

Food Related
Emergency Exercise
Boxed-set
(FREE-B)
Wilted Woes
Situation Manual



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Introduction

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 from employee error, or on purpose from sabotage, fraud or terrorist activities. Regardless of the circumstances, the US [Food and Drug Administration](#) (FDA) and United States Department of Agriculture [Food Safety and Inspection Service](#) (USDA FSIS), collaborating with State and local agencies, work closely to safeguard the American food supply.

Through this working relationship, the 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 scenario begins with the first reports of human illness and then focuses on the epidemiological investigation process to identify the food vehicle. This is the typical approach when there is a human health incident caused by an unintentional contamination of produce with *E. coli* O157:H7. As the epidemiologic process unfolds, the preliminary work on identification of the contaminated food product is introduced. The concurrent activities of both the public health and the regulatory operations from this early stage of investigation are included.

Participants

Through the collaboration and coordination with multiple stakeholders, 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.

Participants in this scenario should include: physicians and other clinical health professionals, hospitals, local, State, Tribal and territorial public health epidemiologists and regulatory environmental health professionals, laboratorians, USDA FSIS, CDC, FDA and industry.

Exercise Objectives

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

- Understand how an epidemiological investigation unfolds and the roles that various public health agencies play
- Clearly state your role and contribution to an epidemiologic investigation of a foodborne public health incident
- Obtain a working knowledge of the specific roles clinical, public health, regulatory and laboratory communities play when engaged in this investigation
- Apply the step-by-step process used to investigate a public health situation that starts with a few cases of clinical illnesses through to the ultimate identification of the food vehicle
- Define the process for collecting and applying the epidemiologic data related to the identification of the contaminated food product
- Assess the limitations of the public health and regulatory sectors and take necessary actions to address these limitations

Introduction

Exercise Structure

This exercise is designed to be an interactive, facilitated tabletop exercise. Participants are encouraged to learn from each other and ask questions of one another. The scenario is based on a real situation and 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 initially developed by Consolidated Safety Services and revised by the Institute of Food Technologists (IFT) on behalf of the Food and Drug Administration CFSAN Food Defense Oversight Team. This scenario was also produced in cooperation with the Centers for Disease Control and Prevention.

This exercise is a multimedia, facilitated tabletop exercise (TTX). Participants will respond to two different modules:

- **Module 1** – Identification of Outbreak
- **Module 2** – Identification of Food

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 findings from today's activities to our job/functions 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.

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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 – Identification of Outbreak

Module 1 – Identification of Outbreak

During the period from January 15–22, three individuals in State A and four individuals in State B had gastrointestinal illness (diarrhea, vomiting and nausea) and sought medical attention. As part of their medical examination, the doctors sent stool specimens to nearby clinical laboratories. Upon testing, the labs isolated *E. coli* O157:H7 in all of the stool samples, and the samples were subsequently sent to their respective State public health laboratories for confirmation and “DNA Fingerprinting” through the identification of the Pulsed Field Gel Electrophoresis pattern (PFGE).

Note: About Pulsed Field Gel Electrophoresis (PFGE)

Standardized molecular subtyping using PFGE helps to further specify or differentiate *E. coli* O157:H7 (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. The restriction enzymes cut DNA at specific locations, and the mixture of DNA fragments is placed on a gel. When electricity passes through the gel, the DNA pieces separate based on size: small pieces of DNA get carried farther down the gel than bigger pieces. 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/>, “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, USDA FSIS, FDA).” The PulseNet team is an important part of disease detection. They 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 patterns 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>

(End note)

The public health laboratories then electronically submitted the information to the CDC PulseNet database. This process is typical for the Federal-State disease surveillance system and usually takes at least 15 days from the onset of illness. By January 30, some of the PFGE patterns had been uploaded to PulseNet.

During the same timeframe in mid-late January, individuals in 11 other states had become sick because of *E. coli* O157:H7 exposure. Like in States A and B, stool samples were collected, and PFGE analyses from the samples were conducted.

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February 8

On February 8, during their review of the PulseNet data, CDC officials noticed the presence of a PFGE subtype cluster of *E. coli* O157:H7. Sixteen of the *E. coli* O157:H7 PFGE patterns that had been uploaded to the national database in the past week from multiple states matched one another.

During this time, epidemiologists in States A and B had also noticed an increase in matching PFGE patterns for *E. coli* O157:H7 above the background level and began to investigate to identify the source and possible mode of transmission.

Note: Outbreak investigation triggers

With limited resources, public health departments may need to make decisions regarding which cases of foodborne illness are further investigated. There are a variety of factors that may affect the decision to pursue an investigation.

First, epidemiologists must consider the “signal to noise” ratio. In other words, is the increase in the number of cases due to a specific pathogen, strain or even PFGE pattern unusual for that location and time of year? The greater the number of cases versus what is “typical,” the higher the likelihood that an investigation would be pursued.

The nature of the illness may also impact the decision to further investigate. Infection with *E. coli* O157:H7 generally has a higher likelihood of resulting in death or severe illness compared to infection with *Salmonella*. The total impact on public health due to an outbreak of *E. coli* O157:H7 versus *Salmonella* is greater; therefore, epidemiologists would be more likely to investigate a potential outbreak of *E. coli* O157:H7, all other factors being equal.

(End note)

February 9

On February 9, the CDC coordinated a conference call with the epidemiologists in the eight states where at least one case of *E. coli* O157:H7 with a matching PFGE pattern had been reported. At this stage there were 20 cases that matched by PFGE. Each state reported the status of its cases, laboratory results and investigation efforts. States with only one reported case indicated that they did not have the resources to further investigate.

Since cases were dispersed over several states, the thought was that food was the likely mode of transmission of this strain of *E. coli* O157:H7. The state epidemiologists decided to begin a coordinated effort to increase surveillance for additional cases. Additionally, states with only one reported PFGE match determined to engage in hypothesis generating interviews to try to identify the food vehicle associated with these illnesses. States A, B and D, each with multiple cases with matching PFGE patterns, had already begun to investigate to identify the source and possible mode of transmission. In this instance, a “case” was defined as a person with *E. coli* O157:H7 infection with a PFGE pattern that matched the outbreak strain where illness (acute onset of vomiting, nausea and/or diarrhea) began on or after January 10.

The chart below summarizes the cases and the laboratory status in the affected states as of the conference call on February 9. At this stage, as the *E. coli* O157:H7 isolates continued to be characterized, there were some laboratory-confirmed cases of *E. coli* O157:H7 that still needed PFGE

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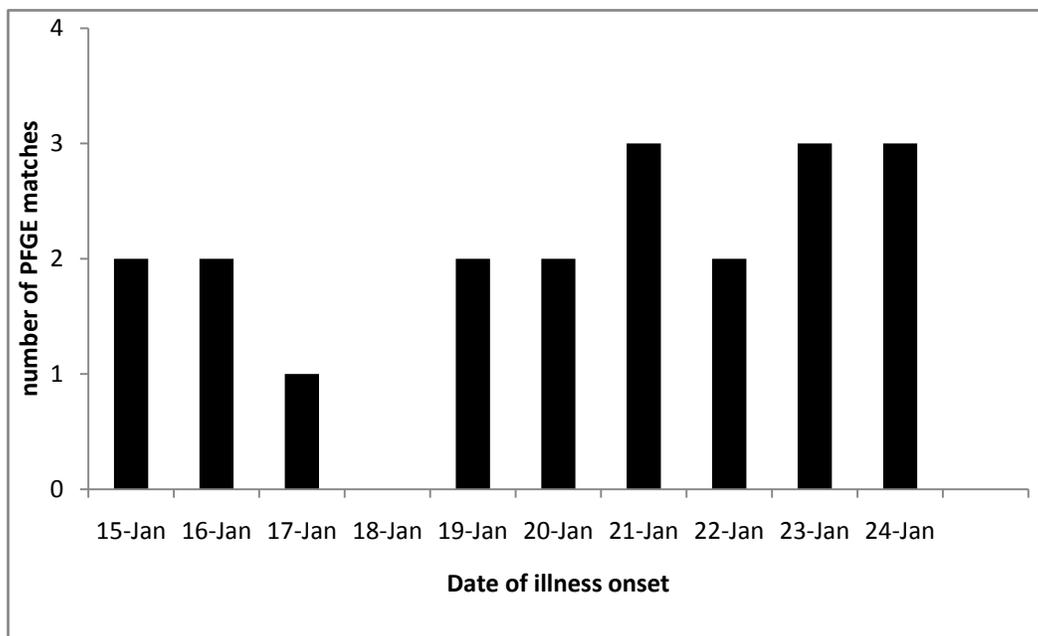
results to determine if the PFGE pattern matched the outbreak strain. As of February 9, there were 35 possible cases in 13 states identified; 20 were confirmed as PFGE matches.

Table 1. Potentially related cases, with illness onset beginning January 15, as reported through February 9

State	Male	Female	Confirmed O157:H7 cases	O157:H7 with outbreak PFGE subtype
A	1	2	3	3
B	0	4	4	4
C	0	1	1	1
D	2	5	7	5
E	1	2	3	1
F	1	0	1	0
G	0	2	2	0
H	2	2	5	3
I	0	1	1	1
J	1	1	2	2
K	1	2	3	0
L	0	2	2	0
M	0	1	1	0
TOTAL	10	25	35	20

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Table 2. Illness onset dates associated with matching PFGE profiles, as of February 9



Also on February 9, the CDC contacted the FDA and USDA FSIS through the embedded agency liaisons to inform them that there was an increase in the number of cases of *E. coli* O157:H7 with matching PFGE patterns and efforts were underway to generate a hypothesis about the source of the illnesses. The CDC also sent a notification to all 50 State health departments in order to raise awareness and encourage them to rapidly identify any additional cases that may be related to the potential outbreak.

Note: About embedded agency liaisons

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

(End note)

The State health departments' foodborne disease epidemiologists and local public health officials contacted the affected people and conducted hypothesis generating interviews.

Note: About hypothesis-generating interviews

As described by CDC at <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.

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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. For ill individuals who shopped at stores with shopper’s/loyalty cards, information may also be requested from the stores regarding all items purchased within a specified timeframe prior to illness onset.

“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.

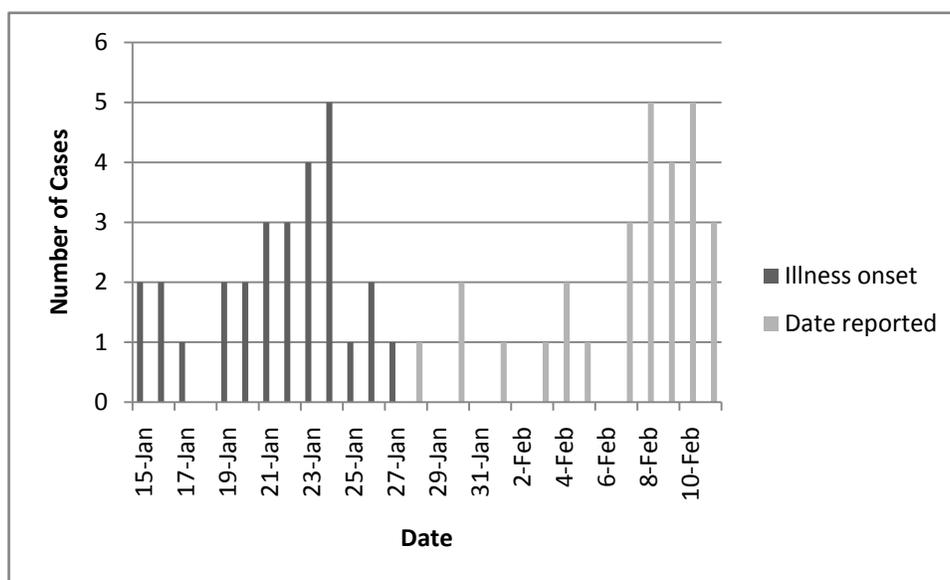
“If the exposure occurred at a restaurant, hotel, or catered event, for instance, interviews will focus on the menu items prepared, served, or sold there. If there is no obvious place of exposure, investigators may use a standard questionnaire, also known as a ‘shotgun’ or ‘trawling’ questionnaire.” 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)

February 11

On February 11, an additional conference call was held by the CDC. The participants included FDA, USDA FSIS and the State and local public health communities from states with affected cases. Since the previous report on February 9, eight more PFGE-matched cases in three of the states were uploaded to PulseNet, bringing the total number of PGFE matches to 28. Also, six new cases were reported from States F and J, bringing the total possible cases to 41, spanning 13 states. Table 3 shows the dates of illness onset for the 28 cases with matching PFGE patterns.

Table 3. Dates of illness onset associated with matching PFGE profiles and dates reported to PulseNet, as of February 11



States A, B, D and H had completed their questionnaires on 13 patients, and States A and B had analyzed the data on food histories from their six cases with good food consumption recollection. The

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information from the interviews in States A and B was synthesized and a “short list” of common foods that the ill people consumed was generated. Foods that none of the cases reported eating were not assessed further. The State A short list had eggs, yogurt, fresh spinach, beef and tortilla chips. The State B short list included eggs, yogurt, lettuce, spinach, chicken, cheese and cereal/granola. State D reported that five of their seven cases were friends who had eaten lunch together in one of their homes, and the menu included a fresh spinach salad, bread and homemade minestrone soup.

Note: About “short lists”

In actuality, “short lists” may not be as short as presented in this scenario. Substantial effort is expended finding common food sources. In this case, individuals are being asked to recall foods eaten almost one month prior. The identification of the “cluster” of individuals in State D who ate together and got ill is a significant development that aids in the investigation.

(End note)

The CDC discussed a review of previous food contamination events and outbreaks to identify the more common food vehicles for *E. coli* O157:H7, including ground beef, various types of produce and raw cookie dough. Given the history of produce-associated outbreaks due to *E. coli* O157:H7, in combination with the short list from States A and B and the cluster of cases that had eaten together in State D, the discussion focused on fresh spinach (i.e., not canned or cooked). Representatives from States A and B indicated that they would re-interview their cases that reported eating spinach and investigate where the spinach was purchased or eaten and see if a common brand of spinach was consumed.

Additional states indicated that they would have their questionnaires completed with 48 hours. Two states asked CDC for assistance in conducting interviews. All states agreed to share interview data with CDC.

The FDA, USDA FSIS and the States also reviewed historical and current information from their various laboratory surveillance samples and environmental testing to see if any *E. coli* O157:H7 with this matching PFGE pattern had been isolated from food or the environment.

February 12

On February 12, another brief multi-agency call was held where six additional PFGE-matched cases were reported, bringing the total number of cases with matching PFGE patterns to 34. State D had analyzed its questionnaire data. All seven of their cases were exposed to spinach. Other items on their short list included eggs and mushrooms. State H indicated that four of their five cases had fresh spinach exposure. No other information was available at this time. With this new information, the hypothesis of spinach as the food vehicle was supported.

Developments

1. CDC notices unusual number of matching *E. coli* O157:H7 PFGE patterns from cases in different states.
2. CDC organizes a multistate conference call; three States report that interviews are underway.
3. CDC notifies State health departments of potential outbreak.

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4. A cluster of illnesses in one state, combined with food histories of other cases initially points to spinach as a vehicle of infection.

Task

Use your allotted time to consider the developments and questions assigned to your group for Module 1.

- Identify any additional requirements, critical issues, decisions and questions you think should be addressed at this time.
- Unanswered questions should be recorded for discussion with the entire group.

Questions for Participant Groups

Clinical Practitioners

1. If you suspect a foodborne illness in one of your clinical patients, what is your standard process for follow up? If you believe it is an enteric pathogen like *E. coli* O157:H7, do you routinely collect a stool sample? What is the threshold for specimen collection? What is the public health impact of treating cases of febrile diarrhea without collecting stool cultures in light of the cost of medical care and tests?
2. What actions would you take, if any, to communicate with the public health authorities if a patient presents with a suspected foodborne illness?
3. Does your laboratory have processes to further submit isolates to the state lab for PFGE analysis? How quickly are the isolates sent to the State lab? Is this a matter of routine for foodborne pathogens?
4. Do you have a methodology in place to communicate with other practitioners if you see an increase in certain disease syndromes?
5. How would you characterize your expertise with foodborne illness agents and disease syndromes?

Epidemiologists

1. Within your organization, when and how would you be made aware of an increase in *E. coli* O157:H7 isolations among your constituent population? Are there multiple routes of communication for information of this kind? If so, please describe them.
2. In your organization, with restricted budgets and human resources, please describe how is the decision made to allocate resources to follow up on apparent increases in clinical cases of foodborne pathogens? Is there a decision tree or other process in place?
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 3 or 4 cases of *E. coli* O157:H7? What would prompt an investigation, and 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? If so, please describe.
4. How do you communicate with your State or local public health epidemiology counterparts, local health departments, health inspectors/health officers and others 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?
5. How systematic is the collaboration between your organization and the laboratories to influence prioritization of work? What rules or processes govern this relationship?

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6. Who would have the authority/responsibility to communicate the findings to the CDC? Do you have systematic communication mechanisms with the CDC outbreak staff to facilitate investigations when needed?
7. How do you determine the type of questionnaire to use for hypothesis generation?
 - a. Do you have a standard template questionnaire, or do you develop them specific to the event data that you have at hand?
 - b. Who is responsible for conducting the interviews? Is this done by local- or State-level epidemiologists?
 - c. Assume that an outbreak investigation is a multi-jurisdiction effort within a single 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. Through which system(s) do you communicate with the clinical community in your jurisdiction to raise awareness of the situation and increase speed of response?
9. 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?
 - a. What amount of data does the regulatory agency require of you before deciding to pursue their part of the investigation (e.g., number of cases, strength of hypothesis, etc.)?
10. Does the fact that females are disproportionately affected lead you to suspect any particular product types, even without conducting interviews? If so, how do you balance this suspicion without it biasing you against investigating other potential sources?
11. What is your risk communication plan for media inquiries prior to an official press release being issued? When does notification go out to local health departments, health care providers and the public?

Food Industry

1. 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 the foundation is established if and when it is needed? If so, please describe the process.
2. For food stores with shopper's/loyalty cards, how quickly can health and regulatory agencies be provided with all of the products purchased by ill individuals?
3. At this point in the outbreak, officials have not issued a public warning about any implicated foods. Because spinach is the suspected vehicle, would you expect to receive notification regarding the investigation? If yes, who would you expect to notify you, and what information would you want provided?
4. Do you know what your local or State public health agency does to monitor public health emergencies and food safety?
5. What 'informal' mechanisms (e.g., Listservs, websites) do you have to keep abreast of local, regional or nationwide food safety events?

State, Local, Tribal, Territorial Regulatory Agencies

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?
 - a. What amount of epidemiological data is needed before you will take action?
3. What activities or background investigation might you undertake when you have the information presented at the end of this module — when you are made aware of a short list of foods that are

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being considered as vehicles for a foodborne outbreak of *E. coli* O157:H7, **before** a food is statistically associated with the outbreak? When would you collect samples of a food product?

4. How do you weigh the evidence and balance the benefit of issuing a public health notice versus the damage that may be inflicted on the industry if the food is erroneously suspected or the outbreak is over by the time the notice is issued? How is this dependent on attributes of the suspected food, such as shelf life?
5. When a certain food is suspected as a vehicle of contamination, what mechanisms are in place to alert the industry? What information is shared and by whom? When does this communication take place? What mechanisms are in place to alert the public?

Federal Agencies (FDA, CDC)

1. How would efforts between States, such as the development of food history questionnaires, be coordinated by your agency?
2. How would you assist State, local, territorial and Tribal governments during the investigation?
3. What activities can you engage in to interact with the State, local, territorial and Tribal food regulatory and public health agencies, and food industry in times when there is not an emergency?
4. How do you weigh the evidence and balance the benefit of issuing a public health notice versus the damage that may be inflicted on the industry if either the food is erroneously suspected or the outbreak is over by the time the notice is issued? How is this dependent on attributes of the suspected food, such as shelf life?
5. When would a traceback/traceforward of the suspect food be conducted to compare the distribution of the food product with the distribution of cases?

Module 2 – Identification of Food

Module 2 – Identification of Food

February 13

On the February 13 multi-agency call, State H reported that the short list from their interviews included cheese, spinach and lettuce, and that all five cases were vegetarians. States A, B and D reported that fresh *bagged* spinach was the spinach source for the cases they had re-interviewed and were working to obtain shopping history data to determine the brands, since the cases did not recollect a specific brand. States J and F also reported spinach exposure, along with lettuce, cheese, cereal and ground beef. As the discussion evolved, the cluster of vegetarians and the predominance of female cases supported other information to continue to point the hypothesis towards spinach, with bagged spinach being the specific product of interest. Additionally 10 more PFGE matches were submitted to PulseNet, bringing the number of cases related to the outbreak to 44, still in 13 states.

Several states agreed to work with the CDC to begin to test the hypothesis by conducting a case control study collecting information and food histories from comparable people who are not sick.

Note: About case control studies

As described by CDC at (<http://www.cdc.gov/outbreaknet/investigations/hypotheses.html>): “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.” The statistical analysis takes into account the frequencies of exposure, the statistical probabilities and the food production and distribution processes. “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)

FDA advised consumers by press release and press conference that they were investigating an outbreak of *E. coli* O157:H7 that seemed to be associated with spinach, and specifically bagged spinach, based on: the fact that spinach appeared on each State’s short list; that re-interviewed cases specifically indicated the consumption of bagged spinach (without an indication of a brand); the severity of *E. coli* O157:H7 infection; and the ongoing nature of this outbreak. FDA also advised the retail and foodservice industries not to sell or serve fresh bagged spinach products until further notice. The multi-agency www.foodsafety.gov page was updated to include the press release and a series of Frequently Asked Questions (FAQs). Several states also posted information and linked to the food safety site.

States J, F and E shared that fresh bagged spinach as the source of spinach as reported by their cases. State and local agencies in the affected states collected any remaining bagged spinach in the households of ill people for testing and collected spinach samples of the same products with the oldest expiration dates from stores. The analytical case-control study was underway, and PFGE patterns matching the outbreak strain continued to be uploaded to PulseNet.

Module 2 – Identification of Food

Note: About samples from open products

When samples from open products (in this case open bags of spinach) are positive for the outbreak strain, it is possible that the bag was contaminated after opening. The weight of evidence is much stronger when a contaminant is found in an *unopened* package of a product.

(End note)

February 14

On the February 14 multi-agency conference call, it was reported that samples from cases presenting with illness in late January were still being processed and PFGE matches continued to be confirmed.

State D reported that the household that had made the spinach salad for the luncheon had used “Brand X” brand of bagged fresh spinach. This was confirmed, with permission from the homeowner, using the shopper card data from the retail store where the spinach was purchased. There was some remaining spinach in the home and the local regulatory authority collected it for testing. States A, B and H reported that their cases had consumed “Brand Y” fresh bagged spinach. States F and J reported “Brand X” spinach was consumed by the sick people in their states. Loose, unbagged spinach was not identified by any of the cases in any of the states. FDA updated its warning to clarify that fresh bagged spinach should be avoided and that other forms of spinach had been excluded from the investigation.

Efforts were underway in all affected states to continue to identify the brand of spinach consumed and to recover any remaining spinach from the households of the ill people. Lot numbers, sell- or use-by dates and any other identifying information were collected. Samples were sent to the State public health laboratories for analysis. The FDA laboratories also assisted States, if needed.

Through a traceback investigation, FDA determined that “Brand X” and “Brand Y” fresh bagged spinach were packaged in the same facility owned by ABC Processing Company. ABC Processing Company also co-packed fresh bagged spinach under three other brand names.

FDA contacted the firm and, with the CDC, discussed the epidemiology and other evidence to date and the implication of ABC Processing Company fresh bagged spinach being the vehicle for this *E. coli* O157:H7 outbreak. Later that day, ABC Processing announced a voluntary recall of all fresh spinach-containing products out of an abundance of caution. At this point the root cause of contamination was not clear, and it was not certain if individuals were still becoming ill. Although the spinach associated with the initial cases was past its shelf life, it was not clear if the contamination was ongoing or only affected spinach produced within a certain timeframe.

February 15–18

On February 15, a joint investigation team of FDA investigators and State regulators arrived at ABC Processing Company to investigate the spinach processing facility, the sources of spinach and distribution information. FDA also collected 22 retained samples of fresh bagged spinach from the plant as well as samples of incoming spinach for *E. coli* O157:H7 analysis. The retained samples were from lots with use-by dates ranging from February 10 (processed on January 26) to February 25 (processed on February 10).

Module 2 – Identification of Food

Note: About the visit to the processing facility

During an outbreak investigation, the FDA works with State regulators to search for the source of contamination. FDA has provided funding to some states to develop “Rapid Response Teams”. In California, the California Food Emergency Response Team (CalFERT) is cross trained with FDA, resulting in greater collaboration and increased efficiency during the investigation. More information about State-FDA collaborations can be found <http://www.fda.gov/ForFederalStateandLocalOfficials/default.htm>,

Since the processing company serves as a common point for implicated spinach, it is possible that contamination occurred during processing. It is also possible that the processing plant received contaminated spinach. At this time, regulators would likely request receiving, production and distribution records (including invoices, sales receipts and production logs). These records aid in a traceback investigation and permit tracing forward once the scope of the investigation narrows. For more information pertaining to tracebacks, see the “How Sweet it Is(n’t)” and “Stealthy Situation” scenarios.

Note: About “retain” samples

Most processors collect “retain” samples off the production lines throughout the day, generally for each Stock Keeping Unit (SKU) they produce (potentially >100 SKUs/day). The primary reason retained samples are collected is for quality observation. Most processors look at quality at defined intervals after packing, e.g. 24 hours, 48 hours, then seven days, twelve days and then at the end of the shelf life. In some cases the evaluation might extend beyond shelf life to look at “worst case” scenarios. These quality evaluations are destructive, meaning that a bag or two is opened and product is removed to perform the quality analysis. Therefore the number of bags from any one SKU produced on a certain day diminishes as time passes and more evaluations are performed. By the time the product reaches the end of shelf life, most bags have already been analyzed.

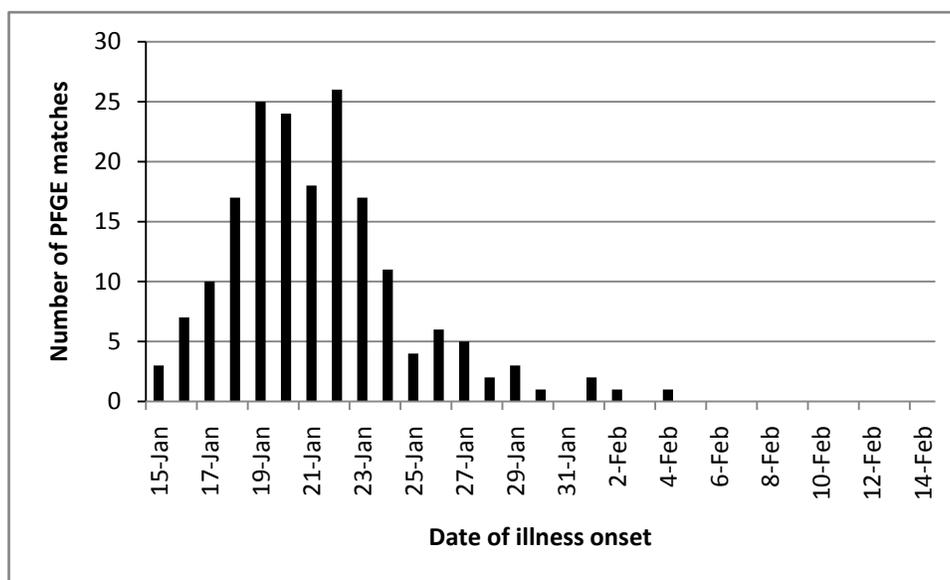
(End note)

February 17

FDA determined that ABC Processing contracts for 100 percent of the spinach production on three large farms with thirteen individual fields. Spinach produced by these farms is only sold to ABC Processing. ABC Processing began identifying the specific farms and fields that supplied spinach for processing during the days in question. Given that the patients with the earliest PFGE match reported illness onsets around January 15, production records from January 1 onward were provided.

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Table 4. Dates of illness onset associated with matching PFGE profiles and dates reported to PulseNet, as of February 24



2/13 FDA advises consumers to avoid spinach

February 24

To date, nine open bags of spinach had been collected from case households in three states, eight of which were analyzed for *E. coli* O157:H7. ABC Processing was the manufacturer of seven of the samples collected, all of which were either “Brand X” or “Brand Y”, including three with a product code beginning P007. Of the eight opened bags tested, two were positive for *E. coli* O157:H7 (both of which had a product code beginning P007). The positive spinach samples had PFGE profiles that were indistinguishable from the outbreak strain.

FDA provided a clarification to the February 13 press release and informed consumers that only spinach processed by ABC Processing Company was implicated in the outbreak. The brand names associated with ABC Processing Company were provided. FDA also stated that fresh bagged spinach processed by other firms was not implicated and can be consumed.

CDC reported that the case control study had enough information to statistically implicate fresh bagged spinach. Ninety-three percent of cases had exposure to fresh bagged spinach compared to only 14 percent of controls. The statistical analysis of this study also indicated an association of ABC Processing fresh bagged spinach consumption with the *E. coli* O157:H7 outbreak.

February 28

As of February 28, a total of 183 people infected with the outbreak strain of *E. coli* O157:H7 had been reported to CDC from 26 states. Among the ill people, 95 (52 percent) were hospitalized, 15 (8 percent)

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had hemolytic uremic syndrome (HUS) and one person died. Eighty-five percent of patients reported illness onset from January 15 to January 24. Fresh bagged spinach was identified as the source of the outbreak. No new cases had been identified since February 16.

None of the samples of fresh bagged spinach collected by the FDA in the ABC processing plant on February 15 was positive for *E. coli* O157:H7. A traceback to the origin of the spinach used in the production of bags with production code P007 was underway and ultimately revealed that production code P007 was processed on January 11 using spinach from three fields. Environmental samples taken from one of the fields was positive for *E. coli* O157:H7 with a matching PFGE pattern.

Note: About the traceback

A traceback involves the examination of supply chain records to identify each prior upstream source of the foods and/or ingredients to identify any commonalities in source. This helps to identify the contaminated food or ingredient and to verify the common source of the outbreak. In this case, finding the outbreak strain in several opened bags of spinach lends great support to the hypothesis that spinach was the vehicle. Had this not occurred, the investigation would have been more complicated.

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. There are several links that need to be made during the traceback. 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. The quantity and quality of records sometimes makes this a difficult process. Exercises, focusing on traceback investigations, include candy and taco.

(End note)

Developments

1. Fresh, *bagged* spinach was implicated as a vehicle.
2. A case control study commenced.
3. FDA publically announced that bagged spinach was implicated in the outbreak.
4. Two brands of spinach were implicated, and samples were taken from consumers' homes for analysis; two opened bags were positive for *E. coli* O157:H7 matching the outbreak strain .
5. The brands of spinach were processed in the same facility, and FDA and State regulators visited the facility; FDA updated the public announcement to focus only on spinach from this processor.
6. FDA collected retained bags of spinach from the plant, but none was positive for *E. coli* O157:H7.
7. The processor recalled all fresh spinach in distribution.
8. The positive open bags of spinach had the same production code, and the traceback investigation showed that spinach used in those bags originated in three farms.
9. Investigation at the farms yielded a positive sample matching the outbreak strain at one farm.

Task

Use your allotted time to consider the developments and questions assigned to your group for Module 2.

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- Identify any additional requirements, critical issues, decisions and questions you think should be addressed at this time.
- Unanswered questions should be recorded for discussion with the entire group.

Questions for Participant Groups

Clinical Practitioners

1. At this point, spinach has been associated with this outbreak as the possible vehicle. Does this information influence your treatment of your existing case(s)? Does this information influence your decision to request stool samples from any new patients that present with foodborne illness symptoms?
2. At this point, would you have any contact with other medical practitioners regarding this outbreak? If so, who?
3. Other than the major media, do you have a system to receive updates and/or information about ongoing foodborne disease outbreaks in your communities?

Epidemiologists

1. Assume the ABC Processing Company is in your state. How do you communicate within your jurisdiction to share information related to the environmental investigation, laboratory data from analysis of both the clinical specimens and the spinach samples and the evolving epidemiologic and analytical data? How is this information utilized to plan next steps?
2. How do State, local, Tribal and territorial epidemiologists provide input to the CDC analytic study in terms of the case definition, criteria for controls and interview questionnaire? Is this dependent on whether you are in State A (and are out in front of the epidemiologic activities) or in a state with the later onsets?
3. As the investigation is continuing, new cases continue to be reported, laboratory results and PFGE tests are updated daily, case interviews are being conducted and an analytic study is underway concurrently. How do you approach the management of these various tasks and allocate resources to follow up on the epidemiologic activities?
4. How do you coordinate the analytic study efforts with the other epidemiology groups in your neighboring jurisdictions?
5. What could be done to shorten the time from the first case to implementation of effective control measures to reduce the number ill and the negative impacts on the entire spinach industry? Are there more efficient ways of receiving/sharing information?
6. How might this investigation have proceeded differently if 10 percent of cases reported eating a brand of spinach that could not be traced back to the three fields implicated?

Food Industry

1. At your facility, do you have a crisis management plan for handling a recall situation based on a foodborne illness? Does that crisis management plan address the kind of situation described here?
2. If your firm is contacted by a regulatory agency because one of your products is associated with illness, how do you put your crisis management plan into motion? How quickly can your firm react?
3. If you were the management of ABC Processing Company, what would you be doing at this point? How would the decision be made to recall? How would the scope of the recall be determined? Would you consider stopping production or holding inventory? Why or why not?

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4. What types of communication would you have with your suppliers, customers and employees? What type of communication would you have with the public through the media or other means? Do you have a relationship with contacts at your local regulatory agency?
5. In this scenario, products you produced, packed, shipped and sold, were implicated as a vehicle in a foodborne illness. How would you be able to trace the origin(s) and destination(s) of the product?
 - a. Would you be able to identify the upstream source of the incoming product? Who is responsible for maintaining records related to such products?
 - b. Can you provide all source and customer distribution records electronically to health and food regulatory authorities within 24 hours?
 - c. How would you quickly and effectively notify your customers about the situation?
6. Do you have a supplier certification program and/or incoming testing criteria to monitor your received products?
7. At your facility, is there a protocol in place for the handling of samples to be tested? Are microbial tests performed? Is this done internally or by an outside laboratory? How is the frequency of microbial testing determined? Who ensures that the protocols are up-to-date and being followed?
8. Who has the authority to halt production if operations are not in conformance with SOPs? How do you identify laboratory resources identified that have the capability to do advanced pathogen testing to support your firms needs in time of emergency? What arrangements (e.g., with other laboratories) have been made in the event that additional (emergency) product testing is needed?

State, Local, Tribal and Territorial Regulatory

1. If a similar event occurred in your jurisdiction, what would you be doing when you were made aware of the bagged spinach being associated with this outbreak? Are there protocols in place for collaboration with other agencies/entities within your jurisdiction in a food emergency event? Are these protocols communicated to appropriate offices and individuals? How would it work in this scenario?
2. Are there systems in place for communication 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 improvise and conduct communications?
3. What type of communication do you have with local media? Consumers? During an outbreak, what type of communications do you have with your staff? Are all aware of the outbreak and the ongoing investigation?
4. How would the collection of spinach samples from consumers' homes work in your jurisdiction? What agency would collect from the homes of the affected individuals? Which agency would collect samples from the processor or retail/foodservice facilities if needed?
5. If it had taken longer to implicate spinach and consumers no longer had contaminated bags of spinach in their homes, how would this have impacted the investigation? What if the implicated product was loose, not bagged spinach?
6. Once a public notification is issued by FDA, what action does your agency take to amplify and reinforce this message? What are the repercussions if the information is later found to be inaccurate?
7. Once consumers are warned not to consume fresh bagged spinach, is there a system in your jurisdiction to communicate that to the retail and foodservice community, so they stop sale of the implicated product? If so, please describe.
8. Would your organization conduct any verification that the product associated with an outbreak was removed from commerce?
9. Do you have routine periodic contact with your regulated industry to build rapport prior to a foodborne illness incident? Do you have mechanisms to communicate with the produce and retail/foodservice industries to update them during an event like this?
10. 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?

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11. Who maintains a list of legislative and administrative authorities that may be used by your agency in the event of a human health emergency?

Federal Agencies (FDA, CDC)

1. With the contemporary electronic communication systems we have, information is usually widely available to those consumers who have access to it. Does your organization have any other mechanisms to reach the underserved populations who may not have access to electronic media to get information about public health issues?
2. Would the investigation have proceeded differently if the opened bags of spinach in consumers' homes did not yield a positive match for the outbreak strain? How would the investigation have proceeded? What impact would this have on human health?
3. At what point would spinach be declared "safe" again? How is this decision made? How is it communicated?
4. Would this situation warrant the implementation of the Incident Command System (ICS)? What would need to happen in order to initiate this? How could this have changed the nature of the investigation?

Wrap Up Activities

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.

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 to 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. At any point during the investigation did you consider that contamination might have been intentional? How would this have changed the investigation?

Appendix A

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 manual; 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>.

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

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

CDC. Multistate outbreak of *E. coli* O157:H7 infections from spinach.

<http://www.cdc.gov/ecoli/2006/september/>

CDC. Foodborne Outbreak Investigations.

<http://www.cdc.gov/outbreaknet/investigations/investigating.html>

Appendix B

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
DNA	Deoxyribonucleic acid
FAQ	Frequently Asked Question
FDA	Food and Drug Administration
HSEEP	Homeland Security Exercise and Evaluation Program
HUS	Hemolytic Uremic Syndrome
IFT	Institute of Food Technologists
PFGE	Pulsed Field Gel Electrophoresis
SKU	Stock Keeping Unit
SOP	Standard Operating Procedure
TTX	Tabletop Exercise
USDA FSIS	United States Department of Agriculture and Food Safety Inspection Service