# ADVISORY COMMITTEE ON THE MICROBIOLOGICAL SAFETY OF FOOD

## **INFORMATION PAPER**

# US Outbreak - Salmonella Saintpaul

The attached article from MMWR Weekly gives information about a recent outbreak in the United States associated with *Salmonella* Saintpaul.

Secretariat September 2008

# Outbreak of *Salmonella* Serotype Saintpaul Infections Associated with Multiple Raw Produce Items --- United States, 2008

On May 22, 2008, the New Mexico Department of Health (NMDOH) notified CDC about four persons infected with Salmonella Saintpaul strains that were indistinguishable from each other by pulsed-field gel electrophoresis (PFGE) and 15 other persons with Salmonella infections whose isolates had not yet been characterized. In the following weeks, cases continued to be reported, and the outbreak expanded to include 43 states, the District of Columbia (Figure 1), and Canada. This report is an interim summary of results from seven epidemiologic studies, traceback investigations, and environmental investigations related to the outbreak. Further data collection and analyses are ongoing. As of August 25, 2008, a total of 1,442 persons had been reported infected with the outbreak strain. At least 286 persons have been hospitalized, and the infection might have contributed to two deaths. The outbreak began late in April 2008, and most persons became ill in May or June. The outbreak appears to be over; however, CDC and state health departments are continuing to conduct surveillance for cases of infection with the outbreak strain. Preliminary epidemiologic and microbiologic results to date support the conclusion that jalapeño peppers were a major vehicle by which the pathogen was transmitted and serrano peppers also were a vehicle; tomatoes possibly were a vehicle, particularly early in the outbreak. Contamination of produce items might have occurred on the farm or during processing or distribution; the mechanism of contamination has not been determined. These findings indicate that additional measures are needed to enhance food safety and reduce illnesses from produce that is consumed raw.

## **Epidemiologic Studies**

A case was defined as laboratory-confirmed infection with *Salmonella* Saintpaul with *Xba*I pattern JN6X01.0048, the outbreak strain. Of the 1,442 cases reported, public health agencies have reported illness onset information for 1,414 patients. Illnesses began during April 16--August 11; most persons became ill in May or June (Figure 2). Complete demographic information is available for 565 ill persons. Of these, 52% were male; 79% were white, 8% were American Indian/Alaska Native, 3% were black, 2% were Asian/Pacific Islander, and 7% reported other or multiple races. Hispanic ethnicity was reported for 22%. Patient ages ranged from <1 to 99 years (median age: 33 years), and the highest incidence was among persons aged 20--29

years. Cases were distributed among 43 states, the District of Columbia, and Canada, with particularly high incidence rates in New Mexico and Texas (Figure 1).

Soon after the first cases were detected in mid-May 2008, additional cases were identified in Texas and the Navajo Nation through PulseNet (the national molecular subtyping network for foodborne disease surveillance). Nineteen ill persons were initially interviewed in detail to generate hypotheses about the source of their illnesses. To identify the source, NMDOH, the Texas Department of State Health Services (TXDSHS), Navajo Nation, the Indian Health Service (IHS), and CDC conducted a multistate case-control study of laboratory-confirmed infections. For this case-control study, a case was defined as diarrheal illness (three or more loose stools in a 24-hour period) that began on or after May 1 in a person infected with the outbreak strain. Controls were well persons in the community matched by age and location using reverse telephone directories and by face-to-face interviews. The matched analysis included 51 case-patients and 106 controls. Using a questionnaire based on hypotheses generated by the preliminary interviews, study participants were asked about foods consumed during the week preceding their illness. On univariate analysis, illness was significantly associated with eating raw tomatoes (matched odds ratio [mOR] = 6.7) and had a borderline association with eating tortillas (mOR = 2.8) in the week preceding illness onset (Table). Illness remained significantly associated with eating raw tomatoes (mOR = 5.6) after adjusting for consumption of tortillas (Table). Illness was not significantly associated with eating salsa (mOR = 1.7), guacamole (mOR = 1.6), or any other food item (<u>Table</u>).

In June, increasing numbers of cases were reported from a growing number of states. State and local health departments identified clusters of illness in restaurants by interviewing ill persons whose isolates had the outbreak PFGE pattern and asking about exposures to suspect foods and about any recent meals at restaurants. Beginning on June 20, TXDSHS and CDC investigated a cluster of 47 ill persons associated with a Mexican-style restaurant in Texas. For this case-control study, a case was defined as diarrheal illness (three or more loose stools in a 24-hour period) in a person who ate at the restaurant in the week before illness began; culture confirmation was not required. Controls were well meal companions. The analysis included 47 case-patients and 36 controls. On multiple logistic regression, illness was significantly associated only with eating salsa (adjusted odds ratio [aOR] = 62.3) (Table). The salsa ingredients included raw tomatoes and raw jalapeño peppers.

Beginning on June 24, TXDSHS and CDC investigated another cluster of 33 ill persons, this one associated with a local Mexican-style restaurant chain in Texas. For this case-control study, a case was defined as diarrheal illness (three or more loose stools in a 24-hour period) in a person who ate at either of two restaurants in the chain during the week before illness began; culture confirmation was not required. Controls were well meal companions and restaurant patrons identified by credit card receipts. The analysis included 33 case-patients and 62 controls. Illness was significantly associated only with eating salsa (aOR = 7.5) (Table). The salsa ingredients included commercially canned tomatoes and raw jalapeño peppers, but not raw tomatoes. These results indicated that jalapeño peppers were a likely source of illness.

Beginning on June 26, to further investigate possible food vehicles, CDC and state and local health departments in 29 states conducted a second multistate case-control

study of laboratory-confirmed infections identified through PulseNet. A case was defined as diarrheal illness (three or more loose stools in a 24-hour period) that began on or after June 1 in a person infected with the outbreak strain. Controls were well persons in the community matched by age and location using reverse telephone directories. The matched analysis included 141 cases and 281 controls. After adjusting for sex, Hispanic ethnicity, and additional age variation, illness was significantly associated with eating at a Mexican-style restaurant in the week preceding illness onset (mOR = 4.6) (Table). Illness also was significantly associated with eating pico de gallo (mOR = 4.0), corn tortillas (mOR = 2.3), and freshly prepared salsa (mOR = 2.1) (Table). Illness was not significantly associated with any other individual food items or ingredients.

Beginning on June 30, the Minnesota Department of Health investigated a cluster of 19 persons with *Salmonella* Saintpaul infection associated with a natural food restaurant. For this case-control study, a case was defined as diarrheal illness (three or more loose stools in a 24-hour period) in a person infected with the outbreak strain who ate at the restaurant in the week before illness began. Controls were well meal companions and restaurant patrons identified by credit card receipts. The analysis included 19 case-patients and 73 controls. On univariate analysis, illness was significantly associated with eating any of several items including salsa, guacamole, red bell peppers, cilantro, and jalapeño peppers. Both types of peppers had been diced before they arrived at the restaurant. On multivariate analysis, illness was only significantly associated with eating raw, jalapeño peppers (OR = 62.0) (Table). This study provided more evidence that consumption of raw jalapeño peppers was a major risk factor for illness.

Beginning on July 7, the North Carolina Division of Public Health, the Mecklenburg County Health Department, and CDC investigated a cluster of 13 ill persons associated with a local Mexican-style restaurant. For the case-control study, a case was defined as diarrheal illness (three or more loose stools in a 24-hour period) in a person infected with the outbreak strain who ate at the restaurant in the week before illness began. Controls were well restaurant patrons identified by credit card receipts. The analysis included four case-patients and 113 controls. On multivariate analysis, illness was significantly associated only with eating guacamole (aOR = 8.7) (Table). The guacamole ingredients included avocado, raw Roma tomatoes, raw red onions, raw serrano peppers, cilantro, salt, and lime juice, but not jalapeño peppers. This study demonstrated that not all of the outbreak illnesses could be linked to eating jalapeño peppers.

During May 22--August 7, state and local health departments in 14 states and the District of Columbia reported a total of 33 restaurant-associated clusters of illness. The median number of laboratory-confirmed cases for all clusters was four; 26 (79%) of the 33 clusters had eight or fewer laboratory-confirmed cases. Raw jalapeño peppers were not served in four of the restaurants, serrano peppers were not served in 19 restaurants, and raw tomatoes of various types were served in all restaurants. Of the four restaurants without raw jalapeño peppers, two had serrano peppers.

During July 11--25, NMDOH, the Arizona Department of Health Services, Navajo Nation, IHS, and CDC conducted a household-based case-control study among non-restaurant--associated cases in New Mexico, Arizona, and the Navajo Nation. A case-

household was defined as a household with a case (defined as diarrheal illness [three or more loose stools in a 24-hour period] beginning on or after June 1 in a person infected with the outbreak strain). Control-households were enrolled systematically from the same community and had no members who reported diarrheal illness on or after June 1. The matched analysis included 41 case-households and 107 controlhouseholds and compared the presence of specific foods in the household regardless of whether the respondent remembered eating them. On univariate analysis, illness in the household was significantly associated with having a raw jalapeño pepper in the household (mOR = 2.9), and illness had a borderline association with having a raw serrano pepper in the household (mOR = 3.0) during the week preceding illness onset (Table). Illness was not significantly associated with the presence of any other food item in the household. A concurrent case-control study that evaluated individual-level exposures asked the case-patient in each case-household and respondents in controlhouseholds about recent food exposures. This study did not identify an association between illness in the case-patients and eating raw jalapeño or serrano peppers. These results suggested that at the time these illnesses were occurring, jalapeño peppers and perhaps serrano peppers were likely vehicles for illness among persons not associated with a restaurant cluster, although persons might not have specifically recalled consuming the peppers.

#### **Environmental and Traceback Investigations**

The Food and Drug Administration (FDA) traced back the processing and distribution pathway for tomatoes associated with several ill persons. These tracebacks did not converge onto a single packer, distributor, or growing area of tomatoes. Tomatoes linked to ill persons and tomatoes randomly collected from the distribution chain in several states were cultured; none of these cultures yielded *Salmonella*.

FDA traced the source of the jalapeño peppers associated with illness in the two previously described Texas restaurant-associated clusters to distributors in Texas that received jalapeño peppers from Mexico. On July 21, FDA reported isolation of the outbreak strain from a jalapeño pepper sample obtained from one of these distributors. The pepper likely was grown on a farm in Tamaulipas, Mexico (farm A); this farm also grew serrano peppers and Roma tomatoes. FDA did not isolate the outbreak strain from environmental samples from farm A, but did isolate the outbreak strain from a sample of serrano peppers and a sample of water from a holding pond used for irrigation from another farm (farm B) in Tamaulipas. Farm B also grew jalapeño peppers, but not tomatoes. Farms A and B provided produce to a common packing facility in Mexico that exports to the United States. In addition, on July 29, the Colorado Department of Public Health and Environment (CDPHE) reported isolation of the outbreak strain from a jalapeño pepper collected from the household of a person in Colorado who had developed illness with the outbreak strain. CDPHE traced this pepper from the grocery store where it had been purchased to another distributor in Texas, which reportedly received jalapeño peppers from farms in Mexico; however, the specific farms have not been identified.

#### **Control Measures**

Since June 3, CDC, FDA, and public health partners have issued multiple public advisories recommending that consumers avoid eating certain produce items. A

limited advisory recommending that consumers in New Mexico and Texas avoid eating certain types of tomatoes was issued on June 3, and the advisory was expanded nationwide on June 7 (Figure 2). After associations were identified between illness and eating jalapeño and serrano peppers, CDC and FDA issued successive advisories recommending that consumers avoid eating jalapeño and serrano peppers grown in Mexico; the first nationwide jalapeño pepper advisory was issued on July 9 (Figure 2). The tomato advisory was lifted on July 17; the jalapeño and serrano pepper advisories remain in effect.

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## **Editorial Note:**

Contaminated produce eaten raw is an increasingly recognized vehicle for transmission of *Salmonella* and other pathogens (1). Each year, approximately 36,000 laboratory-confirmed cases of *Salmonella* infection are reported in the United States through national serotype-based surveillance (2). *Salmonella* Saintpaul is an uncommon serotype, causing, on average, 1.6% of all reported laboratory-confirmed *Salmonella* infections each year. In 2007, only 40 human isolates of the outbreak strain were submitted to PulseNet. This report describes the largest foodborne disease outbreak identified in the United States in the past decade, based on the number of culture-confirmed cases. Because many persons with *Salmonella* illness do not seek care or have a stool specimen tested, many more illnesses likely have occurred than those reported (3).

In this outbreak, epidemiologic studies revealed associations between illness and more than one raw produce item. Although most multistate enteric disease outbreaks have been linked to a single food vehicle, an outbreak attributed to both parsley and cilantro grown on one farm has been reported (4). The initial case-control study identified an association between illness and eating raw tomatoes. Subsequent studies identified an association between illness and eating raw jalapeño peppers, an item commonly eaten with tomatoes in Mexican-style cuisine. Epidemiologic data also suggested an association with raw serrano peppers. These associations triggered product alerts and led to product tracing and microbiologic studies, which indicated that jalapeño and serrano peppers grown, harvested, or packed in Mexico were contaminated with the outbreak strain. The epidemiologic and microbiologic results support the conclusion that jalapeño peppers were a major vehicle by which the pathogen was transmitted, and that serrano peppers also were a vehicle. Consumption of peppers was not implicated in either of the two multistate case-control studies. However, produce items such as peppers that are typically consumed in small quantities as ingredients of other dishes might not be remembered and can be difficult to implicate (5). Neither raw jalapeño nor serrano peppers have been identified previously as a vehicle for a foodborne disease outbreak in the United States. Little is known about the survival and growth characteristics of *Salmonella* on these peppers, although rapid growth in jalapeño pepper extract has been reported (6).

Tomatoes possibly were a vehicle for infection, particularly early in the outbreak. In the initial case-control study, illness was significantly associated with consumption of raw tomatoes and not with foods containing peppers, such as salsa or guacamole. Consumption of jalapeño or serrano peppers was not assessed in this initial study because in hypothesis-generating interviews conducted with 19 case-patients, only five (26%) reported eating peppers other than red or green bell peppers in the week before illness began. In addition, a survey of 75 case-patients in Texas whose illnesses began before June 7, using a questionnaire that asked specifically about pepper consumption, found a relatively low proportion who reported eating raw jalapeño (39%) or raw serrano (8%) peppers in the week before illness began, whereas reported raw tomato consumption was high (85%). Finding the outbreak strain on two types of peppers from two farms supports the possibility of contamination of other produce items, including tomatoes, during growing, processing, or distribution.

Local, state, tribal, and federal response capacity often is strained during large and complex outbreaks, and structure and capabilities vary among jurisdictions. This can cause delays in identifying cases and in conducting investigations. In this outbreak investigation, the median time from illness onset to submission of the PFGE pattern of patients' Salmonella isolates to PulseNet was 17 days; 90% were submitted within 27 days. Faster transfer of bacterial strains to public health laboratories and faster subtyping in those laboratories would result in more timely investigation of cases of infection. Epidemiologic investigations can benefit from faster methods for interviewing ill and well persons, improved interview formats, and rapidly adaptable electronic data gathering and transmission platforms. Improvements in the ability to trace contaminated produce quickly and accurately also would improve the speed of investigations, the speed and specificity of recalls, and the determination of the ultimate causes of contamination. For several years, CDC has been improving the efficiency of epidemiologic investigations through OutbreakNet, the network of public health officials that investigates outbreaks of enteric illnesses nationwide, and through participation in the Council to Improve Foodborne Outbreak Response,\* a multidisciplinary working group.

In addition, FDA has been enhancing the safety of produce by collaborating with state officials, academia, and industry on multiyear initiatives to increase the safety of leafy greens and tomatoes. FDA and its partners are working to improve guidance and policies intended to minimize outbreaks and to improve produce-safety research and education.

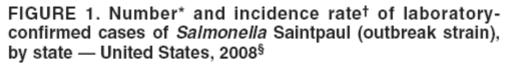
## References

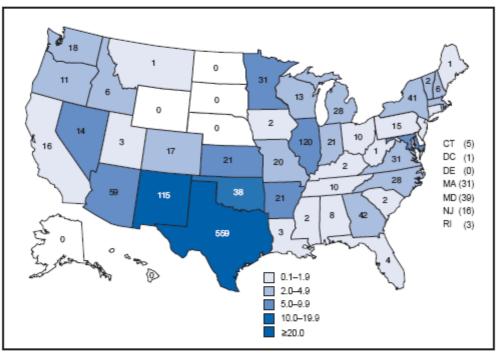
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\* Information available at <u>http://www.cifor.us</u>.

#### Figure 1





\*N = 1,442.

<sup>T</sup>Per 1 million population.

<sup>§</sup>As of August 25, 2008.

#### Figure 2

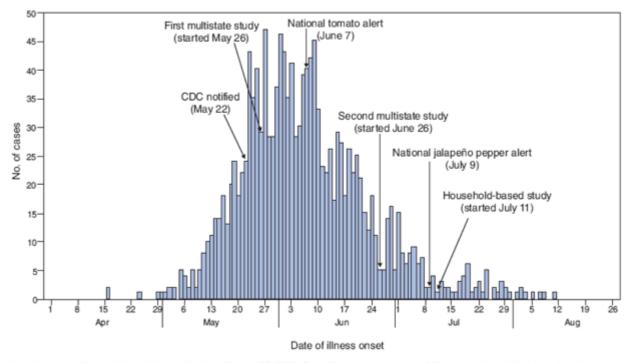


FIGURE 2. Number of laboratory-confirmed cases (n = 1,414) of Salmonella Saintpaul (outbreak strain), by date of lilness onset ----United States, 2008\*

\* Includes cases with onset information received as of August 25, 2008. Some illness onset dates (n = 366) were estimated by subtracting 3 days from the specimen date. Illness that began during July 29-August 25 might not yet be reported.

#### Table

TABLE. Number and percentage of exposures to Salmonella Saintpaul among case patients and controls in seven case-control studies, by implicated food item/exposure -- United States, 2008

| Study (start date) and food item/exposure | Cases  |       | Controls |      | Odds                |                 |
|-------------------------------------------|--------|-------|----------|------|---------------------|-----------------|
|                                           | No.    | (%)   | No.      | (%)  | ratio               | (95% CI*)       |
| First multistate study (May 26)           |        |       |          |      |                     |                 |
| Raw tomatoes                              | 42/48  | (88)  | 67/104   | (64) | 6.7*5               | (1.9-36.0)      |
|                                           | 42/48  | (88)  | 67/104   | (64) | 5.68                | (1.6-30.3)      |
| Tortillas                                 | 39/47  | (83)  | 69/104   | (66) | 2.8 <sup>19</sup>   | (1.0-10.0)      |
| Salsa                                     | 27/48  | (56)  | 47/104   | (45) | 1.7*5               | (0.8-3.8)       |
| Guacamole                                 | 16/50  | (32)  | 26/103   | (25) | 1.6*5               | (0.7-3.5)       |
| First Texas restaurant (June 20)          |        |       |          |      |                     |                 |
| Salsa                                     | 41/43  | (95)  | 8/29     | (28) | 62.3**              | (12.4-632.1)    |
| Texas restaurant chain (June 24)          |        |       |          |      |                     |                 |
| Salsa                                     | 32/32  | (100) | 49/58    | (85) | 7.5**               | (1.1-undefined) |
| Second multistate study (June 26)         |        |       |          |      |                     |                 |
| Eating at a Mexican-style restaurant      | 68/138 | (49)  | 64/278   | (23) | 4.6 <sup>††5</sup>  | (2.1-undefined) |
| Pico de gallo                             | 35/127 | (28)  | 26/257   | (10) | 4.0 <sup>††\$</sup> | (1.5-17.8)      |
| Corn tortilla                             | 51/126 | (40)  | 67/251   | (27) | 2.3 <sup>ttb</sup>  | (1.2-5.0)       |
| Salsa                                     | 60/130 | (46)  | 73/245   | (30) | 2.1***              | (1.1-3.9)       |
| Minnesota restaurant (June 30)            |        |       |          |      |                     |                 |
| Jalapeño pepper                           | 17/19  | (89)  | 8/73     | (11) | 62.0**              | (12.0-321.0)    |
| North Carolina restaurant (July 17)       |        |       |          |      |                     |                 |
| Guacamole                                 | 4/4    | (100) | 42/113   | (37) | 8.7**               | (1.1-undefined) |
| Household-based study (July 11)           |        |       |          |      |                     |                 |
| Jalapeño pepper                           | 26/41  | (63)  | 42/107   | (40) | 2.9*5               | (1.2-7.6)       |
| Serrano pepper                            | 9/41   | (22)  | 9/107    | (8)  | 3.0*5               | (0.9-9.6)       |

\* Confidence interval.

† Univariate analysis.

Matched analysis.
Matched analysis.
Adjusted for consumption of tortillas in the week before illness onset.
Multivariate analysis.
H Adjusted for sex, Hispanic ethnicity, and additional age variation.