



About the Print Version

The print version of the course includes all the substantive content from each screen. It does not include any of the quizzes at the end of each section or the final assessment.

Introduction

An important role of the public health system is to protect the public from diseases spread through the food they eat. Despite the U.S. having one of the best food safety systems in the world, the Centers for Disease Control and Prevention estimates that 48 million Americans get sick every year from foodborne illness. That is one out of every six Americans. In addition, foodborne illness results in 128,000 hospitalizations and 3,000 deaths every year.

As a public health professional, your role is critical to maintaining a safe food supply and addressing foodborne illness. This course will explore the major legal issues that you may encounter in your food safety work. We will start with an overview of foodborne illness surveillance and outbreak investigation, followed by a discussion of the legal aspects of food safety. Because food safety laws vary from state to state (and local health district to local health district), we focus on general food safety legal issues.

Surveillance & Outbreak Investigation

State and local health departments play a critical role in stopping **outbreaks** and preventing them from occurring in the first place. When foodborne illnesses occur, you will investigate the cases, identify the disease, track the spread, and search for the source of the contamination. During this process, you'll gather important personal health information that is protected by privacy laws. In this section of the course, we will

- Review types of surveillance and outbreak investigations
- Explain the basic privacy requirements so you can effectively carry out your jurisdiction's food safety program
- Describe why it's important to document the collection and management of laboratory samples

First, let's briefly review types of surveillance and outbreak investigations.

Surveillance?

Foodborne illness surveillance is the routine monitoring of diseases potentially spread through food. Surveillance is vital in detecting **disease clusters**, outbreaks, and safety concerns in the food supply chain. There are three basic forms of surveillance:

1. Pathogen-specific surveillance

An **outbreak** is when there are more cases of disease than normally expected within a specific place or group of people over a given period of time.

An unusually large number of people sickened by a disease in a certain place and time is known as a **disease cluster**.

2. Complaint-based surveillance
3. Syndromic surveillance

With **pathogen-specific surveillance**, healthcare providers and laboratories must report certain diseases to the public health authority. The list of reportable diseases, defined by state law, may vary between jurisdictions. In addition, state law identifies when to report each disease, what information to include, and how to make the report.

Complaint-based surveillance relies on the public reporting possible foodborne illnesses directly to the public health department.

Syndromic surveillance identifies foodborne illness outbreaks by analyzing data that is collected for another purpose. Examples of data sources include emergency department chief complaints, school absenteeism, sale of over-the-counter drugs, and calls to poison control. Syndromic surveillance is less specific than other forms of surveillance. Because it's usually automated, it can potentially provide more timely identification of outbreaks before laboratory confirmation has occurred.

For more information, see the [Surveillance course](#).

Outbreak Investigation

Once you suspect a possible foodborne outbreak, initiate an investigation. The general goals of an investigation are to

- Identify the **illness agent**
- Identify the people at risk
- Identify the mode of transmission
- Identify the source of contamination
- Determine potential for further transmission
- Identify disease control measures

Investigation of outbreaks often includes interviews of affected people, environmental health assessments of implicated facilities, and tracebacks of food items through the distribution chain to determine the source of contamination. You'll probably collect personal and clinical information during an outbreak investigation. It's vital that you know what data you can share and use under federal and state laws.

For more information, see the [Outbreak Investigation course](#).

An illness agent can be any disease-producing microorganism, a chemical agent (such as cleaning compounds stored next to food or food additives such as MSG), or a physical agent (such as kitchen equipment in poor repair that shreds metal particles into food).

Privacy Laws

Lake City Hospital has seen an increase in patients visiting the emergency department in the past week with abdominal pain and bloody diarrhea. Four patients with these symptoms have tested positive for Shigella. One of the patients is a chef at a local restaurant. Are the emergency department staff restricted in the amount of information they can share about these patients with the local health department? How much

information can a health department investigator share with the restaurant about a contagious employee?

Federal, state, and local laws dictate how information can be collected and shared during surveillance and investigation.

The Health Insurance Portability and Accountability Act (HIPAA) is a federal law that protects patient health data and plays a large role in how your organization must handle an individual's health information. Using its administrative authority, under HIPAA the Department of Health and Human Services (DHHS) created a set of national privacy standards for health information, known as the HIPAA Privacy Rule. These standards provide patients with more control over how their personal health information (PHI) is used and disclosed. Under the HIPAA Privacy Rule, you have obligations to protect this personal data. The HIPAA Privacy Rule may determine how you conduct, process, and collect information from health care providers or institutions required to protect personal information. However, there are exceptions to the HIPAA Privacy Rule that will allow you to do your job.

Protected Information

The Privacy Rule only protects the use and disclosure of certain types of information. This information is called **protected health information** (PHI). PHI includes all information that can be **connected to a specific person** and is related to

- Physical and mental health conditions
- Provision of health care
- Payment for health care

The Privacy Rule lists 18 personal identifiers. If any of these identifiers are associated with medical information, they will trigger protections required by HIPAA's Privacy Rule. Recognized identifiers include names, telephone numbers, email addresses, social security numbers, medical record numbers, and health plan beneficiary numbers.

Personal Identifiers

1. Names
2. All geographic identifiers smaller than a state, with limited exceptions
3. All elements of dates (except year) for dates directly related to an individual; and all ages over 89 and all elements of dates (including year) indicative of such age
4. Phone numbers
5. Fax numbers
6. E-mail addresses
7. Social Security numbers
8. Medical record numbers

9. Health plan beneficiary numbers
10. Account numbers
11. Certificate/license numbers
12. Vehicle identifiers and serial numbers (including license plate numbers)
13. Device identifiers and serial numbers
14. URLs
15. IP address numbers
16. Biometric identifiers, including finger and voice prints
17. Full face photographic images
18. Any other unique identifying number or characteristic

Covered Entities

If you are a covered entity, HIPAA's Privacy Rule applies to you. The following groups are generally considered covered entities:

- **Health plans.** Individual or group plans that provide or pay the cost of medical care (there are exceptions to this).
- **Health care providers.** Medical or health services (physicians, hospitals, clinics, dentists).
- **Health care clearinghouses.** Billing services, re-pricing companies, and community health information systems.

For example, you wouldn't be able to share personal information collected during an outbreak with the local newspaper if your health department provided medical services.

You should find out whether your organization is a covered entity under the HIPAA Privacy Rule. Failure to comply with HIPAA's Privacy Rule can have severe civil, criminal and monetary consequences. The severity of these penalties and the credibility of your department indicate the need to consult with your legal counsel when addressing privacy issues and HIPAA. In addition, there may be state and local privacy laws that restrict the use of information gathered by a health department.

For more detailed information about covered entities, please refer to [Who and What Are Covered Entities](#).

Privacy Requirements

Generally, covered entities can't share protected health information. However, this rule is subject to specific exceptions.

There are two cases when covered entities **must** disclose protected health information:

- When the person asks for their information
- When DHHS investigates a covered entity's compliance with the Privacy Rule

In addition, there may be state or local laws that require disclosing health information for reporting of notifiable conditions or for other public health purposes. There are also several instances when covered entities can disclose or use protected health information without the person's written consent. Permitted disclosures include:

- Exceptions for public health activities
- Judicial and administrative proceedings
- Victims of abuse, neglect, or domestic violence
- Law enforcement under [certain circumstances](#)
- Research data

There are strict guidelines to each of the permitted exceptions. Always consult with counsel when dealing with a HIPAA disclosure.

Common Exceptions

The following two permitted exceptions are most relevant to food safety programs:

- **Public health exception.** This is the provision that allows hospitals, laboratories, and doctors to share protected health information related to reportable food-borne illness with state and local health departments. If a health care provider is unaware of privacy laws and exceptions, you can reference the public health exception for HIPAA and refer them to the relevant state codes.
- **Judicial and administrative proceedings exception.** As the food safety authority, you may be ordered to provide protected health information gathered during your program's investigations. For example, you may be ordered to provide protected health information in proceedings against a food manufacturer whose products were related to a salmonella outbreak. However, you should still consult legal counsel, in case you want to challenge the order.

Judicial and administrative proceedings exception

In judicial and administrative proceedings, you may receive two types of requests.

1. You could receive an order of a court or administrative tribunal directing the disclosure of PHI. You should disclose only the information explicitly requested in this case. All other information remains PHI.
2. You could get a subpoena, discovery request, or be subject to another lawful process. Subpoenas include the additional requirement that the implicated person is notified and given the opportunity to ensure limited use of the information. If you get a subpoena or court order, immediately consult your attorney.

For example, suppose your local health department investigated an E. coli outbreak. Sarah, one of the people who got sick, files a civil law suit against the restaurant linked

to the outbreak. You receive a court order requesting the names and addresses of other people sickened in the outbreak. You can therefore disclose only the names and addresses you collected; you can't share any other PHI you may have gathered during your investigation.

Disclosing information

The Privacy Rule requires that a covered entity use, disclose, or request **the minimum amount of PHI necessary to meet the intended purpose**.

Food Service Employee Scenario

A hospital notifies your local health department that Robert has a communicable disease, Shigella, which is reportable under state law. Robert works as a cook at Leslie's Fabulous Food restaurant. Your department has the power to temporarily restrict Robert's employment.

In this scenario, you would first contact Robert to inform him that he has Shigella. During this phone call you would conduct an interview to gather important epidemiological information, such as travel history, food history, onset of symptoms, and employment. Upon learning that Robert is a cook, you would inform him that he is temporarily excluded from work, and may not return to work until cleared by the health department. If Robert agrees to stay home, you can monitor his compliance. If he doesn't comply, you can contact Robert's employer, Leslie, to inform her of Robert's exclusion from work.

Leslie may ask what is wrong with Robert. What problems could arise if your health department tells her the specific illness Robert has contracted?

The public health exception, which allows disclosure without consent, is limited. Remember, you may only disclose the minimum amount of protected information necessary to achieve the targeted outcome. In this case, simply notifying the employer that the person can't work until cleared would achieve the public health outcome.

Unfortunately, some employees don't have sick leave or can't miss work because they can't afford it. For some illnesses, ill employees may be allowed to report to work as long as they are restricted from food service duties. Consult your state's food code and communicable disease guidelines. In this scenario, the food code requires food service employees ill with Shigella to be excluded from work, so Robert is not eligible to return to work with restricted duties.

This is an opportunity to educate Leslie about food safety. If Robert returns to work as a food handler and Leslie knows he's still sick, you may be justified in closing the restaurant.

Investigation in Schools

Special privacy issues also may arise when you investigate a foodborne illness outbreak in a school. Records kept by the school could provide useful information in the investigation. However, the nurse's records are protected by the Family Education Rights and Privacy Act (FERPA). FERPA is a federal law that protects the privacy of students' education records. FERPA applies to educational agencies and institu-

tions that receive funds under any program administered by the U.S. Department of Education. This includes most public schools and school districts.

If you are unable to obtain written consent for the release of education records, there are certain instances when they can be shared without written consent. We will look at two exceptions. First, de-identified information is not protected under FERPA. De-identification requires the educational institution or agency to remove all personally identifiable information (such as from records kept by the nurse). Then the agency must make a reasonable determination that the student's identity is safe, while taking into account previous information released by the agency or school and information available from other sources.

Second, FERPA allows limited disclosure without consent in connection with a health or safety emergency. The personally identifiable information may be disclosed to appropriate parties, during an emergency, when the information is necessary to protect the health and safety of the student or others. Though this exception has a narrow interpretation, there may be an argument that this exception applies during a foodborne illness outbreak, depending on the circumstances.

If you come across privacy issues related to student records, you should always consult with your legal counsel.

Chain of Custody

When investigating a foodborne illness outbreak, you may have to obtain samples or specimens for laboratory testing. These samples could include the food implicated in the outbreak or specimens from potential outbreak victims. The information derived from these specimens could be useful in regulatory actions, criminal prosecutions, or even terrorism investigations. Even though most foodborne outbreak situations do not end up in court, you should approach each investigation as though the evidence you are collecting might become part of a legal case.

For laboratory results to be admissible in court, you must collect and submit specimens through specified procedures that ensure the chain of custody of the specimen. Chain of custody means that you must document every transfer of the sample to help ensure that the sample was not tampered with. Most jurisdictions already have chain of custody forms that document transfers of laboratory samples.

Summary

In this section, you learned about the key legal issues of foodborne illness surveillance and investigation. During surveillance and investigation activities, you will encounter personal health information protected by law. State health privacy laws and HIPAA restrict what information covered entities may disclose.

In your surveillance and investigation work, you'll also need to understand the chain of custody for lab samples. Chain of custody is the process that accounts for each transfer of a sample to prevent tampering.

Remember, if you come across any of these legal issues during the course of your work, consult with your department's counsel.

Source of Authority

In the previous section, you learned about what information you can share during surveillance and an outbreak investigation. But what about protecting the public's health before an outbreak occurs? What powers do state and local agencies have to prevent food establishments from making people sick?

State

To determine the scope of state government authority you must look to the U.S. Constitution and the concept of federalism. Federalism is the division of power between the federal government and state governments. The basis of federalism in the United States is the 10th Amendment, which states that any powers not "delegated to the United States by the Constitution, nor prohibited by it to the States, are reserved to the States respectively, or to the people."

Under this broad reservation of power, states have police powers. Police powers are the authority to enact and enforce legislation and regulations to protect the welfare, health, and safety of the population. These police powers provide the basis for state food safety regulation.

Examples of state police power in food safety include:

- Licensing requirements for food establishments.
- Inspections of food storage warehouses to ensure compliance with food storage requirements.
- Authority to temporarily restrict employment of food service workers with certain contagious diseases.

Local

Just as distribution of power between federal and state government is defined by the federal constitution, local jurisdictions must look to their state constitution and legislation for the scope of their authority. The extent and independence of local authority varies widely from state to state. Even in local jurisdictions that are defined as having Home Rule, the authority for this independence is delegated by the state. Many local health officers have the authority to license food establishments and restrict ill food workers.

Tribal

On tribal land, state and local agencies don't have jurisdiction. State and local health departments are well-served to offer tribes assistance by providing epidemiologists, remembering that the tribe is in charge of the investigation.

FDA Food Code

With every level of government conducting independent food safety operations, it becomes challenging to develop food safety regulations that are consistent and scientifically sound. State and local agencies have created their own food codes based on the FDA Food Code.

Published by the U.S. Food and Drug Administration (FDA), the FDA Food Code serves as a resource for all levels of government when developing food safety regulations for the retail and food service sector (restaurants, grocery stores, and institutions). The FDA Food Code is updated on a regular basis to provide current best practices and research. For example, the FDA Food Code provides cooking temperatures and duration standards so that harmful organisms, such as E. coli or Salmonella, don't survive. Most states have used it to help develop their food safety regulations. For example, Oregon did not adopt the FDA Food Code in its entirety. It is a resource to help agencies draft regulations based on good science and best practices. All local jurisdictions in the state of Oregon enforce the Oregon Food Sanitation Rules. Some states will have different food codes in different cities and counties.

See the [FDA Food Code](#) for more information.

Administrative Law

While the agency responsible for food safety varies from state to state, the responsibility usually falls to the state health department, the department of agriculture, or a combination of the two. Food safety is a very technical field that requires a diverse array of subject matter knowledge. While the legislature can draft statutes to address general goals and objectives of a food safety program, it relies on administrative agencies—government regulatory bodies like health departments, boards of health, or the Food and Drug Administration—to provide the scientific, economic, or industry expertise.

The administrative agency in charge of the food safety program provides this expertise in the form of detailed rules and regulations. Administrative law governs the activities of administrative agencies. It's made up of **statutes**, **constitutional provisions**, **regulations**, **administrative decisions**, and **case law**. Administrative rules and regulations are legally binding and outline specific requirements and responsibilities needed to carry out food safety statutes. The legislature generally defines the scope of an agency's rulemaking power in the enabling statute—the law that created the agency.

The legislature can also give specific mandates to create regulations in other statutes. For example, the Maryland Food, Drug, and Cosmetic Act granted the Maryland Department of Health and Mental Hygiene authority to create the regulations necessary to carry out the provisions of the statute. Based on this authority, the Maryland Department of Health and Mental Hygiene drafted regulations regarding employee hygiene standards for food processing plants.

To understand the full scope of your agency's rulemaking authority, review the enabling statute and food safety legislation.

Rulemaking

At the state and local level, rulemaking processes and responsibilities vary from state to state. In some cases, statutes requiring agencies to draft regulations may dictate the procedures. Most agencies draft regulations using a structured rule making process, which is based on the **Administrative Procedures Act (APA)** process. Generally, the process includes the following steps:

A **statute** is written law passed by a legislative body.

A **constitutional provision** is a rule or law that comes from the constitution itself and not from statutory or common law.

A **regulation** is a principle, rule, or law designed to control or govern conduct.

Administrative decisions are made by agencies authorized to make rules and regulations.

Case law is established by the outcome of former cases.

The **Administrative Procedures Act** is a federal law governing how federal agencies create regulations.

1. Provide notice of the proposed rule to the public. The notification usually includes the agency's initial analysis and solicits input before drafting the regulation. The notification also includes the time, place, and nature of the rulemaking proceeding.
2. Publish the draft rule.
3. Provide a comment period for the public to provide feedback. Most often, people give written comments, but in some cases, the public agency will hold hearings.

If there are substantial changes from the originally proposed rule, the agency may open a second public comment period.

The Administrative Procedures Act provides a basic model for general procedures when drafting regulations. The exact steps may differ from state to state. However, you should refer to the specific statutes of your jurisdiction before beginning any rulemaking process.

Preemption: Which Laws Apply?

With both federal and state authorities drafting food safety statutes and regulations, how are conflicts between these laws resolved? In the US Constitution, the **Supremacy Clause** states that the Constitution and federal laws override state and local laws. As long as the federal government has authority to create the law in question, federal law supersedes state law when conflicts arise. This relationship is known as preemption. Preemption ensures uniformity and often sets minimum levels of protection. There are two kinds of preemption.

Express preemption occurs when the language of a federal statute specifically states Congress's intent to supersede state law. Sometimes the language of the federal statute does not completely exclude state and local regulation. Some federal statutes create a minimum standard and allow states or locals to draft stricter standards. For example, the 2010 **Patient Protection and Affordable Care Act** set national nutritional labeling requirements for specific classes of restaurants. State and local agencies must petition for an exemption if they want to change or add to the requirements for food sold in these restaurants. The Act has been passed by Congress and carries the weight of law. It preempts state law regardless of whether the Federal government has taken the steps to implement the law.

With implied preemption, agencies must surmise the intent of Congress—it isn't explicitly stated. There are two basic implied preemption scenarios.

1. In field preemption Congress creates a comprehensive set of laws that govern an entire area (or "field") of law and leaves no room for states to regulate. Any state or local rule in an occupied field of law is invalid. Courts determine whether the Federal government has sufficiently occupied a field of law to exclude state and local regulation.
2. Conflict preemption occurs when it is impossible to comply with both the state and federal regulations, or when the state law presents an obstacle to

Supremacy Clause:

"This Constitution, and the Laws of the United States which shall be made in pursuance thereof; and all treaties made, or which shall be made, under the authority of the United States, shall be the supreme law of the land; and the judges in every state shall be bound thereby, anything in the constitution or laws of any state to the contrary notwithstanding."

Patient Protection and Affordable Care Act:

"...no State or political subdivision of a State may directly or indirectly establish under any authority or continue in effect as to any food in interstate commerce... any requirement for the labeling of food that is not identical to the requirement of section 403q..."

Congress's objectives. Courts determine whether conflict preemption exists. In [Crosby v. National Foreign Trade Council](#), the Supreme Court struck down a Massachusetts law that effectively prohibited Massachusetts governmental agencies from buying goods and services from companies conducting business with Myanmar, based on conflict preemption. The Court held that the Massachusetts law undermined the intended purpose of an act passed by Congress that imposed sanctions on Myanmar.

Preemption also applies when state and local laws are at odds on an issue. If you come across a conflict in laws during the course of your food safety responsibilities, be sure to seek legal counsel to determine if there are any preemption issues.

Summary

The concepts presented in this section provide a basis for understanding the source and scope of state and local food safety authority. The US Constitution and the concept of federalism provide the legal framework for the police powers that allow states to exercise their food safety programs. Within this framework, administrative agencies provide considerable expertise in drafting and enforcing regulations. The FDA Food Code is a resource to help agencies draft regulations based on good science and best practices.

State and local authorities should know that where federal and state food safety laws conflict, federal law prevails under the principle of preemption. This same principle applies when state and local food safety laws conflict. In the course of conducting your food safety duties, remember to consult with your legal counsel regarding the exact scope of your legal authority.

Prevention

In the first section we addressed foodborne illness surveillance and outbreak investigation. These measures are usually applied once a foodborne illness has already affected the community. In the second section, we discussed what authority you have to create and enforce rules and regulations. In this section we will discuss the various prevention measures used to help prevent a foodborne illness outbreak. These powers include the authority to inspect food facilities, detain and destroy **adulterated food**, and impose civil fines and criminal penalties.

Employee Training

One way to help prevent outbreaks is to require all food service employees to undergo certified food safety training. The training requirements and monitoring for food handlers varies considerably across jurisdictions. For example, in Oregon any person involved in the preparation or service of food in a restaurant or food service facility must complete a food handler training program. This program is administered in partnership with local health departments. The food handler training program covers various aspects of foodborne illness including symptoms, major causes, prevention methods, proper hand washing technique, and appropriate food temperature control.

In addition, some jurisdictions require food establishments to designate a manager who must receive additional food safety training. Florida requires all public food

Adulterated food is food that is generally, impure, unsafe, or unwholesome. Adulterated food also includes an addition of a substance in a food that is not harmful but should not be in the pure form of the food. For example, a food establishment may add drinking water to milk in an effort to increase profits.

service establishments to have a manager who has completed a food service manager training that addresses basic food protections.

Food safety training appears to be an effective foodborne illness control measure. A recent [study](#) linked the presence of a certified kitchen manager to fewer foodborne illness outbreaks in restaurants.

Licensing

State and local authorities can require licenses and permits for food establishments to operate. State and local licensing authority can vary based on the type of facility. In some states, local governments generally license restaurants while grocery stores are often covered by state authorities. In other states, like Oregon, locals license and inspect restaurants via an intergovernmental agreement with the state. Oregon Department of Agriculture licenses and enforces their own rules with grocery stores, processors, and manufacturers.

When licensing authority overlaps, there is often reciprocity between the state and local government in their licensing requirement. In Maryland, for example, if a restaurant receives a license from the county health department, the state will recognize the license so long as local licensing requirements meet the state's food safety standards.

In applying for a license, a food establishment agrees to the following:

- Comply with the food safety regulations of the jurisdiction
- Allow inspection of the facility
- Pay any licensing fee

The licensing authority often inspects the facility to ensure compliance with regulations before issuing a license and permit to operate. If the licensing authority decides to deny the license, they are often required to provide the following:

- Notice of denial
- Chance for correction of deficiency
- An administrative hearing

The license is non-transferable and evidence of the license must be displayed in a prominent location in the food establishment.

Inspections

There are federal, state, and often local roles in ensuring food safety. To help ensure food facilities are complying with food safety standards, state and local food safety officials have the authority to inspect these businesses. There are several types of facilities you may end up inspecting.

The [US Department of Agriculture](#) (USDA) generally has oversight over agricultural activities before food is processed, and in some cases may also have inspection or investigative roles in foodborne outbreaks. The Food and Drug Administration (FDA) is responsible for inspecting food processing and manufacturing facilities. The FDA [contracts](#) with many state governments to conduct the inspections on its behalf.

The Food Safety and Inspection Service (FSIS) is the public health agency in the **U.S. Department of Agriculture** responsible for ensuring that the nation's commercial supply of meat, poultry, and egg products is safe, wholesome, and correctly labeled and packaged, as required by the Federal Meat Inspection Act, the Poultry Products Inspection Act, and the Egg Products Inspection Act.

According to a 2011 report by The Department of Health and Human Services Office of the Inspector General, in 2009, 59% of domestic facility inspections were conducted by state resources under **contract** with the FDA.

The Food Safety Modernization Act of 2011 (FSMA) is a comprehensive federal food safety statute. The FSMA has increased the number of food facility inspections by the FDA. As a result, there will probably be additional food processing and manufacturing inspections conducted by states under contract with the FDA.

In addition, state and local agencies have the authority to inspect food service establishments such as restaurants and bed and breakfasts. Local agencies usually conduct these inspections. Inspections may take place in the following ways:

- Part of a regular monitoring schedule
- In response to a foodborne illness outbreak
- In response to a complaint of a food safety violation

If your agency conducts inspections, your inspector must conduct them at a **reasonable time**, and provide proper identification and credentials. During the inspection, the inspector may examine and take samples of food, examine equipment, and review records pertaining to the food and supplies used at the establishment. The inspector records his observations and any violations of the jurisdiction's food safety regulations. The inspector must give a copy of his observations to the restaurant and provide a timeline for the remediation of these violations.

In the rare case that admission to a facility is denied by the owner, there are provisions for recourse to compel an inspection or to close a facility. Work with your supervisor and your local counsel to determine the best course of action.

Suspension & Closure

What can you do to remedy food safety violations discovered during a restaurant inspection? One of your most powerful tools is the ability to suspend or revoke the restaurant owner's license to operate, which would shut down the restaurant. There are two situations where this can occur.

Imminent health hazards

First, a restaurant can lose its license when there is an **imminent health hazard** resulting from violations of the food safety code. Imminent health hazards include violations such as lack of hot water, lack of electricity, or a back-up of the local sewage system into the facility. If the restaurant owners do not immediately remedy these violations, enforcement officers can temporarily suspend the restaurant's operation and, in some states, write an Order of Closure. When suspensions or closures occur, the inspector must provide the restaurant owners with a written notice that outlines the violations and informs them of their right to a hearing to challenge the suspension. If the restaurant refuses to close, a written citation and a civil penalty may be imposed. As an inspector, you may need to provide a written plan to ensure correction.

Non-imminent violations

Second, even if the restaurant's violations do not present an imminent health risk,

A reasonable time for inspections should be whenever the establishment is open for business or preparing food.

Imminent health hazard means a significant threat or danger to health when there is evidence to show that a product, practice, circumstance, or event creates a situation that can cause food infection, food intoxication, disease transmission, vermin infestation, or a hazardous condition that requires immediate action to prevent injury, illness, or death.

the inspector may still suspend or revoke the license because recurrent or cumulative violations constitute a risk to the public's health. For this non-emergency closure, the process is different and will vary from state to state and jurisdiction to jurisdiction. Generally, the steps are:

1. Provide the restaurant owner with a written notice to comply.
2. If the owner does not fix the violations, they are given a written notice outlining their infractions and informing them of their right to a hearing.
3. At the hearing, the owner will have an opportunity to challenge the potential suspension or revocation of the license. However, if they do not request the hearing within the required time period, they have waived this right. For example, in California the restaurant has 15 days to request a hearing. After the hearing, the hearing officer must provide the restaurant owner with a written notice of the decision regarding their license.

If a restaurant owner's license is suspended or revoked, they can always apply to reinstate her license or apply for a new one. However, they must fix the conditions that resulted in the loss of the license.

The discussion above provides a general overview of license suspension or revocation. Your jurisdiction's process may vary slightly. To learn more about these procedures, consult your legal counsel.

Criminal Penalties & Civil Fines

Other food safety enforcement tools at your disposal are criminal penalties and civil fines. While both of these tools are meant to deter improper actions, they also serve additional purposes.

- A criminal penalty can be a monetary fine or prison sentence meant to punish a party for their wrongdoings.
- A civil fine is a monetary fine that may be assessed for a violation of certain statutes and regulations as an alternative to criminal proceedings.

Criminal penalties

Violations of food safety regulations are usually misdemeanors. The criminal penalties associated with these misdemeanors vary between jurisdictions. For example, in Virginia, violations of the food code are a class 3 misdemeanor which can result in a fine of up to \$500. In California, violations of food safety regulations are punishable with fines ranging from \$25 to \$1000 per violation. But violations in California can also result in imprisonment for up to six months in the county jail. Generally, each day that the violation persists counts as a separate and distinct criminal offense. So if a restaurant owner is in violation of one regulation for seven days, she has seven unique offenses.

Civil fines

In addition to criminal penalties, courts or statutes may assign civil penalties for violations. For instance, in Virginia, the courts can assign civil penalties up to \$10,000 per violation. Usually, each day the restaurant owner is out of compliance counts as sepa-

rate violation for civil fines.

To learn more about the criminal penalties and civil fines in your jurisdiction, consult with your legal counsel.

Exclusion of Infected Employees

State and local authorities can help prevent the spread of foodborne illness by restricting the employment of food service workers suspected of carrying contagious diseases that can be spread in the course of their work.

At the local level

For example, Jeff, a waiter at a Portland, Oregon restaurant, has Shigella. The local health officer for Multnomah County, where Portland is located, has the authority to **exclude or restrict** Jeff's employment. The local health code allows the county health officer to require food service employees to get tested, if they might be carrying a contagious disease. Exclusion rules vary by pathogen.

Not all local health ordinances specifically address the exclusion of food service employees from work. However, the authority to do so is often in the local health officer's general mandate to control the spread of contagious disease. For example, in Baltimore City, the Health Commissioner can require a medical examination of any individual whom he suspects on reasonable grounds of having, carrying, or being in contact with someone who has a communicable disease. The Baltimore City Health Commissioner also has broad power to prevent the spread of the communicable disease, which would include restricting food service worker employment.

At the state level

In this example, if Multnomah County does not exercise its authority to restrict Jeff's employment, the state government can still act. Oregon law specifically prohibits food service workers affected by, or even suspected of carrying, a communicable disease from working at a food service facility. If an employee might have a contagious disease, Oregon law allows the state health authority to immediately exclude the individual from employment.

To determine the exact scope of your ability to restrict food service worker employment, consult with your legal counsel.

Detention of Food

What can you do to prevent food service establishments from selling food you believe is unsafe?

If during the inspection of a restaurant, you discover food that you reasonably believe to be unsafe, you have the authority to detain this food. Generally, you will need to do the following:

- Mark the food as potentially unfit for consumption
- Include a warning that no one can remove or sell the food until given permission to do so

Exclusion means that an employee is not allowed to report to work.

Restriction means an employee is allowed to return to work, but with a limited set of duties that don't include activities that could transmit infection (the employee can only work in the back office and do paperwork).

Various methods may be necessary to isolate, restrict, or dispose of potentially hazardous food. There are variety of actions to take depending on your local food safety regulations and the severity of the hazard.

“What Would You Do” questions ask you to consider how you would respond to the situation presented and give examples of what other health departments did in a similar situation. There are no right or wrong answers.



What Would You Do?

You are doing a routine inspection. You open the walk-in cooler and find six cow heads staring back at you. They are stored in plastic bags with bits of hide and grass visible. What would you do?

- Ignore the cow heads
- Ask to see the receipts
- Check with the USDA to find out how to verify whether the heads are from an approved source

What They Did

The inspector called the USDA to verify how to identify whether the heads were from an approved source. The USDA told the inspector to look at the cheek to see if it had an incision and to look for the inspection stamp. Because the heads didn't have the stamp, the inspector embargoed the heads so that the USDA could examine them and possibly take legal action.

Destruction of Food

If you find food that presents an immediate threat to human health, you may have the authority to immediately destroy the food or make it unfit for human consumption. For example, in Maryland, the health department considers food that “contains any filthy, decomposed, or putrid substance; is poisonous or otherwise would be injurious to health if consumed; or is otherwise unsafe” an immediate threat.

The owner of the food has a right to sue for monetary damages if the food turns out not to be a threat to the public's health.

Most agencies have a food hold and destruction process. To learn more about this, contact your legal counsel.

Summary

In this section, you learned about the various control measures used to help prevent a foodborne illness outbreak. These powers include the authority to:

- Inspect food facilities
- Require employee food safety training
- Require food establishment licensing
- Detain and destroy adulterated food

- Impose civil fines and criminal penalties
- Exclude contagious food service workers with certain infections

Again, if you come across any legal issues during the course of your work, consult with your counsel.

Procedural Due Process

The U.S. Constitution limits your use of the control measures discussed earlier. The Due Process Clauses of the fifth and fourteenth amendments state that the government shall not take a person's life, liberty, or property without due process of law. What this means is that public health agencies must follow certain procedures when depriving people of their property. Food establishment owners have the right to present their objections to a neutral decision maker, such as a judge. The denial of a food service license, the administrative detainment of food, the destruction of food, the suspension or revocation of a food service license all deprive a person of property, which results in the need for procedural due process. Due process protections are seen, for example, in our discussion of restaurant license suspension. The owner of the license has the opportunity to challenge alleged violations before a neutral decision maker.

To learn more about due process requirements, contact your local counsel.

Additional Challenges

Sometimes there are additional challenges faced by food safety inspectors in the field. This section will describe bribery, assault, and battery and give suggestions for how to deal with those situations when they arise. We'll also discuss liability issues.

Bribery

Bribery is the crime of giving, soliciting, or taking money or some other valuable item in order to influence a government employee or public official in the performance of their duties. In the course of their work, some inspectors have been offered a fifth of bourbon or a free lunch. Don't accept anything that may be conceived of as a bribe. Some inspectors have found that politely refusing the bribe while not calling attention to it works. Often, an explanation that food inspectors can't be favored above the general population is also effective.

For example, two former San Francisco Department of Public Health employees were accused of soliciting fees, allegedly in exchange for helping restaurant and food service managers cheat on their state-required food-handler certification exam. Another example of bribery occurred at an Iowa farm responsible for a 2010 Salmonella outbreak that sickened nearly 2,000 people. A former manager at the farm pleaded guilty to conspiring to bribe a federal inspector to overlook health violations at the facility.

Assault & Battery

While enforcing food safety regulations, you may encounter individuals who are

agitated to the point of threatening violence or physically lashing out. These criminal actions generally fall under the crimes of assault and battery. Traditionally, **assault** is when one person intentionally creates apprehension in another person of imminent harmful or **offensive contact**. **Battery** is actual physical violence or unlawful physical contact.

Offensive contact includes nonviolent touching such as unwanted sexual contact or spitting.

Some jurisdictions send two food safety inspectors into the field together when they anticipate tense enforcement interactions. This provides an additional degree of safety and a witness to the enforcement measures. Other inspectors have asked to speak to the owner's attorney. Some departments have law enforcement accompany the inspectors if they have received threats that imply actual harm. Alternatively, departments have asked to meet with company representatives to resolve actual or perceived issues.

Many times the owner is frustrated and doesn't understand his rights; educating owners about their rights can help reduce threats. Careful documentation of inspection results can help prevent threats or misunderstandings.

States vary in their approaches to the crimes of assault and battery. For example, in Oregon intentionally attempting to place another person in fear of imminent serious physical injury is the crime of menacing, not assault. Consult with your local counsel to learn more about these crimes in your jurisdiction.

Liability

As state and local agencies carry out their food safety responsibilities, conflict is inevitable and lawsuits may be brought against the government and its employees. Sovereign immunity defines what the government is legally liable for. It is the legal doctrine stating that the government can't commit a legal wrong and is immune from civil suits and criminal prosecution. However, governments can waive this immunity. To a certain extent, the federal government has waived this immunity through the Federal Tort Claims Act. Tort is defined as an action that wrongly causes harm to someone, but that is not a crime. Therefore tort law is dealt with in a civil court. Many states have followed suit by drafting their own state tort claims acts, which often cover local governments. Although there is variation from jurisdiction to jurisdiction, there are common principles. Most jurisdictions limit this waiver of liability to certain situations and often set a monetary limit to their liability. These acts protect government employees and the government will represent them, to the extent that their actions were part of their job duties. These laws, however, do not protect employees from liability for intentional torts or criminal actions. For example, if a health department employee assaults a restaurant owner while conducting an inspection, the health department employee could be held both criminally and civilly liable.

For more information regarding your potential liability and your state or local torts claim act, consult with your local counsel.

Summary

In exercising your food safety authority, you may encounter challenges in the field. Bribery, assault, battery, and liability are some of the challenges that we covered in this section. Careful documentation of inspections can help prevent threats or misun-

derstandings, but sending two food safety inspectors or asking for an escort by law enforcement may be necessary. It is important to understand sovereign immunity and the potential liability of your agency while conducting food safety prevention and enforcement activities.

Again, if you come across any legal issues during the course of your work, consult with your counsel.

Course Summary

In this course you learned that the personal information you collect from foodborne illness surveillance and during an outbreak investigation may fall under certain privacy regulations, such as HIPAA or state or local rules. These regulations dictate what information you can freely share and what information is protected. However, there are permitted exceptions to the privacy requirements, including the public health exception and the judicial and administrative proceedings exception. These exceptions allow you to collect protected information from health care providers.

You also learned what the source and scope of state and local authority is to keep the public safe from foodborne illnesses. The US Constitution and the concept of federalism provide the legal framework for the police powers that allow states to exercise their food safety programs. Within this framework, administrative agencies provide considerable expertise in drafting and enforcing regulations.

We also covered several control measures used to help prevent a foodborne illness outbreak, including inspections, licensing, imposing fines, and detaining and destroying food. Procedural due process makes sure that you follow fair procedures when enacting these control measures. In addition, we discussed the enforcement challenges of bribery, assault and battery, and liability.

Finally, we can't stress enough that your legal counsel is a great resource and is there to answer your questions and concerns. Be sure to consult with them about the issues covered in this course.