CALIFORNIA FOOD AND DRUG BRANCH NARRATIVE REPORT

FANCY CUTT FARMS, INC
8420 Lovers Lane (Plant site)
Hollister, CA 95023
(408) 637-8047

P.O. Box 159 (Office)
661 River Road
Chular, CA 93925
(408) 455-0442 (Office)
[redacted] (Residence)

Inspection Dates:7/18/96, 7/19/96, 7/22/96, 7/29/96, 8/1/96, 8/5/96

Reporting Investigator: Tony Munoz, Badge #23

Purpose of Inspection/Investigation: This was assigned as a Food Safety Inspection and Follow-up Investigation on reports from CDC establishing subject firm as a possible manufacturing source of baby green salads suspected in E.coli 0157:H7 outbreaks via epidemiological evidence and tracebacks.

Firm Type: This firm is a medium size organic farming and organic food processing operation. The firm's organic farming operations are certified by QUALITY ASSURANCE INTERNATIONAL, San Diego, CA. (see Exhibit H). The firm is also under daily inspection for salad processing by the San Benito County Agricultural Commissioner's Office. (The daily inspection covers enforcement of the Agriculture Code, Title 3, "Head Lettuce to be Used Commercially for Salad Products", CCR Sections 1438.19 to 1438.45.)

The inspection established firm was engaged in growing spring mix greens (often referred to as "Field Salads" or "Mesclun" or "Baby Greens" or "Salad Greens"). These Field Salads or Mesclun involve a mixture or assortment of any of the following: Red Romaine Lettuce, Baby Spinach, Green Romaine Lettuce, Red Oak Lettuce, Radicchio, Mizuna, Red Leaf Lettuce, Lollo Rossa Lettuce, Arugula, Red Mustard, Green Masturd, Red Chard, Frisee, Tat Soi, ... etc.

The inspection further established that this firm was food processing (chopping the radicchio heads into small pieces on a cutting board) and mixing these processed food components with non-processed food components -- other washed baby greens (raw agricultural commodities) -- into bagged salads labeled organic.

The inspection identified this firm as a small food processing plant (a shed) in Hollister at 8420 Lovers Lane, with main office

in Chular at 661 River Road. The baby greens which this firm processes are grown at three ranches. Two ranches are located in Hollister: Ranch #1 located next to the processing shed totals approximately 26 acres; Ranch #2 located nearby off HWY 156 totals approximately 35 acres; and Ranch #3 located in El Centro, CA., totals approximately 137 acres. According to firm representatives, the firm leases each ranch and has an option to buy the ranch in El Centro. The property where the processing shed and ranch #1 are located is owned by the firm's neighbor -- at the same address -- Tony Bettencourt. The property for Ranch #2 is owned by Sharpe. The property for Ranch #3 in El Centro is owned by David Wyles.

Ownership/Officers:
This firm was incorporated in California in March 1996 (see Exhibit G).

The officers are:

Robert E. Chavez, Chief Executive Officer/President and Agent For Service
Maria Elena Regalado, Secretary
Maria Elena Regalado, Chief Financial Officer
Filimon Regalado, Director
Guillermo Regalado, Director

Inspection History:

7/18/96, 1030 hrs., Thursday

This was the first contact and inspection by the department at this subject firm. I was joined by **Mary B. Acton, USFDA Investigator,** and **Ray Ogi, USFDA Microbiologist.** During this initial inspection, Investigator Acton contacted Mr. **Robert Chavez, President,** by Cell Phone and informed him of reason and purpose of inspection. According to Investigator Acton, Mr. Chavez was located at his Chular office and had no objections to the inspection. Investigator Acton stated that Mr. Chavez could not meet us at the plant site due to planned trip to Las Vegas. **Ms. Maria Elena Regalado and Mr. Guillermo Regalado** were present at the inspection site (8420 Lovers Lane), though. Both of these individuals were also advised of purpose of inspection, provided with business cards, and proper badge identification. Maria stated she was one of the owners, the firm's secretary and treasurer. Guillermo stated he was a partner and supervisor. Both individuals were cooperative in allowing the inspection and in answering questions.

The inspection established that this firm was engaged in the farming and manufacturing of baby green salads labeled "Organic" for commercial distribution. The plant was a metallic and wood framed shed (approx. 36' x 40') with a rectangular shaped room enclosure used for food processing and refrigeration. The West

side of the shed consisted of an opened overhang roof with a stainless steel wash tank [redacted] located underneath. (see photos) The refrigerated compartment room was observed to be maintained at approx. 40 degrees F (via on-site thermometer). The processing room (adjacent to the refrigerated room and within the same rectangular enclosure) contained a roller conveyor dolly leading from the West door (near outside [redacted] wash tank) to two centrifuge and spin dry machines. The processing room also contained a cutting table with an adjacent water trough (see photos). There was a weigh scale and dolly conveyor system for plastic lined boxes (empties and full). There were approx. 2-4 employees working inside the shed.

Additional firm site information consisted of the following:

(a) A portable toilet was located outside adjacent to the shed on the North side. The portable toilet was labeled "Ajax" on the door (Ajax Portable Services, 1601 Lana Way, Hollister, CA 95023. 1-800-345-3353). Inside the toilet portable was a sink with a pump-type lever for washing hands. This water dispenser was not operating during this initial inspection date. (see photos)

(b) A well pump was located nearby the shed adjacent to a house and trailer dwelling. Employees at the site stated that they believed the well depth was 60 to 80 feet. A PVC pipe line originating at the well site fed water to the shed faucet and wash tank.

(c) A cattle corral containing three cows was located next to the well head (within 15 feet).

(d) Additional cattle corrals and cattle herd were also located nearby.

(e) There was farming acreage (approx. 27 acres) next to the shed where baby greens were being grown and harvested. Ditches containing standing water existed along the farm perimeter near the cattle corrals.

(f) A second farm well was located on the cattle grazing fields. This well was used for grazing field flooding and crop sprinkler irrigation. Water from this well was not used directly for washing salads at the shed. The water dispensing pipes used in grazing land irrigation were spaced out at approx. 40 foot intervals and located at ground level. Some had standing water on top of the dispensing orifices.

The following **processing steps** were observed:
1. The baby greens (Red Romaine, Green Romaine, Mizuna, Arugula,

Spinach, Red Oak, Red Parella, Lolla Rossa, Tango, Frisse, Totsoi, ... etc.) are harvested by hand (knife cuttings) in the field and carried or trucked to the shed in re-usable/re-cycled wax lined cardboard boxes or plastic totes. (It was noted that various wax lined cardboard boxes were being used for harvesting with the following brands: 3 FLAGS VEGETABLES, U.S. VEGETABLES FRESH, RADICCHIO ROYAL ROSE, HEGER DESERT VEGETABLES JOE HEGER FARMS, PRIDE OF SAN JUAN S. WYRICK FARMS, RIVER RANCH CALIFORNIA SWEET ANISE, G&A PRODUCE SALES, NATURE'S EDGE... too name a few.)

Note: The farming practices were not fully investigated. It was established that the normal planting to harvest cycle was approx. 30 days, and that plantings were planned by rows, so that planting and harvesting was continuous throughout the growing season. One employee stated that unprocessed chicken manure from a Gilroy poultry farm was used for fertilizer, but that NO cattle manure was used. One of the employees also mentioned that Chilean Nitrate "Bulldog" brand was also used as fertilizer.

Note: This Chilean Bulldog fertilizer comes in 50 lbs. sacks labeled, **"BULLDOG SODA CHAMPION SINCE 1831 Still Nothing Better 16-0-0, SODIUM NITRATE GUARANTEED ANALYSIS Total Nitrogen (N) ....16%, 16% NITRATE NITROGEN, SODIUM ....26%, NON-ACID FORMING PRODUCT OF CHILE, CHILEAN NITRATE CORPORATION, 150 Boush Street, Suite 701, Norfolk Virginia 23510, 1-800-368-9600".** The label also has the warning logo for a flammable OXIDIZER 5.1, CAS NO> 7631-99-4, UN-1498, IMCO CLASS 5.1 .

In addition, it was established firm would be operating all year. Ms. Regalado identified the two Fancy Cutt local farms, the one adjacent to the processing shed (Ranch #1), and a second ranch (Ranch #2) nearby off HWY 156, behind the Sugar Plum Restaurant. Ms. Regalado also stated there was a third ranch (Ranch #3) in El Centro, California, which totaled approx. 80+ acres. Ms. Regalado said baby greens would be grown in El Centro when the weather was too cold locally.

2. The loaded boxes and totes of individual baby greens were stacked at the shed, then dispensed into the [redacted] wash tank according to a "Salad Mix formula" based on the customer order(s).

Note: The water in the tank came from the well pump nearby and was not treated with chlorine or any other antimicrobial agent. The water in the tank was changed once per day. There was a convoluted recirculation PVC piping and filtration system on the tank. During the inspections the filtration system was not operating (see photos and discussion below).

3. The salad greens were stirred in the wash tank by bare hands (two male employees). (Later in the inspection, it was observed that employees began wearing plastic gloves for stirring, but the gloved hands would constantly dip below the glove line -- water level up to arm elbows.)

4. The washed salad greens were collected (fished out) of the wash tank in white colored plastic type laundry baskets and placed on the roller/dolly conveyor. These baskets would then be pushed and rolled by gravity into the enclosed processing room where they would be transferred into white plastic drums for spin drying in one-of-two possible centrifuge machines. The white plastic drums contained many holes for draining out excess water during the spin cycle [redacted]. (see photos)

5. The spin salad greens in the white plastic drums were poured into plastic bag lined boxes with the Fancy Cutt label. The most common unit size for shipping was 3 pounds.

Note: The firm also shipped these same salad mixes inside large cardboard boxes lined inside with Styrofoam (48 x 20 x 12 or 11520 cubic inches) labeled on the outside "CALIFORNIA FLOWERS". The number of individual "Salad Mix" bags within these bulk boxes was 16 bags for a total box weight of 60 pounds. According to employees, the practice by the firm was to write with a pen the product name on the outside, such as, "Salad Mix, Fancy Cutt Farms, Inc." (see box photo)

6. The radicchio heads (cabbage-like) were chopped into small pieces on the cutting table with a knife; the pieces were then washed in the adjacent trough and then fished out for spin drying before introduction into the salad mix requiring radicchio (plastic lined boxes on the conveyor). During the inspection, the chopped radicchio was placed back into the same harvest box before washed. Note: The typical salad mix formulation consisted [redacted] of any of the following individual baby green components: Red Oak, Tango, Lolla Rosa, Green Romaine, Red Romaine, Mizuna, Arugula, Tatsoi, Red Mustard, Spinach, Frisee, Radicchio, ... etc. Salad formulas were based on customer orders. The radicchio was normally the smallest ingredient.

7. The boxed salads were placed in temporary refrigerated storage on-site prior to shipment via refrigerated truck to the San Francisco Airport for A.M. Flight to various East Coast Accounts, such as, Sea Ice, New York City, and Merex, Yonkers, New York. According to Ms. Regalado, 5-6 shipments were made per week to several possible destinations, e.g., Los Angeles, San Francisco, New York, and/or Miami. It was reported that each shipment could

total as many as 1,000 cases (3 lbs each).

REPORT OF OBSERVATIONS/FDA 483

This initial inspection did result in the issuance of a Form 483 Report by FDA Investigator Acton. The 483 was signed and received by Ms. Maria Elena Regalado. Investigator Acton also collected 18 inline samples and finished product (Salad Mix). According to Investigator Acton, the samples were shipped to the FDA's Seattle Laboratory for testing.

I advised Ms. Regalado that I would be issuing a Report Of Observations with similar concerns noted in Investigator Acton's 483. In addition, I advised Ms. Regalado that her company was not registered by our department as an organic food processor. I advised that chopping the radicchio heads on a cutting board into small pieces, then washing and mixing with other salad components was considered food processing. I told her the report would be delivered the next day.

[Note: The Report Of Observations (RO) was delivered to Maria Elena Regalado and Mrs. Golinda Chavez at the corporate office in Chular on 7/22/96, see subject date discussion below.]

In response to the initial inspection, Ms. Regalado asked for guidelines in proper procedures for good sanitation practices and manufacturing. I advised her that I would have our office mail her a packet with an organic food processor registration application, labeling guidelines, and sanitation laws and regulations. I advised Ms. Regalado that the packet would include a copy of the CURRENT GOOD MANUFACTURING PRACTICE IN MANUFACTURING, PACKING, OR HOLDING HUMAN FOOD regulations.

7/19/96, 0940 hrs., Friday

During this inspection I was joined by **Jeff Farrar, DVM, MPH, CA-DHS-FDB Scientist.** Dr. Farrar assisted in the collection of samples. Several inline and finished product samples were collected (see attached EVIDENCE/SAMPLE RECEIPTS and sample descriptions for sample #'s 023071996A, B, C, D, E, F, and G). During this inspection, Ms. **Rosa Regalado, Processing Supervisor,** signed the sample receipt and was present during the inspection. Also interviewed at firm on this date were Mr. **Guillermo Regalado,** who claimed he was part-owner of the business.

Dr. Farrar was assigned to transport the samples to the CA-DHS-Microbial Diseases Laboratory, attn: **Ray Bryant.**

Rosa was cooperative in answering questions. Important information was provided by Rosa regarding the firm history, filtration system on the [redacted] wash tank, and the well pump. Rosa stated the

following:

(a) Rosa stated the same basic salad processing operation at the same site was under different ownership prior to March 1996. She identified her previous employer and firm name as "Gourmet Veg Pack", owned and operated by a "Santos Martinez". According to Rosa, Santos Martinez moved his operation to a place on HWY 129, Aromas, CA. She said she did not know the exact new address for Gourmet Veg Pack.

(b) Rosa stated she suspected the well water had been tested by Primus Lab, Salinas, during Gourmet Veg Pack's occupation of the facility, but did know who kept the records. (Note: Primus Lab is Not State Certified to do Title 22 Water Testing.)

(c) Rosa stated the filtration system on the [redacted] wash tank was not working (filtration pump shut down) from 6/1/96 to the present, 7/19/96. Rosa said she did not understand what part was broken. Rosa stated that the filtration system was in operation between 5/10/96 to 5/30/96. Rosa further stated that the 20 foot tank did not exist at Fancy Cutt prior to 5/10/96, that prior to this date the salads were washed in the troughs. Rosa said she believed the [redacted] tank was purchased in late April or early May from an "Andres ?". Rosa did not know Andres or his whereabouts.

Note: Two (2) of the 7" x 30" filters from the tank filtration system were collected as samples (I.S.#023071996A). These filters had a strong odor -- similar to sewage.

During this inspection I called Ms. Maria Elena Regalado via [redacted] and established an appointment in her office in Chular for 7/22/96, to deliver and go over alleged violations noted in Report Of Observations during the initial inspection.

7/22/96, 1230 hrs., Monday (by APPOINTMENT)

On this date I arrived at firm's office address: 661 River Road, Chular, CA., and met with **Mrs. Golinda Chavez** and **Ms. Maria Elena Regalado.** Mrs. Chavez stated that she was the Secretary for the corporation and the wife of Mr. Robert Chavez, President. The sign on the entrance door at this address read "Emerald Produce, Inc.". (A labor contracting firm owned by Mrs. Golinda Chavez.)

I provided Mrs. Chavez and Ms. Regalado a copy of the Report Of Observations (see attached). Both read the report and indicated they understood the alleged violations. Ms. Regalado signed the RO. Both Mrs. Chavez and Ms. Regalado expressed interest in making all the necessary corrections and in getting their company registered (food processor registration and organic food processor registration). I advised that Erlinda in our San Francisco FDB

Office would mail a packet within one week, that the packet would contain the necessary forms, laws and regulations.

The following **alleged violations** were noted on R.O. and discussed this date:

1. The firm was engaged in manufacturing a food product (Fancy Salad Mix and Chopped Radicchio) without a valid registration with the department. H&SC, Div. 104, Part 5, Article 2, Section 110460.

2. The firm was engaged in the manufacturing of a processed food product labeled as "organic" without first registering with the department. H&SC, Div. 104, Part 5, Article 7, Section 110875.

FOOD GMP DEFICIENCIES

3. The firm lacked valid procedures for how often and when to replace the tank and tub (trough) wash water used for cleaning salad greens and chopped radicchio. The response from one employee was that the water was replaced depending on the daily volume of product, possibly change between 1-3 times daily. The sanitary quality of this process water was unknown. There was no chlorination of the process water to kill bacteria and the source well pump was located near a corral with cattle.

4. The firm's food contact surfaces within the round white plastic baskets (laundry type baskets) were not handled correctly to preclude the potential for cross-contamination in the salad greens from the cement floor water and shoe debris. These baskets were observed stacked (nested) on the cement floor before they were used in conveying washed salad greens from the wash tank to the centrifuge.

5. The firm's practice of placing the cardboard boxes and grey plastic totes inside the process room after they had been used for field harvesting the greens could create the potential for cross-contamination of the salads with bacteria. For example, it was observed that after removing the radicchio from its harvest box for chopping, the chopped radicchio would be returned back into the same box before washing.

6. The firm's single portable toilet station (labeled Ajax 1-800-345-3353) located outside and adjacent to the shed contained one hand washing faucet and sink that was not working -- it did not dispense water.

7. The grounds around the immediate vicinity of the processing plant were not maintained clean. There were numerous growing weeds, litter, and piles of misc. equipment that may constitute an attractant, breeding place, or harborage for pests.

8. The firm's wash tank used for salad greens was not located in an enclosed building to protect from potential pests and/or airborne contamination from the dirt road and cattle located nearby. The tank was located in an open shed. Live birds and a bird nest were observed inside the shed ceiling rafters.

9. The firm's enclosed food processing room located under the shed had two sliding doors without screens to preclude the potential entrance of pests. These same doors were observed to be opened during food processing.

10. The firm's cooler fan fixture located directly over the area where salad greens are centrifuged was observed dripping water (condensate).

11. The glass florescent light tube located on the shed ceiling and directly over the salad greens wash tank was not equipped with a shield to protect against food contamination in case of glass breakage.

12. The firm plant management did not take all reasonable measures and precautions to ensure the correct practices in the following:

(a) The firm did not provide hand-washing facilities for employees to wash thoroughly and/or sanitize before starting work, after each absence from the work station, and at any time when the hands may have become soiled or contaminated. Two employees were observed handling muddy lettuce totes and cardboard boxes, then proceed to handle and hand-arm mix lettuce greens in the wash tank. This practice was observed with and without the use of rubber gloves. There was no glove sanitizing agent available.

(b) One employee did not remove a wristwatch while mixing salad greens in the water wash tank using both his hands and arms.

(c) The firm's personnel assigned responsibility for identifying sanitation failures or food contamination lacked a background of education or experience, or a combination thereof, to provide a level of competency necessary for the production of clean and safe food.
[Two owners interviewed (Maria Elena Regalado and son, Guillermo Regalado) requested guidelines for proper sanitary practices in food processing.]

21 CFR Part 110--CURRENT GOOD MANUFACTURING PRACTICE IN MANUFACTURING, PACKING, OR HOLDING HUMAN FOOD

In addition to the above R.O. items discussion, both Mrs. Chavez

and Ms. Regalado stated that no employees had reported any illness.

Mrs. Chavez informed me the cattle located in the corrals near the processing plant in Hollister were owned by the property owner, a Tony Bettencourt, who lived in the house next to the well pump. I asked Mrs. Chavez to produce a record of distributions for their salads during May and June 1996 for shipments to the Merex and Sea Ice Corporations. (These firms had been previously identified as possible distribution links to the E.coli 0157:H7 outbreaks in tracebacks by CDC's Betsy Hilborn, Hartford, Connecticut.) Mrs. Chavez was cooperative in providing a computer printout.

Note: This printout was initialed by me at the lower left corner at time of receiving and loaned out later the same day to FDA Investigator Acton. The same printout was not returned, but replaced by one collected by Investigator Acton (collected on 7/23/96, see **Exhibit A**).

I advised both Mrs. Chavez and Ms. Regalado that the investigation was ongoing and also involved other firms. I advised that our department would be sending representatives to their Hollister plant site later the same day.

7/22/96, 1500 hrs., Monday

I returned to the Fancy Cutt Farms plant site (Hollister) and met with the following: Stuart Richardson, CA-DHS-FDB Chief; Jim Waddell, CA-DHS-FDB Food Chief; Kevin Riley, CA-DHS, Dr. Jeff Farrar, CA-DHS-FDB Scientist; Mary Acton, FDA Investigator; Ray Ogi, FDA Microbiologist; Dr. Betsy Hilborn, CDC Medical Epidemiologist, Hartford, CT; Dr. Jonathan Mermin, CDC Medical Epidemiologist, Atlanta, GA; Bob Shingai, San Benito County Health Department; Mark Tognazzini, San Benito County Agricultural Commissioner; Dr. Peter Kurtz, CA-DFA; and Dr. Duc Vugia, CA-DHS Chief of Disease Investigations & Surveillance Branch. These individuals were concerned about the E. coli 0157:H7 investigation and were present at this firm site for a brief introduction (less than 1 hour).

CA-FDB Chief, Stuart Richardson, met with Mr. **Robert Chavez, President**, and explained the purpose of the visit and progress of investigation. Chief Richardson assured Mr. Chavez other firms were also under investigation. Mr. Chavez was upset; he used foul language to express his feelings about the investigation at his company, but was cooperative in allowing the inspection. During this inspection Mr. Chavez pointed out that the well used for process water source was 120 feet in depth. Mr. Chavez also pointed out that Ranch #2 off HWY 156, and located behind the Sugar Plum Restaurant, was 25 acres. Mr. Chavez was cooperative in showing his operation.

I left the processing plant site to visit Ranch #2. I established that baby greens were being grown at Ranch #2. Approximately ten (10) male employees harvested the baby greens. There was one portable toilet. I was told by Mr. **Guillermo Regalado** that there was no traceability to ranch from shipping invoices; i.e., salads shipped could not be traced to ranch 1 or ranch 2. Commercial salads were a combination of greens grown at both ranches in Hollister. The exception being those grown during the winter months when the farm in El Centro (ranch 3) was in operation.

7/29/96, 1150 hrs., Monday

This inspection was scheduled to collect additional samples for both E. coli 0157:H7 and E. coli MPN values via the COLILERT Test Method. I contacted **Maria Elena Regalado by phone** from the plant site and received permission from her to continue with the inspection and the collection of additional samples. I advised Ms. Regalado that one of our investigators would be interviewing the cattle owner. Ms. Regalado advised that Mr. Tony Bettencourt was ill with cancer and had speech impairment due to a tracheotomy.

The fact that cattle were located in close proximity to the lettuce farming and salad packing operations were a concern, since it was known that infected cattle can be carriers of E. coli 0157:H7 bacteria. **CDC's Dr. Betsy Hilborn and CA-FDB Investigator Wayland Ho** assisted in this inspection. Dr. Hilborn interviewed the cattle owner, **Tony Bettencourt**. (I was not present during Dr. Hilborn's interview with Mr. Bettencourt.)

Both Investigator Ho and Dr. Hilborn assisted with the collection of samples (see attached list in **EVIDENCE/SAMPLE RECEIPTS** for samples collect on this date). A total of 21 samples were collected. The Sample Receipts were signed by one of the salad process employees, **Mr. Jesus Calderon**, who was present during the inspection. These samples included: process waters; swabs of cutting boards and knifes; well water at various points; wash water from various points in the [redacted] tank recirculation PVC pipe system; wash water from the radicchio wash trough; water from cattle drinking trough; water from puddle in cattle grazing field; and water from puddle over flood outlet/orifice in grazing field.

I took **photographs** during this inspection (see attached). It was established that firm had made corrections to some alleged violations listed in Report Of Observations issued on 7/22/96. These corrections included:

(a) The hand washing sink in the blue colored portable toilet was now operating. Also, there was an additional green colored portable toilet at the site, so both males and females did not have to use the same portable (see photo).

(b) The weeds and rubbish surrounding the plant had been removed (cleaned up). Note: One live white rabbit was observed near the plant site (see photo).

(c) Several paper signs were placed on the walls inside the processing plant in both Spanish and English advising employees to wash hands after using toilet, to not place inprocess baskets on the floor, to throw away lettuce that dropped on the floor, to wash baskets before using them for lettuce, and for employees not to wear jewelry while on duty. (see photos).

(d) The firm also added a blue tarpaulin sheet to a portion of the West side of the shed to help in blocking off field and road dust from getting into the wash tank (see photo). (The roads next to the plant shed and cattle corrals were dusty.)

During this inspection, a processing step not previously noted was observed. It was established that sometimes a wire screen was used to filter out small leaf lettuce pieces (see photo) before washing. The small leaf pieces that shake out the bottom and dropped on the floor were thrown away. According to Mr. Calderon, some customers did not want small leaf lettuce pieces in their salad orders.

On this same date, we (myself, Dr. Hilborn, Investigator Ho) investigated the other ranch site in Hollister (Ranch #2). **Photos** were taken of the well head. We observed a pocket in the well piping with water and green algae (see photo). Two well water samples were collected (see attached **EVIDENCE SAMPLE RECEIPT for I.S.#'s 047072996P1 and P2**). At this farm, we observed that red lettuce, green lettuce, spinach, and radicchio were being harvested. Mr. **Guillermo Regalado** was cooperative in identifying the well site, showing the farm and allowing the sample collection.

8/1/96, 1230 hrs., Thursday

This was an inspection at the Hollister processing plant site. It was necessary to deliver copies of EVIDENCE/SAMPLE RECEIPTS. Mr. **Jose Calderon** received the copies. I advised Mr. Calderon that some previous samples collected from the wash tank (**B2, B3, and G**) had been positive for the generic E.coli. He did not seem to understand the significance of the E.coli findings, so I advised I would try to notify Mr. Robert Chavez about the laboratory findings.

Later the same day I called the Fancy Cutt Farms office and talked to Mrs. **Golinda Chavez** via [redacted] at approx. 1430 hrs. I advised Mrs. Chavez of the following preliminary sample results reported by the laboratory via telephone:

(1) Sample #047072996B2, Wash Tank Water from Recirculating PVC

pipe, was reported at 129.6 E.coli MPN.
(2) Sample #047072996B3, Wash Tank Water from Recirculating PVC pipe, was reported at 816.4 E.coli MPN.
(3) Sample #047072996G, Well Water taken from spigot after repressurization tank at the well head site, was reported at 51.2 E.coli MPN.

I advised Mrs. Chavez the sample results indicated a definite high level of E.coli, the fecal indicator bacteria, in the wash water reservoir and the possible contamination of well water with fecal bacteria. I also told Mrs. Chavez that additional samples would be taken.

Mrs. Chavez stated via telephone conversation that her company had already taken some corrective measures and reported the following:

(1) Mrs. Chavez stated the firm now changed the water in the wash tank on every batch. (The batch definition was not discussed.)
(2) The firm now disinfected the tank and pipes with a chlorine bleach wash on a daily basis. Mrs. Chavez explained that each chlorine wash was followed by a rinse to remove residuals from the equipment before filling the reservoir tank with wash water and lettuce.
(3) Mrs. Chavez stated that her company was considering a testing program for their product.
(4) Mrs. Chavez stated that all the weeds and debris surrounding the plant in Hollister had been cleaned.
(5) Mrs. Chavez stated that a written response to the R.O. was available.
(6) Mrs. Chavez also stated that her company was considering the possible removal of all the pipes (recirculation filtration system) from the [redacted] wash tank.

I advised Mrs. Chavez that I would be doing a reinspection soon to collect additional samples at the well site and verify corrections.

8/5/96, 1145 hrs., Monday (by APPOINTMENT)

During this inspection I was joined by Wayland Ho, F&D Investigator, and Warren Crawford, FDB Northern California Administrator. This inspection focussed on the well head source water and process water salad washing operation. Mrs. **Golinda Chavez** and Ms. **Maria Elena Regalado** were present and cooperative during this inspection. **Photographs** of the well were taken (see attached).

The inspection established that someone (firm employees) had removed all the weeds, ivy and brush surrounding the well head, making it easier to view the pipes. (see photos)

Samples were collected from the well head and process system (see attached **EVIDENCE/SAMPLE RECEIPT**). Mrs. Golinda Chavez signed and received copies of the sample receipts. Water samples were collected at various points in system. Baby Greens were sampled pre and post washing, as were finished salad samples for 8/4/96 and 8/5/96 pack dates. The "8/5/96" salad mix sample represented produce we observed being washed and packed the same day.

During this inspection Mrs. Golinda Chavez provided a written response to the R.O. issued on 7/22/96 (see Exhibit B). Mrs. Chavez wanted to know if our department had inspected all the other salad packers in the area, and she pointed to an unenclosed shed nearby (see report for Specialty Produce). I advised that our department was in the process of investigating and inspecting other salad packers.

11/19/96, 1000 hrs, Tuesday (firm's office by appointment)
I interviewed Mrs. Golinda Chavez and Mr. Guillermo Regalado. I visited the firm's office to request copies of written procedures for the cleaning and disinfecting of equipment currently used, plus copies of labels for the disinfecting and cleaning chemicals used. I also asked if Well records were available and if firm had performed any testing on the water. Mrs. Chavez stated that she would write the procedures and mail to my attention, plus try to establish if any Well records were available and mail those also.

I recommended that firm perform Title 22 testing on the Well water by a State Certified Laboratory. Mrs. Chavez said that she would try to locate a lab to do the testing, and would mail the result.

I asked Mrs. Chavez and Mr. Regalado about the previous owner of the [redacted] wash tank. Mr. Regalado stated that it was purchased from Happy Boys (another salad packer), Old Chitten Road, Watsonville. Mr. Regalado stated that he did not know the exact date, but that it might have been late April or early May 1996. Mr. Regalado also verified that Rosa Regalado's earlier statement (see discussion above) might be correct (i.e., the wash tank and filtration system were in operation between 5/10/96 to 5/30/96).

Both Mrs. Chavez and Mr. Regalado confirmed that Fancy Cutt Farms began their salad manufacturing business on March 1, 1996.

Sample Results:
The two laboratories involved in sample testing reported the following values for E.coli 0157:H7 or the generic E.coli MPN via the Collilert Test Method:

SAMPLES SUBMITTED TO DHS-MDL

1.	023071996A	Fancy Cutt Farms	2 Filters/Wash Tank Re-Circulation System...No E.coli 0157:H7

2. 023071996B	Fancy Cutt Farms	Salad Mix Packed 7/18/96	No E.coli 0157:H7
3. 023071996C	Fancy Cutt Farms	Water/Field Irrigation Well	No E.coli 0157:H7
4. 023071996D	Fancy Cutt Farms	Source Water/Wash Tank	No E.coli 0157:H7
5. 023071996E	Fancy Cutt Farms	Fecal Matter/Cattle Pen near Process Well	No E.coli 0157:H7
6. 023071996F	Fancy Cutt Farms	Water/Salad Wash Tank	No E.coli 0157:H7
7. 023071996G	Fancy Cutt Farms	Water/Radicchio Wash Tub/Trough	No E.coli 0157:H7
8. 023072296A	Fancy Cutt Farms	Fecal Matter/Cow #1 (1 vial)	No E.coli 0157:H7
9. 023072296B	Fancy Cutt Farms	Fecal Matter/Cow #2 (1 vial)	No E.coli 0157:H7
10. 023072296C	Fancy Cutt Farms	Fecal Matter/Cow #3 (1 vial)	No E.coli 0157:H7
11. 023072996A	Fancy Cutt Farms	Wash Tank Water/Top Re-Circ. PVC	No E.coli 0157:H7
12. 023072996A2	Fancy Cutt Farms	Wash Tank Water/Bottom Re-Circ. PVC	No E.coli 0157:H7
13. 023072996A3	Fancy Cutt Farms	Wash Tank Water/Bottom Re-Circ. PVC	No E.coli 0157:H7
14. 047072996B2	Fancy Cutt Farms	Wash Tank Water/Re-Circ. PVC	129.6 E.coli MPN
15. 047072996B3	Fancy Cutt Farms	Wash Tank Water/Re-Circ. PVC	816.4 E.coli MPN
16. 023072996C1	Fancy Cutt Farms	Wash Water/Radicchio, Trough	No E.coli 0157:H7
17. 023072996C2	Fancy Cutt Farms	Wash Water/Radicchio, Trough	No E.coli 0157:H7
18. 047072996D	Fancy Cutt Farms	Well Water/Head,Process Water	<1.0 E.coli MPN
19. 047072996E	Fancy Cutt Farms	Source Water/2" PVC	<1.0 E.coli MPN
20. 047072996F	Fancy Cutt Farms	Source Water/1" PVC	<1.0 E.coli MPN
21. 047072996G	Fancy Cutt Farms	Well Water after r/p tank	51.2 E.coli MPN
22. 047072996G2	Fancy Cutt Farms	Well Water post r/p tank	No E.coli 0157:H7
23. 047072996H1	Fancy Cutt Farms	Water/surface scoop,Cow Trough	No E.coli 0157:H7
24. 047072996H2	Fancy Cutt Farms	Water/Cow Trough (pipetted)	No E.coli 0157:H7
25. 047072996J	Fancy Cutt Farms	Water/Mud Puddle in cattle field	No E.coli 0157:H7
26. 047072996K	Fancy Cutt Farms	Water/Field Flooding Outlet Puddle	No E.coli 0157:H7
27. 047072996L	Fancy Cutt Farms	Lettuce + Wash Water/Tank @ 1340	No E.coli 0157:H7
28. 047072996M	Fancy Cutt Farms	Swab/Knifes,Cutting Board/Radicchio (vial)	No E.coli 0157:H7
29. 047072996N	Fancy Cutt Farms	Swab/Knifes,Cutting Board/Radicchio (vial)	CDC LAB
30. 047072996P1	Fancy Cutt Farms	Well Water/Irrigation @ Ranch #2	<1.0 E.coli MPN
31. 047072996P2	Fancy Cutt Farms	Well Water/Leaky Pocket Valve	<1.0 E.coli MPN
32. 047080596A	Fancy Cutt Farms	Red Romaine after sort (Pre-Process)	*LAB ERROR
33. 047080596B	Fancy Cutt Farms	Mizuna after sort (Pre-Process)	*LAB ERROR
34. 047080596C	Fancy Cutt Farms	Tat Soi after sort (Pre-Process)	*LAB ERROR
35. 047080596D	Fancy Cutt Farms	Red Chard after sort (Pre-Process)	*LAB ERROR
36. 047080596E	Fancy Cutt Farms	Lollo Rossa after sort (Pre-Process)	*LAB ERROR
37. 047080596F	Fancy Cutt Farms	Salad Mix from Wash Tank (In-Process)	83 E.coli MPN
38. 047080596G	Fancy Cutt Farms	Frisee cut from field (Pre-Process)	<1.0 E.coli MPN
39. 047080596R	Fancy Cutt Farms	Radicchio, cut (Pre-Process/Wash)	*LAB ERROR
40. 047080596S	Fancy Cutt Farms	Radicchio, whole (Pre-Process)	7.0 E.coli MPN
41. 047080596T	Fancy Cutt Farms	Fancy Salad Mix (Product/8-5-96)	45 E.coli MPN
42. 047080596H	Fancy Cutt Farms	Fancy Salad Mix (Product/8-4-96)	97 E.coli MPN
		SAMPLES SUBMITTED TO MONTEREY COUNTY LABORATORY	
43. 047080596J	Fancy Cutt Farms	Well Water @ Head	<1 E.coli MPN
44. 047080596K	Fancy Cutt Farms	Well Water @ Hose Bib	<1 E.coli MPN
45. 047080596L	Fancy Cutt Farms	Well Water Post R/P	<1 E.coli MPN
46. 047080596M	Fancy Cutt Farms	Wash Tank Water/Bottom PVC#1	38.4 E.coli MPN
47. 047080596N	Fancy Cutt Farms	WAsh Tank Water/Bottom PVC#2	>200.5 E.coli MPN
48. 047080596P	Fancy Cutt Farms	Wash Tank Water (1st Batch In Tank)	40.6 E.coli MPN
49. 047080596Q	Fancy Cutt Farms	Wash Tank Water from filling PVC Pipe	<1 E.coli MPN

Photographs: The photographs attached are numbered (1-41). They give a good description of the operation and conditions. The following is a brief discussion by photo number "#" :

Exhibit C (7/19/96)--#1 shows the north view of the processing shed. Note the same red pickup truck in both #1 and #2. In #2, the rear side of the shed is seen where the 20 foot wash tank is located below the overhang. The boxes behind the employee wearing the hat were full of baby greens and were being staged for washing. #1 shows the portable toilet that contained a faulty hand washing sink (no water dispensing nor soap nor towels). #5 shows the inside of the same portable toilet.

#3 shows the south side of the shed. Note some weeds and piles of materials.

#4 shows ditch with standing water in baby greens farm. This ditch did have one ditch connection to the cattle corrals.

#6 is a distant view of the cattle corral with one cow and the area where the processing well water head is located. #7 shows the location of the well. Note the weeds and ivy growing around the well head.

#8 shows the [redacted] wash tank full of water and two employees. Lettuce baby greens are dumped in this tank water and stirred by hand. The white PVC pipes are connected to a filtration system which can be viewed in #9 and #10. Two of the filters in this photograph were sampled and tested for E.coli 0157:H7. The filtration system was not in operation, but the PVC pipes were connected to the tank water. The operation of the filtration system was not fully investigated. It appeared that water was drawn out by pump from the bottom PVC pipe, filtered, then pumped back into the tank via top PVC piping. The system appeared to be designed to remove large particulates. The filters had a strong sewage-like smell. The grey plastic totes in the background were full of baby greens staged for washing.

#11, #12, #13, #14, and #15 show the radicchio chopping and washing operation. The soiled box used for harvesting in the field is placed on the cutting table, the radicchio is chopped with a knife, then placed in a field harvest box or dumped into the wash trough located next to the cutting table. The employees were wearing gloves during this photo, but in #12, the right hand thumb finger glove tip is missing. The ribbed pattern in the trough wash tank is difficult to clean and sanitize (#13, #14, #15), and it did contain some algae growth. The cutting table periphery had crevices which would also be difficult to clean and sanitize.

#16, #17, #18, #19, #20, and #21 show the baskets with washed baby greens on the conveyor system in preparation for the spin dry cycle and packaging. #19 shows the spin unit (centrifuge) with loaded drum of baby greens. #18 shows the empty boxes with plastic liners ready to be filled. #19 and #20 show the weighing scale and the waxed paper that is placed over the bagged salads.

#22 and #23 show boxed salads inside the refrigerated compartment.

Exhibit D (7/29/96)--#24 and #25 show the additional portable toilet which was added after the initial inspection on 7/18/96. Note that the weeds seen in #1 have been removed. Also note the addition of the blue colored tarpaulin sheet on the shed overhang next to the [redacted] wash tank.

#26 and #27 show the front view of the shed. Refrigerated trucks are loaded via the back sliding door seen in #26. Note live rabbit in #27.

#28 and #29 show how smaller baby green pieces are removed via a wire screen. Only the larger pieces which are shaken into the grey totes are washed and processed. The smaller pieces which drop to the floor are thrown away.

#30, #33, and #34 show the white paper instructions for employees to wash their hands, not wear jewelry, and not to allow clean baskets in contact with the floor. These signs are written in both English and Spanish. Note that the full grey plastic totes are stacked against the same wall inside the processing shed.

Exhibit E (7/29/96)--#35, #36, #37, and #38 show the well head at ranch 2. Note the pocket with dripping water and algae growth approx. six inches past the gate valve and prior to where the pipe had been severed and blocked.

Exhibit F (8/5/96)--#39, #40 and #41 show the well head at the processing plant area. The photos show that the weeds and ivy seen in #7 had been removed. #39 shows well head and a white PVC pipe leading to Repressurization Tank. #40 and #41 show the spigot where a positive E.coli sample (I.S.#047072996G) was collected. The resampling of the same spigot (I.S.#047080596L) was negative. If you look closely at #40 you will see a severed small black pipe (a cross-connection) leading into the ground. We (Munoz, Ho & Crawford) did not see it connected at time of inspection, nor was it connected in the 7/29/96 inspection. We did connect it temporarily and opened the spigot faucet. We observed that the water was coming up on the dirt road near the cow trough and corral. (The suspicion was it served to replenish the cow trough, although there was no dangling black pipe at the

trough.)

Summary of Observations and Conclusions:
The inspection samples did not produce any E.coli 0157:H7 positives (22 out of 49 total samples collected were targeted for 0157:H7 and were reported negative). This did not necessarily prove that E.coli 0157:H7 was not ever present in the product or environment. It only proved that there was **no E.coli 0157:H7 in the 22 samples.**

With respect to the other 27 samples, two (2) samples did show evidence of insanitary conditions in the form of E.coli positive test results via the Collilert Test Method of the wash tank process water. These insanitary conditions were noted in the salad process wash water before actual start-up (I.S.# 047080596M / 38.4 E.coli MPN and I.S.# 047080596N / >200.5 E.coli MPN). These positive samples were from water in the PVC pipes connected to the main wash tank. These PVC pipes at one time were part of a filtration system that was not operating at the time of our inspections. These two samples results are indicative of **firm not having effective procedures for cleaning and disinfecting the PVC pipes and wash tank equipment.**

Other sample results also established that E.coli existed in the finished washed baby greens salad mix (I.S.#'s 047080596H / 97 E.coli MPN and 047080596T / 45 E.coli MPN). Due to laboratory errors in testing the "Pre-Process" baby green component samples, the source of the E.coli in these positive finished product samples was unknown. The E.coli could have come with the baby greens from the field environment, employee practice, or from the insanitary process water (water in PVC pipes as discussed above). **This unknown factor needs further investigation.**

This firm does not label their salad as "washed" nor "ready to eat". No pathogenic bacteria was detected in the salad samples. However, the salad samples did show evidence of fecal bacteria (E.coli MPN) and this implies possible adulteration via H&SC 110565.

The samples collected on 8/5/96 of the "source water" points established that the source water appeared to be free of E.coli. These samples did not test for full water potability standards and safety (Title 22). And the firm did not have records of ever having tested the water. **This unknown factor needs further investigation and testing.**

The firm is a food processor with respect to chopping the radicchio heads on a cutting board into small pieces before washing. The firm then mixes this processed food with washed raw agricultural

commodities -- the other washed baby green salad components. Based on these inspection observations of the salad processing methods and procedures, **the potential for pathogenic bacterial contamination in the salad exist.**

Another public health concern not investigated involves the practice by the consumer. This involves the following two questions: **Are consumers washing these type of bagged salads before consumption ? or, Are consumers confusing some other brand name salads labeled "ready to eat" with salads in similar size bags packed by this firm, or other firms, not so labeled ? These unknown factors also need further investigation.**

Recommendations:

1. **Regulatory Letter.** (Issue letter listing Laboratory Sample Results and Objectionable Conditions/Alleged Violations -- the problematic PVC piping and defunct filtration system on the [redacted] wash tank.)
2. **Re-Inspection & Re-Sampling.** Due to laboratory errors on pre process samples, it is necessary to resample and test. It is unknown if the washing process adds more E.coli or reduces the numbers. Also, water samples from the well need to be tested for Title 22. No other regulatory agency performs testing on this firm's type of well (non-community well). The tank filtration system and PVC piping needs to be re-inspected as a possible source of bacterial contamination. The firm should be required to investigate their cross-connections on the wash tank and insure they are not contributing bacterial contamination to their salad product.

Attachments:

1. **REPORT OF OBSERVATIONS** dated 7/18/96. 3 Pages.

2. Exhibit A--**Customer Orders & Distribution List** for the months of May and June 1996. 8 Pages.

3. Exhibit B--**Written Response to R.O.** collected on 8/5/96. This written response was provided by Mrs. Golinda Chavez on 8/5/96. 1 Page.

4. **EVIDENCE/SAMPLE RECEIPTS dated 7/19/96** (I.S.#'s 023071996A, B, C, D, E, F, and G.). 2 Pages.

5. **EVIDENCE/SAMPLE RECEIPT dated 7/22/96** (I.S.#'s 023072296A, B, and C.). 1 Page.

6. **EVIDENCE/SAMPLE RECEIPTS dated 7/29/96** (I.S.#'s 023072996A,

A2, A3, C1, C2, and #'s 047072996B2, B3, D, E, F, G, G2, H1, H2, J, K, L, M, N, P1, and P2.). 4 Pages.

7. **EVIDENCE/SAMPLE RECEIPTS dated 8/5/96** (I.S.#'s 047080596A, B, C, D, E, F, G, H, R, S, T, J, K, L, M, N, P, and Q.). 3 Pages.

8. Exhibit C--**PHOTOGRAPHS (x23) TAKEN 7/19/96.** Photos taken at the processing plant (ranch #1). 13 Pages.

9. Exhibit D--**PHOTOGRAPHS (x11) TAKEN 7/29/96.** Photos taken at the processing plant (ranch #1). 6 Pages.

10. Exhibit E--**PHOTOGRAPHS (x4) TAKEN 7/29/96.** Photos taken at the well site at Ranch #2. 2 Pages.

11. Exhibit F--**PHOTOGRAPHS (x3) TAKEN 8/5/96.** Photos taken at the processing plant site well (Ranch #1). 2 Pages.

12. Exhibit G--**CORPORATION STATEMENT OF OFFICERS** from SECRETARY OF STATE (Filed 3/25/96, #96-142668). 2 Pages.

13. COPY OF CA-DHS-FDB **PROCESSED FOOD REGISTRATION #0018769,** Expiration Date: 07/31/97. (Issued 08/27/96). 1 Page.

14. COPY OF CA-DHS-FDB **ORGANIC PROCESSED FOOD REGISTRATION APPLICATION AND REGISTRATION (OPFR) #70279,** Expiration Date: 07/31/97. 1 Page.

15. Exhibit H--**Organic Farming Certification** by QUALITY ASSURANCE INTERNATIONAL, 12526 High Bluff Drive, Suite 300, San Diego, CA 92130. (619) 792-3531. These two certificates certify lettuce, herbs and mixed vegetables grown in Hollister and El Centro, CA. 2 Pages.

16. Exhibit J--Copy of firm's **box labeling** collected on 11/19/96.

Report Written by: ACMunoz 11/19/96

Antonio C. Munoz, Sr. Food & Drug Investigator
San Jose CA-DHS-FDB District Office