

Control Measures and Prevention

CHAPTER SUMMARY POINTS

- Effective control measures include a combination of immediate controls to stop the current outbreak and longer term controls to prevent future outbreaks.
- Effective and timely information sharing among investigation and response partner agencies, impacted food industries, and the public is essential to control foodborne illness outbreaks.
- Appropriate control measures vary depending on whether the implicated food was contaminated
 - At a single local food-service or retail food establishment, or
 - Before being commercially distributed.
- Three strategies used to stop foodborne illness outbreaks are
 - Controlling contaminated foods at their source.
 - Controlling contaminated food products that have left the source (e.g., recalls).
 - Preventing secondary spread of infection.
- To identify appropriate control measures, information from different sources, such as epidemiology, laboratory, and environmental health should be integrated into the outbreak response.
- General control measures are often followed up with more specific controls as investigators learn more about the source(s), contributing factor(s) and root cause(s) (i.e., antecedents, underlying reasons) of the outbreak.
- Investigation and control teams should use the after-action review processes to:
 - Assess the strengths and limitations of past responses.
 - Identify action steps to improve future responses.
 - Track corrective actions using the organization's continuous process improvement programs.
 - Prevent outbreak recurrence by applying lessons learned regarding root cause and contributing factors.
- Foodborne illness investigation reports are used to accurately document actions and conclusions to improve future investigation practices and make changes to prevent future outbreaks.

6.0 Introduction

6.0.1 The purposes of outbreak investigations are to stop the current outbreak, determine how contamination occurred, and implement measures to prevent future outbreaks by addressing the root cause(s) in the implicated, and potentially other, facilities. Whereas the investigation is critical for understanding the cause, effective and timely control measures are critical for stopping the outbreak and preventing reoccurrence of illness. Identifying the root cause(s) of foodborne illness improves the effectiveness of prevention efforts.

The rapid and accurate response to foodborne illness is critical.

Investigators from all three primary disciplines (epidemiology, environmental health, and laboratory) must quickly assess information and identify suspected foods or facilities to prevent additional illnesses.

There are generally two types of foodborne disease outbreaks, and each requires different control measures.

- **Local outbreaks** may be associated with food-preparation errors or contamination of food by food workers at the site of preparation or distribution, e.g., foods prepared at home, food-service, and retail food establishments. Local outbreaks typically are controlled through local actions.

- Outbreaks associated with contaminated **commercially distributed foods** may originate from a commercial food manufacturer or agricultural commodity distributed to multiple sites. The resulting foodborne illness may be linked to a variety of food establishments or to foods prepared in the home. These outbreaks are usually multijurisdictional and require coordinated intervention by local, state, territorial, tribal, and federal agencies and the industry.

6.0.2 Effective communication between team members and with other response partners is essential during all phases of the investigation to ensure opportunities to quickly implement or improve control measures are not missed. The exchange of specific actionable information is paramount to success. Communication within the response team and with other stakeholders during an outbreak response is of primary importance. For all foodborne illness outbreaks, early sharing of information between epidemiologists, laboratory staff, and environmental health specialists is critical to determine what control measures to implement to prevent foodborne illness. Timely food-supply investigations, such as product tracing and environmental assessments, can better define the food vehicle(s) that need to be controlled and identify the contributing factors and environmental root causes that led to foodborne illness (Chapter 5).

6.1 Information-Based Decision Making

6.1.1 Investigation and control teams should be prepared to act at any point in the investigation when credible information identifies opportunities to control or mitigate disease transmission. Controls can be implemented concurrently with product tracing (i.e., traceback,

traceforward) investigations, environmental assessments, or other investigative processes. Waiting for laboratory results, medical diagnosis confirmation, or implication of a specific food may not be necessary before implementation of initial control measures to prevent additional exposures.

6.1 Information-Based Decision Making

Control measures typically progress from general to specific as investigations gather more information and should be implemented immediately whenever their need becomes apparent. General precautionary control measures that have high potential for public health benefit and low impact on business operations are usually not controversial and can be implemented relatively quickly in the field by the regulatory authority. Examples include holding a suspected nonperishable food from sale or screening for and excluding an ill employee. Decisions to implement more costly controls, such as recalling a food from distribution or closing a facility, should be based on clear and convincing evidence that food from the facility caused illness or that an imminent hazard to health exists. These decisions should involve input from the entire response team, including risk communication specialists and legal advisors (Chapter 2). Depending on the complexity of the outbreak, input from federal agencies, trade associations, or other industry and academic experts may be necessary.

6.1.2 Investigation and control teams should use a systematic process to evaluate information and regularly reassess control measure decisions. Sometimes the type of control measures needed to stop an outbreak is readily apparent early in the investigation (e.g., significant food temperature or risk factor violations). More commonly, however, key information is initially unavailable about the source, contributing factors, and root causes of foodborne illness outbreaks.

Typical steps in the evaluation include the following:

- Send a team to the likely source as soon as possible.
- Inform and involve the owner or manager of the implicated establishment.

- Assess potential risks on the basis of information provided by each discipline.
- Assess availability of resources needed to implement controls (e.g., legal authorities, equipment, and staff).
- Identify priority control measures, and clarify expectations among team members about the timeliness and completeness of control efforts.
- Implement control measures.
- Reassess and adjust control measures as additional information is gathered.

The quality of information is related to multiple factors (Chapter 5). Evaluate epidemiologic, laboratory, environmental health, and other evidence together to determine the degree to which the integrated data are consistent with each other, biologically plausible, and sufficiently strong to support implementation of control measures.

6.1.3 Investigation and control teams must balance the likelihood that control measures will prevent further illness against other consequences (Box 6.1).

Inaction or delayed action in the face of ongoing exposure can result in additional illnesses. Conversely, aggressive control interventions, such as recalling food or closing a food establishment, can have legal or economic consequences for food workers, employers, communities, and entire food industries. Investigation and control team members should not delay initiating steps to protect public health if available information indicates the need to act.

6.1 Information-Based Decision Making

Box 6.1. Questions to Address when Considering Control Options

- Is the contaminant causing the disease highly pathogenic, virulent, or toxic? Are susceptible populations exposed?
- Is the causative microorganism highly infectious and likely to be a source of secondary infections in the community?
- How effective, and how costly, is the proposed control measure likely to be?
- Who would play a role in implementing the control (government agency, food industry, or others)? What information will they need to act?
- Is a narrow, focused action possible—such as recalling a specific group of products or notifying only the persons most likely to have been exposed—rather than a more general recommendation to avoid consuming a general category of food or notifying the public?
- Will the actions affect only one business or an entire industry? How much economic or operational burden will be placed on the public who will need to respond on the basis of the proposed action?
- As they ponder these questions, investigation and control team members must recognize that a rapid response is critical if the threat of serious illness and death is ongoing.

Studies not associated with current investigation.

6.2 Communications With the Public

Agencies should anticipate, prepare for, and allocate resources to respond to and manage public concerns related to any public health messaging about the investigation. All members of the outbreak investigation and control team (epidemiology, environmental health, and laboratory) and health department leadership should provide input into the decision to make a public notification (Box 6.2)

6.2.1 Messages to the public about foodborne disease outbreaks should follow best practices for risk communication and provide objective, fact-based information about the outbreak.

- Ideally, before an outbreak occurs, prepare templates for public messages and have them reviewed by appropriate staff, including legal counsel. Use the templates consistently during the investigation. For examples of communication templates, see the CIFOR Clearinghouse (<https://cifor.us/clearinghouse/cifor-toolkit-focus-area-3-communications>).
- Follow agency communication protocols. Prepare communication following the agency's risk communication protocols. Seek assistance from the agency public information officer or the public information officer at another agency if the agency with jurisdictional responsibility does not have this resource.
- Provide information about the disease, including symptoms, mode of transmission, prevention, and actions to take if illness occurs.
- Include information about what is known, what is not known, and what officials are doing to learn more.
- Do not speculate about the outbreak. Sharing preliminary or unconfirmed information with the public may result in undue worry if there is no definite action to be taken (i.e., avoidance of a certain food). Such announcements often result in inquiries from concerned citizens and the media, and the resulting expanded workload can rapidly

6.2 Communications With the Public

Box 6.2. Questions to Address when Considering Whether Public Notification is Necessary

- What is the potential severity of disease and risk for additional illnesses (e.g., secondary infections in the community)?
- Is medical treatment necessary for persons who might have been exposed to the etiologic agent? If so, urgent public notification is critical.
- Is public reporting of suspected illness necessary to determine the scope of the outbreak? If so, public notification might be appropriate.
- Does risk for exposure still exist? People take food home from restaurants, so public notification still might be appropriate.
- Are large numbers of unknown persons likely to be ill with highly infectious agents, such as norovirus or *Shigella*? If so, an advisory that ill persons should stay out of work or restrict activities may help prevent secondary transmission at other food establishments, day care, and healthcare facilities.
- Is the source of the outbreak past its shelf life so no further risk exists to the public? If so, public notification may not be needed.

divert resources from the investigation and control team and increase pressure to quickly name the source of the outbreak.

- Ensure that officials prepare talking points to respond to media inquiries and social media questions, if needed. The Colorado Integrated Food Safety Center of Excellence developed the Communications Toolkit: Media Relations to help agencies work constructively with the media during foodborne illness outbreaks (1).
- Work closely with public information officers to ensure that consistent messaging is used to answer inquiries. This collaboration can reduce the potential for confusion or panic among consumers and industry.
- Maintain effective, accurate, and consistent communication with other agencies (i.e., local, state, territorial, tribal, and federal) involved in, or impacted by, the investigation.

6.2.2 Notify the public when actionable information is available that the public can act on to prevent additional illness (Box 6.3). Attempt to reach all members of the population at risk, including non-English-speaking and low-literacy populations.

- Means of notification depend on the public health risk and the target population and might include press releases, radio, television, fax, telephone, text messaging, email, Web posting, social media, or letters.
- Provide clear and actionable information about how to handle a suspected product (discard, special preparation instructions, or return to place of purchase) or whether the local jurisdiction is interested in obtaining the product from households that still have it.
- Consider notifying area clinicians and healthcare facilities if an increase is expected in the number of people seeking healthcare after public notification.

6.2.3 If public notification is expected to generate considerable public concern and/or media inquiries, consider setting up an emergency hotline for the public and media. Train people answering the phones to give consistent responses. Give them talking points or frequently asked questions and answers. Consider staffing the hotline after hours to answer phones after the early evening news or to respond to questions posed on social media.

6.2 Communications With the Public

Box 6.3. Notifying the Public About Actionable Information

Early public announcements should reinforce basic food safety messages and inform the public about how to contact appropriate authorities to report suspected foodborne illnesses.

Educational materials on food safety targeted at the public are available from the Partnership for Food Safety Education (<http://www.fightbac.org>) and the Centers for Disease Control and Prevention's Food Safety website (<https://www.cdc.gov/foodsafety>). The following specific food safety messages are important to communicate to the public.

- Personal protection from disease outbreak:
 - Thoroughly wash hands with soap and warm water after using the bathroom and before preparing or eating food. Also wash hands after changing diapers, assisting a child at the toilet, and handling animals or animal waste. Hand washing is the single most important measure to protect the public's health.
 - At home or at a social gathering (e.g., potluck dinner), avoid eating food that has not been handled properly (e.g., hot food that has not been kept hot, cold food that has not been kept cold).
- Proper food preparation:
 - Thoroughly cook food; keep hot food hot and cold food cold; thoroughly clean all food-preparation surfaces and utensils with soap and water; avoid contaminating food that will not be cooked, such as salads, with food that must be cooked, such as raw meat or chicken products; and wash hands frequently with soap and water.
 - If you are ill with diarrhea or vomiting, do not prepare food for others until at least 72 hours after you are free of diarrhea or vomiting.
 - Wash hands before and during food preparation.
- Actions if someone in the household or childcare, or institutional setting has diarrhea or vomiting:
 - If a norovirus-like illness is involved, emphasize the importance of thorough cleaning and sanitation of high-risk transmission surfaces, such as toilet seats and flush handles, washbasin taps, and washroom door handles.
- Appropriate community guidance, references, and educational materials are available at <https://www.cdc.gov/norovirus/preventing-infection.html>.

6.3 Communications With Response Partners and Stakeholders

Early communication with healthcare providers, the food industry involved, and others impacted by the outbreak can increase case detection, reduce the risk for secondary transmission, and help identify the source of contamination. If the pathogen causing enteric illnesses is known, use of general communicable disease control measures may limit further spread, even before the mode

of transmission is clear or a food or facility has been implicated. Control measures at this point typically focus on preventing secondary spread by known cases and communicating with healthcare providers and the public about precautionary measures they can take to prevent illness transmission of the identified pathogen.

6.3 Communications With Response Partners and Stakeholders

6.3.1. Effective communication with other agencies involved in the investigation or potentially impacted by the response helps staff from multiple agencies take timely actions to prevent further illnesses. During multistate outbreaks, others involved might include agencies and organizations at the local, state, territorial, tribal, and federal public health and regulatory levels (Chapter 7). A consistent public message alleviates confusion and reduces the potential for panic among consumers.

6.3.2 Communications with healthcare providers should include reminders and instructions to be shared with ill persons about personal hygiene, ways to avoid spreading infection, and infection control precautions for hospitalized patients and residents of long-term-care facilities. Instruct healthcare providers to report suspected illness to local health departments for follow-up and interviews, especially when ill persons work in settings where the risk for disease transmission is most likely, such as in food establishments and childcare and healthcare facilities. Advise healthcare providers about whether to collect clinical samples for analysis, if indicated.

6.3.3 Early communication with impacted food establishments, commodity groups, or food industries likely impacted by the public notification can assist them to

- Prepare for media enquiries.
- Consider how they can cooperate with the investigation to identify the cause(s).

- Implement control measures to prevent further cases.

Food-industry representatives often have detailed knowledge about typical food-handling, storage, and distribution practices that can guide investigation and control efforts. Early sharing of clear, credible, and objective information often motivates firms to voluntarily bolster efforts to comply with standard food safety and communicable disease control measures, such as

- Excluding or restricting ill persons from food handling.
- Eliminating bare-hand contact with ready-to-eat foods.
- Proper handwashing.
- Thorough cooking.
- Effective cleaning and sanitizing procedures.

It is often helpful to provide a written summary identifying key information, including the type of agent (viral, bacterial, chemical, toxic), the exposure time period (particularly if exposure is potentially ongoing), and whether a single point source or multiple different exposures most likely caused the illnesses.

The Communications Toolkit: Industry Relations developed by the Colorado Integrated Food Safety Center of Excellence is an example of resources available to help agencies communicate effectively with the food industry during foodborne illness outbreaks (*1*).

6.4 Control Measures

Although most reported foodborne illness outbreaks are investigated and controlled at the local level, site-specific food-safety controls

may be needed at multiple points along the distribution network and in the impacted communities (Figure 6.1).

6.4 Control Measures

Figure 6.1. Controlling the Source and Communicating with the Public



At the source:

Stop further production of contaminated food at the implicated food establishment.

Control any contaminated food remaining at the establishment.

In distribution:

Remove contaminated food from commercial distribution.

In the community:

Notify the public not to consume contaminated products that may be in their homes.

Appropriate control measures vary depending on whether the implicated food is associated with a food-service/retail food establishment or is a manufactured food that has been commercially distributed. The outbreak response team must determine as soon as possible whether one facility or multiple facilities are involved.

6.4 Control Measures

6.4.1 Implement initial control measures at an implicated facility on the basis of investigation findings and review of what is known about other outbreaks caused by the agent and the food establishment's food-safety history. Credible epidemiologic, laboratory, and environmental health evidence can support early implementation of nonspecific control measures at an implicated facility, even though a specific food has not yet been identified.

- Adjust control measures on the basis of knowledge of the agent and whether a food item is suspected. An outbreak caused by *Clostridium perfringens* has very different contributing factors and control measures than one caused by norovirus. Controls for a *C. perfringens* outbreak focus on time and temperature for food safety, including rapid cooling, proper hot holding, and reheating. Controls for a norovirus outbreak focus on identifying and excluding ill employees. Also ensure proper hand-washing, no bare-hand contact of ready-to-eat foods, disposal or embargo of ready-to-eat foods when bare-hand contact occurs and thorough cooking is not possible, enhanced cleaning and sanitizing procedures, and (possibly) changes in the source of suspected high-risk foods used in the facility. Focusing on pathways commonly linked to the agent are most likely to identify and address the root causes of the outbreak.
- Review the establishment's history for recurring foodborne illness risk factors, previous outbreaks, illness complaints, recall, positive food samples, and correction of serious food-safety hazards. This information can indicate management's capability and willingness to consistently maintain food-safety controls. Understanding the facility's existing level of active managerial or process control can guide how the investigation and control team works with management to implement changes needed to address

contributing factors and the environmental root causes that led to the outbreak.

6.4.2 Coordinate onsite investigation, environmental assessment, and control measures at the implicated facility.

Most foodborne illness outbreaks are local events investigated and controlled by staff from local public health agencies. For large-scale or multijurisdictional outbreaks, staff from multiple disciplines or agencies may be involved. Staff should identify investigation and control objectives and clarify agency roles and responsibilities before arriving at the implicated food establishment. Initial clarification of both types of objectives helps ensure that appropriate staff visit the facility.

- A team approach is often needed to effectively conduct the onsite investigation and implement control measures. When conducting any environmental assessment, at least two environmental health specialists should be deployed in the field to ensure both investigative and control measure objectives are achieved. Environmental assessment teams visiting facilities for the first time must often simultaneously seek to complete multiple objectives. A few examples include communicating with firm management to enlist its cooperation, ensuring the safety of foods being served/sold, placing seizures/embargoes/holds on implicated or suspected foods or leftovers, interviewing food workers, assessing foods served and processes during the period of interest, and collecting documents and samples as needed.
- Rapid initial assessments to identify conditions requiring immediate control measures should be coordinated with ongoing investigation activities. Effective control measures address both the contributing factors that resulted in foodborne illness (what went wrong) and the root cause(s) of the outbreak (why it went wrong at this location).

6.4 Control Measures

6.4.3 Gather samples while they are still available. Early collection of samples while they are still available can greatly aid in determining the root causes of foodborne illness (Chapter 5). Discarding suspected food can help stop the outbreak, but isolating the etiologic agent from the food provides the most convincing evidence a food was the source of the outbreak. Use both epidemiologic data and guidance from the laboratory to inform decisions about what samples to collect and how to handle them.

6.4.4 Control measures for localized events associated with a single food-service or retail food establishment will usually be established by local public health agencies or state and local food-regulatory agencies. Although all of the following control measures are recommended, some may be more appropriate than others in specific outbreaks, and full implementation might not be possible in some jurisdictions. Implementing the most appropriate control measures as completely and promptly as possible improves the effectiveness of those measures. Before using any control measure, the environmental health/regulatory specialist must understand applicable laws and procedures for implementing them (Chapter 2).

- **Inform and engage facility management in implementing controls.** Environmental health specialists should work with the food establishment's person-in-charge (PIC) to implement active managerial controls and create a risk-control plan or consent agreement. Active involvement of the PIC uses his or her expertise and often increases commitment to implement controls to stop the current outbreak and prevent additional outbreaks. The CIFOR Industry Guidelines outlines, clarifies, and explains the recommended role of owners, operators, and managers of food establishments in a foodborne illness outbreak investigation (2).
- **Remove food from sale or prevent consumption.** If evidence from the epidemiologic, laboratory, and environmental assessment/root cause analysis supports the action, implicated or potentially unsafe foods should be embargoed, seized, placed under regulatory hold, or otherwise removed from service or sale. Fully document the information that led to the decision and the process used to make the decision. Issuing a written hold or embargo order establishes clear expectation and regulatory requirements and prevents the establishment owner from serving or destroying the food before the investigation is complete.
- **Clean and sanitize.** If evidence from the outbreak investigation identifies the potential for onsite contamination during the outbreak, the environmental health specialist must ensure involved equipment and areas of the facility are thoroughly cleaned and sanitized. This process includes disassembling all equipment and retraining staff on proper cleaning and maintenance procedures for the equipment. The cleaning and sanitizing process is particularly important if *Salmonella*, *Listeria monocytogenes*, or norovirus contamination of food is suspected. Industry guidance documents are identified under references.
- **Train food managers and workers.** Assess to what degree the presence of food-safety risks is due to inadequate food worker knowledge, inadequate supervision, or lack of active managerial control. Ensure the firm's food-safety management system is adequate to ensure that managers and food workers receive consistent food-safety training appropriate for their job duties. Ensure remedial training is provided, as needed so that food managers and workers have a functional understanding of the disease (e.g., symptoms, modes of transmission) and the food-safety practices (e.g., use of procedures for rapid cooling and thorough cooking

6.4 Control Measures

and reheating of foods) needed to stop the outbreak and prevent recurrence.

- **Modify a food process.** Assess food-production or food-preparation processes at the establishment using both investigation findings and the best available scientific information. Examples of critical steps and controls include process times, temperatures, parameters (pH, water activity level), and label instructions. Implement changes needed to consistently prevent contamination of food or the survival and proliferation of disease-causing microorganisms.
- **Modify the menu.** Eliminate implicated foods from the menu until adequate control measures are in place to ensure food safety. For example, if shell eggs are implicated, remove all foods that contain shell eggs, and substitute pasteurized egg product until the investigation is complete and proper controls are in place.
- **Remove infected food workers.** Ensure that ill or infected food workers are excluded from the workplace or restricted in accordance with the Food Code (3) or other regulatory requirements unless evidence gathered by the investigation team indicates that a longer exclusion period is needed (e.g., evidence exists of ongoing norovirus transmission within the food establishment). Because many food workers are employed by more than one food establishment, ensure ill workers are excluded or restricted from all food establishments where they work.
 - Food establishment management should conduct daily monitoring of worker health to prevent further contamination of food by ill or infected workers. For example,
 - A person ill with vomiting or diarrhea should be excluded from the facility.
 - Pathogen-specific guidance and other information about restricting and excluding food workers is available in the latest version of the Food and Drug Administration (FDA) Food Code (3).
 - In *Salmonella* and *Shigella* outbreaks, fecal samples should be analyzed for the pathogen because of the likelihood of asymptomatic but infectious food workers. Restricting activities of food workers who do not comply with the request might be necessary.
 - Excluding ill food workers is not as simple as it might seem. Food workers may be reluctant to inform managers of illness because of fear of lost wages, reprisal, or leaving their co-workers short-handed. Conversely, managers underappreciating the risk to public health and their firm's economic viability may be reluctant to relieve food workers of their duties or may themselves work while ill.
 - Facilities with a strong food-safety culture ensure that both managers and food workers are well informed about alternatives to coming to work while sick, including alternate jobs that ill food workers can perform and allowing ill employees to trade for shifts when their exclusion has been lifted.
- **Use risk-control plans.** Written risk-control plans or other agreements are used to identify and focus control measures that establishments need for safe operation. Important aspects of these plans include
 - Process changes, such as recipe adjustments or development of a Hazard Analysis and Critical Control Point plan.
 - Worker training.
 - Adequate oversight measures to ensure workers follow proper procedures.
 Plans may require
 - Increased focus on regulatory requirements (e.g., additional measures to ensure appropriate handwashing by all employees).

6.4 Control Measures

- Additional measures above and beyond regulatory minimum requirements (e.g., extra temperature checks and logging of temperature).
- Close food establishments.** Facilities that cannot safely remain in operation must be closed in accordance with applicable local and/or state regulations. A facility linked to an ongoing foodborne illness outbreak, in which significant noncompliance with regulatory food-safety standards is documented, is an imminent or substantial health hazard.
- Communicate findings.** Effective communication of the evidence gathered by the investigation and control team can be a powerful motivator for establishment management to close or significantly modify operations. Voluntary actions are often the most efficient and timely way to reduce risks to the public. If the owner cannot or will not take immediate corrective action to eliminate ongoing food-safety hazards, mandatory closing of the premises may be necessary.
- Notify the public.** As control measures are implemented at the source, public notification can be an effective way to prevent additional illnesses and further disease transmission, but it must be used judiciously. If the outbreak involves only one facility, carefully consider whether public notification is truly necessary. See 6.2 for details.
- Monitor control measures.** The strategy for monitoring short- and long-term correction of the factors within the food establishment that caused the outbreak should be identified in writing. Food establishments should integrate monitoring steps into their food-safety management systems (e.g., Active Managerial Control), and regulatory officials should provide the facility with timely follow up inspections so the effectiveness of control measures can be assessed, modified, or removed when appropriate. Public health officials should maintain enhanced surveillance of potentially exposed populations to ensure controls are effective, secondary spread of infections is not occurring, and systems are in place to prevent reoccurrence.

6.5 Outbreaks Involving Commercially Distributed Foods

6.5.1. Control measures associated with commercially distributed foods typically require coordination of multiple agencies across jurisdictional levels, especially when an implicated food item is subject to recall (Chapter 7). Careful coordination of control measures at the food-manufacturing facility, in distribution channels, and in consumer homes often is needed to stop outbreaks linked to commercially distributed foods. Food manufacturers can range from small facilities with limited local distribution to large, complex facilities capable of producing huge quantities of diverse products daily. Although contaminated products may still be stored onsite at the manufacturing

facility, the probability is much higher that they have moved through various points of often complex distribution networks that can span the globe and include a wide range of locations, including; warehouses, distributors, retail establishments, consumer homes, and food banks. Timely product tracing investigations often identify the point in the production and distribution process where the implicated food became contaminated and where contaminated products may have been distributed after that (Chapter 5). The type of food products involved and the extent of their distribution often determine which regulatory agency leads the implementation and coordination of control measures.

6.5 Outbreaks Involving Commercially Distributed Foods

- **Implement onsite controls at the food-manufacturing facility.** Depending on the scope of the outbreak and probable point of contamination, most of the specific onsite control measures for food-service and retail food establishments also will be appropriate to control contaminated foods and food-safety risks at other points in food-supply chains where contamination was introduced. Given the size and complexity of many of these establishments, timely sharing of the most specific and accurate information available (e.g., product descriptions, lot codes, and periods of interest) is vital to focusing control measures where they are most needed.
- **Determine whether a food recall is needed.** Public health and food-regulatory agencies need to determine whether the contaminated product is still in distribution

or consumer homes and, if so, decide how contaminated products can most effectively be removed from the market and consumers notified when appropriate (Box 6.4).

Food firms have the primary legal responsibility to initiate and conduct effective food recalls. If the food-regulatory agency has adequate information to implicate and accurately identify a contaminated food item, that agency will take the lead on working with the manufacturer to initiate recall activities. Consider the capabilities of the firm and involved agencies to: notify the public when appropriate, conduct recalls, and verify their effectiveness. Past recall experience and prior recall planning are often good indicators of likely future performance by the manufacturer.

Box 6.4. Considerations for Whether to Remove Food from Distribution

Questions to Ask

- Is risk to consumers ongoing?
- Is the product still in distribution based on product tracing information (Chapter 5)?
- Is the product likely to still be in the homes of consumers?
- Do the combined epidemiologic, laboratory, and environmental health data support removing food from the market?

Remove the food if

- Specific exposure information links the illness with consumption of that food (e.g., through a quality analytic study or other epidemiologic method), even if the pathogen has not been isolated from the food. OR
- Definitive lab results show the outbreak pathogen is present in the product. The results must be based on a food sample that is representative of the food eaten by case-patients and has been handled properly to avoid cross-contamination. OR
- An investigation at the source reveals adulterated products or other conditions that pose an imminent hazard to health. OR
- Epidemiologic association is not significant, but the pathogen, chemical, or other contaminant is so hazardous that the risk to the public is very high (e.g., botulism). Under these circumstances, there may be no analytic controlled studies, but if the descriptive epidemiology (e.g., demographic characteristics of case-patients, geographic distribution, or illness onset) suggests an association between the disease and the suspected food, then removing food from the market might be warranted, even in the absence of confirmed laboratory findings.

6.5 Outbreaks Involving Commercially Distributed Foods

- **Contact the federal or state regulatory agency that has jurisdiction over the product.** FDA regulates the safety of most foods moving in interstate commerce, except meat, poultry, fish of the Order Siluriformes (including catfish), and most out-of-shell egg products (which are regulated by the U.S. Department of Agriculture’s Food Safety and Inspection Service [FSIS]) (Chapter 3).

Both FDA and FSIS have developed informational websites to assist their investigation and response partners. FDA developed a general website (4) with Resources for Regulatory Partners, and FSIS developed a website with resources for its investigation partner agencies to improve communication and sharing of information during foodborne illness outbreak investigations (5).

- **Initiating a recall.** State agencies, FDA, FSIS, and the Centers for Disease Control and Prevention (CDC), often contact the manufacturer seeking to obtain its cooperation in initiating a food recall. In addition, the regulatory authority and/or the manufacturer may ask retail facilities to remove the product from their shelves and ask distributors to withhold the product from distribution.

Quickly determining the extent of a recall needed in a large manufacturing plant with multiple processing lines can be difficult. Although industry often wants to limit the recall to the production lots implicated in illnesses, the conditions or extent of contamination observed within the facility may warrant a more comprehensive recall. Was an ingredient identified as a possible source of illness used in multiple food processes? Often, implicated lots will be recalled while a hold is placed on other products until their safety can be determined through an environmental assessment and product sampling. Because recalls often expand as more contaminated products are

identified, some processors will voluntarily recall or be compelled to recall all suspected product to avoid the negative publicity and the economic impact associated with multiple recalls of their products.

Recall of food at the processor level generally requires federal and/or state action. In some jurisdictions, the local health jurisdiction will embargo (impound) the food (tagging the food to make sure it is not moved or sold, or ordering it destroyed). Under the Food Safety Modernization Act (6), FDA can order the embargo of food for up to 30 days without a court order.

- **Remove product from distribution.** Once a decision is made to remove food from the distribution, the food must be removed as quickly and efficiently as possible (Box 6.5). Foods with short shelf lives (e.g., fresh produce, dairy products) generally are consumed within the shelf life or discarded. Foods with longer shelf lives, especially frozen foods and foods that may be frozen, will be available for extended periods of time. Prevent additional exposure by ensuring effective recall practices and public notification.

Conduct product tracing (traceback, traceforward) investigations to better learn where contaminated products were distributed and how contaminated products were used. For example, a contaminated food may have been used as an ingredient in food(s) that were not subsequently treated to destroy the contaminant, and additional recalls may be necessary. An ingredient also may be indicated if a large number of illnesses are not linked to the foods from one implicated facility.

Detailed information and sample forms for use by food establishments are included in the “CIFOR Foodborne Illness Response Guidelines for Owners, Operators and Managers of Food Establishments” (7)

6.5 Outbreaks Involving Commercially Distributed Foods

Box 6.5. Steps to Improve the Effectiveness of Recall Measures and Industry Response

Conduct recall effectiveness checks to assess whether efforts to remove products from distribution channels work.

Share distribution lists of recalled foods among government agencies and with the public

Develop a list of verification or control measures to implement immediately when an outbreak- related or illness-related recall has been identified.

Identify industry needs and develop guidance for

- Interacting with public health or agriculture officials investigating an outbreak. Provide retailers and manufacturers with 24/7 contact numbers and emails for regulators at the local, state, and federal levels, including FDA and USDA's Food Safety and Inspection Service (USDA-FSIS).
- Providing timely notification of customers, appropriate government agencies, and the public of recalls involving particularly hazardous contaminants.
- Mitigating the impact of an outbreak- related or illness-related recalls. Examples: clean out the display cases, follow destruction for recalled product, recommended practices for disposing of returned product.

Develop guidance for communicating with the news media, including the preparation of talking points to answer inquiries. Have a plan for coordinating a news media telebriefing or video briefing, if needed. Identify a spokesperson.

Develop standard templates for press releases and social media messages for use during an outbreak that follow best practices for crisis and emergency risk communication (<https://emergency.cdc.gov/cerc/>).

- **Food regulators should consider ways to immediately notify food facilities in their jurisdiction through text messaging, email, blast fax, or phone calls of recalls associated with high severity hazards (e.g., botulism associated with under processed canned foods) that have a reasonable probability of still being in commercial distribution.** Identifying subcategories of facilities is highly recommended so notices can be targeted to specific facilities (e.g., notices of a seafood recall sent specifically to seafood retail establishments). This process should include food bank donation centers and other sites that might have received food donations.
- **If any distributors or retailers refuse to remove the food, issuance of a public health warning and order to require action might be necessary.** The appropriate agency for this action depends on the type of food and etiologic agent. Passage of the Food Safety Modernization Act gave the FDA the authority to order a responsible firm to recall a human or animal food when FDA determines that 1) there is a reasonable probability that the food is adulterated or misbranded and 2) consumption would cause serious adverse health consequences or death to humans or animals.
- **The agency/jurisdiction should monitor to ensure the recall is effective in stopping illnesses and food is completely removed.** Are illnesses continuing after the recall? If so, why? Is there another contaminated product or lot number that has not been recalled? Was the product purchased after the recall? If so, from where? Was the consumer aware of the recall notice?
- **Assessing recall effectiveness requires close cooperation among local, state, territorial, tribal, and federal agencies to accomplish risk-based recall effectiveness checks across the distribution system.** For example: many large-volume retailers

6.5 Outbreaks Involving Commercially Distributed Foods

routinely sell product to smaller retailers that may use cash for purchases. Participating in recall effectiveness checks can help local and state agency staff maintain proficiency in tracing contaminated products from the source(s) throughout distribution chains. If the product is not immediately removed, determine why.

- Did the manufacturer notify the distributor of the recall?
 - Did the distributor notify retailers of the recall?
 - Was the recall information clear and complete, including all lot numbers, use-by dates, bar codes?
 - Did notifications occur but no action was taken?
 - Was returned recalled product diverted and sold elsewhere?
 - If the recall is not effective, notify appropriate state, federal, and neighboring health and food-regulatory agencies.
 - Issue a public advisory if needed.
- **Post-recall reporting by the food business or manufacturer.** If a food business or manufacturer recalls a product, it should prepare interim and final reports about the recall. The contents of these reports are used to determine the need for further recall actions. The reports should include copies of all notices distributed to the public and through the distribution chain, as well as the following information:
 - Circumstances leading to the recall and actions taken.
 - Extent of distribution of the suspected food (documentation that can support traceforward investigations).
 - Result of recall (percentage of suspected food recovered).
 - Method of disposal or reprocessing of suspected food.
 - Difficulties experienced in recall and actions taken to prevent recurrence of food-safety problems and any recall difficulties.

6.6 Outbreak Wrap-up Activities

6.6.1 Most outbreaks are considered over when two or more incubation periods of the etiologic agent have passed with no new cases. However, outbreak investigation and control activities should not cease when new cases of human illnesses cease to be identified. Clusters with low attack rates and cases from some sources might appear intermittently for years. This is especially common with agricultural products, such as romaine lettuce, where outbreaks have occurred each year, around the same time of year, when products are harvested from the same contaminated farms. PulseNet data should be reviewed and monitored to make

certain control measures have been effective in preventing additional illnesses.

The outbreak is truly over when the source has been identified and controlled so it cannot cause additional illnesses. To prevent additional illnesses and future outbreaks, it is vital that investigation and control teams learn why the outbreak occurred so effective controls can be applied to address the contributing factors and root cause(s). Sharing lessons learned from each outbreak with the food industry in that sector or commodity group can prevent future outbreaks in other locations.

6.6 Outbreak Wrap-up Activities

6.6.2 Restrictions put in place to prevent additional illnesses may be removed when no further risk to the public exists, such as when

- Risk factors in the facility have been eliminated and an effective system has been put in place to prevent their reoccurrence.
- Ill food workers have recovered and are no longer shedding pathogens (refer to the FDA Food Code for specific recommendations on restricted/excluded employees).
- Tests indicate no further contamination within the facility.
- Employees have been trained on proper methods to avoid the contributing factor(s) of foodborne illness.
- Managerial controls are implemented and integrated within day-to-day operations and the facility's operational culture (culture of food safety).

6.6.3 Monitoring plans should be developed to ensure the effective control of the outbreak.

- **Monitor the population at risk** for signs and symptoms of the foodborne illness to ensure the outbreak has ended and the source of illness has been eliminated. Epidemiologists and communicable disease control staff should consider conducting active surveillance, working with healthcare providers to increase their identification of associated cases, and collecting fecal samples from the population at risk. Monitor the Whole Genome Sequence (WGS)–PulseNet database to assess whether closely related cases have occurred in the region or nationally. An outbreak at a food establishment may be caused by a contaminated food ingredient or product that they received. Also monitor WGS-PulseNet over the next year for matching cases. *Listeria*, *Salmonella*, and Shiga toxin-producing *Escherichia coli* outbreaks often reoccur from

the same source. Another outbreak could recur the following year around the same time if contaminated produce from certain farms with unsafe water is the source.

- **Monitor the implicated foods or food establishments** to ensure agreed-to changes in food-safety management systems are maintained and that no additional contamination is occurring.
 - Identify needed changes in writing, such as with a Risk Control Plan or Standard Operating Procedure.
 - Maintain communication with managers of the implicated food establishment and give them additional information if it becomes available.
 - Increase the number of risk-based inspections at the implicated food establishment and sampling of implicated foods, as needed, to monitor the firm's development and implementation of preventive controls.

Outdated, unsafe practices often are difficult to change, and new practices might need to be reinforced multiple times before they become routine. Consider customized training to support the desired behavioral change. Determine whether behavioral change has occurred long term. Consider requiring that the establishment or firm hire a consultant to assist in developing safe systems and in monitoring if the facility has a history of unsafe practices.

6.6.4 Outbreak investigation and control teams should routinely meet and review all aspects of the investigation. Processes that systematically review investigation and control efforts after the response is over have two primary goals (Box 6.6):

1. Improve the effectiveness of future investigations and responses.
2. Prevent recurrence at the facility or in similar types of food operations.

6.6 Outbreak Wrap-up Activities

Box 6.6. Goals of Formal After-Action Meeting

Improve the effectiveness of future investigations and responses:

- Clarify resource needs, structural changes, or training needs to improve future outbreak response.
- Identify factors that compromised the investigations, and seek solutions.
- Identify necessary changes to current investigation and control guidelines and development of new guidelines or protocols as required.
- Discuss any legal issues that might have arisen and the need for new laws to strengthen response (Chapter 2).

Prevent recurrence at this facility or in similar types of food operations:

- Identify the contributing factors and environmental root causes of the outbreak and measures (preventive controls) to prevent additional outbreaks at this and other food establishments.
- Determine whether others need to be notified of lessons learned from the investigation to prevent outbreaks elsewhere.
- Identify the long-term and structural control measures, develop a plan for their implementation, and determine surveillance and follow-up needed to ensure an outbreak does not reoccur.

Assess the effectiveness of outbreak control measures and difficulties in implementing them.

Assess whether further scientific studies should be conducted.

Assessments of the effectiveness of the investigation and control efforts should maintain a balanced approach that identifies strengths to be built upon and areas of improvement to be addressed. The complexity of the review depends on the size and complexity of the outbreak. For a small outbreak associated with a single facility or event, a quick meeting and short written summary may be sufficient.

For a large outbreak involving multiple agencies, a series of meetings resulting in a formal after-action report is appropriate.

Two types of meetings can be used as part of effective after-action review processes:

- **Hot wash/debriefings** involve investigation and control team members to gather input within 1–2 weeks after the investigation's completion while it is fresh in responders' minds. These are often less formal and single-agency in nature. Examples of typical agenda items include

- What went well?
- What did not go well?
- What resources were needed that were unavailable?
- What will be done differently next time?
- What follow-up is needed from root-cause analysis to ensure this does not happen again (Action Plan: who will do what by when)?

- **After-action review meetings** often involve response team members, response partners, and sometimes stakeholders. These meetings are more formal, systematic, and comprehensive and, because of the need to coordinate schedules and information sharing, might occur 1–2 months after the response.

Effective after-action review processes result from planning and the intentional dedication of resources to support these meetings. Share written summaries of each meeting with attendees and interested response partners. Lessons learned from outbreaks should be

6.6 Outbreak Wrap-up Activities

communicated appropriately so they can promote improvement; even the best lessons learned have minimal impact if they are not shared with relevant partners and stakeholders. Link formal action items identified by the process to the agency's continuous process improvement program(s) to ensure appropriate accountability for tracking and correction.

If additional information becomes available in the weeks or months after the outbreak and the official after-action meeting, disseminate that information to the outbreak investigation and control team and appropriate external partners.

6.6.5 Prepare reports for all outbreaks.

The report complexity depends on the size of the outbreak. For small outbreaks, a simple summary (following a template established by the agency) should suffice. Use the report to educate staff and share important investigation findings with others. When combined with other reports, this information can help identify trends across outbreaks that can be useful in future investigations.

Use outbreak reports as an opportunity for continuous quality improvement. If all the after-action reports cite the same areas for improvement, then nothing is being corrected. Outbreak investigation reports provide an opportunity to document both lessons learned during the investigation and the investigation's results.

Well-conducted and documented outbreak investigations guide prevention efforts by identifying foods at risk for contamination, locations within food-supply chains where contamination is introduced, factors directly contributing to contamination, and the root causes)

The final report for a large outbreak should be comprehensive, provide information by all team participants, and be disseminated to all participating organizations. Sample outbreak

and after-action reports are available at the CIFOR Clearinghouse (7).

1. Given that reports, especially those for large outbreaks, are likely to be subject to Freedom of Information Act (8) requests, they should be written with public disclosure in mind. The reports should not identify individuals or other protected information unless necessary and legally defensible. Proper care in writing the report will save time redacting information when the report is released to the public. Some jurisdictions allow or mandate the inclusion of identifying information, so review state and local laws and policies.
2. Submit a final report of the outbreak to CDC's National Outbreak Reporting System and National Environmental Assessment Reporting System databases (9,10). FDA-funded Rapid Response Teams have uploaded after-action reports into FoodSHIELD (11).

Control of contributing factors without addressing the root cause for their presence in the facility can result in a repetitive cycle of short-term correction followed by gradual loss of food-safety controls and outbreak recurrence. Sharing the root causes of outbreaks enables a broad range of food-safety stakeholders (e.g., agencies, food industries, academic institutions, and consumers) to coordinate work within their respective spheres of influence to strengthen food-safety systems worldwide.

6.6.6 The outbreak investigation findings may indicate the need for future research.

For example, investigators may determine that for certain pathogens in certain foods, standard control measures do not seem effective or routine handling practices and their role in outbreaks are not completely understood. The food-safety or public health agency or research centers should consider such observation for in-depth study. Regular review of reports of

6.6 Outbreak Wrap-up Activities

foodborne illness outbreak investigations can identify important trends and areas of undercontrolled risks. Questions raised by stakeholders and researchers include

- How common is this pathogen as identified to the subtyping level by WGS?
- Is there a recurring pattern every year around the same time?
- Is there a high baseline in this region of the country that may indicate an ongoing source that needs to be identified and eliminated?

6.6.7 If unusual findings characterized the outbreak (e.g., unusual exposure, presence of a pathogen in a food where it had not previously been reported or by the magnitude of the outbreak) or new methods were used in its investigation, disseminate the report more widely (e.g., through Epi-X, *MMWR*, or other national forum; peer-reviewed journals). Publish important lessons learned (such as new investigation methods that proved particularly helpful, control measures that seemed particularly effective, actions taken that seemed to shorten the outbreak) in an appropriate national forum.

6.6.8 An outbreak can identify the need for broad education of the public; the food-service, retail, food processing, and agricultural industries; food-safety regulators; or healthcare providers.

Public outreach, including public service announcements, can remind the public about food-preparation precautions. National training programs for food workers and managers are regularly revised to reflect current understanding of the root causes of foodborne illness. Food-safety management systems increasingly hold managers accountable for ensuring that training of food workers is appropriate for assigned job responsibilities. Healthcare providers might need continuing education focused on diagnosing, treating, or reporting foodborne diseases. Such actions can help prevent future

outbreaks or reduce the number of cases or severity of illness during an outbreak.

Trade associations, food-industry organizations, and national conferences often request presentations on outbreak investigations. These events provide an opportunity to educate representatives of the food industry, colleagues, and others about investigation procedures, outbreak management, preventive controls, and CIFOR.

6.6.9 Information gained during an outbreak is used to identify the need for new public health or regulatory policy at the local, state, territorial, tribal, or federal level. Different inspection practices, source controls, surveillance procedures, or recall process controls have been established on the basis of well documented investigation reports.

Ongoing and regular review of outbreak investigation reports, research, and industry practices identifies the need for new policy. FDA regularly updates the Food Code (3) to better address the leading foodborne illness risk factors identified by epidemiologic outbreak data. For example, an analysis of outbreaks by the Environmental Health Specialist Network identified an association between not having a manager certified in food safety and outbreaks (12). Similarly, FDA found an association between the presence of certain foodborne illness risk factors and the lack of a certified manager (13). These findings led to changing the FDA Food Code to require the person in charge of most retail and food-service establishments, those posing more than a minimal foodborne illness risk, be a Certified Food Protection Manager.

Consult other public health and environmental health agencies to determine whether concurrence exists on the need for new policy. If so, present the issue to the appropriate jurisdictional authority by using the appropriate policy development processes.

References

- 1 Colorado Department of Public Health and Environment, Colorado School of Public Health. Communications toolkit. <http://www.ucdenver.edu/academics/colleges/PublicHealth/research/centers/foodsafety/Documents/Media%20Communication%20toolkit-V3-Final.pdf>
- 2 CIFOR. Products. <https://cifor.us/products/industry>
- 3 Food and Drug Administration. FDA Food Code. <https://www.fda.gov/food/guidanceregulation/retailfoodprotection/foodcode/default.htm>
- 4 Food and Drug Administration. Resources for regulatory partners. <https://www.fda.gov/federal-state-local-tribal-and-territorial-officials/resources-regulatory-partners>
- 5 U.S. Department of Agriculture., Food Safety and Inspection Service. Resources for public health partners: foodborne illness investigation. <https://www.fsis.usda.gov/wps/portal/fsis/topics/recalls-and-public-health-alerts/audience-public-health/resources-for>
- 6 Food Safety Modernization Act. Pub. L. No. 111–353, 124 Stat. 3885 (2011).
- 7 CIFOR. Food Safety Clearinghouse. <https://cifor.us/clearinghouse>
- 8 FOIA.gov. <https://www.foia.gov>
- 9 Centers for Disease Control and Prevention. National Outbreak Reporting System (NORS). <https://www.cdc.gov/nors>
- 10 Centers for Disease Control and Prevention. National Environmental Assessment Reporting System (NEARS). <https://www.edc.gov/nceh/ehs/nears>
- 11 FoodSHIELD. <https://www.foodshield.org>
- 12 Hedberg CW, Smith SJ, Kirkland E, Radke V, Jones TF, Selman CA, et al. Systematic environmental evaluations to identify food safety differences between outbreak and nonoutbreak restaurants. *J Food Prot.* 2006;69:2697–702.
- 13 Cates SC, Muth MK, Karns SA, Penne MA, Stone CN, Harrison JE. Certified kitchen managers: do they improve restaurant inspection outcomes. *J Food Prot.* 2009;72:384–91.

