

**Investigation of the *Escherichia coli* O157:H7 Outbreak
Associated with Iceberg Lettuce**

Final Report

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Executive Summary

On September 26, 2008 Michigan Department of Community Health (MDCH) notified the California Department of Public Health (CDPH) that it had issued a public health alert identifying 26 cases of *E. coli* O157:H7 thought to be associated with bagged, institutional-sized packages of iceberg lettuce linked to Aunt Mid's Produce Company Detroit, MI. During the same period, Illinois Department of Public Health (IDPH) reported 11 cases matching the *E. coli* O157:H7 outbreak strain. Approximately 39 individuals associated with this outbreak were sickened in August and September 2008. The cluster of cases was initially identified in three locations: Michigan State University (MSU), East Lansing, MI; Lenawee County Jail, Adrian, MI; and the Ponderosa Steakhouse, Aurora, IL.

Case-control studies were conducted by MDCH and IDPH at MSU and the Ponderosa Steakhouse. Shredded iceberg lettuce served in institutions, restaurants, and sandwich shops was identified as the most likely vehicle of transmission with dates of exposure occurring between August 29 - September 18, 2008 for the MI cases and August 30 - September 18, 2008 for the IL cases. Inmates at the jail had been eating AM lettuce salads for the month of August and therefore it was difficult to identify the exact first exposure date. Based on information and records collected from AM, MDCH traced the iceberg to two potential farm sources; Van Dyk Farms (VDF), Imlay City, MI and Santa Barbara Farms (SBF), Lompoc, CA.

The California Food Emergency Response Team (CalFERT) comprised of staff from both U. S. Food and Drug Administration (FDA) and California Department of Public Health (CDPH) was mobilized on September 30, 2008 to conduct an environmental investigation and identify suspect growing fields at SBF for the time period of interest. CalFERT was mobilized from September 30 - October 2, 2008. Investigative activity after October 2, 2008 was conducted independently by CDPH Food and Drug Branch (FDB) - Emergency Response Unit (ERU).

During the course of this investigation, FDB-ERU staff collected samples consisting of 72 water, 19 sediment, 84 fecal matter, and 14 swabs. These samples were tested for *E. coli* O157:H7 and its shiga toxins. Positive isolates of *E. coli* O157:H7 were further analyzed using pulsed field gel electrophoresis (PFGE) to determine if the isolates genetically matched the identified outbreak strain. None of the 189 samples matched the outbreak strain; however, 18 of these samples were positive for non-outbreak strains of *E. coli* O157:H7. Seventeen of the 18 positive samples were collected from a dairy which was across the Santa Ynez River and approximately $\frac{3}{4}$ mile from the growing fields. The other non-outbreak positive *E. coli* O157:H7 sample was collected from cow feces obtained from a pasture that was not adjacent to any of the growing fields.

Background Information

In September 2008, a foodborne outbreak of *E. coli* O157:H7 was linked to restaurants, institutions, and sandwich shops in Michigan and Illinois. Case control epidemiological studies independently conducted by state health departments in MI and IL identified iceberg lettuce as the most likely vehicle for the outbreak (Attachment 1A). Approximately 49 individuals were sickened (38 in Michigan and 11 in Illinois).

Traceback Implicated Lots

Michigan Department of Agriculture (MDA) determined a range for exposure dates using the onset dates from the first six cases from MSU and Lenawee County Jail. The first six cases were believed to have eaten contaminated iceberg lettuce between August 29, 2008 and September 12, 2008 (Attachment 1B, C). The earliest consumption date for the IL outbreak was determined to be August 30, 2008 (Attachment 2).

MDA conducted a traceback investigation for the implicated iceberg lettuce and identified Van Dyk Farms, Imlay City, MI and Santa Barbara Farms, Lompoc, CA as the sources of iceberg lettuce (Attachments 3 and 1A,B). A traceback document review, conducted by MDA, identified institutionally-packed iceberg lettuce shipments from a single processor, Aunt Mid's, (Attachment 1B).

A case control study was conducted by Dupage County Health Department (DCHD) for the 11 identified Illinois cases. This study revealed a statistically significant association between eating pre-packaged shredded or chopped iceberg lettuce produced by AM (Attachment 2). The DCHD study linked six cases to "Restaurant A". The DCHD Environmental Health staff conducted a traceback for lettuce products delivered to "Restaurant A". Lettuce served to this restaurant was a pre-washed, pre-chopped bagged product from AM (Attachment 2).

SBF supplied numerous shipments of iceberg lettuce (cored, whole head) to AM during August and September 2008 (Attachment 4). The identification of shipments and their corresponding sources were implicated using a time-period approach. Assuming a 14-day shelf life for the lettuce, transportation time, and a 2–4 day period at the points of service, FDB-ERU staff determined that SBF shipments were most probably harvested between, August 7 - 27, 2008. This methodology led to the identification of twelve SBF fields that could have supplied lettuce during the exposure time frames.

VDF supplied bills of lading for two shipments of iceberg (cored, whole head) and romaine lettuce to AM on September 4 and 18, 2008 (Attachment 5). Although the September 4th shipment occurred after the time period of the first case exposures, product was available in the marketplace during subsequent illnesses. The growing fields for the Van Dyk Farm iceberg shipments were identified and inspected by MDA (Attachment 6).

During the time period of interest AM's was processing a variety of salads as shown on the "Non-Iceberg Production" spreadsheet (Attachment 7). AM's process flow chart for the fresh cut lettuce line (line #2) also lists a variety of produce processed on the line, including iceberg lettuce, romaine lettuce, radicchio, and green and red cabbage (Attachment 8). MDA's traceback primarily focused on iceberg lettuce and not the other products being processed on line #2.

Environmental Investigations

Fresh Pak – Aunt Mids

7939 W. Lafayette
Detroit, MI 48209
Phillip Riggio, CEO

Fresh Pak Inc. (d.b.a. Aunt Mid's Produce) is a produce processor and repacker located in Detroit, MI that employs approximately [REDACTED] persons. The firm produces a variety of processed vegetables and fruits. Most products are produced under the Aunt Mid's label, but the facility also packs private labels. Two main processing lines are used for their products. One line is used for specialty products such as mushrooms and tomatoes. The second line (line #2) is used for lettuce, cabbage, and leafy green products. The facility processes a variety of lettuce packages such as chopped romaine and iceberg, shredded iceberg, garden salad (iceberg, carrots, and red cabbage), and romaine blend (iceberg and romaine). The repack area is located in a room separate from the two processing lines.

MDA conducted an environmental investigation of AM (Fresh Pak, Inc.) on September 27, 29, 30 and October 7, 2008 (Attachment 9). The environmental investigation consisted of observations, document collection and review, and sample collection. MDA inspectors collected 21 samples (environmental swabs, raw ingredients, and processed product) at AM for submission to the Michigan State Laboratory (subsequent analyses found the samples to be negative for *E. coli* O157:H7). MDA determined that there were no deviations from AM's HACCP plan or Good Manufacturing Practices (GMPs).

MDA reported to FDB-ERU staff that line #2, the lettuce line, was broken down and cleaned and sanitized once a day (Attachment 10: #11). MDA also reported that this line, "is cleaned prior to starting a new product" (Attachment 11). Since cleaning does not commonly kill pathogens, a sanitation step is needed to ensure that food contact surfaces are exposed to a strong sanitizing agent as a kill step. Therefore, if the line was not both cleaned and sanitized between different commodities and lots, the potential for cross contamination between products from one production lot to another existed.

FDB-ERU staff reviewed the AM sanitation records and logs supplied to them by MDA (Attachment 12) and noted some concerns. For example, AM's "Finished Produce Microbiological Tests" logs were supplied for the sample time period of September 9 - 22, 2008, but records were not available for the production time period of interest for the first exposure date of August 29, 2008 (Attachment 12 C). FDB-ERU staff noted discrepancies on the "Daily Control of Used Chemicals and Their Concentrations" logs (Attachment 12 D). For example, the SOPs written on the logs for the Equipment Sanitizer () were for a mixture of 1 ounce per 4 gallons. This would equate to 21.5 ounces (645 ml) per 86 gallons. However, the daily entries show 100 ml for 86 gallons.

Initially, it was reported that test strips were used to measure the concentration of the sanitizer () used in the lettuce wash water (Attachment 10: #11). AM's Hazard Analysis and Critical Control Point (HACCP) also listed test strips as a method to use to verify the concentration of () the sanitizer used for line #2 wash water (Attachment 12A). However, () the manufacturer of () verified that test strips are not available to measure ppm for peroxyacetic acid (POAA). Upon further investigation it was determined that the concentration of () at AM is verified with a titration test kit (Peracid/Peroxide Test Kit #311). This fact was subsequently verified by MDA (Attachment 13 pg. 4). AM's "Daily Control of Washing Waters" logs document the concentration of () in the range of () ppm, thus within the HACCP critical control point.

MDA provided a record of lettuce suppliers to AM during August and September 2008 (Attachment 14). MDA provided romaine shipments for September 11– 19, 2008 from Bogiatto Produce, Inc., Salinas, CA (Attachment 15). FDB-ERU staff collected Bogiatto documents for romaine shipments to AM's from August 29, 2008 – September 11, 2008 (Attachment 16). Documents for romaine and green leaf lettuce shipment from D'Arrigo Bros., Co, Salinas, CA were also supplied for August 29, 2008 through September 22, 2008 (Attachment 17). Shipments for August 1 – August 28 were not available to FDB-ERU staff for review from these two companies.

Van Dyk Farm

MDA traceback records identified VDF, 7176 Muck Road, Imlay City, MI, 48444 as having supplied iceberg and romaine lettuce to AM on 9/4/08 and 9/18/08 (Attachment 5). MDA reports (Attachment 6) indicated that VDF cultivated approximately () acres in 2008. In 2008, VDF produced romaine, iceberg, and red and green leaf lettuce. The MDA Special Report 9/27/08 – 10/7/08 stated that VDF also supplied iceberg lettuce to AM in August (exact dates unknown). MDA supplied FDB-ERU staff with two bills of lading showing sale of VDF romaine and iceberg lettuce to AM on 9/4/2008 and 9/18/2008. The MDA farm report stated that VDF also supplied AM romaine lettuce on July 17, 2008 and August 1, 2008 (paper documentation for these produce shipments to AM were not available for FDB-ERU review). Furthermore, MDA reported to FDB-ERU staff that VDF "was providing some romaine lettuce to AM in August" (Attachment 18:

#2). Paper documentation of romaine lettuce shipments were not available to FDB-ERU to verify total romaine shipments from VDF to AM during August.

After reviewing the MDA VDF reports, FDB-ERU staff identified a number of potential risk factors, practices and/or conditions at VDF (Attachment 19) that were unresolved. For example, MDA reported that well water was collected in reservoirs and ponds before irrigation. However, there was no record of subsequent testing of well water, irrigation (reservoir) water or environmental sampling. The MDA report also stated that *E. coli* levels had been recorded above background levels in each of the five reservoirs. The report did not define “acceptable background levels” or provide analysis of *E. coli* levels in the reservoirs. The MDA report indicated that irrigation water was chlorinated on the same day that *E. coli* levels were determined above background, but did not clarify whether the chlorinated irrigation water was tested for ppm chlorine concentration after treatment or identify the *E. coli* test used to give same day test results (Note: irrigation water samples that tested above background levels for *E. coli* were not tested for pathogenic *E. coli*). The MDA report also stated that a 7.5 foot fence was installed to prevent animal intrusion onto the growing fields. There was no additional information provided regarding; the identity of animals that had access to the fields, whether or not the fence controlled the problem, the types of animals in the surrounding environment, and any crop damage as a result of animal intrusion. Furthermore, birds and other small animals had access to the reservoirs, but the report did not indicate if fecal samples were available from the farm or the surrounding area.

Santa Barbara Farms

SBF is a Limited Liability Company that consisted of three partners: Ron Berghoefer, Robert Guerra, and Robert Witt. Upon arrival at the farm, CalFERT investigators met with Ron Berghoefer, Vice President of Sales and Marketing, and Robert Guerra, Vice President of Production, to discuss the farm’s operations and review harvest, cooling, and shipping documents and customer lists.

On September 30, 2008, CalFERT investigators visited Santa Barbara Farms, LLC (SBF) at 1200 Union Sugar Avenue, Lompoc, CA 93436. MDA identified SBF as a supplier of iceberg lettuce to Fresh Pak during the time period of interest (Attachment 20). SBF documents show the sale of bin and carton packed iceberg lettuce to numerous other customers for the same time period and harvested from the same fields as sales to Fresh Pak (Attachment 21).

Investigators used the date of onset associated with the first case and determined that the suspect product was most likely produced from August 15-27, 2008. Traceback information indicated that the points of service locations typically used the iceberg lettuce within 3-4 days of processing. Two days was the shortest length of time for product transport from SBF to AM. Therefore, the target dates for shipment to AM were approximately August 14 – 29, 2008. Once at SBF, investigators determined the fields that would have supplied iceberg lettuce for the identified ship dates and determined harvest dates ranged from August 7 – 27, 2008 (Attachment 22).

Iceberg Lettuce Harvesting Operations

On October 1, 2008, CalFERT investigators observed the harvesting, packing, cooling, and storage of iceberg lettuce. Photos documenting the harvest, packing, and cooling operations are provided in Attachment 23. Harvest records for the time period of interest showed that each field was harvested and packed in a mixture of bins and cartons (Attachment 21). Investigators met with Rob Downy, Harvest Manager, to observe the firm's harvesting, coring and packing procedures for iceberg lettuce. This activity was conducted in field 2-4 (a field not implicated during the time period of interest). Investigators also administered an FDB Harvest questionnaire pertaining to field 2-4 (Attachment 24A).

Harvest employees used the blade of their knives to cut the iceberg lettuce off at the base and the opposite end of the knife to core the lettuce. The cored iceberg lettuce was placed on the conveyor of a harvest machine which moved it through a rehydrating sprinkler and subsequently dumped into lined bins on a flatbed truck moving parallel to the harvesting machine. Once the bin was filled, the plastic liner was twisted at the top to seal the bin. The bins were then transported to the cooler. Upon arrival at SBF the lettuce was either placed in the vacuum cooler tube or staged under a shed. There were no time or temperature readings taken when the lettuce arrived at the yard from the field.

The firm's specifications for the chlorine level in the rehydrating spray required that the solution contain greater than [REDACTED] ppm free chlorine at a pH of [REDACTED]. Investigators tested the nurse tank water chlorine level to be 30 ppm free chlorine (Waterworks Free Chlorine High 0-120 ppm, expiration on March 2010) at a pH of 6.5 (pHydrion strips, range 1-14, no expiration date listed). Investigators further tested the nurse tank spray water from the nozzle on the harvest machine and found the free chlorine and pH to be the same. Mr. Downy, Harvest Manager, stated that well water was used to fill the nurse tank. The chlorine levels for this tank documented on the "Knife and Machine Inspection Sheet" ranged from [REDACTED] ppm (Attachment 25). This water was used as the hydrating spray for the lettuce, in the knife dips, and to clean the equipment at the end of the day.

Harvest equipment was owned by SBF and was not shared with other growers. According to Mr. Downy, the equipment was cleaned and sanitized daily. The firm had a Sanitation Standard Operating Procedure (SSOP) for cleaning the harvest machine that was described by Mr. Downy as a pressure washing with chlorinated water from the nurse tank (Attachment 26). FDB-ERU staff noted that cleaning and sanitizing logs for the harvest equipment were adequately maintained by the harvest staff (Attachment 27).

SBF employed seasonal harvest workers who were trained in sanitation, GAPs, and Standard Operating Procedures (SOPs) at the start of each harvesting season. Training was provided in Spanish and English. Job specific training was provided at the beginning of the harvest season and during food safety and sanitation "tailgates" held

weekly at the fields. Workers were issued re-usable gloves and aprons that were replaced at least twice per week. Gloves were disinfected in a bucket of chlorinated water before work and after lunch. Knives were left at the work station when the workers took a break or used the restroom. Workers were not allowed to use knife sheaths. During breaks and at the end of the shift, workers left their knives in the knife dip which contained chlorinated water. The employee who washed the harvest equipment also took the knives and stored them in a SBF harvest truck at the SBF equipment yard each evening. Toilet facilities were maintained by SBF. The toilet facilities were viewed by investigators and were found adequately supplied with soap, water, and towels.

Packing

Iceberg lettuce was field-packed into 24-pack cartons (24 heads per carton) or bulk bins (approximately 1,100 heads per bin). All cartons had the SBF label. Iceberg was never cored prior to packing in cartons. The buyer specified desired product forms including; individually wrapped heads, loose heads in plastic lined cartons, or loose heads in unlined cartons. The bins were lined with plastic and after cooling, some of the air was drawn out of the plastic using a shop vacuum. The end of the shop vacuum tube was stored in a bucket containing a chlorine solution. Investigators tested the free chlorine in this bucket (using Water Works Free Chlorine test strips, 0-750 ppm) and found it was at 25 ppm.

Cooling and Cold Storage

All iceberg lettuce was cooled in a dry vacuum tube (no water shower) located in the yard next to the cold storage building. Condensation is drained out between loads through drains at either end of the tube. Mr. Downy explained that daily, before startup, the operator rinsed the tube with well water (Attachment 28A). The well on the south side of the cooler was used at the cooling facility and test results for 2007 and 2008 showed < 1 MPN/100ml (Attachment 28B). The operator used a broom to sweep debris and standing water down the drain. SBF did all of the maintenance on the cooler. The firm kept daily maintenance log for the vacuum tube. All iceberg lettuce was stored in the cold storage facility onsite prior to shipment. According to Mr. Guerra, the iceberg was held for a maximum of four days at the cold storage facility prior to shipping.

Growing and Field Operations

FDB-ERU investigative teams returned to SBF and the surrounding area in October and November 2008 to collect environmental samples and continue the farm investigation. Rob Guerra assisted the FDB-ERU team and provided the team with farming operation information. FDB-ERU staff completed an FDB Lettuce Farm Questionnaire to document farming practices (Attachment 24B). Initial analysis of epidemiological and traceback data by MDA and FDB-ERU identified 12 growing fields as possible sources for the implicated iceberg lettuce. Eight fields were identified as high priority because their harvest dates were in a timeframe that made the lettuce available to the first

exposure cases. These high priority fields were 13-2, 8-4, 10-2, 3-2, 4-2, 10-1, 6-4, and 5-3. The four fields identified as low priority because of their harvest dates were fields 1-2, 19-2, 17-3, and 2-1.

At the time of this investigation, most of the identified fields were barren and none of the fields were planted with iceberg lettuce. GPS, planting and harvest dates, and significant observations for each of the 12 fields were documented in the FDB Field Observation Spreadsheet (Attachment 29). Table 1 below shows a summary of the sample results for the 189 samples collected during the course of the farm FDB-ERU investigation. All of the samples were analyzed for *E. coli* O157:H7 and tested negative for the outbreak pathogen (Attachment 30). The samples are discussed in more detail later in this report.

Table 1 – Sample Collection Summary

All Samples Collected				
Location	Type	# samples	# FDA	# FDB
Santa Barbara Farms, Lompoc, CA	Well Water	18	0	18
	Surface Water	22	0	22
	Bovine Feces	6	0	6
	Animal feces	1	0	1
	Sediment	17	0	17
Santa Ynez River Moore swabs	Moore swab	4	0	4
	Concentrated Water	2	0	2
Federal Corrections Inst. Lompoc Dairy Facility	Moore swab	2	0	2
	Water	30	0	30
	Sediment	2	0	2
	Sponge Swab	8	0	8
	Cattle & Calf Feces	32	12	20
	Deer Feces	3	3	0
Lompoc Prison Cattle Pasture Nasa/Flats	Bovine/Misc. Animal Feces	42	16	26
Total		189	31	158

All environmental samples collected in this investigation were negative for the outbreak strain of *E. coli* O157:H7. However, there were 18 positive samples for different strains of *E. coli* O157:H7. Table 2 displays samples that tested positive for non-outbreak strains of *E. coli* O157:H7. The samples collected from cow feces or water that contained cow feces. It is common to detect *E. coli* O157:H7 in cow feces. However, none of these samples were collected on the SBF growing fields. As noted, the dairy was located across the Santa Ynez River and approximately ¾ mile from the nearest SBF growing fields and as much as 2 miles away from the furthest SBF growing fields.

Table 2 – Sample Collection Summary for Positive *E. coli* O157:H7 Samples

Positives Summary	Type of Positive	# samples	# isolates	Notes
Note--all positives detected by the California Food and Drug Laboratory (FDL)	Non-O157 <i>E. coli</i> stx 1	7	7	(all Dairy samples: 5 from flushline; 2 from calf sheds)
	<i>E. coli</i> O157:H7, stx 1	2	6	(all Dairy samples: 1 from the flushline; one from the calf sheds)
	<i>E. coli</i> O157:H7, stx 1, 2	9	21	(1 from dairy flush line; 1 from waste water; 1 from cattle pens; 3 from calf sheds; 1 from flushline Moore swab; 2 from pasture feces)
	Matches to outbreak strain:	0	0	
	Total	18		

Primus Laboratories, Salinas, CA. conducted two Ranch audits in 2008 (Attachment 31). Primus Audit Version 2.0 May 16, 2008 page 5 Section 04.02 and 04.02a showed deficiencies for Adjacent Land Use. A score of 0 out of 10 was received for Section 04.02 with the notation that deer were in proximity to growing operations. A score of 0 out of 15 was received for Section 04.02a with the notation that not all measures had been in place to limit animal intrusion, due to the fact that fence gates had not been completed. Deer prints were observed by FDB-ERU staff in and around growing areas.

Leafy Green Marketing Agreement (LGMA) audits for 2007 – 2008 do not note any egregious conditions for fields under cultivation by SBF (Attachment 32).

On October 7-9, 2008 FDB-ERU staff met Mr. Guerra at SBF to continue the farm investigation. The SBF ranch fields were located in Lompoc, CA. Approximately [redacted] acres were farmed in a valley bordered by the Santa Ynez River on the north and foothills to the south. All fields were cultivated under the same growing practices such as irrigation and amendments. The [redacted] acres were divided into approximately 116 fields, Ranches 1-28 (no Ranch 27) and Ranch 39. Approximately 31 wells supplied irrigation water to these fields (Attachment 33). SBF both owns and leases the fields. In 2008, SBF grew iceberg lettuce (~[redacted] acres), artichokes (~[redacted] acres), celery (~[redacted] acres).

acres), cauliflower ([REDACTED] acres), and seed flowers ([REDACTED] acres). No flooding or heavy rains occurred in the area during 2008.

Irrigation methods included furrow, sprinkler, or a combination of both. SBF did not document irrigation methods for specific fields. There were no open irrigation ditches or reservoirs on the ranch. All irrigation water was supplied by ranch wells through an underground pressurized system. The pressure was maintained at 80 lbs. psi. for irrigation. The underground system was connected and pressurized in block areas due to the fact that pipes did not go under asphalt roads. Wells, designated by purple dots, and roads were identified on the ranch map (Attachment 33). The various underground pressurized systems were located within the confines of two parallel (north-south) roads. For each separate underground pressurized system there was more than one well that could have supplied water, either individually or at the same time. Therefore, irrigation water could have been a mixture of all of the wells located on one block. However, Mr. Guerra stated well selection was generally determined by field location within each irrigation block.

SBF followed the well testing protocols of the LGMA listed in lines 393-401 and tested irrigation water within the required time frames per application type (furrow or sprinkler) and testing methods. [REDACTED] tested well water on the SBF Lompoc ranch in 2007 and 2008. FDB-ERU staff reviewed well test results for water used to irrigate the implicated iceberg lettuce fields and SBF's-LGMA well testing program (Attachment 34). All wells tested < 1 MPN/100 ml for *E. coli*. On October 7, 2008 FDB-ERU staff collected 18 water samples from nine wells supplying irrigation water. The samples were analyzed by FDL and found to be negative for *E. coli* O157:H7 and < 1MPN for *E. coli* (Attachment 30).

Mr. Guerra stated that in the 29 years SBF has been farming the Lompoc ranch they have never used any type of organic animal manure, compost, or biosolids. Inorganic fertilizers were supplied by [REDACTED] and Yara North America, Inc., Auburn, CA. [REDACTED] supplied a letter of guarantee that water used for application mixtures was of a potable water source (Attachment 35). However, Mr. Guerra stated that SBF always used ranch well water for all premixed application water.

The 12 identified fields were spread out over a large area (greater than a mile) and therefore animal influence varied among these field locations. Mr. Guerra stated that they did not have a significant animal problem for any of the fields and that there was very little crop damage from animal intrusion. Small rodents (squirrels, gophers), small birds (blackbirds), and deer were common animals on the ranch; however, Mr. Guerra stated that and wild pigs were not a problem in the valley and wild pigs have never been observed in the fields.

FDB-ERU staff observed animal prints on or near some of the fields and this information was noted on the FDB Field Observation Sheet (Attachment 36). No animal feces were observed in the fields. Mr. Guerra noted that deer intrusion was worse in the summer and on fields to the south of Highway 246. An eight foot wire deer fence was installed

one to two years ago along the southwest perimeter of Ranches 10 and 13 and ending on the east side of Artesia Street.

Numerous deer prints were observed on Ranch 19 and along the perimeter of field 19-2. The deer habitat was in the hills to the south of Ranch 19. Deer came onto the cultivated land to eat flowers and other crops. FDB-ERU staff did not see any evidence of crop damage from deer intrusion nor find any deer feces on the ranch to collect for samples. Other tracks such as canine and small animal prints were observed on field 19-2. Small mammal and or bird prints were observed on fields 8-4, 5-3, and 1-2. Canine tracks were also observed on field 13-2. A landfill is located on W. Oliver Avenue, directly across the road that bordered the south side of field 19-3. Runoff from the landfill was collected in a control basin and did not have access to the farmland.

Mr. Guerra had approximately ten cattle grazing on the land directly behind field 10-2, between January and September 2008. On October 7, 2008, FDB-ERU staff collected six cow feces and one small animal feces from this area. Since the cattle had not been on the land for days, finding feces with moisture was difficult. FDL tested the samples for *E. coli* O157:H7 and found them to be negative (Attachment 30).

On October 8, 2008 FDB-ERU staff collected 39 environmental samples (surface water and sediment) from field 8-4 and the nearby vicinity. Field 8-4 was on the northwest side of SBF Lompoc growing area, within ½ mile of the Santa Ynez River and had agricultural ditches along the perimeters. The samples were analyzed by FDL and found to be negative for *E. coli* O157:H7 (Attachment 30).

On October 9, 2008, FDB-ERU staff placed Moore swabs in two locations of the Santa Ynez River (Attachment 37). Two swabs were placed off of the Floradale Avenue Bridge and two swabs off of the 13th Street Bridge on Vandenberg Air Force Base (VAFB). The four swabs were retrieved on October 14, 2008. FDL found all swabs to be negative for *E. coli* O157:H7. At the time of the investigation the Santa Ynez River was 100% effluent from the Lompoc Wastewater Treatment Plant located at 1801 W. Central Avenue, Lompoc, CA, on the south side of the river. However, during the rainy season the river collects runoff water and carries water released from Cachuma Reservoir.

Lompoc Federal Correction Complex (LFCC)

The LFCC, 3600 Guard Road, Lompoc, CA is located on [REDACTED] acres bordered by the northern bank of the Santa Ynez River. SBF fields were on the south side of the river across from the prison property. The prison operated a dairy and cultivated animal and human crops at the time of this investigation. Photos for dairy operations and the surrounding property can be viewed in Attachment 38 .

On October 15, 2008, FDB-ERU staff conducted a phone interview with Art Brazil, Dairy Supervisor to obtain an overview of the LFCC dairy operations. On October 27, 2008, FDB-ERU staff met at the dairy with Ron Tunks, Lead Dairy Man and Ross Henderson-

McBean, Dairy Specialist, California Department Food and Agriculture (CDFA) to gather information about dairy operation practices and to assess the environment around the dairy.

Ross Henderson-McBean supplied copies of the two previous CDFA Milk Plant Inspection reports and well water test results (Attachment 39). Well dairy water source analyses were reported to be at levels of MPN < 1.1/100ml for total Coliforms.

In 2008, the dairy had approximately [REDACTED] heifers and cows. The dairy produced milk for approximately [REDACTED] prisons in California and Arizona. Dairy manure was collected and stored in a static pile on the property, approximately ¼ mile from the dairy operations. The compost piles were across the Santa Ynez River and 1-3 miles from the SBF fields. Prison farming operations cultivated pastures, tomatoes, onions, and feed corn. There was a barb wire fence between the Santa Ynez River and the prison property to contain cattle, but it did not deter deer. David Aguayo, Acting Farm Manager, LFCC, stated that deer did not do enough damage to warrant tactics such as fencing cultivated land. Mr. Aguayo reported that deer frequented the pastures and corn fields. Other common animals on and around the dairy were starlings, blackbirds, cowbirds, coyote, skunks, rabbits, ground squirrels, gophers, migratory birds, and badgers. Birds, starlings in particular, were the most abundant wild animal on the dairy during the investigation. FDB-ERU staff observed hundreds of birds at the dairy. Canisters had been used in the past to deter birds, but this tactic was not effective. Mr. Tunks reported that coyotes were occasionally seen near the dairy. There was a barb wire fence between the banks of the Santa Ynez River on the dairy side which prevented cattle from crossing the river and accessing farmland.

The dairy used VAFB municipal water and well water (with a backflow device) for its operations. On October 27, 2008 FDB-ERU staff collected two dairy well water samples. The samples were analyzed for both *E. coli* O157:H7 and *E. coli* by FDL. The samples were negative for *E. coli* O157:H7 and <1MPN for *E. coli* (Attachment 30).

Manure from the dairy was either flushed with water into ponds or transported to a static compost pile. Waste was removed from the milking barn and one feeding pen by flush lines. The wastewater was carried to a settling pond, transferred to a separator, and then the liquid was sent to a second pond. The separated solids were taken to the compost pile. Liquid wastewater from the second pond was used to irrigate 40 acres of pasture north of the settling pond. Mr. Aguayo stated that there were no collection ditches on this pasture as it was not irrigated to the point of producing runoff. Manure that wasn't removed by flushing was scraped into piles within the pens and later transferred to the compost pile.

The compost pile was static and not composted per Code of Federal Regulations (CFR) Title 14. The compost was not used on human crops such as onions or tomatoes; however, compost from this pile was spread on some of the corn fields and the pasture north of the dairy. The corn was used as silage for the dairy cows. The corn field east of the dairy had a flood control ditch down the middle that continued to the Santa Ynez

River. Mr. Aguayo stated that they did not irrigate enough to cause runoff into this ditch and therefore it was improbable that the compost would be carried into the river during irrigation. Corn and vegetables were furrow irrigated. Irrigation was controlled to prevent runoff from the fields and therefore, agricultural drainage ditches were not present.

On October 27, 2008 FDB-ERU staff collected 17 dairy wastewater samples from the milk barn, feed line flush lines, the first wastewater dairy pond, and the dairy well. FDL tested these samples and found fourteen of the fifteen samples negative for *E. coli* O157:H7. One flush line sample was positive for *E. coli* O157:H7 (stx 1 & 2), however, it did not match the outbreak strain.

On November 5, 2008 FDB-ERU staff collected 55 samples (fecal, sponge swabs, sediment, and wastewater) from the dairy. Samples were analyzed by FDL and FDA San Francisco District Office (SANDO) Lab. All samples tested negative for the outbreak strain *E. coli* O157:H7 by FDL (n= 43) and SANDO Lab (n = 12). Seven (7) samples tested by FDL were positive for *E. coli* O157:H7, but did not match the outbreak strain (Attachment 30).

On November 7, 2008 FDB-ERU staff collected two Moore swabs from the dairy flush line drain (swabs deployed on November 5, 2008). FDL analyzed the swabs and found them negative for the outbreak strain of *E. coli* O157:H7. One swab was positive for a non-matching outbreak strain of *E. coli* O157:H7 (Attachment 30).

Prison Farming and Cattle Operations

On October 28, 2008, FDB-ERU staff accompanied David Aguayo in a survey of the prison property and to gather information about prison farming and cattle operations. LFCC raised beef cattle and cultivated human and animal crops and pastures. Cattle had access to VAFB range land (located west of the prison) and prison pastures. At the time of this investigation there were approximately 60 bulls, 750 beef cattle, and 700 calves on the property. The farm cultivated tomatoes, onions, pinto and lima beans, and corn (for silage). Lima beans were cultivated on VAFB property. Horses (approximately 22) and dogs were used for the cattle operations. Photos for the LFCC farming fields and operations with FDB-ERU sample locations are provided in Attachment 40.

Mr. Aguayo stated that wild pigs had caused damage to the lima bean crop located on the northwest side of the 13th Street Bridge on VAFB. No signs of pigs were observed on this property by FDB-ERU staff. What appeared to be dried pig feces was observed on VAFB property near the river on the east side of 13th Street on VAFB property. No other wild pig signs were observed during this investigation on the prison or VAFB properties.

On November 5, 2008 FDB-ERU staff, David Aguayo, and Shannon Chandler, Wildlife Specialist, USDA, surveyed the prison and VAFB for animal signs. Three samples of

deer feces were collected and tested negative for *E. coli* O157:H7 by FDL (Attachment 30). Numerous animal trails were observed along the Santa Ynez River leading to and from the river into the surrounding natural vegetation. Seven salt blocks were placed on or near animal trails, in an attempt to attract deer and enable the investigative team to collect fecal samples. On November 18, 2008 FDB-ERU staff returned to the salt blocks, but did not find any fecal samples for collection.

On November 5, 2008 FDB-ERU staff collected two water samples from the Santa Ynez River. One sample was obtained from the Floradale Avenue bridge access and the other from the 13th Street bridge access. Approximately 40 liters of river water were collected for each sample at the two locations. After collection, the samples were filtered to reduce each sample volume to approximately 400 milliliters. The filtered samples were then submitted for analysis by FDL and found to be negative for *E. coli* O157:H7.

In 2008, LFCC had 20-50 cattle grazing on Nasa Flats located approximately 1/4 mile from the south side of Highway 46 off of Union Sugar Road. Nasa Flats was located west of SBF Ranch 10 and was approximately 1/2 mile from field 10-2. The cattle did not have access to growing fields. On November 6, 2008 FDB-ERU staff collected 36 cow fecal samples from this area. FDLB analyzed 20 of these samples for *E. coli* O157:H7 and found them to be negative. FDA analyzed 16 of the samples for *E. coli* O157:H7 and found them to be negative (Attachment 30). There were approximately 20 cattle on this property when the samples were collected.

On November 18, 2008 FDB-ERU staff, Andy Falco, Falco K-9 Academy, and David Aguayo visited previously deployed salt blocks on LFCC and VAFB properties. Mr. Falco brought Zero, a biodetection dog trained to locate fecal samples. There were no deer fecal samples next to the salt blocks to collect. However, Zero located fecal samples in adjacent and surrounding areas of the salt blocks. Zero enabled FDB-ERU staff to collect six samples of animal feces (one deer feces and five unknown animal feces). FDL analyzed the samples and found five samples negative for *E. coli* O157:H7 and one sample positive for *E. coli* O157:H7. The positive *E. coli* O157:H7 did not match the outbreak strain (Attachment 30).

Summary of Findings

All of the 189 samples collected in this investigation from the Lompoc Valley growing area and the FLCC Prison property were negative for the *E. coli* O157:H7 outbreak strain. Twenty-seven samples were positive for *E. coli* O157:H7, but they did not match the outbreak strain and were not collected on or in close proximity to SBF fields. These positive samples were collected from the dairy flush lines and calf or cow feces

The investigative team did not find any egregious conditions on the SBF growing fields or in the growing practices conducted by SBF. FDB-ERU determined SBF met the requirements of the LGMA and were following good agricultural practices. Laboratory data showed that all wells tested negative for pathogens during 2007-2008. There was

no evidence of animal intrusion into the growing fields and the investigative team did not find any animal feces on or near the growing fields. SBF supplied thousands of pounds of iceberg lettuce to numerous other customers harvested at the same time and from the same fields as iceberg lettuce that was shipped to AM during the same time period (Attachment 21). There were no illnesses that connected to the other SBF customers during the time period of interest. The source of the *E. coli* O157:H7 responsible for this outbreak was not identified during the SBF investigation.

Attachments

1. Michigan Epidemiological and Traceback Investigations
 - A. Michigan Department of Community Health *E. coli* O157:H7 Cluster Investigation Michigan State University Case Control Study October 8, 2008
 - B. Michigan Department of Agriculture (MDA) *E. Coli* O157:H7 Outbreak, September, 2008 Traceback / Investigation Summary
 - C. LH MI Line List 0809MIEXH-1c Oct. 6, 2008
2. Dupage County Health Department “Shiga-Toxin Positive *E. coli* O157:H7 Outbreak Investigative Report” September 16, 2008
3. Product Report For Santa Barbara Farms # 19978, 19980, 20031, 20033
4. Fresh Pak Purchase Order Detail 8/21/2008 – 9/19/2008
5. Van Dyk Invoices to Aunt Mid’s. Invoice # 6771, 6844
6. Special Report, Van Dyk Farm, September 27, 2008
7. AM’s Line #2 Non-Iceberg Production
8. AM’s Process Flow Diagram – Fresh Cut Lettuce Line
9. MDA Special Report Fresh Pak, Inc. September 27, 2008 and October 7, 2008
10. MDA Answers to FDB Questions November 20, 2008
11. MDA Answers to FDB Questions November 14, 2008
12. AM Sanitation Records and Logs
 - A. Process Hazard Analysis VI. HACCP Master Plan
 - B. Certificate of Analysis for Process Water August 11, 2008
 - C. Finished Produce Microbiological Tests, September 9 -11, 2008
 - D. Daily Control of Used Chemicals and Their Concentrations, July 15 – August 27, 2008
 - E. Pre-Operational Sanitation Check List, July 28 – August 27, 2008
 - F. Daily Control of Washing Waters
13. MDA Answers to FDB Questions December 8, 2008
14. Aunt Mid Lettuce Suppliers
15. Bogiatto Romaine Shipping Documents to AM’s, September 11 -19, 2008
16. Bogiatto Romaine Shipping Documents to AM’s, August 29, 2008 – September 11, 2008
17. D’Arrigo Bros. Co Lettuce Shipping Documents to AM’s, August 29, 2008 – September 22, 2008
18. MDA Answers to FDB Questions October 24, 2008
19. MDA Answers to FDB Questions December 26, 2008
20. Santa Barbara Farms, LLC Sales to Customer August 1 – September 24, 2008
21. Santa Barbara Farms, LLC Packout By Commodity /Style July 1 – September 30, 2008
22. Santa Barbara Field Planting and Harvest Dates
23. Photos: Santa Barbara Harvest, Packing, and Cooling Operations
24. FDB Questionnaires
 - A. FDB Harvest Questionnaire October 1, 2008
 - B. FBD Lettuce Farm Questionnaire October 7, 2008

25. Santa Barbara Farms, LLC Knife and Machine Inspection Sheet
26. SSOP Sanitation of Harvesting Machinery and Equipment
27. Harvest Equipment Sanitation Record Sheets
28. SBF Cooling Operations
 - A. SBF Cooling Daily Pre-Inspection Log
 - B. SBF Cooler N and Cooler S Well Water Test Results
29. FDB: SBF Farm Investigation Oct 7-8, 2008
30. FDLB Sample Summary Results Iceberg SBF Master
31. PrimusLabs Audits May 16, 2008 and June 22, 2008
32. CA LGMA Audit August 14, 2008
33. SBF Ranch Map
34. LGMA Well Water Testing Program
35. [REDACTED] Letter of Guarantee January 18, 2008
36. FDB Field Observation Sheet
37. Photos: Floradale and 13th Street Bridge Moore Swab Deployments
38. FDB Observation Sheets
 - A. FDB Dairy Operations and Surrounding Area October 27-28, 2008
 - B. FDB Dairy Site and Sample Collection November 5-6, 2008
39. CDFA Reports
 - A. Dairy Farm Score Card February 2008 and June 16, 2008
 - B. Dairy Water Source Lab Results February 25, 26, 2008, August 20, 25, 27, 2008