PRODUCE SAFETY PROJECT

BREAKDOWN: LESSONS TO BE LEARNED FROM THE 2008 *SALMONELLA* SAINTPAUL OUTBREAK

NOVEMBER 17, 2008

INTRODUCTION

The U.S. Food and Drug Administration (FDA) and Centers for Disease Control and Prevention (CDC) declared the *Salmonella* Saintpaul outbreak of 2008 officially over on August 28, 2008, some three months after it began. During that time, more than 1,400 persons were reported infected, and if, as suggested by research, this represents an underreporting,[1] the outbreak may have sickened thousands of Americans. Although CDC and FDA initially pointed in early June to tomatoes as the cause of the outbreak based on epidemiological data, no contaminated tomato was ever found. In July, CDC and FDA identified jalapeno and serrano peppers as being responsible for illnesses, and the only microbiological evidence of food contaminated by *Salmonella* Saintpaul was, in fact, found in jalapeno and serrano peppers.[2] However, as a result of the initial identification of tomatoes as the vector for the disease, the tomato industry, a significant sector of this country's agriculture economy, was another major casualty. Estimates of the economic cost to that industry in Florida alone have been more than $100 million and in Georgia close to $14 million.[3] A less tangible, but still very real, impact of the outbreak may well be its long-term effect on consumer confidence in fresh produce in general and fresh tomatoes in particular.

Given the human, economic and public-health costs of this recent food borne-illness outbreak, therefore, it is critical to learn from it.

Given the human, economic and public-health costs of this recent food borne-illness outbreak, therefore, it is critical to learn from it. In fact, members of Congress and representatives from the produce industry have called for post-mortem investigations of the outbreak, and senior FDA officials have promised a thorough and transparent accounting of the public-health system's response.[4] This report represents the first extensive and in-depth review of the public record of the *Salmonella* Saintpaul outbreak. *(See Appendix A)* In conducting this review, the Produce Safety Project (PSP), an initiative of The Pew Charitable Trusts at Georgetown University, has attempted to frame questions that will be critical for any post-mortem analysis to consider and to identify issues that should be addressed. In doing so, three areas of concern have surfaced: policy, the public-health system's organization and outbreak response, and its communications with the media and the public.

EXECUTIVE SUMMARY

For this report, PSP reviewed all of the public statements and Web site postings of the CDC and FDA; the transcripts of the FDA/CDC media calls; press releases and Web site postings by state public-health departments and industry trade associations; and media coverage from around the country. In addition PSP staff attended and monitored the oversight hearings held by Congressional committees.

Based on that review, PSP calls on federal public-health officials to follow through on their commitment to undertake a thorough and comprehensive post-mortem analysis of the *Salmonella* Saintpaul outbreak and report their findings publicly. The analysis should focus on:

- The need for preventive safety standards for fresh produce.
- Reforms needed to address organizational and capacity shortcomings in the public-health system's response to foodborne-illness outbreaks at the local, state and federal levels.
- Procedures and systems needed to ensure accurate risk communication to the public and affected industries.

Preventive Safety Standards for Fresh Produce

FDA officials consistently pointed to this outbreak as further proof of the need for preventive safety controls for produce but said they need Congress to act. In fact, FDA, under its existing statutory authorities, has established similar preventive control systems through its Hazard Analysis and Critical Control Point (HACCP) regulations for seafood and juice, and has proposed on-farm safety measures for shell eggs.[5] Moreover, in early 2007, FDA officials cited those same existing statutory authorities when they unsuccessfully sought approval from the Department of Health and Human Services (HHS) to move forward on produce-safety standards.[6] The recent *Salmonella* Saintpaul outbreak shows the immediate need to establish preventive safety measures using existing legal authority.

Organization and Capacity

Questions about the food-safety system's lack of organization, capacity and coordination and their resulting impact on the effectiveness of the public-health response are raised by comparing the CDC's *Mortality and Morbidity Weekly Report article*[7] on the outbreak (hereafter, "CDC Outbreak Report") with the public statements of FDA and CDC officials during the outbreak. For instance, the epidemic curve (or "epi curve") published in the CDC outbreak report shows that some 50 percent of the confirmed cases began before the FDA nationwide consumer advisory on June 7 recommending that consumers avoid eating certain tomatoes. While there was a drop in cases after that announcement, it appears that the most sustained drop began around June 24. Maybe this drop was a factor of the incubation period for the illness, or maybe it points to an off-target intervention. A post-mortem analysis should examine this question. In addition, the discussion in the CDC outbreak report of cluster investigations in mid- to late-June raises questions about why FDA and CDC officials continued to maintain so steadfastly and for so long that tomatoes were the leading suspect for being the vector for *Salmonella* Saintpaul.

Risk Communications

From the beginning of the outbreak, public-health communication to the media and the public was disjointed and confusing. Five different agencies – two federal and three state – "announced" the outbreak over the course of four days with significant variations in facts and messages. Then, three weeks into the public-communications effort, the CDC significantly changed – with no explanation – the manner in which it presented outbreak data, from raw number of cases in a state, to cases per million in a state, to a range of cases per state. While the change in presentation of data by CDC may have been worthwhile, it begs the question of why established procedures were not in place before this outbreak began. These failures in

communication may well have contributed to the public's decision to stop buying and eating tomatoes altogether in June and July.

To date, much of the analysis of the outbreak has focused on the "traceback," FDA's attempt to locate the source of contamination.[8] As important as that discussion is, if the post-mortem analyses are limited to that aspect, deeper and even more fundamental structural and organizational shortcomings risk being neglected. Indeed, these shortcomings in the nation's food-safety system are not new, having been documented repeatedly during the past decade by many expert bodies, including the National Academies of Science,[9] the Government Accountability Office,[10] and the FDA's Science Board.[11] The key question here is whether the nation's food-safety policymakers will learn the lessons of this outbreak and fix the system. To learn those lessons, they need to undertake a thorough, in-depth and transparent review of what went right this past summer, what went wrong, what could be done better, and what should never happen again.

What follows is an attempt to frame questions for such a review.

I. Policy Shortcomings

The *Salmonella* Saintpaul outbreak underlines once again a threshold issue: the need for a system aimed at preventing food borne-illness outbreaks linked to both domestically grown and imported produce, rather than a system that just responds once outbreaks have begun. When FDA officials unsuccessfully sought HHS approval for produce-safety standards in early 2007, they pointed to an "increasing trend" in produce-related outbreaks of food borne illness despite the various voluntary measures that the Agency had put in place since 1998.[12] Moreover, on average, more illnesses result from an outbreak associated with produce than with those associated with meat, poultry or seafood.[13] In fact, support for FDA action on a produce-safety rule is broad based. Major segments of the produce industry have expressed their public support for FDA action on produce safety since early 2007[14] as have consumer groups before then.[15] Almost every piece of food-safety legislation introduced in the 110th Congress directs the Agency to act in this area.[16] Despite these calls for action, the establishment of mandatory, enforceable safety standards for the growing, harvesting, processing and distributing of fresh fruits and vegetables has not happened.

Indeed, these shortcomings in the nation's food-safety system are not new, having been documented repeatedly during the past decade by many expert bodies, including the National Academies of Science, the Government Accountability Office, and the FDA's Science Board.

More than a decade ago, in October 1997, the Clinton Administration's Food Safety Initiative, identified produce as an area of concern,[17] and, in response, FDA issued a voluntary guidance document in 1998 providing the produce industry with recommendations on how to minimize the risk of microbial contamination.[18] Since then, repeated outbreaks of illness associated with produce have prompted various other FDA guidance documents, letters, and initiatives, all of which have been voluntary.[19] Now, in the wake of the *Salmonella* Saintpaul outbreak, FDA's response so far has been limited to a review of its voluntary guidance, issuing a notice seeking information and scientific data to update and improve the 1998 document.[20]

Throughout the course of the *Salmonella* Saintpaul outbreak, FDA officials cited the need for produce-safety standards but maintained that additional legislative authority was required to issue them, thereby shifting the burden to Congress.

> *We also need Congress to act on FDA's request to give us the authorities we requested last November when we – when we introduced our food protection plan. We – we said many times that the – one of the best things to do is to – is to build in preventative control against food borne illness and the food protection plan called for that authority last November.* [21]

This deferral to Congress, however, is at odds with previous assertions of FDA authority to require preventive safety measures for seafood in 1995 and juice in 2001.[22] For instance, in the proposed seafood HACCP rule, FDA pointed to sections 402 (a) (1), 402 (a) (4), and 701 (a) of the Federal Food, Drug, and Cosmetic Act, as well as section 361 of the Public Health Service Act, as giving it the authority to require preventive food safety measures.[23] Similarly, the FDA relied on its existing authority when it drafted proposed regulations that establish preventive on-farm safety measures for shell eggs.[24] As noted above, FDA officials attempted to move forward with produce-safety regulations in 2007 under existing authority, only to have HHS ignore the Agency's request.[25]

The lack of federal action has resulted in a patchwork-quilt approach to fresh produce safety. For example, lettuce growers in California entered into a "Leafy Green Marketing Agreement" in the wake of the food borne-illness outbreak linked to spinach in fall 2006.[26] The agreement, which establishes safety standards for its participants, is intended to reassure the public about the safety of lettuce and other leafy greens as well as assure the safety of those commodities. In addition, various retailers have established their own safety standards for growers, processors and distributors.[27] And the states are beginning to take action. Florida, acting on its own to bolster confidence in its agriculture sector, adopted mandatory safety standards for tomatoes, which went into effect on July 1, 2008.[28]

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Moreover, federal inaction may well be eroding public confidence in the safety of the food supply. A national survey of 1,002 likely voters in July 2008, commissioned by PSP, found that 82 percent of respondents had heard either a great deal or fair amount about contaminated produce in the wake of the *Salmonella* Saintpaul outbreak.[29] A majority – 57 percent – reported being "worried' about the safety of fresh produce, 60 percent believed government food safety agencies are doing only a fair or poor job, and 75 percent wanted either a "complete overhaul" or "significant changes" when informed that current, federal produce-safety efforts are voluntary.[30]

II. Organizational Shortcomings

The organizational shortcomings evidenced in the recent outbreak are not new. The coordination of the public-health response to multi-state outbreaks of food borne illness has long been identified as needing significant reform. In 1998, the Foodborne Outbreak Response Coordinating Group (FORC-G) was created as part of the Clinton Administration's Food Safety Initiative through a memorandum of understanding (MOU) between the U.S. Departments of Agriculture (USDA), HHS, and the Environmental Protection Agency (EPA).[31] Working with state and local government partners, the three federal agencies agreed in the MOU to create, in effect, "standard operating procedures" to ensure efficient coordination between levels of government and among the federal agencies themselves. Also, the MOU provided, when

need be, for one federal official to be put in charge of a particular outbreak. From all appearances, FORC-G seems to have discontinued its activities with the change of administrations in 2001.

The coordination of the public-health response to multi-state outbreaks of food borne illness has long been identified as needing significant reform.

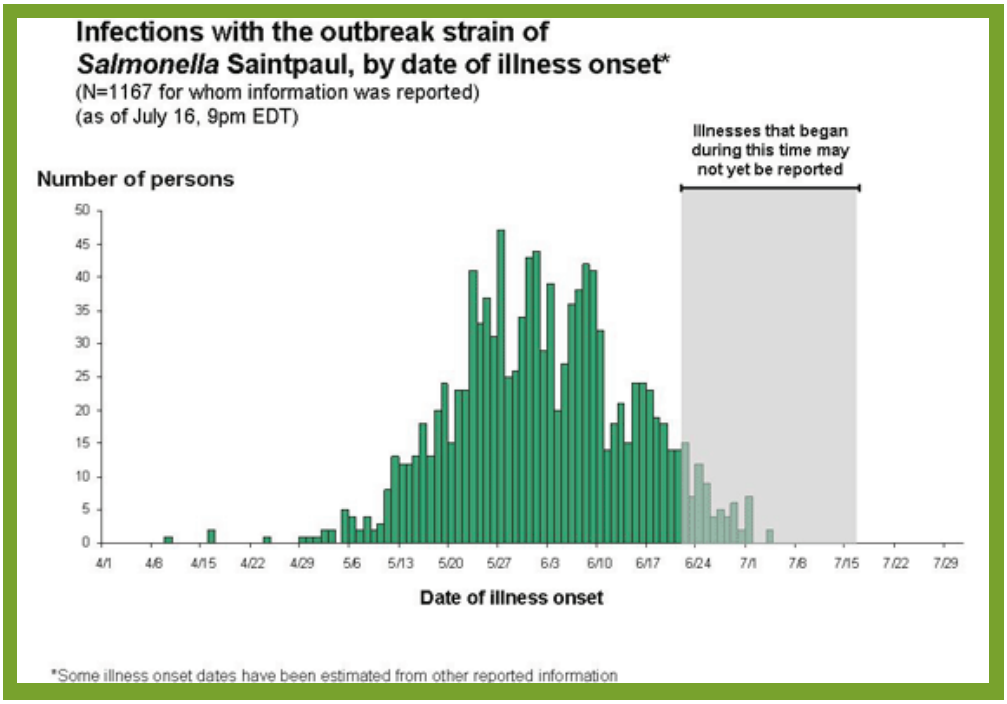
A more recent effort aimed at addressing these long-standing issues has been the establishment of the Council to Improve Foodborne Outbreak Response (CIFOR), a working group chaired by the Council of State and Territorial Epidemiologists (CSTE) and the National Association of County and City Health Officials (NACCHO).[32] In the midst of the *Salmonella* Saintpaul outbreak, CIFOR released for public comment a set of guidelines aimed at improving the capacity and quality of outbreak response by local, state and federal, public-health officials. While the CIFOR recommendations are comprehensive and detailed, it remains to be seen whether they will be implemented by the various levels of government involved, and, if so, be sustained over time.

Despite these efforts, the lack of organization and capacity in the public-health response was readily apparent in the recent outbreak. A major challenge in any multi-state outbreak of food borne illness is the coordination of literally dozens of public-health entities -- from local public-health departments to state public-health laboratories to state public-health and food inspection agencies to the federal public-health and regulatory agencies. In addition, the public-health agencies at the various levels of government must make certain that they are sharing information with other affected agencies, such as state agriculture and environment departments and state consumer-protection agencies. Therefore, it is critical that, before an outbreak occurs, there are systems already in place for the sharing of information, the allocation of resources, development of a response strategy, joint communications, and the designation of leadership. This challenge is further complicated by questions of capacity, competence, and mission orientation.

Problems of coordination and capacity in the recent outbreak response may be seen in an examination of the epidemic curve ("epi curve") published in the CDC outbreak report. One of the reasons to do an epi curve -- a graphic depiction of the course of an outbreak over time -- is to determine if the public-health interventions being taken are having the intended effect. On June 7, when the FDA issued its nationwide consumer advisory to avoid certain tomatoes, CDC reported that 145 persons had been infected since mid-April. [33] However, the CDC's epi curve published in the outbreak report showed that actually more than 800 persons – or 55 percent of the outbreak total – had onset of illness by June 7.[34] In the CDC outbreak report, the authors acknowledged the delay in the reporting and confirming of cases by noting that "response capacity is strained during large and complex outbreaks, and structure and capacities vary among jurisdictions. This can cause delays in identifying cases and in conducting investigations."[35]

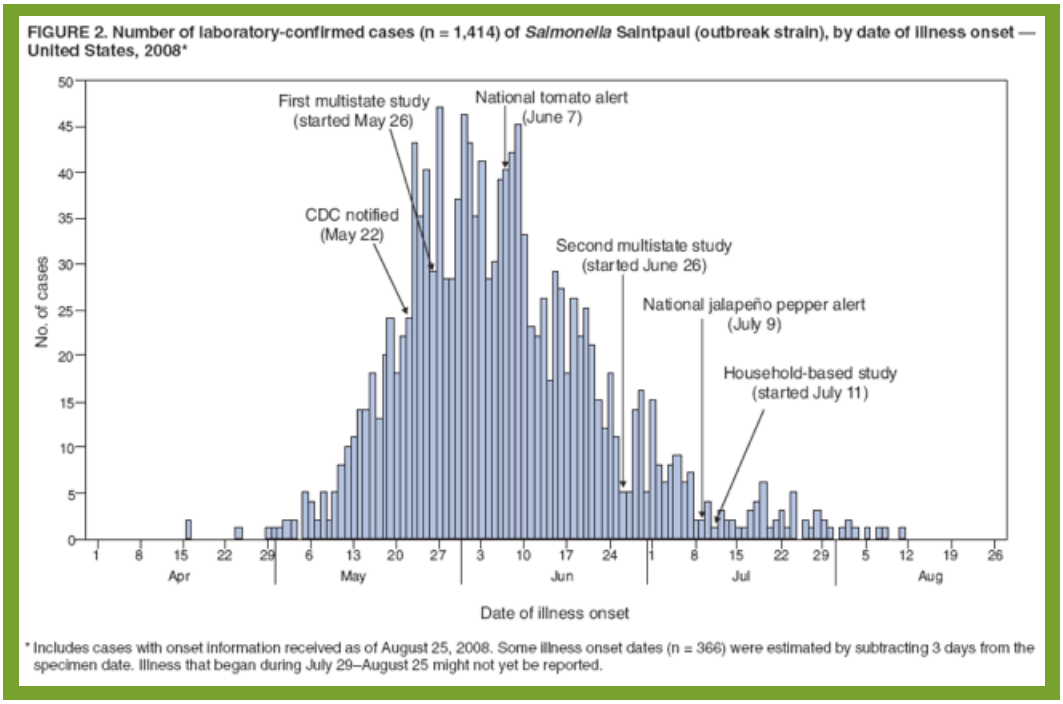
But the lack of capacity at various state and local levels does not appear to be the only question raised by the epi curve. Even the initial epi curve *(See Figure A)* published by CDC on its Web site on July 17[36] showed in broad contours the course of the outbreak: that is, the FDA nationwide consumer advisory to limit fresh tomato consumption to certain kinds, announced on June 7, seemed to have had

Figure A: July 17 presentation of epi curve on CDC website



some, but not a dramatic, effect on the number of people getting sick. It would appear that even the earliest versions of the epi curve could have caused public-health officials to question if their intervention was either too late (it had come after the outbreak was already winding down) or was actually not on target (i.e., something besides tomatoes was the source of *Salmonella S*aintpaul). In addition, the lack of confirmatory data from the traceback investigations– even given the perishable nature of tomatoes – would appear to have been another cautionary note for the federal public-health officials that other commodities might be involved.

Figure B: Epi curve data presented in August 28 MMWR article



When the epi curve published in the outbreak report is examined, *(See Figure B),* the sustained drop in the onset of cases appears to begin around June 24. It can be argued that there was a drop after June 7, but even taking into account the amount of time that likely transpired between consumption of contaminated produce and illness onset, the FDA's consumer advisory does not seem to have been a significant factor in slowing the outbreak's progression. The epi curve suggests a normal bell-shaped curve with the FDA advisory coming shortly after a natural peaking. A thorough post-mortem analysis should include a detailed examination of the public-health effectiveness of the June 7 advisory.

More questions about organization, coordination and effectiveness are raised in trying to reconcile the observations and conclusions in the CDC outbreak report with public statements made by FDA and CDC officials during the outbreak. For instance, the CDC outbreak report reviewed the findings from two cluster investigations undertaken in mid- to late June.[37] They both occurred in Texas and were initiated June 20 and June 24, respectively. The first investigation implicated salsa made with raw tomatoes and raw jalapenos, and the second implicated salsa made with commercially canned tomatoes and raw jalapenos. In the CDC outbreak report, the authors concluded that "[t]hese results indicated that jalapeno peppers were a likely source of illness."[38] On June 27, however, FDA and CDC officials would only say during their press briefing that they were looking at other kinds of produce in addition to tomatoes.[39] And while the cluster investigations were not case-controlled studies, their results would seem to call into question the continued public spotlight on tomatoes into early July. Questions that need to be explored in the post-mortem analyses are how quickly data were shared between local, state and federal public-health agencies; whether public-health officials were fully sharing with each other all of the relevant epidemiological data; and whether independent reviews were undertaken of the initial epidemiological investigations to determine if this data from mid-to-late June called into question those original findings.

In his congressional testimony on July 30, Dr. Lonnie King, Director of CDC's National Center for Zoonotic, Vector-borne & Enteric Diseases, testified how an epidemiological investigation is, by nature, an "iterative process; each step informs subsequent steps and often leads to new investigative avenues."[40] But the question remains whether earlier work was being reviewed and re-evaluated for its soundness and how well data were being shared among local, state and federal epidemiologists. The CDC-generated, case-control questionnaire, dated June 6 and based on earlier data, *(See Appendix B)* asked no questions about peppers. In fact, the question may be whether there are systems in place that allow for quickly going back in these outbreak investigations and re-tracing investigative footsteps. If there are none, then why not: is it due to lack of capacity or institutional barriers or some other factor.

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In fact, on June 26, CDC and 29 state and local health departments initiated a second case- control study, and its results would point to pico de gallo, corn tortillas and freshly prepared salsa.[41] During a media briefing on July 1, CDC officials reported that this new case study was ongoing, but CDC and FDA continued to shine the spotlight on tomatoes, with FDA's representative saying: "As you heard from CDC, the tomatoes are still considered to be the lead suspect and

are our major focus."[42] Moreover, while this case-control study would ultimately find that "illness was significantly associated with eating at a Mexican-style restaurant in the week preceding illness onset," federal public-health officials were only saying at the July 1 briefing that the expansion was to produce "that are commonly served in combination with tomatoes."[43] It should come as no surprise then that reporters, without any further information from government officials, were speculating during the briefing that "radishes" or other common salad items were the new suspect produce items.[44]

Looking at the public statements being made during this period, in light of the CDC outbreak report's account of what was happening behind the scenes, again raises questions about how quickly and how well information was being shared between local, state and federal public-health agencies, and ultimately communicated to the public. As of June 27, this was the CDC statement on its Web site about the likely source of infection: "An epidemiologic investigation comparing foods eaten by ill and well persons has identified consumption of raw tomatoes as the likely source of the illnesses. The specific type and source of tomatoes is under investigation; however, the data suggest that illnesses are linked to consumption of raw red plum, red Roma, or round red tomatoes, or any combination of these types of tomatoes, and to products containing these raw tomatoes."[45] On June 30, the CDC amended the statement: "An initial epidemiologic investigation comparing foods eaten by ill and well persons identified consumption of raw tomatoes as strongly linked to illness. Recently, many clusters of illnesses have been identified in Texas and other states among persons who ate at restaurants. These clusters have led us to broaden the investigation to be sure that it encompasses food items that are commonly consumed with tomatoes."[46] Then on July 7, the CDC amended it further: "An initial epidemiologic investigation comparing foods eaten by ill and well persons identified consumption of raw tomatoes as strongly linked to illness. Recently, many clusters of illnesses have been identified in several states among persons who ate at restaurants. These clusters led us to broaden the investigation to be sure that it encompasses food items that are commonly consumed with tomatoes. Fresh tomatoes, fresh hot chili peppers such as jalapeños, and fresh cilantro are the lead hypotheses. However, at this point in the investigation, we can neither directly implicate one of these ingredients as the single source, nor discard any as a possible source."[47] Again, the post-mortem examination needs to look at how timely and how fully epidemiological data were being shared and also review what the federal public-health officials were communicating to the public.

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During this same time period at the end of June, the state of Minnesota was investigating a cluster of illnesses linked to *Salmonella* Saintpaul. Testifying in August before the Oversight Subcommittee of the House Committee on Energy and Commerce, Kirk Smith, supervisor of the Foodborne Disease Unit of the Minnesota Department of Health, described that state's investigation into its cluster of illnesses.[48] By June 27, the Minnesota state lab had confirmed 10 isolates of *Salmonella S*aintpaul, and three days later, Minnesota health officials learned that several of the ill persons ate at the same restaurant.[49] That same day, June 30, Minnesota public-health officials visited the restaurant to get detailed information

about menu items and ingredients.[50] By July 3, Minnesota's preliminary epidemiological information pointed to jalapeno peppers, according to Smith, and the state shared that information with CDC as well as with FDA. [51] In its outbreak report, CDC acknowledged that "[t]his study provided more evidence that consumption of raw jalapeno peppers was a major risk factor for illness."[52] But it was not until July 7 that federal public-health officials identified raw jalapenos and fresh cilantro as the "lead hypothesis" for new food vehicles for the outbreak.[53] This chronology too raises the question of whether information was being relayed in a timely fashion and whether important qualifiers about the certainty of previously-relied upon data were being communicated or appreciated as soon as they should or could have been.

The PSP review of the publicly available materials related to the *Salmonella* Saintpaul outbreak shows an initial timeline with both promising and disturbing elements. On May 21, the New Mexico state lab confirmed the first three cases of *Salmonella* Saintpaul with the same genetic fingerprint, and within one day notified CDC.[54] That same day, CDC notified all other states to be on the lookout for matching DNA patterns.[55] Within a day of that notification, Texas and Colorado reported matching cases.[56] Then, on May 23, the affected states' public-health officials began exchanging information on conference calls.[57] Clearly, a quick response involving several jurisdictions had begun. But it then took CDC three days – until May 26 – to notify FDA, the food-safety regulatory agency that would have to take the lead in any multi-state investigation and traceback of contaminated produce.[58] The delay then became even more pronounced: FDA did not join the daily conference calls until four days later.[59] What began as a quick and timely response to an outbreak started to slow down. As a result, information and questions that could have been exchanged in real time may well have had to be reconstructed from notes and memory due to time lags. This timeline also points to a significant structural issue in multi-state responses to food borne illness outbreaks: the dichotomy between the epidemiological investigation and the traceback investigation. Because these investigations are conducted by two separate agencies, they tend to be treated as separate processes rather than being seen as two sides of the same coin, needing significant integration.[60]

Despite more than a decade of concern about the public-health response in these outbreaks, the public record suggests significant lack of coordination and communication because of the current public-health organization and structure.

By June 10, fractures were clearly visible between public-health agencies and agriculture departments: State agriculture commissioners from the southeastern states initiated a conference call with the FDA to voice their concerns about how that agency's investigation was harming their states' tomatoes industries and issued a press release, publicly airing their concerns. [61] Then, on June 10, the agriculture commissioners from California and Florida both issued press releases affirming the safety of the tomatoes from their states.[62] These were clear signs that management of the outbreak was losing credibility at the state level.

In short, the review by PSP raises questions about how local, state and federal public-health agencies are organized to coordinate and act together in multi-state food borne-illness outbreaks. Despite more than a decade of concern about the public-health response in these outbreaks, the public record suggests significant lack of coordination and communication because of the current public-health organization and structure. It may well have resulted in a public- health response that was ineffective in protecting the public and caused significant unnecessary economic harm to the tomato industry.

III. Communications Shortcomings

Key to successful communications during any public- health emergency is a unified voice, reflecting a considered assessment of risk and communicating accurate facts and clear recommendations to the public and any affected industry. From the beginning of the *Salmonella* Saintpaul outbreak, the public- health voices were multiple and inconsistent: for instance, as described above, the states of Arizona, New Mexico and Texas, the CDC and the FDA initially issued – over a four-day period -- separate statements announcing the outbreak. During the course of the outbreak, CDC and FDA continued to issue separate statements on a daily basis, with each one referencing that the other had "news" pertaining to its own "news." At the same time, the two agencies continued to hold joint press calls. In addition, states around the nation were issuing separate statements throughout the outbreak. Furthermore, information important for the public's understanding of the outbreak (e.g., the exact location of cases within a given state) was often scattered between federal and state public-health agency Web sites.[63]

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At the beginning of the outbreak, the organizational dysfunctions manifested themselves in the way information about the outbreak was communicated to the public. On May 31, one day after joining the conference calls between state public-health and CDC officials, the FDA told the other participants that it intended to issue a public warning about red plum, red Roma and red round tomatoes.[64] However, instead of a single, unified communication to the public about what was and what was not known, five separate announcements by five different agencies were made over a four-day period. First, the New Mexico Department of Public Health issued a press release on May 31, announcing that "uncooked tomatoes" were the likely cause of the outbreak and that it hoped to provide precise information in the future about what types of tomatoes were involved.[65] It also stated that tomatoes purchased from three specific stores should not be eaten "uncooked." In the New Mexico press release, there was only a vague mention of "other states" being involved. Three days later, on June 2, the CDC issued its first advisory on the outbreak.[66] The agency noted that the cases, to date, were concentrated in New Mexico and Texas but observed that additional cases might be linked to the outbreak and had been reported in seven other states. The CDC identified the "consumption of raw tomatoes" as the likely source of the outbreak based on epidemiological investigation and further linked the outbreak to "large tomatoes, including Roma and red round" ones.[67] Its consumer advice was directed toward New Mexico and Texas, and in those states to "persons with increased risk of severe infection" and "persons who want to reduce their risk of *Salmonella* infection."[68]

The FDA's initial public statement finally came on June 3 when it issued a consumer advisory for New Mexico and Texas and identified raw red plum, red Roma and round red tomatoes as the likely suspect food.[69] The FDA stated that other tomatoes – such as grape, cherry, tomatoes with vines attached – had not been implicated and that consumers could have confidence in their safety. Also, on June 3, Texas public-health authorities issued a press release on what they called a "multi-state outbreak."[70] They reported that the cases in Texas were in six counties

so far, and directed their consumer advice to individuals with increased risk of severe infections such as the elderly and infants. It advised that those individuals should avoid "raw Roma or full-sized round tomatoes," as should persons who want to reduce their risk of "*Salmonella* infection" in general.[71] Finally, Arizona announced on June 3 that it was "part of a multi-state outbreak" even though the day before CDC had listed it as one of seven states where the association to the consumption of tomatoes was still being investigated, and CDC kept it in that still-to-be-determined group in its June 5 advisory update.[72]

In short, the five public-health agencies gave the press and the public a grab bag of information about the outbreak, the likely source of infection and consumer advice to communicate to the public. At one end of the spectrum, there was very specific information that the suspect tomatoes came from three stores in New Mexico; at the opposite end, there was a generalized characterization of "raw tomatoes" as suspect, along with the suggestion that the outbreak was spread over as many as nine states. Sometimes, the consumer advice was directed toward consumers in general and, in other instances, to those at risk for severe infections. This review of the press releases evidences a lack of consensus among the public-health agencies on what needed to be communicated to the public and perhaps even disagreement about the level of risk posed to them. It should not have been surprising, then, in light of these inconsistent messages, that several large retail outlets pulled tomatoes off their shelves and out of their menu items in the middle of the outbreak, and consumers stopped eating all types of tomatoes even though the FDA said repeatedly that grape, cherry, and tomatoes on the vine were safe.[73]

Differing organizational policies and standards were also creating inconsistencies in what and when information was being provided to the media, making the investigation look inept at worst and inconsistent at best. For instance, during a press briefing on June 16, FDA and CDC officials spoke about a cluster of illnesses that they hoped might lead to a resolution of the outbreak.[74] However, citing confidentiality rules and statutes, they declined to identify the location of the cluster in even the most general of terms. But on June 18, the Chicago Health Department publicly identified the Illinois restaurant linked to this cluster.[75] This hide-and-seek approach was repeated a few days later when, on June 20, FDA officials were questioned during another press briefing about a cluster of illnesses in Texas. Again, citing legal restrictions, they declined to comment and instead, told reporters to call the Texas health department.[76] So, instead of providing a single point of comprehensive and accurate information, the public-health response fractured itself.

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Figure C: CDC Map, June 2

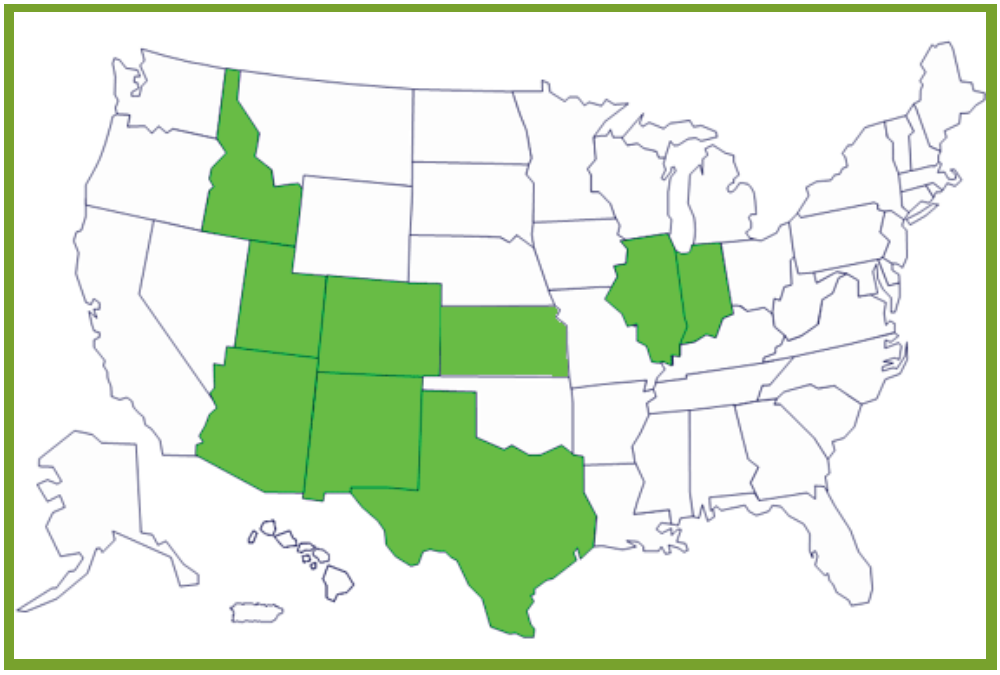
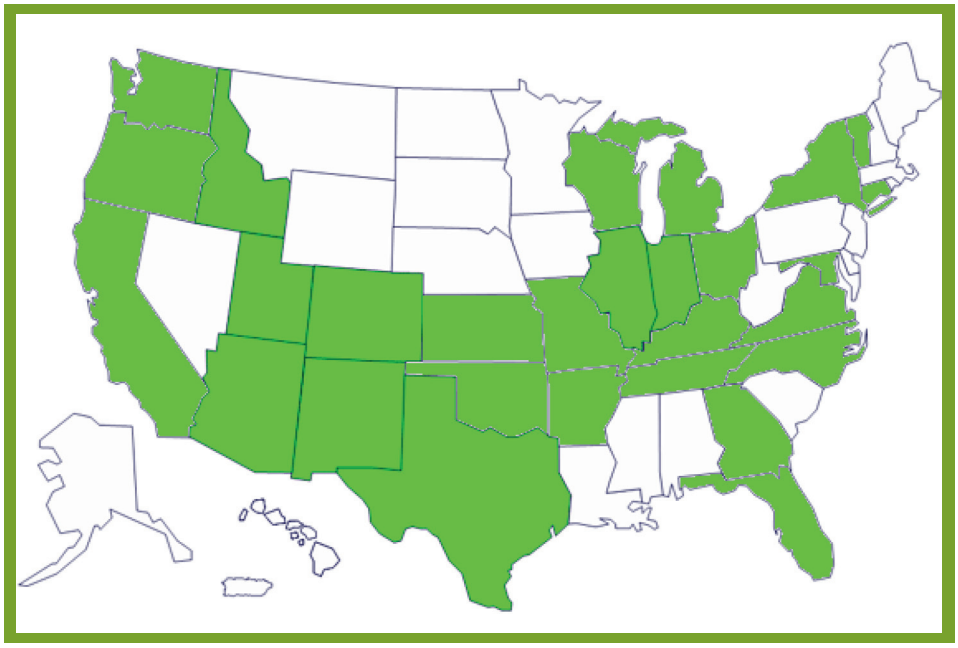


Figure D: CDC Map, June 16



Also key to the successful handling of any outbreak response is to have agreed-upon procedures established and in place regarding how to convey outbreak information. In this regard, the CDC's constantly evolving graphic depiction of the outbreak on its Web site was especially problematic. In the course of three days – June 22 through June 24 – CDC presented the public with three different maps of the outbreak without any accompanying explanation on why it made the changes. On June 2, the day of the first public CDC advisory, the agency published on its Web site a map showing cases in nine states.[77] *(See Figure C)*

The legend accompanying the map reported that there were 21 cases in Texas and 19 in New Mexico; then in separate text, the CDC reported there were an additional 30 suspect cases in another seven states.[78]

In addition, there were puzzling anomalies: only one case was reported in Florida even though FDA officials were saying as of June 18 that they believed the contaminated tomatoes were either from Mexico or Florida.

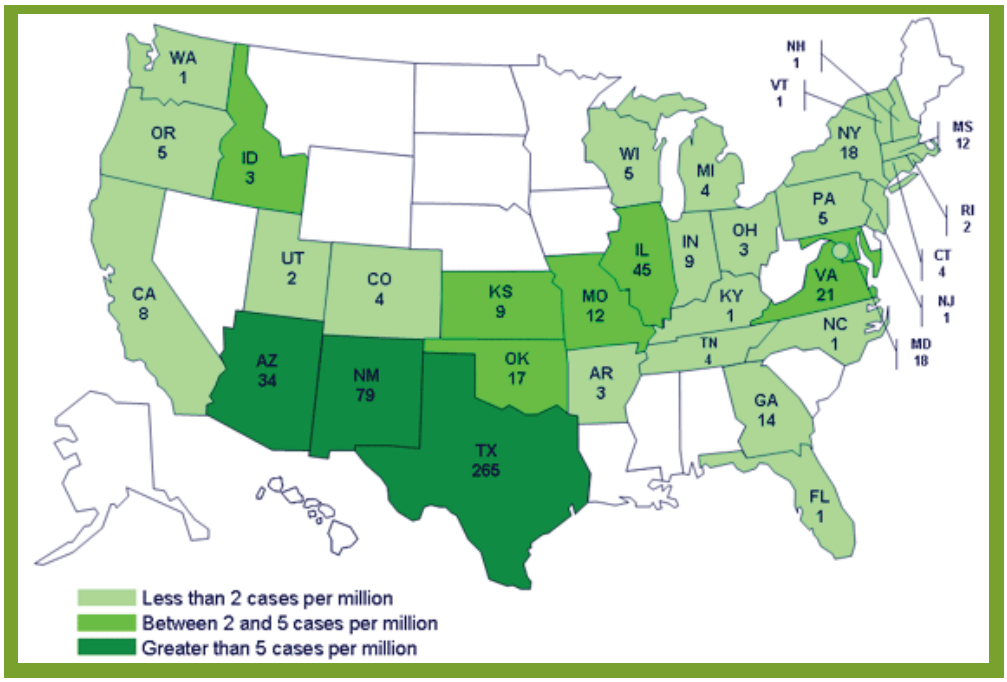
Neither the image of the map nor the accompanying explanatory legend left one with the impression that the outbreak was both widespread and somewhat localized, i.e., spread across a number of states but confined to select areas within the states. For instance, two days earlier, New Mexico had reported in its press release that its cases, to date, were confined to seven counties in that state, and a day later, Texas would report that its 21 cases were in six counties.[79] None of this information was reflected in the initial CDC map. Rather the map conveyed an impression of widespread and statewide outbreaks. In fact, the misleading impression left by this image would become apparent in the succeeding days. By June 16, the outbreak map on CDC's Web site was coast to coast. *(See Figure D)*

The accompanying legend to the map did report the number of cases by state but the visual impression more than overwhelmed the information in the text. And again, the textual information was incomplete, not reporting where the cases occurred in each state or when the onset of the cases had occurred.[80]

Moreover, by June 16, CDC and various states had learned of clusters of illnesses – a cluster of nine illnesses in Illinois and one of approximately 30 in Texas. Both were associated with a restaurant.[81] This lack of detail was becoming a source of frustration for the tomato industry.[82] They were trying to reconcile the pattern of illnesses with the distribution pattern for tomatoes. Without knowing where the illnesses in a state were occurring, they could not match them up with the likely sources for tomatoes. In addition, there were puzzling anomalies: only one case was reported in Florida even though FDA officials were saying as of June 18 that they believed the contaminated tomatoes were either from Mexico or Florida.[83]

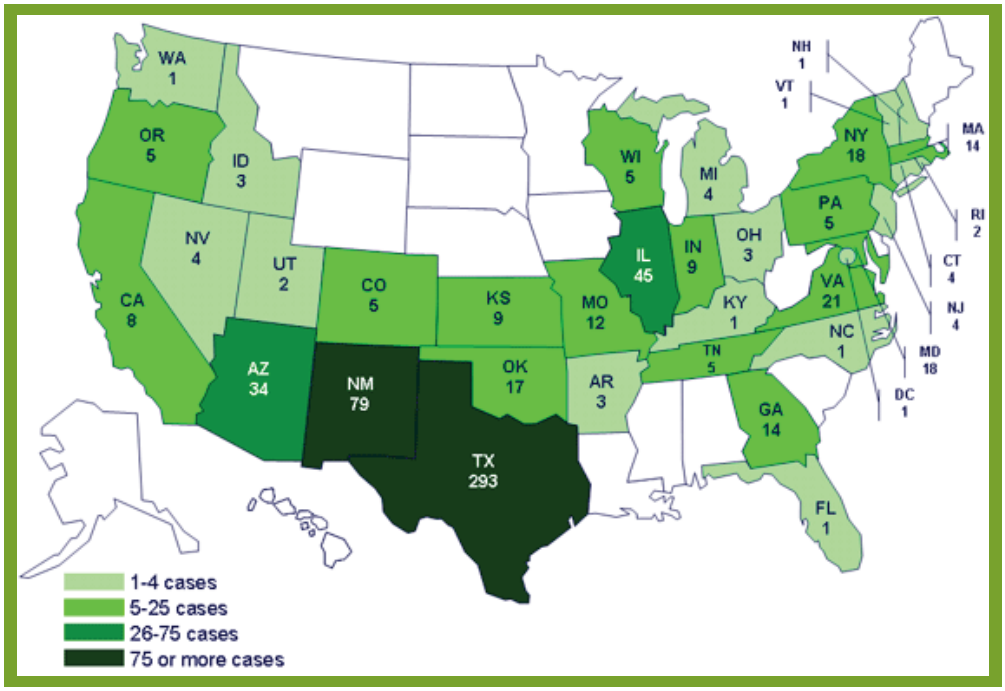
As criticism of the CDC map increased, the agency began its series of changes.[84] Switching from the map that had been in use between June 2 and June 22, the agency introduced on June 23 a tri-color map with the number of reported cases now being listed in each state.[85] *(See Figure E)* The colors represented cases per million of population.

Figure E: CDC Map, June 23



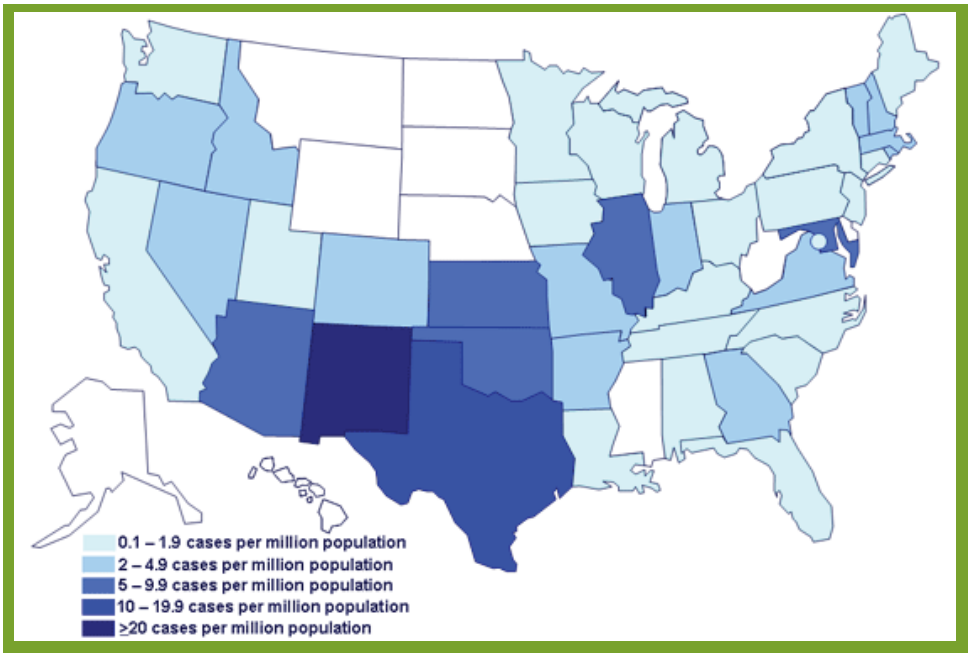
A day later, however, the CDC presented a new, four-color map to the public.[86] *(See Figure F)* Gone was the analysis of cases per million. In its place was a range of cases: 1-4; 4-25; 26 to 75; and 76 or more.[87] Where a day earlier, the most affected states were Arizona, New Mexico and Texas, now there were just two -- New Mexico and Texas -- with the most number of cases (and Arizona and Illinois with the next-highest number).

Figure F: CDC Map, June 24



So, in at three-day period, from June 22 to June 24, CDC offered three different visual ways of understanding and interpreting the outbreak. Then, on July 3, CDC published another "new" map: this one was an "incidence" map, meaning that it expressed rates of illness again in cases per million.[88] *(See Figure G)*

Figure G: CDC Map, July 3



As officials continued to talk about a nationwide outbreak, the maps began to show clearly more localized and concentrated clusters of illnesses.

On July 17, CDC introduced another new graphic image – the "epi curve" – and, for the first time, began communicating detailed data about the onset of the illnesses.[89] *(See Figure H)* In its previous advisories, the CDC had reported only when the first and last onset of illnesses had occurred.[90]

Figure H: CDC Epi Curve, July 17

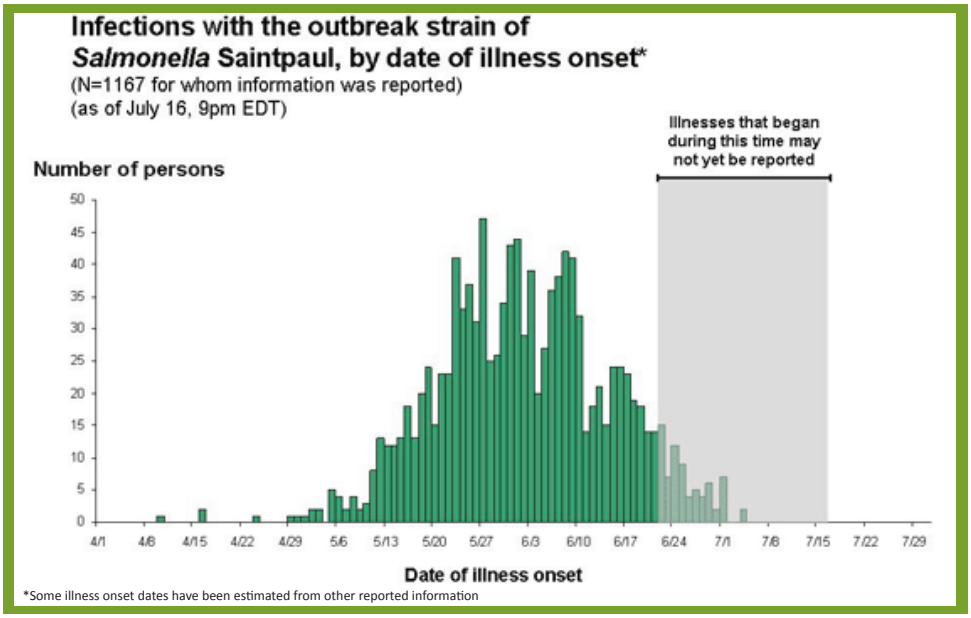
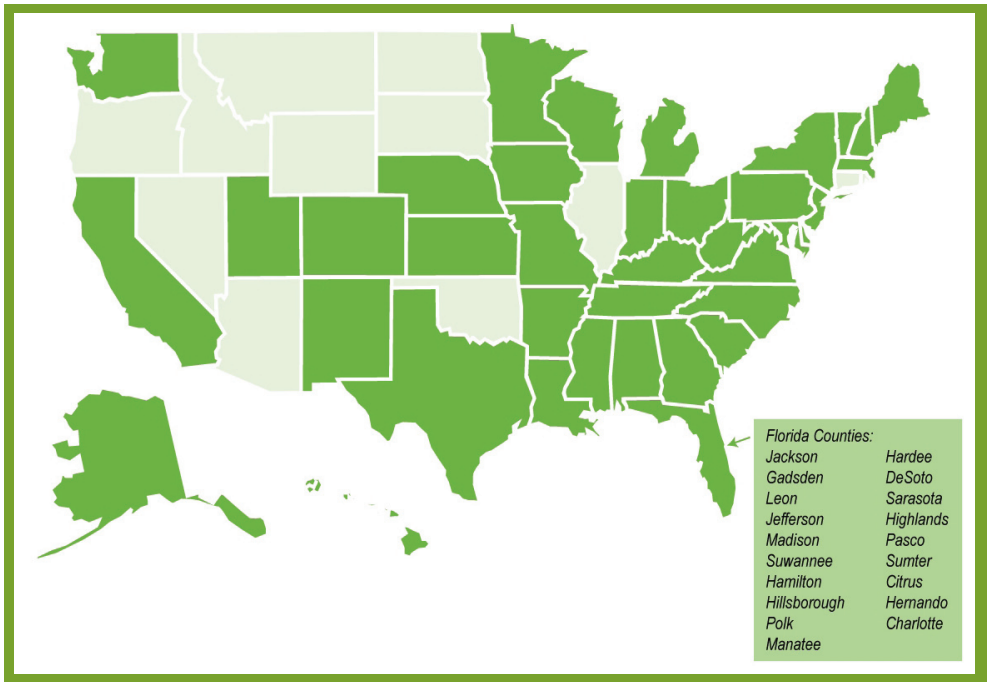
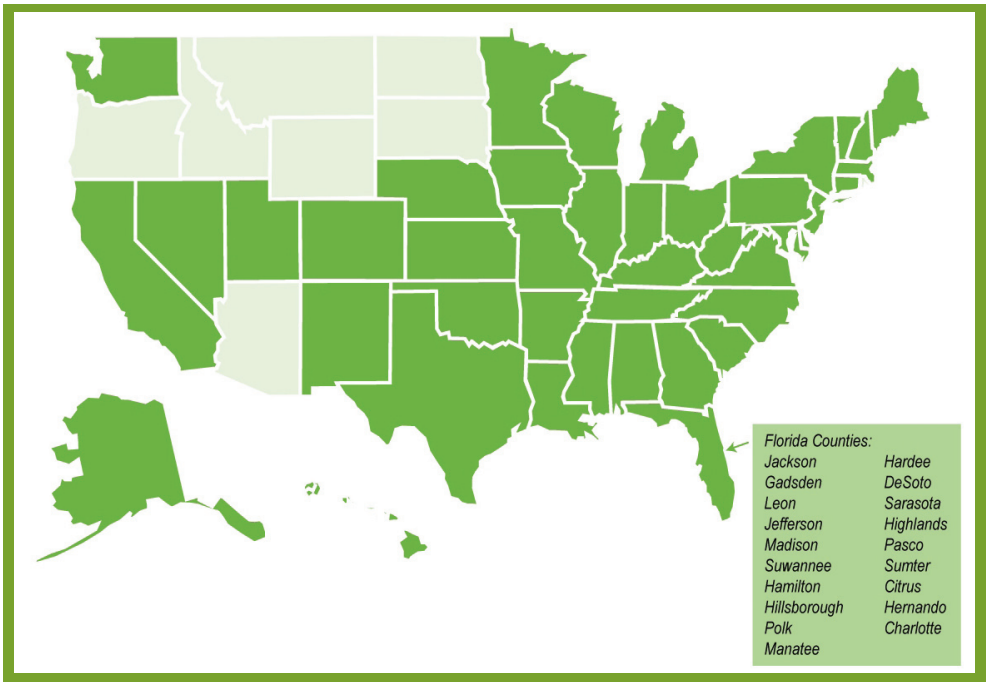


Figure I: "Cleared" Tomato-Growing States as of June 14



This is an example of what a map presentation of FDA's list of states where tomatoes were being safely grown and harvested would have looked like on June 14.

Figure J: FDA's List of "Cleared" Tomato-growing States as of July 1



This is an example of what a map presentation of FDA's list of states where tomatoes were being safely grown and harvested would have looked like on July 1.

While it was commendable that CDC sought during the course of the outbreak to find better and more complete ways to communicate graphically, it is troubling that this determination was not made beforehand; it might have minimized the confusion and frustration experienced by state officials, the produce industry and consumers.

The saga of the CDC map also raises the issue of why FDA did not attempt to communicate graphically the so-called "exclusion" areas where tomatoes grown and harvested were considered safe.[91] Throughout the outbreak the FDA provided this information on its Web site in list form. Such a presentation was not as effective as the CDC map (flawed though it was) in conveying information about the illnesses associated with the outbreak. As a result, FDA's list of "cleared states" never had what appeared to be the intended impact on consumer behavior. Here are two examples of what such a map would have looked like: on June 14 and July 1. *(See Figures I and J)*

Such a graphic presentation of the FDA "cleared" list might have allayed some of the growing public concern about the safety of tomatoes.

CONCLUSION

The nation's food-safety system continues to be plagued by issues of capacity, competence and coordination, and all were in evidence during this past summer's *Salmonella* Saintpaul outbreak. A lack of FDA-mandated preventive safety standards for domestic and imported fresh produce has long been recognized as a major issue. Instead of using this most recent outbreak to move forward, FDA officials continue to say they must wait for Congress to give them explicit authority to act. The outbreak response was marked by a lack of organization, capacity and coordination that calls into question the public-health effectiveness of the response. Finally, messages to the public were often mixed, if not contradictory. These shortcomings have been recognized for years. The time has come to fix the food-safety system, in particular, how it ensures the safety of fresh produce. A careful public post-mortem analysis of the *Salmonella* Saintpaul outbreak can help inform that fix.

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APPENDIX A
Outbreak Timeline

May 11:

- Onset of first illness in New Mexico

May 21:

- New Mexico state lab confirms 3 cases of Salmonella Saintpaul with same genetic fingerprint

May 22:

- New Mexico lab confirms other cases
- New Mexico Department of Health notifies CDC
- New Mexico epidemiologists begin patient interviews
- New Mexico posts information on PulseNet web-board
- CDC requests other states to report cases with matching DNA patterns

May 23:

- Texas and Colorado report matching cases to CDC
- New Mexico issues press release alerting health care providers in state
- Multi-state investigation begins, including daily conference calls

May 24:

- New Mexico health officials hypothesize fresh tomatoes as source

May 26:

- CDC notifies FDA of hypothesis of connection of ill persons with fresh tomatoes

May 27:

- New Mexico begins case control study

May 30:

- FDA joins conference call
- New Mexico Environment Department buys tomatoes in grocery stores to test

May 31:

- FDA tells conference call participants it wants to issue consumer warning about red plum, red Roma and red round tomatoes
- Preliminary results of case-control study show significant association with consumption of raw tomatoes
- New Mexico issues press release associating New Mexico illnesses with fresh tomatoes and identifies three retail sources
- CDC formally notifies FDA of tomato-association and FDA decides to initiate traceback investigation

June 1:

- Tracebacks begin

June 2:

- New Mexico lab starts testing tomatoes
- CDC issues advisory of multi-state investigation (21 ill in Texas; 19 in New Mexico), saying "consumption of raw tomatoes" is likely source of illnesses in New Mexico and Texas based on epidemiology

June 3:

- FDA issues "consumer alert" for New Mexico and Texas, warning not to eat "raw red plum, red Roma or round red tomatoes" but that cherry tomatoes, grape tomatoes, tomatoes with vine still attached and tomatoes grown at home are safe; 30 potentially-linked illnesses in Arizona, Colorado, Idaho, Illinois, Indiana, Kansas and Utah
- Texas issues press release on 21 cases in Texas
- Arizona issues press release on 5 cases in Arizona
- CDC assumes lead from New Mexico of epidemiologic investigation

June 4:

- CDC receives report of first restaurant cluster: four cases in Illinois
- New Mexico issues press release, saying New Mexico tomatoes safe
- CDC releases update advisory, 57 ill in New Mexico and Texas

June 5:

- FDA publishes list of states, territories and countries where tomatoes are grown, harvested and not associated with outbreak
- New Mexico Environment Department issues press release, telling food establishments to stop serving red plum, red Roma or round tomatoes or salsa made with them
- Illinois issues press release on 12 cases in Illinois
- CDC releases advisory update, 71 ill in New Mexico and Texas; 34 potentially linked cases in Arizona, Colorado, Idaho, Illinois, Indiana, Kansas, Oklahoma, Utah, Virginia, Wisconsin

June 6:

- FDA Commissioner Andrew von Eschenbach reports on his blog, "Andy's Take," about how quickly system has worked to find source of illnesses
- Texas issues press release on 56 cases in Texas

June 7:

- FDA expands consumer advisory nationwide
- CDC releases advisory update, 145 ill in 16 states
- New Mexico issues press release on 55 cases in New Mexico

June 9:

- CDC issues advisory update, 167 cases in 17 states
- California issues press release on 2 cases in California
- Oregon issues press release on 3 cases in Oregon
- Alabama issues press release, saying its tomatoes on FDA's safe list
- Major restaurant chains and grocery chains (McDonald's, Wal-Mart, Outback, Taco Bell, for instance) announce they are pulling tomatoes from outlets
- Massachusetts public health department issues statement that no cases of salmonella linked to tomatoes in Massachusetts

June 10:

- Southeastern agriculture commissioners have conference call with FDA to voice concerns about impact on their tomato industries (Alabama press release)
- FDA updates list of tomato-growing areas not associated with outbreak, including Florida counties
- Florida Department of Agriculture issues press release on safety of Florida tomatoes
- California Department of Agriculture issues press release on safety of California tomatoes
- Utah issues press release on 2 additional cases in Utah, but notes both had been outside Utah during likely incubation
- Colorado issues press release on 2 cases in Colorado

June 11:

- Connecticut Agriculture and Consumer Protection agencies issue joint press release, saying Connecticut tomatoes safe
- Agriculture Department commissioners from southeastern states issue statement to FDA, complaining of how outbreak is being handled (Kentucky press release)

June 12:

- FDA updates list of tomato-growing areas not associated with outbreak
- Produce Marketing Association (PMA) publicly requests FDA to add Mexican states to cleared list
- Joint produce industry letter to retailers asking them to use tomatoes
- CDC releases advisory update, 228 cases in 23 states
- West Virginia issues press release, saying its tomatoes on FDA safe list
- Missouri Department of Health issues press release on 2 cases in Missouri
- Missouri Department of Agriculture issues press release on safety of Missouri tomatoes
- First FDA press conference

June 13:

- Joint FDA-CDC press call
  - Traceback complex
  - Tomatoes from southern Florida may be implicated in outbreak
  - Will not identify location of cluster
- District of Columbia issues press release on 1 case in D.C.
- Maryland issues press release on 1 case in Maryland
- Georgia issues press release on 7 cases in Georgia and safety of Georgia tomatoes
- Illinois issues press release on 29 cases in Illinois
- Tennessee issues press release on 3 cases in Tennessee
- Kentucky Department of Agriculture issues press release on safety of Kentucky tomatoes

June 14:

- FDA updates list of tomato-growing areas not associated with outbreak, including Baja Mexico

June 16:

- Joint FDA-CDC press call
  - No specific geographic location from traceback
  - Cluster involves 9 cases; most promising lead; will not identify location
  - Other clusters exist
  - Tomatoes now being harvested in north Florida and not implicated
- CDC issues advisory update, 277 cases in 28 states
- CDC receives report of first large restaurant cluster: approximately 30 illnesses in Texas
- McDonald's announces it is putting tomatoes back into restaurants

June 17:

- United Fresh Produce Association, PMA write Secretary Leavitt asking him to convene meeting with FDA, CDC and industry on outbreak response

June 18:

- Joint FDA-CDC press call
  - Outbreak not over; most recent onset June 5
  - Not large number of new cases; improved surveillance
  - 383 cases from 30 states and District of Columbia
  - Assume contaminated tomatoes came from Mexico or Florida
  - FDA determines "cleared" areas by states coming to it with information on why it should be excluded
- Chicago Health Department identifies cluster of 9 illnesses associated with eating at Adobo Grill
- CDC issues advisory update, 383 cases in 30 states and District of Columbia
- New Hampshire issues press release on 1 case in New Hampshire, but notes person may have been exposed outside of New Hampshire; New Hampshire tomatoes safe
- Indiana issues press release on 8 cases in Indiana

June 18-20:

- Texas reports an additional 134 cases
- Texas information highlights geographic concentration; association of illnesses with Mexican-style foods in restaurants in case-control studies raises questions at CDC about food items commonly consumed with tomatoes

June 19:

- CDC sends Epi-Aid team to Texas
- Joint FDA-CDC press call
  - Outbreak strain has not been identified in Mexico and no illnesses reported in Mexico
  - Reports of cases with onset after June 5
  - Not certain if past peak of outbreak

June 20:

- CDC issues advisory update, 552 cases in 32 states and District of Columbia
- Joint FDA-CDC press call
  - Bulk of new cases from Texas – 256 to date – because of better surveillance
  - Latest onset of illness June 10
  - Some tracebacks now completed to farms in Mexico and Florida; checking for contamination at points between farm and fork
  - Cluster in Texas being investigated
  - Other epidemiological data besides that in New Mexico and Texas point to tomatoes
  - FDA cannot comment on Texas cluster but says Texas Department of Health may be able to
- CDC and Texas begin investigation into cluster of 47 illnesses
- Results indicate salsa in which fresh tomatoes and jalapeno peppers were used
- Michigan issues press release on 2 new cases in Michigan for total of 4
- Massachusetts issues press release on 12 cases in Massachusetts

June 21:

- New Mexico Environment Department issues "embargo" on tomatoes from certain areas in Mexico and Florida

June 23-27:

- Minnesota State Public Health Laboratory receives 10 Salmonella Saintpaul isolates from Minnesota residents

June 23:

- CDC issues advisory update, 613 cases in 33 states and District of Columbia

June 24:

- CDC and Texas begin investigation into cluster of 33 illnesses
  - Results indicate salsa in which canned tomatoes and fresh jalapeno peppers were used
- CDC issues advisory update, 652 cases in 34 states and District of Columbia
- New Jersey issues press release on 4 cases in New Jersey and states New Jersey will not begin harvesting tomatoes until next week
- Massachusetts issues press release on 5 new cases in Massachusetts for total of 17

June 25:

- CDC issues advisory update, 707 cases in 34 states and District of Columbia

June 26:

- CDC and 29 states begin case-control study
  - Results indicate Mexican-style restaurants are linked to outbreak
- CDC issues advisory update, 756 cases in 34 states and District of Columbia
- New Hampshire issues press release on 2 new cases in New Hampshire, but notes both may have been exposed outside New Hampshire

June 27:

- CDC issues advisory update, 810 cases in 36 states and District of Columbia

June 30:

- Massachusetts issues press release on 4 new cases for total of 21
- Several Minnesota patients report eating in same restaurant
- Minnesota public health officials go to restaurant to collect data on food workers, ingredients in menu items, and others potentially exposed
- CDC advises FDA that epidemiological data also implicates jalapeno and serrano peppers
- CDC issues advisory update, 851 cases in 36 states and District of Columbia

July 1:

- Joint FDA-CDC press call
  - As of June 30, 869 cases with 107 hospitalizations
  - Latest onset is June 20
  - Tomatoes still lead suspect
  - Other food items consumed with tomatoes being investigated
  - Can't say what those food items are
  - New case control study with persons ill since June 1
  - FERN network being activated to increase number of labs testing food items
  - Cases in New Mexico, Texas and Arizona account for more than half of outbreak cases
- FDA expands traceback to peppers
- CDC issues advisory update, 869 cases in 36 states and District of Columbia
  - Clusters in Texas and other states of persons who ate at restaurants prompting look at foods eaten with tomatoes

July 2:

- CDC issues advisory update, 887 cases in 38 states and District of Columbia

July 3:

- CDC issues advisory update, 922 cases in 40 states and District of Columbia
- Minnesota sends preliminary epidemiological statistics to CDC pointing to diced jalapenos as source of outbreak
- CDC and FDA provided traceback information, developed by Minnesota Department of Agriculture, on jalapeno peppers used in restaurant

July 4:

- CDC issues advisory update, 943 cases in 40 states and District of Columbia

July 7:

- North Carolina investigates cluster of 13 illnesses
  - Results indicate guacamole made with raw red Roma tomatoes and serrano peppers; no jalapeno peppers used
- CDC aware of 32 clusters in 13 states and the District of Columbia; 26 associated with Mexican-style restaurants
- CDC considering "strong probability" illness caused by more than one food item
- CDC issues advisory update, 971 cases in 40 states and District of Columbia
  - Epidemiological data now suggest fresh tomatoes, fresh hot chili peppers such as jalapenos, and fresh cilantro as "lead hypotheses"
- CDC , states and local health departments start second case-control study investigating foods in Mexican-style restaurants; study showed strong link to fresh produce used in Mexican cuisine but not to single item

July 8:

- CDC issues update advisory, 991 cases in 41 states and District of Columbia
- Minnesota completed case-control study that "unequivocally implicated jalapenos"

July 9:

- Joint FDA-CDC press call
  - Largest foodborne outbreak in last 10 years
  - People with compromised immune systems should avoid raw jalapeno and serrano peppers
  - No change in guidance on tomatoes
  - Traceback ongoing with peppers; taking samples but no positives yet
  - Not always Mexican foods eaten
  - In latest case control, not more than half of sick persons identified jalapeno peppers or cilantro
  - No epidemiologic evidence to remove tomatoes
  - Criteria for clearing tomato growing areas was when tomatoes began to be harvested, i.e., post-outbreak
- CDC issues advisory update, 1,017 cases in 41states and District of Columbia
  - Nationwide case control study of persons who became ill after June 1 points to raw tomatoes, fresh jalapeno peppers, fresh cilantro
  - Three clusters intensively investigated: in one, illnesses linked to consumption of item with fresh tomatoes and fresh jalapeno peppers; in other two, illnesses linked to consumption of item with fresh jalapeno peppers
  - Some illnesses caused by jalapeno peppers, but not all illnesses

July 10:

- CDC issues advisory update, 1,065 cases in 42 states, the District of Columbia and Canada

July 11:

- CDC issues advisory update, 1,090 cases in 42 states, the District of Columbia and Canada

July 14:

- CDC issues advisory update, 1,148 cases in 42 states, the District of Columbia and Canada

July 15:

- CDC issues advisory update, 1,167 cases in 42 states, the District of Columbia and Canada
- Western Growers asks FDA to lift tomato advisory and tell consumers all U.S. produced tomatoes safe

July 16:

- CDC issues advisory update, 1,196 cases in 42 states, the District of Columbia and Canada
- CDC assisting in restaurant-associated cluster investigations in North Carolina, Missouri, Texas and New York City

July 17:

- Joint FDA-CDC press call
  - Decrease in intensity of outbreak in mid-June: May 20-June 10, average of 33 new sick persons a day; June 11-June 20, average of 19
  - FDA "clears" tomatoes
  - Farms identified through epidemiology and traceback are no longer producing; no positive cultures at farms
  - FDA team has gone to specific packer in Mexico
- CDC issues advisory update, 1,220 cases in 42 states, the District of Columbia and Canada
  - Epi curve shows number of persons becoming ill peaked in May and decreased in June
  - Between May 20 and June 10, average number of persons becoming ill daily was 33
  - Between June 11 and June 20, average daily number was 19
  - Outbreak ongoing but fewer cases each day
- FDA lifts its consumer advisory on tomatoes
  - Vulnerable populations should not eat fresh jalapeno or serrano peppers

July 18:

- CDC issues advisory update, 1,237 cases in 43 states, the District of Columbia and Canada

July 21:

- Joint FDA-CDC press call
  - FDA announces finding of contaminated jalapeno pepper at McAllen, TX distribution facility; pepper grown in Mexico
  - Consumers should avoid fresh jalapeno peppers
  - No environmental contamination found at facility
- CDC issues advisory update, 1,251 cases in 43 states, the District of Columbia and Canada
  - Epidemiological data point to jalapeno peppers as "major cause" of illnesses; fresh serrano peppers and fresh tomatoes remain under investigation
- Agricola Zaragosa recalls jalapeno peppers distributed after June 30, 2008
  - Peppers distributed in Georgia and Texas

July 22:

- CDC issues advisory update, 1,256 cases in 43 states, the District of Columbia and Canada

July 23:

- CDC issues advisory update, 1,279 cases in 43 states, the District of Columbia and Canada

July 24:

- CDC issues advisory update, 1,284 cases in 43 states, the District of Columbia and Canada

July 25:

- CDC issues advisory update, 1,294 cases in 43 states, the District of Columbia and Canada
- FDA announces domestic jalapeno and serrano peppers are not implicated in outbreak
  - FDA advises consumers not to eat jalapeno peppers grown in Mexico
  - FDA advises vulnerable populations not to eat serrano peppers grown in Mexico
  - Agricola Zaragosa not source of original contamination

July 28:

- CDC issues advisory update, 1,304 cases in 43 states, the District of Columbia and Canada
- Colorado announces confirmation of jalapeno pepper from ill individual matches outbreak strain
  - Pepper likely purchased on June 24 and individual became ill on July 4
  - First pepper linked directly to ill person

July 29:

- CDC issues advisory update, 1,307 cases in 43 states, the District of Columbia and Canada
  - Colorado detected outbreak strain of Salmonella Saintpaul in jalapeno pepper linked to illness

July 30:

- FDA announces finding contaminated serrano pepper and irrigation water at farm in Mexico
  - Advises consumers not to eat serrano peppers from Mexico
- CDC issues advisory update, 1,319 cases in 43 states, the District of Columbia and Canada
  - After public warning on tomatoes, illnesses occurred at lower rate
  - Three large clusters investigated, and jalapeno peppers do not explain all illnesses
  - In two of clusters, illnesses associated with food items with serrano peppers and fresh tomatoes; in third cluster, illnesses associated with food items with fresh jalapeno peppers and tomatoes
  - Outbreak cannot be accounted for by one food
  - Current information indicates that jalapeno and serrano peppers grown, harvested or packed in Mexico are cause of some clusters and major vehicle in outbreak

August 1:

- CDC issues advisory update, 1,329 cases in 43 states, the District of Columbia and Canada

August 4:

- CDC issues advisory update, 1,330 cases in 43 states, the District of Columbia and Canada

August 6:

- CDC issues advisory update, 1,348 cases in 43 states, the District of Columbia and Canada

August 8:

- CDC issues advisory update, 1,401 cases in 43 states, the District of Columbia and Canada

August 12:

- CDC issues advisory update, 1,405 cases in 43 states, the District of Columbia and Canada

August 15:

- CDC issues advisory update, 1,423 cases in 43 states, the District of Columbia and Canada

August 20:

- CDC issues advisory update, 1,434 cases in 43 states, the District of Columbia and Canada

August 22:

- CDC issues advisory update, 1,438 cases in 43 states, the District of Columbia and Canada

APPENDIX B

Patient name: _____

2008 *SALMONELLA* SAINTPAUL OUTBREAK (*v 6.6.08*)

Case ID # (NM-EDSS ID): _____

Lab Status (Circle all that apply): Serotype Confirmed XbaI (1st enzyme) PFGE Confirmed BlnI (2nd enzyme) PFGE Confirmed

DOB: _____ /_____ /_____ Sex ☐ M ☐ F State _____ County _____ City _____

Phone number(s): _____ Interview by: _____ on _____ /_____ /_____

Respondent was: ☐ self ☐ parent ☐ caretaker ☐ other: _____

Specimen collection date: _____ /_____ /_____

Date of onset of diarrhea: _____ /_____ /_____

Date of onset of first symptom other than diarrhea (e.g., nausea, vomiting, cramps, fever): _____ /_____ /_____

I'd like to ask you some questions about your recent illness from Salmonella.

	Y	?	N			Y	?	N	
A	❐	❐	❐	Any Nausea?	G	❐	❐	❐	Did you visit a health care provider for your illness?
B	❐	❐	❐	Any Vomiting?	H	❐	❐	❐	Did you visit an emergency room for your illness?
C	❐	❐	❐	Any Abdominal cramps?	I	❐	❐	❐	Were you hospitalized overnight? *If yes*, number of hospital nights _____
D	❐	❐	❐	Any Diarrhea?	J	❐	❐	❐	Did you receive antibiotics for your illness?
E	❐	❐	❐	Any Bloody diarrhea?	K	❐	❐	❐	Did the patient die?
F	❐	❐	❐	Any Fever?					

I'd like to ask you some questions about foods you may have eaten in the week before you became ill (*Ask about the 7 days before illness onset*)

	Y	?	N	
A	❐	❐	❐	Did you eat any eggs?
B	❐	❐	❐	Did you eat any ice cream?
C	❐	❐	❐	Did you eat any potatoes?
D	❐	❐	❐	Did you drink any pasteurized ("regular") milk?
E	❐	❐	❐	Did you eat any tortillas?
F	❐	❐	❐	Did you eat any cold breakfast cereals (e.g., Cheerios, Raisin Bran)?
G	❐	❐	❐	Did you eat any raw (uncooked) onions?
H	❐	❐	❐	Did you eat any raw (uncooked) onions as part of fresh salsa, guacamole or pico de gallo?
I	❐	❐	❐	Did you eat any salsa?
J	❐	❐	❐	If yes, Did you eat any homemade salsa?
K	❐	❐	❐	Did you eat any store-bought salsa? If yes, What brand?: _____ Where purchased?: _____
L	❐	❐	❐	Did you eat any avocado?
M	❐	❐	❐	Did you eat any guacamole?
N	❐	❐	❐	If yes, Did you eat any homemade guacamole?
O	❐	❐	❐	Did you eat any store-bought guacamole? If yes, What brand?: _____ Where purchased?: _____
P	❐	❐	❐	Did you eat any ground beef (e.g., burger, tacos, casserole)?
Q	❐	❐	❐	Did you eat any ground beef (e.g., burger, tacos, casserole) prepared at your home or another home?
R	❐	❐	❐	Did you eat any ground beef (e.g., burger, tacos, casserole) at a restaurant?
				If yes, What restaurant(s)?
				1. Restaurant Name_____ 2. Restaurant Name_____
				Restaurant Location_____ Restaurant Location_____
				Name of food/menu item_____ Name of food/menu item_____
				Date of consumption _____ /_____ /_____ Date of consumption _____ /_____ /_____
S	❐	❐	❐	Did you eat any beef other than ground beef (e.g., steak, roast) prepared at your home or another home?
T	❐	❐	❐	Did you eat any chicken prepared at your home or another private home?
U	❐	❐	❐	Did you eat anything prepared at your home or another home from a whole chicken?
V	❐	❐	❐	Did you eat anything prepared at your home or another home from pre-cut chicken parts?
W	❐	❐	❐	Did you eat any lettuce? (*If YES, ask questions W through AE*)

Patient name: _____

X	❒	❒	❒	Did you eat any lettuce in your home or another private home?
Y	❒	❒	❒	Did you eat any lettuce in a restaurant?
Z	❒	❒	❒	Did you eat any lettuce on sandwiches or burgers?
AA	❒	❒	❒	Did you eat any lettuce on tacos?
AB	❒	❒	❒	Did you eat any iceberg lettuce?
AC	❒	❒	❒	Did you eat any romaine lettuce?
AD	❒	❒	❒	Did you eat any mesclun lettuce ("spring mix")?
AE	❒	❒	❒	Did you eat any lettuce or salad mix from a sealed bag or box?
	Y	**?**	**N**	**TOMATO EXPOSURES**
A	❒	❒	❒	Did you eat any raw (uncooked) tomatoes?
_____ *(times)*				If yes, How many times did you eat raw tomatoes in the 7 days before becoming ill?
B	❒	❒	❒	Did you eat raw tomatoes in a restaurant? (*If YES, also ask questions H through O plus AC below*)
C	❒	❒	❒	Did you eat raw tomatoes in your home or another home? (*If YES, also ask questions P through AC below*)
D	❒	❒	❒	Did you eat raw tomatoes on a sandwich or hamburger?
E	❒	❒	❒	Did you eat raw tomatoes in a salad?
F	❒	❒	❒	Did you eat raw tomatoes on tacos?
G	❒	❒	❒	Did you eat raw tomatoes as part of fresh salsa, guacamole or pico de gallo?
	Y	**?**	**N**	**TOMATOES AT A RESTAURANT**
H	❒	❒	❒	If you ate raw tomatoes at a restaurant, which restaurant(s)?
				1. Restaurant Name_____ 2. Restaurant Name_____
				Restaurant Location_____ Restaurant Location_____
				Name of food/menu item_____ Name of food/menu item_____
				Date of consumption _____ /_____ /_____ Date of consumption _____ /_____ /_____
I	❒	❒	❒	If at a restaurant, did you eat cherry tomatoes?
J	❒	❒	❒	If at a restaurant, did you eat grape tomatoes?
K	❒	❒	❒	If at a restaurant, did you eat roma (Italian or plum) tomatoes?
L	❒	❒	❒	If at a restaurant, did you eat regular large, red, round (e.g., beefsteak) tomatoes?
M	❒	❒	❒	If at a restaurant, did you eat sliced tomatoes?
N	❒	❒	❒	If at a restaurant, did you eat diced tomatoes?
O	❒	❒	❒	If at a restaurant, did you eat any other type of cut tomatoes (i.e., wedge cut)?
	Y	**?**	**N**	**TOMATOES AT HOME**
P	❒	❒	❒	If you ate raw tomatoes at your home or another home, where were the tomatoes purchased?
				1. Store Name_____ 2. Store Name_____ 3. Store Name_____
				Store Location_____ Store Location_____ Store Location_____
				Date of purchase_____ Date of purchase_____ Date of purchase_____
				Date(s) of consumption_____ Date(s) of consumption_____ Date(s) of consumption_____
Q	❒	❒	❒	If at home, did you eat cherry tomatoes?
R	❒	❒	❒	If at home, did you eat grape tomatoes?
S	❒	❒	❒	If at home, did you eat roma (Italian or plum) tomatoes?
T	❒	❒	❒	If at home, did you eat regular large, red, round (e.g., beefsteak) tomatoes?
U	❒	❒	❒	If yes, were they purchased with the vine attached?
V	❒	❒	❒	If at home, were the tomatoes washed prior to eating?
W	❒	❒	❒	If at home, were the tomatoes prepared (cut, sliced, diced) prior to eating?
X				If yes, how many hours prior to eating _____?
Y	❒	❒	❒	If yes, were the tomatoes refrigerated after preparation until consumed?
Z	❒	❒	❒	Is the receipt available from your tomato purchase?
				If yes, get info from receipt:
				Date _____ Time _____ Terminal _____ Store # _____ Transaction _____
AA	❒	❒	❒	If no receipt available, did you pay with a credit/debit card? If yes, Transaction # _____
AB	❒	❒	❒	If no receipt available, did you use a store "shopper card"? If yes, Card # _____

Questions continue on next page

Patient name: _____

	Y	?	N	
				TOMATO SAMPLES
AC	❒	❒	❒	Do you still have any of the raw tomatoes or anything prepared with raw tomatoes (e.g., homemade salsa or guacamole) that you ate during the week before your illness left in your home? *If YES, ask patient to hold sample in current location (e.g., if in fridge keep refrigerated) until further instructions provided for sample collection.* Type of sample available: _____
				GROCERY STORES From what grocery stores did the food you ate in the 7 days before you got sick come from? If you don't know, where do you usually buy your groceries? If you have a shopper card for any of these stores, it would be helpful if you could give me that number to help trace the source of any foods we find to be associated with this illness. *(For location, please try to get as much detail as possible – at least street name. "Card number" refers to shopper card. Ask for card number for each store listed)* 1. Store Name_____ 2. Store Name_____ 3. Store Name_____ Store Location_____ Store Location_____ Store Location_____ Card #_____ Card #_____ Card #_____
	Y	?	N	
A	❒	❒	❒	Do you buy food at Walmart or Sam's Club?
	Y	?	N	**DOG EXPOSURES**
A	❒	❒	❒	Do you own a dog? (*If YES, ask questions B through D*)
B				Where do you buy dog food? _____
C				What brand of dog food do you buy? _____
D	❒	❒	❒	Were you responsible for feeding your dog during the 7 days before illness onset?

Now I would like to ask you some questions about other people living in your household:
Was anyone else in your household sick with diarrhea or vomiting in the week before your/your child's illness? ☐ Y ☐ N ☐ DK
If yes, who? Please specify relationship _____
What date did this person become ill? ____/____/_____

Now I would like to ask you some questions about your race and ethnicity:

Do you consider yourself to be Hispanic or Latino or Chicano? ☐ Y ☐ N

What race or races do you consider yourself to be? You may select more than one option.

☐ White ☐ American Indian or Alaskan Native ☐ Black or African American ☐ Asian ☐ Native Hawaiian or Pacific Islander

☐ Another race I didn't mention:_____

If American Indian or Alaskan Native, what is your tribal affiliation? _____

If American Indian or Alaskan Native, do you currently live on the reservation or pueblo at least part of each week? ☐ Y ☐ N

Please fax completed forms to CDC (FAX: 404-639-2205, ATTN: Casey Barton Behravesh)
Questions? Contact Casey Barton Behravesh, dlx9@cdc.gov