

A Recurrent, Multistate Outbreak of *Salmonella* Serotype Agona Infections Associated with Dry, Unsweetened Cereal Consumption, United States, 2008[†]

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MS 12-209: Received 14 May 2012/Accepted 9 July 2012

ABSTRACT

An outbreak of *Salmonella enterica* serotype Agona infections associated with nationwide distribution of cereal from Company X was identified in April 2008. This outbreak was detected using PulseNet, the national molecular subtyping network for foodborne disease surveillance, which coincided with Company X's voluntary recall of unsweetened puffed rice and wheat cereals after routine product sampling yielded *Salmonella* Agona. A case patient was defined as being infected with the outbreak strain of *Salmonella* Agona, with illness onset from 1 January through 1 July 2008. Case patients were interviewed using a standard questionnaire, and the proportion of ill persons who reported eating Company X puffed rice cereal was compared with Company X's market share data using binomial testing. The Minnesota Department of Agriculture inspected the cereal production facility and collected both product and environmental swab samples. Routine surveillance identified 33 case patients in 17 states. Of 32 patients interviewed, 24 (83%) reported eating Company X puffed rice cereal. Company X puffed rice cereal represented 0.063% of the total ready-to-eat dry cereal market share in the United States at the time of the investigation. Binomial testing suggested that the proportion of exposed case patients would not likely occur by chance ($P < 0.0001$). Of 17 cereal samples collected from case patient homes for laboratory testing, 2 (12%) yielded *Salmonella* Agona indistinguishable from the outbreak strain. Twelve environmental swabs and nine product samples from the cereal plant yielded the outbreak strain of *Salmonella* Agona. Company X cereal was implicated in a similar outbreak of *Salmonella* Agona infection in 1998 with the same outbreak strain linked to the same production facility. We hypothesize that a recent construction project at this facility created an open wall near the cereal production area allowing reintroduction of *Salmonella* Agona into the product, highlighting the resilience of *Salmonella* in dry food production environments.

Salmonella is the most common bacterial cause of foodborne outbreaks in the United States, resulting in an estimated 1.0 million infections and 378 deaths annually; the incidence rate has changed little in the last decade (6, 11, 12). Previous outbreaks of *Salmonella* infections have been associated with a wide range of food items, including meat, poultry, eggs, and produce (5). Such outbreaks have been increasingly linked to processed foods in recent years (3, 8, 10). *Salmonella enterica* is not a uniform species, and over 2,500 serotypes of *S. enterica* have been identified, with certain serotypes having an association for certain vehicles.

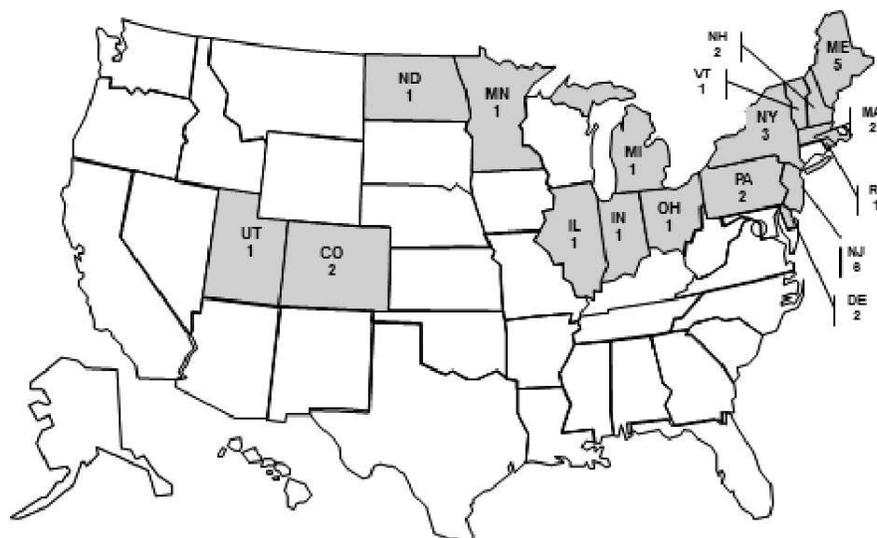
In 2005, *S. enterica* serotype Agona was one of the top 20 most commonly reported serotypes causing human infections (11).

Salmonella Agona has been identified in outbreaks associated with various dry food products. In 1994 there was an international outbreak associated with consumption of corn and soy-based savory snacks that resulted in over 2,000 infections (1, 4, 13). The largest known outbreak of *Salmonella* Agona infections in the United States occurred in 1998 and affected more than 400 patients, many of whom were children. The outbreak investigation identified toasted oats cereal produced by Company X as the likely source of infection (9). Following the investigation of Company X's plant, the implicated production lines were sealed off, all equipment was removed, all surfaces were stripped to bare concrete, decontaminated, and refinished, and new production

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† The findings and conclusions in this report are those of the authors and do not necessarily represent the views of the Centers for Disease Control and Prevention.

FIGURE 1. Thirty-three case patients infected with the outbreak strain of *Salmonella* Agona, United States, by state, 1 January through 1 July 2008.



lines were installed (personal communication, 9 November 2011). The original source of *Salmonella* Agona contamination in the production facility was not identified.

On 5 April 2008, cereal Company X issued a voluntary recall of unsweetened puffed rice and puffed wheat cereals after Company X recovered *Salmonella* Agona from finished product. At the time of product testing no clusters of human illnesses associated with *Salmonella* Agona had been identified. However, on 8 April, PulseNet, the national molecular subtyping network for foodborne disease surveillance, identified 13 persons in 10 states infected with an indistinguishable pulsed-field gel electrophoresis (PFGE) pattern *Salmonella* Agona. Further subtyping of the isolates from Company X revealed the same PFGE pattern of *Salmonella* Agona. This PFGE pattern, JABX01.0001, which is referred to here as the outbreak strain, is the same pattern of *Salmonella* Agona identified during the 1998 outbreak associated with toasted oats cereal (9). As a result of this investigation, Company X permanently ceased production of unsweetened puffed rice and puffed wheat cereals, removed all equipment, and permanently sealed this section of the plant. This report describes the results of the 2008 outbreak investigation.

MATERIALS AND METHODS

Laboratory and environmental testing. Clinical laboratories that isolated *Salmonella* from patient specimens forwarded isolates to their state public health laboratories. Cereal samples collected from case patient homes for pathogen testing were also submitted to state public health laboratories for testing. The U.S. Food and Drug Administration (FDA), in coordination with the Minnesota Department of Agriculture, conducted an inspection at the Company X production facility. As part of this inspection, product samples and environmental swabs were collected and tested. All *Salmonella* isolates were subtyped by PFGE using standard methods (2, 7, 14). After culturing and subtyping, the results were uploaded to PulseNet.

Epidemiology. A case was defined as an infection with the outbreak strain of *Salmonella* Agona, with illness onset from 1 January to 1 July 2008. Case patients were contacted by local public health officials and interviewed using a standard questionnaire to

collect information on food consumption history as well as nonfood exposures, such as animal contact and recreational water exposures, in the 7 days preceding illness. These initial interviews revealed that case patients consumed cereal from Company X. A more specific, targeted questionnaire was developed to assess detailed cereal exposure and purchase history data. In addition, case patients were asked if they had any leftover cereal products in their home, which could be submitted for pathogen testing. The percentage of sales of Company X puffed wheat cereal compared with total dry cereal sales is the market share of Company X puffed wheat cereal. We compared this market share data with the frequency of consumption of this specific cereal by case patients using binomial testing.

Statistical analysis. Statistical analyses were conducted using SAS 9.2 (SAS Institute, Cary, NC). A one-sample exact binomial test was used to test the null hypothesis that ill consumers of cold cereal would not be expected to have eaten the implicated brand of puffed rice cereal at a frequency significantly higher than market share. We report the *P* value as a conservative upper bound to acknowledge nonstatistical sources of uncertainty.

RESULTS

Epidemiology. We identified 33 case patients infected with the outbreak strain of *Salmonella* Agona from 1 January to 1 July 2008 in 17 states (Fig. 1). Among 28 case patients for whom date of illness onset was available, onset dates ranged from 1 January to 13 May 2008 and were evenly distributed in time. Of 29 patients with clinical information, 12 (41%) were hospitalized; there were no deaths associated with this outbreak. Twenty-three case patients (70%) were female. The median age was 65 years (range: 4 months to 95 years).

Of 32 case patients interviewed, 29 (91%) reported routinely consuming dry cereal of any type. Of these 29, 25 (86%) specifically reported consuming dry cereal products recalled by Company X; 24 (83%) of these consumed Company X brand puffed rice cereal and 1 (3%) consumed Company X brand puffed wheat cereal. No other common foods or exposures were identified.

Company X brand of puffed rice cereal represented 0.063% of the total ready-to-eat dry cereal market share in the United States at the time of the investigation (personal

TABLE 1. Environmental inspection laboratory results from Company X cereal production facility indistinguishable from outbreak strain of *Salmonella Agona*^a

Source of environmental specimen	No. of matching isolates
Puffed rice cereal from Company X production facility	7
Puffed wheat cereal from Company X production facility	2
Environmental swab collected from the destoner room	8
Other environmental swab	4

^a A total of 21 isolates matching the outbreak strain were recovered.

communication, 9 November 2011). That is, the likelihood of encountering consumers of this cereal at random among dry cereal eaters is very low. Given the high proportion of case patients who consumed this specific cereal, we performed a binomial comparison of reported Company X brand unsweetened puffed rice cereal consumption with expected consumption based on market share to demonstrate that the proportion of case patients exposed to this product would not likely occur by chance ($P < 0.0001$).

Laboratory and environmental testing. Seventeen puffed wheat and puffed rice cereal samples were collected from case patient homes for laboratory testing. Two (12%) of the cereal samples (one opened bag and one sealed bag) yielded *Salmonella Agona* indistinguishable from the outbreak strain.

During the plant inspection, environmental swabs and product testing yielded 21 *Salmonella Agona* isolates matching the outbreak strain (Table 1). Nine isolates were from cereal samples: seven from puffed rice cereal and two from puffed wheat cereal. Twelve environmental samples also yielded the outbreak strain; eight (75%) were collected from a single area of production where both puffed rice and puffed wheat were made.

Investigation of cereal production facility. During the production of puffed rice and puffed wheat cereals, a puffing gun was used to create the puffed texture and heated the product sufficiently to kill pathogens. After heating, the cereal was moved through a destoner machine just before packaging. The destoner removes dust and unpuffed grains by drawing air from vents near the production room floor. In this area of the production facility, an intact wall had been disrupted in November 2007 to conduct maintenance work; this wall had been sealed off since the renovations undertaken after the 1998 outbreak.

DISCUSSION

This investigation implicated contaminated cereal made by Company X as the cause of a multistate outbreak of *Salmonella Agona* infections in 2008. Only an estimated 3% of *Salmonella* infections are laboratory confirmed and reported to foodborne surveillance systems; therefore the number of identified cases is likely an underestimate of the true number of associated illnesses (6). The outbreak

remained modest in size, despite the national distribution of this contaminated cereal, in part because the implicated products had a very small market share. Since the market share was so small and the proportion of case patients who ate the implicated product was so large, we believe the comparison of sales data with consumption history is meaningful. In this setting, we suggest that shopping and consumption behaviors are associated and that comparing them is informative to this outbreak investigation. In addition, 55% of the case patients affected by this outbreak were ≥ 65 years old, and some consumed this cereal several times a day due to dietary constraints.

This report summarizes the investigation of the second outbreak that was linked to the same puffed cereal manufacturer. This outbreak occurred 10 years after the first outbreak, but patients were infected with a strain of *Salmonella Agona* identical to that identified in 1998. Intervention efforts in 1998 involved stripping all building surfaces to bare concrete, decontamination, and refinishing surfaces with epoxy finishes to seal off implicated areas of the production facility. Preceding the 2008 outbreak, maintenance work at the production facility required opening one of the walls immediately adjacent to the section of the facility where contaminated cereal products were produced in 1998. It is feasible that dust from the disruption of the previously intact wall during plant maintenance activities, perhaps in combination with wet cleaning of the area around the breached wall, may have reintroduced the desiccated outbreak strain of *Salmonella Agona* into the cereal production area. Moist conditions, such as floor drains near the air intakes of vents on the production line, could have brought the pathogen in contact with the cereal product just prior to packaging. Following this outbreak, Company X permanently discontinued production of the implicated puffed rice and puffed wheat cereals and stopped using this section of the plant for food production. This outbreak highlights the resilience of *Salmonella*, suggesting that this organism can persist in dry food production environments for years despite eradication efforts.

ACKNOWLEDGMENTS

We acknowledge the important contributions of Jessica Kumar, the participating state public health departments (Colorado, Delaware, Illinois, Indiana, Massachusetts, Maine, Michigan, Minnesota, North Dakota, New Hampshire, New Jersey, New York, Ohio, Pennsylvania, Rhode Island, Utah, and Vermont), the state public health laboratories, our FDA partners, and the management of Company X.

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