Investigation of an Escherichia coli O157:H7 Outbreak Associated with Dole Pre-Packaged Spinach

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Executive Summary

On September 13, 2006, the Centers for Disease Control and Prevention (CDC) alerted the U.S. Food and Drug Administration (FDA) of a multi-state *Escherichia coli (E. coli)* O157:H7 outbreak that appeared to be associated with consumption of bagged spinach. FDA subsequently notified the California Department of Health Services, Food and Drug Branch (CDHS) on September 13. On September 14, FDA San Francisco District Office and CDHS, working jointly as the California Food Emergency Response Team (CalFERT), initiated an investigation at Natural Selection Foods, LLC (NSF), doing business as Earthbound Farm, located in San Juan Bautista, California. NSF was one of several processors implicated early in the investigation and was ultimately the processor determined to have manufactured the contaminated spinach products. Although other investigations were undertaken by FDA districts as well as state and local health departments around the country, the scope of this report encompasses CalFERT's investigations at NSF and at potential source fields of the contaminated spinach in the central coast region of California.

CalFERT investigators examined the spinach washing, processing, and packaging process at NSF and collected finished product and environmental samples. No *E. coli* O157:H7 was identified in samples taken from the processor. No obvious sources for introduction of the pathogen were identified at the processing facility. However, a number of conditions were observed that may have provided opportunities for the spread of pathogens, if pathogens arrived on incoming spinach. Investigators conducted a traceback of spinach product codes obtained from ill consumers, to identify potential source fields of contaminated spinach. Nationwide, investigations identified thirteen bags of Dole brand Baby Spinach, manufactured by NSF, collected from ill consumer households that contained *E. coli* O157:H7 which matched the outbreak strain by pulsed field gel electrophoresis (PFGE) testing using two enzymes. Product codes were only available for eleven of these bags, all of which were Dole brand Baby Spinach bearing product codes that began with "P227A," indicating production on August 15, 2006. This code traced back to spinach harvested from four fields in Monterey and San Benito counties.

E. coli O157:H7 was found in environmental samples collected near each of the four fields that provided spinach for the P227A product code. However, *E. coli* O157:H7 isolates associated with only one of the four fields (located on the Paicines Ranch in San Benito County) had a PFGE pattern indistinguishable from the outbreak strain. The PFGE pattern was identified in river water, cattle feces, and wild pig feces on the Paicines Ranch, the closest of which was just under one mile from the spinach field. Land on the ranch was primarily utilized for cattle grazing by the large Paicines Ranch grass-fed beef operation. A relatively small amount of land on this ranch was leased for ready-to-eat crop production by Mission Organics. The ready-to-eat produce from this leased acreage was sold as conventional produce but organic growing practices were used, as the leased acreage was in the three year transition phase required for organic certification. Investigators observed evidence of wild pigs in and around the cattle pastures as well as in the row crop growing regions of the ranch. Investigators established that numerous wild pigs thrived alongside grazing cattle in the riparian habitat of the Paicines Ranch. Potential environmental risk factors for *E. coli* O157:H7 contamination identified during this investigation included the presence of wild pigs in and around spinach fields and the proximity of irrigation wells used

for ready-to-eat produce to surface waterways exposed to feces from cattle and wildlife. In the Paicines Ranch area, documented groundwater levels were higher in elevation than the San Benito riverbed on the ranch during March, 2006, fell to the riverbed level in July, 2006, and subsequently fell below the riverbed level later in the growing season. This potentially allowed surface river water from the river flowing into the Paicines Ranch valley to percolate into the ground again and recharge the groundwater basin during that period. Further assessments are needed to determine the likelihood of this occurrence. No definitive determination could be made regarding how *E. coli* O157:H7 pathogens contaminated spinach in this outbreak.

Background Information / Epidemiology

On Friday, September 8, 2006, Wisconsin state health officials identified a cluster of *E. coli* O157:H7 illnesses and submitted the PFGE patterns to CDC via PulseNet. September 12, 2006, CDC confirmed that the *E. coli* O157:H7 strains from infected patients in Wisconsin had matching PFGE patterns (Pulsenet Pattern EXHX01.0124/EXHA26.0015). By September 14, 2006, CDC had received reports from officials in eight states, reporting 50 cases of infection with *E. coli* O157:H7, with many ill individuals recalling consumption of fresh pre-packaged spinach in the week prior to symptom onset. Daily conference calls were instituted with state and federal agencies. Early in the investigation, a number of processors appeared to be implicated. As investigations into consumer illnesses progressed, it became apparent that illness was most often associated with Dole brand Baby Spinach manufactured by NSF at a facility located in San Juan Bautista, California. On September 15, following discussions with FDA and CDHS officials, NSF initiated a recall of all of the products that contained spinach in all of the brands they packed with "Best-if-used-by" (BIUB) dates of August 17 through October 1.

As of January 2007, 205 confirmed illnesses and three deaths were attributed to the outbreak. Of the 103 case patients who were hospitalized, 31 (30.1 percent) developed hemolytic-uremic syndrome (HUS). The peak occurrence of onset of illness occurred between August 30 and September 1, 2006. During the course of the investigation, 45 packages of prepackaged spinach were collected from case households in 14 states, 44 of which were analyzed for *E. coli* O157:H7. NSF manufactured 37 of the bags collected. Thirty-four of these were Dole brand, including 17 with a product code beginning "P227." Of the 44 bags of pre-packaged spinach that were tested, 13 (29.5 percent) were positive for *E. coli* O157:H7. All of the positive bags had PFGE patterns that were indistinguishable from the outbreak strain and all 13 were Dole brand Baby Spinach. Eleven of the 13 (84.6 percent) had a product code with the prefix "P227A," the other two did not have product codes (they had been cut off by the consumer) but were also Dole brand Baby Spinach. The single unopened bag collected from a case household contained baby spinach manufactured by Fresh Express. This product tested negative for *E. coli* O157:H7. For additional information on the epidemiological investigation, please contact CDC.

NSF Processing Facility

At the onset of this investigation, NSF, doing business as Earthbound Farm, operated two processing facilities in San Juan Bautista, California. The first, referred to as the "North" facility, is located at 1721 San Juan Highway, San Juan Bautista, California 95045. The second, referred to as the "South" facility, was located approximately one mile from the North

facility at 1275 San Justo Road, San Juan Bautista, California 95045. During the time period of interest, NSF was in the process of purchasing the South facility from Pride of San Juan, Inc (POSJ) and had taken over all operations at the South facility. NSF production in the South facility started April 1, 2006. Subsequent to this outbreak, NSF canceled the purchase of the South facility. California state law requires all persons engaged in the manufacture of processed foods be registered with CDHS. NSF manufactured food products at the South facility from April 1 through September 15, 2006. Records maintained by CDHS revealed that NSF did not have a valid registration during this time period. NSF management told investigators that they thought they could operate under the registration issued by CDHS to the previous operator (POSJ) while they were in the process of purchasing the facility. NSF had applied for registration with CDHS on September 12, 2006, but no inspection had been conducted. NSF withdrew the application on September 26, 2006.

As the outbreak strain of *E. coli* O157:H7 was identified in several bags of conventional Dole baby spinach product obtained from confirmed cases, the investigation narrowed to one day's production at the NSF South facility. Both North and South facilities processed a variety of prepackaged salads and spring mixes for ready-to-eat consumption, many of which either contained or were composed entirely of spinach (Exhibit 1 – Products Containing Spinach). The North facility processed organic and conventional products while the South facility processed only conventional products.

Investigators worked with William C. Daniels, Director of Quality Assurance (QA) for NSF, and Bryan S. Aguirre, Senior Vice President of Operations, to obtain the majority of NSF information in this report. At the onset of the investigation, Drew Goodman was President and Chief Executive Officer (CEO) of NSF. He held this post until early November 2006, when Charles Sweat, formerly Chief Operating Officer, became President and CEO of the company. Refer to Exhibit 2 for organizational charts of NSF, d.b.a. Earthbound Farm, as it was structured prior to November.

Operating hours at the South facility were Monday through Saturday, from approximately 6:00 a.m. through 2:00 a.m. of the following day. Two production shifts took place during this period. There was a short cleaning shift (approximately four hours) between production days and a more extensive sanitation shift each Sunday. With the exception of the receiving area, the production facility was refrigerated, with a target temperature of less than 41 °F, measured every two hours during production shifts. The Daily Room Temperature log for the month of August of 2006 was obtained by CalFERT (Exhibit 3). This log was designed to record thermometer calibration, time, and temperatures of the outside area, receiving room, preparation room, mixing room, wash room, pack room, and storage area of raw and finished product. The thermometers used to check the temperature were calibrated at the beginning of each shift in an ice water slurry. Raw and finished product storage temperatures were identified as control points on the process flow document obtained, with a target temperature of less than 41 °F. The Daily Room Temperature logs indicated an operating range between 33 – 41 °F. The Daily Room Temperature logs collected indicated that the temperature at the control points were consistently maintained below 41ºF although there were occasions where temperature readings dropped below the minimum specified. On the occasions that the temperatures dropped below 33 °F, the log sheet stated that the issue was brought to a supervisor's attention.

Process Flow

NSF categorized spinach into two sizes, "baby" and "teen," although no products were marketed as "teen" spinach. There are no regulatory standards for the term "baby" and "teen" spinach. The difference between baby and teen spinach was based solely on the size of the leaf, otherwise the products were handled the same. According to Mr. Daniels, baby and teen spinach may have been used interchangeably in processing if demand made it necessary. A bag labeled, "baby spinach" manufactured at NSF, was not necessarily composed of baby spinach under the firm's specifications.

Spinach was field packed in either plastic totes (15 – 20 pounds) or bins (approximately 250 pounds). Spinach was transported from the field in refrigerated trucks except when the fields were close enough to the facility to transport the product by tractor. Product was unloaded at an outdoor loading dock, and then moved to the receiving area. The South facility receiving area was not refrigerated. In the receiving area, a sample was collected from each load and inspected as determined by Standard Operating Procedure (SOP) 106, "Raw Material Inspection and Handling" (Exhibit 4). Raw material grading was conducted based on commodity-specific specifications (see Exhibit 5 for baby spinach specifications). If the product was accepted, each pallet was affixed with a pallet tag with a unique number and the data for that bin or pallet (grade, product type, grower and grower lot number, harvest date, net weight, and expiration date). The tag affixed included a barcode but the South facility had not yet incorporated the barcode tracking technology used in the North facility. According to Mr. Daniels, if the product was rejected, the grower would have been notified and given the option to retrieve the product. If the grower did not retrieve the product, it would have been discarded.

After inspection, the product was cooled. Spinach packed in bins was received on the grounds of the North facility and held outside until it was vacuum cooled. The temperature of the product was recorded before and after cooling and recorded on the Cooling Tube Log Sheet (Exhibit 6). Once cooled, it was sent to the South facility. No water shower was used in the vacuum cooling process for spinach. Spinach packed in totes was received and cooled inside the South facility by forced air. The firm's pre-storage target temperature for cooling was less than 41 °F. After cooling, the spinach was moved to the raw material storage area where it was stored for up to 72 hours prior to reevaluation or processing. The firm used a first-in, first-out system for rotating raw product inventory. According to Mr. Daniels, the first-in, first-out system was monitored by warehouse employees whose task was to send the oldest product to production first.

As pallets of spinach were removed from raw materials storage and sent to the processing lines, each pallet number was recorded by hand on the "Daily Depletion Log" (Exhibit 8). The processing sequence at the South facility began with [redacted] mixing lines (See Exhibit 9 for the Process Flow Quality Assurance Reference, Attachment 1 for a process flow diagram). A mixing line consisted of a conveyor belt onto which salad products were dumped. For mixed salads, employees hand-dumped totes of each product onto the lines in the desired proportions for the salad mix. A mechanical bin-dumper was used to dispense the larger bins of product onto the lines. No physical mixing took place on the line, other than the act of dumping multiple products on one conveyor belt, which resulted in a mixed salad at the end of the process. To produce Dole brand baby spinach, baby spinach, alone, was dumped onto the mixing lines. Subsequently, the product moved over an inspection belt where two

employees watched for visible quality and contamination issues, particularly foreign objects among the products. Contamination observed among product at this or other points in the manufacturing process was classified by the firm into three levels of severity: green, yellow, or red (Exhibit 10). Product then traveled over a singulator, used to separate the leaves so they would not enter the wash flume in clumps.

Each mixing line fed a separate wash flume. NSF used a two stage wash composed of two wash flumes in sequence. The water in the flumes was re-circulated during the day and was drained at the end of the day, after the two processing shifts (NSF water systems diagram, Exhibit 11). The water in each flume was chlorinated (maintained between [redacted] parts per million (ppm) free chlorine) and pH adjusted (maintained at a pH between [redacted]). The chlorine level and pH were manually monitored every half hour during operation and adjusted by addition of chlorine or citric acid as needed. Chlorine and pH levels were recorded on the wash line logs (Exhibit 15). The firm used the same test kit (Hach Pocket Colorimeter II) to measure the water color in the flume as they used to measure the free chlorine content of the flume water. Mr. Daniels told investigators that NSF had determined that the water color measured by the pocket colorimeter provided a gauge that they had found to be a reliable indicator of the turbidity of the water in the flumes. The Hach Pocket Colorimeter II did not offer a turbidity standard for use with the Pocket Colorimeter II test kit. Mr. Daniels said the meter was calibrated using a chlorine standard. Mr. Daniels said they had done some validation of this method, but documentation of that validation was not received prior to the finalization of this report. The target turbidity based on the wash line monitoring log sheets was [redacted]. Mr. Daniels stated that the units for this number were ppm. The results recorded on the wash line monitoring log sheets were not actually turbidity, they were a measurement of water color. If the turbidity (water color as measured using a Hach Pocket Colorimeter) in the flumes approached the designated limit, it was adjusted using one of two methods. In the first method, a portion of the re-circulated water was purged, with a corresponding amount of fresh water added (along with chlorine and citric acid as needed). In the second method, all of the water in the first tank was dumped and the water from the second tank then transferred to the first tank. New water was then added to the second tank, followed by adjustment of pH and chlorine content in both tanks. According to Mr. Daniels, during a production shift NSF staff would likely use the first method because the second method created a half-hour of downtime. The target temperature for water in the second flume was 36ºF, not to exceed 41ºF, and was maintained by recirculating the water through refrigerated chillers. Water in the first flume was chilled prior to being added to the flume but it was not recirculated through chillers. The temperature of the first flume was maintained below 45ºF (documented on the wash line monitoring log sheets) by addition of fresh chilled water or chilled water from the second flume. Investigators did not have an opportunity to test the chlorine and pH content of the flume water in the South facility as NSF stopped production in that facility early in the investigation. Sections of the wash flumes were designed to create turbulence in order to ensure separation of the leaves and to prevent a condition known as "rafting" or "lily padding" where leaves might float along on top of the flume and not get fully exposed to the wash water.

Product exited the flume over a de-watering belt and then was deposited into perforated plastic centrifuge barrels. The product was centrifuged, and then manually dumped onto a conveyor for one of the [redacted] packing lines. Product from a given wash line could feed multiple packing lines simultaneously, or in another case, multiple wash lines could run the same product and together feed a given packing line (Exhibit 12). Determination as to which

packing line a particular centrifuge barrel fed depended upon the raw material needs of each packing line. Once on the packing line, the product was mechanically weighed and deposited into retail bags (4 ounce to 1.5 pounds), retail clamshell packages (5 ounce to 11 ounce), or food service bags (1.5 pounds to 4 pounds). NSF did not use a modified atmosphere pack for bagged spinach. Packages were all run through metal detectors and then packed into boxes. The boxes were palletized and moved to finished product storage where they were stored at a temperature below 41 °F. Products in finished product storage were required to be shipped out within [redacted] hours of processing or else be evaluated and specifically allocated to West Coast customers who required shorter shipping times, according to the firm.

Processing- Procedures, Monitoring, and Controls

The NSF South facility was operating under a Hazard Analysis and Critical Control Point (HACCP) plan. According to the NSF hazard analysis document (Exhibit 13) and HACCP Plan (Exhibit 14) obtained by CalFERT, there were [redacted] processing critical control points (CCPs) at the South facility. The location of CCP1 was [redacted]. The hazard of concern was microbiological (e.g., *E. coli*, *Salmonella,* and *Listeria*) and the control measure was chlorination of the wash water with a critical limit of [redacted] free chlorine set for both conventional and organic product. The firm also monitored and controlled the pH (maintained between [redacted]), the turbidity (actually water color as measured using a Hach Pocket Colorimeter, maintained at less than [redacted]), and the temperature (maintained at less than 41 °F) and recorded these factors on the wash line logs (Exhibit 15). Review of the NSF wash line log sheet for the month of August 2006 showed that overall no major deviations (from limits set by NSF per parameter) were observed for pH, free chlorine levels, temperature, and turbidity (water color as measured using a Hach Pocket Colorimeter) levels in [redacted] flumes [redacted] (Attachment 2 lists deviations observed on the wash line logs). The location for CCP2 was [redacted], with the hazards of concern being foreign materials. Control measures were the use of functioning metal detectors, a preventive maintenance program in place, and internal audits.

Production output records were obtained from NSF for the South facility for the month of August 2006. Daily production volumes ranged from a low of [redacted] pounds on August 7 to a high of [redacted] pounds on August 24, 2006. The average daily production volume for the month of August was [redacted] pounds. The production volume on August 15, 2006, was [redacted] pounds. The weekly average for the week of August 14-19 was the highest during August at [redacted] pounds. The lowest average was calculated for the period between August 1 and August 5, 2006, (this average only included five days as our initial production period of interest bracket did not include July 31) and was [redacted] pounds.

Among the documents collected from NSF were a collection of e-mail exchanges representing short reports on production matters at the South facility. All e-mails sent during the month of August 2006 were requested, but according to Mr. Daniels, these e-mails were not sent every day. Most of the e-mails received were provided in Spanish and were translated by CDHS staff. The subjects of these e-mails were the routine problems encountered in daily production. Starting on August 13, there were a number of days where the South facility experienced personnel shortages (August 13 = nine absent; August 15 = seven absent; August 16 = five absent; August 17 = one absent, three on light duty; August 18 = one absent; August 20 = two absent). On August 17, the e-mail said that they received

help from the drivers because they did not have enough people for shift B. NSF management told investigators that the "drivers" were the forklift drivers who had been trained in Good Manufacturing Practices (GMP)'s. On August 18, the e-mail said that a new employee had started, and on August 20, the facility had six new workers. On August 22, the email noted the anticipated arrival of five temporary employees to work the B shift. There were no reports of worker shortage in the remaining e-mails. Personnel records reviewed by CalFERT investigators revealed that a number of the absences were reported as being due to personal illness or illness in the family. CalFERT investigators could not determine the nature of these illnesses.

Contamination Procedures

According to Mr. Daniels, contamination was most often observed at the inspection stations located after the mixing lines. Foreign objects observed among products at any point in the manufacturing process were documented, classified, and acted upon. Through September of 2006, observed contamination was classified into three levels of severity: green, yellow, and red. The firm's practices have since changed such that only green and red are used. SOP 112, "Contaminated Product Procedure," dated September 28, 2006, lists the new practices (Exhibit 10). Examples of green contamination would be a stick or a small non-sharp piece of wood. In Mr. Daniels' words, green contamination could not cause harm to a consumer. Red contamination refers to any foreign object observed that has potential to cause harm. This could include sharp pieces of wood, plastic, or metal, and any item resembling feces. When the classification of "yellow" contamination was in use, it referred to contamination with questionable potential to cause harm.

Mr. Daniels informed investigators that when red contamination was observed at an inspection station, the production line was halted and all product on the mixing line, wash line, and six centrifuge barrels ahead of the mixing line was discarded. The line was then cleaned and sanitized before production could resume. If a second instance of red contamination from the same lot of product were observed, then the entire lot was thrown out. If a lot caused two red contamination events, then the plant QA Manager was informed in order to authorize disposal of the lot. While the South facility was operating, Maria Ventura was in training as the QA Manager, but Greg Komar, QA Manager at the North facility, had authority in this position over both facilities. The two facility QA Managers reported to Mr. Daniels, Director of QA. (Refer to Exhibit 2 for the organizational charts). Mr. Daniels estimated that instances of red contamination classifiable as "fecal" were observed about five times per year in the North and South facilities together. He emphasized that an inspector would err on the side of caution, for example, a suspicious clump of dirt might have been classified as fecal, even if it was not a certainty. If red or green contamination was encountered anywhere throughout the process, then the NSF form QA 45, titled, "Foreign Object Investigation Form," should have been filled out. Investigators reviewed Foreign Object Investigation Forms provided by the processor for all incidents of red contamination that occurred at the South facility from their first day of production at the facility on April 1, 2006, through the final production day on September 15, 2006 (Exhibit 16). No contamination classified as "fecal" was observed in the documents provided. Of 54 incidents of red contamination documented between April 29, 2006 and September 6, 2006, 30 were plastic materials, 18 were metal (9 of which were blades or knives), 2 were feathers, 1 was glass, and 3 were not classified on the record and the item attached could not be identified on

the copy investigators received. No red contamination was reported during the P227A processing shift.

Cleaning and Sanitation

The South plant had a dedicated cleaning shift at the end of each production day. Cleaning began at approximately 2:00 a.m. and lasted about four hours. A more extensive sanitation shift took place each Sunday. The "EB–South Master Sanitation Schedule San Juan Bautista" was used to log completion of items during the weekly cleaning conducted every Sunday (Exhibit 17). Copies of this schedule were collected for the period of NSF's operation at the South facility. This document consisted of a list of rooms with subsets of areas within that room that required sanitation periodically (weekly, biweekly, monthly, or yearly). Each area was followed by a row of boxes which were filled in with the dates when the sanitation was completed.

The "EB–South Daily Master Sanitation Schedule" was used to log completion of items done during the daily sanitation shift (Exhibit 18). This schedule was obtained for the time period of July 30, 2006 through September 2, 2006. This document consisted of a schedule of sanitation activities with a checkbox for a supervisor to initial when the activity or operation had been completed. Each sheet of records showed the room type (e.g., mixing room) and location per room (e.g., Radicchio Line) where the sanitation activities took place.

Neither the daily schedule nor the master schedule were rigorous checklists that itemized every task done by the cleaning crews. These logs did not record sanitation of processing lines, conveyor belts, and food contact surfaces. While the frequency of Sanitation Standard Operating Procedures (SSOP) 001, 002, 003, 004, 011, 017, 018, 020, and 024 (corresponding to: trim line chopping tables and chutes, trim line conveyor belts, trim line "translicer," sorting shaker, trash barrels and bins, facility drains, facility eating areas, facility bathrooms, and facility hydro-vac cooling tubes) was set as daily in the SSOP, there was no specific correlation to these areas on the daily sanitation log. However, it is possible they could fall under one or more of the categories (e.g., room type and room location) outlined on the daily schedule. Discrepancies were observed between the sanitation schedules and certain SSOP's on the frequency of cleaning and sanitation for certain areas. For example, under SSOP 015, floors were required to be cleaned on a daily and a monthly schedule. However, the master sanitation schedule received by investigators listed bi-weekly for floors, monthly for assembly mezzanine floors, and quarterly for shipping cooler floors. Under SSOP 017, the drains were listed on a daily and a weekly schedule. On the master sanitation schedule, however, the frequency was bi-weekly. Mr. Daniels informed investigators that the SSOPs and sanitation schedules were not modified for the new plant; instead experienced employees from the original NSF facility (the "North Facility") were transferred to the South facility to ensure consistency of cleaning and sanitation activities between the two locations.

NSF conducted adenosine triphosphate (ATP) testing to verify sanitation (Exhibit 19). Test results were collected for the period between July 15, 2006 and August 30, 2006 (Exhibit 20). According to Mr. Daniels, ATP testing should have been conducted on a daily basis at five or more sites each day, randomly selected from the group of sampling sites used by the microbiology lab for environmental sampling (please see "Microbiological Testing" section below for details). Sites that failed the ATP test were supposed to be re-cleaned and re-

sanitized and then tested again. During the time frame for which results were obtained, the frequency of ATP testing varied from once a week to five times a week. On a given day on which testing was done, between 5 and 16 samples were collected. During the production week of August 14 -19, 2006, ATP testing was conducted on one day, Monday, August 14. The next ATP testing did not occur until August 26, 2006. The records collected showed only one occasion where a failed test was not repeated until the location passed. On August 10, 2006, a sample collected from the Mezzanine Line 3 Scale Vibrator failed but the documentation did not show that a re-test was ever done. NSF did not document the re-cleaning of the Mezzanine Line 3 Scale Vibrator so it was not possible for investigators to verify that corrective action was taken in this instance. Mr. Daniels could not determine exactly why the re-test was not conducted. He repeated that the SOP required that the area that failed would be re-cleaned and re-sanitized and then tested again, but he could not provide a record showing that this had been done.

The firm owned two tote washing machines, one located at each plant (i.e., North and South). Records for washing totes and bins at the South facility were requested by CalFERT for the month of August 2006. Documents received were for tote washing only and for the period from August 1, 2006 through August 14, 2006 (Exhibit 21). The firm stated that they were unable to locate the remaining documents. No logs were maintained for bin washing.

The tote washing log was designed to serve the North facility and included an area to designate the types of totes being washed (conventional or organic) as a water wash step was required prior to shifting from washing conventional to washing organic totes. The records obtained showed that only conventional totes were washed at the South facility and that no one filled in the verification check box on the tote washing logs.

Microbiological Testing

NSF contracted with a third party, Primus Group, Inc. (Primus), that conducted routine environmental sampling of the processing facility equipment and wash system water at the South facility on a [redacted] basis, as well as [redacted] *Listeria* (generic) tests, and [redacted] raw and finished product testing. SOP 011, "Third Party Microbiological Testing" provides critical limits for these tests and lists the actions to be taken when the critical limits are exceeded (Exhibit 22). Samples of the processing facility equipment were collected at a series of pre-set locations (Exhibit 23 – Sample Rotations) and were analyzed for Total Plate Count (TPC). These locations were divided into groups and the groups were rotated. Sample results were obtained for the sampling done on August 7 (n=39), 14 (n=30), 21 (n=31), 28 (n=35) and September 7 (n=25) and 11 (n=30), 2006. The majority of these samples revealed total plate counts below ten colony forming units (CFU)/50cm^2. The exceptions were as follows: on August 7, the L2 spinner No. 4 result was 39 CFU/50cm^2; on August 21 the L4 Flume No. 2 result was 120 CFU/50cm^2; on September 7 the L2 autospinner No. 9 result was 180 CFU/50cm^2, the L2 incline belt No. 3 result was 20 CFU/50cm^2, the L2 shaker before scales No. 3 result was 16 CFU/50cm^2, the L2 shaker before scales No. 4 was 13 CFU/50cm^2; and on September 11, the L3 flume No. 2 result was 30 CFU/50cm^2 (Exhibit 24 - results). None of these results exceeded the critical limit listed in SOP 011. Samples were also collected from flume water and analyzed for TPC. The flume water tests were supposed to be conducted on a weekly basis but tests were only conducted on July 27, August 19, and September 14, 2006. Sample results ranged from less than one to 565 CFU/mL (Exhibit 25). Only two of the flume water samples in this date range exceed the critical limit listed in SOP

011, the first on July 27 taken from A1 tank No.1(550 CFU/mL) and the second on August 19 taken from B2, tank No. 1 (565 CFU/mL). SOP 011 required that for findings between [redacted] Most Probable Number (MPN), the required action was a "focus on better cleaning." Mr. Daniels explained that the units used in the SOP (MPN) were incorrect and had been transferred from a previous version when they should have been changed. No log of this action was collected. NSF conducted *Listeria* sampling on September 7, 2006. Results were reported as negative (Exhibit 26). NSF conducted microbiological analysis on raw and finished product samples on a [redacted]. Samples were sent to Primus for TPC analysis on July 27, 2006 (Exhibit 27). Sample results for raw spinach ranged from 4,300,000 CFU/g to 16,000,000 CFU/g. Sample results for finished product (reported as "baby spinach") ranged from160,000 CFU/g to 5,100,000 CFU/g. The critical limit listed in SOP 011 for raw and finished product testing was [redacted] MPN. All sample results received exceeded these levels. As explained above, Mr. Daniels explained that the units used for this test in the SOP were incorrect. Mr. Daniels also said that the critical limit for raw and finished product testing was based on an older version of the SOP when the firm tested for total coliforms, not TPC. The required "Action if Limit is Exceeded" directed by SOP 011 for both raw and finished product was, "See improvement from Raw to Finish products."

NSF provided investigators results of environmental and raw spinach samples collected in the South facility on September 17, 19, 21, and 25, 2006, which were tested for *E. coli* O157 by JL Analytical, Inc (JL) (Exhibit 28). All results were negative.

Water – Fresh and Waste (Wash) Water

The water system for the South facility was registered with the California Department of Health Services - Office of Drinking Water as a non-transient, non-community water system. The documentation for this system was never changed from the existing POSJ name after NSF assumed control of operations at the facility. Investigators obtained the POSJ water system (No. 3500917) monthly report to the Office of Drinking Water for the months of July, August, and September 2006 (Exhibit 29). These documents included a monthly summary on the distribution system for coliform monitoring and coliform reporting. The September results included the quarterly report for disinfection residual compliance. According to the document, routine testing showed absence of coliforms and *E. coli* in the water and the firm was meeting the standards set for disinfectant residual in systems using chlorine or chloramines.

Mr. Joseph Torquato, NSF Facilities Engineer, explained that water used in the South facility was from a well, pumped into an enclosed holding tank (NSF water systems diagram, Exhibit 11). There was no meter on the South facility well or any other way to determine how much water was being drawn. Water from the South facility well was also used for POSJ farming irrigation operations. Mr. Torquato said that POSJ used three types of water for irrigation: Blue Valve water (Central Valley Project surface water used for irrigation, see Attachment 11, an addendum report relating to irrigation water issues), water from the NSF South facility well, and effluent water from the NSF south discharge water holding pond. The holding pond was filled with processing waste water. From inside the plant, waste water was deposited into trench drains and carried outside to a lift station, which pumped the water to a settling tank. From there it was pumped to the holding pond. According to Mr. Daniels, the process waste water for the NSF South facility belonged to POSJ. The "Process Waste Water" document provided to investigators by NSF included influent and effluent waste water data

from June through September of 2006 (Exhibit 30). Mr. Torquato told investigators that the figures reported on the form were provided by POSJ.

NSF operations at the South facility ceased September 15, 2006 and did not resume. CalFERT investigators observed processing equipment and collected wastewater samples there on September 21 and 22. Samples (n=13) of waste water and sediment were collected from the lift station, settling tanks, and holding pond. All samples were negative for *E. coli* O157:H7. Inside the plant, hoses used for washing equipment were observed to lack backflow prevention. All hose bibs along the outside of the building also lacked backflow prevention devices. The firm's chiller system for wash flume water was located outside the facility. The overflow pipe on one of its two tanks was open to the air and lacked a screen. A sight tube for the chiller tanks (to determine water level) had mold growing inside it. Also observed in the area were a number of chiller system flexible plastic hoses, stored uncapped with their ends touching the concrete pavement. Management stated that the facility was not processing and if it had been, the hoses would not have been stored as observed.

Product Coding and Traceability

The code used on the retail bags of Dole brand Baby Spinach was translated by NSF management for investigators. For example, in the code P227A01, (P or J), P = South processing facility, J = North processing facility; 227 = Julian date for August 15; A = shift identification (A or B); and 01 = bagging/clam shell packing machine identification (01–07). NSF also labeled retail packages with a "Best if Used By" (BIUB) date that corresponded to the production date plus the shelf life. For the Dole brand Baby Spinach, the shelf life was 15 days, so the BIUB date for the example above was August 30.

Tracing From Product Codes to Fields

Epidemiological analysis provided by CDC to FDA on September 13, 2006, implicated retail bags of baby spinach as the cause of consumer illnesses in this multi-state *E. coli* O157:H7 outbreak. Early in the investigation, a number of processors appeared to be implicated. As investigations into consumer illnesses associated with consumption of pre-packaged spinach progressed, it became apparent that illness was most often associated with Dole brand Baby Spinach manufactured by NSF. Forty-five packages of leftover spinach-containing products were collected from case-patient households in 14 states. Attachment 3 lists the product codes obtained from these packages. Thirty-seven of the packages were manufactured by NSF. Thirty-four of those were Dole brand, 17 of which had product codes beginning "P227A". Thirteen of 44 (29.5%) spinach packages tested were positive for *E. coli* O157:H7 with a PFGE pattern that matched the outbreak strain. All thirteen positive bags were Dole brand Baby Spinach and eleven of the thirteen (84.6%) bore codes beginning with "P227A". No code could be identified for the other two matching Dole brand bags, as it had been cut off by the consumer.

The inventory tracking system used by NSF allowed the firm to determine the source fields of raw products entered into production during a specific shift and day by manually linking several different documents. Beginning with a product code from a consumer bag of Dole brand Baby Spinach, for example, P227A03: NSF could identify fields that supplied baby spinach for production shift A on August 15, 2006, at the South NSF facility ("P"). It was not possible to determine just those source fields that supplied a specific bagging machine ("03"

in this example). Nor was it possible to narrow the field inputs that went into a specific varietal pack during a shift – the firm only tracked raw product input by shift.

To trace a product code, data from the firm's Daily Depletion Log was cross-referenced with the firms receiving log (Raw Receipts Log, Exhibit 31). Depletion logs were hand written lists of pallet numbers, representing all types of raw materials utilized during a shift (baby spinach, green romaine, mizuna, etc.). For the P227A processing shift, the depletion log lists 243 pallet numbers. By matching pallet numbers from the depletion log to those in the receiving log, the type of product, source field location, identity of grower, and date received can be determined for each pallet.

NSF conducted a traceback from product code P227A to growing fields and provided the results to investigators (Exhibit 32). Four fields on the Paicines, Wickstrom, Taix, and Eade Ranches were identified as having supplied baby spinach used during the "A" shift on August 15, 2006. Investigators verified the four fields to be an accurate traceback for P227A through an analysis of processing records. An individual bag of baby spinach produced during the P227A shift might have contained spinach from one or any combination of the four fields that supplied that shift, depending on the depletion times for different lots of spinach from raw materials storage and the processing sequence.

While the P227A code was implicated by laboratory results from opened bags of product and the date range of case patient illnesses fit the expected shipping times, shelf life, and consumption of this code, baby spinach from the implicated Paicines field (Paicines lot 1) was received and processed at NSF through September 6, 2006. A relatively small amount (1002 pounds) of the spinach from Paicines lot 1, harvested on August 14, went into P227A; the remainder went into other product codes. Other types of leafy greens were also harvested from Paicines lot 1 and supplied to NSF between August 10 and September 13, 2006, (see Attachment 4 for a comparison of receipt dates of Paicines products to processing dates of product codes other than P227A obtained from case-patient households).

NSF: Receiving and Processing of P227A Baby Spinach

The fields on the Paicines, Wickstrom, Taix, and Eade Ranches were the only sources of the baby spinach utilized during shift A on August 15, 2006. There was no spinach classified as "teen" utilized during shift A, although baby and teen spinach may be used interchangeably in processing if necessary, according to Mr. Daniels. The Raw Product Receiving Log documented the receiving time and conditions for raw materials. Exhibit 33 contains the Raw Product Receiving Logs for the South facility from the month of August. Raw product from the Wickstrom Ranch was harvested in bins which were received and vacuum cooled at the North facility. Exhibit 34 contains the Raw Product Receiving Log for the baby spinach from the Wickstrom Ranch received on August 14, 2006. In tracing the baby spinach used in product code P227A back to its origin, the following information was observed. Baby spinach from the Paicines, Taix, and Eade Ranches was received in totes and forced-air cooled at the South facility. The recorded temperature range for forced air cooled product during the month of August 2006 was 37 to 42°F (Exhibit 7). Baby spinach from the Wickstrom Ranch was received in bins and vacuum-cooled at the North facility before it was transferred to the South facility. The recorded temperature range for vacuum cooled product during August was 36 to 38°F (Exhibit 6).

According to Mr. Daniels, all raw materials received at NSF were subject to certain internal quality criteria, set forth in SOP 106, titled "Raw Materials Inspection and Handling" (Exhibit 4). These criteria were listed on the "Earthbound Farm Field Grading Criteria" form (Exhibit 35) and the "Conventional Baby Spinach Raw Product Specifications" form (Exhibit 5). These grades should not be confused with official United States Department of Agriculture (USDA) grading standards which were not used by NSF. The Earthbound Farm Field Grading Criteria rated product on a scale from "A" to "D," with A being the best quality and D the worst. If the quality of the raw material exceeded the acceptable range for those defects listed on the Field Grading Criteria, the procedure directed rejection of the load. When a product was received with a C or D grade, it was reevaluated and, if possible, mixed with a product of higher quality to produce a finished product of acceptable quality. Paicines Ranch spinach was received on August 14, 2006, at 70ºF, in a refrigerated truck, and was graded D for "water log" and "insect damage." Taix Ranch spinach was received on August 14, 2006 (4 different receipts), at 54 - 63ºF, in flatbed trucks, and was graded B for "long stem," "dry spots," and "half leaf." Taix Ranch is located within one mile of the processor, hence the use of unrefrigerated trucks. Eade Ranch spinach was received on August 14, 2006, at 58ºF, in a refrigerated truck, and was graded D for "insect damage," half leaf," and "water log." Wickstrom Ranch spinach was received on August 14, 2006 (three different receipts), at 58 – 65 ºF, in flatbed trucks, and was graded B for "insect damage," "dry spots," "discoloration," and "weeds." All spinach used in product code P227A was processed within one day of receipt.

The D graded receipts from the Paicines and Eade Ranches both appeared on the firm's Raw Product Disposition Report (Exhibit 36), which documented the condition of those products considered "Out of Specification" and the action taken: "use" or "dump." The Raw Product Disposition Report was produced by NSF to provide feedback to growers of the products. Only those products received with grades of C or D appear on the disposition report, in addition to products put on "hold." Paicines and Eade spinach were marked with the action, "use." Mr. Daniels said that the receipts from Paicines graded D, for water log, indicated that the spinach had a physiological condition in which the spinach leaves retained water. This condition, characterized by a "spongy" thick leaf, would have resulted in a product that was susceptible to mechanical damage. Mr. Daniels explained that water logged spinach was commonly seen when the weather was hot and it generally affected the entire load. This condition was not one of the defects listed on the Earthbound Farm Field Grading Criteria. Mr. Daniels informed investigators that water log was not on the field grading criteria list because a water logged load would be 100 percent afflicted and would receive a "D" grade by default. He said that they could have processed water logged spinach by mixing it with a higher grade of product or by running smaller quantities of the product through the process at one time.

Of 243 pallets of raw product used in processing during shift A, 108 were pallets (approximately 36,700 pounds) of baby spinach. The other pallets were a variety of products, including but not limited to red chard, arugula, green romaine, beets (leaves), and mizuna. Attachment 5, compiled by investigators, depicts quantities of baby spinach from the Paicines, Wickstrom, Taix, and Eade fields used in shift A and shift B. Attachment 6 depicts the depletion times (and quantities) of spinach from the four fields used during shift A and shift B, broken down by field. The timeframes of depletion in the chart were obtained from the Daily Depletion Logs. Timeframes were recorded at irregular intervals. Information for product code P227B was obtained by investigators through a traceback analysis of

processing records for that shift. While baby spinach from the four identified fields was used in shift A, only baby spinach from the Paicines and Eade Ranches was used in shift B, along with "teen" spinach from additional field sources. All P227 product positive samples were for shift A and Dole Baby Spinach was not produced during shift B.

On August 15, 2006, Dole brand Baby Spinach (six ounce retail bags) was produced only on packing lines 01, 02, and 03. A review of packing records revealed that lines 01 – 03 appeared to have been dedicated to producing Dole brand products during shift A, while lines 04 – 07 produced a variety of other brands (no Dole brands) during shift A. Refer to Exhibit 37 for the "Pack Out Monitoring Form: Safety," on which the type of product and production timeframes were hand-recorded for each of the seven packing lines. Refer to Attachment 7 to see those products produced over time on packing lines 01, 02, and 03 during shift A (this chart was created by investigators through analysis of processing records). Dole brand Baby Spinach was the first item produced during shift A on the three packing lines. Production of the spinach began at about 7:00 a.m. and continued for five to seven hours on the three lines. Packing for shift A ended between 4:00 p.m. and 5:00 p.m. (the seven packing lines varied in their stop times). Packing for shift B began between 5:00 p.m. and 6:00 p.m.

In addition to six ounce retail bags of Dole brand Baby Spinach, the raw baby spinach from the four implicated fields utilized during shift A on August 15, 2006, was incorporated into a number of other P227A spinach-containing products on the seven packing lines. Spinach from Paicines, as one of the four fields, may have gone into the products. These included five ounce retail Dole Spinach with Red Leaf (on packing lines 02 and 03), five ounce retail Dole Spinach with Radicchio (03), five ounce retail Dole Spring Mix (01, 02, 03), two pound food service RAVE Spinach (04), four pound food service Pride of San Juan spinach (04), three pound food service Pride of San Juan Spring Mix (04, 05, 06, 07) and six ounce retail Emerils Spinach (07), to name a few. Exhibit 1 is a list of all spinach containing products manufactured by NSF. Attachment 8 compares the depletion data for spinach from the four fields with the production data for packing lines 01 – 03 (which were producing only Dole brand products during shift A, all of which contained spinach). Lines 04 – 07 were not implicated by the 11 packages of P227A coded spinach that had PFGE patterns matched to the outbreak strain. The bags with PFGE patterns matching the outbreak strain ended with the following packing line (bagging machine) numbers: "01" on four packages, "02" on four packages, and "03" on three packages. The bagging machine number is unknown for one package. Refer to Exhibit 38 for Packout Output Report, which quantifies each item produced during the two shifts on August 15, 2006. There were 6,960 cases (six six-ounce bags per case), amounting to 15,660 pounds of retail Dole Baby Spinach (SKU: RBSDL66) produced during shift A on August 15 and none during shift B. A small amount of six-ounce Dole Baby Spinach with bilingual packaging (SKU: RBSDLB66) manufactured for Canadian distribution was also produced during shift A: 120 cases, amounting to 270 pounds.

Shipping of Dole Brand Products

Dole brand products produced by NSF were shipped to either the Dole distribution center in Marina, California, or to the Dole distribution center in Springfield, Ohio. All Dole brand Baby Spinach with product code P227A was shipped out from NSF to Marina and Springfield between 12:00 p.m. August 15, 2006, and 5:00 a.m. August 16, 2006 (Exhibit 39). CalFERT investigators obtained records documenting the distribution of products throughout the Dole distribution system to their final destinations. P227A Baby Spinach was shipped to locations

throughout the United States and also to Ontario, Canada. Baby spinach went through one to three Dole distribution centers and possibly one or more sub-distributors before reaching the customer. Dole distribution centers that received P227A Baby Spinach from Marina or Springfield (on the second or third leg of its journey through the Dole system) included those in Yuma, Arizona; Atlanta, Georgia; New York City (Bronx), New York; and Redding, California.

CalFERT Environmental Sampling: NSF

Environmental sampling was conducted at both NSF facilities prior to the point in the investigation when the focus narrowed to the South facility. Environmental swab samples were collected from the North facility in the raw material receiving area (n=1), the vacuum cooling tubes (n=4), and the tote and bin washing area (n=2). In the South facility, nine environmental swab samples were collected from locations throughout the processing area. Eight Dole brand finished product retention samples, Baby Spinach Organics (J242A25; J242A26), Baby Spinach and Radicchio (two samples of P242A03), Baby Spinach and Radicchio (two samples of P242B03), and Baby Spinach and Red Leaf (two samples of P242B01), were also collected. The retention samples were the oldest baby spinach-containing products available, processed August 30, 2006. No *E. coli* O157:H7 was detected in any of these samples.

Harvester Investigations

Each of the four implicated fields traced from P227A was harvested by a different firm. These firms all used mechanical harvesters. The harvesting machines varied in detail by model but all could be generally described as a modified tractor with a rotating cutting blade (bandsaw) set in front, followed by a series of conveyors. All four machines observed had booms in front of the cutting blade from which either chains or ropes dangled, designed to frighten away any animals that might be in front of the machine. The front unit could be raised and lowered by the driver so that during harvesting, it could be set just above the ground, but when maneuvering at the end of beds, it could be raised. The blade was maintained between a quarter-inch and 1.5 inches above the ground for harvesting, depending on the stem length of the crop. Each machine observed also had a set of spray nozzles that was mounted above a conveyor belt. Chlorinated water was sprayed from these nozzles onto the product. According to the individuals interviewed, the purpose of the spray was primarily to prevent the product from wilting. The chlorine levels of the water spray varied by harvester and are addressed in the harvester specific sections of this report. For three of the four harvesters observed, there was a gap between the first conveyor belt and the second. The spinach was "blown" across the gap by means of upward facing fans mounted between the two belts. According to firm representatives, this air gap served to remove heavier contaminants from the product. The conveyor belts also were designed to help remove smaller debris and undersized leaves. The machines observed all had a waste chute under the belt to remove the debris that fell through the links. Three of the four harvesters field packed product into totes (15-20 lbs) for NSF; the fourth field packed into bins (approximately 250 lbs). The totes and bins were made of plastic. NSF was responsible for cleaning and sanitizing the totes and bins (see NSF "Processing Facility" section for details). NSF conducted weekly Good Agricultural Practices (GAP) harvest audits on contracted harvest crews (Exhibit 40).

Pride of San Juan, Inc. (POSJ)

375 Sixth Street, Hollister, California 95034
Contact: Steven F. Wyrick – CEO; Gary T. Shingai – Harvesting Supervisor
Implicated Field Harvested: Taix Ranch

POSJ harvests spinach and other baby leaf product using mechanical harvesting machines. The model observed was manufactured by Ramsay Highlander Inc. Mr. Shingai said that POSJ owns [redacted] Ramsay Highlander machines. He said that they didn't know which of the two machines was used to harvest the Taix Ranch. The harvester observed had a boom in front of the bandsaw from which chains dangled. The POSJ machine did not have an air gap between the first conveyor belt and the link belt.

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POSJ Ramsay Highlander Harvest Machine

Mr. Shingai informed investigators that the chlorinated water sprayed onto product during harvest had a target level of [redacted] ppm total chlorine. POSJ did not keep records monitoring the chlorine content at the time of harvest.

Mr. Shingai stated that POSJ used a "spotter" crew while harvesting spinach. The spotter crew consisted of two employees, one on each side of the bed being harvested. The spotters walked in front of the harvester with garbage bins and picked out any foreign objects observed in the spinach beds. Mr. Shingai informed investigators that POSJ does not do any manual harvesting using knives or sickles.

Mr. Shingai told investigators that the harvesters were cleaned after each day of use at the POSJ yard but would not have been cleaned in between fields harvested on the same day. He said that the machines would be pressure washed, brushed with a foaming detergent, and then rinsed. The water used to pressure wash the machine was either from a well or from the

San Benito Water District ("Blue Valve" water), and was added to a nurse tank to which chlorine was added with a target level of [redacted] ppm total chlorine (Exhibit 41).

Mr. Shingai informed investigators that employees wore hairnets and gloves while working in the field. The gloves used were of the single-use disposable type. Employees were reportedly given a two hour GAP, sanitation, and SOP training on a yearly basis (Exhibit 42). Attendance at this training was documented on a sign-in sheet (Exhibit 43). Refresher sessions were given each week during the regular safety meeting and lasted from a half hour to one hour. These refresher sessions took place on Fridays when employees were picking up their checks. Attendance at these sessions was also documented on a sign-in sheet (Exhibit 44). Mr. Shingai said that employees would be excluded from working if they exhibited symptoms of gastro-intestinal (GI) illness as determined by the crew foreman. Mr. Shingai said that portable toilets were brought to the side of the fields for employee use during all harvests. He said that the toilets were serviced every other day. CalFERT investigators did not observe any portable toilets during this visit.

CalFERT Environmental Sampling: POSJ

On November 11, 2006, CalFERT investigators collected four environmental swab samples from various portions of one of the two harvesting machines described above. No *E. coli* O157:H7 was detected in any of these samples.

Seco Packing Company, LLC. (Seco)

510 Broadway Street, King City, California 93930
Contacts: Kevin A, Silacci – Harvesting Supervisor; Vanessa Delbosque – Human Resource and Safety Manager; Jesse Ramirez – Safety Coordinator
Implicated Field Harvested: Wickstrom Ranch

Seco was unique among the four firms visited in that their harvester machine packed into bins instead of totes (see NSF Processor Facility section for details of the distinction between bins and totes). The model observed was manufactured by Valley Fabrication (located in Salinas, California) and had tracks instead of tires. Mr. Silacci said that Seco owned [redacted] harvester machines used for conventional harvesting. The Wickstrom Ranch was harvested by machines numbered 01 and 14.

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Bins Containing Spinach Harvested By Seco Packing Company

According to Mr. Ramirez, the spraying array on the harvester machine had a target level of [redacted] ppm total chlorine. On November 1, 2006, investigators observed Seco during a harvest. The most recent log entry at the time investigators were in the field was 50 ppm total chlorine. Investigators checked the spray water and detected 50 ppm total chlorine and 20 ppm free chlorine at a pH of 6.5. Seco monitored the chlorine level of this spray on a daily basis during harvesting operations (Exhibit 45).

During the harvest, two employees walked in front of the harvester on either side of the bed being harvested. These spotters picked out any foreign objects observed in the spinach beds. Mr. Silacci informed investigators that Seco did not do any manual harvesting.

Mr. Silacci told investigators that the harvesters were cleaned after each day of use. He said that Seco had a concrete slab on the Brown Ranch near the Wickstrom Ranch where equipment located in that area was cleaned. The cleaning procedure for the harvesting machines included the machine being dry cleaned, then pressure washed, brushed with "Suds N Stuff" detergent, and rinsed. The water used to pressure wash the machine was from a well and was added to a nurse tank. Chlorine was added to the nurse tank with a target level of [redacted] ppm total chlorine. A log was kept of the cleaning (Exhibit 46).

Employees wore hairnets, gloves, sleeve guards, and aprons while working in the field. The gloves used were re-usable. Employees were required to remove their equipment when they left the field for any reason. Prior to returning to the field, they were required to dip their gloves in a hand dip containing sanitizer. The firms last log entry for the hand dip indicated

that it contained 190 ppm total chlorine. Investigators checked the chlorine levels during their visit on November 1, 2006, and found that the concentration was greater than the strips being used could detect (200 ppm total chlorine and 120 ppm free chlorine).

According to Mr. Ramirez, employees were given GAP, sanitation, and SOP training upon hiring. This training was part of a 45 minute new hire training. An additional 1.5 hour training session was provided to supervisors and above. Mr. Ramirez said that employees were given 10 – 20 minutes of additional training each month devoted to food safety issues including Seco's illness exclusion policy (Exhibit 47). Employees were trained to stay home if sick. Mr. Silacci reported that only harvest foremen and supervisors received sick leave. Mr. Ramirez said that if employees came to work with symptoms of GI illness, they would be sent home and a log would be kept. He claimed that this had not happened in the 2006 harvest and he attributed it to the training. Portable toilets on a trailer were parked on field access road for employee usage. Mr. Silacci said that the toilets were serviced every other day. CalFERT investigators did not observe any objectionable conditions with the portable toilets present on the day of their visit.

CalFERT Environmental Sampling: Seco Harvesting

On November 11, 2006, CalFERT investigators collected six environmental swab samples from various portions of harvesting machine number 14 at the end of a harvest. No *E. coli* O157:H7 was detected in any of these samples.

Mission Organics, LLC. (Mission Organics)

1140-A Abbott Street, Salinas, California 92902
Contacts: Otto Kramm – Partner; Austreberto Lopez – Harvest Supervisor; Jaime Ramirez – Harvest Foreman
Implicated Field Harvested: Paicines Ranch

Mission Organics uses harvester machines manufactured by Valley Fabrication. Mr. Kramm said that Mission Organics owns [redacted] harvester machines of various models. Mission Organics harvested into plastic totes.

According to Mr. Kramm, the spraying array on the harvester machine had a target level of [redacted] ppm free chlorine. The firm did not keep a log of the chlorine levels but had free chlorine test strips (Water Works Free Chlorine High strips, range 0-120 ppm). Investigators checked the spray water on October 25, 2006, and detected 40 ppm free chlorine at a pH of 6.0.

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Valley Fabrication Harvesting Machine Pictured With Empty Totes Prior to Harvesting and Packing

During the harvest two employees walked in front of the harvester on either side of the bed being harvested. These spotters picked out any foreign objects observed in the spinach beds. Mr. Kramm informed investigators that Mission Organics sometimes used sickles for manual harvesting but not on a daily basis. These sickles had a basket attached to catch the product. Mission Organics did not keep a record of sickle usage nor of the cleaning of the sickles. Mr. Kramm said that the sickles were used to harvest around a hazard or other problem in a field. He said that after use, the sickles were cleaned along with the harvester.

Mr. Kramm told investigators that the harvesters were cleaned at the yard after each day of use. They may have been used in multiple fields during a day, and if so, they would not have been cleaned between fields. The exception was if the machine moved from a conventional field to an organic field. The cleaning procedure for the harvesting machines started in the field where employees dry cleaned the machine and removed discarded product and debris. The machine was then moved to the yard area where they pressure washed the machine, then brushed it with detergent, and finally rinsed it. The water used to pressure wash the machine was from a well and was added to a 2000 gallon nurse tank. The water in the nurse tank was chlorinated. No logs were kept of the chlorine content of the water in the nurse tank but investigators checked the chlorine level and found ten ppm free chlorine.

According to Mr. Kramm, employees wore hairnets, gloves, sleeve guards, and aprons while working in the field. The gloves used were re-usable. Employees were required to remove their equipment when they left the field for any reason. Prior to returning to the field, employees were required to dip their gloves in a hand dip containing sanitizer. The firm did not keep a log of the chlorine concentration in the hand dip. Investigators checked the chlorine levels on October 25, 2006, and found that the concentration was greater than the test strips could detect (greater than 120 ppm free chlorine).

According to Mr. Kramm, the Mission Organics harvesting crew works year-round and travels to the areas where Mission Organics harvests. Mr. Kramm said that their retention rate for the baby leaf harvesting crew was close to 100 percent. Mr. Kramm said that the harvesting

employees received regular food safety updates from NSF auditors; he estimated at least monthly. Mr. Ramirez said employees were excluded from working if they displayed symptoms of GI illness but added that employees generally did not come to work if they had those types of symptoms. On October 25, 2006, when investigators observed a Mission Organics harvest, trailer mounted portable toilets were parked on the dirt road adjacent to the field for employee usage. Mr. Kramm said that the toilets were serviced twice a week. CalFERT investigators did not observe any objectionable conditions with the portable toilets present on the day of their visit.

Sebastian Harvesting, Inc. (Sebastian Harvesting)

Highway 101 North, Soledad, California 93960
Contacts: John Y. Bryce – Vice President of Operations; Carson Braga – Harvesting Manager; Laura Penera – Human Resource Manager
Implicated Field Harvested: Eade Ranch

Sebastian Harvesting uses several types of harvester machines. The model observed was manufactured by Ramsay Highlander Inc. and was the same type that would have been used to harvest the Eade Ranch. The harvester had tracks instead of tires. Mr. Bryce said that Sebastian owns [redacted] Ramsay Highlander machines and leased another for the 2006 harvest season. The machines were referred to by number. The machine used to harvest the implicated field was machine number two. Mr. Braga said that they harvested into totes and cardboard boxes. He said that the customer determined the type of container used and if a liner was to be used in the cardboard boxes.

According to Mr. Braga, the spraying array on the harvester machine had a target level of [redacted] ppm free chlorine. The most recent log entry at the time of our visit was 80 ppm free chlorine. Investigators checked the spray water and detected 40 ppm free chlorine at a pH of 7.0. Mr. Braga said that the firm did not monitor the chlorine level of this spray until after the outbreak.

During the harvest, two employees walked in front of the harvester on either side of the bed being harvested. These spotters picked out any foreign objects observed in the spinach beds. Mr. Braga informed investigators that harvest employees sometimes used sickles for manual harvesting but not on a daily basis. These sickles had a basket attached to catch the product. Sebastian Harvesting did not keep a record of sickle usage nor of the cleaning of the sickles. Mr. Braga said that after use, the sickles were cleaned along with the harvester.

Mr. Braga told investigators that the harvesters were cleaned after each day of use at the Braga Home Ranch. He said that the conventional fields they farmed were large enough that they would not switch fields in the middle of a day but that some of the organic fields were smaller and they might have moved from one organic field to another without cleaning the equipment. Mr. Braga said that after the outbreak occurred, Sebastian Harvesting created written procedures for the daily harvester wash (Exhibit 48). The cleaning procedure for the harvesting machines included the machine being dry cleaned, then pressure washed, brushed with detergent, then rinsed. The water used to pressure wash the machine was from the Braga Home Well No. 3. [redacted] ounces of Hasa Multi-Chlor was added to 1000 gallons of water in the nurse tank (theoretical yield = [redacted] ppm) with a target free chlorine level of [redacted]

ppm. Logs were kept of the harvester cleaning (Exhibit 49) but they did not include a test of the chlorine concentration.

According to Mr. Braga, employees wore hairnets, gloves, sleeve guards, and aprons while working in the field. The gloves used were re-usable. Employees were required to remove their equipment when they left the field for any reason. Prior to returning to the field, employees were required to dip their gloves in a hand dip containing sanitizer. The firm did not log the chlorine concentration in the hand dip prior to the outbreak. The last log entry for the hand dip on the day investigators observed a harvest (October 26, 2006) indicated that it contained 140 ppm free chlorine. Investigators checked the chlorine levels and found that the concentration was greater than the test strips could detect (greater than 120 ppm free chlorine).

According to Mr. Braga, employees were given approximately one hour of GAP, sanitation, and SOP training upon hiring and then during weekly 15 – 20 minute tailgate sessions, they were given additional food safety-related training. Mr. Braga said employees were excluded from working if they displayed symptoms of gastro-intestinal illness. On the day investigators observed a harvest, portable toilets on a trailer were parked on the dirt road that ran alongside the field for employee usage. The toilets were serviced three times per week according to the invoice from Safe Sanitation, Inc for services rendered in the month of August. (Exhibit 50). CalFERT investigators did not observe any objectionable conditions with the portable toilets present on the day of their visit.

Field Investigations

Early epidemiological information led CalFERT investigators to ten fields located on nine different ranches in California. The focus of investigations later narrowed to the four fields that supplied baby spinach for NSF product code P227A. One hundred eleven environmental samples were collected at the other six fields, all of which were negative for *E. coli* O157:H7. The remaining four fields under investigation were located on the Paicines, Wickstrom, Taix, and Eade Ranches. Extensive investigations and sampling were conducted at the four fields, which are located in Monterey and San Benito counties in California.

Independent environmental sampling was conducted in fields by IEH Laboratories and Consulting Group (IEH) for NSF and JL for Mission Ranches. IEH collected 368 samples of product, feces, and water, among other items at fields under investigation between September 22 and October 5, 2006. No *E. coli* O157:H7 was detected in these samples. JL, working as an expert consultant for Mr. Kirk Wagner, an attorney retained by Mission Ranches, attempted to duplicate samples collected by CalFERT investigators at the Wickstrom Ranch. Results of the JL tests at Wickstrom were provided to investigators; the samples were all negative for *E. coli* O157:H7. JL also conducted duplicate sampling at the Paicines Ranch. Mr. Brad Sullivan, an attorney retained by Mission Organics informed investigators that Earthbound Farms and Mission Ranches both own 42.5 percent stakes in Mission Organics. Mr. Sullivan explained that at the time investigators were collecting the field samples, Earthbound had retained JL to conduct the duplicate sampling at the Paicines Ranch. Mr. Sullivan said that he has not received a copy of those results. Investigators were unable to obtain copies of the results of the duplicate sampling.

Paicines Ranch: Lot 1

Mission Organics, LLC
1140-A Abbott Street
Salinas, California 93902

Paicines Ranch is located just west of Cienega Road at its intersection with Airline Highway, south of Hollister, in San Benito County. Otto Kramm, COO and Dan Soliman of Mission Organics, LLC, were interviewed during the investigation at the Paicines Ranch. The following individuals hosted investigators at the Paicines Ranch during one or more occasions, although they were not employees of Mission Organics: Kevin A. Silacci, Spinach Supervisor for Mission Ranches and John W. Eade Jr., QA Food Manager for Growers Express. Mr. Kramm stated he asked Mr. Silacci and Mr. Eade to host investigators at Paicines on a day when he was unavailable. Mission Organics, Mission Ranches, and Growers Express are separate entities; however, there is one common partner of the three firms and of NSF: Stan Pura. Mr. Kramm explained that Mission Ranches representatives were present for the investigation at Paicines because, like Mission Organics, they supplied spinach to NSF and were hosting CalFERT investigators at other fields. Growers Express had a previous business relationship with Mission Organics: the company had conducted food safety auditing for Mission Organics several years before, in a different location, for lettuce being harvested and sold to Growers Express. Mission Organics had no existing business relationship with Growers Express at the time of the investigation.

Gordon Brock, Vice President Business Development, and Lucio Premi, Research and Development, from JL were present at Paicines to replicate samples collected by investigators during field investigations. In addition, the following individuals associated with the nearby Paicines Grass-Fed Beef Ranch were interviewed: Chris Ketchum, Manager; Sallie Calhoun, Owner. Investigators made numerous visits to the Paicines Ranch, the Paicines Grass-fed Beef Ranch, and the surrounding areas for investigations between September 20 and November 29, 2006.

Mission Organics grew and harvested baby spinach on lot 1 (see Exhibit 56, the Paicines Ranch map, as well as the definition of lot in Glossary of Terms) of the Paicines Ranch. This lot was 50.9 acres in size and was one of four source fields that supplied spinach for processing into product code P227A. Lot 1 of the Paicines Ranch was subdivided into smaller portions, labeled A – U, planted with a variety of different crops (baby leaf, baby mustard, and baby spinach) on different dates (Exhibit 51). Well No. 1 is located in the center of the Paicines Ranch Lot 1 and was used as a reference point for the sub-division of the field. The sub-sections were sequentially denoted as A – I starting at the well, going south. Starting at the well and going north, the sub-sections were sequentially denoted as J – U (Attachment 9). All product grown on the Paicines Ranch was supplied solely to NSF. The baby spinach from the Paicines Ranch that supplied product code P227A was grown on segment A of lot 1. This segment was approximately 2.8 acres with a wet date of July 22, 2006, (a wet date is when seeds are first watered, usually within a couple of days of planting). It was harvested on August 14, 2006, (Lot 1 Harvest Record, Exhibit 52). The grower code for this spinach was "PA001A1".

Crops on the Paicines Ranch were grown in an organic fashion, but were sold as conventional products. Paicines Ranch was transitioning from conventional to organic, but

the land had not yet been cultivated using organic techniques for the three year period required to achieve organic certification. There were a variety of crops planted on lot 1 with staggered planting dates, all of which were harvested for NSF. Segments A, B, D, I, O, J, and U of lot 1 were planted entirely with spinach. Harvest dates ranged from August 14 to September 5, 2006. Segments C, E, H, K, N, Q, and R were planted with crops classified by the grower as baby mustard, including green chard, red chard, and mizuna. Each segment contained a combination of these crops; for example, segment E was planted with two beds of green chard, two beds of red chard, and two beds of mizuna. Harvest dates for the baby mustard ranged from August 10 to August 28, 2006. Segments F, G, L, M, P, and S were planted with crops classified by the grower as baby leaf, including lolla rosa, green oak, green romaine, red thunder, tango, and red leaf (red wood and red cloud). Harvest dates for baby leaf ranged from August 25 to September 11, 2006.

Lot 2 of Paicines Ranch, adjacent to lot 1, was planted by Mission Organics with the same assortment of crops as listed above, including spinach (Exhibits 53). Wet dates for spinach on lot 2 ranged from August 31, 2006 to September 11, 2006, but spinach was never harvested from this field, due to the onset of the outbreak. Baby mustard and baby leaf were harvested from lot 2 beginning September 9, 2006 and September 13, 2006, respectively. Harvests of these crops were halted by Mission Organics at the request of NSF following the harvest of each on September 25, 2006, due to ongoing federal and state investigations at the ranch, according to Mr. Kramm (Lot 2 Harvest Record, Exhibit 54).

Mr. Kramm explained that the acreage of crops planted on the Paicines Ranch was determined by the projected demand of the processor, NSF. Prior to planting, the processor projected the need for certain conventional products and allocated quotas of these products to Mission Organics. Mission Organics then planted the necessary acres on the Paicines Ranch to fulfill this demand. Lots 3 – 6 on the ranch were fallow during the 2006 growing season, as there was only demand enough from the processor to fill lots 1 and 2.

Spinach grown on the Paicines Ranch was irrigated with well water via sprinklers. Well test records dated July 31, 2006 showed total coliform at 2 MPN/100 ml in well number 1, an absence of total coliform in well number 2, and *E. coli* at less than 1 MPN/100 ml for both wells (Exhibit 55). Available records indicate that none of the three agricultural wells used for irrigation at Paicines Ranch were grouted. Paicines wells number 1 and number 2 are connected by plumbing and can be used to water any cultivated field on the ranch that is east of the river.

The cultivated fields on Paicines Ranch were near where the San Benito River flows through the ranch. Flow in the San Benito River in the area of Paicines Ranch was regulated by Hernandez Reservoir, which was approximately 40 miles south of the Ranch. Winter runoff was captured in the reservoir, then released in the dry season for percolation into streambeds to recharge groundwater. The Paicines area groundwater basin tended to fill up during the winter with percolation from the San Benito River (Attachment 11). As part of their routine monitoring program, the San Benito County Water District monitored groundwater levels in the area via well number 2 during 2006 (labeled by the San Benito County Water District as Observation Well for Water Level Changes number 5). Documented groundwater levels at Paicines Ranch were higher in elevation than the San Benito riverbed in March 2006. Because groundwater levels were higher than the riverbed at this time, water in the river would flow past the area rather than percolating into the ground. Over the course of the

growing season, groundwater levels tended to drop as water was pumped for irrigation. In July, the groundwater level dropped to the same level as the riverbed, and in subsequent months it fell below the riverbed level. This potentially allowed surface river water to percolate into the ground again and recharge the Paicines area groundwater basin during that period.

Heat treated, palletized chicken manure was applied to the field using a machine spreader during pre-plant on July 15, 2006. The pellets (called 8-1-1 fertilizer) were manufactured by True Organic Products, Inc., located in Helm, California. Please refer to the "Chicken Pellet Manufacturer: True Organic Products, Inc." section of this report for additional information.

CalFERT Investigators determined that Mission Organics did not contract for a third-party GAP audit on the Paicines Ranch in the time since Mission Organics took up the lease from the landowner, prior to the 2006 growing season.

The Paicines fields sit in a valley surrounded by hills. Lots 2 – 4 extend in sequence to the south of lot 1, while lot 5 sits adjacent to lot 2 on its west side. Lot 6 is separated from the rest, located southwest of lot 1, across the San Benito River at a higher elevation. Refer to Exhibit 56, a Paicines Ranch map of crop fields, obtained from Mission Organics. Grape vineyards stretch across the hills on the east side of the valley. The San Benito River runs northward through cattle grazing areas on the west side of the valley, approximately one-half mile from lot 1 at its closest point. The San Benito River is listed as being impaired by fecal coliforms and sediments/silt by the State of California, Central Coast Regional Water Quality Control Board (CCRWQCB), as designate for the U.S. Environmental Protection Agency (EPA) under provisions of the federal Clean Water Act. Cattle as well as wild animals have free access to this waterway both on the free range cattle ranch adjacent to the row crop growing region and at various points upstream. Pescadero Creek also runs through the cattle ranch, where it empties into the San Benito River. A diversion canal, used to divert water from the San Benito River into the Paicines Reservoir, runs parallel to and just east of Cienega Road on the opposite side from the crop fields. Seasonal and year-round creeks flow through the cattle pastures on the ranch. Mr. Kramm reported no flooding events during the year prior to the outbreak.

The Paicines Reservoir is located in a grazing area approximately one mile north of lot 1, at a higher elevation. The reservoir is owned by the San Benito Water District and is used to augment groundwater recharge during the dry season. Cattle drink from the reservoir, and according to Mr. Kramm, it was not used for irrigation. A smaller reservoir is located approximately one mile south of the field and adjacent to the San Benito River (slough area). According to Mr. Kramm, this water was not used for irrigation either; the reservoir functions to collect irrigation runoff from the fields, which is then piped into the San Benito River.

There were no composting or waste management facilities observed on or near the Paicines Ranch. Worker housing is located approximately 100 feet uphill and west of lot 1. Another worker housing area is about 50 feet to the east of Cienega Road. Both of the housing areas were on septic systems. No leakage of the septic systems was observed at the time of the investigation.

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San Benito River on the Paicines Ranch: Cattle Crossing

Approximately 2,000 head of cattle graze on the rangeland of the Paicines Ranch, the majority of which is west of lot 1. The rangeland covers 8,000 acres and consists of grassy pastures on the hills, along with patches of dense vegetation surrounding the San Benito River. Cattle and wildlife have access to the river at multiple points on the ranch. The cattle grazing areas closest to lot 1 include one directly across the paved road leading to the ranch office, just north of lot 1, and a second about 700 feet west of the field, on the other side of a hill below worker housing. No cattle have been present in the pasture just north of lot 1 since July 21, 2006. Cattle were observed grazing in the irrigated pasture 700 feet west of the field during investigations. Goats, sheep, and a young calf were brought into pens September 27, 2006, (new fencing was installed) across Cienega Road from lot 1. Livestock trucks do not travel on the dirt roads between lots, but they travel out of the ranch via the paved road from the ranch office that passes just north of lot 1. Dogs were seen in kennels near the worker houses. Investigators observed diverse wildlife in the cattle grazing areas on the ranch. Wild pig sightings and signs (tracks, fecal material, and rooting) were most commonly observed, followed by ground squirrels, deer, cottontail rabbits, coyotes, and raccoons. Small birds and raptors (owls, hawks, and eagles) were also frequently observed. Refer to Attachment 12, and addendum report from USDA Wildlife Services, which contains a detailed account of wildlife issues observed on the Paicines Ranch.

All cattle pastures on the ranch were enclosed by fences. Crop fields were partially surrounded by fences, along borders where they abutted cattle pasture or wildlife habitat. Field (mesh wire) fencing with barbed wire at the top and bottom extended along the western

border of the crop fields as a whole, separating them from the areas of dense vegetation where cows grazed along the San Benito River. Lot 1 was open to the paved road on its northern border, but the grazing area on the other side of the road had a barbed wire fence. The eastern and southern borders of the crop fields (lots 1 – 5) had no fencing. The vineyards to the east of the fields had no fencing around them. Many areas of the ranch had new fencing, but investigators observed that in some areas wildlife had penetrated the fences through holes created by washes from irrigation runoff or by digging under the fence (wild pigs, in particular).

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Field Fencing with Barbed Wire on Paicines Ranch

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Hole Under Field Fencing on Paicines Ranch, Apparently Repaired With Posts in the Ground

The grower reported animal sightings limited to small birds in the field while the spinach was growing in lot 1. During the investigation, there were no food crops growing in lot 1. The field had been tilled. No animal tracks were observed by investigators in the hardened dirt of the field; however wildlife tracks (primarily pig, but also some deer, raccoon, coyote, rodent, rabbit, and bird) were observed in the immediate vicinity of other crop fields on the ranch during visits in September and October. Fresh wild pig tracks were observed in recently prepared row crop beds south and west of lot 1. Wild pig tracks were also observed on the dirt road next to Paicines Ranch lot 5, where it bordered lot 3. The tracks went from the road into lot 5, which had vegetation (not crops) growing in it at the time. Wild pig fecal material and rooting were observed in a field belonging to a different grower, located approximately 1.7 miles south of lot 1, while decaying spinach plants were still present in the field. Coyote feces were seen on the dirt road between the crop fields and the river, near the small irrigation collection pond. Growers from both vineyards (southeast and northeast of the field) reported damage to their vineyards caused by pigs during thinning and harvesting in late summer and fall. Wild pig tracks observed on the roads and through prepared beds in lot 1 during visits in September indicated that the wild pigs could be crossing from the riparian areas to the vineyards on the far side of lot 1.

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Pig Tracks on Dirt Road, Heading Into Mission Organics Lot 5, Paicines Ranch

CalFERT Environmental Sampling: Paicines Ranch

Investigators collected 351 environmental samples in and around the Paicines Ranch, including cattle feces, wild pig feces, other animal feces, soil, and water. Of these, 45 (13 percent) samples were found positive for *E. coli* O157:H7 and 26 of these 45 (58 percent) matched the outbreak strain as determined by PFGE analysis (Attachment 10). Positive *E. coli* O157:H7 sample locations are mapped in Figure 1. Locations of positive samples that were PFGE matched to the outbreak strain are mapped in Figure 2.

Investigators sampled the San Benito River downstream of the Paicines Ranch and at a number of points upstream in the 40 mile stretch between the ranch and the Hernandez Reservoir. The reservoir was also sampled. Two samples of river water taken approximately 25 miles upstream were positive for *E. coli* O157:H7, but did not match the outbreak strain. The samples were taken in an area where grazing cattle and wildlife had access to the river, both above and below the sampling point. All other water samples from the San Benito River taken downstream and upstream of Paicines were negative for *E. coli* O157:H7. The CDC addendum report, "Irrigation Water Issues Potentially Related to 2006 *E. coli* O157:H7 in Spinach Outbreak," explores regional water issues in depth (Attachment 11).

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Figure 1: Paicines Ranch Positive *E. coli* O157:H7 Sample Locations

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Figure 2: Paicines Ranch Positive *E. coli* O157:H7 Samples PFGE Matched to the Outbreak Strain

Chicken Pellet Manufacturer: True Organic Products, Inc. (TOP)

20225 West Kamm Ave
Helm, California 93627

The following individual was interviewed during the investigation at TOP: Jake Evans, Owner. On February 20, 2007 a CalFERT investigator met with Mr. Evans at his facility in Helm, California.

Mission Organics purchased [redacted] tons of 8-1-1 chicken pellets in bulk bags (approximately one ton each) from TOP (Exhibit 57). Mission Organics was responsible for the spreading of the pellets on Paicines Ranch. The 8-1-1 chicken pellet blend spread on Paicines Ranch on July 15, 2006, was produced from feather meal and chicken manure that were both supplied by Foster Farm chicken ranches in the San Joaquin area. On July 6 – 7, 2006, the chicken pellets were shipped to the Paicines Ranch via a common carrier. Chicken manure was the only animal manure composted or stored at the 35 acre facility. Lot numbers were not assigned to finished products or shipments. Mr. Evans stated that he is able to track raw ingredients to shipment by date of incoming raw ingredients. Mr. Evans stated that he can trace shipment of finished product to raw ingredients using the shipping date. This is possible because there are usually only two shipments per year of raw manure.

Mr. Evans stated that his company did not have an organic composting certification, but did follow the composting requirements for the National Organic Program (NOP). Mr. Evans supplied composting temperature logs for chicken manure composted in January 2006 and incorporated into the 8-1-1 pellets sold to Mission Organics in July 2006 (Exhibit 58). An October 12, 2006, lab analysis showed a [redacted] carbon to nitrogen ratio (C:N) (Exhibit 59). The NOP standards for C:N ratio is between 25:1 and 40:1. True Organics composting operations were not monitored by an outside agency.

The chicken manure was composted on site by TOP. Chicken manure was the only animal manure composted or stored at the 35 acre facility. The composted chicken manure (containing chicken litter) and feather meal were combined in a mixer. This mixture was then pelletized and dried to produce the final product. The pelletizer heated the mixture to 180-200 ºF. The pellets were carried on a conveyor belt, transferred onto the dryer belt, and then entered the multi-level dryer chamber. Gas burners heated air which blew on the pellets for approximately 30 minutes. On February 20, 2007, the air temperature of the dryer chamber was [redacted]. Mr. Evans stated that the target temperature was [redacted]. Before being dumped into an outside concrete bunker, the pellets moved over a screen to remove partial pellets. Mr. Evans stated that the [redacted] heat process was the critical control point for a pathogen kill step. Finished product was sold in either bulk bags (bags weighed approximately 2,000 pounds) or in bulk trailers. Shipping was either arranged by the grower or TOP. TOP did not do any spreading or hauling of finished products.

One loader was designated for finished product only and was not used for raw ingredients, according to Mr. Evans. This loader was pressure washed with hot water each day. After washing, the loader bucket and arms were sprayed with 100 percent household bleach. The tires of the finished-product loader did not enter the bunker when removing product for shipment. Once a month the raw ingredient loaders were washed and sanitized as described above.

Prior to August 2006, Mr. Evans collected one sample a month from the finished product conveyor belt for microbial testing. Only one type of product was sampled during this time. The products were tested for *E. coli* and *Salmonella*. Test results for April, May, and June 2006 were < 3MPN for *E. coli* and negative for *Salmonella* (Exhibit 60). Beginning August 9, 2006, TOP began testing finished products for *E. coli* O157:H7 and testing more than one product per month. August 9, 2006, and August 28, 2006, tests for 8-1-1 finished products were negative for both *E. coli* O157:H7 and *Salmonella* and < 3 MPN for *E. coli* (Exhibit 61). A few handfuls of finished product were composited for each sample tested. The 8-1-1 blend used on the Paicines Ranch in July 2006 was not tested. TOP SOPs requires retesting of lots with positive pathogen sample results (Exhibit 62). During the audit of the firm's records, there were no positive pathogen test results observed by CalFERT investigators.

Wickstrom Ranch: Lot 817

Mission Ranches Company, LLC
100 Broadway Street
King City, California 93930

Wickstrom Ranch is located at the intersection of Carpenteria Road and Quarry Road, in the city of Aromas, California in San Benito County. The following individuals were interviewed during the investigation at Wickstrom Ranch: Kevin Silacci, Spinach Supervisor, Mission Ranches Company, LLC (Mission Ranches) and Seco Packing Company, LLC (harvesting arm of Mission Ranches); John Hitchcock, Ranch Supervisor, Watsonville, Mission Ranches (growing arm); John W. Eade Jr., QA and Food Manager, Growers Express (separate entity providing food safety training and audits); and Stan Pura, Partner, Mission Ranches and Growers Express. Gordon Brock, Vice President Business Development, and Lucio Premi, Research and Development, from JL were present at Wickstrom to replicate samples collected by investigators during field investigations. Investigators made five visits to the Wickstrom Ranch area for investigations between September 19 and October 3, 2006.

Spinach from lot 817 of Wickstrom Ranch was grown by Mission Ranches and harvested by Seco. Lot 817 was one of four source fields that supplied spinach used at NSF in product code P227A. Lot 817 is 7.5 acres in size, subdivided into A and B. The baby spinach supplied to P227A was grown on section A, with a wet date of July 24, 2006, harvested August 14, 2006, grower code [redacted] (Exhibit 63). According to grower records, this was the only crop of spinach harvested from lot 817 during the 2006 growing season. Seco also supplied baby spinach from [redacted] to another processor, Taylor Farms.

While on the field, the spinach was irrigated via sprinklers with well water from Brown Ranch, located about 1.5 miles from the field. Investigators observed that the casing on the well was damaged. Brown Ranch well tests (Exhibit 64), dated September 18, 2006, showed an absence of *E. coli* (*E. coli* < 1 MPN/100 ml). The grower did not regularly take environmental or product samples. Chemical fertilizer was used on the Wickstrom 817. According to Mr. Hitchcock, no manure or compost was used. The grower reported that there were no flooding events during the year prior to the outbreak.

An audit of the ranch, conducted by Primus in June 2006, gave the ranch a passing score (Exhibit 65). A review of the audit by CalFERT investigators revealed no significant findings.

Bordering the south side of Wickstrom Ranch is a railroad track built on a berm, which separates the ranch from Quarry Road. About 150 feet west of lot 817 is the Pajaro River, lined with foliage and tall trees. The bed of the Pajaro River was significantly lower (15 – 20 feet) than the field. Lot 817 is bordered to the northeast and southwest by additional growing areas on the Wickstrom Ranch. A dirt road separates lot 817 from the adjacent lot (816) to the southwest (Exhibit 66). At the time of the investigation, about half of a romaine crop was left unharvested in lot 816 due to quality problems, according to the grower. Some of the romaine appeared stunted or damaged with broken leaves. Immediately to the east of lot 817 are several buildings, including trailers and a tile factory, that are on septic systems. Investigation of these systems was not pursued after *E. coli* O157:H7 with matching PFGE patterns to the outbreak strain was found in samples from the Paicines Ranch based on an assessment of the probability of finding *E. coli* O157:H7 in low-usage human septic systems. There was evidence that the road between lots 817 and 816 was used by the public to gain access to the Pajaro River. Motorized vehicle tracks were seen at the river and an area with toilet paper was observed near a trail along the river. Investigators observed workers with shovels and bags cleaning in this area during one of the ranch visits. There was also evidence of apparent homeless camps along the river below the field. Two strawberry greenhouses were located approximately 400 feet north and at a higher elevation from lot 817. A pile of horse manure/shavings compost was observed near these greenhouses. It appeared to be trucked into the location and not formally "composted."

There was no crop in lot 817 at the time of the investigational visits. No fencing was present around lot 817. The grower reported animal sightings limited to small birds in and around the field. Investigators observed canine tracks, rodent burrows, and a jack rabbit adjacent to the field. Several cattle were seen grazing on a hill in a fenced pasture about 50 feet from the field on the opposite side of Quarry Road. A drainage pipe was identified under the railroad berm, which could potentially lead from the pasture to lot 817. On the other side of the Pajaro River, about one-third mile west of lot 817, were several trailer homes with dogs chained in the yard. There were also several houses in this area, one of which had an attached animal corral with goats inside.

CalFERT Environmental Sampling: Wickstrom Ranch

CalFERT investigators collected 44 environmental and product in and around Wickstrom Ranch, including water, Moore swabs (Pajaro River), soil/sediment, and romaine lettuce from an adjacent field. One (2 percent) Moore swab sample was positive for *E. coli* O157:H7. However, the PFGE pattern of the isolate did not match the outbreak strain (Attachment 10). The positive sample location is mapped in Figure 3.

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Figure 3: Wickstrom Ranch Positive *E. coli* O157:H7 Sample Location

Taix Ranch: Lot 1TA1

POSJ
375 Sixth Street
Hollister, California 95034

Taix Ranch is located on San Justo Road near Prescott Road, in the city of San Juan Bautista, California, in San Benito County. The following individuals were interviewed during the investigation at the Taix Ranch:

Stephen F. Wyrick, CEO, POSJ. (grower and harvester); Gary T. Shingai, Harvest Manager, POSJ; and Colleen Little, Safety Director, POSJ. Investigators made six visits to the Taix Ranch area for investigations between September 20 and October 4, 2006.

Spinach from lot 1TA1 of the Taix Ranch was grown and harvested by POSJ. Lot 1TA1 was one of four source fields that supplied baby spinach used by NSF for processing into product code P227A. The Taix Ranch lot 1TA1 is 27 acres in size. Baby spinach from the Taix Ranch that supplied product code P227A had a wet date of July 18, 2006, and was harvested on August 14, 2006, along with associated grower lot code [redacted] (Exhibit 67). The first spinach from 1TA1 supplied to NSF during the 2006 growing season was harvested August 11, 2006, (sent to the processor that day). The last harvest of spinach sent to NSF from 1TA1 for the season was the harvest on August 14, 2006. POSJ did not supply spinach from this harvest to any other processors.

Spinach grown on the Taix Ranch lot 1TA1 was irrigated with well and Blue Valve water via sprinklers. Colleen Little, POSJ's food safety manager, said a Primus GAP audit had been conducted of Taix Ranch on August 1, 2006 (Exhibit 68). Well test records, dated September 18, 2006, showed an absence of coliform and *E. coli* (Exhibit 29). Tests conducted by Primus of the spring mix in the field on September 21, 2006, were negative for *E. coli* O157:H7 (Exhibit 69). Chemical fertilizer was used. The grower reported that there were no flooding events during the year prior to the outbreak.

Taix Ranch is bordered by San Justo Road on the northeast side with farmland on the opposite side of that road (Exhibit 70). The ranches sit on farmland between the two NSF processing facilities. Taix Ranch is adjacent to the South facility. A reservoir sits just north of a neighboring ranch next to San Justo Road, within a quarter mile of Taix. San Juan Canyon Creek (also referred to by growers as the "canal"), which collects spent NSF processing water and drainage from the nearby hills, runs along the southwest side of Taix Ranch. The San Benito River flows past the Taix Ranch, approximately one-half mile northeast of lot 1TA1. Neighboring crop fields separate 1TA1 from the foliage surrounding the riverbed area. Steer/bull pens are located at Nyland Ranch, 130 San Juan Highway, San Juan Bautista, approximately one-half mile south of Taix Ranch. No composting or waste management facilities were observed near the ranch.

Baby greens (a generic term that includes such items as immature green and red lettuces, mustard greens, and kale) were observed growing in Field 1TA1 during investigations. These were voluntarily destroyed by the grower prior to harvest. No fencing existed around the field. Animal presence in and around the fields was limited to birds and squirrels, according to the grower. Investigators observed blackbirds and swallows in the fields.

Grazing cows were seen on the hills to the south, approximately one-half to one mile away on Nyland Ranch. San Juan Highway and San Juan Canyon Creek (Canal) separate Taix Ranch from the hills.

CalFERT Environmental Sampling: Taix Ranch

CalFERT investigators collected 133 environmental and product samples in and around Taix Ranch, including baby greens, cattle and bird feces, soil/sediment, Moore swabs, drag swabs, and water. Of these, four samples (3 percent) of soil adjacent to cattle feces at the Nyland Ranch were found positive for *E. coli* O157:H7. However, the PFGE patterns of the isolates did not match the outbreak strain (Attachment 10). Positive sample locations are mapped in Figure 4. Investigators sampled the San Justo and San Luis Reservoirs in San Benito County, which feed the Blue Valve water supply system. Samples were negative for *E. coli* O157:H7 at the time of investigation (Attachment 10). The addendum report, "Irrigation Water Issues Potentially Related to 2006 *E. coli* O157:H7 in Spinach Outbreak," elaborates on the reservoirs and the Blue Valve system (Attachment 11).

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Figure 4: Taix Ranch Positive E. coli O157:H7 Sample Locations

Eade Ranch: Lot 6

Braga Ranch, General Partnership
33750 Moranda Road
Soledad, California 93960

Eade Ranch is located south of San Lucas, California, approximately five miles east of Highway 101 on Cattlemen Road, near the intersection of Cattlemen and Pine Valley Roads in Monterey County. The following individuals were interviewed during the investigation at Eade Ranch: John Y. Bryce, Vice President of Operations, Braga Ranch (grower); Rod Braga, Managing Partner, Braga Ranch; Burt Silva, Ranch Manager, Braga Ranch; Carson Braga, Harvesting Manager, Sebastian Harvesting; Laura Penera, Human Resources Manager, Braga Ranch and Sebastian Harvesting (worker training, health); Raul Garnica, Director of Harvest, Earthbound Farm; Christopher Glynn, Supply Management Senior Manager, Earthbound Farm. Investigators made five visits to the Eade Ranch area for investigations from September 21 through October 4, 2006.

Spinach from lot 6 of the Eade Ranch was grown by the company, Braga Ranch, GP and harvested by Sebastian Harvesting, a related company to Braga Ranch. The Eade Ranch Lot 6 was one of the four source fields that supplied baby spinach used by NSF for processing into product code P227A. Lot 6 is 42.1 acres in its entirety and is subdivided into sections A through E, all of which were planted with spinach. The baby spinach supplied to P227A was grown on section C which was eight acres with a wet date of July 21, 2006 and was harvested on August 14, 2006 (Exhibit 71). The first spinach supplied to NSF from lot 6 during the 2006 growing season was harvested on May 30, 2006. Lot 6 supplied spinach to NSF throughout June of 2006. Additional spinach was planted and the next harvest supplied to NSF occurred on July 31, 2006. The last harvest supplied to the processor from lot 6 for the season occurred on August 14, 2006. Sebastian Harvesting also supplied half of the spinach from the Eade 6 section C harvest to another processor, Ready Pac of Irwindale, California. Spinach was irrigated via sprinklers with well water from Eade well number 2. Investigators observed that well number 2 was not grouted and lacked good drainage and a concrete slab. Test records for well number 1, dated April 20, 2006, showed an absence of *E. coli* (*E. coli* <1 MPN/100 ml), with total coliform = 1 MPN/100 ml (Exhibit 72). No results were provided for well number 2 on this date. Following the outbreak, tests dated September 20, 2006 report well number 2 negative (<1 MPN/100 ml) for both total coliform and *E. coli* (Exhibit 73). No environmental or product sampling was conducted, according to the farm manager.

Chemical fertilizer was used on the Eade lot 6. No manure/compost was used. The grower reported that there were no flooding events during the year prior to the outbreak. NSF did not provide oversight during the growing process, but inspected the field three to five days prior to harvest.

An audit of the ranch, conducted by Primus in April 2006, gave the ranch a passing score (Exhibit 74). That audit reported that the ranch used composted animal manure fertilizer. According to Mr. Bryce, Braga Ranch has not used compost on the Eade Ranch in the past ten years. Mr. Bryce said that the Primus auditor made a mistake on the audit and he is working with them to correct that mistake.

Adjacent fields to lot 6 (lots 5 and 7) were planted with onions (Exhibit 75). To the east, at a higher elevation, was a field of bell peppers. A catch pond below the bell pepper field retained irrigation run-off. A 300-400 foot wide buffer zone of bare ground separated the bell pepper field from cattle pastureland above it on the hills. Cattle graze in the hills during spring. In May, as the grass supply decreases after the rain stops, most of the cattle are moved to a feedlot located 1.6 miles south of lot 6 section C, which contained about 3,500 head of cattle between June and September. A small herd of goats, a few horses, and some dogs were also observed on the premises.

West of Eade lot 6 is a dirt farm road, followed by railroad tracks, Cattlemen Road, another farm field, and the Salinas River. The river is three-fourths to one mile west of the field, at a lower elevation than the field. Approximately one-fourth mile northeast of the field is a reservoir used for pre-planting irrigation and dust control on the farm roads. No composting or waste management operations were observed in the area. Investigators observed a pile of compost stored approximately two and one-half miles north of the subject field, which was gone a few days later.

Red leaf lettuce was observed growing in section C of Eade lot 6 during field investigations. The field was not fenced. The pastureland on the hills to the east was enclosed with barbed wire fencing. The farm manager reported seeing coyotes, ground squirrels, hawks, and small birds around the field areas. He stated they put out 100 warfarin bait stations for ground squirrels. Investigators observed tracks of raccoon, coyote, and birds on roads, near ponds, and in mud near a standpipe in the irrigation system. The area near the catch pond had a large number of ground squirrel burrows. On October 4, 2006, wild pig tracks were observed at the catch pond above (east side) lot 6C and at another pond on the property. Wild pig tracks were also observed in the sand by the Salinas River, west of the field. Pig scat collected near the river contained partially digested carrots. In early October, the farm manager reported they started having problems with feral pigs around lot 9, which was planted with carrots. Lot 9 is about 1-1.3 miles north of lot 6C.

CalFERT Environmental Sampling: Eade Ranch

CalFERT investigators collected 102 environmental and product samples in and around Eade Ranch, including red leaf product, cattle feces from the feedlot, wild pig feces (collected in the river), water, and sediment. Of these, nine samples (nine percent) of cattle feces from the feedlot and one sample (one percent) of water from a cattle water trough were positive for *E. coli* 0157. No matches to the outbreak PFGE pattern were identified in these samples (Attachment 10). Positive sample locations are mapped in Figure 5.

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Figure 5: Eade Ranch Positive E. coli O157:H7 Sample Locations

Third Party Laboratory Techniques Discussion

A number of the firms involved in this investigation made use of third party laboratories during the course of this investigation, either as part of their own food safety monitoring or in an attempt to duplicate CalFERT sampling. A variety of methodologies were used by these third party laboratories for detection of *E. coli* O157:H7. Presumptive testing by Primus involved enrichment of a sample for 20 hours and then testing for *E. coli* O157:H7 using the "RapidChek" test kit. Following presumptive positive test results, the confirmatory methodology used a commercially available latex agglutination test (E. coli Pro O157). JL, which is wholly owned by IEH, provided sampling and testing services for Mission Ranches. The samples were pre-enriched for eight hours and then each sample was tested using both a lateral flow test (manufactured by Neogen, AOAC approved for recovery of *E. coli* O157:H7 from foods) and multiplex Polymerase Chain Reaction (PCR) technique. Samples that showed a reaction for *E. coli* O157:H7 were purified using immunomagnetic bead separation. The resulting concentrated sample was tested by multiplex PCR using a different set of primers.

IEH provided sampling and testing services to NSF. IEH reported using the same technique but using a USDA Food Safety Inspection Service (FSIS) Bacteriological Analytical Manual (BAM) approved method to confirm positive results. There are many quick tests in the market place for analysis of *E. coli* O157:H7. However, tests vary in sensitivity and specificity, as well as the matrices for which they have been validated.

Summary of Observations

CalFERT investigators collected information, records, environmental samples, and product samples at the NSF processing facility, implicated harvesters, and implicated fields pertaining to this *E. coli* O157:H7 outbreak associated with Dole brand Baby Spinach.

NSF Processing Facility Investigation

Dole brand Baby Spinach, manufactured at NSF on August 15, 2006, with product codes beginning "P227A", traced back to four fields located in Monterey and San Benito counties in California. The fields were located on the Paicines, Wickstrom, Taix, and Eade Ranches. NSF operated two processing facilities, both located in San Juan Bautista, California at the time this investigation began. NSF initiated operation in the South facility on April 1, 2006. Information and documents obtained from NSF revealed the firm did not update nor review procedures (HACCP plan, SOPs, SSOPs) already in use at the North facility prior to initiation of production at the South facility. The firm intended for these procedures to apply to both facilities, but the procedures were not customized for South facility operations. Environmental samples that were collected by CalFERT investigators from the North NSF facility (n = 7) and from the South NSF facility (n = 9) were negative for *E. coli* O157:H7. Finished product retention samples (n = 8), manufactured at the South NSF facility on August 30, 2006, were also collected and found negative for *E. coli* O157:H7. During the production week from August 14 – 19, 2006, the NSF South facility had the highest weekly production volume of the month. Between August 13 – 20, 2006, production email exchanges revealed that the South facility underwent a string of personnel shortages, including nine absent employees on Sunday, August 13, the date of the weekly extended sanitation shift. Personnel records revealed that a number of employee absences were due to illness or

illness in the family. Investigators were unable to determine the nature of the illnesses. NSF did not conduct ATP testing on a daily basis as required by the firm's SOP. No ATP testing was conducted from August 15 – 25, 2006. One ATP test collected from a scale vibrator failed on August 10, 2006, and no retest was documented. While the firm maintained flume water within its specifications for pH, chlorine, and temperature for the entire period of time reviewed, the parameter recorded as turbidity and used to determine the frequency of water changes was actually a measure of water color as determined using a Hach Portable Colorimeter. Mr. Daniels maintained that they had found the measurement of water color to be an acceptable substitute for turbidity but no validation of this method was provided and the firm did not have a turbidity standard for calibration. NSF maintained logs recording the washing of the harvesting totes for the month of August, but NSF was only able to provide logs from August 1 – 14. NSF did not keep a record that documented the washing of harvesting bins.

Harvester Investigations

The four harvesters of spinach that supplied P227A product codes were investigated: POSJ.; Seco Packing Company, LLC; Mission Organics, LLC; and Sebastian Harvesting, Inc. During operations observed, the blade of the spinach harvester was maintained between a quarter-inch and 1.5 inches above the beds on which spinach is planted. The driver of the harvesting machine had to rely on the spotters who walked in front of the machine to remove debris or to signal to lift the blade. The harvesting machines were observed to be complex pieces of equipment that incorporated numerous moving food contact surfaces. Cleaning and sanitation of these machines was observed to be a detailed process and all of the harvesters conducted the cleaning and sanitation outdoors.

Field Investigations

Extensive investigations and sampling were conducted at the four fields that supplied product code P227A, located on the Paicines, Wickstrom, Taix, and Eade Ranches.

On the Paicines Ranch, crop fields were partially surrounded by fences. Lot 1 was irrigated with well water. The wells were not grouted. Lot 1 of Paicines sits in a valley surrounded by hills. The San Benito River flows through the Paicines Ranch, approximately one-half mile west of lot 1. In the Paicines Ranch area, documented groundwater levels were higher in elevation than the San Benito riverbed during March 2006; fell to the riverbed level in July 2006, and subsequently fell below the riverbed later in the growing season. This potentially allowed surface water from the river flowing into the Paicines Ranch valley to percolate into the ground again and recharge the Paicines area groundwater basin during that period. The wells used for irrigation on the Paicines Ranch drew from the groundwater basin there. The San Benito River is listed by CCRWQCB as being impaired by fecal coliforms and sediments/silt. Cattle and wild animals have free access to the river, both on the cattle grazing area adjacent to the row crop growing region and at various points upstream. Seasonal and year-round creeks flow through the cattle pastures on the ranch and potentially recharge ground water during certain times of the year. The Paicines Reservoir, located in a grazing area within one mile of lot 1, is used to augment groundwater recharge during the dry season.

Approximately 2,000 head of cattle graze on the Paicines Ranch in the hills and patches of dense vegetation along the San Benito River. Wild pigs and wild pig signs (tracks, fecal material, and rooting), were observed in the cattle grazing areas, in addition to deer, small mammals, and birds. In the hardened dirt of lot 1, no animal tracks were observed by investigators. However, wild pig tracks were observed in and around other lots on the Paicines ranch. Wild pig fecal material and rooting were seen in a field belonging to a different grower, located approximately 1.7 miles south of lot 1. Coyote feces were seen near the lots. Growers from two nearby vineyards reported damage to their vineyards caused by pigs during thinning and harvesting in late summer and fall.

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Pig Rooting and Tracks, in Field Belonging to Neighboring Grower to Mission Organics

CalFERT investigators collected 351 environmental samples on the Paicines Ranch, including cattle feces, wild pig feces, other animal feces, soil, and water. Of these, 45 samples (13 percent) were positive for *E. coli* O157:H7 and 26 (58 percent) of these 45 matched the outbreak strain as determined by PFGE analysis. PFGE pattern matches were found in cattle feces, wild pig feces, soil, and river water samples.

On the Wickstrom Ranch, no fencing was present around lot 817. Investigators observed that the well used for irrigation of lot 817 had a damaged casing. The Pajaro River flows past the ranch, approximately 150 feet west of the field, in a riverbed that is 15-20 feet lower in elevation than the field. Several cattle were seen grazing on a hill in a fenced pasture about 50 feet from the field. Beyond the Pajaro River, approximately one-third mile from the field, trailer homes with chained dogs and a house with corralled goats were observed. A pile of horse manure/shavings was observed 400 feet north and at a higher elevation than the field. Forty-four environmental and product samples were collected, including water, Moore swabs, soil/sediment, and romaine lettuce from an adjacent field. One (two percent) Moore swab sample from the Pajaro River was positive for *E. coli* O157:H7. However, the PFGE pattern of this sample did not match that of the outbreak strain.

On the Taix Ranch, no fencing existed around lot 1TA1. The crops grown there were irrigated using well and Blue Valve water. San Juan Canyon Creek runs along the southwest side of Taix Ranch, containing spent NSF processing water and drainage from the nearby hills. The San Benito River flows past the Taix Ranch, approximately one-half mile northeast of lot 1TA1. Steer/bull pens and cows grazing in hills were observed one-half to one mile south of lot 1TA1, on Nyland Ranch. CalFERT investigators collected 133 environmental and product samples in and around the Taix Ranch, including baby greens, cattle and bird feces, soil/sediment, Moore swabs, drag swabs, and water. Of these, four samples (three percent) of soil adjacent to cattle feces at the Nyland Ranch was found positive for *E. coli* O157:H7. However, the PFGE pattern of the isolate did not match the outbreak strain. Investigators sampled the San Justo and San Luis Reservoirs in San Benito County, which feed the Blue Valve water supply system. Samples were negative for *E. coli* O157:H7.

On the Eade Ranch, lot 6C was not fenced. Crops were irrigated with water from a well that was not grouted and lacked good drainage and a concrete slab. The Salinas River flows past Eade Ranch, approximately three-fourths to one mile west of the field, at a lower elevation than lot 6C. To the east of lot 6C, past a neighboring field at a higher elevation, was a 300 – 400 foot wide buffer zone of bare ground, followed by cattle pastureland on the hills. A feed lot was located 1.6 miles south of lot 6C, home to approximately 3,500 head of cattle between June and September. A small herd of goats, a few horses, and some dogs were also observed on the feedlot premises. Pig tracks were observed at the catch pond above the east side of lot 6C and at another pond on the property. Pig scat was collected near the Salinas River and contained partially digested carrots. The farm manager reported problems with feral pigs during October around lot 9, which was planted with carrots. Lot 9 is about 1-1.3 miles north of lot 6C. CalFERT investigators collected 102 environmental and product samples in and around the Eade Ranch, including red leaf product, cattle feces from the feedlot, wild pig feces (collected from the edge of the river), water, and sediment. Of these, nine samples (nine percent) of cattle feces from the feedlot were positive for *E. coli* O157:H7, and one sample (one percent) of water from a cattle water trough was positive for *E. coli* 0157. The PFGE patterns of these samples did not match that of the outbreak strain.

Glossary of Terms

Field: A "field" is a contiguous stretch of land used for growing crops, usually bordered by a dirt road or fence. It may be as small as a couple acres or as large as 50 or more acres. A field is usually separated from an adjacent field by a dirt road.

Grower: In this report, "grower" is used to refer to a business entity that leases or owns a particular "ranch" and cultivates crops on that land. The grower is responsible for all aspects of that cultivation, from preparing the land through harvesting. The grower usually contracts with separate business entities for services such as pesticide application or harvesting.

Harvester: In this report, "harvester" is used to refer to a business entity that is responsible for cutting spinach in the field and packing it into bins or totes. The harvester is usually a separate entity from the grower, but not always.

Lot: In this report, "lot" is used synonymously with "field." Growers number the different fields or lots on a ranch, calling them, for example: "Lot 1, Lot 2, Lot 3," etc. A lot may be

further delineated into sections "A, B, C," etc. by growers to distinguish areas in which different types of crops are planted or areas in which the same crop has been planted on different dates.

Moore Swab: A "Moore Swab" is a piece of sterilized cotton gauze with a string attached. Moore Swabs are left in flowing water for an extended period of time (usually 4 – 6 days) prior to collection and analysis. These swabs appear to "capture" *E. coli* O157:H7.

Ranch: A "ranch" is a delineated region of agricultural land with a specific name, usually owned by one entity. Investigators observed that a ranch may consist of land used to grow crops, or it may also include land used for domestic animal grazing or domestic animal operations. Growers generally lease land from a ranch owner to use for growing crops. Crops are tracked in growers' and harvesters' records by their growing locations, using ranch name and lot number.

Exhibits

Exhibit 1	NSF: List of Manufactured Products That May Contain Spinach
Exhibit 2	NSF: Organizational Charts; 3/23/06, 3/30/06
Exhibit 3	NSF South: Daily Room Temperature Check records, 8/1/06 - 8/31/06
Exhibit 4	NSF: SOP 106, Raw Material Inspection and Handling, Issued 10/23/06
Exhibit 5	NSF: Conventional Baby Spinach Raw Product Specifications, Issued 10/3/04
Exhibit 6	NSF North: Vacuum Cooling Tube Records, 8/1/06 - 8/31/06
Exhibit 7	NSF South: Pressure Cooling Tube Logs, 8/1/06 - 8/31/06
Exhibit 8	NSF South: Daily Depletion Log, 8/15/2006
Exhibit 9	NSF: Process Flow: Quality Assurance Reference (QAR) 002, Issued 3/30/06
Exhibit 10	NSF: SOP 112, Contaminated Product Procedure, Issued 9/28/06
Exhibit 11	NSF South: Water Systems Diagram
Exhibit 12	NSF South: Site Diagram, Equipment Area Layout
Exhibit 13	NSF: Hazard Analysis, Revised 2/20/06
Exhibit 14	NSF: HACCP Plan, Revised 3/14/06
Exhibit 15	NSF South: Wash Line Monitoring Records, 8/1/06 - 8/31/06
Exhibit 16	NSF South: Foreign Object Investigation Records, 4/29/06 - 9/12/06
Exhibit 17	NSF South: EB–South Master Sanitation Schedule San Juan Bautista, 5/7/06 - 9/10/06
Exhibit 18	NSF South: EB–South Daily Master Sanitation Schedule, 7/30/06 - 9/2/06
Exhibit 19	NSF: SOP 005, ATP Microbiological Testing, Issued 6/21/05
Exhibit 20	NSF South: ATP Testing Results, 7/15/06 - 8/31/06
Exhibit 21	NSF: Tote Washing Logs, 8/1/06 - 8/14/06
Exhibit 22	NSF South: SOP 011, Third Party Microbiological Testing, Issued 5/9/06
Exhibit 23	NSF South: Third Party Microbiological Testing Sample Rotation Schedule; Printed 10/4/06, 10/5/06
Exhibit 24	NSF South: Primus Labs Environmental Sample TPC Analysis Results; 8/7/06, 8/14/06, 8/21/06, 8/28/06, 9/7/06, 9/11/06
Exhibit 25	NSF South: Primus Labs Flume Water Sample TPC Analysis Results; 7/27/06, 8/19/06, 9/14/06

Exhibit 26	NSF South: Primus Labs Environmental Sample *Listeria* Analysis Results, 9/7/06
Exhibit 27	NSF South: Primus Labs Quarterly Raw and Finished Product Samples TPC Analysis Results, 7/27/06
Exhibit 28	NSF South: JL Analytical Services Post-outbreak Raw Product and Environmental Sample Analysis Results; 9/17/06, 9/19/06, 9/21/06, 9/25/06
Exhibit 29	NSF South: POSJ water system (no. 3500917) Monthly Report/ Bracewell Engineering Well Water Sample Analysis Results, Well #1, July - August, 2006
Exhibit 30	NSF South: Process Waste Water Volume, 6/1/06 - 10/1/06
Exhibit 31	NSF South: SJB2 (South Facility) Raw Receipts Log; 8/14/06, 8/15/06
Exhibit 32	NSF South: Traceback of Spinach in Product Code P227A03 to Fields
Exhibit 33	NSF South: Raw Product Receiving Log, 8/1/06 - 8/31/06
Exhibit 34	NSF South: Raw Product Receiving Log, Mission Ranches/Seco (Wickstrom Ranch), 8/14/06
Exhibit 35	NSF: QAR 126: Earthbound Farm Field Grading Criteria, Revised 9/29/05
Exhibit 36	NSF: Raw Product Disposition Report, 8/1/06 - 8/31/06
Exhibit 37	NSF South: Pack Out Monitoring Form: Safety, 8/1/06 - 8/31/06
Exhibit 38	NSF South: Packout Output Report, 8/1/06 - 8/31/06
Exhibit 39	NSF South: Product Distribution Records, All Products Manufactured 8/15/06
Exhibit 40	NSF: Harvest Audits, Good Agricultural Practices Summary, 7/10/06 - 8/26/06
Exhibit 41	Pride of San Juan Harvesting Nurse Tank Chlorine Level Log, 8/5/06 - 8/21/06
Exhibit 42	Pride of San Juan Yearly Safety Training Outline, 7/20/06
Exhibit 43	Pride of San Juan Yearly Safety Training Sign-in Sheet, 4/2006
Exhibit 44	Pride of San Juan Weekly Safety Refresher Training Sign-in Sheet, 6/7/06 - 8/25/06
Exhibit 45	Seco Packing Harvest Spray Water Chlorine Log, 7/15/06 - 9/4/06
Exhibit 46	Seco Packing Harvester Sanitation Log, 7/15/06 - 9/8/06
Exhibit 47	Seco Packing Safety Training Log, 5/12/06 - 9/18/06
Exhibit 48	Sebastian Harvesting Harvesting Machine Sanitation SOP, 10/2006
Exhibit 49	Sebastian Harvesting Harvesting Machine Sanitation Log, 8/8/06 - 8/20/06
Exhibit 50	Sebastian Harvesting Crew Toilet Maintenance Invoice, Serviced 8/2006
Exhibit 51	Mission Organics: Paicines Lot 1 Planting Records by Field Section, 7/22/06 - 8/14/06
Exhibit 52	Mission Organics: Paicines Lot 1 Harvest Record All Crops, Harvested 8/10/06 - 9/11/06
Exhibit 53	Mission Organics: Paicines Lot 2 Planting Records by Field Section, 8/15/06 - 9/11/06
Exhibit 54	Mission Organics: Paicines Lot 2 Harvest Record All Crops, Harvested 9/9/06 - 9/25/06
Exhibit 55	Mission Organics: Primus Labs Well Water Sample Analysis Results, Paicines Ranch Well #1 and #2, 7/31/06
Exhibit 56	Mission Organics: Paicines Ranch Map
Exhibit 57	True Organic: Chicken Pellet Invoices and Purchase Related Documents; 7/6/06, 7/7/06
Exhibit 58	True Organic: Chicken Pellet Production Temperature Logs, 1/3/06 - 1/26/06

Exhibit 59	True Organic: Manna Pro Corporation Chicken Manure Carbon/Nitrogen Lab Analysis, 10/12/2006
Exhibit 60	True Organic: Manna Pro Corporation *E. coli* and *Salmonella* Test Results; 4/10/06, 5/23/06, 6/28/06
Exhibit 61	True Organic: Manna Pro Corporation *E. coli* and *Salmonella* Test Results; 8/9/06, 8/28/06
Exhibit 62	True Organic: SOP Part 5.0 (Lab Analysis) and Part 6.0 (Lot Release and Recall), Revised 10/1/06
Exhibit 63	Seco Packing: Baby and Teenage Spinach Harvest Records, Multiple Ranches Including Wickstrom, 7/17/06 - 9/2/06
Exhibit 64	Driscoll Strawberry Associates, Inc. for Mission Ranches: Primus Labs Well Water Sample Analysis Results Brown Ranch; 4/19/06, 9/18/06
Exhibit 65	Mission Ranches: Wickstrom Ranch Primus GAP Audit, 6/7/06
Exhibit 66	Mission Ranches: Wickstrom Ranch Map
Exhibit 67	Pride of San Juan: Spinach Harvest Records, Multiple Ranches Including Taix, 7/17/06 - 9/1/06
Exhibit 68	Pride of San Juan: Taix Ranch Primus GAP Audit, 8/1/06
Exhibit 69	Pride of San Juan: Taix Product Tests by Primus, 9/21/06
Exhibit 70	Pride of San Juan: Taix Ranch Map
Exhibit 71	Sebastian Harvesting: Eade Ranch Spinach Harvest Records, 6/1/06 - 9/1/06
Exhibit 72	Braga Ranch: Monterey County Well Water Sample Analysis Results, Well Eade #1, 4/24/06
Exhibit 73	Braga Ranch: Monterey County Well Water Sample Analysis Results; Well Eade #1, #2, #3, #4, Reservoir; Tested 9/18/06
Exhibit 74	Braga Ranch: Eade Ranch Primus GAP Audit, 4/19/06
Exhibit 75	Eade Ranch Map

Attachments

Attachment 1	NSF South Facility Process Flow Diagram
Attachment 2	List of Wash Line Log Deviations (Translated)
Attachment 3	All Product Codes Obtained Off Packages From Case-Patient Households (CDC)
Attachment 4	Chart: Paicines Receipts
Attachment 5	Chart: P227 Quantities of Baby Spinach Used in Shift A and B
Attachment 6	Chart: P227 Spinach Depletion Times
Attachment 7	Chart: P227 Packing Line Production
Attachment 8	Chart: P227 Spinach Depletion Times Compared to P227 Packing Line Production
Attachment 9	Chart: Paicines Lot 1 Sections Layout, Products, Acres
Attachment 10	Environmental Samples From Farms and Watersheds
Attachment 11	CDC Addendum Report
Attachment 12	USDA Wildlife Services Addendum Report