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