
ENVIRONMENTAL INVESTIGATION OF A
LISTERIA MONOCYTOGENES OUTBREAK IN
DECEMBER 2014 AND JANUARY 2015,
ASSOCIATED WITH COMMERCIALY
PRODUCED CARAMEL APPLES

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AGENCIES INVOLVED

California Department of Public Health (CDPH), Food and Drug Branch (FDB), Emergency Response Unit (ERU)
CDPH, Food and Drug Laboratory Branch (FDLB)
CDPH Division of Communicable Disease Control (DCDC), Infectious Disease Branch (IDB), Disease Investigations
Section (DIS)
United States Department of Health and Human Services Food and Drug Administration (FDA), including:
FDA San Francisco District Office (San-DO)
FDA Los Angeles District Office (Los-DO)
FDA Coordinated Outbreak Response and Evaluation (CORE) Response Team 2
United States Department of Health and Human Services Centers for Disease Control and Prevention (CDC)

DATES OF INVESTIGATION

12/12/14-2/26/15 Including:

- 12/23-24/14: Onsite Inspection at Bidart Bros., Shafter, CA
- 12/23-26/14: Onsite Inspection at Happy Apples, Orosi, CA
- 12/30-31/14: Onsite Inspection at California Snack Foods, South El Monte, CA
- 12/23/14- 02/26/15: Recall Effectiveness Checks

EXECUTIVE SUMMARY

On 12/12/14, the California Department of Public Health (CDPH), Food and Drug Branch (FDB), Emergency Response Unit (ERU) was notified by CDPH, Infectious Diseases Branch (IDB) of a multi-state foodborne outbreak of *Listeria monocytogenes* (PulseNet Cluster ID 1411MLGX6-1WGS & 1411MLGX6-1) that was epidemiologically linked to the consumption of commercially produced caramel apples. A total of 35 case patients from 12 states were associated with this outbreak including three case patients in California. Illness onset dates ranged from October 17, 2014, to January 6, 2015. Seven of these case patients died.

Early epidemiological and traceback work completed by California, Michigan, Minnesota, Texas, and FDA identified Bidart Bros in Shafter, CA as a common link between multiple caramel apple manufacturing facilities. The final traceback diagram identified 12 case patients who consumed caramel apples produced with apples provided by Bidart Bros. On 12/22/14, Bidart Bros. recalled all processor grade apples produced during the 2014 season. Bidart Bros. later expanded the recall to include all Granny Smith and Gala apples produced in 2014.

On 12/23/14, the California Food Emergency Response Team (CalFERT) team initiated an investigation at Happy Apples Company in Oroshi, CA. The team collected 147 raw ingredient and packaging samples including sprinkles, flour, sugar, clamshell packaging, and wooden sticks. The team also collected 100 environmental samples from food contact and non-food contact surfaces throughout the facility. One of the environmental swabs tested positive for *L. monocytogenes* and that strain matched the outbreak by Pulsed Field Gel Electrophoresis (PFGE) and Whole Genome Sequencing (WGS). Records obtained during the investigation at Happy Apples showed that 53% of all apples used during 2014 were sourced from Bidart Bros.

On 12/31/14, the CalFERT team conducted sampling and a focused inspection at the Bidart Bros. facility in Shafter, CA. The team collected 110 environmental samples from food contact and non-food contact surfaces throughout the facility. Seven environmental swabs tested positive for *L. monocytogenes*, with six of the seven samples collected from food contact surfaces. All seven of these samples shared PFGE patterns with the clinical cases.

CDPH-ERU also collected a single leftover caramel apple sample from a California case patient in Felton, CA who had died. Before the sample was collected by CDPH, the product had been stored in the consumer's refrigerator for several weeks, and then in a garbage bag for several days at ambient temperature. Traceback on this sample determined the Happy Apple facility in Oroshi, CA likely produced this product using Bidart Bros. apples. *Listeria* was not detected in this sample.

Several of the companies that received apples by Bidart Bros., including the California caramel apple producers, initiated sub-recalls of their own. The CDPH-ERU recall team conducted recall effectiveness checks for all of the recalled apple and caramel apple products that were distributed in California. In all, the recall team contacted 207 distributors and identified 10,600 California retail locations that received the recalled products. The recall team published this retail list on the California Food Recall webpage and sent the list to local health agency partners for retail-level recall effectiveness checks.

This investigation determined that Granny Smith apples distributed by Bidart Bros. were the most likely source of the *Listeria monocytogenes* that caused 35 cases of Listeriosis in 12 states associated with the consumption of caramel apple products. The caramel apple traceback, conducted by multiple states and coordinated by the FDA, found that Bidart Bros. was the only apple supplier that distributed to all caramel apple processors related to this outbreak. The onsite investigation at Bidart Bros. identified multiple locations where *L. monocytogenes* was present in the packing facility, including several food contact surfaces. PFGE and WGS analyses determined that these samples were highly related to the outbreak strain. As of April 2015, Bidart Bros. management reported that they were no longer growing apples, were in the process of removing the orchard, and had closed the packing facility.

BACKGROUND

On 12/12/14, the California Department of Public Health (CDPH), Food and Drug Branch (FDB), Emergency Response Unit (ERU) was notified by CDPH, Infectious Diseases Branch (IDB) of a multi-state foodborne outbreak of *Listeria monocytogenes* (PulseNet Cluster ID's 1411MLGX6-1WGS & 1411MLGX6-1) that was epidemiologically linked to the consumption of commercially produced caramel apples. Clinical case isolates in this outbreak consisted of three Pulsed Field Gel Electrophoresis (PFGE) patterns (GX6A16.0135/GX6A12.0349, GX6A16.0012/GX6A12.0696, and GX6A16.0012/GX6A12.0126). On 12/18/14, caramel apples emerged as a potential food vehicle of interest. As of that date, nine of nine case patients interviewed with an outbreak specific questionnaire reported exposure to caramel apples and additional case patients indicated caramel apple exposure in preliminary interviews. A facility in Oroshi, CA produced Happy Apples, one of the brands mentioned by patients.

According to PulseNet, a national microbiological subtyping network that performs molecular surveillance of foodborne infections maintained by the Centers for Disease Control and Prevention (CDC), one of the three PFGE patterns (GX6A16.0135/GX6A12.0349) had been previously associated with a 2014 outbreak associated with stone fruit. The other two patterns were extremely rare.

EPIDEMIOLOGICAL SUMMARY

This outbreak associated with caramel apple consumption had a total of 35 illnesses reported in the following 12 states (with case counts); Arizona (5), California (3), Colorado (1), Minnesota (4), Missouri (5), Nevada (1), New Mexico (6), North Carolina (1), Texas (4), Utah (1), Washington (1), Wisconsin (3). The CDC designated cluster codes for this outbreak were 1411MLGX6-1WGS & 1411MLGX6-1. Illness onset dates ranged from 10/17/14 to 1/16/15. Out of the 35 illnesses reported, 11 were associated with a pregnancy (occurred in a pregnant woman or newborn infant). There were 34 hospitalizations associated with this outbreak. A total of seven case patients died during the outbreak and Listeriosis was identified as a contributing factor in three of these deaths.

Public health laboratories performed Pulsed Field Gel Electrophoresis (PFGE) testing of the clinical samples to determine genetic similarity between the isolates. Cases included in this outbreak included patients with *Listeria* infections having any of the following three, closely related PFGE patterns: GX6A16.0135/GX6A12.0349, GX6A16.0012/GX6A12.0696, or GX6A16.0012/GX6A12.0126. CDC and state laboratories also analyzed the *L. monocytogenes* isolates from several patients using whole genome sequencing (WGS) to analyze the entire genetic sequence of the organism. CDC experts compared the WGS sequences to one another and determined that the strains were very closely related.

Local health departments interviewed case patients about their food exposures in the timeframe leading up to their illness. Out of the 31 cases interviewed for this outbreak, 28 (90%) reported eating commercially produced, prepackaged caramel apples before their illness onset. Brands identified by case patients included Happy Apples, Carnival, and Merb's Candies. The three case patients who did not report eating caramel apples did report eating whole or sliced plain green apples, not covered in caramel; however, the brand or supplier of the apples consumed could not be determined.

Simultaneous to investigation of this outbreak in the United States, Canadian Food Inspection Agency (CFIA) officials identified an additional case infected with *Listeria* whose clinical isolate had a PFGE pattern indistinguishable from the patterns associated with this outbreak and was closely related by WGS. After conducting follow up investigations, CFIA reported that the case patient also had exposure to an unspecified brand of commercially produced caramel apples.

ONSITE INVESTIGATIONS

HAPPY APPLES

FIRM DESCRIPTION

On 12/23/14, a team of California Food Emergency Response Team (CalFERT)¹ members initiated a joint investigation at Happy Apples, 41899 Rd 120, Oroshi, CA. The investigation at the facility included a focused inspection as well as sampling of ingredients, packaging, and environmental surfaces. David M. Valenzuela, Production Manager at the Oroshi, CA facility, represented Happy Apples throughout the inspection.

Happy Apples did not officially employ Mr. Valenzuela at the time of inspection due to his seasonal employment. He informed the team that the Facility Manager, John Mayer, was onsite at the Oroshi facility only during the operational season and worked at the Happy Apples' headquarters in Union, Missouri the rest of the year. Mr. Valenzuela was very familiar with the procedures and practices at this facility due his position during operation, so Happy Apples President, Edward Reidy, arranged for Mr. Valenzuela to meet the investigation team at the Oroshi facility and authorized him to provide access to the facility, information, and records related to the investigation.

The Happy Apples facility, in Oroshi, CA, operated on a seasonal basis during apple season, approximately August through October. For the 2014 season, the last day of production at this facility was 10/25/14. At the time of inspection, the facility had not produced any product since 10/25/14. The facility employed nine employees on a seasonal basis. When not in operation, there were generally no employees present at the Oroshi facility.

The facility consisted of four main buildings. There were two cold storage warehouses. One was used for finished product storage and the other was used for receiving apples. One of the ambient temperature warehouse buildings was used for storing ingredients and washing apples and the adjacent ambient temperature building was used for caramel apple manufacturing. A driveway separated the cold storage and processing areas (Figure 1).

¹ CalFERT is a team of investigators, microbiologists, chemists, and epidemiologists, from the FDA and California state agencies, whose purpose is to jointly investigate foodborne outbreaks.

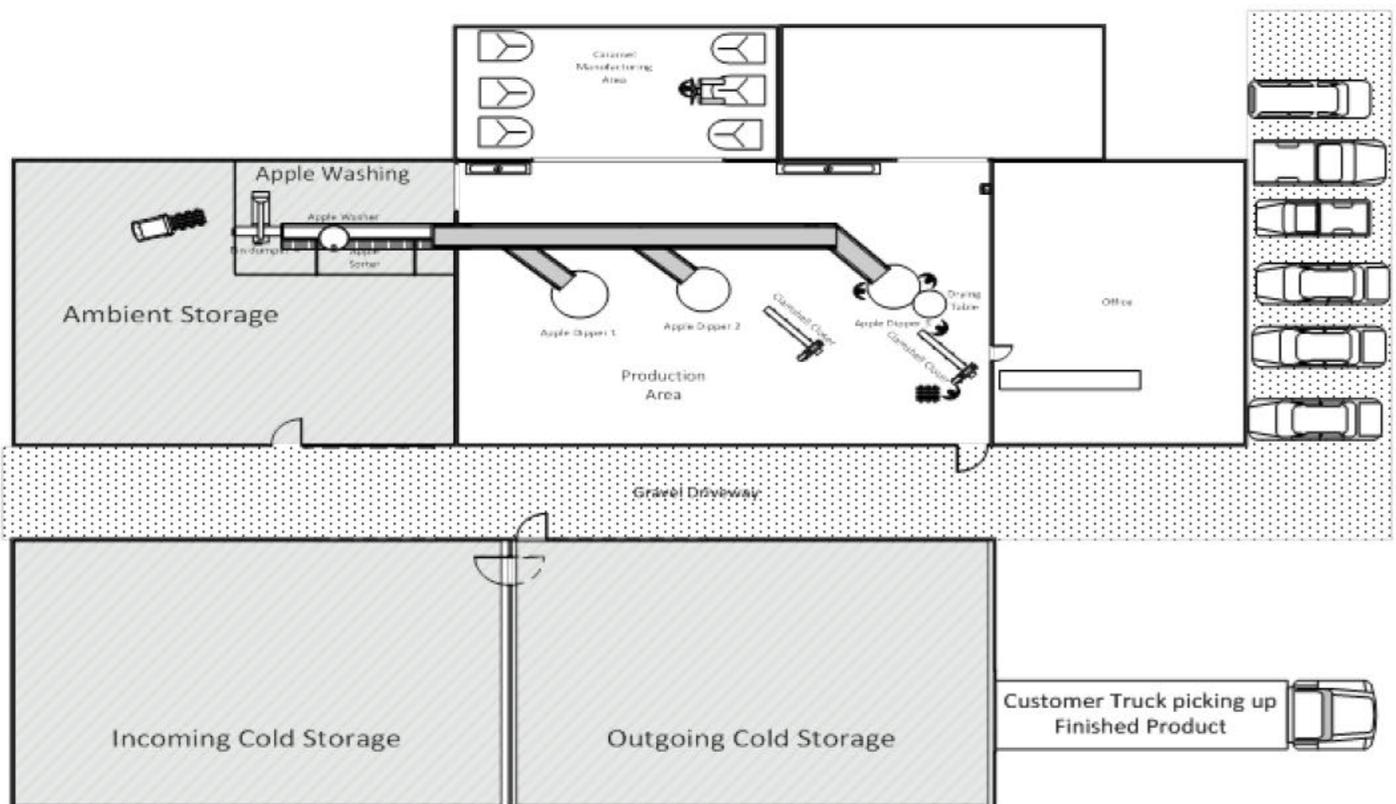


FIGURE 1 - HAPPY APPLE COMPANY FACILITY LAYOUT

PROCESS FLOW

RECEIVING AND STORAGE OF RAW MATERIALS

APPLES

The Happy Apples facility in Orosi sourced 53% of all apples used during 2014 from Bidart Bros. (Figure 2). The other 47% were mostly early season shipments sourced from companies located in Washington. For the 2014 season, the shipments from Washington ended on 9/11/14, over a month prior to the beginning of this outbreak. Mr. Valenzuela confirmed there would have been no Washington apples used during the time period associated with illness. Apples from Bidart Bros. were being used, almost exclusively during this time.

The majority of the apples received at the Orosi Happy Apples facility were stored onsite in the cold storage warehouse. Some apples were temporarily stored in cold storage at [REDACTED] in [REDACTED], CA, when Happy Apples needed additional storage.

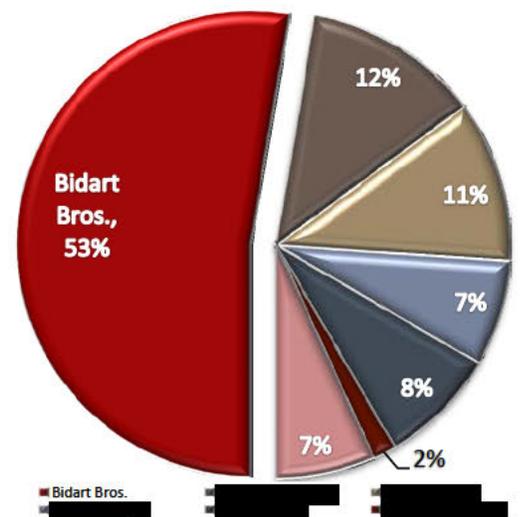


FIGURE 2 - HAPPY APPLES SUPPLIERS DURING 2014 BY PERCENTAGE OF TOTAL APPLES USED

CORN SYRUP

Happy Apples received corn syrup in bulk at the beginning of the season from a local supplier. The product was stored onsite in a bulk tank and piped to the caramel-making kettles as needed.

DRY INGREDIENTS AND PACKAGING

The Orosi Happy Apples facility received all dry ingredients (such as toppings, flour, etc.), labeling, and packaging from Happy Apple's Headquarters in Missouri. A truck contracted by Happy Apples delivered these items to the Orosi facility before the season started and they were stored onsite in a portion of the ambient temperature warehouse. Mr. Valenzuela informed the investigation team that the company was storing the ingredients on hand at the time of inspection for use during the next season.

The firm did not perform any microbial testing on the raw ingredients or packaging.

PROCESSING OF CARAMEL APPLE COMPONENTS

APPLES

Granny Smith apples were received at the Happy Apple facility in Orosi, CA from multiple suppliers and stored onsite in a cold storage warehouse. When ready for use, a Happy Apple employee would use a bin dumper to put the apples onto a sorting and wash line. The equipment sorted the apples by size (Figure 3) and scrubbed them with foam rollers while spraying them with [REDACTED] water (Figure 4). Employees verified the [REDACTED] concentration was [REDACTED] parts per million (ppm) [REDACTED] per [REDACTED] during processing using an electronic sensor. After washing, a conveyor carried the apples through an [REDACTED] water rinse, past drying fans, and onto the caramel apple dipping machines.

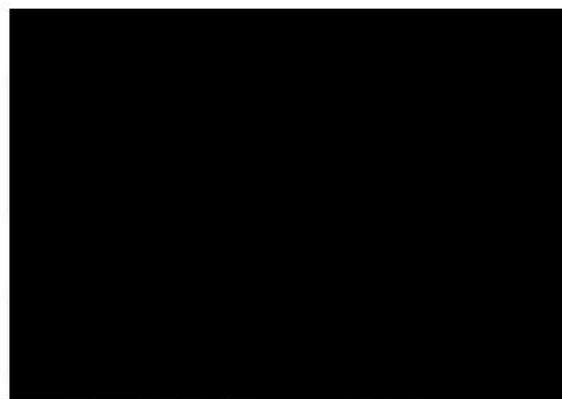


FIGURE 3 – APPLE SORTER

CARAMEL

Happy Apples made all caramel onsite, in copper kettles, in their kitchen area. The ingredients in the caramel were primarily corn syrup and sugar (Exhibit A). According to information provided by Mr. Valenzuela, the employee making the caramel heated [REDACTED] [REDACTED] re to [REDACTED] [REDACTED] r several minutes, and then he [REDACTED] t [REDACTED] ixture to 232° F-234°F for a second cooking phase. After cooking, the employee [REDACTED] of the apple dipping machine. In addition to caramel apples, the facility produced candy apples. Candy apples were [REDACTED].

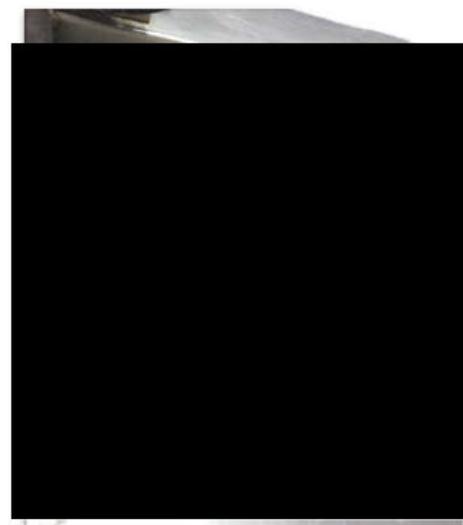


FIGURE 4 – FOAM SCRUBBERS

FINAL ASSEMBLY OF CARAMEL APPLES

A conveyor carried apples to the caramel apple dipping machines in the processing room (Figure 5). An employee

[REDACTED] The machine then [REDACTED], using [REDACTED]. The apple dipping machine [REDACTED], then [REDACTED] if needed. The equipment dropped the apple into a chute where [REDACTED].

[REDACTED]. Another worker then took the apples off the [REDACTED] and placed them in a plastic clamshell package with a label. The packaged product moved through a mechanism to close and seal the packaging before a final employee placed the package into a cardboard case. See Attachment A for a product flow diagram.

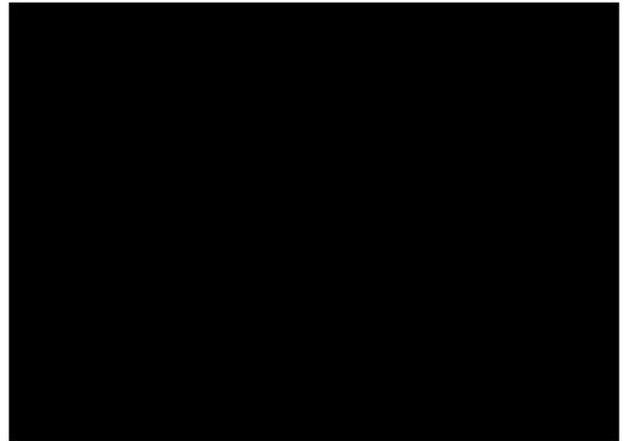


FIGURE 5 - APPLE DIPPING MACHINE (ARROWS INDICATE PRODUCT FLOW)

LABELING

This facility produced both caramel apples and candy apples in multiple configurations. This facility packaged a large majority of the final product in a single apple, clamshell-type, plastic package with Happy Apples brand labeling. In addition to the Happy Apple products, this facility also produced labeled products under the Kroger brand. The company also produced a relatively small number of clamshells containing three apples under both brands (Figure 6). The Kroger branded product was supplied to [REDACTED] for distribution.

The firm stamped a best by date on each package produced. The best by date was [REDACTED] from the production date for all products and brands. This best by date served as a lot coding system as well (Exhibit B).

| | |
|--|--|
| | |
| <p>Happy Apples Brand Grand Gourmet Caramel Apples</p> | <p>Happy Apples Brand Caramel Apple 3-Pack</p> |
| | |
| <p>Happy Apples Brand Caramel Apple Single Pack</p> | <p>Kroger Branded Caramel Apple 3-Pack</p> |

FIGURE 6 - SAMPLE HAPPY APPLE LABELS

The firm did not conduct microbial testing of the finished product.

WATER

The team did not observe any plumbing or other water system concerns at the time of inspection.

The facility used water from an onsite well. This water was [REDACTED] when used for production, washing, sanitizing, and other uses around the facility, except for [REDACTED] as described above. The firm tested the well water annually for coliforms and other contaminants and verified these measurements met drinking water standards.

PEST CONTROL PROGRAM

The investigation team did not observe any pest control concerns at the time of inspection.

The team observed "Tin Cat" type rodent traps throughout the facility along the exterior walls and near entrances. Also, plastic strip curtains were present in doorways between the production area and the outside; and between the warehouse and production areas to reduce accidental pest intrusion. The team did not observe any insect traps or attractants. Mr. Valenzuela did not recall the name of the pest company, but did state that the pest company came monthly and that the company did not note any unusual or excessive pest activity. Pest control records were not available for review at the time of inspection.

FOOD SAFETY TRAINING FOR EMPLOYEES

Mr. Valenzuela informed the team that employees received on-going training in proper hygiene, cleaning, and food safety. Happy Apples management trained all employees at the beginning of the season and conducted trainings throughout the season on any new procedures. Retraining was provided as needed. No records were available to verify the training topics or frequency of the trainings. At the time of the inspection, the facility was not in operation, so the team could not verify the effectiveness of these trainings.

FOOD WORKER HEALTH AND HYGIENE

At the time of inspection, the team observed a dedicated hand-washing sink in the facility just outside the employee break area. The sink area was sufficiently stocked and in a suitable condition with warm, running water. The facility was not operating when inspected, so the investigative team could not directly observe employee practices.

FACILITY CLEANING AND SANITATION

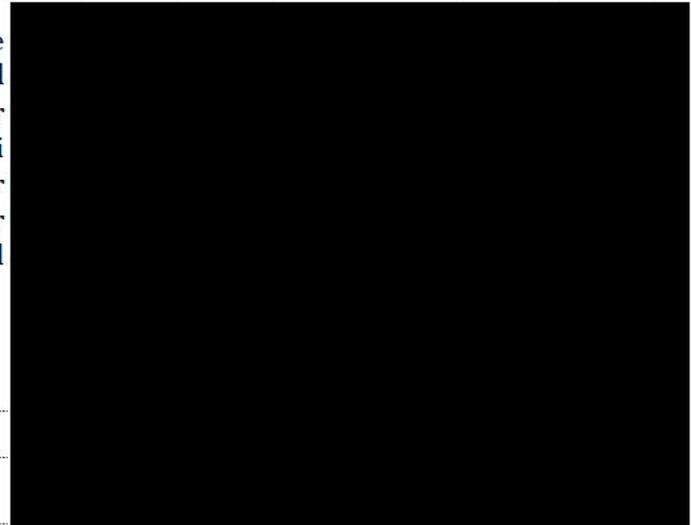
Happy Apples conducted environmental microbial testing once yearly. The investigational team reviewed the microbial testing from the pre-season testing Happy Apples conducted in 2014 and the results were negative for all organisms tested. The firm did not conduct any additional microbial testing throughout the season.

All employees shared responsibility for cleaning and sanitizing all surfaces and floors daily, after production. Additionally, facility management visually inspected all food contact surfaces for cleanliness prior to beginning production for the day.

The investigation team inspected logs verifying the sanitations and inspections during the 2014 season. According to the records reviewed and the statements of Mr. Valenzuela, employees had cleaned the facility after the last run for the 2014 season, on 10/24/14, approximately two months prior to this investigation. At the time of the investigation, many areas had product residue and did not appear to have been cleaned. Exhibit C shows some of those areas.

PRODUCT DISTRIBUTION

Happy Apples distributed all products to wholesale distributors and grocery store distribution centers and did not sell directly to consumers. Customer owned trucks or common carriers received all final products from the Orosi facility and transported them to other locations for distribution. According to records provided by the firm, their main customer in 2014 was [REDACTED] ([REDACTED] % of distributed product) (Figure 7).



SAMPLING

INGREDIENT AND PACKAGING SAMPLING

During the inspection, the team collected 147 raw ingredient and packaging samples at the Happy Apples facility. The samples included sprinkles, flour, sugar, clamshell packaging, and wooden sticks. These samples were submitted to the CDPH Food and Drug Laboratory Branch (FDLB) in Richmond, CA on 12/24/14.

FIGURE 7 - 2014 CUSTOMERS OF HAPPY APPLES' OROSI FACILITY

On 1/14/15, FDLB reported to ERU that they did not detect *L. monocytogenes* in any of the samples (Attachment 2).

ENVIRONMENTAL SAMPLING

During the inspection, the team also collected 100 environmental swabs from food contact and non-food contact surfaces throughout the facility (Attachment 2). These samples were submitted to FDLB in Richmond, CA on 12/24/15.

On 1/14/15, FDLB reported to ERU that *L. Monocytogenes* was isolated from one environmental sample (IS 710122314-E086). The strain of *L. monocytogenes* isolated from the sample had a PFGE pattern indistinguishable from the outbreak pattern and a whole genome sequence (WGS) very closely related to the outbreak sequences (Attachment 2). The team collected this sample from a puddle of water on the floor, under the wash line for incoming apples (Exhibit D). Mr. Valenzuela stated this water puddle was left over from washing during the season and had not dried since the last day of processing. ERU and FDA management notified Happy Apples of this positive finding on 1/14/15. Any product manufactured in the area where the positive environmental sample was collected was well past the [REDACTED] shelf life at the time of notification, so the firm did not initiate a recall based on this result.

REGULATORY ACTIONS

FDA investigative staff issued a List of Inspectional Observations (FDA Form 483) regarding the conditions observed during the inspection that presented food safety concerns. The observations included; torn and cracked foam pads throughout the wash line and plastic cups used to hold apples with food residue, despite reportedly being cleaned after the last batch of apples.

BIDART BROS.

The traceback investigation conducted by multiple states and the FDA identified Granny Smith apples from Bidart Bros. as the likely source of this outbreak (See Traceback, below).

On 12/23/14 and 12/24/14, a CalFERT team conducted a focused inspection at the Bidart Bros. cooling and packing facility in Shafter, California. Bidart Bros. was closed for the season and did not expect to process apples again until September 2015.

FIRM DESCRIPTION

Bidart Bros. warehoused and packed Granny Smith and Gala apples. All apples packed by Bidart Bros. were grown in company owned orchards within a three mile radius of the packing location. During the 2014 season, Bidart Bros. harvested Granny Smith apples from 8/11/14 to 10/6/14. These Granny Smith apples were packed between 8/13/14 and 10/31/14. Bidart Bros. harvested Gala apples from 7/17/14 to 7/26/14. These Gala apples were packed between 7/21/14 and 8/8/14.

The Bidart Bros. packing facility consisted of a cold storage area which could also be used as controlled atmosphere (CA) storage (reduced oxygen levels/ [REDACTED] [REDACTED] and a packing room. The cold storage area occupied approximately [REDACTED] square feet while the packing room was approximately [REDACTED] square feet. Approximately [REDACTED] employees worked in these areas during the packing season.

Because the firm was closed for the season, most of the food contact surfaces had been cleaned, removed, and stored in other areas of the facility. A portion of the equipment was dismantled, under repair, or being painted.

APPLE PACKING

The apple packing process was described as follows:

1. Apples were picked by hand from trees (apples were not collected from the ground) and transported in wooden bins back to the packing facility by straddle trucks.
2. The apples were then [REDACTED], [REDACTED], [REDACTED] and [REDACTED]. The drenching process was used to reduce post-harvest decay and delay aging.
3. The apples were either placed in CA storage or cold storage depending on the expected use date.
4. Prior to packing, bins of apples were a [REDACTED].
5. The apples were then conveyed across a wash line ([REDACTED] fruit wash), brushed, rinsed, and dried.
6. The apples were then graded, waxed, and color sorted prior to tray packing and cold storage.

See Attachment 3 for additional details regarding the apple packing process described during this investigation.

Although not currently in use, multiple areas of worn and exposed foam padding (used to prevent bruising on conveyor lines) were observed in poor sanitary condition. These areas were described as being direct food contact surfaces.

ENVIRONMENTAL SAMPLING

During the investigation, the team collected 110 environmental swabs from food contact and non-food contact surfaces throughout the Bidart Bros. facility (Attachment 4). These samples were submitted to the FDA Pacific Regional Lab Southwest (PRL-SW) in Irvine, CA. Samples were analyzed for *Listeria monocytogenes*. FDA staff reported that seven samples tested positive for *Listeria monocytogenes*. Six of the seven positive samples were from food contact surfaces including brushes and a storage bin (Figure 8). FDA reported that all seven of the positive environmental samples collected at the Bidart Bros. facility were closely related to the outbreak strains by WGS (Attachment 5).

| Sample Number | Description | Food-Contact Surface? |
|---------------|--|-----------------------|
| 3 | Black color polishing brush, held on north side of bins | Yes |
| 39 | Red color drying brush, held on north side of bins | Yes |
| 41 | Red color drying brush, held on north side of bins | Yes |
| 44 | Red color drying brush, held on west side of bins | Yes |
| 63 | Auto line [REDACTED] Lane 2 | Yes |
| 100 | Main packing line drain | No |
| 106 | Inside area of non-painted Bidart wooden bin, stored along west wall of Common Storage | Yes |

FIGURE 8 – SUMMARY OF POSITIVE SAMPLES AT BIDART BROS.

REGULATORY ACTIONS

FDA investigative staff issued a List of Inspectional Observations (FDA Form 483) regarding the conditions observed during the inspection that presented food safety concerns. The observations included; worn and exposed foam padding on conveyor lines, chipping paint, and a canvas bucket conveyor system in poor repair.

CALIFORNIA SNACK FOODS

California Snack Foods recalled Karm'l Dapples on 12/27/14 (Exhibit E) due to their apple supplier, Bidart Bros., recalling apples they had used to produce caramel apples. A CalFERT team conducted an inspection and sampling at the California Snack Foods facility in South El Monte, California on 12/30/14 and 12/31/14. Caramel apples manufactured at this facility were not associated with illnesses, however, the focused inspection and sampling was to ensure that the Bidart apples used to make caramel apples did not contaminate the facility.

The team met with multiple members of management throughout the inspection and was accompanied during the inspection and sampling by Jason Nelson, Vice President of Sales.

SAMPLING

PRODUCT SAMPLING

The team collected 33 product samples during their inspection (Attachment 6). These samples were submitted to the CDPH Food and Drug Laboratory Branch (FDLB) in Richmond, CA on 12/31/14.

On 1/14/15, FDLB notified ERU that they had detected *L. monocytogenes* in one red caramel apple with peanuts sample (IS# 710123014-P006) (Attachment 6). FDLB also reported that the PFGE pattern associated with this sample (GX6A16.0493/GX6A12.0975) did not match any of the outbreak patterns or recent clinical isolates in PulseNet.

CalFERT Management notified California Snack Foods on 1/14/15 of the positive finding. Since the product was past its shelf life and there were no indications of larger food safety concerns at this facility, California Snack Foods chose not to initiate a recall based on these results.

ENVIRONMENTAL SAMPLING

The CalFERT team also collected 60 environmental samples from food contact and non-food contact surfaces during their inspection (Attachment 6). These samples were submitted to FDLB in Richmond, CA on 12/31/14.

On 1/14/15, FDLB notified ERU that they had not detected *L. monocytogenes* in any of the environmental samples collected.

REGULATORY ACTIONS

Members of the CalFERT team conducted a food safety inspection as part of this investigation (Attachment 7). The team observed areas that presented potential food safety concerns, and a four-item Notice of Violation (NOV) was issued to Mr. Nelson on 12/31/14. The items of particular concern to this investigation were observations of grime and product accumulation on equipment that had been described by management as "clean", as well as other areas of insufficient sanitation and improper sanitation chemicals. See NOV attached to Attachment 7 for more information on these observations.

ADDITIONAL SAMPLING

CONSUMER PRODUCT SAMPLING CONDUCTED BY CDPH

On 12/19/14, ERU staff collected one leftover product sample from a California case patient associated with this outbreak (CA_M14X06515). The sample (IS 094121914-P001) consisted of an open 3-pack of Happy Apples caramel apples with only two apples remaining in the package. Before the sample was collected by FDB, the product had been stored in the consumer's refrigerator for several weeks, and then in a garbage bag for several days at ambient temperature. According to information received at the time of sampling, the case patient or a relative had consumed one apple from the 3-pack. The case patient purchased the product at Safeway in Felton, CA on both 10/27/14 and 10/31/14, verified through shopper card records. This sample was submitted to FDLB in Richmond, CA on 12/22/14. On 1/14/15, FDLB reported to ERU that *L. monocytogenes* was not detected in sample IS 094121914-P001 (Attachment 8 & 9).

TRACEBACK

Due to this outbreak affecting multiple states, the FDA's Coordinated Outbreak Response and Evaluation (CORE) Network coordinated the traceback activities for this investigation. CDPH-ERU collected and reviewed documents from California firms and case patients and subsequently provided them to CORE for further analysis and incorporation into the national traceback diagram.

CALIFORNIA CASE TRACEBACK INVESTIGATIONS

California case patient (CA_M14X06722) reported consumption of Happy Apples brand caramel apples purchased on 10/14/14 at a Walmart location in Rocklin, CA (5454 Crossings Dr., Rocklin, CA 95677). ERU assisted with collection of the case patient's receipts (Attachment 10) and traceback of the product. Based upon records collected during the investigation, Bidart Bros. was the most likely supplier of the apples used to manufacture the Happy Apple brand caramel apples consumed by this case.

California case patient (CA_M14X06515) reported consumption of Happy Apples brand caramel apples purchased on 10/27/14 and 10/31/14 at a Safeway location in Felton, CA (6255 Graham Hill Road, Felton, CA 95018). ERU assisted with collection of the case patient's shopper card records (Attachment 8) and traceback of the product. Based upon records collected during the investigation, Bidart Bros. was the most likely supplier of the apples used to manufacture the Happy Apple brand caramel apples consumed by this case.

OVERALL TRACEBACK SUMMARY AND CONCLUSIONS

Bidart Bros. supplied Granny Smith apples to multiple caramel apple manufacturers and other customers during the 2014 season. The traceback investigation conducted by FDA-CORE determined that all 12 case patients investigated likely consumed caramel apples produced with apples supplied by Bidart Bros. The caramel apple manufacturers that purchased from Bidart Bros. had distributed caramel apples through major, national chains, as well as smaller chains and independent stores nationwide. These retail locations, in turn, supplied the case patients. The only convergence for the genetically similar *L. monocytogenes* causing these patients' Listeriosis was caramel apples made with Granny Smith apples that were sourced from the Bidart Bros. cooling and packing facility in Shafter, CA.

RECALL ACTIVITIES AND PRESS RELEASES FROM REGULATORY AGENCIES

RECALLS

BIDART BROS. RECALL

On 12/22/14, Bidart Bros. recalled all processor apples produced during the 2014 season due to the *L. monocytogenes* found in the facilities of their customers and the epidemiologic link between apples from Bidart Bros. and human Listeriosis cases. On 1/9/15, after being informed of the *L. monocytogenes* contamination found throughout their packing plant and positive *L. monocytogenes* results in whole Granny Smith apples collected in Missouri, Bidart Bros. expanded their 12/22/14 recall to include all sizes and all grades of apples produced at their facility in 2014 (Exhibit F). In response to the recalls, ERU's recall team contacted 146 distributors, and identified 7,845 retail locations that received the recalled apples. The recall team listed these retail locations on the California Food Recall webpage² and sent the retail list to California local health departments so they could conduct recall effectiveness checks at the retail level.

HAPPY APPLE RECALL

On 12/24/14, in response to the Bidart Bros. recall of processor apples, Happy Apples recalled all caramel apples with best by dates between 8/25/14 and 11/23/14 (Exhibit G). The recall included all apples produced during the time in which the firm may have used Bidart Bros. apples to make their caramel apples. In response to this recall, ERU's recall team contacted 57 distributors, and identified 2,329 retail locations that received the recalled products. The recall team listed these retail locations on the California Food Recall webpage and sent the retail list to California local health departments so they could conduct recall effectiveness checks at the retail level.

CALIFORNIA SNACK FOODS RECALL

On 12/27/14, in response to the Bidart Bros. recall of processor apples, California Snack Foods recalled all caramel apples with best by dates between 8/15/14 and 11/28/14 (Exhibit E). The recall included all apples produced during the time in which the firm may have used Bidart Bros. apples to make their caramel apples. In response to this recall, ERU's recall team contacted four distributors, and identified 426 retail locations that received the recalled products. The recall team listed these retail locations on the California Food Recall webpage and sent the retail list to California local health departments so they could conduct recall effectiveness checks at the retail level.

² FDB Food Recall Webpage – <https://www.cdph.ca.gov/HealthInfo/Pages/fdbFr.aspx>

PRESS RELEASES FROM REGULATORY AGENCIES

CDC

On 12/19/15, the CDC issued a press release outlining the investigation and current epidemiologic information³. In this press release, they advised consumers not to consume any commercially produced caramel apples due to association with Listeriosis. CDC updated this information on 12/22/14 and 12/31/14. On 1/8/15, the CDC issued a press release indicating specific brands of caramel apples that were associated with Bidart apples and referenced the recalls discussed above. On 2/12/15, CDC announced that the outbreak was over since there had been no new cases.

FDA

On 12/19/15, the FDA issued a press release outlining the investigation⁴. In this press release, they echoed CDC's warning against consuming commercially produced caramel apples. The FDA updated this information throughout the investigation on a schedule similar to CDC's updates.

CDPH

On 12/25/14, CDPH issued a press release warning against consumption of Happy Apple brand caramel apples with best by dates between 8/25/14 and 11/23/14 (Attachment 11). The press release also reflected CDC's warning against consumption of all commercially produced caramel apples and informed the public that a California case patient associated with the outbreak had died. CDPH issued this press release to coincide with the Happy Apples recall discussed above.

³ <http://www.cdc.gov/listeria/outbreaks/caramel-apples-12-14/>

⁴ <http://www.fda.gov/Food/RecallsOutbreaksEmergencies/Outbreaks/ucm427573.htm>

SUMMARY OF OUTBREAK INVESTIGATION FINDINGS

Evidence collected during this investigation determined that Granny Smith apples supplied by Bidart Bros. (and subsequently processed into caramel apples) were the most likely source of the *Listeria monocytogenes* that led to 35 illnesses, including seven deaths, three of which had Listeriosis listed as a contributing factor. The traceback investigation focused on 12 cases that consumed caramel apples in eight states. Each of these cases consumed a caramel apple manufactured using an apple that was supplied by Bidart Bros.

Listeria monocytogenes was isolated in multiple products originating from the Bidart Bros. facility in Shafter, CA, and sampled at various points in commerce. PFGE patterns from these samples were indistinguishable from the outbreak patterns and were highly related to the clinical cases via WGS analysis. The onsite investigation by CalFERT at Bidart Bros. found multiple locations where *L. monocytogenes* was present in the packing facility. The positive environmental samples included food contact and non-food contact surfaces and showed the presence of this pathogen in the packing plant. The variety of locations from which the team collected these positive samples showed that Bidart Bros.' sanitation procedures did not effectively and reliably eliminate this pathogen from the facility. These environmental conditions may have provided harborage and a chance for the pathogen to establish itself within the facility.

The investigation also found *L. monocytogenes* with indistinguishable PFGE patterns and highly related WGS in the facility of a Bidart Bros. customer, Happy Apples. This indicates that the raw product from Bidart Bros. most likely caused the *L. monocytogenes* contamination at the Happy Apples processing facility and subsequent human illness.

One factor that may have increased the risk associated with these caramel apples was the use of foam rollers at both Bidart Bros.' packing facility and Happy Apple's manufacturing plant. The use of foam rollers with porous surfaces, that were not easily cleanable, increased the risk of possible harborage for microorganisms, including pathogens such as *L. monocytogenes*. This harborage increased the risk of spreading small numbers of pathogenic bacteria from incoming products to all other products coming into contact with the rollers.

CORRECTIVE ACTIONS

On March 3, 2015, Bidart Bros. management stated they planned to remove the majority of apple orchards under their control and close the apple packing facility for the foreseeable future.

ATTACHMENTS AND EXHIBITS

ATTACHMENTS

- ATTACHMENT 1 – Happy Apples Product Flow Diagram
- ATTACHMENT 2 – Happy Apples Laboratory Results Summary
- ATTACHMENT 3 - Bidart Bros. Farm Investigation Questionnaire (Packing and Cooling Operations)
- ATTACHMENT 4 – Bidart Bros. Sampling Locations
- ATTACHMENT 5 – Bidart Bros. Environmental Testing Results - WGS
- ATTACHMENT 6 – California Snack Foods – Laboratory Results Summary
- ATTACHMENT 7 – California Snack Foods - Inspection Report
- ATTACHMENT 8 – CA_M14X06515 Consumer Sample - Evidence Receipt/Shopper Card Data
- ATTACHMENT 9 – CA_M14X06515 Consumer Sample - Laboratory Results Summary
- ATTACHMENT 10 – CA_M14X06722 Consumer Purchase – Evidence Receipt/Sales Receipt
- ATTACHMENT 11 – CDPH Press Release

EXHIBITS

- EXHIBIT A - Happy Apples Caramel Recipe
- EXHIBIT B – Happy Apples Lot Coding
- EXHIBIT C – Happy Apples Cleaning Deficiencies Observed
- EXHIBIT D – Happy Apples – Photos of Positive Sample
- EXHIBIT E - California Snack Foods Recall Press Release
- EXHIBIT F - Bidart Bros. Recall Press Release
- EXHIBIT G – Happy Apples Recall Press Release