CHAPTER

9

Legal Preparedness for the Surveillance and Control of Foodborne Disease Outbreaks

9.0.1. Public Health Legal Preparedness

Legal preparedness is an indispensable part of comprehensive preparedness for public health threats. The Centers for Disease Control and Prevention (CDC) defines public health legal preparedness as attainment by a public health agency or system of specified legal benchmarks or standards of preparedness for specified public health concerns. Public health legal preparedness has four core elements: a) laws and legal authorities, b) competency in understanding and using law, c) coordination across sectors and jurisdictions in the implementation of law, and d) information about best practices in using law for public health purposes.

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9.0.2. Ensuring Legal Preparedness for Foodborne Disease Outbreaks

State and local public health officials should ensure their agencies and jurisdictions are legally prepared for surveillance and control of foodborne disease outbreaks. This means:

- They should have the laws and legal authorities needed to conduct all functions essential to effective surveillance and control (e.g., surveillance, reporting, enforcement, prevention, mitigation, investigation, and regulation).
- Their professional staff should be trained and demonstrate competence in applying those laws.
- They should have mutual aid agreements or memoranda of agreement in place to facilitate investigation and response across jurisdictions and jointly by public health and other agencies.
- They should have access to information about and apply best practices in using their relevant legal authorities.

The adequacy of state and local legal preparedness for foodborne disease outbreaks should be evaluated regularly through exercises and after-action reports after responses to actual outbreaks.

As part of ensuring their jurisdictions' legal preparedness, state and local health officials should consult with their legal counsel and with counterparts in other government agencies and private organizations that have legal authorities or legal duties relevant to successful surveillance and control of foodborne disease outbreaks. These include such public entities as food-regulatory and law enforcement agencies, legal counsel to municipal and state governments, and local and state courts and court administrators. Relevant private entities include private laboratories, food wholesalers, grocery retailers, and restaurants and other food vendors. Food-industry entities should be prepared to address both the regulatory requirements and the way their internal policies on sharing information might be affected by them[1]. Where possible, these entities should be included in foodborne disease exercises to test their understanding of their legal authorities and duties related to outbreaks.

9.0.3. The Constitutional Setting for Foodborne Disease Surveillance and Control

As government bodies, public health agencies operate in the context of the U.S. Constitution, the fundamental law of the land. Some of the principal constitutional features relevant to public health agencies are the three-branch system of government, federalism, and protection for civil liberties and property rights. Public health agencies belong to the executive branch and are broadly charged to implement laws enacted by the legislature and as interpreted by the courts. In the federal system, the Constitution enumerates specified powers for the federal government and reserves other powers to the states (tribes are autonomous or sovereign bodies). In addition, state and local governments possess inherent police powers to protect the health and safety of the public. Finally, the Fourth, Fifth, and Fourteenth Amendments protect citizens from unreasonable searches and from deprivation of life, liberty, and private property without due process of law. State constitutions, statutory law, and court rulings provide additional protections relevant to the conduct of foodborne disease surveillance and operations by public health agencies.

9.0.4. Legal Basis for State and Local Public Health Agencies in Surveillance and Control of Foodborne Disease

The primary role of local and state public health agencies is protection and promotion of the public's health. The legal authority supporting that role stems from statutory,

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regulatory, and case (judge-made) law, as well as from the general police powers. Important legal parameters for public health practice were articulated in the 1905 U.S. Supreme Court ruling in the case *Jacobson v. Massachusetts*:

- With compelling reason, individual liberties can be subordinated to the well-being of the community.
- The police power of the state authorizes issuance and enforcement of reasonable regulations to protect the health of the community.
- Courts defer to the authority that legislative bodies give to public health agencies if exercised on the basis of persuasive public health and medical evidence.
- Public health agencies cannot act in an arbitrary manner nor pose unreasonable risks for harm.

In general, these parameters apply to state and local public health agencies' surveillance and control of foodborne disease outbreaks. Those activities, however, are further authorized and conditioned by the statutes, regulations, ordinances, and case law of the individual jurisdictions. Some of these laws relate specifically to foodborne diseases, but in many jurisdictions, public health agencies rely on laws (state statutes and local ordinances) that authorize general infectious disease surveillance.

9.0.5. Legal Basis for CDC in Surveillance

CDC operates under congressionally enacted statutory law and, especially in the case of foodborne disease surveillance, under provisions of the Public Health Service Act (the Act). CDC is not authorized to mandate reporting of diseases and conditions either by state and local governments or by private entities.

Among many other provisions, the Public Health Service Act authorizes CDC to gather data on nationally notifiable diseases pursuant to guidelines CDC develops in partnership with state and local public health agencies and professional societies. Many of these data come from state and local public health agencies. CDC partners with the Council of State and Territorial Epidemiologists (CSTE) to establish (and modify as needed) case definitions for diseases. These guidelines and case definitions, however, are not legally binding. CDC does not collect personal identifiers on routine surveillance data that it receives from public health departments.

The Act also authorizes CDC to perform laboratory tests on specimens received from state and local governments (and from other sources) to identify pathogens, confirm serotypes or molecular subtypes, and perform diagnostic assays and report findings to appropriate state and local health departments. Virtually all enteric disease specimens tested in CDC laboratories are initially tested in state or local public health laboratories.

By providing botulinum antiserum, CDC learns of cases of botulism and verifies that the appropriate state or local health department is aware of them.

9.1. Legal Framework for Mandatory Disease Reporting

9.1.1. Statutes and Regulations

9.1.1.1. Authorization by legislature

The legislature generally gives broad statutory authority to the state health department to collect information and require reports of conditions of public health importance, without specifying the exact diseases or infections.

In addition to broad authority, states typically have several disease-specific statutes, such as

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those for human immunodeficiency virus/acquired immunodeficiency syndrome, tuberculosis, and vaccine-preventable diseases, which authorize surveillance and control activities. All states have statutes addressing response to bioterrorism incidents.

9.1.1.2. Regulatory process for maintaining and updating list of reportable diseases

Every state has an oversight body or entity authorized to promulgate reportable disease regulations (typically a board of health established by statute). The reportable disease list is revised or updated after study of, and public input on, the proposed changes.

The list of reportable diseases and conditions and laboratory findings is maintained and updated by epidemiologists and health officers in state and local agencies, with review and approval by the oversight body. Required reporting of specific laboratory test results (rather than regulatory language of "any positive test for …") generally means the list must be regularly updated.

Reportable disease regulations are established within the context of the basic public health compact. In return for allowing the government to collect medical and personal information without consent about selected conditions, the public requires the government to maintain confidentiality of the records and to prevent or minimize public health threats.

9.1.2. Reporting Processes

9.1.2.1. Time frame and content of reports

Statutes and regulations usually specify the time frame for reporting (e.g., within 7 days of diagnosis, within 24 hours, immediately), means of reporting (e.g., electronic laboratory reporting, phone, e-mail, fax), and the information to be reported (e.g., diagnosis; personal identifying and locating information; and date of onset or diagnosis, regardless of whether the case is suspected or confirmed).

9.1.2.2. Sources of reports

Regulations specify what entities are required to report. The usual sources of mandatory reports are:

- Laboratories, including
  - Hospital-based laboratories,
  - Clinical laboratories,
  - National or regional commercial referral laboratories,
  - Local or state health department laboratories, and
  - CDC laboratories;
- Hospitals (e.g., hospitalized patients reported by infection control practitioners);
- Emergency departments;
- Office-based health-care providers;
- Long-term–care facilities or nursing homes; and
- Schools and child-care centers.

An agency also might receive reports, for example, from other state health departments.

Arrangements and ongoing communication should be established with national or regional commercial and clinical laboratories to ensure results for relevant cases are received by the investigating agencies, even when those tests are conducted out of state. The same communication channels should be established with hospitals that are out of state but that serve a population within the community affected by the outbreak.

The source of a report does not affect the legal status of the information—if it is required it is protected by statutes and regulations. Conversely, reports to the agency of illness not listed as a reportable condition might not be subject to disease surveillance regulations and confidentiality protections (see section 9.1.5. below).

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9.1.2.3. Reporting methods

A state or municipality can use any of a variety of methods for reporting. Specifics vary from one locale to another. These methods include:

- Telephone;
- Hardcopy (fax or mail);
- Electronic batch reports sent by e-mail;
- Internet-based, highly secure disease reporting to websites maintained by state or local public health agencies; and
- Automatic electronic submission through health information exchange.

9.1.2.4. Required submission of laboratory specimens

Some public health agencies have adopted regulations that require hospital and clinical laboratories to submit isolates of specific pathogens to a state or local health department laboratory for further testing. One example would be a requirement for submission of all *Escherichia coli* O157:H7 isolates for pulsed-field gel electrophoresis testing. This requirement improves surveillance for foodborne disease as common subtypes are identified. In some locales, voluntary submission of specimens to the central referral laboratory achieves the same goal.

9.1.3. Accessing Medical and Laboratory Records

Typically, broad authority to conduct surveillance includes authority to investigate and control diseases of public health significance, including review of relevant and pertinent medical and laboratory records and reports (i.e., information that is not necessarily included in the basic case report).

9.1.4. Enforcement

Because nonreporting by health-care providers is common, redundant reporting systems have been established (e.g., *Salmonella* infection is reportable by both physicians and laboratories) to ensure a case will be reported. Nonetheless, failure to comply with reporting regulations is punishable. This is rarely enforced because penalizing a health-care provider might not result in future compliance and might reverberate throughout the clinical sector (i.e., might be counterproductive to the system).

Penalties or sanctions, however, might be imposed if lack of a report leads directly to an outbreak (for example, a food worker with hepatitis A is not reported, and immune globulin is thus not administered to restaurant customers). In most cases of nonreporting, the public health agency explains the regulatory requirement and its rationale and asks for future compliance, rather than seeking penalties or sanctions.

Reporting is difficult to enforce with a laboratory or health-care provider outside the agency's jurisdiction, such as when state X seeks reports from a referral laboratory in state Y. In this situation, lack of reporting usually results from misunderstanding of how to report.

Occasionally a laboratory will state it complies with requirements of the public health agency in which it is physically located—which might or might not require reporting of the particular disease, infection, or laboratory result.

9.1.5. Protection of Confidentiality

Personally identifying information in disease reports and investigation records is confidential and exempt from disclosure in response to freedom of information requests. If personally identifying information can be redacted and no other exemptions from disclosure apply, such records might have to be released. In redacting personally identifying information, descriptors such as age, sex, race/ethnicity, residence, and date of diagnosis can make the person identifiable. Preparing final outbreak investigation summary reports without any personally identifying information can speed

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up and simplify release of those reports to attorneys or media when they are requested.

Occasionally a public health agency must respond to a media inquiry in which the media has learned the identify of a particular case from another source. The agency's response to the media inquiry must be carefully structured to avoid unintentional confirmation of the patient's name.

The public health agency generally is restricted from sharing personal identifying information with other government agencies without the consent of the reported person, except:

- Virtually every state has an exception for sharing information with law enforcement agencies when investigating a bioterrorism incident.
- Many state statutes contain an exception for sharing information when, in the agency's judgment, sharing is necessary to protect the public health.
- State and local public health agencies often expect that when they provide epidemiologic and laboratory data to federal agencies, such as the Food and Drug Administration FDA) or the U.S. Department of Agriculture (USDA), they will receive from those agencies results of related product investigations. However, this might not happen if the results of the investigations contain trade secrets or commercial confidential information or are part of an ongoing legal enforcement action or criminal prosecution.

Reporting statutes typically provide for punishment of government employees for a breach of confidential information held by the public health agency.

Health information protected by the Health Insurance Portability and Accountability Act of 1996 might be disclosed by the reporting source without individual authorization to a public health agency authorized by law to collect or receive such information, including a contractor (e.g., academic institutions) to which a government agency has granted authority. This disclosure without individual authorization does not include disclosure of protected health information for research purposes.

The legal requirement to report relieves the reporting source (e.g., physician) of concern that reporting breaches the privacy of the doctor–patient relationship. Explaining this to physicians often results in better compliance with reporting requirements.

9.1.6. Cross-Jurisdiction and Cross-Sector Coordination

Effective reporting of foodborne disease cases hinges on coordination of reporting across jurisdictions (e.g., local, state, tribal, and federal governments) and across sectors (e.g., health care and public health). State and local health officials should periodically assess the need for memoranda of agreement (or other legal agreements) with partners in other jurisdictions and sectors to ensure timely and effective reporting. CDC has created several resources for assessing and improving cross-jurisdictional and cross-sector coordination.[2]

9.2. Legal Framework for Surveillance and Investigation of Foodborne and Enteric Diseases

9.2.1. Sources of Surveillance Information

Reports of food-related illness may come to the attention of the state or local health agency in a variety of ways, such as:

A. Surveillance reports for enteric diseases, such as *Salmonella*, *Shigella*, and *Campylobacter*;

B. Request for antitoxin for botulism;

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C. Reports of food poisoning or gastrointestinal illness in individuals or defined groups, such as diarrhea and vomiting among residents of a nursing home or school or among attendees at a work-related meeting;

D. Reports to poison control centers;

E. Reports of enteric disease suspected of being caused intentionally;

F. Complaints of alleged contaminated, adulterated, or improperly cooked food purchased from stores or in restaurants and reported voluntarily by the general public;

G. Syndromic surveillance using deidentified emergency department or pharmacy data; and

H. Reports directly from the food industry of consumer complaints of illness or injury.

9.2.2. Statutes and Regulations Governing Surveillance and Investigation

Confirmed or probable cases identified from items 9.2.1 a–e above are subject to the reporting statute(s) and regulations of the health agency. Items 9.2.1 f and g generally do not have as strong a level of legal protection as do named case reports because they are either voluntary, unconfirmed disease reports (item f) or diagnoses for which names are not collected cannot be confirmed (item g).

Routine investigation of enteric diseases to confirm the diagnosis and determine the source of exposure, risk factors for infection, and contacts of a contagious patient is usually considered part of surveillance and disease control activities authorized by state and local statutes.

CDC may participate in an investigation of an outbreak of enteric disease within a state if invited by the state. States usually expect CDC to help coordinate large multistate outbreaks of enteric disease.

Methods for detecting a foodborne disease outbreak resulting from an unannounced intentional act of contamination are the same as those for detecting a "regular" (i.e., unintentional contamination) foodborne disease outbreak. The legal authorities to conduct outbreak detection activities are the same—at least initially—regardless of the intentionality of the contamination (e.g., disease surveillance and reporting requirements). However, once intentional contamination is suspected, additional state criminal, antiterrorism, and emergency response laws most likely will enhance or control the course of the outbreak investigation and response (see section 9.4).

9.3. Legal Framework for Measures and Methods to Prevent or Mitigate Foodborne Disease Outbreaks

9.3.1. General

Because of a) improvements in laboratory and communication technologies that can be used to link cases previously termed "sporadic" and b) globalization of food-production industries, more multistate and international foodborne disease outbreaks are being discovered, thus changing the locus of outbreak investigations and control measures.

9.3.2. Federal Roles and Authorizations

The changes noted above have resulted in an increasingly direct, leading role in the control of foodborne diseases by several federal agencies: U.S. Department of

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Health and Human Services (CDC and FDA), U.S. Department of Agriculture (Food Safety Inspection Service and Animal and Plant Health Inspection Service), U.S. Environmental Protection Agency; and when bioterrorism is suspected, U.S. Department of Justice and U.S. Department of Homeland Security.[3] These agencies undertake regulatory and nonregulatory actions over food safety at various stages along the farm-to-table continuum related to:

- Safety of food, feed, and animals on the farm;
- Plant and animal health on the farm, including animal vaccines;
- Pesticide use on the farm;
- Food processing;
- Slaughter and processing of meat and poultry products and egg products;
- Labeling, transportation, storage, and retail sale of food; and
- Cruise ships, trains, buses, airplanes (i.e., all interstate transportation) and the servicing areas for these transportation vehicles (21 CFR 1240 and 1250).

These agencies also coordinate and collaborate in multistate investigations.

The following sections briefly review the authorizations that are particularly pertinent to foodborne disease outbreak investigations and control.

9.3.2.1. Federal Food, Drug, and Cosmetic Act

The primary legislation by which FDA exercises authority over food is the Federal Food, Drug, and Cosmetic Act (FFDCA). A goal of FDA is to prevent contamination of food product before distribution, but the legislation allows it to pursue:

- Voluntary compliance through the issuance of inspectional observations, untitled letters, and warning letters;
- Civil action, such as an injunction to prevent future violations of the FFDCA (i.e., continued distribution of adulterated food);
- Seizure action to remove specific lots of adulterated food;
- Mandatory recall of violative food that presents a certain risk to public health;
- Criminal action against an individual or company that violates the FFDCA, such as by causing food to become adulterated by inadequate processing and handling;
- Administrative detention of certain food for up to 30 days (the FDA has had this authority since the Bioterrorism Act of 2002; administrative detention does not require a court order); and
- Suspension of the registration of a facility so that food from the facility cannot be introduced into commerce.

FDA's authority under the FFDCA is limited by the requirement for interstate commerce in some circumstances. However, under the Public Health Service Act, FDA can regulate intrastate commerce in some additional circumstances. State agencies might in some instances be swifter than FDA because they might require less evidence of problems before taking action than the requirements imposed on FDA by its legislation.

Amendments to the FFDCA in 2007 require FDA to establish a registry for reporting by individuals, companies, and local and state agencies of food that can cause serious adverse health consequences or death to humans or animals.

9.3.2.2. FDA Food Safety Modernization Act

The FDA Food Safety Modernization Act (FSMA), signed into law in January 2011, amended the FFDCA to enhance the federal

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government's ability to prevent and respond to contamination in the food supply. The law addresses prevention, inspection, compliance, and response activities. It also adds authorities to ensure that imported products are as safe as domestically produced food. FSMA also requires FDA to build an integrated national food-safety system in partnership with state and local agencies.

- Prevention. FSMA directs FDA to create minimum standards for safely producing and harvesting fruits and vegetables. FSMA requires food facilities to implement preventive and control plans that, for example, identify possible hazards, prevention measures to control hazards, and actions to be taken when hazards arise. The law also requires FDA to establish regulations to protect against intentional contamination of food.
- Inspection and Compliance. FSMA mandates inspection frequency of food facilities on the basis of risk and requires that the frequency of inspection increases as risk increases. The law gives FDA clear authority to access records, such as food-safety plans. FSMA further requires that FDA create an accreditation program for food-testing laboratories and that certain foods be tested in accredited laboratories.
- Response. FSMA gives FDA a number of new authorities to respond to food-safety events, including mandatory recall authority and suspending food-facility registration. The law also expands FDA's authority to administratively detain products, track and trace domestic and imported foods, and require additional recordkeeping for high-risk foods. FSMA directs CDC to improve surveillance for foodborne disease and to establish Integrated Food Safety Centers of Excellence in five state health departments and their partnering academic institutions.
- Partnership with Government Agencies. FSMA creates a system of collaboration among domestic and foreign government agencies. The law directs FDA to create and implement strategies to enhance the food safety capacity of state and local governments, including a new multiyear grant program. FSMA allows FDA to rely on other federal, state, and local agencies in conducting inspections required by the law.

The FDA website (www.fda.gov) provides details about the law and updates on the status of FSMA implementation.

9.3.2.3. Acts Authorizing USDA-FSIS

FSIS operates under the authority of the Federal Meat Inspection Act (FMIA), the Poultry Products Inspection Act (PPIA), and the Egg Products Inspection Act (EPIA). Following the provisions of these Acts, FSIS sets standards for food safety and inspects and regulates all raw and processed meat and poultry products, and egg products sold in interstate commerce, including imported products.

- FMIA. Prohibits the sale of adulterated or misbranded meat and meat products for food and ensures that animals used for meat and meat products are slaughtered and processed under sanitary conditions.
- PPIA. Ensures the inspection of domestic and imported poultry products and requires that plant facilities are sanitary and that product labels are accurate.
- EPIA. Mandates continuous inspection of the processing of liquid, frozen, and dried egg product.

9.3.3. Roles and Legal Authority of State and Local Public Health Agencies

Environmental health specialists, laboratorians, and epidemiologists should understand their respective roles and legal authorities for

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various public health actions. In addition, they should know how and when they need to obtain expert legal counsel and upper-level management support and decision-making.

In instances in which improper food preparation at the local level results in foodborne disease, the broad authority of public health agencies to control epidemics and end nuisances, as well as specific authority they have to inspect restaurants and ensure proper food safety, is used to:

- Close restaurants;
- Embargo, seize, or destroy contaminated food or require removal of contaminated lots from retail stores;
- Require changes in food preparation; and
- Temporarily remove infectious persons from the workplace.

These actions are taken through agency authority granted by rule or through administrative orders. Such orders should contain time limits and specify the conditions for removing them. If necessary, agencies can seek enforcement through court orders.

9.4. Public Health Investigations as the Basis for Regulatory Actions or Criminal Prosecution

9.4.1. Role of Data in Regulatory Action

Epidemiologic and laboratory data can provide strong evidence linking illness to consumption of a particular food, resulting in a traceback investigation. When involving multiple states, federal regulatory agencies typically lead the traceback investigation.

Because of the need to link epidemiologic data with product information to take actions that protect the public health, the roles of state and local public health agencies and CDC must be coordinated with the roles of federal regulatory agencies.

9.4.2. Joint Investigation and Collection of Evidence in Criminal Prosecutions

Some investigations are initiated by public health officials but widen to other interests and agencies when a public health event results from a potential criminal act. Joint investigation by regulatory and nonregulatory public health and law enforcement agencies may be hindered by the different legal powers and investigatory practices each agency brings to such an event. For example, officials from regulatory and nonregulatory public health agencies are authorized to collect and test samples to determine their public health threat, whereas law enforcement officials can consider samples subject to seizure as evidence. Regulatory and nonregulatory public health and law enforcement officials all must conform to constitutional standards (e.g., Fourth and Fifth Amendments) about collection of evidence, especially in situations requiring a joint investigation by regulatory and nonregulatory public health and law enforcement agencies.

Laboratory specimens must be collected and submitted using procedures that ensure the chain-of-custody of the specimen, defined by one author as follows: "Everyone handling the sample [or specimen] must be able to demonstrate it is, and has been, identified as coming from the person [or item] in question to be admissible and probative in court."[4]

State and local health officials, in collaboration with counterparts in law enforcement agencies, should periodically assess the need for

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memoranda of understanding to clarify the roles of public health and law enforcement agencies in conducting joint investigations. State and local health and law enforcement officials who have roles in investigating foodborne disease outbreaks should understand, and demonstrate competence in applying, their legal authorities in conducting joint investigations. Valuable resources for improving competency in joint investigations include CDC training curricula[5] and sample memoranda of understanding.[6]

9.5. CIFOR Legal Preparedness Resources

CIFOR has created several resource documents to further assist state and local public health agencies in improving their legal preparedness to conduct surveillance for foodborne diseases and respond to outbreaks within their jurisdictions and across multiple states and other jurisdictional boundaries. The CIFOR law project has the following three components, each designed to address a discrete, but related, research need and audience.

- Analysis of State Legal Authorities for Foodborne Disease Detection and Outbreak Response. This document describes and analyzes the types of state legal authorities currently available to conduct foodborne disease surveillance and outbreak response activities. It highlights the patchwork of state laws and regulations across several topic areas—public health, communicable disease, food safety, food regulation, agriculture, environmental health, and general government authority—on which public health professionals and their legal counsel must rely to accomplish foodborne disease surveillance and outbreak response activities.
- Practitioners' Handbook on Legal Authorities for Foodborne Disease Detection and Outbreak Response. This document is intended as a practical guide for public health professionals who perform key roles in foodborne disease surveillance and outbreak response. The handbook presents information and resources for practitioners charged with implementing their jurisdiction's legal authorities related to foodborne disease events. The handbook is a primer on the array of possible legal authorities (e.g., communicable disease laws, food safety laws) that might be available and provides practitioners with checklists for identifying relevant agency actors and laws within their jurisdictions.
- Menu of Legal Options for Foodborne Disease Detection and Outbreak Response. This document provides a menu of legal options for state public health officials and policy makers to consider when reviewing their jurisdiction's legal authorities to conduct foodborne disease surveillance and outbreak response actions. The menu includes legal provisions relevant to activities conducted during foodborne disease surveillance and outbreak response—outbreak detection, outbreak investigation, outbreak control, and outbreak documentation. This is intended to be a resource for states to use in filling gaps and clarifying or enhancing their legal authorities.

All of the documents are available through the CIFOR website at www.cifor.us.

9.6. References

1 Council to Improve Foodborne Outbreak Response (CIFOR). CIFOR Industry Guidelines: Foodborne Illness Guidelines for Owners, Operators, and Managers of Food Establishments. Washington, D.C.: National Association of County and City Officials, 2013.

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