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Environmental Investigation of *Salmonella* Enteritidis, Phage Type 30 Outbreak Associated with Consumption of Raw Almonds

Final Narrative Report- March, 2001 – February, 2002

Background

One hundred fifty seven cases of infection with *Salmonella* Enteritidis, Phage Type 30 (SE PT30) in Canada and 11 cases in the US were reported to the California Department of Health Services, Food and Drug Branch (DHS-FDB) by the US FDA. A case control study conducted by Health Canada, Bureau of Infectious Diseases, Division of Enteric, Foodborne and Waterborne Diseases showed the highest association of illnesses with consumption of whole, raw almonds (OR 21.1, 95% CI 3.6 to infinity). The dates of onset of illness ranged from October 2000 to July 2001. Age distribution ranged from 1- 80 years. Cases occurred in the Canadian provinces of Ontario, New Brunswick, Nova Scotia, British Columbia, and Quebec and in four US states (West Virginia, New York, Massachusetts, and Minnesota). The whole, raw almonds implicated in this outbreak were received at the distribution center of a bulk foods retail market (Bulk Barn Foods, Ltd.) from a single California processor (Hughson Nut Company). On April 12, 2001, the Canadian Food Inspection Agency (CFIA) issued a Health Hazard Alert, "warning the public not to consume California Natural Supreme Almonds as they may be contaminated with *Salmonella* bacteria."

Investigators

DHS-FDB - Michael Gutierrez, Jeff Farrar, Carol Myers
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California Regional Water Quality Control Board - Jarrod Ramsey-Lewis
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Summary

The environmental investigation of the almond processor (Hughson Nut Company) implicated in the Canadian investigation yielded two of eight environmental equipment swabs positive for SE PT30. Almonds from two lots ready for shipment to Canada (lot #D3222 and D3250) were also tested with lot D3250 testing positive for SE PT30. On May 7, Hughson Nut Company issued a voluntary recall of Natural Whole Brown Almonds (D3214, D3215, D3223, D3227, D3231, D3233, D3236, D3237, D3240, D3248, D3249, D3253, and D3263) covering all raw almonds shipped after February 16, 2001. This voluntary recall was issued to all 23 consignees in CA, WI, IL, OH, NJ, MA and Canada, Spain, France, Belgium, and the Netherlands.

A traceback investigation of all SE PT30 positive lots identified by CFIA, FDA and DHS-FDB (D3112, D3141, D3163, D3208, D3219, D3222, D3250, D3257, D3241) and processed by Hughson Nut revealed four huller/shellers who provided nuts during this period. Environmental swabs of equipment were collected at the four huller/shellers. Four of eight environmental swabs from one huller/sheller, West Valley Hulling & Shelling (WV), tested positive for SE PT30. The traceback investigation from WV to the growers who supplied almonds, identified four farms (Baker Farms, Hansen Farms, Henry Lara Farms, and Gowens Farm) consisting of 23 fields. Ten drag swab samples (Baker Farms- 7, Hansen Farms- 2, Lara Farms- 1) from 23 fields were positive for SE PT30 (43%).

Further extensive environmental testing of the three farms did not result in identification of the source of the SE PT30 contamination, (see Attachment 02). Intervention measures were implemented for the positive farms, huller/shellers, and processors to assist in preventing further distribution of contaminated almonds. Research projects were implemented by the Almond Board of California in addition to industry-wide training in their Food Quality and Safety Program

(Good Agricultural Practices, Good Manufacturing Practices, Sanitation Standard Operating Procedures, Hazard Analysis and Critical Control Points Program).

Traceback

Whole Raw Almonds were sold by Hughson Nut, to Bulk Barn Foods, Ltd. whose main distribution warehouse is located in Richmond, Canada in the province of Ontario. Bulk Barn operates no stores in the US. Almonds were sold to Bulk Barn Foods in 50 pound unlined, cardboard boxes. A total of 296,500 pounds of almonds were sent to Bulk Barns Foods in 15 shipments beginning October 13, 2000 and ending March 4, 2001 (see Attachment 03). A traceback was initiated by DHS-FDB using lot codes from positive samples obtained by CFIA, Hughson and DHS-FDB. The traceback identified four hulling and shelling firms (see Attachment 04). One hulling and shelling firm (WV) tested positive for SE PT30 (four of eight environmental swabs). A second huller/sheller (Almond Tree Hulling) tested positive (one of five environmental swabs) for *Salmonella* Ohio (not the outbreak organism). The traceback investigation from WV to the growers identified four farms (Baker, Hansen, Lara, and Gowan Farms), consisting of 23 fields that were the likely source of almonds processed during the time period of interest.

Almond Processors

Hughson Nut Company: Hughson receives almonds from September through December, depending on crop size and harvest dates. They will process nuts during the rest of that calendar year and continue into the next calendar year. The season would be designated by the harvest year, so product processed at Hughson during 2000-2001, came from the 2000 harvest. Hughson receives raw shelled almonds from approximately 50 growers using approximately six huller/sheller facilities. The major supplier of nuts to Hughson Nut is WV. Hughson receives no imported nuts. Hughson attempts to sell all almonds processed in one season (covering 2 calendar years) before the next harvest comes in. This results in very little carryover from season to season.

Almonds are received and handled by Hughson Nut according to the contract with the grower. Almonds from "pool growers" are commingled with other "pool growers" but separated by variety, (see Attachment 05). "Pool" almonds are purchased from the grower and are the property of Hughson Nut. "Pool growers" account for approximately 8 of the 12 million pounds of almonds processed at Hughson each year. Commingled almonds from pool growers are sold by Hughson to Hughson customers. Almonds received from "contract or custom growers" are kept separate by grower throughout the process. Almonds from "contract growers" are run as a fee-based service by Hughson. After packaging, the almonds are sent to a customer designated by the "contract grower" or they can be held by Hughson at the direction of the grower. If held at Hughson, a storage fee is charged to the grower. Almonds involved in this outbreak were traced to "pool grower" shipments.

When received at Hughson, almonds are usually in unlined four-foot by four-foot by four-foot wooden bins. Containers are tagged with a "pallet tag," (see Attachment 06) at Hughson. The nuts may be immediately fumigated with Phostoxin, for insects, or held for fumigation at a later time. Fumigation occurs onsite in a fumigation tunnel or in bins in a sealed plastic liner (see Attachment 07). After fumigation, twigs, dirt, and hull or shell fragments are removed by the destoner. Almonds are then mechanically sized and an incoming USDA inspection of the product is conducted. There are seven USDA grades including: US Fancy, Extra No.1, No.1, Select Sheller Run, Standard Sheller Run, No.1 Whole & Broken, and No.1 Pieces (see Attachment 08). Immediately after sizing, nut samples are mechanically collected for the USDA inspector to verify the grade by checking levels of moisture (), decay, rancidity, presence of insects, foreign matter, mold, and any breakage or blemish. After sizing and grading, each bin is given a "run tag" number. This number will start with the letter "A," (or another letter depending on the "run," see Attachment 09). Following the letter, a seasonal consecutive number is assigned such as D3250.

[REDACTED]

After grading and sizing, (see Attachment 11) nuts are held in cold storage (approximately 42°F) in plastic lined four-foot by four-foot by four-foot heavy cardboard bins until needed. When an order is received, the size, variety and grade needed are pulled from cold storage and run through a metal detector (gravity table room, see Attachment 12)) and three electronic sorters (E-sort room, see Attachment 13)). These will sort for blemish, fungi, and breaks. The nuts will also be run through human hand sort tables. Almonds run through the e-sort room would get another run tag number beginning with the letter E. Previous run tags may be removed or the previous run number will be marked out. Product is tracked by run numbers in a computer tracking system. After electronic sorting, the nuts can be returned to the beginning and rerun, or they can be processed (roasted, blanched or cut), or they can be packaged (see Attachment 14) and delivered to the buyer as raw almonds. Any one of these functions would result in a new run number. Almonds implicated in this outbreak were packaged after electronic sorting and delivered to the Canadian retailers' distribution center as "Browns" or Raw Unprocessed Almonds.

Hughson also has the capability to complete additional processing (roasting, blanching) for customers. Roasted almonds are dry heat roasted at [REDACTED] (time and temperature are at customer request). The capacity of the roaster is approximately 500 pounds per hour. Blanching occurs by washing the almonds in boiling water for approximately six minutes, this separates the skin from the nut. The nuts are then run over rubber rollers that remove the skin and are then air dried to six per cent moisture. Small amounts of nuts exceeding the moisture level ([REDACTED]) can be dried in a perforated bin with [REDACTED] air blown through it. Large amounts of nuts over the moisture level are sent to a commercial dryer.

Almonds are packaged in 25, 50, and 2000 pound cardboard boxes. The 25 pound box with a plastic liner is the standard box for processed nuts, except roasted nuts that are put into plastic-lined, vacuum-packed, nitrogen-flushed boxes (also 25 pound). Natural Unprocessed and Blanched Whole Almonds are normally packed in a 50 pound unlined box. Almonds sold to other processors for further processing are sold in 2000 pound plastic lined cardboard bins. Seventy five to eighty per cent of all products from Hughson Nut are packed in 25 and 50 pound cases. Each container is coded with a lot code, (see Attachment 15) (see Attachments 16, 17, 18). Product specifications and a Hazard Analysis Critical Control Points plan for Natural Whole Almonds are included as Attachment 19.

Samples: Almonds from sealed boxes were sampled and tested by CFIA and four codes tested positive for SE PT30 (D3208, D3219, D3222, and D3250). Hughson collected almond samples from their reserve library (50 lot codes sampled) and received positives for *Salmonella* from lots coded D3112, D3141, and D3222. Isolates of these positive samples were forwarded to California Microbial Diseases lab (MDL) and U.S. Centers for Disease Control and Prevention lab (CDC) and were identified as SE PT30.

On April 25, 2001, eight sterile environmental swabs (Solar-Cult® from Solar Biologicals, Inc. , Neutralizing Buffer) were used to aseptically swab Hughson Nut processing equipment. Three environmental swabs were used to swab equipment in the sizer room, one swab was used on equipment in the gravity table room, and four environmental swabs on equipment in the electronic sort room. One swab collected from the dump into the sorter (in the sizer room) and one swab collected from a conveyor to a sizer (in the electronic sort room) were positive for SE PT30. Control samples of collection bags, gloves, swabs, etc. were collected with each sampling conducted by DHS-FDB and FDA and in all instances tested negative for *Salmonella*.

On April 27, eleven 100 gram samples of almonds from 11 individual lots (lots D3094, D3112, D3124, D3141, D3155, D3163, D3180, D3208, D3222, D3219, and D3250) held by Hughson as

reserve samples (representing product previously shipped to Canada) were aseptically collected by DHS-FDB and tested at MDL. Lot D3163 tested positive for SE PT30. Finished product destined for shipment to Canada, but placed on voluntary hold by Hughson Nut (at Hughson Nut), was also sampled (30- one pound samples per lot of D3222 and D3250) and tested by FDA. One composite of 15 subsamples of Lot D3250 tested positive for SE PT30.

Outbreak Intervention: Hughson ceased operations on April 24, 2001. The firm conducted a complete cleaning and disinfection (C&D) of all equipment, implements, and the interior of the structures. Initial cleaning consisted of washing with soap (Formula 939/cleaner/degreaser made by Fuller Brush Co.). Directions on the container were followed (two to four ounces of cleaner in a gallon on water). Scrubbing was completed by hand, using brushes, rags, and in many cases toothbrushes in hard to clean areas. This process was followed by a water rinse then disinfection with Fullsan 375 Sanitizer made by Fuller Brush Company (0.34 ounce per gallon of water). Upon completion of the C&D, 45 environmental swabs were collected from each room and equipment within the rooms, to verify the effectiveness of the C&D. All were negative for *Salmonella*. Processing packing and shipping operations were resumed on July 1, 2001.

Almond Huller/shellers

West Valley Huller and Sheller: WV was one of four hulling/ shelling facilities identified during the Hughson traceback (see Attachment 20, 21, 22). This firm receives almonds in hull directly from the grower. As a fee-for-service firm, WV cleans, sizes, hulls, and shells the almonds. The nuts are kept separate by grower and usually by field. Nuts are owned by the grower and upon completion of shelling are sent wherever the grower designates (this may be a handler, who may sell direct to the consumer, or a processor). Hulls are sold for dairy feed and shells are sold for animal bedding see Attachment 23). During the receiving season, almonds may remain in the yard directly on the ground (in a "stockpile") until needed. If the almonds remain in the yard for an extended period they may be covered by a tarp and fumigated (Phostoxin) for mold and fungus. Huller/sheller facilities may be extremely dusty, with cleanup usually occurring at the beginning and end of the season. Occasionally, during the season, an air blow-down of the equipment might occur as needed. Water is not used during the hulling/shelling process as moisture on the nut can result in fungal growth (see Attachments 24, 25).

Samples: Of eight environmental swabs collected by DHS-FDB from hulling and shelling equipment at WV, four tested positive for SE PT30. Two of the SE PT30 positive swabs were collected from equipment in the nut receiving area, one from equipment in the hulling area, and the last swab was collected from equipment in the shelling area.

Outbreak Interventions: After receiving the positive environmental swab results, WV agreed to voluntarily cease operations and complete a C&D. The C&D consisted of a high-pressure cold water rinse of all equipment, followed by a high-pressure wash with cold water and 3M Brand, Quat Disinfectant Cleaner Concentrate (one ounce Quat to three ounces water). Following the C&D, 10 environmental swabs were collected and tested for *Salmonella* as verification of the C&D (all tested negative). Immediately following the C&D, WV resumed operations. WV would complete a C&D only after each BHL run. WV also instituted an on-going testing program that consisted of weekly environmental equipment swabs (10 swabs per week), in addition to post C&D environmental sampling.

As a result of the weekly environmental sampling program, a sample collected on October 22, 2001 was confirmed as positive (on November 6) for *Salmonella* (this sample was not submitted to a lab for serogrouping). This sample (one of ten environmental swabs) was collected from Stages 1 and 2 of plant hulling equipment by plant personnel. Operations were ceased and a plant wide C&D was completed, followed by a second set of ten environmental swabs. On October 30 one swab from the second set of samples was also found positive for *Salmonella* (no serogrouping or serotyping was attempted). A second plantwide C&D was completed, followed again by a third set of 10 environmental swabs. All swabs in the third set of samples were negative for *Salmonella*. BHL product had been run from October 20 to 22 followed by non-

outbreak implicated product. Product run from October 22 until October 30 had gone to three handlers (approximately 1,432,290 pounds). WV was directed to sample and test product held as reserve samples in the plant for *Salmonella*, with no positives reported to DHS-FDB as a result of the testing. Equipment environmental swab collections continued with no positive *Salmonella* results.

Almond Tree Hulling Company: As one of four hulling and shelling facilities identified during the Hughson traceback, five environmental swabs were collected on August 13 from various points on hulling and shelling equipment located in this facility. One swab tested positive for *Salmonella* Ohio. The firm ceased operations on August 29, 2001 and instituted a complete C&D, followed by environmental swab sampling to validate the C&D. The C&D consisted of an air blow down of all equipment, walls, and floors, followed by three high pressure water washes of 350 PSI at 160°F. Quat Disinfectant Cleaner Concentrate, manufactured by 3M was then misted on at two liters of concentrate per 100 gallons of water. Fifteen pooled samples with two swabs in each sample (taken by the plant manager on September 1, 24 hours after the C&D) tested negative for *Salmonella*. Almonds in the plant during this period were sampled (eight, one pound samples), and tested negative for *Salmonella*. The plant resumed operations on September 2, 2001. As part of an agreed upon protocol (Almond Tree Hulling, FDA, DHS-FDB) the firm also instituted daily environmental swab sampling and testing of equipment (twenty swabs pooled into four samples) and random sampling and testing of shelled almonds (30x100 gram samples, by run or stockpile). Testing continued to the end of the season (January, 2002). Almond Tree has reported no positive samples as a result of the sampling and testing.

Salida Hulling Association/ Pohl & Holmes, Inc: These two (of four) huller/shellers were linked by traceback as suppliers to Hughson Nut Company during the time period of interest. Environmental swabs of equipment at both facilities were negative for *Salmonella*. No further action was taken at these firms.

Almond Growers

Baker Farms/ Hansen Farms/ Lara Farms/ Gowan Farms: The Hughson traceback identified four growers as possible suppliers of almonds during the time period of interest. The fields of two growers, Hansen Farms and Baking Farming, are adjacent. The third grower, Henry Lara Farms is separated from Baker/ Hansen fields by a distance of approximately one mile (between them are fields of melons, almonds and a county road). The fourth grower (Gowan's Farm) is separated from Baker/ Hansen by a distance of approximately two miles to the south and from Lara Farms by approximately two miles to the north. Field testing (discussed later in this report) of Gowan's orchards resulted in negative findings for SE PT30. This growing area is in west Fresno County along the Highway 5 corridor, off Panoche Road, (see Attachment 26). There are no known livestock or poultry farms within several miles of the implicated growing fields. Baker Farming includes 3,800 acres of almonds, Hansen Farms includes 1,150 acres of almonds, Lara Farms includes 640 acres of almonds. Each field is 150 acres and is a quarter section. This area includes Sections 3 – 11, 13 – 18 and 20 of Township 15S and Range 13E, and Section 1, 6, 12 & 13 of Township 15S and Range 12E. All fields are in almonds, except approximately eight Baker-owned (leased) fields in melons, corn or tomatoes. Baker also has approximately five and a half fields in pomegranates and grapes at this location.

The land is alluvial plane within three miles of the coast range. The soil is comprised mostly of Cerini clay loam. USDA soil surveys note Cerini soils as 27-35% clay and because of this are noted as moderately slow in permeability and runoff as medium. The effective rooting depth is sixty inches or more. Normal pH ranges between 6.6 and 8.4, salinity at 0-4 mmhos/cm. Soil pH was measured on Baker Farms ranging from 7.4- 8.5 (see Attachment 39).

The source of irrigation water for the three farms is the California Aqueduct. The California Aqueduct is a water distribution system that uses 700 miles of open, concrete lined canals to transport water from northern California to other areas of California. Pipe-lines off the aqueduct transport water to the individual fields. Hansen and Baker use one sand or screen filter (see Attachment 27) for each one or two fields to filter particulates. Lara uses no filters. Baker and

Hansen irrigate using an automated microsprinkler system (see Attachment 28). Henry Lara uses a larger conventional Rainbird type sprinkler (see Attachment 29). The irrigation schedule is set so each field is irrigated within a two day period. Irrigation may begin as early as late March depending on rainfall, and continue to two to three weeks before harvest. Approximately three to four acre-feet of water are applied to each tree per season. At least four times per year, chlorine (in the form of calcium hypochlorite) may be run through the drip lines to clean the lines of bacterial growth (three gallons of chlorine are added to 15,000 gallons of water). As Lara Farms didn't use drip lines, there was no need for line chlorination.

Normally, two or three varieties of almond trees are planted in each field to insure maximum pollination. Bees are also introduced in January or February to aid with pollination. The popular varieties in California are the Nonpareil, Carmel, Monterey (which are early blooming varieties) and Butte, Mission, Padre (later blooming). Orchard life is estimated at approximately 25 years. Baker Farms and Hansen Farms plant more trees per acre than is usual (110 vs. approximately 90 per acre). Many growers are now planting new orchards at this higher density. This can result in higher yields, but may also result in more shade to the ground and possibly cooler ground temperatures and higher humidity.

Commonly used synthetic fertilizers are nitrogen, potassium, and boron (for tree growth and nut production). Nitrogen and potassium are usually applied during the early spring then again early in the summer months using commercial liquid products via the drip system. Potassium, as potassium sulfate, is normally applied after the third year of tree growth, also via the drip system and also during early spring. Boron is normally applied by foliar application, by ground or air, in October. All three growers stated they had not used natural fertilizers on any of their almond orchards. A review of documentation provided by the California Regional Water Quality Control Board revealed that bio-solids were applied to four fields owned by Baker Farming in 1993, prior to almond tree plantings, (see Attachment 30).

BHL accomplish weed management by ground-rig (grower owned) application of Round-Up®. Dormant spray (oil, plus an insecticide) may be applied to control peach twig borer, San Jose scale, and early season mites during December through January. Also during the winter months (December or January) any almonds remaining on the trees (mummies) are removed by machine or by hand (using poles) to reduce overwintering sites for navel orangeworm. Zinc may also be applied, by ground or air, as a fungicide for brown rot during bloom. Prior to harvest, a hull split spray may be applied, also by ground or air (it is also functions to control navel orangeworm).

Aerial applications for all growers were by contract with Robinson Ag-Spray, Inc. A water tank located near the Baker ranch airstrip was used to store water for mixing with the pesticides to be applied to the three farms. The source of water used in aerial applications was the California Aqueduct. All three farms generally receive aerial applications at the same time using the airstrip at Baker Ranch as the mixing and loading point for all three. A review of records at Robinson Ag-Spray revealed no obvious sources of the pathogen (see Attachment 31). Pesticides are not used within approximately one month of harvest. Vertebrate pests (squirrels and field mice) are controlled by applications of Phostoxin in the rodent burrows.

Predator mites were also applied to the three farms by air to control the two-spotted mite. Applications to Baker Farms occurred on June 3, and July 24, 2000, Hansen Farms on April 28, and May 30, 2000, Lara Farms on May 28, May 31 and June 25, 2000 (see Attachment 31). Predator mites, used by BHL, are raised by the Visalia Insectory located in Visalia, CA. The Visalia Insectory maintains four temperature-controlled greenhouses for the growth of predatory mites, two-spotted mites, and soybeans. The soybeans are used as a growth media for the two-spotted mite and the two-spotted mites are in turn used as feed for the predatory mites. The soybeans are grown in a commercial soil product (Supersoil) with municipal water used for irrigation. The Supersoil is supplied by Rod McLellan Company-Supersoil Division, Bakersfield, CA. The Supersoil is made from green waste, sawdust, peatmoss, bark, and sand; it is not

sterilized, nor does it contain manure. After each use, the Supersoil is thrown out and the trays used for holding the soil are dipped in a five per cent solution of Clorox and water.

Harvest of almonds begins with the third year of bloom, during late August or early September (see Attachment 32). Early blooming varieties are harvested first (Non-pareil, Carmel, Monterey) followed by the later blooming varieties (Padre, Butte or Mission). Irrigation to trees to be harvested is ceased two to three weeks before harvest. This insures the ground will be solid for harvesting equipment and stresses the trees to complete hull split. The rows between the trees are graded and swept, by mechanical means, to keep the ground level and free of weeds and other debris. A mechanical shaker shakes each individual tree with the nuts falling onto the ground. The nuts are left on the ground to dry for a period of seven to ten days. A sweeper pushes nuts along with dirt, twigs, and anything on the ground into a line between the rows. At the rear of the sweeper is a blower that blows nuts remaining in the row or directly under the tree into an adjacent, unswept row. The windrow process generates a large amount of dust and particulate matter (see Attachments 33, 34). A mechanical harvester follows and picks up whatever is in the windrow and deposits it into a holding bin. The nuts are then transferred to a "bankout," a vehicle that transfers the nuts from the harvester to an elevated conveyor that deposits them into a trailer for delivery to the huller/sheller. Hullers have said that as much as 20% of a load can be dirt and debris (see Attachment 35). Each variety or tree is harvested one time, however, due to multiple varieties within a field, each field undergoes the harvest process two to three times. Prior to sending to the huller, moisture levels will be taken on a sample of almonds. If moisture levels exceed six per cent, the almonds will be sent to an offsite commercial dryer. A commercial dryer was not used for almonds implicated in this outbreak.

Samples: During the month of July, 2001, environmental swabbing (twelve swabs) of harvest equipment (chosen at random) used by the four growers was completed. This equipment had not been used since December of the previous year. All results were negative for *Salmonella*. Next, four environmental drag swabs were collected from each 150 acre field (23 fields) implicated by traceback to positive lots of almonds. A sterile four ply, three inch by three inch cotton gauze swab (Solar-Cult® from Solar Biologicals, Inc., pre-moistened with double strength skim milk) attached to a sterile cord was pulled on the ground to the side of the sampler in the almond field. The sampler walked approximately 50 feet in the rows and up on the berms between the trees in the orchards. Two samplers each pulled one swab diagonally into the field, beginning at one corner. These two swabs were then placed into one sterile plastic bag provided with the sampling kit. The same procedure was completed at the opposite corner of the same field, with those swabs placed into the same sample bag. Thus four swabs from two opposite corners of each field comprised one sample. Twenty-three fields from four different growers were sampled. Ten fields from three growers tested positive for SE PT30, these included Baker Farms fields 7-3, 8-4, 9-2, 16-1, 16-3, 16-4, 18-4 (of 16 fields tested), Hansen Farms fields 15-2, 15-4, (of four fields tested) and Lara Farms field Panoche east (of two fields tested). See Attachment 36 for field longitude and latitude and Attachment 37 for a map of the results of the testing. Positive fields ranged in age from the seventh to twelfth leaf. Only one bio-sludge applied field was implicated in the traceback and it tested negative for *Salmonella*.

Seventeen soil samples from the three positive farms were collected and analyzed for heavy metals in an attempt to determine whether bio-solids may have been applied to other fields. Samples were collected using a ground coring device. Three soil cores (see Attachment 38) were collected at one site and mixed in a five gallon plastic bucket. One two-pound sample was collected from the bucket and placed into a sterile bag. Samples were collected either on the berm in line with the trees or in the row between the trees. Samples depths were varied between two and six inches. All equipment pieces were disinfected by submerging and scrubbing in a solution of TSP (Totally Superior Product, manufactured by America's Finest Products in Santa Monica, CA.) and water (1/4 cup to one gallon cold distilled water). Although the results were noted by personnel from the Regional Water Quality Control Board as "inconclusive," they do tend to indicate that bio-sludge was probably not recently applied to fields other than the four known fields. The test results are included in Attachment 39.

Three Moore swabs (sterile cotton gauze rolled to approximately three inches in diameter and eight inches long) were used to sample water for bacteria from the California Aqueduct. The swabs were located at the two points where water is pumped from the aqueduct to the three positive growers. The swabs remained in the aqueduct for periods of four to nine days. All swabs were negative for *Salmonella*. Sand was collected from sand filters or screen filters were swabbed (five swabs, and two sand samples) from filters feeding positively tested fields. All tested negative for *Salmonella*. Thirteen water samples were collected from emitters in SE PT30 positive fields. None tested positive for the outbreak organism. One sample (from an emitter in field 15-2, Hansen Farms) was positive for *Salmonella* Arizonae. Water used by the aerial applicator (for all 3 positive farms) was sampled at the water holding tank and at the reservoir prior to filling the tank, as well as a Moore swab in a water holding pond near the pump station (all on Baker property). Mud and organic material on the bottom of the reservoir was also collected. All tested negative for *Salmonella*. Five environmental swabs were collected from the airplane spray tank owned by Robinson Ag-Spray, as well as a mobile external mixing tank and all tested negative for *Salmonella*.

Other Samples

On July 23, 2001 sampling (cloacal swabs) of live migratory waterfowl occurred at a wildlife refuge, approximately 15 miles from the growing area. There were no positive results for *Salmonella* among 33 samples collected. Birds sampled included 18 Cinnamon Teals, 6 Mallards, 3 Coots, 3 Redheads, 2 Gadwalls, and 1 Pintail. An environmental swab (collected by Baker Farms personnel) of the cloacal area of a crow killed by Baker Farm personnel tested positive for SE PT30. On July 23, owl pellets were collected from the ground under multiple owl nesting boxes in the orchards on Hansen Farms and pooled into one sample. This sample also tested positive for SE PT30. Owls are encouraged in the orchards as a means of rodent control.

On August 1 and again on September 12, rodents in the growing fields of the three implicated farms were live trapped and fecal samples were collected. Trapping occurred, either within or immediately adjacent to positive fields. Fecal collections were pooled by species into seven samples, collected from over 212 animals. Among species trapped were *Reithrodontomys* *Megalotis*, *Peromyscus* *Maniculatus*, *Mus* *Musculus*, and *Dipodomys* *Heermanni*. Although no samples were positive for *Salmonella*, blood samples collected from the rodents were positive for Hantavirus.

A Moore swab was deposited in a pond at a small sewage treatment facility (Property Service Inc.) in a commercial area approximately four miles from the growing area. This sample was negative for *Salmonella*. Predator mites (one sample), mite growing media (three samples), feed for mites (one sample), and source water used in the mite insectory (one sample) were aseptically collected from the Visalia Insectory (supplier to Baker, Hansen and Lara Farms) and all were negative for *Salmonella*. Eight environmental drag swabs were aseptically collected from a pomegranate orchard, a vineyard, a dirt road near the vineyard, a water collection pond, and a water spraying truck, all located on Baker Farm. All samples were negative for the outbreak strain however, the water collection pond did test positive for *Salmonella* Arizonae.

Intervention Measures for the 2001 Season

DHS-FDB, FDA, and each firm agreed upon a protocol for handling almonds from the positive growers during the 2001 harvest season.

Hughson Nut Company: The Hughson protocol called for collecting and testing a four pound composite sample of almonds from the square root of the number of bins in a load (example- one, four pound sample is collected from four bins in a load of 16 bins). This sampling procedure was conducted for each almond variety, from every field, once per season. Testing would only be for the presence of *Salmonella*. The result would be that each field would be tested at least twice, as there are usually two to three varieties per field. Only one field (not BHL) tested positive for

Salmonella Group C1 (not the outbreak organism). All nuts from this grower were blanched or treated with the sterilant Propylene Oxide (PPO).

Each lot of nuts grown on the implicated fields and received by Hughson Nut from WV would be tested for the presence of *Salmonella*. Initial testing (positive or negative for *Salmonella*) would occur at Hughson, using the bioMerieux mini VIDAS, (see Attachment 40). Positive isolates would be sent to Silliker Labs for confirmation and serogrouping. Group D isolates would be forwarded to MDL for serotyping, and SE isolates would be forwarded to CDC for phage typing and PFGE analysis. To date no *Salmonella* positives have been received from environmental swabbing or almond sampling (1,052 total samples) at Hughson Nuts.

The Hughson protocol stated Raw (Brown skin) Almonds from the positive growers would not be shipped until the almonds received treatment sufficient to kill *Salmonella* such as:

1. Roasting or blanching
2. PPO treatment or
3. Shipping to a known customer that will roast or blanch the almonds.

Hughson also agreed to C&D any equipment immediately after processing almonds from BHL fields, followed by environmental swabbing to validate the C&D. It was also agreed that weekly environmental swab sampling of all process equipment would occur. Fifteen environmental swabs were collected weekly and tested at Hughson Nut. All equipment swab samples have, to date, tested negative for *Salmonella*. See a copy of the protocol included as Attachment 41.

West Valley Huller/sheller: WV protocol called for holding all nuts from the positive growers until there was enough product for a complete run. Lots of almonds from BHL would be hulled and shelled consecutively, with no other growers' almonds run during that period. At the end of the BHL run, WV would cease operations, complete a C&D, and swab equipment as a validation of the C&D. A C&D would consist of an air blow down of all equipment, floors, and walls. This would be followed by area wide fogging of the building with quaternary ammonia. WV personnel would follow this up with hand spraying of all equipment with quaternary ammonia, (see Attachment 42). Environmental swabbing of equipment by firm personnel would verify the C&D. Swabs would be tested at Hughson Nut using the Hughson protocol. WV also agreed to implement the Huller/sheller Good Manufacturing Practices and the Huller/sheller and Processor Clean Up and Sanitizing Procedure, (see Attachments 43, 44).

Baker Farms/ Hansen Farms/ Henry Lara Farms: Almonds would be harvested and stockpiled (approximately five stockpiles per field), and samples (from each stockpile) of unhulled almonds would be collected for *Salmonella* testing prior to sending to the huller. Using sterile gloves, the grower would collect approximately 15 handfuls of almonds from each stockpile, place them into one gallon, plastic bags (approximately five to seven pounds). The bag was sealed and the sample was submitted to Hughson Nuts for *Salmonella* analysis. Almonds from the implicated growers would be run at WV as contaminated regardless of the test results. See a copy of the grower protocol included as Attachment 45. See also Attachments 46 and 47 for grower test results. For a product flow chart see Attachment 48.

Panoche Creek Packing: For the 2001 season, all shelled almonds (by WV) from Hansen Farms, fields 14-1 and 14-3 were sold to Panoche Creek Packing. Ownership at Panoche Creek stated all Hansen almonds would be sent to Triple H in Bakersfield for blanching.

Shelled nuts were trucked from WV to Panoche Creek- Madera in bins, held and when needed, forwarded to Triple H in the same bins for blanching. The blanched almonds were then transferred to Panoche Creek- Firebaugh for sizing, sorting, packaging and shipping.

At the time this report was completed, Panoche Creek had received all contracted shipments of almonds from Hansen Farms. This totaled 1,102,049 pounds. A total of 947,443 pounds had been blanched at Triple H. Of this, 760,475 pounds had been shipped to customers. Remaining

at the Madera facility were 157,606 pounds that would be blanched at Triple H (see Attachment 49).

Samples: The FDA Center for Food Safety and Applied Nutrition agreed that blanching of the final product was destructive to SE PT 30 and for this reason no testing of product or equipment was conducted.

Triple H: Almonds from Hansen Farms implicated fields (14-1 and 14-3) were purchased for distribution by Panoche Creek Packing and per agreed protocol, blanched at Triple H.

Triple H has the capability to blanch, size, sort, and package, shelled almonds. This is provided as a fee-for-service to the grower. Almonds from Hansen Farms were received in four foot by four foot by four foot bins (2,350 pounds) from the Panoche Creek- Madera facility. The almonds were blanched at Triple H and returned to the Panoche Creek- Firebaugh facility also in bins. Blanching involves submersing the almonds in water heated to approximately 190°F for three to six minutes (actual time and temperature is dependent on the variety). After this process (which separates the skin from the nut), the skin is removed by running the nuts through a tumbler and a vacuum dryer. Triple H does not fumigate the almonds at any point in the process. Samples: As blanching was agreed to be destructive to SE PT30, environmental samples were not collected.

Bactericidal Treatment

There is currently no EPA or FDA approved treatment of almonds for *Salmonella*. Walnut growers have used PPO as a sterilant (for control of bacteria, molds, and insects). Some almond handlers had proposed using PPO in almonds as well. Non validated studies have been completed by a major supplier of PPO in the US. Preliminary results suggest that PPO is effective against *Salmonella*. Heat treatment (roasting) has also been used as a bactericidal treatment, though validation studies have not been completed. With no currently approved process available, Hughson Nut proposed the use of PPO, roasting, or blanching as temporary bactericidal measures. DHS-FDB and FDA have agreed with these temporary measures and have recommended validation studies be completed as quickly as possible, (see Attachment 50).

Research and Education Activities Implemented by the Almond Board of California

The Almond Board of California (ABC) instituted an education and research program to assist almond processors and growers. This program included:

1. Food Quality and Safety Program - The program includes the Good Agricultural Practices (GAP), Good Manufacturing Practices (GMP), Hazard Analysis and Critical Control Points, and Sanitation Standard Operating Procedures manuals.
2. PPO validation study (conducted at the Cosmed Group, Inc., a contract sterilizer, of Sparks, NV.)
3. Thermal death time curve study (also conducted by the Cosmed Group, Inc.)
4. *Salmonella* field survival and background study (conducted by UC Davis)
5. Handler sampling program – A blind study to collect almond samples from seven handlers from different geographical areas of California. Approximately 2,000 one-pound samples (shelled almonds) have been collected using USDA aseptic sampling procedures. All samples were collected at the point of receiving at the handler. Samples were collected from throughout the season and tested for *Salmonella* at the DFA of California lab (DFA) in Fresno, California. Samples were submitted to the lab without a farm identifier. Positive *Salmonella* isolates were forwarded from DFA to MDL for confirmation and serotyping. To date, twelve *Salmonella* isolates (out of 2,000 tested samples) have been forwarded and have resulted in four positives for *Salmonella* Montevideo, two *Salmonella* Brandenburg, one *Salmonella* Thompson, one *Salmonella* Newport, one *Salmonella* New Brunswick, and one *Salmonella* 48:Z4,Z23- (two are pending). This project has been funded to continue through the 2003 season under the same parameters as in 2002.

Inspections of Handlers, Huller/shellers, Processors

DHS-FDB has conducted 24 follow-up inspections of central California almond firms. Two inspected firms were processors, three were handlers and 19 were huller/shellers. These facilities were inspected for compliance with California law. Numerous violations were observed in these facilities. Lack of cleaning and sanitation and the failure to register as a food processor were frequent observations.

Outbreak Timeline

April 12, 2001 - The CFIA issued a public warning not to consume California Natural Supreme Almonds (Whole, Unroasted) sold in bulk at Bulk Barn stores in Ontario, New Brunswick and Nova Scotia. The almonds were noted as having been imported from Hughson Nut Company in California. The warning stated the almonds may be contaminated with *Salmonella* bacteria. Bulk Barn initiates a voluntary recall of this product from all stores (see Attachment 51).

April 16, 19, and 20, 2001 – The Almond Board of California (a grower enacted federal marketing order, under USDA jurisdiction) issued “Handler Alerts” (see Attachments 52, 53, 54).

April 24, 2001 –Hughson Nut Company ceased processing, packing and shipping of almonds.

April 24, 2001 – Inspection of Hughson Nut by DHS-FDB and FDA.

May 7, 2001 – Hughson Nut Company issued a voluntary recall of Natural Whole Brown Almonds lot coded D3214, D3215, D3223, D3227, D3231, D3233, D3236, D3237, D3240, D3248, D3249, D3253, and D3263. This included all raw almonds shipped after February 16, 2001. This voluntary recall was issued to all twenty-three consignees in CA, WI, IL, OH, NJ, MA and Canada, Spain, France, Belgium, and the Netherlands. Hughson requested all consignees to identify and recall any of these products that may still be in commerce. Hughson notified consignees they would be reimbursed by check or credit for all returned goods and freight charges (see Attachment 55). A recall audit was performed by FDA to verify the Hughson recall.

May 18, 2001 - A second warning was issued by CFIA not to consume California or Carmel variety Raw Whole Almonds purchased after March 9, 2001. The almonds with reddish brown skins were said to be potentially contaminated with *Salmonella* bacteria. It listed the almonds as having been imported from Hughson Nut Company in California. The warning stated the product had been voluntarily recalled from the retail level by the importer, BakeMark Ingredients Canada Ltd. (see Attachment 56).

May 22, 2001 – A protocol was set up by Hughson for receiving and sterilizing the returned almonds (see Attachment 57).

July 1, 2001 – Following a C&D and testing to validate the C&D, Hughson resumed packing, shipping and processing almonds.

August 9, 2001 – ABC Handler mass mailing (see Attachment 58)

August 22, 2001 – Amended protocol submitted by Hughson Nut for handling almonds from BHL.

Recommendations

Growers:

1. All growers should implement GAP's, as well as the ABC Food Quality and Safety program.
2. All growers should develop and practice a recall program.
3. All growers should avoid the application of uncomposted manure, biosolids, and primary or secondary treated sewage effluent.

Huller/shellers:

1. WV should continue protocol for handling BHL product as agreed to by WV, DHS-FDB, and FDA.

2. Register under the DHS-FDB Processed Food Registration program. As they are not considered a processor if only hulling only shellers are required to register.
3. Implement the ABC Food Quality and Safety Program.
4. Adhere to the GMP's.
5. Implement written procedures for routine C&D of equipment (preferably between growers).
6. Implement a valid C&D verification program.
7. Develop and implement an ongoing worker food safety training program.
8. Develop and practice a recall program that includes a method for accurately linking farms and fields to outgoing product.
9. Implement an effective pest control program (with monitoring logs).

Handlers/ Processors:

1. Hughson, Triple H and Panoche Creek should continue the protocol for handling BHL product as agreed to by these handlers and DHS-FDB and FDA.
2. Adhere to the federal GMP's.
3. Implement the ABC Food Quality and Safety Program.
4. Implement equipment C&D on a routine basis (preferably between growers, or as frequently as possible).
5. Implement a valid C&D verification program.
6. Develop and implement an ongoing worker food safety training program.
7. Develop and practice a recall program that includes a method for accurately linking farms and fields to outgoing product.
8. Implement an effective pest control program (with monitoring logs).

Almond Board of California:

1. Complete study to establish temperature-death-time curves for inactivation of *Salmonella* by heat
2. Complete study to validate PPO inactivation of *Salmonella* on almonds.
3. Continue ABC Food Quality education/ training efforts.
4. Continue research to identify the cause of the contamination in almonds, the prevalence of *Salmonella* in almonds at the huller/sheller, and geographic magnitude of the contamination.
5. Continue research into other feasible lethal processes.

Attachments

- 01 Firm/Facility Description
- 02 Samples
- 03 Hughson to Bulk Barn Shipments
- 04 Huller/Sheller Identification
- 05 Almond Varieties
- 06 Hughson Pallet Tag
- 07 Hughson Fumigation Tunnels
- 08 Hughson Sizer Room
- 09 Hughson Run Designations
- 10 California Almond Rejection, 1985 to 2000
- 11 USDA Shelled Almond Standards
- 12 Hughson Gravity Table Room
- 13 Hughson E-Sort Room
- 14 Hughson Boxing Room
- 15 Hughson Code Breakdown
- 16 Hughson Plant Layout
- 17 Hughson Almond Process Flow Diagram
- 18 Hughson "Pool Grower" Flow Diagram
- 19 Hughson HACCP plan
- 20 WV
- 21 WV Pre-cleaner
- 22 WV Equipment

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| 23 | WV- Hulls and Shells |
| 24 | WV Plant Layout |
| 25 | WV Product Flow Chart |
| 26 | Location of Growing Area |
| 27 | Baker Farms – Irrigation Filters |
| 28 | Baker Farms – Microsprinkler |
| 29 | Lara Farms – Rainbird type sprinkler |
| 30 | California Regional Water Quality Control Board report, January 26, 1998 |
| 31 | Chemical applications, Implicated Growers |
| 32 | Almond on Tree |
| 33 | Sweeper |
| 34 | Sweeper |
| 35 | Windrow |
| 36 | Growing Area- Longitude/ Latitude |
| 37 | Field Drag Swab Results |
| 38 | Soil Core Samples |
| 39 | Biosolid Testing Results |
| 40 | Hughson Test Methods |
| 41 | Hughson- Baker, Hansen, Lara Protocol |
| 42 | WV C&D Procedures |
| 43 | Almond Hullers and Processors Assoc, Good Manufacturing Practices |
| 44 | Almond Hullers and Processors Assoc, Sheller and Processor Clean Up and Sanitizing Procedure |
| 45 | Baker/ Hansen/ Lara Almond Protocol |
| 46 | Baker Farms Test Results |
| 47 | Lara Farms Test Results |
| 48 | BHL Almond Distribution- 2001 |
| 49 | Panoche Creek Packing- Hansen Almond Status |
| 50 | PPO Data |
| 51 | April 12, 2001 Canadian Health Hazard Alert |
| 52 | April 16, 2001 ABC Handler Alert |
| 53 | April 19, 2001 ABC Handler Alert |
| 54 | April 20, 2001 ABC Handler Alerts |
| 55 | May 7, 2001 Hughson Nut Voluntary Food Recall |
| 56 | May 18, 2001 Canadian Media Release |
| 57 | May 22, 2001 Hughson Recall Protocol |
| 58 | August 9, 2001 ABC Handler Mailing |