

# **Investigation of Caldwell Fresh Foods *Salmonella* Newport Outbreak Associated with Alfalfa Sprouts**

October, 2011

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## Executive Summary

On May 13, 2010, the California Department of Public Health – Infectious Diseases Branch (CDPH–IDB) reported nine cases of *Salmonella* Newport to the California Department of Public Health – Food and Drug Branch (CDPH–FDB). By May 20, 2010, 22 individuals from 10 states: AZ (1), CA (11), CO (1), ID (1), IL (1), MO (1), NM (1), NV (2), OR (1), and WI (2) were identified as cases with matching pulsed field gel electrophoresis (PFGE) pattern to the outbreak strain of *Salmonella* Newport. The PFGE pattern was identified as *Salmonella* Newport 1005SDCJJP-1 (Pulse Net reference # JJPX01.0949).

Epidemiological data revealed that a number of the California cases and at least one of the Oregon cases had exposure to alfalfa sprouts purchased from Trader Joe's or Wal-Mart. A traceback conducted by the Oregon Department of Public Health determined that Trader Joe's only received alfalfa sprouts from one supplier, JH Caldwell and Sons (d.b.a. Caldwell Fresh Foods), Maywood, CA under the brand name Nature's Choice.

On May 20, 2010 CDPH–FDB and the U.S. Food and Drug Administration (FDA) initiated a California Food Emergency Response Team (CalFERT) investigation at Caldwell Fresh Foods in Maywood, CA. CalFERT investigators obtained sprout manufacturing information and collected environmental, product and seed samples. CalFERT investigators also conducted an environmental investigation that focused on alfalfa sprout production.

CalFERT investigators collected 298 samples during the investigation. One hundred seventy-eight samples were collected at Caldwell Fresh Foods; 100 seed samples at Pacific Grain and Foods, Fresno, and 20 retail samples of alfalfa sprouts collected from Trader Joe's stores.

Environmental swabs, sprout products, and germinating seed samples collected at Caldwell Fresh Foods were subsequently analyzed by FDA Pacific Regional Lab Southwest (PRL-SW), Los Angeles, and found to be negative for *Salmonella*. CalFERT investigators also collected 60 alfalfa seed samples at Caldwell Fresh Foods and 100 alfalfa seed samples Pacific Grain and Foods, Fresno. These seed samples were identified as seed lot 269511, supplied by Max Leimgruber, Brawley, CA. The CDPH–Food and Drug Laboratory Branch (CDPH–FDLB) in Richmond, CA analyzed the seeds and found one of the 60 seed samples collected at Caldwell Fresh Foods and five of the 100 seed samples collected at Pacific Grain and Foods to have matching PFGE patterns to that of the outbreak *Salmonella* Newport strain. Records obtained from Max Leimgruber indicated that alfalfa seeds (lot 269511) were also sold to New World Produce in Austin, TX. A seed sample collected by FDA at New World Produce was found to be positive for *Salmonella* Newport and had indistinguishable PFGE pattern to that of the outbreak strain.

## Background Information

In May 2010 a foodborne outbreak of *Salmonella* Newport was epidemiologically linked to alfalfa sprouts produced by Caldwell Fresh Foods. As of June 17, 2010, 42 persons were sickened in 11 states (AZ, CA, CO, ID, IL, MO, NM, NV, OR, WI, and PA). No deaths were reported.

Caldwell Fresh Foods disseminated a recall press release on May 21, 2010 (Attachment 1) for all alfalfa sprouts produced and distributed by the facility. Records obtained from Caldwell Fresh Foods for the product indicated the alfalfa sprouts were produced from one seed lot (lot 269511) sold by Max Leimgruber, Brawley, CA. This same seed lot was sold to New World Produce, Austin, TX and Pacific Grain and Foods, Fresno, CA. New World Produce processed sprouts from this lot. Pacific Grain and Foods had not further distributed the seeds.

Seed samples collected by CalFERT investigators from Pacific Grain and Foods and Caldwell Fresh Foods were found to be positive for *Salmonella* Newport and had indistinguishable PFGE patterns to that of the outbreak strain (Attachment 2). Seed samples collected by FDA from New World Produce were found to be positive for *Salmonella* Newport and had indistinguishable PFGE patterns to that of the outbreak strain.

## Traceback

In May, 2010, CalFERT investigators initiated a traceback based on the epidemiological information supplied by CDPH–IDB. Trader Joe’s was the most common source of alfalfa sprouts identified during case interviews. Therefore, investigators focused the traceback on the CA cases who only bought sprouts at Trader Joe’s stores. Information obtained from this case group established the first onset date of illness during the last week of March 2010 and the last onset date on April 28, 2010.

Trader Joe’s provided CalFERT investigators with invoices documenting the movement of alfalfa sprouts from Caldwell to Trader Joe’s distribution centers located in Stockton, CA and Fontana, CA (Attachment 3 & 4). The Stockton distribution center supplied Trader Joe’s stores in Fair Oaks and Pleasanton; whereas, the Fontana distribution center supplied the Brea and La Mesa Trader Joe’s stores. A representative of Trader Joe’s confirmed that Caldwell was their only supplier of alfalfa sprouts during the implicated time period. Trader Joe’s also provided investigators with a computer generated spreadsheet which documented the distribution of alfalfa sprouts from the distribution centers to the Trader Joe’s stores involved in the traceback between 3/15/2010 to 4/30/2010 (Attachment 5). The traceback verified Caldwell sprouts were the only sprouts available at the specified Trader Joe’s stores during the implicated time period.

## Environmental Investigation

### J.H. Caldwell and Sons

dba: Caldwell Fresh Foods  
4035 East 52<sup>nd</sup> Street  
Maywood, CA 90270  
(323) 589-4008

### Company Profile

Caldwell Fresh Foods manufactures and distributes alfalfa sprouts and fresh-cut produce for fajita and stir-fry mixes. The produce mixes contain: bell peppers, carrots, onions, celery, and bok choy. Production of the produce mixes occurs in separate processing rooms with minimal opportunity for contact with the alfalfa products. Caldwell distributes alfalfa sprouts to 25 customers in California (Attachment 6 - Exhibit N). Caldwell Fresh Foods is also a contract manufacturer of sprouts and fresh cut products for [REDACTED] and Trader Joe's.

On May 20, 2010, CalFERT Investigators were deployed to Caldwell Fresh Foods to collect environmental, product and seed samples related to the *Salmonella* Newport outbreak. Maurie Thomas, General Manager; Steve Knight, HACCP Coordinator; and Luz Martinez, Office Manager were present at the facility during the investigation. Investigators observed the processing of alfalfa, clover, and broccoli sprouts, and collected documents related to the suspect lot of alfalfa seed (lot #269511). Sprout seeds received from International Specialty Supply, Cookeville, TN were used intermittently, but the inventory of these seeds had been expended by the date of investigation.

### Alfalfa Sprout Production

CalFERT investigators conducted an inspection at the Caldwell Fresh Foods facility (Attachment 6). All alfalfa seeds were held in a dry storage area at ambient temperature prior to sprouting. The firm utilized footbaths containing a [REDACTED] parts-per-million (ppm) quaternary ammonia solution at the entrance of each processing room. CalFERT investigators measured the footbath at the entrance to the alfalfa processing room and found it to be greater than 200 ppm quaternary ammonia (QAC QR Test Strips).

The firm was growing two types of alfalfa sprouts; washed/ready-to-eat and living sprouts, at the time of the inspection. The sprout growing room consisted of [REDACTED] growing drums containing four compartments and misting heads in each drum. The firm stated they did not mix different seed lots while growing. However, investigators observed that alfalfa sprouts were germinating in 3 compartments of the drums, and clover sprouts in the 4th compartment of the same drum.

The firm maintained a seed sanitizing protocol (Attachment 6 – Exhibit A) and demonstrated the sanitizing procedure at the time of inspection. The procedure included a guidance chart to ensure the correct concentration of the seed sanitizer mixture that included: calcium hypochlorite (manufactured by [REDACTED]), municipal water, and seeds. Seed sanitizing records were documented daily (Attachment 6 – Exhibit G) and records of verification maintained (Attachment 6 – Exhibit C). These records were reviewed by investigators to verify that Sanitation Standard Operating Procedures (SSOP's) were being implemented properly. The firm verified their concentration with a 1:200 dilution ratio. A reading of 100ppm on a test strip was equivalent to 20,000 ppm solution (Attachment 6 – Exhibit B). This procedure is consistent with the FDA guidelines for sprout seed sanitation.

Seeds were soaked for 15 minutes in 20,000 ppm calcium hypochlorite, rinsed with municipal water, placed in a plastic bin, and transferred into the compartments within the growing drum. While in the drum, the seeds were misted with municipal water every [REDACTED] minutes. Growing drums continuously turned in a clockwise direction at a slow revolution. The water that drains from the drums is categorized as “spent irrigation water.”

After [REDACTED] hours of germination, Caldwell Fresh Foods employees collect [REDACTED] quarts of irrigation spent water from the drums into a sterile plastic bag for pathogen testing (Attachment 6 – Exhibit D). Irrigation water from several drums was mixed together. This practice was done on a rotating schedule for each of the drums throughout the growing process. [REDACTED] Laboratories in Commerce, CA picks-up the sample within 1 to 2 hours of collection. Caldwell Fresh Foods maintains a “Hold and Release” program that restricts the release of products until test results are received from the laboratory (Attachment 6 – Exhibit E). The test results of the irrigation spent water within the implicated time frame were negative for *Salmonella* and *E. coli* (Attachment 6 – Exhibit K).

The firm utilized a monthly environmental swabbing program for bags, growing trays, and processing tables. In addition, empty sprout cups are also swabbed monthly. Pacific Coast Analytical Services, Sylmar, CA performs the analysis of the environmental testing on a rotating monthly schedule (Attachment 6 – Exhibit L). The master sanitation schedule and daily sanitation records dating back to February 15, 2010 (Attachment 6 – Exhibit M) were reviewed by investigators. There were no sanitation deficiencies identified.

CalFERT investigators reviewed invoices and records for seed lots used for sprout production since February 15, 2010. The firm received alfalfa seed lot # SACG from International Specialty Supply, Cookeville, TN on November 5, 2009 (Attachment 6 – Exhibit I) and alfalfa seed lot# 269511 from Max Leimgruber, Holtville, CA on January 7, 2010 (Attachment 6 – Exhibit J). The table below summarizes the information from seed sanitizing records of the two alfalfa sprout seed lots that were used.

	<b>Seed Lot # SACG</b>	<b>Seed Lot # 269511</b>
Purchased:	11/05/09	01/07/10
1 <sup>st</sup> Sanitized:	11/17/09	01/25/10
Last used:	05/10/10	05/20/10
<b>Seed Sanitizing Dates:</b>		
February 2010	15,19-22 and 24-28	None used
March 2010	1	3-8,10-12,14,15,17-22, 24-29 and 31
April 2010	16-19,22-26,29 and 30	1-5,7,9-12,14 and15
May 2010	1-3 and 5-10	12 - 20

On May 21, 2010, investigators conducted a follow-up inspection at the Caldwell Fresh Foods facility. Investigators observed the firm manually scrubbing food contact surfaces and drums with industrial strength foam detergent, followed by rinsing, and acid-quat sanitizer. The sprout production room was shut down and no further production was being conducted. Environmental swab samples were submitted to [REDACTED] after the firm fully cleaned and sanitized the plant. Production was scheduled to begin with a new seed lot (lot unknown) after environmental sampling results were received with a negative result.

### **Max Leimgruber Seeds**

798 Vencill Road  
Holtville, CA92250  
(760) 356-2472

Max Leimgruber conducts business as a seed broker and does not grow or mill seeds. The implicated alfalfa seed (lot 269511) was grown by Dan Mar Farms, Brawley, CA. Dan Mar Farms provided seed from lot 269511 to K-F Seeds, Brawley, CA for cleaning and milling. Information received from Dan Mar Farms indicates the effected seeds were intended for agricultural purposes. However, Mr. Leimgruber subsequently bought the implicated seeds from Dan Mar Farms after they were milled and packaged into 50 lb. bags by K-F Seeds (Attachment 6 – Exhibit J). Mr. Leimgruber arranged for the milled seeds to be picked up and delivered directly to the shipper who transported them to Caldwell Fresh Foods, Pacific Food and Grain, and New World Produce. All other alfalfa seed from lot 69511 produced by Dan Mar Farms was sold for agricultural purposes.

### **Alfalfa Sprout and Environmental Sampling**

#### **Trader Joe’s Retail Stores**

Initial reports indicated Nature’s Choice sprouts had been consumed by some of the identified cases. On May 18, 2010 CalFERT investigators collected 20 surveillance samples of Nature’s Choice alfalfa sprouts packaged in 4 oz. cups. The sprouts contained Use by Dates of 5/26/10 and 5/27/10. Nature’s Choice is the brand used by

Caldwell Fresh Foods for Trader Joe's. Five sprout samples were collected from 4 different Southern California Trader Joe's. The samples were analyzed by CDPH-FDLB and found to be negative for *Salmonella* (Attachment 7).

### **Caldwell Fresh Foods, Los Angeles**

On May 20, 2010 CalFERT investigators collected 118 samples in the sprout processing room at the Caldwell Fresh Foods facility. All samples were collected aseptically. The samples consisted of environmental sponge swabs (51), spent irrigation water (3), finished product (32), and in-process product (32). All samples were analyzed by the FDA, PRL-SW, Los Angeles LOSDO laboratory and found to be negative for *Salmonella* (Attachment 8).

On May 26, 2010 CalFERT investigators aseptically collected 60 one-pound samples of alfalfa seed identified as lot 269511. The samples were collected from 16 bags (50 lbs bags) of embargoed seed. FDLB analyzed the samples and found one sample to be positive for *Salmonella* Newport with an indistinguishable PFGE pattern to that of the outbreak strain (Attachment 2). Alfalfa seeds, lot 269511, were supplied to Caldwell Fresh Foods by Max Leimgruber.

### **Pacific Grain and Foods, Fresno**

On June 8, 2010, 100 – 1 lb. bags of alfalfa seed, identified as lot 269511, were collected from Pacific Grain and Foods. This alfalfa seed lot (269511) was identified as being used at Caldwell Fresh Foods during the case exposure time frame and supplied to Pacific Grain and Foods by Max Leimgruber (Attachment 9). Five of the 100 seed samples tested positive for *Salmonella* Newport and had an indistinguishable PFGE pattern to that of the outbreak strain (Attachment 2).

### **CDPH-FDB Regulatory Action**

CalFERT investigators conducted inspections, placed products under embargo, witnessed Voluntary Condemnation and Destruction (VC&D) of product, and alfalfa seed sampling during this investigation.

### **Embargoes**

On May 20, 2010, 800 lbs. of alfalfa seeds (lot 269511) and all alfalfa sprout products manufactured, packaged, and held at Caldwell Fresh Foods were embargoed (Attachment 10). On May 27, 2010, 4,000 lbs. of alfalfa seeds (lot 269511) held at K-F Seeds, Brawley, CA, were embargoed (Attachment 11). On June 8, 2010 2,000 lbs. of alfalfa seeds (lot 269511) held at Pacific Grain and Foods was embargoed (Attachment 12).

## **Voluntary Condemnation and Destruction (VC&D)**

On May 21, 2010, CalFERT investigators observed the Voluntary Destruction and Condemnation (VCD) of all embargoed alfalfa sprouts held at Caldwell Fresh Foods. In-progress sprout products were destroyed at the facility in the dumpster and denatured with bleach. Finished products were loaded into the Caldwell Fresh Foods delivery truck. A CalFERT investigator followed the truck to [REDACTED] in Vernon, CA where the product was destroyed under CDPH supervision (Attachment 13).

## **Product Recall**

On May, 20, 2010, CalFERT discussed and received verification from Caldwell Fresh Foods of their intention to recall all fresh sprout products produced prior to May 21, 2010 from the marketplace. The formal recall was publically announced on May 21, 2010, and CDPH followed up the announcement with the issuance of a public advisory the same day. The recalled products included Nature's Choice, Caldwell Fresh Foods, California Fresh Exotics, brand sprouts produced by Caldwell Fresh Foods. During the investigation, CDPH investigators conducted a traceforward of all affected products distributed by Caldwell Fresh Foods.

## **Conclusion**

During March and April, 2010, Caldwell and Sons produced alfalfa sprouts from seed received from both International Specialty Supply (ISS) and Max Leimgruber. Illnesses occurred during periods in which sprout products produced from both seed lots were available to consumers and during periods when the ISS and Leimgruber sprouts were the only product available due to reasonable shelf life considerations. Unopened samples of Leimgruber seeds obtained from Caldwell and Sons and Pacific Grain, had indistinguishable PFGE patterns from the outbreak strain of *Salmonella* Newport. ISS seeds had been expended and were not available for analysis.

Of the 298 total samples collected by CalFERT investigators 6 seed samples tested positive for *Salmonella* Newport and had an indistinguishable PFGE pattern to that of the outbreak strain (Pulse Net reference # JJPX01.0949). Seed samples were collected from unopened bags of alfalfa seed lot 269511. All of the positive seed samples were sold and distributed by Max Leimgruber, Brawley, CA.

Caldwell Fresh Foods was observed in compliance with GMPs standards and was conducting operations in accordance with FDA's "Guidance for Industry: Reducing Microbial Food Safety Hazards For Sprouted Seeds." CalFERT investigators found no GMPs violations or unsanitary conditions related to sprout production at Caldwell Fresh Foods during the course of the investigation.

## Attachments

1. FDA Press Release May 21, 2010
2. CDPH Lab Results of Seed Samples Collected at Caldwell Fresh Foods and Pacific Grain and Foods
3. Invoices from Caldwell to Trader Joe's Distribution Centers in Fontana, CA for the Period of March 1, 2010 to April 30, 2010
4. Invoices from Caldwell to Trader Joe's Distribution Centers in Stockton, CA for the Period of March 1, 2010 to April 30, 2010
5. Distribution Records of Alfalfa Sprouts from Distribution Centers to Trader Joe's Stores in La Mesa, Brea, Pleasanton, and Fair Oaks for the Period of March 15, 2010 to April 30, 2010
  
6. JH Caldwell and Sons CDPH Inspection Report
  - Exhibit A: Caldwell Seed Sanitizing Procedures
  - Exhibit B: Caldwell Calcium Hypochlorite Solution Testing Procedures
  - Exhibit C: Caldwell Sprout Seed Wash Verification Records
  - Exhibit D: Caldwell Sampling Procedures for Alfalfa Sprout Irrigation Water
  - Exhibit E: Caldwell Alfalfa Sprout Hold and Release Policy
  - Exhibit G: Caldwell Alfalfa Seed Sanitizing Records
  - Exhibit I: International Specialty Supply Invoices
  - Exhibit J: Max Leimgruber Invoices
  - Exhibit K: Caldwell Irrigation Water Testing Results (Oct 2009 to May, 2010)
  - Exhibit L: Caldwell Environmental Testing Procedures and Results
  - Exhibit M: Caldwell Master Sanitation Schedule
  - Exhibit N: Caldwell Customer Distribution List
  
7. CDPH Lab Results of the Alfalfa Sprouts Collected at Trader Joes Stores
8. Emails Documenting the Caldwell Sample Collection and Laboratory Results

9. Bill of Ladings of Seeds from Max Leimgruber to Pacific Grain and Foods
10. Embargo Notice: Caldwell Fresh Foods 5/20/2010
11. Embargo Notice: K-F Seeds 5/27/2010
12. Embargo Notice: Pacific Grain and Foods 6/8/2010
13. VC&D: Caldwell Fresh Foods 5/21/2010