CHAPTER

2

Legal Preparedness for the Surveillance, Investigation, and Control of Foodborne Illness Outbreaks

CHAPTER SUMMARY POINTS

- The authority to identify, investigate, and control foodborne illness outbreaks is shared across local, state, and federal, governments and requires ongoing cooperation. Legal preparedness is the assurance that agencies and jurisdictions are equipped with sufficient legal authorities to conduct effective disease surveillance and control and have staff trained to use these authorities.
- Local and state statutes and regulations authorize the reporting and investigation of foodborne illnesses. The communicable disease control regulatory process is often used to specify diseases and conditions to be reported, the information to be reported, and the process for making a report. State laws and regulations also address the confidentiality of disease reports and enforcement of reporting requirements.
- Local and state agencies need to regularly access confidential records when investigating reports of foodborne illness. They must navigate differing local, state, and federal legal authorities and requirements as they seek to access and share information with other government agencies and respond to media inquiries.
- Shared goals of the public and private sectors are to prevent as many outbreaks as possible and to mitigate those that occur. In the public sector, local, state, and federal agencies accomplish those goals by working independently and together to exercise their legal authorities to, among other things, inspect, seize or destroy foods, and close establishments.
- Although reporting, surveillance, and mitigation of foodborne illness outbreaks are well established in local, state, and federal law, issues continue to arise that demonstrate differences among state and federal laws and the need for ongoing communication and collaboration among state, local, and federal officials who are united in the common goal of protecting the public's health.
- During foodborne illness investigations, public officials may find issues that require the initiation of administrative actions or even civil or criminal proceedings. Data collected during a foodborne illness investigation can become the basis for further action by local, state, and federal agencies.

URLs and email addresses in this chapter are valid as of July 3, 2019.

2.0 Introduction

2.0.1 Understanding and appropriately using law is a fundamental part of protecting the public's health from foodborne illness. Local, state, and federal government agencies share the authority to identify, investigate, and control foodborne illness outbreaks, but each level of government and each agency within it has specific roles, responsibilities, and legal authorities. The success of a public agency's efforts to combat foodborne illness also greatly depends on its cooperation and communication with multiple parties in the food, agriculture, healthcare, and laboratory sectors. Ultimately, the goal is to become more effective at protecting public health and preventing disease by leveraging legal authorities across local, state, and federal jurisdictions.

2.0.2 This chapter addresses legal preparedness in the various aspects of foodborne illness outbreak surveillance and control—reporting, surveillance, investigation, mitigation, and prevention—through the perspective of local, state, and federal agencies. It also discusses critical issues that arise during outbreak investigations, such as confidentiality of data and use of public health investigations as the basis for regulatory actions or criminal prosecutions.

2.1 Public Health Legal Preparedness

Legal preparedness is an indispensable part of a comprehensive preparedness plan for public health threats. The Centers for Disease Control and Prevention (CDC) defines public health legal preparedness as the attainment by a public health agency or system of specified legal benchmarks or standards of preparedness for specified public health concerns (*1*). Public health legal preparedness has four core elements:

- Laws and legal authorities;
- Competency in understanding and using law;
- Coordination across sectors and jurisdictions in the implementation of law; and
- Information about best practices in using law for public health purposes.

These core elements apply to all areas of public health, especially in the areas of food safety and foodborne illness outbreaks. Because the U.S. food system is highly complex, public health, food, and agriculture officials responding to foodborne illness outbreaks face the challenge of rapidly gathering and processing information to identify and mitigate the source of an outbreak while protecting confidentiality and preserving rights.

2.1.1 Legal preparedness within the context of surveillance, investigation, and control of foodborne illness outbreaks requires state and local officials to ensure their agencies and jurisdictions have the following:

- Laws and legal authorities needed to conduct all functions essential to effective surveillance, investigation, and control (e.g., reporting, enforcement, prevention, mitigation, investigation, and regulation).
- Trained professional staff with demonstrated competency in applying relevant laws.
- Mutual aid agreements or memoranda of understanding in place to facilitate investigation and response across jurisdictions and agencies.
- Access to information about model practices in using relevant legal authorities and applying them.

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Box 2.1. Partnering with Your Agency's Attorney *(2)*

To prepare for an outbreak:

- Meet with your agency's attorney to discuss specific legal authority and responsibilities contained in local, state, and federal law relative to disease reporting, investigations, and food-regulatory actions (e.g., permit suspension and closure, employee restrictions).
- Identify outbreak settings or conditions for which legal assistance might be needed.

Outbreak settings or conditions for which legal assistance might be needed:

- There is a reasonable chance the public's health is or might be threatened without specific public health intervention.
- Your ability and authority to address the situation is unclear.
- The event or circumstance could expose your agency or organization to potential liability, or political pressure.

In an outbreak situation in which you might need legal assistance:

- Contact your agency's attorney as soon as possible for legal input.
- Be candid and open; give all the facts—don't allow for surprises.
- Proactively include your agency's attorney in discussions rather than seeking ratification of decisions later.

If you do not understand or you disagree with the advice provided by your agency's attorney, ask for clarification or discuss other options with him or her rather than requesting different advice from another attorney.

The adequacy of local and state legal preparedness for foodborne illness outbreaks also should be evaluated regularly through exercises and after-action reviews from actual outbreaks.

As part of ensuring their jurisdictions' legal preparedness, local and state officials should consult with their legal counsel (Box 2.1) and with counterparts in other government agencies that have authority relevant to ensuring successful surveillance and control of foodborne illness outbreaks. These include food and agriculture regulatory and law enforcement agencies, legal counsel to local and state governments, and local and state courts and court administrators.

Private organizations also must be aware of their legal duties regarding food safety and disease reporting). These duties vary by state. Relevant private entities include private laboratories, food firms, hospitals, and other health institution food services. Food-industry entities should be prepared to address both regulatory requirements and the way these requirements might affect their internal policies on sharing information (*3*). Where possible, both public and private entities should be included in foodborne illness exercises to test their understanding of their legal authority and duties related to outbreaks.

2.1.2 As government entities, public health, food, and agriculture agencies operate within the context of the U.S. Constitution, state constitutions, federal and state statutes and regulations, local charters and ordinances, court decisions, and more. Thus, these agencies are empowered and limited within this context and must navigate the country's foundational legal principles, i.e.,

- **A system of checks and balances.** Public health, food, and agriculture agencies belong to the Executive Branch and are broadly charged with implementing laws enacted by the legislature and interpreted by the courts.
- **Federalism.** The U.S. Constitution enumerates specified powers for the federal

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government and reserves other powers to the states (tribes are autonomous or sovereign bodies). In addition, state and local governments possess inherent police powers to protect the health and safety of the public.

- **Protection for civil liberties and property rights.** The Fourth, Fifth, and Fourteenth Amendments protect citizens from unreasonable searches and from deprivation of life, liberty, and private property without due process of law. State constitutions, statutory law, and court rulings provide additional protections relevant to the conduct of foodborne illness surveillance and operations by public agencies.

2.1.3 The legal authority supporting local and state public health agencies' role in the protection and promotion of the public's health stems from constitutional, statutory, regulatory, and judicial case law, as well as from the general police powers. However, these powers are not unlimited. Important legal parameters for public health authority and practice were articulated in the foundational 1905 U.S. Supreme Court ruling in *Jacobson v. Massachusetts* (*4*):

- With compelling reason, individual liberties can be subordinated to the well-being of the community.
- The police power of the state authorizes issuance and enforcement of reasonable regulations to protect the health of the community.
- Courts defer to the authority that legislative bodies give to public health agencies if that authority is exercised on the basis of persuasive public health and medical evidence.
- Public health agencies cannot act in an arbitrary manner or pose unreasonable risks for harm.

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

2.1.4 CDC operates under congressionally enacted statutory law and, especially in the case of foodborne illness surveillance, under provisions of the Public Health Service Act (*5*). CDC is not authorized to mandate reporting of diseases and conditions by state and local governments or by private entities. However, states do mandate reporting pursuant to state laws.

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

The Public Health Service Act also authorizes CDC to perform laboratory tests on specimens received from state and local governments (and from other sources) to identify pathogens, confirm serotypes or molecular subtypes,

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perform diagnostic assays, and report findings to appropriate state and local health departments. Virtually all enteric illness specimens tested in CDC laboratories are initially tested in state or local public health laboratories.

Additionally, CDC may participate in an outbreak investigation within a state if invited by the state. Multistate investigations are typically led by CDC or the state health department where most of the cases occurred.

2.2 Legal Framework for Surveillance and Disease Reporting

Investigation of enteric illnesses to determine the source of exposure, risk factors for infection, and contacts of a person with a contagious disease is usually considered part of surveillance and disease control activities authorized by local and state statutes. Likewise, state and local authority to mandate disease reports arises from state law. The regulatory process is used to specify diseases and conditions to be reported, the information to be reported about a case, and the process for making a report. State laws and regulations also address the confidentiality of disease reports and enforcement of reporting requirements (Box 2.2).

Box 2.2. Communication with Laboratories and Hospitals

Ongoing communication arrangements should be established with national or regional commercial and clinical laboratories to ensure that the investigating agencies receive results for relevant cases, even when those tests are conducted out of state. Similar communication channels also should be established with in-state and out-of-state hospitals that serve a population within the community affected by the outbreak.

2.2.1 Local and state health agencies learn about foodborne illnesses through a variety of sources that vary in reliability and traceability. As discussed further in Chapter 4, these include

- Reports through the state's mandatory disease and conditions reporting system;
- Surveillance reports for enteric pathogens;
- Requests for antitoxin for botulism;
- Reports of food poisoning or gastrointestinal illness in individuals or defined groups, such as diarrhea and vomiting among residents of a nursing home or hospital, attendees at schools or childcare centers, or attendees at a work-related meeting;
- Reports to poison control centers;
- Reports of enteric illness suspected of being caused intentionally;
- Complaints of suspected foodborne illness or alleged exposure to contaminated, adulterated, or improperly cooked food purchased from stores or in restaurants and reported voluntarily by the public;
- Syndromic surveillance using de-identified emergency department or pharmacy data; and
- Reports directly from the food industry of consumer complaints of illness.

2.2.2 The state legislature generally gives broad statutory authority to the state health department to collect information and to require reports of diseases, conditions, and outbreaks of public health importance. Generally, the state legislature also gives the state health department the authority to adopt rules or regulations that specify which diseases or conditions must be reported, who must report them, and how to report (Table 2.1).

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The list of reportable diseases and conditions and laboratory findings is maintained and updated by epidemiologists and health officers in state and local agencies, with review and approval by the body overseeing the health department.

In addition to broad authority, states typically have several disease-specific statutes, such as those for human immunodeficiency virus/acquired immunodeficiency syndrome, tuberculosis, and vaccine-preventable diseases, which authorize surveillance and control activities. All states also have statutes addressing reporting and response to bioterrorism incidents.

Table 2.1. Reporting Processes Typically Specified by Statutes and Regulations

PROCESS	REQUIREMENT	COMMENT

Sources of reports	The usual sources of mandatory reports are
	• Laboratories
	  ○ Hospital-based laboratories;
	  ○ Clinical laboratories;
	  ○ National or regional commercial referral laboratories;
	  ○ Local or state health department laboratories; and
	  ○ CDC laboratories;
	• Health care institutions
	  ○ Hospitals (e.g., hospitalized patients reported by infection control practitioners);
	  ○ Emergency departments; and
	  ○ Long-term–care facilities or nursing homes;
	• Physicians;
	• Schools and childcare centers;
	• Food establishments (e.g., restaurants); and Other state health departments.
		The source of a report does not affect the legal status of the information; if it is required information, it is protected by statutes and regulations.
		
		Conversely, reports to the agency of an illness not listed as a reportable condition might not be subject to disease surveillance regulations and confidentiality protections.

Time frame and content of reports	Statutes and regulations usually specify the following aspects of disease reports: • Time frame for reporting (e.g., within 7 days after diagnosis, within 24 hours after diagnosis, immediately); and • Information to be reported (e.g., diagnosis; personal identifying and locating information; date of onset or diagnosis regardless of whether the case is suspected or confirmed).	
Reporting methods	A state or municipality can use a variety of methods for reporting. Specifics vary from one locale to another. These methods include • Internet-based, highly secure disease reporting to websites maintained by state or local public health agencies; • Reports sent by email; • Automatic electronic submission through health information exchange; • Telephone; and/or • Hard copy (fax or mail).	

2.2 Legal Framework for Surveillance and Disease Reporting

Table 2.1. Reporting Processes Typically Specified by Statutes and Regulations *Continued*

PROCESS	REQUIREMENT	COMMENT
Required submission of laboratory specimens	Many public health agencies have adopted regulations that require laboratories to submit isolates of specific pathogens to a state or local health department laboratory for further confirmatory and/or genomic testing, such as pulsed-field gel electrophoresis and/or whole-genome sequencing, to improve surveillance for foodborne disease (see also 6).When the clinical laboratory does not obtain isolates, some states require or request submission of primary clinical material or enrichment broths. The regulations often include a time frame for submission of such materials. With the increasing development and use in clinical settings of culture-independent diagnostic tests (CIDT), which do not produce an isolate, there is growing concern that the supply of isolates to health departments will be depleted, hindering public health surveillance activities. To address these concerns, states have begun to amend their laws. A few states have added language that gives specific submission instructions to a clinical laboratory that has used CIDT methods to make a diagnosis. Other states have expanded their list of acceptable materials for submission beyond only an "isolate" to include "specimen," "primary clinical material," "enrichment broths," and other alternative materials to submit if the preferred isolate is not available. States may continue to amend their disease reporting laws, in various ways to fit the needs of the jurisdiction, as CIDT continues to develop for a broader number of pathogens.	In some locales, voluntary submission of specimens achieves the same goal.

2.2.3 Reliable reporting by persons and institutions mandated to submit disease reports is the foundation of the reporting system. When enteric illnesses are not reported, a foodborne illness outbreak may be missed. Because of the problem of nonreporting, redundant reporting systems have been established to ensure a case will be reported (e.g., a *Salmonella* infection might be separately reported by physicians, laboratories, and healthcare institutions). Because health agencies want to encourage compliance, ongoing education and communication with persons and institutions mandated to report is imperative to reinforce the importance of reporting requirements.

Education is the preferred method to obtain reporting compliance, but when violations arise, statutes and regulations mandating disease reporting also contain enforcement and penalty provisions. Depending on the jurisdiction and the frequency and severity of nonreporting, sanctions can range from notification to a state licensure board to civil fines and/or criminal penalties.

Reporting may be difficult to enforce with a laboratory or healthcare provider outside an agency's jurisdiction, such as when a state seeks reports from a reference laboratory located in another state. In that situation, lack of reporting usually results from misunderstanding of how to report. Occasionally a laboratory will assert that it complies with requirements of the public health agency in the state in which it is physically located—which might or might not require reporting of the specific disease, infection, or laboratory result. Again, ongoing communication with the parties required to report and coordination with the state health agency in the parties' home state can improve reporting.

2.3 Protection of Confidentiality and Authority to Access Records

State and local health agencies need to regularly access confidential records when investigating reports of foodborne illness. However, when doing so, federal and state laws mandate the protection of confidential personal information during these public health investigations.

Typically, the broad authority to conduct surveillance includes authority to investigate and control diseases of public health significance, including review of relevant and pertinent medical and laboratory records and reports (i.e., information that is not necessarily included in the basic case report). Although medical and laboratory staff might be concerned about potential violations of federal Health Insurance Portability and Accountability Act (HIPAA) (*7*) and state privacy laws in releasing records, exceptions for public health and other government agencies allow access to records. Consulting with an agency attorney is advisable whenever questions or concerns arise about accessing or disclosing confidential information (Box 2.3).

Box 2.3. Prepare for Questions about Authority to Access Information

Staff in an organization that might be required to provide information to local, state, and federal officials about foodborne illnesses and outbreaks might not be familiar with the authority of government officials to access individually identifying and other privacy-restricted information under certain provisions of state and/or federal law.

These organizations might include those (e.g., childcare, elder care) that, depending on state law, might not have routine interaction with disease reporting and outbreak investigation systems.

Consult with your agency's attorney to prepare memorandum or information sheets tailored to different types of organizations that specify state and federal authority to access information.

2.3.1 HIPAA and its associated regulations limit access to a person's protected health information (PHI) (*7, 8*). PHI is information that can be used to individually identify a person through demographic data, diagnosis, treatment, or payment for treatment (*9*).

Important exceptions to HIPAA allow public health and other government agencies to access PHI, including

- **Required by Law.** Entities covered by HIPAA (e.g., doctors, healthcare plans) may use and disclose PHI without individual authorization if required by law (e.g., statute, regulation, or court order).
- **Public Health Activities.** Covered entities may disclose PHI under several circumstances related to public health activities, including
  - Public health authorities authorized by law to collect or receive information for preventing or controlling disease, injury, or disability;
  - Persons who might have been exposed to or contracted a communicable disease when notification is authorized by law; or
  - Entities subject to Food and Drug Administration (FDA) regulation for purposes such as tracking products or product recalls.

These exceptions in effect authorize a covered entity (e.g., doctor) to disclose otherwise confidential PHI. Explaining these exceptions to physicians or their staff often results in better compliance with reporting requirements. HIPAA does not restrict the use of de-identified information, which does not identify a person or provide a basis for identification (*10*).

2.3 Protection of Confidentiality and Authority to Access Records

2.3.2 Local and state health agency staff must know the requirements of their freedom of information laws and the exemptions from them. Personal identifying information (PII) (e.g., name, age, sex, race, ethnicity, residence, or date of diagnosis) in disease reports and investigation records is generally confidential and exempt from disclosure in response to freedom of information requests. Each state can define what it considers to be PII. The goal is to avoid releasing data that make it possible to directly or indirectly identify the affected person if the released data are combined with other information. When there are a large number of cases, it might be possible to release data *other than names and residences* in response to freedom of information requests. When there are too few cases among the population of a given area, an agency might have a policy of not releasing data to guard against potential identification of an individual person. This determination should be made in each instance in conjunction with agency epidemiologists, statisticians, and attorneys.

In addition to potential restrictions on sharing PII, state laws might restrict sharing of other types of information, such as confidential commercial information and predecisional/deliberative information. Furthermore, the federal Privacy Act can restrict the sharing of certain personal privacy information (PPI) by federal agencies (*11*).

Occasionally a public health agency must respond to a media inquiry in which the media have learned the identity of a particular case from another source. The agency's response to the media inquiry must be carefully structured to avoid unintentional confirmation of the patient's identity. Preparing final outbreak investigation summary reports without any PII can hasten and simplify release of those reports to attorneys or media.

2.3.3 A public health agency may be restricted from sharing PPI with other government agencies without the consent of the reported person. However, these restrictions are subject to several exceptions:

- Local and state health agencies are generally permitted to share information with other state, local, and federal agencies to confirm and track cases.
- Many state statutes contain an exception for sharing information when, in the agency's judgment, sharing is necessary to protect public health.
- Virtually every state has an exception for sharing information with law enforcement agencies for investigation of intentional contamination or a bioterrorism incident.

2.3.4 The U.S. Department of Health and Human Services (DHHS), FDA, has formalized arrangements for information sharing with local and state regulatory agencies. FDA provides nonpublic information to state and local agencies under 20.88 agreements (*12*) and to certain state and local officials who have been commissioned by FDA (Box 2.4).

- 20.88 agreements are authorized under 21 CFR 20.88. 20.88 agreements allow FDA to share certain nonpublic information with state and local government officials. These agreements allow for the sharing of confidential commercial information, PPI, and predecisional information (PDI), and predeliberative information but not trade secret information. The receiving agency must commit to keep this information confidential (*12,13*). FDA offers several types of 20.88 agreements:
  - Single-Signature Long-Term Information Sharing Agreements (Food and Feed, Pharmacy Compounding, Drug Security) (Long-Term 20.88) allows for the sharing of nonpublic information proactively or

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on request related to food, animal food, cosmetics, pharmacy compounding, drug security with all employees who report to the signatory.

- Case-Specific 20.88 allows for the sharing of nonpublic information related to a particular incident involving an FDA-related industry (e.g., food, drugs, devises, biologics). A Case-Specific 20.88 can be expedited if FDA is made aware of the need for urgent processing. Each employee who will need access to the information must sign.
- 20.88 with Associations allows for proactive or upon request sharing of nonpublic deliberative processes and predecisional information only. Examples may include draft rules and/or draft guidance.

- **Commissioning.** FDA's commissioning process enables a state or local health, food, or drug official to be commissioned as an officer of DHHS (*14*). Commissioned officials may receive nonpublic information solely for the purpose of their work on behalf of FDA as a commissioned official. They may generally disclose that information to other FDA-commissioned officials (in their capacity as FDA commissioned officials) and FDA employees (*15*). Such information remains FDA information. Commissioning also authorizes state or local officials to conduct inspections under the Federal Food, Drug, and Cosmetic Act (FFDCA) (*16*).

2.3.5 The U.S. Department of Agriculture (USDA) Food Safety and Inspection Service (FSIS) has a process for sharing information with government partners. FSIS Directive 2620.5 addresses "procedures needed to share information concerning FSIS regulated products with State or local agencies, foreign government officials, and international organizations responsible for food inspection programs and laboratories" (*17*). To request outbreak-related information from FSIS, send an email to FoodborneDiseaseReports@usda.gov.

Box 2.4. Cross-Jurisdiction and Cross-Sector Coordination

Effective reporting of foodborne illness cases hinges on coordinated reporting across jurisdictions (e.g., local, state, tribal, and federal governments) and across sectors (e.g., healthcare and public health). Local and state health officials should periodically assess the need for memoranda of agreement (or other legal agreements) with partners in other jurisdictions and sectors to ensure timely and effective reporting. CDC has created several resources for assessing and improving cross-jurisdictional and cross-sector coordination *(18,19)*.

2.4 Legal Framework to Prevent or Mitigate Foodborne Illness Outbreaks

Shared goals of the public and private sectors are to prevent as many outbreaks as possible and to mitigate those that do occur. Changes in technology and food production have brought opportunities and challenges. Improvements in laboratory and communication technologies have enabled agencies to link cases that previously were thought to be sporadic and to identify and address implicated foods and sources. However, with continued globalization of food-production industries, more multistate and international foodborne illness outbreaks are being discovered, thus expanding the focus of outbreak investigations and control

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measures. This section reviews the roles of local, state, and federal, agencies and the legal authorities empowering them to act.

2.4.1 U.S. law authorizes several federal agencies to undertake regulatory and nonregulatory actions over food safety at various stages on the continuum of food production, importation, processing, transportation, storage, and sale. Agencies regulating food have the authority to inspect, recall, and seize unsafe foods. All agencies coordinate and collaborate with states and localities in the prevention of foodborne illness and in multistate investigations. This section focuses on CDC, FDA, USDA, and the Environmental Protection Agency (EPA) and their legal authority related to food safety (see Chapter 3 for each federal agency's roles and resources).

- **DHHS, CDC**
  The Public Health Service Act (*5*) authorizes CDC to identify and monitor foodborne diseases and to investigate foodborne illness outbreaks in coordination with local and state health agencies. CDC can lead investigations into multistate foodborne illness outbreaks and, when invited, work in partnership with the state where the most cases have occurred.

- **DHHS, FDA**
  The FFDCA (*16*) authorizes FDA to regulate domestic and imported food, except meat, poultry, and processed egg products (i.e., frozen, dried, and liquid eggs), which are regulated by USDA.

  - **FFDCA**
    The primary legislation by which FDA exercises authority over food is the FFDCA. A goal of FDA is to prevent contamination of food products before distribution. FFDCA also empowers FDA to pursue:

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

In some circumstances, FDA's authority under the FFDCA is limited by the requirement that food be in interstate commerce. However, under both the FFDCA and the Public Health Service Act, FDA can regulate intrastate commerce in certain instances. Even when authority exists for FDA action, relying on state agency action might be faster when state authorities are more expansive or flexible than FDA's authorities.

Amendments to the FFDCA in 2007 require registered food facilities that manufacture, process, pack, or hold food for human or animal consumption in the United States to report to FDA's Reportable Food Registry when a reasonable probability exists that the use of, or exposure to, an item of food will cause serious adverse health consequences or death to humans or animals (*20*). FFDCA was further amended in 2011 by the Food Safety Modernization Act (*21*).

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- **FDA Food Safety Modernization Act**
  The FDA Food Safety Modernization Act (FSMA), signed into law in January 2011, amended the FFDCA to enhance the federal government's ability to prevent and respond to contamination in the food supply (*21*). The law addresses prevention, inspection, compliance, and response activities.

  FDA, the agency primarily responsible for implementing FSMA, has developed a series of rules and guidance documents to address the law's requirements. As of April 2018, FDA has finalized the following rules:

  - Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food (*22,23*).
  - Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals (*24,25*).
  - Foreign Supplier Verification Programs (*26,27*).
  - Mitigation Strategies to Protect Food Against Intentional Adulteration (*28,29*).
  - Sanitary Transportation of Human and Animal Food (*30,31*).
  - Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption (*32,33*).
  - Accredited Third-Party Certification (*34,35*).

  FDA has also implemented a Voluntary Qualified Importer Program (*36*). It is a fee-based, voluntary program that provides importers meeting specified criteria with expedited review and import entry of human and animal foods. In addition to rules, FDA has issued multiple guidance documents regarding implementation of FSMA and its rules. The FDA website (https://www.fda.gov/Food/GuidanceRegulation/FSMA/default.htm) provides details about the law, rules and updates on the status of FSMA implementation.

- **FDA Food Code**
  Although the FDA Food Code is not a federal law or regulation, this model code may be adopted or adapted by states, tribes, and localities as the basis for their jurisdictions' food-safety rules for retail and food-service establishments (e.g., restaurants, grocery stores, institutions) (*37*). The Food Code assists jurisdictions in updating their rules to be consistent with federal food-safety policy, although each jurisdiction undergoes its own rulemaking process to adapt the code to fit the jurisdiction's legal framework. Currently, FDA revises the Food Code every 4 years.

- **USDA, FSIS**
  USDA-FSIS has the legal authority to regulate meat, poultry, and egg products on the basis of the following statutes:

  - Federal Meat Inspection Act (*38*).
  - Poultry Products Inspection Act (*39*).
  - Egg Products Inspection Act (*40*).

  Each of these Acts is intended to protect the health and welfare of the consuming public by preventing the introduction of adulterated or misbranded meat, poultry, or egg products in interstate commerce. In addition, in states that do not have meat or poultry inspection programs "at least equal to" the federal programs, Federal Meat Inspection Act and Poultry Products Inspection Act provide for federal regulation and inspection of wholly intrastate operations and transactions to the same extent as if such operations and transactions were conducted in interstate or foreign commerce.

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In carrying out its duties under these Acts, USDA-FSIS may pursue the following actions:

- Regulatory action for federally inspected facilities, such as retention of product, withholding actions, and notices of intended enforcement, suspension, or withdrawal;
- Civil action, such as an injunction to prevent future violations of the Acts (e.g., continued distribution of adulterated or misbranded products);
- Detention and seizure action to remove specific products from commerce;
- Criminal action against an individual or company that violates the Acts; or
- Voluntary compliance through notices of warning.

Specifically, in response to a foodborne illness outbreak, if a basis exists to conclude that a USDA-FSIS-regulated product contains a pathogen or is otherwise harmful to human health, and an outbreak investigation has identified a specific product, USDA-FSIS may recommend a product recall (*41*). A recall is a firm's action to remove a product from commerce to protect the public from consuming misbranded or adulterated products. Although it is a firm's decision to recall a product, USDA-FSIS coordinates with the firm to ensure it has properly identified and removed the recalled product from commerce by verifying the effectiveness of the firm's recall activities. USDA-FSIS also notifies the public about product recalls.

Alternatively, if after review of investigative findings, a basis exists for USDA-FSIS to conclude that a USDA-FSIS-regulated product contains a pathogen or is otherwise harmful to human health, but the investigation has not identified a product that can be recalled (e.g., no specific brand name of product identified), then USDA-FSIS may issue a public health alert (*41*).

Further, depending on the evidence collected, and how strongly human illness is linked to a USDA-FSIS-regulated product, USDA-FSIS may take actions other than recommending a product recall or issuing public health alert. These actions may include increasing or enhancing inspection activities; increasing the frequency of microbial testing; conducting a Public Health Risk Evaluation; performing an in-plant Food Safety Assessment; or taking any of the actions listed above, such as effecting a regulatory control action or detaining and/or seizing product (*41*).

- **USDA, Animal and Plant Inspection Service (APHIS)**
  USDA-APHIS is charged with protecting animal and plant resources from agriculture pests and diseases, including those that impact public health. USDA-APHIS operates under multiple statues, including
  - **Animal Health Protection Act.** This Act authorizes the prevention, detection, control, and elimination of diseases and pests in animals to protect animal health, public health and welfare, and economic and environmental concerns (*42*).
  - **Plant Protection Act.** This Act permits regulation to prevent the introduction or dissemination of plant pests in the United States, including certain biological control organisms (*43*).
- **EPA**
  EPA establishes the limits for pesticide residues in foods under the Food Quality Protection Act (*44*). EPA is also authorized to set standards for drinking water in the Safe Drinking Water Act (*45*).

2.4 Legal Framework to Prevent or Mitigate Foodborne Illness Outbreaks

2.4.2 State public health, agriculture, and food and drug agencies each play a role in mitigating and preventing outbreaks of foodborne illness. Each agency operates under one or more specific statutory and regulatory authorities. How these roles and authorities are structured and the assignment of responsibilities between the state and its localities vary by state. Local health departments in general operate under two frameworks: independent home rule and delegated authority.

State and/or local agencies are authorized to undertake a range of actions to mitigate and prevent outbreaks, including

- Requiring changes in food preparation;
- Temporarily removing persons with infectious illnesses from the workplace;
- Embargoing, seizing, or destroying contaminated food or requiring removal of contaminated lots from retail stores;
- Closing food establishments representing an imminent public health threat; and
- Issuing press releases

These actions are taken through agency authority granted by statute and implemented through rules or through administrative orders. In issuing an administrative order closing a restaurant, for example, such an order should contain time limits for the closure and specify the conditions that would permit the restaurant to reopen. If necessary, agencies can seek enforcement of their administrative orders through the court.

2.5 Evolving Legal Issues

Even though reporting, surveillance, and mitigation of foodborne disease outbreaks is well established in state and federal law, issues continue to arise that demonstrate differences in state and federal law. Such issues further demonstrate the ongoing need for communication and collaboration among local, state, and federal officials who are united in the common goal of protecting the public's health.

2.5.1 Food sovereignty initiatives are based on the idea that people should have the ability to democratically control their own food and agriculture policies. For some groups, the concept is tied to reducing poverty and providing healthy food through ecologically sound and sustainable metrics. These groups also focus on strategies to resist and dismantle corporate food production and increase local food production and control. For other groups, deregulation is the primary focus of food sovereignty laws.

For example, Maine enacted a law in October 2017 authorizing municipalities to "adopt ordinances regarding local food systems and community self-governance that set forth provisions that apply exclusively to direct producer-to-consumer food exchanges and other traditional foodways" (*46*). The provisions essentially remove state oversight from certain food-production areas. The state, however, retains authority to implement and enforce rules related to the inspection of meat and poultry producers. This version of the statute took effect after USDA questioned whether the original version of the law would have enabled Maine to maintain its "at least equal to" status and continue to operate its meat and poultry inspection programs. The law also requires that anyone who "grows,

2.5 Evolving Legal Issues

produces, processes or prepares food or food products intended for any wholesale distribution or retail distribution outside of" a municipality to comply with state and federal food-safety laws, rules, and regulations (*46*).

2.5.2 While acknowledging the differing positions of the federal government and many states on the legality of marijuana use for medical and nonmedical purposes, food-safety concerns exist that are related to the incorporation of marijuana, hemp derivatives, and cannabidiol in food (edibles). States are continuing to work on the application of food-safety laws to the producers of such edibles. Some states subject those who produce edibles to state food worker restrictions and/or to local and state kitchen-related health and safety standards used for retail food establishments.

2.5.3 Cottage food laws collectively refer to state laws and regulations that allow for the sale, with restrictions, of certain foods produced in private homes. The foods eligible for sale typically are considered safe from bacterial contamination and do not require time or temperature safety measures for production and/or storage (*47*). Examples include baked goods, candies, condiments, preserves, and dry mixes. Cottage food laws are viewed as promoting economic opportunities for home- and farm-based food businesses, while providing some regulatory safeguards of these businesses. As of June 2018, 49 states and the District of Columbia have some type of cottage food law; New Jersey did not have such a law (*48,49*).

Although cottage food laws vary among states, these laws generally address the types of foods permitted to be sold, who can sell, limits on sales, and labeling licensing, permitting and/or inspection requirements (*50*). In many states efforts are ongoing to expand the permitted foods or alter restrictions on sales. Any move to change existing cottage food laws, either by expanding them or adding limitations, should be done so with food safety and the public's health in mind.

2.6 Public Health Investigations as the Basis for Further Action

The goal of a foodborne illness outbreak investigation is to identify and control the source of the outbreak. In the course of the investigation, officials may find issues that require the initiation of regulatory or administrative actions or even civil or criminal proceedings.

2.6.1 Data collected during a public health investigation can become the basis for further action by the health agency or other state and federal agencies. For example, if epidemiologic and laboratory data provide evidence linking illness to consumption of a particular food, an informational traceback investigation can result to identify the source of that food. Given the national and international scope of food production, the informational and regulatory traceback investigations might involve multiple state and federal regulatory agencies. Violations of federal or state law that are identified during a regulatory traceback investigation may lead to further action, such as seizure of the implicated foods or injunctive remedies.

Local and state agencies also can initiate administrative actions over persons or businesses that violate state or local regulations. For example, if a restaurant has repeated food handling or food storage violations, it may be subject to administrative hearings leading to suspension or revocation of its food-service license.

2.6 Public Health Investigations as the Basis for Further Action

2.6.2 If during an investigation it is suspected or confirmed that a foodborne illness outbreak was caused because of criminally negligent behavior, intentional contamination or bioterrorism, additional state criminal, antiterrorism, and emergency response laws will enhance or dictate the course of the outbreak investigation and response. If the outbreak is multistate, then federal response resources and laws apply, and local and state public health agencies must work closely with other state and federal agencies.

Joint investigations by public health, food, agriculture, and law enforcement agencies can be hindered by the different legal powers and investigatory practices each agency brings to such an event. For example, officials from public health agencies are authorized to collect and test samples to determine their public health threat, whereas law enforcement officials can consider samples subject to seizure as evidence. Public health, food, agriculture, and law enforcement officials all must conform to constitutional standards (e.g., Fourth and Fifth Amendments) about collection of evidence, especially in situations requiring a joint investigation. Laboratory specimens collected for regulatory purposes must be collected and submitted using procedures that ensure the chain-of-custody of the specimen is admissible in court (*51*). Chain-of-custody is a process that may be followed for evidence to be legally defensible and includes the following main elements: properly identifying the evidence, a neutral evidence collector, tamper-proofing and securing evidence at the collection site, and keeping physical control of the evidence.

Local and state officials, in collaboration with law enforcement agencies, should periodically assess the need for memoranda of understanding to clarify the roles of public health, food, agriculture, and law enforcement agencies in conducting joint investigations. Local and state officials who have roles in investigating foodborne illness outbreaks should understand and demonstrate competence in applying their legal authorities in conducting joint investigations. Resources for improving competency in joint investigations include CDC training curricula (*52*) and sample memoranda of understanding (*53*).

2.7 CIFOR Legal Preparedness Resources

CIFOR has created several resource documents to further assist local and state public health agencies in improving their legal preparedness to conduct surveillance for foodborne illness and respond to outbreaks within their jurisdictions and across multiple states and other jurisdictional boundaries. The CIFOR Law Project created the following three documents, each designed to address a discrete, but related, research need and audience. All the documents are available through the CIFOR website: https://cifor.us/products/law-project

- **Analysis of State Legal Authorities for Foodborne Disease Detection and Outbreak Response.** This document describes and analyzes the types of state legal authorities available to conduct foodborne illness surveillance and outbreak response activities. It highlights the patchwork of state laws and regulations across several topic areas—public health, communicable disease, food safety, food regulation, agriculture, environmental health, and general government authority—on which public health professionals and their legal counsel must rely to accomplish foodborne illness surveillance and outbreak response activities.

2.7 CIFOR Legal Preparedness Resources

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

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