INVESTIGATION REPORT COVER SHEET

INVESTIGATION NAME: Mango_AgricolaDaniella_SalBraenderupWorthington_IDB_082012		ASSIGNMENT DATE (S): August – October 2012
ERU LEAD: Brandon Adcock #710 and Amber Barnes #171		
FIRM NAME: Multiple firms		
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REPORTING PERSON / AGENCY: California Department of Public Health, Food and Drug Branch (FDB) and Infectious Diseases Branch (IDB)

ACTIVITY: ☒ OUTBREAK INVESTIGATION ☐ PRODUCT CONTAMINATION INVESTIGATION ☐ PFR ENVIRONMENTAL ☐ RETAIL ENVIRONMENTAL ☒ TRACEBACK INVESTIGATION ☐ TAMPERING ☐ COMPLAINT ☐ SAMPLING ☐ TECHNICAL ASSISTANCE ☐ OTHER:

CDC cluster code 1208CAJBP-1 – *Salmonella* Braenderup – PFGE pattern JBPX01.0101
CDC cluster code 1208CATDY-1 – *Salmonella* Worthington – PFGE pattern TDYX01.0009

ERU ELECTRONIC FILE LOCATION:

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OVERVIEW:

As of October 11, 2012, the California Department of Public Health (CDPH), Infectious Diseases Branch (IDB) reported 127 persons infected with the outbreak strain of *Salmonella enterica* serovar Braenderup (*S.* Braenderup) in 15 states with possible links to mango consumption. A similar outbreak during the same time period was reported in Canada that strongly implicated mangoes. Concurrently, IDB was monitoring a cluster of *Salmonella enterica* serovar Worthington, also reported to be highly associated with mango consumption. A traceback investigation was initiated by the CDPH, Food and Drug Branch (FDB) to determine the source of the suspect mangoes. The traceback investigation identified a Mexican mango supplier, Agricola Daniella, as providing mangoes to retail locations where many of the California case patients reported purchases. Mangoes were also implicated by the analyses of four fresh mango samples that tested positive for *Salmonella* spp. and the finding of *Salmonella* spp. in environmental samples obtained from the Agricola Daniella mango packing facility located in Mexico.

BACKGROUND:

Throughout July and August 2012, IDB monitored a cluster of *S.* Braenderup illnesses in California. Hypothesis generating interviews identified the following commodities as items of interest; lettuce, tomatoes, strawberries, watermelon, cantaloupe, and mangoes. During this period, IDB provided updates to FDB on a weekly basis.

On 8/20/2012, IDB provided FDB with an update regarding the cluster of *S.* Braenderup illnesses in California. Sixty-one cases had a matching Pulsed Field Gel Electrophoresis (PFGE) pattern (JBPX01.0101). Fresh Mango consumption was indicated as a possible source of *S.* Braenderup illness in 73% of the cases. Additionally, IDB and FDB were notified that the Canadian Food Inspection Agency (CFIA) was investigating a similar cluster of illnesses in Canada that strongly implicated fresh mangoes as well.

On 8/21/2012, IDB was notified by the U.S. Food and Drug Administration (FDA), Coordinated Outbreak Response and Evaluation (CORE) team that there were a total of 84 cases across the country, including the 61 cases in California. FDA CORE indicated that mangoes were an exposure vehicle of interest.

On 8/22/2012, IDB initiated a case-control study of California cases to further assess possible exposures. The California case definition included any California resident ill with *S.* Braenderup with a PFGE pattern matching the outbreak, and an onset or specimen collection date of 7/1/2012 or later. Controls were from a randomized list of patients who had been previously identified with non-Typhi and non-Braenderup *Salmonella* infection with onset or collection dates from 7/1/2011 through 6/30/2012.

On 8/22/2012, CFIA reported 14 Canadian residents with same PFGE pattern as the outbreak seen in the United States. For these cases, the only common exposure was Mexican mangoes purchased at one retail chain.

On 8/23/2012, FDB launched a traceback investigation.

On 8/24/2012, FDB was informed that the preliminary analysis of the IDB matched, case-control study indicated that mango consumption was the only risk factor significantly associated with illness. Analysis revealed that 59% of case patients versus 22% of control patients reported mango consumption. The odds ratio for mango exposure was 4.6 and the p-value was 0.001.

On 8/24/2012, CFIA issued a Health Hazard Alert for mangoes in response to a recall initiated by North American Produce Sales in Vancouver, BC. As more information became available, CFIA updated the health alert to include all mangoes imported under the Daniella brand name.

Upon notification of the "Daniella" brand mango recall initiated in Canada, FDB contacted Splendid Products in Burlingame, CA by phone. After providing a summary of the current epidemiological and traceback information, Splendid Products initiated a voluntarily recall of "Daniella" brand mangoes distributed in the United States and Canada. Splendid Products submitted a press release on 8/29/2012. Additional recalls associated with fresh mangoes and food products containing mangoes occurred throughout September 2012.

As of October 11, 2012, IDB reported 127 persons infected with the outbreak strain of *S.* Braenderup in 15 states. California was identified as having the majority of cases (n=102; ~80%). California case patients were recorded in 22 counties with illness onset dates between 7/6/2012 and 8/20/2012. A cluster of *Salmonella* Worthington, with 17 cases in the United States (13 in California), was also reported to be highly associated with mango consumption. The XbaI PFGE pattern designation was TDYX01.0009, and the CDC cluster code was 1208CATDY-1. See "Exhibit A" for the Interim Report from IDB.

SUMMARY OF ACTIVITY:

On 8/23/2012, FDB began a traceback investigation using an initial list of ten cases selected by IDB. The selection criteria used by IDB ensured that cases were from various geographical areas, had excellent recollection of food history, had exposure to mangoes in the period of incubation for *Salmonella*, and were clearly able to identify purchase location(s). In some cases, receipts were available that verified purchase date and location. The traceback investigation revealed that firms in Sinaloa, Mexico, including Agricola Daniella, were common sources for many of the mangoes of interest. Investigators with FDB continued traceback activities in coordination with FDA. As the investigation on the original ten cases was completed, an additional six cases were added to the traceback activity on 9/6/2012. A total of 14 cases were ultimately included in the traceback. In the process, case patients were eliminated if retail locations could not provide documents related to mango shipments.

FDB completed a traceback investigation for the following California case patients:

Case	Illness Onset Date	Point of Mango Purchase
CA004	7/20/2012	[redacted]
CA008	7/14/2012	
CA024	7/26/2012	
CA027	7/26/2012	
CA028	7/24/2012	
CA036	8/1/2012	
CA039	7/25/2012	
CA043	7/20/2012	
CA055	7/30/2012	
CA056	7/26/2012	
CA058	7/30/2012	
CA071	7/29/2012	

CA072	7/23/2012	[redacted]
CA073	8/8/2012	

FDB identified all reported purchase locations (17 retail sites in total) for the selected case patients. Sixteen of the retail locations were grocery stores (both chain & independent) and one was a restaurant (identified as serving a mango product to a case). FDB investigators contacted purchase locations and reviewed receiving documentation for mangoes during July 2012, which included invoices, bills of lading, and other available records. This documentation provided information as to when the retail location could have received the suspect mangoes. Investigators then traced back the suspected mangoes to their original source by reviewing shipping and receiving records obtained at each level of commerce. When there were multiple suppliers of mangoes to the retail location in any given time period of interest, all sources available during the time period of interest were traced back to their origins.

A timeline for shipments to the retailer was developed (Exhibit B) based upon the documentation received from the retailer and the information outlined above. This determined the period of interest for the collection of records in each subsequent level of the traceback. Factors taken into consideration for the time period of interest included using a first-in first-out stock rotation and the shelf life of mangoes as reported by the mango industry (approximately two weeks). FDB focused attention on the shipments received by distributors in the two weeks prior to receipt of the shipment(s) of interest by the retail location(s). Using a similar procedure, FDB identified sources of mangoes, including exporter(s) and/or mango packing facilities located in Mexico. FDA communicated with the firms in Mexico when necessary.

With the exception of one on-site investigation, all documents were obtained via phone calls, faxes, and e-mail communication. Based on the trace back investigation, Agricola Daniella in Mexico was identified as providing mangoes to a majority of the selected case patients (Exhibit C). Of the 14 cases included in the traceback investigation, only three were linked to mangoes that did not originate from Agricola Daniella.

FINDINGS AND CONCLUSIONS:

Testing Results – Regulatory Agencies:

- On August 27, 2012, FDB collected a single, fresh mango (intact) from a case patient's home in Watsonville, CA. This sample was analyzed by the CDPH, Food and Drug Laboratory Branch (FDLB) for *Salmonella* and was found negative for the pathogen.
- FDA collected a total of 83 domestic samples of fresh mangoes from multiple distribution centers and warehouses in California, Arizona, and Texas. Three of the 83 product samples tested positive for *Salmonella* spp.
- On August 28, 2012, a fresh mango sample was collected by [redacted] (a distributor in San Diego, CA), and tested positive for *Salmonella* spp. The isolate from this sample was provided to FDA for serotyping.
- In August 2012, Mexican health officials with the Servicio Nacional de Sanidad Inocuidad y Calidad Agroalimentaria (SENASICA) conducted an on-site inspection and collected environmental samples at Agricola Daniella. The testing found multiple environmental samples that were positive for *Salmonella* spp. Seven different *Salmonella* serotypes (*S.* Bardo, *S.* Group C2 Monophasic, *S.* Javiana, *S.* Kotu, *S.* Mbandaka, *S.* Montevideo, and *S.* Saphra) were found to be present in the facility, but none of them matched the outbreak strain.

In total, four fresh mango samples tested positive for *Salmonella* spp. (three collected by FDA and one collected by [redacted]). The serotypes were reported as *S.* Gaminara (FDA sample), *S.* Javiana (FDA sample), S. Rubislaw (FDA sample), and *S.* Newport [redacted]. These *Salmonella* serotypes did not match the serotype associated with this outbreak.

Testing Results – Mango Distributors:

- On August 29, 2012, Splendid Products conducted in-house testing of 26 recalled mangoes on hold in Nogales, AZ from various lots. All results were negative for *Salmonella* and were reported by Splendid Products to FDB and FDA on September 4, 2012.
- As described under the "Testing Results – Regulatory Agencies" section above, [redacted] (collected a single mango from each of 71 mango lots being warehoused in California. These results were reported to FDB and FDA on September 4, 2012. One of 71 mangoes tested positive for *Salmonella* spp. This isolate was provided to FDA, as noted above, and was reported as *Salmonella* Newport.

Throughout this investigation neither *S.* Braenderup nor *S.* Worthington was isolated from fresh mango samples in the United States. Significant epidemiological data identified mangoes as the suspect vehicle. In addition, four mango samples tested positive for *Salmonella* spp., and *Salmonella* spp. was detected in the packing facility in Mexico as

reported by Mexican officials. In response, FDA issued an Import Alert on 9/12/2012, for all mangoes packed at the Agricola Daniella facility in Mexico (Import Alert 99-23). The Import Alert ensures that all mangoes presented at the Mexico border for entry into the United States are held unless independent testing verifies the mangoes are *Salmonella* free.

The handling of mangoes by distributors in California was limited to warehousing and distributing entire cases. All of the mangoes were sold in intact cases to California retail locations. Although instances of poor first-in, first-out rotation were observed in the distribution chain, the significant majority of case patients investigated had purchased mangoes from retail locations that were sourced from Agricola Daniella and packed in Mexico. Due to the complexities of the distribution routes and the practice of commingling mangoes at the retail level, it is possible that those case patients that did not consume mangoes directly from Agricola Daniella may have eaten mangoes that were cross-contaminated by mangoes from Agricola Daniella. Epidemiological and traceback data collected during this investigation indicates that mangoes packed in Mexico by Agricola Daniella likely caused illness in California consumers.

SUPPORTING DOCUMENTATION:

Exhibits:

a. IDB Interim Report
b. Traceback Time-Line
c. Traceback Diagram

ENFORCEMENT ACTIONS: ☐ NOV ISSUED ☐ EMBARGO ☐ VC & D ☐ REG. LETTER ☐ REFERRAL ☐ OTHER:

RECOMMENDATIONS: ☒ NAI ☐ MINOR VIOLATIONS / FIRM CORRECTING ☐ OTHER:

COMMENTS / FOLLOW-UP ACTION: Mangoes packed by Agricola Daniella were placed under Import Alert by FDA, and due to the growing season are not expected to be imported into the United States until mid-2013. FDB will continue to monitor for Salmonellosis in California residents.

ERU LEAD SIGNATURE:	INV.#	REPORT DATE:
Brandon Adcock [redacted]	710	11/29/2012
Amber Barnes [redacted]	171	
SUPERVISOR SIGNATURE: Michael D. Needham #094 [redacted]		**DATE REVIEWED:** 4/17/2013
SUPERVISOR DISPOSITION: No further action indicated		