

A Multistate Outbreak of Human *Salmonella* Agona Infections Associated With Consumption of Fresh, Whole Papayas Imported From Mexico—United States, 2011

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Background. Nontyphoidal *Salmonella* causes ~1 million food-borne infections annually in the United States. We began investigating a multistate outbreak of *Salmonella* serotype Agona infections in April 2011.

Methods. A case was defined as infection with the outbreak strain of *Salmonella* Agona occurring between 1 January and 25 August 2011. We developed hypotheses through iterative interviews. Product distribution analyses and traceback investigations were conducted. The Food and Drug Administration (FDA) tested papayas from Mexico for *Salmonella*.

Results. We identified 106 case patients from 25 states. Their median age was 21 years (range, 1–91). Thirty-nine of 61 case patients (64%) reported Hispanic/Latino ethnicity; 11 of 65 (17%) travelled to Mexico before illness. Thirty-two of 56 case patients (57%) reported papaya consumption. Distribution analyses revealed that three firms, including Distributor A, distributed papaya to geographic areas that aligned with both the location and timing of illnesses. Traceback of papayas purchased by ill persons in four states identified Distributor A as the common supplier. FDA testing isolated the outbreak strain from a papaya sample collected at distributor A and from another sample collected at the US-Mexico border, destined for distributor A. FDA isolated *Salmonella* species from 62 of 388 papaya import samples (16%). The investigation led to a recall of fresh, whole papayas from Distributor A and an FDA import alert for all papayas from Mexico.

Conclusions. This is the first reported *Salmonella* outbreak in the United States linked to fresh, whole papayas. The outbreak highlights important issues regarding the safety of imported produce.

Keywords. *Salmonella*; outbreaks; papaya.

Salmonella is a common cause of gastrointestinal illness in the United States. The pathogen causes an estimated 1 million food-borne illnesses and 380 deaths each year [1]. Although eggs and poultry are common food vehicles for *Salmonella* infection, fresh produce, such as sprouts, tomatoes, and melons, have all been implicated in outbreaks [2–8]. Recent data indicate that 13% of *Salmonella* outbreaks are attributable to contaminated produce [9].

In July 2010, an outbreak of gastrointestinal illnesses caused by *Salmonella* serotype Agona was detected by PulseNet, the national molecular subtyping network for food-borne disease surveillance [10]. Bacterial isolates from 119 ill persons shared 1 of 7 similar pulsed-field gel electrophoresis (PFGE) patterns,

or DNA fingerprints, 6 of which had never been seen in the PulseNet database. Ill persons were concentrated in California, Illinois, and Texas; several reported travel to Mexico, and many were of Hispanic ethnicity or had shopped at Hispanic markets. Interviews with case patients suggested fresh produce items as possible vehicles, including cantaloupe, mango, and papaya. However, the investigation conducted during 2010 was not able to link illnesses to a specific food source.

In April 2011, PulseNet detected another cluster of *Salmonella* Agona infections yielding PFGE patterns similar to those of the unsolved 2010 outbreak; the demographic characteristics and geographic distribution of ill persons also resembled those in the 2010 outbreak. This report describes the investigation of the 2011 outbreak, which was ultimately linked to consumption of contaminated fresh, whole papayas imported from Mexico.

METHODS

Detection of the Outbreak

On 1 April 2011, PulseNet identified a cluster of 18 *Salmonella* Agona infections with PFGE pattern *Xba*I JABX01.0653. Cases

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were identified in 10 states, with illnesses occurring between 31 January and 29 March 2011. Concurrently, PulseNet detected a cluster of 6 *Salmonella* Agona infections with PFGE pattern *XbaI* JABX01.0663 and a single case of *Salmonella* Agona with PFGE pattern *XbaI* JABX01.0660. Each of these patterns had been part of the *Salmonella* Agona cluster investigated in 2010; none of these PFGE patterns had been detected by PulseNet before 2010. *Salmonella* Agona infections associated with PFGE pattern *XbaI* JABX01.0122 reemerged in May 2011; this pattern was first seen in 1999, but only 6 cases had been detected before 2010 when it was also included in the cluster investigation. Given that these cases shared epidemiologic characteristics with those of patterns *XbaI* JABX01.0653, *XbaI* JABX01.0663, and *XbaI* JABX01.0660, all 4 patterns were investigated together as a single cluster. State and local public health officials and the Centers for Disease Control and Prevention initiated a multistate investigation of the outbreak.

Case Definition

A case was defined as a *Salmonella* Agona infection in a US resident with illness onset date (or isolation date if onset unknown) between 1 January and 25 August 2011, yielding an isolate with any of the 4 PFGE patterns (JABX01.653, JABX01.663, JABX01.0660, or JABX01.0122) that defined the “outbreak strain.”

Case Finding

PulseNet was used to detect cases. The Centers for Disease Control and Prevention also queried PulseNet databases in Latin America and the Caribbean. PFGE of *Salmonella* Agona isolates was performed at PulseNet-affiliated public health laboratories using standardized methods [11]. The resulting PFGE patterns were submitted to the national PulseNet database and compared.

Hypothesis Generation

We used an iterative process to interview patients about foods and other exposures in the week before illness onset to generate hypotheses about potential causes of the outbreak. The initial questionnaire for the investigation elicited information about exposures reported during the 2010 outbreak investigation, such as exposure to tropical fruits and vegetables. Other questions included foods more commonly available in ethnic markets or used in Latin cuisine, as well as items historically associated with salmonellosis outbreaks. As the investigation progressed, the questionnaire was further refined to focus on exposures that were commonly reported by previously interviewed case patients. Brand and other detailed food product information were solicited. Four increasingly targeted versions of the questionnaire were deployed over the course of the investigation. When the investigation progressed without the emergence of a leading hypothesis, a single interviewer conducted open-ended interviews with 13 recent case patients to obtain detailed exposure histories and identify any unusual exposures in common among case patients.

Exposure frequencies for case patients were compared with data compiled in the 2006–2007 Foodborne Diseases Active

Surveillance Network (FoodNet) Population Survey, which assessed baseline food consumption frequencies in the week before interview for a sample of US residents [12]. This comparison aided hypothesis generation by identifying which food exposures were reported by case patients more frequently than would be expected. Exposure frequencies for case patients were compared with those in FoodNet survey participants of similar age and ethnicity, using the binomial test with differences considered significant at $P < .05$.

Distribution Analysis and Traceback

The US Food and Drug Administration (FDA) used product information obtained through case-patient interviews for product distribution analyses. Aggregated data from case patients who definitively recalled the time and place of purchase of suspect foods were cross-referenced with distribution records contained in import information databases for these foods. This assessment ultimately identified which distribution firms were supplying products of interest to geographic regions with high concentrations of case patients during the time of the outbreak.

Product traceback investigations were conducted using information collected from case patients with detailed purchase histories, such as brand, date, and location of purchase. Food production pathways of suspect products were assessed to determine whether a common source or point of convergence among the paths could be identified.

Environmental Investigation

From 11 July to 14 July 2011, FDA and Texas state investigators inspected 3 distribution firms at the Texas-Mexico border to collect environmental and product samples; these firms were suspected of being involved in the distribution of implicated food product on the basis of the distribution analysis. From 28 July to 2 August 2011, a single packing house in Mexico (and the associated plantation) that supplied produce to the United States via 1 of the suspect distribution firms was also inspected, and additional environmental samples were obtained.

Laboratory Testing

In response to the outbreak investigation, the FDA initiated an import bulletin from 12 May to 24 August 2011 that increased sampling and testing of fresh papaya, cantaloupe, and mango imported from Mexico. Samples collected as a part of the environmental investigation and through the import bulletin were cultured to identify *Salmonella* spp; serotyping and PFGE were performed on all *Salmonella* spp identified.

RESULTS

Case Patients

One hundred six cases from 25 states were identified (Figure 1); illness onset ranged from 1 January 2011 to 25 August 2011 (Figure 2). The states with the most cases were Texas, Illinois, New York, and Georgia. The median age of the case patients was 21 years (range, <1 to 91 years); of 100 patients for whom

information was available, 39 (39%) were <5 years and 10 (10%) were <1 year old. Sixty of 106 patients (56%) were female. Ten of 65 (15%) with available information were hospitalized; none died. Of 61 patients for whom information was available, 39 (64%) reported Hispanic/Latino ethnicity. Eleven of 65 (17%) with available information reported international travel during the 2 weeks before illness; all reported traveling to Mexico. No outbreak-associated infections were identified outside the United States.

Hypothesis Generation

General enteric and/or targeted interviews were conducted for 56 of 106 case patients (53%). Foods commonly reported by case patients were compared with data in the FoodNet Population Survey. Papaya (57% vs 11%; $P < .01$), mango (41% vs 25%; $P = .03$), and cilantro (46% vs 17%; $P < .01$) were each consumed more frequently by case patients than expected.

Open-ended interviews were conducted with 13 case patients. Nine of 13 (69%) reported papaya consumption in the week before illness onset, and 11 of 13 (85%) reported having papaya in the house in the 2 weeks before illness onset. Five individuals reported that the case patient was the only member of the household who consumed papaya during that time. Four of 13 (31%) were able to definitively recall the location where the papaya was purchased. Three of 13 (23%) reported mango consumption, and 5 of 13 reported having mango in the house in the 2 weeks before illness onset. Each of these 5 case patients also reported either consuming papaya or having papaya in the house in the 2 weeks before illness onset. Four of thirteen (31%) reported consumption of cilantro, and 7 of 13 (53%) reported having cilantro in the house during the time period of interest.

Thirty-two of 56 interviewed case patients (57%) reported fresh papaya consumption. Four of these 32 patients (12.5%) were able to recall the variety or brand of papaya consumed before illness, and all 4 (100%) reported consumption of Maradol papayas, the variety commonly grown in Mexico.

Distribution Analysis and Traceback

Initial traceback investigations conducted by the Texas Department of State Health Services Rapid Response Team indicated that papaya consumed by case patients in the state were imported from Mexico. Distribution analysis using this information and import database records showed that only 3 firms distributed papaya to geographic areas that aligned with both the location and timing of illnesses (distributors A, B, and C). Subsequent traceback using information collected from ill persons who purchased papayas in Texas, Illinois, Georgia, and Maryland identified distributor A as the common supplier of the purchased papayas.

Environmental Investigation and Product Testing

During import bulletin sampling and testing, FDA isolated the *Salmonella* Agona outbreak strain from a papaya sample collected at distributor A and from another sample collected at the US-Mexico border, destined for distributor A. Overall, 10 *Salmonella* strains were isolated from 62 of 388 samples (16%) collected as part of the import testing. The samples that yielded *Salmonella* originated from 38 facilities, including distributors and packing houses; these facilities were dispersed over nearly all the major papaya-producing regions in Mexico. The PFGE patterns of these isolates were reviewed in PulseNet and

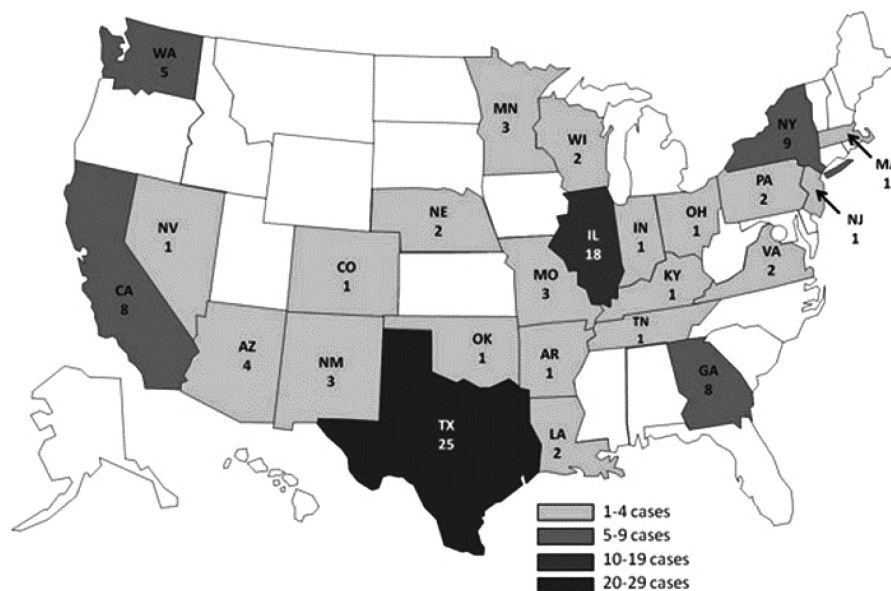


Figure 1. Outbreak-associated *Salmonella* serotype Agona cases by US residence, from 1 January to 25 August 2011 (n = 106).

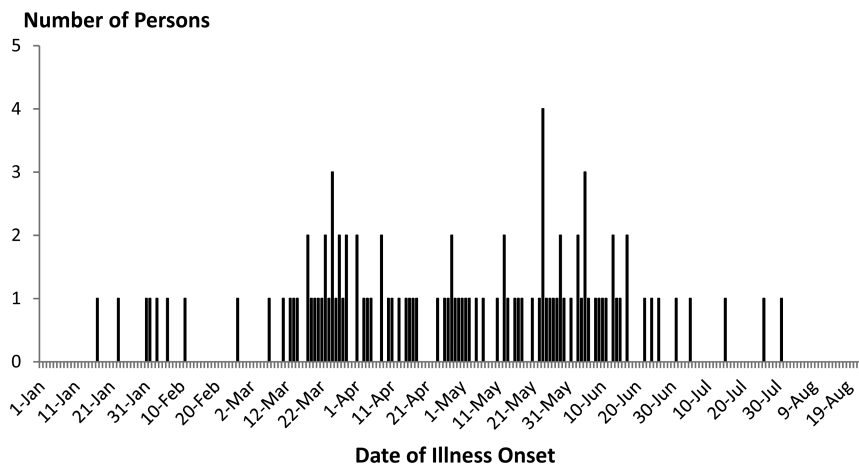


Figure 2. Outbreak-associated *Salmonella* serotype Agona cases in the United States by week of illness onset, from 1 January (Jan) to 25 August (Aug) 2011 (n = 103; onset data missing for 3 patients).

investigated, but no concurrent *Salmonella* outbreaks linked to papaya consumption were identified.

During 11–14 July 2011, an FDA inspection team and investigators from the Texas Department of State Health Services Regulatory Services Division inspected distributor A in McAllen, Texas, which had been identified as potentially being the source of contaminated produce. Approximately 140 environmental samples were retrieved from various areas of the facilities, including coolers, cooling and heating rooms, conveyer belts, and areas where the papayas are sorted and repackaged; none yielded *Salmonella*.

An FDA inspection team was also deployed to 1 of 8 plantations in Chiapas, Mexico associated with distributor A that supplied papaya for distribution at the firm. Swab samples were collected in the plantation’s packing house and from standing water/sediment in drainage ditches on the farm. Eight of 17 environmental samples (47%) yielded *Salmonella* spp; however, none were *Salmonella* Agona. The team reported 10 observations relating to water handling issues at the packing house and the plantation, including drainage system deficiencies and resultant standing water, sanitization deficiencies, cross-connections, and improper storage of tree props to prevent ground contamination.

Product Recall and Public Health Impact

Distributor A halted distribution of papaya on 20 July 2011 in response to the outbreak. On 23 July, the FDA placed the plantation supplying papayas to distributor A on import alert, preventing the distributor from importing papaya into the United States until repeated testing demonstrated that the product was no longer contaminated [13]. On the same day, distributor A voluntarily recalled all fresh, whole papayas sold before that date. The recall included papayas marketed under 4 brand names. In response to the high proportion of samples which yielded *Salmonella* during the import bulletin sampling, the FDA initiated a broader import

alert on 25 August 2011, which detained all papayas imported into the United States from Mexico [14].

DISCUSSION

In this report, we describe a multistate outbreak of *Salmonella* Agona linked to consumption of contaminated fresh, whole papayas imported from Mexico. This outbreak represents the second known *Salmonella* outbreak associated with papaya worldwide [15] and the first such outbreak in the United States. By combining information derived from case-patient interviews with that obtained from analysis of distribution records, we identified papayas from Mexico as the source of the 2011 outbreak. The compelling epidemiologic and laboratory evidence linking papayas imported from Mexico and distributed by distributor A led distributor A to issue a nationwide voluntary recall of all fresh, whole papayas. In addition, the high proportion of papaya samples that yielded *Salmonella* species during the import bulletin led the FDA to issue an import alert that affected all papayas imported to the United States from Mexico. The alert prevented import and distribution of papayas from Mexico in the United States except by distributors that could demonstrate through repeated third-party laboratory analyses that the papayas they distributed were not contaminated.

The definitive point of *Salmonella* Agona contamination remains unknown; however, multiple on-farm practices that could have led to contamination were identified. The inspected plantation and packing house were cited during FDA inspections for multiple violations of sanitary practices, including the presence of pooled standing water at the farms, which can contribute to growth of *Salmonella* species, as well as temporary storage of papaya in unclean and potentially contaminated materials. Papaya stored in this way and consequently contaminated would be transferred to wash tanks and, given that records regarding sanitization of the tanks’ wash water were questionable, may

have contaminated papaya subsequently placed in the tanks. It is likely that one of these infractions or similar ones ultimately led to contamination of the papaya that caused the outbreak.

Although environmental testing during this investigation did not identify *Salmonella* Agona, environmental sampling conducted during a 2012 investigation isolated the outbreak strain of *Salmonella* Agona. In July 2012, a multistate investigation was initiated after PulseNet identified a similar cluster of *Salmonella* Agona infections; the associated PFGE pattern was one that had been included in the 2011 investigation. Between 2 July and 1 August 2012, a total of 30 cases were identified, with cases concentrated in Texas and California. Travel to Mexico and papaya consumption were commonly reported by case patients, although papayas could not be confirmed as the source. In collaboration with the government of Mexico's National Service for Agro-Alimentary Public Health, Safety and Quality and the Federal Commission for the Protection from Sanitary Risks, the FDA repeated assessments at plantations in Mexico associated with distributor A, this time detecting the outbreak strain during environmental sampling.

Several challenges particular to outbreaks involving bulk produce were apparent during this investigation. Bulk produce, in contrast with bagged produce, may be more often purchased and eaten by consumers without recognition of the variety or brand of the item. This was evident in the difficulty case patients exhibited in recalling variety and brand information for purchased papaya. Brand name and variety information facilitates traceback of a food product from the place of purchase to the factory/farm of origin, and the lack of this data can complicate the traceback process. In addition, bulk produce from multiple farms is often aggregated and comingled during packing and distribution, adding another layer of complexity to determining the route of produce items from farm to market [16]. Comingling of whole papayas from multiple farms within packing plants was also evident in this investigation.

This outbreak was ultimately solved by combining use of interviews to identify suspect food vehicles with traceback, analysis of distribution records, and product testing. In the case of this outbreak, papayas were purchased from 4 geographic regions in the United States, and only distributor A supplied papayas to all these regions during the time of the outbreak, suggesting a link between distributor A and the food causing the outbreak. In addition, papaya is the only food processed by distributor A, further strengthening the link between the firm and the food vehicle of the outbreak. Traceback investigations also identified distributor A. These findings justified examination of the distributor, which ultimately led to the isolation of the outbreak strain from distributor A papayas.

The demographic characteristics of case patients identified during this outbreak have implications for clinicians. Case patients included a large proportion of children <5 years of age, an age group known to be at increased risk of infection due to

Salmonella spp [17]. They also included children <1 year of age, an age group with particular potential for severe diarrheal disease owing to increased risk of dehydration. Clinicians can help parents of young children prevent diarrheal disease by advising them of practices for safe selection and consumption of fresh produce [18] Box 1]. Parents should also be reminded of techniques for oral rehydration at home in case of dehydration in children; severe symptoms, particularly in infants, should prompt medical evaluation in accordance with guidelines to assess appropriateness of laboratory testing and/or enhanced therapies [19].

The outbreak underscores important issues regarding US consumers and the safety of imported foods, particularly produce; between 2005 and 2014, import volumes of fruits and vegetables grew by an average of 3.7 and 4.5% per year, respectively [20]. Furthermore, 18 multistate outbreaks involving 1439 illnesses were linked to imported food between 2010 and 2014 [21]. Food-borne outbreaks have been linked to imported produce items, such as strawberries, cantaloupes, raspberries, and mamey pulp [22–26]. Importation of food from other countries where the US food safety system has limited inspection capabilities necessitates some reliance on the food safety systems within those countries, not only for supply of products free of potentially infectious organisms, but also for investigation of the sources of products found to be contaminated during outbreak investigations. In addition, long distances and numerous sites of product handling between point of origin and market can complicate traceback.

Effective investigation of outbreaks associated with imported foods will require both further development of techniques such as distribution analysis and strengthening of cross-border relationships between food safety agencies, as with the formal produce safety partnership established between the United States and Mexico in 2014 [27]. Such efforts, within a context of public health infrastructure robust in the areas of disease surveillance and traceback, probably likely become increasingly critical in preventing illness from imported food.

Box 1. Steps to Safe and Healthy Fruits and Vegetables^a

- Check fruits and vegetables for bruising and damage.
- Throw away fruits and vegetables that are spoiled or have been recalled.
- Wash your hands, kitchen utensils, and food preparation surfaces, including chopping boards and countertops, before and after preparing fruits and vegetables.
- Clean fruits and vegetables before eating, cutting, or cooking, unless the package says that the contents have been pre-washed.
 - Wash or scrub all fruits and vegetables under running water—even if you do not plan to eat the peel—so dirt and germs are not transferred from the surface to the inside when you cut the produce.
 - Dry fruit or vegetables with a clean paper towel.
- Keep fruits and vegetables separate from other foods that could contaminate them, such as raw meat and seafood.
- Refrigerate fruits and vegetables that you have cut up, peeled, or cooked as soon as possible, or within 2 hours. Refrigerate within 1 hour if the temperature outside is above 90°F(32.2°C). Chill them at 40°F (4.4°C) or below in a clean container.

^aAdapted from Centers for Disease Control and Prevention, "Fruit and Vegetable Safety" [18].

Notes

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