MULTISTATE FOODBORNE OUTBREAK INVESTIGATIONS

GUIDELINES FOR IMPROVING COORDINATION AND COMMUNICATION

National Food Safety System Project
Outbreak Coordination and Investigation Workgroup
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OUTBREAK COORDINATION AND INVESTIGATION WORKGROUP

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Mission Statement

To improve coordination, cooperation and communication among local, state and federal agencies with respect to multistate foodborne outbreak investigations.

Goals

- To develop a model for coordinating, cooperating, and communicating before, during, and after a multistate foodborne outbreak investigation.

- To inform the public, industry, and trade groups about multistate outbreak coordination process and encourage their active cooperation.

Background

In response to the growing concerns over foodborne illnesses and the coordination of food safety activities at all levels of government, a meeting of governmental agencies was convened in Kansas City in 1998. The meeting was attended by epidemiologists, laboratory scientists, environmental health specialists, food regulators and agriculture representatives from local, state and federal agencies. The purpose was to develop ways to integrate overlapping responsibilities and mutual goals for food safety in the United States. From that meeting, six working groups were created to address problem areas identified by the meeting participants as part of the National Food Safety System (NFSS) project. The Outbreak Coordination and Investigation Workgroup, one of the six, was charged with improving coordination among agencies with regard to multistate outbreaks of foodborne illness and developing guidelines for the coordination of investigations of these outbreaks. These guidelines, developed over 2 years, represent the efforts of representatives from the U.S. Department of Health and Human Services' (HHS) Centers for Disease Control and Prevention (CDC) and Food and Drug Administration (FDA); the U.S. Environmental Protection Agency (EPA); the U.S. Department of Agriculture's (USDA) Food Safety and Inspection Service (FSIS), and state and local epidemiologists, laboratory scientists, and agriculture officials.

Audience

Local, state and federal agencies, including public health, epidemiology, environmental, laboratory, and agriculture representatives, industry, professional organizations, and the public.

Introduction

In recent years, the reported incidence of foodborne-disease outbreaks that extend beyond state borders has increased. This is the result of many factors, including wider food distribution networks, contamination prior to the point of service, and better surveillance methods. Investigations of these large, multistate outbreaks often involve numerous agencies with differences in approaches, missions and regulatory jurisdictions that need to be recognized and understood by participants in the investigations. Historically, governmental agencies have worked independently within their scope of responsibility; many local, state and federal agencies, therefore, are not well informed regarding the coordination needed among the various agencies during multistate foodborne outbreaks. To address these new situations, communication and coordination within and among local, state and federal government agencies need to be improved, and new mechanisms and processes need to be developed to achieve this improvement.

Identifying and investigating a multistate foodborne outbreak, conducting traceback and source investigations, developing and implementing control measures, and taking steps to prevent recurrence are all activities that require close coordination between the many different players. Local, state, and federal agencies have recognized the need for improving coordination efforts in this process.

These guidelines provide a framework for local, state and federal agencies to effectively respond to multistate foodborne outbreaks. The scope of this document is intended to cover the following foodborne hazards: microbial, microbial toxin, toxic chemical, pesticides, and foreign objects. The concepts and principles of this document can work equally well for recognizing and responding to public health emergencies associated with any of these hazards.

This document currently covers surveillance, illness investigation and product investigation. Other important topics related to multistate outbreaks are being developed and are listed in the table of contents.

Chapter 1. RECOGNITION
Detecting Multistate Foodborne Outbreaks

Key Points:

- **The recent increase of widely dispersed foodborne outbreaks requires improved surveillance and response systems.**
- **Early detection of potential multistate outbreaks, using distinguishing characteristics or indicators, can lead to earlier notification, intervention, and prevention of illnesses.**
- **Enhancing current surveillance systems to identify multistate outbreaks as early as possible will maximize control and prevention efforts.**

The increasing numbers of reported multistate outbreaks of foodborne illness, many detected by improved surveillance and laboratory techniques such as FoodNet and PulseNet, highlight the fact that early and frequent communication among investigating agencies is critical in controlling outbreaks and preventing additional illnesses. Although preliminary investigations of foodborne illness may not determine whether the outbreak is truly multistate, several potential indicators may alert investigators to a heightened awareness of such outbreaks and can result in earlier detection. These potential indicators are listed in Table 1.

Table 1. Indicators that may lead to early detection of multistate foodborne outbreaks

Indicator	Feature of Widely Disseminated or Multistate Foodborne Outbreak
Geographic area affected	Multiple cases and/or clusters in several counties, states, or even countries occurring over a similar time period
Point of contamination	Early in the production/distribution chain
Implicated food	Widely distributed food (nationally or internationally)
Pathogen	Emerging or rarely encountered in the affected geographic areas
Point of sale or service	Tourist facility, airport, convention center, restaurant or grocery chain

A foodborne outbreak investigation can begin only after cases are detected and reported through disease surveillance. All states require certain diseases to be reported to local or state health officials. Disease reports are usually transmitted from health care providers and laboratories to local, county, or state health departments. Information is then passed from state health departments to federal agencies. Prompt submission of information surrounding epidemiologic investigations, analysis and interpretation of data is critical in detecting widely dispersed outbreaks.

In addition to epidemiologic or laboratory surveillance, a parallel environmental health surveillance system monitors the safety of food products by conducting facility inspections, sampling foods, and monitoring consumer complaints.

Table 2 lists specific activities that can improve and hasten the detection of multistate foodborne-disease outbreaks.

Table 2. Activities that can improve the detection of multistate foodborne outbreaks

- Timely and complete reporting of foodborne disease cases/clusters.
- Collection and analysis of specimens from infected persons and foods for culturing and other studies to identify the etiologic agent of foodborne outbreaks.
- Referral of specimens to local, state or federal public health laboratories for serotyping and molecular fingerprinting.
- Serotyping and molecular epidemiology studies of isolated pathogens (e.g., PFGE, viral sequencing) from human and food samples.
- Real-time analysis of surveillance data at local, state, and national levels to detect geographically and temporally related illness clusters (e.g., PHLIS, SODA, and PulseNet).
- Sharing of information on pathogen identification.
- Rapid hypothesis-generating investigation(s).
- Prompt completion of local and multistate case-control and/or cohort studies to determine if there is a common exposure.
- Early alerts to surrounding county, city, and state agencies (epidemiology, environmental health, and laboratories).
- Early involvement and communication with experienced personnel.

Expanded surveillance requires additional training and resources at local, state and federal agencies. Training should be ongoing and should emphasize interagency cooperation and coordination. Resources at the local and state levels should include adequate staffing for conducting epidemiologic, environmental, and laboratory surveillance and data analysis. To identify potential multistate outbreaks as early as possible and prevent further illness, it is imperative to communicate information to other involved agencies when the outbreak is detected and the investigation is ongoing rather than waiting until it has been completed. States are encouraged to review surveillance data from counties to determine those jurisdictions that may be underreporting or not reporting at all.

Chapter 2. OUTBREAK RESPONSE
Section A. Foodborne Illness/Outbreak Investigation

Key Points:

- **Communicate early, often, and accurately.**
- **Foster regular, horizontal and vertical communications among local, state and federal agencies.**
- **Understand roles/responsibilities of agencies responsible for food safety activities.**
- **Develop and use standard procedures to allow interagency consistency.**
- **Identify agency/department leaders and points of contact early in outbreaks.**
- **Develop and maintain contact lists.**

Many references are available on how to conduct a foodborne outbreak investigation. The purpose of this document is to present a model for coordinating, cooperating, and communicating before, during, and after a multistate foodborne outbreak investigation and to inform the public, industry, and trade groups about the multistate outbreak coordination process and encourage their active cooperation.

This chapter will focus on four factors identified at the local, state and federal levels as critical to a successful multistate investigation: 1) communication (including early alerts, emergency contact lists and conference calls), 2) clearly defined roles and responsibilities, 3) standardized procedures, and 4) resources.

COMMUNICATION

Communication is one of the most important factors in the coordination of multistate foodborne outbreak investigations. Table 3 provides a list of suggestions for improving communication and cooperation at all levels during a multistate foodborne outbreak.

Table 3. Suggestions for improving communication and coordination efforts during multistate foodborne outbreak investigations

- Develop communication protocols or standard operating procedures (SOPs) for the following groups:
  - Health care professionals and community sources
  - Consumers
  - Media
  - Industry

- Develop emergency contact lists and identify the contact for your agency (Appendix A, B, C, D). Update as needed for each outbreak investigation. Distribute contact lists to other agencies.

- Develop standardized templates for sharing information with other agencies (Appendix E).

- Include questions from a nationally standardized questionnaire for foodborne outbreak investigations. This may be useful if a multistate case control study is conducted.

- Complete the CDC Outbreak Reporting form (Reference section) as soon as possible after the investigation has begun and/or the investigation has been completed and forward to the appropriate state agency (to be forwarded to CDC) or send directly to CDC.

- Develop a resource notebook with specific examples of public health information for communicating with the public and other health professionals during a foodborne outbreak. FDA, CDC, and FSIS have examples of some of these available on their websites.

- Develop a list of data points that should be completed in each investigation, including epidemiologic, environmental and laboratory elements (Appendix F).

- Develop a laboratory reference sheet that includes the following information for common foodborne pathogens: food sample and human specimen collection protocols, pathogen-specific standard laboratory tests and analyses, equipment lists, and storage and shipping needs for specimens and isolates.

- Foster working relationships and host meetings with other agencies, the media, consumer groups and industry not related to specific outbreak investigations.

- Participate in multistate, multi-agency conference calls during an outbreak investigation and provide training for staff in conference call etiquette.

Early Alerts

In addition to identifying multistate outbreaks as early as possible to prevent further illness, investigators must communicate information to other agencies as soon as possible rather than waiting until the investigation has been completed. Tables 4 and 5 provide guidelines for determining when to notify other health and regulatory agencies. Each agency may need to modify this guide according to its particular requirements and for different types of outbreaks. These tables may be used in conjunction with Appendices J and K to determine which federal agency should be notified.

Table 4. Guidelines for notification of other agencies

Stage	Stage Description (Outbreak Detection)	Agency Level	Agencies to be notified (Regulatory agency depends upon nature of suspected vehicle)
1	▪ Local cluster(s) of suspected foodborne/ waterborne illness detected	Local	▪ Affected and surrounding county, city health departments (epi, EH, lab) ▪ State health department
2	▪ Clusters detected in multiple counties ▪ An increase in sporadic cases statewide ▪ Matching serotype, subtype, PFGE pattern	Local/ state	▪ Surrounding state health departments (epi, EH, lab) ▪ CDC ▪ Federal regulatory agency district offices (FSIS, FDA, EPA)
3	▪ Clusters detected in multiple states ▪ Food product or water suspected or implicated ▪ Increase in sporadic cases (regionally or nationally) with matching serotype, subtype, PFGE	Local/ state/ federal	▪ CDC ▪ State and local health departments ▪ FSIS, FDA, EPA district and headquarters offices ▪ Foreign countries will be notified by federal agencies as appropriate

An Early Alert Fax/Email Template can be used by any agency to notify surrounding counties, state epidemiology and food safety offices, and FSIS or FDA district offices when an outbreak is detected. Appendix E is an example of such a template; agencies may use this form or develop their own. In addition, CDC's recently developed EPI-X is an early alert network for health agencies to provide electronic notification to each other and CDC.

Table 5. Early alert situations

CDC and the appropriate Federal Regulatory Agencies (FSIS, FDA, or EPA) should be notified when any of the following occur:

- An unusual or virulent pathogen or a chemical or pesticide is suspected in an outbreak or detected in a product.
- A pathogen, chemical, or pesticide is found in a food that may be distributed in interstate commerce.
- An outbreak occurs on an international or interstate airplane, bus, train, or vessel.
- Intentional product contamination is suspected.
- The suspected food item is:
  - Imported
  - Previously implicated in multistate outbreaks
  - Prepackaged
  - Transported across state lines
  - Regulated by FDA (Appendices J & K)
  - Manufactured in an FSIS-regulated facility (Appendices J & K)

Emergency Contacts

Emergency contacts should be identified at local, state and federal levels before a foodborne outbreak occurs. Appendix A provides a list of federal agency emergency headquarters contacts. For both FSIS and FDA, early alerts should be sent to the local FSIS and FDA district offices (Appendices B & C), who will then notify FSIS and FDA headquarters. A template has been included in Appendix D for agencies to identify local and state contacts for notification during a foodborne outbreak.

Multistate, multi-agency conference calls

During the early phases of a multistate foodborne outbreak, efforts will focus upon the epidemiologic phase of the investigation in each state. In this phase, CDC may convene regularly scheduled conference calls between epidemiologists (local, state, federal) in the affected states to provide updates on the progress of the investigations in each state and to provide epidemiologic and laboratory guidance and support. If an outbreak is thought to be associated with an interstate product, FSIS and/or FDA and EPA (if appropriate) should also be included in the early phases of the investigation.

Regulatory agencies should be included in these conference calls so that they can understand the methods, findings and conclusions and so that the implicated product(s) can be removed from the

market as rapidly as possible to prevent additional illnesses. Tables 6 and 7 outline the essential items that should be covered in early-phase and later-phase conference calls.

Table 6: Conference calls in the early phase of a multistate foodborne outbreak investigation

- Calls may be initiated by a local, state or federal health agency, usually hosted by CDC or one of the states.
- Epidemiologic investigations discussed.
- Epidemiologic and laboratory guidance provided.
- Multistate case control studies may be discussed and planned.
- Information exchanged on methods, findings and conclusions.
- Discussion and coordination of media issues.

Additionally, CDC may ask two or more of the affected states and/or local health departments to conduct a standardized epidemiologic study to identify the item responsible for the outbreak. If a food item is determined to be associated with the outbreaks, the focus of the investigation shifts to the product investigation phase, which may include food product sampling and analysis, tracebacks, facility inspections, food preparation reviews, and farm/source investigations.

Table 7. Conference calls in the later phase of a multistate foodborne outbreak investigation

- Multistate conference calls may be initiated by a local, state or federal regulatory agency, usually hosted by FDA, FSIS or EPA.
- Facility inspections, product sampling and analysis, food preparation reviews, traceback and source investigations discussed.
- Environmental and food laboratory guidance provided.
- Exchange of methods, findings and conclusions, regulatory actions.
- Discussion and coordination of media issues.

In this phase of the investigation, the appropriate regulatory agency (FDA/FSIS/EPA) may convene regularly scheduled conference calls between food regulators in the affected states to plan the approach to the environmental investigation, share the current status of the investigations, and provide environmental/regulatory guidance and support. CDC and state and

local epidemiology staff should be included in these conference calls to provide updates on the ongoing epidemiologic investigations. Multi-state conference calls are an important tool for improving coordination and communication among the different agencies. Appendix G provides guidelines for conference call etiquette. It is recommended that staff members participating in these calls receive training in conference call etiquette.

ROLES AND RESPONSIBILITIES

As more multistate foodborne outbreaks are identified, it is critical that investigators understand their own role as well as the roles that other agencies have in these investigations. Each federal agency has a different mission and authorizing legislation, resulting in different approaches before, during, and after an investigation. Appendix H lists the responsibilities of the federal agencies involved in foodborne outbreak investigations. A similar list should be developed within each state/locality describing state and local agency roles and responsibilities. Appendices I (a) and (b) outline the involvement by agency level during the stages of a multistate foodborne outbreak and the different areas of investigation: epidemiology, laboratory and environmental.

Individuals and agencies participating in these investigations should be knowledgeable of the functions of all the agencies involved (Table 8).

Table 8. Defining roles and responsibilities

- Know the lead contact person in each agency involved in the investigation.
- Understand the roles and responsibilities of each agency responsible for food safety activities.
- Understand the laws governing release of confidential information in your state. Be aware that there are different laws governing commercial and medical confidential information, which may prevent the sharing of some information between agencies and limit public disclosure.

Federal Regulatory Agencies and Jurisdictions

Local, state and federal agencies should be able to determine which federal regulatory agency has jurisdiction over a suspected or implicated food product. Appendices J & K provide guidelines for determining which agency to notify when a food item is suspected or implicated. Appendix H also outlines the federal agency jurisdictions.

If bottled water or ice is suspected or implicated in a multistate outbreak, FDA and EPA should both be notified. FDA has regulatory jurisdiction over the packaged product (if it moved in interstate commerce), and EPA has jurisdiction over the water source. In cases of a multistate waterborne outbreak associated with drinking (tap) water or recreational water, EPA should be

notified.

For any food (including animal feed) or water product that has been contaminated with a chemical or pesticide or if contaminated water is suspected, EPA and FDA or FSIS should be notified. EPA should be provided with the pesticide product that is involved and the EPA registration number and/or the exact product name (if known). If water is used in the processing or manufacture of a food product implicated in a multi-state foodborne outbreak, EPA and either FSIS or FDA should be notified.

If product is available, samples should be taken according to prescribed procedures. FDA, FSIS, and EPA (depending upon the product) should be consulted about how the product should be sampled, how much product is needed, and how and where it should be shipped.

STANDARDIZED PROCEDURES

Each agency should approach foodborne outbreak investigations in a standardized manner. A standardized approach is critical in responding in a timely manner to multistate outbreaks and can save time and resources. National surveillance systems must receive information in a standardized format in order to be incorporated into a large database. In addition, CDC, in cooperation with the states, has developed a nationally standardized foodborne outbreak questionnaire, available on the CDC web site. Local and state agencies may conduct an investigation, only to discover later that the outbreak is part of a multistate outbreak. Large multistate case-control studies are time and resource intensive, and the need to re-interview case-patients and controls can be obviated by the use of standardized questionnaires.

Basic Operating Procedures

Any agency responsible for responding to foodborne outbreaks should develop a procedure manual for responding to such outbreaks. A suggested table of contents for a basic operating procedures manual for multistate foodborne outbreak coordination is provided in Appendix L. In addition, several health departments have developed manuals, and some of these are listed in the Reference section.

RESOURCES

For an outbreak investigation to be successful, agencies need adequate resources in epidemiology, laboratory and environmental health. CDC has developed a Core Capacity document (unpublished) that outlines the resources necessary to conduct foodborne surveillance and investigations. This document has been distributed to all state health departments. Investigatory agencies at all levels should openly discuss their resources and priorities throughout the investigation to minimize delays. Agencies may be able to help others with procedures such as sample collections, laboratory tests, or conducting interviews.

Chapter 2. OUTBREAK RESPONSE
Section B. Product Investigation

Key Points:

- **Product investigations include food preparation reviews, traceback investigations, and inspections.**
- **A traceback investigation is the method used to determine the source and scope of the product/processes associated with the outbreak and document the distribution and production chain of the product that has been implicated in a foodborne illness or outbreak.**
- **A source or product investigation may be conducted to determine possible points of contamination.**
- **Tracebacks can be conducted for epidemiologic and/or regulatory purposes. Federal regulatory agencies coordinate multistate tracebacks.**
- **Federal agencies will review results using criteria from three areas (epidemiologic, environmental and laboratory) before initiating a traceback for regulatory purposes.**
- **The cooperation of industries should be fostered before outbreaks occur to facilitate tracebacks and source/farm investigations when they are needed.**

A product investigation begins when a specific food is suspected or implicated in a foodborne illness outbreak. Product investigations can involve facility inspections, a food preparation review, and environmental and traceback investigations. Local and state environmental health investigators and inspectors from regulatory agencies initially conduct product investigations. If a product falls under federal jurisdiction, FDA or FSIS will coordinate inspections with the local and state investigators.

A food can be implicated or associated with a foodborne outbreak through one or more of the following methods: epidemiologic or statistical, laboratory and/or a thorough food preparation review (Table 9).

Table 9. Methods used to implicate or associate a product with a foodborne outbreak

- An epidemiologic investigation shows an association (not necessarily statistical) between a food and illness.
- A laboratory analysis of the implicated food sample tests for the same pathogen, toxin, or contaminant (same serotype or PFGE pattern) that was detected in clinical specimens.
- A food preparation review identifies a possible vehicle(s) and contributing factors that could have resulted in the illness under investigation.

Traceback investigations

A traceback investigation is used to determine the source of the product associated with the outbreak and document the distribution and production chain of the product that has been implicated in a foodborne illness or outbreak (Table 10). A subsequent source or product investigation may be conducted to determine possible points of contamination. A source may be determined to be a consumer, retailer, restaurant or food service, water source, farm, estuary, harvester, transporter, producer, processor or manufacturer.

Table 10. Purposes of traceback investigations

- Identify the source and distribution of foods in order to alert the public and remove contaminated product from the marketplace.
- Distinguish between two or more vehicles.
- Compare distribution of illnesses and distribution of product in order to strengthen an epidemiologic association. This is referred to as an "epi" traceback.
- Determine potential route or source of contamination by evaluating common distribution sites, processors or growers.

An increase in the recognition and investigation of food products associated with multistate foodborne outbreaks has led to a greater need for traceback investigations. Participants at all levels of outbreak investigations have expressed frequent concern about the inadequate epidemiologic, environmental or laboratory evidence to support initiation of a traceback investigation. Other difficulties associated with these investigations include poorly defined roles and responsibilities, insufficient resources available to conduct the investigations, inadequate record keeping about product distribution, and legal and organizational barriers to sharing of data

and information. Traceback investigations can require extensive resources and can result in irreparable damage to food firms. Therefore, it is critical that each piece of the investigation (epidemiologic, laboratory, and environmental) is thorough, complete, and accurate.

A regulatory traceback investigation of a product can be initiated when epidemiologic, environmental or laboratory evidence implicates a food product and other contributing causes (e.g., cross-contamination, ill food workers at the point of service) are not likely (Table 11). If a food is implicated in a multistate outbreak, the responsible federal regulatory agency will need to confirm the epidemiologic association before initiating a multistate traceback investigation or regulatory response.

Table 11. Factors to be considered before initiating a traceback investigation

- Adequate epidemiologic, laboratory and environmental evidence
- Disease severity
- Risk of ongoing exposure
- Reliable exposure information (date and place)
- Availability of shipping records
- Availability of resources for conducting traceback investigations

Before initiating a multistate traceback investigation, the federal regulatory agencies may request a written summary of the results of the epidemiologic, environmental and laboratory investigations from the agencies that conducted the investigations (Table 12). The summaries should include the available information that has been listed in the Checklist for Communicating Findings (Appendix F). The federal agencies may also request that CDC and/or other epidemiologists evaluate the epidemiologic data.

Table 12. Information requested and reviewed before initiating a multistate traceback investigation

- A written epidemiologic summary to address the items specified in Appendix F (if available).
- Environmental or inspection reports, including a complete food preparation review, for local, state and/or federal investigators to determine if contamination at the point of service is a probable cause of the outbreak.
- Laboratory confirmation, if possible, of the agent(s) isolated from patients and/or the food product.
- Copies of invoices and other distribution information collected by local and state investigators.

Coordination of multistate tracebacks

During the early phases of an outbreak investigation, an "epidemiologic" traceback is sometimes conducted. Epidemiologists may use product distribution data as a tool to test hypotheses, distinguish between multiple vehicles, and strengthen an epidemiologic association. A traceback that begins for epidemiologic reasons can quickly develop into a regulatory or "product" investigation as appropriate evidence is obtained.

Multistate and interstate traceback investigations will be coordinated at the federal level by the agency (FSIS or FDA) having regulatory authority for the food product. If product distribution records are being requested in the course of an epidemiologic investigation, the local district offices of FDA or FSIS should be notified. This early contact is critical for coordinating and conducting tracebacks. The local, state or federal agency requesting the traceback data should consult with the federal regulatory agency (FDA or FSIS) in determining what information will be needed if the traceback becomes a regulatory or product traceback. This will save time and duplication of effort if a traceback is initiated later by the federal agencies. Federal agencies may need to take regulatory action in some instances, and documentation of the events and data are required.

When the local district offices (FSIS or FDA) are notified of an outbreak or a request for traceback investigation, they will immediately notify their contacts in headquarters. The Epidemiology Branch of FSIS (USDA) and the Division of Emergency and Investigational Operations, DEIO (FDA) will be the federal agency contact points for all food-related emergencies and traceback investigations. The contact information for these offices is given in Appendix A. For both FDA- and FSIS-initiated tracebacks, the investigation will be conducted by the local District offices (Appendices B & C). Federal headquarters offices will coordinate the investigations with the district offices and other agencies.

As the number of multistate outbreak investigations increases, the number of traceback investigations will also increase, requiring additional resources at all levels of government. The methods described in the FDA "Guide to Traceback of Fresh Fruits and Vegetables Implicated in Epidemiological Investigations, July 1998" should be used in all tracebacks of fresh fruits and vegetables. A revised version of this document (available in the spring of 2001) will include additional guidance for other commodities. These methods may also be applicable to other commodities that do not have labeling or packaging.

Sharing traceback information

One of the most difficult obstacles in the coordination and communication of traceback investigations is sharing of information. According to current federal law, FDA and FSIS must treat as "commercial confidential" traceback information (customer and distribution information), whether collected for epidemiologic or regulatory reasons. Therefore much of this information cannot be shared with other agencies unless it can be protected from being released publicly. This is equivalent to patient health information that is also protected by law. Releasing commercial confidential information can unfairly harm a company and an industry. Regulatory

agencies can be sued for destroying a company's reputation, and federal regulators can suffer severe criminal penalties for releasing this information.

For USDA-regulated products, a code is printed on the product label. If this code is available, the product can easily be traced to the manufacturer and a recall can be initiated. Information regarding recalled USDA-regulated product (brand name, manufacturer, lot numbers) is public information. However, if a pathogen is detected in a product in a meat processing facility (these are monitored and tested by USDA) and that product has never reached the market (held at a plant), the public has never been at risk from the product. That information is not public and cannot be released.

For FDA-regulated products that are packaged, the name of a distributor or manufacturer may appear on the label; the product can easily be traced back to the manufacturer and a recall can be initiated. Information , such as labeling, lot numbers, and brand name, regarding a recalled FDA-regulated product is public information. This does not include the list of customers who received the product that is under recall. The list of customers, or consignees, is confidential and is protected from public release by law. The list of states that may have received the product is usually available to the public. For most fresh produce, packaging and labeling are rarely available. Tracebacks are the only way to determine the potential sources of the product (not necessarily the source of the contamination). If a source or sources of the product can be determined through a traceback investigation, an investigation is conducted at those firms or farms.

A recall and/or a traceforward is rarely undertaken for fresh produce for several reasons: 1) the product is not readily identifiable by consumers (no packaging, labels, or lot codes); 2) the product has a short shelf life and is usually no longer available in the marketplace when it is implicated in an outbreak; and 3) the contamination of fresh produce is usually sporadic and does not pose an ongoing risk to consumers. When a fresh produce product is implicated in an outbreak and there is a real or potential risk to the public's health, an entire industry is usually adversely affected as a result.

Confidentiality Agreements

All federal agencies are charged with protecting public health. It is imperative that information be shared between agencies working on the same investigations. The FDA is currently developing formats for agreements with other federal and state agencies that will allow the sharing and protection of commercial confidential information, including traceback information.

FDA and CDC, as sister agencies under the U.S. Department of Health and Human Services, have signed an agreement that assures the confidentiality of regulatory and health data that are shared between the agencies. Many states have also signed agreements with FDA that will allow this information to be shared and protected. In addition, many state food regulatory agencies have individuals who are "commissioned" by the FDA. In essence, these persons are issued FDA credentials and are able to receive information as FDA investigators. They can request and receive certain investigatory information, including traceback information, but cannot share the

information with others in their agency unless they are also “FDA Commissioned Officers” and have been approved by FDA to receive that information. These FDA Commissioned Officers can lose their credentials for releasing confidential information.

The role of industry in traceback investigations

Local and state agencies and trade groups are encouraged to work with industries in their area to facilitate the traceback of implicated products through improved product distribution record keeping throughout the distribution system. Industry should take an active role in developing and implementing systems to trace products from farm to table. A quick and accurate traceback system that can identify implicated shipments can minimize impact to the industry by potentially reducing the amount of product that may need to be recalled and by ruling out other shipments of product that might otherwise be implicated.

Investigation of firms

For multistate outbreaks or any outbreak linked to product that was shipped in interstate commerce, federal regulatory agencies have jurisdiction over the products and the responsible firms (e.g., processing, packing, or distributing companies). It is the responsibility of the federal regulatory agency to conduct an investigation at the firm(s). State regulatory investigators in the state where the firm is located are usually included in these outbreak response investigations.

Investigators in regulatory agencies are trained and required to list observations and not to make conclusions during an inspection or investigation. Investigations that are conducted in response to a foodborne outbreak require additional preparation by the investigators so that their observations are relevant to the situation. Federal and state regulatory agencies are encouraged to consult with experts in epidemiology, traceback, and microbiology, particularly those who have knowledge about the outbreak investigation, as well as experts in food and water processing, manufacturing, and farming.

State and federal regulatory agencies should have an understanding of the outbreak, (e.g., distribution of the illnesses, dates of exposure, microbiology of the pathogen). These agencies should discuss and review the epidemiologic findings before conducting an investigation at the firm. In some instances, it may be appropriate to involve experts in specific areas (e.g., microbiologists, water or plant engineers, epidemiologists) to assist in the investigation as they may have a particular perspective that otherwise would not be available.

Appendix A. Federal Emergency Contacts

Agency	Contact Office	Phone Number(s)	Fax Numbers
HHS			
Centers for Disease Control and Prevention, Atlanta, GA	Main Emergency Number (24 hour operator)	404-639-3311	
	Foodborne and Diarrheal Diseases (bacterial and unidentified pathogens)	404-639-2206	404-639-2205
	Parasitic Diseases	770-488-7750	770-488-7761
	Viral Diseases/ Hepatitis	404-371-5900	404-371-5221
	Viral Diseases/ Gastroenteritis Branch (Norwalk-like viruses)	404-639-6307	404-639-3866
	Vessel Sanitation Program	770-488-7070 800-323-2132	770-488-4127
	Division of Quarantine	404-639-8110	
Food and Drug Administration Rockville, MD	Emergency Operations (emops1@ora.fda.gov)	301-443-1240 (24 hours)	301-443-3757
USDA			
Food Safety and Inspection Service Washington, DC	Emergency Response Branch	202-690-6413 After Hours pager 800-759-8888 PIN 4124058	202-690-6414
EPA			
Environmental Protection Agency Washington, DC	Office of Research & Development	513-569-7689	
	Office of Ground Water and Drinking Water	202-260-7096	
	Office of Pesticide Programs	703-305-7576	703-305-4646

Appendix B. FSIS (USDA) District Offices

District	Phone Number	Fax Number	Area of Responsibility
Alameda	510-337-5000	510-337-5081	CA
Salem	503-399-5831	503-399-5636	AK, AS, GM, NMI, HI, ID, OR, WA
Boulder	303-497-5411	303-497-7306	AZ, CO, NM, NV, UT
Minneapolis	612-370-2400	612-370-2411	MN, MT, ND, SD, WY
Des Moines	515-727-8960	515-727-8991	IA, NE
Lawrence	785-841-5600	785-841-5623	KS, MO
Springdale	501-751-8412	501-751-9049	AR, LA, OK
Dallas	214-767-9116	214-767-8230	TX
Madison	608-240-4080	608-240-4092	MI, WI
Chicago	630-620-7474	630-620-7599	IL, IN
Pickerington	614-833-1405	614-833-1067	KY, OH, WV
Philadelphia	215-597-4219	215-597-4217	PA
Albany	518-452-6870	518-452-3118	CT, ME, MA, NH, NJ, NY, RI, VT
Beltsville	301-504-2136	301-504-2140	DE, DC, MD, VA
Raleigh	919-844-8400	919-844-8411	NC, SC
Atlanta	404-562-5900	404-562-5877	FL, GA, PR
Jackson	601-965-4312	601-965-4993	AL, MS, TN

Appendix C. FDA District Offices

District	Phone Number	Fax Number	Area of Responsibility
Atlanta	404-253-1169	404-253-1205	GA, SC, NC
Baltimore	410-962-3396	410-962-2219	MD, VA, DC, WV
Chicago	630-978-5763	312-886-3280	IL
Cincinnati	513-679-2700	513-679-2771	OH, KY
Dallas	214-655-5310	214-655-5331	TX, OK, AR
Denver	303-231-6466	303-236-3551	CO, UT, WY, NM
Detroit	313-927-8268	313-226-3076	MI, IN
Florida	407-475-4700	407-475-4768	FL
Kansas City	913-599-9635	913-752-2413	KS, NE, IA, MO
Los Angeles	714-667-7216	949-798-7690	So. CA, AZ
Minneapolis	612-392-4314	612-334-4134	MN, ND, SD, WI
New Orleans	504-240-4500	504-253-4566	LA, MS
Nashville	615-781-5385	615-781-5383	TN, AL
New England	781-939-2380	781-279-1742	VT, NH, ME, MA, CT, RI
New Jersey	973-905-4205	973-526-6069	NJ
New York	718-340-7000	718-662-5660	NY
Philadelphia	215-597-4390	215-597-0875	PA, DE
San Francisco	510-337-6700	510-337-6859	No. CA, NV, HI
Seattle	425-486-8788	425-483-4996	WA, OR, ID, MT, AK
San Juan	787-729-6943	787-729-6809	PR, VI

Appendix D. TEMPLATE FOR LOCAL AND STATE CONTACTS

Agency	Contact Name/Office	Phone Number	Fax Number	Email

Appendix E.

Foodborne/Waterborne Outbreak Early Alert Fax/Email Template

To: **Fax:**

From: **Phone:**

CC: **Date:**

This is an early alert/heads up on an investigation we are conducting. The information contained in this fax should be considered preliminary and confidential. This information should not be shared or distributed without permission from the sender. If you have similar cases, please notify the appropriate agency or agencies in your jurisdiction.

The _____ Health Department is currently investigating an outbreak that is suspected to be

foodborne _____
waterborne_____
of unknown source/vehicle _____

Number of cases _____ **Number of clusters_____**

Earliest onset date_____ **Latest onset date_____**

Pathogen/Agent _____ (suspected/confirmed)

Food/Water Product _____ (suspected/implicated/lab confirmed)

Place(s) of Exposure _____

Details:

Our agency's lead contact is:

Name:
Phone Number:
Fax Number:

Confidential

Appendix F. Checklist for Communicating Findings

Epidemiologic Investigation:

__ Definition of illness (or case definition if case-control study)

__ Number of ill persons (or number of cases if case-control study)

__ Number hospitalized and any fatalities

__ Number exposed

__ Dates, times of onset of illness and exposures

__ List of symptoms, duration and frequency

__ Location(s) of illness occurrence

__ A copy of the questionnaire

__ Description of study design

__ Criteria used to select or exclude study participants

__ Number of persons enrolled in study

__ If matching is used, criteria for matching

__ List of foods and other variables assessed

__ Portion size of food consumed (if available)

Analysis and Results

__ Plot of the epi curve

__ Food-specific attack rate (if cohort study)

__ 2 x 2 contingency table(s)

__ Pertinent measures of association and statistics

__ How potential confounding factors were controlled

__Dose-response effect (if data available)

Environmental Investigation:

__ Identification of suspected agent and vehicle

- If a pesticide is suspected, collect the exact product name and EPA registration number and active ingredients (if known).

__ Review of food worker illnesses and absences

__ Collection of food worker specimens (if appropriate. See food worker under "Laboratory samples")

__ Food preparation review of implicated foods, including times and temperatures

__ Assessment of water supply, potential cross connections

__ Assessment of sewage disposal system and any opportunities for wastewater backup into food, sinks, or equipment

__ Assessment of traps and drains as a potential source of contamination

__Results of surface swabs, if collected

__ Labels and descriptive information on products, where available

__ Records of sale/shipment for one shelf life of product (harvest-to-table shelf life)

__ Results of samples of the implicated food, where available and appropriate

__ Results of environmental swabs (surface and utensil swabs)

__ Results of sample controls

__ Food worker/food safety training/knowledge

__ List possible contributing factors

Laboratory Investigation

Clinical Specimen and Food Sample Collection:

__ Clinical samples for suspected agent from symptomatic and asymptomatic exposed individuals

- Stools
- Vomitus
- Serum
- Urine
- Other, specify_____

__ Specimen(s) from food workers
- Stools
- Swabs from hands, nose and throat

__ Food samples
- Home samples
- Restaurant or point of sale/service (POS) samples
- Unopened container/packages of the same lot as suspected product(s)
- Samples from production facility

__ Environmental samples
- Swabs from POS,
- Swabs from production/distribution facility
- Water samples from POS
- Water samples from production facility

Standard Criteria:

__ Additional samples and isolates

__ Analytical methods used

__ Enumeration and/or quantification of results

__ Laboratory-confirmed cases match case definition

__ Secondary testing results (serotyping, PFGE, antibiotic sensitivity)

__ Sharing/confirming of secondary testing results from appropriate epi surveillance (PulseNet, federal, and/or state labs). Determine if there are a sufficient number of historical patterns to estimate variability

__ Name of laboratories analyzing specimen(s) and sample(s)

__ Results of laboratory analysis and controls

Appendix G. Conference Call Etiquette

Host

1. Make and distribute agenda at least 2 days before the conference call, when possible.
   The agenda should include
   Name and affiliation of the facilitator/convenor
   Format for reporting information

2. Distribute handouts in advance.

3. Identify host/leader of call.

4. Identify and notify point of contact in all relevant agencies.

5. Take attendance, make introductions.

6. Explain jargon, abbreviations.

7. Stay on topic, stay on time.

8. Solicit everyone's input.

9. Record and distribute a summary of the call including action items and plans for the next meeting, if known.

All Participants

1. Do not put the conference call on hold. Some phones will play background music when on hold, disrupting the call.

2. Do not use a cell phone, as this often disrupts the call and makes other participants unable to hear.

3. Identify yourself and affiliation when you log on to the call.

4. After identifying yourself, please put your phone on mute and leave it on mute until you wish to speak. After speaking return the phone to mute.

5. Explain jargon, abbreviations.

6. Stay on topic, stay on time.

7. Identify self and organization before speaking.

Appendix H. Roles and Responsibilities of Federal Agencies in Foodborne Outbreak Investigations

- **FSIS** The Food Safety and Inspection Service (FSIS) of the U.S. Department of Agriculture (USDA) is responsible for assuring that meat, poultry, and pasteurized processed egg products are not adulterated or misbranded. FSIS has the regulatory authority to coordinate a voluntary recall of meat, poultry and pasteurized processed egg products linked to outbreaks of foodborne disease. During foodborne illness outbreaks, FSIS is available to assist local, state and other federal agencies in their investigations. FSIS epidemiology officers can assist in tracing the origin and distribution of meat, poultry and egg products and can provide laboratory assistance to identify the contaminant(s) in the implicated product. FSIS has experience in working with state health and agriculture departments and knowledge of production practices of meat, poultry, and pasteurized processed egg products. FSIS can provide coordination, laboratory support, technical consultation, regulatory support, and media relations.

  FSIS's main objective is to remove quickly from commerce product that is known to be contaminated with harmful agents. If illnesses are associated with meat, poultry, or egg products, health department officials should contact the local FSIS Offices (Appendix B). The district offices will contact Human Health Sciences Division, Emergency Response Branch (7:30 a.m. to 4:30 p.m.) at 202-690-6413. For after- hours emergencies contact the epidemiologist on call by beeper 1-800-759-8888 (pin #4124058).

- **FDA** The Food and Drug Administration (FDA) regulates the safety of all foods, including shell eggs, that move in interstate commerce, except for meat, poultry, and pasteurized processed egg products regulated by FSIS. FDA's objectives in outbreak investigation and response are verification of the association of illness with a regulated product, identification of the source of the product and its extent of distribution, prevention of any further exposure to the contaminated product, and initiation of regulatory action as indicated. In addition, to determine contributing factors so similar problems can be avoided in the future, FDA has the regulatory authority to coordinate a voluntary recall of FDA-regulated products that are linked to outbreaks of foodborne disease. FDA works with other federal agencies as well as state and local agencies to assure efficient and expeditious investigation and response. FDA can provide coordination, field investigators, laboratory support and surveillance, technical consultation, regulatory support, and media relations. Additionally, FDA provides policy, technical, and scientific support to these investigations. FDA scientists, consumer safety officers, and laboratory personnel provide technical and scientific advice/support to field investigators during an outbreak investigation.

  Twenty District Offices located in five Regions carry out FDA's investigation and outbreak response activities. The FDA District Offices are the primary points of contact for state and local government agencies and the food industry (Appendix C). The District Offices are equipped with a 24-hour answering service. FDA's outbreak response is coordinated by the Division of Emergency and Investigational Operations (DEIO). DEIO can be contacted 24 hours a day, seven days a week at 301-443-1240.

- **CDC** The Centers for Disease Control and Prevention (CDC) works closely with state and local public health epidemiologists and laboratorians to identify illnesses and clusters of illness that may be foodborne, to conduct the rapid epidemiologic investigations needed to implicate foods or other sources of infection, to determine risk factors for illness, and to develop prevention and control strategies. CDC does this by epidemiologic consultation with the state and local epidemiology offices, on-site emergency assistance in epidemiologic investigations, provision of reference diagnostic support to the state public health laboratory, and development and application of subtyping protocols for foodborne pathogens. CDC is not a regulatory agency but works with regulatory agencies during outbreak investigations to determine the origins of contaminated food and the reasons for the contamination. Epidemiologists and microbiologists in state public health departments have phone, FAX, and e-mail addresses for their routine CDC contacts. In an emergency, CDC may be contacted 24 hours a day at 404-639-3311.

- **EPA** The U.S. Environmental Protection Agency (EPA) maintains the capability to respond to waterborne disease outbreaks. Generally these outbreaks are identified by either a state or county health department, who in turn contacts the state environmental agency and CDC. If CDC agrees that the disease may be associated with drinking water, it or the state or both will contact EPA to request assistance in identifying the causes of the outbreak.

  EPA has established a coordination system for responding to outbreaks. The National Risk Management Research Laboratory (NRMRL) in the EPA's Office of Research and Development (ORD) should be contacted at 513-569-7689. The NRMRL is responsible for providing staff in response to outbreaks and, through the Water Supply and Water Resources Division (WSWRD), provides a field response team and laboratory analytical capabilities, either directly or through support contract. Additionally, contact should be made with the EPA's Office of Ground Water and Drinking Water (202-260-5543/7096) to allow a coordinated outbreak response.

  In addition, WSWRD and other elements of ORD will respond to requests from Regional Offices, municipalities and state agencies if water quality problems are associated with individual water utilities. Frequently these problems are associated with violations of the Maximum Contaminant Levels under the Safe Drinking Water Act but have not been categorized as waterborne outbreaks.

  EPA's Office of Prevention, Pesticides & Toxic Substances administers the Toxic substances Control Act, the Pollution Prevention Act, and the Federal Insecticide, Fungicide & Rodenticide Act (FIFRA) and has a system of criminal and civil penalties to enforce these measures. Through cooperative enforcement agreements, all but two states have assumed primary enforcement responsibilities for pesticide violations under FIFRA, subject to EPA oversight. Through this system, EPA ensures that pesticides used on crops/food are registered, not adulterated, and used according to label directions. Investigations are done on pesticide incidents and incidents of chemical contamination. In cases of pesticide incidents or emergencies, the Office of Pesticide Programs (OPP) should be contacted at 703-305-7576.

Appendix I (a). Multistate Foodborne Disease Outbreak Matrix by Agency Level

Level	Surveillance	Detection	Investigation	Food Association	Traceback	Source Investigation
Local	• Reportable disease • Sporadic cases	• Cluster identification • Complaint follow-up	• Assemble team • Active case finding • Patient interviews • Verify diagnosis	• Descriptive epi • Statistical association • Environmental investigation • Match lab isolates • Alert other agencies	• Collect source information • Share findings with state/ federal	• Support state/ federal investigation
State	• Consult with local staff • Receive reports from local staff • Identify trends	• Consult with local staff • Receive reports from local staff	• Assist local staff • Expand investigation • Coordinate investigation	• Alert other agencies • Assist local staff • Statewide coordination • Alert public	• Collect source information • Share findings with federal	• Support federal source investigation • Conduct source investigation • Identify contributing factors
Federal	• Consult state/local staff • Public health labs • FDA/USDA labs • SODA, FoodNet, PulseNet, Food Pesticide Labs	• Consult state/local • Conduct additional lab tests • Epi aid	• Coordinate investigation • Epi aid • Lab testing • Alert other agencies	• Coordinate investigation • Verify food association • Expand investigation • Alert public/ recall	• Collect source info at all levels of distribution • Analyze trace information • Identify source	• Lead source investigation • Identify violations & contributing factors • Implement enforcement/ interventions

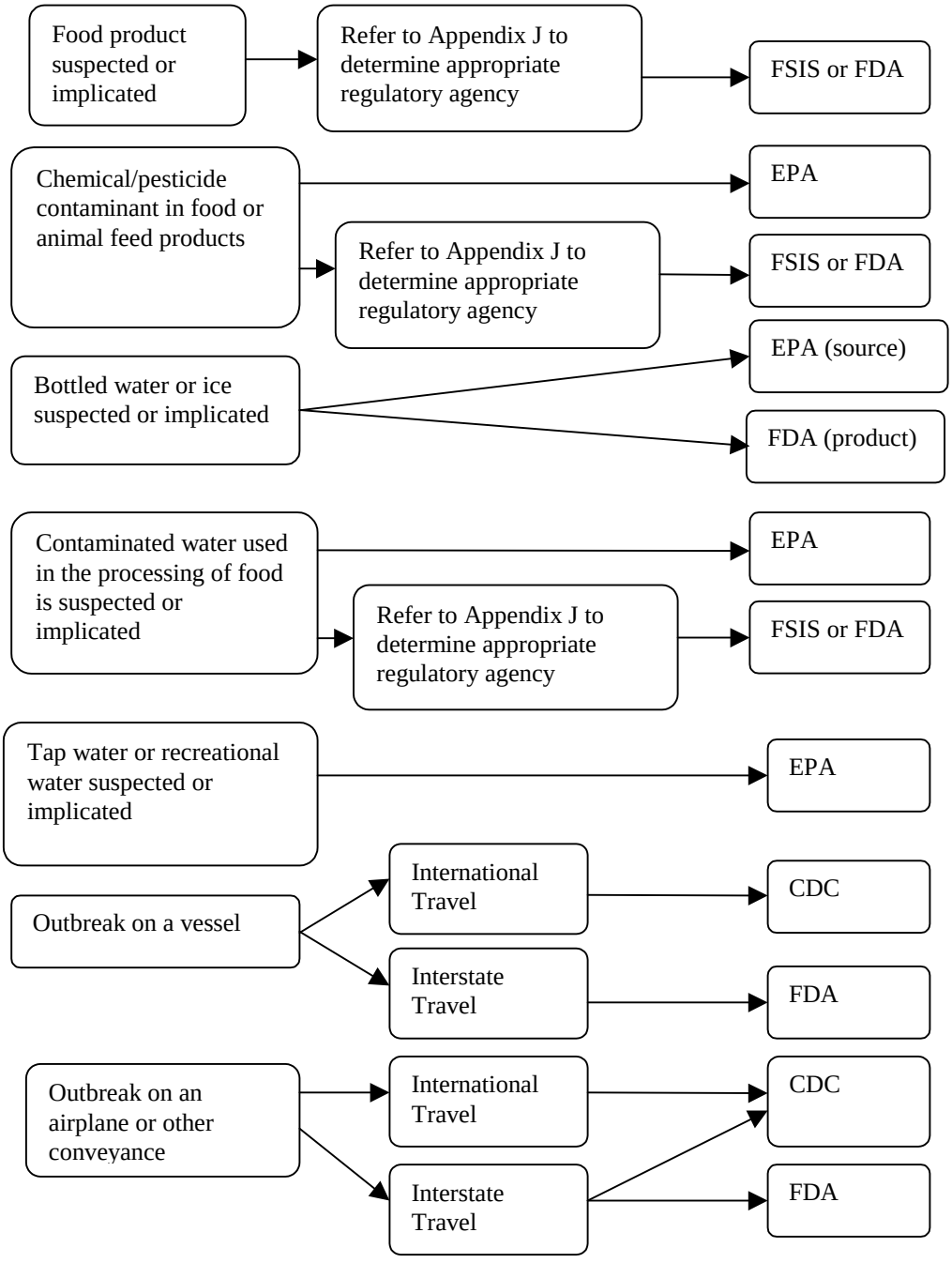
Appendix I (b). Multistate Foodborne Disease Outbreak Matrix by Function

Function	Surveillance	Detection	Investigation	Food Association	Traceback	Source Investigation
Epidemiology	• Passive (reportable-SODA) • Active (FoodNet) • Complaint response	• Cluster identification • Complaint follow-up • Verify diagnosis	• Expand investigation • Case finding • Assemble team • Coordinate investigation	• Descriptive epi • Statistical association • Verify food association • Alert public/recall	• Determine source(s)	• Support environmental investigation of source
Laboratory	• Clinical labs • PulseNet • Public Health labs • Food pesticide labs • FDA/USDA labs	• Match patient isolates • Secondary tests • Review of previous isolates (PFGE patterns) • Food samples	• Match patient isolates • Secondary tests	• Analyze food/ environmental samples • Match patient and food isolates	• Share findings and support investigation	• Analyze food/ environmental samples
Environmental	• Complaint response investigation • Inspection data	• Alert epidemiology • Complaint follow-up	• Expand investigation • Investigate place of preparation	• Investigate place of preparation • Verify food/water association • Determine if contamination occurred at point of preparation • Alert public/recall	• Collect source information throughout distribution • Collect and analyze traceback information • Determine source	• Lead source investigation • Identify contributing factors/violations • Collect samples • Implement enforcement/interventions

Appendix J. FDA/USDA Jurisdictional Overlap for Commercial Food Products

PRODUCT	FDA	USDA
Red meat products	Nonspecified red meats, e.g., bison, rabbit, game animals, zoo animals, elk, wapiti, moose	Cattle, sheep, swine, goats, horses, mules, other equine
Poultry	Nonspecified birds: wild turkeys, wild ducks, wild geese, emus, ratites	Domesticated birds: chicken, turkey, ducks, geese, guineas
Other meat products	Products containing <3% red meat (wet) and closed faced meat sandwiches	Products containing 3% or more red meat (wet) and open-faced meat sandwiches
Other poultry products	Products containing < 2% poultry (wet)	Products containing 2% or more poultry (wet)
Eggs	Shell eggs, products containing egg products and other egg processing not covered by USDA (e.g., restaurants, cake mix plants, bakeries). Enforcement of shell egg labels/ labeling	Pasteurized processed egg products, egg processing plants (washing, sorting, breaking, and pasteurizing)
Soup	All soup not covered by USDA	Soup containing 3% or more red meat or 2% or more poultry (e.g., chicken noodle)
Other products	Cheese, onion, mushroom, pizza, spaghetti sauces (less than 3% red meat), spaghetti sauce with mushrooms and 2% meat, pork and beans, sliced egg sandwich (closed faced), frozen fish dinner, rabbit stew, shrimp flavored instant noodles, venison jerky, buffalo burgers, alligator nuggets	Pepperoni pizza, meat lovers stuffed crust pizza, meat sauces (3% or more red meat), spaghetti sauce with meatballs, open faced roast beef sandwich, hot dogs, beef/veg pot pie, chicken sandwich (open faced)
Exceptions to the above	All foods involved in an outbreak aboard an interstate vessel, plane, train, bus	

Appendix K. Determining Federal Regulatory Jurisdiction



Appendix L. Suggested Table of Contents for a Basic Operating Procedure Manual for Multistate Foodborne Outbreaks

A. Contact Lists
   1. Local and state agencies (Health, Environmental, Agriculture)
   2. FSIS and FDA District Offices
   3. Federal agencies (CDC/HHS, FSIS/USDA, FDA/HHS, EPA)

B. Roles and Responsibilities of Food Safety Agencies
   1. Federal agency jurisdictions
   2. Flow diagram for determining federal regulatory jurisdictions

C. Public health communication information/agent fact sheets
   1. Press kit (contacts, sample press releases)

D. Outbreak Investigation Procedures
   1. Outbreak investigation procedures
   2. Critical data points to collect
   3. Conference call etiquette
   4. Lab reference sheet (collection, shipping, storage, methods)
   5. Guidelines for multistate outbreak coordination

E. Outbreak Investigation Forms
   1. Early alert fax template
   2. Standardized questionnaires
   3. Food prep review/environmental investigation template
   4. CDC outbreak reporting form

F. Reference Materials/Bibliography

G. Glossary

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Massachusetts foodborne illness investigations and control manual
http://www.state.ma.us/dph/fpp/refman.htm

FDA Bad Bug Book http://vm.cfsan.fda.gov/~mow/intro.html

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CDC Infectious Disease website: http://www.cdc.gov/ncidod/diseases/index.htm

CDC Foodborne Outbreak Response and Surveillance Unit
http://www.cdc.gov/ncidod/dbmd/fddb/outbreak

CDC Form 52.13 Foodborne Outbreak Report Form (Rev 8/99)
http://www.cdc.gov/ncidod/dbmd/fddb/outbreak/report_f.htm

Epidemiologic Case Studies: http://www.cdc.gov/phtn/casestudies/dnload.htm

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Acronyms Commonly Used in Food Safety

AFDO – Association of Food and Drug Officials

ANSI – American National Standards Institute

APHL – Association of Public Health Laboratories (formerly ASTPHLD – Association of State and Territorial Public Health Laboratories)

CDC – Centers for Disease Control and Prevention

CFSAN – Center for Food Safety and Applied Nutrition (FDA)

CSTE – Council of State and Territorial Epidemiologists

DEIO – Division of Emergency and Investigational Operations (FDA)

EIR – Establishment Inspection Report

EPA – Environmental Protection Agency

FDA – U.S. Food and Drug Administration

FIFRA – Federal Insecticide, Fungicide, and Rodenticide Act

FOIA – Freedom of Information Act

FORCG – Foodborne Outbreak Response Coordination Group

FQPA – Food Quality Protection Act

FSIS (USDA) – Food Safety Inspection Service (U.S. Department of Agriculture)

HACCP – Hazard Analysis Critical Control Points

IAFP (formerly IAMFES) – International Association for Food Protection formerly International Association of Milk, Food and Environmental Sanitarians

IAMFES (now IAFP)- International Association of Milk, Food and Environmental Sanitarians (now International Association for Food Protection)

IOM – Investigational Operations Manual (FDA)
IOM – Institute of Medicine

ISO – International Standards Organization

NACCHO – National Association of County and City Health Officials

NAIN – National Antimicrobial Information Network (EPA)

NCID – National Center for Infectious Diseases (CDC)

NEDSS – National Electronic Disease Surveillance System (formerly NETSS National Electronic Telecommunications Surveillance System

NFSS – National Food Safety System

NPTN – National Pesticide Telecommunications Network (EPA)

NSSP – National Shellfish Sanitation Program

OPP – Office of Pesticide Programs (EPA)

OPPTS – Office of Prevention, Pesticides and Toxic Substances (EPA)

ORA – Office of Regulatory Affairs (FDA)

ORD – Office of Research and Development (EPA)

ORO – Office of Regional Operations (FDA)

OW – Office of Water (EPA)

PFGE – Pulsed-Field Gel Electrophoresis

PHLIS – Public Health Laboratory Information System

SODA – Salmonella Outbreak Detection Algorithm

TSCA – Toxic Substances Control Act

WHO – World Health Organization

Glossary

2 x 2 table - a tabular cross-classification of data such that subcategories of one characteristic are indicated horizontally (in rows) and subcategories of another characteristic are indicated vertically (in columns). Tests of association between characteristics in the columns and rows can be readily applied. Also known as a contingency table. The simplest contingency table is the fourfold or 2 x 2 table. Contingency tables may be extended to include several dimensions of classification.

	ill	not ill
Exposed	a	b
Not Exposed	c	d

Agent - a factor, such as a microorganism, chemical substance, or form of radiation, whose presence, excessive presence, or (in deficiency diseases) relative absence is essential for the occurrence of a disease. A disease may have a single agent, a number of independent alternative agents (at least one of which must be present), or a complex of two or more factors whose combined presence is essential for the development of the disease.

Antibiogram - a record of the resistance of microbes to various antibiotics.

Asymptomatic - without symptoms or producing no symptoms.

Attack rate - the cumulative incidence of infection in a group observed over a period during an epidemic; the proportion of ill among those exposed. This "rate" can be determined empirically by identifying clinical cases and/or by means of seroepidemiology. Because its time dimension is uncertain or arbitrarily decided, it should probably not be described as a rate.

Carrier - A person or animal that harbors a specific infectious agent in the absence of discernible clinical disease and serves as a potential source of infection. The carrier state may occur in an individual with an infection that is inapparent throughout its course (known as healthy or asymptomatic carrier) or during the incubation period, convalescence, and postconvalescence of an individual with a clinically recognizable disease (known as incubatory carrier or convalescent carrier). The carrier state may be of short or long duration (temporary or transient carrier or chronic carrier).

Case - A particular instance of a disease, health disorder, or condition under investigation. A variety of criteria may be used to identify cases, e.g., individual physicians' diagnoses, registries and notifications, abstracts of clinical records, surveys of the general population, population screening, and reporting of defects such as in a dental record. The epidemiologic definition of a case is not necessarily the same as the ordinary clinical definition.

Case-control study - the observational epidemiologic study of a person or persons with the disease (or other outcome variable) of interest and a suitable control (comparison, reference) group of persons without the disease. The relationship of an attribute to the disease is examined

by comparing the diseased and nondiseased with regard to how frequently the attribute is present or, if quantitative, the levels of the attribute, in each of the groups. In short, the history of exposure to suspected risk factor is compared between "case patients" and "controls," persons who resemble the case patients in such respects as age and sex but do not have the disease or condition of interest.

Case definition – the characteristics (typically time, place, person, and clinical features or symptoms) of the case being studied. This definition might be different in different phases of an investigation. For example, a broad definition might be used early in the course of an investigation to capture all possible cases; later in the investigation, the definition might be narrowed to capture only definite cases. Often, a "possible" and a "confirmed" case definition are generated, with the latter being, for example, a positive laboratory test result in addition to symptoms.

Case finding - the process of identifying all possible cases; this typically uses a broad case definition (see above) and occurs early in the investigation. Later in the investigation, case finding might be performed to assess the extent of the outbreak.

Chain of custody - a record which establishes the complete chronological disposition of an entity of concern, e.g. a sample or a document.

Cluster - aggregation of relatively uncommon events or diseases in space and/or time in amounts that are believed or perceived to be greater than could be expected by chance. Putative disease clusters are often perceived to exist on the basis of anecdotal evidence, and much effort may be expended by epidemiologists and biostatisticians in demonstrating whether a true cluster exists. With modern molecular laboratory techniques, clusters of infections with "identical" organisms are being uncovered; the significance of these clusters is currently a topic of discussion.

Cohort study - the analytic method of epidemiologic study in which subsets of a defined population can be identified who are, have been, or in the future may be exposed or not exposed, or exposed in different degrees, to a factor or factors hypothesized to influence the probability of occurrence of a given disease or other outcome. The main feature of cohort study is observation of large numbers over a long period (commonly years) with comparison of incidence rates in groups that differ in exposure levels. The alternative terms for a cohort study, i.e., follow-up, longitudinal and prospective study, describe an essential feature of the method, which is observation of the population for a sufficient number of person-years to generate reliable incidence of mortality rates in the population subsets. This generally implies study of a large population, study of a prolonged period (years), or both. However, traditional outbreak investigations often begin with a cohort study, with the study population being those in attendance at a particular meal or who had eaten at a restaurant during a particular time and exposure being defined as eating a particular item or meal.

Commercial confidential – trade secrets that are protected by law from public disclosure (e.g., monitoring records, customer lists, and traceback information). Unlawful release of this information can result in legal punishment including imprisonment.

Common source outbreak - outbreak due to exposure of a group of persons to a noxious influence that is common to the individuals in the group. When the exposure is brief and essentially simultaneous, the resultant cases all develop within one incubation period of the disease (a "point" or "point source" outbreak).

Confidence intervals (CI) - the computed interval with a given probability, e.g., 95%, that the true value of a variable such as a mean, proportion, or rate is contained within the interval. This is a measure of statistical significance; if a confidence interval includes the value 1.0, the study findings are said to be not statistically significant at the given level of certainty.

Confirmation - diagnosis of most diseases can be confirmed only if etiologic agents are isolated and identified from specimens obtained from ill persons.

Confirmed cases - usually cases that have met the case definition (see above) for symptoms AND in which infection is verified by laboratory test (e.g., culture)

Confirmed outbreak - clusters (see above) which are confirmed by laboratory or epidemiologic study to be caused by a common agent or to have occurred among persons who have shared a common exposure.

Confounding -

1. A situation in which the effects of two processes are not separated. The distortion of the apparent effect of an exposure risk brought about by the association with other factors that can influence the outcome.
2. A relationship between the effects of two or more causal factors as observed in a set of data such that it is not logically possible to separate the contribution that any single causal factor has made to an effect.
3. A situation in which a measure of the effect of an exposure on risk is distorted because of the association of exposure with other factor(s) that influence the outcome under study.

Contaminant - an infectious agent or a chemical or physical hazard.

Contamination - the presence of an infectious, chemical, or physical agent or substances in or on water, milk, and food that has the potential to cause harm, including illness or injury.

Contamination factors –

1. Natural toxin
2. Poisonous substance intentionally added.
3. Poisonous or physical substance accidentally or incidentally added.
4. Addition of excessive quantities of ingredients that under these situations are toxic.
5. Toxic container or pipelines.

6. Raw product or ingredient contaminated by pathogens from animal or environment.
7. Ingestion of contaminated raw products.
8. Obtaining foods from polluted sources.
9. Cross-contamination from raw ingredient of animal origin.
10. Bare-hand contact by food worker.
11. Handling by an intestinal carrier of enteric pathogens.
12. Inadequate cleaning of processing or preparation equipment or utensils.
13. Storage in contaminated environment.

Contributing factors - factors that contribute to contamination and survival of the etiologic agents and perhaps also to their growth or amplification. These include

1. Factors that introduce or otherwise permit contamination
2. Factors that allow survival of or fail to inactivate the contaminant
3. Factors that allow proliferation of the etiologic agents.

Controls - subjects with whom comparison is made in a case-control study, randomized controlled trial, or other type of epidemiologic study. Selection of appropriate controls is crucial to the validity of epidemiologic studies and has been much discussed.

Culture confirmed - see confirmation.

Diarrhea (specific characteristics, number within a period of time) - an abnormally frequent discharge of semisolid or fluid fecal matter from the bowel. In foodborne disease outbreaks, diarrhea is most commonly defined as 3 or more loose, watery stools in a 24-hour period. Diarrhea can also be further described by such things as the presence of blood, greasy texture, or dark color.

Epi curve - a graphic plotting of the distribution of cases by time of onset. Epi curves help characterize an outbreak and give clues about the source of the outbreak (e.g., common or point source, secondary spread)

Epi traceback – a preliminary investigation of product distribution. It is used by epidemiologists to help distinguish between two or more implicated products, to strengthen an association, or to develop hypotheses.

Etiologic agent - see agent

Exposure -

1. Proximity and/or contact with a source of a disease agent in such a manner that effective transmission of the agent or harmful effects of the agent may occur.
2. The amount of a factor to which a group or individual was exposed, sometimes contrasted with dose, the amount that enters or interacts with the organism.

Note: Exposures may be beneficial as well as harmful; e.g., exposure to immunizing

agents.

Firm - any individual, partnership, corporation, or association that deals in articles subject to the FD&C Act.

Food preparation review - a review done on each food or menu item that has been implicated in an outbreak. The review focuses on possible means of contamination, growth, or survival of pathogens. Food preparation reviews include a detailed step-by-step observation of the processes used in making, serving, storing, and transporting the implicated food item. Measurements such as times, temperatures, pH, size of containers/cooking vessels/cooling/storage containers, and amounts of ingredients/products must be included in a food preparation review. An example is given in the Procedures to Investigate Foodborne Illness, 5th edition, IAMFES.

Food-specific attack rate - a comparison of the illness rate among those who ingested specific foods at an event or meal with the illness rate of those who were at the event or meal but did not ingest these items. A food-specific attack rate table is used for cohort studies when the entire group at the event is known and interviewed about illness and exposure.

Food worker - person directly involved in producing, harvesting, processing, packaging, preparing, or storing the food under investigation.

FoodNet – Foodborne Disease Active Surveillance Network; a surveillance network coordinated by CDC, FDA, and FSIS/USDA among several state health departments, designed to provide more accurate estimates of the number and source of cases of foodborne illness in the United States.

HACCP (Hazard Analysis and Critical Control Point) - a prevention-based food safety system that identifies and monitors specific foodborne hazards--biological, chemical, or physical properties--that can adversely affect the safety of the food product. This hazard analysis serves as the basis for establishing critical control points (CCPs), those points in the process that must be controlled to assure the safety of the food. Further, critical limits are established that document the appropriate parameters that must be met at each CCP. Monitoring and verification steps are included in the system, again, to assure that potential risks are controlled. The hazard analysis, critical control points, critical limits, and monitoring and verification steps are documented in a HACCP plan.

Host -

1. A person or other living animal, including birds and arthropods, that affords subsistence or lodgment of an infectious agent under natural conditions. Some protozoa and helminthes pass successive stages in alternate hosts of different species. Hosts in which the parasite attains maturity or passes its sexual state are primary or definitive hosts; those in which the parasite is in a larval or asexual state are secondary or intermediate hosts. A transport host is a carrier in which the organism remains alive but does not undergo development.

2. In an epidemiologic context, the host may be the population or group; biological, social, and behavioral characteristics of this group that are relevant to health are called "host factors."

Hypothesis -

1. A supposition arrived at from observation or reflection that leads to refutable predictions.
2. Any conjecture cast in a form that will allow it to be tested and refuted.
3. Initial interviews with ill persons in an outbreak are often done to generate hypotheses about the cause of the outbreak and are typically more open-ended than interviews of case-patients and controls.

Implicated food - Food thought to be the outbreak vehicle, i.e., food thought to have made people ill, based on laboratory results and/or epidemiologic evidence.

Incubation period - The time interval between invasion by an infectious agent and appearance of the first sign or symptom of the disease in question.

Infection - the entry and development of multiplication of an infectious agent in the body of humans or animals. Infection is not synonymous with infectious disease: the result may be inapparent or manifest. The presence of living infectious agents (e.g., pediculosis, scabies) on exterior surfaces of the body is called infestation. The presence of living infectious agents upon articles of apparel or soiled articles is not infection, but represents contamination of such articles.

Intentional contamination - a deliberate adding of a contaminant to food in quantities sufficient to cause illness. Contaminants added because of sabotage, mischievous acts, and intents to cause panic or blackmail a company fall into this category.

Investigator -

Epidemiology: Any person involved in determining the agent, mode of transmission and factors leading to an illness or outbreak.

Regulatory: A person specially trained to collect evidence of violations of regulatory requirements. This evidence is collected for use in possible enforcement actions by the regulatory agency.

Market withdrawal - a firm's removal or correction of a distributed product that involves a minor violation for which FDA would not initiate legal action, or which involves no violation (e.g., normal stock rotation practices).

Matching - the process of making a study group and a comparison group comparable with respect to extraneous factors. Individual matching relies on identifying individual subjects for comparison, each of whom resembles a study subject on the matched variables. Matching is performed to reduce confounding (see above). Studies using matching in the interview phase must use matching in the analysis phase.

Measure of association - a quantity that expresses the strength of association between variables. Commonly used measures of association are differences between means, proportions or rates, the rate ratio, the odds ratio, and correlation and regression coefficients.

Odds ratio (OR) – the ratio of two odds. The term odds is defined differently according to the situation under discussion. Using a standard 2 x 2 table, the odds ratio (cross-product ratio) is ad/bc.

	Case	Control
Exposed	a	b
Not exposed	c	d

Outbreak - an epidemic limited to localized increases in the incidence of a disease, e.g., in a village, town, or closed institution; upsurge is sometimes used as a euphemism for outbreak.

Pathogen - organism capable of causing disease (literally, causing a pathological process).

PCR - polymerase chain reaction – a form of molecular testing which allows the specific identification of an organism from small quantities of its DNA.

Pesticide - any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest. Pests can be insects, mice and other animals, unwanted plants (weeds), fungi, or microorganisms like bacteria and viruses. Though often misunderstood to refer only to insecticides, the term pesticide also applies to herbicides, fungicides and various other substances used to control pests. Under United States law, a pesticide is also any substance or mixture of substances intended for use as a plant regulator, defoliant, or desiccant. Common pesticides include algaecides, antifouling agents, antimicrobial agents, attractants, biocides, disinfectants and sanitizers, fungicides, fumigants, herbicides, insecticides, miticides, microbial pesticides, molluscicides, nematicides, ovicides, pheromones, repellents, rodenticides, defoliants, desiccants, insect growth regulators and plant growth regulators http://www.epa.gov/opp00001/whatis.htm .

PFGE – pulsed-field gel electrophoresis – a molecular method that allows for the specific classification of pathogens by "fingerprinting" the DNA from the pathogen; this method generates visually observable patterns which can be digitized and then compared with other pathogens of the same genus and species. Pathogens with patterns characterized as "indistinguishable" may have similar sources. Two persons or items yielding indistinguishable organisms are more likely to be related (i.e., be part of the same outbreak) than if the organisms with different PFGE patterns are isolated.

Point source outbreak – see common source outbreak

Proliferation/amplification factors – factors that allow proliferation of the etiologic agents:

1. Allowing foods to remain at room or warm-outdoor temperature for

several hours.
2. Slow cooling.
3. Inadequate cold-holding temperature.
4. Preparing foods a half-day or more before serving.
5. Prolonged cold storage for several weeks.
6. Prolonged time and/or insufficient temperature during hot holding.
7. Insufficient acidification
8. Insufficiently low water activity.
9. Inadequate thawing of frozen products.
10. Anaerobic packaging or modified atmosphere.
11. Inadequate fermentation.

Protocol – procedure

PulseNet – the National Molecular Subtyping Network for Foodborne Disease Surveillance; a network of laboratories throughout the United States that perform testing on foodborne pathogens using standard methods (currently PFGE) and compare results via images on a computer network.

p-value – a measure of the chance that the observed results would occur if the null hypothesis were true. The probability associated with a statistical hypothesis will help decide if there is a significant association between exposure and illness or if the results are due to chance (coincidence).

Questionnaire – a predetermined set of questions used to collect data on (e.g.) clinical characteristics, social status, or occupational group. This term is often applied to a self-completed survey instrument, as contrasted with an interview schedule.

Recall – A firm's voluntary removal or correction of a marketed product(s), including its labeling and/or promotional materials, that FDA or FSIS considers to be in violation of the laws it administers, and for which the agency would initiate legal action (e.g., seizure or the full range of administrative and civil actions available to the agency). "Recall" does not include a market withdrawal or stock recovery.

Regulatory authority – Agency that regulates (permits/licenses and inspects) the substance or establishment under consideration.

Relative Risk (RR) –-

1. The ratio of the risk of disease or death among those exposed to the risk among the unexposed; this usage is synonymous with risk ratio.
2. Alternatively, the ratio of the cumulative incidence rate in the exposed to the cumulative incidence rate in the unexposed, i.e., the cumulative incidence ratio.
3. The term relative risk has also been used synonymously with odds ratio and, in some

biostatistical articles, has been used for the ratio of forces of morbidity. The use of the term relative risk for several different quantities arises from the fact that for "rare" disease (e.g., most cancers) all the quantities approximate one another. For common occurrences (e.g., neonatal mortality in infants under 1500 g birth weight), the approximations do not hold.

Reservoir of infection –

1. Any person, animal, arthropod, plant, soil, or substance, or a combination of these, in which an infectious agent normally lives and multiplies, on which it depends primarily for survival, and where it reproduces itself in such a manner that it can be transmitted to a susceptible host.
2. The natural habitat of the infectious agent.

Sample size determination – the mathematical process of deciding, before a study begins, how many subjects should be studied. The factors to be taken into account include the incidence or prevalence of the condition being studied, the estimated or putative relationship among the variables in the study, the power that is desired, and the allowable magnitude of type I error.

Serotype (or serovar) – a subdivision of a species or subspecies distinguishable from other strains therein on the basis of antigenic character.

Source -

1. Source of contamination – the person, animal, object, or substance from which an infectious agent passes to a host. The source of infection such as an overflow of a septic tank contaminating a water supply or an infected cook contaminating a salad should be clearly distinguished from the source of contamination.

2. Source of product – the firm/farm where the product originated. The source of the product is determined through a product traceback investigation. It is not necessarily the source of the contamination or infection.

Sporadic case – occurring irregularly, haphazardly from time to time, and generally infrequently, e.g., cases of certain infectious diseases; also, a case NOT associated with a known outbreak.

Statistically significant association – statistical methods allow an estimate to be made of the probability of the observed or greater degree of association between independent and dependent variables under the null hypothesis. From this estimate, in a sample of given size, the statistical "significance" of a result can be stated. Usually the level of statistical significance is stated by the p-value.

Stop sale – a hold order that can be placed on implicated food that originates from an unapproved source, or that may be unsafe, adulterated, not honestly presented, not labeled according to law or otherwise not in compliance with food regulations. A stop sale prevents the

food from being sold to the public.

Strength of association – the magnitude of the measure of association (see above); for example, the size or value of the odds ratio is a measure of the strength of association between an exposure and an illness or other outcome—the larger the odds ratio, the stronger the association.

Study design – the procedures and methods, predetermined by an investigator, to be adhered to in conducting a research project.

Subtype – see serotype

Surveillance – the continuing scrutiny of all aspects of occurrence and spread of a disease that are pertinent to effective control. Included are the systematic collection and evaluation of 1) morbidity and mortality reports; 2) special reports of field investigations of epidemics and of individual cases; 3) isolation and identification of infectious agents by laboratories; 4) data concerning the availability, use, and untoward effects of vaccines and toxins, immune globulins, insecticides, and other substances in control; 5) information regarding immunity levels in segments of the population; and 6) other relevant epidemiologic data. A report summarizing these data should be prepared and distributed to all cooperating persons and others with a need to know the results of the surveillance activities. The procedure applies to all jurisdictional levels of public health from local to international. Serologic surveillance identifies patterns of current and past infection using serologic tests.

Active surveillance – agencies regularly contact reporting sources to elicit reports of illnesses. An active surveillance system is likely to provide more complete illness reporting but is more labor intensive and costly to operate.

Passive surveillance – agencies receive disease reports from physicians, the public, and institutions as mandated by state law.

Survival factors - factors that allow survival or fail to inactivate the contaminant:

1. Insufficient time and/or temperature during cooking or heat processing.
2. Insufficient time and/or temperature during reheating.
3. Inadequate acidification.
4. Insufficient thawing followed by insufficient cooking.

Suspected Case- an illness meeting part of the case definition (see above); for example, specific symptoms (and, perhaps, exposure to a food item of interest) but no laboratory test confirming the cause of the illness; can also refer to laboratory-confirmed illness in persons who are not known to have the exposure of interest.

Suspected Outbreak – a cluster of cases linked by time or space which have not been confirmed to be caused by the same agent or item (exposure) but which have characteristics (e.g., an unusual organism or exposure) which makes it likely that the cases are linked not by chance alone.

Suspected food - food from an implicated meal that is a likely vehicle for the causative agent. These foods are often identified in a food specific attack rate table.

Symptomatic - demonstrating clinical signs or symptoms; e.g., having diarrhea, abdominal pain, fever.

Time/temperature abuse - Insufficient time and/or temperature during cooking or heat processing; insufficient time and/or temperature during reheating.

Traceback (also referred to as a product or regulatory traceback) – the method used to determine the source and scope of the product/processes associated with an outbreak and document the distribution and production chain of the product that has been implicated in a foodborne illness or outbreak.

Traceforward - once the source of an implicated food item is established, investigators may do a "traceforward" to document the distribution of all implicated lots of food from the source. This can help epidemiologists with case finding and can be used to test hypotheses about the outbreak. Traceforwards should only be used when there is a reasonable degree of confidence that the traceback correctly identified the source of the implicated product. A product recall also involves a traceforward to determine the suppliers that received the product.

Vector - in infectious disease epidemiology, an insect or any living carrier that transports an infectious agent from an infected individual or its wastes to a susceptible individual or its food or immediate surrounding. The organism may or may not pass through a developmental cycle within the vector.

Vehicle (of infection transmission) - the mode of transmission of an infectious agent from its reservoir to a susceptible host. This can be (e.g.) person to person, food, or vector-borne.

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