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December 22, 2010

To: The Record

From: Emergency Response Unit

Re: **Investigation of Union International Food Company *Salmonella* Rissen  
Outbreak Associated with White Pepper**

The Food and Drug Branch is providing the following report of  
an investigation conducted by the Emergency Response Unit.

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**Investigation of Union International Food Company *Salmonella*  
Rissen Outbreak Associated with White Pepper**

December 2010

Prepared by: The California Department of Public Health Food and Drug Branch  
Emergency Response Team

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## Executive Summary

As of June 4, 2009, a total of 87 individuals had been sickened in five states (CA, NV, OR, WA, and ID) with *Salmonella* Rissen (a rare serotype) associated with consuming pepper products manufactured by Union International Food Co. (UIFC), Union City, CA. Sixty-five of these individuals became sick in California. Illness onset dates ranged from December 9, 2008 to April 29, 2009. An investigation by the California Food Emergency Response Team (CalFERT) directly linked UIFC to the multi-state outbreak.

On March 27, 2009, the Oregon Public Health Division reported isolating *Salmonella* Rissen from pepper samples collected from Zien Hong Restaurant in Oregon where a case (i.e. a sickened individual identified in the outbreak) had eaten. The samples were collected from opened containers of Lian How Ground White Pepper and Lian How Ground Black Pepper. The labels on these products identified UIFC as the manufacturer. These samples were subsequently determined to match the outbreak strain (CDC Pulse Net reference # TEEX01.0014) using Pulse Field Gel Electrophoresis (PFGE). *Salmonella* Rissen was also isolated from pepper samples collected from restaurants in WA and NV that identified UIFC as the manufacturer. A sample of ground, Uncle Chen Brand White Pepper (a UIFC retail product) collected at a market in Kent, WA was also found to contain indistinguishable PFGE patterns to that of the outbreak strain.

The California Food Emergency Response Team (CalFERT) comprised of staff from both U. S. Food and Drug Administration (FDA) and California Department of Public Health (CDPH) initiated an investigation on March 27, 2009. CalFERT investigators collected environmental and product samples, firm manufacturing information, and reviewed product processing and shipping documentation. At the same time, CDPH-FDB investigators conducted an inspection at the facility to determine compliance with Good Manufacturing Practices (GMP).

A total of 391 product and environmental samples were collected at UIFC. Sixty-three (16%) of these samples were positive for *Salmonella*. Twenty-five of the 63 samples (40%) were further tested and found positive for *Salmonella* Rissen and had indistinguishable PFGE patterns to that of the outbreak strain. Ground white pepper and whole white pepper seeds collected from intact and/or in-process containers were the only products collected from the UIFC facility that were a PFGE match to the *Salmonella* Rissen outbreak strain.

## Background Information

In mid-March 2009, the California Department of Public Health (CDPH) Infectious Disease Branch (IDB) learned of a multi-state *Salmonella* Rissen outbreak. Public health officials in the effected states were collecting and analyzing data to determine a common source that may have led to these illnesses. The foodborne outbreak of *Salmonella* Rissen was linked to UIFC Lian How brand white pepper. As of March 27, 2009, when CalFERT initiated its investigation, 42 persons were sickened: California (33), Nevada (4), Oregon (4), and WA (1). No deaths were reported at that time.

On March 28, 2009 CDPH issued its first press release warning consumers about potentially contaminated UIFC products (Attachment 2). UIFC issued its first press release on March 30, 2009 (Attachment 3) which included recall of white and black pepper and 10 other spices. UIFC issued subsequent press releases that included all products processed at the Union City facility (Attachment 3). CDPH also issued subsequent press releases to include products identified in UIFC's expanded recalls (Attachment 4).

Epidemiological work for the outbreak was conducted by CDPH-IDB. At the conclusion of the epidemiological investigation in June 2009, there were 87 total cases: California (65), NV (10), OR (8), WA (3), ID (1). One death was linked with this outbreak.

## **Retail Tracebacks**

### ***Oregon***

On March 20, 2009, Oregon Public Health Division sampled previously opened 5 lb containers of Lian How White Ground Pepper and Lian How Black Ground Pepper obtained from Zien Hong Restaurant, Portland. A case had reported eating at this restaurant prior to illness. On March 26, 2009, Oregon Public Health Laboratory (OPHL) reported that both of these samples tested positive for *Salmonella* Rissen.

On April 2, 2009, FDA investigators collected Lian How White Ground Pepper and Lian How Black Ground Pepper from intact, previously unopened containers at Zien Hong restaurant (Attachment 5). Pepper from both these containers was used to fill shakers that were placed on customers' tables. Analysis of the white pepper samples lead to the isolation of *Salmonella* Rissen. The black pepper tested negative for *Salmonella*. The Lian How labeling identified UIFC as the pepper manufacturer. The positive white pepper sample was later determined to have indistinguishable PFGE patterns to that of the outbreak strain (Attachment 6).

CalFERT investigators conducted a traceback investigation and determined that the pepper sampled from Zien Hong was from UIFC. Zien Hong invoice [REDACTED] dated March 13, 2009, showed the purchase of Lian How White and Black pepper from Jinhay Trading Corp., Portland, OR (Attachment 7). Invoice [REDACTED] shows the sale of white and black pepper from UIFC to Jinhay Trading Co. (Attachment 8). UIFC Sales Journal shows Jinhay Trading Co. receiving 20 cases (#6 – 5 lb) of White Pepper (Attachment 9).

### ***Nevada***

On March 11, 2009, health staff from Washoe County District Health Department, Reno, NV, collected Lian How White Ground Pepper and Lian How Black Ground Pepper from previously opened 5 lb jugs at the Grand Sierra Resort, Reno, NV (Attachment 10). At the time of the sample collection, four cases had recalled eating at the Grand Sierra Resort before onset of their illnesses. Laboratory analysis indicated that the white

pepper sample had an indistinguishable PFGE pattern to that of the outbreak strain (Attachment 11). The black pepper sample tested negative for *Salmonella*. SYSCO invoice numbers [REDACTED] and [REDACTED] show shipments of Lian How White Pepper 5 lb jugs to Grand Sierra Resort, NV (Attachment 12). UIFC Invoice numbers [REDACTED] and [REDACTED] collected from UIFC document the sale of cases of white pepper to SYSCO (Attachment 13). UIFC Sales Journal for January 1, 2008 – March 30, 2009, lists numerous shipments of Lian How White Pepper in 5 lb jugs to SYSCO, Pleasant Grove, CA (Attachment 14).

## **Washington**

On April 1, 2009, investigators from the FDA Seattle District Office (SEA-DO) collected a retail sample (consisting of 6-5 oz closed containers) of Uncle Chen ground white pepper from 99 Ranch Market, 18230 E. Valley Hwy, Kent, WA (Attachment 15). This sample tested positive for the *Salmonella* Rissen Group C1 (Attachment 16). This isolate was further tested and found to have indistinguishable PFGE patterns to those of the outbreak strain (Attachment 6). Documents collected from 99 Ranch Market by FDA investigators showed the purchase of white pepper from UIFC (Invoice [REDACTED] dated 11/4/2008 - Attachment 15). UIFC Sales Journal shows the sale of one case (24/5 oz) of Uncle Chen 5 oz containers of white pepper to 99 Ranch Market on 11/04/2008 (Attachment 17).

## **White Pepper Seed Traceback**

Since 2007, UIFC had purchased whole white pepper seed and ground white pepper from two sources; Pax Spices and Labs Inc., Baldwin Park, CA and Harris Freeman & Co., Anaheim, CA (Attachment 18). At the time of this investigation, whole white pepper seed Lot HFV 173H-VWP was being ground at UIFC (Attachment 19). Lot HFV 173H-VWP was supplied to UIFC by Harris Freeman & Co., Inc., Anaheim, CA (Attachment 20). This lot was shipped from the Port of Oakland to UIFC on August 18, 2008. The shipment originated from Vietnam and was labeled on the 50 kg bags as “Steam Washed”. A Certificate of Analysis (COA) supplied by Harris Freeman Vietnam Co., Ltd., Quality Assurance Department, located in Dong Nai Province, Vietnam indicated this lot of white pepper seed tested negative for *Salmonella* (Attachment 20).

Bags of Lot HFV 276H-VWP were also in the UIFC facility at the time of this investigation, but were intact and had not been processed (Attachment 21). This lot was shipped from the Port of Oakland on January 13, 2009 to UIFC brokered through Harris Freeman & Co., Inc. A COA supplied by Harris Freeman Vietnam Co., Ltd., Quality Assurance Department located in Dong Nai Province, Vietnam indicated this lot of white pepper seeds tested negative for *Salmonella* (Attachment 21).

UIFC did not keep processing records for the grinding of whole white pepper seed; therefore, the firm was unable to identify specific lots of whole white pepper seed to the ground white pepper product. CalFERT investigators found 10 of the 400 bags (50 kg each) remaining from Lot HFV 173H-VWP. Investigators determined that Lot HFV 173H-VWP was most likely the lot of whole white pepper seed that produced the ground

white pepper related to this outbreak because this seed lot was; 1) received in August 2008 and 2) the white pepper seed the firm had been grinding and shipping for months prior and up to the outbreak.

FDB sample 061040709-A53 collected from an unopened bag of whole white pepper seed (Lot 173H-VWP) was submitted to Food and Drug Laboratory Branch (FDLB). The sample was analyzed and found positive for *Salmonella* Rissen and had indistinguishable PFGE patterns to that of the outbreak strain (Attachment 22). All seed samples were collected using aseptic sampling techniques. For each bag sampled, investigators wore a new pair of sterile gloves, used a new sterile scoop, and did not touch the outside of the seed bag when collecting the sample. All samples were collected by investigators trained in aseptic sampling techniques. Numerous in-process ground white pepper from this seed lot also tested positive for the outbreak strain as described in the "Environmental Investigation" section of this report.

UIFC received other shipments of ground white pepper and whole white pepper seed in 2007 and 2008. However, these shipments were not within the timeframe of case exposures and onset dates, and were determined to be unrelated to the outbreak. Moreover, there was no evidence of these products at UIFC facility during the time of this investigation.

## **Environmental Investigation**

UF Union International Food Company (UIFC)



### ***Company Profile***

CalFERT investigators were first deployed to UIFC on March 27, 2009. Mr. Daniel Y. Chen, Vice President and Manager and his wife Pei-Ling Huang, Chief Financial Officer and Secretary were the most responsible persons at the facility and worked with the investigators throughout the five month investigation. [REDACTED]

[REDACTED] Fremont, CA was hired as a consultant and worked closely with FDB-ERU staff throughout the investigation.

The primary focus of the CalFERT environmental investigation revolved around white pepper operations and overall sanitation of the facility. The FDB-Food Safety Inspection Unit (FSIU) staff reviewed and observed the processing of oils and sauces and the repackaging of dry spices at the facility as well.

The firm employed seven people, who supported the firms manufacturing and repackaging operations that included shelf-stable sauces, edible oils, spices, nuts, dried foods, and teas. The dry spices and sauces were under the brand names of "Uncle Chen" and "Lian How" (Attachment 23). The products were either repackaged from larger containers to smaller containers or processed (white pepper seed grinding) on-site using a variety of mixing and packaging machinery. The edible oils (including;

sesame oil, soybean oil, and various blends of the two) were blended and bottled on-site. The spices and nuts were repackaged on-site from larger to smaller containers. Dried food products and teas were warehoused and distributed from this location. UIFC distributed products for wholesale and retail use throughout the western United States.

Attachment 24 is a diagram of the [REDACTED] sq. ft UIFC facility consisting of offices, restrooms, warehouse areas, sauce mixing room (Room [REDACTED]), white pepper grinding room (Room [REDACTED]), sauce/oil room (Room [REDACTED]), spice re-packaging area, and a room that served both as a warehouse and sauce fermenting room (Room [REDACTED]). Room [REDACTED], located at [REDACTED] in Union City, was unknown to FDB investigators until April 21, 2010. Prior to the discovery of Room [REDACTED] which was adjacent to the main warehouse, Mr. Chen had repeatedly told FDB investigators that his facility consisted of the main warehouse and Rooms [REDACTED] and [REDACTED] located at [REDACTED] in Union City.

Overall, the firm's sanitation and operational procedures were observed to be inadequate for the sanitary production of food. CalFERT investigators observed white pepper dust in all of the processing and mixing rooms, and on equipment. Pepper dust was also evident in the warehouse area, including; pallets, bulk containers and heating ducts located just below the ceiling.

### ***Dry Spice Re-packaging***

UIFC used two label brands for their re-packaged dry spices, Lian How and Uncle Chen. Generally, the Lian How brand was for wholesale packaging in sizes of 5–30 lbs. The Uncle Chen brand was packaged in smaller retail 5 oz sizes with the exception of Uncle Chen 5 and 10 lb plastic bags of ground white pepper. UIFC used plastic containers or plastic bags (heat sealed) for packaging the dry spices (Attachment 23). UIFC also co-packed dried spices for other companies.

Dry spices were re-packed by hand (Attachment 25) in a hallway that was located behind the wall of Room [REDACTED] and adjacent to the warehouse. Plastic strip curtains hung from the doorways of Rooms [REDACTED]. CalFERT investigators found these curtains to be unsanitary in that they were coated with dirt, pepper dust, and an accumulation of filth. Repackaging of dry spices involved the transfer of product with a stainless steel scoop from the bulk container to another container resting on a scale. A cardboard funnel (not a smooth and easily cleanable surface) was used to direct spices into the container. Once filled, an employee either placed a screw-top lid on the plastic container or heat-sealed a plastic bag containing the product. The plastic containers did not have a tamper proof lid or a seal underneath the lid.

CalFERT investigators found the spice repackaging area and equipment used for re-packaging to be in unsanitary condition. For example, a heavy accumulation of white pepper dust was observed on all equipment in the pepper grinding room. The firm also stored ground white pepper in un-lined cardboard drums. These and other GMP violations were noted on the Notice of Violations (NOVs) issued by FDB-FSIU staff (Attachment 26). Mr. Chen stated that he did not have written or other formally understood Standard Operating Procedures (SOPs) or Sanitation Standard Operation

Procedures (SSOPs) for the dry spice repackaging operations or any other operations at the facility.

CalFERT investigators observed the repackaging area in an unclean and unsanitary condition. Spice dust (primarily white pepper dust) was on the table, scales, walls, telephone, scoops, and floor. Mr. Chen stated that the stainless steel scoops used to re-package spices were washed and sanitized once daily and not between different products or different lots of products. Mr. Chen explained the sanitation process for the dry spice repackaging scoops as follows: scoops were washed in the stainless steel sink in Room [REDACTED] (sauce mixing room) with [REDACTED] (a sanitizer) and water after all re-packing was completed for the day. Mr. Chen stated that he did not know the target concentration for the sanitizer or the sanitizer strength when mixed. The funnel used when filling the 5 lb plastic jugs was made of cardboard and therefore was made of material that could not be properly sanitized. The scale used for weighing the bulk spices for repackaging contained an accumulation of spice debris and did not appear to be cleaned on a regular basis. The above GMP deficiencies were noted on the NOVs.

### ***White Pepper Grinding***

White pepper was the only spice ground at UIFC. Room [REDACTED] was designated as the grinding room for white pepper. Bulk bags of white pepper seed were dumped into a hopper, transferred to the grinder, and then sent to another hopper before being deposited into round cardboard drums. The grinder provided three different meshes of grind, each with a separate exit chute. CalFERT investigators observed ground pepper in unlined and unlabeled drums. Labels on drums indicated that they had previously contained other spices (e.g. Tenderized Unseasoned), therefore presenting the possibility of cross-contamination (Attachment 27). Drums containing ground white pepper were also observed uncovered in Room [REDACTED]. Room [REDACTED] did not have a ventilation system, exhaust fans, or any means to reduce levels of pepper dust or prevent the spread of pepper dust to other areas of the facility. Air vents in the ceiling of Room [REDACTED] did not have screens and thus exposed uncovered product to the outside environment.

CalFERT investigators observed Room [REDACTED] to have a large accumulation of pepper dust on equipment, floors, ladders, conduits, and walls (Attachment 28). Mr. Chen stated that he did not keep records for lots of white pepper ground nor was the grinding equipment cleaned and sanitized between lots of pepper seed. Mr. Chen stated that white pepper had not been ground for a couple of weeks. Mr. Chen stated that he did not have SOPs or SSOPs for processes, equipment, and sanitation related to white pepper grinding operations. Due to the lack of ventilation, exhaust fans, and regular cleaning, the entire facility (with the exception of the front offices) was observed to contain layers of white pepper dust.

The sink and drains of Room [REDACTED] were completely dry and covered with white pepper dust. At one point, Mr. Chen stated that Room [REDACTED] was sprayed with hot water, but later stated that the only water used in the room was when the floor was mopped. The layers of white pepper dust in Room [REDACTED] and the fact that Mr. Chen said there had been no grinding of pepper for a couple of weeks were evidence that Room [REDACTED] was not being cleaned and sanitized on a regular basis.

## Samples and Results

The table below summarizes test results for samples collected at UIFC by CalFERT investigators and analyzed at either the FDLB or the US FDA San Francisco District Office (SAN-DO) lab.

Table 1: Summary of Samples and Analytical Results

<u>Testing Labs</u>	Total # Samples	Total # Environmental Samples	Total # White Pepper Seed	Total # White Pepper Ground	Total # Black Pepper Ground	Total # All Other Samples
<b>FDLB &amp; SAN-DO</b>	391	116	104	20	53	98
<b>Total # positive for <i>Salmonella</i> (Poly B or C-1)</b>	63	46	1	16	0	0
<b>Total # Samples tested for <i>S. Rissen</i> Outbreak Strain</b>	25	19	1	5	0	0
<b>Total # Matched for <i>S. Rissen</i> Outbreak Strain</b>	25	19	1	5	0	0

Between March 27 and April 7, 2009 CalFERT investigators aseptically collected 391 environmental, raw ingredient, in-process, and finished product samples at UIFC (Attachment 22). Environmental samples were collected (using neutralizing sponge swabs) from walls, floors, and equipment. In-process and finished product samples were collected either in their original containers or collected in sterile whirl-pak bags using sterile plastic scoops.

A total of 63 samples collected by CalFERT at UIFC tested positive for *Salmonella* (Table 1). Twenty-five of these *Salmonella* samples (40%) were further tested for the outbreak strain, *Salmonella* Rissen. All 25 samples (100%) tested positive for *Salmonella* Rissen and were a PFGE match to the outbreak strain, TEEX01.0014. These samples were collected from the dry spice re-package area, in-process products, raw ingredients, and on equipment and structures in the sauce and grinding rooms.

93 of the 391 samples collected by CalFERT investigators were from Room [REDACTED] (white pepper grinding room), the spice repacking area, restrooms, and sauce mixing room on March 27-28, 2009 (Attachment 22). Fifty-five (59%) of these samples were positive for *Salmonella*, 22 of these were further tested and all 22 (100%) had indistinguishable PFGE patterns to that of the *Salmonella* Rissen outbreak strain.

The following is a list of some of the sample locations or products collected that yielded positive *Salmonella* Rissen results:

#### Room 2

- white pepper seed hopper
- white pepper seed elevator
- in-process ground white pepper in cardboard bins
- the shovel used to move ground white pepper
- the equipment control panel
- the roof support pole
- the ribbon mixer used to mix wasabi powder

#### Warehouse

- Lian How ground white pepper in 5 lb jug (unopened) in Warehouse
- Uncle Chen white ground pepper in 5 lb plastic bag (unopened)

#### Hallway in front of Room 3

- the floor underneath the dry spice packing table

In addition, 2 environmental samples collected from the paper funnel used to fill the 5 lb jugs and a sample from the scale in the dry spice packaging area tested positive for *Salmonella* Serogroup C1, but were not further analyzed for serotype or PFGE. For this investigation, all Serogroup C1 samples that were further analyzed were determined to be *Salmonella* Rissen with indistinguishable PFGE matches to that of the outbreak strain.

Samples collected from inside and outside the ribbon mixer in Room [REDACTED] tested positive for *Salmonella*. Mr. Chen did not have any logs showing what products were processed in this mixer or the last time it was used for processing. Wasabi powder was mixed by the firm, but investigators were unable to determine which mixer was used to blend the spices to make the wasabi powder. This ribbon mixer was identified as a potential source of cross contamination to other products with *Salmonella*.

CalFERT investigators also collected 12 raw ingredient samples (e.g. ground chilies, paprika, minced garlic, curry powder) other than pepper from bulk containers at UIFC's warehouse. These samples were collected On March 31, 2009, and April 1-2, 2009. All samples were negative for *Salmonella* (Attachment 22).

CalFERT investigators collected raw ingredients, finished product, and environmental samples on April 6, 2009. A total of 78 samples were collected, seven (9%) of which tested positive for *Salmonella* Rissen. Two of the *Salmonella* Rissen samples were further analyzed and determined to have indistinguishable PFGE patterns to those of the outbreak strain (Attachment 22). These samples were collected in Room [REDACTED] the sauce mixing room, and were collected from the wall and the south roll up door. Environmental samples collected at this time were done after UIFC employees had cleaned and sanitized Rooms [REDACTED]. Twenty of the 78 samples were sponge swab samples collected from Room [REDACTED]. Areas yielding positive *Salmonella* results were collected from the walls, floor crack, and the slicer grinder machine (Attachment 22).

Twenty sponge swab samples were also collected on the same day from Room [REDACTED] the sauce/oil bottling room. All of these samples were negative for *Salmonella*. Ten sponge swab samples were also collected from the warehouse. All of these samples were negative for *Salmonella*. Twenty-eight finished sauces and oils sampled and all were negative for *Salmonella*.

On April 7, 2009, CalFERT investigators collected 208 (inclusive in the 391 total samples) raw ingredient and finished product samples. Fifty samples of ground black pepper tested negative for *Salmonella*. One hundred samples of whole white pepper seed from bags of Harris Freeman White Pepper Seed Product of Vietnam - "Steam Washed" Lot # HFV173H VWP, SL No 111 50 kgs were collected. One sample from bag #110 (intact) tested positive for *Salmonella* Rissen with an indistinguishable PFGE pattern to that of the outbreak strain. Fifty-eight finished product samples of oils, spices, and sauces were collected and all tested negative for *Salmonella*.

### ***FDB Regulatory Action***

FDB Food Safety Inspection Unit (FSIU) investigators conducted a general inspection to verify compliance with California law and Good Manufacturing Practices (GMP's). Investigators issued NOVs, placed products under embargo, and witnessed Voluntary Condemnation and Destruction (VC & D) of product (Attachment 26) at UIFC during this investigation. On May 21, 2009 a Preliminary Injunction was issued and filed with the Superior Court in Alameda County (Attachment 29).

### ***Notice of Violations (NOVs)***

FDB-FSIU investigators issued two NOVs (March 27, 2009/April 21, 2009 and May 19, 2009) resulting from inspections conducted at UIFC. The following were the most egregious items noted on the NOVs:

1. The firm manufactured, sold, and offered for sale adulterated food products.
2. The finding of *Salmonella* on food contact surfaces
3. Heavy accumulations of white pepper dust throughout the facility and on equipment used to package and process food
4. The firm failed to ensure that the physical facilities of the plant were maintained in a sanitary condition.
5. The firm failed to use effective measures to prevent the cross-contamination of work-in-process and finished food.
6. The firm failed to exclude pests from the facility.

### ***Embargoes***

On March 28, 2009 FDB-FSIU investigators placed all products listed on the March 28, 2009 Press Release under embargo (Attachment 2). Positive sample results obtained during the investigation showed that Lian How and Uncle Chen brands of white pepper could potentially be contaminated with *Salmonella*. The FDB inspections found the facility and equipment contained heavy accumulations of white pepper dust and inadequate sanitary procedures in place to prevent cross-contamination from one spice

to another during the repackaging of spices into plastic jugs and bags. Any product processed at the firm that came into contact with white pepper dust had the potential to be contaminated with *Salmonella*.

On April 21, 2009 all food products manufactured, packaged, or re-packaged at [REDACTED] were embargoed. Also placed under embargo were all products located in Room [REDACTED] that could have been manufactured, packaged, or repackaged at [REDACTED] Union City. Room [REDACTED] was not registered with CDPH.

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

All sauces, oils, and opened containers of repackaged dry spices that were held or in-process at the firm or returned as a result of the recalls were voluntarily destroyed by the firm. All previously opened and returned recalled dry spices were voluntarily destroyed by the firm. The VC&D operations were conducted under the supervision of FDB-FSIU investigators. Dry spices that were returned by customers in their original unopened cases were reconditioned by an irradiation process that was approved by FDB. Samples from each lot of irradiated product were tested for *Salmonella* using methodology outlined in the Bacteriological Analytical Manual (BAM).

### ***Preliminary Injunction***

On May 21, 2009 a Preliminary Injunction was issued and filed with the Superior Court of Alameda County. The significant provisions of the Preliminary Injunction mandated UIFC to: 1) purchase raw ingredients from vendors with approved Hazard Analysis and Critical Control Point (HACCP) plans; 2) develop HACCP plans for raw ingredients, finished product, and environmental testing; 3) develop written Sanitation Standard Operating Procedures (SSOPs) and Standard Operating Procedures (SOPs); 4) maintain production and distribution records, and 5) conduct a thorough cleaning and sanitation of the facility. UIFC was ordered to submit plans and protocols described above to CDPH.

### **Conclusion**

The investigation and sampling at UIFC indicated that the white pepper at the firm was contaminated with *Salmonella* Rissen. Of the 391 environmental samples collected at UIFC, 63 tested positive for *Salmonella*. Twenty-five of the 63 positive *Salmonella* samples were further analyzed and were found to have indistinguishable PFGE patterns to that of the outbreak strain. Laboratory analyses confirmed that all of the positive samples came from either a white pepper product or from an area that was exposed to white pepper dust. *Salmonella* Rissen matching the outbreak strain was found in or on equipment, walls, floors, raw ingredients (including white ground pepper and whole white pepper seed), finished white ground pepper, and in-process white ground pepper. A sample of white pepper seed obtained from a lot that was being processed at the time of this investigation also had an indistinguishable PFGE pattern match to the outbreak strain.

The firm lacked proper SOPs and SSOPs to ensure that the cleaning and sanitizing of equipment and facility structures was completed between specific lots and batches of product. Without these procedures, cross-contamination of a contaminated raw ingredient to an uncontaminated ingredient or in-process product could occur. All of the positive samples came from either a white pepper product or from an area that was exposed to white pepper dust. Furthermore, the firm did not have any type of air filtering system in the white pepper grinding room to prevent the spread of white pepper dust to other areas of the facility. UIFC then packaged and distributed adulterated white pepper to a variety of customers. These adulterated foods led to 87 known illnesses in the western United States.

## Attachments

1. CDPH-IDB The Report
2. CDPH Press Release March 28, 2009
3. UIFC Press Releases March 30, April 2, 3, and April 14, 2009
4. CDPH Press Releases March 30, and April 4, 2009
5. FDA Collection Reports [REDACTED] and [REDACTED] from Zien Hong Restaurant
6. FDA Final Lab Results
7. Zien Hong Restaurant Invoice [REDACTED] from Jinthay Trading Corporation March 13, 2009
8. Jinthay Trading Corporation Invoice [REDACTED] from UIFC
9. UIFC Sales Journal for the period of November 1, 2008 to December 31, 2008
10. Washoe County Health District Epidemiological Investigation Report of Grand Sierra Resort
11. University of Nevada School of Medicine, Nevada State Health Laboratory Report-PFGE Results
12. Invoices from Sysco to Grand Sierra Resort in Nevada for the period of November 20, 2008 – February 26, 2009
13. Invoices from UIFC to Sysco for the period of December 15, 2008 – March 9, 2009
14. UIFC Sales Journal for the period of January 1, 2008 – March 30, 2009 for sales to Sysco
15. FDA Collection Report for Sample [REDACTED]
16. FDA Summary Report for Sample [REDACTED]
17. UIFC Sales Journal for the period of January 1, 2008 – March 30, 2009 for sales to 99 Ranch Market
18. FDA White and Black Pepper Traceback Diagram
19. Photo of White Pepper Seed Bag Lot HFV 173H-VWP
20. UIFC Invoices from Harris Freeman & Co., Inc. for White Pepper Lot # HFV 173H-VWP
21. UIFC Invoice from Harris Freeman & Co., Inc. for White Pepper Lot # HFV 276H-VWP
22. CalFERT Final Lab Results
23. Photos Uncle Chen and Lian How Products
24. UIFC Floor Diagram
25. Photos of UIFC Hand Pack Area
26. FDB Forms
  - A. NOVs: March 27, 2009, April 21, 2009, and May 19, 2009,
  - B. Embargo Notices: March 28, 2009 and April 21, 2009
  - C. VC&D: May 8, 18, and 19, 2009
  - D. Complaint Investigation Report, April 2, 2009
27. Photos of UIFC Cardboard Drums with Labels
28. Photos of UIFC Room [REDACTED] and Dust
29. County of Alameda District Attorney Stipulated Preliminary Injunction