Module Objectives

By the end of this module, participants will be able to evaluate the environmental approaches used in an effective foodborne outbreak response.

- Describe environmental assessment as a means to identify contributing factors and their environmental antecedents as part of a foodborne illness outbreak investigation
- Discuss product tracing activities to identify and eliminate foods that may cause foodborne illness
- Explain the control measures available to reduce or eliminate foodborne illness associated with an outbreak
Performance Objectives
By the end of this module, participants will be able to evaluate the environmental approaches used in an effective foodborne outbreak response.

Enabling Learning Objectives
By the end of this module, the instructor shall accomplish the following learning objectives in support of the performance objective:

- Describe environmental assessment as a means to identify contributing factors and their environmental antecedents as part of a foodborne illness outbreak investigation.
- Discuss product tracing activities to identify and eliminate foods that may cause foodborne illness.
- Explain the control measures available to reduce or eliminate foodborne illness associated with an outbreak.

The Environmental Investigator
Of the three core disciplines involved in a foodborne outbreak response, the environmental investigator must shift from a regulatory, inspection-based, mindset to an investigative mindset. They must shift from normal activities while never abandoning the principles that contribute to their success as a food safety professional. On a day-to-day basis, the environmental investigator conducts preventative activities conducting food safety inspections and related duties. These inspections seek to expose hazards throughout the food processing system that, left unchanged, could lead to foodborne illness. These are cross-sectional inspections and may identify risks at the point-in-time of the inspection and expose factors associated with equipment and processes that could lead to foodborne illness into the future. These activities provide a sound basis to understand food safety from a preventative aspect, however, without a change in approach and assistance from the epidemiology and laboratory investigators, and an understanding of the common correlations between causative agents, contributing factors, and food vehicles, their efforts during a foodborne outbreak investigation may fall short of expectations.
During a foodborne outbreak investigation, the environmental investigator’s efforts will focus on the environmental assessment, product tracing activities and will formulate and implement many of the control measures to mitigate the impacts of the foodborne disease outbreak. These three activities are not conducted in a silo and are very interrelated to the environmental investigator.

**Cross-Disciplinary Activities**

- **Epidemiologic Investigator**
  - Focus the epidemiologic investigation
  - Assists with product tracing

- **Laboratory Investigator**
  - Identifies appropriate environmental and food samples for collection and analysis
The environmental investigator can provide valuable insight to the epidemiologic investigator by verifying information collected during case-patient interviews and lead to a better-informed hypothesis during the initial phases of the response. As the response continues, the epidemiologic investigator and the environmental investigator may work together to trace product from the ill person to the source of illness and back up the food supply chain to remove contaminated product from the market.

The laboratory investigator may provide valuable insight to the environmental investigator regarding the collection of food and environmental samples regarding how they should be collected, preserved and shipped.

The Environmental Assessment

The environmental assessment is an activity developed over many years of foodborne outbreak investigation that prompts a change in mindset necessary for an effective investigation.

The FDA identifies an environmental assessment as "an in-depth, multi-disciplinary, systems-based approach to determining how contamination may have occurred, and proliferated so it can be prevented in the future."

https://www.fda.gov/Food/RecallsOutbreaksEmergencies/Outbreaks/ucm235425.htm

The CDC defines an environmental assessment as “the systems-based component of a foodborne illness outbreak response that fully describes how the environment contributed to the introduction and/or transmission of agents that cause illness or could cause illness.”

https://www.cdc.gov/nceh/ehs/nears/ea-definitions.htm

The environmental assessment prompts the investigator to look to the past and piece together evidence that may indicate a causative factor for foodborne illness. As mentioned earlier in this module, the environmental investigator may need to change their mindset in a foodborne disease outbreak but they must bring the “tools of the trade” and apply them in a different fashion.
The regulatory inspection is a risk-based inspection using a defined set of parameters. These parameters generally associate with risk of foodborne illness. If the parameter is met, the likelihood of foodborne illness is low. These inspections are a picture of the operation at a point in time and may, or may not, reveal problems that are ongoing or occur at times other than when the regulatory inspections occur.

Hazard Analysis – Critical Control Point or HACCP was developed in the late 1950’s by the Pillsbury Corporation, the Natick Research Laboratories and NASA. The program was
developed to build quality control into the food products to be used in the manned space program. At its inception, HACCP consisted of three principles that continue to be the core of HACCP effectiveness:

- identification and assessment of hazards associated with food from farm to fork;
- determination of the critical control points to control any identified hazard; and
- establishment of a system to monitor the critical control points.

In the mid-70’s, the FDA incorporated the concepts of HACCP into low acid and acidified food processing regulations and by the late 1980’s, HACCP became the predominate food safety system used in the United States. In 1989, The National Committee on Microbiological Criteria for Foods published the first widely distributed document incorporating the seven principles of HACCP in use today.

The seven principles of HACCP can be found: [https://www.fsis.usda.gov/Oa/background/keyhaccp.htm](https://www.fsis.usda.gov/Oa/background/keyhaccp.htm)

The regulatory inspection and HACCP are described to demonstrate the inherent knowledge that is attributed to the environmental investigator. This skillset is vital to the investigatory process as part of a foodborne outbreak response. It is the mindset of the environmental investigator that must be adjusted to conduct an effective environmental assessment.

Environmental Assessment

![Environmental Assessment](image-url)
The environmental assessment is an analysis, usually retrospective, conducted during a foodborne outbreak response to uncover past events that led to foodborne illness. The environmental assessment identifies the contributing factors that lead to foodborne illness and the underlying reason for the contributing factors.

Contributing Factors

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<th>Contributing Factors</th>
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<td>Contamination</td>
<td>• How pathogens or other hazards are introduced into food</td>
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<tr>
<td>Survival</td>
<td>• How pathogens survive a process to kill or reduce them</td>
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<tr>
<td>Proliferation</td>
<td>• How pathogens in food grow</td>
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Contributing factors fall into three categories. The contributing factor of contamination is the result of a pathogen or other hazard being introduced into a food. The contributing factor of survival occurs when a process that is required to eliminate or reduce pathogens fails. The contributing factor of proliferation is the result of pathogens growing in food and producing a sufficient number of pathogens to cause illness or produce toxin that can
cause illness. Contributing factors leading to foodborne illness may occur at any point along the farm to fork continuum.

Note to the Participants

The CDC offers training to environmental health staff addressing the role of environmental assessments within the broader context of outbreak investigations. The Environmental Assessment Training Series (EATS) can be found at the following web address: https://www.cdc.gov/nceh/ehs/elearn/eats/index.html

Instructional Note

The farm to fork continuum slide sets up the next four slides. Mention to participants that any contributing factor may occur along the continuum and that the next slides will provide examples. The instructor may add to the examples using more recent examples and may call on participants to add examples to the discussion.

Source: https://www.cdc.gov/ncer/ehs/near/ea-definitions.htm
Contributing Factors at the Source

• *Salmonella* Enteritidis in eggs (2010)
• *Cyclospora* in cilantro (2015)
• *E. coli* outbreak associated with romaine lettuce (2018)

**Instructional Note**

• *Salmonella* Enteritidis infection outbreak of 2010 was notably the last major outbreak involving whole shell eggs. 1939 cases in 11 states were reported as associated with the outbreak. Note that the attributed cases that were assigned to this outbreak resulted by subtracting the ongoing background cases observed through the FoodNet reporting system.
• *Cyclospora cayetanensis* outbreak associated with consumption of cilantro in 2015 sickened 546 in 31 states. The highest cases count was in Texas (179).
• A multi-state outbreak of Shiga-toxin producing *E. coli* O157:H7 linked to romaine lettuce in 2018 caused 197 illnesses, 89 hospitalizations and 5 deaths in 35 states. The outbreak was linked to the Yuma growing region of Arizona. There was a similar outbreak in 2012 resulting in 58 illnesses and no deaths. (unpublished information)
The following are some examples of the contributing factor of contamination at the source:

- **Salmonella** Enteritidis infection outbreak of 2010 was notably the last major outbreak involving whole shell eggs. 1939 cases in 11 states were reported as associated with the outbreak.

- **Cyclospora cayetanensis** outbreak associated with consumption of cilantro in 2015 sickened 546 in 31 states. The highest cases count was in Texas (179).

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**Contributing Factors at Processing**

- Listeriosis Linked to Whole Cantaloupes (2011)
- Listeriosis Linked to Blue Bell Ice Cream (2015)
- Multidrug-Resistant *Salmonella* Heidelberg
The following are some examples of contributing factors at manufacturing/processing:

- **Listeria infection linked to cantaloupe in 2011 caused 147 illness in 28 states and resulted in 33 deaths. The FDA and Colorado officials identified multiple places where contamination could have occurred but the most likely cause of contamination of the cantaloupe was a produce washer designed for potatoes.**

- **Listeria infection linked to Blue Bell ice cream was a multi-state outbreak that spanned 5 years. 10 cases were linked to the outbreak and all were hospitalized. Of the ten hospitalized, 3 died. Root cause analysis found that contamination of the ice cream was likely due to contaminated equipment (foodsaftynews.com 2016).**

- **Multistate Outbreak of Multidrug-Resistant Salmonella Heidelberg associated with Foster Farms brand chicken occurred in 2014. 634 cases with a hospitalization rate of 38% was associated with the outbreak. USDA FSIS determined some of the cause of infection was process associated and implemented process control measure have been effective to minimize *Salmonella* contamination of raw chicken (CDC 2014).**
Contributing Factors at Distribution

Salmonella Enteritidis
Infections from Ice Cream

Instructional Note

One of the largest outbreaks in United States history occurred in 1994 and was the result of improperly cleaned and sanitized transport tanks that previously transported unpasteurized eggs. The Schwan’s Salmonella Enteritidis outbreak sickened 224,000 persons. (Hennessy 1996)

Mention that the Food Safety Modernization Act (FSMA) identifies transportation as a major concern and are writing regulations on the “Sanitary Transportation of Human and Animal Food” (Effective June, 2016). This rule is one of seven foundational rules proposed in FSMA to prevent practices during transportation that pose a food safety risk.

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Contributing Factors at Point of Service

- Chipotle Mexican Grill Norovirus Outbreak (2017)
- Chipotle Mexican Grill *E. coli* O26 Outbreak (2016)
- Jack in the Box *E. coli* O157:H7 Outbreak (1993)

Instructional Note

There are numerous examples of contributing factors occurring at the point of service. A recent, very notable outbreak occurred in 2017 at Chipotle Mexican Grill – the pathogen, Norovirus. This was the final outbreak in a series of three outbreaks, the first involving Norovirus and the second involving *E. coli* O26. Several news outlets reported that a self-identified employee stated that the manager of the restaurant in question told employees to work when they were sick.

The *E. coli* outbreak demonstrates the concept of foodborne illness occurring at the point of service even though contamination probably occurred further back in the food supply chain. While the source of illness was never confirmed, the illnesses occurring at several restaurants in several states makes it likely that contamination occurred prior to the point of service.

The 1993 Jack in the Box *E. coli* outbreak is another example of two contributing factors leading to foodborne illness at the point of service. The outbreak sickened over 700 people, leading to 171 hospitalizations and 4 deaths. Contamination of ground beef occurred at five slaughterhouses in the United States and one in Canada. At the point of service, undercooking led to the contributing factor of survival as the corporate people stated cooking to an adequate temperature to kill pathogens made the hamburger meat tough. In the year and one half following the outbreak, Jack in the Box lost approximately $160 million in court and lost sales. (https://billmarler.com/key_case/jack-in-the-box-ecoli-outbreak/)
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Environmental Antecedents

The environment assessment leads to the identification of contributing factors and a food source but does not stop there. The environmental assessment delves deeper into the root cause analysis and tries to understand the underlying reasons for the contributing factors. These underlying reasons are variables within the system that are able or likely to change. When a
variable is not operating as expected, it may lead to a contributing factor and foodborne illness. The variables identified in the environmental assessment process are equipment, economics, processes, food, and people. These underlying factors are environmental antecedents. There may be more than one environmental antecedent leading to the contributing factor causing illness.

The farm to fork continuum upon which our food is delivered for consumption can be looked at as a system. Recall the farm to fork continuum is defined broadly as source, manufacturing/processing, distribution and point of service. At each point, variables are affecting the system, either positively or negatively. Each point can be broken down into the components of: inputs, process, and outputs/outcomes. The process components are where the variables impact the overall system. The system at the point of service, specifically a retail food service establishment, can be described by the following graphic.

The upper part of the graphic represents the components of the system as described above. The outer circle describes the process and the inner circle identifies the variables on the system. If these internal system variables fail, they invariably lead to a contributing factor, oftentimes leading to foodborne illness. These variables are the underlying factors of foodborne illness and answer the question of why a foodborne illness occurred. These underlying factors are environmental antecedents.
Several cases of Salmonella infection have occurred at Restaurant A. Table groups will be assigned a contributing factor of either contamination, survival, or proliferation. Review Slide 7-14. Using the contributing factor assigned, describe two process failures and possible environmental antecedents that would have lead to the contributing factor.

Contributing Factor: CONTAMINATION
Process Failure: STORAGE leading to contamination of lettuce

Environmental Antecedents:

- **Equipment:** Inadequate refrigerators to keep produce away from raw meat.
- **Economics:** Ownership will not invest in providing more refrigeration.
- **Processes:** Raw meat stored over lettuce.
- **Food:** Lettuce have a water activity that supports viability of *Salmonella sp*.
- **People:** Staff not trained as to the proper storage of product under refrigeration.
### ACTIVITY WORKSHEET

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The environmental assessment is a retrospective investigation, a recreation of events that may have led to foodborne illness. The environmental investigator must piece together all available information. The information from epidemiology and laboratory partners provides some of the most important clues to refine the assessment. Understanding the pathogen (laboratory) and associating the pathogen with food (epidemiology) can lead to a more rapid and refined investigation.

During this process the environmental investigator may need to understand food process flow, review records, and obtain information from the responsible party (owners and managers) and other staff through the interview process.

The environmental assessment may lead to the need to collect food and environmental sample. Recall from module 5 that sampling should be the combined decision of the outbreak response team with strong evidence implicating a food or environmental source of contamination prior to initiating sampling.
A food process diagram may be helpful when investigating a complex food or multiple foods sharing the same ingredients. By tracing back from the service through the various processes, observations of people and processes may be identified where a contributing factor occurred. **Investigating at the point of the contributing factor may reveal the associated environmental antecedent.** The environmental investigator must always be aware that the entire farm to fork continuum must be examined during an investigation as one or more contributing factors may occur at any point along the continuum.

Food process diagrams may show the ingredient and where it is inserted in the process (similar to a recipe). Capturing the ingredients will help to ensure that you can get all of the information that the investigator may need for tracing.

The process flow is also helpful in even simple menu items, while the investigator may think a food is prepared one way, by doing the interview with the person responsible for preparing the meal the investigator may find out that they have a completely different process (and the employees process may vary from the manager/chefs process)

Doing this early can also help focus where to do the facility observation, where were the critical control points, where were the potential points of failure, etc.
Reconstructing the flow of food through the food establishment can identify points where a contributing factor(s) may have occurred. Taking a “follow the food” approach will provide a systematic means to evaluate the entire establishment and not overlook an important component of the process. Taking the time to draw the establishment, identify equipment, identify processes and flow patterns can be used by the investigator to verify activities and discuss food processing actions with the person in charge and staff to assist with the investigation. It may be beneficial to involve the food service staff as much as possible during this aspect of the investigation.
Interviewing

The Effective Interviewer

- Informed
- Prepared
- Engaging
- Apply proper questioning techniques
- Avoid leading question
- Avoid bias
- Consider communication barriers

Instructional Note

The instructor should read through the bulleted list and expand on questioning techniques to include bias, the avoidance of leading questions verbal and nonverbal communication patterns. Stress that working with the outbreak response team will enhance the interview process.

Mention that these interview skills can be used for the person-in-charge or line staff. Ask participant to consider the interviewing video in Module 6 and see if the epidemiologic interview techniques have relevance when conducting an interview associated with the environmental assessment or other environmentally-related activities. Many are the same.

Observations made during the field visit may provide information regarding the facility and the processes observed but it will fall short of drawing the inferences necessary to piece together what may have happened in the past to result in foodborne illness. The ability to effectively interview the person(s) in charge and other staff will provide a more robust picture of the events that occurred in the past. Interviewing is a skill, inherent in some and gained through study and practice in others. An effective interviewer will possess the following attributes:
• They are informed. The effective interviewer understands the situation and is able to describe the situation to others. They are informed by the other disciplines on the team and are ready to share appropriate information.

• They are prepared. The effective interviewer reviews the questionnaire to be used and practices questioning with team members.

• They are engaging. The effective interviewer is able to draw in the person being interviewed and build a rapport and credibility. They make sure that the person being interviewed understands the importance of their information. They are not judgmental or accusatory. They explain that the interview is part of a larger investigation and that no conclusions have been made that implicate their facility or a food prepared therein. They remind the person being interviewed that the purpose is to identify where the system failed and develop interventions to keep it from happening again, whether or not the system failure was at the facility or from a distributor or processor.

• They avoid leading questions. The effective interviewer avoids questions that prompt the “proper” response. They may ask the respondent to demonstrate their response at the point in the facility in question.

• They apply proper questioning techniques. There are various ways to interview and applying the proper questioning will be helpful in gaining useful information. Interview questions may be open-ended or closed-ended. Open-ended questioning may be applied when a process is to be explained. Closed-ended questions are effective in verifying information.

• They avoid interviewer bias. They apply this strategy to verbal and nonverbal communications. They are aware of the tone of their voice as well as physical expressions that may indicate negative feeling towards the interviewee.

• They consider communication barriers prior to engagement. They use interpreters as necessary and understand cultural characteristics of the interviewee and adjust their interview accordingly.

Field interviews may provide a brief window to capture some of the most valuable and telling data. Be prepared to interview at the onset of the environmental assessment. Keep questions very open and general and be personable and friendly. Authoritative, stern or confrontational demeanors will limit good interview data. The time for regulatory actions, control measure implementation or critique will take place later during the process and should be avoided during the interview process. Interviews with employees should be in absence of the manager, if possible. Take detailed notes during interviews to avoid ambiguity when compiling the results of the interviews.

The effective interview is a means to fill in the gaps of information necessary for a proper response. Working with your response team members to build an understanding of the situation will assist the environmental investigator with their responsibilities to the team. As mentioned prior, interviewing is a skill, inherent is some and gained through study and practice in others. The team should pick the person with the knowledge, skills, and attitude to conduct an effective interview, regardless of tenure or leadership position.

**Reporting**

When the outbreak is over, the work of the outbreak response team is not. Reporting the outcomes of the investigation is an important task that must not be overlooked. The reporting
process is initiated by conducting or participating in a debriefing session with other members of the investigation team.

All members of the outbreak investigation team should be debriefed about the results of the investigation. The complexity of the debriefing depends on the size of the outbreak. For a small outbreak associated with a single facility or event, a conference call may be sufficient. For a large outbreak involving multiple agencies, a more formal debriefing meeting is appropriate.

Module 10 discusses the reporting process in depth but it is important for the environmental investigator to contribute the following to the report:

- Background of the outbreak
- Environmental assessment investigation and results
- Information from interviews, observations, sampling and records review
- Food flow/process diagrams
- Conclusions and findings, including contributing factors and their environmental antecedents
- Recommended control measures
- Follow-up assessment of the effectiveness of the control measures in affecting the establishment's food safety set point, and
- Recommendations for outbreak investigation improvement to enhance future outbreak investigations

Lastly, environmental assessment data collected as part of the outbreak investigation should be reported to CDC’s National Environmental Assessment Reporting System (NEARS). NEARS is a companion surveillance system to the National Outbreak Reporting System (NORS); it captures environmental assessment data from foodborne illness outbreak investigations to improve your food safety programs. For more information please visit https://www.cdc.gov/nceh/ehs/nears/index.htm.
Product tracing, oftentimes referred to as traceback and trace forward, is an effective tool to support the foodborne outbreak response team. It may be used as investigation tool or a regulatory tool but the concept of operation is the same, the initial outcomes may differ but generally lead to removal of food from distribution. In either case, product tracing can be resource intensive. Compelling evidence, including an assessment of risk, should drive the use of product tracing. The environmental assessment process and product tracing are closely tied together during an outbreak investigation. The next sections will break down the triggers for both type of product tracing.

**Instructional Note**

Mention to participants that product tracing is a tool to trace product throughout the food chain and historically and conventionally, traceback and trace forward have been used to describe the activity. Each type of product tracing will be discussed in more detail as we move through the section. Make sure they understand that each tracing effort is looking for an implicated food and these activities may overlap- hence the use of the Venn diagram.
Investigational product tracing is generally initiated by the epidemiologic investigator and involves tracing products consumed by the case-patient to a common food exposure. It may be used early on in an investigation to aid with hypothesis-confirming activity. It may be as simple as verifying a food source and a point of service or as complicated as tracing back from a case-patient to a point of service, to a distributor, transporter, repacker, processor and a source. Investigational product tracing can add a level of specificity to the epidemiologic investigation when no other epidemiologic tool is available. An example of this is when a commonly-consumed food is identified through epidemiologic association from multiple points of service. Product tracing can first identify a brand of food and then trace it to a common source.

Product tracing to support an epidemiologic investigation should be considered for the following reasons:

1. There is strong laboratory evidence that a cluster of cases likely represents a common source outbreak with multiple points of service identified.
2. Epidemiologic association are identified with one or more commonly consumed food(s) that are available from multiple sources, and case-patients have limited recall regarding brands consumed.
3. The food source cannot be clearly implicated by traditional laboratory, epidemiologic or environmental investigation methods. A borderline statistical association may exist but a small number of cases may preclude further epidemiologic study.
This slide is an example of an investigational product tracing that led to the identification of organic basil as the food vehicle in a *Cyclospora* outbreak. A small sample size identified strawberries, cilantro and basil as possible food sources linked to infection. Discussions with grocery store owners, restaurant managers and distributors were able to trace food items back to suppliers of one of the implicated foods leading to identification of basil. The product tracing investigator must understand that it may require going back several steps to identify the convergence.

Source: Shih et al. (2009)
As the name denotes, this type of product tracing is a function of the regulatory/environmental discipline of the foodborne outbreak team. From a regulatory aspect, **tracing is conducted back to the source of the contributing factor leading to foodborne illness and identify product to be removed from distribution.** From the identified point of the contributing factor, the product is **traced forward to identify all points where recall activity is necessary.** Additionally, finding the source of the outbreak, and conducting an environmental assessment to discover the root cause(s), may lead to institutional controls necessary to eliminate further outbreaks of a similar nature.

As mentioned, product tracing is generally a difficult task as it takes resources to review records and interview responsible persons to gather the necessary information to find the source of the outbreak and the distribution of product and mitigate the impacts of the outbreak. Time is certainly a factor. The team must move fast to identify the source and eliminate the food from consumption. Moving rapidly is important as recall wains with time and records are discarded.
Product tracing investigations do not always lead to finding the source of the outbreak. The following slide will demonstrate:

**Instructional Note**

To reinforce the concept stated above, mention to participant of the economic principle of good-fast-cheap. Put the terms on a white board with each word in the corner of a triangle. Tell the participant to pick two as you cannot have all three. A project can be good and cheap but it will not be fast. A project can be fast and cheap but it will not be good. Finally, a project can be fast and good but it will not be cheap. This principle holds for the product tracing investigation. If you want it done fast with good results, it will not be cheap as it takes a lot of person-power to conduct the activity.
This slide is an actual draft product tracing schematic of the *E. coli* O157:H7 outbreak involving consumption of romaine lettuce grown in the Yuma growing region of Arizona. 197 cases were identified in 35 states. Associated with this outbreak were 89 hospitalizations and 5 deaths. No recall ever occurred. Product was traced from 15 points of service through 9 distribution centers.
to 3 processors involving 19 farms and multiple growing fields. The exact source of the outbreak was never determined.

**Product Tracing Diagram**

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Would You Initiate Product Tracing? Why?

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**Factors Influencing Product Tracing**

Product tracing may occur on a limited basis at the local jurisdictional level without much or any involvement from state or federal partners. This may occur sporadically but may be the result of an outbreak from locally-sourced foods. Product tracing generally occurs as the result of multijurisdictional outbreak response where the implicated food is identified. In either case, product tracing should not be initiated without the timely collection and evaluation of epidemiologic data. There should be compelling reasons to initiate product tracing and determinations should be made by epidemiology and regulatory/environmental partners throughout the food safety system. Prior to product tracing initiation, environmental team members should ascertain if records are available. Involving the regulatory/environmental agency associated with food safety inspections of the identified establishments is important due to their familiarity with the identified facilities. They understand the operation and will know about their record-keeping practices. Some challenges with product tracing are provided on the upcoming slide. These challenges are universal and early identification may lead to system change.
As previously mentioned, lack of timely information may preclude effective product tracing. Pathogen-specific surveillance can take time to acquire and epidemiologic information attained through interviews may add to the length of time between onset of symptoms and action. The longer the period of time to act will result in lost data due to lack of recall in case-patient and loss of information by the industry.

There is an inherent barrier to providing information by the industry when the result of the product tracing may implicate their facility/operation. It takes a skillful interviewer to work through this challenge or a competent attorney.

Successful product tracing takes the collaboration of many agencies and personnel. These agencies may have competing priorities, resource constraints and varying levels of experience conducting product tracing activities. Furthermore, some agencies may not wish to engage in these activities as they may lack the relationships with state and federal agencies or they feel that the small number of cases in their jurisdiction does not warrant their involvement.

As identified in the last product tracing diagram associated with the E. coli outbreak, a lack of records may lead to less than desirable information. Recall could be unpredictable when a lot of time has passed or implication of the facility may have a negative impact of the facility.

The inability to share records between regulatory agencies may pose a significant problem. An example of this is the FDA inability to share records outside of their agency. Without proper credentialing by other agencies working with the FDA sharing of information is precluded.

Comingling of foods can make a difficult product tracing activity impossible. This may occur at the point of service or further down the supply chain. Furthermore, some foods are
considered stealth as recall of consumption is lacking if the food ingredient is not evident. Spices are a stealth food.

Promising Practices in Product Tracing

Promising Practice - Blockchain

- Distributed ledger technology that allows all members of a supply chain to record transactions in a decentralized data log maintained on a network of computers, rather than a physical ledger or a single database.
- Early adopters include Walmart, Kroger, McCormick and Company, Tyson Foods, Nestlé and Dole.
- United Arab Emirates

As was evident in the 2018 Romaine lettuce outbreak, product may be difficult to trace utilizing outdated methods of tracking foods along the food chain. A new and innovative means of tracking food may come from the use of Blockchain technology. **Blockchain is a distributed ledger technology that allows all members of a supply chain to record transactions in a decentralized data log maintained on a network of computers, rather than a physical ledger or a single database.** IBM is working with a number of food companies to incorporate Blockchain to track foods. Kroger, McCormick and Company, Tyson Foods, Nestlé and Dole are some of the companies working with IBM to implement distributed ledger technology. ([https://www.ibm.com/blogs/blockchain/2017/09/ill-only-eat-blockchain-cereal-with-a-food-safety-label-on-the-box/](https://www.ibm.com/blogs/blockchain/2017/09/ill-only-eat-blockchain-cereal-with-a-food-safety-label-on-the-box/)) As of November 2017, the United Arab Emirates (U.A.E.) is moving towards the regulatory adoption of Blockchain to track foods.
Control Measures

Factors to Consider:

- Virulence and Pathogenicity of the Foodborne Illness Agent
- Population Susceptibility
- Number of Cases Involved
- Economic Impact
- Political Considerations

As the source(s) of foodborne illness are identified by the response team and the contributing factor(s) attributed to the illness recognized, their focus shifts from investigation to control of the outbreak. There are many ways to control an outbreak but, first and foremost, the controls must fit the circumstances of the outbreak. Factors that must be considered include, but are not limited to the following:

- The virulence and pathogenicity of the agent causing illness must be considered. Is immediate intervention necessary because the outbreak is caused by a highly pathogenic microorganism known to cause death or serious complications; or a highly virulent microorganism, easily spread and likely to be a source of secondary infections in the community?
- Are there susceptible populations involved? Are there clusters of foodborne illness in institutions with the elderly or immunocompromised individuals?
- The number of cases involved. Is the impact of the outbreak overwhelming by the sheer number of people involved irrespective of the pathogenicity and/or virulence of the agent causing disease?
- Will control strategies have a far reaching economic impact? This is not to mean that actions should be based on economics, but certain control strategies may be non-specific and when implemented they may impact other industry partners without implicated foods. This concept will become more evident further along in this section.
- Are political considerations impacting implementation of controls? Simply put, politics occur when you choose your actions to exert influence. During a foodborne outbreak response, there are many parties that may want to influence team actions. Certainly, the food purveyor directly associated with the implicated food will attempt to influence what control strategies are implemented. Cases associated with the outbreak as well as others that are peripherally associated may try to exert influence on control strategies.
Categories of Control Measures

There are four broad categories of control measures implemented by outbreak response teams. Any control measure contemplated should be measured by the entire response team and consequences for action considered prior to implementation. The four broad categories of control measures are:

- Notification
- Removal of food from distribution
- Exclusion/Restriction of ill food workers
- Prophylaxis

Each of these control measures will be discussed in depth in the following sections. Foodborne disease outbreak falls into two general, and oftentimes interrelated categories, each requiring specific control measures. Retail food service establishments (point of service) are one generally-recognized source of outbreaks, the other source are those originating from commercially-distributed foods further up the supply chain. Furthermore, recall from module 2 that there are numerous agencies involved in foodborne outbreak response/control and this creates a complex matrix of accountable agencies that may be responsible for implementing controls.
Notification can be a powerful method to stop the consumption of a suspected or identified food associated with foodborne illness. This control measure may occur at any level of government and should follow the response pattern. That is, if the sole responder is a local public health agency, notification should occur at the local level. If a multi-jurisdictional outbreak is occurring within a single state or if a state-level public health agency is coordinating the response of many local public health agencies, it may be preferred to have the state agency deliver notification.
Likewise, if a federal agency is coordinating the response, it may be preferred to have a coordinated notice emanating from the federal agency. Since all outbreaks have a local response component, notification should always include a local component, or, at least the local jurisdiction should be afforded the opportunity to provide notification.

At the local and state level, a public health agency or food regulatory agency may provide notice in the event of a foodborne illness. The local authority should only provide notice when there is clear and convincing evidence of ongoing threat of illness associated with the outbreak. Information must be based on sound risk characterization and messaging should employ risk communication strategies to convey the message to the public. At the local level of government, messaging may be unstructured due to the lack of clear policy establishing triggers for specific controls as compared to some state and all federal agencies. Therefore, it is important to involve the entire team when compiling information for notification and to utilize a trained PIO to create the message. Communication strategies will be discussed in Module 9.

The three primary federal agencies involved in foodborne outbreak response have very structured approaches with public notification.

The CDC’s Health Alert Network (HAN) is the primary method of sharing cleared information about urgent public health incidents with public information officers; federal, state, territorial, tribal, and local public health practitioners; clinicians; and public health laboratories. A structured, hierarchical approach of four tiers is utilized as follows:

- **A Health Alert** provides vital, time-sensitive information for a specific incident or situation; warrants immediate action or attention by health officials, laboratorians, clinicians, and members of the public; and conveys the highest level of importance.
- **A Health Advisory** provides important information for a specific incident or situation; contains recommendations or actionable items to be performed by public health officials, laboratorians, and/or clinicians; may not require immediate action.
- **A Health Update** provides updated information regarding an incident or situation; unlikely to require immediate action.
- **An Info Service** provides general public health information; unlikely to require immediate action.

The information provided herein and additional information regarding the HAN network may be found at: [https://emergency.cdc.gov/han/index.asp](https://emergency.cdc.gov/han/index.asp).

The CDC also maintains a secure, web-based communications network that serves as a powerful communications exchange between CDC, state and local health departments, and other public health professionals. Epi-X (epidemic information exchange) provides rapid reporting, immediate notification, and coordination of health investigations for public health professionals. This platform is used by over 1200 public health professionals in support of disease investigations to coordinate response. Epi-X is a secure network and is not used for notification to the public but it can coordinate information and lead to more consistent messaging regarding foodborne outbreaks.

The FDA may issue safety alerts and consumer advisories in conjunction with the foodborne outbreak response. The safety alert often will accompany a recall of a food – whether it was voluntary or on the advice of the FDA. The FDA refers to this as a “public warning” when recall is necessary due to an emanate health threat associated with a product recall. Consumer advisories may be issued with or without product recall and may be issued when there is strong
suspicion that a food is associated with an outbreak. The USDA-FSIS, the FDA’s regulatory counterpart will follow roughly the same notification procedures.

At the federal level, the CDC, FSIS, and FDA work many of the multistate outbreaks cooperatively. These collaborative efforts generally bring input from all three core disciplines to formulate notification. This collaborative system may be challenging at times but federal partners understand the significance of working together to provide public notice.

Instructional Note

Remind participants that not all consumer advisories have positive outcomes. An example of this was a Salmonella Staintpaul outbreak investigation in 2008. Early on in this investigation it appeared that contaminated tomatoes were the likely cause of the outbreak and the FDA issued a consumer advisory not to eat tomatoes. As a result of the advisory, illness declined but continued. The tomato industry demanded that their product be cleared from implication as it was unlikely that all tomatoes could be causing illness and more specificity to the consumer advisory regarding where product originated. The FDA did modify the advisory to exclude some growers but many of the regions that were cleared were not growing tomatoes during the presumed exposure period.

Additional investigation implicated Serrano and Jalapeno peppers but it took nearly a week for the FDA to remove the consumer advisory on tomatoes. The CDC and FDA defended their position on the advisory as many of the cases reported eating red salsa and peppers were initially overlooked as a potential cause of foodborne illness. To add to the problem, the FDA's hunt for contaminated tomatoes was hampered by poor record-keeping and the common practice of mixing and processing tomatoes from many different farms together as quoted from a Wall Street Journal article (https://www.wsj.com/articles/SB121677198766575559). This notice, initially implicating tomatoes, resulted in hundreds of million dollars lost by the tomato industry.
Food may be removed from distribution using a variety of methods at each level of government. An embargo or hold may be initiated by a regulatory agency to temporarily detain a product suspected or capable of causing foodborne illness. This detention of product may occur as part of the regulatory inspection process or as part of the environmental assessment. Authorities to detain foods may range from front-line inspectors to court orders, depending upon agency or jurisdiction. In the case of the FDA, the determination to detain product is a regional director’s action and may occur rather quickly.
Another widely known method to remove product from distribution is product recall. Product recall is an activity under the auspices of the FDA and its counterpart, the USDA-FSIS. There are two types of voluntary recall, the firm-initiated recall and the FDA-requested recall. Recalls under FDA jurisdiction are guided by the Code of Federal Regulations - 21CFR7.45. The firm-initiated recall is a consultative process with the FDA and the removal of food from distribution will be considered a recall only if a violation of the federal code is involved.

A FDA-requested recall is seldom used but may be necessary to protect the public’ health in situation where a firm-initiated recall was warranted but not established. The Commissioner of the FDA or their designee will request a firm to initiate a recall when the following determinations are made:

- That a product that has been distributed presents a risk of illness or injury or gross consumer deception.
- That the firm has not initiated a recall of the product.
- That an agency action is necessary to protect the public health and welfare.

Instructional Note

As this slide is reviewed mention that the first time a mandatory recall has occurred is with a product called kratom. In April 2018, and as the result of repeated efforts to have Triangle Pharmanaturals issue a voluntary recall, the FDA ordered a mandatory recall of products containing powered kratom manufactured, processed or packed by Triangle Pharmanaturals. A citation is provided in the manual.
FSMA provided the FDA with mandatory recall authority and, until April, 2018, this authority was not used. In April 2018, and as the result of repeated efforts to have Triangle Pharmanaturals issue a voluntary recall, the FDA ordered a mandatory recall of products containing powered kratom manufactured, processed or packed by Triangle Pharmanaturals.

(https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm603517.htm)

All recalls conducted under the FDA Codes are provided the following classifications:

1) Class I is a situation in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious adverse health consequences or death.
2) Class II is a situation in which use of, or exposure to, a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote.
3) Class III is a situation in which use of, or exposure to, a violative product is not likely to cause adverse health consequences.

The FDA has established regulatory procedures for monitoring and auditing recall effectiveness. The recall and its effectiveness is the responsibility of the firm. In certain circumstances when the circumstances require an all-out effort, the FDA will directly assist with recall efforts and enlist the support of their state local partners. Recall audits are conducted on most Class 1 recalls and are assigned at the monitoring district level of the FDA.

Another action to remove product from distribution is the issuance of a cease and desist order. This is usually an administrative or judicial order halting the manufacture, processing or distribution of a food product.

**Facility Closure**

Facility Closure

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<th>Broad Public Health Power - State and Local Public Health</th>
<th>Regulatory Powers – State Public Health and Agriculture</th>
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<td>Administrative Order Suspending Registration – FDA</td>
<td>Revoke Grant of Inspection – FSIS</td>
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<td><strong>Closure Procedures</strong></td>
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The most severe means of removing food from distribution is facility closure. Most, if not all state and local jurisdictions have authority to close facility. Specific food regulatory codes may exist or general broad powers of public health agencies may be employed to close facilities.

The federal government agencies utilize specific measures to close facilities. The FDA and USDA-FSIS use a process to revoke operational approval as a means of closing all or part of a facility.

A Federal Grant of Inspection is an authorization issued by the USDA-FSIS to allow the operation of a facility under their jurisdiction and authorize inspection activity by USDA-FSIS employees. If facilities fail to comply with the standards set by the FSIS, the Administrator may file a complaint and request to revoke the Grant of Inspection. Without the Grant of Inspection, facilities may not continue to operate.

The FDA uses a similar system. The FSMA requires that facilities engaged in manufacturing, processing, packing, or holding food for consumption in the United States submit additional registration information to FDA, including an assurance that FDA will be permitted to inspect the facility at the times and in the manner permitted by the Food, Drug and Cosmetic Act. Renewal of the registration is required every-other-year. If FDA determines that food manufactured, processed, packed, received, or held by a registered food facility has a reasonable probability of causing serious adverse health consequences or death to humans or animals, the FDA may issue an administrative order to suspend the registration. Without registration a facility may not continue to operate.

Restriction or Exclusion of Ill Food Employees

Exclusion and restriction of food employees from any possibility of contaminating food is a well-known and effective method of control. Persons with an enteric illness can shed viruses,
bacteria, or parasites for weeks after symptoms end. Infected skin lesions can be a reservoir for pathogens and their toxins and can be transmitted to food through improper hygienic practices.

Identification of ill food employees may come from a variety of mechanisms. Medical care providers, with or without laboratory confirmation, may diagnose a person with reportable enteric illness and notify the public health system. Notification can be expedited if the medical care provider has knowledge of the cases employment and understands the importance of exclusion in preventing additional illness.

Ill food employees may be identified through the environmental assessment process, especially with certain foodborne diseases well known for being transmitted by ill food handlers such as Norovirus and *Staphylococcus* food intoxication. Environmental investigators must be well-trained in questioning skills and observant to pick up on the activities and characteristics of employees working while ill.

Food establishments with a strong culture of food safety may have a high preponderance of employees self-reporting illness. FDA has developed and guidance for food establishment managers and staff to encourage practices that minimize the opportunity for food employees to contaminate food due to working while ill. The Employee Health and Personal Hygiene Handbook is provided through the following link: https://www.fda.gov/downloads/Food/GuidanceRegulation/RetailFoodProtection/IndustryandRegulatoryAssistanceandTrainingResources/UCM194575.pdf.

This is a Handbook and only provides guidance of what to do in the event an ill food worker self-reports or is observed by a manager. **Specific model regulation is found in the FDA Food Code under employee health.** Restrictions and exclusions for specific disease and population groups have been developed. (https://www.fda.gov/downloads/Food/GuidanceRegulation/RetailFoodProtection/FoodCode/UCM374510.pdf)

The **food code is a model regulation and must be adopted by either federal, tribal, state or local authorities to have the effect of law.** Participants are urged to review their regulations to understand the exclusions and restriction available to minimize the contamination of food or the spread of secondary infection to others. At the local level, public health entities may have broad policy to protect the public’s health. Restriction and exclusion decisions should be made with the input of the outbreak response team, including leadership and legal, as each outbreak is unique and a “one size fits all” approach will generally not be appropriate.
Some regulatory periods are extremely restrictive and require a medical care provider be part of the process. An example of this would be the requirement of two “clear” stool samples prior to returning to work. Other exclusion or restriction periods do not follow such restrictive guidelines. Exclusion of food workers with Norovirus infection for 48 hours after symptoms stop is a good example of this occurrence. It places considerable responsibility on the employee. Also, many have noted that Norovirus may be shed in the stool for 21 days or longer in asymptomatic persons.

Post-Exposure Prophylaxis

With certain foodborne illnesses, especially with Hepatitis A virus (HAV) infection, controlling the spread of disease requires post-exposure prophylaxis of persons exposed to a food contaminated with HAV or to a food handler known to be infected with the virus. **Timely**
epidemiologic investigation and product tracing investigations to determine where and when contaminated products were sold is necessary to identify exposed cases and to administer either HAV vaccine or immune globulin (IG) within two-weeks of consumption. Whether vaccine or IG is administered is dependent upon the cases age and condition and the availability of the prophylactic agent. **Risk communication may be necessary** to alert the public of possible exposure.

Set up processes with area hospitals, physicians, local health departments, specialty clinics, or other healthcare providers to provide prophylaxis at **point of dispensing (POD)**. Have tested plans in place for large-scale prophylaxis. During preparations of public communications about prophylaxis, consider the number of people likely exposed and the anticipated response to the prophylaxis offer when planning, including community medical staff, vaccine/product supply, crowd control management, and health department phone staffing.

**Summary**

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<thead>
<tr>
<th>The environmental assessment is a means to identify the contributing factors and their environmental antecedents as part of a foodborne illness outbreak investigation</th>
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<tbody>
<tr>
<td>Product tracing activities can identify and eliminate foods that may cause foodborne illness</td>
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<td>Control measures may reduce or eliminate foodborne illness associated with an outbreak</td>
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Coming Up Next

Multistate and Complex Outbreak Investigation