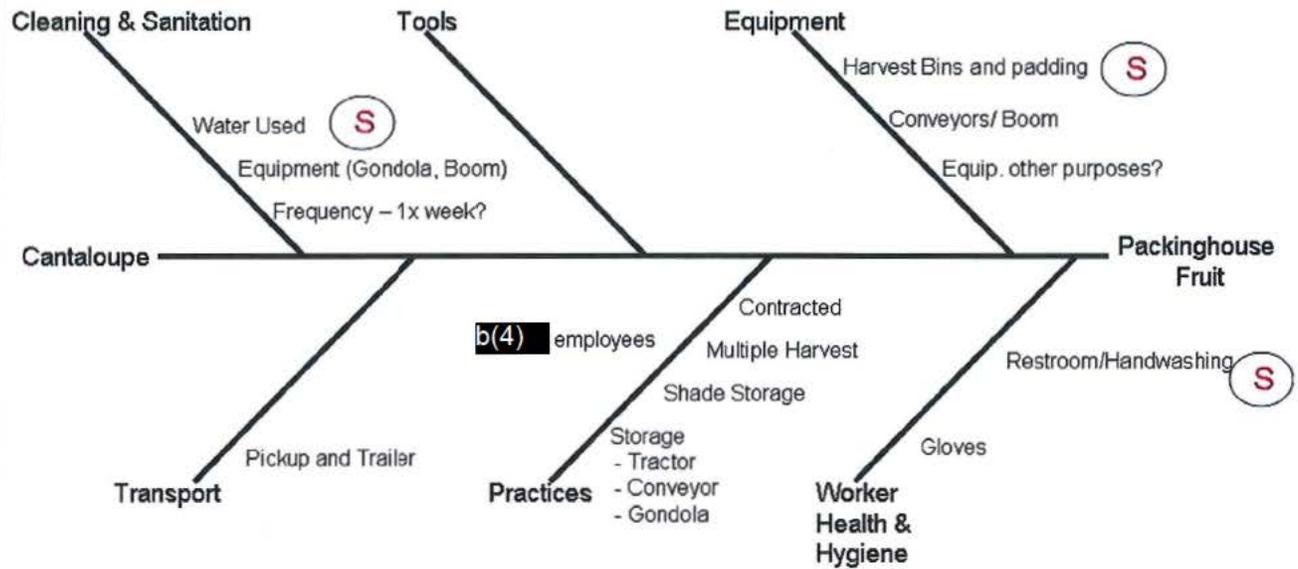
- Rainfall events

(S) = sample site

Root Cause Analysis: Harvest Operations

Ln Sources:

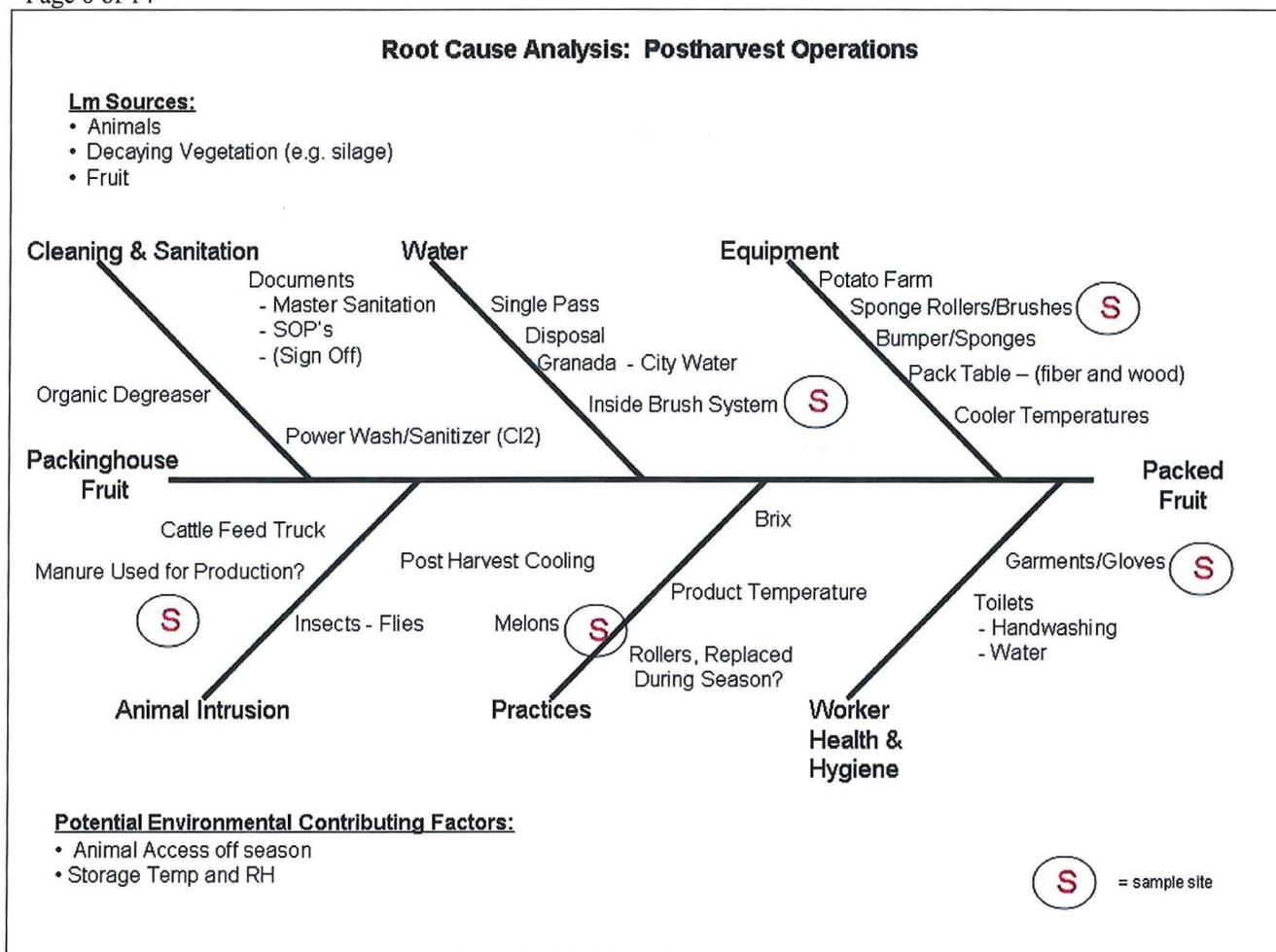
- Ruminant Animals
- Decaying Vegetation (e.g. silage)



Potential Environmental Contributing Factors:

- Rainfall events

(S) = sample site



The team then divided into three groups to accomplish specific tasks the following day. The Groups were divided as follows:

- Team A- Edith Gonzalez (lead), Tracy DuVernoy, Clark Wilson (9/22/11)
- Team B- Felix Marrero (lead), Norm Fogg, Ken Newens, Meredith Bradbury (9/22/11)
- Team C- Kathryn Mogen (lead), Jim Gorny, Jeff McCollum, Sheila Merriweather, Mitch Yergert (9/22/11)
- Team D- Felix Marrero (lead), Tracy DuVernoy, Meredith Bradbury (9/23/11)
- Team E- Kathryn Mogen (lead), Sheila Merriweather, Clark Wilson (9/23/11)

Teams A and B were tasked with leading sampling teams in the collection of cantaloupes, water, soil, drag swabs and any other items of interest that they observed. The team leads met with their teams and discussed sterile sampling techniques and equipment needs. I was responsible for leading a team in an in-depth interview with Ryan Jensen, Co-owner to discuss all on-farm and pack house operations in detail. The interview team met in the afternoon on 9/21/11 to review what information was needed and to develop a strategy for interviewing the firm.

The team attempted to locate some of the firm's fields in the afternoon on 9/21/11 to see an overview of the land and get some preliminary information before the following day. The team was able to locate one of the firm's fields (New Field), but did not have enough geographic information to visit Carlton Field and XY Field on that day.

Environmental Assessment: Day 1

On 9/22/11 the team met at the Jensen's main office in Holly, CO. After introductions were made, the two sampling teams left with Eric Jensen to begin sample collection at Carlton Field (see **Samples Collected**). During the sample collection process, environmental assessment observations were made (see **Environmental Assessment**). The interview team met with Ryan Jensen to collect more information regarding on-farm practices (see **General Discussion with Management**). After concluding the interview, the interview team collected additional samples at the firm's packing house (see **Samples Collected**). The interview team also visited the XY Field to see the layout of the field and determine if there were any obvious routes of contamination (see **Environmental Assessment**).

Environmental Assessment: Day 2

On 9/23/11 the Environmental Assessment team met at Jensen Farms New Field at 7:00 AM to conduct a brief environmental assessment of the New Field. Two groups of three members each collected cantaloupe samples from the field (see **Samples Collected**). A third group of four members drove around the perimeter of the field and made visual observations of possible routes of contamination (see **Environmental Assessment**). Eric Jensen and a consultant from (b)(4) accompanied the groups on the sample collections in the field. At the conclusion of the field assessment the groups thanked Mr. Jensen for his time and cooperation. A few observations were discussed verbally with Mr. Jensen at that time (see **General Discussion with Management**).

GENERAL DISCUSSION WITH MANAGEMENT

On the morning of 9/22/11, the interview team met with Ryan Jensen (referred to as Mr. Jensen in this section), his lawyer Mike Callahan and his environmental consultant (b)(6) of the (b)(4) at the firm's main office located at 28948 CR 30.5 Holly, CO 81047. The FDA/State interview team consisted of Jim Gorny, Jeff McCollum, Sheila Merriweather, Mitch Yergert and myself. We discussed the farm's operations in three sections: agricultural field operations, harvest operations and post-harvest operations. All questions on the FDA Farm Questionnaire form were also discussed with Mr. Jensen (see attached form FDA 3623). The following is a summary of the information provided during this interview with Mr. Jensen:

Background Information

The firm has three fields on which they grew cantaloupes during the 2011 growing season: New Field (120 acres), Carlton Field (b)(4) acres) and XY Field (b)(4) acres) for a total of approximately (b)(4) acres. All three parcels of land are leased by the firm. Each field is equipped with one well, except for XY Field which has two wells to service its larger surface area. Mr. Jensen showed us analysis results from samples the State of Colorado collected from each well and the packing shed on 7/13/11. We did not see results from the New Field in those that were provided to us. The Carlton well had 13.5 coliform MPN and the XY west well had 1 coliform MPN. The cantaloupe packing shed uses City of Granada municipal water and the state's water test results were negative. Mr. Jensen stated that each of the field wells are over 50 feet deep.

Only (b)(4) acres at the Carlton Field and (b)(4) acres at the New Field were still in production during the previous FDA inspection on 9/10/11. This year is the first year that Jensen Farms leased the New Field (previously used as an alfalfa field), but they have been leasing Carlton and XY for several years. (b)(4)
(b)(4)

The firm is audited by (b)(4), a third-party auditor. Mr. Jensen said that (b)(4) audited the packing house one week before harvest began and that the audits are required by some customers. He said that the Frontera Produce (the firm's sole distributor of cantaloupe) food safety representative came to the firm to help them prepare for the (b)(4) audit and was present throughout the audit. Mr. Jensen said that the firm received a score in the high (b)(4) out of 100) and that they receive written results of the audits. These results were not reviewed during the discussion.

Jensen Farms does not currently use biosolids on any of its fields and has never used biosolids in the past. Mr. Jensen said that he believes sludge has been used on fields adjacent to his fields within the last 15 years.

Mr. Jensen said that he does not remember any unusual rain events this year and that it has been a very dry summer. He also said that he does not remember seeing any animals in his cantaloupe fields.

Agricultural Field Operations

(b)(4)

(b)(4) No manure or fumigants have ever been used by the firm.

The farm planted the fields on (b)(4) occasions beginning on 4/15/11 and ending five weeks later. All equipment used on the fields is dedicated for cantaloupe production including tractors, booms, trailers and packing house equipment.

Harvest Operations

The farm began harvesting cantaloupes on 7/26/11 and ended on the day of the previous FDA inspection on 9/10/11. About b(4) employees are hired by b(4) to work the harvest at Jensen Farms, and about b(4) of employees return each growing season. All fields are equipped with portable restroom facilities for the harvest employees. The toilets are serviced by a contracted company that Mr. Jensen could not remember the name of, but stated that the supervisor he deals with is named b(6)

b(4)
b(4)

Mr. Jensen said that the firm aims to yield about b(4) cases/acre.

All equipment used for harvesting operations is cleaned on a b(4) basis using industrial strength b(4) and a b(4) sodium hydrochlorite sanitizer. The equipment is cleaned at the Jensen Farm's main office in Holly, CO using municipal water. The farm owns the trailers and b(4) but leases its tractors. All leased tractors were brand new this year. Some of the trailers have an b(4) bottom that Mr. Jensen said he was told was b(4) when he purchased them. The trailers are constructed of fiberglass with wooden doors and are only used for hauling cantaloupes. After the harvest season the trailers are cleaned, turned upside down and stored in the parking lot at the farm's main office.

Post-Harvest Operations

b(4)

In previous years the firm used a b(4) process to cool and rinse the cantaloupes utilizing b(4) b(4). This year the firm purchased some used equipment to wash and dry cantaloupes from an equipment supplier, b(4) b(4). The equipment was installed before the start of this year's harvest by b(4). Mr. Jensen said that he thinks that the equipment was formerly used on a potato farm. He said that the firm purchased new b(4) rollers for the drier and new bristle brushes for the brush machine when the equipment was installed. Mr. Jensen said that the brushes and rollers were to be replaced by b(4) at the end of the current production season as well. He also said that Jensen Farms cleaned and sanitized the equipment before using it. He said that the reason they replaced the firm's b(4) with this new processing system was to b(4) b(4).

Mr. Ryan Jensen said that all equipment at the packing house is washed with a power-washer with water and b(4). He said all equipment at the packing house is sanitized with a b(4) sodium hydrochlorite solution every night after production. He said usually several employees will stay after production to clean.

The following observations were discussed with Mr. Ryan Jensen at the time they were made at the pack house, as well as briefly with Mr. Eric Jensen at the close-out of the environmental assessment:

- There is a condensate drain line from the "Old" cooler that drains onto the cement near the pack house equipment. There is a slit trench drain cut into the unsealed concrete floor beneath the packing equipment where the water from the condensate drain should flow out to the gravel parking lot. Condenser drain lines are a known harborage for listeria and could be a possible source of contamination of the equipment.

Img_0183.jpg JTM, 9/22/11

Condensate drain line from the "Old" walk-in cooler that is still in use. The line drains onto the unsealed cement floor in the corner of the processing area near the **b(4)** drier.

b(4)

Img_0185.jpg JTM 9/22/11

Slit trench drain cut in cement under the conveyor where it meets the **b(4)** drier before the grading table. Water collects in slit trench and drains to the gravel parking lot.

b(4)

Img_0211.jpg JTM, 9/22/11

Slit trench runs next to and under the conveyor belts for the length of the production line from the **b(4)** rollers through the grading tables and to the gravel parking lot. Water pools in the trench drain and is designed to run out through this drain.

b(4)

- The **b(4)** rollers on the drier equipment are not cleanable. They are not easily removed from the roller bar assemblies as they are attached to the roller bars with **b(4)** that left a sticky residue when removed. There are several areas on the equipment used to wash and dry the cantaloupes that do not appear to be easily cleanable.

Img_0175.jpg, 9/22/11 JTM

Drier with roller bar assemblies after **b(4)** had been removed and equipment was cleaned. **b(4)** is attached to each metal roller bar with **b(4)**. Excess residue was seen on the surfaces of the roller bars after cleaning.

b(4)

Img_0178.jpg JTM, 9/22/11

Deep crevices in the roller bar assembly as it attaches to the side of the drier equipment. [b(4)] had been removed from each metal roller bar before the environmental assessment. Equipment had been cleaned and sanitized, but still appeared to be in need of cleaning.

b(4)

Img_0156.jpg JTM, 9/22/11

Dirt and residue build-up on cross bar between cantaloupe washer equipment and drier equipment. Equipment had been recently cleaned and sanitized by firm. Uncleanable [b(4)] covers the side near the elevator conveyor opposite the photograph.

FIELD ASSESSMENT

An in-depth environmental assessment was conducted at Carlton Field on 9/22/11 by the two sampling teams lead by Edith Gonzalez and Felix Marrero. A brief environmental assessment was conducted at New Field by all members of the EA team present on 9/23/11. The team that I lead on 9/22/11 was able to visit the XY Field briefly, but did not conduct an assessment at this field because it was not in production at the end of the harvest season. Following is a brief summary of the environmental assessment and observations made by team members at each field.

Carlton Field (9/22/11): [b(4)] acres of cantaloupe [b(4)]
[b(4)]

Several areas of interest were investigated on and around the Carlton Field.

- There is a small livestock auction facility located near the northwestern corner of the field. There was a depression in the field between the auction site and the field ostensibly to catch field run-off or other water. There were no obvious routes of contamination observed to the field from this auction site.

- Evidence of animals was seen on and around the field including duck, bird, coyote, raccoon, snakes and amphibians. Both bird and coyote droppings were collected and found negative for listeria.
- A pond borders the south side of the field and is at a lower elevation than the field. Water from the pond does not enter the field. A second pond was seen in an adjacent overgrown property on the field's east side, but did not appear to be a source of water entering the field.
- Soil on the field appeared to be a heavy clay/sand mixture that was very dry at the time of the field assessment.
- The field is irrigated with well water obtained from one well. There are irrigation ditches on all four sides of the field, but water from these ditches is intended for use on nearby alfalfa fields. There was no evidence to suggest that water from the irrigation ditches entered the field.
- An agricultural firm located approximately ¼ mile northwest of the field receives train cars of treated sewage/sludge from New York City for use on agricultural fields. While the Carlton Field does not use biosolids, it was assumed that biosolids are transported along Hwy. 50 and Cnty. Rd. 19/21 to reach nearby fields on which it is field spread. No evidence of spillage or other contamination from this source was observed.

New Field (9/23/11)-^{b(4)} acres of cantaloupe **b(4)**
b(4)

One acre near the center of the field was planted with watermelon as observed by Norm Fogg, CSO, while the rest of the field was planted solely with cantaloupes. The watermelons are only used for personal use and there was no evidence of further distribution.

- On the north side of the field there was a small cow pen and pasture with goats in it during the assessment. Cows could be seen grazing in the distance. The field is located across an irrigation ditch and a farm road. No route of contamination from this pasture to the field was observed.
- Evidence of animals was observed in and around the field included snakes, rabbits and coyotes. Deer had been reported in the area, but no evidence of deer was seen during the assessment. A state-managed wildlife area is located adjacent to the southwest and south perimeters of the field.
- Human waste and toilet paper were observed by CSO Norm Fogg in a silage area (approximately 100 feet from the well) 54 located on the opposite side of the road bordering the south perimeter of New Field.
- One well is used to feed the drip irrigation system for this field. Backflow prevention was seen on the outlet that feeds the irrigation ditch from the well.
- One shallow pond was located on the south perimeter of the field near the well. The pond does not appear to be used for irrigation and no routes of entry to the field were observed.
- The soil appeared to be a heavy sandy loam with fair drainage.
- No biosolids were applied to this field or known adjacent fields.

XY Field (9/22/11)-^{b(4)} acres of cantaloupe **b(4)**
b(4)

No routes of contamination were observed during the brief visit and drive around the XY Field. There were two wells (only one of which was viewed by the team). The well was used to feed the drip irrigation systems in the cantaloupe fields, but also fed into the cement-lined irrigation ditch used by other fields. No evidence of animals on the property was observed by the team. A river and natural area surrounding the river bordered the northern edge of the field, but was at a lower elevation and would not be a hazard to the field in flood conditions.

SAMPLES COLLECTED

On 9/22/11 the EA group was divided into three sampling teams to collect a wide variety of environmental samples in the fields and packing house at Jensen Farms. Mr. Eric Jensen and ^{b(4)} consultant were present throughout the sample collection at Carlton Field. Mr. Ryan Jensen and ^{b(6)} ^{b(4)} Consultant, were present throughout the sample collection at the packing house. The following samples were collected by the teams:

Team A: Edith Gonzalez (lead), Tracy DuVernoy, Clark Wilson

- INV642093- 20 cantaloupes collected in a "Z" pattern from the Carlton Field. 10 subs were collected for enumeration purposes and ten subs were collected for L. mono identification. The subs were analyzed by DEN-LAB and found to be negative.

- INV642094- 6-100 ml water samples collected from various locations on the Carlton Field for L. mono identification, including the following: 2 subs from the well used as the sole water source at the field, 1 sub from an irrigation drip line, 3 subs from an on-site reservoir (standing water source). The subs were analyzed by DEN-LAB and found to be negative.
- INV642095- two subs of bird feces collected from the Carlton Field for L. mono identification. The subs were analyzed by DEN-LAB and found to be negative.

Team B: Felix Marrero (lead), Norm Fogg, Ken Newens, Meredith Bradbury

- INV711687- 14 drag swabs collected from the perimeter borders and interior rows of the Carlton Field for L. mono identification. The subs were analyzed by DEN-LAB and found to be negative.
- INV711688- 1 sub of unidentified animal excreta collected from the Carlton Field. The sample was analyzed by DEN-LAB and found to be negative.
- INV711689- 8-1 quart subs of soil collected from various locations in the Carlton Field collected for L. mono identification. The subs were analyzed by DEN-LAB and found to be negative.

Team C: Kathryn Mogen (lead), Jim Gorny, Mitch Yergert, Sheila Merriweather, Jeff McCollum

- INV713450- 19 environmental sponge swabs collected from the packing equipment and surrounding area at the cantaloupe packing house in Granada, CO for L. mono identification. The subs were analyzed by DEN-LAB and found to be negative.
- INV714449- 10 cantaloupes collected from the firm's walk-in cooler at the packing house in Granada, CO. The cantaloupes were in various stages of decomposition as the cantaloupes had been packed on 9/8/11 and the cooler had been shut off due to a power outage for an unspecified amount of time before collection on 9/22/11. Collected for L. mono identification and enumeration purposes. The subs were analyzed by DEN-LAB and found to be positive for L. mono on 5 out of 5 tested. Three subs that were used for enumeration had results showing >.14 MPN (Most Probable Number), >10 MPN and >11 MPN.

On 9/23/11 the following samples were collected from the New Field. Eric Jensen and an **b(4)** consultant were present throughout the sampling investigation at New Field.

Team D: Felix Marrero (lead), Tracy DuVernoy, Meredith Bradbury

- INV711690- 10 cantaloupes collected in a "Z" pattern on one section of the New Field for enumeration purposes. The subs were analyzed by DEN-LAB and found to be negative.
- INV711691- unidentified animal excreta collected by Norm Fogg from the New Field. The sample was analyzed by DEN-LAB and found to be negative.

Team E: Kathryn Mogen (lead), Sheila Merriweather, Clark Wilson

- INV713448- 10 cantaloupes collected in a "Z" pattern on one section of the New Field for L. mono identification. The subs were analyzed by DEN-LAB and found to be negative.

VOLUNTARY CORRECTIONS

An observation was discussed verbally with Mr. Jensen during the inspection on 9/10/11 regarding the need for cleaning on the **b(4)** roller apparatus. On 9/22/11 it was observed that the firm had dismantled the drier on the cantaloupe processing line and discarded the **b(4)** rollers. All equipment on the cantaloupe processing line had been cleaned and sanitized with **b(4)** hydrochlorite sanitizer, according to Mr. Jensen.

ADDITIONAL INFORMATION

On 10/11/11, a phone conversation was held between Kathryn Mogen, CSO and **b(6)** Owner of **b(4)** **b(4)**. The conversation was held in order to discuss the equipment that was installed at Jensen Farms before the start of the 2011 harvest season by **b(4)**. The new equipment was a **b(4)** **b(4)** and a **b(4)** **b(4)**. **b(6)** stated that the equipment was newly installed at **b(4)**.

b(4) Both nieces were removed from b(4)
b(4)

b(6) stated that he took the equipment back to his facility, cleaned them, replaced any parts that needed replacing and sold the equipment to Jensen Farms on or around the second week of July 2011. He stated that he had replaced the brushes on the brush washer with "less abrasive" bristles so as not to damage the exterior of the cantaloupes. He said that he was asked by Jensen Farms to fit the equipment with a b(4) that they planned to use with the equipment. He said that the last time he visited the packing shed at Jensen Farms (post-harvest) he noticed the b(4) was not in operation or attached to the equipment as he had originally installed. He stated that he was unaware if the firm used the b(4) system this season.

b(6) said that he did not replace the b(4) on the b(4) rollers in the drier because he stated that the felt was in good condition and only needed to be replaced b(4). The b(4) is an actual b(4) that has to be special ordered from the manufacturer in b(4).
b(6)

b(6) said that it is used in many different food processing systems for different applications.

b(6) said that he does not instruct firms in how to maintain or clean/sanitize the equipment as that is up to the firm to decide. The equipment was not sold with any manuals to instruct the user in proper maintenance/cleaning methods. b(4)

b(4) services the equipment if there are any malfunctions or maintenance issues.



Kathryn M. Mogen, CSO
Denver District Office

EXHIBITS

1. CD-R containing original photograph files taken during three days of the environmental assessment (9/21/11-9/23/11). Official FDA sealed and enclosed in FDA 525.

ATTACHMENTS

- FDA 484 Receipt for Samples, signed by Eric S. Jensen, Owner on 9/23/11
- FDA 3623 Farm Questionnaire, completed by Sheila Merriweather of CFSAN, reviewed and edited by myself and the interview team