

PRACTITIONERS' HANDBOOK ON LEGAL AUTHORITIES

FOR FOODBORNE DISEASE DETECTION AND OUTBREAK RESPONSE

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Association of Public Health Laboratories (APHL)
Association of State and Territorial Health Officials (ASTHO)
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NOTICE

The Handbook was researched and compiled during September 2011–August 2012, unless otherwise indicated, and reflect the laws and regulations current at the time. They may reflect only selected portions of laws and regulations and are not intended to be exhaustive of all relevant legal authorities and theories. This resource is for informational purposes only and is not intended as a substitute for professional legal or other advice.

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INTRODUCTION

Overview

This section provides information about CIFOR and the genesis of the Practitioners' Handbook on Legal Authorities for Foodborne Disease Detection and Outbreak Response and other elements of the CIFOR project on state foodborne disease detection and response laws.

Council to Improve Foodborne Outbreak Response

The Council of State and Territorial Epidemiologists (CSTE) and the Centers for Disease Control and Prevention (CDC) convened the Council to Improve Foodborne Outbreak Response (CIFOR) in 2005. CIFOR is a multidisciplinary collaboration of eight national associations and three federal agencies whose goal is to improve methods at the local, state, and federal levels to detect, investigate, control, and prevent foodborne disease outbreaks. CIFOR identifies barriers to rapid detection and response to foodborne disease outbreaks and develops projects that address these barriers.

CIFOR is co-chaired by CSTE and the National Association of County and City Health Officials. The CIFOR member organizations represent epidemiology programs, environmental health programs, public health laboratories, and regulatory agencies involved in foodborne disease outbreak surveillance and response. A complete list of the member organizations is included in the Acknowledgements section of this document.

Legal Authorities Handbook Project Background

A key objective for CIFOR and its member organizations is to examine the legal authority needed to conduct ongoing foodborne disease surveillance and respond to foodborne disease outbreaks and the capacity to implement those legal authorities effectively. The Handbook uses the term "legal authority" to mean a grant of power or the imposition of a duty by statute, regulation, or other document, such as an executive or administrative order.

Agencies and jurisdictions may have insufficient legal authorities or encounter legal barriers to conducting foodborne disease surveillance and outbreak response activities. A state may lack clear authority to collect all the data necessary to conduct effective foodborne disease surveillance and investigation activities. State and local public health personnel may be limited by law regarding the types of information and persons with whom they can share it during an outbreak investigation.

Agencies and jurisdictions also may lack the capacity to implement the legal authorities they do have. Implementation challenges can include lack of experienced staff who understand the scope of the health agency's legal authorities or are confident in using the authorities available to them.

INTRODUCTION

Components of the CIFOR Law Project

The Practitioners' Handbook on Legal Authorities for Foodborne Disease Detection and Outbreak Response (the Handbook) is part of a larger CIFOR project aimed at creating tools that agencies and jurisdictions can use to improve their legal preparedness to conduct surveillance for foodborne diseases and respond to outbreaks within their jurisdictions and across multiple states and other jurisdictional boundaries. To achieve this, CIFOR has identified the following three components to the CIFOR law project. Each is designed to address a discrete, but related research need and audience.

- **Practitioners' Handbook on Legal Authorities.** 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 may be used in their jurisdictions. It provides practitioners with checklists for identifying relevant agency actors and laws within their jurisdictions.
- **Analysis of State Legal Authorities.** This document describes and analyzes the types of state legal authorities available for conducting foodborne disease surveillance and outbreak response activities. It demonstrates the patchwork of state laws and regulations across an array of topic areas—public health, communicable disease, food safety, food regulation, agriculture, environment, and general government authority—on which public health professionals and their legal counsel must rely to conduct foodborne disease outbreak surveillance and response activities.
- **Menu of Legal Options.** This document provides a menu of legal provisions 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 effective performance of each of the principal functions of foodborne disease surveillance and outbreak response: outbreak detection, outbreak investigation, outbreak control, and outbreak documentation. This menu is intended as a resource for states to use in filling gaps and clarifying or enhancing their legal authorities.

CHAPTER 1 | OVERVIEW OF THE HANDBOOK

1.0 Chapter Overview

This chapter introduces the *Handbook* and identifies the key foodborne disease outbreak functions featured in the document: outbreak detection, investigation, control, and documentation. It introduces four key concepts—authority, process, rights, and compliance—that are a framework with which to analyze and describe legal provisions related to foodborne disease outbreak detection and response activities. This chapter also gives an overview of the other chapters in the *Handbook*.

1.1 Purpose and Use

The *Handbook* is a practical guide for public health professionals who perform key roles in foodborne disease detection and response activities. Epidemiologists, laboratorians, sanitarians, environmental health specialists, attorneys, and others working in state or local governments can benefit from the *Handbook*. The document presents practical information and resources for these practitioners and others charged with implementing their jurisdictions' legal authorities related to foodborne disease events. It is intended as a primer on the array of potential legal authorities (e.g., communicable disease laws, food safety laws) that may be available to them as they undertake foodborne disease detection and response activities in their states and communities.

The *Handbook* describes in general the types of legal authorities possibly available for conducting various surveillance, investigation, and control activities. Because each state and locality has its own unique laws and regulations, identifying and understanding the relevant statutes, regulations, ordinances, orders, or policies in a jurisdiction are important. The *Handbook* includes a series of checklists to assist readers in identifying relevant actors (e.g., health officials, agriculture officials, regulated businesses, doctors), agencies (e.g., health agency, animal health agency), and legal authorities (e.g., statutes, regulations, policies) within their jurisdictions. Readers should discuss their jurisdictions' legal authorities and review and complete the *Handbook's* checklists with the aid of an attorney or other qualified professional. **This resource is for informational purposes only and is not intended as a substitute for professional legal or other advice.**

1.2 Scope

The *Handbook* is based in part on CIFOR's foundational publication, *Guidelines for Foodborne Disease Outbreak Response*. In that document CIFOR identified key foodborne disease surveillance and outbreak response functions for which every jurisdiction should have either the internal capacity to directly undertake or access to personnel and resources to conduct those functions. The *Guideline* functions have been adapted for this project as

- **Outbreak Detection.** Identifying individual cases or clusters of foodborne disease through disease surveillance systems and activities.
- **Outbreak Investigation.** Determining the specific foodborne disease agent, the contaminated food, the number and distribution of ill persons, and the process by which the contamination occurred.

- **Outbreak Control.** Identifying and implementing measures to mitigate or stop the foodborne disease event.
- **Outbreak Documentation.** Creating a report or other documentation of the foodborne disease event to record information about the specifics of the outbreak, identify lessons learned, and take enforcement action as needed.

In keeping with the scope of the CIFOR law project, only these four key functions are covered in the *Handbook*. This document does not cover ongoing inspections, licensing and regulation, or ongoing food safety education and communication functions, which also are discussed in the *CIFOR Guidelines*. These functions are all vital components of a state’s overall food safety system and each has relevant legal authorities and requirements associated with it. Readers should work with their legal counsel to understand whether, and the extent to which, a particular law or regulation can be used to support their various foodborne disease detection and response activities.

1.3 Organization

The *Handbook* is organized into the following sections:

- **Chapter 2 (Organization of Foodborne Disease Detection and Outbreak Response Activities)** describes the various ways in which foodborne disease detection and response activities are structured among state agencies and various levels of government.
- **Chapter 3 (Legal Authorities)** identifies the various types of legal authorities used in the conduct of foodborne disease detection and response activities.
- **Chapter 4 (Outbreak Detection)** focuses on legal authorities for disease surveillance systems and activities that identify individual cases or clusters of foodborne diseases.
- **Chapter 5 (Outbreak Investigation)** discusses legal authorities and requirements for determining the specific foodborne disease agent, the contaminated food, the number and distribution of ill persons, and the process by which the contamination occurred.
- **Chapter 6 (Outbreak Control)** discusses the legal authorities for identifying and implementing measures to stop or mitigate the foodborne disease event.
- **Chapter 7 (Outbreak Documentation)** focuses on the requirements for creating a report or other documentation of the foodborne disease event to record information about the specifics of the outbreak, identify lessons learned, and take enforcement action as needed.
- **Chapter 8 (Legal Authorities Checklist)** compiles all of the individual chapter checklists into one comprehensive checklist for identifying relevant legal authorities supporting foodborne disease detection and response activities and determining where gaps in authorities exist.

The *Handbook* also includes two appendices. Appendix 1 is a glossary of key terms and acronyms used in the document. Appendix 2 discusses tips for researching legal authorities for foodborne disease detection and response activities.

1.4 Features

The *Handbook* includes a number of features designed help public health practitioners quickly identify and understand the salient concepts in each chapter.

1.4.1 Four Key Concepts Framework

The *Handbook* identifies four key concepts as a framework by which to analyze and describe legal provisions related to foodborne disease outbreak detection and response activities:

- **Authority.** What action is authorized and by whom?
- **Process.** What is the process for undertaking the action?
- **Rights.** What are the rights of parties affected by the action?
- **Compliance.** What measures, if any, are available to make parties comply with the action?

The framework is discussed in more depth in Chapter 3 “Legal Authorities.”

1.4.2 Chapter Features

Each chapter in the *Handbook* includes the following features:

- Discussion and examples of legal provisions related to the chapter topic.
- Checklist to help public health practitioners identify relevant legal authorities and key issues and questions to discuss with counsel.
- Call-out boxes that define key terms and highlight specific issues or examples.
- List of resources that direct practitioners to additional information about the topic.

CHAPTER 2 | ORGANIZATION OF FOODBORNE DISEASE DETECTION AND RESPONSE ACTIVITIES

2.0 Chapter Introduction

Foodborne disease surveillance and outbreak detection and investigation are shared responsibilities among federal, state, and local governments. Federal authorities and agency activities, depending on the issue, can expressly direct and indirectly influence state and local foodborne disease detection and response activities.

The organization varies for state and local programs charged with implementing and enforcing laws governing foodborne disease surveillance and response. Programmatic responsibility for conducting key foodborne disease surveillance and response functions is divided among various divisions or offices within a state agency, among different agencies, and between state and local governments.

This chapter focuses on the different ways states and localities are structured to conduct public health and regulatory activities related to food safety.

2.1 Federal Agency Roles and Authorities

Federal agencies play a key role in ensuring safety of the U.S. food system and in identifying and responding to foodborne disease events in partnership with state and local agencies. During multijurisdictional outbreaks, federal agencies and the legal authorities supporting their activities contribute to outbreak identification, investigation, and response.

2.1.1 Federal Agency Roles

A number of federal agencies are involved in the regulation of food and surveillance of foodborne disease and outbreak response in the United States. Depending on the agency and the particular federal statutes and regulations it is implementing, an agency might act as a regulatory entity, provide technical assistance to state and local governments and private entities, promote food-related goods and services, or a combination of these. The federal agencies most involved in food safety and foodborne disease issues are listed alphabetically and briefly described below. For more detailed information about the agencies' various roles in food and food safety, see the listed websites.

- **Centers for Disease Control and Prevention (CDC)**—CDC works in partnership with state and local governments to monitor foodborne disease and investigate outbreaks. The agency leads and supports key national epidemiologic and laboratory surveillance networks, such as FoodNet, FoodCore, PulseNet, National Voluntary Environmental Assessment Information System (NVEAIS), Laboratory-based Enteric Disease Surveillance (LEDS), and the Foodborne Disease Outbreak Surveillance System (FDOSS). CDC provides technical assistance and consultations to state, tribal, local, and territorial governments in single jurisdiction outbreaks. At the request of involved states, the agency leads, coordinates, and supports states during multistate outbreaks. CDC also provides educational materials on food safety and foodborne disease for the public. (CDC website: www.cdc.gov)

Chapter 2 Key Definitions

Traceback—A method of investigation used to determine the source and distribution of a product suspected in a foodborne disease outbreak and identify points where contamination could have occurred.

- **U.S. Department of Agriculture (USDA)**—USDA comprises a number of agencies and offices that collectively work to provide a safe, sufficient, and nutritious food supply; protect natural resources; and support the agricultural economy and rural communities. The USDA’s Food Safety and Inspection Service (FSIS) is the agency responsible for ensuring that the country’s commercial supply of meat, poultry, and processed egg products is safe, wholesome, and correctly labeled and packaged. FSIS oversees a national program of inspection, investigation, and enforcement of meat, poultry, and processed egg product safety laws. During a foodborne disease investigation, FSIS provides epidemiologic and laboratory testing assistance and coordinates the traceback of contaminated foods during investigations involving FSIS-regulated products. FSIS has the authority to take enforcement and regulatory control action against food manufacturers and distributors. FSIS also provides consumers with information about meat and poultry safety issues. (USDA website: www.usda.gov)
- **U.S. Environmental Protection Agency (EPA)**—EPA comprises a number of offices tasked with protecting human health and the environment. EPA is responsible for setting safe drinking water standards and overseeing their implementation by state, local, and private water suppliers. Waterborne disease can result from bacterial, viral, parasitic, and chemical sources. Cases of waterborne diseases are reported to state and local health agencies and CDC through reportable conditions forms. EPA also is responsible for establishing permitted pesticide residue levels on food or feed; if these levels are violated, then the food or feed can be seized and applicators or producers subject to prosecution. The U.S. Food and Drug Administration (FDA) enforces pesticide residue levels for plant-based foods, and USDA/FSIS enforces pesticide tolerance for meat, poultry, and egg products. (EPA website: www.epa.gov)
- **U.S. Food and Drug Administration (FDA)**—FDA regulates the safety of most foods, with the exception of meat, poultry, and pasteurized egg products in some circumstances, which are regulated by USDA as described above. The agency conducts research into foodborne contaminants, inspects food-processing plants, conducts food industry postmarket surveillance and compliance activities, and publishes the Food Code. During a foodborne disease outbreak in which an FDA-regulated product is suspected as the cause, the agency identifies the source of the product and the extent of its distribution, conducts tests and tracebacks, and conducts factory investigations of the suspected product. FDA works to prevent further exposure to contaminated products and can initiate regulatory action, including new authority granted under the FDA Food Safety Modernization Act (FSMA, described below) to issue mandatory recalls for food and feed. Before enactment of FSMA in 2011, FDA did not have mandatory recall authority, except for infant formula. (FDA website: www.fda.gov)

2.1.2 Federal Laws and Regulations

A number of federal laws and regulations govern the food and food safety issues. Some of the key legal authorities are briefly described below, but this list is by no means complete. Other or additional federal laws and regulations may apply depending on the type of food (e.g., milk, poultry, or egg products) or source of the food (e.g., imported).

Practice Tip

Handbook readers should work with their legal counsel to identify and understand whether and how federal laws and regulations apply to the particular situation with which they are involved.

- **Federal Food, Drug, and Cosmetic Act (FFDCA).** The FFDCA is the federal law that governs all food in the United States except meat, poultry, and egg products in some circumstances, which are regulated

by USDA/FSIS.¹ FFDCA also governs the safety and effectiveness of drugs, biological products (e.g., blood and vaccines), medical devices, and animal drugs and feed. The law also regulates cosmetics and medical and consumer products that emit radiation.

- **FDA Food Safety Modernization Act (FSMA).** FSMA, signed into law in January 2011, amended the FFDCA to enhance the federal government’s ability to prevent and respond to contamination in the food supply.² 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 control plans that, for example, identify possible hazards, the preventive 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.
 - **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.

2.2 Structuring State and Local Foodborne Disease Detection and Response Activities

The responsibility for conducting key foodborne disease surveillance and response activities at the state and local levels is divided among various offices or divisions within an agency, among different agencies, and between state and local governments.

State health departments and agriculture departments are the two state agencies primarily involved in food safety and foodborne disease outbreaks. Surveillance and investigation of foodborne disease outbreaks are conducted by epidemiology units within health agencies and by state laboratories, primarily in health agencies but also within agriculture agencies.

¹ FDA. “Regulatory Information: Legislation” webpage, www.fda.gov/RegulatoryInformation/Legislation/default.htm (accessed October 23, 2012). All information discussing FFD&CA in this section is taken from this webpage.

² FDA. “Background on the FDA Food Safety Modernization Act (FSMA)” webpage, www.fda.gov/Food/FoodSafety/FSMA/ucm239907.htm (accessed October 23, 2012). All information discussing FSMA in this section is taken from this webpage.

Environmental health or retail food safety units within health agencies also have prominent roles in detecting and investigating outbreaks of foodborne disease by responding to public complaints of foodborne disease, conducting environmental assessments during formal outbreak investigations, and imposing control measures during outbreak response. These offices also are key in performing routine licensing, inspection, technical assistance, and education and outreach activities.

Agriculture agencies have responsibilities primarily for promoting and regulating the production of food commodities—plant and animal. They are tasked with inspecting and grading food commodities. In some states, separate animal health agencies are responsible for monitoring and reporting diseases in livestock and other animals.

Describing State Health Agency Structure

The *Handbook* uses the following terms to describe how state agencies are structured:

- **State Agency Structure**—Describes the type of agency structure in which the state public health agency resides:
 - **Independent**—State public health agency exists as an independent state agency.
 - **Part of Larger Agency**—State public health agency is a component of a larger umbrella agency.
- **Governed by a State Board of Health**—Describes whether the state health agency is directed by a state board of health or other executive body.
- **Joint Agencies**—Health agency functions are combined with environmental protection and environmental health functions in one agency.

☑ Practice Tip

Handbook readers should identify the respective roles of the state health and state agriculture departments in food safety and foodborne disease outbreak detection and response. Users also should identify other state agencies or boards, such as environmental protection agencies or animal health boards, with operational and legal authorities affecting food safety and foodborne disease outbreak detection and response.

2.3 Dividing Authorities Between State and Local Governments

Just as states divide responsibilities differently for food safety and foodborne disease surveillance and response activities between health and agriculture agencies, they also use different approaches in dividing these responsibilities between state and local governments.

2.3.1 Health Agencies

The division of responsibilities between state and local health agencies primarily reflects the structural relationships between those agencies. These structural relationships may have their origin in state statutes, which can have detailed provisions addressing the respective powers and duties of state and local health departments. In some states, local public health agencies have primary responsibility for detection and investigation of foodborne disease outbreaks, and state agency staff provide technical assistance and support to localities. In significant or widespread outbreaks state staff can engage in more active roles in investigation and response. In other states, foodborne disease outbreak activities are

State–Local Health Agency Structures

The organizational and operational links between state and local public health agencies are as follows:

- **Centralized**—State health agency provides local public health services.
- **Decentralized**—Local health departments often collaborate with the state health agency but are organizationally independent of the state agency.
- **Shared/Mixed**—Local public health services are subject to the shared authority of the state agency, as well as the local government and/or local boards of health. Local public health services are provided through agencies organized and operated by units of local governments in some jurisdictions and by the state in other jurisdictions.

run by the state either directly or through state agency regional offices. In still other states, state and local leadership on the issue is mixed.

☑ Practice Tip

Handbook readers should understand how state and local public health agencies work together and identify the legal and operational requirements that dictate interactions between the two levels of government.

2.3.2 Agriculture Agencies

Although state health agencies frequently have statutorily defined relationships to local health departments—or at least significant operational contacts with local governments—state agriculture agencies generally do not have similarly extensive statutory or operational ties with local governments.

State agriculture agencies may have regional offices and laboratories within a state to provide assistance to local governments, businesses, growers, and the general public, but the legal mandate and practice to work through local governments is generally not the same as it is for health agencies. When agriculture agencies are charged with administering food safety laws, however, they can have legal and operational interactions with local governments through the local health agency.

☑ Practice Tip

Handbook readers should identify and understand how the agriculture agency in the state relates legally and operationally to local health departments and other units of local government.

2.4 Underlying Structures of Legal Authorities

Variations in how states structure their implementation of food safety and foodborne disease outbreak activities might or might not reflect the underlying legal authorities that direct and allow agencies to take action. Thus, an agriculture agency may be responsible for administering laws located within the health title of a state's statutes. This seeming incongruence can reflect changes to government organizational structures or responsibilities over time that might not have been likewise reflected in the organization of statutes and regulations. These differences also can result in differences in how laws are administered.

☑ Practice Tip

Handbook readers, regardless of the agency or level of government in which they are located, should recognize the organizational structures and the body of laws and regulations under which they operate. Understanding these structures and legal authorities is crucial for identifying and analyzing authorities, processes, rights, and compliance measures.

CHAPTER 2 | Checklist: Organization of Foodborne Disease Detection and Response

Checklist for Organization of Foodborne Disease Detection and Response Activities		
Issue/Question	Response	Legal Authority/Citation
Agency Roles		
Identify the state agencies involved in foodborne disease outbreak detection and response activities, and briefly describe their roles. (Consider health, agriculture, environment, and other agencies and boards.)		
Structures and Interactions		
How do state health agencies interact with other state agencies? Do any statutory or regulatory provisions exist that mandate, permit, or prevent interactions?		
How is the relationship between state and local health agencies structured (e.g., centralized, decentralized, shared/mixed)?		
How do local health agencies interact with other state or local agencies? Do any statutory or regulatory provisions mandate, permit, or prevent interactions?		

CHAPTER 2 | Resource List

Practice Resources

- CIFOR. *Guidelines for Foodborne Disease Outbreak Response* (2009), Chapter 3: www.cifor.us/CIFORGuidelinesProjectMore.cfm
- Association of Food and Drug Officials (AFDO): www.afdo.org
- Association of Public Health Laboratories: www.aphl.org
- Association of State and Territorial Health Officials (ASTHO): www.astho.org
- Council of State and Territorial Epidemiologists (CSTE): www.cste.org
- National Association of County and City Health Officials: www.naccho.org
- National Association of State Departments of Agriculture: www.nasda.org
- National Association of State Public Health Veterinarians (NASPHV): www.nasphv.org
- National Environmental Health Association (NEHA): www.neha.org

Legal Resources

- FDA. Laws Enforced by FDA: www.fda.gov/RegulatoryInformation/Legislation/default.htm
- USDA. Laws and Regulations: www.usda.gov/wps/portal/usda/usdahome?navid=LAWS_REGS&navtype=SU

CHAPTER 3 | LEGAL AUTHORITIES

3.0 Chapter Introduction

A state's legal authority to conduct foodborne disease surveillance and response activities is distributed across different types of statutes and regulations. It is not possible to review just one title or chapter in a statute or regulation to effectively capture all the legal authorities that states can use to conduct their foodborne disease surveillance- and response-related activities.

This chapter identifies and discusses five types of legal authorities potentially available to support surveillance and response actions. It closes by identifying a framework to assist public health practitioners in understanding legal authorities to conduct foodborne disease surveillance and response activities.

3.1 Identifying Types of Legal Authorities

The *Handbook* discusses five primary types of legal authorities:

- **General Governmental Laws.** This group of laws includes general governmental provisions that apply to any agency or person, such as public records and confidentiality laws.
- **General Public Health Laws.** These laws empower the health agency and other agencies, as well as specific officials (e.g., state health agency director), to take action to prevent and respond to public health threats.
- **Communicable Disease Laws.** These laws define the surveillance and control measures for a range of communicable diseases and conditions, not just for foodborne or enteric diseases.
- **Food and Food Safety Laws.** These laws govern the production, distribution, storage, sale, and serving of various foods in different types of establishments.
- **Express Foodborne Disease Statute or Regulation.** This is a comprehensive or unified statute or regulation that specifically addresses all aspects of foodborne disease surveillance, investigation, control and documentation.

Other laws may be relevant in an outbreak depending on the nature of the event (e.g., a public health emergency), the type of food suspected or known to be contaminated (e.g., eggs, shellfish, dairy, water), and the setting (e.g., farm, processor, transporter, church).

These five primary types of legal authorities describe broad categories of authorities. In practice, a law may fit into more than one category. A state or locality may rely on a specific type of legal authority (e.g., general authority of the state health board to

Chapter 3 Key Definitions

Legal Authorities—The *Handbook* uses the term “legal authorities” to collectively refer to statutes, regulations, ordinances, orders, and policies that authorize governments or other specified actors to engage, or prohibit them from engaging, in the actions identified.

identify and mitigate public health hazards) to sustain their activities in more than one functional area (e.g., outbreak detection, outbreak control). Each of the five types of legal authorities is described in detail in the sections below.

Practice Tip

Handbook readers should identify the various types of legal authorities that can be used to support their foodborne disease detection and response activities.

3.2 General Government Laws

This group of laws includes general government provisions that apply to any agency or person, such as public records and confidentiality laws.

EXAMPLE: Minnesota Statute §13.03 Access to Government Data*

“All government data collected, created, received, maintained or disseminated by a government entity shall be public unless classified by statute, or temporary classification pursuant to section 13.06, or federal law, as nonpublic or protected nonpublic, or with respect to data on individuals, as private or confidential.”

Other examples of general government laws include

- Authorities granted to state and local agencies or agency officials (health, agriculture, environment, animal health, and others as indicated by the state).
- General government or agency emergency powers and authorities (i.e., powers that become effective upon a gubernatorial or presidential declaration of emergency).
- Authorities permitting interjurisdictional cooperation activities, compacts, and agreements.
- Civil and criminal penalties for violating statutes and regulations.

3.3 General Public Health Laws

General public health laws empower the health agency, other agencies, and specific officials (e.g., state health agency director) to take action to prevent and respond to public health threats. This group of laws authorizes and proscribes the powers and duties of an agency and authorizes government action to identify and mitigate public health hazards.

EXAMPLE: Oregon Revised Statute §431.110 General powers of Oregon Health Authority*

“[T]he Oregon Health Authority shall:

(1) Have direct supervision of all matters relating to the preservation of life and health of the people of the state. ...

(3) Make sanitary surveys and investigations and inquiries respecting the causes and prevention of diseases, especially of epidemics....

(5) Have full power in the control of all communicable diseases. ...”

*This example is included for information only. It may not reflect current law or be a complete statement of the law in the state.

Types of general public health authorities include:

- General state and local government authorities to protect public health.
- Authorities granted to state and local agencies or agency officials (health, agriculture, environment, animal health, and others as indicated by the state) to protect public health.
- Authorities to abate public health and other nuisances. These laws may be construed to include foodborne disease outbreaks, therefore permitting state or local health agencies to address the outbreak under this authority.
- General government or agency emergency powers and authorities (i.e., powers that become effective upon a gubernatorial or presidential declaration of emergency) to respond to public health and other emergencies.

General public health authorities may either expressly mention foodborne disease outbreaks or broadly include outbreaks of infectious diseases as events justifying application of the state's public health authorities.

3.3.1 State Agency and Actor Legal Authorities

Legal authorities governing specific state agencies (e.g., state health agency, state laboratory) and actors (e.g., health directors, epidemiologists, environmental health sanitarians) establish the powers and duties for them. State public health agencies, health directors, or boards of health are the entities most frequently granted specific and general powers related to foodborne disease events, food safety, and communicable diseases.

Agriculture agencies, agriculture directors, or boards of agriculture also commonly have a broad grant of authority to protect public health, especially as it relates to the safety of the food supply, and guard against contagious animal diseases and conditions.

3.3.2 Local Agency and Actor Legal Authorities

Local agencies and actors can be granted specific powers to protect public health in state law. Because local government units are a creation of the state, the powers of the locality depend on the authorities granted to it by the state.

In some states, local powers and duties related to protecting the public health, identifying and mitigating communicable diseases, or preventing foodborne disease outbreaks are specifically granted to a locality or a local health agency or entity in the state's statute. In other states, more than one type of local health agency structure is authorized; these include, for example, city, county, and district health agencies.

The types and extent of public health authorities granted to a local jurisdiction also relate to the type of structural relationship between the state health agency and local health agencies (i.e., centralized, decentralized, shared/mixed) as discussed in Chapter 2.

3.4 Communicable Disease Laws

Communicable disease laws specifically relate to the identification, reporting, and control of infectious diseases and conditions.

EXAMPLE: Texas Health and Safety Code §81.041. Reportable Diseases*

“(a) The board shall identify each communicable disease or health condition that shall be reported under this chapter.
(b) The board shall classify each reportable disease according to its nature and the severity of its effect on the public health.
(c) The board shall maintain and revise as necessary the list of reportable diseases.
(d) The board may establish registries for reportable diseases and other communicable diseases and health conditions. The provision to the department of information relating to a communicable disease or health condition that is not classified as reportable is voluntary only. ...
(f) In a public health disaster, the commissioner may require reports of communicable diseases or other health conditions from providers without board rule or action. The commissioner shall issue appropriate instructions relating to complying with the reporting requirements of this section.”

Types of communicable disease laws include

- Communicable disease case reporting, investigation, and post-investigation reporting.
- Animal communicable disease case reporting, investigation, and post-investigation reporting.
- Foodborne and waterborne disease surveillance, investigation, control, and reporting.
- Clinical laboratory requirements to submit positive specimens or isolates

Communicable disease laws define the surveillance and control measures for a range of communicable diseases and conditions, not just for foodborne or enteric diseases. Included in this category of legal authorities for the purposes of the *Handbook* are laws addressing the identification, reporting, and control of infectious diseases in animals, with emphasis on enteric diseases and conditions (which enter the body through the mouth and usually cause intestinal tract disease) that are transmissible from animals to humans.

All states have some type of statutory or regulatory authorities related to the identification, reporting, and control of communicable diseases and conditions. Specific foodborne and enteric pathogens are included in states’ lists of notifiable conditions, in accordance with the list of nationally notifiable conditions developed by CSTE and CDC.

3.5 Food and Food Safety Laws

These laws govern the production, distribution, storage, sale, and serving of various foods in different types of establishments, such as food processors, food retailers, and restaurants.

EXAMPLE: Indiana Code “Food: Sanitary Requirements for Food Establishments”
§IC 16-42-5-19 Diseases; employees

*This example is included for information only. It may not reflect current law or be a complete statement of the law in the state.

*This example is included for information only. It may not reflect current law or be a complete statement of the law in the state.

“ Sec. 19. A person who has a communicable or infectious disease may not work in a food establishment in any capacity in which epidemiological evidence indicates the person may spread the disease. ...”

Food and food safety laws include

- Food and food safety authorities regarding food items and food establishments.
- Foodborne disease surveillance, investigation, control, and reporting.
- Ongoing licensing, and routine inspection requirements for food operations and food establishments (e.g., licensing and inspection of retail food establishments).
- Ongoing education and training requirements (e.g., food manager certification).

3.5.1 Types of Food and Food Safety Laws

Food and food safety laws can be broadly classified into several categories:

- **Food Laws.** These types of laws govern the safety of food as it is produced, manufactured, processed, packaged, transported and stored. These laws can be seen as a state’s analog to the Federal Food, Drug and Cosmetic Act (FD&C Act).
- **Food Establishment Sanitary Statutes.** State statutes that govern the sale of food through establishments like restaurants, retail food stores, wholesale food operations, and mobile food service vehicles. These statutes can contain some of the FDA Food Code.
- **Food Code Regulations.** A state may adopt some or most provisions of the FDA’s Food Code into the state’s regulations and other state-specific modifications to the Food Code. These regulations may be in lieu of or supplemental to food establishment sanitary statutes described above.
- **Product-specific Laws.** State statutes and regulations governing specific agricultural products including but not limited to meat, seafood, flour, corn, rice, milk and dairy products, and eggs. These statutes and regulations may contain relevant legal authorities governing foodborne disease detection and outbreak response activities, but which are not included in this review.

3.5.2 Similarities among State Food and Food Safety Laws

States may have similarities among their food and food safety laws stemming from either required or desired conformity with federal laws or model laws or language that states have adopted in whole or in part. Generally, a state will have a statute or statutes that contain the same or similar language to the federal FD&C Act, as well as regulations that adopt portions of one of the versions of the FDA Food Code with state-specific modifications. Additionally, retail food establishment and food establishment sanitary statutes can reflect similar language and concepts to those contained in the FDA Food Code model regulation; states may adopt statutes in addition to the regulatory code language to provide legislative authority for the state’s food code regulation.

3.6 Express Foodborne Disease Detection and Outbreak Response Laws

No state has a comprehensive or unified set of statutes or regulations that expressly address foodborne disease surveillance or outbreak response in the same way that states have developed pathogen-specific or disease-specific statutory schemes as they have for tuberculosis and HIV/AIDS, for instance. Instead, states rely on a mix of legal authorities drawn from a variety of sources (e.g., general public health laws,

communicable disease laws, and food and food safety laws) to conduct key foodborne disease outbreak functions (detection, investigation, control, and documentation).

This mix of statutes, regulations, policies, and guidances provides a patchwork of authorities and procedures that might or might not be sufficient for the surveillance and response needs of any given foodborne disease outbreak event.

In one respect, using an array of legal authorities to address foodborne disease events makes sense given the multifaceted nature of these outbreaks. With the complexity and sheer volume of the global food system, identifying the disease agent, the food “vehicle” through which the agent was delivered, and the number of persons sickened and identifying the source of contamination, such as a farm, processing facility, retail food store, restaurant, or food worker, and then controlling the outbreak are tremendous undertakings that requires a broad range of legal and nonlegal (e.g., agency policies and guidances) tools.

Elements of Comprehensive Foodborne Disease Surveillance and Response Authority

The CIFOR *Menu of Legal Options* provides policy makers with a checklist of the key legal authorities needed for comprehensive foodborne disease outbreak detection and response activities and drafting options for adding to or amending their jurisdiction’s legal authorities.

Practice Tip

Relying on legal authorities that might not be designed or well suited for the context of foodborne disease surveillance, investigation, control, and outbreak reporting can limit or delay the public health response to an outbreak. Having to assemble legal authorities to support a foodborne disease outbreak response also is a source of uncertainty for public health practitioners charged with detecting, investigating, and controlling outbreaks.

Therefore, *Handbook* readers need to understand the body of statutes, regulations, and other sources of legal authority available to them and the scope of power they authorize. Users also need to know the process required for using and enforcing the legal authorities. Finally, readers should know the attorneys assigned to their agency or office and establish an ongoing working relationship with those persons before an event occurs.

3.7 Other Laws

Other bodies of laws, including agricultural and environmental laws, may have pertinent legal authorities for foodborne disease detection and response activities. Other types of legal authorities can include

- Drinking water, waterborne diseases, and source water protection.
- Specific animal disease identification and control programs (e.g., brucellosis, scrapie).
- Plant diseases.
- Pesticides and other chemical contaminants to food.
- Fish consumption advisories.
- Civil and criminal penalties for violating statutes and regulations.

3.8 A Framework for Understanding Legal Authorities

Four key concepts provide a framework by which any legal provision related to foodborne disease outbreak detection and response activities can be described and analyzed:

- **Authority:** *What action is authorized and by whom?* For example, does a health officer have authority to order medical tests for a food worker suspected of being infected with a potential foodborne pathogen?
- **Process:** *What is the process for undertaking the action?* For example, does the health agency have to give written notice or get a court order before it requires the food worker be tested?
- **Rights:** *What are the rights of parties affected by the action?* For example, is the food worker entitled to a hearing or to appeal an order for testing?
- **Compliance:** *What measures, if any, are available to make parties comply with the action?* For example, can the health agency mandate testing or require quarantine in lieu of testing the health worker?

Public health practitioners can use this framework—authority, process, rights, and compliance—to understand their jurisdictions’ laws to conduct foodborne disease outbreak detection and response activities. These four concepts also can help practitioners in their discussions with agency legal counsel to understand the key considerations needed for agency action. This framework is used explicitly or implicitly throughout the *Handbook* to describe legal authorities supporting key foodborne disease outbreak functions: detection, investigation, control, and documentation.

CHAPTER 3 | Checklist: Sources of Legal Authorities to Conduct Foodborne Disease Detection and Outbreak Response Activities

Sources of Legal Authorities to Conduct Foodborne Disease Detection and Outbreak Response Activities		
Issue/Question	Response	Legal Authority/Citation
Identify generally the body of legal authorities that can be used to support foodborne disease outbreak detection and response activities in your jurisdiction. Consider the following types of legal authorities:		
• General Government Laws		
• General Public Health Laws		
• Communicable Disease Laws		
• Food and Food Safety Laws		
• Express Foodborne Disease Statute or Regulation		
• Other Laws		
Review these various types of authorities with legal counsel to gain a general understanding of the scope of each authority and the circumstances under which it can be used.		

CHAPTER 3 | Resource List

Practice Resources

- CIFOR. *Guidelines for Foodborne Disease Outbreak Response* (2009), Chapters 3 and 9: www.cifor.us/CIFORGuidelinesProjectMore.cfm
- CDC Public Health Law Program: www.cdc.gov/phlp/index.html
- The Network for Public Health Law: www.networkforphl.org

CHAPTER 4 | OUTBREAK DETECTION

4.0 Chapter Introduction

The outbreak detection function represents the processes and channels through which a suspected foodborne disease outbreak is recognized and communicated to government public health officials. Outbreak detection methods include epidemiological and laboratory surveillance and illness complaints.

This chapter focuses on two elements within the outbreak detection function: surveillance and disease reporting requirements. Issues related to accessing records and confidentiality requirements are discussed in Chapter 5, “Outbreak Investigation.”

4.1 Detecting Intentional Contamination

Methods for detecting a foodborne disease event 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 become available that enhance or control the course of the outbreak investigation and response going forward.

☑ Practice Tip

Handbook readers should be aware of how an act of intentional contamination can change the legal landscape in the state.

4.2 Surveillance

Surveillance methods are used to identify cases and clusters of potential foodborne disease across an array of food types and at all points in the food system—from farm to fork.³ Surveillance for foodborne disease outbreaks is conducted by monitoring public complaints of foodborne diseases, through laboratory surveillance for enteric agents, and theoretically through syndromic surveillance (gathering data on nonspecific health indicators).⁴ Epidemiologic methods are used to confirm outbreaks of foodborne disease by investigating illness complaints from the public and by demonstrating links between laboratory-detected cases of enteric illness.

CHAPTER 4 Key Definitions

- **Clusters**—An unusual aggregation of cases grouped in time or space.
- **Enteric Illness**—Illness of the intestinal tract caused by food or waterborne bacteria, viruses, or contaminants that enter the body through ingestion.
- **Isolate**—The pure strain of a virus or bacteria that is separated from a sample.
- **Outbreak**—Two or more cases of a similar illness shown by investigation to result from a common exposure, such as ingestion of a common food.
- **Surveillance**—The systematic collection, analysis, interpretation, and dissemination of data for public health action.
- **Syndromic Surveillance**—The process of using individual and population health indicators that are available before confirmed diagnoses or laboratory confirmation to identify outbreaks or health events and monitor the health status of a community.
- **Zoonoses**—Diseases or conditions that can be passed from animals to humans.

³ CIFOR, *Guidelines for Foodborne Disease Outbreak Response* (2009) at p. 82.

⁴ Syndromic surveillance for foodborne illness has not been shown to be effective. CIFOR *Guidelines* at p. 99.

Several federal foodborne disease outbreak monitoring systems have been developed to help state health agencies rapidly detect outbreaks, identify foodborne pathogens, facilitate sharing of information about outbreaks, and collect data on outbreak patterns and exposures over time.

A specific jurisdiction's laws might or might not have an explicit statute or regulation that authorizes the use of epidemiologic and laboratory findings to identify foodborne disease events. Instead, the authority to conduct disease surveillance activities is most commonly seen in laws directing and authorizing the state public health agency to identify and control communicable diseases without specifying the types of practices or methods that should be employed.

Although terms such as “surveillance” and “epidemiology” might not explicitly appear in the text of statutes or regulations, the activities and requirements contained in these authorities describe fundamental public health surveillance activities. In some states, the reportable disease statute specifies the types of information, procedures, and deadlines for reporting.

Practice Tip

Handbook readers should identify the statutes and regulations in their states that support the authority of public health officials to conduct surveillance for foodborne disease cases and outbreaks.

4.3 Disease and Condition Reporting Requirements

All states have laws requiring certain persons and entities to report specified cases of communicable diseases and conditions. Although all states have adopted most of the conditions contained in the list of nationally notifiable conditions, which is annually reviewed and published by CSTE and CDC⁵, many states have not adopted all of the nationally notifiable conditions. Foodborne pathogens and enteric diseases are included in all states' lists of reportable conditions. In addition to this list, states may add other diseases and conditions that must be reported.

⁵ Available through the CSTE website, <http://www.cste.org/resource/resmgr/PDFs/CSTENotifiableConditionListA.pdf> (accessed February 16, 2013).

Examples of Federal Foodborne Disease-Related Monitoring Systems

FDOSS (Foodborne Disease Outbreak Surveillance System): CDC collects reports of foodborne disease outbreaks caused by enteric bacterial, viral, parasitic, and chemical agents. State, local, and territorial public health agencies report these outbreaks to FDOSS through the National Outbreak Reporting System (NORS). NORS, launched in 2009, is a Web-based platform designed to support reporting to CDC by state and territorial public health agencies of enteric disease outbreaks transmitted through food, water, person-to-person contact, or direct contact with animals. (NORS was called the electronic Foodborne Outbreak Reporting System [eFORS] during 1998–2008.)

OutbreakNet: A national collaboration of epidemiologists and other public health officials who investigate outbreaks of foodborne, waterborne, and other enteric illnesses in the United States. The purpose of OutbreakNet is to ensure rapid, coordinated detection and response to multistate outbreaks of enteric diseases and promote comprehensive outbreak surveillance.

PulseNet: An international surveillance network comprising national, state, and local public health and food-regulatory agency laboratories that conduct standardized molecular subtyping of foodborne disease pathogens (i.e., DNA fingerprinting) and maintain centrally accessible databases of patterns. PulseNet also functions as a communication hub for laboratories involved in food and foodborne disease monitoring.

USDA/FSIS Consumer Complaint Monitoring System (CCMS): An electronic database for capturing consumer complaints. USDA/FSIS has used this database to record, triage, and track complaints about FSIS-regulated meat, poultry, and egg products. CCMS helps to identify and trace adulterated product in commerce and allows the agency to respond and mitigate possible food-safety hazards.

National Voluntary Environmental Assessment Information System (NVEAIS): NVEAIS is a new system that will be used to identify factors that can be routinely monitored to prevent or reduce the risk for foodborne disease outbreaks. Information collected through NVEAIS will be used to establish a detailed characterization of food vehicles and monitor food vehicle trends; identify and monitor contributing factors and their environmental antecedents; and provide a basis for hypothesis generation regarding factors that may support foodborne outbreak events. NVEAIS will provide food safety programs and the food industry with information to guide the planning, implementation, and evaluation of foodborne disease prevention activities.

Some states include specific conditions that must be reported in the text of the statute, whereas others define the reportable conditions in their regulations.

4.3.1 Persons Required to Report

Reportable conditions laws can specify the persons and entities required to report under the law. Persons or entities required to report can include: physicians, clinical laboratories, dentists, nurses, hospitals, and coroners.

State food safety and food establishment statutes and regulations typically require owners or persons in charge of food establishments to report incidents in which food employees have transmitted foodborne disease or in whom a food-transmissible infectious disease or condition has been diagnosed or is suspected.

4.3.2 Timeframe for Reporting

The timeframe for reporting the various reportable conditions is specified in either statute or regulation. States generally have at least a two-tier system of reporting deadlines—immediate/within 24 hours and from 3 to 7 days. Foodborne pathogens and enteric diseases appear in both tiers of the states' lists.

4.3.3 Information to be Reported

The type of information to be reported and the format for reporting infectious diseases and conditions is commonly specified in regulation, although some states also identify this information in their statutes as well. Basic information, such as case-patient name, address, and contacts, is required for all reportable conditions.

Practice Tip

Handbook readers should identify their communicable disease reporting statutes and regulations to determine the persons and entities required to report; the diseases and conditions that must be reported; the timeframes for each; and penalties, if any, for failing to report a communicable disease as required by state law.

4.4 Submission of Isolates

Submitting isolates (samples of the foodborne pathogen) from clinical laboratories also is an important component in foodborne disease surveillance and investigation. In some states, submission of isolates is specifically required by statute or regulation.

Practice Tip

Handbook readers should identify whether the state has any statutes or regulations requiring the submission of isolates and the circumstances under which they must be submitted.

4.5 Cluster and Outbreak Reporting Requirements

Some states expressly require that suspected clusters or outbreaks of unexplained illnesses be reported to public health officials. State communicable disease regulations can require reporting of infectious or noninfectious outbreaks or clusters of diseases. Foodborne disease is one of the types of outbreaks that should be reported.

☑ Practice Tip

Handbook readers should identify whether the state has any statutes or regulations that require clusters or outbreaks to be reported and the requirements for making these reports.

4.6 Communicable Diseases in Animals

States have legal requirements mandating that certain persons or entities report confirmed or suspected cases of specified communicable diseases in animals or livestock. Included in this list are enteric zoonoses and other zoonotic diseases or conditions. Either the state department of agriculture or the state animal health agency is responsible for receiving and acting on the reports.

Persons most often required to report communicable diseases in animals are owners and veterinarians. In some states, explicit directions are included for cases in which a communicable animal disease is a danger to humans. In these instances, individuals or the department of agriculture/animal health are also required to report the condition to state or local public health officials.

☑ Practice Tip

Handbook readers should identify whether the state has any statutes or regulations requiring the reporting of communicable diseases in animals, the persons or entities required to report, the diseases and conditions that must be reported, and the penalties for failing to report as required.

CHAPTER 4 | CHECKLIST: Legal Authorities for Conducting Foodborne Disease Detection Activities

Legal Authorities for Conducting Foodborne Disease Detection Activities		
Issue/Question	Response	Legal Authority/Citation
Surveillance		
Identify the statutes and regulations that support public health officials' authority to conduct surveillance activities for foodborne disease cases and outbreaks.		
Reporting of Communicable Diseases or Conditions		
Identify communicable disease reporting statutes and regulations to determine the persons and entities required to report; the diseases and conditions that must be reported; the timeframes for each; and penalties, if any, for failing to report a communicable disease.		
Submission of Isolates		
Identify whether the state has any statutes or regulations requiring the submission of isolates; the circumstances under which they must be submitted; and penalties, if any, for failing to submit an isolate.		

Legal Authorities for Conducting Foodborne Disease Detection Activities

Issue/Question	Response	Legal Authority/Citation
Cluster or Outbreak Reporting		
Determine whether the state has any statutes or regulations requiring that clusters or outbreaks be reported; the requirements for making these reports; and penalties, if any, for failing to report.		
Communicable Diseases in Animals Reporting		
Identify whether the state has any statutes or regulations requiring the reporting of communicable diseases in animals; the persons or entities required to report; the diseases and conditions that must be reported; and the penalties, if any, for failing to report as required.		

CHAPTER 4 | Resource List

Practice Resources

- CIFOR. *Guidelines for Foodborne Disease Outbreak Response* (2009), Chapters 2 and 4: www.cifor.us/CIFORGuidelinesProjectMore.cfm

CHAPTER 5 | OUTBREAK INVESTIGATION

5.0 Chapter Introduction

The outbreak investigation function is the process of determining the disease agent, the food “vehicle” (or other vehicle, such as water), the number and distribution of ill persons, and the mechanism and underlying cause of the contamination. Investigation processes at the local and state levels include initial and follow-up data collection through interviews, record reviews, laboratory testing, and environmental assessments and then data analysis.

Two areas of legal authorities are discussed in this chapter: (1) authorities and processes for investigating an outbreak and (2) access to records and privacy considerations.

5.1 Authority to Investigate a Foodborne Disease Outbreak

States generally have some type of authority and mandate to investigate health hazards; however, the degree of specificity and the extent to which particular powers are specified can vary. General public health and agency laws that grant health and other agencies general power to protect public health or control communicable diseases are the broadest grant of legal authority. Communicable disease laws and food/food safety laws can have more specific grants of authority that permit health or other agencies to conduct investigations.

Some states have supplemental legal authorities in addition to their communicable disease laws to conduct health investigations. A state can permit agencies to conduct epidemiologic or toxicologic investigations to probe illnesses, conditions, and exposures that are or might be a threat to public health.

Legal authorities to conduct investigations may be located in statutes and regulations intended for licensing and ongoing inspections of food production operations or food establishments. This fact may limit the circumstances under which, and the extent to which, the authority to inspect or investigate is allowed depending on how a state interprets its laws. Public health practitioners should consult with their attorneys to clearly understand whether, and under what circumstances, inspection or investigation provisions contained in licensing or routine inspection laws might be suitable for use during a foodborne disease investigation.

CHAPTER 5 Key Definitions

Administrative/Judicial Process—The rights of a person or business to reasonable opportunity to be informed about, comment on, and challenge a government’s action.

Practice Tip

Handbook users should identify and become familiar with the various types of legal authorities that permit public health or other designated officials to investigate the sources and extent of foodborne disease outbreaks.

5.2 Required Processes for Investigating an Outbreak

State statutory or regulatory provisions might or might not specify use of certain investigative methods or processes during a foodborne disease outbreak. Specific investigative measures authorized or mandated by

law can include the types of records to be reviewed; sampling, testing, examining, or creating a photographic or other visual record; and other investigation methods.

5.3 Types of Investigative Measures Authorized

State communicable diseases or food and food safety laws might contain several types of investigative measures. These include accessing premises and vehicles and examination, testing, and sampling of persons or premises. States might have similar legal authorities regarding investigative measures because states have adopted language the same as, or similar to, that of federal laws and regulations or model codes such as the FD&CA and the Food Code.

5.3.1 Access to Premises and Vehicles

Food/food safety laws can contain one or more provisions that specifically permit state or local agency personnel to enter and inspect premises and vehicles that are covered under a specific law (e.g., retail food establishments). Inspections are permitted primarily during normal business hours or at reasonable business hours.

5.3.2 Examination and Testing Persons

Laws generally permit the examination and testing of persons known to be, or suspected of being, infected with a food-transmissible disease. State communicable disease laws also permit the examination and testing of individuals.

5.3.3 Testing and Sampling of Premises and Environment

Food and food safety laws commonly permit the taking of food samples and environmental samples from food establishments for testing. Laws may also allow the gathering of other evidence, such as photographs, to document the conditions in the premises.

Practice Tip

Handbook readers should identify and understand the various investigative measures authorized under different statutes and regulations in their states.

5.4 Administrative and Judicial Processes and Rights

Although communicable disease and food and food safety laws might not mandate the types of investigative methods or organizational structures to be employed during an event, these laws do contain express provisions governing the rights of persons and entities during an outbreak investigation.

5.4.1 Process and Rights Regarding Persons

Some laws allow persons being examined to have their own physicians present and to receive copies of examination and laboratory test results. Laws also may expressly permit persons to refuse examination and testing as a matter of religious belief. Where testing and examination are refused, state law can allow agencies to require persons infected, or suspected of being infected, with a communicable disease to be prohibited from handling food or excluded from the food establishment until they have medical clearance that they are no longer infected or infectious. States also have general authorities to impose isolation (for ill persons) and quarantine (for persons suspected of being exposed or infected); however, the imposition of these control measures is accompanied by substantial administrative and judicial processes requirements.

5.4.2 Process and Rights Regarding Premises and Properties

When premises and tangible property are investigated the owner has administrative and judicial process rights. Depending on the circumstances of an event and the legal authority used to investigate a foodborne disease event, owners of premises or property may be entitled to advance notice of an inspection or investigation. In some instances, the law may give the owner process rights, such as requesting a hearing before the order to conduct the investigation is granted.

Practice Tip

Handbook users should work with their legal counsel to determine the circumstances under which specific investigative measures of persons, premises, or property can be used; the process required, if any, for conducting the investigation; the rights of the person or entity being investigated; and the penalties, in any, for failing to comply with authorized investigative measures.

5.5 Access to Records and Privacy Considerations

The ability of public health officials to access records, such as medical records, laboratory test results, and sanitary inspection results, is fundamental to their ability to detect, investigate, and respond to foodborne disease outbreaks. Public health officials need access to records, such as medical records and laboratory test results, to identify infected persons and implicated foods and to craft appropriate control measures.

Concerns about confidentiality and privacy can cast doubt over the ability of public health officials to access records, and about how much and what types of information they can disclose while communicating with the public and others about the foodborne disease outbreak. The issue of sharing information across state lines multiplies these concerns.

5.5.1 Federal Open Records and Privacy Laws

Questions about the reach and applicability of certain federal open records and privacy laws can create barriers to accessing and sharing records during a foodborne disease investigation. The sections below discuss two important federal laws and how they affect foodborne disease investigations.

5.5.1.A Federal Freedom of Information Act

Federal Freedom of Information Act (FOIA) laws permit persons to access records held by federal executive branch agencies, except where all or portions of the records are protected from public disclosure by an exemption or exclusion in the law. Each federal agency receives and responds to its own FOIA requests. The Department of Justice's Office of Information Policy oversees agencies' overall compliance with FOIA.

During a foodborne disease event, some exemptions to FOIA may prevent federal agencies from releasing certain kinds of information to state and local governments.

Exemptions to FOIA Disclosure Requirements

A number of exemptions to FOIA allow agencies to disallow a request for information because the release could harm government or private interests. Such exemptions include information that concerns a business' trade secrets or other confidential financial or commercial data or information that, if disclosed, could invade another person's personal privacy. However, even if an exemption applies, agencies are permitted to use their discretion in releasing information if no foreseeable harm would result in releasing the information and a law does not otherwise prohibit the disclosure.

5.5.1.B Health Insurance Portability and Accountability Act and the Privacy Rule

Concerns about the applicability of federal privacy laws—the Health Insurance Portability and Accountability Act (HIPAA) in particular—can result in delays and gaps in gathering data during foodborne disease investigations. Specific federal rules created to implement HIPAA, known collectively as the Privacy Rule, create basic protections and a series of regulatory permissions for uses and disclosures of certain types of health information. The Privacy Rule is overseen by the Office for Civil Rights in the Department of Health and Human Services.

The Privacy Rule prohibits “covered entities” from disclosing “protected health information” to any third parties, unless the rule otherwise permits the disclosure. Covered entities are health plans, health-care clearinghouses, and any health-care provider (e.g., doctor, hospital) who electronically transmits health information in connection with transactions for which the Secretary of Health and Human Services has adopted standards under HIPAA. Protected health information (PHI) is individually identifiable health information held or transmitted by a covered entity in any form—electronic, paper, or oral. PHI includes demographic data; common identifiers (e.g., name, address, birth date, Social Security number); information relating to a person’s past, present, or future physical or mental health condition, health care provided to them, or payment for health care; and data that identifies the person or that could be reasonably used to identify the person.

Exceptions to the HIPAA Privacy Rule

In a number of circumstances identified in the Privacy Rule, covered entities are authorized, but not required, to disclose PHI without first seeking the permission of the person who is the subject of the PHI. Depending on the facts in a particular case, these exceptions could be used to access data and records relevant to foodborne disease investigations.

- ***Public Health Activities.*** Covered entities may disclose PHI to public health officials authorized by law to collect or receive such information for preventing or controlling disease, injury, or disability. The rule also allows disclosure to entities subject to FDA regulation regarding FDA-regulated products or activities for purposes, such as adverse event reporting, tracking of products, product recalls, and postmarketing surveillance. The rule also permits disclosure to persons who may have contracted or been exposed to a communicable disease when notification is authorized by law.
- ***Serious Threat to Health or Safety.*** The Privacy Rule allows covered entities to disclose PHI that they believe is necessary to prevent or lessen a serious and imminent threat to a person or the public when such disclosure is made to someone they believe can prevent or lessen the threat (including the target of the threat).
- ***Judicial and Administrative Proceedings.*** The Privacy Rule permits covered entities to disclose PHI in a judicial or administrative proceeding if the request for the information is through an order from a court or administrative tribunal.

5.5.2 State Open Records Laws

All states have some type of open records laws in addition to specific provisions in other state statutes relating to records access, disclosure, and confidentiality. Routine food sanitation and food establishment inspection reports are generally considered public documents and are made publically available, frequently through state and local health agency websites.

Exceptions to Open Records Laws

Personally identifiable information and medical records typically are excluded from the definition of a public record. Information about trade secrets and other proprietary information about a food operation or a food establishment are likewise commonly excluded from the definitions of public records or otherwise made unavailable to the public. Materials that are predecisional (i.e., notes, preliminary findings of an investigation) may not be considered public records; however, final reports and orders are considered public documents.

5.5.3 Access to Data for Public Health Investigations

Some states' open records laws or other statutes include an exception or grant express authority to allow state or local officials investigating disease outbreaks and other public health hazards to access records that might otherwise be considered private, confidential, or unavailable.

Practice Tip

Handbook users should identify their state statutes and regulations governing access to records and privacy considerations. They should consult with legal counsel to determine the type and amount of information, and manner in which public health officials can release information while investigating and responding to a communicable disease outbreak. Users should also work with counsel to determine if the state's various records and privacy laws address whether any specific process is required to access information (e.g., court order required), the rights of parties who are the subject of the information to challenge release of the information, and any penalties for failing to release information or for the misuse of information.

5.5.4 Sharing and Release of Data during Public Health Investigations

Some states' laws might have express statutes that specify the conditions under which public health officials may release or share information obtained during communicable disease or other public health investigations. These provisions, for example, may authorize state or local public health administrators to release information obtained during an investigation of a reportable disease or a disease outbreak to other authorized state, local, or federal officials; health-care practitioners; law enforcement personnel; and the exposed person and other persons potentially exposed, among others. This type of provision provides clear permission and guidelines for the release and sharing of information during a public health investigation.

If a state does not have express authority for public health officials to share information during an outbreak, they may have general legal authorities allowing state or local agencies generally to share information among governments. These general government authorities might or might not explicitly address sharing information across state lines, as is necessarily required in multistate outbreaks.

5.5.5 Interjurisdictional Cooperation and Agreements

States may have laws recognizing a variety of legal mechanisms to permit agencies and jurisdictions to act cooperatively. A state may have general legal authorities permitting it to enter into interjurisdictional or interstate agreements, contracts, compacts or other types of arrangements. A compact is a contract between two or more states or countries that binds the jurisdictions to agree on a policy issue, adopt a standard, or cooperate on a common matter. Some states permit state agencies to enter into contracts and agreements with agencies in other states or even with agencies in other countries. States also have legal authorities that permit state agencies or local governments to enter into other types of interstate agreements such as mutual aid or data sharing agreements. Specific provisions of state law may also allow agencies or localities to share information across state lines in a disease investigation or in an emergency.

☑ Practice Tip

Handbook users should work with their legal counsel to identify all the operational and legal mechanisms available to public health agencies to share information with other agencies, governments, or jurisdictions during the surveillance or investigation of or response to an outbreak. Users should identify any existing compacts or interstate agreements in the states and whether these are suitable for use during foodborne disease outbreak investigation.

CHAPTER 5 | CHECKLIST: Legal Authorities for Conducting Foodborne Disease Outbreak Investigations

Legal Authorities for Conducting Foodborne Disease Outbreak Investigations		
Issue/Question	Response	Legal Authority/Citation
Authorities to Investigate		
Identify and become familiar with the various types of legal authorities that permit public health or other designated officials to conduct investigations into the sources and extent of foodborne disease outbreaks.		
Do any of the above measures require that certain types of investigative procedures or structures (e.g., interagency response team) be used?		
Investigative Measures Authorized		
Identify and understand the various investigative measures authorized under different statutes and regulations in the state.		
Determine the circumstances under which specific investigative measures of persons, premises, or property can be used; the process required, if any, for conducting the investigation; the rights of the person or entity being investigated; and the penalties, if any, for failing to comply with authorized investigative measures.		
Access to Records and Privacy Considerations		
Identify statutes and regulations governing access to records and privacy considerations.		
Determine the type and amount of information, and manner in which public health officials can release information while investigating and responding to a communicable disease outbreak.		
Determine whether the state's various records and privacy laws address whether any specific process is required to access information (e.g., court order required); the rights of parties who are the subject of the information to challenge the release of the information; and any penalties for failing to release		

Legal Authorities for Conducting Foodborne Disease Outbreak Investigations

Issue/Question	Response	Legal Authority/Citation
information or for the misuse of information.		
Sharing Records		
Identify all operational and legal mechanisms available to public health agencies to share information with other agencies, governments, jurisdictions, or states during the surveillance or investigation of or response to an outbreak.		

CHAPTER 5 | Resource List

Practice Resources

CIFOR. *Guidelines for Foodborne Disease Outbreak Response* (2009), Chapter 5:
www.cifor.us/CIFORGuidelinesProjectMore.cfm

Legal Resources

National Center for Interstate Compacts: www.csg.org/NCIC/default.aspx

CHAPTER 6 | OUTBREAK CONTROL

6.0 Chapter Introduction

The outbreak control function involves identifying and implementing measures to stop and mitigate foodborne disease events. Control measures include recalling, embargoing, or destroying hazardous or suspected foods and excluding or restricting infected food personnel.

States' laws contain a number of specific legal provisions addressing potential control measures. Yet, even with control measures, the legal authorities might not originally have been designed to address a foodborne disease outbreak. For instance, certain control measures might apply only when violations are found during routine food safety inspections.

Legal authorities related to outbreak control activities discussed in this chapter include authorities to respond to and control an outbreak and communication requirements during an outbreak.

6.1 Authority to Control an Outbreak

The degree of specificity and the extent to which specific control measures are authorized to respond to communicable disease outbreaks in general and foodborne disease outbreaks in particular varies among states. States' laws and regulations related to control measures are generally more robust and explicit than are the body of laws and regulations addressing disease surveillance authorities, in part because of the greater number of laws and regulations that contain specific control measures. In larger part, however, control measures tend to be more explicitly defined because they involve personal and property rights, and the conditions under which these rights may be altered or denied during a communicable disease or foodborne disease outbreak.

6.1.1 Required Control Methods or Organization

Statutory or regulatory provisions may require that use of certain response methods or organizational structures during a foodborne disease outbreak response (e.g., legal requirement to create a multiagency task force to investigate an outbreak). Laws do permit agencies to undertake response and control measures generally and identify a number of specific control measures when responding to communicable disease outbreaks and unsanitary conditions and other violations of food and food safety laws.

6.1.2 Control Measures and Process—Persons

Food and food safety laws and communicable disease laws can permit several types of measures to control persons infected with, suspected of having, or exposed to a communicable disease.

CHAPTER 6 Key Definitions

- **Embargo**—An order by an agency that prevents food from being used, sold, or discarded until the order is lifted by the agency or a court.
- **Exclusion**—An order preventing a food worker who is sick or suspected of being sick from handling food or from attending work at a food establishment.
- **Isolation**—Process in which a person or animal that is known to be ill from a contagious disease is kept away from others.
- **Quarantine**—Process in which a person, animal, food product, or building that might have been exposed to a contagious disease agent is kept apart from others to prevent disease spread.
- **Recall**—A voluntary or mandatory act to remove a product from sale or distribution.

6.1.2.A Food Employee Restrictions

The imposition of restrictions on a food establishment employee is a control measure authorized in states that have adopted some version of the Food Code. These measures generally can be implemented without prior notice and hearing requirements.

6.1.2.B Exclusion of a Food Employee

Food establishment employees can be excluded from the food establishment while they are infected with or during the incubation period for food-transmissible diseases and other infectious diseases or conditions specified by state law. These measures can be implemented without prior notice and hearing requirements. The exclusion measure generally can be lifted upon certification by a physician that the employee is no longer infected or contagious.

6.1.2.C Quarantine, Isolation, and Other Restrictions

All states have the legal authority to impose quarantine, isolation, and other restrictions on persons who are infected or suspected of being infected or who have been exposed to a communicable disease. Use of quarantine or isolation as a control measure in a foodborne disease outbreak is unlikely; however, this legal authority could be used for that purpose if circumstances necessitate its use. The imposition of isolation, quarantine, or other measures designed to restrict the movements of persons requires considerable legal due process protections. (See section 6.1.5 below.)

6.1.3 Control Measures and Process—Products and Animals

Implementing measures to limit access to infected, contaminated, or implicated food products is a primary tool used in responding to and controlling foodborne disease outbreaks. States have statutory or regulatory authority to implement one or more of the following control measures. Food and food safety laws are the primary sources for these authorities.

6.1.3.A Recall

State food and food safety laws can permit health or agriculture officials to recall foods that are found to be adulterated within the meaning of the law in that jurisdiction. Some states have explicit recall authority permitted by statute.

6.1.3.B Embargo, Seizure and Quarantine

Health and agriculture officials can be legally authorized in food and food safety laws to embargo and quarantine food products within their agency's regulatory purview. Livestock and other animals may be subject to quarantine measures imposed by agricultural and animal health officials, such as state veterinarians. State laws generally give owners of embargoed or quarantined products and animals due process protections, such as notice, hearings, and the right to appeal an agency's control measure.

6.1.3.C Condemnation and Destruction

States can have legal authority in their food and food safety laws to order the condemnation or destruction of food, animals, and tangible personal property that is determined to be infected, contaminated, or implicated in an outbreak. Owners of the affected items generally are entitled to due process rights, and in some states, entitled to compensation for certain destroyed property.

6.1.4 Control Measures and Process—Premises

State public health officials generally have some type of legal authority to impose control measures on premises found to be unsanitary or harbors for infection, contamination, or other threats to public health. These legal authorities are commonly found in food and food safety laws, but some states' communicable disease laws also permit these or similar types of control measures. General state and local nuisance laws also may permit control measures on premises. Specific control measures include the following:

6.1.4.A Posted and Public Notices

Health officials may be authorized to post and publish notices informing the public about health hazards at a food establishment or other premises in which food is produced, sold, or otherwise handled.

6.1.4.B Decontamination

Health and agricultural officials can order the decontamination of premises and any equipment or tangible property if these have been determined to be infected or otherwise contaminated.

6.1.4.C Suspension of License/Permit and Closure

Food establishments and other premises involved in the production or sale of food can be temporarily or permanently closed by a public health agency or officer upon a showing that the facility constitutes a danger to public health. Closure can be achieved by suspending or revoking a food facility's permit or license. The food facility may opt to voluntarily close the establishment.

Practice Tip

Handbook readers should identify authorized control measures related to persons, property, and premises; the process associated with implementing those control measures; the rights of parties affected; and penalties for failing to comply with the control measures.

6.1.5 Administrative and Judicial Processes

Communicable disease laws and food and food safety laws generally include some level of process and review for persons and entities affected by a control measure. Some type of written notice—either before or contemporaneous with—is generally required at the institution of control measures. Persons and entities affected by the control measures are given the right to a hearing or to appeal the order instituting control measures.

Exceptions to Notice and Review Provisions

States also may have some type of provision granting exceptions to the notice and review process in the case of controlling a current or imminent public health hazard. These provisions permit a public health or other agency to take immediate action while still requiring some type of administrative or judicial review process once the control measures are in place.

6.2 Communication Requirements during an Outbreak

Both formal and informal communication mechanisms are crucial in identifying and disseminating public health messages about foodborne disease outbreaks. Sound public health practice dictates that health agency staff regularly communicate as appropriate with affected persons and businesses, other agency staff, levels of government, and the public. Statutes or regulations may require that agencies involved in an outbreak response undertake communication activities and may specify the types of communications.

6.2.1 Reporting and Notice Requirements

Types of required communications include mandated notice and reporting of communicable diseases and conditions to public health officials from parties, such as physicians, food establishment owners or persons in charge, and veterinarians. (See also Chapter 4, “Outbreak Detection.”)

6.2.2 Notices to Other Agencies and Government Bodies

State law may mandate that agency officials notify other agencies about communicable disease outbreaks. Such notification occurs, for example, where communicable animal diseases are a risk to human health; state agriculture agency or animal health agency personnel are legally required to inform public health officials about the outbreak.

6.2.3 Public Notices

Legal authorities or mandates to post public notices or otherwise inform the public about foodborne disease events are found primarily in communicable disease and food and food safety laws. State laws usually include general authorities that permit or require public notice about communicable disease events and food safety events.

Practice Tip

Handbook readers should identify where public health officials and others are required by law, regulation, or policy to issue specific types of communications during a foodborne disease outbreak.

Officials communicating with the media should clearly understand what information they legally can and cannot release to the media or the public (e.g., whether they can name a food establishment where a foodborne disease outbreak is being investigated).

CHAPTER 6 | CHECKLIST: Legal Authorities for Foodborne Disease Outbreak Control Activities

Legal Authorities for Foodborne Disease Outbreak Control Activities		
Issue/Question	Response	Legal Authority/Citation
Authority to Control an Outbreak		
Identify the control measures authorized, the process associated with implementing those control measures, the rights of parties affected, and penalties for failing to comply for:		
• Persons		
• Premises		
• Property		
Do any of the control measures authorized require use of certain types of investigative procedures or structures (e.g., interagency response team)? If so, what are they?		

Legal Authorities for Foodborne Disease Outbreak Control Activities

Issue/Question	Response	Legal Authority/Citation
Communications Requirements during an Outbreak		
Identify where public health officials and others are required by law, regulation, or policy to issue specific types of communications during a foodborne disease outbreak.		

CHAPTER 6 | Resource List

Practice Resources

- CIFOR. *Guidelines for Foodborne Disease Outbreak Response* (2009), Chapter 6: www.cifor.us/CIFORGuidelinesProjectMore.cfm

CHAPTER 7 | OUTBREAK DOCUMENTATION

7.0 Chapter Introduction

In the aftermath of a foodborne disease outbreak, outbreak follow-up activities include documenting information about the event and response, creating and disseminating after-action reports, and beginning enforcement actions as needed.

This chapter focuses on follow-up reporting and documentation requirements.

7.1 Postevent Reporting and Documentation

State laws may explicitly require that public health agencies and other involved parties create summary reports of communicable disease outbreaks and require them to file reports with specified officials (e.g., governor, legislature, state board of health) either directly after an event or annually. State health agencies may also require local or district health agencies to report outbreaks to the state.

CHAPTER 7 Key Definitions

- **After-action Report**—A report prepared to analyze an organization's response to a specific event.
- **Documentation**—Written materials that create an official record.

7.2 General Reporting Requirements

State agencies also may be subject to a general requirement to present an annual report to the governor or state legislature. Although these annual reports typically mandate inclusion of budgetary and performance indicators, agencies have used this format to summarize or highlight activities related to foodborne disease outbreaks.

7.3 Public Information Publications and Other Information Distribution

State laws may contain specific language authorizing state or local agencies to publish and distribute information for the public in the interest of public health and to educate them about public health issues.

☑ Practice Tip

Handbook readers should identify whether their state laws, regulations, or policies require public health officials to submit a report or some other type of documentation in the aftermath of a foodborne disease outbreak event.

CHAPTER 7 | CHECKLIST: Legal Requirements for Outbreak Documentation Activities

Legal Requirements for Outbreak Documentation Activities		
Issue/Question	Response	Legal Authority/Citation
Identify whether the state's laws, regulations, or policies require public health officials to submit a report or some other type of documentation in the aftermath of a foodborne disease outbreak event.		
If so, is the content and frequency specified? What information is required?		

CHAPTER 7 | Resource List

Practice Resources

- CIFOR. *Guidelines for Foodborne Disease Outbreak Response* (2009), Chapter 3: www.cifor.us/CIFORGuidelinesProjectMore.cfm

CHAPTER 8 | COMPREHENSIVE CHECKLIST OF LEGAL AUTHORITIES FOR FOODBORNE DISEASE DETECTION AND OUTBREAK RESPONSE ACTIVITIES

8.0 Chapter Introduction

This list compiles the checklists from the foregoing chapters and is provided for users who wish to have one checklist to review.

Organization of Foodborne Disease Detection and Outbreak Response Activities		
Issue/Question	Response	Legal Authority/Citation
Agency Roles		
Identify the state agencies involved in foodborne disease outbreak detection and response activities, and briefly describe their roles. (Consider health, agriculture, environment, and other agencies and boards.)		
Structures and Interactions		
How do state health agencies interact with other state agencies? Do any statutory or regulatory provisions mandate, permit, or prevent interactions?		
How is the relationship between state and local health agencies structured (e.g., centralized, decentralized, shared/mixed)?		
How do local health agencies interact with other state or local agencies? Do any statutory or regulatory provisions mandate, permit, or prevent interactions?		
Sources of Legal Authorities to Conduct Foodborne Disease Detection and Outbreak Response Activities		
Issue/Question	Response	Legal Authority/Citation
Identify generally the body of legal authorities that can be used to support foodborne disease outbreak detection and response activities in your jurisdiction. Consider the following types of legal authorities:		
<ul style="list-style-type: none"> General government laws 		
<ul style="list-style-type: none"> General public health laws 		

<ul style="list-style-type: none"> Communicable disease laws 		
<ul style="list-style-type: none"> Food and food safety laws 		
<ul style="list-style-type: none"> Express foodborne disease statute or regulation 		
<ul style="list-style-type: none"> Other laws 		
Review these types of authorities with legal counsel to get a general understanding of the scope of each authority and the circumstances under which it can be used.		

Legal Authorities for Conducting Foodborne Disease Detection Activities

Issue/Question	Response	Legal Authority/Citation
Surveillance		
Identify the statutes and regulations that support public health officials' authority to conduct surveillance activities for foodborne disease cases and outbreaks.		
Reporting of Communicable Diseases or Conditions		
Identify communicable disease reporting statutes and regulations to determine the persons and entities required to report, the diseases and conditions that must be reported; the timeframes for each; and penalties, if any, for failing to report a communicable disease.		
Submission of Isolates		
Identify if the state has any statutes or regulations requiring the submission of isolates; the circumstances under which they must be submitted; and penalties, if any, for failing to submit an isolate.		
Cluster or Outbreak Reporting		
Determine whether the state has any statutes or regulations requiring that clusters or outbreaks be reported; the requirements for making these reports; and penalties, if any, for failing to report.		
Communicable Diseases in Animals Reporting		
Identify whether the state has any statutes or regulations requiring the reporting of communicable diseases in animals; the persons or entities required to report; the diseases and conditions that must be reported; and the penalties, if any, for failing to report as required.		

Legal Authorities for Conducting Foodborne Disease Outbreak Investigations

Issue/Question	Response	Legal Authority/Citation
Authorities to Investigate		
Identify and become familiar with the various types of legal authorities that permit public health or other designated officials to conduct investigations into the sources and extent of foodborne disease outbreaks.		
Do any of the above measures require that certain types of investigative procedures or structures (e.g., interagency response team) be used?		
Investigative Measures Authorized		
Identify and understand the various investigative measures authorized under different statutes and regulations in your state.		
Determine the circumstances under which specific investigative measures of persons, premises, or property can be used; the process required, if any, for conducting the investigation; the rights of the person or entity being investigated; and the penalties, in any, for failing to comply with authorized investigative measures.		
Access to Records and Privacy Considerations		
Identify statutes and regulations governing access to records and privacy considerations.		
Determine the type and amount of information, and manner in which public health officials can release information while investigating and responding to a communicable disease outbreak.		
Determine whether the state's various records and privacy laws address whether any specific process is required to access information (e.g., court order required), the rights of parties who are the subject of the information to challenge the release of the information, and any penalties for failing to release information or for the misuse of information.		
Sharing Records		
Identify all the operational and legal mechanisms available to public health agencies to share information with other agencies, governments, or jurisdictions during the surveillance of investigation of or response to an outbreak.		

Legal Authorities for Foodborne Disease Outbreak Control Activities

Issue/Question	Response	Legal Authority/Citation
Authority to Control an Outbreak		
Identify the control measures authorized, the process associated with implementing those control measures, the rights of parties affected, and penalties for failing to comply for:		
• Persons		
• Premises		
• Property		
Do any of the control measures authorized require use of certain types of investigative procedures or structures (e.g., interagency response team)? If so, what are they?		
Communications Requirements During an Outbreak		
Identify where public health officials and others are required by law, regulation, or policy to issue specific types of communications during a foodborne disease outbreak.		

Legal Requirements for Outbreak Documentation Activities

Issue/Question	Response	Legal Authority/Citation
Identify whether the state's laws, regulations, or policies require public health officials to submit a report or some other type of documentation in the aftermath of a foodborne disease outbreak event.		
If so, is the content and frequency specified?		

APPENDIX 1 | KEY TERMS

Note: The definitions given are valid as they are used in this Handbook, but different definitions may be used in other contexts. Many of the definitions used in the glossary are the same as those in Appendix 1 of the CIFOR Guidelines for Foodborne Disease Outbreak Response.

Administrative/Judicial Process: The rights of a person or business to reasonable opportunity to be informed about, comment on, and challenge a government's action.

Adulterated: A legal term meaning failure of a food product to meet federal or state standards. Adulteration usually refers to noncompliance with health or safety standards as determined in the United States by the Food and Drug Administration (FDA) and the U.S. Department of Agriculture (USDA).

After-action Report: A report prepared to analyze an organization's response to a specific event.

Case: A countable instance in the population or study group of a particular disease, health disorder, or condition under investigation.

Case Definition: Standardized criteria used to decide whether a person with a particular disease or health-related condition should be included as a case in an outbreak investigation. The case definition specifies clinical criteria and limitations on time, place, and person.

Cluster: An unusual aggregation of cases grouped in time or space. The term is commonly used in pathogen-specific surveillance, when multiple persons with infections caused by similar microbial strains are identified by a public health laboratory. The purpose of identifying a cluster is to trigger further investigations to determine whether cases are epidemiologically linked and therefore may represent an outbreak. The number of cases needed to form a cluster cannot be absolutely defined; cluster definition can vary by type of agent, novelty of the subtype, season, and resources available for further investigation.

Contributing Factor: A food safety practice or behavior that most likely contributed to a foodborne disease outbreak.

Documentation: Written materials that create an official record.

Embargo: An order issued by a permit-issuing official or his/her designated representative at a state or local agency that prevents food from being used, sold, donated, discarded, repackaged, or otherwise disposed of until the order is lifted by the permit-issuing official, his/her designated representative, or court of competent jurisdiction.

Enteric Illness: Illness of the intestinal track caused by food or waterborne bacteria, viruses, parasites, or chemicals that enter the body through ingestion.

Exclusion: Preventing a food worker who is sick or suspected of being sick from handling food or from attending work at a food establishment.

Food Code: A reference guide published by FDA. The guide instructs retail outlets, such as restaurants and grocery stores, and institutions, such as nursing homes, how to prevent foodborne disease. It consists of a model code adopted to varying degrees by nearly 3,000 state, local, and tribal jurisdictions as the legal basis for their food inspection program for safeguarding public health. It ensures that food is safe and unadulterated (free from impurities) and honestly presented to the consumer. It also provides references and public health reasons and explanations for code provisions, guidelines, and sample forms. FDA first published the Food Code in 1993 and revises it every 4 years.

Food Establishment: An operation that (1) receives, stores, prepares, packages, serves, or vends food directly to the consumer, or otherwise provides food for human consumption, such as a restaurant; satellite or catered food location; catering operation if the operation provides food directly to a consumer or to a conveyance used to transport people; market; vending location; institution or food bank; and (2) relinquishes possession of food directly, or indirectly through a delivery service such, as home delivery of grocery orders or restaurant takeout orders, or delivery service that is provided by common carriers.

Food Safety: The procedures ensuring that growing, processing, manufacturing, transporting, storing, preparing, and serving food that is fit for human consumption. Food safety procedures include voluntary measures and regulatory directives from government agencies and surveillance for foodborne disease outbreaks and response activities.

Food Safety Regulatory Agency: Government agencies at the local, state, or federal level that are granted regulatory oversight of some aspect of the food industry. The goal of food-regulatory agencies is to ensure the public's food supply is safe from pathogenic microbes, chemicals or other hazardous substances.

Foodborne Disease: Any disease caused by ingestion of contaminated food. Although some agents are more likely than others to be transmitted by food, identification of foodborne, waterborne, person-to-person, or animal-to-person transmission requires investigation. Furthermore, multiple modes of transmission may be involved in any single outbreak.

Foodborne Disease Surveillance: Surveillance of diseases or conditions that might be foodborne. Thus, all diseases of enteric origin may be tracked by this mechanism, including norovirus infection (which involves substantial person-to-person transmission), listeriosis (which may have a diarrheal stage but generally is detected by blood culture), or botulism (which presents as neurologic disease).

Imminent Hazard: An important threat or danger to health that exists when evidence is sufficient to show that a product, practice, circumstance, or event creates a situation that requires immediate correction or cessation of operation to prevent injury based on (1) the number of potential injuries and (2) the nature, severity, and duration of the anticipated injury.

Impound: To take possession of or to seize and hold in the custody of the law.

Interjurisdictional: Activities between two or more different levels of government (e.g., federal, state, local, tribal) or between two or more governments (e.g., state to state; state to tribal).

Isolate: The pure strain of a virus or bacterium that is separated from a sample.

Isolation: Process in which a person or animal that is known to be ill from a contagious disease is kept away from others.

Jurisdiction: A government entity with the legal authority to interpret and apply the law. Also refers to the limits or territory within which that authority may be exercised.

Legal Authority: Statutes, regulations, ordinances, orders, or policies that authorize or prohibit governments or other specified actors to engage in the actions identified.

Multijurisdictional: Requiring the resources of more than one local, state, territorial, tribal, or federal public health or food regulatory agency to detect, investigate, or control. A multijurisdictional investigation may involve a foodborne disease outbreak or the distribution or recall of a contaminated food product.

Outbreak: Two or more cases of a similar illness shown by an investigation to result from a common exposure, such as ingestion of a common food. An outbreak is a cluster with a clear association among cases, with or without a recognized common source or known disease agent. Single cases of certain rare and serious conditions, such as gastrointestinal anthrax, botulism, or cholera, elicit an outbreak-like response.

Quarantine: Process in which a person, animal, food product, or building that may have been exposed to a contagious disease agent is kept apart from others to prevent disease spread.

Recall: A voluntary or mandatory action of removing a product from retail or distribution. The action is conducted by a manufacturer or distributor to protect the public from products that may cause health problems or possible death.

Regulations: Rules developed by executive branch agencies. Executive branch agencies are authorized by the legislative branch (e.g., Congress, state legislatures) to develop regulations to implement the laws and statutes passed by the legislative body. Regulations are developed by local, state, and federal agencies and international bodies (e.g., World Health Organization).

Reportable Conditions (Notifiable Diseases): The list of diseases based on state laws or regulations that health-care providers (e.g., physicians and their medical staff, laboratories, and hospitals) should report to local or state health agencies. The list of notifiable diseases and legal obligation for reporting differs from state to state. States can report notifiable diseases to CDC, which maintains a list of nationally notifiable diseases, but compliance is voluntary. CDC reports selected diseases to the World Health Organization in compliance with International Health Regulations.

Statutes: Written laws passed by a local, state, or federal legislative body. Statutes are contrasted with regulations (which are made by executive branch agencies) and case law (which are decisions made by judges in civil and criminal cases).

Surveillance: The systematic collection, analysis, interpretation, and dissemination of data for public health action.

Syndromic Surveillance: The process of using individual and population health indicators that are available before confirmed diagnoses or laboratory confirmation to identify outbreaks or health events and monitor the health status of a community.

Zoonoses: Diseases or conditions that can be passed from animals to humans.

APPENDIX 2 | RESEARCHING LEGAL AUTHORITIES FOR FOODBORNE DISEASE DETECTION AND OUTBREAK RESPONSE

Researching Legal Authorities

State legal authorities to conduct foodborne disease surveillance and outbreak response activities are distributed across a number of statutes and regulations; it is not possible to review just one title or chapter in a statute or regulation to effectively capture the authorities used by states to conduct their foodborne disease-related activities.

To fully understand the types of authorities used by states, the following issues should be considered and researched:

- General state and local government authorities to protect public health.
- Government authorities granted to state and local agencies or agency officials (health, agriculture, environment, animal health, and others as indicated by the state).
- Foodborne disease surveillance, investigation, control, and reporting.
- Communicable disease case reporting, investigation, and postinvestigation reporting.
- Animal communicable disease case reporting, investigation, and postinvestigation reporting.
- Food and food safety authorities regarding food items and food establishments.
- Public records and confidentiality.
- Interjurisdictional cooperation and agreements.

In addition to the foundational issues listed above, other relevant and important legal authorities exist that address the conduct of foodborne disease outbreak and response activities and of ongoing food safety regulation, education, and training activities. Depending on the nature of the outbreak (e.g., intentional, waterborne), the food involved (dairy, poultry, grain), and the source or site of the contamination (e.g., farm, processing plant), the following issues also might be relevant:

- Ongoing licensing and routine inspection requirements for food operations and food establishments (e.g., licensing and inspection of retail food establishments).
- Ongoing education and training requirements (e.g., food manager certification).
- General government or agency emergency powers and authorities (i.e., powers that become effective upon a gubernatorial or presidential declaration of emergency).
- Civil and criminal penalties for violating statutes and regulations discussed in the document.
- Drinking water, waterborne diseases, and source water protection.
- Commodity or food product-specific statutes and regulations (e.g., eggs, dairy products, grains, meat, poultry).
- Specific animal disease identification and control programs (e.g., brucellosis, scrapie).
- Plant diseases.
- Pesticides and other chemical contaminants to food.
- Fish consumption advisories.

Research Strategies

Index and Contents Review of Statutes and Regulations

Once the appropriate statutes or regulations have been identified, a table of contents/index and contents review of the statutory and regulatory materials will help to further identify the controlling and relevant authorities. The general statutory and regulatory titles reviewed can include

- Public health and/or health
- Agriculture
- Environment
- Animal health
- Organization of state and local governments
- Public records and privacy
- Regulation of businesses
- Interstate/interjurisdictional compacts and agreements

Key Term Searches

In addition to the index and contents review, searches can be conducted for specific terms to confirm that all relevant authorities had been identified through the contents review and to identify relevant authorities outside of the primary statutory and regulatory titles reviewed. The following search terms, and their variants, can be used

- Cluster
- Communicable
- Condemn
- Contagious
- Embargo
- Epidemiology, epidemiologist
- Foodborne
- Food safety
- Interagency, interjurisdictional, interstate
- Isolates
- Laboratory
- Morbidity, mortality
- Notifiable
- Outbreak
- Privacy
- Public records, freedom of information
- Quarantine, isolation
- Recall
- Reportable
- Sentinel
- Specimens
- Surveillance
- Syndromic
- Zoonosis