

Food Related Emergency Exercise Bundle

**(FREE-B)   
Stealthy Situation**

**Situation Manual**

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# Introduction

## **Purpose**

To protect the health of the American public, it is crucial that we ensure that food products are safe for consumption. Everyone involved in the food chain, from farmer through consumer, has a responsibility to keep the food supply safe.

At any point during production or distribution, food can be contaminated either accidentally or on purpose from sabotage, fraud or terrorist activities. Regardless of the circumstances, the United States Department of Health and Human Services [Food and Drug Administration](http://www.fda.gov) (FDA) and United States Department of Agriculture [Food Safety and Inspection Service](http://www.fsis.usda.gov/) (FSIS), collaborating with State and local governments, work closely to safeguard the American food supply.

Through this working relationship, FDA and USDA FSIS continuously seek new ideas and strategies to reduce the incidence of human health emergencies and to support food defense-related innovation. In light of food defense concerns, it is incumbent that local, State and Federal governments and industry partners understand the roles and responsibilities of all participating entities.

This exercise is a comprehensive scenario, scheduled to take two days, and includes the epidemiological investigation, traceback and recall identification and implementation, role of regulatory agencies, and other issues associated with a cluster of illness linked to a foodservice establishment. The food product causing illness is a multi-ingredient product, containing both USDA- and FDA-regulated components, and illness is associated with institutional and foodservice settings in different jurisdictions.

## **Participants**

Many will benefit from participating in this scenario. We encourage as many of the following groups to participate in this exercise so that they can contribute to the overall understanding of the scenario, develop and/or strengthen working relationships with other organizations and benefit from the collective dialogue. Specific participant groups include: private and public health clinical practitioners, hospitals, health care providers; laboratorians; local, State, Tribal, and territorial epidemiologists and regulatory agencies; school officials; foodservice/processing industry representatives; and risk communicators.

## **Goal**

This tabletop exercise provides participants with an overview of actions taken at the local, State, Tribal, territorial, and Federal, level when a food-related incident occurs. It will focus on the role that key personnel play in containing the problem and protecting consumers. A large amount of information in this tabletop exercise will be generated from discussions among participants as they go through a hypothetical scenario. During the tabletop exercise, participants will assess plans, policies and procedures, and think about how they would realistically apply them in the event of an incident. This tabletop exercise will help to facilitate discussion among various participating entities, such as emergency response, State and local entities and the private sector.

## **Exercise Objectives**

At the conclusion of this tabletop exercise, you will be able to:

* Define your role in interacting with a large, diverse team of professionals who must work together to address a complex and urgent food contamination incident.
* Map the process and flow of a food-borne disease investigation from the initial epidemiologic signals through the traceback and recall phases, with periodic public communication.
* Understand the importance of gathering and cataloging critical information needed when making decisions in rapidly developing situations.
* Coordinate your efforts with other professionals engaged in the investigation.
* Use a collaborative approach to efficiently utilize the skills of each agency and discipline and identify proactive solutions.
* Understand the importance of internal and external communications and dialogue and have ideas about how to improve both in your organization.

## **Exercise Structure**

This exercise is designed to be an interactive, facilitated tabletop exercise. Participants are encouraged to ask questions of each other and learn from one another. It has been designed by a group of subject matter and instructional design experts to provide participants with a real-life, plausible food safety scenario. While this scenario has been simplified in order to present the information in an effective way, the scenario itself and the discussion questions have been designed to encourage participant dialogue and surface topics that are critically important to reacting to such incidents. The exercise has also been developed to provide participants with an opportunity to explore important topics like interagency collaboration, jurisdictional issues and risk communication. The information in this scenario reflects the policies and procedures currently in use and is accurate as of May 2011. If there has been an update to the procedure in your jurisdiction, please be sure to make the group aware of the change and work with the facilitator to ensure that all participants understand the update.

This exercise was developed by the Institute of Food Technologists (IFT) on behalf of the Food and Drug Administration CFSAN Food Defense Oversight Team. The entire series of modules includes the following:

* **Module 1** **–** Onset of illness
* **Module 2** **–** Identification of common exposure
* **Module 3** **–** Foodservice investigation
* **Module 4** **–** Agency collaboration
* **Module 5 –** Traceback

The Food and Drug Administration CFSAN Food Defense Oversight Team appreciates the support of the USDA FSIS, which served as subject experts and provided insight and guidance on the development of this scenario.

This scenario was also produced in cooperation with the Centers for Disease Control and Prevention.

## **Exercise Guidelines**

As with any learning experience, it is important that this exercise is conducted in a safe learning environment so that all participants can share and explore concepts with one another, while discussing multiple solutions and options for a given issue. This exercise will operate under the following guidelines:

* This will be an open, low-stress and non-public learning environment and is not intended to set precedents.
* Participants will listen to and respect the varying viewpoints of all of the other participants.
* The scenario we will discuss is plausible and the events occurred as presented. Suspend your disbelief, and feel free to discuss differing policies and procedures during the breakout discussion.
* Today’s facilitator is not necessarily a subject matter expert, and participants are expected to provide the expertise needed to ensure that our discussion is accurate and thorough.
* We will apply our findings from today’s activities to our job/function and share key findings with colleagues.

## **Roles and Responsibilities**

**Lead Planner –** The person who has overall responsibility for the tabletop exercise, including convening the Planning Team and all pre- and post-exercise needs

**Participants –** Respond to the scenario based on their first-hand, experiential knowledge; current plans and procedures of their individual entity, agency or jurisdiction; and insights from training and experience.

**Evaluator(s) –** Record the highlights of the discussion at each breakout table. These people do not participate in the exercise but capture the essence of the dialog for use in the After Action Report. They are chosen based on their expertise in the areas they are to observe.

**Facilitator –** Generally leads the exercise, provides situation updates and moderates discussions. They also provide additional information and resolve questions as needed. Key officials may also assist with the facilitation as subject matter experts during the exercise.

**Group Leader –** Representative from each table (volunteered by the group) who will lead the group as it explores discussion questions and the breakout activities.

**Group Recorder/Reporter –** Representative from each table (volunteered by the group) who will ensure that the group discussions are kept on time, record the key themes discussed at the table, and will be responsible for reporting out during the large group dialogue.

# Module 1 – Onset of Illness

**May 14–20**   
**Wala County, State A Saturday, May 14 – Tuesday, May 17**

On Saturday, May 14, the Jackson Tigers Little League Baseball team in Wala County, State A, was coming off its first winning season in five years. All 15 team members, their parents and six coaches celebrated by dining at Restaurant A for some Mexican-style quick-service food. To make it easier, the head coach pre-ordered chicken taco dinners for everyone. These meals featured chicken tacos, beans, rice, chips and green chili salsa, and ice cream sundaes for dessert.

On Monday morning, May 16, nine team members stayed home from school. They all suffered from a fever and diarrhea, and three were also vomiting. Individually (and not knowing that the others were ill), parents gave their children fluids and hoped for improvement. In the Watson household, both father and son were ill.

By Tuesday morning, May 17, the nine students were still absent from Jackson Elementary and several teachers mentioned the absences to the school nurse, who called the nine parents to check on the children. The nurse told the parents that some other members of the Jackson Tigers were also home sick. Learning this information, some of the Jackson Tiger parents called each other and decided that their children should go to the doctor since they all were experiencing similar symptoms. The various physicians examined the sick children and spoke with the parents, who relayed that nine members of the Jackson Tigers team were also sick with similar symptoms. These similarities led the physicians to believe that the children contracted a viral or microbial communicable disease that could be transmitted person-to-person or via food or water. Along with treatment information, stool samples were collected for laboratory analysis.

Also on Tuesday, May 17, the Jackson Elementary School nurse was visited by eight more students with fevers and diarrhea. None of these students were members of the Little League team. The nurse sent the eight students home from school.

On May 18, 16 more Jackson Elementary School students who were not on the baseball team visited the school nurse with gastro-intestinal (GI) illness. The nurse was alarmed at the rate of absenteeism and illness at her school and contacted the school foodservice director to inform him about the preponderance of gastrointestinal illness among the students. The foodservice director assessed the school’s food safety records for anything that might have indicated a problem in the school cafeteria. The nurse also contacted other school nurses in the school district to see if they had observed a similar increase in absenteeism. By statute in this state, “A local school authority shall report a child attending school who is suspected of having a reportable disease.” The nurse didn’t know the nature of the illnesses, but due to the number of affected students, she contacted the local health department.

The local health officials, when informed of the illnesses at the school, began to investigate. In talking with the other schools in the district and the clinical professionals, the epidemiologists identified 11 possible suspect cases from other schools, including seven high school students and two adults from the same community as Jackson Elementary.

The local health authorities began an epidemiologic investigation. Due to the cluster of illnesses on the Little League team, on Thursday, May 19, and Friday, May 20, the epidemiologists conducted hypothesis-generating interviews with the sick students and their parents to try to determine the route of exposure. The epidemiologists quickly moved to interview the cases that were not associated with the baseball team, from Jackson Elementary and the larger community. These interviews were designed to gather information on the multiple exposures that the ill people may have had and to identify common opportunities for the exposure. The local health officials were also engaged in collecting stool samples from sick individuals for transport and analysis at the State public health laboratory.

**NOTE: About Hypothesis-generating Interviews**

**As described by CDC at** [**http://www.cdc.gov/outbreaknet/investigations/sources.html**](http://www.cdc.gov/outbreaknet/investigations/sources.html)**, “Once the mode of transmission is determined, detailed questions follow. When exposure to a food is suspected, the investigators next must consider the large number of foods that may be the source (also called the ‘vehicle’ of infection). The number of different food items is vast, so the investigation needs to narrow the list to the foods that the ill people actually ate before they got sick, and then further narrow it to the specific foods that many of the ill people remember eating. Health officials interview persons who are ill to find out where and what they ate in the days or weeks before they got sick. These interviews are called ‛hypothesis-generating interviews.’” These interviews ask about what and where the ill people ate in the period before they got sick, their shopping habits, travel history and other relevant information.**

**“The time period they ask about depends on the pathogen’s incubation period — the time it takes to get sick after eating the contaminated food. This varies for different pathogens. Which foods they ask about depends on what investigators already know about the exposure.**

**If the exposure occurred at a restaurant, hotel or catered event, for instance, interviews will focus on the menu items prepared, served or sold there. If there is no obvious place of exposure, investigators may use a standard questionnaire, also known as a ‛shotgun’ or ‛trawling’ questionnaire.” By comparing the lists from person to person, epidemiologists are able to further narrow the list to those foods that many people remember eating in common.**

**(End note)**

By Thursday, May 19, a major private clinical laboratory in Wala County began analyzing 12 stool specimens: six from the elementary school Little League players, five from some of the other ill students and one from the sick adult. Initial results were expected by Saturday or Sunday.

On Friday, May 20, the local Wala County newspaper got wind of the situation and contacted the school system and the local Wala County Health Department for information. The school superintendent and the county health officer provided the newspaper with a brief statement that indicated the situation was under investigation.

**May 14–20**

**State A, Green County**

Meanwhile, the cafeteria at ABC College (in Green County, State A), began its annual “final exam” special: buy-one-get-one-free chicken enchilada dinners, beginning on Saturday, May 14, and continuing for one week. Many of the students took advantage of this special offer. By Monday, many students were feeling ill with fever and diarrhea, but, in the way of young “indestructible” people, they passed it off as nerves about exams or a “stomach bug.” However, by Wednesday afternoon, May 18, many were still feeling sick, and 27 students visited the campus infirmary with GI symptoms, including fever and diarrhea. The physician on staff and the nurse practitioner grew concerned at the significant increase in ill students with the same symptoms and suspected a communicable disease. The ill students were given treatment, five of them were admitted to the infirmary for overnight observation and 17 stool samples were collected and sent to a private clinical laboratory for analysis. As the rumors about the illness circulated in the dorms and study areas, more students went to seek care. Between Thursday, May 19, and Friday, May 20, 71 more students visited the infirmary with similar symptoms. On Friday, the physician on staff contacted the local health authorities and the ABC college administration to report the situation. Late on Friday, May 20, the local health authorities decided to begin an investigation to identify a common source of infection and stop the disease transmission, while awaiting diagnostic laboratory results.

**May 20–25**

**State B, Madison County**

On Friday, May 20, in State B, Jane Smith, the supervisor of the microbiology laboratory of a private clinical laboratory company finalized the lab’s weekend schedule to balance equipment usage and technician time. On this day, she noticed that the number of stool samples submitted for analysis had tripled.

By late Monday, May 23, Smith noticed than an unusually high number of samples analyzed were positive for *Salmonella*. Per standard procedure, on Wednesday, May 25, the cultures from the initial samples were sent to the State public health laboratory for serotyping confirmation and DNA fingerprinting via Pulsed Field Gel Electrophoresis (PFGE). More samples were also sent on the following days. The isolation of *Salmonella* from stools of ill patients is not unusual, although the frequency seemed higher than average, so management decided not to take any further action.

**NOTE: About Pulsed Field Gel Electrophoresis**

**Standardized molecular subtyping using PFGE helps to further specify or differentiate *Salmonella* (or another organism). Each type of bacteria has unique DNA which, when cut with one or more restriction enzymes, results in a pattern of bands. This process creates a banding pattern or “fingerprint.” After a PFGE pattern is generated, the image is uploaded to PulseNet. As described at** [**http://www.cdc.gov/pulsenet/**](http://www.cdc.gov/pulsenet/)**, “PulseNet is a national network of public health and food regulatory agency laboratories coordinated by the Centers for Disease Control and Prevention (CDC). The network consists of: State health departments, local health departments, and Federal agencies (CDC, FSIS, FDA).” The PulseNet team is an important part of disease detection. Team members match bacterial PFGE patterns from different states. This helps the team know if people in different locations are getting sick from the same source of bacteria.**

**Although PFGE patterns are quite specific, some patterns are more commonly observed than others. In order to identify a potential outbreak, it is important to know the “baseline” — the frequency with which a particular pattern is observed. The more unique or unusual a pattern is, the greater the likelihood that an increased prevalence may signal an outbreak. It is important to understand what is “normal” for specific patterns (taking into account other factors, such as time of year, geographical distribution, etc.) so that these spikes are appropriately identified.**

**Once the PulseNet team has found PFGE patterns that look the same, they make a dendrogram, or bacteria family tree. Bacteria with similar patters may originate from the same place. The dendrogram lets PulseNet find bacteria that are closely related using their PFGE patterns.**

[**http://www.cdc.gov/pulsenet/whatis.htm#pfge**](http://www.cdc.gov/pulsenet/whatis.htm#pfge)

**(End note)**

By Tuesday, May 24, the supervisor noticed a daily increase in samples submitted since May 20. Since this laboratory company has five branches across the state, Smith researched to see if other branches were experiencing a similar increase in samples submitted. Late on Tuesday, May 24, Smith learned that four of the five had a significant increase in number of samples submitted. Mindful of the increased volume in her laboratory and the overtime costs, the laboratory supervisor reported the overall company increase in samples to the manager, who contacted the headquarters to report the increase.

## **Developments**

1. Onset of illness (illness in two counties in two different states)
2. Stool samples collected
3. School nurse contacts Wala County Health Department
4. Hypothesis-generating interviews begin
5. Multiple clinical labs see increase in sample submission; detect *Salmonella*
6. Local newspaper reports story

## **Table Activity**

1. Identify a group leader and group recorder/reporter at your table. Use your allotted time to consider the developments and questions assigned to your group for Module 1.
2. Identify any additional requirements, critical issues, decisions and questions you think should be addressed at this time.
3. Unanswered questions should be recorded for discussion with the entire group.
4. Your facilitator will indicate which of the comprehensive list of questions below you are to discuss for this module.

## **Questions for Participant Groups**

**NOTE: In this and subsequent modules, questions marked with an (\*) are particularly well suited for exercises conducted with representatives from multiple jurisdictions. (End note)**

**Private and Public Health Clinical Practitioners, Hospitals, Health Care Providers**

1. If you suspect a foodborne illness in one of your clinical patients, what is your standard process for follow up?
2. If you believe it may be *Salmonella* or pathogenic *E. coli*, do you routinely collect a stool sample? What is your threshold or decision process for specimen collection?
3. What actions would you take, if any, to communicate with the following groups if multiple patients present with a suspected foodborne illness?
   1. Public health authorities
   2. Epidemiologists
   3. Environmental health sanitarians
   4. Laboratory
   5. School districts and universities, if relevant
   6. Hospitality community (hotels, restaurants, etc)
   7. State/local regulatory agencies
4. Would more information from the food safety agencies be of assistance to you in raising awareness and recognizing possible food-related illnesses?\*

**Private and Public Laboratorians**

1. Do private laboratories have processes to further submit confirmed isolates to the State lab for stereotyping and PFGE analysis? Is this matter of routine for foodborne pathogens? What dictates or influences this decision?
2. Who is responsible for monitoring for significant increases in the number of samples submitted or specific tests ordered, as a possible signal detection system? What happens if this type of increase is observed? Who is alerted?
3. If the number of specimens submitted exceeds the capacity of the laboratory, what actions are taken to ensure timely testing? What plans do you have for surge capacity?

**Local, State, Tribal and Territorial Epidemiologists**

1. Within your organization, when and how would you be made aware of an outbreak or an increase in isolations for a particular pathogen among your constituent population?\*
2. What are your processes and procedures for evaluating the trigger information you receive and allocating resources to investigate or follow up?
3. If you were in Wala or Green County, would your policies have resulted in an investigation based on the information in this module?
4. Are there multiple routes of dialogue for more information about possible outbreaks between the constituent groups? Do the existing mechanisms serve your needs?
5. When you are aware of a communicable disease situation, what system(s) do you have to communicate with the clinical community *in your jurisdiction* to raise awareness of the situation and increase speed of the response?
6. What system(s) do you have to communicate with the clinical community *outside your jurisdiction* to raise awareness of the situation and increase speed of response?\*
7. What tools/resources do you use to keep abreast of local, regional or nationwide food safety events?
8. What if the kids on the baseball team had not had access to medical care? How would the lack of cluster information and epidemiologic data impact the overall investigation?
9. At this stage, is your organization providing information to the risk communicators?

**School Officials**

* College and elementary nurses
* School foodservice directors and administration

1. If you suspect a foodborne illness or communicable disease is affecting students or teachers in your district (or your employees), what is your standard process for follow up?
2. Does your school/school district have school nurses? If not, who is responsible for monitoring illnesses (e.g., the school secretary)?
3. At this point in the outbreak, there is no implicated food and no public warning, although there is public attention as a result of media coverage. If you were a responsible official at the elementary school or the college in this scenario, what, if anything, would you communicate to the following groups at this time (as applicable)? Do you have names and contact mechanisms to reach these groups?
   1. School officials in neighboring districts
   2. Board of Education/Superintendent of Schools for your district
   3. Faculty, staff and administration
   4. Parents/students
   5. Do you have names and contact mechanisms to reach these groups?
4. What are your procedures or processes for establishing the trigger or threshold levels of affected individuals in a possible communicable disease situation when a school would contact the local health authorities? Would your processes have generated a notification in this case?
5. Do you have a standard operating procedure or a crisis management plan to handle a foodborne illness outbreak in your school?
6. What, if anything would you be doing at this point if you were the school or college foodservice facilities mentioned here?
7. Do you have certified food safety managers in the cafeterias? Would these illnesses be communicated to them? How might they assist in an investigation?
8. What mechanisms do you have to develop rapport with your local regulatory and public health agencies? Is there an organization in your area that supports the establishment of these types of contacts during periods when there is not an emergency, so that foundation is available if and when it is needed? If so, please describe the process. At what point, if any, would you contact them if you suspected that there was an issue with foodborne illness in your school?
9. What tools/resources do you use to keep abreast of local, regional or nationwide food safety events?\*
10. How would you characterize your familiarity/experience with foodborne illness agents and disease syndromes?
11. At this stage, is your organization providing information to the risk communicators?

**Local, State, Tribal, Territorial Regulatory Agencies**

* Environmental Health Sanitarians
* Food program inspectors

1. In a food-related human health emergency, what is the role and responsibility of your agency? Are there processes and procedures for you to execute that role?
2. What would you be doing in the early stages of this scenario, when there are clinical cases of a foodborne pathogen but no implicated food?
3. What tools/resources do you use to keep abreast of local, regional or nationwide food safety events?
4. Are there multiple routes of dialogue for more information about possible outbreaks between the constituent groups? Do the existing mechanisms serve your needs?

**Foodservice/ Processing Industry**

1. What, if anything, would you be doing at this point if you were the foodservice facilities mentioned here?
2. How do you develop and implement a food safety culture in your organization?
3. Do you have certified food safety managers? What types of training do they receive? What is their role in an outbreak investigation?
4. If needed, can you reach your suppliers quickly? What product information do you expect them to be able to provide, and within what timeframe?
5. What is your relationship and degree of interaction with local and State regulators? Who in your establishment/facility is responsible for maintaining this relationship? If a relationship does not exist, how would you determine who to contact if the need arose?
6. In a situation like this, it may be necessary to identify if any employees were ill during the previous two-week period. In your establishment, how would you review the schedule to identify any ill employees and dates they worked?
7. In a situation like this, it may be necessary to determine if any product samples should be taken from your establishment and sent to a private laboratory on your behalf. How would you determine what product or ingredients may be remaining and what to sample from your food products and ingredient lists?

**Risk Communicators**

1. At this point, would the other groups above be communicating with you proactively? If so, which ones?
2. How do you coordinate public comments between your different agencies and organizations involved? At this stage, which organization has the lead for releasing public information?

# Module 2 – Identification of Common Exposure

**May 20–25**

**Wala County, State A, Friday**

By Sunday, May 22, the epidemiologists continued the initial hypothesis-generating interviews. The epidemiologic investigation identified that the Little League teammates practiced and played together several times a week for at least three weeks before they became ill. The teammates shared snacks, electrolyte drinks and water at their practices and games. During the week, school lunches were also available for purchase at the cafeteria. Additionally, the shared meal at the Mexican-style quick-service Restaurant A was identified as a point of possible common exposure.

Over the weekend and into Monday, May 23, and Tuesday, May 24, the interviews continued with the other ill individuals in the community. The local public health epidemiologists, the school foodservice director and the school nurse keep each other appraised of their ongoing activities and events.

**NOTE: About Foodborne Illness**

**According to the CDC, there are 48 million foodborne illness cases each year in the U.S.(**[**http://www.cdc.gov/foodborneburden/2011-foodborne-estimates.html**](http://www.cdc.gov/foodborneburden/2011-foodborne-estimates.html)**), and restaurants are associated with a significant number of them (2009. Journal of Food Protection, 72(2):381-391). Of the 9,040 foodborne disease outbreaks reported to the CDC from 1998 to 2004, a few more than half were associated with foodservice establishments, including restaurants, delicatessens, cafeterias and hotels (http://cid.oxfordjournals.org/content/43/10/1324.full).**

**In some cases, outbreaks of foodborne illness may be caused by unsafe or incorrect behaviors and practices during preparation, whether in homes, at restaurants or in supermarkets where food is prepared. Since cases of illness were not limited to the Little League team, the cafeteria food and the shared meal at Restaurant A were suspect.**

**(End note)**

On Monday, the results of the students’ stool sample analyses were sent to their respective physicians from the private laboratories. *Salmonella* had been isolated from the first 12 of the stool specimens submitted. All 12 strains were sent to the State public health laboratory on Monday for PFGE typing and serotyping. The physicians contacted the epidemiologists at the health department to report the findings.

On Tuesday, May 24, the results of the hypothesis-generating interviews were analyzed. The epidemiology team reviewed the food histories of the 12 cases that had their stool specimens analyzed (six from the Little League team, five other students and one adult) and confirmed that 10 of the 12 had eaten the chicken taco meal at Restaurant A in the 24–72 hours prior to illness onset. Relative to this, only seven of the 12 ate the school-prepared lunches, and only six ate the snacks provided at the Little League practices and games.

The epidemiologists used the analysis of the initial interviews and the laboratory information to develop a preliminary direction for the investigation’s focus. The discussion centered on the common exposures. There were multiple commonly consumed items, such as produce, dairy and meat that all cases had eaten, and as such, these items could not be ruled out as potential sources of infection. Therefore, a more focused interview process to narrow the hypothesis and identify the implicated source of the illnesses was the next approach for the epidemiological staff. A new questionnaire was developed, asking more specific food history questions related to the short list of foods generated from the first open-ended questionnaires. This allowed a more complete analysis to identify the common exposure point for the outbreak.

While the epidemiologists were continuing their efforts to implicate the source of the illnesses, a decision was made by the health officer to brief the environmental sanitarians on the status of the outbreak investigation because of the high degree of exposure of the case patients to Restaurant A, and the affected population consisting of a large percentage of children.

Tuesday evening, public health investigators contacted their counterparts in the local environmental health program to inform them of the status of the clinical specimens and interviews to date, and the preliminary possibility of an association with Restaurant A. As a preliminary step, the regulatory environmental health professionals decided to investigate Restaurant A the next morning – Wednesday, May 25. The environmental health sanitarians contacted the restaurant’s management and informed them of a potential outbreak that may be associated with their establishment.

The restaurant manager was quite concerned and asked for as much information as possible. The manager contacted his corporate office and began gathering food safety records and information.

The Wala County health officer continued to update the local media with press statements, case counts and efforts to investigate. The possible link to Restaurant A was not made public at this point, as the epidemiologic investigation was not complete.

After repeated requests and citizen interest, the Wala County health officer held a media briefing. The reporters were somewhat frustrated that the health officials had not yet identified the cause. The reporters had done their homework and identified that the Little League team went to Restaurant A, and they were not shy about asking questions. The health officer stated that Restaurant A was one of the possible connections to this outbreak. Although she emphasized that the epidemiology was not complete or conclusive, the media latched on to the possible association.

**May 21–24**

**State A, Green County**

Saturday through Monday, May 21–23, after the numerous telephone calls and efforts to obtain parental permissions to consult with the few college students who were minors, the epidemiologists in Green County were able to conduct 29 hypothesis-generating interviews of the sick college students to try to identify the source of common exposure. This was complex because students made multiple visits to the cafeteria and the students’ recollection of what meals they had eaten two to four days prior to the onset of illness was fuzzy. By Tuesday, May 24, a short list of foods consumed in common at the cafeteria by the ill students was developed. The list included:

* Visits to the self-service salad bar with iceberg lettuce, onions, green peppers, mushrooms, shredded cheddar cheese, and Italian and French dressing
* Chicken enchilada dinners with chicken and cheese enchiladas topped with green chili salsa, rice and chips
* Scrambled eggs
* Roast beef sandwiches, with roast beef, iceberg lettuce and horseradish sauce

The interviews also included information on meals the students had eaten off campus or cooked themselves. No commonalities were seen to indicate an exposure outside of the school cafeteria. Over the weekend of May 21 and 22, 33 more students reported to the infirmary with GI symptoms consistent with the others. Stool samples from 11 of them were obtained and sent for analysis.

On Sunday, May 22, the clinical laboratory informed the physician at the infirmary that 17 of the initial stool samples were positive for *Salmonella*, and that cultures were being sent to the State public health laboratory for confirmation, serotyping and PFGE analysis first thing on Monday morning. On Monday morning, the physician at the infirmary informed the local public health authorities of the lab results, maintaining patient confidentiality, while complying with public health law.

In the meantime, the ABC College administration maintained communication with the infirmary to monitor the situation over the weekend. The administration reviewed possible environmental causes of the illnesses. The college foodservice director conducted an internal investigation, review and evaluation of internal food safety practices and looked for any anomalies that could help with the investigation. He noted that the chicken enchilada dinner special was a new menu item for the cafeteria with some new ingredients…and the addition of this menu item coincided with the illness timeline.

On Monday, May 23, the ABC College administration issued a notice to all students about the illnesses, and instructed anyone who had experienced these symptoms to visit the infirmary immediately.

The enterprising reporters on the school newspaper posted the school’s notification on their blog, which was also picked up by the reporters from the local radio station and reported as an outbreak at ABC College. The ABC College administrator issued a press statement to update the facts, indicating that all efforts were underway to address the issue and that the administration was working in collaboration with the local health authorities. The county health officer and college administration received numerous additional media inquiries.

With the hypothesis-generating interviews indicating a source at the cafeteria and the presumptive *Salmonella* isolations, on Tuesday, May 24, the public health epidemiologists informed their sanitarian colleagues in the environmental health/food protection branch about the outbreak and its possible origins in the school cafeteria.

The environmental health sanitarians contacted the ABC College foodservice director and informed him of the interview results to date that linked the illnesses to food consumed at the ABC College cafeteria. The school foodservice director provided the administration with an update and recommendations on what action to take based on the available data. The sanitarians also started to plan an investigation at the ABC College cafeteria to try to identify the cause of the contamination.

**May 25–26**

**State B, Madison County**

On Thursday, May 26, the microbiology laboratory supervisor at the private clinical lab reviewed the *Salmonella* serogroup data for the first of the stool samples for the prior week. About 89 percent were identified as the same serogroup: serogroup C2. This is not a particularly common serogroup of *Salmonella*; Madison County usually only sees six cases per year. Identifying this many cases at one time indicated the possibility of an outbreak. The supervisor informed her manager of the results. The laboratory manager contacted the other branches who also reported a high number of *Salmonella* with serogroup C2. The laboratory manager gave a heads-up call to the local public health lab, who contacted the State public health laboratory to inform them to expect an increased number of cultures for PFGE analysis. The State public health laboratorian informed the epidemiologist at the state of the information to date. The State epidemiologist was alerted to the possibility of a *Salmonella* outbreak, and asked the State public health laboratory to prioritize the PFGE analysis of the samples they had in-house. The State epidemiologist also contacted the local health districts in the state to keep them updated on this situation.

## **Developments**

1. Analysis of Little Leaguers and other Wala County victims’ hypothesis-generating interviews points to Restaurant A. Restaurant A is contacted.
2. Doctors in Wala County contacts health department after seeing spike in patients with Salmonellosis.
3. Hypothesis-generating interviews of college students in Green County begin. Cafeteria food is suspected.
4. Private lab in Madison County (State B) notes the unusual increase in *Salmonella* of the same serogroup (C2) and contacts the State lab.

## **Table Activity**

1. Identify a group leader and group recorder/reporter at your table. Use your allotted time to consider the developments and questions assigned to your group for Module 2.
2. Identify any additional requirements, critical issues, decisions and questions you think should be addressed at this time.
3. Unanswered questions should be recorded for discussion with the entire group.
4. Your facilitator will indicate which of the comprehensive list of questions below you are to discuss for this module.

## **Questions for Participant Groups**

**Private and Public Health Clinical Practitioners, Hospitals, Health Care Providers**

1. As more potential cases report for treatment, are your triage procedures any different? With a continuing influx of cases with apparently the same symptoms that may have the same cause, are your patient care follow-up practices any different?
2. What is the impact of HIPPA on the information sharing necessary for this investigation?
3. Upon receiving the laboratory reports showing multiple patients were infected with *Salmonella*, the doctors in Wala County contacted the local health department. Is this typical? What would prompt you to take such action?

**Private and Public Laboratorians**

1. As the lab may be handling an increased workload with some possibly related cases, how are the priorities assigned? How do you factor in the efficiencies of batching with the public health need to identify the causative agent or organism as quickly as possible?
2. Do you have a resource list of other laboratories in your area and their capabilities for surge capacity?
3. If you are a private lab with multiple facilities, does your organization have a plan to address surge and workload fluctuations?
4. If you are a public facility, do you have partner organizations who can assist with surge capacity? Is the FERN laboratory network a resource for surge capacity? If so, how do you engage with that resource?
5. In Madison County (State B), the management at the private clinical lab contacted the local public health lab. Is this typical? Are there formal relationships between public and private labs?

**Local, State, Tribal and Territorial Epidemiologists**

1. In your organization, with limited budgets and human capital, please describe how the decision is made to allocate resources to follow up on apparent increases in clinical cases of foodborne pathogens. Is there a decision tree or another process in place?\*
2. Much of this module involves weekend work by the public sector. What is the justification process or rationale in your organizations to authorize weekend work during a public health emergency?\*
3. What would you or your organization be doing if you were in State A or B when you first became aware of the cluster of illnesses? If you would consider an investigation, who would undertake the investigation and analysis if a similar outbreak were to occur in your jurisdiction? At this point, would you communicate with others within your jurisdiction?
4. How systematic is the collaboration between your organization and the laboratories to influence prioritization of work? What rules or processes govern this relationship? How do you communicate with the public health laboratory, if there is a disease outbreak and dialogue is necessary for rapid results?
5. How do you communicate with your other State or local public health epidemiology counterparts in the early stages of an outbreak? Is there a coordinated process to communicate with other jurisdictions in geographic proximity to you? If so, please describe. Would this process be consistent throughout an investigation of a foodborne illness outbreak?\*
6. Do you have a standard template questionnaire or will you develop one specific to the event data that you have at hand? How do you determine the type of questionnaire to use for hypothesis generation?
7. Assume that this outbreak, as described, is a multi-jurisdiction effort within your state. Are the questionnaires harmonized between intra-state agencies for ease of data analysis, and how does this process happen under the pressures of a public health emergency?\*
8. As the investigation develops and a preliminary hypothesis is generated, do you have systems in place to communicate with the regulatory organization in your jurisdiction to make them aware of the implicated food(s) and coordinate your response?
9. What, if anything, would you communicate to the following groups at this time?
   1. State and local public health officials
   2. Other local/State regulatory agencies
   3. CDC
   4. Consumer groups, schools, hospitality community
   5. Food industry
10. What is the impact of the health officer publicly speculating on the source of illness at this point? How do you work with your public affairs staff when you need to get a message out or respond to inquiries?

**School Officials**

* College and elementary nurses
* School foodservice directors and administration

1. At this point, a common pathogen associated with this outbreak has been identified. What, if anything, would you communicate to the following groups at this time (as applicable)?
   1. School officials in neighboring districts
   2. Board of education/superintendent of schools
   3. Faculty, staff and administration
   4. Parents/students
2. If you were informed that the food in your cafeteria may be linked to an ongoing outbreak, who would you contact for advice on what action to take (e.g., should certain foods be put on hold and not served, should the cafeteria be closed or should it serve only pre-packaged food from a trusted source, etc.)? Who would make that decision: the foodservice director or the school officials (president, principal or school superintendent/school board)?
3. When the media is searching for information about an ongoing situation related to your school or institution, how do you implement your communication plan? How are media requests handled in your organization? Do you have the necessary contact information and protocols to react rapidly and correctly to a media inquiry during a food safety incident?\*
4. Do you have a “continuity of operations” plan to see that your students get fed in the event that you have to shut down your cafeteria due to a foodborne illness incident?

**Local, State, Tribal, Territorial Regulatory Agencies**

* Environmental Health Sanitarians
* Food program inspectors

1. What is your action plan once you receive word that there is a *Salmonella* outbreak, but the source of the *Salmonella* is not yet identified?
2. What, if anything, would you communicate to the following groups at this time?\*
   1. Public Health Officials
   2. Other local/State regulatory agencies
   3. CDC, FDA and USDA
   4. Consumer groups, schools, hospitality community
   5. Food industry

**Foodservice/ Processing Industry**

1. If you represent the college foodservice operation, what systems do you have in place to communicate when the college clinical practitioners have made you aware that there may be a problem associated with students who consumed food in your facility? If so, what actions, if any, are you taking?
2. For commercial foodservice operators, what systems or procedures do you have in place to address the situation here, when you have just been informed that your facility may be implicated in a foodborne illness, but you do not yet know the food vehicle or cause?
3. Knowing that it may or may NOT be your facility involved, what can you do at this point to evaluate your current practices? Would you consider sending retained samples for private lab analysis at this point, without knowing an implicated product?

**Risk Communicators**

1. When the public is clamoring for the “answers” and advice about how to protect themselves and the source is ambiguous, how do you present the information that is known and use it as a teachable moment to the public that it takes time to conduct these investigations, for laboratory analysis, etc.?
2. What can be done during times when there is not an outbreak to get the attention of the public and use our risk communication platform to educate and inform about emergency situations like this?

# Module 3 – Foodservice Investigation

**May 25–27**

**State A Wala County**

The environmental health sanitarians in Wala County initiated an investigation at Restaurant A. In order to help identify the source of the foodborne outbreak, the environmental investigation started at the point of service.

Restaurant A was one unit of a regional restaurant chain with 14 company-owned establishments in three states (A, C and D), with an average of 500 transactions per day per unit. The menu consisted of chicken, beef and vegetarian Tex-Mex cuisine served in a quick-service format.

The sanitarians first reviewed prior inspection reports for Restaurant A. The restaurant had only minor deficiencies in the three years since it opened; its management was certified in food safety practices and the company implemented a strong employee training program. Early on Wednesday, May 25, the sanitarians visited the restaurant to conduct an investigation related to the possible outbreak. A routine inspection was conducted, which focused on the practices and behaviors most closely linked to foodborne outbreaks, including personal hygiene practices; cooking, cooling and holding temperatures; sanitation and cross-contamination; and raw material supply. The sanitarians took several environmental swabs of the food contact surfaces. The manager on duty accompanied the sanitarians on the inspection and was helpful and cooperative. Again, few deficiencies were noted.

After the inspection was conducted, the sanitarian spoke privately with the manager about the chicken taco meals and its possible association to the Little League team’s illness. The sanitarian asked for the manger’s continued cooperation by requesting access to records for food preparation: raw material sourcing, copies of any HACCP plans and other food safety SOPs, and recipes from the period a few days before illness onset. The manager committed to discussing this request with the corporate headquarters and responding to the sanitarian by early the next morning.

During the evening of May 25, Restaurant A management conferred with the corporate office, who instructed them to allow access to any records needed on-site for sanitarian review, and compiled information and conducted research that could be needed if the outbreak was definitely linked to their establishment. Data were gathered relative to absenteeism and sick employees during the previous few weeks, ordering and receiving records, supplier certifications, corporate raw material and ingredient specifications and internal food safety records. The establishment also gathered data on the number of transactions (and day and time) for the chicken taco meals served. This prepared them to compare the number of chicken taco meals served that were associated with illness to the number of meals served to individuals who did not become ill during the same timeframe.

The sanitarians returned to the office at the end of the day to participate in a conference call with county epidemiology staff. The epidemiologists reported that 10 additional stool samples from the school were positive for *Salmonella* serogroup *C2*.

On May 26, the sanitarians returned to Restaurant A to investigate the in-house preparation process, raw material sources and related records for the time period of exposure of the initial Little League cases. They used the employee interview template from the CIFOR outbreak investigation guidelines to interview the employees. The sanitarians asked for records of any ill employees during the past two weeks, internal food safety records that document practices and behaviors, and product supplier and receiving records. The sanitarians worked with the manager to understand the restaurant procedures and product assessment, including formulations, what is prepared in-house versus what is purchased as ready-to-eat food, and the nature of the kill step, whether at the supplier or in the establishment. The management also provided information on the scope of the product supply, differentiating what is commonly sourced for all of the units in Restaurant Chain A, and what is individually sourced at each unit. They obtained the following recipes and supplier information from the manager for the components of the chicken taco meal and ice cream sundaes that the team ate.

| **INGREDIENT** | **IN-HOUSE PREPARATION** | **SUPPLIER/SPECIFICATION** | **KILL STEP** |
| --- | --- | --- | --- |
| Chicken Tender Strips | Place 5 lb. frozen pre-cooked seasoned chicken tender strips in steamer for 20 minutes.Hold on steam table for no more than 4 hours for use. | Continental Foodservice Distributors; 20 lb. case of Peabody Poultry company frozen fully cooked seasoned chicken tenders | Fully cooked by processor to 165F |
| Shredded Iceberg Lettuce | Open bag and store in clean combo container in walk-in until use in the line. Hold on the cold line for no more than 6 hours. | Continental Foodservice Distributors; Produce Queen brand; 5 lb. bag of pre-washed chopped iceberg lettuce. | Disinfecting wash by processor; no kill step |
| Shredded Cheddar Jack Cheese | Open bag and store in clean combo bin in walk-in until use on the line. Hold on the cold line for no more than 6 hours. | Continental Foodservice Distributors; 3 lb. bag of Lechers brand 1/8-inch shredded Cheddar and Monterey Jack Blend | Pasteurized by processors |
| Corn Tortillas | Store at room temperature, between 50–70F. Warm in warming drawer before use. | Continental Foodservice Distributors; produced by Mamacita’s Tortilla Factory, fried corn tortillas; 12 to a sleeve, 48/case. | Baked at processor |
| Green Chili Salsa | Open bag and store in clean combo bin in walk-in until use. Hold on the cold line for no more than 6 hours. | Continental Foodservice Distributors; Fresh salsa; produced by Miguel’s Mexican Specialties fresh and refrigerated; ½ gallon bags; 2 bags per case | No thermal kill step; pH 5.9 |
| Beans | Place frozen package in the steamer to heat for 45 minutes. Hold on steam table for no more than 4 hours. | Continental Foodservice Distributors; Refried beans produced by Miguel’s Mexican Specialties; vacuum packaged and frozen. 5 lb. beans per package; 2 packages/case | Heated to 165F by processor |
| Rice | Place 5 lb. frozen rice in steam table pan in steamer for 30 minutes. Hold on steam table for no more than 4 hours. | Continental Foodservice Distributors; produced by Specialty Rice Company; 20 lb. case frozen pre-cooked rice | Fully cooked to 190F by processor |
| Chips | Open package, place in serving bowls and deliver to table. | Continental Foodservice Distributors; Mamacita’s Tortilla Factory, corn tortilla chips; 2 lb. bag; 4 bags/case | Fried by processor |
| Ice Cream Mix | Follow manufacturer’s instructions on the soft serve machine to freeze the mix. | Continental Foodservice Distributors; Denny’s Dairy ultra-pasteurized frozen soft serve ice cream mix; vanilla | Pasteurized by processor |
| Ice Cream Topping; Fudge and Caramel | Place in stainless steel topping pumps. | Continental Foodservice Distributors; Albert’s brand chocolate and caramel topping; 1 gallon/ case | Thermally processed by processor; a­w 0.83 |
| Whipped Cream | Store refrigerated. Shake before use. | Continental Foodservice Distributors; refrigerated canned whipped cream topping; 8 cans/case | Pasteurized by processor |

The sanitarians began to review the records beginning with May 11, three days prior to the Little League end-of-season celebration meal. The record review revealed the following:

* Invoices were available for goods received by date, with Continental Distributor product numbers, but manufacturer lot numbers were not available on the invoices. Lot numbers were not recorded upon receipt at Restaurant A, but some cases were marked with lot information by the processor/manufacturer.
* The walk-in cooler and refrigerator temperatures were recorded once daily and ranged from 40-43F for the period from May 11 through May 18.
* The temperature recording records for the products on the hot holding steam table units required a temperature check twice per shift, and indicated a temperature range of 138F–144F. A temperature of 121F on May 16 at 6:00 pm was noted. A service call was made and an electrical element replaced. The unit was taken off-line when the temperature drop was noted.
* The employee absenteeism rate was consistent during the time period of concern with prior time periods. The managers didn’t remember anyone being ill on the job.

The sanitarians also collected food samples from Restaurant A:

* Frozen Chicken Tender Strips; unopened case; lot code 987-6
* Shredded Iceberg Lettuce; sealed bag; processing date 05/23
* Shredded Cheddar Jack Cheese; combo bin in the walk-in; no lot code
* Shredded Cheddar Jack Cheese; unopened 3 lb. bag; lot code 00145
* Corn Tortillas; unopened sleeve; production date 05/15
* Green Chili Salsa; plastic container in the walk-in; no lot code
* Green Chili Salsa; unopened bag; production date 05/18
* Beans; unopened frozen package; production date 05/02
* Rice; unopened case; lot code 03312011AB
* Chips; unopened bag; production date 05/12
* Ice Cream Mix; unopened bag; lot code 1104301050am

The samples were shipped overnight to the State laboratory for *Salmonella* analysis. (In some cases, food samples are collected when available and held prior to analysis until the epidemiologic data narrows down the implicated food product.)

Restaurant Chain A began to contact its suppliers to determine if they had received reports of other illnesses associated with any products and also to ascertain if the same ingredients or food products were provided to other foodservice establishments or sourced specifically for them. If the food items were distributed outside of the chain, then there might be cases in addition to those who had eaten at their restaurants.

The county health officer continued to respond to press inquiries, stating that *Salmonella* was the cause of the outbreak, while trying to explain the ongoing nature of the epidemiologic investigation and the multiple avenues of approach. Although the public message did NOT implicate Restaurant Chain A, the units in the county experienced a drop off in sales due to the negative publicity.

The Wala County Health Department notified the school system of this ongoing outbreak, the possible link to the restaurant, and that the preliminary investigation indicated that their cafeteria(s) was more than likely not implicated as the source of the exposure.

Late on Friday, May 27, the State public health laboratory informed the epidemiologists and sanitarians that the PFGE patterns of the original 12 isolates (submitted on May 23) were completed and uploaded to the PulseNet database at the Centers for Disease Control and Prevention (CDC). The preliminary reading by the State laboratory indicated that all had a matching pattern.

**May 25–27**

**State A Green County**

The local environmental health sanitarians visited the ABC College cafeteria on Wednesday and Thursday and investigated possible sources of foodborne contamination.

The sanitarians reviewed the prior inspection reports for this facility. There were some deficiencies in the past three years related to personal hygiene practices, hot holding temperatures on the buffet lines and steam table lines in the kitchen and out-of-date or expired product on the shelves. Early on Wednesday, May 25, the sanitarians visited the cafeteria and conducted an investigation related to the possible outbreak. The investigation focused on the factors most closely linked to foodborne outbreaks such as:

* Personal hygiene practices
* Cooking, cooling and holding temperatures
* Sanitation and cross-contamination
* Raw material supply, focusing on the “short list” items developed thus far

The environmental health sanitarians requested various records from the cafeteria management to verify the food safety practices and behaviors in place. They also asked for copies of the HACCP plans and other food safety policies and procedures.

| **INGREDIENT** | **IN-HOUSE PREPARATION** | **SUPPLIER/SPECIFICATION** | **MICROBIAL KILL STEP** |
| --- | --- | --- | --- |
| Self-Service Salad Bar Produce | Open bag and place in cold holding salad bar unit in stainless steel pans. | Continental Foodservice Distributors; Produce Queen Brand; 5 lb. bag of pre-washed iceberg lettuce; onions; green peppers, mushrooms. | Disinfecting wash by supplier; no kill step |
| Salad Dressing | Open plastic jar, transfer to clean pump bottle and place on the line. | Continental Foodservice Distributors; Violetta’s ½ gallon jars; 2/case | < pH 3.8 |
| Shredded Ranchero Cheese | Open bag and place in cold holding salad bar unit in stainless steel pans. | Continental Foodservice Distributors; 3 lb. bag of Madison’s Pasture 1/8 inch shredded Cheddar and Monterey Jack Blend | Pasteurized at processor |
| Chicken Tender Strips | Place 5 lb. frozen pre-cooked seasoned chicken tender strips in steamer for 20 minutes. Hold on steam table for no more than 4 hours for use. | Continental Foodservice Distributors; 20 lb. case of Peabody Poultry company frozen fully cooked seasoned chicken tenders | Fully cooked by processor to 165F |
| Flour Tortillas | Store at room temperature, between 50-70F. Warm in warming drawer before use. | Continental Foodservice Distributors; produced by Mamacita’s Tortilla Factory, flour tortillas; 12 to a sleeve, 48/case. | Baked at processor |
| Tomatillo Salsa | Open bag and store in clean combo bin in walk-in until use. Hold on the cold line for no more than 6 hours. | Continental Foodservice Distributors; Fresh tomatillo salsa; produced by Juanita’s Fresh Sauces and Soups; refrigerated; ½ gallon bags; 2 bags per case | No heat kill step; pH 5.8 |
| Rice | Place 5 lb. frozen rice in steam table pan in steamer for 30 minutes. Hold on steam table for no more than 4 hours | Continental Foodservice Distributors; produced by Specialty Rice Company; 20 lb. case frozen pre-cooked rice | Fully cooked to 190F by processor |
| Chips | Open package; place in steam table pan for plating. | Continental Foodservice Distributors; produced by Mamacita’s Tortilla Factory, corn tortilla chips; 2 lb. bag; 4 bags/case | Fried at processor |
| Scrambled Eggs | Open box of liquid pasteurized eggs and scramble. Hold on steam table for no more than 4 hours. | Continental Foodservice Distributors; produced by Healthy Liquid Pasteurized Egg Company; 1 gallon bag-in-box; 2 per case. | Pasteurized at processor |
| Roast Beef | Open package of sliced roast beef. Store on cold line for no more than 4 hours. | Continental Foodservice Distributors: produced by Best Deli Meats, Inc. 2 lb. per package; 5 packages/case | Fully cooked at processor to 145F |
| Mustard | Place squeeze bottle on sandwich line. | Continental Foodservice Distributors; 6 1 qt. squeeze bottles/case | < pH 4.6 |
| Wheat Bread | Open package and remove slices as needed. | Continental Foodservice Distributors; Wheat Bread; 4 loaves/case | Baked at processor |

The sanitarians observed food handling and other kitchen practices and noted the following deficiencies:

* One of the handwashing sinks was out of soap and paper towels.
* The temperatures of the iceberg lettuce and green peppers on the salad bar were 48F and 50F, respectively, which was above the maximum temperature for cold products.
* The salad dressing in the walk-in was past the manufacturer’s suggested use-by date.

Samples of the following foods were collected for analysis: shredded iceberg lettuce from the salad bar, unopened packaged iceberg lettuce, roast beef on the sandwich line, unopened ranchero cheese, unopened frozen chicken strips and steamed chicken strips off the hot holding line. The manager indicated that he didn’t have any of the green chili salsa left because the four-day special on chicken enchiladas was a big success.

The ABC College foodservice director gathered data on internal food safety practices and procedures, records of ill employees over the last two weeks and supplier records for the last few months to provide to the public health authorities. The ABC College administration decided to serve solely pre-packaged prepared foods in the cafeteria until the source of this outbreak was identified.

The college administration and county health officer continued to provide the media with updates and interviews to keep the concerned public informed.

On Friday, May 27, the State public health laboratory called to let the Green County epidemiologists know that the PFGE results for the initial seventeen samples were a match and subsequently uploaded to the PulseNet database. The local health authorities and the campus infirmary were told that the last new related case came in on May 22, with no new cases for the past three days.

**State B**

On Saturday, May 27, and Sunday, May 28, the State public health lab was serotyping and conducting PFGE analysis on the 16 isolates from the private labs in State B that arrived on Wednesday, Thursday and Friday, May 25–27. The first isolates that arrived on Wednesday and Thursday were complete and 14 of 16 had matching PFGE patterns and serotypes. The lab manager contacted the State epidemiologist to report the results.

No one was surprised when they received the updated information about the PFGE matches. Two of the counties in State B, where the majority of confirmed cases existed, were prepared to conduct interviews to try to identify a common source. Other counties with one or two cases chose not to follow up and allocated resources elsewhere.

## **Developments**

1. Restaurant Chain A and ABC college cafeteria were inspected by respective authorities.
   1. Both establishments provided product-specific information and provide food samples for analysis.
   2. Restaurant Chain A provided records of suppliers, recipes, meals served, food preparation practices and employee absenteeism.
   3. ABC College decided to serve only pre-packaged, prepared foods.
2. County conference calls were conducted.
3. PFGE patterns uploaded to PulseNet appeared to match.
4. Communication with local media continued.
5. Epidemiologists in two counties in State B prepared to interview cases.

## **Table Activity**

1. Identify a group leader and group recorder/reporter at your table. Use your allotted time to consider the developments and questions assigned to your group for Module 3.
2. You should also identify any additional requirements, critical issues, decisions and questions you think should be addressed at this time.
3. Any unanswered questions should be recorded for discussion with the entire group.
4. Your facilitator will indicate which of the comprehensive list of questions below you are to discuss for this module.

## **Questions for Participant Groups**

**Private and Public Health Clinical Practitioners, Hospitals, Health Care Providers**

1. As the number of new cases is winding down and the existing cases are recovering, what actions are you taking at this time?
2. Are there communication/dialogue systems in place to enable sharing of information amongst your peers in your community or jurisdiction, in an outbreak or public health emergency as the situation is proceeding, without compromising confidentiality?
3. As media attention grows, do you expect to see an increase in the number of patients who suspect they might be affected? Does the fact that there is an outbreak impact your treatment of these patients? If so, how?

**Private and Public Laboratorians**

1. Are there systems in place to preliminarily identify clusters or PFGE patterns that appear to be a match? If so, what are they? To whom are results communicated, and what actions are expected?
2. Are there communication channels with the private laboratories, either by calling or blast fax to make them aware of an ongoing event and to maintain dialogue during an event of this type without compromising confidentiality?
3. If you operate a public laboratory, what is the turnaround and processing time for the PFGE analysis and serotyping of *Salmonella*? What is your PFGE capacity, and do you typically batch them together for efficiency?
4. Understanding the resource constraints, is it possible that the laboratory analytical process could delay identification of clusters in ongoing outbreaks?
5. What are the limitations of molecular analyses of this type? How can you rapidly further characterize the isolates?

**Local, State, Tribal and Territorial Epidemiologists**

1. Assume that you are participating in the Restaurant Chain A outbreak investigation. How do you communicate within your jurisdiction to share information related to the following:
   1. the environmental investigation
   2. laboratory data from analysis of both the clinical specimens and the various food samples
   3. the evolving epidemiologic and analytical data\*
2. How are you made aware of the PFGE results? How frequently are you provided with updates?
3. How do you coordinate the analytic study efforts with the other epidemiology groups in your neighboring jurisdictions?\*
4. How do you communicate with the CDC when a situation is evolving like this one? Other than uploading PFGE images to PulseNet, would CDC have already been engaged? If so, how?
5. What if the private laboratory had used the rapid test methods to confirm the *Salmonella*, but no isolates were available for serology or PFGE? How would that change your investigation?
6. Based on the data presented, was there anything identified so far in the on-site investigation and record review of either foodservice facility that would raise a red flag to you?

**School Officials**

* College and elementary nurses
* School foodservice directors and administration

1. If you are at the college and there are no new cases being reported, what actions are you taking at this point?
2. ABC College decided to serve only pre-packaged, prepared foods. Would you have made this decision? What policies would govern this action? At this point in an evolving foodborne illness that involves your students, would you consider closing the cafeteria? Who would make that decision: the foodservice director or the school officials (president, principal or school superintendent/school board)?
3. If you are at the school district and the health department is still reporting new cases, what, if any, actions are you taking at this point?
4. Would you be communicating with the parents in the affected communities now that the diagnosis of *Salmonella* is known?
5. Has your communication with the school officials in neighboring districts, the Board of Education/Superintendent of Schools, the faculty, staff and administration, and the parents/students changed?
6. At this point, with the information at hand, what would be the protocol for talking to the media? Who would the school spokesperson be? Who would help him or her prepare remarks and be prepared for questions? Would there be efforts to coordinate the messages with the health department? Are there mechanisms in place to do so?\*

**Local, State, Tribal, Territorial Regulatory Agencies**

* Environmental Health Sanitarians
* Food program inspectors

1. Are there protocols in place for collaboration with other agencies/entities within your jurisdiction during a food emergency incident, including the laboratory and epidemiology organizations? Are these protocols communicated to appropriate offices and individuals? How would it work in this scenario?
2. Are there systems in place for dialogue with other regulatory agencies in neighboring jurisdictions in your state and between the State and local officials? If so, based on the information in this scenario, what would be happening at this point? If no systems are in place, how would your agency communicate?\*
3. Do you have routine periodic contact with your regulated industry to build rapport prior to a foodborne illness incident?
4. What authority do you have to collect food samples? How can regulators reach out and engage the regulated industry as soon as possible? What information sharing boundaries or constraints exist?
5. Who maintains a list of contacts and backup contacts in other agencies (Federal, State and local) that would be partners in dealing with a food-related human health emergency?\*
6. Who maintains a library of legislative and administrative authorities that may be used by your agency in the event of a human health emergency?

**Foodservice/Processing Industry**

1. Does your organization have a crisis management plan to handle a recall based on a foodborne illness? Does that crisis management plan address situations as described here?
2. If your organization is contacted by the regulatory agency about a possible illness that implicates your product (or a product consumed at your facility), how do you put your crisis management plan into motion? How quickly can your organization react?
3. If you were the management of Restaurant Chain A, what would you be doing at this point? What would the conversations be related to potential recalls and inventory management? What types of communication would you have with your suppliers, customers and employees? Would you have any communication with the public through the media at this point?
4. If samples are collected for routine testing, do you “hold” the lots or cases until test results are relayed? When samples are collected by regulatory authorities, do you expect to hear if the result is “OK” or only if there is a problem?
5. If you possessed a contaminated product, how long would it take you to determine the previous source and immediate recipient of the product? What kinds of documents would have this information? Are they only in paper form, or are records electronic?

**Risk Communicators**

1. Since Restaurant Chain A was mentioned in the media, even without a definitive association with the outbreak, what can you do, if anything, to minimize the backlash to the chain and the brand damage at this point?
2. Now that the public health epidemiology group, the laboratory group and the sanitarians are all engaged in this investigation (and each from different agencies or organizations), how do you streamline communications (both inquiries and outgoing messaging) to be consistent and be perceived by your citizens as speaking with one voice from the “government”?

# Day 2 Touch Point

1. What are some potential roadblocks that you might face in the event that you were faced with a scenario similar this with respect to coordination between jurisdictions?\*
2. What systems/networks/listservs exist to facilitate dialogue between jurisdictions about food-related events?\*
   1. Which are used most frequently, and what is involved in being included in the dialogue?
3. What are some public resources and information that you recommend this group monitor regularly to stay informed about food safety events?\*
4. How can you tell who is “in charge” at the various stages of this investigation? How can you coordinate and centralize within your jurisdiction? Between jurisdictions?

# Module 4 – Agency Collaboration

**May 30**

**States A, B and D, Wala and Green Counties and the CDC**

The State A public health laboratory supervisor, when reviewing the PFGE patterns for uploading into PulseNet, noted that the 10 recent uploads from Wala County and the 17 recent uploads from Green County also appeared to match each other. The laboratory contacted the PulseNet team at CDC. The CDC PulseNet team thoroughly reviewed the PulseNet database and historical baseline levels of *Salmonella* patterns for this serotype and PFGE banding pattern and confirmed that case uploads to PulseNet from two different non-contiguous counties in State A appeared to have the same PFGE pattern, which is not one of the more common patterns seen in PulseNet. There were also 24 recent uploads of the same pattern from State B and eight from State D, two states in the same general region of the country as State A. The serotyping confirmed the isolate as *Salmonella* serotype Muenchen (*S*. Muenchen). CDC contacted States B and D via email to make them aware of the possible link to a larger outbreak.

Later that day, a conference call was held with the State A laboratory and epidemiology representatives, the county epidemiology staff in Wala and Green Counties, the State B and D epidemiologists and CDC’s PulseNet and OutbreakNet teams. On the call, Wala and Green County officials indicated that they were investigating individual clusters of illness, one from a Little League team that had eaten at a quick-service restaurant, and another of students at a local college who ate in the cafeteria. They shared their hypothesis-generating questionnaires and preliminary data. Additionally, they reported that the local environmental health sanitarians were in the process of investigating the college cafeteria and the quick-service restaurant.

State B reported that sporadic cases in several counties in the state appear to have matching PFGE patterns to those of State A. The information shared by State A helps State B with the development of its questionnaires.

The OutbreakNet team at the CDC suggested that the group speak the next day and that the FSIS and the DHHS FDA embedded liaisons to CDC participate, in addition to the local/State environmental health staff. The goal of the call was to provide the group with a thorough update and collaboratively plan next steps. After the call, the CDC distributed a nationwide Epi-X notification to all State and county health departments to raise awareness of this outbreak. The FDA notified the USDA Food and Nutrition Service (FNS) that a school may be involved but that it didn’t appear to be an issue with the food in cafeteria.

**NOTE: About Epi-X**

**The Epidemic Information Exchange (*Epi-X*) is the Center for Disease Control and Prevention's secure, Web-based communications network that serves as a powerful communications exchange between CDC, State and local health departments, poison control centers, and other public health professionals. The system provides rapid reporting, immediate notification, editorial support and coordination of health investigations for public health professionals.**

[**http://www.cdc.gov/mmwr/epix/epix.html**](http://www.cdc.gov/mmwr/epix/epix.html)

**NOTE: About Embedded Agency Liaisons**

**The Federal agencies (in this case CDC, FDA and FSIS) each have employees physically located at the other agencies to serve as liaisons. In this case, both FDA and USDA employees are stationed at CDC headquarters in Atlanta, Ga., and a CDC employee is stationed at FDA headquarters in Washington, D.C. Their role is to facilitate communication and collaboration between the agencies.**

**(End note)**

**May 31**

**States A, B, and D, Wala County, Green County, CDC, FSIS, FDA**

The CDC OutbreakNet Team hosted a conference call providing a comprehensive update to participants. They reviewed the data available in PulseNet, and asked each State and local jurisdiction to report their total case numbers, status of laboratory analysis and environmental investigation. In summary, the following was reported on this call:

* Wala County discussed the Little League cluster, Restaurant Chain A, and agreed to share the results of the hypothesis-generating interviews. Representatives described the food items consumed at Restaurant Chain A and indicated the food samples that were collected for analysis at the State lab. Wala County also reported that cases were still being reported as of May 26.
* Green County reported that they were not aware of any new cases since May 22. They described the main cluster at the college cafeteria and agreed to share the short list that they developed as a result of the early interviews. Green County also indicated that they sent some food samples for analysis at the State lab, and noted that the chicken enchilada dinner special was only offered through May 20. Discussion then focused on the possible common food ingredients, but the list was too broad for any more specific hypotheses.
* State A reported that, with the information at hand, the two counties’ outbreaks could have been related to one food source, although there were more cases to interview and laboratory and analytical studies to conduct. Commonalities on the lists of food items from the two clusters included: pre-cooked seasoned chicken tender strips, shredded iceberg lettuce, different types of tortillas and chips from the same processor, green chili salsa and rice. The shredded cheeses had two different brand names, but there was the potential they were produced in the same plant and labeled differently. State A also reported that the PFGE analysis was ongoing and uploads to PulseNet would continue.
* State B reported that they had a significant increase in samples submitted for PFGE analysis and that the matching PFGE patterns appeared to result from sporadic cases spread over five counties in the state.
* State D reported that analysis of any additional *Salmonella* in the PFGE process would be expedited and asked the local health officials to interview the cases to gather food histories.
* FSIS committed to conducting an investigation at the poultry processor that produced the chicken strips.
* FDA committed to reviewing the information for the processors of the produce, tortillas, cheese, salsa and rice, and to contacting the cheese manufacturers to determine if the two types of cheese were produced in the same facility.
* The CDC indicated that it would begin to post the case counts and an epidemiological curve on their website at this stage. *(For examples of epidemiological curves and the information used to generate them, review the “Wilted Woes” scenario.)*
* State A reported on the public communications coming from their State and local jurisdictions to date.
* FDA and FSIS agreed to issue a statement indicating that the outbreak was under investigation and released it to the regional media.
* The FDA, FSIS, CDC and States A and B hosted a “heads-up” call with some of the major industry trade associations where the CDC reviewed the epidemiology and the status of the investigation that implicated a food vehicle.
* All agreed to hold another call in 48 hours when more information became available.

**June 2  
States A, B, and D, Wala County, Green County, CDC, FSIS, FDA**

Prior to a follow-up call, the CDC distributed several charts of the numbers of cases reported by state and the numbers of PFGE matches in PulseNet, as well as an epidemic curve of onset dates and a visual representation of the geographical spread of the cases. New cases were still being reported. The CDC requested updates on the numbers of cases from each state and discussed the numbers in the PulseNet database that were a match. State B uploaded 22 *Salmonella* patterns, 20 of which matched the *S*. Muenchen ones related to this outbreak. State A submitted 11 more matches and State D had six more. Additionally, the CDC indicated that there were two matches to this PFGE pattern from food surveillance sampling, one from flour in 2008 and one from cilantro in 2009. These were not associated with an outbreak at the time.

On the call, the following information was reported and discussed:

* Wala County reported that it was continuing interviews for common exposure points and suggested that a case-control analytical study be conducted.
* Green County also continued its interviews and agreed that a case-control study would be beneficial at this point.

**NOTE: About Case-Control Analytic Studies**

**Investigators analyze (study) information they collect from ill persons and comparable well persons to see whether ill persons are more likely than people who did not get sick to have eaten a certain food or to report a particular exposure. If eating a particular food is reported more often by sick people than by well people, it may be associated with illness. Using statistical tests, the investigators can determine how strong this association is, how likely it is to have occurred by chance alone, and whether more than one food might be involved.**

**(End note)**

* State A indicated that the analysis of the food samples taken at Restaurant A was underway and results were expected on June 3. The analysis of the food samples from the ABC College cafeteria was one day behind.
* State B and its local health entities reported that their hypothesis-generating interviews were underway.
* State B indicated that there weren’t any Restaurant Chain A units in the state, and that the cases interviewed did not have any travel history or Restaurant Chain A exposure. However, the interviewees did have both poultry product exposure in foodservice and Tex-Mex cuisine exposure in quick service restaurants, particularly chicken taco salads. The preliminary short list they generated from the interviews they conducted included: chicken sandwiches and taco salad with commercial fresh prepared salsa from quick service restaurants, fresh cut iceberg lettuce and yogurt.
* State D indicated that interviews were underway and that they were investigating the information shared by the other jurisdictions.
* FSIS indicated that the investigation of the poultry processor indicated no deficiencies or positive samples to date through the comprehensive FSIS inspection and testing program. Additional samples of finished product at the plant were collected as a precaution and were under analysis.
* FDA indicated that their preliminary data gathering showed that the two cheese types on the Wala and Green County lists were not made by the same processor or in the same production facility.
* The State and Federal agencies were still updating the public information, even though no vehicle was identified. The public information officers and media spokespeople were badgered about why the investigation to identify the cause was taking so long, with people continuing to become sick. The college cafeteria and the school system were still being targeted.

At this point, the food product implicated in this multi-state outbreak could not be identified. There was a preponderance of poultry and Tex-Mex food items, with such common ingredients as iceberg lettuce, salsa, tortillas and cheese. Based on the past history of outbreaks and type and degree of food processing, there was an active discussion centering on the possibility of the iceberg lettuce, the chicken or the commercial fresh salsa and its ingredients as the vehicles.

As a starting point to identify the source food or ingredient that may be causing the outbreak, it is not unusual to take the short list of foods and examine or track and trace their supply, even before a specific food is found to be statistically implicated or contaminated. By tracking and tracing a few of the foods, common or disparate sources can help to further narrow the list if possible contaminated products.

State B indicated that the sanitarians had information about the brand and type of salsa and the source of the chopped iceberg lettuce used at the Tex-Mex establishments associated with illness. They already knew that the same brand of produce was used in State A by Restaurant Chain A and the ABC College.

## **Developments**

1. CDC OutbreakNET engaged and conference call with three states conducted.
2. Multi-agency (CDC, FDA and FSIS) and multi-state conference call conducted.
3. USDA FNS notified of potential link to a school.
4. CDC issued a nationwide notification to public health agencies.
5. Informational call with food industry trade associations held.
6. FDA and USDA FSIS released a statement to the regional media regarding the outbreak.
7. Case control study initiated.
8. Investigation focused on chicken, salsa and iceberg lettuce.

## **Table Activity**

1. Identify a group leader and group recorder/reporter at your table. Use your allotted time to consider the developments and questions assigned to your group for Module 4.
2. Identify any additional requirements, critical issues, decisions and questions you think should be addressed at this time.
3. Unanswered questions should be recorded for discussion with the entire group.

## **Questions for Participant Groups**

**Public and Private Clinical Practitioners, Hospitals, Health Care Providers** (Alternatively, this group may join the other groups as “observers” to gain insight into the processes and procedures in place.)

1. Is there any type of review process that is engaged in at your facility or organization to evaluate the “detection” systems for multiple illnesses related to the same event? Is there a system to evaluate your response to the surge and actions related to the public health community after an event like this?

**State, Local, Tribal and Territorial Epidemiologists**

1. Who would have the authority/responsibility to communicate the findings to the appropriate regulatory agency and CDC? Do you have systematic dialogue mechanisms with local regulatory agencies and the CDC outbreak staff to facilitate investigations when needed?
2. How hard is it to change or update from using your own local or State questionnaire and move to a common questionnaire? In a multi-state outbreak, how can we commonly test hypotheses across jurisdictions to have meaningful, consistent data to analyze? Is there a list of subject matter experts and up-to-date contact information, perhaps from a local academic institution, extension service, etc., maintained to assist with issues such as data analysis, questions or communications? What types of expertise could you envision for such a list?\*
3. How systematic is the collaboration between your organization and the laboratories testing food samples to influence prioritization of work? What rules or processes govern this relationship?
4. If interviews are well underway in other states, would their results influence your investigation? If so, how? When interviewing cases, do you harmonize your efforts with those of other jurisdictions? What policies, processes or guidelines govern your approach to the investigation?
5. At this point, how are you communicating with your public affairs staff/risk communicators?

**Private and Public Laboratorians**

1. How often do you upload information into PulseNet? What is a best practice in terms of regular review and analysis of PulseNet data for your jurisdiction?
   1. Would an outbreak of this nature alter your practices?
2. What policies and procedures govern the prioritization of sample analyses?
3. At this stage of the outbreak, would you expect that your laboratory would need to use alternative resources (i.e., other laboratories) to process the expected number of samples? What is the “tipping point” for this action, and who is responsible for making that decision?

**School Officials** (college and elementary; nurses, school foodservice directors and administration) (Alternatively, this group may join the other groups as “observers” to gain insight into the processes and procedures in place.)

1. As it becomes clear that the foodborne disease outbreak was not caused by behaviors or practices in your foodservice facility, how does this affect your operations? If you were the college cafeteria, what would you be serving at this point? Would you shut down?
2. Does the health department clear your school cafeteria as not being implicated in the foodborne illness event? Is this provided as an official document or informally?
3. How do you communicate this information to parents and students?
4. How do you communicate this to the media?

**Local, State, Tribal and Territorial Regulatory Agencies**

1. How systematic is the collaboration between your organization and the laboratories testing food samples to influence prioritization of work? What rules or processes govern this relationship?
2. How might the information shared during the multi-state conference calls influence your investigation?\*
3. What information would you expect from the Federal agencies at this point in the investigation?
4. How do you maintain dialogue with the facilities you are investigating? How quickly are they made aware of the findings of the investigation? Are there components of an investigation that cannot be shared with firms under investigation?
5. At this point, how are you communicating with your public affairs staff/risk communicators?

**Federal Agencies**

1. If you were the CDC, what information would you include on the notification to State and county health departments at this point? What information would you request from them, if any?
2. If you were the FDA or FSIS, how would you be coordinating with the CDC and the State environmental health programs to support the investigation efforts and provide the agency’s expertise at this point?
3. Would you examine the institution of an Incident Command System to manage this emergency at this point?\*
4. If you were CDC, FSIS or FDA, when would you contact the USDA Food and Nutrition Service if a school participating in the National School Lunch Program is involved in a foodborne illness outbreak investigation?
5. At this point, how are you communicating with your public affairs staff/risk communicators?

**Foodservice/Processing Industry**

1. If you worked for Restaurant Chain A or ABC College, what would you do now that you know that the chicken, salsa or chopped iceberg lettuce that you used may be the vehicle for *Salmonella*?
   1. What would you tell your customers?
   2. What information would you request from your vendors?
   3. What information would you want from the CDC or government agencies in relation to their investigation as it progresses?
2. What protocols do you have in place for random sampling/testing of products that you routinely use?
3. For manufacturers and distributors, have you ever had to use the FDA Reportable Food Registry? Have you ever used the FSIS Incident Management System for this purpose?
   1. If so, would you expect to use it in this case? If not, what is your familiarity level with it, and where would you go to find more information about the requirements?
4. If you were the management of the restaurant, would you still be serving customers at this point? Would you stop serving certain items?

**Risk Communicators**

1. It is difficult when the situation expands to multiple jurisdictions and even more health and regulatory authorities providing information to the media outlets. Now that this is recognized as a multi-state outbreak, how can the local and State public affairs staff coordinate with the Federal risk communicators to harmonize messages and collaborate?
2. What would you, in your organization, be doing at this point to continue to communicate with the public when there still isn’t a vehicle associated with the outbreak and any real actionable consumer messages?

# Module 5 – Traceback

**June 3  
States A, B, and D, Wala County, Green County, CDC, FSIS, FDA**

On the June 3 conference call, 10 new cases were added by the states, and PFGE matches to the outbreak strain of *S.* Muenchen continued to increase as the samples worked their way through the laboratory analysis system.

Wala County reported a positive *Salmonella* with a PFGE match to the outbreak strain in the sample obtained from the *intact* package of green chili salsa that was in the walk-in cooler in the Restaurant A (the opened sample of green chili salsa that was obtained at the same time was negative for *Salmonella*). This salsa was made by Miguel’s Mexican Specialties, located in State A. All of the other food samples were negative for *Salmonella*, including the frozen pre-cooked chicken.

Green County reported that they did not have a sample of the tomatillo salsa, because there was none remaining at the ABC College cafeteria.

State B and its local agencies reported that they were able to determine that all three facilities associated with cases used commercial fresh-made salsas, purchased pre-mixed from the vendor (two from Miguel’s Mexican Specialties and one from Juanita’s Fresh Sauces and Soups) and received chopped iceberg lettuce from Produce Queen via Continental Foodservice Distributors.

FDA indicated that it established an Incident Command Structure (ICS) to focus resources and effectively and efficiently manage the regulatory outbreak investigation. An incident commander establishes teams to manage several areas of the investigation, including internal and external communication via a Joint Information Center (JIC); analytical evaluation of all related data; including lab results; inspectional history and epidemiologic data; and field investigation, laboratory and information management. The CDC, the States and local agencies provided liaisons and key contact individuals, including epidemiologists, risk communicators and sanitarians to the incident command structure, either in person or virtually.

The incident commander established the field team’s ICS roles and responsibilities to carry out this investigation and the chain of command for the FDA team to report to the ICS system. The JIC assigned risk communicators from each agency to meet via phone and develop a coordinated message. The CDC coordinated postings for cdc.gov and foodsafety.gov with the JIC. State A indicated that its State Secretary of Health was anxious to release a press statement to supplement the media statements made up to this point. Through the JIC, FDA also updated information about the agency’s activities related to this outbreak.

With the positive match to the outbreak strain in the intact salsa container in Restaurant A, it became essential to determine the source of the *Salmonella* and remove any contaminated food or ingredients from commerce. State A and the FDA agreed to conduct a joint inspection at Miguel’s Mexican Specialties, located in State A, to review the food safety systems in place, obtain the product ingredient list, and investigate the raw material sourcing and tracking. This way, they could potentially identify a source of contamination at Miguel’s and/or trace back the contaminated food upstream in the supply chain.

The FDA began a dialogue with Miguel’s Mexican Specialties requesting that the company consider recalling the green chili salsa, out of an abundance of caution. Miguel (of Miguel’s Mexican Specialties) conferred with his legal counsel and agreed to recall all of the green chili salsa in distribution and halt production of that product. A press release announcing the recall was written by the firm and reviewed by FDA. FDA has new authority now, as a result of the Food Safety Modernization Act, to compel a recall if a firm does not voluntarily take this action when deemed appropriate.

State B, in cooperation with the FDA, inspected Juanita’s Fresh Sauces and Soups plant with the same goal in mind.

FDA and CDC hosted a call with the produce industry trade associations and representatives to inform them of the outbreak, the possible food vehicles, the positive salsa sample and the progress to date. The agencies communicated to the industry that the ingredients and the manufacturing methods for the salsa products were being evaluated. The industry was informed of the implementation of ICS structure and a single point-of-contact at the FDA and the CDC was provided for the industry to communicate through. The industry was asked to provide any insights on the possible source of the *Salmonella*. Contacts for the industry groups were identified to streamline communications. The industry contacts were told that they would be notified immediately before new public communications were issued by the Federal agencies.

The FDA was also planning an inspection of Continental Foodservice Distribution warehouses that delivered to Restaurant Chain A and ABC College, to evaluate the temperature control and inventory management systems.

**June 4  
States A, B, C and D, Wala County, Green County, CDC, FSIS, FDA**

FDA’s Incident Command obtained the customer list and distribution records from Miguel’s for the green chili salsa and established an audit check system for FDA and State investigators to ensure that the product was not being used by Miguel’s customers.

**NOTE: About Audit Checks**

**An audit check is when the environmental health sanitarians physically go to the locations where the recalled product was shipped and ensure that it is removed from commerce, segregated or destroyed. It is best executed when the collaborating regulatory jurisdictions (sanitarians) efficiently divide up the workload to cover as many locations as possible without duplication. (End note)**

FDA and States A and B conducted investigations at both Miguel’s Mexican Specialties and at Juanita’s Fresh Sauces and Soups. The investigations included an inspection and a review of the comprehensive environmental sampling program for *Salmonella* hiding in niches in the processing environment. More than 150 environmental samples were taken at each location. As the shelf-life of the fresh salsa was 14 days, there weren’t any retained samples remaining from the May 14–16 timeframe when the first exposure likely occurred. Samples of green chili salsa and tomatillo salsa were obtained from the retained samples of production from May 19, as well as samples of the in-house raw materials used in each product respectively, including fresh cilantro, jalapeno and serrano chiles, garlic and salt. The states submitted the recipe cards from each facility to the FDA analytical team of the ICS for comparison and review.

*The recipe card for the green chili salsa at Miguel’s Mexican Specialties said:*

* Fresh cilantro
* Diced green chiles, canned
* Fresh jalapeno chiles
* Lime juice – bottled
* Minced garlic – bottled
* Salt

*The recipe card for the tomatillo salsa at Juanita’s Fresh Sauces and Soups said:*

* Tomatillos, canned
* Onion, white
* Cilantro, fresh
* Lime juice concentrate
* Sugar
* Serrano chiles, canned
* Salt

Based on the ingredients in the two salsas, the common ingredients were fresh cilantro and salt. There weren’t fresh chili peppers in the tomatillo salsa, so that made the jalapeno and serrano chilis unlikely to have been contaminated. The FDA had a positive cilantro sample in 2009 with a matching PFGE pattern to this strain. As illnesses continued, the JIC engaged in a discussion related to what to tell the consumers in the affected region of the country at this time, with the data in hand. The decision to make a broad announcement about particular commodity before definitive proof of the food item as the source of the outbreak always has multiple facets and implications. After much deliberation, the FDA issued a warning to consumers in States A, B, C and D not to eat fresh cilantro or products containing fresh cilantro at this time. This clarified to the consumers in these states that the focus shifted from the individual foodservice establishments to an upstream source. In States A, B and D, FDA instructed retailers to remove fresh cilantro from their shelves and foodservice facilities and processors in those states were instructed not to use fresh cilantro until otherwise notified. Any products in commerce with fresh cilantro in them were recalled. Miguel’s Mexican Specialties and Juanita’s Fresh Sauces and Soups voluntarily recalled of all of their fresh products that contained fresh cilantro, via a press release. They contacted their downstream customers and informed them of the recall.

FDA and CDC held several conference calls with key industry representatives to explain the status of the investigation. FDA also held a media teleconference and posted, with CDC, updated information on [www.foodsafety.gov](http://www.foodsafety.gov) and each agency’s respective website.

**June 5–6**

On a conference call with all parties, no new cases were reported. PulseNet uploads were almost complete and there were PFGE matches in all three states.

The CDC reported that the preliminary review of the case control study conducted by States A, C and D, indicated a positive association of the cases with consumption of Tex-Mex style food with salsa. The case-control study did not implicate iceberg lettuce as a vehicle, and no iceberg lettuce was offered with the chicken enchilada dinner at the college, keeping the focus on the salsas. The case definition was a PFGE match to the outbreak strain and specimen collection dates between May 16 and June 3.

The CDC and public health officials in the multiple affected states conducted an epidemiologic study by comparing foods eaten by 43 ill and 97 well persons. Analysis of this study indicated that eating salsa at foodservice establishments was associated with illness. Ill persons (86 percent) were significantly more likely than well persons (28 percent) to report eating fresh, commercially prepared salsa at foodservice establishments in the week before becoming ill.

Comparison of fresh, commercially prepared salsa consumption and iceberg lettuce consumption between sick and well individuals provided statistical evidence of the association of these foods with the outbreak.

| **FOOD EATEN** | **ILL** | **WELL** | **TOTAL** | **ODDS RATIO** |
| --- | --- | --- | --- | --- |
| Ate Salsa |  |  |  |  |
| + | 37 | 27 | 64 |  |
| - | 6 | 70 | 76 |  |
|  |  |  |  | 15.99 |
| Ate Iceberg Lettuce |  |  |  |  |
| + | 25 | 62 | 87 |  |
| - | 18 | 35 | 53 |  |
|  |  |  |  | 0.78 |
|  |  |  |  |  |
| Total Participants | 43 | 97 | 140 |  |

These numbers were used to calculate an odds ratio of 15.99 for fresh commercially prepared salsa and an odds ratio of 0.78 for iceberg lettuce, suggesting that illness was about 16 times more prevalent in the group that consumed salsa than the general population.

Green County reported no positive food samples from the ones collected at the ABC College cafeteria.

The FDA representative of the ICS and State A and B reported collection of environmental, product and raw material samples at the two salsa plants and began a records review. The representative also reported collection of receiving records and distribution records from the plants. The FDA conducted a traceback to attempt to further identify the specific salsa ingredient that may be the *S.* Muenchen vehicle.

**NOTE: About Traceback Investigations**

**A traceback involves examination of the supply chain records to identify each prior upstream source of the foods and/or ingredients to identify any commonalities in sourcing of the ingredients for the two salsa firms. This will help to identify the contaminated food or ingredient and to verify the common source of the outbreak. Conducting a traceback is a painstaking effort to gather the shipping and receiving documents, quantities and lot numbers for the specific food product or products, as far upstream in the supply chain as possible, beginning at the point of service. In a traceback, production codes must be common to the distribution points, raw material must be common to the initial point of distribution, ranch(es) must be common to the raw material and code, and links must lead back to a common source.**

**(End note)**

Starting with Restaurant Chain A, the receiving records obtained from Restaurant Chain A by the FDA and State A indicated that they received a shipment from Continental Foodservice Distributors of four cases of fresh green chili salsa on Tuesday, May 10, with a production date of 05/06, and six cases on Friday, May 13, with a production date of 05/11. Although product rotation seemed to be well managed at Restaurant A, there weren’t any records and no one was sure when the four cases received on May 10 were used and when the newer delivery of six cases were first opened.

Records obtained from Continental Foodservice Distributors by the FDA and the State A investigators indicated that they received 20 cases from Miguel’s Mexican Specialties on Monday, May 9, and 20 more cases on Wednesday, May 11.

Records obtained from Miguel’s Mexican Specialties indicated that fresh cilantro was received weekly from Joe’s Refrigerated Distribution, in State C, each Wednesday, for use in several of the company’s products. Records showed receipt of 20 5-lb. boxes on Wednesday, May 4, and 25 5-lb. boxes Wednesday, May 11. Fresh jalapeno chiles were also received on Wednesdays, and 1010-lb. boxes were received on Wednesday, May 4, and Wednesday, May 11.

A review of records from ABC College indicated that they received a shipment from Continental Foodservice Distributors of six cases of tomatillo salsa from Juanita’s Fresh Soups and Sauces on Friday, May 13, with a production date of 05/11 in anticipation of the chicken enchilada special. ABC college cafeteria did not usually serve the tomatillo salsa.

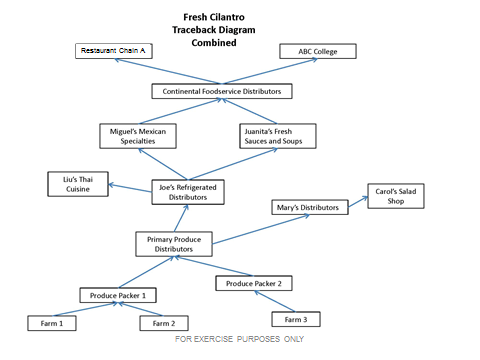
Continental Foodservice Distributors received the tomatillo salsa from Juanita’s on Tuesday, May 10, in time to meet the ABC College order.

Records from Juanita’s Fresh Sauces and Soups indicated that fresh cilantro was received weekly from Joe’s Refrigerated Distribution, in State C, on Tuesday for use in several of the company’s products. Records showed receipt of 35 5-lb. boxes on Tuesday, May 3, and 35 5-lb. boxes Tuesday, May 10.

The FDA incident commander then dispatched investigators to join with State C in visiting Joe’s. A review of the receiving documents from Joe’s Refrigerated Distribution indicated that they received the fresh cilantro and jalapenos from Primary Produce Distributors, in State K. Invoices indicated receipt of cilantro in waxed cardboard boxes twice weekly.

FDA dispatched investigators to Primary Produce Distributors in State K. Primary Produce received cilantro from two different packing houses, in order to keep up with demand. The cilantro was not co-mingled between the two packing houses, and the records were able to track and trace which shipments were from packer #1 and from packer #2 and which packer’s product was further shipped to the distribution chain. Records indicated that from April 25 through May 26, all cilantro that was shipped to Joe’s came from produce packer #2.

*The diagram below illustrates the traceback and flow of cilantro from the farm to the tables at the foodservice facilities.*



**June 10**

A conference call was held by the FDA incident commander and the CDC and State and local partners. Everyone was updated on the traceback results, and the diagrams were shared. The source of the cilantro was narrowed to Primary Produce Distributors. Primary Produce Distributors obtained their cilantro from two produce packers, representing three farms. The records from the upstream packing houses and farm fields were unable to distinguish from which farm the contaminated cilantro originated. FDA engaged in a farm investigation at each of the three possible farms to see if the source could be further identified. This took approximately three weeks.

The FDA also reported the results of the food samples taken by the FDA, the states and the environmental sampling at Miguel’s and Juanita’s. There were three positive *Salmonella* samples with a matching DNA fingerprint. One positive was from a food contact surface in the processing equipment at Juanita’s Fresh Sauces and Soups; one was from the sample of the fresh cilantro taken from Miguel’s Mexican Specialties; and one was from a sealed bag of tomatillo salsa from Juanita’s. There were no positive jalapeno pepper samples.

The laboratory results, the traceback and the epidemiologic analysis all pointed to the cilantro as the vehicle of infection in this foodborne illness outbreak. Working with the FDA and the States, both Joe’s Refrigerated Distributors and Mary’s Distribution recalled all the cilantro that they had shipped to upstream customers that was received from Primary Produce.

The CDC indicated that the outbreak epidemic curve showed that the *Salmonella* Meunchen isolations were starting to taper off to baseline levels, but were not yet back to normal at this stage. The FDA made a public announcement to consumers in the affected states about the results of the investigation, the positive cilantro sample that was a match to the outbreak, and the distribution source of the cilantro. All processors and foodservice/retail facilities were told not to sell or serve fresh cilantro from Primary Produce Distributors.

**June 12–16**

FDA and the State regulatory inspectors conducted a farm investigation to try to identify the pathway of contamination of the cilantro. Ultimately, after intense investigation and environmental sampling, it was identified that the contamination of the cilantro likely occurred via contaminated pesticide application water from a pond on farm #3. There were no new cases reported for two weeks, and the CDC waited one more week to indicate that case counts had returned to baseline levels. The FDA incident command analytical team, in conjunction with the CDC, documented and summarized all of the evidence in this outbreak. A close-out conference call was held with all regulatory and public health partners to review actions and make suggestions for improving the process for the next time.

## **Developments**

1. PFGE match to unopened container of green chili salsa
2. ICS established by FDS
3. FDA and State inspect salsa manufacturers
4. Recall initiated
5. Produce trade associations engaged
6. Fresh cilantro identified as common ingredient in both salsa recipes
7. Consumer warning for cilantro initiated
8. Cilantro traceback conducted
9. Environmental and product samples from salsa manufacturers have positive PFGE matches to the outbreak strain
10. Producing farm identified
11. Consumer warning for cilantro modified
12. Close-out conference call

## **Table Activity**

1. Identify a group leader and group recorder/reporter at your table. Use your allotted time to consider the developments and questions assigned to your group for Module 4.
2. Identify any additional requirements, critical issues, decisions and questions you think should be addressed at this time.
3. Unanswered questions should be recorded for discussion with the entire group.
4. Your facilitator will indicate which of the comprehensive list of questions below you are to discuss for this module.

## **Questions for Participant Groups**

**Public Health and Private Clinical Practitioners, Hospitals, Health Care Providers** (Alternatively, this group may join the other groups as “observers” to gain insight into the processes and procedures in place.)

1. Would you be informed when the food vehicle is identified through any mechanism other than the major media? Would a communication system that closes the loop with you be beneficial?
2. Once you learn what the food vehicle is, does this affect your future consultations with certain patient groups or your response to the next possible foodborne disease outbreak?

**Epidemiologists**

1. As the investigation moves from the epidemiology stage to the environmental stage, does your organization have good dialogue mechanisms to be kept apprised of the environmental investigation?
2. Do you work collaboratively with the environmental health/regulatory components and the laboratory to combine all of the evidence from the lab, the epidemiological and the field investigation to have a consolidated report of the findings and ultimate cause?
3. Does your jurisdiction have a review process to examine (after the fact) the actions taken and establish systems for improvement the next time?

**Private and Public Laboratorians**

1. Since the investigation concurrently has laboratory results coming from private labs, public health laboratories and the environmental investigation, does your organization have good communication mechanisms to keep each other informed of the developments?
2. Do you work collaboratively with the environmental health/regulatory components and the epidemiologists to combine all of the evidence from the lab, the epidemiological and the field investigation to have a consolidated report of the findings and ultimate cause?
3. Does your jurisdiction have a review process to examine (after the fact) the actions taken and establish systems for improvement the next time?

**School Officials** (college and elementary; nurses, school foodservice directors and administration) (Alternatively, this group may join the other groups as “observers” to gain insight into the processes and procedures in place.)

1. After an event like this, do you have systems in place to evaluate the actions taken and establish a plan for improvement if any is indicated?
2. Would the external communications as described here during this scenario have served your student and parent constituents well? If not, what would you do differently?
3. What process do you use to assure your students and their parents that no recalled product was prepared or served in your operation? Do you communicate how you safeguard the food in your operation to parents and students (e.g., your food safety plan)?

**Federal Agencies**

1. What threshold must be reached before an ICS is established? Is it scalable?
2. In outbreak situations, it is always a challenge to determine when to issue a public statement, particularly if you are in the stage of the investigation where there is no food vehicle and few, if any, consumer-actionable messages to convey.
   1. In your organization, how are these decisions evaluated?
   2. What are the advantages to being transparent to the public and advising them that the investigation is ongoing? What are the disadvantages?
   3. How is the public health threat weighed against the evidence when determining whether or not to issue a nationwide alert or consumer warning?
   4. How is the impact on the affected industry considered?
   5. Do you agree with issuing a general message to avoid the consumption of cilantro?
3. When alerts and warnings are issued, is input sought from State and local agencies? Are they provided with advance copies? How do you ensure that a consistent message is being disseminated?
4. How is the scope of a recall determined? Who participates in these negotiations? How is the public health threat weighed against the economic loss to the industry or firm?
5. What could you do if the Miguel’s refused to issue a voluntary recall of the salsa?

**State, Local, Tribal, Territorial Regulatory Agencies**

1. What could you do if the Miguel’s refused to issue a voluntary recall of the salsa? Who would need to make these decisions and take these actions? What authorities do you have in your jurisdiction to control a violative product in commerce?
2. How is the scope of a recall determined? Who participates in these negotiations? How is the public health threat weighed against the economic loss to the industry or firm?
3. What policies and procedures are in place to identify the correct representative to the FDA ICS?
4. In outbreak situations, it is always a challenge to determine when to issue a public statement, particularly if you are in the stage of the investigation where there is no food vehicle and few, if any, consumer-actionable messages to convey.
   1. In your organization, how are these decisions evaluated?
   2. What are the advantages to being transparent to the public and advising them that the investigation is ongoing? What are the disadvantages?
   3. How is the public health threat weighed against the evidence when determining whether or not to issue a nationwide alert or consumer warning?
   4. How is the impact on the affected industry considered?
   5. Do you agree with issuing a general message to avoid the consumption of cilantro?

**Foodservice/Processing Industry**

1. If your firm produced or handled the implicated product (either the farm, produce supplier or the salsa manufacturer), how would you know when the problem began? How much product could potentially be affected? Provide thoughts for each segment of the flow of food from upstream of your facility through your facility and distribution chain.
2. If you were the manufacturer, how would you go about identifying and notifying customers, if at all? To what extent would the Reportable Food Registry be used?
3. With respect to the risk communication aspects of this scenario, what criteria would you like to see the public sector use to identify when and what to release publicly during an outbreak of this type? What information would you communicate directly?

**Risk Communicators**

1. Have you ever worked across an interagency JIC? How would you incorporate your review and clearance procedures with a multi-agency effort?
2. What is your responsibility as public health risk communicators to inform the public when the outbreak is over; to engage citizens in returning to confidence in the recalled product in particular and the food supply in general?
3. What is your role in maintaining the “brand” of our food safety mission and agencies?

# Wrap Up Activities

We will spend the remaining time synthesizing what we discussed today, identifying important action steps to include in the After-Action Report and Improvement Plan (AAR/IP) and obtaining your feedback on the overall exercise. An AAR/IP is an important tool used to evaluate the exercise addressing outcomes, strengths, weaknesses and lessons learned. The facilitator will let you know when to expect to receive the final AAR/IP. The AAR/IP should be treated as a “For Official Use Only” document and only shared with those having a need to know.

At your table, please take a few minutes to discuss the questions below as directed by the facilitator. We will then take some time as a large group to identify common themes and takeaways. At the conclusion of this discussion, we ask that you complete the feedback form that will be provided by your facilitator.

**Wrap Up Discussion Questions**

1. What is the most important thing you learned today in terms of managing an outbreak that impacts multiple jurisdictions?
2. What information do you need make informed decisions during such an event? If you don’t have that information, how do you get it or what needs to be done to make a decision without it?
3. Do you think this exercise will prompt your organization to evaluate your protocols, policies and procedures?
4. What top three actions should be taken to ensure proper event management based upon what you have learned from this exercise?
5. What went right, and what can you improve on at each stage of the outbreak investigation?
6. What are the roles and responsibilities of the various clinical, public health, regulatory and laboratory communities engaged in this investigation?
7. What could be done through all phases to reduce the time from the first signal to implementation of effective controls to final resolution in order to protect public health and reduce the economic impact on the entire industry?
8. What are some key lessons related to risk communication that you discussed today? What can you commit to doing to ensure that your organization supports a consistent, multi-jurisdictional, science-based message in the event of a foodborne illness outbreak?
9. How can you work to build relationships with the CDC, FDA, other government agencies and the industry so that you have a consistent line of communication open at all times?

# Appendix A: Resources

CDC. National Outbreak Reporting System. Guidance document for NORS users. <http://www.cdc.gov/outbreaknet/pdf/NORS_Guidance_5213_06232009%28compliant%29.pdf>

IAFP. Procedures to Investigate Foodborne Illness <http://www.foodprotection.org/files/other-publications/procedures-forms.pdf>

CIFOR. Diagnosis and Management of Foodborne Illnesses: A Primer for Physicians and Other Health Care Professionals <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5304a1.htm>; <http://www.cifor.us>.

CIFOR. Guidelines for Foodborne Disease Outbreak Response. <http://www.cifor.us/CIFORGuidelinesProjectMore.cfm>

CIFOR. Toolkit for the Guidelines for Foodborne Disease Outbreak Response. <http://www.cifor.us/toolkit.cfm>

Hedberg, CW et al. 2008. Timeliness of enteric disease surveillance in 6 US states. Emerging Infectious Disease. 14(2):311-313

CDC. Foodborne Outbreak Investigations. <http://www.cdc.gov/outbreaknet/investigations/investigating.html>

Epi-Ready Foodborne Illness Response Strategies <http://www.neha.org/epi_ready/>

FDA. Food Safety [www.fda.gov/Food/FoodSafety/Foodborneillness/ucm235425.htm](file:///C:\Documents%20and%20Settings\azychowski\Local%20Settings\Temporary%20Internet%20Files\Content.IE5\V2GN4AKJ\www.fda.gov\Food\FoodSafety\Foodborneillness\ucm235425.htm)

FDA. Foodborne Illness Environmental Assessments <http://www.fda.gov/Food/FoodSafety/FoodborneIllness/ucm235425.htm>

CDC. Outbreak Surveillance Data. <http://www.cdc.gov/outbreaknet/surveillance_data.html>

CDC. Foodborne Outbreak Investigations. <http://www.cdc.gov/outbreaknet/investigations>

FDA. Foodborne Illness. <http://www.fda.gov/Food/FoodSafety/FoodborneIllness/default.htm>

# Appendix B: Acronyms Used

AAR After-Action Report

AAR/IP After-Action Report and Improvement Plan

CDC Centers for Disease Control and Prevention

CIFOR Council to Improve Foodborne Outbreak Response

DHHS Department of Health and Human Services

DHS Department of Homeland Security

DNA Deoxyribonucleic acid

EMS Emergency Medical Services

ERT Emergency Response Teams

FBI Federal Bureau of Investigation

FDA Food and Drug Administration

FNS Food and Nutrition Service (of USDA)

FSIS Food Safety Inspection Service

GI Gastro-intestinal

HazMat Hazardous Materials

HSEEP Homeland Security Exercise and Evaluation Program

ICS Incident Command Structure

JIC Joint Information Center

PFGE Pulsed Field Gel Electrophoresis

SITMAN Situation Manual

USDA United States Department of Agriculture