Testimony before the Committee on Agriculture Subcommittee on Horticulture and Organic Agriculture

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CDC Response to the Multistate Outbreak of *Salmonella* Saintpaul

Statement of

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Introduction

Good afternoon, Chairman Cardoza and Members of the Subcommittee. I am Dr. Lonnie King, Director of the National Center for Zoonotic, Vector-borne, and Enteric Diseases, at the Centers for Disease Control and Prevention. Thank you for the invitation to address the Subcommittee on CDC's activities related to the prevention of foodborne disease and CDC's role in the response to the current outbreak of *Salmonella* Saintpaul infections associated with fresh produce. First, let me offer my sympathies to all the families who have been adversely affected by this outbreak. Second, I understand the frustration of many in the food producing and serving industries, who work very hard to produce and serve safe produce. This investigation has been especially difficult and prolonged. We have faced many challenges with this particular foodborne outbreak. I will discuss these challenges in more detail after describing the CDC's response to the *Salmonella* Saintpaul outbreak.

Background

Foodborne disease presents a continuing challenge to public health. CDC estimates that approximately 76 million U.S. residents get sick, 325,000 are hospitalized, and 5,000 die each year from foodborne illness. Overall, foodborne diseases appear to cause more illnesses but fewer deaths than previously estimated in the 1980's. More than 250 different foodborne illnesses have been described. Most are caused by a variety of bacteria, viruses, and parasites. Some foodborne illnesses are caused by toxins or chemicals.

As an agency within the Department of Health and Human Services (HHS), CDC leads federal efforts to gather data on foodborne illnesses, investigate foodborne illnesses and outbreaks, and

monitor the effectiveness of prevention and control efforts. CDC is not a food safety regulatory agency but works closely with the food safety regulatory agencies, in particular with HHS's Food and Drug Administration (FDA) and the Food Safety and Inspection Service within the United States Department of Agriculture (USDA). CDC also plays a key role in building state and local health department epidemiology, laboratory, and environmental health capacity to support foodborne disease surveillance and outbreak response. Notably, CDC data can be used to help document the effectiveness of regulatory interventions.

Much of what CDC does depends on critical partnerships with state and local public health departments who collect surveillance data and investigate most outbreaks themselves. CDC has worked with the Association of Public Health Laboratories (APHL) and the Council of State and Territorial Epidemiologists (CSTE) to strengthen networks for foodborne disease surveillance. For example, PulseNet, the national network for molecular subtyping of foodborne bacteria coordinated by CDC, empowers every state health laboratory to test strains of bacteria from sick persons in that state, and to compare them with DNA "fingerprint" patterns in the national database at CDC. This has greatly improved the ability to detect clusters of illness that may be related, even if they are dispersed across multiple states.

OutbreakNet is the group of public health officials at State health departments and CDC who regularly investigate foodborne outbreaks. The OutbreakNet team at CDC coordinates the investigation of the large, multistate clusters and works with the foodborne disease epidemiologists in each state to evaluate clusters that PulseNet detects. The OutbreakNet team at CDC also manages the electronic Foodborne Outbreak Reporting System (eFORS). Established in 2001, eFORS is a web-based outbreak surveillance system through which state and local

health departments voluntarily submit completed reports of foodborne disease outbreak investigations to CDC.

CDC's Environmental Health Specialists Network (EHS-Net), a collaborative effort with FDA and nine states, assists state health departments in their efforts to improve the practice of environmental health service programs; participants assess policies and practices of retail foodservice establishments that could lead to or prevent foodborne outbreaks. FoodNet is a network that is a collaborative effort among CDC, 10 states who participate in CDC's Emerging Infections Program, the Department of Agriculture's Food Safety and Inspection Service (UDSA/FSIS), and FDA; it provides the most accurate surveillance data for determining the burden of infections, conducts scientific studies to better understand the sources for the many illnesses that occur outside the outbreak setting, and monitors trends in infections as new control measures are instituted. We have PulseNet to detect possible outbreaks, OutbreakNet to investigate and report them, and FoodNet to track general trends and define where more effective prevention strategies are needed.

CDC also works with a broad range of other partners to improve capacity and knowledge regarding foodborne disease control and prevention. In collaboration with the National Environmental Health Association (NEHA), CDC conducts team training programs for local and state health department officials including specialists in environmental health, laboratory, and epidemiology. CDC works with the World Health Organization (WHO) and a variety of other international partners to conduct similar training programs in other countries through the WHO Global Salmonella Surveillance program. CDC supports the Council to Improve Foodborne Outbreak Response (CIFOR) which was created to help develop model programs and processes that will facilitate the investigation and control of foodborne disease outbreaks. CSTE and the

National Association of County and City Health Officials (NACCHO) are co-chairing CIFOR, and it includes representatives from CDC, FDA, USDA, APHL, NEHA, the Association of State and Territorial Health Officials, and the Association of Food and Drug Officials.

Salmonella

Salmonella is a group of bacteria that is widespread in the intestines of birds, reptiles, and mammals. *Salmonella* bacteria have been known for over 100 years to cause human illness. *Salmonella* is the second most common bacterial cause of foodborne diseases in the country, causing 15 reported laboratory-confirmed infections per 100,000 population in 2007, as measured in FoodNet. There are many different kinds, or serotypes, of *Salmonella* bacteria. Serotyping is a classification system based on differences in structures on the surfaces of bacteria or other disease-causing agents. Serotyping divides *Salmonella* into more than 2500 different serotypes, some common and some rare. For example, during 1996-2006, *Salmonella* serotype Typhimurium and *Salmonella* serotype Enteritidis typically caused 41% of reported *Salmonella* illnesses each year in the United States. *Salmonella* serotype Saintpaul is relatively uncommon, causing only 1% (about 400) of all reported laboratory-confirmed *Salmonella* infections each year. Each serotype can be further sub-divided into many more subtypes based on their DNA.

Salmonella infections have often been associated with meat, poultry, eggs, and raw milk; these products are derived from animals that can carry *Salmonella*. *Salmonella* has also been associated with fresh produce and other plant-derived foods. Fresh produce can be an important source of other types of foodborne infections as well; for example, *Escherichia coli* 0157, another bacterial agent, caused a large outbreak of illness linked to spinach in 2006. *Salmonella*,

like other pathogens that are commonly foodborne, can also be transmitted in other ways, such as from contact with reptiles or other animals or between children at a child care center.

Many foodborne infections, including *Salmonella*, occur in persons without obvious connections to each other. These are called sporadic cases; determining the source of a single sporadic case can be very difficult. Cases of similar infections can also occur as a group or "cluster." Epidemiological investigation of clusters of possibly related cases permits public health officials to determine if the cases were connected and, specifically, if they were linked to food. A cluster of foodborne illnesses is considered an outbreak if an investigation demonstrates that two or more infections caused by the same agent are linked to the same food.

In general, for a foodborne illness to be recognized by the public health surveillance system, a patient must seek medical attention, the physician must decide to order diagnostic tests, and the laboratory must conduct the test using the appropriate procedures and report the results to a health department. Many ill people do not seek medical attention, and of those who do, many are not tested. Therefore, many cases of foodborne illness are neither diagnosed nor reported. For example, *Salmonella* infection has been estimated to cause about 1.4 million foodborne illnesses annually, however, only about 40,000 laboratory-confirmed cases of *Salmonella* are reported to CDC each year.

Regular reporting about detection of *Salmonella* serotypes from ill persons is critical in determining whether a change in incidence has occurred signaling a possible outbreak. Each serotype can be further divided by DNA analysis into subtypes. The subtypes are distinguished by different DNA fingerprint patterns. The fingerprint pattern is determined with a test known as pulsed-field gel electrophoresis (PFGE). PFGE is a very good method for discriminating

between epidemiologically unrelated isolates of this serotype. Public health laboratories determine the serotype and PFGE patterns for *Salmonella* strains and share the patterns through PulseNet. PulseNet plays a vital role in surveillance for and investigation of widely dispersed foodborne illness outbreaks that were previously difficult to detect. The laboratories participating in PulseNet are in state health departments, some local health departments, USDA, and FDA. When a clinical laboratory detects *Salmonella* from an ill person, a sample is sent to a State or local PulseNet laboratory where it is serotyped and DNA fingerprinted. The laboratory compares the fingerprint pattern to that of other *Salmonella* strains from people in that area and uploads the pattern electronically to the national PulseNet database maintained at CDC, where it can be compared with the patterns from all over the country. This gives us the capability to detect an unusual number of *Salmonella* cases with the same pattern in a single area or in multiple states. The system can identify patterns even if the affected persons live far apart, which is important given the widespread U.S. food distribution systems. The pattern causing the current outbreak is usually quite uncommon, and was identified only 25 times in 2007, among the 400 *Salmonella* Saintpaul infections that were reported.

It is important to recognize there is an inherent delay between when a person becomes ill with *Salmonella* infection and when the results of testing are reported to PulseNet**.** In the current *Salmonella* Saintpaul outbreak, the median number of days between when the illness began and when the fingerprint pattern was reported to PulseNet has been 16 days. It takes time for a person to become ill, seek medical care, submit a sample for testing; it then takes time for the clinical laboratory to detect *Salmonella* and send the strain to the public health laboratory; it then takes time for the public health laboratory to perform serotyping and DNA fingerprinting.

The Salmonella Saintpaul Outbreak

On May 22, 2008, the New Mexico Department of Health contacted CDC to report that they were investigating illness in 4 persons with *Salmonella* Saintpaul strains that had the same DNA fingerprint pattern, and that *Salmonella* strains from 15 more persons were still being characterized. The DNA fingerprint determined by PFGE was rare. It usually occurs no more than 2-3 times a month in the whole United States, so 4 or more in one location was unexpectedly high. New Mexico posted the information about the unusual number of *Salmonella* Saintpaul cases to the PulseNet web board on May 22, so that all state laboratories could quickly compare the DNA fingerprint pattern with that of their own strains, and CDC requested that states report any strains that matched the DNA fingerprint pattern. That next day, Texas and Colorado reported cases with this PFGE pattern, and investigators in the New Mexico Department of Health, the Navajo Nation, the Indian Health Service, the Texas Department of State Health Services, and CDC began a multistate investigation. Daily multistate conference calls began and continued through July, with states being added to the calls as their cases were identified. The investigation was initially coordinated by the New Mexico State Health Department, because most identified cases were in that state. On June 3, after more states in different regions of the country reported cases, CDC assumed this role of the investigation.

The initial steps in an epidemiological investigation are to collect information from which hypotheses can be generated about the possible source of the outbreak. As cases with the same DNA fingerprint pattern were identified, epidemiologists interviewed patients to determine what specific foods or other exposures they may have had in common. The New Mexico Department of Health, Texas Department of State Health Services, and the Indian Health Service conducted

hypothesis-generating interviews from mid- to late- May among 19 ill persons from whom *Salmonella* Saintpaul with the DNA fingerprint matching the outbreak strain had been isolated during May 2008. These interviews collected information about possible sources of infection, including attendance at gatherings, travel, daycare contact, contact with reptiles and/or other household pets, contact with farm animals, sources of drinking water, history of swimming, eating at restaurants, and specific food consumption history for approximately 200 food items; the interviews also included open-ended questions about what ill persons had eaten, meal by meal, in the days before they became ill. The preliminary results of this first series of interviews indicated raw tomatoes were the most commonly consumed food item (reported by 84% of ill persons) leading to the hypothesis that they were a possible source of the illnesses. CDC informally advised the FDA on May 26 of the hypothesis of a possible association between ill persons and the consumption of raw tomatoes.

In the next steps of the investigation, analytic epidemiologic studies were conducted to test the hypotheses generated by case finding. These studies compare the frequency with which ill persons report exposure to a particular food item to the frequency with which healthy persons (or controls) report that exposure. If the ill group is more likely than the well group to report exposure to a particular food, a statistical test can show how likely this finding would have occurred by chance alone. Additional information about the likelihood of that particular food actually being contaminated, the biological plausibility of it causing the illnesses, the fit of the cases with the distribution of the food, and other factors may enter into the professional judgment of whether the food with a statistically significant association with cases is likely to explain the outbreak. Preliminary findings from these types of studies guided subsequent next steps of the investigation while additional statistical analyses are being conducted on the data gathered. It is

important to keep in mind at this stage of investigation, as analyses are conducted and interpreted, that initial findings and hypotheses may change. As is common in outbreak investigations but especially true for foodborne outbreaks, the process of case finding, hypothesis generating, and hypothesis testing is an iterative process; each step informs subsequent steps and often leads to new investigative avenues.

In the next phase of the investigation, in late May, the New Mexico Department of Health, the Texas Department of State Health Services, and the Indian Health Service, in consultation with CDC, conducted a multi-state case-control study. The data from the earlier 19 hypothesis generating interviews were used to identify which foods were most frequently consumed by the ill people. The questionnaire used in this case-control study included the 14 foods[1] reported by half or more of the ill people in the hypothesis-generating interviews. These questionnaires were administered to approximately 150 people. By May 31, preliminary results of the case-control study demonstrated that illness was significantly associated with consumption of raw tomatoes (88% of cases consumed raw tomatoes compared with 64% of the controls, a very strong statistical difference). FDA was formally notified of this significant association between tomatoes and infection. Statistical analysis of these data showed that illness was associated with consumption of raw tomatoes independent of consumption of tomatoes in salsa, guacamole, or pico de gallo.

The next step in the investigation was to trace the implicated food back to its sources, looking for points where contamination might have occurred, and to determine if there is a single farm, processing location, or other point in distribution system that could explain all the illnesses

[1] Food items examined included tomatoes, eggs, ice cream, potatoes, milk, tortillas, cold breakfast cereal, raw onions, salsa, avocado, guacamole, ground beef, chicken, and lettuce.

providing additional evidence supporting the food item as a cause of the outbreak. Tracing the implicated food back from consumption through preparation, to distributors, and source can also help determine how the contamination occurred, stop distribution of the contaminated product, and prevent further outbreaks from occurring. On May 31, 2008, FDA decided to initiate investigations attempting to trace the tomatoes reported to have been eaten by ill persons back to their sources. Tracebacks began on June 1, 2008. Throughout the investigation there has been ongoing communication between CDC and FDA regarding these traceback investigations.

On June 4, CDC received the first report of a possible restaurant cluster. Four cases in Illinois appeared to be related to exposure to a single restaurant. Such clusters were otherwise absent in the early part of the outbreak. The outbreak continued and expanded. Over the next few weeks, hundreds more cases were reported from an increasing number of states. The average number of persons who became ill between May 20 and June 10 was 33 per day. New information emerged as each case was reported and interviewed by local or state health department authorities.

On June 16, CDC learned about the first recognized large cluster linked to a single restaurant, approximately 30 illnesses, in Texas. Between June 18 and June 20, Texas reported an additional 134 cases. This surge in the number of cases from Texas highlighted the geographic concentration in the Southwest and in Native American and Hispanic persons, which did not have a clear explanation. This information, along with the strong association between illness and consumption of Mexican-style foods in restaurants coming from continued analysis of the case-control studies, and the apparent continuation of the outbreak after the alert regarding tomatoes, led to the hypothesis that a food item commonly consumed with tomatoes could be causing illnesses. Epidemiologists decided to focus the investigations on the recently identified clusters

and to conduct a case-control study of persons nationwide who became ill in June. CDC offered assistance to the Texas Department of State Health Services; a CDC Epi-Aid team arrived in Texas on June 19.

By July 7, 32 clusters of *Salmonella* Saintpaul infections with the PFGE pattern of the outbreak strain had been identified in 13 states and the District of Columbia. Twenty-six were associated with Mexican-style restaurants. Most clusters had fewer than 5 ill persons. Three clusters had more than 10 ill persons, and analytic studies have been conducted on these. In one of these larger restaurant clusters, illnesses were linked to consumption of an item containing fresh tomatoes and fresh jalapeño peppers. In the other two, illnesses were linked to an item containing fresh jalapeño peppers but neither raw tomatoes, nor fresh cilantro. Among the 22 smaller clusters with data on the presence of food items in the venue, four did not serve jalapeño peppers. Together, these investigations indicated that jalapeño peppers caused some illnesses, but did not appear to explain all illnesses. Raw tomatoes, fresh serrano peppers, and fresh cilantro also remained under investigation. We were strongly considering the probability that more than one food item caused illness.

CDC and state and local health departments conducted a second case-control study to investigate the possibilities that illness was related to consuming foods in Mexican-style restaurants, and that illness was associated with consuming, in a restaurant, event, or home, a range of produce items that are often served with tomatoes, including freshly made salsa, fresh jalapeño peppers, and fresh cilantro. This was a large multistate study, with over 400 interviews, with 141 interviews from persons who had become ill on or after June 1 and 281 interviews from healthy controls available for preliminary analysis. The study showed that illness was strongly associated with

eating at a Mexican-style restaurant. In a preliminary statistical analysis that considered the entire dataset, consumption of fresh tomatoes, jalapeño peppers, and cilantro were each shown to be risk factors in subgroups but no single suspect exposure statistically dominated the others in explaining all cases. Thus, this study indicated a strong link to fresh produce items used in Mexican cuisine but did not point clearly to one specific item.

As new restaurant-associated clusters were reported, CDC and state health departments investigated them aggressively. By July 16, CDC investigators were assisting state and local health officials in field investigations of restaurant clusters in North Carolina, Missouri, Texas, and New York City. In addition, another CDC team was investigating illnesses in New Mexico.

As the epidemiological investigation expanded, the FDA also expanded their traceback and sampling efforts. FDA began their tracebacks on peppers identified by the outbreak investigations conducted by the states and CDC. CDC sent two medical epidemiologists to FDA to directly participate in analyzing findings from the tracebacks and connect them with the CDC epidemiologic data. On July 21, the FDA announced that they had isolated the outbreak strain of *Salmonella* Saintpaul from a sample of jalapeño peppers. The epidemiologic data from a Texas cluster of ill persons led to this specific traceback investigation. In most *Salmonella* outbreaks that are linked to a particular food, however, *Salmonella* is never detected in the food. Detection of *Salmonella* in a food item that was implicated in an epidemiologic study provides strong evidence that this food item caused illnesses, though it does not exclude other foods as possible causes of illness.

Throughout the investigative process, to ensure that information was disseminated to the public as accurately and quickly as possible about health threats and other information related to this

outbreak, CDC and FDA coordinated their communication strategies and messages and discussed these strategies in daily calls with state health officials. We balance the rapid release of information on sources of illness against the potential negative consequences to consumers, food growers, producers, and industry. Continued collaborations and communications between federal agencies, state and local health departments, and all relevant stakeholders are essential.

Challenges Confronting the Outbreak Investigation

Every outbreak response is a challenge for everyone involved. This outbreak was particularly challenging in a number of ways. As already mentioned, it takes time for a case to be reported to public health authorities and then investigated. For half the cases in this outbreak, it took more than 16 days from when the person became ill to the when the DNA fingerprint of their *Salmonella* was added to the PulseNet database. The resulting delay sometimes prevented interviews from occurring while memories were still fresh. The precision of interviews by epidemiologists depend on the observations and memories of people about what they ate and what ingredients the dishes contained. People often have difficulty remembering exactly what foods they ate, and remembering specific ingredients in those foods is even more difficult, especially if the dish was prepared by someone else, or eaten in a restaurant. Another challenge has been that the foods in question are often eaten together – many salsa, guacamole, and pico de gallo recipes contain tomatoes, jalapeño peppers, and cilantro, so exposure to one item often means exposure to all three. When food items are mixed together and consumed in the same dish, all the items may be statistically linked to illness. In that case, it can be difficult or impossible to separate out the risk from individual foods without additional information such as microbiological culture or traceback of the foods. Although laboratory testing of foods might

help identify the source of an outbreak, perishable foods that were consumed by ill persons were often not available to test. This is in contrast to outbreaks from frozen or processed foods which may still be present in someone's freezer or pantry weeks later. Finally, the traceback of fresh produce, such as tomatoes, through the supply chain can be very difficult and labor intensive. Doctor Acheson will be able to say more about this.

Status of Investigation

As of July 27, 1304 persons infected with *Salmonella* Saintpaul with the same fingerprint have been identified in 43 states, the District of Columbia, and Canada. At least 252 persons were hospitalized. Two deaths were possibly linked to the outbreak: A man in his eighties who died in Texas from cardiopulmonary failure had an infection with the outbreak strain at the time of his death. A man in his sixties who died in Texas from cancer had an infection with the outbreak strain at the time of his death.

Three larger clusters were intensively investigated as of July 7. In one, illnesses were linked to consumption of an item containing fresh tomatoes and fresh jalapeño peppers. In the other two, illnesses were linked to an item containing fresh jalapeño peppers and no other of the suspect items. Since then, detailed investigations of three other clusters indicate that jalapeño peppers do not explain all illnesses. In two of these more recent investigations, illnesses were linked to an item containing fresh serrano peppers and tomatoes, but not jalapeño peppers. In a third, illnesses were linked to an item that contained fresh jalapeños and tomatoes. Other clusters are under active investigation. At present, the information indicates that jalapeño peppers and serrano peppers grown, harvested, or packed in Mexico are the cause of some clusters and could be a major food vehicle for the outbreak. The U.S. Food and Drug Administration is advising

consumers that jalapeno and serrano peppers grown in the United States are not connected with the current *Salmonella* Saintpaul outbreak and consumers may feel free to eat them without concern of illness. By themselves, tomatoes cannot explain the entire outbreak, nor do jalapeño peppers explain all the clusters. The outbreak appears to be ongoing, but with fewer new illnesses each day. New, very active field investigations by CDC in collaboration with State and local health departments, and FDA tracebacks on jalapeño peppers and tomatoes are providing new information almost daily. It appears likely that more than one food vehicle is involved. Although rare, more than one food has been implicated in foodborne outbreaks in the past, as observed in a group of 1998 outbreaks traced to imported parsley and cilantro from a single farm.

Conclusion

The current outbreak investigation of *Salmonella* Saintpaul is the largest foodborne outbreak in the United States in the past decade. The investigation has been especially complex, difficult, and prolonged. The outbreak appears to be slowing, but we are not able to say with confidence that the outbreak is over because of the reporting delay. The event illustrates how a large and widespread outbreak can occur, appearing first as individual cases, then as small clusters, and finally with large numbers of persons becoming ill if a widely consumed food is contaminated. It also illustrates the importance of existing public health networks: the laboratories performing PulseNet fingerprinting; the epidemiologists conducting the investigation; the environmental health aspects of the outbreak; the multi-disciplinary approach to the investigation; and the close communication and collaboration among local, state, and federal officials.

CDC is prepared to continue working with regulatory authorities, state and local partners, food and environmental microbiologist scientists, and the food industry to find long-term solutions to this challenging problem.

Thank you again for the invitation to testify before you today. I will be happy to answer any questions you may have.