Julia Bradsher
Gerald Wojtala
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Christopher Weiss
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Editors

Regulatory Foundations for the Food Protection Professional

INTERNATIONAL FOOD PROTECTION TRAINING INSTITUTE

Springer

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Contents

Chapter 1
Introduction

Julia Bradsher, Gerald Wojtala, Craig Kaml, Christopher Weiss, and David Read

Introduction

Foodborne illness remains a major threat to human health, especially as our food supply becomes more global in nature. Each year in the United States alone, roughly one in six Americans (or 48 million people) gets sick, 128,000 are hospitalized, and 3,000 die of foodborne illnesses (CDC 2014). In terms of cost to the US economy, foodborne illness poses a $77.7 billion economic burden annually (Scharrf 2012).

In recent years, the US Food and Drug Administration (FDA) has renewed its focus on creating an integrated food safety system (Chap. 4), or IFSS, to help protect the nation's food supply (FDA 2009). The IFSS, which encompasses inspections, laboratory testing, foodborne illness prevention, and response, will be built on collaboration by a variety of partners, including regulatory agencies at the federal, state, local, tribal, and territorial levels, along with public health partners. Industry has the primary role for producing safe food, so industry must be included as a partner in public sector integration.

Some of the ways the IFSS is currently being achieved include the development, adoption, and uniform application of model programs such as the Manufactured Food Regulatory Program Standards (MFRPS), the Voluntary National Retail Food Regulatory Program Standards (VNRFRPS), and the Animal Feed Regulatory Program Standards (AFRPS), along with the activities of the Partnership for Food Protection (PFP), which comprises food protection professionals engaged in collaboration, solution-sharing, and problem-solving (FDA 2014). Program Standards are covered in Chap. 5, while the PFP is covered in Chap. 4.

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Key to the success of the IFSS is the creation of a consistent, accessible, competency-based training system for the estimated 45,000 federal, state, local, tribal, and territorial US regulatory food protection professionals who are responsible for ensuring the protection of the US food system.

In response to the recognized need for a training system to support the IFSS, the International Food Protection Training Institute (IFPTI) designed a competency-based, career-spanning curriculum framework with the support of FDA and in collaboration with a team of regulatory officials and university academicians. The curriculum framework represents the interrelationship among the various content areas in which regulatory food protection professionals (FPPs) should have training across their careers. Competencies were validated by the IFPTI curriculum team and experts from the Association of Food and Drug Officials (AFDO) and mapped onto the framework (Fig. 1.1), creating a body of knowledge that can provide guidance to learning and education paths for careers in food protection. The framework can be used to identify desired performance outcomes, identify training that an FPP needs to successfully perform his or her job, identify gaps in existing courses and training, and serve as a course/training quality review mechanism. (*Note: The curriculum framework is an evolving document and is periodically revised/amended as the food regulatory sector undergoes changes. The framework depicted in Fig.* 1.1 *represents the version of the framework at the time this book was submitted for publication.*)

The structure of *Regulatory Foundations for the Food Protection Professional* is based on the entry-level track of the IFPTI curriculum framework. Most chapters of the volume mirror entry-level content areas of the framework (the bottom-level

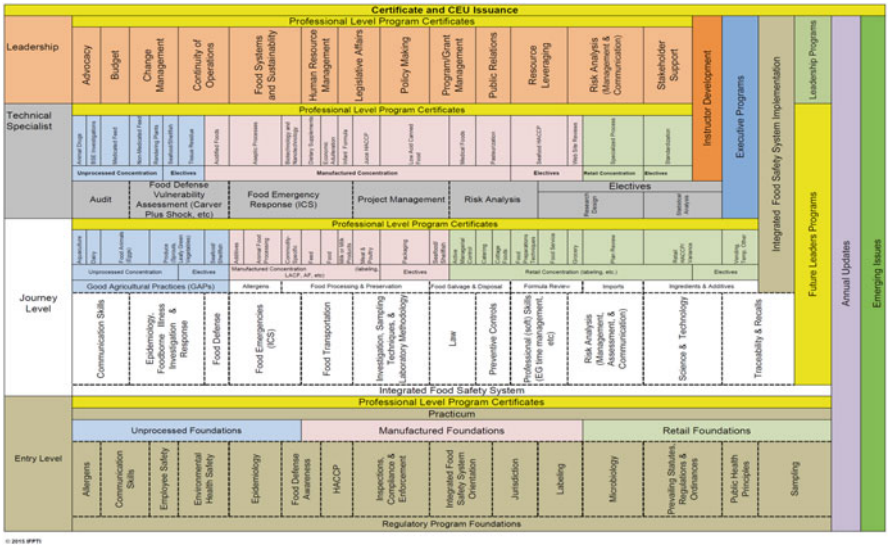

Fig. 1.1 IFPTI's curriculum framework

track. However, two chapters were included in the volume that do not appear on the framework. The editors determined that the area of Program Standards (Chap. 5) warranted a separate chapter, and Chap. 22 (International Food Regulation Foundations) was included due to the increasingly global nature of the food supply chain.

The entry-level food protection professional category generally includes (1) recent college graduates entering the food protection profession, (2) new hires of regulatory agencies who have been on the job for up to approximately 2 years, and (3) individuals in certificate and degree programs (community college, 4-year college/university, etc.) who plan on entering the profession. The content of each chapter, then, is uniquely tailored to the entry-level individual, i.e., the chapters present basic information needed by the entry-level professional.

For the purpose of this volume, the term FPP is used to represent a variety of job titles (inspector, regulator, sanitarian, etc.) across a variety of regulatory agencies (federal, state, local, tribal, and territorial); however, we have chosen to use the term FPP throughout this book in order to achieve consistency.

This volume can be used both for introductory level learning and as a job aid throughout one's career in food protection.[1] The volume targets the FPP in the public (regulatory) sector; however, an FPP in a private sector company who needs to comply with food safety regulations will benefit from this volume. Similarly, while focusing on the US regulatory system, the science and concepts contained in the volume should apply globally.

The chapters in the volume have been sequenced to reflect the progression of the farm-to-fork food supply chain. However, the chapters in the volume are standalone readings and can be read in any order that suits a particular need or purpose.

The approach to this volume is a practical introduction to more than 20 food protection content areas from an entry-level regulator's perspective, as opposed to an in-depth treatment of one particular food protection subject such as Microbiology, Hazard Analysis and Critical Control Points (HACCP), or Epidemiology. Additionally, the volume is competency-based and therefore serves as a practical guide that the entry-level FPP can use in the field.

Each chapter in the volume begins with a list of the contributing authors, a set of learning objectives which mirror the major content sections of the chapter, a list of keywords used in the chapter, and an abstract. (In many cases, the chapter introduction, or the first paragraph of the chapter introduction, serves as the chapter abstract.) Each chapter contains a conclusion, followed by a take-home message, which represents the key points that the FPP should absorb from the chapter. Each chapter also features an end-of-chapter activity, which could be a series of multiple choice questions, true-false questions or discussion questions, etc. Each chapter closes with a list of references cited in the chapter, along with any appendices added onto the chapter.

[1] For the purpose of this volume, the primary term used is *food protection*, rather than *food safety*. The authors understand food protection to be a broader term that encompasses both *food safety* and *food defense*, so where these terms are used, the use is intentional.

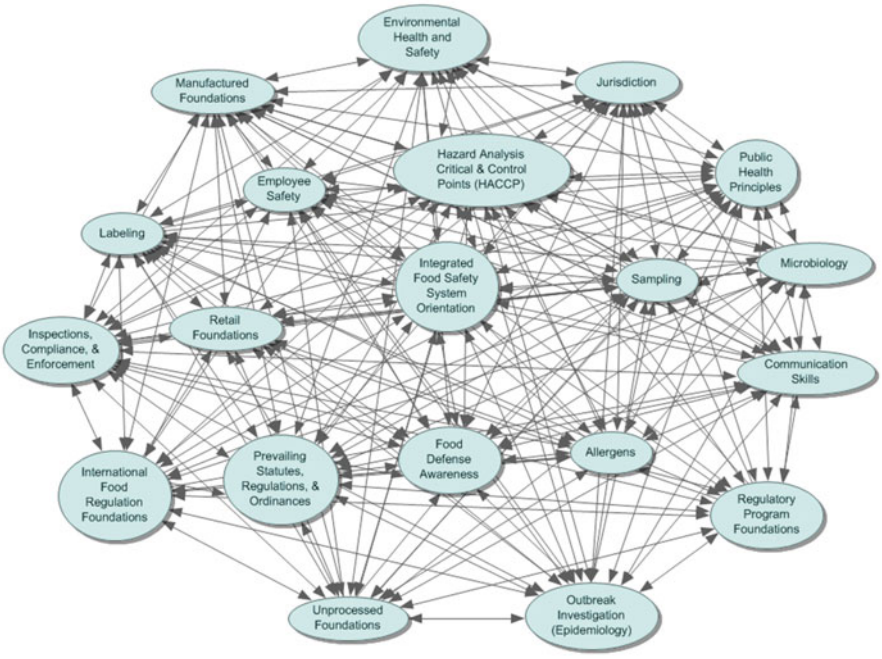

Fig. 1.2 The interrelation of chapter content areas

We recognize that some, if not all, of the volume chapters are interrelated. This is a reflection of the interconnectedness of the complex global food supply chain and is the most salient feature of a truly integrated food protection system. The interdependence of the chapter content areas can best be illustrated by Fig. 1.2.

Our thanks go out to the many chapter authors who contributed to this volume. The authors bring a cumulative total of hundreds of years of experience in the field of food protection. We hope you gain from their practical advice and wisdom. Food protection is critically important to our society, and well-functioning regulatory systems are essential in our modern world. To those professionals who have chosen to make a career in this field, we hope you find this volume a valuable introduction to the food safety regulatory system and how an IFSS system works.

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Chapter 2
Regulatory Program Foundations

Neal Fortin, Scott Gilliam, and Cathy Weir

Learning Objectives

- Explain the history and evolution of food laws.
- Examine the relationship between federal and state laws.
- Discuss how the Bill of Rights and statutes place limits on the scope and nature of regulatory authority.
- Discuss the scientific background of food safety regulation.
- Discuss the essential elements of risk assessment and how industry, academia, and government are linked together.
- Identify the collective role industry, academia, and government have to ensure safe food.
- Explain best practices of industry, academia, and government working together.

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Introduction

This chapter offers an overview of the foundational legal knowledge needed by the food protection professionals (FPPs) who help regulatory programs to carry out their missions. Topics covered in the chapter include the history and evolution of food laws, the relationship between federal and state laws, how the law places limits on regulatory authority, how scientific principles play a key role in food safety regulation, and how industry, academia, and government work best when they work together.

The History and Evolution of Food Laws (Neal Fortin)

Throughout recorded history, governments have found the need to impose laws on the sellers of food. The reason is straightforward. As long as there has been food trade, the adulteration and mislabeling of food has been a concern (Fortin 2009).

The earliest adulteration was comparatively simple. Lack of technical ability limited the possibility of intentional adulteration. Moreover, food was largely unprocessed, which presented less opportunity for adulteration. Whole coffee beans, for instance, provide less opportunity for adulteration than ground coffee, which has a history of adulteration with everything from floor sweepings to nutshells. History reveals that more adulteration occurs with high-value items such as tea, cocoa, and coffee than similar, lower-value foods (Hutt and Hutt 1984).

The history of food law provides important lessons. Vigilance is necessary by government regulators and purchasers because adulteration and mislabeling of food has been with us for a long time and will most likely remain with us for the foreseeable future. Extra scrutiny should be given to food that is processed and higher in value. Increasing steps in processing and handling increases the opportunity for adulteration.

The earliest laws were simple. Do not poison or misrepresent food. Today, food production systems are sophisticated, complicated, and international. Accordingly, food laws must keep pace with the increasing complexity of the food regulatory systems. Some people, organizations, associations, producers, manufacturers, retailers, etc., lament the complexity of our regulatory systems, but the regulations are largely a mirror that reflects the complexity of the global food system.

US food protection law is an evolutionary product. As new food protection problems emerged, Congress enacted new requirements, which were typically pasted onto existing statutes. As a consequence, food protection law is not homogenous, but a conglomeration of various requirements (Fortin 2009).

For most of the twentieth century, food law was largely reactive. The law authorized condemnation of food that was or might be injurious to health, for instance. This regulatory scheme was preventive only to the extent that the risk of government action created a protective incentive to avoid adulteration.

The Food Safety Modernization Act (FSMA, Public Law 111-353), for the first time in US history, shifts the focus of food law from *reaction* to food protection problems to *prevention* of such problems. With FSMA, Congress gave the US Food and Drug Administration (FDA, www.fda.gov) a legislative mandate to require comprehensive, science-based, preventive controls across the food supply. FSMA requires that all FDA-regulated food companies implement hazard analysis and preventive controls unless specifically exempt.

The Relationship between Federal and State Laws

The US Constitution sets up the structure of the US legal system by both empowering and limiting the government's authority. The Constitution divides federal power among three branches of government. The legislative power is vested in the US Congress by Article I. Article II places the executive power in the president. Article III vests the judicial power in the courts. This division of power was designed to create checks and balances to protect against tyranny.

Although Congress and state legislatures have the primary authority to enact laws, they often delegate this authority to administrative agencies. This delegation of authority is particularly true for areas requiring technical expertise, such as food laws. The laws promulgated by administrative agencies are called regulations or administrative rules (Fig. 2.1).

Typically, an administrative agency promulgates the detailed regulations that are necessary to translate the legislative mandate into operating standards. The regulations must stay within the scope of the authority delegated by the legislature in statute and must be consistent with other relevant constitutional and statutory requirements. Generally, regulations have the full force of law found in the enabling statute.

In addition to the lateral division of power between the three branches of federal government, the Constitution divides the power of government vertically between federal and state governments. "Federalism" is the term for this division of power.

The federal government only holds those enumerated powers delegated to it by the Constitution. Other powers are reserved to the states or to the people. Federalism also limits the ability of a state to interfere with or burden other states. An important

Fig. 2.1 Lawmaking leading towards agency regulations

example is that states cannot regulate or tax commerce in a way that places an undue burden on interstate commerce.

The Supremacy Clause of the Constitution provides that the Constitution and the federal laws are the supreme law of the land. Any provision of federal, state, or local law in direct conflict with the Constitution can be invalidated. Similarly, as a general matter, federal laws preempt state and local laws if they conflict with the federal law.

However, federal law can only preempt state law where the federal law is enacted under one of the federal government's listed powers under the Constitution. Nonetheless, the growth of national and international commerce has led to expansive prominence of federal power. In particular, the Commerce Clause of the Constitution grants Congress broad power to regulate commerce. "Commerce" covers direct interstate commerce and any activities indirectly affecting interstate commerce. Given the nature of the US economy, nearly all commerce is interstate or has an interstate impact.

States retain control over all matters not specifically delegated to the federal government. Of note is that only the states possess the power to regulate specifically for the health and safety of the people, which is referred to as traditional *police power*. The authority to make food protection laws is part of the traditional police powers.

Nevertheless, the federal government may regulate food protection even though that falls under the police power, because food protection also falls under federal authority via the power to regulate interstate commerce. For example, the federal government could not regulate the minimum cold-holding temperatures of foods based on health and safety powers, but may do so under the power to regulate interstate commerce.

Although the federal law is the supreme law of the land, the states are free to regulate any arena that has not been preempted by federal law. Of course, any additional restriction passed by a state must not place an unreasonable burden on interstate commerce.

The chief executive (the president or governor) bears the ultimate responsibility for executing the laws enacted by the legislative branch of government. This responsibility is carried out by the administrative agencies that are part of the executive branch of government, such as the US Department of Agriculture (USDA, www.usda.gov) and the US Department of Health and Human Services, under which falls FDA.

In addition to the Constitution and the enabling statutes, administrative agencies must comply with a number of procedural statutes. Three important statutes regulating agency procedure are the Administrative Procedure Act, which specifies requirements for rulemaking and agency adjudication; the Federal Advisory Committee Act, which requires that agency advisory committees be constructed to provide balance, avoid conflict of interest, and provide opportunity for comment from the public, i.e., those outside the committee; and the Freedom of Information Act, which provides the public with a right to access agency information. Every state has procedural statutes that set requirements for state and local agencies in some of the areas similar to those that fall under federal laws.

How the Bill of Rights and Statutes Place Limits on the Scope and Nature of Regulatory Authority

The first ten amendments of the US Constitution are known as the Bill of Rights. They protect individual rights by setting restrictions on the activities of the government. The Bill of Rights is generally applicable to the states. The US Supreme Court has applied most, but not all, of the Bill of Rights' restrictions on state governments through the 14th Amendment. For example, a state law that abridges the freedom of speech, press, or assembly would be in violation of the 14th Amendment, but for ease of reference, the underlying Bill of Rights amendment is usually named. In the preceding example, the First Amendment protects the freedom of speech, press, and assembly.

The power of state governments to regulate for the health and welfare of the people, called *police power*, is extensive. Generally, state health safety laws will be upheld if the laws are reasonable attempts to promote the public's health and safety. Even when restricting property rights and individual autonomy, the US Supreme Court has stated that "the police power is one of the least limitable of governmental powers" (Queenside Hills Realty Co., Inc. v. Saxl 1946). Although the courts have interpreted the state police power broadly, there are limits. In the case of a federal law, the federal government has limited, enumerated powers. If the subject matter of legislation does not fall within any of the enumerated areas of federal authority, then either the matter is one that is reserved to the states or is a matter beyond the constitutional reach of government altogether. If Congress or a state legislature enacts a law inconsistent with any constitutional provisions, the courts may be asked to invalidate the law as being "repugnant to the Constitution."

The complexities of constitutional law are beyond the scope of this chapter. Nonetheless, the FPP should be aware of the fundamentals of the Bill of Rights as they pertain to food protection issues.

First Amendment issues involve the right of free expression of speech in conjunction with food advertising and claims. The Fourth Amendment protects against unreasonable searches and seizures. Fourth Amendment protection is particularly relevant to how agencies conduct inspections, because an inspection is a form of a search. However, the courts have generally upheld the validity of laws granting government agencies the right to inspect food establishments. The limits of inspections are more controversial, such as an agency's right to take photographs or the right to access records.

The Fifth Amendment contains three provisions that are particularly pertinent to food regulation:

- Self-incrimination—No person shall be compelled to be a witness against him or herself in any criminal case.
- Due process—No person shall be deprived of life, liberty, or property without due process of law.
- Just compensation—No private property shall be taken for public use without just compensation (e.g., an inspector taking a product for sampling may need to compensate for the product).

The Fifth Amendment due process provision stands for the principle that government must act fairly and according to clear procedures. In the procedural application of the law, the basic components of due process fairness are *notice* and the *opportunity to be heard*.

Notice means that the government must give adequate information about legal requirements to the persons affected so that they can avoid the consequences of noncompliance. Generally, fair notice means that a law must be published before being enforced. The law must also be written clearly enough so that people subject to the law can understand what the law requires. A law that is so vague that reasonable people may not understand the meaning lacks basic fairness.

Due process also requires that when the government takes action affecting a person's rights or entitlements, the person must be given notice of the intended action and an opportunity to challenge the determination. For example, a government agency cannot revoke a food establishment license without giving the owner notice of the action and, under most circumstances, an opportunity to challenge the action before the license is revoked. In an emergency situation, the licensing agency may unilaterally revoke a license, but the agency must then give the owner an opportunity to challenge the revocation in a later hearing.

Agencies may seize or embargo food for being adulterated or misbranded. If a seizure is a "taking" under the Fifth Amendment, then the government would be constitutionally required to compensate those persons whose private property was seized. However, in keeping with the broad authority the Constitution grants to government to protect the public's health and safety, generally government seizure of private property to prevent harm does not require compensation (Mulger v. Kansas 1887).

The US Supreme Court has also interpreted *due process* to mean that no person shall be denied equal protection of the laws. Equal protection of the law refers to an evenhanded application of law. Equal protection may be violated directly by the words of the law or by the application of the law. For example, an ordinance may be a valid safety measure in words, but if the implementation discriminates, then the law may violate equal protection.

Nonetheless, equal protection does not require identical treatment. Government may classify people into groups and treat these groups differently. For example, for workers in food establishments, the law places special restrictions on persons suffering from certain communicable diseases. This distinction does not violate equal protection because the government may differentiate between individuals and groups if there is sound reason to do so.

A privacy right, a right to be left alone, has been considered in regard to public health laws on topics such as immunization, fluoridation, and compulsory HIV testing. However, efforts to expand the right of privacy as a basis for invalidating public health and safety laws have not succeeded. The constitutional right to privacy has been applied by the Supreme Court only in situations involving the personal intimacies of the home, the family, marriage, motherhood, procreation, and child-rearing.

The Scientific Background of Food Safety Regulation (Scott Gilliam)

Food protection knowledge has developed as a result of centuries of trial and error by humans. Our ancestors somehow knew that eating certain plants or animals could make them sick, but how did they know it? Often, these bits of information were passed down from one generation to the next. Sometimes people learned about food protection issues in school or from reading books, but in many cases, knowledge about avoiding certain food items goes back to people consuming hazardous foods and either dying or becoming very ill. These instances were very difficult lessons to learn for society as a whole. As our ancestors became more enlightened and learning became important for society, scientific inquiry evolved, and the relationship between our environment and illnesses became more complex.

In the 1800s, a serious outbreak of disease sickened many Londoners, and many people died from unknown causes. Dr. John Snow, a physician, was concerned that a second large cholera outbreak had begun and encouraged other physicians to begin keeping statistics about disease cases, including the number of deaths and other important information such as where individuals lived, their occupations, where they visited, etc. Over time, Snow was able to identify through these methods that the source of illness in the Soho area was a sewage-contaminated public water well where area residents obtained drinking water. This finding was the beginning of the new science of "epidemiology," and the first organization devoted to this endeavor was called the London Epidemiological Society. Epidemiology provided a means for scientifically tracking important information that can be used to identify cause and effect and help decision-makers develop solutions to prevent foodborne illness from happening again.

Scientific advancements have significantly impacted food protection. For example, three early scientists were credited for helping develop the "germ theory," which holds that specific microscopic organisms are the cause of specific diseases rather than the result of decomposition. Louis Pasteur was a chemist and microbiologist well known for his discoveries of the principles of vaccination, fermentation, and pasteurization. Pasteur was credited with the creation of the rabies and anthrax vaccines, but is most known for creating the process for preserving wine and milk that is still widely used today. Robert Koch was a German scientist who developed improved laboratory techniques and identified causative agents for tuberculosis, cholera, and anthrax. Koch, known as the founder of "bacteriology," also created generalized principles for medical microbiology that are still used to this day. Joseph Lister, a physiologist and surgeon, is known as the inventor of the antiseptic surgical techniques that dramatically reduced infection mortality rate (Harvard University Library Open Collections Program 2014).

Another area of scientific inquiry that has significantly impacted food protection is chemistry. The field of chemistry originally related to what is now known as metallurgy and primarily addressed the extraction of metals from raw ore.

Today, the area of food chemistry primarily deals with three primary components of food: carbohydrates, lipids, and proteins, with the overall purpose of improving production, preparation, distribution, evaluation, and utilization of food (Dommel 2014).

The work of many dedicated scientists, innovators, and entrepreneurs has allowed the food industry to develop in many areas, such as massive yield increases in crop and livestock production to enormous production capacity increases to increased shelf stability. Without the basis of various scientific principles and the incorporation thereof by the industry, consumers would not have the safe and wide selection of foods we enjoy today.

Although the mainstream food industry has embraced various scientific principles, there were landmark laws enacted in 1906, such as the Meat Inspection Act and the Pure Food and Drug Act, which forced the industry to make changes to protect the consuming public. A book, "The Jungle" written by Upton Sinclair is credited with exposing the problems in the meat packing industry and nudging Congress to act to protect the public.

The Essential Elements of Risk Assessment and How Industry, Academia, and Government Are Linked Together

With every food protection-related decision, there should be some level of understanding of the risk of not taking a food protection precaution versus the cost of controlling the hazard. Quality assurance programs need to weigh these risks versus cost factors when implementing protective measures.

The variables of potential loss and probability of occurrence are often difficult to measure. In some cases, FDA has established tolerance levels that take some of the decision-making out of the equation. For example, there is a zero-tolerance policy for *Listeria monocytogenes* (*LM*) in fresh, ready-to-eat fruit, and industry must make every effort to reduce the probability of *LM* contamination.

However, in some cases, there are no preset tolerance levels, and so individual companies must decide what level of risk is acceptable. Usually, the probability that consumers will become ill is low; however, if consumers become ill, the consequences to the public and to food companies are significant. For example, Jensen Farms of Colorado was found to be the source of a large outbreak of *LM* in 2011 that sickened well over a 100 people, and killed over 30 individuals, in multiple states. The company issued a voluntary recall of a certain type of cantaloupe, and two food processing companies (one in Kansas, the other in New York) were forced to issue recalls because the cantaloupes used during their processing activities originated from Jensen Farms (CDC 2012). The owners of the company were criminally charged, and Jensen Farms ultimately filed for bankruptcy in the wake of the *Listeria* outbreak (Booth 2012).

In the food industry, a commonly-used safety method is called Hazard Analysis and Critical Control Points (HACCP). This method has been required for many years

for companies that process meat, seafood, and juice and will expand under FSMA. HACCP was developed by the Pillsbury Company for the US National Aeronautics and Space Administration (NASA) to ensure that food taken into space was safe for consumption by astronauts. HACCP is relatively simple in principle and provides a means for identifying hazards and control measures to protect food from contamination. (HACCP is the subject of Chap. 11.)

The US government also uses risk assessment in determining acceptable limits of contamination. A "zero-tolerance" policy, which means there can be no contamination in any food, is cost-prohibitive and is not realistic with our current level of technology and knowledge. These limitations are why FDA has established "defect action limits" on certain foods. These limits usually involve field contamination, such as insect parts or dirt, and are low risk, i.e., not likely to cause harm to consumers.

Hurdle technology is an approach that uses multiple barriers to prevent pathogen growth. This concept is already widely-used in mainstream food processing, but is often not understood or used by small operations or new start-up companies. The idea is to combine multiple partial hurdles to pathogen growth so as to create conditions in which pathogens cannot survive and multiply.

Most research for new food protection technologies originates in postsecondary research settings, generally colleges of agriculture and food science. Improved testing methods continue to emerge with better and faster equipment that helps the food industry and government to make informed and timely decisions. Research funding continues to be competitive as corporations continue to seek ways to improve their systems and products. Government research funding also provides the means for new information to assist with policy-making decisions. The research findings, when shared with all parties, can be a means for the government and all of industry to make improvements to protect the economic viability of the industry as whole.

Industry trade associations, as well as professional food protection and public health associations, also play a pivotal role in food protection. These are dedicated groups that represent their constituents on many different issues and serve on committees such as the Conference for Food Protection (CFP, www.foodprotect.org), a national organization consisting of members from regulatory, industry, academia, and the public who meet and debate a variety of issues related to the advancement of food protection. Recommendations that come out of the CFP every two years are provided to FDA for potential inclusion in the next model *Food Code* (www.fda.gov/FoodCode).

Many of the food industry leaders who participate in these organizations are also leaders themselves in promoting food protection. These leaders recognize that having strong internal food protection programs is good for their brand and good for profitability at the end of the day. Foodborne illness outbreaks and recalls are very expensive to a company, not just in direct event costs, but also in lost customers and a tarnished image.

Public food protection professionals are responsible for ensuring that the food industry conducts itself properly and is in compliance with the many different local, state, and federal food regulations. A company is responsible to the consumer for complying with these rules, and the government is there to conduct spot checks to

ensure compliance. The many different regulatory agencies also provide support in the form of education, individual site visits, and consultative services.

The main federal agencies that have oversight for food protection are the USDA Food Safety Inspection Service (FSIS, www.fsis.usda.gov), FDA, and the Centers for Disease Control and Prevention (CDC, www.cdc.gov). FSIS is the agency mainly responsible for regulating meat and poultry processing in the United States. FDA is responsible for regulating all the remaining food categories, including raw shell eggs and dairy products. CDC is the primary agency for investigation of disease outbreaks including foodborne illness.

Most food protection inspections across the country are conducted by state and local regulatory agencies. The makeup of these organizations is highly variable from state to state, but ultimately FSIS and FDA rely on state and local partners for the sheer volume of inspection work completed each year. FSIS and FDA provide contracts with state regulators to cover the cost of some of this work. Under FSMA, FDA is creating the Integrated Food Safety System (IFSS) to improve our collective ability and capacity to provide better oversight of food protection in a more comprehensive manner.

The Collective Role Industry, Academia, and Government Have to Ensure Safe Food (Cathy Weir)

To solve today's food protection issues, there is a need to move beyond the traditional way of doing things and put in place a more collaborative approach. Examining the contributions individually made by government, food industry, and academia brings justification for stakeholders to work collectively.

What is the role of food industry? Industry is responsible for producing safe food by complying with food regulations in all aspects of their food production, processing, and distribution systems. Food manufacturers drive innovation and make investments in technology, logistics, and management systems to prevent foodborne illness. The food industry is highly motivated to uphold high-quality, safe food systems to meet consumer expectations. This is a continuous process that reflects consumer satisfaction in terms of product sales.

What is the role of academia? Academic research organizations have traditionally worked across multi-institutional alliances to provide unbiased, science-based information to all stakeholders. Because today's food protection issues are complex and generally connected to multiple food sectors, the issues require devoted risk assessment experts to provide solutions. University research and collaborative teams can study food protection from farm-to-fork, utilize multidisciplinary facilities and equipment, follow up with education and training programs, and validate improvements. Thus, academia is able to facilitate partnerships and take on cooperative research that takes into account the interest of government,

industry representatives, consumer groups, and other key stakeholders. This approach leads to shared knowledge and an increased understanding of hazards in food.

What is the role of government? Governments have an obligation to protect citizens by putting in place controls that reduce foodborne hazards. Foodborne illness is an important public health issue that annually costs Americans billions of dollars in health care, lost wages, and unfavorable productivity. US food law applies numerous regulations along the food chain, yet food protection problems continue. Today, governments are seeking new ways to address food protection challenges with partnerships such as academic-designed training programs, volunteer commodity-led prevention guidelines, and industry input to identify risk assessment priorities.

Due to the nature and complexity of ensuring safe food, stakeholders across all aspects of food production, food processing, food handling, food transportation, food consumption, food research, inspection, and rulemaking must collaborate. In the past, government and industry were seen as unlikely collaborators. However, today FDA is implementing FSMA, in part, based on demands by industry. Industry leaders requested an overhaul of the US food protection system and asked to work together with government to better protect our food supply (Mackay 2009). FSMA language specifies partnership obligations among stakeholders, including governments at all levels, international trade partners, consumers, and the food industry. To support this broad approach, recent initiatives have been developed including adopting many of the voluntary food protection guidelines initiated by the food industry and validated with university research.

Best Practices of Industry, Academia, and Government Working Together

The USDA has a long history of working with private organizations (e.g., farmers, food industry) and universities within the Land-Grant System, where more than 100 US colleges and universities devote resources to solving public needs, especially rural, agricultural issues (USDA 2014). An example of these partnerships includes application of the principles of risk assessment where food-related data from industry is used in academic research to drive risk-based hazard knowledge and to develop current scientific information. The USDA has effectively completed risk assessments that have incorporated applicable production, storage, and handling practices from farm-to-fork. This information, along with specific adverse health effects reported by government surveillance systems, has resulted in measures being put in place by industry and reinforced government controls to reduce pathogens in food and animal production systems.

Risk assessment leaders across industry, academia, and government have formed consortiums, supported by federal funding, that include multistate, multifunctional organizations. These collaborations have provided the scientific underpinning for several updates to food protection policies and regulations.

An example of risk research application came about when food industry experts developed Hazard Analysis and Critical Control Points (HACCP). This progressive system was designed to proactively prevent hazards by monitoring food preparation processes as a way to avoid negative findings in final inspection results. Innovations like the HACCP system have been voluntarily adopted by individual companies and industry associations to support food protection. The HACCP initiative has been found to reduce foodborne illness through preventive measures and complements government control efforts. As a result, this effective science-based program is being adopted by numerous food sectors across the globe.

To solve today's complex food protection problems, there is a need to leverage resources across a variety of organizations including the USDA, FDA, industry associations, and universities. FDA has developed commodity- and industry specific research programs to develop appropriate safety controls. For example, the Produce Safety Alliance (PSA, http://producesafetyalliance.cornell.edu/) was established to provide fundamental, science-based microbial risk assessment data to aid farmers, packers, and regulatory personnel in establishing HACCP controls that reduce risks.

Further, challenges related to food protection concerns go beyond US borders and require international stakeholder participation, particularly at large-scale standard setting forums, such as Codex Alimentarius meetings. Recent experience has shown that globally-traded food increases the risk of spreading foodborne pathogens (Käferstein et al. 1997). To engage government representatives from countries with the least amount of resources, the Codex Trust Fund was established. This fund, supported in part by the United States, has helped in gaining relevant food hazards and health risk input from developing countries when developing food standards. In this way, national governments take into consideration science-based food protection research in setting standards (World Health Organization 2013).

Conclusion

Preventing the contamination and spread of foodborne illness throughout the food supply chain requires collaboration and diligence at all stages and levels of production, processing, transportation, distribution, selling, and handling of food and food products.

The collective role of industry, academia, and government is essential for effective food protection systems. There is a need for comprehensive scientific risk research to engage all stakeholders and gain relevant food hazard data including production, storage, and handling from farm-to-fork. The US government identifies partnerships with industry, consumers, government, and international organizations as essential to building a working food protection system. The FSMA obligation to

build partnerships with stakeholders, including representatives of the food industry, will also result in expanded technical and scientific expert engagement from academia.

FPPs need to have an appreciation for the complexity and interrelationship of food supply chain components, risks involved, preventive measures, laws, statutes, regulations, the science involved, the role of various stakeholders, and the importance of roles that they, as FPPs, play regarding the well-being of consumers.

Take-Home Message

Food law and science are the fundamental infrastructure that enables the FPPs to protect the public from foodborne illness. History teaches us that food laws have always been necessary, but it is essential to understand both the scope and limits of food regulatory authority. Our food safety system works best when it is based on collaboration with industry, academia, and government.

Activity

Chapter review questions.

1. Name the three equal branches of the federal government.
2. Partnerships among government and food industry include relevant risk information such as production, storage, and handling practices from _____to _____.
3. The United States provides funding for some countries to participate in international standard setting meetings such as _____.
4. The Food Safety Modernization Act (FSMA) requires FDA to consider _____ concerns when developing their comprehensive plans.
5. A license revocation without an opportunity for a hearing would implicate what amendment of the US Constitution?
6. Discuss the concept of Federalism and what it means to food protection regulation.

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Answer Key

1. Executive, legislative, and judicial
2. Farm-to-fork
3. Codex meetings
4. Industry
5. The Fourth Amendment
6. "Federalism" is the term for the division of power between federal and state governments. See the chapter for more detail.

Chapter 3
Prevailing Statutes, Regulations, and Ordinances

Steven Mandernach, Dan Sowards, and Virginia Veneziano

Learning Objectives

- Discuss the various sources of law in the United States.
- Examine how rules and regulations differ from statutes (laws).
- Discuss the differences between federal, state, local, tribal, and territorial authorities.
- Discuss the role of model laws, regulations, and guidance documents.

Introduction

Numerous laws (statutes), rules, and regulations have been adopted at various levels of government in order to ensure the safety of our food supply, fair dealing, and economic protection. This chapter will provide an overview of the intent and authority of these laws, rules, and regulations; examine the different levels of authority (federal, state, local, tribal, and territorial); explain how laws, rules, and regulations

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are generally created; and address the role of *model* regulations and guidance documents. Laws, rules, regulations, and model/guidance documents all play a role in helping regulatory agencies and food protection professionals (FPPs) advance the mission of protecting the public health.

Sources of Law

In the United States, there are various sources of law: constitutions (the US Constitution and state constitutions); statutes and ordinances (laws passed by the Congress, state legislatures, counties, and city councils); and administrative regulations (adopted by agencies through the authority of statutory law). As seen in Fig. 3.1, constitutions are above statutes and administrative rule. Case law (derived from decisions of certain courts), however, can impact any of the levels. For example, case law can be an interpretation of the US Constitution, an interpretation of a statute, or an interpretation of an administrative regulation.

Constitutions

Constitutions are the basic organizational documents for the United States and each state. A constitution is similar to the rules of play for a board game. Constitutions contain organizational information on government, provide for the powers of the

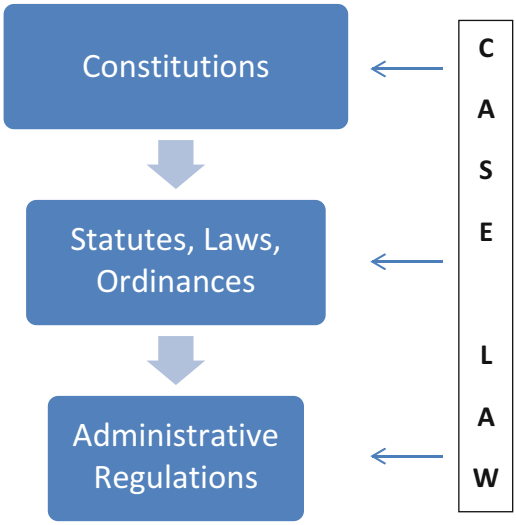

Fig. 3.1 Sources of law in the United States

parts of the government, and address limitations on what the government can do, including protections of civil rights and civil liberties. The US Constitution and state constitutions also provide the framework of how laws are made within respective jurisdictions and provide the limitations on the topics that lawmakers can address.

Several provisions of the US Constitution directly impact food safety regulations, such as due process provisions, the Supremacy Clause, and the Commerce Clause (discussed in Chap. 2). The US Senate has a webpage devoted to the US Constitution, along with explanations of the various provisions, at http://www.senate.gov/civics/constitution_item/constitution.htm. For example, the 5th Amendment provides due process protection from the federal government, and the 14th Amendment expands due process and other civil rights to protect against state and local government actions. Primarily, the due process rights impacting food regulations are procedural due process, which ensures an opportunity for a hearing before an impartial decision-maker and the opportunity to present evidence. Additionally, most state constitutions also contain due process provisions, which may be even broader than the provisions in the US Constitution.[1]

The Supremacy Clause of the Constitution (Article VI) provides that federal law shall be the supreme law of the land and has regulatory authority over state law. Because of the Supremacy Clause, federal labeling law preempts state law. Finally, the Commerce Clause (Article I, Section 8 of the Constitution) grants the Congress the authority to regulate foreign and interstate (between the states) commerce. Over the years, both the Congress and the US Supreme Court have broadly interpreted the Commerce Clause. Recent Supreme Court decisions indicate that the Congress has authority to pass laws in any area involving commerce. The Congress had authority, under the Commerce Clause, to enact the Food, Drug, and Cosmetic Act (FD&C Act, Public Law 75-717) in 1938. The FD&C Act was primarily the result of sulfanilamide poisoning which killed more than 100 people in 1937. The sulfanilamide had been prepared as an elixir and sold without testing. However, at the time there were no laws pertaining to drug testing or experiments designed to investigate side effects or to establish drug safety. The FD&C Act established rules not only for drugs, but also for food additives, genetically modified foods, homeopathic medications, bottled water, cosmetics, and the approval and marketing of medical devices.

Statutes

Ideas for laws come from a variety of sources such as constituents, industry groups, or government agencies. Typically, a lawmaker has the law drafted into statutory form and then introduces the proposal (generally called a bill) formally into one of the chambers of the Congress, i.e., the House (also called the Assembly in some

[1] Even "model" guidance documents, such as the FDA Food Code (www.fda.gov/FoodCode/), contain provisions that can help ensure that procedural due process is protected.

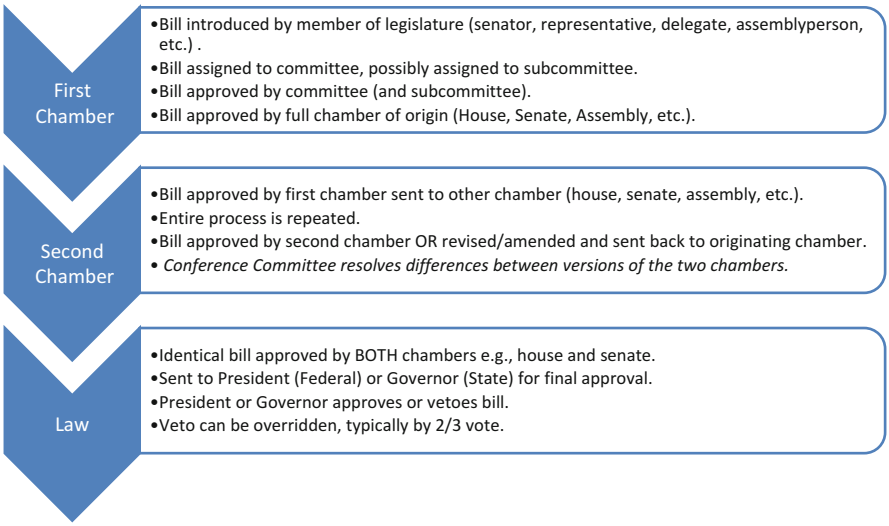

Fig. 3.2 The state and federal lawmaking process

states) or the Senate. The federal legislature, along with every state except Nebraska, has both a House and Senate (a *bicameral* legislature), and generally the House has more members than the Senate.

After being introduced, a bill is typically assigned to an appropriate committee for consideration, e.g., education committee. Committees often further refer individual bills to smaller subcommittees for consideration, e.g., elementary education (K-6) subcommittee. In order to advance into law, a bill will have to overcome several hurdles: passing through a committee, passing through the chamber of origin, going through a similar process in the other legislative chamber, and finally being approved (signed) by the president on the federal level or governor on the state level (Fig. 3.2).

Approved bills are often codified or placed within a formally-organized volume of laws such as the US Code (USC) at the federal level or a similar state code at the state level (bills with short-term impact such as budgets or appropriations bills are not codified.) Examples of codified federal food laws include the FD&C Act, which is codified at 21 USC 301-1012 (section 1 of the FD&C Act is 21 USC 301.) Many states have a state law equivalent to the food portions of the FD&C Act. States with state meat inspection programs will also have adopted a state meat and poultry inspection act. Quite often, both the FDA and state authorities will have concurrent jurisdiction over non-meat and poultry food manufacturing and storage facilities.

The FD&C Act has been amended over 20 times to include provisions related to drug efficiency and marketing studies, food quality protection, animal drugs, pediatrics, the use of animal species in drug testing, generic drugs, food allergen labeling, nutritional labeling and education, infant formulas, and others. The law was also amended to include the 2011 Food Safety Modernization Act (FSMA,

Public Law 111-353), the first significant food safety law to be passed in more than 70 years.

FSMA was primarily designed to require food supply chain participants, both nationally and internationally, to adopt *preventive* thinking, planning, and systems. Important provisions of FSMA pertain to inspections of records, registration of food facilities, hazard analysis and risk-based preventive controls, performance standards, standards for produce safety, protection against intentional adulteration, authority to collect fees, a national agriculture and food defense strategy, food and agriculture coordinating councils, building domestic capacity, sanitary transportation of food, new dietary ingredients, harvest processing of raw oysters, imports, and alcohol-related facilities. FSMA also requires foreign suppliers of food imported into the United States to conform to the same requirements as domestic suppliers.

Local Laws: Ordinances

Generally, local jurisdictions such as counties and cities have the ability to pass laws. Typically, these laws are referred to as ordinances and can be codified into a local government code. The ability of a local government to adopt ordinances related to food, however, varies greatly between states. For example, Iowa only allows food regulations to be adopted by the state, whereas Missouri's food regulations are nearly entirely adopted at the city or county level. Some states have very strong "home rule" provisions in the state constitution or state law that prohibit the state from regulating many areas involving public health, safety, and welfare. Most commonly, local governments with the authority in the food area adopt a retail food code (affecting mainly restaurants and/or grocery stores), yet do not routinely adopt food processing standards (affecting wholesale food manufacturing plants). Food processing standards are typically adopted at the state level.

How Rules and Regulations Differ from Statutes (Laws)

Administrative Law (Regulations)

Regulations, which have the effect of law, are typically more detailed requirements developed by state or federal agencies and are referred to by a variety of titles, most commonly rules, or administrative rules. The Congress and state legislatures have turned to rulemaking with the recognition that experts must draft the detailed or technical regulatory requirements and that rulemaking is often influenced by changing circumstances.

Although the regulatory process may vary slightly from state to state, the procedure is generally as follows. First, a statute must grant a particular agency the

authority to develop regulations. For example, the US Congress may enact a food safety law and then delegate authority to the US Department of Health and Human Services (HHS) to develop regulations in order to enforce the law. After being drafted by an agency, proposed regulations are then published (e.g., in the Federal Register or state equivalent), to provide notice of the proposed rulemaking and to invite an opportunity for comment within a certain period of time. This process may also include public hearings and other methods of soliciting public comments, and the timeline for receiving comments may also be accelerated or even waived for "emergency rulemaking." Based on the public comments, the proposed regulations may be amended by the agency. Generally, the agency will publish a follow-up notice that describes the comments received along with the agency's response to the comments. Once the final regulation is adopted, the agency will submit the rule for publication with an effective date. Final federal rules will be published in the Federal Register and codified in the Code of Federal Regulations, which is updated annually.

Other requirements involving the adoption of regulations exist, such as submitting the draft and final regulations to the Office of Management and Budget (OMB), which is one of the executive offices of the White House, or submitting the regulation to the state governor's office for review. Additionally, an agency cannot create regulations or rules in a capricious manner and must develop rules according to the Administrative Procedures Act. Similar to statutory law, rules and regulations are subject to judicial interpretation (Fig. 3.3).

Generally, courts can invalidate an agency's rulemaking for two reasons: the agency has exceeded its statutory authority, or the agency's rule is arbitrary and capricious, i.e., not based on a rational reason. Procedural violations, such as

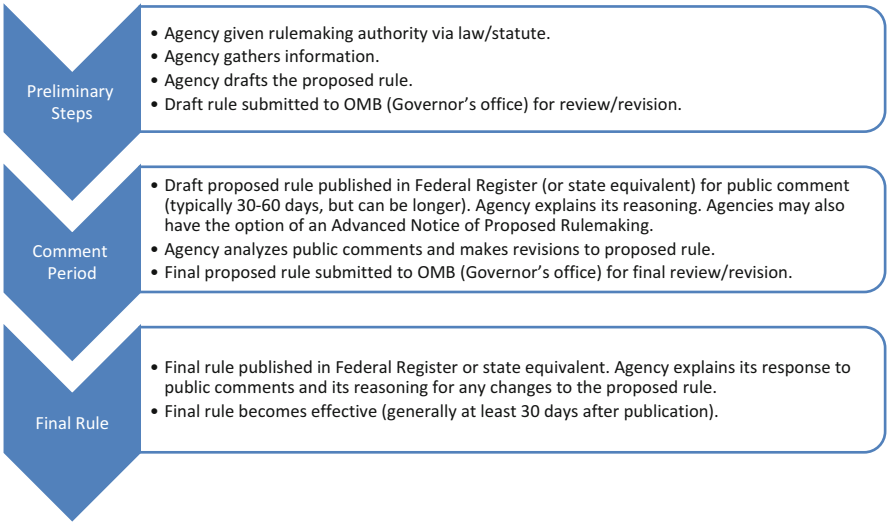

Fig. 3.3 The state and federal rulemaking process

improper notice and comment by the public, can also result in an invalid rule. Exceeding statutory authority means the agency has gone beyond the rulemaking delegation provided to the agency by the Congress or the legislature. For example, a state legislature may approve a law allowing the state department of health to adopt regulations related to "food." However, if the department then adopts regulations related to tattoo ink, a court may rule that the agency has exceeded its statutory authority.

The Differences between Federal, State, Local, Tribal, and Territorial Authorities

Federal Authorities

There are a number of federal agencies with varying degrees of authority over food safety. However, the principal authorities lie within the FDA, the US Department of Agriculture Food Safety and Inspection Service (FSIS, www.fsis.usda.gov), and the US Centers for Disease Control and Prevention (CDC, www.cdc.gov).[2] These authorities are codified in federal law as follows:

- FDA: Federal Food, Drug, and Cosmetic Act, Public Law 75-717; 52 Stat. 1040 (1938); 21 U.S.C. 301 et seq. (as amended by the Food Safety Modernization Act, January 4, 2011); Fair Packaging and Labeling Act, Public Law 102-329, 106 Stat. 847 (1992) 15 U.S.C. 1451 et seq.
- FSIS: Federal Meat Inspection Act Public Law 59-242, Stat. 1260 (1967), 21 U.S.C. 661 et seq.; Poultry Products Inspection Act of 1957, Public Law 85-172, 21 U.S.C. 454 et seq.
- CDC: Public Health Service Act 37 Stat. 309 (1912) 42 U.S.C. 201 et seq.

On a number of occasions, the Congress has assigned the FDA the authority to ensure national uniformity in food safety and labeling by expanding that authority through *preemption*, i.e., preventing state and local authorities from revising or modifying certain federal requirements. For example, certain labeling requirements for foods and dietary supplements cannot be changed by state or local governments. This preemption enables a food manufacturer to print a single label for a product that can be sold nationally without changes that might be made to the label for each state in which the product is sold. The same is also true for certain commodities, such as shell eggs. However, states are able to impose requirements if there is no similar provision in federal rules. For example, some states require that labels of certain beverages include a statement about the value of the container deposit.

[2] The Federal Trade Commission (FTC) has authority over the advertising of foods. Simply put, the advertising must be truthful and not misleading. The FTC often requests laboratory and/or tests or the results of studies to determine if certain advertising claims for a food are truthful.

No federal rule preempts these state requirements, which is why soft drink cans have "ME-CT-VT-MA-NY-OR-IA-5¢, MI-10¢, CA-CRV" printed on the can or bottle.

On the other hand, FSIS has preemptive authority over the safety and labeling of all amenable types of meat and poultry such as chicken, pork, beef, and turkey. States are prohibited from enacting any laws or adopting any rules that vary from federal requirements for these species. Many states of states have programs dealing with the slaughter and processing of meat and poultry within their borders, covering close to 2,000 small or very small plants (NASDA 2014). All of these programs are run cooperatively with FSIS (the programs do not vary from federal requirements) and are deemed either "equal to" or "same as" FSIS inspection, depending on how the product is produced, sold, or distributed (interstate vs. intrastate). A "mark of inspection" can be found on any meat or poultry product that has been inspected under FSIS authority,[3] along with USDA FSIS legend and plant number where the product was produced.

CDC implements the requirements of the US Public Services Act, which includes the regulation of food safety on interstate carriers such as ships, trains, and buses. Additionally, CDC is the primary federal agency involved in the investigation of foodborne illness outbreaks found to cross state lines. The agency provides considerable support, when requested by a state or local jurisdiction, with respect to any foodborne illness investigation. CDC also has a cadre of environmental health specialists who reside within some state agencies to provide support with respect to food safety and environmental health issues.

The FDA and FSIS have civil and criminal authorities to enforce federal food safety and labeling laws and regulations. Recently, the Congress enacted FSMA, which expands FDA authority to embargo foods, require mandatory recalls (as opposed to voluntary recalls by the manufacturer), issue administrative penalties, inspect foreign food manufacturers who wish to ship product to the United States, and require many types of food establishments to develop and implement a food safety plan to *prevent* food contamination and the resulting illnesses.

The FDA does not have authority to embargo or stop the use of food processing equipment. However, FSMA granted FDA the authority to revoke a facility's registration, which has the effect of stopping the facility from manufacturing and selling. Additionally, court-issued injunctions can temporarily prevent a firm from manufacturing a certain product until the firm comes into compliance, and an injunction can be made permanent if the firm is found to have committed multiple offenses. What is more, FSIS has the authority to "tag" processing equipment in a plant under its jurisdiction, which has the effect of shutting down the facility until the firm comes back into compliance. Both FDA and FSIS can embargo (stop sale) foods that are suspected of being adulterated or misbranded, although FDA must follow up an embargo/stop sale with a hearing, while FSIS does not.

[3] State-inspected meat products *may* show a state seal and not the USDA legend, if the product is not considered "interstate." Additionally, some states may have jurisdiction over plants that ship interstate, and those products will have a USDA legend showing a state designation.

FDA also has the authority to review the safety of all ingredients used in foods, including packaging materials where chemicals may migrate into the food. Many long-used ingredients are not required to go through stringent safety testing and are regulated as "GRAS," meaning "generally recognized as safe," such as water or salt. However, as companies develop new ingredients, the FDA has the responsibility to ensure that those ingredients are safe at the levels used in the food. This process is used for regulating food additives and color additives. FSIS, along with states, relies on FDA to determine the safety of food additives.

Both FDA and FSIS are charged with the enforcement of the various federal laws dealing with intentional contamination of the food supply, including the use of weapons of mass destruction, such as ricin. The agencies work side by side with the Federal Bureau of Investigation (FBI, www.fbi.gov) in such situations.

Even though the FDA has no authority to inspect or otherwise regulate retail food establishments, the agency has developed the Model Food Code, a model code and reference document to help state and local agencies regulate retail operations such as restaurants, food stores, food vendors, and foodservice operations in schools, hospitals, assisted living facilities, and childcare centers. The Food Code is updated every few years, and changes to the Code are based largely on recommendations made by the Conference for Food Protection (CFP, www.foodprotect.org), a national organization consisting of scientists, policy makers, industry, consumers, and academia (FDA 2013a).

State and Local Authorities

Generally, state and local food safety agencies are free to enact laws, ordinances, and rules dealing with food safety and labeling. However, in areas where federal law has preemptive authority, any enforcement conducted at the state and local level must be done through the use of laws and regulations identical to those at the federal level.

FDA has a credentialing process whereby state and local employees can be given the authority to enforce federal law and to view (federal) documents that otherwise would remain off limits. Even so, many states have "sunshine" laws (or Freedom of Information Acts) that prevent FDA credentialing because any evidence reviewed by states would then become available to the public in those states.

Some states adopt federal regulations by reference through a clause in their state law that automatically adopts federal regulations as state rules; however, some states cannot adopt federal rules by reference and must rewrite all or portions of the federal regulation into a state rule. The federal regulations typically adopted include those on good manufacturing practices (GMPs), low-acid canned food, acidified foods, food and color additives, infant formula, seafood HACCP (Hazard Analysis and Critical Control Points), juice HACCP, and bottled water. Some state constitutions have a non-delegation clause that prevents adoption of future, not yet written, updates, and each revision of a federal law or model.

States are also free to fill voids in food safety regulation that have not been addressed at the federal level. For example, many states have adopted laws and regulations dealing with food salvage, smoked fish, and vended water (in addition to federal bottled water regulations).

States have traditionally had stronger enforcement authorities than those found at the federal level. These authorities include embargo/stop sale authorities that are used frequently, administrative penalties that are often used in place of civil or criminal actions, and summary closure authority to immediately shut down an operation that poses an imminent health hazard. In order to make civil and criminal actions easier and faster, states normally gain the cooperation of state and county courts and the offices of the state's attorneys general rather than gain the support of the US Department of Justice (www.justice.gov), through which the FDA must go to engage in any civil or criminal prosecutions.

Most states have the authority to collect samples during inspections, and many state and local jurisdictions have laboratories capable of analyzing those samples. The FDA has laboratories to conduct analyses, and many states have laboratories that meet requirements to be part of the Food Emergency Response Network (FERN, www.fernlab.org) which can also provide surge capacity for analyses of samples across the network.

Nearly all state and local jurisdictions, either working independently or in a coordinated effort, conduct foodborne illness investigations. While CDC has primary jurisdiction at the federal level for outbreaks crossing state boundaries, the agency coordinates with the FDA, FSIS, and state and local agencies to provide expertise and technical assistance. At the state level, food inspection programs coordinate with epidemiological teams and laboratory services, sometimes across agency boundaries when food safety is handled within a department of agriculture rather than a department of health. Many illness investigations begin with local health departments, who often are the first receivers of information through surveillance systems and the first to respond. (Investigations are covered in greater detail in Outbreak Investigations, chap. 8)

State and local governments have the authority to regulate restaurants and grocery stores (as well as other operations that serve food directly to consumers like school cafeterias, hospitals, and temporary food vendors at fairs or similar events). Currently, this regulation is done primarily through the adoption of one of the various versions (1993–2013) of the Model Food Code. As previously mentioned, FDA does not have authority to inspect at retail; however, the agency jointly developed the Model Food Code with input from states, locals, academia consumers and regulated industry. Even so, the states and locals are free to pick and choose which chapters of the Food Code to adopt and enforce and are free to add and/or delete provisions. Nearly all states have adopted some version of the Food Code. Even though there is no federal preemption with the Food Code, there is a "push" from FDA and industry for states to be as uniform as possible.

Many local health departments have also adopted versions of the Food Code, and a number of states require their local health departments to be uniform with state requirements. Areas that may differ from one jurisdiction to another include date-marking of foods, the manufacture and sale of smoked and cured meat,

requiring variances for certain types of food processing performed in retail settings, mandatory training of managers and employees and/or the number of hours of training required, the regulation of temporary foodservice establishments and farmers markets, and the regulation of home-based businesses (cottage foods).

Some states require mandatory food worker training and/or manager certification, and some jurisdictions still require a "health card" for individual food workers, though the public health value of these cards is quite limited. Local agencies in resort areas often require food workers to be vaccinated against Hepatitis A. Some states and many locals conduct "plan reviews" before retail facilities can open for operation or undergo extensive remodeling. Local plumbing codes may also vary from one jurisdiction to the next.

States and locals have the authority to require licenses and permits of manufacturers, wholesalers, and retailers. The license/permit fees vary, with some states and locals charging thousands of dollars, and others charging as little as $25.00 or exempting fees altogether for certain establishments. Some local jurisdictions actually fund most or all of their environmental health programs with the funds generated from the permitting of retail establishments, while other jurisdictions use a combination of fees, fines, and tax dollars.

Many states have meat inspection programs, which are reviewed annually by FSIS to ensure that the programs remain equivalent to the federal inspection program. Although federal law was recently amended to permit, under certain circumstances, the interstate shipment of state-inspected meat and poultry, for the great majority of establishments inspected under these programs, the product can only be sold intrastate, i.e., within the state where the product was manufactured. Many states also permit the slaughtering and sale of non-amenable species, such as deer, exotic game, rabbits, snakes, and alligators. These non-amenable species are under the jurisdiction of the FDA (if interstate sales) and of the states issuing permits and conducting inspections. The species are sometimes inspected (pre- and post-mortem) by state veterinarians. However, since 50 % of the cost of operating the state programs is paid by FSIS, some states are reluctant to utilize "meat inspection" staff to conduct inspections of non-amenable species, so there is great variability of inspection of non-amenable species between states (Bungo 2013). This reluctance is a problem area that has yet to be completely addressed, although AFDO has model regulations that can be followed.

Under current federal law, there is a means by which states can appeal to the federal government to avoid federal requirements that are preemptive. For example, if a state produces a product on which the state economy relies heavily, the state may be able to obtain an exemption from certain federal food labeling requirements.

Tribal (Native American) Requirements

By federal law, Native American reservations are autonomous, i.e., not subject to most federal and state laws and therefore free to pick and choose how the reservation enforces various laws within the reservation. Tribes are free to adopt the Model

Food Code or implement some other means of food safety regulation. Today, less than half of the Native American tribes have adopted some version of the Model Food Code. However, there are instances where casinos on Native American soil have contracted with the Indian Health Service (www.ihs.gov), a branch of the federal government charged with providing various kinds of assistance to the tribes, to conduct food safety inspections using the latest version of the Model Food Code.

Jurisdictional Interaction and Integration of the Food Safety System

FSMA addresses the concern that the federal government alone cannot ensure food safety without the assistance of state, local, and tribal governments. Consequently, what is required is an integrated system under which all jurisdictions make a coordinated effort to conduct inspections and foodborne illness investigations, collect and analyze samples, train inspectors, and educate industry and consumers. Jurisdictions often overlap, highlighting the importance of sharing information and establishment of inspection inventories to eliminate duplication of efforts and complement agency regulatory programs. Many organizations and associations strongly encourage forms of collaboration, such as the FDA contracting with states to conduct manufacturing and wholesale inspections for the FDA, since neither the states, locals, nor the FDA can ensure enough food safety resources by themselves. In fact, a 2008 survey of state and local food safety programs conducted by AFDO found that states and locals conducted 4,619,256 inspections (manufacturing, wholesale, retail), collected 394,070 samples, and were involved in 1,244 recalls (AFDO 2013).

State and local agencies must also work with the FDA in the regulation of imported foods. Although the FDA has the primary responsibility to ensure adulterated and misbranded foods do not enter US commerce, the agency does not have the resources to guarantee that importation of adulterated foods does not occur. Less than 1 % of imported food is inspected by the FDA (FDA 2013b), and state and local regulatory officials often find adulterated/misbranded products in commerce within their respective jurisdictions. The key to preventing such products from reaching the consumer is coordination of efforts. Currently, several states have partnership agreements with the FDA regarding the regulation of imports. The FDA is increasingly accepting laboratory findings from the states and issuing import alerts on violative imported foods.

The Role of Model Laws, Regulations, and Guidance Documents

In addition to statutory law, a government agency may use model laws and guidance documents to further explain a rule or regulation. These interpretive guidelines do not have the effect of law, but do indicate how the regulatory authority is likely to

view compliance or enforcement of a regulation. Industry often looks to agency model guidance to determine best practices to comply with regulations. The FDA, for example, has drafted a guidance document to help industry meet the regulatory requirements pertaining to acidified foods. The guidance serves as a tool for developing policies, procedures, and practices that meet the expectations of regulatory agencies.

The FDA Model Food Code provides food control jurisdictions at all levels of government with a scientific, technical, and legal basis for regulating retail and food service establishments like as restaurants, grocery stores, and institutions such as nursing homes. Federal, state, local, tribal, and territorial regulatory agencies use the Model Food Code to develop or update their own food safety rules and to be consistent with national food regulatory policy (FDA 2014). (Note: an array of guidance documents from the FDA is available here: http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/default.htm.)

The Rapid Response Team (RRT) Best Practices Manual, available through the FDA Office of Partnerships, helps facilitate the creation of integrated RRTs for more coordinated, efficient, and timely responses to foodborne outbreaks or other food-related emergencies on a national basis. The RRT program is a cooperative effort between the FDA and state partners. The FDA provides funding to states for improving rapid response to all-hazards food or feed emergencies and invests in strengthening food program infrastructure. State agencies in turn form and train teams that are made up of individuals with a range of expertise such as food inspectors, epidemiologists, laboratory personnel, environmental health specialists, veterinarians, feed control officials, and other food-related professionals. A key initiative of the RRT program is to develop models that can be used and adopted by other states; the RRT Best Practices Manual is a product of that initiative (FDA 2013c).

Conclusion

Many laws and regulations have been adopted at the federal, state, and local levels to protect public health by helping to ensure a safe food supply, e.g., the Food, Drug, and Cosmetic Act (FD&C Act), the Food Safety Modernization Act (FSMA), and local ordinances. The process of adopting laws and regulations at all levels includes many steps and opportunities for public and industry input. Agencies adopt model regulations (such as the Model Food Code) and guidance documents (such as best practices manuals) to help the food industry comply with laws and regulations, promote uniformity across jurisdictional lines, and represent the agencies' current thinking in an area. Together, all of these activities help provide the regulatory framework for the integrated food safety system (IFSS) in the United States.

Take-Home Message

Agencies adopt regulations, as long as the agency is granted the authority to do so via a statute or ordinance. Uniformity in laws and regulations assists in enforcement across jurisdictions, makes compliance more achievable for the food industry, and advances the integrated food safety system in the United States.

Activity

Which is the best category for each of the items below: (a) a federal law or regulation? (b) a state or local law or regulation? (c) a federal guidance document? (d) none of the above?

- Juice HACCP
- Embargo
- Posting inspection scores
- FSMA
- Good manufacturing practices (GMPs)
- FDA Model Food Code
- Pasteurized Milk Ordinance
- Licensing
- Reportable Food Registry
- *Trans* fat bans at restaurants
- National Shellfish Sanitation Program

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Answer Key

What is the best category for each of the items below: (a) a federal law or regulation? (b) a state or local law or regulation? (c) a federal guidance document?

• Juice HACCP	a
• Embargo	b
• Posting inspection scores	b (state and local)
• FSMA	a
• Good manufacturing practices (GMPs)	a
• FDA Model Food Code	c
• Pasteurized Milk Ordinance	c
• Licensing	b (state and local)
• Reportable Food Registry	a
• *Trans* fat bans at restaurants	b (local)
• National Shellfish Sanitation Program	c

Chapter 4
Integrated Food Safety System (IFSS) Orientation

Joe Corby, Ron Klein, Gary Elliott, and John Ryan

Learning Objectives

- Discuss the impact of integrating the US food safety system and the benefits of integration.
- Discuss efforts to integrate the nation's food safety system.

Introduction

The integrated food safety system (IFSS) is a vision of joining government food safety resources and authorities at all levels into a more unified and coordinated system. Food protection professionals (FPPs) at all levels of government, regulatory

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agencies within the supply chain, and stakeholder engagement play key roles not only in avoiding duplication of efforts but also in strengthening the safety of food throughout the increasingly global food supply chain. This chapter will explore the impact of integration on the food protection system, the history and evolution of food safety laws, and the national efforts to create an IFSS.

The Impact and Benefits of Integrating the US Food Safety System

Integrating resources to create the IFSS offers the best chance for: (1) improving the food safety system in a cost-effective manner, (2) eliminating duplication of efforts, and (3) allowing government officials to meet food safety challenges in a more strategic fashion. The challenge of creating the IFSS can be seen in Fig. 4.1, a visual display created by the International Food Protection Training Institute (IFPTI) that represents the components of an integrated food safety system.

The inner circle of the wheel represents the ultimate goal of an IFSS (safe food). Moving outward from the center, the light green ring represents the stakeholders that play a critical role in ensuring safe food, including retailers, law enforcement officials, food processors, distributors, and consumers. All of these stakeholders rely on, and help develop and advance, the "tools" represented in the dark blue ring, ranging from laws/regulations, voluntary guidance documents or model codes, training and certification programs, and performance standards. The outer ring

Fig. 4.1 IFPTI visual display of an IFSS (unpopulated)

Fig. 4.2 IFPTI visual display of an IFSS (populated)

represents the three different types of "actions" that can be taken to help ensure safe food. To illustrate, a manufacturer could *prevent* a foodborne illness from occurring by establishing preventive control measures (e.g., a Hazard Analysis and Critical Control Points HACCP Plan); a local health department could *intervene* in a problematic situation (e.g., conducting an inspection at a restaurant after receiving consumer complaints about filthy conditions); or a regulatory agency such as FDA could *respond* to a problem after the problem has occurred (e.g., recalling an adulterated product that caused injury or harm). Figure 4.2 depicts the fully-populated IFPTI display of an IFSS.

The vision within an IFSS is that the federal government, working in collaboration with state, local, tribal, and territorial governments, will provide leadership by setting standards, evaluating programs, and providing technical support, training, and funding if needed. The federal government would also continue to conduct food safety activities in a coordinated fashion with state and local agencies, without duplicating efforts. For example, federal agencies could focus on imported foods, while state and local agencies could focus efforts on domestic food establishments. An IFSS could yield numerous benefits: coordinated response efforts, leveraging of resources, enhanced ability to respond to multistate outbreaks, improved risk assessment at domestic food facilities, greater food surveillance through integration of inspection information, and improved and more efficient rapid response capacity.

Integration is designed to address the problem of fragmentation in our food safety system that exists at all levels. Today there are approximately 70 mutual agreements related to food safety involving approximately 15 federal agencies. There are about 75 state agencies that perform food safety inspection work, and many other agencies play smaller parts in inspection efforts. Additionally, there are approximately 2,800 county, city, and township food safety agencies (IFPTI 2012).

The original vision of the IFSS was formally presented by the Association of Food and Drug Officials (AFDO, www.afdo.org)[1] at a national food safety meeting in Sacramento in 1997. The idea was embraced by the US Food and Drug Administration (FDA, www.fda.gov) and soon led to the formation of the National Food Safety System project (NFSS). Unfortunately, the NFSS effort lost funding and the project was scrapped. AFDO, however, continued to promote the IFSS concept for over a decade. More recent FDA-promoted national efforts included the FDA Food Protection Plan (www.fda.gov/Food/GuidanceRegulation/FoodProtectionPlan2007/) and the FDA Import Safety Action Plan (www.fda.gov/downloads/ICECI/EnforcementActions/EnforcementStory/UCM129822.pdf), which recognized the importance of partnerships with state and local government agencies. The biggest push toward integration, however, has resulted from the passage of the Food Safety Modernization Act of 2011 FSMA, (Public Law 111-353), which mandated FDA to work with its state and local government partners.

Efforts to Integrate the Nation's Food Safety System

Cooperative Programs

There are working examples of cooperation and collaboration between federal and state agencies and other stakeholder groups that demonstrate what is possible with respect to full integration of the food safety regulatory system. For instance, the FDA, the US Centers for Disease Control and Prevention (CDC www.cdc.gov), and the US Department of Agriculture Food Safety and Inspection Service (USDA FSIS www.fsis.usda.gov) have collaborated with state and local regulatory agencies, academia, industry, and consumers through the Conference for Food Protection (www.foodprotect.org) on the development and publication of the FDA Food Code (www.fda.gov/FoodCode/) since its initial release in 1993. The Food Code, which underwent a sixth revision in 2013, has provided the foundation and the national standard for retail food safety regulation at state, local, and tribal levels. The FDA Grade "A" Pasteurized Milk Ordinance (http://www.fda.gov/downloads/Food/GuidanceRegulation/UCM209789.pdf) is another model code with a history of cooperation and collaboration that dates back to the 1920s.

There are three distinct federal-state cooperative programs related to food safety under FDA's purview: the Milk Safety Program (http://www.fda.gov/ForFederalStateandLocalOfficials/PartnershipsContracts/ucm303972.htm), the National Shellfish Sanitation Program (http://www.fda.gov/food/guidanceregulation/federalStatefoodprograms/ucm2006754.htm), and the Retail Food Protection

[1] AFDO is an international nonprofit organization composed of food safety officials from various federal, state, and local agencies, along with food industry officials and consumer advocates.

Program (http://www.fda.gov/Food/GuidanceRegulation/RetailFoodProtection/ucm2006807.htm). These three programs have shown relative success in building the cooperation and collaboration needed for the integration of food safety efforts and standards. Making the IFSS a reality will require looking at and building upon such programs that are already in place.

The cooperative partnerships with the states are linked to FDA signing separate memoranda of understanding (MOUs) with the National Conference on Interstate Milk Shipments (NCIMS, www.ncims.org), the Interstate Shellfish Sanitation Conference (www.issc.org), and the Conference for Food Protection. There are two distinct units within FDA that work with state and local regulatory authorities on these cooperative programs, the Center for Food Safety and Applied Nutrition (CFSAN) (http://www.fda.gov/aboutfda/centersoffices/officeoffoods/cfsan/default.htm) and the Office of Partnerships (http://www.fda.gov/ForFederalStateandLocalOfficials/StateActionInformationNewsletterSAIL/), which serves as the primary contact for states through the Regional Retail Food, Milk, and Shellfish Specialists.

Milk Safety Program

Research conducted at the beginning of the twentieth century led to processes and practices, such as pasteurization, to help control the spread of disease caused by milk. The research also led to the creation of the first model codes to assist state and local governments in the prevention of foodborne illness, including the Grade "A" Pasteurized Milk Ordinance, published in 1924 and revised numerous times, most recently in 2015.

NCIMS was created in 1946 to develop a certification program for interstate milk shippers. The first NCIMS was held in 1950 and represented the beginning of federal, state, and industry cooperation on a milk safety program. The NCIMS continues to be held every 2 years.

The roles and responsibilities of FDA under the Milk Safety Program include:

- Promoting adoption of the regulatory standards of the model Grade "A" Pasteurized Milk Ordinance.
- Certification of state personnel to implement the state's pasteurized milk and milk products program.
- Training.
- Biennial evaluation of state milk control programs.
- Evaluation and approval of milk laboratories.
- Conducting check ratings and single service audits for sanitation compliance by listed shippers.

National Shellfish Sanitation Program (NSSP)

Not unlike the Milk Safety Program, the cooperation between federal and state regulatory programs for shellfish began in 1925 with a conference in Washington, DC. The NSSP was created when the US Public Health Service was asked to help state and local public health officials to control disease associated with shellfish. States and FDA looked at the success of the NCIMS and used the program as a model for developing a similar organization for shellfish, the NSSP. In 1982, the Interstate Shellfish Sanitation Conference (ISSC) was formed in Annapolis, Maryland, composed of state regulatory officials, industry officials, FDA, and other federal agencies including the National Marine Fisheries Service (NMFS www.nmfs.noaa.gov) and the Environmental Protection Agency (EPA www.epa.gov).

The primary components of the NSSP aimed at keeping contaminated shellfish out of the consumer marketplace include: inspecting facilities that handle shellfish, determining areas that are suitable—and not suitable—for harvesting shellfish, and performing laboratory testing of shellfish and water samples. States generally take the lead role through licensing, compliance, enforcement, and other authorities, while FDA participates through regional shellfish specialists, seafood specialists at the FDA Center for Food Safety and Applied Nutrition, and laboratory personnel that provide states with technical assistance, guidance, and training.

Retail Food Protection Program

The FDA Retail Food Protection Program (http://www.fda.gov/Food/GuidanceRegulation/RetailFoodProtection/ucm2006807.htm) provides assistance to thousands of state, local, territorial, and tribal agencies responsible for regulating the retail food industry, which generates enormous revenue annually. While state, local, territorial, and tribal agencies are responsible for permitting, inspecting, and enforcing regulations, FDA works closely with these agencies through the Retail Food Protection National Team (http://www.fda.gov/forfederalstateandlocalofficials/partnershipscontracts/ucm303970.htm), which comprises retail food specialists, trainers, and food safety experts.

FDA activities under the Retail Food Protection Program include: (1) developing and promoting the FDA Food Code and the Voluntary National Retail Food Regulatory Program Standards, (2) providing training and guidance to state and local food safety authorities and to the food industry, (3) identifying research needs, and (4) ensuring food safety at national events (sporting events, political conventions, inaugurations, etc.) and in disaster areas.

Development of the Retail Food Program was similar to that of cooperative programs related to milk safety and shellfish sanitation. Similar to the NCIMS and the ISSC, the retail food segment held a Conference for Food Protection (CFP, www.foodprotect.org) in 1971, sponsored by FDA and the American Public Health Association (www.apha.org). The focus of this first conference was microbiological

aspects of food safety for individuals representing industry, government, and consumers. The second CFP, held in 1984, addressed not only the microbiology of food safety, but also toxicological issues. By the 1988 CFP, organizational by-laws and a constitution had been approved, and the CFP served as an effective forum for current and future food safety issues. To this day, the conference is well attended, and voting members have made many pertinent recommendations to FDA regarding the development and revision of the Model Food Code.

Cooperative Agreements

Cooperative agreements related to the Manufactured Food Regulatory Program Standards (MFRPS) were made available to states beginning in 2011. These agreements help manufactured food regulatory programs at the state level maintain conformance with the MFRPS, which will help state regulatory programs focus their activities on reducing foodborne illness resulting from manufacturing, processing, or holding facilities.

The Manufactured Food Regulatory Program Alliance (MFRPA, http://www.afdo.org/mfrpa) was formed in 2013 under the Alliance for Advancing a National Integrated Food Safety System Cooperative Agreement Program between FDA and AFDO. This alliance, consisting of state food manufacturing program managers, works collaboratively with FDA to accomplish the following objectives:

- Establish a network of state manufactured food program managers.
- Conduct surveys of state, local, tribal, and territorial manufactured food programs.
- Identify and track state laws and regulations.
- Provide task-oriented guidelines, as needed.
- Identify and support pilot programs in states, as needed, to support implementation of the MFRPS.
- Build community relations and networks.
- Provide training and outreach.
- Update, enhance, and improve the Directory of State and Local Officials.
- In support of FSMA, work with FDA to establish operational partnerships that assist in the capacity-building of state and local agencies, as well as establishing and implementing strategies for improving state and local food safety efforts (AFDO 2013a).

Other cooperative agreements assist state, local, tribal, and territorial agencies to achieve conformance with the Voluntary National Retail Food Regulatory Program Standards (VNRFRPS). The VNRFRPS apply to retail food regulatory programs and are focused on helping the retail food industry reduce the risk of foodborne illness.

The International Organization for Standardization (ISO) and the International Electrotechnical Commission (IEC) 17025:2005 Accreditation for State Food Testing Laboratories Cooperative Agreements provide funding to food testing laboratories to help laboratories achieve and maintain accreditation by an impartial and internationally-recognized accrediting body. Funding under the agreement is also available to help

laboratories expand the scope of their accreditation. The addition of accredited food testing laboratories will increase the analytical capacity of FDA and enhance efforts to protect the food supply. Data-sharing will be used for surveillance purposes and during responses to foodborne outbreaks and recalls. Laboratory accreditation will also assist state agencies in achieving conformance with Standard 10 of the MFRPS, which pertains to regulatory laboratory services.

The cooperative agreements for food safety and security monitoring provide funding to Food Emergency Response Network laboratories (FERN, www.fernlab.org). FERN integrates federal, state, and local food testing laboratories into a network that is able to respond to emergencies involving biological, chemical, or radiological contamination of food (FERN 2013a). FERN has the ability to gather laboratory testing data, look for patterns in the data, and alert authorities to potential foodborne illness outbreaks. The FERN Steering Committee comprises representatives from state agriculture; environmental, public health, and veterinary laboratories; FDA, CDC, USDA FSIS; the USDA Agricultural Marketing Service; the Federal Bureau of Investigation; EPA; the Department of Homeland Security; and the Department of Defense (FERN 2013b). The FERN Cooperative Agreement funding allows registered FERN labs to conduct increased sample analyses when response events require a large volume of testing of implicated food products.

Under a cooperative agreement to build an integrated food and animal feed laboratory system, the Association of Public Health Laboratories (APHL, www.aphl.org) is collaborating with AFDO and the Association of American Feed Control Officials (AAFCO, www.aafco.org) to strengthen and integrate food and feed testing laboratories and help these laboratories achieve and maintain ISO/IEC 17025:2005 accreditation. Other objectives of this agreement include: developing laboratory training programs around accreditation; reaching national consensus on the sharing of analytical data; improving communication among federal, state, and local testing laboratories and with their associated regulatory and public health programs; expanding a proficiency testing program for feed laboratories; and strengthening partnerships with clinical laboratories to improve the rapid submission of isolates to the public health system (AFDO 2013b).

Finally, a cooperative agreement between FDA and state regulatory agencies has helped develop rapid response teams (RRTs), which coordinate integrated, multiagency responses to food and feed emergencies. There are currently 18 RRTs within the program, representing a total of 14 FDA Office of Regulatory Affairs districts across the US. Since 2008, RRTs have conducted integrated, multiagency responses to all-hazards food (and feed) emergencies and have involved federal, state, and local partners not only across jurisdictions, but also across disciplines such as environmental health, epidemiology, laboratory, law enforcement, and emergency management. The second edition of the *RRT Manual of Best Practices* (called the RRT Playbook) is available upon request from FDA (FDA 2014). RRTs also play a role in FDA's Coordinated Outbreak Response and Evaluation (CORE) Network, which utilizes all key, strategic FDA resources in place in the field to manage outbreak response, along with surveillance and post-response activities (FDA 2013c).

Cooperation Among Federal Agencies

Cooperation among federal agencies is every bit as important as the cooperative relationships between federal, state, local, tribal, and territorial agencies. While these cooperative relationships are not technically cooperative programs or cooperative agreements, the relationships have an important impact on the quest for a truly integrated food safety system. FDA, for example, has cooperative relationships: with CDC regarding the collection of epidemiological data and information related to foodborne illness outbreaks; with USDA regarding updating the Food Code; and with the National Marine Fisheries Service regarding the Seafood Inspection Program, which advances commercial grade standards for fishery operations, develops health and sanitation standards for the industry, provides inspections, grades products, provides certification services, and helps ensure the proper labeling of fish and fishery products.

Interagency Food Safety Analytics Collaboration

CDC, FDA, and the USDA FSIS recently created the Interagency Food Safety Analytics Collaboration (IFSAC) to improve coordination of federal food safety analytics efforts and examine priorities related to food safety data collection, analysis, and use. One of IFSAC's primary objectives involves estimating the most common food sources responsible for specific foodborne illnesses (CDC 2014a). Multiple sources of data are needed to make these estimates, including data from outbreak investigations, infections not associated with outbreaks, and food product testing (CDC 2014b).

Federal-State Cooperation

For many years, federal-state food safety programs have been designed so that states are actively involved in a cooperative fashion regarding the development of policy and procedures. Some examples of these federal-state cooperative programs include:

USDA Cooperative Programs—State meat and poultry inspection programs operate under a cooperative agreement with USDA FSIS. Under the agreement, a state program must enforce requirements "at least equal to" those imposed under the Federal Meat Inspection Act and the Poultry Products Inspection Act (USDA FSIS 2004). USDA FSIS covers up to 50 % of the operating funds and provides guidance and training to states when needed. State food safety programs and state grading and certification programs also operate under cooperative agreements with the USDA Agricultural Marketing Service (AMS, www.ams.usda.gov) in a multitude of areas that include Good Agricultural Practices inspection (GAPs), fruit and vegetable

grading programs, egg grading and inspection, and country of origin labeling. USDA AMS provides program oversight, training, and funding.

FDA Contracts—FDA provides contracts to state agencies for the purpose of conducting manufactured food inspections, animal feed inspections, egg inspections, and tissue residue inspections. Each state negotiates with FDA the cost for performing this work and receives an agreed-upon funding. In some states the funding is used for staff, inspection equipment, and training.

Pesticide Data Program (*PDP*)—The PDP, initiated in 1991 by USDA AMS, includes a number of state programs that collect and test produce and other consumable products for pesticide residues. The PDP produces an annual summary of the results, which are used by EPA to support its dietary risk assessment process and pesticide registration process.

Environmental Protection Agency (*EPA*)—EPA's Office of Pesticide Programs provides cooperative agreement funding in support of state pesticide programs conducted by State Pesticide Regulatory Agencies. These agreements are designed to integrate the enforcement and regulation of pesticides under federal law (the Federal Insecticide, Fungicide, and Rodenticide Act of 1910) and help establish primacy of state regulatory programs.

50-State Workshops and Other Working Groups

In 1998, FDA hosted a 50-state workshop that was open to officials from all 50 states, five US territories, and the District of Columbia. The workshop allowed these officials an opportunity to identify strategies for addressing the challenges of a global food supply. Foundational to the workshop was the realization that a fully-integrated national food safety system, which utilized the resources and authorities of government at all levels, was needed.

The first 50-state workshop in 1998 was part of the "National Food Safety Initiative" that originated from a report to President Clinton in 1997. The theme of the meeting was creating a shared vision to make the nation's food supply safer than ever. Workgroups were formed to address issues such as information and data sharing, minimum standards, laboratory operations, and outbreak response. The entire effort was called the National Food Safety System project (NFSS) and continued up until 2001, when budgetary dollars for the project ceased to exist.

In 2007, FDA developed a comprehensive Food Protection Plan to address changes in food sources, production, and consumption. The plan presented a strategy to protect the nation's food supply from both unintentional contamination and deliberate attack. The Food Protection Plan built in prevention first, then intervention, and finally response. In addition, the plan recognized the importance of leveraging the resources of other stakeholders, including state and local government agencies (FDA 2013a).

Starting in 2008, 50-state workshops were initiated again under the auspices of the Partnership for Food Protection (PFP, http://www.fda.gov/ForFederalStateandLocalOfficials/FoodSafetySystem/PartnershipforFoodProtectionPFP/default.htm). The PFP, which was originally established to work on projects recommended at the 2008 50-state workshop, became the entity that would build the foundation of the IFSS. The PFP initially established a coordinating committee to manage all of the project activities designed to build the integrated system under the oversight of the PFP steering committee. FSMA called for enhanced partnerships and provided a legal mandate for developing the IFSS. This was a critical element that was missing during the 1998 NFSS project. PFP workgroups work on projects that support the development of the IFSS and are actively contributing to FSMA initiatives that support enhanced partnerships. Workgroups established through the PFP have addressed topics such as information technology, national standards, training and certification, performance measures and outcomes, response, and recalls.

In 2013, a new governance structure was established for the PFP. The coordinating committee was disbanded, and the steering committee was renamed the PFP governing council and took on many of the responsibilities of the former coordinating committee. The governing council is comprised of FDA, USDA, CDC, and state and local regulatory officials.

In addition to the PFP, a number of other groups were formed to assist in the enormous task of building and supporting this new national food safety system. In 2009, the White House announced the creation of a new Food Safety Working Group to advise the President on how to upgrade the US food safety system. The group, which is chaired by the Health and Human Service (HHS) Secretary and the Secretary of Agriculture, recommended a new, public health-focused approach to food safety based on three core principles: (1) prioritizing prevention, (2) strengthening surveillance and enforcement, and (3) improving response and recovery (President's Food Safety Working Group 2014).

Another group created to help build the national food protection system is the Council of Association Presidents (CAP, http://www.fda.gov/ForFederalStateandLocalOfficials/CommunicationbetweenFDAStateLocalandTribalOfficials/ucm250303.htm), which comprises 11 major state and local public health and regulatory professional associations. Members of CAP, whose outreach capacity reaches virtually every state and local public health official, include the presidents of the following associations:

- Association of American Feed Control Officials (AAFCO)
- Association of Food and Drug Officials (AFDO)
- Association of Public Health Laboratories (APHL)
- Association of State and Territorial Health Officials (ASTHO)
- Council of State and Territorial Epidemiologists (CSTE)
- National Association of City and County Health Officials (NACCHO)
- National Association of Local Boards of Health (NALBOH)
- National Association of State Animal Health Officials (NASAHO)
- National Association of State Departments of Agriculture (NASDA)

- National Environmental Health Association (NEHA)
- US Animal Health Association (USAHA) (FDA 2013b)

An additional group supporting the nation's food safety system is the FDA Integration Task Force, which was established in 2011. Members of the task force include senior officials from FDA's Office of Regulatory Affairs (ORA), CFSAN, the Center for Veterinary Medicine, and state and local agencies that are involved in the Partnership for Food Protection. The task force was asked to help ensure full adoption of an IFSS by giving priority to:

- The strengths and weaknesses of current federal-state partnership, taking into account the perspectives of officials from FDA and state and local agencies.
- Current federal policies and practices that are fostering or impeding development of full partnership.
- Specific actions FDA leadership can take to institutionalize the communication and operational practices required to achieve full partnership.
- An agenda for taking full advantage of FSMA's mandate for an integrated food safety system that strengthens the state and local role in the food safety system and builds a full partnership (FDA 2013d.)

Federal-State Contracts

FDA contract inspections, which have been in existence for many years, provide states with funding for resources and training while allowing FDA to increase coverage of the agency's food and feed establishment inventory and redirect agency resources to other priorities. These contract programs include:

- Egg Inspection Contract Program—to help states inspect egg-producing facilities for measures aimed at preventing *Salmonella* Enteritidis.
- Food Inspection Contract Program—to help states inspect food manufacturing facilities for compliance with state or federal rules and/or regulations that are specific to a particular commodity such as low-acid canned foods or seafood.
- Feed/Bovine Spongiform Encephalopathy (BSE) Inspection Contract Program—to help states inspect firms that manufacture, render, or transport animal feeds.

Grants

Various grants have been offered by FDA in order to help foster activities contributing to an IFSS. To illustrate, grants for Food Protection Task Force meetings have been available to states to help foster communication, cooperation, and collaboration among food safety stakeholders. Funding from these grants allows states to

provide a forum for all stakeholders of the food protection system—regulatory agencies, academia, industry, consumers, legislators, etc.—to help integrate an efficient statewide food safety and defense system (FDA 2012).

Alliances

Following passage of FSMA in 2011, several stakeholder alliances were developed to provide a forum for developing and delivering required training to industry and regulatory officials in specific food producing and manufacturing areas. The following alliances are actively involved with FDA:

The Seafood HACCP Alliance (SHA, http://www.afdo.org/Default.aspx?pageId=1186198) is a collaborative training program involving representation from three federal agencies (FDA: the USDA Cooperative State Research, Education, and Extension Service; and the US Department of Commerce Seafood Inspection Program). The Alliance also represents all respective state agencies through the AFDO regional affiliates, the ISSC, seafood industry trade associations, the National Fisheries Institute and the Seafood Products Association, and instructors from numerous academic, Extension Service, and Sea Grant College programs across the nation. The collaborative working structure is known as the SHA Steering Committee through which commercial, regulatory, or food safety expertise can be shared.

The Produce Safety Alliance (PSA, http://producesafetyalliance.cornell.edu/) is a collaborative project between Cornell University, USDA, and FDA designed to provide fresh produce growers, packers, and grower cooperatives with training and educational opportunities related to best practices and guidance.

The Food Safety Preventive Controls Alliance (FSPCA, http://www.iit.edu/ifsh/alliance/) is a broad-based public/private alliance consisting of key industry, academic, and government stakeholders. The mission of the FSPCA is to support safe food production by developing a nationwide core curriculum, along with training and outreach programs to help companies comply with preventive controls under FSMA related to human and animal food.

Finally, the Sprout Safety Alliance (SSA, https://www.iit.edu/ifsh/sprout_safety/) is a public/private alliance that will develop a core curriculum, along with training and outreach programs for stakeholders in the sprout production community related to sprout safety.

Integration Case Studies

AFDO began to track episodes of successful food safety integration and placed this information on the AFDO website, www.afdo.org. Many of these episodes are recorded by FDA, state agencies, and news blogs related to food safety. There are many

examples of successful integration including efforts related to identifying the source of an illness, investigating foodborne illnesses, recalling contaminated food from the marketplace, closing food companies because of rodent infestation, and sharing surveillance information. The following case studies demonstrate the importance of integration.

Gel Candies Case Study

When it was reported that a 4-year-old New Jersey girl had died from choking on a gel candy purchased from a grocery store, state food safety officials began to review surveillance data from FDA and other sources concerning the product. The data revealed that numerous children from around the world had been victims of choking deaths caused by the candy product. It was further revealed that the gel candy contained the ingredient konjac, which prevented the candy from dissolving when placed into one's mouth, and instead would become lodged in the throats of children, causing them to choke.

Due to these deaths, state agencies had the authority to take immediate action against the products. Many states coordinated recalls of the product and removed the candy from sale within their states. One state supervised the destruction of over 60 t of the candy. States also issued press releases and consumer alerts, in English and non-English languages, to alert the public as broadly as possible. FDA placed import alerts on this product to prevent any additional importation into the USA, and the agency also banned the ingredient konjac so that such episodes could never occur again.

Infant Formula Case Study

FDA alerted state agencies that numerous infants had died in China due to adulterated infant formula that failed to contain the required nutrients indicated on the label, causing malnutrition. Although FDA determined that the product had not been marketed in the USA, state agencies decided to perform routine inspections and investigations in Chinatown areas to confirm the product was not being sold. In one state, the product was in fact being sold, and a determination was made that the product had been smuggled into the country. The state immediately notified FDA and coordinated a recall. In addition, the state took enforcement action against the retailers and issued a press release with local Chinese-language media to alert consumers.

These two cases demonstrate the effectiveness of integration: states utilizing their unique authorities to stop the sale of the product, the sharing of surveillance data, the use of state resources to remove and destroy the product, the use of media

outlets to alert consumers including those that do not speak English, and FDA preventing additional importation of the product. These integrated efforts most certainly saved children's lives.

FDA/NY Agriculture and Markets Import Initiative

A vulnerability assessment performed by New York State (NYS) officials resulted in the opinion that imported foods were a potential threat to citizens of that state. New York has a very diverse population and is a large importing state. The NY Department of Agriculture and Markets formalized an initiative with FDA/NY District whereby state officials would receive import training along with federal officials and then conduct inspections of imported food products at import entry points and in domestic wholesale and retail food establishments. Six individuals were hired, trained, and assigned to this effort, and the inspectors were commissioned and credentialed with FDA.

The NYS inspectors conducted independent and joint surveillance and inspections of imported foods. This included efforts with FDA, USDA Smuggling Interdiction Trade and Compliance (SITC) and FSIS, and the US Fish and Wildlife Service. These efforts resulted in the recall of numerous imported foods found to be in violation. During the 12-year period from 2000 to 2012, the NY Department of Agriculture and Markets coordinated 2,619 recalls of imported food products from 73 different countries. Of the 2,619 recalls, 510 were class I recalls, 1,685, class II, and 424 were class III. The agency averaged 201 imported food recalls per year during that period (AFDO 2014). This innovative effort, which has garnered national attention and is still in effect today, demonstrates integration at its most effective.

Conclusion

History demonstrates that coordination among government at all levels is crucial to food safety. The concept of integration is not new, but requires a true and complete reform of our food safety system and will lessen the need for independent efforts. Fortunately, FSMA has provided a congressional mandate to integrate our food safety system, and much has been accomplished to advance the system. A leadership structure has been established through FDA and the Partnership for Food Protection, and state agencies are implementing important program standards. There are many stakeholders with important roles in food safety, and these stakeholders can all make significant contributions, particularly when public health is at stake. Multistate outbreaks, national recall efforts, and strategic workplanning are too important to be addressed by a non-integrated food system. Stakeholders are wise to begin building the integrated framework in order to serve our nation in a much-improved manner.

Take-Home Message

A nationally-integrated food safety system will dramatically improve government oversight of our food supply. However, moving forward with the integrated food safety system will require assessments of the existing food safety structure, good communication, an evaluation of effective practices already in place, and enhanced collaboration and cooperation efforts by all stakeholders, including leaders within the system, at a new level of engagement. The success of this approach is made clear by the multitude of cooperative programs, efforts, and field activities that have occurred since the vision was first presented by AFDO in 1998. FSMA contains many provisions related to capacity-building and integration at all government levels. However, it will take leadership and much more effort to achieve a truly-integrated food safety system.

Activity: Case Study

You are a program manager for a food protection agency and have a rather robust surveillance sampling program for *Listeria monocytogenes*.

On a number of occasions, you collect samples of prepackaged sandwiches from a convenience store, which are confirmed positive for the presence of *Listeria monocytogenes*.

The prepackaged sandwiches are manufactured at a commissary-type manufacturing plant which is under both USDA FSIS and FDA jurisdiction. You license the portion of the facility which also falls under FDA jurisdiction. You have worked with this company on five separate occasions where you have found *Listeria monocytogenes* in their prepackaged sandwiches and have coordinated recalls with them each time.

During the five previous occasions where you found *Listeria monocytogenes* in the product, you have ordered the establishment closed. They were allowed to reopen only after a recognized food safety expert supervised the cleaning and disinfection of the plant environment and equipment and after testing of the product, equipment, and environment verified the absence of *Listeria*.

Now, after five recalls and after closing the establishment on five separate occasions, you are alerted by your food laboratory that another prepackaged sandwich from this company is confirmed to be contaminated with *Listeria monocytogenes*.

Now what do you do?

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Answer Key: (Possible answers)

- Since the plant has had multiple positive samples and has been closed following each episode, the agency must consider stronger enforcement action. The plant should be closed as before, but the agency should now consider court action, such as an injunction, which would prohibit the plant from marketing product containing *Listeria monocytogenes*. If the plant were to violate this, the plant would be subject to Contempt of Court and possible civil and/or criminal penalties.
- As part of the injunction action the agency might wish to consider ordering the plant to have a "Hold and Test" program requiring the plant to test every lot of product before marketing the product.
- As the plant would be closed again, the agency might require the firm to hire the services of a recognized food processing expert to locate the root cause of the adulteration, recommend stricter processing and sanitation controls, and identify poorly-designed equipment that is difficult to clean and in need of replacement.
- A comprehensive environmental testing program should be conducted by the plant to determine possible contamination sources.
- The agency should discuss the issue with FDA, which also regulates the portion of the facility the agency licenses. The issue should also be discussed with USDA/FSIS officials who regulate another portion of the plant, as the *Listeria monocytogenes* adulteration problem may be prevalent in the plant. In an IFSS, recalls, inspections, compliance, and enforcement actions would be coordinated between the regulatory agencies.

Chapter 5
Regulatory Program Foundations: Program Standards

Ellen Buchanan, Tressa Madden, Christopher Smith, Alan Tart, and Amanda Buell

Learning Objectives

- Discuss the overarching concepts of national program standards.
- Discuss the interdependencies of various program standards.
- Illustrate a systems approach using the program standards.

Introduction

Model program standards provide foundations upon which regulatory programs can be built and continuously improved and are important in the development of an integrated food safety system (IFSS). Standards for federal, state, or local agencies

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do not carry the legal authority of laws, statutes, ordinances, or regulations. Rather, standards serve as a guide for agency managers in the design and management of a food safety regulatory program. As a result, regulatory agencies can measurably improve their existing programs and better focus on those factors that contribute to foodborne illness. Food protection professionals (FPPs) should be aware of the role that program standards play in the overarching goal of food safety. This, in turn, can help improve industry and consumer confidence in food protection programs and enhance uniformity within and between regulatory agencies.

The standards addressed in this chapter include national standards created by the US Food and Drug Administration (FDA, www.fda.gov) for various regulatory programs (retail food regulatory programs, manufactured food regulatory programs, and animal feed regulatory programs), public health-related standards from the US Centers for Disease Control and Prevention (CDC, www.cdc.gov) and the Public Health Accreditation Board (PHAB), the International Comparability Assessment Standards (ICAT), and standards proposed by the Food Safety Modernization Act (FSMA) related to third-party auditors.

National Program Standards

Voluntary National Retail Food Regulatory Program Standards (VNRFRPS)

In the US, state, local, tribal, and territorial agencies are responsible for the regulation of the retail food industry—restaurants, grocery stores, schools, and hospitals—while FDA provides technical assistance to these agencies. In the late 1990s, FDA held a series of meetings with several agencies, along with industry and consumer groups, to gather feedback and ideas on how to increase uniformity in retail food regulation, a primary need identified by FDA and all stakeholder groups (FDA 2013a), along with a way for regulatory programs to measure improvement and be recognized for that improvement. Encouraging regulatory agencies to adopt the FDA Food Code (www.fda.gov/FoodCode/) remains one of the primary goals of FDA, but in this case, the goal was even broader. FDA sought to develop a mechanism that could be universally implemented and that was inclusive of every major function (e.g., regulations, training, quality assurance, foodborne illness investigation, etc.) of a retail food protection program. Out of these meetings and information sharing, the VNRFRPS began to take shape and were developed into the model that is largely still in practice today.

The VNRFRPS serve as a guide to regulatory food program managers in the design and management of a retail food regulatory program and provide a means of recognition for those programs that meet these standards. Program managers and administrators may establish additional requirements to meet individual program needs (FDA 2013a).

The VNRFRPS are designed to help food regulatory programs enhance the services they provide to the public. When applied in the intended manner, the program standards should:

- Identify program areas where an agency can have the greatest impact on retail food safety.
- Promote wider application of effective risk factor intervention strategies.
- Assist in identifying program areas most in need of additional attention.
- Provide information needed to justify maintenance of or increase in program budgets.
- Lead to innovations in program implementation and administration.
- Improve industry and consumer confidence in food protection programs by enhancing uniformity within and between regulatory agencies (FDA 2013a).

The VNRFRPS consist of nine (U.S. Food and Drug Administration 2013c) individual standards, each encompassing a major aspect of a regulatory retail food safety program. Jurisdictions can enroll in the program and then measure themselves against each of the standards to determine their strengths, as well as identify gaps in their food safety program. This self-assessment and gap analysis provides the program with a measuring stick that can be used to plan program improvement. The standards do not have to be accomplished in order; progress toward the standards can be tailored to the specific needs of the jurisdiction. As of October 2014, more than 630 jurisdictions in the US—at the state, territory, district, county, city, town, or other level—had enrolled in the VNRFRPS (FDA 2014a).

VNRFRPS Standard 1: Regulatory Foundation

Standard 1 applies to the regulatory foundation used by a retail food regulatory program. The regulatory foundation includes any statute, rule, ordinance, or other prevailing set of regulatory requirements that governs the operation of a retail food establishment. In order to achieve conformance with Standard 1, a jurisdiction must examine its own food safety regulations to determine if the regulations are comparable to the FDA Food Code. The jurisdiction's regulations do not have to be exactly the same as the Food Code, but must establish an equivalent level of protection. The desired outcome of this standard is the adoption of a sound, science-based regulatory foundation for the food safety regulatory program and the uniform regulation of industry (FDA 2013a).

VNRFRPS Standard 2: Trained Regulatory Staff

Standard 2 applies to the essential elements of a training program for food safety regulatory staff. The essential elements in this standard include new employee initial training, coursework, field inspection work (conducted both with a trainer and

individually), standardization, and continuing education. A jurisdiction has flexibility in how its training program is structured. FDA online courses or a combination of equivalent courses could be utilized by FPPs. The courses must cover topics such as prevailing regulations, food microbiology, communication skills, and foodborne illness investigation. As indicated above, Standard 2 also incorporates a process for "standardization." Standardization is an assessment of the employee in the field to evaluate his or her inspection techniques, communication abilities, and rule interpretation/application. The desired outcome of this standard is a trained regulatory staff with the skills and knowledge necessary to conduct quality inspections (FDA 2013a).

VNRFRPS Standard 3: Inspection Program Based on HACCP Principles

Standard 3 is intended to focus a jurisdiction's inspection program on hazard analysis and critical control points (HACCP) principles. In order to achieve conformance with this standard, the program must focus inspections on the status of risk factors, determine and document compliance with the risk factors, and target corrective actions, both on-site and long-term (e.g., embargo or destruction of foods from unapproved sources, temperature controls, handwashing, prevention of hand contact with ready-to-eat foods, etc.). In addition, a jurisdiction must have a way to categorize food establishments based on risk and assign them an inspection frequency related to that categorization.[1] The desired outcome of this standard is a regulatory inspection system that uses HACCP principles to identify risk factors and to obtain immediate and long-term corrective action for recurring risk factors (FDA 2013a).

VNRFRPS Standard 4: Uniform Inspection Program

Standard 4 is intended to guide program management in the implementation of an ongoing quality assurance (QA) program. In order to achieve conformance with this standard, there must be an ongoing QA program that ensures a minimum level of competency in ten quality elements. These quality elements focus on areas such as proper completion of inspection reports, correction and follow-up regarding risk factor violations, and taking appropriate compliance and enforcement actions. This standard is also intended to guide program staff in the documentation of corrective action when problems are noted during the evaluations (e.g., remedial staff training).

[1] For example, a nursing home that prepares food for the elderly (a population highly susceptible to foodborne illness) would be inspected more frequently than a convenience store that sells hot dogs.

The desired outcome of this standard is to ensure high-quality inspections during which inspection personnel are uniform in their interpretation and application of laws, rules, and policies (FDA 2013a).

VNRFRPS Standard 5: Foodborne Illness and Food Defense Preparedness and Response

Standard 5 is intended to guide a program in the establishment and implementation of a system to detect, collect, investigate, and respond to complaints and emergencies that involve foodborne illness, injury, and intentional or unintentional food contamination. The criteria in this standard address the jurisdiction's relationship with epidemiologists and communicable disease personnel, laboratory support, emergency responders, and others who could be involved in foodborne illness and food defense response situations. This standard also addresses the jurisdiction's understanding of jurisdictional lines and responsibilities, particularly as they relate to food recall and trace-back procedures, the policies and procedures in place regarding the investigation of food-related complaints, recalls, and media management. This standard requires that a foodborne illness and/or defense exercise be conducted by the jurisdiction if any actual event has not occurred in the previous year. The desired outcome of this standard is that the program has a systematic approach for the detection, investigation, response, documentation, and analysis of food-related incidents that involve illness, injury, or unintention, or deliberate food contamination (FDA 2013a).

VNRFRPS Standard 6: Compliance and Enforcement

Standard 6 is intended to guide a retail food regulatory program in the establishment and implementation of compliance and enforcement activities. Compliance and enforcement activities include all voluntary and regulatory actions taken to achieve compliance with regulations. In order to achieve conformance with this standard, a program must establish policies and procedures for compliance and enforcement. This standard does not dictate which tools the jurisdiction should have available, but only that the jurisdiction has step-by-step procedures to use certain tools along with a mechanism to ensure that the tools are being used appropriately. Examples of compliance and enforcement tools that a jurisdiction might implement include the closure of establishments, embargo of food, and administrative and/or civil penalties. In addition to establishing policies and procedures, program staff must assess whether FPPs are consistently implementing the jurisdiction's compliance and enforcement policies and procedures. The desired outcome of this standard is an effective compliance and enforcement program that is implemented consistently and progressively to achieve compliance with regulatory requirements (FDA 2013a).

VNRFRPS Standard 7: Industry and Community Relations

Standard 7 examines the jurisdiction's activities with its regulated industry and community. Conformance with this standard is achieved by implementation of education and outreach activities such as food safety task forces (which include regulatory, industry, and consumer representatives), industry training initiatives, and other activities designed to educate and solicit feedback from various stakeholder groups. The desired outcome of this standard is enhanced communication with industry and consumers through forums designed to solicit input to improve the food safety regulatory program. Another desired outcome of this standard is the reduction of food safety risk factors through educational outreach and cooperative efforts with stakeholders (FDA 2013a).

VNRFRPS Standard 8: Program Support and Resources

Standard 8 applies to a jurisdiction's staffing and resources. This standard includes an assessment of the amount of inspection staff needed for the number of inspections conducted within the jurisdiction. A staffing level of one employee or full-time equivalent should be devoted to food protection work for every 280–320 inspections performed. Standard 8 also assesses the resource needs, such as funding and equipment, necessary to effectively implement the food safety program. The desired outcome of this standard is that sufficient resources are available to support a risk-based retail food regulatory program (FDA 2013a).

VNRFRPS Standard 9: Program Assessment

Standard 9 is an assessment of program effectiveness. There are two components incorporated in Standard 9: the risk factor study and the intervention strategy. The risk factor study provides a method to assess the success of a jurisdiction's program in reducing the occurrence of foodborne illness risk factors. A risk factor study is an analysis of the occurrence of foodborne illness risk factors in regulated establishments. Foodborne illness risk factors are those conditions which are most likely to lead to foodborne illness if left uncontrolled. The top five foodborne illness risk factors are food from unsafe sources, time/temperature abuse, improper cooking temperatures, contaminated equipment and cross-contamination of food, and poor personal hygiene.

The risk factor study serves two primary purposes. The first purpose is to identify risk factors that are in need of priority attention and develop appropriate intervention strategies to reduce the occurrence of those risk factors (FDA 2013a). For example, if a jurisdiction conducts a risk factor study and finds that a high number of establishments have problems with cooling foods, an intervention strategy could

be implemented to address the problem. That intervention strategy could include the development of educational tools (brochures, reminder signs, etc.), stronger emphasis during inspections, training courses for workers, and the purchase of demonstration tools (e.g., chill sticks) that could be used by FPPs during inspections. Future risk factor studies could then be used to evaluate the effectiveness of those intervention strategies.

The second purpose of the risk factor study is to evaluate trends over time (FDA 2013a). Standard 9 requires that risk factor study data be collected at least every 5 years to provide sufficient data to analyze. For example, the FDA conducted nationwide risk factor studies in 1998, 2003, and 2008 with the goal of seeing a 25 % reduction in risk factor occurrence over the 10-years period. While this goal was not achieved overall, the trend analysis provided detailed information regarding areas where improvement is being made and where additional attention is needed (FDA 2009).

A risk factor study can be conducted either through an evaluation of regularly -conducted inspection data or through a special survey of randomly-selected establishments in the jurisdiction. In either case, having a staff that is properly-trained in collecting the data is of the utmost importance.

Changing/Revising the VNRFRPS: Conference for Food Protection (CFP)

Changes/revisions to the VNRFRPS are made through the Conference for Food Protection (CFP, www.foodprotect.org), a parliamentary-style organization that operates through committees, councils, and a general assembly and comprises representatives from the food industry, government, academia, and consumer organizations. Any stakeholder can submit an "issue" to the biennial CFP meeting and ask that the conference consider a change to the standards. Issues related to the Retail Program Standards are debated in council 2—administration, education, and certification. Council 2 is comprised of appointees from all stakeholder groups with equal representation from the regulatory and industry sectors. FDA, CDC, and USDA representatives have non-voting, consultant status on this council. Issues submitted to the Conference for Food Protection, and debated within a council, can be accepted as submitted, accepted after amendments made by the council, or rejected by the council by majority vote. The issues then go before the general assembly, which represents regulators from all the 50 states and territories. If the general assembly agrees with the council's recommendation, the issue is sent to the FDA for further consideration. If the general assembly does not agree with the council's recommendation, then the issue may be revisited by an ad hoc committee formed by the executive board of the CFP, which comprises members from federal, state, and local food regulatory agencies, along with industry, consumer, and academia representatives. More information about the CFP Councils can be found at www.foodprotect.org/administration/councils/.

Manufactured Food Regulatory Program Standards (MFRPS)

The VNRFRPS were written for retail food regulatory programs and are a voluntary set of standards. In contrast, the Manufactured Food Regulatory Program Standards (MFRPS) were developed by FDA, along with selected state program managers, and are used as a guide for continuous improvement for state food manufacturing programs (FDA 2014b). Although the MFRPS were patterned after the VNRFRPS—and there is significant overlap—differences between the respective sets of standards do exist. There are nine VNRFRPS, yet ten MFRPS. This is because, in the MFRPS, *laboratory support* is its own standard (MFRPS Standard 10). In the VNRFRPS, laboratory support is a component of VNRFRPS Standard 5—Foodborne Illness and Food Defense Preparedness and Response. The requirements, the documentation necessary to demonstrate compliance, and the intended outcomes are similar for some VNRFRPS and MFRPS standards; however, differences between the standards also exist due to the differences in administering a manufactured food regulatory program versus a retail food regulatory program. The MFRPS were first published and piloted in 2007 and updated in 2010 and 2013 (FDA 2013b). Like the VNRFRPS, the MFRPS represent a platform that facilitates integration between states and FDA, establishes a uniform basis for measuring and improving the performance of regulatory programs, and helps agencies direct their regulatory activities to reduce foodborne illness hazards. Additionally, the MFRPS are used as a contracting/auditing tool by FDA for states performing contract FDA inspections.

MFRPS Standard 1: Regulatory Foundation

Standard 1 is a cataloging standard for state regulatory programs to inventory which authorities in the Food, Drug, and Cosmetic Act (FD&C Act, Public Law 75-717) and the Code of Federal Regulations (CFR, www.ecfr.gov) and the state may have adopted, by reference or directly, and to inventory any authorities held within the state that are not found in the FD&C Act or the CFR (FDA 2013b). For example, in Oregon there is a state regulation addressing blue green algae. FDA, however, does not have blue green algae in its regulations.

MFRPS Standard 2: Training Program

Standard 2 provides foundational, specialized, and continuing education requirements for a state manufacturing regulatory program field staff. The three-level approach provides for natural progression for all employees, from new hires to fully-trained staff. The standard combines online courses, face-to-face classroom training, and joint inspections as training methods. In Standard 2, earning certificates and

demonstrating competencies ensure that an investigator/inspector has the knowledge, skills, and abilities to conduct manufactured food inspections (FDA 2013b).

MFRPS Standard 3: Inspection Program

Standard 3 addresses the elements of an effective inspection program for food plants. The standard calls for:

- A risk-based inspection program, where plants are inspected based upon their manufacturing processes and compliance history.
- Written inspection protocols for conducting manufacturing inspections.
- A written recall plan.
- Methods to capture and catalog consumer complaints.
- A process for industry to file complaints about an inspection/inspector.

By fully developing each of these five requirements in Standard 3, a state food program should have some level of confidence that the program focuses inspection resources on high-risk plants, products, and processes and prevents unsafe products from reaching consumers (FDA 2013b).

MFRPS Standard 4: Inspection Audit Program

Standard 4 is the quality assurance (QA) arm of the manufactured food regulatory program. The standard provides for the state program to monitor and document its own activities, identify gaps, and take corrective actions. Three activities are monitored for quality: field inspections, inspection reports, and sampling. The standard also provides specialized forms and worksheets to help rate these three activities. A written correction action plan, developed by the state program and tailored to its specific needs, can help address any deficient areas (FDA 2013b).

MFRPS Standard 5: Food-Related Illness and Outbreak Response

Standard 5 describes how a state program investigates food-related illnesses, outbreaks, and other hazards related to manufactured foods. Standard 5 provides an opportunity to coordinate roles and responsibilities with other jurisdictions that may have authority to investigate and resolve food-related illnesses and outbreaks. This standard may be implemented in one of three ways: contracting for the work with a third party, having the authorities assigned via state statute, or creating a

memorandum of understanding (MOU) with the lead agency in the state if the authority is not assigned to the one seeking to meet the standard.

The first option is rare, even though the option is mentioned in the standard. The second implementation option is considered direct authority and is usually assigned to a State Department of Health. The third option occurs when the State Department of Agriculture is enrolled in the MFRPS and not the lead agency in an illness or outbreak investigation that resulted from a manufacturing facility. An MOU would be needed to outline the roles and responsibilities of both agencies (FDA 2013b).

MFRPS Standard 6: Compliance and Enforcement Program

Standard 6 addresses a state program's strategies, procedures, and actions to enforce compliance with laws and regulations. The secondary objective for Standard 6 includes monitoring and evaluating the effectiveness of these enforcement actions by tracking and trending chronic and critical violators. By outlining what authorities a state may have, integration efforts can be harmonized, and duplication of efforts can be eliminated. Compliance and enforcement is one area where integration generally succeeds, due to states and FDA having different authorities and strategies (FDA 2013b).

MFRPS Standard 7: Industry and Community Relations

Standard 7 directs the state manufactured food regulatory program to provide targeted outreach to affected industries, consumers, academia, and other food protection agencies. There is no prescriptive format for this outreach, only that the outreach takes place, is documented, and evaluated for impact on the community and industry stakeholders. Examples of outreach include, but are not limited to, an agency website, a food safety task force, a monthly newsletter, providing a guest lecturer at a local college or university, providing a speaker at a meeting related to food manufacturing, or organizing a food safety conference (FDA 2013b).

MFRPS Standard 8: Program Resources

Standard 8 addresses a program's resource shortages by systematically identifying constraints to meeting any of the standards. The constraints can include lack of funding, equipment, or staff. Standard 8 helps state programs assess whether resources are adequate to fully implement the standards; resources are sufficient to promulgate rules to protect public health; resources are adequate to fully train staff to conduct inspections in accordance with Standard 3; and resources are sufficient to implement the QA program outlined in Standard 4 (FDA 2013b).

MFRPS Standard 9: Program Assessment

Standard 9 is the self-assessment standard for the MFRPS. The requirements for Standard 9 include the initial self-assessment, a written strategic plan identifying gaps in all of the MFRPS, target dates for eliminating the gaps, and an annual progress review (FDA 2013b).

MFRPS Standard 10: Laboratory Services

Standard 10 describes elements needed by regulatory laboratories to fully support a manufactured food regulatory program. If the state laboratory has QA programs accredited by the International Organization for Standardization (ISO, www.iso.org), the laboratory is automatically considered fully compliant with Standard 10. If the laboratory is not ISO accredited, it must have current accreditation from the American Association for Laboratory Accreditation (A2LA, www.a2la.org). State laboratories must be able to analyze a variety of samples (food, environmental, and clinical). If using a servicing laboratory, an MOU is required with the companion lab. Generally, agriculture department food safety laboratories analyze inputs (food and environmental samples), and health departments analyze outputs (clinical specimens) (FDA 2013b).

Changing/Revising the MFRPS

Changes to the MFRPS are considered by the MFRP Alliance, which was formed through a cooperative agreement grant between the FDA and the Association of Food and Drug Officials (AFDO, www.afdo.org). The MFRP Alliance has an executive board, elected by state manufactured food regulatory program managers who are enrolled in the standards, and appointed committees that consider recommendations for changes to the standards. Industry plays a much lesser role in changing the manufactured standards compared to changing the retail standards. The MFRPA also includes staff members from FDA's Office of Regulatory Affairs (ORA), who serve as non-voting technical advisors. A state food laboratory manager is also appointed to serve as a technical advisor to facilitate collaboration and coordination with food laboratories. Similar to the retail program standards, any recommendations from the MFRP Alliance on changing the standards—based on evolving science or needed changes—are sent to the FDA for consideration, and the FDA will determine whether to accept or reject the recommendation or look further into the issue. The MFRPS are an official FDA document and must be approved by the Office of Management and Budget (OMB, www.whitehouse.gov/omb) every 3 years to remain viable. (To illustrate, the 2010 standards were reviewed and updated in 2013.) This process makes the standards document itself a *continuous improvement system*, which will be discussed later in this chapter.

Animal Feed Regulatory Program Standards (AFRPS)

The FDA, in partnership with the Association of American Feed Control Officials (AAFCO), developed the Animal Feed Regulatory Program Standards (AFRPS) in order to establish a uniform foundation for the design and management of state programs responsible for the regulation of animal feed (FDA 2014c). By implementing the feed standards, a state program will be able to achieve and maintain programmatic improvements that help ensure the safety and integrity of the US animal feed supply.

The AFRPS are composed of eleven standards that serve as an objective framework to evaluate and improve components of a state feed program. The standards cover the state feed program's regulatory foundation, training, inspection program, auditing, feed-related illness or death and emergency response, enforcement program, outreach activities, budget and planning, laboratory services, sampling program, and assessment and improvement of standards implementation.

Centers for Disease Control and Prevention (NPHPS and EnvPHPS)

The CDC National Public Health Performance Standards (NPHPS) provide a framework to help public health bodies assess their capacity and performance, identify areas for improvement, strengthen state and local partnerships, and ensure that a strong system is in place for addressing public health issues (CDC 2014). The CDC's Environmental Public Health Performance Standards (EnvPHPS) are a set of standards that describe the optimal performance and capacity for *environmental public health systems and programs* (CDC 2013). The EnvPHPS complement the NPHPS, with both sets of standards helping health departments focus their efforts on identifying the strengths/weaknesses of the programs and determining gaps between the current services provided and the optimal level of service described in the standards.

Both the NPHPS and the EnvPHPS are informed by CDC's 10 Essential Public Health Services. These 10 services identify the actions necessary to protect and improve environmental public health programs and systems:

1. Monitor environmental and health status to identify and solve community environmental public health problems.
2. Diagnose and investigate environmental public health problems and health hazards in the community.
3. Inform, educate, and empower people with regard to environmental public health issues.
4. Mobilize community partnerships and action to identify and solve environmental public health problems.
5. Develop policies and plans that support individual and community environmental public health efforts.

6. Enforce laws and regulations that protect environmental public health and ensure safety.
7. Link people to needed environmental public health services and ensure the provision of environmental public health services when otherwise unavailable.
8. Ensure a competent environmental public health workforce.
9. Evaluate effectiveness, accessibility, and quality of personal and population-based environmental public health services.
10. Research for new insights and innovative solutions to environmental public health problems (CDC 2011).

Public Health Accreditation Board (PHAB)

Public health departments may become "accredited" by the Public Health Accreditation Board (PHAB, www.phaboard.org). Public health department accreditation is defined as the development of a set of standards, a process to measure health department performance against those standards, and reward or recognition for those health departments who meet the standards. Accreditation documents a public health department's ability to deliver the 10 Essential Public Health Services. Like the 10 Essential public Health Services, public health accreditation is broadly related to the entire public health program, whereas, for example, the VNRFRPS are related specifically to retail food regulatory programs.[2]

One health department that received PHAB accreditation is the Hennepin County (MN) Public Health Department. Having completed continuous improvement projects in meeting the VNRFRPS, the Environmental Health unit was able to apply the processes to satisfy the PHAB requirements. Table 5.1 provides examples of how Hennepin County aligned the FDA VNRFRPS with specific provisions required for PHAB accreditation, and how this alignment can serve as a model for other regulatory agencies across the nation.

Table 5.1 Aligning retail standards with PHAB standards

VNRFRPS	PHAB
Standard 2: Trained regulatory staff "Trained regulatory staff with skills and knowledge necessary to conduct quality inspections"	Domain 8: maintain a competent public health workforce
Standard 7: Industry and community relations "Enhanced communications with industry and consumers through forums designed to solicit input"	Domain 4: engage with community to identify and address health problems
Standard 8: Program support and resources "Resources available to support risk-based retail food safety program"	Measure 11.2.4: seek resources to support agency infrastructure and processes, programs, and interventions

[2] FDA, in collaboration with the National Association of County and City Health Officials (NACCHO, www.naccho.org), published, in 2014, a comprehensive cross-walk of the retail program standards and the PHAB standards.

FSMA's Proposed Rule on Third-Party Auditors

In July 2013, the FDA published a proposed rule (Docket # FDA-2011-N-0146) to help implement Section 307 of the Food Safety Modernization Act (FSMA), which addresses the accreditation of third-party auditors and the certification of foreign food facilities. The FDA will use certification from accredited auditors to determine whether to admit certain imported foods into the USA and to determine whether an importer qualifies for a voluntary program allowing for expedited review and entry of food. Under the proposed rule, the FDA would recognize accreditation bodies, which would in turn accredit third-party auditors to conduct food safety audits and issue certifications for foreign food facilities. This process will help ensure the safety of FDA-regulated food moving in international trade in a more efficient manner. The FDA plans to draft model accreditation standards, including education and experience requirements for third-party auditors and their audit agents. Third-party auditors can include foreign governments, foreign cooperatives, and other third parties. The FDA will make the draft standards available for public comment. Although the use of accredited third-party auditors is not required by the FDA, the agency anticipates that the accreditation system will increase reliance by importers on audits by accredited third parties.

International Comparability Assessment Tool (ICAT)

FDA has developed a process for determining whether a foreign food safety system is comparable to that of the USA, through a self-assessment tool (the International Comparability Assessment Tool or ICAT) that can be completed by countries requesting systems recognition. FDA used the MFRPS as a model in creating the draft ICAT, which includes US references corresponding to each element and describes the US system with respect to each of the elements under each of the ten standards. Countries are given the opportunity, through submitting an ICAT assessment, to demonstrate how the country's system may differ from that of the USA and how the country's system, though different, provides similar food safety outcomes with respect to each element (FDA 2013c).

Analysis of a country's ICAT assessment will be combined with an in-country systems recognition assessment in order to validate the information presented in the ICAT. During the in-country assessment, a team of FDA scientists, auditors, and investigators will visit government agencies and food processing facilities to conduct interviews, review records, observe the implementation of written policies, and observe the enforcement of food safety regulations. These efforts will allow FDA to ensure that a country's food safety program offers the same level of public health protection as the system implemented by FDA in the US (FDA 2013c).

In late 2012, New Zealand became the first country to have its system recognized by the US (FDA 2012).

Interdependencies Among Program Standards

Some standards are interrelated, and progression toward one will lead to progression toward another, either directly or indirectly. For example, the basic structure of the jurisdiction's inspection form is referenced in both VNRFRPS Standard 3 and Standard 6. Other standards build on each other in a logical order. For instance, development of a strong training and standardization program (VNRFRPS Standard 2) would be logical to implement prior to the implementation of a quality assurance program (VNRFRPS Standard 4).

Similar interdependencies can be seen among the MFRPS. To illustrate:

- MFRPS Standard 6 cannot be fully implemented until MFRPS Standard 3's risk-based inspection program is developed. The evaluation of the critical and chronic violators and the reduction in enforcement actions would suggest the risk-based inspection program is working as needed to protect public health.
- MFRPS Standard 4 should not be implemented prior to the staff training addressed in MFRPS Standard 2. There is no benefit to auditing inspectors who have not been fully trained. What is more, the audit findings in MFRPS Standard 4 should feed back into the training in MFRPS Standard 2 so any gaps in knowledge can be identified.
- MFRPS Standard 7 has an outreach requirement that should be implemented (at least partially) by evaluating MFRPS Standard 6 statistics and target industries with compliance and enforcement issues.
- MFRPS Standard 5 should have a complete look through an "MFRPS lens" after each outbreak, i.e., the state program should assess whether the program has the regulatory foundation to prevent another outbreak, whether new regulations are needed, and whether staff is sufficiently trained to respond to the next outbreak or illness.
- MFRPS Standard 1, after new rule promulgation, should be used to update and modify the inspection program and protocol in MFRPS Standard 3.
- The laboratory analysis conducted via MFRPS Standard 10 should reflect the industries inspected under MFRPS Standard 3.

Interrelationship across program standards can also be seen. To illustrate, environmental health programs that do not have nationally-recognized standards in place may find the VNRFRPS the best place to begin. The VNRFRPS provide a step-by-step tool to identify program gaps, develop strategies for addressing gaps, and measure the progress and impact of program improvements. Once this approach is underway, it can be used as an example or model for other environmental health programs. In a similar fashion, retail food regulatory programs that are already enrolled or considering enrollment in the VNRFRPS may find it beneficial to consider the 10 Essential Environmental Public Health Services. Besides being complementary, these two initiatives encourage people working in food safety programs to think more holistically and could be a catalyst for career advancement and leadership opportunities. Table 5.2 demonstrates the interrelationship between the 10 Essential Environmental Public Health Services and the VNRFRPS.

Table 5.2 10 Essential Environmental Public Health Services and the corresponding FDA VNRFRPS (source: unpublished FDA white paper)

10 Essential Environmental Public Health Services	Corresponding VNRFRPS Standard
1. Monitor environmental and health status to identify community environmental public health issues	• Standard 5—Foodborne Illness and Food Defense Preparedness and Response • Standard 3—Inspection Program Based on HACCP (Principles) • Standard 8—Program Resources
2. Diagnose and investigate environmental public health problems and health hazards in the community	• Standard 3—Inspection Program Based on HACCP • Standard 5—Foodborne Illness and Food Defense Preparedness and Response • Standard 8—Program Resources
3. Inform, educate, and empower people about environmental public health issues	• Standard 7—Industry and Community Relations
4. Mobilize community partnerships to identify and solve environmental public health problems	• Standard 7—Industry and Community Relations
5. Develop policies and plans that support individual and community environmental public health efforts	• Standard 3—Inspection Program Based on HACCP • Standard 7—Industry and Community Relations
6. Enforce laws and regulations that protect environmental public health and safety	• Standard 1—Regulatory Foundation • Standard 3—Inspection Program Based on HACCP • Standard 4—Uniform Inspection Program • Standard 6—Compliance and Enforcement
7. Link people to needed environmental public health services and assure the provision of these services when otherwise unavailable	• Standard 7—Industry and Community Relations
8. Assure a competent environmental public health workforce	• Standard 2—Trained Regulatory Staff • Standard 4—Uniform Inspection Program • Standard 6—Compliance and Enforcement • Standard 8—Program Resources
9. Evaluate effectiveness, accessibility, and quality of personal and population-based environmental public health services	• Standard 9—Program Assessment
10. Research for new insights and innovative solutions to environmental public health concerns	• Self-assessment against all eight standards, development of strategic plan to address identified gaps, and Standard 9 foodborne illness risk factor study to measure effectiveness of interventions

A Systems Approach to Using National Program Standards

Meeting national program standards creates a more consistent and accountable approach to inspections. However, the ability to achieve the standards may depend on factors related to the type of agency (state, local, tribal, or territorial), the size of the agency staff, internal agency policies and procedures, agency resources, support from management or legislative bodies, and training of field staff.

Systems Approach at State Agencies

State agencies generally have a larger staff and more resources to devote to national program standards as compared to local, tribal, or territorial agencies. In many cases, upper management will expect the state agency to comply with the standards and will provide appropriate directives and resources. Generally, FPPs who are lead workers are assigned to work on specific sections of the standards. Generally, one staff person is designated the coordinator, or point person, and reports directly to management. The coordinator identifies the specific work needed to be accomplished, sets up meetings, delegates assignments, and checks in on workers assigned to different sections of the standards. For small agencies, it is difficult to keep up with routine work when a portion of the staff is performing work to meet standards.

A state program may be enrolled in multiple sets of standards depending upon the program's responsibilities. Many state food safety programs regulate retail food and manufactured food facilities. Consequently, program staff may inspect both types of facilities, and program managers may participate in the governance for the VNRFRPS and MFRPS. A program may also have environmental health responsibilities and are strives to meet the 10 Essential Public Services, or state feed regulatory programs may strive to meet the AFRPS. Some food and feed regulatory programs are housed in the same agency and are sometimes managed by the food regulatory programs. These states are challenged to develop programs that achieve all standards in an efficient and effective manner.

In 2013, the Partnership for Food Protection (PFP) National Standards Workgroup published a National Standards Crosswalk Resource Paper (http://www.fda.gov/downloads/ForFederalStateandLocalOfficials/FoodSafetySystem/UCM369991.pdf) that identified and summarized standards that applied to the grade "A" milk and milk products, manufactured foods (excluding meat and poultry), retail foods, and molluscan shellfish. The resource paper provides a side-by-side comparison of how program elements are addressed by each program. The paper is a resource for states that are responsible for implementing multiple programs and for identifying opportunities to harmonize standards where possible, across programs (PFP 2013).

Fig. 5.1 Plan-do-check-act model (source: US Department of Energy https://ecenter.ee.doe.gov/EM/SPM/Pages/Step4.aspx)

Systems Approach at Local Agencies

Some local agencies may have difficulty in pursuing national standards due to staff size, limited resources, or other local challenges. In other local agencies, the management may expect staff to meet the standards despite a lack of dedicated resources and an already full workload. Some larger cities and counties will have adequate resources to meet the standards.

Success Strategies for Both State and Local Agencies

One approach that can be used by agencies is a model of continuous or quality improvement. One of the more commonly used continuous improvement models is called the plan-do-check-act model or PDCA (Fig. 5.1). Although this chapter is not a complete guide to PDCA, the chapter does provide a short overview that can help agencies as they approach the adoption of national program standards.

Utilizing the PDCA model allows for a thorough, 360° analysis of a problem that can identify potential solutions. During the "plan" phase, objectives are clarified, predictions are made, and decisions are made about what needs to be done. During the "do" phase, decisions made during the planning phase are carried out and observed. During the "check" phase, results and observations are analyzed, and preparations are made for the "act" phase, where adjustments are made and a new cycle of planning begins.

The PDCA model can be used for entire national program standards or for a single part of the standards. However, the model is often used to make a small improvement first, leading up to larger improvements in the future. An incremental approach can lessen the burden on already-stressed agency resources. Using the strategic model allows for efficiency and structure, allows management to check in and get the "broad picture" of a current status, and helps an agency see both where the agency has to go and where the agency has been.

Conclusion

National program standards serve the important function of helping food regulatory programs—whether at the state, local, tribal, or territorial level—adopt best practices, form partnerships, and make efficient use of resources, which all help in the achievement of a truly nationally-integrated food safety system. National standards have been developed for retail regulatory programs, manufactured food regulatory programs, animal feed programs, environmental public health agencies, and regulatory laboratories. A systems approach is recommended to help regulatory programs tailor policies and procedures to the national set(s) of standards.

Take-Home Message

A food protection professional (FPP) may work for a state or local jurisdiction that is enrolled in national program standards related to food safety (manufactured food, retail food, animal feed, etc.). Enrollment in these national programs helps develop uniformity among food regulatory programs and helps promote the continuous improvement of participating agencies.

Activity

Which VNRFRPS or MFRPS applies to each of the following scenarios?

1. A food program manager puts a new ongoing quality assurance program in place to ensure that all staff members are uniform in the way they conduct inspections.
2. A food program manager implements new policies regarding how inspections are conducted to ensure that inspectors are requiring corrective actions of risk factor violations, e.g., inadequate cooking temperatures, improper handwashing, etc.
3. A food program manager is interested in upgrading state food regulations. She uses the current version of the FDA Food Code as a basis for the changes that are made.
4. A food program manager would like to evaluate the regulatory actions taken by inspectors in that state. The actions include establishment closures, food embargoes, and warning letters.
5. A state laboratory receives accreditation from the International Organization for Standardization (ISO) for its quality assurance (QA) programs.
6. A county environmental health director implements a new program to ensure that all staff members meet a minimum standard in the courses they take per year for continuing education.

7. A food program manager would like to conduct an evaluation of risk factor occurrence in the establishments within the state. The data will be used to implement new training strategies for operators.
8. A food program manager is interested in the implementation of a new advisory group that would provide feedback on proposed food safety educational materials and rule changes. This group would include representatives from industry and consumer groups.
9. A food program manager is concerned that the number of inspectors for the establishments in the county is inadequate. The program manager is looking for a way to calculate the number of staff needed per inspections conducted.
10. An environmental health director seeks to upgrade the program's response to foodborne illness investigation and response. The director works with the health department's communicable disease staff to implement new memorandums of understanding between the agencies.

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Answer Key

1. Standard 4
2. Standard 3
3. Standard 1
4. Standard 6
5. MFRPS Standard 10
6. Standard 2
7. Standard 9
8. Standard 7
9. Standard 8
10. Standard 5

Chapter 6
Microbiology (*of the Food Code*)

David McSwane, Yvonne Salfinger, Brian Nummer, and Angela Winslow

Learning Objectives

- Describe where potentially contaminating microorganisms can be found in the environment.
- Describe the foods commonly associated with microbial hazards.
- Describe common methods used to detect pathogens.

Introduction

Humans share both external and internal environments with an enormous number of microorganisms. Microorganisms are living organisms that are too small to be seen with the human eye and include bacteria, parasites, and fungi. Our environments

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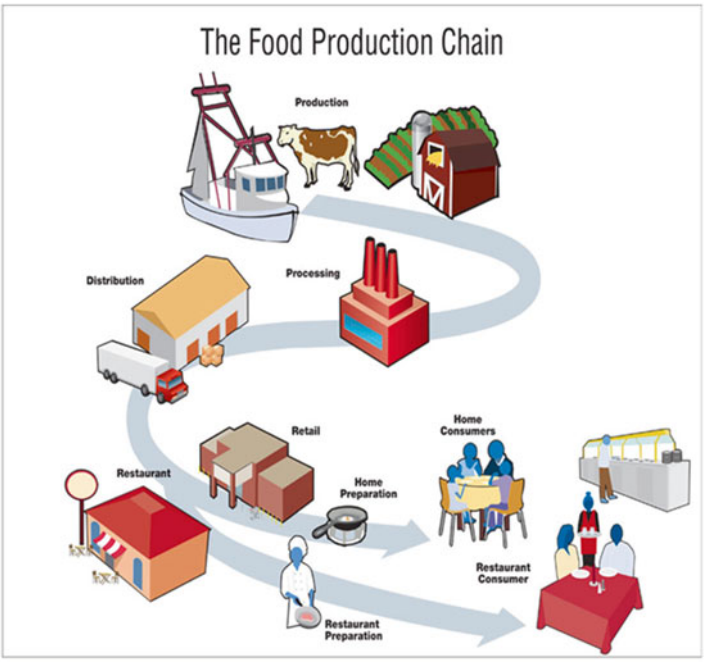

Fig. 6.1 Points of the food production chain. Source: Centers for Disease Control and Prevention, http://www.cdc.gov/foodsafety/outbreaks/investigating-outbreaks/figure_food_production.html

may also contain viruses and prions, which are microscopic agents capable of infecting living organisms, but are not living.

Many of these microorganisms and viruses have no impact on human health, and some are actually beneficial to human health. For example, bacteria within our gastrointestinal system help to break down the food we consume so that we can absorb nutrients more efficiently. Additionally, some microorganisms are important to the entire food industry. For example, certain species of bacteria are essential for the production of foods like cheese, yogurt, and wine.

Where Microorganisms Can Be Found in the Environment

Foodborne illness is commonly caused by the consumption of contaminated food. Common sources of contaminants include soil, water, air, plants, animals, and humans. Additionally, food can become contaminated at a variety of points along the supply chain as the food flows from the farm to the consumer's table (Fig. 6.1).

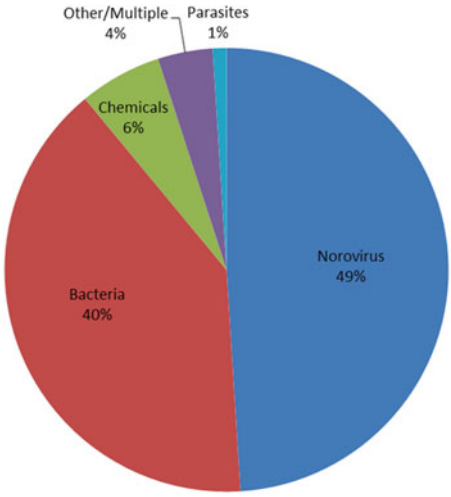

Fig. 6.2 Known causes of foodborne illness outbreaks, USA, 2006–2010 (source: CDC, http://www.cdc.gov/features/dsnorovirus/figure3.html)

The Complexity of Foodborne Pathogens

There are numerous reasons why pathogens are difficult to control. Some pathogens have the ability to cause foodborne illness without changing the appearance, odor, or taste of the food. Some foodborne pathogens—called spore-forming bacteria—are difficult to eliminate because the pathogens form spores, meaning the bacteria create an outer layer that protects against extreme conditions such as dryness and temperatures related to cooking, heating, or freezing. Some pathogens can multiply quickly, while other pathogens grow slowly. Some pathogens (such as viruses and parasites) require a living host, while other pathogens (such as bacteria) can grow on inanimate surfaces. Some pathogens can produce a harmful chemical or toxin In Food On Once the pathogen becomes established inside the human body, which can cause serious infections, illness, or even death. Finally, some pathogens pose a significant challenge because the pathogens have a very low infective dose, especially in the very young, the elderly, and individuals who may have a weakened immune system.

Foodborne pathogens are also influenced by poor personal hygiene. The risk of foodborne illness increases if food workers (1) do not practice good handwashing, (2) do not wear clean clothing and hair restraints, (3) do not avoid bare hand contact with food, and (4) do not wear disposable gloves. Improper cleaning and sanitizing of manufacturing/processing equipment and utensils can also lead to the spread of foodborne pathogens, as can the purchase of food or ingredients from unapproved sources. Industry should only buy foods and food ingredients from suppliers that comply with federal, state, and local food safety laws and regulations, and consumers should only purchase food items from food establishments and retail food stores that are regularly inspected and follow the recommended practices contained in the FDA Food Code. Finally, another challenge to the prevention of foodborne pathogens is the wide range of food items where pathogens can originate—including raw fruits and vegetables, eggs, unpasteurized milk, meat and poultry, and undercooked seafood. Figure 6.2 illustrates the known causes of foodborne illness outbreaks in

Table 6.1 Foodborne illnesses and associated foods

Common name of illness	Food source(s)
Anisakiasis or anisakidosis	Raw or undercooked fish, squid, cuttlefish, octopus
B. cereus food poisoning	Meats, stews, gravies, vanilla sauce
Campylobacteriosis	Raw and undercooked poultry, unpasteurized milk, contaminated water
Botulism	Improperly-canned foods, especially home-canned vegetables, fermented fish, baked potatoes in aluminum foil
C. perfringens food poisoning	Meats, poultry, gravy, dried or precooked foods, time- and/or temperature-abused foods
Intestinal cryptosporidiosis	Uncooked food or food contaminated by an ill food handler after cooking, contaminated drinking water
Cyclosporiasis	Various types of fresh produce (imported berries, lettuce, basil)
E. coli infection ("traveler's diarrhea")	Water or food contaminated with human feces
Hemorrhagic colitis or *E. coli* O157:H7	Undercooked beef, unpasteurized milk and juice, raw fruits and vegetables, contaminated water
Hepatitis	Raw produce, contaminated drinking water, uncooked foods and cooked foods not reheated after contact with an infected food handler, shellfish from contaminated waters
Listeriosis	Unpasteurized milk, soft cheeses made with unpasteurized milk, ready-to-eat deli meats
Noroviruses (viral gastroenteritis, winter diarrhea, acute nonbacterial gastroenteritis, food poisoning/ infection)	Raw produce, contaminated drinking water, uncooked foods and cooked foods not reheated after contact with an infected food handler, shellfish from contaminated waters
Salmonellosis	Eggs, poultry, meat, unpasteurized milk or juice, cheese, contaminated raw fruits and vegetables
Shigellosis or bacillary dysentery	Raw produce, contaminated drinking water, uncooked foods not reheated after contact with an infected food handler
Staphylococcal food poisoning	Unrefrigerated or improperly-refrigerated meats, potato and egg salads, cream pastries
Trichinellosis or trichinosis	Undercooked meat, especially from wild game such as bear and wild boar, rare domestic pig
Vibrio parahaemolyticus infection	Undercooked or raw seafood such as shellfish
Vibrio vulnificus infection	Undercooked or raw seafood such as shellfish and oysters
Yersiniosis	Pork (including "chitlins"), unpasteurized milk, oysters

Adapted from foodborne illnesses: what you need to know, http://www.fda.gov/Food/FoodborneIllnessContaminants/FoodborneIllnessesNeedToKnow/default.htm and Bad Bug Book, http://www.fda.gov/downloads/Food/FoodborneIllnessContaminants/UCM297627.pdf

the US from 2006 to 2010, while Table 6.1 lists the most common types of foodborne illnesses and the foods associated with these illnesses. (Chap. 20, Retail Food Establishments, contains a table on biological and chemical hazards associated with retail food establishments.)

Foodborne Pathogen Growth

Foodborne bacteria need six conditions in order to multiply or grow in food. An easy way to remember these conditions is by using the acronym FAT TOM which stands for:

*F*ood: Bacteria need a source of food, especially food containing proteins or carbohydrates.
*A*cidity: Bacteria grow best in foods with low acidity.
*T*ime: Bacteria need time to grow. A single bacterium can multiply into over one billion bacteria in just 10 h.
*T*emperature: Bacteria grow best between 41 °F (5 °C) and 135 °F (57 °C).
*O*xygen: Some bacteria need oxygen to survive, and some bacteria must live in an oxygen-free environment. Other types of bacteria are adaptable and can grow with or without oxygen.
*M*oisture: Bacteria need moisture to grow (International Dairy-Deli-Bakery Association 2013).

Symptoms of Foodborne Illness

The symptoms of foodborne illness caused by viruses, bacteria, and parasites are numerous and varied and include abdominal cramps/pain, blurred/double vision, diarrhea, fever, nausea, vomiting, and even death. Depending on the type of illness, the onset of symptoms can occur anywhere from 1 h to weeks after ingestion of the implicated food, and the duration of symptoms can be anywhere from a handful of hours to numerous days or weeks. In fact, in the case of some illnesses like hepatitis A, symptom onset can occur anywhere from 15 to 50 days after ingestion, and the symptoms can last for months (FDA 2014a).

Viruses

Viruses—which are some of the smallest pathogens known to man—can contaminate raw and ready-to-eat foods that are consumed without being cooked or processed in some way to eliminate the virus. When a virus invades a living cell, the

Table 6.2 Top five pathogens contributing to domestically acquired foodborne illness (source: CDC, http://www.cdc.gov/foodborneburden/2011-foodborne-estimates.html)

Pathogen	Estimated number of illnesses	% of foodborne illnesses
Norovirus	5,461,731	58 %
Salmonella, nontyphoidal	1,027,561	11 %
Clostridium perfringens	965,958	10 %
Campylobacter spp.	845,024	9 %
Staphylococcus aureus	241,148	3 %
Subtotal		91 %

virus takes over the cell's machinery, forcing the cell to reproduce the virus in massive numbers (University of Rochester 2014).

According to the US Centers for Disease Control and Prevention (CDC), norovirus (which consists of a group of noroviruses) accounts for an estimated 58 % of foodborne illnesses in the US each year (Table 6.2), along with more than 14,000 hospitalizations and almost 150 deaths (CDC 2014). Noroviruses have a low infective dose, which means a person may experience an illness when only a small number of viral particles are inhaled or ingested. This level can be as low as 10–100 particles. Because such small numbers of the organism cause illness, norovirus can spread rapidly through confined populations like those on cruise ships or in nursing homes (CDC 2011). Norovirus is very contagious and can be transmitted via an infected person, contaminated food or water, or by contacting contaminated surfaces (CDC 2013a). Foods most commonly involved in norovirus outbreaks include leafy greens such as lettuce, fresh fruits, and shellfish such as oysters. However, any food served raw or handled after being cooked can become contaminated (CDC 2013b).

Another common virus associated with foodborne illness is the hepatitis A virus (HAV), which is presumed to have an infectious dose of 10–100 particles. HAV is excreted in feces of infected people and can produce clinical disease when susceptible individuals consume contaminated water or foods. Cold cuts and sandwiches, fruits and fruit juices, milk and milk products, vegetables, salads, and shellfish are commonly implicated in HAV outbreaks, with water, shellfish, and salads being the most frequent sources. Infected workers in food processing establishments and restaurants are often the source of HAV contamination (FDA 2012).

Bacteria

Bacteria, which are larger than viruses, are found in every habitat on Earth: soil, rocks, oceans, etc., and some bacteria live in or on organisms such as plants, animals, and humans. Unlike viruses, bacteria can reproduce through binary fission, meaning a bacteria cell divides into two identical cells. Under the right conditions, some bacteria such as *Escherichia coli* (*E. coli*) can divide every 20 min (Society for General Microbiology 2014). According to CDC, bacteria accounted for 40 % of the known causes of foodborne illness outbreaks in the US from 2006 to 2010 (Fig. 6.2).

Parasites

Parasites are microscopic organisms that live in or on a living host. Some examples of foodborne parasites include *Anisakis* spp., *Cyclospora cayetanensis*, and *Trichinella spiralis*. Parasitic infections are far less common than either bacterial or viral foodborne illnesses, accounting for just 1 % of the known causes of foodborne illness outbreaks in the US from 2006 to 2010 (Fig. 6.2). However, parasites are common in certain species of fish; undercooked meat products, especially wild game animals; and produce that has been irrigated with polluted water. Parasites can also be transmitted by cross-contamination of ready-to-eat (RTE) food with raw animal foods, consumption of contaminated drinking water, and contaminated hands, equipment, or utensils.

Foods Associated with Microbial Hazards

Foods that are associated with foodborne illness-causing pathogens are commonly called time/temperature control for safety food (TCS food or TCS). According to the FDA Food Code, TCS food is defined in terms of whether the food requires time/temperature control for safety to limit pathogen growth or toxin formation. TCS takes into consideration pH (acidity), water activity (a_w), pH and a_w interaction, heat treatment, and packaging (FDA 2013a). The following are types of TCS foods:

- Animal foods (meat, poultry, fish, and dairy) that are raw or heat-treated using commercial sterilization, pasteurization, or similar methods.
- Plant foods that are heat-treated or consist of raw seed sprouts.
- Cut melons.
- Cut leafy greens (lettuce, spinach, etc.).
- Cut tomatoes or mixtures of cut tomatoes that are not modified in a way (sliced, diced, chopped, etc.) that supports pathogenic microorganism growth or toxin formation.
- Garlic-in-oil mixtures that are not modified in a way so that they are unable to support pathogenic microorganism growth or toxin formation (FDA 2013b).

RTE foods also pose unique challenges for food safety. These foods are commonly eaten without being washed, cooked, or prepared in some way to destroy pathogens prior to consumption. As a result, safe food-handling practices should be in place along the flow of food preparation to avoid contamination of RTE foods.

Common Methods Used to Detect Microbial Hazards

A variety of methods can be used to detect pathogens in foods, but the methods must be effective enough to isolate the target organism against other organisms naturally present in the food. Additionally, the methods must be validated based on the food

commodity, technique, or instrument used in order to avoid false negatives. The current validated microbiological procedures include the FDA Bacteriological Analytical Manual (BAM, http://www.fda.gov/food/foodscienceresearch/laboratorymethods/ucm2006949.htm), the US Department of Agriculture (USDA) Food Safety and Inspection Service Microbiological Laboratory Guidebook (MLG, http://www.fsis.usda.gov/wps/portal/searchhelp/help/!ut/p/a0/04_Sj9CPykssy0xPLMnMz0vMAfGjzOINAg3MDC2dDbz8LQ3dDDz9wgL9vZ2dDdwNTfULsh0VASWBaOU!/?1dmy&current=true&urile=wcm:path:/fsis-content/internet/main/topics/science/laboratories-and-procedures/guidebooks-and-methods/microbiology-laboratory-guidebook/microbiology-laboratory-guidebook), the International Organization for Standardization (www.iso.org), and the AOAC International (www.aoac.org).

Conventional methods of detection include isolation and enumeration. Isolation involves the use of culture media to resuscitate and/or increase the number of certain organisms, select for specific groups of bacteria, inhibit the growth of other bacteria, or differentiate pathogens from other microorganisms. Enumeration—or counting—involves diluting bacteria and evenly distributing (spreading) the bacteria onto a nutrient medium (a Petri dish) in order to grow colonies of the bacteria. The plates are kept under certain temperature conditions, and the number of bacteria colonies is ultimately counted (Bassiri 2014). Other methods of detecting the presence of pathogens in foods include immunological techniques (a quantitative reaction of an antigen with its antibody) and molecular techniques (looking for the pathogen's DNA).

After isolation and enumeration, a series of biochemical tests may also be performed in order to identify certain microorganisms, that have individually distinct characteristics, including color changes or other types of reactions. Conventional biochemical testing can be done with the use of a series of test tubes, or the process can be automated for more rapid identification. Automation is also used to detect pathogens using immunological assays; one assay commonly used in food microbiology is the ELISA assay (enzyme-linked immunosorbent assay), which is commercially-available for many foodborne pathogens.

Once bacteria have been identified, using conventional, culture-based methods or molecular methods, strains can be traced in order to pinpoint outbreak strains using pulsed-field gel electrophoresis (PFGE). PFGE generates a "fingerprint" which is unique to a given bacterium and which can be uploaded into a national surveillance database maintained by the CDC called PulseNet (www.cdc.gov/pulsenet/). PulseNet is accessible by state health laboratories and federal agencies in order to compare bacterium fingerprints. This data-sharing allows for the detection of local and multistate outbreaks and can significantly reduce outbreak detection time.

To illustrate the use of PulseNet in a multistate investigation, in mid-December 2007, the Florida Department of Agriculture and Consumer Services, Bureau of Food Laboratories, uploaded a *Listeria monocytogenes* DNA fingerprinting to the PulseNet database from a contaminated chicken wrap sandwich. Later on, this DNA fingerprinting was linked to a Connecticut patient with listeriosis. A series of interviews revealed that the patient had traveled to Florida and had eaten chicken salad.

Meanwhile, another case in the Midwest was associated with the same DNA fingerprinting with a patient who did not travel to Florida but who had also eaten chicken salad. After USDA investigation, the source of contamination was determined and a New York company recalled 286,320 pounds of fresh and frozen meat and poultry products (Marcus et al. 2009).

Another technology used to identify pathogens isolated from food is called *whole genome sequencing*, which reveals the complete DNA makeup of an organism. This technology, which is currently being used by FDA during foodborne illness outbreaks, performs the same function as PFGE but has the ability to differentiate virtually all strains of foodborne pathogens, even between closely-related organisms (FDA 2014b). As of May 2015 the FDA's whole genome sequencing network has sequenced more than 12,200 *Salmonella spp*. isolates and 3,100 *Listeria spp*. isolates. The technology is currently sequencing an average of over 800 isolates each month (FDA 2014c).

Common Measures Used to Control Microbial Hazards

Pathogenic microorganisms may be found naturally in the ingredients used to make food products, the equipment used to process and prepare foods, and the final food product. These types of contaminants can also be transferred from one food item to another via cross-contamination. Measures to prevent and control microbial contamination must begin when food is harvested/manufactured and must continue until the food is consumed or discarded. There are generally two methods of controlling microbial hazards in foods: elimination of growth and reduction of growth.

Elimination Methods: Heating and Freezing

Elimination of microorganisms is the preferred method of controlling microbial hazards, since the microorganism is destroyed and rendered incapable of being revived. The main elimination method available is heat. In foodservice, cooking is the main process used. According to the FDA Food Code, foods must be cooked—and sometimes held—at specific minimum temperatures and for minimum amounts of time in order to destroy organisms of public health concern. In most cases, a temperature of at least 145 °F (63 °C) or above for 15 s is required; however, some foods require higher cooking temperatures to destroy organisms of public health concern (FDA 2013c). The Food Code also provides options for heating at lower temperatures for longer times, e.g., heating beef roasts at 130 °F for 112 min (FDA 2013d).

Another elimination method is freezing, which is used primarily with fish. According to the Food Code, raw or partially-cooked fish should not be served or sold in RTE form unless the fish is frozen and stored at a specific temperature—or

below—for a specific amount of time, depending on the type of fish (FDA 2013e). Freezing will destroy parasites found in fresh fish, but has no effect on bacteria or viruses. Bacteria cannot grow while frozen, but will start to grow when food reaches certain temperatures when it thaws.

Reduction Methods: Acidity, Water Activity, and Temperature Acidity

Acidity plays a very important role in food safety and is generally indicated by the food's pH value. Acidified foods are regulated by Title 21 of the Code of Federal Regulations, Parts 114 and 108. The pH scale ranges from 0 to 14; any pH below 7 falls in the acidic range, while those above 7 are in the basic range, i.e., a low pH value indicates a high acidity level. Foods with a pH level at or below 4.6 are naturally acidic (or called acid foods), do not support growth of the deadly botulism organism, and are far less frequently the source of foodborne illness. Additionally, foods that have a pH level of less than 4.2 will not support the growth of any of the most common foodborne illness bacteria. Foods that have a pH greater than 4.6 are called low-acid foods and include most vegetables and meats (Rushing 2014). Some foods, however, can be acidified to reduce the pH and make the foods safe. For example, vinegar is added to sushi rice to safely store the rice at room temperature for extended periods. Fermented foods (such as some types of sauerkraut, pickles, and olives) are low-acid foods that have been processed in such a way to reduce the pH of the food to 4.6 or below. Pickled foods are low-acid foods that, either through fermentation or being marinated in an acid solution (usually vinegar), have had pH levels reduced to 4.6 or below (FDA 2010).

Water Activity (a_w)

Water activity (a_w) is another important intrinsic factor in minimizing microbial growth. Water activity is the measurement of water that is available to microorganisms for growth and has a measurement scale of 0 (no water present) to 1.0 (pure water with maximum water availability). Bacteria normally require a very high water availability to be able to grow quickly. *Staphylococcus aureus*—the pathogen most tolerant of low water availability—will grow at an a_w of 0.83 but will not produce toxin if the a_w is 0.86 or below. No microbial growth at all occurs when the a_w is below 0.6 (Adams and Motarjemi 1999a). Water activity can be reduced in two ways. The first is to simply reduce moisture by drying and dehydration. The second method is to bind water using additives such as salt or sugar. The more salt or sugar a food contains, the lower the water activity, and the less the food will support microbial growth.

Temperature

Individual microorganisms have a minimum temperature below which the microorganism cannot grow, a maximum temperature above which the microorganism cannot grow, and an optimum temperature at which the microorganism grows best. Most foodborne pathogens are *mesophiles* and have an ideal growth temperature of approximately 98.6 °F/37 °C, generally the temperature of the human or animal body. The minimum growth temperature for mesophiles is around 46.4 °F/8 °C, so if a food product is stored below 50 °F/10 °C, the pathogen will either grow very slowly or not at all. Some pathogens, such as *Listeria monocytogenes*, are classified as *psychrotrophic* pathogens, in that the pathogens can grow—albeit very slowly—at temperatures as low as around 39.2 °F/4 °C. No microorganisms will grow in properly-frozen foods below 0.4 °F/−18 °C, although some may survive the freeze and resume growth upon an increase in temperature. Additionally, no pathogenic bacteria will grow at a temperature above 140 °F/60 °C, and this upper limit helps define the "danger zone" of 41 °F(5 °C) to 135 °F(57 °C). Food items that are ready-to-eat should not be stored within the danger zone due to the potential for bacterial growth (Adams and Motarjemi 1999b).

Conclusion

Microorganisms (bacteria, viruses, and parasites) are ubiquitous in and on food products, food ingredients, food environments, and food handlers. The food protection professional (FPP) should be aware of the common microbial hazards that cause foodborne illness and of the foods commonly associated with microbial hazards. The laboratory is a tool that can be utilized by FPPs for detection of pathogens that can cause illness. The FPP should be aware of the ways microbial hazards are controlled, so that potentially-dangerous products can be detected rapidly and withdrawn from sale. Using PFGE, outbreaks associated with a particular food product can be more rapidly detected, especially across state boundaries. Additionally, whole genome sequencing may become the standard future technology for detecting outbreaks.

Take-Home Message

An understanding of common pathogens, foods associated with these pathogens, and common techniques to detect and control these hazards will serve the FPP well in carrying out his or her responsibilities.

Activity

Search the CDC's website (www.cdc.gov) for outbreaks related to viruses, bacteria, and parasites. Determine contributing factors and methods recommended to control the outbreak and prevent a recurrence.

HandWashing Activity

There are several products on the market, such as Glo Germ (www.glogerm.com/) and GlitterBug (http://www.glitterbug.com/), that can be used to illustrate contaminated hands and demonstrate the effectiveness of handwashing with the use of the Glo Germ or GlitterBug powder, gel, or liquid and an ultraviolet light (UV) or black light. Place the powder, gel, or liquid on the hands and look at them under a UV light in a dark room. The fluorescent material on the hands represents bacteria. Wash hands thoroughly and then look at them again under the UV light. Notice how the fluorescent material may still be seen around nails, between fingers, on the back of the hands, and on wrists and forearms. This represents bacteria that may remain after improper handwashing. Wash hands thoroughly and then look at the hands again under UV.

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Chapter 7
Public Health Principles

James Rutherford, John Luke, Melinda Wilkins, and Sarah Rockhill

Learning Objectives

- Discuss foodborne illness.
- Discuss how pathogens can be transmitted.
- Discuss risk factors that contribute to foodborne illness.
- Discuss how public health agencies help prevent foodborne illness.

Introduction

Due to the ever-increasing level of complexity in our global food supply system, as well as the enormous costs and impacts associated with foodborne illness, every food protection professional (FPP) needs to understand the importance of food safety from a public health standpoint and the role that public health agencies play in preventing foodborne illness. This chapter provides a brief historical overview of food-related illness and the impact of foodborne illness, along with an overview of how foodborne pathogens are transmitted to individuals. Additionally, the chapter explores the numerous ways by which public health agencies help prevent foodborne illness outbreaks.

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Historical Overview

During the early twentieth century, contaminated food, milk, and water caused many foodborne illnesses such as typhoid fever, tuberculosis, botulism, and scarlet fever (CDC 1999). In fact, in 1900, diarrheal and other gastrointestinal illnesses were the third leading cause of death in the USA (CDC 2014a). Dense urban areas were especially prone to large illness outbreaks due to overcrowding and lack of sewer systems and water treatment facilities. Solid and liquid waste was often emptied directly onto streets, leading to frequent contamination of the water supply.

Thanks largely to Upton Sinclair's novel *The Jungle*, which exposed unsanitary conditions related to the food industry, public awareness—and public outrage—increased and led to passage of the Pure Food and Drug Act (Public Law 59-384, 34 Stat. 768) and the Federal Meat Inspection Act in 1906 (Public Law 59-242, 34 Stat. 674). These laws served as the foundation for the regulation of food safety in the US. A number of public health reforms were also implemented, including the development of modern sewage disposal systems, urban zoning laws which separated residential areas from industrial areas, refuse collection and management services, and drinking water filtration and chlorination.

Thanks to these initial forms of regulation, many of the sources of foodborne illness were soon identified; various control measures such as handwashing, sanitation, pasteurization, and refrigeration were incorporated; and the incidence of diseases decreased markedly. To illustrate, the incidence of typhoid fever in 1900 was about 100 per 100,000 people; by 1920, this decreased to 33.8, and by 1950, to just 1.7 (CDC 1999). Today, typhoid fever, cholera, and botulism, which were once ubiquitous in the USA, are relatively rare outside of the developing world.

Foodborne Illness

Despite technological advancements in the production and storage of food, the US Centers for Disease Control and Prevention (CDC www.cdc.gov) estimates that each year, one in six Americans will experience foodborne illness, which equates to roughly 48 million people each year nationwide. Additionally, foodborne illness causes 128,000 hospitalizations and 3,000 deaths annually in the USA (CDC 2014b, c). Worldwide, foodborne disease is a growing public health problem and encompasses a wide spectrum of illnesses caused by microbial, parasitic, or chemical contamination of food (World Health Organization 2014a).

In addition to the health implications caused by foodborne illness, there is also a substantial economic impact. A recent study estimated that foodborne illness poses a $77.7 billion economic burden in the US annually due to medical costs, pain, suffering, functional disability, and illness-related death. However, this figure does not take into account the costs to the food industry, including reduced consumer confidence in food products and companies, product recalls, and litigation.

The figure also does not consider the cost to public health agencies (federal, state, local) that respond to foodborne illnesses and outbreaks (Food Safety News 2014). Public confidence after a major foodborne outbreak may never be fully restored, and many establishments go out of business after just one outbreak incident.

Common symptoms of foodborne illness include diarrhea and/or vomiting, typically lasting 1–7 days. Other symptoms include abdominal cramps, nausea, fever, joint/back aches, and fatigue. What some people call the "stomach flu" may actually be a foodborne illness caused by a virus or bacteria in contaminated food or drink (Minnesota Department of Health 2010). Most individuals with foodborne illness will recover without any special treatment; however, certain types of foodborne illness require treatment with antibiotics, and severe types of foodborne illness can even lead to kidney failure, respiratory failure, premature delivery, and even death (FDA 2014a).

The length and duration of foodborne illness depend on the type of pathogen present, the amount of pathogen present, and an individual's susceptibility to the illness, i.e., the state of his or her immune system. When the immune system is strong and functioning properly, humans are generally less susceptible to disease. When a person with a healthy immune system becomes infected with a pathogen, the person's symptoms may be less severe or have a shorter duration. On the other hand, a person with a compromised or weak immune system is at a much higher risk of developing illness and may have more severe symptoms. Reasons for a weakened immune system include having an autoimmune disease, taking immunosuppressive drugs to treat cancer or other health conditions, having a chronic health condition, being very young or old, and being pregnant.

Pathogen Transmission

Pathogens are viruses, bacteria, and other microorganisms that cause disease in humans. Pathogen transmission refers to how a pathogen is passed from one body (the host or reservoir) to another (a susceptible host). Potential hosts or reservoirs include humans, animals, and environmental hosts such as plants, soil, and water. A pathogen leaves its host through a *portal of exit*, which can be the respiratory tract, urine, fecal matter, or bodily secretions, e.g., blood from a cut or wound, and enters another body through a *portal of entry* on a susceptible host (CDC 2012a). For example, a person ill with influenza coughs on a crowded bus, and the three people standing nearest inhale the influenza virus directly into their own respiratory tract. In this example, the portal of exit is the mouth of the ill person and the portal of entry is the nose/lungs of the nearby passengers, both functioning as part of the respiratory tract.

Pathogen transmission can either be *direct* or *indirect*. In direct transmission, the pathogen is transferred from a reservoir to a susceptible host through direct contact such as skin-to-skin contact or contact with soil or vegetation harboring pathogens. Indirect transmission, on the other hand, involves an intermediate step

between the portal of exit and the portal of entry, typically through air particles (e.g., coughing, sneezing, or air currents) or through an intermediate object called a *vector* or a *vehicle. Vectors* are living animals, most commonly biting insects such as mosquitoes, fleas, or ticks. *Vehicles* are inanimate objects and include water, biologic agents such as blood, and fomites, which are certain inanimate objects that are capable of carrying pathogens, such as clothing, bedding, and handkerchiefs (CDC 2012a).

Food is a common example of a vehicle for transmitting pathogens. In fact, virtually any type of food can be the source of foodborne illness (Fig. 7.1), especially when there is a lack or failure of a "kill step," typically a point in the food manufacturing process where pathogens are eradicated from the food product (usually by killing the pathogen). Traditional "kill steps" have included cooking, pasteurization, washing, and irradiation (Caywood 2009).

Risk Factors Contributing to Foodborne Illness

Knowing about portals of exit and entry and the ways that foodborne pathogens can be transmitted can help FPPs identify potential food safety risks and determine appropriate control or intervention measures. FDA has identified certain *risk factor categories* associated with foodborne illness outbreaks. Identification of these factors resulted from data collected during visits by FDA personnel to approximately 850 foodservice and retail food establishments conducted over a 10-year period. These risk factors include employee health and hygiene; inadequate cooking and holding temperatures; and contaminated equipment (FDA 2014b). Although the risk factors were identified through visits to retail and foodservice facilities, the factors can also be applied to food manufacturing facilities and other points along the food supply chain, such as growing areas, storage, distribution, and transportation.

Fig. 7.1 Causes of illness in 1,565 single-food commodity outbreaks, 2003–2008 (CDC 2012b)

Employee Health and Hygiene

The cause of a foodborne outbreak can sometimes be traced to a sick or infected person handling a food product. As a result, public health agencies generally have regulations in place that prevent ill workers from continuing to work with food. Food products can also become contaminated when food handlers fail to wash their hands or wear gloves prior to handling the food.

Inadequate Cooking/Holding Temperatures

Bacteria grow best between certain temperatures, typically the "danger zone" between 40° and 140 °F (USDA 2013a). As a result, some food needs to be cooked at a temperature of 140 °F or above (or microwaved at 165 °F or above) (Foodsafety.gov 2014a), while other types of food such as meat, poultry, and casseroles need to be cooked at a higher temperature-such as 160 °F or 165 °F (Foodsafety.gov 2014b). Hot foods need to be held at a temperature of 135 °F or above, while cold foods need to be held at a temperature of 41 °F or below (San Bernardino County 2012) (Figs. 7.2 and 7.3).

Contaminated Equipment

Pathogens can be spread via contaminated surfaces that contact food, such as utensils, tables, blades, conveyors, and other equipment used in processing. As a result, all equipment needs to be cleaned and sanitized on a regular basis (San Bernardino County 2012). Pathogens can live (or remain in an active state) on inanimate objects long enough to be transmitted to a food product.

Fig. 7.2 Approximately 900 pounds of the dairy product to the right were sent to a landfill for disposal due to improper storage temperatures on a truck (Source: Indiana State Department of Health, Food Defense Program)

Fig. 7.3 Taking thermal readings of refrigerator contents using a digital thermometer (Source: CDC Public Health Image Library image # 13851/CDC/Amanda Mills)

How Public Health Agencies Help Prevent Foodborne Illness

There are approximately 2,565 local public health agencies/departments in the USA and 50 state health departments, along with state departments of agriculture and public health agencies at the tribal and territorial levels. Federal public health departments, such as CDC and FDA, help ensure that all levels of government are able to provide essential public health services, act when health threats span more than one state, and help states that lack certain expertise or resources to respond to a public health emergency (CDC 2013).

In the vast majority of states, local health departments are led by local government, which makes most fiscal decisions. In some states, however, some local health departments are governed at the state level, while in the remaining states, local health departments are led by *both* state and local authorities (CDC 2013).

Local and state health and state agriculture agencies play key roles in preventing foodborne illness outbreaks. These agencies inspect food manufacturing and food retail establishments, maintain a trained and educated staff of FPPs, educate the public about food safety, collect information about potential cases of foodborne illness (surveillance), conduct enforcement activities (recalls, embargoes, seizures), and investigate cases of suspected foodborne illness.

Inspections

Inspections of facilities involved in *all* points of the food chain (processing, distribution, retail, etc.) play a key role in ensuring a safe food supply. During an inspection, FPPs identify critical food safety issues, help confirm a link between foodborne illness disease and unhygienic conditions, and take appropriate steps to control or remedy these issues. Today, inspections focus on events that are most likely to cause a foodborne illness or outbreak, which is a more effective approach than the traditional "floors/walls/ceilings" inspections, where the FPP based the inspection merely on observable evidence of violations, typically related to cleanliness, housekeeping issues, and pest control. Nobody likes to eat in a dining area with a dirty carpet, but dirty carpets are not likely to make anyone sick. However, a plate that looks clean but was not properly sanitized could make someone sick. Inspections are covered in greater detail in Chap. 12.

Trained and Educated Staff

The world of food safety is constantly changing. New technologies emerge that assist in detecting and minimizing the effect of harmful organisms before the organisms have a chance to cause a foodborne illness. Likewise, new sources of foodborne illness are emerging and evolving. For example, in the past, peanut butter and cantaloupe were not considered sources of widespread foodborne outbreaks. However, in recent years, both have been involved in major outbreaks (CDC 2012c, d).

Because the FPP can help keep both industry and the public informed of food safety issues, he or she must stay up-to-date on the latest food safety information available, be adequately trained in food safety principles, and be well-versed in the regulations and policies for the jurisdiction where he or she is employed. Most agencies have specific training requirements before an inspector is assigned to conduct inspections. Typically, this preparation includes training courses, both online and instructor-led, as well as accompanying veteran FPPs during inspections. Some jurisdictions, in fact, require a certain number of contact hours or continuing education units throughout the FPP's career.

Consumer Education

Public awareness is another useful tool in helping prevent the spread of foodborne illness. Many public awareness campaigns are carried out with the help of the Partnership for Food Safety Education (PFSE, www.fightbac.org), which brings together public and private sectors to support the work of health and food

safety educators. One of PFSE's public awareness campaigns is Be Food Safe (www.befoodsafe.gov), developed in cooperation with USDA. The campaign provides educators with the tools to inform consumers about foodborne illness and raise the level of awareness of the dangers associated with improper handling and undercooking of food (USDA 2013b).

Surveillance Activities

Public health agencies monitor foodborne illness through a variety of mechanisms, but primarily through two types of surveillance systems: complaint-based systems and pathogen-specific systems. (Surveillance is discussed in greater detail in Chap. 8.) Complaint-based surveillance systems involve reports of foodborne illness symptoms to the local public health agency by an individual or a group of individuals experiencing symptoms believed to be caused by ingestion of contaminated food or water. Complaint-based systems can allow agencies to respond quickly to potential outbreaks. However, complaint data are not typically shared between jurisdictions, so identifying outbreaks that occur across jurisdictional lines can be difficult.

A pathogen-specific surveillance system tracks cases of foodborne illness that have been confirmed through laboratory testing and then reported back to a local or state public health agency. When an ill individual seeks medical care, his or her healthcare provider may take a sample from that patient and send the sample to a laboratory, which can identify the genetic code, or DNA fingerprinting, of illness-causing pathogens. Laboratories can also identify linkages between cases when two samples have the same DNA fingerprint, even if the cases occur in different states at different times. One limitation to pathogen-specific surveillance, however, is the potential length of time for agencies to receive laboratory results. Such a delay can occur because individuals often do not visit their healthcare provider until days after the onset of symptoms, and laboratories may need days to confirm a diagnosis, depending on the pathogen(s). In fact, the average time from onset of symptoms to outbreak confirmation is estimated to be 2–3 weeks (Council to Improve Foodborne Outbreak Response 2009).

Other, less frequently used surveillance systems include syndromic and sentinel systems. The objective of syndromic surveillance is to identify illness clusters early, before diagnoses are confirmed, and to mobilize a rapid response. An example of syndromic surveillance would involve a greater-than-expected number of emergency department visits for specific symptoms. Syndromic surveillance was primarily developed for early detection of a large-scale release of a biologic agent (CDC 2004). In a sentinel surveillance system, a network of carefully-selected health facility sites serving a relatively large population (e.g., a network of large hospitals) share data and information regarding day-to-day experiences, which can serve as an early warning for outbreaks (World Health Organization 2014b).

The Internet is also emerging as a tool for detecting potential foodborne illness outbreaks and diseases. To illustrate, researchers at the New York City Department of Health and Mental Hygiene, Columbia University, and Yelp analyzed close to 300,000 food review posts on Yelp, looking for keywords such as "diarrhea," "sick," and "vomit." Health officials ultimately used the results of the analysis to investigate more than 100 possible foodborne outbreaks. This led to follow-up interviews and health inspections at a handful of restaurants (Advisory Board Company, The 2014a). Another team of researchers concluded that an online tool called Google Flu Trends could predict surges in hospital flu visits more than a week before the CDC could make such a prediction, while another study found that using Twitter could help track cholera outbreaks in Haiti quicker than traditional methods (Advisory Board Company, The 2014b).

Enforcement Activities

If a food product is found to pose a health risk to consumers, the product may be *recalled*, i.e., removed from warehouses and stores and from customers after purchase. Manufacturers or distributors may voluntarily initiate a recall; however, recalls can be requested or mandated by the FDA or USDA if the product is regulated by the federal agency. Recalls can also be requested by state food protection regulatory agencies, such as agriculture and health departments. Recalls are classified into three categories based on the severity and relative health risk related to the product. A Class I recall is a situation where there is a reasonable probability that a product will cause serious adverse health consequences or death; a Class II recall is a situation where a product may cause temporary or medically-reversible adverse health consequences, or where the probability of serious adverse health consequences is remote; a Class III recall involves a situation where a product is not likely to cause adverse health consequences (FDA 2014c). State food protection agencies may check food establishments, grocery stores, warehouses, etc., to verify that a recalled product has been removed from commerce.

If the soundness or safety of a product is in question, state food protection agencies may sometimes place an *embargo* or "hold order" on a product until the product has been determined safe for human consumption. If the product is not deemed safe to consume, the product can be destroyed or returned for reconditioning. The embargo process is especially common for imported goods. Every jurisdiction has different regulations and procedures for placing an embargo on food, and the FPP needs to be aware of the requirements in the area he or she inspects or regulates.

Sometimes the forced removal or *seizure* of a product from a store, warehouse, or port may be necessary to ensure the product does not reach the consumer. This removal is typically done when cooperation with the holder of the product is not possible. Most jurisdictions are required to obtain a court order before seizing products, and plans must be made regarding how the food is to be destroyed or stored prior to the product being seized.

Investigation

Once a case of foodborne illness is reported to a health agency, the case may be investigated by agency staff. Not every case of foodborne illness will be investigated due to the number of reported cases and the limited funding and staffing faced by many state and local health agencies. However, the chance of an investigation being conducted is greater if any of the following situations are involved:

- Severe illness and/or death.
- Illness affecting a more vulnerable segment of the population (e.g., elderly individuals, pregnant women, or children).
- Widespread illness, suggesting a commercially distributed product.
- Illness that suggests potential bioterrorism or intentional contamination.
- Political pressure applied from inside or outside the responding agency.

When a public health agency receives a foodborne illness complaint, an interview is typically initiated with affected individuals or their friends or family members. The goal of the interview is to assess the symptoms of the illness, establish a timeline of events, and identify all the foods and beverages that the person consumed within a given timeframe (i.e., a food history). The information gathered in an interview is collected according to a prescribed methodology, i.e., interviewers ask the same questions in the same manner and record the information in the same format. Consistency is highly important when interviewing potential cases, because variations in interviewing technique can introduce errors that can confound an investigation.

Foodborne illness investigation may involve multiple individuals, including, but not limited to, a public health nurse and/or an epidemiologist to interview persons who became ill and to collect stool samples, a microbiologist to detect the presence of a pathogen, an environmental sanitarian, a food inspector or investigator, a veterinarian if animals are involved, laboratory personnel to prepare and test samples, specialists in food manufacturing processes, and public relations personnel to make sure that accurate and consistent information is provided to the media and to the public.

A foodborne illness investigation can also involve multiple agencies, especially where the outbreak involves a large geographic area. To illustrate, a recent outbreak of a rare illness known as Haff disease in Mississippi resulted in multiple state agencies being in constant communication due to jurisdictional issues. (Haff disease is associated with the consumption of buffalo fish, though no exact cause or toxin has ever been isolated.) The State Department of Health had jurisdiction over the fish processing and epidemiological aspects. The Department of Agriculture regulated the sale of buffalo fish in retail establishments. Because buffalo fish is wild-caught, the Department of Wildlife had the authority to stop the harvest of the fish. The Department of Marine Resources was involved because buffalo fish is an aquatic animal. Finally, the Department of Environmental Quality had to determine when the waters were safe to fish. Clearly, different agencies offer specific areas of expertise, which can prove to be a tremendous asset during an investigation. (Note: all victims of the Haff disease outbreak survived, though most were hospitalized for several days.)

The primary goals of a foodborne illness outbreak investigation are to identify the cause of the outbreak, minimize the impact of the outbreak, and prevent such an incident from recurring. An outbreak investigation may reveal that a basic piece of information had been overlooked, or the investigation may identify a gap in the food supply chain that warrants a corrective action, such as replacing a certain piece of equipment or training certain employees on personal hygiene.

Conclusion

Foodborne (and water-related) illness can occur and spread in a variety of ways and can have tremendous impact on public health. Public health agencies at all levels of jurisdiction serve an important role in the detection and prevention of foodborne outbreaks along with state departments of agriculture. Agencies license and inspect foodservice and production operations, investigate cases of foodborne illness, conduct surveillance of potential outbreaks, create educational and training materials, and conduct public awareness campaigns related to food safety.

Take-Home Message

Public health agencies at all levels (federal, state, local, tribal, and territorial) play a crucial role in monitoring and mitigating foodborne illness outbreaks, as well as investigating the source of the illness and educating the public about preventive and protective measures. The FPP needs to understand that preventing food- and water-related illness is one of the primary objectives of his or her job and can help educate others on methods and practices that can detect, monitor, prevent, and contain the spread of such diseases.

Activity

Chapter review questions.

1. Contracting *Salmonella* from eating a contaminated food item is an example of:
   (a) Direct transmission.
   (b) Indirect transmission.
2. When comparing surveillance systems, match the following characteristics to the correct surveillance system—complaint-based or pathogen-specific.
   (a) Usually initiated by a citizen phone call to a state or local health agency.
   (b) Usually initiated by a laboratory notification to a state or local health agency.

(c) Is usually based on an individual or group of individuals experiencing gastrointestinal illness who have not sought medical care.
(d) Is based upon a clinical sample collected by a healthcare worker.
(e) The pathogen causing illness has been identified by a laboratory.
(f) The cause of illness has not yet been determined.
(g) Can lead to DNA fingerprint analysis.
(h) Allows for a faster response to a potential outbreak.

3. Why might a local health agency *not* investigate a case of foodborne illness?
4. What major risk factors contribute to foodborne illness, according to FDA research conducted at foodservice and retail food establishments?

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Answer Key

1. B—Indirect, because food is the intermediate vehicle
2. Complaint-based surveillance—a, c, f, h
   Pathogen-specific surveillance—b, d, e, g
3. There are many potential reasons. Examples include:
   (a) The case is found to be sporadic (not part of an outbreak).
   (b) The illness is not severe.
   (c) There is minimal risk that transmission is ongoing.
   (d) The illness is not affecting a vulnerable segment of the population (such as the young, elderly, and/or immunocompromised).

(e) The health department is lacking resources to pursue the individual cases of foodborne illness (focusing on outbreaks).
(f) There is nothing unusual about the pathogen, the illness, or the mode of transmission.

4. Major risk factors contributing to foodborne illness include:

(a) Employee health and hygiene.
(b) Inadequate cooking/holding temperatures.
(c) Contaminated equipment.

Chapter 8
Outbreak Investigations (Epidemiology)

Melinda Wilkins, Ernest Julian, Kim Kutzko, and Sarah Rockhill

Learning Objectives

- Discuss the function of epidemiology in the context of food safety.
- Discuss appropriate surveillance techniques.
- Explain the steps involved in a foodborne illness investigation.
- Identify methods used to control and/or prevent the recurrence of foodborne illness.

Introduction

Epidemiology is the study of the distribution and determinants of health-related states or events in specified populations and the application of this study to the prevention and control of health problems (Last 2001). Epidemiology is considered a

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basic medical science with the goal of improving the health of populations (Bonita et al. 2006). Food protection professionals (FPPs) apply epidemiologic principles to analyze and understand surveillance data, detect, investigate, and control foodborne illness (FBI) outbreaks and to prevent outbreaks. This chapter will cover surveillance systems currently used at the local, state, and national levels to monitor ongoing illnesses and identify clusters of foodborne illness, the process of investigating a foodborne illness outbreak, methods used to control foodborne illnesses, and prevention methods.

Epidemiology in the Food Safety Context

Ancient history has demonstrated that people died from adulterants in their food almost as far back as records are available. However, a science-based public health approach to food safety is only about 100 years old (Lasky 2007). The history of epidemiology in food safety follows closely the history of modern approaches to food safety. As the industrialization of the food supply began to happen over the course of the twentieth century, so, too, did the increased role of epidemiology in understanding foodborne illness. Epidemiologists today play a vital role in the detective work and investigation of foodborne illness outbreaks. However, they also have an important role in the development and implementation of policy and preventive strategies to prevent foodborne illness outbreaks (Lasky 2007).

Appropriate Surveillance Techniques

Surveillance Defined

Surveillance, in a public health context, can be defined in several different, but similar, ways. A classic textbook definition is the systematic collection of data pertaining to the occurrence of specific diseases (or events), the analysis and interpretation of these data, and the dissemination of consolidated and processed information to contributors to the surveillance program and other interested people (Friis and Sellers 2009). The US Centers for Disease Control and Prevention (CDC www.cdc.gov) goes one step further and offers a definition that includes how the data is used: “Public health surveillance is the systematic, ongoing collection, management, analysis, and interpretation of data followed by the dissemination of these data to public health programs to stimulate public health action” (CDC 2012).

Data Collection, Analysis, and Dissemination

The collection of data is systematic and ongoing, not random, periodic, or haphazard. The data collected via a robust surveillance system establishes the baseline (expected) level of the event(s)/outcome(s) under surveillance. This baseline level is essential so that an increase above baseline can be detected by a vigilant epidemiologist or by an automated detection algorithm, depending on the system. Once collected, the data must be *analyzed and interpreted* in order to be useful. When an unexpected increase in the number of cases of disease (or events) is detected, this result should trigger further investigation into the possible explanations (an actual outbreak, a change in laboratory techniques, or a change in reporting/data collection). Finally, the information collected, analyzed, and interpreted must be disseminated to the people/agencies responsible for responding, such as public health and food safety officials, and to the reporting units themselves (often laboratories, hospitals, and local public health departments). Concerning cases of foodborne illness (FBI), the timely collection, analysis, interpretation, and dissemination of data is critical in order to identify an "outbreak" as soon as possible to reduce the risk of ongoing exposure (Outbreak Investigation Step 1, covered later in the chapter).

Local Health Department FBI Surveillance

Local health departments (LHDs) are considered the "frontline" for public health. At the local level, individual citizens interact directly with public health officials. Thus, if a person, or their health-care provider, believes he or she have become ill after eating at a local restaurant, the LHD is often contacted to register a complaint or concern. The structure and capabilities of "complaint-based" foodborne illness surveillance systems across the USA depend on agency authorities, resources, and training and also require high levels of cooperation across the health system. States vary in the approach in which they implement a complaint-based reporting system. Some states have independent, local public health agencies with a decentralized complaint-based reporting system, while other states have developed a centralized complaint-based system. Complaint-based reporting can be a very robust and timely surveillance system for FBI, but, to date, the system is not widely automated or organized into statewide or nationwide systems (Li et al. 2011).

The laboratory-based surveillance system is another system that also operates primarily at the local level. Although coordinated at the state level, LHD personnel are responsible for the follow-up of certain cases of FBI reported within that local jurisdiction. If a person living in County A becomes ill, seeks medical attention, has a biologic sample collected (usually stool) and tested, and the laboratory identifies a reportable pathogen, the laboratory will automatically report this information to the state and/or local health department. This reporting process takes about 2 weeks. The County A LHD will then follow up with the patient to collect additional

information including demographic, contact and referrer information, symptoms, exposure history (food, travel, animal exposure), and outcome (resolved, hospitalized, died). This information is entered into the reporting system and sent to the state health department.

State Health Department FBI Surveillance

The laboratory-based surveillance system is coordinated at the state health department (SHD) level, where the analysis, interpretation, and dissemination of surveillance data occur. At the state level, multi-jurisdictional outbreaks can be identified if the cases are spread out across several counties. The SHD, in turn, feeds the summarized data up to CDC via the National Electronic Disease Surveillance System (NEDSS, http://wwwn.cdc.gov/nndss/script/nedss.aspx).

SHDs also maintain syndromic surveillance systems. While laboratory-based systems are based on a laboratory-confirmed *diagnosis*, syndromic systems are based on *symptoms*, well before a diagnosis is available. These pre-diagnostic systems are designed to detect large-scale increases in illnesses within a population by recognizing an increase of similar symptoms clustered by time and location. Syndromic surveillance systems are not designed to detect individual cases of illness, only large increases in particular symptom classes in the population. The advantage that a syndromic system offers is speed. These systems are usually designed to collect chief complaint data from emergency departments, and the data is transmitted and analyzed in near real time. This is in contrast to the 2-week reporting timeframe generally utilized by laboratory-based systems. The symptom categories are designed to detect groups of symptoms related to bioterrorism agents, and the systems, often called "early event detection systems," were designed to quickly detect a large-scale release of a bioterrorism agent. Syndromic systems complement the more traditional laboratory-based surveillance systems (Henning 2004).

National FBI Surveillance Systems: FoodNet

The Foodborne Disease Active Surveillance Network, or FoodNet (http://www.cdc.gov/foodnet/about.html), is a network established in 1995 and is a collaborative program among CDC, ten state health departments, the US Department of Agriculture Food Safety and Inspection Service (USDA FSIS), and the US Food and Drug Administration (FDA). FoodNet is an active surveillance program, meaning that personnel actively solicit information from clinical laboratories in participating states. FoodNet conducts surveillance for *Campylobacter*, *Cryptosporidium*, *Cyclospora, Listeria*, *Salmonella*, Shiga toxin-producing *Escherichia coli* (STEC)

O157 and non-O157, *Shigella*, *Vibrio*, and *Yersinia* infections diagnosed by laboratory testing of samples from patients. FoodNet has four main objectives:

- Determine the burden of foodborne illness in the USA.
- Monitor trends in the burden of specific foodborne illness over time.
- Attribute the burden of foodborne illness to specific foods and settings.
- Disseminate information that can lead to improvements in public health practice and the development of interventions to reduce the burden of foodborne illness.

Individuals use FoodNet for active surveillance; surveys of laboratories, physicians, and the general population; and population-based epidemiologic studies. Information from FoodNet is used to assess the impact of food safety initiatives on the burden of foodborne illness (CDC 2013a).

PulseNet

PulseNet (http://www.cdc.gov/pulsenet/) is a national laboratory network made up of over 85 laboratories in the US. PulseNet connects foodborne illness cases together to detect and define outbreaks using DNA "fingerprinting" of the bacteria making people sick (CDC 2013b). The fingerprint is created using a standardized laboratory process called pulsed-field gel electrophoresis (PFGE). Every state has at least one public health laboratory that can perform PFGE analysis and share the results with PulseNet. PulseNet puts all the "fingerprints" into a database and tracks what is being reported to CDC daily and compares the fingerprints to what was reported in order to identify any changes. This means that PulseNet keeps a cumulative database representing nearly half a million isolates of bacteria from food, the environment, and human foodborne illness. Since being established in 1996, PulseNet has revolutionized the detection and investigation of foodborne disease outbreaks, especially in multiple sites across the country which, before PulseNet, often went undetected or were detected only after the outbreaks grew very large (CDC 2014a).

Steps Involved in a Foodborne Illness Investigation

Suspected foodborne illness outbreaks are typically identified through complaint-based reporting, laboratory-based reporting, or syndromic surveillance systems. Once a foodborne illness outbreak is suspected, an outbreak investigation is conducted in order to identify the source of the outbreak and to help prevent the spread of illness. Outbreak investigation involves forming a team consisting of people from a variety of disciplines such as environmental health, communicable disease, laboratory, and epidemiology. Although each outbreak investigation is different, the steps listed below provide a general overview of the common steps in an outbreak

investigation for which the discipline of epidemiology is used. The steps of an outbreak investigation may occur simultaneously or may be repeated during the course of the investigation. Additional resources describing the outbreak investigation process are found at the end of this chapter.

Step 1: Establish Existence of an Outbreak/Verify the Diagnosis

The first step in an outbreak investigation is to determine that the suspected outbreak is a "true" outbreak and to verify information describing the case(s). According to CDC and the Council of State and Territorial Epidemiologists, a foodborne illness outbreak is an incident in which two or more people experience a similar illness after ingestion of a common food, and epidemiological analysis implicates the food as the source of the illness. Two exceptions to this outbreak definition are (1) a single case of botulism or (2) chemical poisoning linked to a food. These two exceptions are considered to be an outbreak (CDC 2014b). Another way to define an outbreak is the existence of a greater number of cases of illness than typically expected during a limited period of time. However, the FPP must keep in mind that not all reports will be "true" outbreaks or that illness may be due to non-foodborne transmission.

The source of the outbreak report often determines the initial information collected in order to establish the existence of the outbreak. For complaint-based reports, the following information should be gathered:

- Illness symptoms.
- Date and time of illness onset.
- Date symptoms resolved.
- Demographic characteristics of the individual (name, age, gender, occupation, etc.).
- Description of the suspected source (restaurant or other location, event date, and time).
- Medical care sought, if any.
- Laboratory testing, if any.
- Diagnosis by a medical professional, if any.
- Food or food packaging, if available.
- Other persons who shared the exposure (both those who are ill and well).
- A 5-day food history (a listing of all foods consumed) is recommended by the Council to Improve Foodborne Outbreak Response in cases of diarrheal illness (CIFOR 2014).

This information is used to determine if the symptoms and incubation period (the period of time between exposure and illness) are consistent with the reported exposure. For example, some people may associate their illness with the last meal/food consumed (i.e., the last meal bias), which can ignore the true exposure.

Initial information collected based on laboratory-based reporting differs from complaint-based reports. In laboratory-based reporting, the cause of illness, typical

incubation period, and typical modes of transmission of the agent are known. Case investigation forms should be reviewed and summarized to determine if the people presenting symptoms share any demographic, geographic, or other exposure histories. In this case, historical data should be reviewed to determine if the current number of cases is more than what is typically reported in the area during a similar time frame.

Step 2: Construct Case Definition

A case definition provides the investigator with a way to systematically describe and identify new cases of illness in order to generate a hypothesis about the cause of the outbreak. The elements of a case definition differ according to the specific outbreak, but most often include clinical signs and symptoms, the pathogen or toxin, and, if known, other criteria such as a DNA fingerprint. Epidemiologic information about person (age, gender, occupation), place (neighborhood, city, event, restaurant), and time (dates during which exposure may have happened) is included. The case definition is revised throughout the course of an investigation to reflect the amount of information known. The early case definition is often broad:

> A person with diarrhea (3 or more loose stools in a 24-h period) and at least one other symptom (fever, abdominal pain, or nausea) who attended the Smith Reunion on Saturday, October 10th, 2013.

The definition narrows as more information is gathered during the investigation:

> A person diagnosed with *Salmonella Enteriditis*, with an illness onset between Sunday, October 11 and Tuesday, October 13, 2012, and who consumed chicken alfredo from the October 10, 2013 Smith Reunion.

There are three subcategories that can also be used to help further classify cases based on the certainty of diagnosis: confirmed/definite, probable/presumptive, and suspect/possible. Using the example above, a case could be defined as "a case of laboratory-confirmed *Salmonella Enteritidis* with onset of illness after October 11, 2013, and PFGE pattern (XXXX)"; "a probable case of laboratory-confirmed *Salmonella Enteritidis* with onset of illness after October 11, 2013"; or "a suspect case of diarrheal illness in a person who consumed chicken from the Smith Reunion on Saturday, October 10, 2013."

Step 3: Conduct Case Finding/Develop Line Listing

The case definitions aid investigators in searching for more cases of illness related to the outbreak. Identification of additional cases is important, since the cases initially reported likely represent a subset of the actual number of people who may be ill. Not all cases need to be identified during an outbreak, but a significant sample should be obtained for hypothesis generation. Methods used to conduct case findings can be considered to be active or passive, and a combination of both active and passive methods is often used in outbreak investigations. Active methods include contacting groups that may have been exposed or reviewing emergency room records for similar illnesses. A line listing (see Table 8.1) is one way to easily organize and summarize information about possible cases and identify possible sources of exposures.

Information can be obtained from medical records and/or from questionnaires/interviews. Line listings can be paper or electronic, but should include information relating to the case definition (time, person, and place) and suspected exposures. Each row in the list represents one person and each column represents information about the case such as gender, age, date of illness onset, and risk factors such as foods eaten, etc. Information should be tabulated for people who are ill and those who are not ill, but shared the suspected exposure (i.e., anyone who attended the event or consumed the suspected food, regardless of illness). New information should be added to the line listing as it is obtained throughout the investigation.

Step 4: Perform Descriptive Epidemiology/Develop Hypotheses

Epidemiologists use information from the line listing to characterize the outbreak in terms of time, person, and place (descriptive epidemiology). Demographic characteristics include age, gender, occupation, special dietary habits, or ethnicity. For example, an outbreak of *E. coli* 0157:H7, where the majority of the cases occur in vegetarians, may indicate increased likelihood of an exposure to lettuce or sprouts versus undercooked beef.

The characteristics of place can include residence, event or restaurant location, and area seated during the suspected event. An epidemiologic curve (epi curve) is a histogram that is generated to describe the outbreak in terms of time. The epi curve graphs the number of cases of illness by onset day/time. The epi curve can provide information that indicates the type of outbreak, such as a point source or person-to-person and whether the outbreak is ongoing (Figs. 8.1 and 8.2). If a common meal is involved, the epi curve can be used to determine the incubation period, which is the period of time between exposure and symptom onset.

Once the descriptive analysis is performed, the results are used, along with environmental health inspection reports and knowledge regarding the agent, to develop a hypothesis (an educated guess/unproven theory) about the possible agent and/or

Table 8.1 Example line listing

				Symptoms						Menu items consumed							
ID	Ill (Y/N/DK)	Onset date	Onset time	N	V	D	F	Age	Gender	Item 1	Item 2	Item 3	Item 4	Item 5	Item 6	Item 7	Item 8
1	N							5	M	Y	N	N	Y	Y	N	Y	N
2	**Y**	11/1/2013	8:30 p.m.			Y		33	F	**Y**	**Y**	N	N	**Y**	N	**Y**	**Y**
3	**Y**	11/2/2013	5:30 a.m.			Y	Y	35	M	**Y**	**Y**	**Y**	**Y**	**Y**	N	**Y**	**Y**
4	**Y**	11/1/2013	9:45 p.m.			Y	Y	42	F	**Y**	**Y**	**Y**	N	**Y**	**Y**	N	**Y**
5	**Y**	11/1/2013	11:00 p.m.	Y				48	M	**Y**	**Y**	N	N	**Y**	**Y**	N	**Y**
6	N							3	F	Y	N	Y	Y	Y	N	Y	N

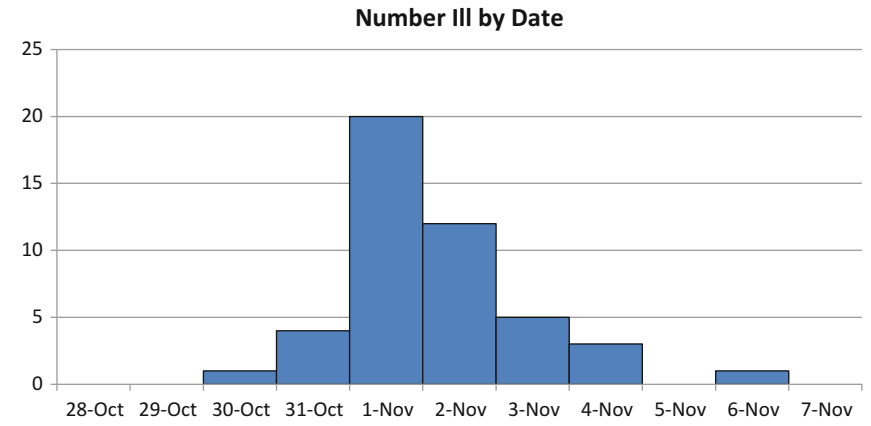

Fig. 8.1 Epi curve, point source

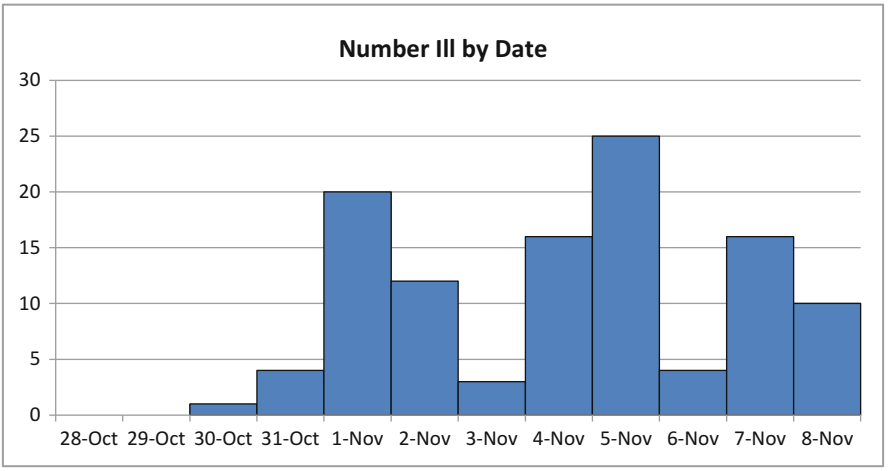

Fig. 8.2 Epi curve, person to person

source of the outbreak. Constructing a hypothesis helps investigators to clearly identify what information is known and what information is missing. However, a hypothesis is limited by the quality of the information available and may change throughout the investigation.

Generating a hypothesis to identify a specific food item as the source of an outbreak can be a complex process. In general, information regarding consumption of food items is subject to recall bias because a person may not remember complete details of their recent food consumption. Imagine an individual having to answer detailed questions about what he or she ate and drank for breakfast, lunch, and dinner 3 weeks ago. Further complicating the issue is the fact that a single,

specific ingredient of a larger food item may be the source of a foodborne illness outbreak. For example, if a person ate spaghetti with meat sauce, the source of the outbreak could be the tomatoes used in the sauce, the meat in the sauce, the spaghetti, or any other ingredient.

Step 5: Implement Control and Prevention Measures

The rapid implementation of control measures is one of the most important aspects of an outbreak investigation and is discussed in greater detail at the end of this chapter. In general, control measures are designed to end the current outbreak and to prevent future outbreaks. Descriptive statistics can be used to target control measures throughout the course of the investigation.

Once the most likely source of contaminated food is determined, two FPPs should be sent to the site: one individual can ensure that immediate control measures are in place to stop the distribution of contaminated product, while the second individual can investigate the cause of the outbreak and determine exactly what foods were served, how the foods were prepared, and the individuals who prepared and served the same foods.

Step 6: Evaluate Hypotheses/Perform Additional Studies as Needed

After an initial hypothesis is formulated and additional information is collected, epidemiologists analyze this information to determine if the source of illness has been correctly identified. One of two possible study designs (case control or cohort) is used to determine if ill persons are more likely than people who were not ill to have eaten a certain food or report a particular exposure. If results show that eating a particular food is reported more often by sick people than by well people, the food may be associated with illness (Missouri Department of Health and Senior Services 2014).

Next, epidemiologists use statistical tests to determine the strength of the association between the food and illness (i.e., how likely the illness is to have occurred by chance alone). Sometimes epidemiologists find no statistical association between the illnesses and any particular food, even when all the clues clearly point to foodborne transmission. In fact, investigators identify a specific food as the source of illness in about half of the foodborne illness outbreaks reported to CDC. However, even if no statistical association is found, the illness or outbreak may still be foodborne, yet the source could not be determined. If the outbreak has ended, and no source of the outbreak has been identified, the source of the outbreak is declared unknown. If people are still getting sick, investigators must keep gathering information and studying results to find the cause of the illness (Missouri Department of Health and Senior Services 2014).

Step 7: Communicate Findings

Good communication among all of the staff members working on the outbreak investigation is an important part of the process. Throughout the investigation, FPPs should communicate findings within their agency and to partner agencies. Outbreaks should be quickly reported to state and federal agencies in order to quickly identify outbreaks caused by widely-distributed contaminated food products. In certain outbreak situations, information is released to the general public to help with case findings or to prevent additional illness; typically, there is a designated spokesperson who speaks to the media. Epidemiologists need to have an accurate list of foods served in order to ask the right questions and identify the source. FPPs need information from epidemiologists and the lab in order to determine the right facility and food and implement appropriate control measures to prevent additional illnesses.

Step 8: Maintain Surveillance/Deciding an Outbreak Is Over

The length of an outbreak can vary depending on the source and agent. The FPP should be on the lookout for any new cases of illness for one to two incubation periods after the last reported case. If new cases arise, the investigation should be restarted to determine if the original outbreak was not completely controlled or if there is a second contamination involving another food, ill individuals, or location(s) linked to the first outbreak.

When the outbreak investigation is complete, a final report summarizing the outbreak must be written. The content of a final report is dependent on the nature of the outbreak, but in general the report should have seven sections (Table 8.2).

Information contained in the final report is submitted, by the state health department, to CDC as part of the National Outbreak Reporting System (NORS, www.cdc.gov/nors/). CDC uses this data to monitor national outbreak trends and to make recommendations to prevent similar outbreaks in the future.

Methods Used to Control and/or Prevent the Recurrence of Foodborne Illness

The primary purpose of any foodborne illness outbreak investigation is to prevent additional illnesses, long-term disabilities, and deaths caused by a facility or product in question and to prevent a recurrence of the factors that led to the outbreak. Early detection, rapid response, and close collaboration/communication are critical to limiting the number of individuals who become ill and reducing the economic burden on the food industry.

Table 8.2 Outbreak report sections

Section	Description
Investigation summary	A general overview of the investigation, the who, what, where and when.
Outbreak description	How the outbreak was first reported, steps taken to confirm and control the outbreak, and the individuals who assisted in the investigation.
Background	A brief description of the facility or event involved in the outbreak.
Methods	How the investigation was conducted. Summaries from epidemiology, environmental health, and laboratory can be included.
Results	Relevant results from epidemiology, environmental health, and laboratory.
Discussion	The conclusion(s) regarding the source of the outbreak.
Recommendations	Control recommendations made to the facility and any follow-up actions.

FDA Efforts

In recent years, FDA has helped improve response to foodborne illness outbreaks through the creation of rapid response teams (RRTs) across the US under a multi-year cooperative agreement between FDA and state regulatory agencies. Since 2008, RRTs have conducted integrated, multiagency responses to all-hazards food (and feed) emergencies and have involved federal, state, and local partners, not only across jurisdictions, but also across disciplines such as environmental health, epidemiology, laboratory, law enforcement, and emergency management. Highlights and successes of these RRTs have included linking a dry dog food product to illnesses in dogs and humans; responding to an oil spill off the coast of Texas; using novel traceback methods to identify a single blueberry grower in Minnesota; and confirming in-shell hazelnuts as the source of a multistate *E. coli* outbreak. The second edition of the RRT Manual of Best Practices (called the RRT Playbook) is available upon request from FDA (FDA 2014). RRTs also play a role in FDA's Coordinated Outbreak Response and Evaluation, or CORE Network, which utilizes all key, strategic FDA resources in place in the field to manage outbreak response, along with surveillance and post-response activities (FDA 2013a).

Avoiding the Last Meal Bias

One way to help identify the source of a foodborne illness is to avoid the common consumer error of blaming the last meal consumed, or the "last meal bias" (CIFOR 2014). The vast majority of the time, the last meal consumed is not the source of sickness, as certain pathogens may take days to cause illness. For example, the

symptoms (diarrhea, fever, cramps, etc.) caused by *Salmonella*—which kills approximately 450 people in the US each year—can develop anywhere between 12 and 72 h after infection (CDC 2014c). If the FPP runs off to the last facility where food was consumed because this meal/facility is what the consumer blames, and this incident is not the cause, the source of the outbreak will not be determined and illnesses may continue. For this reason, at least a 3-day food history (5 days for a diarrheal illness) should be obtained and assessed for the most likely cause of illness.

Employee Education/Training

Changing behavior can be difficult, and employees may use routine unsafe practices unless management and health and regulatory officials ensure that new safe practices are implemented. Food facility management needs to inform all employees that symptoms must be reported and ill employees must be restricted or excluded from food preparation areas, day care centers, health-care facilities, etc. until at least 48 h after the cessation of symptoms. Ill employees may be difficult to identify, as the employees may be reluctant to admit to being ill, knowing that an outbreak has occurred and that the employees may be the cause.

Employees should also be instructed in proper handwashing methods, since the employee may shed the pathogen and contaminate food for weeks. All food handlers should avoid hand contact with ready-to-eat foods such as salads. Preparing food for anyone when ill, including family members, should also be avoided, especially if family members work in high-risk facilities. Employees should also be taught about methods to control the spread of infection, e.g., wearing a mask or using certain disinfectants.

Facilities should also have an adequate sick policy to ensure that ill employees are excluded or restricted from preparing food. Some food establishments have a policy that an employee must find a replacement if he or she is ill. Some regulatory jurisdictions are experimenting with requiring a certain number of days of sick time for food preparation employees to reduce the likelihood that a minimum wage employee will come to work when ill because the employee cannot afford to lose the income.

Facility managers should be trained and certified in food safety, and employee training should be implemented and periodically verified for accuracy and relevance. Research has found an association between the lack of a certified manager and foodborne outbreaks and/or foodborne illness risk factors, including research from CDC and FDA (see Additional Resources at end of chapter). In fact, the Conference for Food Protection (www.foodprotect.org) recommended in 2012 that the FDA Food Code include a provision for a manager certified in food safety. FDA accepted the recommendation and the 2013 Food Code includes the requirement for a certified food protection manager.

Temperature Control

Improper cooling, holding, and reheating temperatures can contribute to foodborne illness. Refrigeration units can operate at unsafe temperatures, especially during heat waves where air conditioning is insufficient to maintain ambient temperature. Some refrigeration equipment can only operate at a maximum external temperature of 78–80 °F. Slow leaks of refrigerant can result in foods being kept at an unsafe temperature. Facilities should have steps in place to measure and record temperatures, or utilize an automatic alarm system, to ensure that refrigeration units continue to operate at the appropriate temperature. Follow-up inspections may be required, especially if refrigerant is added in order to address a problem; a slow leak may again result in foods at unsafe temperatures.

Improper cooling is frequently implicated in foodborne outbreaks. If cooking in advance followed by cooling is necessary, then the distance between shelves in walk-in refrigerators could be reduced to allow for cooling in shallow containers. Often shelves in walk-in refrigerators are approximately two feet apart, which promotes cooling in large containers or stacking of hot foods, which can, in turn, lead to unsafe cooling times and temperatures. Procedural changes could also be made to rapidly cool foods, or a blast chiller could be purchased.

Equipment Cleaning

Thorough cooking, proper cooling, proper hot and cold holding, and thorough reheating kill pathogens and prevent pathogen growth. However, all food contact surfaces should also be properly-cleaned and sanitized, especially frequently-contaminated and difficult-to-clean surfaces such as cutting boards, grinders, choppers, blenders, and meat slicers.

There are many types of equipment that can be unsafe and can contribute to outbreaks. For example, a difficult-to-clean meat slicer in Georgia was implicated in ongoing salmonellosis cases. Sharing of this information led to identification of similar, impossible-to-clean meat slicers in Washington State and Rhode Island that also contributed to ongoing salmonellosis outbreaks (PritzgerLaw 2010). This incident contributed to NSF International (www.nsf.org) changing the standard for the construction of new slicers. Illnesses would have continued and the standards would never have been changed if the root cause of these outbreaks had not been determined and the information had not been shared with other state and federal officials and NSF. Thousands of unsafe slicers continue to pose a hazard in food establishments, however. More information about unsafe slicers can be found at http://www.fda.gov/downloads/Food/GuidanceRegulation/UCM240674.pdf.

Distribution Issues

The possibility of contaminated ingredients entering the facility must always be considered. Outbreaks thought to be local in scope are often found to originate from nationally-or regionally-distributed contaminated food products or ingredients. To illustrate, a 2012 salmonellosis outbreak—caused by a frozen tuna product sold in restaurants and grocery stores—affected more than 400 individuals in 28 states and the District of Columbia (Marler Clark 2014).

FPPs also need to determine if there are other food establishments under the same ownership. If a regionally- or nationally-distributed contaminated food product is the cause of an outbreak, then illnesses may also have occurred at these other locations with foods from the same sources. If unsafe practices led to the outbreak, these same unsafe practices may exist in other establishments under the same ownership. Credit card receipts, reservation lists, and inspection records can help the FPP make these determinations.

Many establishments have trusted suppliers that provide evidence that their products have been tested and were produced under a Hazard Analysis & Critical Control Points (HACCP) system—the topic of Chapter 11 of this book. While supplier assurances and testing are desirable, verification of the safety of ready-to-eat products needs to occur since suppliers obviously have an incentive to state that their products are safe.

Enforcement Actions

The first priorities during an investigation at a food establishment are to embargo suspect leftovers to prevent additional illnesses and to take samples of suspect foods and ingredients to determine the cause of the outbreak. A suspect product is often embargoed and later disposed if not implicated in the outbreak, as opposed to being served and allowed to cause additional illnesses.

Closing a facility or limiting operations (e.g., requiring cooking and immediate service instead of cooking foods a day or more ahead of time) may be necessary in situations where imminent hazards to health cannot be immediately eliminated; where the facility has a history of recurring serious hazards or a history of noncompliance; or if critical controls are not implemented.

Communication with Other Agencies and with the Public

FPPs also need to determine if notification of other agencies or food establishments is warranted or a public advisory or recall is needed. If contaminated foods are likely to be in consumers' homes and illness is likely to occur, then a public advisory is needed.

Similarly, if steps can be taken to prevent illness, or if medical treatment is needed, then public notification should occur. Such is the case when an ill food handler with hepatitis A has been preparing food with his or her bare hands, and shots of immune globulin can be given within 2 weeks of exposure to prevent illness from occurring. If a contaminated food product in commerce is possibly the source of the pathogen, appropriate local, state, and federal agencies should be notified, even if the source is unconfirmed.

Recall Audit Checks

If a recall of a high hazard food is necessary, recall audit checks to ensure that recalled products are removed from sale should be conducted. Generally, a recall audit check is where the FPP makes a personal visit, makes a telephone call, or sends written correspondence to a recalling firm—or a user in the chain of distribution—to verify that notification of the recall has been received and that appropriate recall steps have been taken (FDA 2013b). Often, recalled products are not removed from sale for a variety of reasons: manufacturers or distributors may not notify food establishments that a certain product is being recalled; the product may be removed from one part of a store and not from another area; the product may be returned to the store and mistakenly put back on the shelves; or a recalled product may be delivered after the shelves have been cleared of recalled products and the shelves restocked without realizing that the delivered product has been recalled. Additionally, the scope of a recall may expand and a facility may believe that the new notification is a repeat of the initial notification and not remove the new recalled items from sale. For all of these reasons, audits should be performed to ensure that hazardous products are removed. If recalled items are not removed, the cause for the nonremoval should be determined, and appropriate individuals and agencies should be notified. For example, FDA should be notified if a retail facility has not removed a recalled product from sale because the facility was not notified by its distributor. If the distributor did not notify the retail facility, the distributor may have failed to notify its other customers.

Conclusion

Epidemiology offers the scientific framework upon which many of the day-to-day activities of a food protection professional can be based. Outbreaks cannot be detected without having robust surveillance systems in place to establish the baseline or expected levels of foodborne illnesses in a population. Following preestablished outbreak investigation steps will help everyone involved remain focused and work toward common goals during an often stressful and time-pressured event. The data generated by the investigation will accurately direct the efforts of the

investigators to quickly identify the problems within the food facility. The effectiveness of intervention and prevention methods must be measured and evaluated and based on epidemiologic data.

Take-Home Message

Understanding the vectors/vehicles of spreading foodborne illness and the processes used to determine the source(s) of foodborne illness is essential for the FPP to establish his or her role in the control of foodborne illness and to ensure that safe food-production practices are in place. The FPP should develop a tentative determination that will guide the investigation and help determine the root cause of the outbreak. The FPP should also work with the epidemiology team on follow-up activities to help avoid a similar outbreak from occurring.

Activity

Six coworkers attend a sporting event one night after work, and all of them eat food from the same concession stand. The next morning, five of the six individuals wake up feeling sick, call their supervisor, and take a sick day from work. The supervisor contacts a local health official, who assigns someone to conduct a preliminary investigation.

What questions or issues should the investigator consider?

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Answer Key

Possible questions/issues to consider:

- Did the coworkers eat the same food item from the concession stand, i.e., hot dog, popcorn, etc.?
- Did the coworkers eat the same food from a location other than the concession stand at the sporting event?
- Were there any factors at the concession stand that might have contributed to foodborne illness, e.g., improper cooking methods, time and/or temperature abuse, dirty conditions, poor personal hygiene, etc.?
- Did any of the concession workers become sick?
- Is there something at the coworkers' building/workplace that could be a factor?
- Have other area health departments received similar calls?

Chapter 9
Environmental Health and Safety

David McSwane, Jeffrey French, and Ron Klein

Learning Objectives

- Examine common categories of environmental health hazards (biological, chemical, physical, and radiological).
- Explain how epidemiology and toxicology inform our understanding of environmental hazards.
- Describe the components of risk analysis.
- Describe basic safety issues related to emergency response operations.

Introduction

The goal of environmental health is to create an environment that will provide optimal public health and safety, ecological well-being, and quality of life for current and future generations (Gordon 2014). Environmental health programs employ a combination of prevention and control strategies to manage and mitigate environmental hazards.

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Prevention programs focus on why the hazard was created, while control programs focus on treating and characterizing the impact of the hazard after the hazard has occurred. The food protection professional (FPP) should have a basic understanding of how environmental health and safety are informed by the fields of epidemiology and toxicology, and he or she must understand how risk assessment plays a crucial role when responding to environmental health and safety hazards. FPPs must also utilize various safeguards when responding to environmental disasters and participating in emergency response operations.

Common Categories of Environmental Health Hazards (Biological, Chemical, Physical, and Radiological)

Hazards from environmental sources can be broken down into four general categories: biological, chemical, physical, and radiological. The effects these hazards have on human health can vary widely, depending on the type of hazard, route and duration of exposure, and the health status of individuals at the time of the exposure.

Biological Agents

Biological agents include bacteria, viruses, parasites, plants, and animals. Bacteria, parasites, plants, and animals are living organisms, while viruses require a living host to reproduce.

Bacteria are unicellular or multi-cellular microscopic organisms that lack chlorophyll, multiply by simple fission, and, with some species, develop highly-resistant resting (spore) phases (Cambridge Dictionary of Biology 1991). Bacteria require specific conditions to survive and multiply (i.e., moisture, pH or acidity level, temperature, food) at varying levels depending on the species. Bacteria are commonly found in air, water, soil, sewage, as well as in and on insects, rodents, and birds.

Opportunities for bacterial contamination of food and water can be numerous. Bacteria can originate from the raw materials within food products or can be introduced into food products from the surrounding environment during harvesting, processing, and handling. Bacterial infections can result when pathogenic microorganisms in food or water are ingested and grow within the body, typically in the intestinal tract. Adverse effects from contaminated food or water can range widely from mild gastrointestinal distress to more chronic, long-term health issues or even death depending on the bacterial agents involved, the level of bacteria present in the contaminated product, and the susceptibility of the affected individual. Leading bacterial pathogens linked to foodborne illness in the USA include *Salmonella*, nontyphoidal; *Clostridium perfringens*; *Campylobacter* spp.; *and Staphylococcus aureus* (CDC 2014).

Viruses are extremely small particles not visible with traditional microscopes and that lack the ability to reproduce by themselves. Viruses can exist in foods without growing, so no food, water, or air is needed for their survival. However, viruses require living cells as hosts in order to reproduce (National Seafood HACCP Alliance 2011).

Viruses are responsible for a wide range of human illnesses. Norovirus is the leading cause of acute gastroenteritis (i.e., vomiting and diarrhea) in the USA, causing an estimated 19–21 million illnesses, 56,000–71,000 hospitalizations, and 570–800 deaths annually (CDC 2013). Like bacteria, viruses can be transmitted through food and water contaminated from infected people or from environmental sources (e.g., shellfish from contaminated growing areas).

Viral foodborne illnesses often result from contamination of food products by infected people. Poor hygienic practices can lead to contamination of food products via the fecal and oral routes. As with bacteria, viruses can cause acute, relatively minor illness or more debilitating chronic problems depending on the susceptibility of the infected individual. For example, norovirus infections typically result in gastrointestinal illnesses which, although unpleasant, typically resolve in 12–24 h. Hepatitis A infections, on the other hand, can result in liver damage and, in some cases, cause death (FDA 2012).

Parasites are organisms that live on or in other organisms. Although thousands of different parasites exist in the environment, only a small portion, primarily parasitic worms and protozoa, are known to infect people through the consumption of contaminated food or water (National Seafood HACCP Alliance 2011). Life cycles of parasites require utilization of other organisms as hosts (e.g., fish, swine). Consuming food products made from those animals can cause individuals to become infected with the parasites. Food products can also be infected with parasites through exposure to sources such as raw sewage or infected individuals that use inadequate personal hygiene practices.

All parasites can be killed by thorough cooking or freezing of food. As a result, human infections can occur when food containing viable parasites or parasitic eggs or cysts is consumed raw or undercooked or the product has not been adequately frozen. According to the FDA Food Code, cooking—and sometimes holding—food at specific minimum temperatures and for minimum amounts of time destroys organisms of public health concern. In many cases, a temperature of at least 145 °F (63 °C) or above for 15 s is required; however, some foods require higher cooking temperatures to destroy the organisms (FDA 2013a). The Food Code also provides options for heating at lower temperatures for longer times, e.g., heating beef roasts at 130 °F for 112 min (FDA 2013b).

Freezing is used to destroy parasites found in fresh fish. According to the Food Code, raw or partially cooked fish should not be served or sold in ready-to-eat form unless the fish is frozen and stored at a specific temperature—or below—for a specific amount of time, depending on the type of fish (FDA 2013c). Fish used in sushi must been held at −4 °F (−20 °C) or below for 7 days (or variations of lower temperatures for shorter time).

Parasitic infections can manifest in various parts of the human body (such as the liver and lungs) but most often occur in the gastrointestinal tract, primarily the intestines. Effects of parasitic infections can vary widely from mild discomfort to debilitating illness, and most parasitic infections will require some form of medical treatment to eradicate the parasite from the body. If left untreated, parasitic infections can greatly diminish overall health and, in extreme cases, can result in death.

Chemical Hazards

Chemical hazards associated with food products can be naturally occurring or can result from contamination from outside sources. Chemical agents typically include (A) naturally occurring toxins, (B) heavy metals, (C) allergens, and (D) intentionally- or unintentionally-added chemicals.

Naturally-Occurring Toxins

Toxins are defined as poisonous substances of biological origin (Cambridge Dictionary of Biology 1991). Certain types of disease-causing bacteria produce wastes that are toxic to humans, as is the case with *Staphylococcus aureus* and *Clostridium botulinum*. Bacteria that form toxins can be introduced into food when the food is prepared under unsanitary conditions or by food handlers who do not practice good personal hygiene (e.g., *Staphylococcus aureus*) or in low-oxygen packaged foods that are not adequately processed to eliminate bacteria such as *Clostridium botulinum*. Consuming toxins can cause a foodborne intoxication. Adverse effects from foodborne intoxication can range widely from mild gastrointestinal distress to more chronic long-term health issues or even death depending on the bacterial agents involved, the level of bacteria or toxins present in the food product, and the susceptibility of the affected individual. For example, most foodborne bacteria produce enterotoxins that affect the gastrointestinal tract. However, *Clostridium botulinum* bacteria produce a neurotoxin that affects the central nervous system.

Toxins can also originate from natural sources. For example, certain types of algae produce a biotoxin that, when consumed by small fish, is deposited in the skin and flesh of the fish. If the small fish is eaten by a larger fish, the toxin is passed along and accumulates in the consuming fish. Ciguatoxin poisoning is caused when people eat tropical reef fish such as mahi-mahi or snapper. When filter-feeding shellfish such as oysters, mussels, and clams feed on toxic algae, the toxins can accumulate in the internal organs of the shellfish. Most cases of seafood intoxication, such as paralytic shellfish poisoning (PSP) and diarrhetic shellfish poisoning (DSP), are caused by the consumption of contaminated shellfish harvested for recreational purposes or illegally-harvested from polluted waters.

The degree to which the human body reacts to intoxications can vary greatly. In mild cases, the recovery can occur without medical treatment once the toxin has been eliminated from the body. In other cases, as with scombrotoxin poisoning, extremely sensitive individuals may require hospitalization. Tetrodotoxin, common in certain puffer fish, can cause death at very low levels in less than an hour (FDA 2012).

Heavy Metals

Heavy metals such as lead, copper, mercury, and cadmium are naturally-occurring metals that are toxic to organisms at elevated levels. Heavy metals are also produced by industrial processes and pollution. For example, elevated concentrations of methyl mercury in oceans and other water bodies have been linked to the atmospheric deposition of the heavy metal from the combustion of coal by power plants. Mercury is taken up by the producers in an ecosystem and is passed on to consumers at a higher trophic level, i.e., a higher position an organism occupies in a food chain (Science Daily 2014). Mercury increases in concentration when transferred from one trophic level to the next in an ecosystem. This phenomenon is known as biomagnification. When organisms take up contaminants more rapidly than their bodies can eliminate the contaminants, the excess can accumulate in the body. This is known as bioaccumulation. Certain types of fish, such as swordfish, shark, and tuna, bioaccumulate methyl mercury in their flesh, which can pose potential health risks to consumers who eat these foods.

Acute exposure more often occurs in cases where large amounts of metals like lead are ingested directly over short periods, as with ingestion of lead-based paint by toddlers. Chronic exposure to heavy metals can result in debilitating conditions such as fatigue, weakness, joint and muscle pain, and constipation. Damage to the brain and nervous system can also occur. Consumption of large amounts of contaminated foods by pregnant women can result in miscarriages and birth defects. The US Environmental Protection Agency (EPA, www.epa.gov) issues guidance to inform consumers of risks and recommended intake limits of foods likely to contain elevated heavy metal concentrations, such as methyl mercury levels in fish (EPA 2013a).

The human body will not typically shed most heavy metals on its own. Chelation therapy, the use of specific compounds administered to patients that will bind with the heavy metals and ultimately remove the metals from the body in urine, is effective but, can also include serious side effects (EPA 2013b).

Allergens

A food allergy is a malfunction of the immune system called “hypersensitivity.” When the immune system mistakes food for something harmful, the system overreacts by releasing histamine and other chemicals in the body. This allergic reaction is not only

uncomfortable, but can be life-threatening. Anaphylaxis is a major allergic reaction. Symptoms often come on suddenly (acute) and involve more than one part of the body (e.g., lungs, heart, throat, stomach). A person's blood pressure may drop, causing loss of consciousness. Anaphylaxis is life-threatening and requires immediate medical treatment—typically via an injection of epinephrine (adrenaline), followed by treatment by a medical professional. At this time, there is no cure for food allergies. The only way to prevent an allergic reaction is for the affected person to completely avoid the problem food (University of Michigan 2014).

The Food Allergen Labeling and Consumer Protection Act (FALCPA, Public Law 108-282, Title II) identifies eight major food allergens in the USA: milk, egg, fish, Crustacean shellfish, tree nuts, wheat, peanuts, and soybeans. Although FALCPA applies only to packaged foods regulated by the FDA, the USDA has clearly stated that, in order to achieve consistency, the agency would also follow the FALCPA labeling requirement for USDA-regulated products. The requirements under FALCPA also apply to items packaged by foodservice establishments and offered for human consumption; FALCPA does not apply, however, to food items placed in a wrapper, container, or box in response to a customer's order, e.g., a fast-food establishment (FDA 2006).

FALCPA requires that major allergens be declared, in plain English, on ingredient labels. Additionally, in the case of tree nuts, fish, and shellfish, the particular type must be declared (e.g., walnut, salmon, shrimp). A complete list of tree nuts, along with a link to a complete list of seafood items, can be seen in an FDA Guidance for Industry document (FDA 2006).

Intentionally- or Unintentionally-Added Chemicals

Chemicals can also be intentionally added to food products via fertilizers, pesticides, and herbicides (often used in agricultural operations), drugs that are used to treat certain animals such as cows and fish, and preservatives or coloring agents used in food processing plants. Regulatory agencies like USDA and FDA establish action levels and publish industry guidance to help ensure that these chemicals are properly used.

Unintentionally-added chemicals can include cleaners or sanitizers that come into contact with food due to a lack of good manufacturing practices. This can be especially problematic with the importation of food products from countries that may not utilize adequate controls over the use of food chemicals.

Synthetic chemicals such as pesticides, detergents, and sanitizers can also be toxic to humans if consumed in high enough concentrations. These substances are commonly-used by the food industry to control pests and keep surfaces clean and sanitary. However, the chemicals must be stored and used carefully to prevent contamination of food and food-contact surfaces.

The effects of chemicals—either intentionally or unintentionally added to foods—can vary widely from mild to severe depending on the chemical involved,

the amount of the chemical, the health of the affected individual, and the individual's immune system.

Physical Hazards

According to the National Seafood HACCP Alliance (2011), a physical hazard is any extraneous matter not normally found in food that could cause physical injury. Glass (from bottles, jars, and other containers) and metal (machinery, wire, hooks, staples) are common physical hazards associated with food. Physical hazards can also include stones, insulation, bones, gunshot, plastic, and personal effects (FDA 2013d).

Glass and metal fragments can enter food products during processing or at retail operations. For example, overhead lights may break and glass could fall into a food product, or, in certain operations, hammer mills or cutting blades may become damaged and metal fragments may enter a food product. Most food processors operate under some form of HACCP (Hazard Analysis and Critical Control Point) program where steps are taken to protect against physical hazard inclusion and to monitor products for physical hazards. In addition, Good Manufacturing Practices require workers to eliminate potential hazards from their person, such as rings, earrings, jewelry, nail polish, and buttons.

The effects of consuming food containing a physical hazard can vary. A common assumption is that most injuries would be relatively minor (e.g., a chipped tooth or a small cut to the mouth). However, substantial bodily harm could result from ingestion of sharp pieces of glass or metal, which could reach the lower digestive tract and cause internal damage and bleeding.

Radiological Hazards

Food products contain certain levels of radioactive isotopes, depending on the type of food and the geographic location where the product was produced. For example, the EPA has reported extremely low levels of radiation in milk samples; however, consuming enough milk to approach a level of concern would be virtually impossible, even for a person who drinks a lot of milk (FDA 2014). Humans are exposed to an estimated 360 millirems (mrem) of radiation annually, of which about 10 mrem originates from consumer products such as food. As a reference point, radiation levels below roughly 25,000 mrem have little discernible effect on the human body (Washington Military Department 2007). Humans are also exposed to limited radiation through medical procedures such as X-rays.

Although typical environmental levels of radiation in food generally do not pose risks to consumers, risks can result in the event of accidental release of nuclear material into the environment. In such an event, food products can become contaminated with high levels of radioactive material from airborne material falling onto crops or livestock directly or through contaminated rainwater or snow (International Food Safety Authorities Network 2011). Additionally, long-term ingestion of food or water containing high levels of radioactive material can adversely affect the body, leading to organ dysfunction or various forms of cancer. The World Health Organization (WHO) categorizes the primary long-term threat to human health from a nuclear accident affecting the food supply as a likely increase in various forms of cancer to exposed populations (International Food Safety Authorities Network 2011). In January 2013, the FDA proposed new rules as part of the Food Safety Modernization Act (FSMA) in which "radiological" was added to the list of hazards typically included in hazard analyses and HACCP plans for food processing facilities.

How Epidemiology and Toxicology Inform Our Understanding of Environmental Hazards

Food protection professionals need a reliable source of accurate information to help them identify and eliminate or control hazards in the general environment and workplace that can adversely affect human health. Two important tools for generating this information are epidemiology and toxicology. Epidemiology is the study of the distribution and determinants of health-related states or events in specified populations and the application of this study to the prevention and control of health problems (Last 2001). Epidemiology is considered a basic medical science with the goal of improving the health of populations (Bonita et al. 2006). Food protection professionals (FPPs) apply epidemiologic principles to analyze and understand surveillance data; to detect, investigate, and control foodborne illness outbreaks; and to prevent outbreaks. Occupational epidemiology studies the role of exposure to hazards in the workplace.

Environmental toxicology is a multidisciplinary field that studies how exposure to toxic chemicals can adversely affect the health of people, plants, and animals. The adverse effects of toxic substances can result from direct exposure to these agents or indirectly through air, water, and soil. Adverse effects for humans can be physiological or genetic, can range from mild to severe, and in worst-case situations, may cause death.

All substances have the potential to be toxic or poisonous. However, the dose—not the mere presence of a toxic agent in a sample—determines whether or not the substance is actually toxic. Toxic agents can produce acute effects (sudden symptoms that last for a short time) and chronic effects (delayed symptoms that can last

for many months or years). Toxicologists determine the relative toxicity of various compounds. This determination is made based on various factors, such as:

- *Potential sources of exposure*—industrial waste, agricultural chemicals, waterborne toxicants, air pollutants, and food additives.
- *Route of exposure*—Inhalation through the lungs, ingestion via the gastrointestinal tract, and absorption through the skin.
- *Amount of the toxic substance that enters the body*—Toxic chemicals can be detected by laboratory analysis of environmental samples in very small concentrations [parts per billion (ppb) or parts per trillion (ppt)], and the concentration determines whether the substance is a concern to public health.
- *Where the compound goes in the body*—Some toxic agents have a localized effect on the body, and the symptoms are restricted to the site of initial exposure (e.g., lungs, skin, digestive tract). Other toxicants, however, have a systemic effect where the adverse effects occur at sites far removed from the initial site of exposure (e.g., liver, kidney, central nervous system, reproductive system).
- *Types of chemical interactions that occur when two chemicals are present at the same time*—Some toxic agents work against each other where one substance interferes with the effects or stimulates the breakdown of other chemicals. Some toxic agents are additive, with the effects of each chemical added to one another. Finally, some toxic agents work together and one substance multiplies the effect of the other.
- *How the body handles the compound*—The human body handles toxic substances by metabolism, excretion, or storage.
  - Toxins are metabolized or detoxified by a variety of enzymatic processes which occur in the liver. Liver disease and enzyme deficiencies reduce the body's ability to metabolize toxic substances and increase the host's susceptibility to the effects of toxic agents. Metabolism neutralizes toxins and makes them less fat-soluble so that they can be excreted from the body via the kidneys.
  - Compounds can be excreted in either an unchanged form or as a metabolized by-product by the kidneys. Kidney disease reduces the body's ability to excrete toxic agents.
  - Some substances are neither metabolized nor excreted by the body. Instead, they are stored in the body in their original state, such as lead is stored in bones or polychlorinated biphenyls (PCBs) stored in fat cells.

Risk Analysis

According to the Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO), risk analysis must be the foundation on which food control policy and consumer protection measures are based. Risk

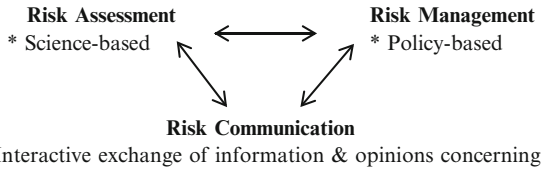

Fig. 9.1 Risk analysis framework (source: Food Standards Australia New Zealand, http://www.foodstandards.gov.au/science/riskanalysis/pages/default.aspx)

analysis (Fig. 9.1) is a process containing three components: risk assessment, risk management, and risk communication (FAO WHO 2014).

The world is not risk-free, and the goal of environmental health and protection programs should not be to achieve "zero risk." The pursuit of zero risk as a standard or goal is frequently unnecessary, not economically practical, and unattainable. In addition, the pursuit of zero risk may create unfounded public concern when set as the goal but not achieved (Gordon 1995).

An effective risk analysis requires an interdisciplinary approach and a team of stakeholders that may include epidemiologists, laboratorians, toxicologists, economists, attorneys, political and administrative leaders, public information officers, academicians, consumer advocates, and media. The size and makeup of the risk analysis team depends upon the risk to be analyzed, along with the level of public interest and concern. For example, a risk analysis of a single product, which may be adulterated by a single contaminant, may only require an epidemiologist and regulatory specialist to determine if the product is safe for human consumption; the results of the analysis could be communicated through a public information specialist via media or through the regulatory project manager and epidemiologist at a public meeting.

Risk Assessment

Risk assessment is the scientific evaluation of known or potential adverse health effects resulting from human exposure to foodborne hazards. The process consists of the following steps:

- Hazard identification—Identifying known or potential health effects associated with a particular hazard. Clinical, epidemiological, and animal studies can be used to provide evidence linking hazards with adverse human health effects.
- Hazard characterization—Evaluating (through quantitative or qualitative means) the adverse effects associated with the hazards. For chemical, biological, or physical agents, a *dose-response assessment* is recommended. Generally, low doses of a particular hazard elicit no response; however, at some level of dose—often referred to as the threshold level—responses begin to occur in a small fraction of the study population or at a low probability rate (EPA 2012a).

- Exposure assessment—Evaluating (through quantitative or qualitative means) the degree of intake likely to occur, i.e., measuring how much of a particular hazard people are exposed to at a particular period of time and how many people are exposed. The assessment takes into account the route of exposure (eating, drinking, inhaling, absorption through the skin or eyes, etc.) (EPA 2012a); the media in which the hazard is found; and the magnitude, time, and duration of actual or anticipated exposure.
- Risk characterization—Integrating the hazard identification, hazard characterization, and exposure assessment in order to estimate the adverse effects likely to occur in a given population (WHO 2014). Some examples of information typically included in a risk characterization are (1) the nature and presence or absence of risks, (2) information about how the risk was assessed, and (3) where assumptions and uncertainties still exist. This information is used by risk managers to make policy choices such as setting "exposure limits" or "acceptable daily intake" for substances believed to pose risk (GAO 2001; Frumkin 2010).

Risk Management

Risk management is the process of weighing policy alternatives in consultation with all interested parties and, if needed, selecting appropriate prevention and control options. Risk management considers not only risk assessment, but also other factors relevant to the protection of consumer health and relevant to the promotion of fair trade practices (FAO WHO 2014).

Risk Communication

Risk communication involves the interactive exchange of information and opinions concerning hazards and risks, risk-related factors, and risk perceptions among risk assessors, risk managers, consumers, industry, academia, and any other interested parties (FAO WHO 2014).

Case Example: Fukushima Daiichi Nuclear Disaster

The disaster stemming from the Fukushima Daiichi nuclear plant (Fig. 9.2), which occurred after a major earthquake in Japan on March 11, 2011, demonstrates how risk analysis can help inform risk perception and decisions. Shortly after the earthquake and resulting tsunami, questions were raised about the immediate impact of radiation released from the damaged Fukushima reactors on Alaska's seafood and wild foods. Seafood is a major segment of Alaska's economy and a primary source of nutrition, along with other wild foods such as marine vegetation, birds, caribou,

Fig. 9.2 Fukushima Daiichi nuclear plant (OSHA, https://www.osha.gov/radiation-japan/japan_nuclearplant.jpg)

and berries, for rural Alaskans. The possibility of radiation contamination of seafood and wild foods raised considerable concern among domestic and international seafood buyers, seafood consumers, and subsistence food users.

An interdisciplinary approach was taken to work through various parts of the risk analysis, which was coordinated by the Alaska Department of Environmental Conservation's (ADEC) Food Safety and Sanitation Program Manager. Participating agencies included the Department of Health and Social Service's Section of Epidemiology, the Alaska Seafood Marketing Institute, the Alaska Department of Fish and Game, the US Fish and Wildlife Service, the EPA, the FDA, and the National Oceanic and Atmospheric Administration's National Marine Fisheries Service. People participating in the analysis included epidemiologists, toxicologists, fish and wildlife scientists, environmental scientists, seafood product specialists, and public information officers.

Cancer is considered by most people to be the primary health effect from radiation exposure. However, other adverse health effects include genetic mutations (changes in DNA "blueprints"), burns, nausea, fatigue, vomiting, hair loss, skin burns, diarrhea, damage to the nervous system, loss of consciousness, and even death (EPA 2012b).

The primary contaminants of concern associated with the radiological release from the power plant to the air and seawater were identified as iodine-131 and cesium-137. The fate and transport of these radioisotopes were evaluated through review of air and water models produced by federal response agencies. Limited data on air transport and deposit of radionuclides was available through the EPA (Klein 2011). Two primary resources of concern were selected: birds, which are used as a subsistence food, and seafood, which has commercial and subsistence importance. However, other local resources such as seaweed, berries, and marine mammals were also taken into consideration.

Scientific and regulatory literature was consulted for toxicity, dose, and intake information on the radioisotopes of concern. Human toxicity data relied on FDA-derived intervention levels for radionuclides in food. The scientific literature was examined for toxicity data for birds and finfish.

The exposure assessment did not suggest that finfish or migratory birds of concern would be exposed to contamination. The radiation release from the Fukushima nuclear accident was found to pose no risk to Alaska's fisheries, wild foods, and human health. Since there did not appear to be a plausible exposure route, no risk management decisions were necessary. Risk communication, however, was determined to be necessary in order to provide information on the risk analysis to stakeholders.

Agencies worked together to provide a single message to stakeholders. Seafood buyers, consumers, processors, and Native Alaskans were identified as the targeted audiences. Information on the risk analysis was conveyed to stakeholders largely through fact sheets disseminated through electronic media and press communications (Klein 2011).

Emergency Response Operations

Food protection professionals (FPPs) who are government employees may be called in to help with an emergency response situation, whether the situation is man-made, technological, or natural disasters like floods, fires, or earthquakes. As a result, FPP training should include topics related to emergency preparedness that are not part of the FPP's general, daily duties.

When an incident involves response from multiple agencies, cross-jurisdictional coordination is critical. Oftentimes, an emergency response operation will utilize the National Incident Command System (ICS), which helps enable effective, efficient incident management by integrating facilities, resources, equipment, personnel, and procedures. ICS has become the standard for emergency management across the US. The system is designed to be used from the time an incident occurs until the requirement for management and operations no longer exists (FEMA 2014). FPPs may be assigned various roles and responsibilities in the event that an ICS is activated.

The US Occupational Safety and Health Administration (OSHA, www.osha.gov) sets and enforces standards for safe and healthy working conditions. The agency, which is part of the US Department of Labor, provides training, outreach, education, and assistance related to employee safety (OSHA 2014a). OSHA provides Occupational Safety and Health Standards that are continuously updated and address topics that could very well be a factor during an emergency response situation (OSHA 2014b).

Before an FPP becomes involved in an emergency response operation, he or she should identify any education and/or training that may be required for the particular type of operation; identify whether any type of medical clearance is required; think about potential hazards that may be encountered; and identify any personal protective equipment (PPE) that may be required, such as protective eyewear and footwear, ear plugs, hard hats, masks, etc.

Conclusion

Environmental health is the study of biological, chemical, physical, and radiological hazards—both natural and man-made—in the environment and the diseases and injuries caused by these hazards. The effects of these agents range from mild to severe and can be fatal in worst-case situations. Humans are exposed to environmental hazards through the air they breathe, food and water consumed, and contaminants absorbed through the skin. The goal of environmental health practitioners, including food protection professionals (FPPs), is to create an environment that provides optimal health and safety, ecological well-being, and quality of life for current and future generations.

Take-Home Message

Food protection professionals need not be fully-trained epidemiologists or toxicologists. However, a basic understanding of environmental hazards can prove to be critical in properly assessing public health risks and developing strategies for managing those risks. Environmental hazards come from a variety of natural and man-made sources and are commonly placed into biological, chemical, physical, and radiological categories. Hazards can range in magnitude from small-scale issues such as contaminated food and water affecting a small group of people to unexpected and widespread environmental disasters that can affect entire communities. Without adequate background knowledge, the FPP could expose the public to unnecessary risks. Likewise, the FPP runs the risk of putting him or herself in harm's way if hazards and risks are miscalculated.

Activity

Place the following environmental hazards in their proper categories (biological, chemical, physical, or radiological) and identify the most common routes of human exposure for each hazard.

1. Scombrotoxin
2. Norovirus
3. Glass
4. Iodine-131
5. Peanuts
6. Methyl mercury

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Answer Key

1. Scombrotoxin. Hazard: Chemical. Scombrotoxin is a chemical toxin formed by spoilage bacteria in which histidine is converted to histamine.

   Most common route of exposure: Consumption of food products containing high levels of scombrotoxin such as tuna or mahi-mahi.

2. Norovirus. Hazard: Biological. Norovirus is one of the primary biological pathogens responsible for foodborne illnesses in the USA each year.

   Most common route of exposure: Consumption of contaminated food products via poor food handling practices by persons utilizing inadequate personal hygiene (e.g., lack of hand washing).
3. Glass. Hazard: Physical. Glass can enter food products through damaged lighting, product containers, or bottles.

   Most common route of exposure: Ingestion of food products containing small pieces or shards of glass.
4. Iodine-131. Hazard: Radiological. Iodine-131 is a radioactive isotope that forms within nuclear fuel rods during fission. Inadequate safety controls can allow the isotope to escape into the environment (EPA 2013c).

   Most common route of exposure: Consumption of water or food products contaminated with iodine-131 as a result of accidental release of nuclear material into the environment.
5. Peanuts. Hazard: Chemical. Peanuts are one of the eight major food allergens identified by FDA.

   Most common route of exposure: Peanut can be unintentionally added to a food product through cross-contamination during the manufacturing process.
6. Methyl mercury. Hazard: Heavy metal. Methyl mercury is deposited in surface waters, primarily from the combustion of coal, and can bioaccumulate in the tissues of certain fish.

   Most common route of exposure: Consumption of certain types of fish, such as swordfish, that contain high levels of methyl mercury.

Chapter 10
Jurisdiction

Daniel Gump, Virginia Veneziano, Jeffrey French, and Ellen Buchanan

Learning Objectives

- Explain the jurisdictional responsibilities of federal agencies tasked with the oversight of food protection.
- Differentiate the jurisdictional responsibilities of state agencies tasked with the oversight of food protection.
- Discuss the jurisdictional responsibilities of local, tribal, and territorial agencies tasked with the oversight of food protection.
- Discuss potential jurisdictional overlap.
- Articulate the importance of networking and open communication across jurisdictional boundaries.

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Introduction

Providing a safe food supply and ensuring public health is an enormous task that falls to regulatory agencies at many levels: federal, state, local (city, county, etc.), tribal, and territorial. In most routine situations, agencies operate autonomously; however, there are occasions where jurisdictional overlap occurs, which highlights the importance of interagency communication, work planning, emergency response, and partnerships.

Jurisdictional Responsibilities of Federal Agencies Tasked with the Oversight of Food Protection

There are two federal agencies with primary authority over manufactured foods: the US Department of Agriculture Food Safety and Inspection Service (USDA FSIS, www.fsis.usda.gov) and the Food and Drug Administration (FDA, www.fda.gov). Secondary federal agencies with authority related to food protection include the Department of Homeland Security Customs and Border Protection (CBP, www.cbp.gov), the Environmental Protection Agency (EPA, www.epa.gov), the Department of Commerce National Marine Fisheries Service (NMFS, www.nmfs.noaa.gov), the Public Health Service (PHS, www.usphs.gov), the Alcohol and Tobacco Tax and Trade Bureau (TTB, www.ttb.gov), and the USDA Animal and Plant Health Inspection Service (APHIS, www.aphis.usda.gov). The USDA's Agricultural Marketing Service (AMS, www.ams.usda.gov) is often thought of as having regulatory authorities over some aspects of food safety. However, this is a misnomer. Among AMS authorities are its fee-for-service grading, certification, and verification of *quality* inspections of certain commodities, such as seafood.

The Centers for Disease Control (CDC, www.cdc.gov), while not involved in the regulation of food (except on conveyances like cruise ships), plays a critical role, because the federal agency is charged with surveillance and investigation of foodborne illness outbreaks. To execute the agency mission, CDC does not have to establish jurisdiction; rather, jurisdiction is assumed.

The USDA FSIS enhances public health and well-being by protecting the public from foodborne illness while ensuring that the nation's meat, poultry, and egg products are safe, wholesome, and correctly labeled and packaged (USDA 2014). USDA FSIS jurisdiction and authority for these three product lines are established in the Federal Meat Inspection Act, the Poultry Products Inspection Act, and the Egg Products Inspection Act. In the late 1960s, Congress passed preemptive legislation for consumer protection, expanding USDA jurisdiction and authority to cover all meat and poultry products intended for commercial sale, including those produced solely in intrastate commerce. Any FSIS-regulated products must be manufactured under inspection, meaning an on-site inspector is present (1) during slaughter to conduct an antemortem and postmortem inspection on each animal and (2) daily during processing operations. A number of state regulatory agencies operate meat

inspection programs under USDA FSIS oversight. States that receive USDA FSIS's approval may inspect state meat facilities as long as they meet "equal to" (for intrastate sale) or "same as" (for interstate sale) requirements.

The FDA has jurisdiction and authority over all other (approximately 80 %) manufactured food product lines moved through *interstate* commerce, including game meat, food additives, and dietary supplements. When an FDA-regulated food product in the marketplace crosses state lines during distribution, or if any ingredient or material used in labeling or packaging crosses state lines, the entire product is considered to be in interstate commerce and falls under FDA jurisdiction. Examples would include smoked fish caught and processed in Michigan yet using salt from Illinois, or water that is bottled in Massachusetts using plastic from Maine. Additionally, if any component crossed state lines in the past, or if the product is intended to cross state lines in the future, the product is also considered to be in interstate commerce. If a food is solely manufactured and distributed within a single state (such as a local wholesale manufacturer or retailer), the food is considered to be in *intrastate* commerce and is not subject to FDA oversight and authorities but rather state and local public health authorities.

While establishing jurisdiction may appear easy, there are some jurisdiction designations that are not clear-cut. For example, the USDA has authority for sandwiches with meat as an ingredient. However, under a cooperative agreement to eliminate duplication of effort, the FDA has authority if the product is sold as an open-face sandwich with meat. EPA has authority over public drinking water systems; however, if this same water is bottled and enters interstate commerce, the FDA has jurisdiction. The FDA has jurisdiction over fish hatcheries, unless the fish hatchery produces catfish, where the USDA has responsibility. If a food manufacturing facility produces foods with meat and foods without meat (e.g., a soup manufacturer), both the USDA and FDA will have a presence through inspection (continuous or random, depending on the agency), enforcement, and any recall activities. Occasionally, there seem no logical way to determine why a certain agency has jurisdiction since some of these decisions have been based on decisions made at different points in history by the legislature or through agency agreements. (See Appendix for a detailed table on USDA vs. FDA jurisdiction adapted from the FDA Operations Manual.)

Three product line areas where jurisdictional authority is split between FDA and state food regulatory programs are known as the FDA State Cooperative Programs. These three programs—shellfish, dairy, and retail foods—are federal programs carried out by state governments. State agency personnel are standardized by the FDA on a 3-year rotating schedule, ensuring the state can successfully execute the cooperative program. If the state is not participating in the shellfish or the dairy cooperative programs, these industries located within the state may not introduce their products into interstate commerce; as a result, there is much incentive for a state to participate, not only from a public health standpoint, but an economic standpoint, as well.

CBP is responsible for securing the border and facilitating lawful international trade and travel. Both the USDA and FDA maintain a presence at the US borders for food being imported into the country. These two agencies work closely with CBP to

increase consumer confidence and ensure that only wholesome food is imported into the country. Information and knowledge from systems that track the entry of goods is shared by these three agencies.

EPA authority includes, but is not limited to, ground water and drinking water. EPA sets national drinking water standards to which public drinking water systems must conform. Not unlike FDA and USDA cooperative programs, EPA delegates authority and oversight to the states to enforce these federal requirements; however, EPA does not actually perform the work. EPA regulations that govern public drinking water systems (40 CFR Part 141) are the same regulations used by the FDA to govern bottled water (21 CFR Part 165). EPA sets requirements for the use of chemicals (such as sanitizers and pesticides) that can be used in food establishment settings; the agency also sets pesticide residue limits in foods.

Jurisdictional Responsibilities of State Agencies Tasked with the Oversight of Food Protection

Jurisdictional areas and responsibilities related to food protection and public health can differ from state to state. A state may have agencies or departments with separate jurisdictions that operate autonomously from one another. To illustrate:

- A state department of agriculture may regulate grade "A" milk, cheese, animal feed, farms, and livestock.
- A state department of health may be charged with conducting inspections at daycare facilities, restaurants, manufacturing warehouses and processors, tattoo parlors, hospitals, and salons.
- A state department of consumer protection may have the authority to investigate consumer complaints, perform inspections in manufacturing and retail firms, and enforce weights and measures laws.

Additionally, a state agency may contain multiple divisions, each having separate and distinct jurisdiction. For example, a state public health department may have divisions devoted to community health, family health, healthcare quality and safety, infectious disease, healthcare access, and emergency response, along with a public health laboratory. Another state, however, may combine these responsibilities into one regulatory agency responsible for all matters in the realm of food safety and public health.

Listed below are general categories that are typically regulated by state agencies:

- Manufactured food processing establishments. This is a broad category that may include:
  - High-risk food processors (low-acid canned food manufacturers, acidified food manufacturers, water activity-controlled food manufacturers, vacuum-packed or modified atmosphere food manufacturers, certain juice manufacturers, and wholesale or retail bakeries).

  - Seafood processors, both wholesale and retail.
  - Retail smoked/cured/fermented or dried meat manufacturers.
  - Low-risk food manufacturers (beverage/juice drink manufacturers, fruit processors, wineries, breweries, honey and syrup processors, and most candy manufacturers).

- Food warehouses, which include:
  - Wholesale warehouses, which supply high volumes of food products to regional or national retailers. There may, or may not, be exposed foods or repacking done for customers at wholesale warehouses, so the hazards associated with inspections at these facilities vary greatly.
  - Retail warehouses, which supply low-volume amounts of food products to smaller retailers, sometimes on a "cash-and-carry" basis. Retail warehouses may or may not have exposed foods or engage in repacking operations.

- Retail food stores. These stores include independently-owned or chain grocery stores, convenience stores, candy stores, retail meat markets, beverage stores, drug stores with retail food sales, and bakery outlets. Food processing/manufacturing practices are often conducted at these facilities, presenting a varying degree of hazards. Exposed foods are common and food handling is a routine part of daily operations.
- Food service operations within institutional establishments. These operations would include cafeterias or other food service entities in hospitals, schools, prisons, nursing homes, and colleges/universities.
- Food salvage operations. These establishments take in damaged or distressed food items and sort, recondition, repack, and/or relabel these food items for public sale and consumption. The food items may have previously been exposed to fires, floods, vehicle accidents, roof leaks, and/or environmental hazards. Products may also originate from a factory closeout or overstock.
- Home or cottage industry food processors. This is a growing area in the food industry, where individuals make or grow food products at their homes and sell the products at various venues. Responsibilities and enforcement vary greatly from state to state as to what, if any, regulation is required for cottage food operations. Typically, these types of businesses are low-volume operations with a varying degree of associated hazards. Many states restrict the types of foods that can be legally produced, the types of packaging that can be used, and the way products may be sold by these types of facilities. State licenses or permits may be required, and inspections may be mandatory.

The frequency of inspections by state agencies depends on the hazards that exist in the facility or the volume of food sold by the establishment. High-risk and/or high-volume food establishments are typically inspected much more frequently than their low-risk, low-volume counterparts. This risk-based approach makes sense for agencies to best utilize their inspectional resources, although differences between agencies may exist due to variable resources, legislative mandates, localized industries and practices, and competing priorities (FDA 2010).

Another area of typical state jurisdiction is as primary or secondary responders to disaster or emergency situations involving state regulated/licensed facilities. Examples include fires, floods, power outages, water interruptions, vehicular accidents, roof leaks, building collapses, gas or vapor leaks, and widespread intentional contamination events. All of these examples require the state regulatory agency to examine the safety or wholesomeness of any food affected by the disaster or incident.

States also have jurisdiction over the investigation of consumer complaints at state-regulated facilities. Typical consumer complaints fall into the categories of foodborne illness (both suspected and verified), product misbranding and/or adulteration, employee health practices, improper food handling, and environmental sanitation issues. With certain types of consumer complaint investigations, there may be agency overlap, depending on the types of regulatory agencies present and their authorities within the state.

Many states have a food laboratory associated with their agriculture or health departments. These labs operate closely with agency field staff and provide chemical and microbiological analyses of food products associated with illnesses, product adulteration, or misbranding. Agencies may set sample schedules for field staff collection of routine or "surveillance" samples. In some cases, field staff can collect and submit food or environmental samples at their discretion, depending on what is encountered during their field work.

In some cases, state retail food regulatory agencies exercise oversight of local regulatory agencies (typically county or district health departments) through written agreements. The goal with such oversight programs is to ensure consistency across the state regarding inspection procedures, interpretation, and enforcement of rules and to provide advice, training, and support to local jurisdictions. In states where public health accreditation programs exist, the state agency performs audit functions of local agency food programs to determine if accreditation standards are being met (thus ensuring state financial support to local units of government).

Different state departments also share authority or work together in certain cases. For example, a state department of public health may work with the state department of agriculture or consumer protection if an outbreak should occur at a manufacturing facility. The state agriculture or consumer protection department would be charged with conducting the environmental inspection at the suspected firm and embargoing any suspect product, while the public health department would lead the epidemiological investigation related to consumer illness.

Jurisdictional Responsibilities of Local, Tribal, and Territorial Agencies Tasked with the Oversight of Retail Food Protection

Local Agencies

In many states, direct oversight of retail food service establishments rests with local county and municipal regulatory agencies. Oversight typically includes some mechanism of permitting or licensing food service establishments in which prerequisite

documentation and information is required (e.g., construction plans, proposed menus and processes, etc.) and reviewed by the agencies prior to the granting of licenses or permits. Retail food establishments include, but are not limited to, restaurants, catering operations, markets, food banks, vending machines, and institutions with kitchens such as schools and healthcare facilities (FDA 2013a).

Once licensed or permitted, establishments are subject to regular inspection by local food regulatory specialists at a frequency generally based on the complexity of the foods and processes being utilized in the establishment (commonly referred to as "risk-based inspections"). The types of establishments that fall under local jurisdiction can vary by state or locality. However, retail establishments that prepare and serve food to the public generally fall under local jurisdiction. Examples of these establishments include restaurants, food stands, nursing home kitchens, banquet halls, hotel food service bars, catering kitchens, mobile catering trucks, vending machines, bars and night clubs, school cafeterias, grocery delis, and meat markets. Additionally, food service at local, temporary events (e.g., street festivals, carnivals, fairs, sporting events, and concerts) may also be primarily subject to permitting and inspection by local agencies.

Local authority usually involves oversight of all retail food sanitation practices within permitted facilities. Inspection activities typically include direct observation of employee practices, monitoring food temperatures at cooking, holding, and storage, and observation of conditions within the facility. Violations or deficiencies encountered are usually recorded on an inspection report, which is reviewed with the facility manager at the end of the inspection. In some states, cities, or counties, inspection reports or additional documentation is required to be publicly displayed in the food service establishments. Local food regulatory agencies in North Carolina, for example, not only issue inspection reports to facility management, but also require that a grade card be prominently posted in the facility at all times. The cards are issued at the completion of each inspection and include a letter grade (A, B, or C) and a corresponding numerical score (e.g., Grade "A" ranges from 90 to 100 points). Establishments earning grades below "C" are not allowed to operate until problems are corrected. Local news media and retail food regulatory agency websites often report inspection results or inspection scores, which can increase the incentive for compliance.

Enforcement remedies for local agencies typically involve citations on inspection reports, disposal of adulterated food products (voluntary or involuntary), official notice of intent to suspend operating permits, or immediate suspension of such permits if deficiencies pose serious or immediate risks to consumers. Suspension of operation permits or licenses can effectively prevent an establishment from operating until violations are corrected. The potential of suspension can serve as additional incentive for the prompt correction of deficiencies.

Local food regulatory specialists are often the primary point of contact for food-related complaints from the public and can spend a substantial amount of time investigating such complaints. Likewise, local regulators are often the primary investigators in cases of foodborne illness outbreaks within their jurisdictions. Prompt, thorough investigations can bolster public confidence in local agencies, which are often seen as the face of public health protection.

Tribal Nations

The Indian Health Service (IHS, www.ihs.gov) is a federal agency responsible for providing federal health services for approximately two million American Indians and Alaska Natives and represents the principal federal health advocate for Indian people. According to IHS, there are approximately 566 federally recognized Native American tribal nations in 35 states within the USA (IHS 2014a). The IHS Division of Environmental Health Services conducts activities to prevent and control food-borne illness (IHS 2014b). Federally-recognized tribes are sovereign nations that are subject only to certain federal law and the Constitution. This sovereignty allows each tribal nation to adopt and enforce its own laws including those related to food protection (Daly 2013a); as a result, mechanisms for regulation of food protection within each tribal nation can and do vary.

The assistance provided to tribal nations by IHS staff varies at the discretion of particular nations. Primarily, IHS food regulatory specialists act as consultants even in cases where they are conducting inspections of food service operators on tribal lands. For example, if food protection issues are encountered in an establishment, IHS staff can only recommend that appropriate corrections be made and can take no independent enforcement action. Any such action must be approved or initiated by the tribal government (Daly 2013b). IHS also provides much of the food protection training for tribal personnel, such as ServSafe or similar programs in cases where tribal governments request such training.

The FDA reported that, as of 2010, 345 of the federally-recognized tribes had food service operations on their lands. Within those nations, 60 % used the inspectional services of the IHS, 21 % were inspected by the tribal governments themselves, and 19 % used state inspection services (Fig. 10.1) (FDA 2013b).

In some instances tribal governments contract with state or local food regulatory agencies to conduct inspections of food service facilities within tribal boundaries. The Cherokee Nation in western North Carolina, for example, has established memoranda of understanding (MOUs) with environmental health departments from several surrounding counties. Local food regulatory specialists inspect retail food

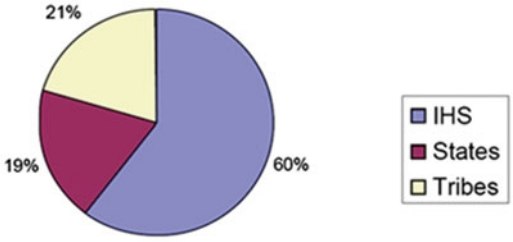

Fig. 10.1 Government entities responsible for inspecting food establishments on 345 tribal lands, February 25, 2010. Source: US Food and Drug Administration. http://www.fda.gov/Food/GuidanceRegulation/RetailFoodProtection/FoodCode/ucm108156.htm

service establishments within the Cherokee Nation, issue inspection reports, and post grade cards in these establishments as regulators do with similar establishments within their counties (Breedlove 2013).

US Territories

Similar to tribal nations and US states, US territories (e.g., Puerto Rico, the US Virgin Islands, American Samoa, etc.) manage their own food protection regulatory programs or contract with other agencies. The government of Guam, however, manages a unique food regulatory system. The Guam Division of Environmental Health oversees inspection of food service establishments on the island and also exercises oversight of other public health-related businesses such as tattoo establishments, public swimming pools, and prescription drug outlets. In essence, Guam officials have combined the typical duties of state, county, and local regulators into one overall agency. Additionally, Guam maintains close contact with US federal agencies, such as the FDA Pacific Regional Office. The FDA provides the primary source of food protection training for Guam officials, and FDA staff work with the local officials to meet the FDA Voluntary National Retail Food Regulatory Program Standards. Although Guam has developed its own food protection rules and regulations, the territory is in the process of adopting the Guam Food Code which is based on the 2005 US Food Code (Naval 2013).

Potential Jurisdictional Overlap

Defining the role of the USDA FSIS and FDA helps to illustrate the similarities in the programs and demonstrate how these agencies may work together and share jurisdictional responsibilities. For example, the USDA FSIS has responsibility over slaughter plants and examines meat before and after slaughter, including swine, sheep, lamb, cattle, goats, horses, and mules. The USDA FSIS also has responsibility over domesticated birds, including chickens, turkeys, domestic ducks, guineas, ostriches, and emus. In addition, the USDA FSIS inspects products that are determined to contain 2 % or more poultry or 3 % or more of red meat. The regulation of processed meats and poultry products including hams and sausage and “open-faced” sandwiches also falls under USDA FSIS authority.

On the other hand, the FDA is responsible for the inspection of game and zoo animals, rabbits, bison, and animals in the deer family, including elk and moose. The FDA also has responsibility over wild turkeys, wild ducks, wild geese, and products determined to contain less than 3 % of red meat or less than 2 % of cooked poultry. Additionally, the FDA has authority over “closed faced” sandwiches based on an interagency MOU.

The USDA FSIS and FDA share inspection duties regarding eggs and egg products. The FDA is responsible for shell eggs (including pasteurized shell eggs) and

egg-containing products that do not meet the USDA FSIS definition of "egg product." Products that meet the this definition of "egg product" include frozen, dried, or liquid eggs, with or without ingredients, and eggs removed from the shell in order to be processed at facilities called "breaker plants." The FDA has jurisdiction in egg processing establishments not covered by the USDA FSIS, such as restaurants and bakeries.

The USDA FSIS and FDA often work collaboratively in cases of outbreaks of *Salmonella enteritidis* by inspecting facilities to follow up on illness outbreaks. The USDA FSIS and FDA also work together on diversion of suspect eggs, breakers, recall of marketed eggs, and destruction and quarantine of flocks. This coordination demonstrates the jurisdictional crossover between the these two agencies and the fact that these agencies often work together to keep the nation's food supply safe.

Another example of jurisdictional overlap is evident in the potential discovery of cows infected with mad cow disease. In this situation, the USDA FSIS, with involvement from the USDA APHIS, tracks the source of the herd of the infected animal and recalls the meat product, while the FDA helps ensure that the disease does not spread to animal feed, which is an FDA-regulated product.

In many instances, federal authority may overlap with state and/or local authorities. Section 301(a) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) states that adulterated and misbranded products may not be introduced or delivered for introduction into interstate commerce. In addition, Section 301(k) of the FD&C Act grants FDA statutory jurisdiction over products that have been shipped in interstate commerce and thereafter become adulterated.

Federal, state, and local jurisdictions often overlap, and all three often work in conjunction with one another, especially during foodborne illness outbreak incidents. For example, if a firm is associated with an outbreak, the FDA often works with the appropriate state to isolate the cause and embargo product as necessary, since both the FDA and the state have jurisdiction over the firm. A local health department may also have jurisdiction over the facility and therefore become involved in the outbreak investigation. In addition, many states perform manufactured food inspections in FDA-regulated facilities on behalf of the FDA, under either state or FDA authority (if state authority is not equivalent to that of the FDA) and in accordance with inspection protocols outlined in the FDA Investigations Operations Manual (http://www.fda.gov/iceci/inspections/iom/default.htm).

Networking and Communication Across Jurisdictional Boundaries

Effective food protection oversight in the US comprises a network of agencies at all levels working in combination and concert. Effective food protection cannot occur with any agency operating in a vacuum with little or no contact with other agencies in the network. People in their daily lives rely on and support one another directly and indirectly through various channels or networks. The same can be said for governmental agencies tasked with protecting food supplies. No single regulatory

agency can effectively manage 100 % of the tasks required to adequately protect food supplies for a given population; as a result, cooperation and communication among agencies is crucial.

Formal Cooperation

Formal agreements such as a memorandum of understanding (MOU) or a written contract are often created by and between food regulatory agencies in order to more effectively allocate resources and avoid duplication of regulatory efforts. Such arrangements require direct and often frequent communication between the agencies involved. Federal agencies such as the FDA and USDA often establish MOUs and contracts with state-level food protection agencies. In those situations, state inspection staff members are trained in federal regulations and standards, and their inspections are recognized as federally-compliant by the respective federal agency. In such arrangements, federal funds and equipment are often provided to assist the state agency.

Federal agencies may also establish MOUs with foreign government agencies to ensure the safety of food products imported into the USA. A good example is the MOU between the FDA and foreign processors of raw molluscan shellfish. Currently there are MOUs in place with Canada, New Zealand, Mexico, and South Korea; oversight agencies in each of those countries regulate the growing, harvesting, and processing of raw oysters, clams, and mussels in accordance with the guidelines established by the Interstate Shellfish Sanitation Conference, of which the FDA is a part. The FDA monitors compliance of the foreign shellfish control authorities in the MOU countries, primarily through periodic on-site review of those agencies. In cases where noncompliance is found, the FDA can effectively prevent the interstate shipment of raw shellfish originating from the country. This stoppage is accomplished by the removal of the offending country's certified shellfish firms from the FDA's Interstate Certified Shellfish Shippers List (ICSSL, http://www.fda.gov/food/guidanceregulation/federalstatefoodprograms/ucm2006753.htm), updated monthly by the FDA.

Another formal method of cooperation that the FDA uses with state and local FPPs is "commissioning and credentialing." This program was developed to allow state employees to conduct certain activities subject to federal jurisdiction. This includes viewing and copying establishment records, taking samples, conducting FDA inspections, and viewing FDA documents, including trade secrets.

Informal Cooperation

Formally-recognized agreements between agencies are not always required for frequent communication and cooperation to occur. Quite often there may be "gray" areas in which certain processes or products result in confusion as to the agency

responsible. Often, agencies contact one another to clarify any of these gray areas. Such contact is especially common between local agencies, such as county health departments, and state agencies as local inspectors often encounter an extremely wide variety of products on a daily basis.

Mechanisms for Facilitating Communication and Cooperation

Communication and cooperation can be fostered through formal training. Often larger agencies at the federal or state levels provide formal training opportunities for local or municipal agencies through mandatory or voluntary programs. Through such training, participants become familiar and build relationships with staff in the facilitating agencies. When issues or questions arise, those contacts and relationships can be beneficial, often to both agencies involved. Due to financial constraints within agencies at all levels, on-site training opportunities can be limited, especially when travel costs are prohibitive. In fact, web-based training opportunities have increased dramatically over the past few years, often as a result of budget limitations. However, even excellent training online training can severely limit contact and interaction between individuals.

Professional association and educational meetings and conferences can also facilitate interagency communication. Such gatherings often feature a variety of topics and bring together individuals from a wide range of backgrounds. Some states require certain FPPs to attend these types of meetings as a way to receive continuing education. North Carolina, for example, requires local county health department FPPs to obtain 15 hours of continuing education annually to maintain authorization to practice in the state.

Environmental health education districts have been established by specialists across the state, and those districts sponsor quarterly educational seminar meetings at which local specialists can obtain continuing education hours and can meet and build relationships with other specialists. Educational forums not necessarily sponsored by or directly associated with government entities can also establish relationships across agency boundaries. For example, the International Food Protection Training Institute (IFPTI, www.ifpti.org) and the National Environmental Health Association (NEHA, www.neha.org) offer training programs that regularly bring together FPPs from across the country and address a wide variety of topics and issues.

Formal meetings such as the Association of Food and Drug Officials (AFDO, www.afdo.org) annual meeting, the Interstate Shellfish Sanitation Conference (ISSC, www.issc.org), and the Conference for Food Protection (www.foodprotect.org), along with conferences devoted to interstate environmental health, can all foster cooperative relationships and can also provide opportunities for contact with academic and industry representatives.

Cooperation and communication between regulatory agencies is important, but can prove to be difficult. In some cases, agencies may tend to territorialize their

responsibilities and avoid cooperation with others, especially during periods of shrinking budgets and increasing demand for services. FPPs should be aware of these situations and work to break down such barriers to cooperation.

Conclusion

Federal, state, local, tribal, and territorial agencies have jurisdiction over various food protection issues and activities. Often, determining jurisdictional authority can be confusing and may depend on the specific type of food product or food protection activity in question. Jurisdictional overlap is commonplace and highlights the importance of collaboration and communication between agencies at all levels.

Take-Home Message

The food protection professional (FPP) needs to understand and appreciate the many different jurisdictional lines of regulatory authority as applied to food protection. At times, these jurisdictional lines are not clearly defined, and jurisdictional overlap can occur. FPPs should be able to respect and work not only within their jurisdiction, but also across jurisdictional lines, when appropriate. Collaboration and cooperation with other jurisdictional agencies and personnel can help leverage resources and strengthen the safety of our food supply.

Activity

For each of the images below, discuss where jurisdiction lies (e.g., with the USDA, FDA, state and/or local agencies, etc.). Note: keep in mind that there may be jurisdictional overlap (Figs. 10.2, 10.3, 10.4, 10.5, 10.6, 10.7, 10.8, 10.9, 10.10, and 10.11).

Fig. 10.2 Avocado at a US port of entry

Fig. 10.3 Hard-boiled eggs found in a retail food service establishment

Fig. 10.4 Chocolate chip cookie being processed in a large manufacturing facility

Fig. 10.5 Shrimp in the seafood case of a retail grocery store

Fig. 10.6 Roll in the display case of a local retail bakery

Fig. 10.7 Potato chips being processed in a food manufacturing facility

Fig. 10.8 Frozen sausage pizza with greater than 3 % meat by weight, being processed in a manufacturing facility

Fig. 10.9 Green and red peppers in a food service establishment

Fig. 10.10 Spaghetti and meatballs from a can, containing greater than 3 % meat by weight

Fig. 10.11 Almond milk sold from a dispenser at a local grocery store

Appendix A: FDA and USDA Jurisdiction Table (Adapted from Exhibit 3-1 in the FDA Investigations Operations Manual, 2013)

FDA jurisdiction	USDA jurisdiction		
21 USC 392(b) Meats and meat food products shall be exempt from the provisions of this act to the extent of the application or the extension thereto of the Meat Inspection Act. The FDA is responsible for all non-specified red meats (bison, rabbits, game animals, zoo animals, and all members of the deer family including elk (wapiti) and moose). The FDA is responsible for all non-specified birds including wild turkeys, wild ducks, and wild geese.	The Federal Meat Inspection Act regulates the inspection of the following amenable species: cattle, sheep, swine, goats, horses, mules, or other equines, including their carcasses and parts. It also covers any additional species of livestock that the Secretary of Agriculture considers appropriate. Mandatory Inspection of Ratites and Squabs (including emu) announced by the USDA FSIS, April 2001.	The Poultry Products Inspection Act (PPIA) defines the term poultry as any domesticated bird. The USDA has interpreted this to include domestic chickens, turkeys, ducks, geese, and guineas. The Poultry Products Inspection Act states poultry and poultry products shall be exempt from the provisions of the FD&C Act to the extent they are covered by the PPIA. Mandatory Inspection of Ratites and Squabs announced by the USDA FSIS, April 2001.	The Egg Products Inspection Act defines egg to mean the shell egg of domesticated chicken, turkey, duck, goose, or guinea. Voluntary grading of shell eggs is done under USDA supervision (the FDA enforces labels/ labeling of shell eggs).
Products with 3 % or less raw meat; less than 2 % cooked meat or other portions of the carcass; or less than 30 % fat, tallow, or meat extract, alone or in combination. Products containing less than 2 % cooked poultry meat; less than 10 % cooked poultry skins, giblets, and fat and poultry meat (limited to less than 2 %) in any combination.* Closed-face sandwiches	Products containing greater than 3 % raw meat; 2 % or more cooked meat or other portions of the carcass; or 30 % or more fat, tallow, or meat extract, alone or in combination.* Open-face sandwiches	Products containing 2 % or more cooked poultry; more than 10 % cooked poultry skins, giblets, fat and poultry meat in any combination*	Egg products processing plants (egg breaking and pasteurizing operations) are under USDA jurisdiction

(continued)

FDA jurisdiction	USDA jurisdiction		
The FDA is responsible for shell eggs and egg-containing products that do not meet the USDA's definition of "egg product." The FDA also has jurisdiction in establishments not covered by the USDA, e.g., restaurants, bakeries, cake mix plants, etc. Egg processing plants (egg washing, sorting, packing) are under FDA jurisdiction.			Products that meet the USDA's definition of "egg product" are under USDA jurisdiction. The definition includes dried, frozen, or liquid eggs, with or without added ingredients, but mentions many exceptions. The following products, among others, are exempted as not being egg products: freeze-dried products, imitation egg products, egg substitutes, dietary foods, dried no-bake custard mixes, eggnog mixes, acidic dressings, noodles, milk and egg dip, cake mixes, French toast, sandwiches containing eggs or egg products, and balut and other similar ethnic delicacies. Products that do not fall under the definition, such as egg substitutes and cooked products, are under FDA jurisdiction.

(continued)

FDA jurisdiction	USDA jurisdiction		
Cheese pizza, onion and mushroom pizza, meat flavored spaghetti sauce (less than 3 % red meat), meat flavored spaghetti sauce with mushrooms, (2 % meat), pork and beans, sliced egg sandwich (closed-face), frozen fish dinner, rabbit stew, shrimp-flavored instant noodles, venison jerky, buffalo burgers, alligator nuggets, noodle soup chicken flavor.	Pepperoni pizza, meat-lovers stuffed crust pizza, meat sauces (3 % red meat or more), spaghetti sauce with meatballs, open-faced roast beef sandwich, hot dogs, corn dogs, beef/ vegetable pot pie.	Chicken sandwich (open-face), chicken noodle soup.	

*These percentages are based on the amount of meat or poultry product used in the product at formulation

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Additional Resources

Congressional Research Service (2014) The federal food safety system: a primer. http://www.fas.org/sgp/crs/misc/RS22600.pdf. Accessed 1 June 2015

Answer Key

1. FDA
2. State or local
3. FDA and state
4. State or local
5. State or local
6. FDA and state
7. USDA
8. State or local
9. USDA
10. State or local

Chapter 11
Hazard Analysis and Critical Control Points (HACCP)

Brian Nummer, Daniel Gump, Steven Wells, Scott Zimmerman, and Angela Montalbano

Learning Objectives

- Identify food safety hazards (chemical, biological, physical, radiological) and list some of their controls.
- Distinguish between mandatory HACCP requirements and voluntary usage of a HACCP plan.
- Describe the preliminary steps taken in designing a HACCP program.
- Describe the seven principles of HACCP plans and how they are implemented.
- Describe verification and validation of HACCP systems.
- Discuss the role played by the food protection professional as related to HACCP.
- Describe the renewal and evaluation of a HACCP system.

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Introduction

Hazard analysis and critical control points, or HACCP, is a systematic, organized approach to the identification, evaluation, and control of food safety hazards (FDA 1997a). HACCP manages food safety through the analysis and control of certain hazards during all facets of the food supply chain: from the production of raw materials to handling, manufacturing, shipping/transportation, and consumption (FDA 2013a).

HACCP for food safety was pioneered by the Pillsbury Company with the cooperation and participation of the National Aeronautics and Space Administration (NASA), the US Army, and the US Air Force to prevent astronauts from being exposed to unsafe food during space flights (FDA 1997b). The National Advisory Committee on Microbiological Criteria for Foods (NACMCF), created in 1988 to provide impartial scientific advice to federal agencies, published the first definitive guide on HACCP in 1997 (NACMCF 1997).

Today in the USA, HACCP is required for all establishments engaged in wholesale meat and poultry operations under the jurisdiction of the US Department of Agriculture Food Safety and Inspection Service (USDA FSIS), as well as processors of seafood, produce, and juice under the jurisdiction of the US Food and Drug Administration (FDA). HACCP is also an important tool that can be employed in retail and food service operations under the FDA Model Food Code. Facilities operating *without* an adequate HACCP system—yet subject to HACCP regulations—are considered to be producing products that are "adulterated" for failure to be produced under sanitary conditions in accordance with federal regulations.

The HACCP system is global and has been recognized internationally for many years. Guidelines for the application of a HACCP system have been created by the Food and Agriculture Organization (FAO) of the United Nations and the World Health Organization (WHO), which serve as references regarding food safety requirements in international trade (FAO and WHO 2006; FAO 1997).

HACCP as a system consists of all of the controls necessary to prevent, eliminate, or minimize hazards identified in a food system. The system will contain preliminary information on the product(s) and processes, hazard analysis, HACCP plan(s), and prerequisite programs. Preliminary information includes information on the food, the processes involved (including a process flowchart), the packaging, and the consumer of the product. A HACCP plan is the written document that includes a hazard analysis and controls based on the principles of HACCP (FDA 1997a). Prerequisites include programs such as Good Manufacturing Practices (GMPs), which describe how processors operate at all stages of production, and Standard Operating Procedures (SOPs), which address how processors meet the goals of their GMPs.

Food Safety Hazards

There are various types of hazards related to food protection: chemical, biological, physical, and radiological. Hazards can be an inherent characteristic of the food product or can be introduced at a step in the production process. High-risk hazards are addressed in HACCP plans, which focus on the raw materials and the processes involved, while lower-risk hazards are often addressed in prerequisite programs (PRPs), which focus more on the production environment, i.e., people and facility (Fig. 11.1).

Hazards are determined for a product/process using a hazard analysis protocol where illness data, scientific reports, regulatory code, and other information are used to make a determination that a hazard is likely to occur. An effective HACCP system relies on having one or more controls for each identified hazard.

Chemical hazards may be naturally occurring or may be added during the production or processing of food. High levels of toxic chemicals are likely to cause acute cases of foodborne illness, while chronic illness may result from lower levels. Naturally-occurring chemical hazards include shellfish toxins and toxic mushroom species, while added chemical hazards include pesticides, antibiotics, preservatives, cleaning compounds, and certain metals like copper, mercury, and lead (FDA 2013b). Unintentional chemical hazards can include cleaners and sanitizers, pesticide residues, lubricants, and other chemicals used inside a food operation.

Biological hazards consist of pathogenic organisms: bacteria such as *E. coli* O157:H7, *Salmonella* spp., and *Listeria monocytogenes*, parasites such as *Trichinella spiralis*, and viruses such as hepatitis A and *Norovirus* (FDA 2013b). Many biological hazards, however, are able to survive the food production process.

Physical hazards consist of extraneous matter not normally found in food that could cause physical illness and/or injury. Some examples of physical hazards

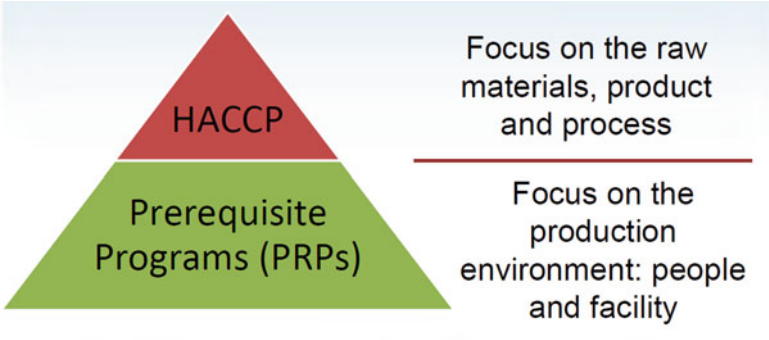

Fig. 11.1 HACCP and prerequisite programs (PRPs) (Source: Land O'Lakes, Inc. HACCP and the Critical Role of Prerequisite Programs, May, 2012 PowerPoint presentation)

include glass, wood, stones, metal fragments, insulation, bones, plastic, and personal effects. Physical hazards can cause cuts, bleeding, infection, choking, broken teeth, and trauma (FDA 2013b).

Radiological hazards consist of radium-226,228; uranium-235,238; strontium-90; iodine-131; and cesium-137. These radiological hazards were recently added to the list of hazard groups through the Food Safety Modernization Act (FSMA) and represent examples of known or reasonably likely hazards that may be associated with the facility, raw materials, ingredients, or finished products (FDA 2013c).

Mandatory HACCP Requirements Versus Voluntary Usage of a HACCP Plan

HACCP began as a voluntary system by the food industry in the USA as early as the 1960s. Beginning in the 1990s, however, a shift from the voluntary nature of HACCP to a more mandatory nature began. In 1995, FDA established regulations (21 CFR 123) that mandated implementation of HACCP systems for fish and seafood products. The final regulation, which applies to both domestic and foreign fish and fishery wholesale processors, became effective in 1997. However, the regulation does not apply to the harvest or transportation of fish or fishery products and does not apply to processes such as evisceration, heading, or freezing intended solely to prepare fish for holding on a vessel. Retail operations are also exempt from the regulation.

Soon thereafter, the USDA mandated HACCP for meat and poultry processing plants through 9 CFR 417. This regulation was put into place to reduce the occurrence and numbers of pathogenic organisms on meat and poultry products and to reduce the number of foodborne illnesses associated with the consumption of meat and poultry. The USDA HACCP regulation applies to all meat and poultry slaughter and processing plants, but exempts retail meat facilities.

In 2001, FDA issued a regulation for mandatory HACCP procedures involving the processing and importing of fruit and vegetable juice and juice products (21 CFR 120). Processing has been defined as activities directly related to the production of juice products. However, harvesting, picking, and transporting of the raw ingredient of juice products have been exempt, along with retail establishments that make and sell juice directly to consumers and do not sell or distribute juice to other businesses (FDA 2014).

The implementation of a food safety program based on HACCP is also required for all US school food service operations participating in the National School Lunch or Breakfast Programs, per Section 111 of the Child Nutrition and Women, Infants, and Children (WIC) Reauthorization Act of 2004 (Public Law 108-265).

In 2001, FDA instituted a voluntary HACCP program for Grade A fluid milk and milk products under the cooperative federal/state National Conference on Interstate Milk Shipments (NCIMS, www.ncims.org) program. The agreements adopted by

the NCIMS program apply to Grade A raw milk and milk products for pasteurization, pasteurized and ultra-pasteurized milk products, and condensed and dry milk products, along with other types of milk products.

The newly-legislated Food Safety Modernization Act (FSMA, Public Law 111-353) has introduced the mandatory use of preventive food safety controls, such as HACCP, in the food industry. FSMA requires what is essentially enhanced HACCP for every food establishment unless the establishment is exempt. The FDA mandate for seafood and juice HACCP, along with the USDA mandate for meat and poultry HACCP, is still required.

Regarding retail and food service establishments, the FDA Food Code establishes that the implementation of HACCP should be a voluntary effort unless the establishment conducts certain specialized food processing activities such as smoking, curing, packaging foods in a reduced oxygen atmosphere, or using food additives as a method of food preservation (FDA 2013d). In this case, the HACCP plan looks more like a product/process HACCP similar to that established for food manufacturing. When using HACCP on a voluntary basis in retail or food service facilities, some state or local regulatory jurisdictions use a risk-based inspection protocol (FDA Food Code, Annex 5) to review the validity of the HACCP processes.

Some states and counties across the USA, however, are beginning to require approved HACCP plans. The management of these facilities should check with the local health department to determine whether a HACCP plan is mandatory. One exception to the voluntary HACCP for food service operations involves schools that participate in the National School Lunch or Breakfast Programs. These schools, per Section 111 of the Child Nutrition and WIC Reauthorization Act of 2004 (Public Law 108-265), are required to implement a food safety program based on HACCP principles.

The FDA Center for Food Safety and Applied Nutrition (CFSAN) published guidelines for the voluntary use of HACCP by food service and retail establishments in 2006. These establishments include restaurants, cafeterias, health care facilities, convenience stores, and grocery stores with specialized departments such as a deli or produce section. The FDA CFSAN guidance, however, differs from normal HACCP protocols in its "process approach," i.e., focusing not on a specific food product but rather on the food preparation process (flow), along with the number of times that a food passes through the temperature "danger zone" between 41 and 135 °F. A typical food "flow" at a retail establishment could involve the following steps: receiving, storing, preparing, holding, and serving (FDA 2006).

Preliminary Steps in Constructing a HACCP Program

The first steps to establishing an effective HACCP system are to have strong management support and a high level of commitment from everyone involved. Management commitment would include providing adequate funding, training resources, and personnel devoted to HACCP issues. Once this commitment has

been established, the next step would be to assemble a *HACCP Team* consisting of individuals who have specific knowledge and expertise appropriate to the product and process (FDA 1997a). The team should possess a wide area of expertise covering all plant operations. HACCP team members could include:

- Plant managers
- Production supervisors
- Quality assurance (QA) supervisors
- Maintenance supervisors
- Packaging supervisors
- Sales managers
- Warehouse managers
- Shipping supervisors
- Sanitation operators
- Engineers
- Microbiologists

HACCP team members must then establish a reporting structure within the team. This approach ensures a timely review of required records, proper corrective actions when a critical limit has been exceeded, and proper maintenance of required records.

Once a team and a reporting structure have been established, a product list must be created. The list would include a description of the products produced in the facility, the means by which the products are distributed, and the intended use of the products by customers. When the products are identified, an in-plant flow diagram (Fig. 11.2) can be created for each item and verified by a HACCP-trained individual within the team. The flowchart must be kept up-to-date and modified if line or product changes occur. A common first step in the flow diagram, for example, might be "receiving" ingredients, which refers to receipt of product by the processing establishment and, where applicable, ingredients and product packaging material.

The next step for the HACCP team to consider is identifying the facility's GMPs (Good Manufacturing Practices) and SOPs (Standard Operating Procedures). The Code of Federal Regulations specifies minimum or foundational GMPs for food operations that might address the following:

- Safety of water
- Condition and cleanliness of food contact equipment
- Procedures to prevent cross-contamination
- Maintenance of toilet, handwashing, and hand sanitizing stations
- Protection from adulterants
- Labeling, storage, and proper use of toxic compounds
- Employee health conditions
- Pest control

Operators under the jurisdiction of the FDA Model Food Code usually do not have these same GMP requirements, since most of these policies are captured prescriptively in the Food Code itself. The remainder of needed GMP programs (including those for retail and food service referred to as good retail practices in the

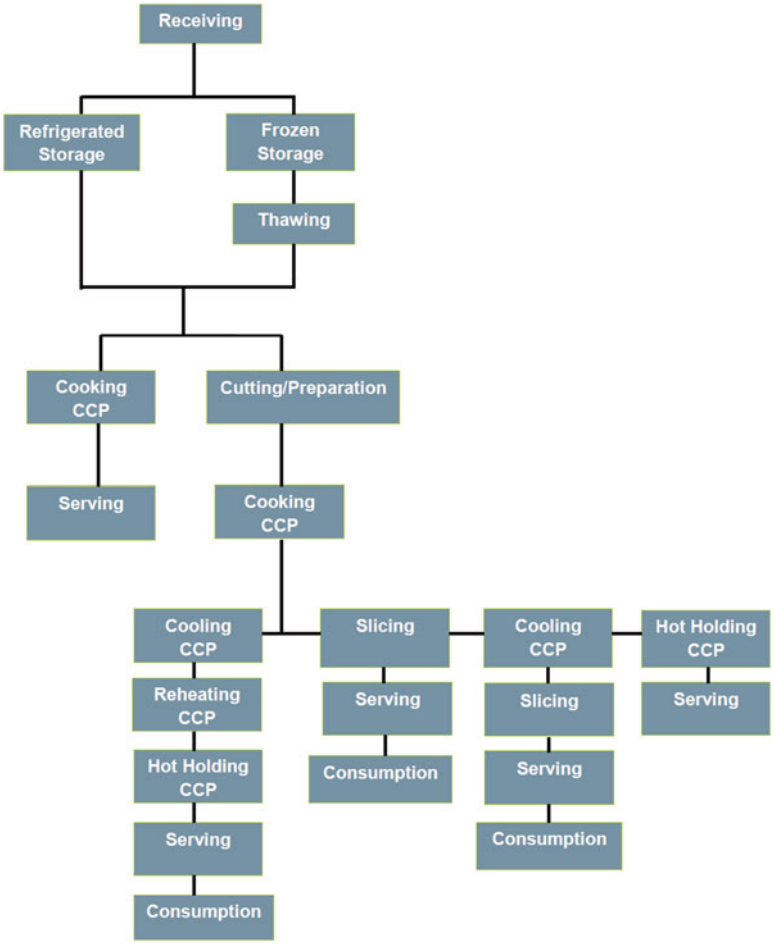

Fig. 11.2 Example flow diagram (Source: FDA, 2001 Food Code—Annex 5: HACCP Guidelines, http://www.fda.gov/Food/GuidanceRegulation/RetailFoodProtection/FoodCode/ucm089302.htm)

Food Code) is determined by the operation's hazard analysis. These operational GMPs or SOPs are required to provide control for all likely hazards. Some examples of operational GMPs are:

- Control of measurement devices (e.g., thermometers and calibration)
- Labeling
- Receiving foods
- Refrigeration control
- Pest control
- Documentation control

The Seven Principles of HACCP Plans

The seven principles—or steps—of HACCP have been universally accepted by government agencies, international organizations such as the Codex Alimentarius Commission, trade associations, and food industries. The seven principles, listed in sequence, are to (1) conduct a hazard analysis, (2) identify critical control points (CCPs), (3) establish critical limits for each CCP, (4) establish monitoring procedures, (5) establish corrective actions, (6) establish verification procedures, and (7) establish recordkeeping and documentation procedures (FDA 1997b; USDA FSIS 1998).[1]

1. Once the product flowchart has been constructed and verified and plant GMPs and Sanitation Standard Operating Procedures (SSOPs) are established, a *hazard analysis* is conducted. The analysis involves determining the food safety hazards associated with the food and the process and identifying any chemical, biological, physical, or radiological hazards that are reasonably likely to cause injury or illness if not effectively controlled in the HACCP plan. Potential control measures for these hazards are also identified at this step. Multiple hazards involving one product may be combined together and covered under one HACCP plan.
2. Determining *critical control points* (CCPs) for each hazard is the step or procedure in the food process at which a control measure can be taken to eliminate, prevent, or reduce the hazard to an acceptable level.
3. Establishing *critical limits* involves identifying the maximum or minimum parameter to which a chemical, biological, physical, or radiological hazard must be controlled to eliminate, prevent, or reduce the hazard to an acceptable level. An example of a critical limit is cooking a product to a specific temperature for a specific amount of time. Often, manufacturers establish and follow *operating limits*, which is a criterion that is more stringent than a critical limit and used by an operator to reduce the risk of deviation. Figure 11.3 represents an example of an operating limit in relation to a critical limit. The critical limit in this example of pasteurization has been set at 160 °F; however, the operating limit has been set at 165 °F. Failure to meet the operating limit of 165 °F is not a deviation that requires a corrective action; however, failing to meet the operating limit alerts the operator that a critical limit is close to being reached.
4. Establishing *monitoring procedures* is necessary to ensure that the food process is controlled at each CCP. Proper monitoring procedures can provide an early warning that the critical limit of a CCP is not going to be met, providing the establishment with an opportunity to take action to restore process control. Monitoring can be continuous (recording temperatures during cooking steps) or noncontinuous, as in visual, periodic temperature checks recorded manually. Noncontinuous examples could also include monitoring pH values or ingredient specifications. The use of noncontinuous monitoring must be done at a time and frequency sufficient to ensure that process control is maintained.

[1] USDA lists recordkeeping as Principle 6 and verification procedures as Principle 7.

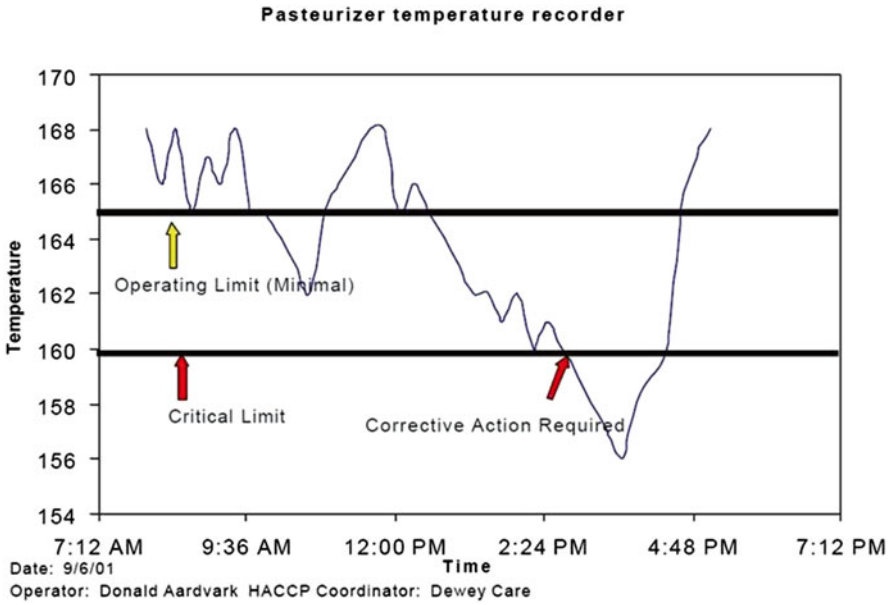

Fig. 11.3 Operating limits versus critical limits (Source: Juice HACCP Training Curriculum, First edition, August 2002. Developed by the Juice HACCP Alliance as recognized by the Food and Drug Administration, https://www.iit.edu/ifsh/degrees_and_training/pdfs/juicehaccpfirstedition.pdf)

5. Establishing *corrective actions* involves defining actions/procedures to take when a monitoring procedure acknowledges a deviation from a defined critical limit. Corrective actions should be preplanned, and the establishment must determine a safe disposition of the affected product (release, rework, or destruction) and correct the cause of the deviation.
6. Establishing *verification procedures* ensures that the seven steps of HACCP are fully implemented. Verification activities include ensuring that measurement devices are calibrated, observing employees performing HACCP processes, and reviewing records for completeness and adherence to the stated HACCP goals.
7. Establishing *recordkeeping and documentation* procedures is crucial to the HACCP system. Records/documentation generally pertains to conducting a hazard analysis and determining critical control points and critical limits, verification activities, corrective actions, and all GMPs. Records (written or stored on a computer) demonstrate HACCP compliance, aid in recalls, identify trends that could result in a deviation from critical limits, facilitate ingredient traceback, and serve as evidence in potential legal action.

Once all of the documentation has been created, verified, and validated, the facility is ready to implement the HACCP plan and commence production under that HACCP system. Implementation, however, involves significant training and education of staff. Each responsible employee must have the knowledge, understanding,

and ability to perform their role within the HACCP system. In fact, the FDA Model Food Code makes training a required SOP for all HACCP systems under the facility's control.

Verification and Validation of the HACCP System

Verification and validation principles are often the most confusing aspects of the HACCP system. Verification activities include those mentioned above related to the HACCP plan. However, there are also activities related to verifying that the entire HACCP system is implemented as desired. These activities include microbiological lab studies, employee training, monitoring customer complaints, and process audits. Often verification at this level means "Are you really doing what you say you will do?"

Validation can be defined as "Is what you are doing making your food product and process safer?" Validation activities include ensuring all critical items and controls are identified and are science-based. For example, USDA/FSIS requires each CCP be scientifically-referenced and those references included in the HACCP documentation. Validation usually involves a gap audit to determine whether a GMP or SOP program is missing. This gap audit can be a self-audit or a third-party audit.

Acceptable sources for the validation phase include scientific literature, product testing results by the establishment, experimental research results, scientifically-based regulatory requirements, official FDA (Food Code) or FSIS guidelines, computer modeling programs, and data generated by process authorities. Companies have a great deal of flexibility in validating their HACCP plan. A company could use a combination of the sources listed above as long as there is satisfactory control of the hazards identified in the analysis, along with proper monitoring, recordkeeping, and documentation.

The FPP Role in HACCP

Food protection professionals are generally responsible for ensuring a firm's compliance with all codes or mandated standards, including HACCP. In most cases, agency-specific (USDA FSIS, FDA, state or local agency) regulators are charged with the inspection of food firms operating under HACCP. Essentially, the regulators perform third-party audits of the entire HACCP system, including implementation of the system and proper documentation.

An example review process is outlined in the Food Code, Annex 5: HACCP Guidelines: (1) scientific or technical validation, (2) ongoing verification (performed during normal production under the HACCP plan), (3) documented, periodic system validations, and (4) regulatory agency verification. The first three phases are the

responsibility of the establishment, and the fourth is performed by the responsible regulatory agency, which essentially reviews the operator's documentation plus validations and verifications from the first three steps.

Initial Documentation Review

This phase takes place when a HACCP plan is first operational, i.e., at the beginning of food production in a new facility or when an existing processing establishment begins processing new food products not covered by existing HACCP plans. In this phase, the establishment must have all required documentation such as a product description, flowchart, hazard analysis, HACCP plan(s), and any required prerequisite program documents. Next, the initial documents must be valid (meet regulations and evidence-based science). At this point, a judgment is made as to the adequacy that the documented HACCP system will control the known hazards. When the FPP does not possess the specialized knowledge to fully review a HACCP system, he or she can seek a subject matter expert (SME) for assistance. SMEs can be found within the regulatory ranks and can be outside consultants, scientists, or academic cooperative extension specialists.

Implementation Review

After an initial documentation review, an operator will commence production under the HACCP system. The main question a regulator should ask is "Is the plan, as written, being implemented by the establishment?" This review usually consists of verifying that all records are kept and are kept accurately, and that no deviations are left uncorrected. Most often this review is done in a selective sampling manner, rather than comprehensively.

An implementation review usually includes an in-person observation review. The FPP will watch a process from start to finish and observe for proper control of food safety hazards. Direct observation may provide insight into proper monitoring, measurement device calibration, adherence to SOPs, and all actions of employees within the HACCP-based process.

Annual HACCP Renewal and Evaluation

Both the National Advisory Committee on Microbiological Criteria for Foods (NACMCF) and Codex Alimentarius standards for HACCP require that the entire HACCP system be reviewed and renewed on an annual basis. The system does not need to be completely rewritten or even modified; rather, the system, along with its

verifications and validations, must be reviewed on a system-wide basis. Whenever any significant changes or alterations occur in the process that could affect the hazard analysis (creating different CCPs or critical limits), this reassessment needs to be conducted. Changes or alterations could include new or different raw materials or ingredients, revised operational methods, packaging changes (e.g., using a modified atmospheric packaging system), or changes in consumer destination (e.g., infants vs. general public).

Conclusion

Most developed countries have adopted the HACCP standard and have benchmarked the standard to the Codex Alimentarius guidelines and/or recommendations from the NACMCF. The HACCP-based food safety system is risk-based and places the greatest controls on the greatest risks. The HACCP system has proven extraordinarily robust, working for food companies of all sizes. HACCP plans should be reviewed annually, in order to incorporate emerging or changing risks/hazards and appropriate controls and to ensure that controls are supported by current, sound scientific evidence.

Take-Home Message

HACCP is a worldwide standard food safety system that can adapt to new hazards and new controls, can apply to operations of all sizes, and can apply to virtually every operation within the farm-to-fork supply chain. The HACCP approach in identifying and controlling food safety hazards is essential to preventing foodborne illnesses and instilling consumer confidence in the safety of the food supply.

Activity

For each step in the HACCP process, indicate whether each question is true or false.

The questions listed below are based on FDA and USDA FSIS HACCP publications referenced in previous paragraphs, as well as information accessible through the FDA website provided in the publication titled “A Model HACCP Plan for Small-Scale, Fresh-Squeezed (Not Pasteurized) Citrus Juice Operations” from the Institute of Food and Agricultural Sciences, Cooperative Extension Service, University of Florida. The publication is available at: http://university.uog.edu/cals/people/Pubs/FS07500.PDF

Pre-HACCP

1. Prior to developing a HACCP plan, it is important to assemble a HACCP team that has thorough knowledge of all stages of the establishment's food production process. T___ F___
2. The HACCP team should develop a "flow diagram" of all steps in the production process so that the HACCP team can make an accurate assessment of all hazards reasonably likely to occur in the production process. T___F___
3. Typically, the first step in a "flow diagram" is "receiving." T___F___
4. Pre-HACCP activities might include evaluations of the effectiveness of the establishment's "sanitation plan." T___F___

HACCP Implementation Steps (note: the term, "step" is interchangeable with "principle")

1. There are six important steps of HACCP implementation plus one that is not very important. T___F___

Step One—Conduct a Hazard Analysis

1. The hazard analysis is concerned with two main hazards reasonably likely to occur: *biological* and *chemical* hazards. T___F___
2. In the hazard analysis process, *physical* hazards are not as important as *biological* or *chemical* hazards. T___F___
3. Many *biological* hazards can survive the food production process and cause a foodborne illness to consumers. T___F___
4. *Chemical* hazards are toxic substances such as pesticides, certain toxins, cleaning compounds, accidentally or intentionally introduced into the production process, that can cause food-borne illness. T___F___
5. While small pieces of metal are not considered significant *physical hazards*, pieces of glass are. T___F___
6. While the HACCP team may use multiple sources (scientific literature, expert opinion, laboratory records, illness data) when evaluating hazards of significance or those hazards reasonably likely to occur in a specific production process, it is not really necessary. T___F___
7. It is *not relevant* for the HACCP team to consider factors (pH and temperature) which influence growth of common foodborne pathogens. T___F___

Step Two—Determine the Critical Control Points (CCPs)

1. A critical control point (CCP) is a point, step, or procedure in a food process at which a control measure can be applied, and, as a result, a food safety hazard can be prevented, eliminated, or reduced to acceptable levels. T___F___
2. Examples of clearly defined CCPs could include pasteurization of milk and the use of metal detector systems designed to remove metal fragments from food products. T___F___

Step Three—Establish Critical Limits

1. A critical limit is the maximum or minimum value (safe tolerance levels) to which a physical, biological, or chemical hazard must be controlled at a critical control point to prevent, eliminate, or reduce it to an acceptable level. T___F___
2. Exceeding critical limits indicate that a health hazard may exist or could develop. T___F___
3. Critical limits pertain to temperature controls only. Time is not a factor. T___F___
4. CCP limits must be scientifically-based. T___F___

Step Four—Establish Monitoring Procedures

1. Monitoring is not necessarily a scheduled task. T___F___
2. Critical limits of a CCP are monitored to determine if the CCP is under control, but it is not necessary to record the values. T___F___
3. Anyone can perform CCP monitoring including new employees not familiar with the production process. T___F___
4. The critical monitoring philosophy is "Close is good enough for me." T___F___
5. Continuous monitoring devices such as time/temperature recording thermometers are acceptable. T___F___
6. In addition to time and temperature, monitoring measurements could include visual observations and pH levels. T___F___

Step Five—Establish Corrective Actions

1. Corrective actions are taken when monitoring activities indicate that critical limits or tolerances are not met. T___F___
2. Corrective actions do not have to be taken when values for critical limits are close. T___F___
3. For severe hazards, a corrective action could include stopping the production line. T___F___
4. Corrective actions do not have to be identified and documented. T___F___
5. Corrective action responsibility and authority must be clearly identified in the HACCP plan. T___F___

Step Six—Establish Verification Procedures

1. The HACCP plan is reviewed to determine if any changes are needed in CCPs, critical limits, or other procedures. T___F____
2. Verification activities can include an evaluation of equipment calibration procedures. T___F___

Step Seven—Establish Recordkeeping and Documentation Procedures

1. An adequate recordkeeping system is an integral part of the HACCP plan. T___F___
2. Records should be designed to document the effectiveness of the HACCP plan. T___F___
3. Process control records should be readily accessible to record critical limit observations/values. T___F___

4. Records in which values for critical limits for CCPs are made do not have to be signed or initialed. T___F___
5. Records that document critical limit values do not have to be reviewed by a designated, responsible establishment employee. T___F___

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National Advisory Committee on Microbiological Criteria for Foods (1997) Journal of Food Protection 1998;61(9):1246–1259. http://www.fsis.usda.gov/wps/wcm/connect/dccfe894-36bb-4bd9-b27a-a7f5275a22cd/JFP0998.pdf?MOD=AJPERES. Accessed 8 Jul 2014

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U.S. Food and Drug Administration (2013b) FDA Food Code 2009: Annex 4—Management of food safety practices—achieving active managerial control of foodborne illness risk factors. http://www.fda.gov/Food/GuidanceRegulation/RetailFoodProtection/FoodCode/ucm188363.htm. Accessed 18 Dec 2014

U.S. Food and Drug Administration (2013c) FDA Food Safety Modernization Act. Frequently asked questions and answers. http://www.fda.gov/downloads/Food/GuidanceRegulation/UCM345224.pdf. Accessed 18 Dec 2014

U.S. Food and Drug Administration (2013d) 2013 Food Code, Chapter 3. http://www.fda.gov/downloads/Food/GuidanceRegulation/RetailFoodProtection/FoodCode/UCM374510.pdf. Accessed 9 Jul 2014

U.S. Food and Drug Administration (2014) Guidance for industry: juice HACCP hazards and controls guidance first edition; Final guidance. http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Juice/ucm072557.htm. Accessed 12 Jun 2014

Additional Resources

21 CFR 110. Current good manufacturing practice in manufacturing, packing, or holding human food

9 CFR 416. Sanitation

U.S. Food and Drug Administration (2001) Guidance for industry: the juice HACCP regulation—questions & answers. http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Juice/ucm072981.htm. Accessed 19 May 2014

U.S. Food and Drug Administration, Center for Food Safety and Applied Nutrition (2011) Fish and fishery products hazards and controls guidance. http://www.fda.gov/downloads/food/guidanceregulation/ucm251970.pdf. Accessed 27 Feb 2014

Answer Key

Pre-HACCP
(1) True (2) True (3) True (4) True
HACCP Implementation Steps
(1) False
Step One—Conduct a Hazard Analysis
(1) False (2) False (3) True (4) True (5) False (6) False (7) False
Step Two—Determine the Critical Control Points (CCPs)
(1) True (2) True
Step Three—Establish Critical Limits
(1) True (2) True (3) False (4) True
Step Four—Establish Monitoring Procedures
(1) False (2) False (3) False (4) False (5) True (6) True
Step Five—Establish Corrective Actions
(1) True (2) False (3) True (4) False (5) True
Step Six—Establish Verification Procedures
(1) True (2) True
Step Seven—Establish Record Keeping and Documentation Procedures
(1) True (2) True (3) True (4) False (5) False

Chapter 12
Inspections, Compliance, and Enforcement

Kristin DeMarco Shaw, Byron Beerbower, and Cynthia Walker

Learning Objectives

- Articulate the importance of facility inspections.
- Explain the steps involved in a facility inspection.
- Identify appropriate enforcement when necessary.

Introduction

Inspections of facilities involved in all facets of the food supply chain—including production, processing, handling, distribution, and retail—are crucial to ensuring a safe food supply. During an inspection, the food protection professional (FPP) can identify critical food safety issues, help confirm a link between foodborne illness disease and unhygienic conditions, and take appropriate steps to control or remedy these issues. Topics in this chapter include the steps involved in a facility inspection, the tools and equipment used during an inspection, and the methods of enforcement that are available when compliance with food safety requirements becomes problematic.

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The Importance of Facility Inspections

Prior to the early 1900s, there were few standards or regulations for either processing or selling food. Upton Sinclair's *The Jungle*, however, exposed the filthy conditions of meat processing plants and led to passage of the Pure Food and Drug Act (Public Law 59-384) and the Meat Inspection Act (Public Law 59-242), which created sanitary standards for meat processing plants and authorized the US Department of Agriculture (USDA) to conduct ongoing monitoring and inspection of processing operations (Center for Foodservice Learning 2010–2011). Adding to the nation's focus on food safety were the developments of refrigeration and pasteurization, which helped reduce foodborne illnesses such as typhoid fever, scarlet fever, and botulism caused by contaminated food, milk, and water.

Today, no matter the jurisdiction—federal, state, local, tribal, or territorial—there are rules and regulations that have been formulated to prescribe minimum performance standards for all aspects of food safety. Generally, these requirements are aimed at minimizing cross-contamination, specifying employee health standards, and decreasing the incidence of foodborne illness. Because consumers cannot verify that facilities are meeting these requirements, the facilities must undergo the process of inspection. The application of minimum standards during a regulatory inspection allows for compliance verification by a governmental entity representative who is trained and experienced in food safety.

The issuance of a license or permit—across all aspects of the commercial food system—indicates that the operator accepts the responsibility to conduct business according to a prescribed set of standards, which helps maintain the public trust in the food supply. Without such trust, confusion, suspicion, and economic instability can result. For example, sales at all restaurants within a jurisdiction can decline, even when a foodborne illness outbreak occurs at only one establishment in that jurisdiction.

There are several documents created by federal agencies that identify food safety standards. One such document is the US Food and Drug Administration (FDA) Food Code (www.fda.gov/FoodCode), which provides regulatory agencies with a sound technical and legal basis for regulating restaurants, supermarkets, and certain residential health facilities that serve meals. Another standard document is the FDA Current Good Manufacturing Practices in Manufacturing, Packing, or Holding Human Food (21 CFR Part 110) (http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=110). Other documents include the FDA Guide to Minimize Food Safety Hazards of Fresh-Cut Fruits and Vegetables (http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ProducePlantProducts/ucm064458.htm) and the USDA audit-based program to verify conformance to the FDA guide on fresh-cut fruits and vegetables (http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=stelprdc5097151). Generally, these guidance pieces—along with similar documents created at the state and local levels—are amended and updated as scientific evidence related to food safety emerges.

Facility inspections provide an unbiased snapshot view of the food facility, food processes, and food employee practices in real time. During an onsite visit, an inspector is able to examine the workplace, including the physical elements, equipment, and processes that occur during routine operations. Often, workers and operators become too familiarized with their work environment and no longer notice when conditions are less than ideal and need attention. Employees who handle food can develop habits that become automatic due to repetitive actions over time, and inspectors are in the position to indicate whether such habits need to be corrected. For example, food handlers may become accustomed to wearing jewelry on the job, even though this practice is generally prohibited.

Instead of the traditional floor/wall/ceiling checklist approach, where FPPs generally focused on readily-observable conditions, inspections nowadays are generally "risk-based," meaning that the FPP focuses on the firm's monitoring of identified risk factors, hazard controls, and development and implementation of corrective actions. After all, it is ultimately the establishment's responsibility to produce safe food on a continual basis, so today's inspections involve determining if adequate controls are in place and are being followed—even when the inspector is not present.

FPPs have the authority to access processing records and collect food and environmental samples, as needed. Often, these activities allow regulators to verify what happens in the establishment over time (not just the day of the inspection). Records review and sampling can also verify the safe sources of food, determine the validity of a consumer complaint, or identify the cause of a foodborne illness outbreak.

FPPs also serve as the representative of consumers who do not have the practical ability themselves to observe food preparation or food storage in order to make an informed decision regarding food safety within a food service establishment. Trained FPPs are able to make the hard decisions that are necessary—such as closing a facility—that allow the public to be protected from risky and threatening situations that the public may not recognize.

An effective regulatory program can also help facility personnel achieve continuous improvement within their operation. Operators may not relish a regulatory inspection; however, maintaining the safety and quality of the food served can ensure the long-term success of a business.

The Steps Involved in a Facility Inspection[1]

Throughout the inspection process, the FPP must document significant findings, including minor observations that have a potential to become significant food safety issues. Having too much information is better than not having enough information

[1] One common step during an inspection—collecting samples—is discussed in Chap. 13 (Sampling).

or missing something important. FPPs generally use a notebook during an inspection to document information, dating and numbering each page and using legible handwriting. Electronic note-taking can be used when FPPs are provided with technological resources. Many electronic inspection systems with field devices allow observations to be noted—and reports to be generated—in real time.

Preparing for the Inspection

Prior to arrival at the facility, the FPP should understand the nature and scope of the inspection that he or she has been assigned to conduct. A review of the establishment's history will help focus the inspection and allow the inspector to identify the operational status of the establishment, the timing of the inspection, applicable regulations for special processes conducted on-site, and any necessary technical advice needed prior to the inspection. Any previously-cited violations, along with a history of complaints, can provide the FPP with insight into issues/problems that have occurred in the past and may still be an issue. This pre-inspection review is especially helpful to an inspector who may be new to a facility.

Preparing for the inspection can also allow the inspector to develop a personal safety plan, assemble and train an inspection team (if more than one FPP will be required), and gather inspection materials. The following is a partial list of equipment, tools, and supplies that each inspector may require to complete an inspection:

- Calibrated thermometer(s)—(thermistor, thermocouple, infrared, etc.)
- Flashlight (with spare batteries)
- A notebook to document findings
- Appropriate outer garments (lab coats/jackets, hair restraint, aprons, boot coverings, etc.)
- Personal protective equipment (safety glasses, hearing protection devices, bump caps, steel-toed boots, etc.)
- Testing materials (sanitizer strips for chlorine, iodine, and/or quaternary ammonium and pH test strips)
- Meters to measure light, water activity, and/or pH
- Magnifying glasses
- Flour slick or sieve
- Clipboard
- Pens and pencils
- Camera
- Ruler or tape measure
- Phone
- Sampling equipment
- Technical outreach/educational material

Arriving at the Facility

Upon arrival at the establishment, an FPP should assess any safety concerns before entering the firm and make sure that he or she has the appropriate materials, equipment, and information mentioned in the previous section. In addition, arriving on-site during active processing allows inspectors to focus on risks and controls, rather than conducting an inspection during downtime, when the focal point of the inspection would focus on low-risk activities, process control plans, or the environment.

Upon entering the facility (generally through the front door, which is a security requirement for many firms), the FPP should present his or her credentials, introduce him or herself, explain the purpose of the visit, and ask to meet with the most responsible person at the facility. Many establishments will require an FPP to sign in; however, an inspector must be careful not to sign away necessary authorities that support the inspection process, such as taking photographs, copying records, or collecting samples. Knowledge of these and other legal authorities is essential.

- Maintaining good communication skills (covered in Chap. 17) throughout an inspection puts the operator at ease and can help set the tone of the entire inspection. During the opening conversation with the responsible staff person, the inspector should explain the process of inspection—where he/she would like to start and what he/she would like to see—and extend an invitation to the individual to accompany the inspector in order to discuss any observations. The opening conversation should also include a menu review or a production schedule review to determine if new products or processes have been undertaken since the last inspection. Previous violations should be reviewed with the individual to determine if corrections have been made or if violations remain. The inspector can also request certain processing records to help become familiar with the operation such as a process flowchart, the firm's hazard analysis, the food safety plans, or the HACCP documents. In order to focus on higher-risk foods during the inspection, some of the questions the FPP should be able to answer at this stage are:
  - Which food produced at this facility has the highest risk?
  - Have any of the types of food products made at the firm been involved in recent outbreaks?
  - Where are end products going (are there high-risk consumers)?
  - What is the volume of production of products?

Preparing for the Walk-Through

One of the key components of an inspector's job is to lead by example, especially with regard to good hygienic practices. Hands should be washed and sanitized prior to stepping into the processing areas of a facility. There may be requirements for restraining hair (wearing a head net, hair and beard net, or hat) and/or removing jewelry depending on the type of facility being inspected. Additional

personal protective equipment that must be worn on processing floors may include a bump HAT, a smock or lab coat, footwear covers, and protective devices for eyes and/or ears.

Conducting a Walk-Through

A walk-through visual inspection of the premises should be conducted for the FPP to become familiar with the operation and plan the inspection strategy. The walk-through visual inspection can help an inspector assess the size of the facility, number of employees, raw materials being used, employee practices (e.g., personal hygiene, handwashing, personal property, etc.), manual and automated processes (manufacturing, receiving, storage, packaging, etc.), potential sources of contamination, manufacturing flow, general housekeeping, evidence of pests, and environmental conditions both inside and outside the facility (FDA 2014a).

The walk-through can allow the inspector to determine inspection priorities by identifying which products or processes occurring on-site have potential for the greatest risks. The inspector can note the flow of food, from raw products to finished products or from more potentially-hazardous products to less. However, there may be special processing situations that require starting with finished products and following the flow backward to the raw products to determine potential sources of cross-contamination. During the walk-through, the inspector can also assess sanitary facilities and controls such as the facility's plumbing system, water supply, handwashing facilities, and waste management system. Additionally, a walk-through provides the FPP with an opportunity to ask general questions of the responsible employees during production.

Assess Effectiveness of Control Measures

After the walk-through, the FPP should be able to outline the flow of food through the production processes, analyze the high-risk steps, and conduct an independent hazard analysis (see Fig. 12.1). An effective assessment of the facility's controls during an inspection focuses on the likely, potential hazards for each product or process. This assessment has the following key components:

- Hazard identification: Are there microbial, chemical, or physical hazards present?
- Hazard characterization: Is there a history of this type of hazard?
- Exposure assessment: Can the hazard be introduced during the process?
- Risk characterization: How likely can the hazard occur?
- Facility control: Does the facility have control over the most significant factors that contribute to foodborne illness, such as food from unsafe sources, inadequate

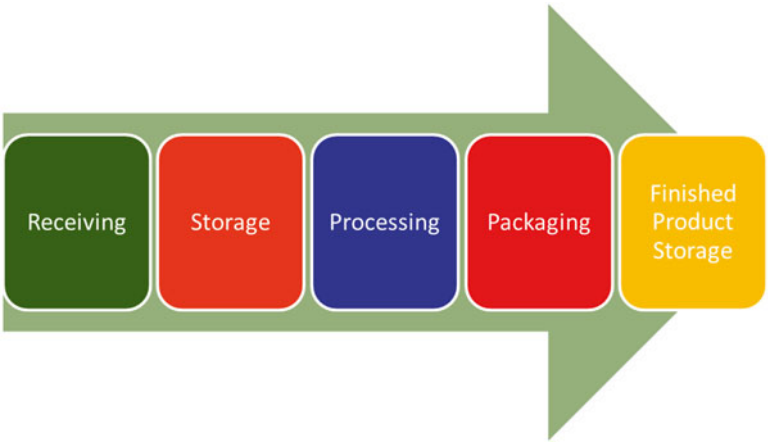

Fig. 12.1 Perform a risk analysis by critically looking at each production step

cooking, improper holding temperatures, contaminated equipment, and poor personal hygiene (FDA 2009a)?

Once this assessment has been made by the FPP, the inspection can now focus on the potential areas of concern, thus establishing the depth of the inspection. It is useful to review the facility's hazard analysis at this stage for comparison. A good portion of time during the inspection requires evaluating the food safety management systems of an establishment to determine if there are controls in place over hazards that would otherwise cause food to be unsafe for human consumption. The FPP should systematically review the facility's control plans and procedures for the high-risk areas identified and then verify they are being followed. Some of the facility's plans may include:

- Standard operating procedures (SOPs)
- Standard sanitation operating procedures (SSOPs)
- Supplier control plan
- Allergen control plan
- Process control plan
- Sanitation control plan
- Employee training plan
- Recall plan
- HACCP plan
- Food safety plan

With this information in hand, the FPP can now gather evidence that verifies whether the control is in place and is being addressed. Evidence of the control of risk factors takes various forms. For instance, a review of temperature control logs can show whether critical temperatures were reached in a cooking or cooling step, invoices for ingredients and receiving logs can show whether food is received from

an approved source and in proper condition, and cleaning and sanitizing logs can verify if the establishment's foundational sanitary practices can be relied upon. The FPP should carefully document all the findings as the inspection progresses.

Evaluating Sanitary Conditions

A reliance on basic sanitary conditions is crucial to any process control. Therefore, during the inspection, the FPP should evaluate and document various sanitary conditions in the facility. The building housing the operation should be suitable in size, construction, and design to facilitate maintenance and sanitary operations, and attention should be given to any construction defects such as broken windows or cracked floorboards. Toilet facilities should be inspected for cleanliness, adequate supplies, and handwashing signs (FDA 2014b). Adequate lighting should be provided in locker rooms, restrooms, and all areas where food is examined, processed, or stored and where equipment or utensils are cleaned. Appropriate ventilation equipment should be utilized to minimize odors and vapors in areas where food could become contaminated. All equipment, utensils, and surfaces coming into contact with food should be maintained and kept clean. The FPP should evaluate the facility's cleaning operations (cleaning tools, records, frequency, etc.) and should also assess whether employees exhibit potentially unsanitary behaviors and practices related to handwashing, glove use, hair restraints, personal jewelry, food, and tobacco. Finally, the FPP should evaluate whether the firm has appropriate pest control procedures in place, along with an appropriate waste management system.

Documenting Inspection Findings

An FPP should document all violations as the violations are observed, including those violations that are corrected on site. Documentation of supporting evidence, such as temperature of foods or location of equipment that is violative, must also be included on the inspection report. All inspection reports should adhere to the following general principles:

- Documented observations should be clear, specific, significant, and correlate to regulated products or processes being inspected.
- Observations of questionable significance should not be listed, but should be discussed with the firm's management.
- Observations should not be repetitious.
- Observations should be ranked in order of significance.
- Observations made during a prior inspection that have not been corrected are appropriate to include in the inspection report (FDA 2014c).
- Exhibits and attachments (photos, labels, etc.) supporting the observations should be included in the report.

Each observed violation has the potential to become an enforcement action—even where the firm has corrected the violation during the inspection itself—therefore, every violation must be documented in a consistent manner. Even violations that seem trivial at first glance need to be documented, because a violation being repeated over time may lead to significant harm to public health or a significant expenditure of time and/or funds by the inspector or regulatory authority. Accurate documentation—especially related to continuous violations—may also be needed in a court proceeding or administrative hearing.

Every effort should be made by the FPP to discuss all observations with the responsible employee as they are observed, or on the same day, to minimize surprises, errors, and misunderstandings when the report is issued. The managers or persons in charge may use this opportunity to ask questions about the observations, request clarification, and inform the inspection team what corrections have been or will be made during the inspection process. However, there may be instances where same-day discussion of observations may not be possible due to the volume of documents collected, or where document review reveals observations on a different day than the documents were collected (FDA 2014d).

Conducting an Exit Interview

Although the inspector may have identified violations to the accompanying person in charge (PIC) while conducting the inspection, the inspector must review and discuss the findings during an exit interview. The exit interview should be conducted with the responsible employee or a member of management who can make decisions for the establishment with regard to correcting violations and accepting a compliance schedule.

Although all cited violations should be discussed—even violations corrected on-site—the exit interview should focus on the observations or violations that pose the greatest food safety risks. Referencing the appropriate section of the applicable code or regulation when citing violations, along with the public health rationale behind the violation, will help the facility personnel understand why the situation is violative. During the exit interview, communication should be kept open, and the manager/responsible employee should be allowed to ask questions and offer any additional information.

Planning for Corrective Actions and Follow-Up

When violative conditions are found within an establishment, plans for corrective actions must be addressed. The compliance schedule includes items to be corrected immediately, as well as those to be corrected by a later date. The nature of the violations and the complexity of the corrective action needed will help determine the time frame for compliance.

In retail or food service establishments, a risk control plan can be used when uncontrolled hazards become chronic. A risk control plan is a written management plan developed by the operator (with inspector input) for controlling specific, out-of-control foodborne illness risk factors. The plan is most effective when the violation is behavioral or procedural in nature and can be monitored by managerial control.

FPP(s) may issue enforcement actions when immediate hazards exist or where compliance is not obtained voluntarily. Fines, suspension of permits, administrative actions, and closures are examples of enforcement actions that may result from a routine inspection. An FPP(s) must be knowledgeable about the jurisdictional authority and procedures related to these actions.

The FPP should indicate to the responsible employee/manager when follow-up inspections will be performed and what is to be expected related to the documented violations. In most cases, a copy of the completed inspection report and compliance schedule for corrections is provided to the management, along with contact information of the inspector.

Applying Appropriate Enforcement When Necessary

Because the goal of any food facility is to sell safe food, regulatory authorities expect that firms will maintain voluntary compliance with food safety laws and regulations. However, when a firm is found to be noncompliant with a law or regulation, further steps must be taken to bring the firm into compliance. These steps are generally referred to as *enforcement* by most jurisdictions.

The basis for any enforcement policy is built upon the legal concepts of *due process* and *equal protection*. Most regulatory authorities have *due process* administrative procedures that outline steps to ensure that the individual/firm is made aware of any violation and given the opportunity to demonstrate compliance. *Equal protection* helps ensure that procedures are applied uniformly and fairly.

Additionally, due process is enhanced through *progressive enforcement*, a process whereby lesser punitive actions—such as a warning letter—are taken in order to allow the firm an opportunity to correct a first-time violation. If the firm fails to correct the violation, progressive enforcement is implemented with each step requiring more action and follow-up both by the regulatory authority and by the firm. The goal of progressive enforcement is to start with the least aggressive measures and move through a process of an increasingly punitive nature in order to gain compliance.

Each violation will need to be evaluated against the enforcement policy of the FPP's agency. Enforcement policies generally address the following questions:

- Does the violation rise to the level of enforcement?
- Was the violation corrected during the inspection?
- Was the violation a onetime-violation, or a repeat violation?
- Is the violation the result of a lack of management control (e.g., no handwashing taking place) or the result of a physical condition (e.g., a leaky roof)?
- Can the violation be prevented through appropriate training?

Depending on agency policy, multiple violations can be recorded separately or recorded as just one violation. For example, food is generally required to be held in hot cases at a temperature of 135 °F (57 °C) or higher. If one hot case is found to be holding food at 100 °F (37 °C) and another case is found to be holding food at 50 °F (10 °C), agency policy will dictate whether these are two different violations, or two instances of the same violation.

The most important determinant of whether to take enforcement action(s) is the protection of public health. Food safety laws and regulations generally address a continuum of violations, ranging from minor violations with little or no public health significance to major violations with significant potential for public harm. The FPP should determine whether a violation presents an imminent public health hazard and requires an immediate enforcement action such as a stop sale/operation order, license suspension or revocation, or prosecution. For example, rats gnawing and defecating on food throughout the building creates an imminent public health hazard that could be addressed by summarily suspending the establishment's license to operate and seizing food to prevent the product from reaching consumers.

A violation may not be an imminent public health hazard at the time of inspection, but if continued or repeated might lead to an imminent public hazard or harm. From an enforcement point of view, these types of violations are typically related to a lack of active managerial control, such as insufficient employee training or improper equipment cleaning/maintenance. For example, a firm's hand sinks are properly supplied with hot and cold water, but the valves might be leaking into the sink. The leak itself is not a public health hazard; however, if the leak is large enough, the sink may become unusable and would prevent employees from washing their hands.

Types of Enforcement

There are numerous types of enforcement actions that regulatory authorities can use to bring a firm into compliance. The enforcement actions available depend on the nature of the violation(s), along with agency policy.

Potential actions include, but are not limited to the following:

- Scheduled reinspection
  - Reinspection usually focuses on significant violations and does not involve an inspection of the entire facility. (Some agencies charge a fee for reinspection.)
- Warning letter or notification to correct the violation(s)
  - Warning letters are generally issued after a firm fails to correct a violation or repeats a violation that was corrected during a previous inspection.
- Compliance review meeting with the firm's supervisory staff
  - Compliance review meetings are the firm's opportunity to meet with the regulatory authority to discuss the violations and corrective plans.

- Request for a written corrective action plan
  - A corrective action plan may be the result of a compliance review meeting or exist as a stand-alone action. The corrective action plan should include sufficient details to demonstrate that the firm is aware of the violation(s), what its plan is to correct the violation(s), how the firm will monitor the violation(s), and how the firm will verify that the corrective plan is being followed.
- Administrative or civil penalties
  - Administrative or civil penalties may be issued by the regulatory authority, if permitted by law. These types of penalties are issued directly through the regulatory authority, not through a court process, and are often increased for repeated violations. Appeals to administrative or civil penalty assessments may be made through the judicial process.
- Hearing in court or before a public health board
  - Hearings in court or before a public health board are often one of the last steps in a progressive enforcement process and involve the most severe violations and penalties. These proceedings are, in most cases, adversarial in nature and may involve a variety of legal representatives.
- Order to stop sale(s) and/or operations
  - A written order to either stop selling a food item or to close a facility is a severe penalty. In many cases, the regulatory authority's management team develops the written orders.
- Product seizure or embargo[2]
  - The purpose of seizure or embargo of a food product is to prevent the product from being moved in commerce. Seized products may be detained and remain in control of the regulatory agency in order for the agency to conduct a laboratory analysis of the product, make a final determination about the condition of the product, or arrange for the disposal of the product.
- License suspension or revocation
  - License suspension or revocation means that a firm is no longer able to complete the activities that the firm is licensed to conduct, such as manufacturing, storing, delivering, transporting, or selling food. Because license suspension or revocation is such a severe action, the firm in question is generally given the opportunity for a hearing on the suspension/revocation order. The timing of the hearing is likely outlined in the law or in the administrative procedures covering the regulatory authority.

[2] These terms are often used interchangeably.

- Consent agreement
  - A consent agreement is a legal document developed by both the firm and the regulatory authority that outlines the tasks that a firm will take to address violations.
- Consent decree
  - A consent decree is essentially a consent agreement, but the decree is overseen by a court, and failure to comply with the decree can result in more severe consequences.
- Injunction
  - An injunction is similar to a consent decree; however, an injunction is imposed by a court without agreement by the defendant.
- Criminal prosecution
  - This action involves a legal representative preparing for a hearing before a judge in an appropriate court system.
- Mandatory training
  - With this option, a firm is required to successfully complete training related to food safety. Mandatory training is sometimes combined with a compliance review meeting or a warning letter at the start of a progressive enforcement process.
- Adverse publicity via public notification/press release
  - This notification to the public of potential health hazard(s) can be completed by the firm (if cooperating with the regulatory authority) or by the regulatory authority (if the firm is not cooperating).
- Destruction order
  - A destruction order directs a firm to destroy product(s) and in many cases requires court oversight due to the "taking" of a firm's product(s) and activities.
- Import alert
  - An import alert, which is generally issued by federal regulatory authorities, limits the importation of food(s) manufactured by firms outside of the US.
- Debarment
  - Some offenses can result in a person or company being debarred from engaging in a food business, either on a permanent basis or for a specific period of time, depending on the applicable law/regulation.

No matter the violation, the facility must still be granted with due process, i.e., given the chance to take corrective action or to appeal the violation report.

Recalls

Another type of enforcement action is a recall. A recall can be a voluntary action taken by a firm to remove a product from commerce; however, recalls can be mandated by a regulatory agency. An FPP may spend time following up on recalls by performing effectiveness checks—verifying that distributors and retailers of the product were notified appropriately and took action to remove the products from commerce. A numerical classification of I, II, or III is assigned to a recall based on the health hazard posed by the product being recalled.

A Class I recall involves a situation where there is a reasonable probability that the use of or exposure to a product will cause serious adverse health consequences or death (FDA 2009b). Class I recalls require the establishment to prepare a press release for issuance to the Associated Press and report the recall within 24 h to the FDA Reportable Food Registry (RFR, http://www.fda.gov/Food/ComplianceEnforcement/RFR/default.htm), an electronic portal. The RFR helps FDA protect public health by tracking recall patterns and targeting inspections. If the recalled product has not been distributed to the public, the recall does not have to be reported to the RFR. The RFR applies to all FDA-regulated categories of food and feed, but does not apply to dietary supplements and infant formula.

A Class II recall involves a situation in which use of or exposure to a product may cause temporary or medically-reversible adverse health consequences, or where the probability of serious adverse health consequences is remote (FDA 2009b). Class II recalls have been conducted due to lead contamination and undeclared colorings.

A Class III recall involves a situation in which use of, or exposure to, a product is not likely to cause adverse health consequences (FDA 2009b). Class III recalls have involved mold contamination, minor labeling problems, decomposition, and economic fraud.

Conclusion

Properly-conducted inspections provide food facilities with a clear summary of the state of compliance with safe food practices. An inspection report includes a list of food safety violations and documents any corrective action taken to remedy the violations. Inspections involve a sequence of steps, from pre-inspection research to an initial walk-through to risk assessment to violation documentation and exit interview. If warranted, enforcement actions are imposed by the regulatory agency. Inspections should be viewed as a collaborative effort between the FPP and the facility being inspected in order to help ensure a safe food supply.

Take-Home Message

Preparing for a properly-conducted food inspection involves reviewing the history of the facility being inspected, reviewing the food safety rules and regulations that apply to the facility, and gathering the necessary inspection tools and equipment. Maintaining a professional demeanor and practicing good communication skills with the responsible employee or management help the facility and the regulatory agency form a collaborative relationship with the overarching goal of a safe food supply. If food safety violations are found, appropriate enforcement actions are initiated.

Activity

Below are photos taken during actual inspections by FPPs.

For each image, answer the following two questions:

1. Are there any potential food safety issues shown in the photo?
2. For each food safety issue identified, which response(s) would be appropriate corrective actions taken by the establishment, educational opportunities, etc.? (Figs. 12.2, 12.3, 12.4, 12.5, 12.6, 12.7, 12.8 and 12.9).

Fig. 12.2 Meat department workstation with slicer and cuber, wet towels, and personal food

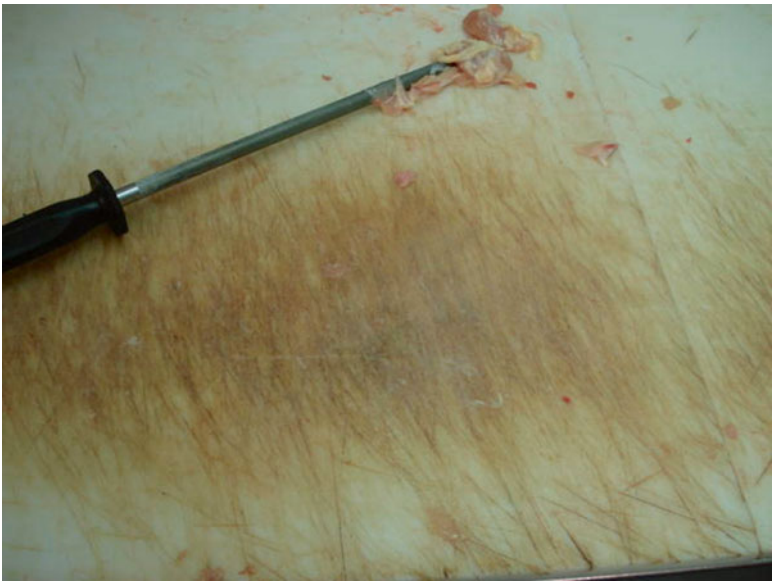

Fig. 12.3 Heavily scored, plastic, raw meat cutting board

Fig. 12.4 Rotisserie chicken preparation station with flies on the chicken

Fig. 12.5 Frozen chicken thawing in a utensil washing sink

Fig. 12.6 Submerged drain of a utensil washing sink

Fig. 12.7 Clutter/equipment outside the backdoor area of a food establishment

Fig. 12.8 Pie-filling station

Fig. 12.9 Employee handwashing station

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U.S. Food and Drug Administration (2014b) Investigations operations manual 2014. Section 5.4.3.1 – Plant construction, design and maintenance, p 260. http://www.fda.gov/downloads/ICECI/Inspections/IOM/UCM150576.pdf. Accessed 22 Dec 2014

U.S. Food and Drug Administration (2014c) Investigations operations manual 2014. Section 5.2.3 – Reports of observations, p 228. http://www.fda.gov/downloads/ICECI/Inspections/IOM/UCM150576.pdf. Accessed 22 Dec 2014

U.S. Food and Drug Administration (2014d) Investigations operations manual 2014. Section 5.2.3 – Reports of observations, p 229. http://www.fda.gov/downloads/ICECI/Inspections/IOM/UCM150576.pdf. Accessed 22 Dec 2014

Additional Resources

State of Florida (2001) Department of Business and Professional Regulation, Division of Hotels and Restaurants. Good Retail Practices. http://www.myfloridalicense.com/dbpr/hr/forms/documents/5022_086.pdf

U.S. Food and Drug Administration. Inspections, Compliance, Enforcement, and Criminal Investigations. Inspection Guides. http://www.fda.gov/ICECI/Inspections/InspectionGuides/default.htm. Accessed 22 Dec 2014

Answer Key

1. Meat department in a grocery store (workstation with slicer and cuber)

Food safety issues	Potential corrective actions
Unclean towels are draped over equipment and worktable surface.	Remove towels and clean and sanitize equipment and table surfaces. Explain to the person in charge (PIC) or manager the proper method of handling and storing work towels.
There is evidence of workers eating in the work area (foam tray with food and eating utensil on worktable surface).	Remove foam tray and eating utensil from room. Items belong in the employee area or break room. Explain to the PIC or manager the potential risks of allowing employees to eat in the work areas.

2. Plastic, raw meat cutting board

Food safety issues	Corrective actions
The cutting boards are not clean and are heavily scored, making cleaning and sanitizing very difficult.	Replace cutting boards or have cutting boards professionally resurfaced, if possible. Explain to the PIC or manager the proper maintenance, cleaning, and sanitizing of cutting boards and the potential risks caused by improper maintenance.

3. Rotisserie chicken preparation station

Food safety issues	Potential corrective actions
Flies are on the chickens and other surfaces.	Investigate to determine if there are any opened, unscreened doors or windows in the facility allowing pest entry. Thoroughly clean and sanitize the work area to eliminate pest attractants.
Chickens have been contaminated by flies.	Discard chickens.

(continued)

(continued)

Food safety issues	Potential corrective actions
Container of marinade appears to be a reused plastic beverage container. The container is not labeled with contents.	Discard the unapproved container and use only food grade containers to hold food products. Instruct management that all ingredient containers need to be labeled as to their contents.
The tray holding the chickens is not clean and exhibits old marinade residues.	Thoroughly clean and sanitize the tray.
The seasoning container is not clean.	Adhering debris on the seasoning container may be a sign of poor employee practices (e.g., lack of handwashing). Explain handwashing techniques and discuss the importance of effective handwashing.
The tray holding the chickens is not easily cleanable and may not be made of food-grade material.	Replace with an appropriate food grade tray or container.
Working with raw chickens next-to-wrapping film, which could be used to wrap ready to eat foods, introduces the potential for cross-contamination.	Prepare the rotisserie chicken in an area that will not cause cross-contamination issues.

4. Frozen chicken thawing station

Food safety issues	Corrective actions
Three-compartment warewashing sink is being used to thaw whole chickens.	Explain the proper way of thawing food products.
Flies are on the chicken, on equipment, and on other surfaces.	Investigate potential pest entry and eliminate any attractants. Explain the importance of effective pest control.
Unclean dishes and utensils are piling up in the warewashing sink, creating a potential pest attractant.	Clean, sanitize, and properly store equipment and utensils.
Chickens have been contaminated by flies.	Discard chickens.

5. Drain area of a utensil sink

Food safety issues	Corrective actions
The equipment sink drain is plugged, and the drain pipe is not properly constructed to prevent back siphonage.	Clear drain and reconfigure/cut the drain pipe to eliminate potential back siphonage.
The drain area is not clean.	Thoroughly clean the drain piping and the surrounding floor and wall surfaces.

6. Food establishment perimeter area

Food safety issues	Corrective actions
There is an accumulation of debris (totes, crates, racks, displays, bicycles, etc.) outside the facility perimeter which may act as a pest harborage.	Remove debris from around the facility perimeter. Explain to the PIC or manager the importance of pest control.

7. Pie-filling station

Food safety issues	Corrective actions
Buckets of pie fillings are stored open and uncovered directly on the floor then as needed are placed directly on the work table.	Ingredient containers should not be placed directly on the floor.
The buckets are not labeled for contents.	All ingredient containers should be labeled as to the contents.

8. Employee handwashing station

Food safety issues	Corrective actions
The facility is in operation and the handwashing sink is not usable. The sink appears to be nonfunctional (missing a faucet) and is filled with extraneous items.	A properly functional (complete plumbing) and supplied handwashing sink must be provided for employee use during operation.

Chapter 13
Sampling

Rita Johnson, Lisa Hainstock, and Angela Montalbano

Learning Objectives

- Explain the importance of compliance.
- Describe the steps involved in collecting a food or environmental sample and submitting the sample for laboratory analysis.
- Describe the role of the laboratory in the sampling process.

Introduction

A properly-collected food or environmental sample can be essential in determining compliance with food safety requirements. A food protection professional (FPP) should be skilled in food and environmental sample collection and how to submit samples to laboratories for analysis. Collecting, submitting, and analyzing samples involve precise, meticulous steps, techniques, and recordkeeping to ensure the validity of the sample. The laboratory analysis plays a key role in helping

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determine the source or cause of a foodborne illness outbreak and can help guide specific regulatory action—or legal action—against a manufacturer, processor, or distributor of food.

The Importance of Compliance

Sampling is a surveillance and public health tool. Laboratory results of a sample are used for a variety of purposes. Environmental and finished product samples collected by the food industry as part of a food safety management system or by regulators during routine monitoring may be used to determine if preventive controls in place at the firm are being followed and are effective and whether a firm is in compliance with applicable laws and regulations. If problems are identified, industry and regulators can then determine if control measures—such as removing a product from commerce—should be taken to prevent illness or injury.

Sampling of food and/or ingredients at various points along the manufacturing process (in-line sampling) can help identify how potential contamination can be introduced. For instance, comparing sample results of lunchmeat collected before and after slicing could indicate the introduction of a pathogen during the slicing process. Industry and regulators can use samples to identify the time and location of process failure points, which can help identify the extent of product being contaminated and which product lots should be recalled.

Environmental sampling can be used to identify potential niches for pathogens. In the lunchmeat/slicing example mentioned above, a pathogen-positive sample collected from under the blade guard on the slicer might be indicative of inadequate cleaning and sanitization, leading to a recall of all lunchmeat processed on that line after the last time the product tested pathogen-free. Additional sampling after implementing corrective measures can show that the process has been adequately addressed, and the firm can resume processing on that line.

Samples can be used to link pathogen cases of human or animal illness. This linking is often done by comparing laboratory sample results with other clinical or food sample results completed by other laboratories. Isolates from samples can be sent for specialized laboratory analyses to delineate between strains of organisms. Laboratory data combined with epidemiological data is often a critical component in identifying sources of illnesses and mitigating additional illness cases.

Sampling can be used to determine whether imported ingredients and/or food items should be cleared to enter into commerce. If a history shows adverse sample results for certain foods from certain regions, these foods can be given more priority for sampling more frequently. The results could also trigger a ban or "import alert" on a food altogether.

Sampling can also be useful when investigating consumer complaints. For example, an individual allergic to walnut may file a complaint with a regulatory agency after having a severe allergic reaction to a food product. Sampling could then be initiated by a regulatory agency to verify ingredients or information listed on the product label, which could help support, or refute, the individual's claim.

Collecting a Food or Environmental Sample and Submitting the Sample for Laboratory Analysis

Obtaining valid sample results requires a properly-trained staff, proper equipment, and a proper sampling protocol from start to finish. Multiple teaching methods such as videos, publications, agency protocols, observation, and hands-on training can be utilized to achieve competencies related to sample collection procedures, documentation, chain of custody, transport, and the role of the laboratory.

Competent and Trained Personnel

All members of a sampling team must demonstrate good aseptic (sterile, uncontaminated) technique. Aseptic technique involves tasks that, when properly-performed, ensure that no contamination is introduced beyond that which may already be present in the sample. These tasks include proper handwashing, applying sterile gloves, opening sterile equipment, utilizing proper collection techniques, and documentation (which, ideally, includes a photograph of where the sample was collected).

Training in the proper packing of a sample for transport is also important. Samples must be properly-positioned or supported in a shipping container to prevent any damage prior to arrival at the laboratory. Additionally, an adequate amount of cooling media is needed to maintain temperature control during shipment, if the sample is a perishable item or lack of temperature control will affect the nature of the sample.

Sampling Equipment

Sampling equipment generally includes, but is not limited to:

- Sterile-packaged gloves
- Scoops, generally used for taking samples from a bulk container
- Spoons
- Tweezers, used to pick up small items like rodent droppings or debris
- Swabs, used for sampling in hard-to-reach places
- Various sizes of sampling bags/containers
- Neutralizing broth, a sterile liquid that is used to neutralize the effects of chemical sanitizers or antiseptics on the microorganisms in a sample
- Sampling sponges (Fig. 13.1)

Additional supplies/equipment may also be needed, such as a camera, scribe/log sheet to record required documentation, trash bags, lab coats, shoe covers, hair

Fig. 13.1 Taking a sample with a sponge

Fig. 13.2 Protective clothing helps prevent food from becoming contaminated by FPPs and also protect FPPs from environmental hazards

restraints, face masks, protective eyewear, protective clothing (Fig. 13.2), etc. (A more detailed list is located in Appendix A of this chapter, and a sample log sheet is included in Appendix C.) A mobile cart to transport various supplies throughout the facility may also be needed in large facilities. When possible, shoe covers, hair restraints, carts, etc. from the food facility itself should be used, so as not to give the appearance that a contaminated piece of sampling equipment was brought into the facility. If the FPP brings in his or her own cart, the cart should be cleaned and sanitized and wrapped in a clean plastic bag prior to entering the facility.

Preparation for Aseptic Sampling

The first step in any sampling procedure is handwashing. Proper handwashing technique should include the following steps: wet hands with clean running water, apply soap, lather the hands and forearms—including fingers and under nails—by rubbing

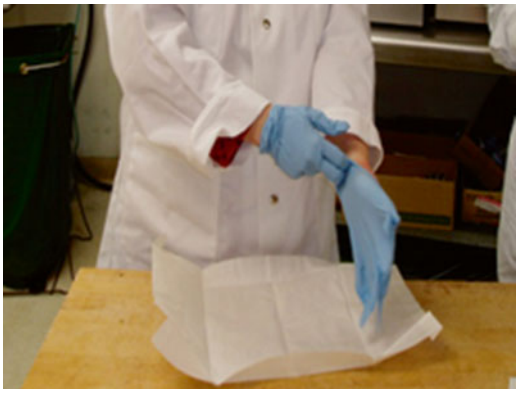

Fig. 13.3 Applying sterile gloves

them together, scrub for at least 20 s, rinse and dry using a clean towel or hot air (CDC 2013a).

After handwashing and before each sampling event, sterile gloves (Fig. 13.3) should be applied in order to help ensure that the sample does not become contaminated. The gloves will be packaged in such a way—with the cuffs folded up at the factory—that no part of the FPP's hands touches the outside of the gloves. If gloves become potentially-contaminated, the gloves should be discarded and a new, sterile package of gloves should be opened. Practicing the application of sterile gloves before each sampling event can ensure proper aseptic technique, especially if sampling is not done regularly.

All sterilized equipment and supplies will have an expiration date and code number. Expired items cannot be used, and items are to be opened without contaminating the sterile item inside. For instance, while removing a sterile sponge from the bag, no portion of the sterile sponge should touch the outside of the bag. Each sampling supply's information (lot code and expiration date) should be recorded for each different lot of sampling equipment. One sterile item from each lot, unopened, is to be sent to the designated laboratory as a control for that item. In some cases, an ambient air control sample is required. In that case, a sterile container is opened and allowed to sit exposed to the surrounding air, then closed and properly-labeled. Usually this control is required during "*for cause*" environmental sampling of food contact areas, which is sampling done after the presence of a pathogen has been discovered in an official food sample.

Collecting a Food Sample

Proper sampling methods vary according to the commodity, but samples for microbiologic testing should always be collected aseptically. The volume of the sample to collect depends on the organism being sought, along with the specific

Fig. 13.4 Sample sealing

food item. Generally, the designated lab will inform the FPP of this information, along with shipping temperatures and shipment timetables. For example, environmental samples are generally collected in large numbers, approximately 100–400 samples per facility.

Each sample container must be properly labeled, generally with the following information: date of collection, specific product name, sample number (cross-checked with a specialized form), name of person who collected the sample, witnesses, and why the sample is being analyzed.

Samples should be sealed immediately (Fig. 13.4) and maintained at the appropriate temperature. Additional documentation may be required, but not necessarily on the sample collection container, such as lot number or product code, volume of the lot, area where the sample was collected, etc.

Whether being transported directly or being shipped to the designated laboratory, samples must be properly packed to avoid damage and, when necessary, to arrive at the laboratory at the proper temperature. Adequate amounts of cooling media strategically placed around the sample(s) will ensure even temperature control. Samples that are damaged or not maintained at the appropriate temperature cannot be used for analysis. There may also be a critical time element involved with a sample, i.e., time between collection and analysis, in order to consider the results valid.

Procedures for Collecting Environmental Samples (Commonly Done as a Team)

An environmental sample visit should begin with a detailed explanation of the purpose of the visit and what documentation is required from the firm. Appendix B contains an example of a handout sheet to give to the most responsible person at the

Fig. 13.5 Using a swab to collect an environmental sample

firm prior to an environmental sampling event. The sampling team will generally include a swabber sampler (Fig. 13.5), a swabber sampling assistant, a photographer, an individual to record location/sample number, a packer/shipper, and a person for data entry.

An operational meeting with the team taking an environmental sample is recommended prior to the sampling day. During the operational meeting, any information, such as products, processes, process flow, information from the most recent inspection of the location, and equipment placement can be shared. An example of a list of items to cover with the sampling team prior to the sampling is included in Appendix A under "Inspection Lead."

Sampling Zones: The 4 Zone Concept

The 4 Zone Concept (Fig. 13.6), which is common protocol throughout the USA, defines four sampling zones that are the same, regardless of which organism is being sought in the food facility. The zones are prioritized from the highest risk (Zone 1) to the lowest risk (Zone 4):

Zone 1 contains all direct food contact surfaces, such as slicers, mixers, conveyors, utensils, racks, work tables, etc. These surfaces are exposed to the product during normal operations.

Zone 2 encompasses the areas directly adjacent to Zone 1: all non-food contact surfaces in the processing area such as the exterior of equipment, equipment framework, food carts, equipment housing, gears, ventilation/air handling equipment, floors, and floor drains.

Zone 3 is the area immediately surrounding Zone 2, e.g., hallways and doorways leading into food production areas, or, in a large production room, areas further away from food-handling equipment than typical Zone 2 areas.

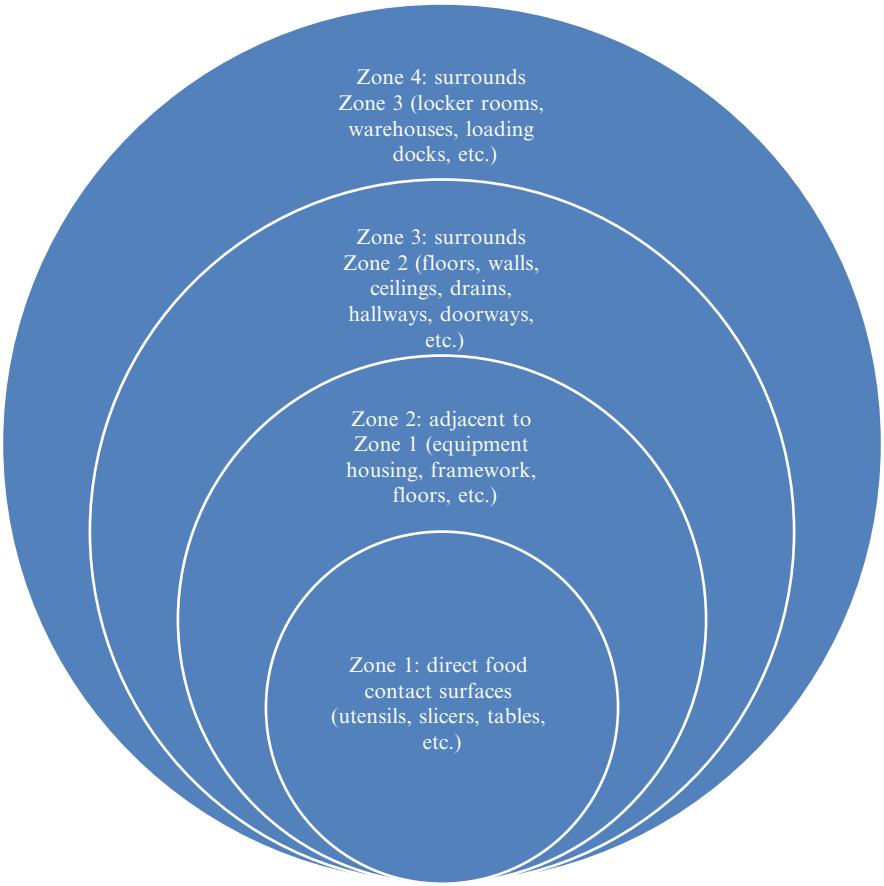

Fig. 13.6 Environmental Monitoring Zone Concept (Adapted from *Understanding the Environmental Monitoring Zone Concept*, Michigan Department of Agriculture and Rural Development) (2012). http://www.michigan.gov/documents/mdard/Understanding_the_Environmental_Monitoring_Zone_Concept_375002_7.pdf. Accessed 19 December 2014

Zone 4 is the area immediately surrounding Zone 3, areas outside of the processing room that generally do not contribute to direct product contamination, unless there is a breach of employee hygiene. Examples of Zone 4 areas could include loading docks, cafeterias, warehouses, and employee locker rooms.

Most environmental samples collected should be taken from Zones 1 and 2, and to a lesser degree Zone 3, depending on the organism. To look for *Listeria* species, environmental sampling would focus on Zones 1 and 2, while checking for *Salmonella* would focus primarily on Zones 2 and 3. Very few, if any, environmental samples should be taken from Zone 4 (Michigan Department of Agriculture 2012).

In addition to documentation required for food samples, the FPP should also state from which Zone, 1 through 4, the sample was collected, along with the exact location where the sample was collected. This information should be as specific as possible so that in the event of a positive sample, the FPP will know exactly where the sample was taken. The FPP must also document the exact time the sample was collected in the event there is a specified time frame from collection to analysis.

Sample Results

In routine situations, time between sample collections and laboratory results could be from 1 week to 3 weeks for an official sample result, but can vary between state and federal laboratories. Negative results are the quickest; positive results take longer. If there is a presumptive positive sample result, this indicates a definitive result cannot be stated initially. A presumptive positive is further processed to determine if the actual result is positive or negative. Once the presumptive positive result is determined to be definitely positive, additional time may be needed to have the result verified, i.e., checked against the laboratory's control for the specific organism in question to ensure there was no laboratory contamination of the sample.

The Role of the Laboratory in the Sampling Process

The laboratory plays an integral role in the sampling process by providing valuable data on the safety and quality of food products or the environment in which they are grown, processed, manufactured, stored, served, or sold. The laboratory also plays a part in food-related emergency response, disease identification, contamination events, and outbreak investigation. Analysis of food or environmental samples by the laboratory may provide proof that a pathogen is present, identify the causative agent (i.e., pathogenic bacteria), provide results that can be used to indicate how the causative agent may have been introduced and proliferated in the food chain, and evaluate the effectiveness of controls and/or preventive measures.

Competent Staff and Equipment

A laboratory must have competent personnel who demonstrate the knowledge, skill, and experience in appropriate and approved laboratory methods. This competency is necessary for laboratory results to be admissible in support of regulatory or enforcement actions. The laboratory must also have the appropriate equipment, instrumentation, and materials to conduct analyses appropriate for the programs that the laboratory supports.

Laboratory Accreditation

Laboratories must be able to demonstrate competency in carrying out sample analysis. One way to demonstrate competency is by meeting the standard established by the International Organization for Standardization and the International Electrotechnical Commission (the ISO/IEC 17025 standard). This standard applies to the laboratory management system, administration, and technical operations. A laboratory that is accredited to the ISO/IEC 17025 standard has been assessed by an independent accrediting body to verify that the standard is met. A substantial focus of the accreditation is on quality systems, including testing programs that are proficient, analysts who are appropriately trained to perform specific testing, and systems that address failures in the quality system. The standard is applicable to all laboratories, regardless of the number of personnel or the extent of the laboratory's testing activities. Laboratory customers and regulatory authorities use this ISO/IEC standard to confirm or recognize the competency of laboratories. Additionally, the U.S. Food and Drug Administration (FDA), as mandated by the Food Safety Modernization Act (FSMA, Public Law 111-353), has been charged with using accreditation to this standard as a means of demonstrating equivalency among laboratories, regardless of agency affiliation.

Approved Methods

Depending on the pathogen or contaminant being analyzed, a laboratory must be able to utilize approved methods, such as those found in FDA's Bacteriological Analytical Manual (FDA-BAM, http://www.fda.gov/Food/FoodScienceResearch/LaboratoryMethods/ucm114664.htm). The FDA-BAM provides detailed descriptions of methods that are endorsed by FDA for the analysis of food and environmental samples. FPPs must be in communication with lab personnel regarding whether the methodology used in obtaining results is in accordance with approved standards. Test results must be unambiguous, and the terminology used for test requests should be mutually agreed upon. A checklist of available tests on a request form is one way to clearly indicate what is needed.

Many laboratories use methods that are not in FDA-BAM and/or FDA-approved, partly because manuals cannot keep up with advancements in technology. If alternative methods are used, the methods must be shown to be appropriate for the intended purpose. If laboratory results are obtained using methodology that does not comply with approved methods, FPPs should consider whether the noncompliance affects the legal admissibility of the results and any subsequent enforcement or regulatory actions. Such a determination must be made in collaboration with the lab, state, and federal officials.

Pulsed Field Gel Electrophoresis (PFGE)

Pulse field gel electrophoresis (PFGE) is a method that provides molecular DNA "fingerprint" patterns for the most common foodborne pathogens. Pathogenic organisms should all be sent to a laboratory capable of performing PFGE testing and subsequently uploading the results to the US Centers for Disease Control and Prevention (CDC) PulseNet data network (www.cdc.gov/pulsenet/). Uploading the patterns onto the PulseNet database allows comparison with other clinical and/or food sample isolate patterns across the US and can help determine possible linkage between foodborne illness cases and consumption of certain food products. PFGE analysis can also aid in epidemiological investigation by providing rapid detection of outbreak-related cases, distinguishing outbreak strains from other strains, and tracking contamination within a food system. The use of PFGE is currently considered the "gold-standard" for subtyping many pathogenic organisms (Cornell University 2014).

Multiple Locus Variable-Number Tandem Repeat Analysis (MLVA)

Multiple locus variable-number tandem repeat analysis (MLVA) is another technique used by laboratory scientists to generate a DNA fingerprint for a bacterial isolate. Scientists usually perform MLVA after conducting a PFGE to find out more specific details about the type of bacteria that may be causing an outbreak. MLVA can connect suspected, fast-evolving bacterial strains to an outbreak when other methods of DNA fingerprinting, such as PFGE, do not make such a connection. CDC PulseNet uses MLVA as a complementary technique to PFGE, allowing scientists to see more detailed differences between bacteria that have similar PFGE patterns (CDC 2013b).

Culture-Independent Diagnostic Tests (CIDT)

One way that technology is evolving, is the development of new clinical laboratory diagnostic tests known as culture-independent diagnostic tests (CIDT). These tests do not rely on a pure bacterial culture as do conventional diagnostic tests. CIDT can identify the bacteria making a person sick without using pore cultures, which means doctors can find out what is making a patient sick without waiting for up to 3 days for the bacteria culture to grow in a laboratory (CDC 2013c). As a result, there may be a rapid diagnosis for the patient. However, there is no longer a culture

available to track the outbreak using PFGE, and linking cases may be difficult without having more comparative results. These diagnostic tests may change how epidemiological investigations are performed and the role that laboratories have in these investigations.

Laboratory Consultation with FPPs on Sample Collection

Laboratory personnel are often the best source of guidance for regulators regarding sampling methods, equipment, and sufficient sample quantity. The adequacy and condition of the sample received for examination are of primary importance. If samples are improperly collected, are mishandled, or are not representative of the sampled lot, the laboratory results will likely be meaningless from a regulatory standpoint (UNIDO 2013). Some samples may be degraded by temperature, light, air, moisture, or even the type of container used for the collection. Additionally, if the sample size is too small, the laboratory may not have sufficient product to analyze.

FPPs should consult with the laboratory *prior to* collecting samples, to ensure the sample team is using the appropriate sampling equipment and materials, utilizing sampling methods that avoid contamination or mishandling, and following appropriate shipment protocols. Sampling materials and methods may depend on the food or environment that is being sampled, along with the potential contaminant being sought. Another reason for FPPs to consult with the laboratory prior to collecting samples is to determine the best days/times to submit a sample (i.e., schedule a work plan) and to ensure that the lab is adequately prepared for the estimated number and types of samples that will be submitted. If the lab is not prepared for the volume of samples submitted, analysis could be delayed while the lab obtains additional sample media, supplies, or staff. Some samples, such as environmental swab samples, are time-sensitive and must be tested within a range of time in order to be useful. Discarding samples because the samples could not be analyzed within a prescribed time frame or did not arrive in a condition that maintains sample integrity is in no one's best interest.

Chain of Custody

Each individual who handles the sample during the entire sampling process (collection, transport, submission, and analysis) must maintain *chain of custody* documentation that ensures the identity and integrity of a sample or other evidence taken for analysis from the point where the sample is collected to the point where the results are reported. Chain of custody also demonstrates that a sample has been secured during storage until tested and that a method was used to detect tampering during shipping. The laboratory is an integral part of sample chain of custody and must document handling of the sample up to the point that the sample is no longer in the laboratory's possession, such as when the sample is transferred to another lab or

when the sample is discarded. The laboratory is also responsible for maintaining chain of custody documentation in case the documentation is needed for future legal action or is requested via subpoena or a Freedom of Information Act (FoIA) request. All information on the chain of custody form must be consistent with the sample seal or tag (sample number, date, sampler's name, etc.) and the information on the sample collection report.

Rejecting Samples

Laboratories can reject samples for a variety of reasons, the most common of which include:

- No chain of custody documentation
- Illegible, inaccurate, or insufficient documentation
- Leakage or damage
- Insufficient temperature control
- Insufficient sampling amount
- Failure to use sterile containers
- Frozen samples thawing between collection and arrival at the lab
- Decomposed samples
- Refrigerated samples being frozen after shipment to the laboratory
- The sample not being received within a required time frame

Timely Reporting

The turn-around time in which laboratory results can be expected should be discussed with the laboratory in advance. The time will be highly-dependent upon the test method used and competing priorities within the laboratory. Laboratories generally report analytical results to customers as soon as possible once the results have been finalized; however, FPPs should understand that laboratories require time for sample receipt, testing, data entry, report generation, and report disbursement. It is important for the regulatory or public health customer to communicate to the laboratory in high-priority situations, so no delays in reporting are encountered.

Surge Capacity

Surge capacity refers to the ability of a laboratory to handle a sudden increase in workload. During a food emergency, a laboratory's capacity to rapidly analyze large numbers of samples may be challenged. Therefore, a laboratory should have a good working relationship with other laboratories to assist with large sample numbers or

testing for unusual contaminants and should be aware of additional laboratory resources that may be available during an emergency.

A memoranda of understanding (MOU) or other agreement between laboratories can increase the number of samples that can be tested and reduce the turn-around time. Laboratories may enter into cooperative agreements with other laboratories to provide surge capacity; however, if the analytic results are to be used for enforcement purposes, the methods and materials should be approved by federal regulatory authorities, and the laboratories should be ISO-accredited.

A number of states have laboratories that may be members of the Food Emergency Response Network (FERN, www.fernlab.org), which is jointly-administered by the U.S. Department of Agriculture Food Safety and Inspection Service (USDA FSIS) and FDA. FERN was created to provide an integrated national approach to detect, respond to, and recover from a bioterrorism event or public health emergency involving food. The network supports a number of programs, all centered on enhancing surge capacity during a food emergency.

Maintaining Records

Original records such as requests for testing, test reports, and the supporting data must be maintained by the laboratory in accordance with a defined record retention procedure. Record retention time periods should be mutually agreed upon by the agency and the laboratory. The agency receiving the results from the laboratory should also retain the results for an agreed-upon period of time.

Potential Regulatory Action

Laboratory analysis can help determine a regulatory agency course of action. However, prior to taking any regulatory action, the agency must be able to ensure the legal integrity of all samples obtained and analyzed, so that the sample results can stand up under court examination, if needed. Examples of sample integrity include proper shipping methods and proper shipping temperature. Coordinating with the laboratory to ensure the sample can be analyzed upon arrival at the laboratory is imperative for maintaining sample integrity. (Note: Potential regulatory actions are covered in detail in Chap. 12, Inspections, Compliance, and Enforcement.)

Once a food sample has been determined to represent a violation, the course of action will vary depending upon the analysis:

- Production of the product may be ceased.
- An inspector may return to the manufacturer to review the manufacturing process and help determine appropriate preventive controls/measures.

- The product may be seized, embargoed, or destroyed.
- The product can be recalled.
- Additional sampling can be conducted.
- The product can be relabeled.
- An import alert can be issued.
- An agency penalty can be issued.
- A warning letter can be sent to the manufacturer.
- A public notification may be issued.

Conclusion

Sampling of food or the environment can be one of a number of useful "tools in the toolbox" to help FPPs ensure a safer food supply. Procedures for sample collection, transportation, and analysis must be strictly followed in order to ensure the integrity of the sample and to ensure that the laboratory results are reliable and actionable, if necessary. Successful completion of food or environmental sampling events requires proper training, adequate logistical preparation, meticulous recordkeeping, and skill on the part of FPPs.

Take-Home Message

Sampling begins with an assignment that details the type of sample that will be taken. No matter the assignment, however, a well-prepared sampling kit, with appropriate sampling equipment, is essential. Aseptic technique must be used where necessary. Proper documentation with a sample report and chain of custody are essential. Sampling can be the basis to enforcement action taken against a firm.

Activity

1. Your sampling team has been assigned to obtain three samples of imported candy. The candy is shipped in bulk plastic-lined cardboard boxes. The candy is to be analyzed for lead and filth. The samples will be obtained, taken to your office, and transported to the laboratory the following day by a different team member.

   List the sampling equipment and documents that you may need.
2. Your sampling team has been notified that there is a *Listeria monocytogenes* foodborne illness outbreak at a local delicatessen. A raw vegetable salad has

been identified by the epidemiologists as the likely source of the outbreak. After your initial walk-thru and inspection, you notice that there is a deeply-scored cutting board with dried food residue on the underside sitting on a food prep table where vegetables are prepared, next to a garbage can. The floor tiles underneath the prep table are soiled with dried food residue as well. After discussion your team decides to sample Zones 1, 2, and 3 in the vegetable cutting food prep area. A control sample of the neutralizing broth must be taken. One of your teammates will be delivering the samples to the UPS store for delivery to the laboratory.

List the sampling equipment and documents that you may need.

3. True or False: The person collecting the sample must have knowledge and training in aseptic (sterile, uncontaminated) techniques.
4. True or False: Environmental sampling for *Salmonella* should focus on Zones 2 and 3.
5. Why would environmental samples being shipped to a laboratory need to be held at a specific temperature during shipping?

Appendix A

Sampling Supplies Checklist

	
Aseptic wipes	
Batteries	
Cameras	
Clipboards	
Compass	
Composition notebooks	
Cooler boxes (for samples)	
Disposable plastic rulers	
Ear plugs	
Face masks	
FDA seals	
Flashlight(s)	
Folding table and folding chairs (if needed)	
Frozen blue ice	
Gloves, disposable	

(continued)

	
Gloves, sterile	
Hair covers	
Hand sanitizer	
Lab coats, disposable	
Neutralizing broth	
Packing material	
Packing tape	
Paper towels	
Post-it® notes (or other brands)	
Safety glasses	
Sample bags	
Scissors	
Seals	
Permanent markers/colored pens	
Shoe covers	
Small cooler	
Sampling sponges (pre-moistened and dry—on a stick)	
Sterile spatulas	
Storage bins	
Swabs	
Telescopic pole	
Trash bags (black and clear)	
Whirl-Pak® bags	
Ziploc® bags (or other brands)	

Appendix B

Handout to Operators

Dear Sir or Madam,

We are from the {Specific Regulatory Authority}. We are at your facility today to conduct environmental sampling. We will take up to {max number of samples you anticipate to collect} environmental samples, including our sample controls. These samples will be packed in cooling media to arrive at our Food Laboratory in {City and State} by {time and date} for analyses. Results may take up to 2 weeks; you will be informed of all sample results.

A member of our sampling team will inform you of which organism we will be testing for at your establishment. You are welcome to have a staff member accompany the team. We will have a designated person to liaison with you or your designated staff member if we or you have any questions during the environmental sampling process.

We will do our best to minimize intrusion in your work areas and at times may ask that a piece of equipment be turned off temporarily so an environmental sample can be obtained from a particular unit.

Our sampling team will have {insert number} people fulfilling various roles, along with members at a separate location within your facility who will conduct data entry of each sample into our information technology system and prepare the samples for shipment.

Before we leave your facility, we will need the following documentation:

- Name of product(s) produced this day
- All lot numbers produced this day
- The amount of product produced under each lot number
- Brand and type of product and package sizes
- Lot numbers and/or source/supplier of all ingredients used to process your product

We thank you in advance for your cooperation in this matter. Environmental sampling is a good monitoring tool in the prevention of foodborne illnesses, and we are pleased that we are able to assist you in your endeavor to produce a safe food product.

Appendix C

Sample Log Sheet

[Firm name] at [Firm address, city, state, zip code] [Firm number] [Sampling date]

SAMP #	Area of Firm	Zone (1-4)	Specific location -details, include direction such as NE corner of meat room prep table	Time/ Photo #	(SS) Or (s)/initial	Computer-generated Sample # (14 digits)

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Additional Resources

ISO/IEC 17025:2005 (2010) General requirements for the competence of testing and calibration laboratories. http://www.iso.org/iso/catalogue_detail.htm?csnumber=39883. Accessed 19 Dec 2014

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Answer Key

1. Medium scoops (3), hand sanitizer, sterile gloves, Whirl-Pak® bags (3), sample labels (3), reports (3), location sheet, permanent marker and pen, camera, chain of custody form.
2. Sterile gloves (3 sets), sterile swab, wet sponge, dry sponge, neutralizing broth (2), Whirl-Pak® bags (4), inventory sheet (for equipment make, type, lot code, expiration date), sample reports, sample labels, hand sanitizer, location sheet, marker and pen, camera, chain of custody form.
3. True
4. True
5. Certain samples may need to be held at a specific temperature (typically at cold, low temperatures) in order to maintain the integrity of the sample.

Chapter 14
Labeling

Dan Sowards, Kristin DeMarco Shaw, Shirley Jankowski, and Jim Sevchik

Learning Objectives

- Describe the origins, development, and implementation of modern food labeling requirements.
- Examine food label requirements.
- Describe the impact of science on food labeling requirements.
- Discuss trends and food labeling.

Introduction

Food labels provide valuable information to consumers and provide a source of advertising for the food industry; however, the accuracy of the label information (e.g., allergens, ingredients, calories, nutrients, health claims, etc.) can have both public health and economic implications. As a result, the food protection professional (FPP) must be able to review food labels for any form of *misbranding* as defined by food laws and regulations. Misbranding, according to Section 502 of the

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Food, Drug, and Cosmetic Act (FD&C Act) includes, but is not limited to, false or misleading advertising, failing to identify the name and location of the manufacturer, and prescribing or recommending a dosage that is dangerous to health. The FPP also needs to be aware of certain "visual" requirements, such as font size and the location of certain information, and stay informed of the current and emerging trends related to food labeling.

Origins, Development, and Implementation of Modern Food Labeling Requirements

Food labels have changed considerably over time. Early regulations in colonial America were enacted at the state and local level as a means to exert control over weights and prices for food commodities, as well as to provide an indicator of quality control. Municipalities required regulatory marks that identified the product owner by name and described the quality of the product prior to sale. By the latter part of the eighteenth century, many states had enacted broad statutes that addressed adulteration of food products, but written labeling requirements were not commonly required until the twentieth century (Harvard University 2001).

Prior to the industrialization of food production, consumers generally had relationships with the people who produced their food. However, the development of rapid transportation and the advent of processes like canning and packaging and large-scale refrigeration allowed food to be produced, distributed, and sold in mass quantities, far from where the food was initially made, to strangers who had no way of knowing the quality of the product they purchased. Unscrupulous manufacturers could make alterations in their packaged product that would economically favor production costs and would only nominally change the perceived quality at the consumer level. Product adjustments that resulted in lower-quality foods had the power to drive market costs down and affect fair competition in the marketplace. Producers who would otherwise provide pure foods were driven to engage in similar misbranding or adulteration of their products in an effort to remain competitive (Porter and Earl 1992).

By the 1890s, various states had developed rudimentary requirements for the labeling of various foods and the ingredients that could be safely used. However, there was no uniformity or agreement among the states, nor between the states and the federal government, either in terms of what should be included on labels or what was "safe." Food companies, in some instances, were unable to ship their products to other locations without the risk of condemnation and seizure of the products. Further, without some semblance of uniformity in labeling requirements, the consumer was at the mercy of marketers as to what was being purchased and consumed. In 1896, a number of states decided to meet to address labeling issues and seek uniformity in state pure food laws. The states decided to meet annually in a formal way, expanded the meeting to include federal and industry attendees, and formed an association to advance regulatory uniformity. This annual meeting became the present day Association of Food and Drug Officials (Burditt 1996).

Early labeling regulations were enacted to protect consumers from acts of adulteration and misbranding of products. Adulterated food can be defined as food that is generally impure, unsafe, or unwholesome. Prior to the development of standards of identity for food products, most misbranding was related to deceptive practices—the use of false weights and measures or passing off substandard products as top quality (Law 2004). Section 402 of the FD&C Act defines numerous ways that a food product can be adulterated based on labeling, including the omission of any valuable constituent, substituting a valuable ingredient without including an appropriate disclaimer, and adding an ingredient in order to increase the bulk or weight of the product, reduce the strength or quality of the product, or make the product seem to be of better value.

The passage of the Pure Food and Drug Act (PF&D Act) of 1906 was the first federal statute to address misbranding of food products and prohibit false or misleading statements on food labels (Harvard University 2001). The PF&D Act was similar to the previous state pure food laws and included requirements for accurate product labeling and identification of the presence of mixtures or impurities on the label. The Act also outlawed interstate trade of adulterated or misbranded foods (Law 2004). The PF&D Act did not require any additional information, such as the name of the food or manufacturer, the ingredients, or the quantity of product contained within. Although the US Food and Drug Administration (FDA) had informally promulgated definitions of standards of the identity of foods prior to passage of the PF&D Act, the law did not authorize FDA to set standards. The Act did, however, provide FDA with criminal and civil enforcement authority over misbranded products (Campbell et al. 1996).

The Federal Meat Inspection Act was also passed in 1906 and required labeling practices for beef, pork, sheep, and goats that were more stringent than what the PF&D Act required for all other food products. Labels on beef had to include manufacturer information and could not contain superfluous product descriptions (e.g., the use of adjectives such as "best") unless such descriptions could be proven by the manufacturer. Beef producers were eligible to use an official seal of approval on products that had been tested and approved by the US Department of Agriculture (USDA), lending credence to claims of the quality of a product.

The FD&C Act of 1938 was enacted in an effort to increase regulatory specificity for most food products. This legislation established FDA authority to require the labeling of food products, primarily from section 403 of the Act, which describes the conditions for misbranding (Fortin 2009). The provisions of the FD&C Act provide the backbone of modern food labeling regulations. Key provisions of the Act include:

- Mandatory labeling of the name of the food, ingredient statement, net quantity, and the name and address of the manufacturer or distributor
- Mandatory standards of identity
- Labeling of imitation foods
- Nutrition information for special dietary foods
- Prohibition of any false or misleading claims (Fortin 2009)

Additional authority was granted to FDA in the Fair Packaging and Labeling Act (FPLA, Public Law 89-755) enacted in 1967. The FPLA provides additional regulations to prevent consumer deception (or to facilitate value comparisons) with respect to descriptions of ingredients, slack fill of packages, use of "cents-off" or lower price labeling, or characterization of package sizes on food, drugs, and cosmetics (Federal Trade Commission 2014).

Consumer demand for more information regarding the content of food products, along with advancements in science and nutrition establishing links between diet and health, initiated passage of the Nutrition Labeling and Education Act (NLEA) in 1990 (Fortin 2009). Prior to passage of NLEA, health claims on food labels were considered unapproved drug claims under the FD&C Act. NLEA amended the FD&C Act to allow health claims for certain foods and dietary supplements under limited conditions. NLEA also required that all food products—with the exception of raw fish, fruits, and vegetables, along with restaurant and cafeteria food—had to be labeled to declare calorie, fat, cholesterol, sodium, protein, carbohydrate, vitamin A, vitamin C, calcium, and iron content. In addition, NLEA mandated changes in label declarations for sulfites, sweeteners, colors, spices, non-dairy and allergenic substances, net contents, and metric labeling (Fortin 2009).

NLEA also specified labeling requirements to reduce consumer confusion about serving sizes, including the use of common household measurements (e.g., cups or tablespoons) and uniformity of serving sizes to reflect the amount a person actually consumes. Health claims linking the effect of a nutrient or food to a disease-related condition were allowed, but only when supported by scientific evidence and under specific conditions, such as when the food is a sufficient source of the applicable nutrient (Fortin 2009).

The implementation of NLEA increased consumer confidence in health claims overall. Although manufacturers may utilize health claims to market their products, the role of the substantiated health claim is to provide consumers with information about a product that may reduce the risks of certain diseases and conditions.

NLEA also contained new requirements for the labeling of fruit and vegetable juices. These changes can be found in the Code of Federal Regulations (CFR) under 21 CFR sections 101 and 102. The new requirements addressed concerns for misleading statements along with confusing vignettes that may have implied pure juice when the actual product contained only a small amount of fruit or vegetable juice. Some drinks had depicted graphics of fruits or vegetables but contained no juice. The changes require that a product labeled with the common name "juice" that is not further qualified be composed of 100 % fruit or vegetable juice. Products that are not 100 % juice must list a qualifying term after the word "juice" such as "drink," "aid," or "beverage." Additionally, the percent of juice contained in the beverage must be declared above the Nutrition Facts Panel. Added sweeteners are not permitted in a product labeled as a "juice" but are allowed in products labeled with qualifying terms such as "juice drink."

The Dietary Supplement Health and Education Act of 1994 (DSHEA, Public Law 103-417) sets forth regulatory procedures for labeling dietary supplements,

including the addition of a disclaimer that FDA has not evaluated the health claim and that the intent of the product is not to prevent, diagnose, cure, or treat any disease. Most of the provisions of DSHEA were incorporated as amendments to the FD&C Act.

Currently, the primary federal agency responsible for food labeling regulations is FDA, which oversees the majority of domestic and imported foods sold in interstate commerce. Other federal agencies with regulatory oversight of food labels include the USDA Food Safety Inspection Service (USDA FSIS) with oversight of meat, poultry, and processed egg products, the US Federal Trade Commission (FTC) with the mandate to prevent unsubstantiated or deceptive information in advertising (Schmidt et al. 2005), and the Alcohol and Tobacco Tax and Trade Bureau (TTB) which oversees the labeling of beer, wine, distilled spirits, other alcohols, and tobacco products. Individual states, territories, tribes, and a number of local jurisdictions have also adopted statutes, rules, and ordinances to enforce food labeling requirements.

Regulations for the labeling of meat, processed eggs, and poultry products are found in laws specific to USDA, although many of the requirements are the same as with FDA. The USDA FSIS must approve most labels prior to marketing for any USDA-regulated products. (This pre-approval is also true for the 28 state meat inspection programs that are authorized and under the oversight of FSIS). Labels on raw meat and poultry products must include instructions for safe handling and cooking and a warning label stating that, due to bacteria in the product, mishandling the product or improperly cooking the product could result in illness. Additional labeling requirements for USDA-regulated products include the official inspection legend, the establishment's inspection number, and any other applicable warning statements, such as "keep refrigerated" and "keep frozen" (Fortin 2009).

Preemption

In most cases, federal preemption requires state and local laws to be identical to federal rules. There are some exceptions where states are permitted to adopt more stringent regulations, but food labeling is not one of those areas. Therefore, when a state or local government is "preempted" by federal law or regulation, the state or local regulation must conform to federal law or rules. For example, NLEA overrides state and local food labeling laws; as a result, the state or local law must be uniform with the FD&C Act (Law 2004). However, states have the authority to enforce food laws through actions such as injunctions, seizure, embargo, recalls, fines, or administrative penalties.

An illustration of federal preemption occurred in the state of Texas in the early 1990s. The state was in the final stages of adopting new regulations that would have defined such terms as "cholesterol-free," "low cholesterol," "fat-free," "low-fat," as well as other nutrient content claims. However, the preemption clause in NLEA

required Texas to withdraw their proposed regulations and not proceed to final adoption. Texas could have proceeded (and later did) to adopt nutrient content regulations that were identical to those adopted later by FDA. Other examples of federal preemption include health claims under DSHEA, the labeling of shell eggs, and the labeling of beef and poultry products under the authority of the USDA FSIS. There are exceptions to federal labeling preemption related to food warnings and container deposit requirements.

Food Label Requirements

The FD&C Act and the FPLA are the primary federal laws governing food products under FDA's jurisdiction. FDA food labeling requirements are found in 21 CFR 100. The following information summarizes label components required for retail food packages intended for distribution in the US. Labeling includes all labels and any other written, printed, or graphic matter that accompanies the product. In addition to product packaging, labeling also includes point-of-purchase displays, retail shelf labels, brochures, and websites.

The Principal Display Panel (21 CFR 101.1)

The principal display panel (PDP) is the area of the package—typically the front label—that the consumer is most likely to see when purchasing the product. There are two required elements on the PDP: (1) a statement of identity and (2) the net quantity of contents (Fig. 14.1).

The statement of identity is the name established by law or the commonly-accepted name of a food. If the product does not have a common or usual name, then an appropriate, descriptive name can be used if not misleading. The statement of identity must generally be parallel to the base of the package in bold print using prominent lettering and must include a flavor declaration as specified by 21 CFR 101.22. The flavor declaration addresses a product's recognizable or characterizing flavor and may include information about the addition of artificial and/or natural flavors. The PDP may also be required to contain a description of the form of the food in the package (e.g., sliced, halves, etc.) depending on the product. Further requirements for a product's statement of identity, including lettering size, can be found in 21 CFR 101.3.

The net quantity of contents describes the amount of food in the package. The quantity is expressed by weight, volume, or pieces using both US and metric units and is generally preceded by terms such as "Net Wt, Net, Net Contents, or Total Net Wt," depending on the type and size of the food product. The net quantity of contents must appear in the lower 30 % of the PDP, generally parallel to the base of the

Fig. 14.1 Principal display panel (*Source*: the HV Food Products Company, https://www.hidden-valley.com/products/dressings/original-ranch/original-ranch/#nutri-facts. Used with permission)

container using a prominent and bold typeface, and the size of the lettering depends on the area of the PDP. The PDP area is calculated as follows, measured in square inches or square centimeters:

- For rectangular or square containers: height × width
- For cylindrical containers: 40 % of height × circumference
- For containers of other shapes: 40 % of the total surface of the container (excluding tops, bottoms, flanges, and shoulders)
- For containers with an obvious PDP such as the top of a circular package: the area of the entire surface [i.e., circular package top: Area = pi × r^2 (with pi = 3.14, r = radius)]

Further requirements regarding print and font size, including requirements for multipacks or variety packs, are spelled out in 21 CFR 101.105.

Information Panel (21 CFR 101.2)

The information panel (Fig. 14.2) is the label that is immediately to the right of the PDP or is the back label if there is not enough space on the right side due to the shape of the package. There are three required elements that must appear together

Fig. 14.2 Information panel (*Source*: the HV Food Products Company, https://www.hiddenvalley.com/products/dressings/original-ranch/original-ranch/#nutri-facts. Used with permission)

either on the PDP or the information panel: (1) a Nutrition Facts Panel, (2) a list of ingredients/allergens, and (3) information about the company.

Nutrition Facts Panel (21 CFR 101.9)

The Nutrition Facts Panel generally includes information regarding the serving size, servings per container, calories, calories from fat, negative and/or positive nutrients, percentage of daily value, and other nutritional information. Further requirements for the Nutrition Facts Panel, including print/font size, can be seen in 21 CFR 101.9.

Ingredient List/Allergens (21 CFR 101.4)

All ingredients contained in the food product must be listed in descending order of prominence, unless the ingredient is present in an amount of 2 % or less, in which case an appropriate qualifying statement such as "Contains less than __ %" may appear. Ingredients must be listed using the common or usual name or the name established by law. Additional requirements pertaining to the ingredient listing of additives such as spices, flavorings, colorings, and chemical preservatives can be found in 21 CFR 101.4. Incidental additives present at insignificant levels generally

do not need to be listed, as long as they have no technical or functional effect in the final food product and are not a major allergen—milk, egg, fish, shellfish, tree nuts, wheat, peanuts, and soybean—or sensitizing agents, such as sulfites or gluten.

The Food Allergen Labeling and Consumer Protection Act (FALCPA, Public Law 108-282) dictates that any major allergen present in a food product be declared in plain English on the label. If a product contains tree nuts, fish, or shellfish, the particular species must be declared, e.g., walnut, salmon, or shrimp. Manufacturers can comply with the law in one of three ways:

1. Listing the common names of sources of the allergens in the ingredient list itself (e.g., "rice, sugar, freeze-dried strawberries, *wheat*,[1] malt flavoring, *milk*, etc.").
2. Listing the common names of sources of the allergens parenthetically immediately after the ingredient name (e.g., "sodium caseinate (milk), semolina (wheat), albumin (egg), etc.").
3. A separate "Contains" statement listing the common names of sources of the allergens immediately after or adjacent to the list of ingredients, using a font size at least as large as the ingredient list (e.g., "Contains milk and soy").

Company Information

Company information includes the name and location (city or town, state, or country if outside of the US and zip code) of the manufacturer, packer, or distributor. Including a telephone number or website is optional. If the name provided on the label is not the actual manufacturer, then a qualifying phrase must be included, such as "Manufactured for" ("Mfd. For") or "Distributed by" ("Dist. By"). If the company is not listed in a current city/town directory, then a street address is required.

Claims

Product Claims

Food labels often contain statements related to the product that are *not* required elements of the label. These statements, which are optional, are called *product claims* and can be classified into the following categories: health claims, qualified health claims, nutrient content claims, structure/function claims, fresh claims, negative claims, and dietary guidance—health statements. Table 14.1 provides a list of the different types of claims, a description of the claim, and an example.

Claims are jointly-regulated by FDA and FTC. The two agencies have developed a liaison agreement, where FDA oversees labeling and FTC oversees advertising

[1] FALCPA does **not** require allergens to be printed in boldface type, although some companies follow this practice.

Table 14.1 Product claims

Type of claim	Description	Examples
Health claims	Describes the relationship between a food and reducing the risk of disease or a health-related condition.	Three grams of soluble fiber from oatmeal daily in a diet low in saturated fat and cholesterol may reduce the risk of heart disease. This cereal has two grams per serving.
Qualified health claims	Health claims that include qualifying language to prevent consumers from being misled about the level of support for the claim.	Supportive but not conclusive research shows that consumption of EPA and DHA omega-3 fatty acids may reduce the risk of coronary heart disease. One serving of (name of food) provides (x) grams of EPA and DHA omega-3 fatty acids. [See nutrition information for total fat, saturated fat, and cholesterol content].
Nutrient content claims	Expresses the level of a nutrient in a food.	• Contains 100 calories. • High in oat bran. • Low-fat.
Structure/function claims	Describes a nutrient's effect on the structure or function of the human body, with no reference to a disease.	• Calcium builds strong bones. • Antioxidants maintain cell integrity.
Fresh claims	Implies that a food is raw or unprocessed.	• Not frozen. • Not heat processed.
Negative claims	Implies the absence of an item.	No artificial flavor, color, or preservatives.
Dietary guidance—health statements	Describes the relationship between health and a type or group of food(s).	Choose fiber-rich fruits, vegetables, and whole grains often.

Adapted from FDA's Food Labeling Guide, Revised January 2013: http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/ucm2006828.htm

and marketing materials. FDA requires that all label claims be truthful and not misleading, while FTC prohibits communications that are misleading or false advertising. These requirements and prohibitions apply to all forms of labeling, including product packages, point-of-purchase displays, shelf labels, and website materials. Additionally, the requirements and prohibitions apply to all forms of communications, including print, broadcast, website, direct mail, telemarketing scripts, call center scripts, and blogs. All claims, especially health claims, must be based on competent and reliable scientific evidence. In addition, health claims cannot be made if the levels of total fat, saturated fat, cholesterol, or sodium exceed the amounts established by regulation.

Claims can either be express or implied. Express claims are those that are either specifically defined by regulation, e.g., "low-fat," or claims that are written out on

the label or labeling, but not yet defined by regulation, e.g., "natural." Implied claims are those that are not specifically stated on the label, but leave the consumer with the impression that a claim has been made. To illustrate, "helps you feel good" has some implied meaning to the consumer not only related to the consumer's overall health, but also regarding the manufacturer of the product.

The Impact of Science on Current Food Labeling Requirements

The science behind food labeling has had a direct effect on the safety of foods and the enforcement of the misbranding and adulteration sections of the FD&C Act, along with similar state and local laws and ordinances. Consumers (and industry) expect an even playing field when comparing one product to another and the good science behind the regulations that has helped to ensure that such comparisons are valid.

There are thousands of ingredients available for use in foods, ingredients that are commonly thought of as a "food," and ingredients that are considered as "food additives." These ingredients include components that become part of a food through the manufacturing process or packaging, as well as ingredients added intentionally. Under the FD&C Act, FDA has authority to review the safety of food ingredients, including ingredients in packaging materials that can migrate into the food.

Food ingredients must either be approved by FDA as defined in the Food Additive Amendment, section 409 of the FD&C Act; be considered generally recognized as safe (GRAS) based on a long and safe history of use, as evaluated by scientific experts; or be previously sanctioned as an approved substance for use in foods prior to 1958 by FDA or USDA. A food additive is considered GRAS if there is not a food safety issue related to consumption of the ingredient in any amount or as commonly consumed. However, some ingredients are safe only when the amount consumed is limited. For example, folic acid is known to help prevent anencephaly (several types of brain damage) in infants if a woman consumes a diet containing 0.4 mg before becoming pregnant. However, the consumption of excessive folic acid can be harmful to some people with underlying health problems. Since folic acid could be included in just about any food, FDA adopted a regulation for the fortification of cereal products, limiting the amount of folic acid so that the total diet of foods consumed would not exceed an established safe level. The amounts of many other food additives are limited as well, again for safety reasons.

Food manufacturers are permitted to file with FDA what is known as a "GRAS Self-Affirmation," in which the company has done the safety studies for use of the ingredient at a given level and has concluded that the use of the food additive is safe within those parameters. FDA then has the authority and responsibility to review the safety data provided by the company to ensure that the evidence satisfactorily

documents the safety. FDA can reject—and has rejected—company submissions over the years.

Another example of the use of science in food labeling is the requirement for nutrition labeling. Scientists have determined over the years, and are still determining, the effects of certain nutrients, such as sodium, cholesterol, fat, protein, and carbohydrates, on human health. In the 1980s, health claims had not been approved for use on any food, and a plethora of unsubstantiated claims began to appear in the marketplace. Soon afterward, the Congress passed NLEA, which required health claims only with FDA approval (Hasler 2008). NLEA also led to the Nutrition Facts Panel seen on most packaged foods today. Scientific studies determined the optimal and/or safe levels for various nutrients, based upon consumption of a "normal" diet of 2,000 cal per day. For the most part, a "healthy" diet was determined by limiting the consumption of certain "negative" nutrients, such as fat, saturated fat, cholesterol, sugars, and sodium. Later on, scientists determined that certain types of fat, for instance, were more harmful than others, which then led to additional labeling requirements for trans fats.

In order to give the consumer adequate information for a healthy diet, FDA developed a twofold system, again based upon science, whereby daily values were determined for various nutrients. When combined with the scientific determination of serving sizes, this information gives the consumer enough information to make healthy dietary choices. This system was not meant to be a "good food/bad food" determination, but a simple method that consumers could use to assess and limit intake of nutrients known to be unhealthy at certain levels of consumption.

Another labeling requirement based upon science, is the requirement for the labeling of allergens. Science has determined that there are eight major allergens that are capable of causing serious illness or death in susceptible individuals: peanuts, tree nuts, milk, egg, fish, shellfish, wheat, and soy. At the same time, FDA has not been able to rely on science to set threshold amounts at which allergic reactions are triggered. Consequently, all packaged food items must list the presence of any major allergen. Another ingredient, phenylalanine, must be listed separately, since certain individuals can develop phenylketonuria, a metabolic genetic disorder.

Fig. 14.3 Radura symbol (*Source*: FDA, http://www.fda.gov/food/ingredientspackaginglabeling/irradiatedfoodpackaging/ucm261680.htm)

Food irradiation is a technology that improves the safety and extends the shelf life of foods by reducing or eliminating microorganism and insects. FDA has evaluated the safety of irradiated food and has found the process to be safe. Additionally, the World Health Organization (WHO www.who.int), USDA, and CDC have also endorsed the safety of irradiated food (FDA 2014). However, there are people who dispute the safety of irradiation and allege that the process destroys nutrients. Consequently, the Congress mandated that irradiated foods bear the international symbol for irradiation, the radura symbol (Fig. 14.3), along with the statement "Treated with radiation" or "Treated by irradiation" (FDA 2014).

In the early 1990s, FDA began receiving petitions from the industry to permit the sale of genetically engineered (GE) foods (GMOs). One of the first uses of GMOs was the "flavr savr tomato," which increased the shelf life of ripe tomatoes (no longer commercially available). As a result, FDA developed guidelines for the submission of petitions for the use of new food additives or novel foods such as GE ingredients that introduce new characteristics (e.g., allergens or toxins) that are distinctly different from conventional foods. GMO is still a very controversial issue today, especially for crops where new genes have been added to make the crops resist certain diseases. In fact, some state legislative bodies have attempted to require a food label declaration of any genetically modified ingredients.

Trends and Food Labeling

Dietary and perceived safety trends, along with scientific research efforts, have a strong influence on the design of a food label. To illustrate, in March 2014, FDA proposed revisions to the Nutrition Facts label regulations, based on recent consumer research, food consumption trends of the American public, and recommendations by the FDA Obesity Working Group. Some of the proposed rules include redefining "single serving size," increasing the calorie count font, reducing the sodium daily value, requiring that "added sugars" be listed, and requiring daily values for potassium and vitamin D (Sherod 2014).

Food marketing and advertising experts are constantly searching for the newest consumer trend related to food consumption. The label changes and advertising adjustments can involve a subtle change or a complete and rapid new marketing strategy. The changes may involve colors, vignettes, or new positive or negative statements. The consumer will ultimately decide the value of these changes, and regulatory officials along with consumer interest groups will look for misleading or deceptive practices.

The question is—what are some of the trends that influence label changes? Also, does the new label deliver hyperbole or fiction? The consumer interest in better nutrition has a significant influence on the food label. Consumers generally agree with the science that tells us that certain foods are good for health, such as fruit, vegetables, high-fiber foods, whole grains, nuts, and olive oil. Food manufacturers highlight these ingredients

on the principal display panel hoping to catch the consumer's eye and influence a purchase. Substances such as probiotics or live good bacteria are touted for digestive benefits. The organic food movement has grown as consumers attempt to avoid synthetic pesticides. However, some consumers may have certain perceptions about food that are not necessarily based on science, such as "free-range chickens." Consumers may feel that a free-range chicken provides a better choice because the chicken was treated in a more humane manner and not subjected to caged chicken conditions.

Some food ingredients that receive negative media attention can cause the food industry to alter their formulas, even in the absence of government regulation. High-fructose corn syrup is an example. Advertising for a sweetened food may boast that the product "contains no high-fructose corn syrup."

Some consumers prefer food items that are labeled with the term "natural," even though the government has not established a uniform definition of what constitutes a natural ingredient. Farmers' markets and the cottage food industry, which generally do not use added colors or preservatives and utilize small-batch home processing, satisfy consumer desire for minimally-processed foods, which may be viewed as healthier or more natural than commercially-processed foods.

Conclusion

Food labeling is an important part of overall food safety. Consumers depend upon accurate food labeling for health reasons and for choosing which products to purchase.

Enforcement of food labeling requirements—principal display panel, information panel, nutrition facts, ingredient list, health claims, etc.—is necessary to ensure an even playing field among regulated industry, to ensure that only truthful and non-misleading statements are made for individual food products, and to ensure that mislabeled (misbranded) foods are not introduced into commerce and do not pose a risk to consumer health.

Regulations play a key role in food labeling by protecting the economic expectations of both consumers and the food industry, providing accurate product information that aids informed decision-making, allowing consumers to determine whether a product may contain allergens, and helping consumers with comparison shopping between brands (Fortin 2009).

Take-Home Message

Food protection professionals need to have an understanding of laws and regulations pertaining to food labeling and how these laws/regulations ensure an even playing field among the industry and safe food for consumers.

Activity

1. Who is responsible for determining the serving size to be placed on the label of a packaged food?

   (a) The manufacturer by using NLEA guidance
   (b) FDA
   (c) Consumer organizations
   (d) State FPPs

2. All of the following allergens are major allergens triggering mandatory labeling except:

   (a) Tree nuts
   (b) Milk
   (c) Corn
   (d) Soybeans
   (e) Peanuts

3. The name and address of the manufacturer or distributor of a packaged food must be located in the bottom one-third of the principal display panel.

   True/False

4. Which one of the following "common or usual" names for a beverage complies with FDA labeling requirements?

   (a) Sweetened orange juice
   (b) Joggin in a Jug
   (c) Diluted apple juice
   (d) Mixed fruit juice drink

5. "Cholesterol-Free" is an example of what kind of label claim?

   (a) Health claim
   (b) Nutrient content claim
   (c) Structure/function claim

6. Which of these food labeling items is NOT preempted by federal law/regulations?

   (a) Net weight
   (b) Nutrition content
   (c) Warning statements
   (d) High in fiber

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Answer Key

(1) B (2) C (3) False (4) D[2] (5) B (6) C (7) E

[2] A nutritive sweetener cannot be added to orange juice. Therefore, selection "A" would not comply. The name "Joggin in a Jug" is a fanciful name that fails to properly describe the nature of this food. Since a single strength juice cannot be diluted, selection "C" would be out of compliance. The correct answer is selection "D." The term "juice" is qualified by identifying the beverage as a "drink." This permits the addition of sugar and/or water. However, the percent of juice in the finished product must be listed above the Nutrition Facts Panel.

Chapter 15
Allergens

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Learning Objectives

- Define food allergy.
- Explain the allergen provisions of the Food Allergen Labeling and Consumer Protection Act (FALCPA) and the Food Safety Modernization Act (FSMA).

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- Discuss preventive control measures that can be utilized to minimize allergen hazards.
- Recognize that there may be additional requirements pertaining to allergens at the state and/or local level.

Introduction

An estimated 2–8 % of the US population has a food allergy, and research strongly suggests that the condition is increasing among children (Branum and Lukacs 2009; Gupta et al. 2011; Sicherer et al. 2010). Because food allergens can have potentially-lethal implications for consumers, food protection professionals (FPPs) should have a basic understanding of the condition, the allergen labeling requirements of the 2004 Food Allergen Labeling and Consumer Protection Act (FALCPA), and the provisions of the Food Safety Modernization Act (FSMA) related to allergens and preventive controls. Additional requirements pertaining to food allergens may also exist at the state or local level.

Food Allergy Defined

A food allergy is a malfunction of the immune system called a "hypersensitivity." When the immune system mistakes food for something harmful, the system over-reacts by releasing histamine and other chemicals in the body. This allergic reaction is not only uncomfortable, but can be life-threatening (University of Michigan 2014).

A food allergy is not the same thing as food *intolerance*. According to the American Academy of Allergy, Asthma & Immunology (2011), food intolerance takes place in the digestive system and occurs when a person is unable to properly break down certain foods due to enzyme deficiencies, sensitivity to food additives, or reactions to naturally-occurring chemicals in foods. Often, people with intolerances can eat small amounts of the food without causing symptoms, which generally include gassiness, abdominal pain, or diarrhea (AAAAI 2014). Gluten intolerance[1] is sometimes confused with celiac disease, or thought of as a food allergy. Celiac disease is a digestive condition that involves an immune reaction to gluten-containing foods such as wheat, barley, and rye. The immune reaction occurs initially in the small intestine, damaging the villi and causing abdominal pain, bloating, or diarrhea. The villi are projections lining the inner wall of the small intestine and help the body absorb nutrients from food. As celiac disease progresses, malnourishment and inflammatory damage to other systems can occur (AAAAI 2014). At this time, more study is needed to determine if gluten intolerance might cause lasting effects in the body, similar to celiac.

[1] FDA recently issued a final rule allowing the use of the term "gluten-free" on food labels where the food product meets all the conditions described in the rule (FDA 2013a).

Unlike an intolerance or celiac disease, a food allergy can cause a serious or even life-threatening reaction by eating a microscopic amount of a food. A food-allergic reaction occurs when the body's immune system mistakenly identifies a food protein as harmful, or an invader, and overreacts by producing antibodies called immunoglobulin E (IgE). These IgE antibodies travel to cells that release chemicals, which cause the allergic reaction. Symptoms of an allergic reaction can include skin symptoms (hives, itchiness, swelling), gastrointestinal symptoms (vomiting, diarrhea), or respiratory symptoms (difficulty breathing). A serious allergic reaction that can happen very quickly (within minutes) is called anaphylaxis (an-a-fil-ax-is), and symptoms may include difficulty breathing, dizziness, or a drop in blood pressure causing loss of consciousness. Without proper medical treatment (an injection of adrenaline, or epinephrine, followed by a call to 911), anaphylaxis can be fatal (AAAAI 2011). Unfortunately, there is no current cure for food allergy. The only way to prevent an allergic reaction is to completely avoid the problem food (University of Michigan 2014). The need for avoidance highlights the importance of accurate ingredient labels on packaged food items regulated by the US Food and Drug Administration (FDA) and the US Department of Agriculture (USDA).

Over the past decade, measures to protect allergic consumers have been incorporated into laws, regulations, and guidelines at the national, state, and local levels. The disease impacts not only the food industry but also our educational system (schools, day cares), our transportation system (commercial airlines), and our entertainment facilities (sporting venues, theme parks). In fact, food allergy has often been recognized as a disability under federal disability laws such as the Americans with Disabilities Act (U.S. Department of Justice 1997, 2003, 2012) and the Rehabilitation Act of 1973 (U.S. Department of Education 2012).

Undeclared food allergens account for a significant portion of recalls of FDA- and USDA-regulated products. In fact, a recent report indicated that allergens comprised 60 % of recalls under the FDA's jurisdiction and 65 % of recalls under the USDA's jurisdiction during the second quarter of 2013 (Food Safety News 2013).

The Allergen Provisions of the Food Allergen Labeling and Consumer Protection Act and the Food Safety Modernization Act

Food Allergen Labeling and Consumer Protection Act

The Food Allergen Labeling and Consumer Protection Act (FALCPA, Public Law 108-282, Title II) identifies eight major food allergen sources in the USA: milk, egg, fish (e.g., bass, flounder, or cod), crustacean shellfish (e.g., crab, lobster, or shrimp), tree nuts (e.g., almonds, pecans, or walnuts), wheat, peanuts, and soybeans. Research has shown that peanuts and tree nuts (Fig. 15.1) are responsible for the majority of fatal food-allergic reactions (Bock et al. 2001, 2007). Other countries have an

Fig. 15.1 Major food allergens in the USA include peanuts (*left*) and tree nuts such as almonds (*right*)

expanded list of allergens. Canada, for example, identifies mustard and sulfites as major allergens (Anaphylaxis Canada 2011-2014), while the European Union includes sesame and lupin (Anaphylaxis Campaign 2012). US law, however, addresses sulfites separately.

Although FALCPA applies only to packaged foods regulated by FDA (both domestic and imported), the USDA (through the Food Safety Inspection Service, or FSIS) has indicated that, in order to achieve consistency, the agency would also follow FALCPA labeling requirements for USDA-regulated products (USDA 2014). The requirements under FALCPA also apply to items packaged by foodservice establishments and offered for human consumption; FALCPA would not apply, however, to food items placed in a wrapper, container, or box in response to a customer's order, e.g., at a fast-food establishment (FDA 2006).

FALCPA requires that major allergen sources be declared, in plain English, on ingredient labels, even if the major allergens are part of traditionally collective ingredients such as flavorings, colorings, and spices. Additionally, in the case of tree nuts, fish, and shellfish, the particular allergen source must be declared, e.g., walnut, salmon, or shrimp (FDA 2006). FALCPA requirements do not apply to any other food not identified as one of the eight major allergen sources even though other foods have been shown to cause allergic reactions (e.g., sesame, mustard, and other types of seeds). However, standard ingredient labeling requirements would still apply to food items that are not major allergens.

Manufacturers can comply with the FALCPA requirement in one of the three ways:

1. By listing the allergen source, in plain English, in the ingredient list itself, e.g., INGREDIENTS: rice, sugar, freeze-dried strawberries, **wheat**,[2] malt flavoring, **milk**, etc.
2. By listing the allergen source, in plain English, in a parenthetical immediately after the ingredient name, e.g., sodium caseinate (**milk**), semolina (wheat), albumin (**egg**), etc.

[2] FALCPA does not require that major allergens be listed in **boldface** type, although some companies choose to do so.

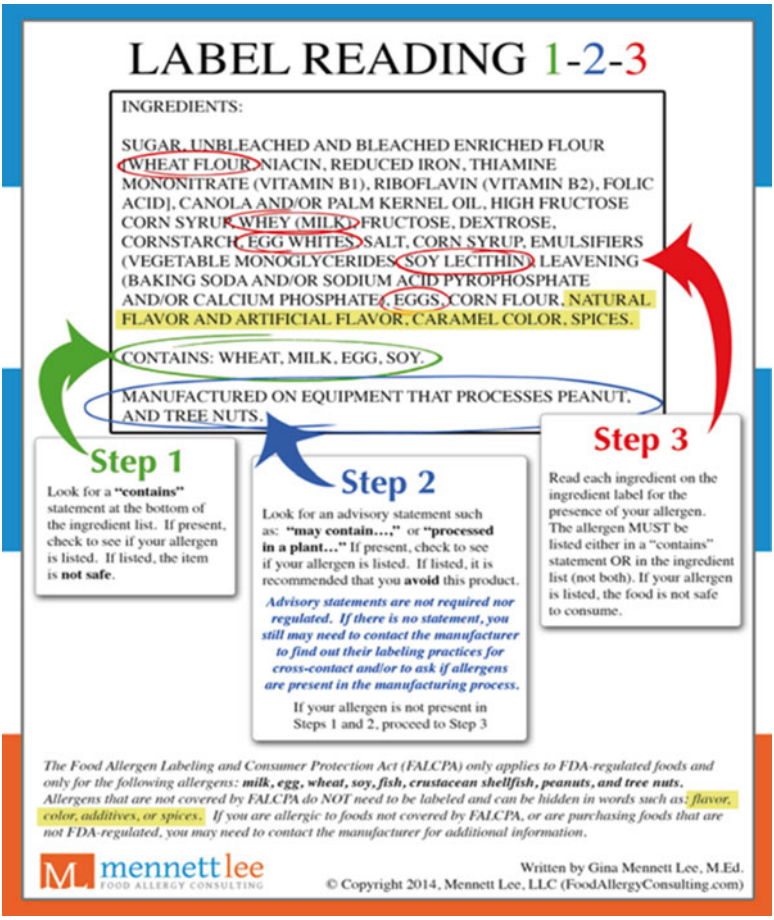

Fig. 15.2 Allergens on food labels (Written by Gina Mennett Lee, M.Ed. © 2014, Mennett Lee, LLC. Used with permission)

3. By having a separate "Contains" statement immediately after or adjacent to the list of ingredients (in a font size at least as large as the ingredient list), e.g., **Contains milk and soy**.

Figure 15.2 presents a visual guide created by a food allergy consumer advocate to help individuals identify major allergens on food labels. The figure demonstrates the three ways that allergens can be identified per FALCPA: in the ingredient list, in a parenthetical after an ingredient name, and in a separate "Contains" statement following the ingredient list.

FALCPA creates a mechanism for companies to obtain an *exemption* from allergen labeling requirements for an ingredient by submitting scientific evidence to FDA showing either (1) that the food ingredient does not contain allergenic protein

or (2) that the ingredient does not cause an allergic response that poses a risk to human health. There is also a statutory exemption for all highly-refined oils, which are generally considered to be safe for consumers with food allergy (Hahn and McKnight 2014).

Companies that do not comply with FALCPA could be subject to civil or criminal penalties under the Federal Food, Drug, and Cosmetic Act. FDA also has the authority to seize packaged food products that are not FALCPA-compliant, along with the authority to request and even require that the food product be recalled by the manufacturer or distributor in the case of an undeclared allergen. Food protection professionals should also be aware that consumers who suspect that an FDA-regulated food product is not FALCPA-compliant can report the product via an FDA consumer complaint center.

Although FALCPA has greatly improved the ability of food-allergic individuals and their families to read and interpret food labels, the law does not regulate the use of precautionary allergen statements, sometimes termed supplemental allergen labeling, such as "may contain," "manufactured in a shared facility," and "processed on the same equipment." Consumers often feel as if these types of statements are confusing and misleading and sometimes criticize companies for using the statements on food labels. While the FDA has been studying the "may contain" issue for a number of years, standardization of the statements, along with guidance for their use, appears unlikely in the near future. Nevertheless, such precautionary language cannot be allowed to substitute for compliance with good manufacturing procedures.

An emerging area of study, which could have tremendous impact on the use of precautionary "may contain" statements, is the issue of allergen threshold levels, defined as the eliciting dose or minimal quantified amount of ingested allergen that will provoke an immunologic reaction. The FDA, in fact, collected public comments on the threshold issue, and research strongly suggests that establishing levels for major allergens is achievable, i.e., can be defined at individual and population levels (Taylor et al. 2010; Blom et al. 2012). Defining such a threshold could benefit multiple sectors of society: food-allergic individuals and their caregivers or family, the food industry, policymakers, and government officials.

Food Safety Modernization Act

The Food Safety Modernization Act (FSMA, Public Law 111-353) placed greater importance on the control of major food allergens. Section 103 of FSMA requires manufacturing facilities to identify and evaluate known or reasonably foreseeable hazards and develop a written analysis of the hazards. For the purpose of FSMA, a hazard includes natural toxins, pesticides, drug residues, decomposition, parasites, *allergens*, and unapproved food and color additives, whether these hazards occur naturally, may be unintentionally-introduced, or are intentionally-introduced

through an act of terrorism. Along with a written analysis of hazards, facilities are also required to develop preventive control procedures, practices, and processes to significantly minimize or prevent the hazards identified in the written analysis. With the implementation of FSMA, facilities will be required to demonstrate in writing that the facility has a formal food safety plan designed to minimize the risk of allergen cross-contact and thus an unlabeled allergen in a food or beverage product. Prior to FSMA, the control of allergens was considered more informally in the prerequisite component of a food manufacturing facility's good manufacturing practices (GMPs).

Preventive Control Measures That Can Be Utilized to Minimize Allergen Hazards

There are a variety of measures put into place by food manufacturers aimed at preventing allergen cross-contact during the manufacturing process. First and foremost, manufacturers should conduct an initial assessment to determine where allergens exist in the plant/facility and at which point the allergens are introduced into the manufacturing process. An effective allergen control plan is based on such an assessment.

Manufacturers generally implement any or all of the following measures in order to reduce the risk of allergen cross-contact:

- Segregating allergenic foods/ingredients from all other products, starting when the item is received by and stored in the facility and throughout the entire manufacturing process, including when sanitation operations are being conducted.
- Marking or tagging allergens (with a color-coding system) so as to visually alert facility personnel.
- Dedicated manufacturing/processing equipment and lines.
- Dedicated tools, containers, and utensils.
- Use of a documented rework[3] plan including uses for rework, maintaining usage records, and other rework controls to track allergens.
- Adjusting the schedule of processing runs and product changeover.
- Restricting certain personnel from certain areas/sections of the facility.
- Employing effective cleaning and sanitation procedures, including evaluation of sanitation effectiveness.
- Training personnel on allergen awareness and control.
- Verifying product traceability.

[3] Rework generally occurs at manufacturing facilities. Rework is when a food item, due to some factor in the manufacturing sequence, is reprocessed. For example, in the event of a packaging defect, the food item is removed from the faulty packaging and reprocessed.

Fig. 15.3 Testing for the presence of allergens (Used with permission)

- Reviewing the accuracy of final product labels (Food Allergy Research and Resource Program 2014)
- Testing products and ingredients for the presence of major allergens (Fig. 15.3)

Manufacturers should regularly review the allergen control plan and update the plan accordingly. Changes to protocols or, the addition of new ingredients, products, or even equipment within a facility may require alteration to the allergen management procedures previously in place. Additionally, when changes are made to the supply chain, manufacturers should evaluate the new supplier's allergen control plan and adjust their own plan accordingly.

At the retail level, controlling allergen cross-contamination is challenging for a variety of reasons. First, foodservice employees may not be trained to identify major allergens on packaged food labels. Second, there are many points along the "farm to restaurant fork" chain where cross-contamination can occur, including purchasing the ingredient, receiving, storage, thawing, preparing, cooking, holding, cooling, reheating, and finally serving/distributing the food item. Foodservice establishments may not purchase ingredients from reputable, trusted suppliers who have procedures in place to prevent cross-contamination (Anaphylaxis Canada 2012). Finally, there may be miscommunication between foodservice staff and consumers affected by food allergy. Restaurant staff sometimes fail to take the issue of food allergy seriously and fail to inform the manager or chef of the situation. Additionally, food-allergic consumers sometimes fail to communicate their condition to the appropriate foodservice personnel (Weiss and Muñoz-Furlong 2008).

Food Code

The FDA Food Code (www.fda.gov/foodcode) is a scientifically sound model that assists retail foodservice operations (restaurants, grocery stores, and institutions such as nursing homes) in developing or updating their own food safety rules to be consistent with national recommendations (FDA 2014). The Food Code began recognizing food allergens in 2005 by (1) defining major food allergens as those ingredients identified in FALCPA and (2) recommending that a person in charge of a food establishment such as a restaurant have an understanding of major allergens and the symptoms of an allergic reaction. The 2009 Food Code expanded requirements of the person in charge to ensure that employees are properly-trained in food safety issues, including food allergy awareness, as related to the employees' assigned duties. This should improve the process by which retail establishments such as restaurants address the needs of customers affected by food allergy. Sixteen states have adopted the 2005 Food Code, while 16 have adopted the 2009 Food Code (FDA 2013b).

Additional Requirements Pertaining to Allergens at the State and/or Local Level

Two states, Massachusetts and Rhode Island, have passed laws requiring restaurants to display a food allergy awareness poster in the employee area (Fig. 15.4), add a notice on their menus or menu boards alerting the consumer to inform the staff of any food allergy, and have restaurant managers be knowledgeable about food allergies as related to food preparation. The Massachusetts law (Massachusetts General Laws, Part I, Title XX, Chapter 140, Section 6b) went into effect in 2011, with the Rhode Island law being enacted the following year (Rhode Island General Laws, Title 23, Section 1, Chapter 20.12). A third state, Maryland, was scheduled to implement a similar poster requirement in 2014 (Maryland Statutes, Title 21, Subtitle 3, Part IV, Section 21-330.2). Other requirements related to food allergy and restaurants have been adopted at more local levels. New York City not only requires restaurants to display a food allergy awareness poster for their employees, but in multiple languages, including Chinese, Korean, Russian, and Spanish (Local Laws of New York City, Chapter 1, Title 17, Section 17-195). Westchester County, NY, requires food allergy notification to be posted on printed menus, menu boards, or signs that direct customers to speak with specific staff prior to ordering if the customers have a food allergy (Westchester County Sanitary Code, Section 873.582). The city of St. Paul, MN, used to require a food allergy awareness poster for restaurant employees, though just in English (St. Paul, MN Allergen Awareness Poster Ordinance, Section 331A.12). However, the poster requirement is no longer in effect due to changes in authority related to the inspection of retail food establishments in that city.

Fig. 15.4 Massachusetts restaurant poster (© 2009, Food Allergy Research & Education. Used with permission)

Conclusion

Scientists generally predict that the prevalence of food allergy will continue to increase, especially among children, until a cure can be found. Since strict avoidance of the allergen is the only way to prevent an allergic reaction, consumers rely on the accuracy of food labels and the ability of manufacturers to implement effective allergen control measures. Two federal laws, FALCPA and FSMA, specifically address food allergens: FALCPA requires major allergens to be labeled in various ways, while FSMA associates allergens with hazards, thus requiring food manufacturers to develop and implement an allergen control plan.

Take-Home Message

The FPP must take the issue of food allergens seriously, due to the potential impact on human health. Allergic reactions can be lethal and can only be prevented by strict avoidance of the offending allergen. Therefore, during food establishment inspections, FPPs must evaluate how allergenic ingredients are managed by the operation, including preventing cross-contamination, proper cleaning of food contact equipment, and reviewing the accuracy of food labels. Beginning in 2006 under FALCPA, major allergens had to be declared on all packaged food items regulated by FDA, and USDA followed FDA's lead. Under FSMA, allergens are classified as hazards; as a result, manufacturing facilities will need to create preventive control plans to prevent allergen cross-contamination.

Activity

Indicate whether each statement is *true* or *false*.

1. Major food allergens, as defined by FALCPA, include sesame.
2. Food intolerance can cause an immediate, life-threatening reaction.
3. Under FSMA, *hazards* include *allergens*.
4. Food allergy in the US appears to be increasing.
5. A packaged food item with *walnut* as an ingredient must contain the following allergen warning: "Contains tree nuts."
6. Manufacturers often use dedicated production lines as a way to avoid allergen cross-contamination during the manufacturing process.
7. All restaurants in the US must display an allergen awareness poster in their staff areas.
8. All restaurants in the US must include allergen information on their menus and menu boards.
9. FALCPA requires major allergens to be listed in boldface type on the food label.
10. The FDA Food Code recommends that restaurant managers receive training in food allergy.

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Answer Key

1. False
2. False
3. True
4. True
5. False
6. True
7. False
8. False
9. False
10. True

Chapter 16
Employee Safety

Jim Topie, Ellen Buchanan, Tressa Madden, and Michael Fagel

Learning Objectives

- Identify potential hazards that may endanger inspector safety and health.
- Discuss the various types of controls that can help ensure personal safety.
- Discuss how personal actions, property, and equipment contribute to inspector safety.

Introduction

Although employers are required, by the Occupational Safety and Health Administration Act of 1970 (OSHA, www.osha.gov), to maintain a place of employment free from hazards, food protection professionals (FPPs) can sometimes find themselves in a wide range of settings that present potential safety hazards:

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walking in wet, slippery environments, climbing ladders, working around extreme temperatures, brushing against moving pieces of equipment, working around sharp objects, moving cautiously around live animals, rummaging in dark basements, or being threatened by an irate store owner. The FPP must be aware that conditions or practices that could lead to injury, or even death, are nondiscriminate and can affect not only an establishment's employees but also individuals who may be present at the establishment as a visitor, including contractors, delivery personnel, and the FPP himself or herself.[1]

Hazards That May Endanger Inspector Safety and Health

Air Quality

In the 1970s, energy conservation efforts dictated changes in building designs, resulting in less fresh air being introduced into the work space, and an increase in indoor air contaminates. Many employee illness complaints due to work environments can be traced to irritants like smoke and odors combined with poor air circulation. Additional indoor air contaminants can include acetic acid, carbon dioxide, carbon monoxide, formaldehyde, nitrogen oxides, ozone, radon, and volatile organic compounds (De Pavia 2004).

Another potential hazard associated with air includes Legionnaires' disease, which occurs when an individual breathes in a mist or vapor containing the bacteria *Legionella*. The bacteria are found naturally in the environment, usually in water. The bacteria grow best in warm water, like the kind found in hot water tanks and large plumbing systems (CDC 2013).

Sick building syndrome is a condition associated with complaints of discomfort such as headache; nausea; dizziness; dermatitis; eyes, nose, throat, and respiratory irritation; coughing; difficulty concentrating; sensitivity to odors; muscle pain; and fatigue. The specific causes of the symptoms are often not known, but are sometimes attributed to the effects of a combination of substances or individual susceptibility to low concentrations of contaminants. The symptoms are associated with periods of occupancy and often disappear after the worker leaves the worksite (OSHA 1999a, b).

Corrosives

OSHA regulations (29 CFR 1910.1200, Appendix A, Section A.2—Skin Corrosion/Irritation) define a corrosive substance as a chemical that produces destruction of skin tissue at the site of contact. For example, a chemical is considered to be corrosive if,

[1] The terms *employee* and *FPP* in this chapter are used interchangeably when referencing OSHA.

when tested on the intact skin of albino rabbits by prescribed methods, the chemical destroys or changes irreversibly the structure of the tissue at the site of contact following an exposure period of 4 h. The term does not refer to action on inanimate surfaces. Generally speaking, corrosive materials have a very low pH (acids) or a very high pH (bases). Strong bases are usually more corrosive than acids. Examples of corrosive materials are sodium hydroxide (lye) and sulfuric acid. A number of corrosive substances could be found in food manufacturing environments.

Liquids

During the course of their regulatory duties, FPPs could become exposed to dangerous liquids such as oil used for deep frying at a retail facility, extremely hot or boiling liquids used to clean equipment or processing lines, or even liquids that are flammable or combustible. OSHA regulations (29 CFR 1910.106) define flammable liquids as any liquid having a flash point below 100 °F (37.8 °C), while combustible liquids are those having a flash point at or above 100 °F (37.8 °C), with some exceptions. Both flammable and combustible liquids are further categorized into classes depending on their specific flash point and/or boiling point (Fig. 16.1).

Pesticides

Pesticides used in food environments may contain synthetic chemicals, and FPPs may not want to be exposed to such chemicals for a variety of reasons. Pesticides (e.g., rodenticides, insecticides, and herbicides) can be hazardous to humans if not properly stored, handled, applied, or disposed. Additionally, some individuals are more sensitive to certain chemicals, either through inhalation or touch.

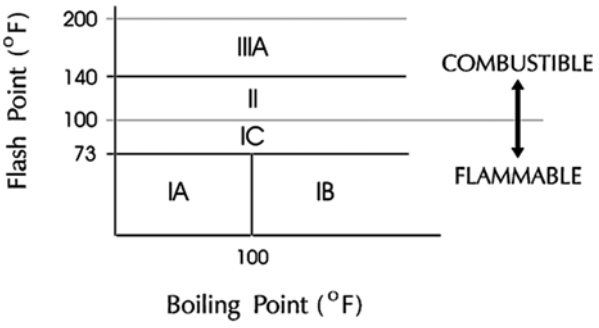

Fig. 16.1 Flammable and combustible liquids (*Source*: OSHA https://www.osha.gov/dte/library/flammable_liquids/flammable_liquids.html)

FPPs can come into contact with pesticides both inside and outside of manufactured and retail food production or food service and storage facilities, grain elevators, flour mills, silos, and other similar operations. Storage and use of pesticides must follow the specific label directions. Pesticides are registered and regulated by the US Environmental Protection Agency (EPA, www.epa.gov), while the US Food and Drug Administration (FDA, www.fda.gov) enforces tolerance levels set by the EPA in food products.

Mechanical/Moving Components and Equipment

A wide variety of mechanical motions and actions may present hazards. Examples of mechanical components include conveyor belts, cutting/mixing equipment, moving parts or gears, and forklifts. FPPs should never attempt to take equipment apart or put equipment back together; assembly and disassembly should be conducted by the designated food establishment employee. According to OSHA, any machine part, function, or process which many cause injury must be safeguarded, and the safeguard should meet the following minimal requirements. First, the safeguard should prevent an individual's hands, arms, or any body part from coming into contact with dangerous moving parts. Second, the safeguard device should be made of durable material and should be secured firmly to the machine in use, in order to prevent the safeguard from being easily removed. Third, the safeguard should be designed to prevent any objects from falling into moving parts. Next, the safeguard cannot hinder a worker from performing his or her job quickly and comfortably. Additionally, the machine safeguard should not have to be removed in order to lubricate the machine. Finally, the safeguard should not be a hazard itself, i.e., should not contain any sharp or jagged edges or pieces (OSHA 2014a).

Moving components in a manufacturing or retail food facility can also include forklifts. FPPs should also recognize that forklift drivers may not know that a person is present because the driver is focused on the task at hand or may have pallet loads blocking his or her view. Drivers should be given plenty of room, and individuals should look both ways while crossing the path of a forklift.

Confined Work Spaces

An FPP may find himself or herself dealing with a confined work space, which is an area where the configuration hinders entering, exiting, or working within the space. Confined work spaces are not designed for constant employee occupancy, but rather, on an intermittent basis as needed for cleaning or repair. Some examples of confined spaces are underground vaults (processing waste holding tank), silos, storage tanks, pits (maraschino cherry ponds), process vessels (retorts), and storage bins. Confined work spaces may require a permit, especially if the space contains a recognized safety or health hazard such as unguarded machinery or exposed live wires (OSHA 2014b).

Electrical Safety

The National Safety Council ranks electrocutions fourth (9 %) in causes of industrial fatalities, with an estimate of 600 people dying every year of electrical causes. Most of these accidents involve low voltage of 600 V or less (Oklahoma State University 2014). Inattention to electrical hazards can lead to burns, shocks, and electrocution. FPPs must always be mindful of any potential electrical risks, both on and off the job. All electrical cords and equipment should be inspected before use, and FPPs should never attempt to repair any electrical cords or equipment unless he or she has been specifically trained to do so. FPPs should also never touch a wire, even if the wire appears to be insulated; should always assume a wire is live, and should never operate electrical devices in water.

Diminished Visibility

Appropriate precautions should be taken when visibility is diminished or obstructed. The FPP may have to rummage through a dark room with rats and/or cockroaches or may have to tread in spaces with insufficient or poor lighting such as storage cellars or steam tunnels. FPPs should always have access to a functioning flashlight. At night, the inspector should park in a well-lighted location or in an open area that will offer greater brightness and the safest walking route to the inspection destination.

Fall Hazards

According to OSHA, falls are among the most common causes of serious work-related injuries and deaths. Employers are required to assess the workplace to prevent individuals from falling off of platforms, off elevated work stations, or into holes in the floor and walls. Employers are required to incorporate certain safety measures within the work operation if a fall hazard is present, such as providing guard rails, safety and harness lines, safety nets, stair railings, hand rails, and floor hole covers (OSHA 2014c).

FPPs must be careful when, for example, climbing ladders or riding a man-lift to the top of a grain silo with food establishment employees. If a ladder is needed, the FPP should make sure the device is properly placed and always use 3-point contact (two hands and a foot, or two feet and a hand) when climbing or descending the ladder (OSHA 2013). FPPs should also recognize that some surfaces, such as floors in a processing facility, can be wet and slippery, or that debris and equipment can cause “trip and fall” accidents.

Along with the risk of the FPP falling or slipping, there is also the risk of falling overhead objects. Facilities generally use a guardrail system to prevent materials from falling from one level to another, and OSHA requires that certain equipment and materials be kept clear of any areas such as roof edges (OSHA 2014c).

Hazardous Waste

In the event that the FPP is assigned to help with certain operations that may expose the FPP to hazardous waste, he or she needs to be aware of the Hazardous Waste Operations and Emergency Response (HAZWOPER) standard established by OSHA. The HAZWOPER standard applies to any employee who is exposed or potentially exposed to hazardous substances, specifically during:

- Cleanup operations conducted at the federal, state, or local level.
- Operations conducted at treatment, storage, and disposal facilities regulated by the Resource Conservation and Recovery Act or by certain agencies having agreements with the US Environmental Protection Agency (OSHA 2014d).

Weather-Related Hazards

FPPs may find themselves exposed to severe weather-related conditions, which highlights the need to be prepared and trained for such events. During an emergency flood response, the FPP may have to wade through floodwaters or backed-up sewage after a storm. The hazards in floodwaters can be numerous (sewage, chemicals, pesticides, etc.). Physical hazards can also be present during a flood situation, including debris, ground erosion, and unforeseen items underwater. The FPP should avoid direct skin contact with floodwaters, and be equipped with appropriate personal protective equipment (PPE, discussed later in this chapter). Potential hazards during hurricane-like conditions can include sharp jagged debris, floodwater, electrocution, bodily fluids, human remains, and unstable surfaces. Hazards associated with winter storms include driving accidents, carbon monoxide poisoning, hypothermia and frostbite, exhaustion, back injuries due to slips and falls, electrocution, burns, and falling objects, along with dust and chemicals during windy conditions.

Animals

FPPs may find themselves in situations where animals, both wild and domesticated, can threaten personal safety. This is more likely to occur when FPPs conduct inspections on farm-type settings, where the FPP can be chased by the farmer's dog(s) or be attacked by a variety of animals found in the wild. Insects and rodents can be a concern inside and outside buildings.

Noise

Facilities related to food manufacturing can often use extremely loud machinery or equipment. Even short-term exposure to loud noise can cause a temporary change in hearing (one's ears may feel stuffed up) or a ringing in one's ears (tinnitus).

Although these short-term symptoms generally disappear after leaving the noisy area, repeated short-term exposures to loud noises could cause permanent hearing loss or tinnitus (OSHA 2014e).

Controls to Help Protect Personal Safety

There are essentially three types of tools or controls that can aid in the control of potential personal safety hazards and help the FPP stay safe during an inspection: engineering controls, administrative controls, and personal protective equipment, or PPE. Engineering controls, such as a hood around noisy equipment, a lab ventilation hood (Fig. 16.2), machine guards, and substitution/redesign techniques, are used to eliminate, minimize, or redirect certain hazards. These controls are mostly in place for plant employees.

Administrative controls include written standard operating procedures (SOPs), safe work practices, signs, warnings, alarms, exposure time limits, "buddy" systems, work permits, employee training, and monitoring of the use of any hazardous materials. Another type of administrative control is a safety data sheet (SDS), which is part of OSHA's Hazard Communication Standard. These sheets are required to be on hand wherever hazardous substances are used in the workplace. There are 16 required elements on an SDS, including the physical and chemical properties of the substances, first-aid measures, handling and storage measures, disposal considerations, and any relevant toxicological/ecological information regarding the substance. There is a recommended format for the SDS, with the most important information being found at the top of the page. The use of this recommended format increases the likelihood that, in the event of an accident, an individual will not be left searching the page to locate the information needed (OSHA 2014f).

An additional form of administrative control is a safety orientation session given for the benefit of an FPP. For example, a food establishment may require that any visitor to the facility, including FPPs, attends a safety session or watches a safety video prior to entering the establishment.

Fig. 16.2 Lab ventilation hood (*Source*: OSHA, https://www.osha.gov/SLTC/etools/hospital/lab/images/bsc.jpg)

PPE can be essential to protect FPPs from harm. The list of PPE is extensive, and generally includes items such as:

- Hard hats
- Bump caps (generally lighter and thinner than hard hats)
- Hearing protection
- Safety shoes or protective footwear, e.g., work boots, non-slip footwear
- Protective eyewear, safety glasses
- Protective gloves
- Extrication gloves
- Water-resistant outerwear
- Protective aprons
- Flashlights
- High-visibility clothing, e.g., high-visibility safety vests
- Fall protection gear, e.g., safety harnesses, belts, and anchors
- Respirators (Fig. 16.3)

Some states may have specialized PPE as well. For example, FPPs in cold-weather states may be equipped with homing beacons, a winter survival kit, extra layers of clothing, and even bear repellant in the event the FPP becomes stranded during a winter storm.

People who are required to work in situations where physical injury may occur to the head must wear protective head gear. Hard hats meet OSHA's guidelines, while bump caps do not. Often a food warehouse or food processor requires a bump cap—a lightweight kind of hard hat used in environments where someone might bump or scrape his or her head on low fixtures or equipment—in addition to a hair net. A hard hat may be required on the job site if new construction or remodeling is taking place or during an emergency weather response (e.g., assessing tornado damage). A hard hat can protect the head from falling objects or debris, bad weather, and electric shock.

Fig. 16.3 Respirators and accompanying equipment (*Source*: OSHA https://www.osha.gov/SLTC/respiratoryprotection/index.html)

Some food establishments are required to meet FDA Good Manufacturing Practices (GMPs) or FDA Retail Food Code by requiring that hair be effectively restrained. This restraint is commonly accomplished through the use of a hair net or a soft cap. In either setting (manufacturing or retail), the use of hair restraints is actually twofold. Not only does the policy keep hair out of food, but the practice also promotes employee and FPP safety by keeping hair from catching in any operating equipment.

According to OSHA, eye injuries alone cost more than $300 million per year in lost production time, medical expenses, and worker compensation. Eye and face protection must be utilized whenever necessary to protect against chemical, environmental, radiological, or mechanical irritants and hazards and should also be utilized in dusty environments such as at feed elevators or locations where silo dust may be present (OSHA 2014g).

How Personal Actions and Property Contribute to FPP Safety

An FPP might handle items that may be contaminated with pathogenic bacteria or viruses, might collect samples of filth like rodent feces, and might collect swabs of human specimens. These types of activities highlight the importance of proper handwashing with soap and clean, running water (Fig. 16.4) to help prevent the spread of disease. If soap and clean water are not accessible, an alcohol-based product containing at least 60 % alcohol (e.g., a hand sanitizer) can be used to clean hands. Appropriate hand hygiene practices include not only cleansing hands, but also keeping fingernails trimmed and clean (CDC 2012).

Feet, footwear, and socks should be kept clean and dry. Walking in wet, slippery environments like meat processing rooms may get feet wet, which can contribute to fungi and infections.

Cross-contamination is the spread of germs from one surface to another by contact. There are a few basic infection-control practices that can reduce the chance of being exposed through cross-contamination. Surfaces that may have been in contact

Fig. 16.4 Handwashing (*Source*: FDA, http://www.fda.gov/forconsumers/consumerupdates/ucm378393.htm)

with blood or other body fluids should be disinfected. Gloves should be changed after coming into contact with a contaminated surface, and the FPP should not touch personal items that could be contaminated when wearing gloves (CDC 2011).

According to OSHA, back injuries account for a significant amount of human suffering, productivity loss, and economic burden. In fact, back disorders are one of the leading causes of disability for people in their working years and afflict over 600,000 employees at a cost of $50 billion annually, according to the CDC National Institute for Occupational Safety and Health. Factors associated with back disorders include poor posture, twisting while lifting, bending while lifting, bad body mechanics, and heavy lifting (OSHA 2014h).

Driving is generally a part of the FPP profession, and defensive driving courses or training may be required on an annual or recurring basis. FPPs should always be observant of other drivers on the road, should have his or her vehicle serviced on a regular basis, and should report any mechanical problems to his or her supervisor at once, especially if inclement weather can be expected.

Choosing the appropriate clothing to wear during an inspection can help avoid safety hazards at a food establishment. To illustrate, long, loose sleeves are not recommended if an FPP needs to confirm that an auger is clean. Similarly, a long inspection jacket could cause an FPP to trip or fall when getting in or out of a vehicle or while climbing steps. Clothing items like scarves and neck ties could get caught in machinery, as can jewelry items.

Conclusion

The FPP must always be aware of what is happening around him or her and follow procedures that will aid in protection from injury, illness, or death from a broad range of hazards. The FPP also needs to be aware of how personal property and personal protective equipment play a role in inspector safety. Utilizing the information provided in this section should aid in the advancement of employee safety. If unsure of any personal safety policies and procedures, the FPP needs to contact his or her supervisor.

Take-Home Message

Whether new on the job or experienced, the FPP must always be alert to potential personal safety hazards that could arise during the course of his or her job, including severe weather conditions, equipment components, and exposure to hazardous substances. FPPs should receive safety training when hired, along with annual refresher training in order to continue to be well-prepared during the course of their jobs.

Activity

You have been asked to conduct inspections at the following types of facilities. For each scenario, what safety considerations might arise, and what types of PPE might be needed?

1. A flour mill
2. A warehouse
3. A meat department in a grocery store
4. A temporary concession stand at a county fair
5. A cookie processing facility

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Additional Resources

U.S. Occupational Safety & Health Administration (1999) OSHA technical manual (OTM). Table of contents. https://www.osha.gov/dts/osta/otm/otm_toc.html

Answer Key (Potential Answers—Additional Answers May Also Apply)

1. A flour mill
   Possible safety considerations: confined spaces, climbing, dust exposure, poor air quality, visibility issues, or overhead objects
   Potential PPE: flashlight, respirator, safety harness, safety glasses, bump cap, or hard hat
2. A warehouse
   Possible safety considerations: climbing, slippery floors, forklift traffic, noise, or overhead objects
   Potential PPE: non-slip footwear, hearing protection, bump cap, or hard hat
3. A meat department in a grocery store
   Possible safety considerations: moving equipment, wet or slippery floors, or overhead objects
   Potential PPE: protective outerwear, non-slip footwear, or bump cap
4. A temporary concession stand at a county fair
   Possible safety considerations: tight quarters, open fryers, or tripping hazards
   Potential PPE: non-slip footwear
5. A cookie processing facility
   Possible safety considerations: tripping/falling hazards, noise, moving equipment, or overhead objects
   Potential PPE: non-slip footwear, hearing protection, bump cap, or hard hat

Chapter 17
Communication Skills

Alan Tart, William Lachowsky, Tressa Madden, and Paul Dezendorf

Learning Objectives

- Identify effective ways to establish a rapport with clients during inspections.
- Describe how active listening can be used during inspections.
- Distinguish between and identify when to use strategic and non-strategic questions, direct and non-direct questions, and open-ended and closed-ended questions.
- Describe how different cultures communicate differently.
- Describe effective negotiation practices.
- Discuss strategies to deal with hostile people and resolve situations.

Introduction: The Importance of Effective Communication

Open, honest, and clear two-way communication between a food protection professional (FPP) and industry management and employees is essential to determine the strengths and weaknesses of food safety management systems being implemented.

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Reviewing previous inspection reports can help the FPP prepare questions and strategies for an effective inspection. During inspections, both verbal and non-verbal forms of communications are important in helping the FPP set an example and identifying food safety priorities. Professional and effective communications can help prevent industry management and employees from viewing the FPP as an authority figure. This will also create a more interactive, productive inspection which will not be viewed as a one-way interrogative process. Effective communication facilitates a trusting and open environment, which will, in turn, assist the FPP in gathering vital information about the food operation.

An FPP can enhance the effectiveness of communication during the inspection by utilizing the following communication techniques:

- Establishing interactive rapport
- Practicing active listening
- Asking effective questions
- Recognizing cultural differences that can impact communication
- Using negotiation skills

Establishing Rapport

The first few minutes of the interaction between the FPP and industry management and employees are critical to set the tone for the current and future inspections. Miscommunication or misunderstanding at the beginning of the inspection could result in the manager or responsible personnel[1] becoming anxious and feeling overpowered by the FPP.

At the beginning of the inspection, the FPP should introduce him or herself and present identification or credentials pursuant to agency or company policy. The FPP should then describe the purpose of the visit to the manager or responsible personnel.

During this introduction, the FPP should create a professional and empathetic relationship with the manager. Establishing rapport with industry management and employees can enhance cooperation, teamwork, and persuasion during the inspection process.

Tips to establish good rapport include:

- A firm handshake
- Looking the manager in the eye when presenting a business card
- Engaging in “small talk” at the beginning of the inspection
- Listening carefully
- Using appropriate body posture

[1] The US Food and Drug Administration (FDA) Model Food Code refers to this individual as the person-in-charge, or PIC, regarding retail food establishments. For manufacturing establishments, the FPP will typically meet with a member of management, i.e., plant manager. For the purposes of this chapter, the terms *manager* or *responsible personnel* will be used.

- Being engaging, supportive, and enthusiastic
- Asking questions and giving positive feedback about the food operation

"Small talk" involves engaging in quick, informal conversation that is unrelated to the topic of food safety or the inspection itself. Small talk can create a connection between the FPP and responsible personnel, enhance an already established relationship, and balance the power between the FPP and the manager. This interaction is intended to ease anxiety, create an atmosphere of mutual respect, and facilitate open, honest, two-way communication. When meeting a manager for the first time, it is important to build a "connection." For example, the FPP might engage in small talk by asking how the business is going, or how the manager got started in the food business. It is important, however, not to engage in too much small talk, as doing so may be perceived by the manager as a waste of his or her time.

Being attentive to the manager and listening to what he or she is saying during all phases of the inspection is important. This attentiveness demonstrates respect for and interest in what the individual is saying, builds rapport, and is especially important when discussing a food safety situation or issue in the establishment. (Active listening will be discussed in more detail later in this chapter.)

Body language is as important to establishing rapport as verbal communication. For example, the first impression a person may make is often based on facial expression(s). A smile will resonate in one's voice and actions. First impressions are powerful, and an initial smile can help the FPP be seen positively by management and/or employees. A smile can also reflect enthusiasm, which can help industry management and employees to feel understood and appreciated. Beyond facial gestures, the FPP should be aware of tone of voice, rate of speech, and other bodily gestures, since these elements all impact communication.

The FPP should also give the manager and employees oral compliments or praise in response to a positive outcome at the establishment and, if possible, an explanation of why the positive outcome was important. For example, a response to a positive outcome could be "I can see that you are effectively training your employees on proper cooling and have implemented good practices. This will help ensure that safe food is served, which will, in turn, keep customers safe and ensure your establishment's good reputation."

Active Listening

Consider the following scenario:

FPP John hurriedly walks through a food preparation area looking for violations. Pam, a restaurant manager, follows behind John, trying to keep up. John asks Pam one question after another about what he is seeing, but never makes eye contact with her. How does this make Pam feel?

Pam may feel that John's main objective is to find violations, not to review the food safety management system in place. Pam may feel minimized and devalued,

which could lead to a breakdown of communication. Worse, these feelings could cause Pam to "clam up" for fear that her answers would be used to build a case against her establishment.

This type of communication is counterproductive to the inspection process. By practicing "active listening," a FPP can help to create an environment that fosters the open, honest, two-way communication that is essential to fully understand the processes that are occurring.

Active listening is a method of communication that helps to:

- Understand what the other person is saying
- Identify issue(s) of concern
- Understand what the other person is feeling
- Improve the accuracy of responses to questions
- Make the overall communication process more efficient

Active listening requires multiple strategies at the same time, as depicted in Fig. 17.1. These strategies include, but are not limited to, focusing on the speaker, watching for non-verbal cues, checking for understanding, evaluating what is being heard, and controlling emotions (Anderson and Killenberg 2008).

Strategy #1: Focus on the Speaker

Focusing on the speaker can help ensure mutual understanding and can help avoid feelings of defensiveness on the part of the manager. Some techniques to support this strategy include:

- Minimize distractions.
  - *Are there activities going on that distract the speaker and/or the listener*?

Fig. 17.1 Active listening

- Stop any activities while listening.
  - *Do not check electronic devices* (*text messages or email*).
- Go to a quiet place to talk.
  - *Talking in a quiet location helps eliminate background noise*.
- Set aside any preconceived thoughts about the manager or the procedure being evaluated.
  - *Focus on the moment, rather than what might have happened in the past*.
- Set aside any preconceived thoughts about the subject.
  - *Some subjects are sensitive*; *focus on the speaker's statements, rather than on the risks or controversies associated with the subject being discussed. For example*, *focus on what was found in the inspection underway rather than results of similar types of inspections or other general patterns in the industry*.
- If necessary, take notes in order to record and remember key information.
  - *Review the notes with the manager to make sure the information is accurate and to dispel any notion that the FPP is* "*building a case*" *against the facility*.
- Allow the speaker to take their time when talking.
  - *Sometimes taking sufficient time can help bring out information that otherwise might be passed over by the speaker.*
- Try not to interrupt.
  - *Interrupting a person can be perceived as rude and inconsiderate and prevents the speaker from finishing his or her thoughts*.

Strategy #2: Watch for Non-verbal Cues

Non-verbal communication is important; however, individuals are often unaware of non-verbal cues (Trenholm and Jensen 2011). For most people, paying attention to non-verbal cues requires conscious attention and practice until the cues can be picked up automatically. *Watching for non-verbal cues* begins with techniques that focus on one's own body language, which helps to notice and interpret the body language of other people. Techniques to support this strategy may include:

- Consider gestures.
  - *Does the FPP appear impatient or frustrated when talking with the manager or responsible personnel*?

- Consider facial expressions.
  - *For some individuals, facial expressions are difficult to control, making it difficult to appear neutral and interested.*
- Consider tone.
  - *When speaking to a manager, is the FPP stiff, tense, or on edge? Does the FPP's voice sound terse or exude frustration?*
- Ensure that body language as a whole encourages interaction.
  - *Body language is made up of many components. All body language should give the same message and encourage interaction* (Burgoon and Bacue 2003).

Strategy #3: Evaluate What Is Being Heard

Respectful *evaluation* during the communication process adds to the listener's credibility and can help clarify information that may seem contradictory to what the listener believes. A technique to support this strategy includes:

- Continual questions and comments.
- Respond with questions (or comments) during the process rather than responding with a list of questions at the end (Dickson and Hargie 2006).

Strategy #4: Controlling Emotions

Controlling emotions is a necessary part of good interviewing. Techniques to help control emotions include avoiding judgmental comments, minimizing the extent to which emotion spills over into body language, and maintaining the pace and flow of communications (Hoppe 2006).

- Avoid judgmental comments such as "Are you kidding?" or "No, that's not correct."
  - *Judgmental comments can put the other person on the defensive and break down communication.*
- Minimize the extent to which emotions spill over into body language.
  - *Stay relaxed, focused, calm, and professional. In tense situations, taking a break may help ease emotions on both sides. If needed, the FPP could use a pretext such as "Let me retrieve a document from my vehicle and then we can continue" to allow time to cool down.*

- Maintain the pace and flow of the communications.
  - *Some people are more comfortable with an even pace and flow. For example, periods of silence tend to break up the conversation as well as possibly allow misunderstandings to occur, as people may tend to "fill in the blanks" with their own assumptions. Avoid asking a series of questions without pausing, but rather pace the questions by allowing the other person to respond to each question in turn.*

Strategy #5: Check for Understanding

Checking for understanding should start when communication begins and should continue throughout the conversation. Techniques to support this strategy may include:

- Repetition.
  - *Repeating words helps increase confidence that what is being said is being discussed.*
- Paraphrasing.
  - *Reword or simplify what is being said without changing the meaning.*
- Ask for clarification.
  - *Clarification often serves to acknowledge that the speaker has knowledge that is important.*
- Ask for a demonstration.
  - *Many people are more concrete in their communications and often feel more comfortable demonstrating while talking.*
- Summarize what is being said.
  - *Summarization helps with note-taking as well as giving positive feedback to the speaker* (Abbe and Brandon 2014).

Asking Effective Questions

Gathering quality information in an efficient manner is critical to the job of an FPP. The most commonly used tools to gather and understand information are *questions/checklists*. Some people may assume that questioning simply involves asking questions; in reality, questioning is a highly-sophisticated art and science with well-established protocols (Lopez 1975).

Asking appropriate questions during inspections allows the FPP to gather information about the behaviors and practices of food production/service and operational procedures to determine if the food being served or sold is safe. The different types of questions, and when the questions might be used during inspections, are described in Table 17.1. FPPs should focus on utilizing strategic, open-ended, and direct questions during the course of a conversation, should ask closed-ended and indirect questions on a limited basis, and should avoid asking non-strategic questions if possible. The FPP should also be able to change the type of question being asked in the event that an initial question does not elicit an appropriate response.

As a general rule, the FPP should never ask questions for which the answer is readily available by visual observations, i.e., a non-strategic question.

Consider a scenario where a food handler is standing at a food preparation table conducting a three-step process with shrimp:

Step 1. Dipping the raw shrimp in water
Step 2. Dipping the shrimp in bread crumbs
Step 3. Placing the breaded shrimp on a tray

The FPP asking the individual "So what are you doing there?" would likely not facilitate communication, since the three-step process is clearly visible. What the FPP really needs is information to fill in the gaps of knowledge. This situation is where effective questioning comes in handy. For example, the FPP could ask, "Who supplies your shrimp?" (strategic, open-ended, and direct) or "What happens to the shrimp after it leaves the food preparation area?" (strategic and open-ended).

Examples of questions that can be asked at the *beginning* of inspections include:

- What processes are going on right now?
- What products are being produced right now?
- Is there currently anything in or on the stove that is cooking or reheating?
- Are there any leftovers from last night still in the cooler?
- Is there anything in the cooler that was prepared earlier today?
- Was a shipment received this morning?
- Is anything being prepared right now?

Although some of these questions are closed-ended, the questions are strategic. Depending on the responses, the FPP may have an opportunity to assess critical processes such as cooling, reheating, receiving, and preparation early on in the inspection and prevent these operational steps from going unevaluated during the inspection. If certain processing steps are not discovered until later in the inspection, the FPP may not be able to effectively assess the steps. For instance, some control measures such as cooling or reheating require a critical amount of time; as a result, in order to properly assess the control measure, the inspection must cover the critical time period.

Follow-up questions can contribute to effective communications. For example, if the FPP wants to know if the establishment has an employee health policy that complies with applicable federal, state, and/or local regulations, he or she may ask, "Does this organization have an employee health policy?" If the manager replies, "Yes," the

Table 17.1 Questions used during inspections (Modified from FDA Communication Skills for Regulators, web-based course: http://www.accessdata.fda.gov/orau/commregulators, Accessed 18 March 2014)

Question	Description	Example	When used	Reason used
Strategic	Elicits new information rather than the repetition of previously known information. Used when information cannot be determined through visual observations.	"I see you are portioning out chicken. Who is your supplier?"	All phases of the inspection.	Encourages discussion and maximum exchange of information.
Nonstrategic	Focuses on information that is already readily available or obvious.	FPP to food handler: "What are you cooking?" when it is obvious that the food handler is cooking chicken on the grill.	Never.	Not used. Nonstrategic questions are unnecessary and could break down communications.
Open-ended	Requires more than a "yes" or "no" answer. Usually begins with "what," "how," "when," "why," or "describe".	"How do you prepare your meatloaf?"	All phases of the inspection.	Stimulates thinking and encourages discussion and maximum exchange of information.
Closed-ended	Usually prompts a "yes" or "no" answer.	"Do you cook food to the proper temperature?" "Do you have an employee health policy?"	Seldom.	Generally discourages discussion and information exchange. Could be used during a survey when a "yes" or "no" answer is desired or at the beginning of an inspection to establish priorities.
Direct	Elicits a short statement of fact, not a "yes" or "no" answer. Often used after an open-ended question to confirm facts or clarify what was heard.	"Thank you for telling me how you prepare your chicken. What temperature do you cook it to?"	All phases of the inspection, especially as a follow-up to open-ended questions.	Seeks or clarifies specific information or facts. Shows interest in what is being discussed.

(continued)

Table 17.1 (continued)

Question	Description	Example	When used	Reason used
Indirect	Often begins with phrases like "I'd be interested to hear more about…" or "Would you mind telling me about…" Invites the responder to answer without the feeling of being directly confronted.	"Would you mind telling me about the last inspection?" (vs. Why did you receive such a low score in your last inspection?")	Seldom.	Sometimes used when dealing with a sensitive topic or when a softer approach is needed to get strained communication back on track.

FPP could ask a follow-up question such as "Could you please describe this policy?" Depending on how comprehensive the answer is, the FPP may need to follow up the response with a series of open-ended but direct questions to hone in on the policy being implemented, e.g., "What symptoms do you require employees to report?"

Culture and Communication

Research by the US Food and Drug Administration (FDA, www.fda.gov.) Oral Culture Learner Project suggests that food employees can be classified as either oral culture learners or print culture learners (FDA 2014a, b). The difference between these two types of learning cultures is related to the way an individual prefers to receive and process information, the preference being based on the individual's education, background, and other factors.

Oral culture learners generally prefer obtaining new information from people they know or with whom they have a relationship. These types of learners place greater emphasis on emotion and being able to personally relate to the information being provided. Oral culture learners are able to process many ideas at once, yet like to focus on the big picture as opposed to the small details.

In contrast, print culture learners do not need a personal connection with the information being presented. These types of learners are motivated by facts and generally seek out new information by looking for written material (for instance, an article, handout, or website) on the subject. Print culture learners also tend to focus on one concept at a time and categorize concepts in a very orderly fashion (e.g., first this, then that; step 1, then step 2; etc.).

Print culture learners are comfortable learning a concept and applying the concept to various settings and circumstances. For example, a print culture learner could receive training in a classroom setting or on a computer and apply the concepts

learned in the kitchen. In contrast, an oral culture learner would learn better if taught in the kitchen where the concepts will be applied.

The majority of food safety training materials and instructional methods commonly in use today are designed by and for print culture learners. If an oral culture learner is taught through print communication like pamphlets, posters with a lot of words, online computer courses, etc., the "message" being delivered may be misunderstood or unconvincing. To ensure control of the foodborne illness risk factors (which include poor personal hygiene, improper holding temperatures/cooling, inadequate cooking temperatures, contaminated equipment/cross-contamination, and food from unsafe sources), the desired food safety practices or procedures must be taught in a way that can be easily understood and compelling enough to bring about behavior change. The materials and instructional methods designed as part of FDA's Oral Culture Learner Project (link provided at the end of this chapter) are specifically designed to help food handlers understand the reasons why following proper food safety and practices is important to prevent illnesses, deaths, and loss of income and reputation resulting from outbreaks.

Using Negotiation Skills During Inspections

Effective negotiation is a vital skill for FPPs. Negotiation involves back-and-forth communication designed to reach an agreement and can be utilized by FPPs to help bring food safety issues under control. Negotiation is often involved when determining the time frame for correcting any food protection violations. Sometimes, due to the cost involved of correcting a violation, management may request extra time to come into compliance. However, the request for additional time must be balanced against the risk to consumers. In other cases, regulatory agencies may be more amenable to an extended time frame for correction, subject to agency rules and policies. In general, taking into account the following four strategies should assist the FPP during a negotiation process.

First, negotiations involve human beings who have emotions. Managers or employees involved in inspections may be angry, worried, fearful, or nervous. Understanding their thoughts and feelings can help establish an effective working relationship built on trust, understanding, and respect. Such an understanding can also help the FPP avoid assigning blame to a specific individual.

Second, individuals will be more open to successful negotiation if they are made to feel like an active participant in the inspection process. This engagement provides the manager/employee with a stake in the outcome and shows that his or her interests are being respected. Active participation by the manager/employees can also involve brainstorming with the FPP and discussing multiple solutions to a specific food safety issue at the facility.

Third, shared and compatible interests should be identified. For example, the FPP and the personnel involved want the inspection to run in a smooth and efficient

manner. Keeping this mutual interest in mind can help achieve the ultimate goal of negotiation, i.e., agreement among all stakeholders.

Fourth, the FPP should remain objective and avoid any premature judgment about the facility. One way of remaining objective is to rely solely on objective food safety criteria, such as the FDA Food Code, along with state/local food codes and any applicable regulations. This approach will also prevent facility personnel from thinking that the FPP is "making up" or misinterpreting rules.

Dealing with Hostile Situations

During an inspection, the FPP normally works with food establishment employees that are very hospitable. However, the FPP may have to work with a person with a hostile attitude or who may be suffering from personal tension that can escalate into hostile or dangerous behavior. In fact, inspectors are often taught to strategically park their vehicle so that the car cannot be blocked in, is aimed in the direction that will be used when leaving, and allows for leaving the facility quickly.

There are several proactive ways to de-escalate potential hostile encounters. One way is to share information by communicating with other FPPs and supervisors. There may be situations where problem establishments are already known, or individual persons in charge may have a history of volatile, disrespectful, or unfriendly behavior with inspectors. Understanding any relevant history can help the FPP develop an appropriate plan of action.

Since the tone of the inspection is often set during the first few minutes, the FPP must establish an open dialogue with the manager, maintaining a professional and personable approach. Additionally, appropriate communication skills (e.g., active listening, eye contact, choosing words carefully, avoiding hasty comments, showing empathy, remaining calm, using appropriate body language, etc.) can help prevent a hostile encounter. Additional strategies to help prevent a hostile situation include:

- Being aware if the emotional temperature is, or appears to be, rising
- Letting the manager or responsible personnel vent to some extent
- Listening
- Knowing when to stop talking
- Avoiding argument
- Avoiding defensive behavior
- Understanding that the problem may have started prior to the current inspection
- Keeping one's ego in check
- Being accompanied by another person, such as the FPP's supervisor, during the inspection

If an inspection becomes volatile, the FPP should immediately stop the inspection and leave the facility. The inspection can always be rescheduled, and the FPP should call 911 if they feel their personal safety is threatened. A law enforcement

official may be available to escort the FPP during a potentially-hostile inspection. The FPP should also report a hostile event to their supervisor.

Conclusion

There are certain strategies that can help foster effective communication. Establishing rapport, being an active listener, asking the right kinds of questions, negotiating, and understanding cultural differences are important skills required for effective risk-based inspections. Establishing rapport with the manager or responsible personnel can help the inspection process run more smoothly. Active listening improves the ability to gather information and improves the professional relationship between the manager and the FPP. Skilled questioning opens the scope of discussions and provides the information necessary to make accurate inspection assessments. Negotiating skills can help FPPs and industry personnel reach mutual agreements. Being aware of cultural issues can help the FPP relate to food industry employees. Lastly, being able to diffuse hostile situations is a vital skill necessary to ensure personal safety.

Take-Home Message

During inspections, good communications skills enable people to understand situations, work quickly and efficiently, collaborate, achieve desired outcomes, and avoid conflict. By incorporating the strategies covered in this chapter, the FPP should be able to establish effective two-way communication with food establishment employees. Effective communication will help the FPP determine regulatory compliance and convey the public health significance of any violations.

Activity 1: Active Listening Self-Assessment

Using Table 17.2, think about a real or potential scenario where you have communicated (or will communicate) with a manager in order to gather and evaluate information. Ask yourself each question, and place a check ✓ in the appropriate box (Always, Usually, or Not enough). If the majority of checks are in the Always box, you might be an effective communicator.

Table 17.2 Active listening self-assessment (Adapted from FDA Communication Skills for Regulators, web-based course: http://www.accessdata.fda.gov/orau/commregulators, Accessed 18 March 2014)

Ability to focus on the speaker	Always (at least 90 % of the time)	Usually (between 60 and 90 % of the time)	Not enough (less than 60% of the time)
I think about why I am listening to what is being said by the manager			
When I hear extraneous sounds, I do not allow myself to be distracted			
I listen to the manager without judging or criticizing him or her either verbally or non-verbally			
I give verbal and/or non-verbal indications throughout the entire discussion that lets the manager know he or she has my full attention			
I let the manager finish and avoid interrupting him or her either verbally or through nonverbal cues such as looking at my watch			
I take notes as needed to help me focus the discussion and remember details			
Ability to listen beyond the facts	*Always*	*Usually*	*Not enough*
I listen for cues that tell me what the manager may be feeling, such as frustration			
I try and use the manager's non-verbal communication as cues to what he or she may be feeling			
I think about what the manager *means* rather than what the manager *says*			
I recognize that different words and phrases have different meanings for different people			
Ability to check for understanding	*Always*	*Usually*	*Not enough*
I restate or paraphrase messages to confirm understanding			
I easily ask additional questions to seek more information as needed			
I evaluate how well I am listening based on how the other person reacts to my responses. For example, does the person seem frustrated because I miss his or her meaning?			
Ability to control emotions	*Always*	*Usually*	*Not enough*
When I hear provocative words, I remain calm and professional			
I always try and put myself in the other person's place in order to understand his or her perspective			

(continued)

Table 17.2 (continued)

Ability to focus on the speaker	Always (at least 90 % of the time)	Usually (between 60 and 90 % of the time)	Not enough (less than 60% of the time)
Ability to evaluate what you hear	*Always*	*Usually*	*Not enough*
I evaluate whether the information is relevant			
I evaluate whether the information is current and accurate			
I can differentiate between fact and speculation			
I listen for consistency between what I hear and what I heard earlier			
I check for consistency between what I hear and what I see			

Activity 2: Effective Questioning

For each of the scenarios below, choose the more effective question for the FPP to ask (Adapted from FDA Communication Skills for Regulators, web-based course: http://www.accessdata.fda.gov/orau/commregulators.)

1. The FPP would like to know as much as possible about how the operation cools food.
   (a) Do you cool food properly?
   (b) How do you cool food?
2. The FPP would like to know if the operation cooks hamburger to the proper temperature.
   (a) How do you cook hamburger?
   (b) Do you cook hamburger to 155 °F for 15 s?
3. The FPP observes oysters being shucked and would like to verify if the oysters are from an approved source.
   (a) Could you tell me about your oysters?
   (b) Where do you purchase your oysters?
4. The FPP would like to verify the policy in place for hand washing.
   (a) Do you have a handwashing policy that describes when employees should wash their hands?
   (b) Could you describe your handwashing policy?
5. The FPP would like to establish rapport with the manager by engaging in small talk.
   (a) Are peanuts used in this facility? I'm allergic.
   (b) So, how did you get started in the food industry?

Activity 3: What Kind of Learner Are You?

Are you an oral culture learner or a print culture learner? For each item, place a check in the box in Table 17.3 that best describes you. Total the number of checks in each column to determine which type of learner you are or which type of learning you may prefer.

Table 17.3 Oral vs. print culture (Adapted from U.S. Food and Drug Administration FD 218 course, Risk-based Inspection Methods at Retail, participant manual)

Oral culture		Print culture	
You like receiving new information verbally.	☐	You like receiving new information through books, fliers, and handouts.	☐
You are more likely to understand new information if you have a personal connection to the information or if the information is from someone you trust.	☐	You do not need a personal connection in order to understand new information. The source of the information is less important than the factual basis of the information.	☐
You more easily understand or accept new information when told in a story.	☐	You are more driven by facts, not stories. "Just skip to the chase!"	☐
You show emotions or share personal stories with people you do not know well.	☐	You only show emotions or share personal stories with someone you know well.	☐
You are comfortable focusing on lots of ideas at once.	☐	You are comfortable focusing on one idea at a time.	☐
You focus on the big picture, not the details.	☐	You break down information into orderly parts (first this and then that). Details are important.	☐
You learn better by practicing new information in the appropriate context, e.g., learning about cooking while in a kitchen.	☐	You are okay with receiving new information in a different context than it will be applied.	☐
To adopt a new way of doing something, you must first understand the purpose and be given examples showing that the new way of doing something is the best way.	☐	"Because it is the law or policy" is sufficient basis for changing the way you do something.	☐
You rely on multiple senses to learn and remember new information.	☐	You primarily read and write to learn and remember new information.	☐
When you need information, you ask people you trust.	☐	When you need information, you look for a book or article on the subject.	☐
Total			

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Answer Key

Activity 2: b, a, a, b, b

Chapter 18
Unprocessed Foundations

Christopher Weiss, David Read, Steve Steinhoff, and Julie Henderson

Learning Objectives

- Define types of unprocessed foods generally found in on-farm settings.
- Discuss hazards associated with unprocessed foods.
- Discuss control measures used to address hazards associated with unprocessed foods.
- Discuss the regulation of unprocessed foods.

Introduction

The IFPTI Curriculum Framework identifies a number of content areas for training food protection professionals (FPPs). The unprocessed training content areas of the Curriculum Framework cover activities that occur in the agricultural

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production arena related to milk, produce, shell eggs, and shellfish, i.e., farm-level activities involving agricultural or wild harvested commodities that may require further processing before consumption by the consumer. Each area is regulated by federal and state laws and rules, although on-farm production of produce has not been commonly regulated (the new federal produce safety rule will change that). There are many examples of farm commodity production including, but not limited to leafy greens, fruits, nuts, and vegetables. There are also significant livestock production systems, but these won't be covered in this chapter.

The US Food and Drug Administration (FDA, www.fda.gov) regulates a number of food commodities after the commodities leave the farm including milk, produce, shell eggs, and shellfish. The US Department of Agriculture (USDA, www.usda.gov) regulates off-farm meat and poultry slaughter and processing. States are also actively engaged in regulation of these commodities, although many states lack authority for on-farm inspections other than for dairy farms where milk is produced. The regulation of each of these commodities will be discussed separately since the regulatory frameworks are different.

Unprocessed Foods Generally Found in On-Farm Settings

Processing food—whether through heating, freezing, pasteurizing, preserving, etc.—generally inactivates disease-causing pathogens. However, there are three of the four food categories identified above that sometimes may not undergo any or undergo minimal processing until reaching the consumer and are therefore referred to as *unprocessed*. These food categories include produce, shell eggs, and shellfish.[1] While some shellfish are sold live, most shellfish products are processed before being sold to the consumers, e.g., cooked in food processing facilities. Milk and milk-based products are further processed to ensure safety prior to sale to consumers.

At a general level, milk, produce, shell eggs, and shellfish are regulated at the site of their production or growth sites for similar scientific, operational, and historical reasons. All four of these food categories provide a rich source of nutrients for growth of microorganisms, including food pathogens; all are produced or grown in agricultural environments containing many and variable potential sources of contamination; all are produced or grown by very small to very large food businesses; all may present serious food safety risks prior to entering commerce; and all have been involved in historical events that tipped the food protection scale toward requiring regulatory oversight. However, each of these food categories has characteristics that uniquely qualify the food to be regulated at the production level. As a result, unprocessed foods are subject to increasing regulation and oversight beginning at the point where the food is grown or produced.

[1] For the purpose of this chapter, the term *shellfish* refers to bivalve molluscan shellfish, which includes oysters, clams, mussels, and scallops. This is consistent with the 2013 National Shellfish Sanitation Program (NSSP) Guide for the Control of Molluscan Shellfish.

Milk

In 1924 the US Public Health Service developed the Pasteurized Milk Ordinance (PMO) as guidance for voluntary adoption by local and state regulatory officials. However, in 1938, milk-borne illness outbreaks still constituted 25 % of all disease outbreaks that were attributed to infected foods or contaminated water (FDA 2011). The regulation of milk evolved into a state-federal cooperative regulatory program known as the National Conference on Interstate Milk Shipments (NCIMS, www.ncims.org). States require that Grade "A" milk and milk products (i.e., bottled milk, cream, sour cream, cottage cheese, yogurt, and some dry milk powders) be in reasonable and verified compliance with production, processing, and product requirements contained in the PMO. Most milk is produced as Grade "A" fluid milk; Grade "B" milk has less stringent standards, but can only be used in the manufacturing of butter, cheese, or other products. An interstate milk shipper must be certified by the state rating agency as meeting the sanitation compliance and enforcement ratings required for listing in the Interstate Milk Shippers List.

The NCIMS meets every 2 years to deliberate proposed revisions to the PMO submitted by interested parties such as state or local regulatory agencies, the FDA, the USDA, producers, processors, or consumers (NCIMS 2014). Proposed changes accepted by the conference are submitted to the FDA for approval prior to inclusion in the PMO.

Regulating the sanitation of the milk production environment on farms may minimize, but will not eliminate, contamination of milk by pathogens. For this reason, milk must be cooled immediately after milking. As a general requirement, milk that leaves the cow at a temperature of approximately 101 °F (Florida Dairy Farmers 2014) must be cooled to under 45 °F within 2 h after completion of milking (EPA 2012). This cooling is the primary food safety control for unprocessed milk on the dairy farm.

Except for cheeses that meet the aging requirements contained in the Code of Federal Regulations (Part 133, 21CFR), the federal agencies that regulate milk require it to be pasteurized if it is intended for human consumption. Pasteurization inactivates microbial pathogens in milk by heating it to a scientifically-established time-temperature combination (e.g., 161 °F for 15 s for continuous, high temperature short time). Although milk entering interstate commerce must comply with federal pasteurization requirements, some states allow the sale and consumption of unpasteurized (raw) milk within the state. The sale of unpasteurized milk remains a controversial and unresolved issue from a public health standpoint.

Minimizing contamination of milk with pathogenic microorganisms is important, because milk is a rich source of nutrients needed for microorganisms. Milk contains abundant moisture, proteins, lactose, a compound sugar that some bacteria (e.g., lactic acid bacteria) can convert to an energy source, and minerals such as calcium, phosphorus, potassium, and sodium required for bacterial cell function or growth. Common pathogens associated with unpasteurized milk include *Campylobacter jejuni*, *E. coli* O157:H7, *Listeria monocytogenes*, and *Salmonella* (FDA 2014a).

Milk is produced in an agricultural environment that may contain a variety of disease-causing microorganisms. Because food safety risks presented by milk are

associated primarily with the production environment, the regulation of milk at its production site (i.e., dairy farm) is heavily focused on controlling or minimizing environmental contaminants. Dairy farm regulatory requirements include good manufacturing practices (GMPs) related to equipment standards, animal health oversight, and sanitation/hygiene procedures. The list is extensive, but includes:

- Proper veterinary care to ensure milking animals are healthy and that drugs are administered in a safe manner
- Milking personnel health and hygiene to ensure that hands and clothing are clean
- Clean water for the animals and cleaning operations
- Properly-designed and maintained milk-handling equipment that can be cleaned and inspected effectively
- Systems to remove manure from areas where animals congregate
- Proper chemical management to ensure equipment is properly cleaned and sanitized and to prevent potable water contamination
- Control of insects, rodents, and other disease vectors
- Clean udders, flanks, and tails on milking animals so that manure and other contaminates don't enter the milk supply while the animal is being milked
- Clean equipment to reduce bacterial load
- A well-maintained facility to preclude contamination of the milk from the environment

The safety of milk can be put at risk when it is adulterated with residues of therapeutic drugs used to treat an illness or disease of milking animals. In dairy animals, antibiotics are most often used to treat mastitis, which is the most common disease in adult dairy cows. Some drugs are prescribed and administered by veterinarians in accordance with product-specific label instructions. Product labels include "withhold times" as well as directions for administration of a drug. In addition, veterinarians may "extra-label" drugs originally developed for species other than cows, to prescribe a higher dose of the drug than what is on the regular label, or to treat a different disease than is on the label. Veterinarians will either administer the prescribed drugs directly or prescribe them for use on lactating cattle by the farmer. Other medications are sold over-the-counter, purchased, and administered to lactating cattle by farmers.

To improve efforts to exclude antibiotic drug residues from entering the human milk supply, dairy plant operators have been required to test all unpasteurized milk shipments received from farms for the presence of drug residues since 1992. If present, the test will identify residues of the most common drugs administered to dairy cows. A tanker truck goes from farm to farm picking up milk and adding milk from multiple farms to the tanker. When this milk shipment arrives at the plant, it is tested for drug residues. If the milk in that shipment is found to contain drug residues, the entire milk shipment must be discarded, and the dairy producer that caused the violation is identified and is subject to mandatory enforcement sanctions. The way the individual farm is identified is by testing the individual samples of milk that are picked up from each farm at the time the tanker is loaded.

The primary practice used by farmers to prevent adulteration of unprocessed milk with drug residues is to exclude the milk from treated cows from sale until the

drug treatment is complete and the drug is no longer in the cow's system. The period when milk must be withheld from sale is commonly referred to as the drug's "withdrawal time". Withdrawal times are determined through research conducted by drug manufacturers and veterinarians and are a required component of a drug label. However, in some cases, drug residue has been detected in the cow's milk after the established withdrawal time.

Most drug residue contamination of milk is accidental or inadvertent. Individual animals may metabolize the drugs at rates not encountered during the establishment of withdrawal times; milk from a treated cow may accidentally not be diverted from the milk supply; or the dose of therapeutic drug administered may be inaccurate or inappropriate. Because testing the milk of individual cows is impractical and there is no drug screening test that is reliable or approved when used to detect drug residue in milk from an individual dairy animal, farmers must rely on withdrawal times in determining when to resume selling the milk from cows treated with therapeutic drugs.

Produce

Traditionally, produce has not been subject to strict US regulation. However, a number of foodborne illness outbreaks since the late 1990s have been traced to produce. In fact, the FDA reports that there were 131 outbreaks associated with contaminated produce alone between 1996 and 2010, causing more than 14,000 illnesses and 34 deaths (FDA 2014c). Additionally, the environment in which produce is grown or produced presents a range of potential food safety issues. Regulation of produce is a provision of the 2011 Food Safety Modernization Act (FSMA, Public Law 111-353).

Produce is the most recent and possibly the most critical addition to the short list of foods that will be regulated at the growing or production site. In most cases, milk, shell eggs, and shellfish are further processed to minimize or eliminate pathogens after production and prior to consumption, but produce is not. Produce is generally consumed in an unprocessed form. Because there is no kill step for many fruits, vegetables, and leafy greens at any point along the farm-to-table continuum, good agricultural practices and preventive regulation of produce growing conditions, harvesting, packing, and holding are the sole, essential food safety intervention. Pathogens most commonly associated with produce include *Clostridium botulinum*, *Escherichia coli* O157:H7, *Salmonella* spp., *Shigella* spp., *Listeria monocytogenes*, *Cryptosporidium* spp., *Cyclospora* spp., hepatitis A virus, and norovirus.

The Produce Safety Alliance (PSA, http://producesafetyalliance.cornell.edu/) is a collaborative project between Cornell University, the USDA, and the FDA designed to provide fresh produce growers, packers, and grower cooperatives with training and educational opportunities related to best practices and guidance. Additionally, the Sprout Safety Alliance (www.iit.edu/ifsh/sprout_safety/) is a public–private alliance that will be developing a curriculum, training, and outreach programs for stakeholders in the sprout production community.

Since the early 1990s, multiple agencies and organizations have developed guidance documents related to fresh produce including the produce industry, the FDA, and the USDA Agricultural Marketing Service (AMS, www.ams.usda.gov). For example, the United Fresh Produce Association (UFPA, www.unitedfresh.org) has issued five editions of "Food Safety Guidelines for the Fresh-Cut Industry." During this same timeframe, the FDA and USDA issued "Guidance to Minimize Microbiological Food Safety Hazards for Fresh Fruits and Vegetables." This document is often referenced as guidance on good agricultural practices (GAPs). The guidance addresses microbial food safety hazards and good agricultural and management practices common to the growing, harvesting, washing, sorting, packing, and transporting of most fruits and vegetables sold in an unprocessed (or minimally-processed) form (FDA 1998).

GAPs guidance and the proposed produce rule under the Food Safety Modernization Act (FSMA) recommend that growers develop, maintain, and update a food safety plan. A food safety plan and standard operating procedures (SOPs) are recommended for storage and handling areas, field areas, facility and equipment cleaning and sanitation, and employee training. There are no proposed requirements for a hazard analysis, and growers are encouraged to align their food safety plans according to the size, complexity, and inherent risks of their produce operations.

Additional steps that should be taken to minimize the risk of produce contamination and improve the management of businesses that grow, pack, or hold produce include an evaluation of land use prior to its conversion for the production of fresh fruits and vegetables, and an evaluation of past and current uses of adjacent land that may affect the safety of the produce and the creation and maintenance of a food safety plan by the produce grower. Evaluating may reveal potential sources of contamination that may make the land unsuitable for growing unless steps are taken to eliminate or appropriately mitigate the contamination sources.

As stated by the FDA in the proposed produce rule, agricultural water is defined as water used in growing activities, including irrigation water applied using direct application methods; water used for preparing crop sprays; water used for growing sprouts; and water used in the harvesting, packing, and holding activities, including water used for washing or cooling harvested produce and water used to prevent dehydration of produce. Water that would normally not contact the edible portion of produce in the growing process is not considered agricultural water (FDA 2014b). Agricultural water for growing produce presents varying amounts of risk depending on the source of the water and whether the water can be expected to contact the edible portion of the commodity being grown.

Surface water from ponds, lakes, or rivers presents contamination risks from sources such as raw human sewage, animal waste, pollutants from recreational activities, agricultural runoff, storm water runoff, improper pesticide container disposal, inadequate employee restroom or handwashing facilities, or petroleum product residue from roads or equipment. Land adjacent to the land used to grow produce (e.g., a cattle feed lot) may also be a source of contaminated agricultural surface water. Risks with ground water from wells are associated with well construction,

proximity of the well to a contamination source (e.g., an animal yard), and the elevation of the well location relative to potential contamination sources. Agricultural water obtained from a municipal source presents the least inherent contamination risk, but should be monitored as part of an establishment's sanitary standard operating procedures (SSOPs). As currently proposed, the produce rule will require growers to monitor agricultural water using generic *E. coli* as an indicator organism and discontinue the use of agricultural water found to exceed an established microbial limit until the contamination source is identified and corrected, or the water is treated in accordance with rule requirements (FDA 2014b).

Whether water can normally be expected to come into contact with the edible portion of the produce being grown depends on the growth habit of the plant, whether the plant is being irrigated, and, if so, how irrigation water is applied. If produce is irrigated as part of the growing process, plants with a growth habit where the edible portion is close to the ground (e.g., cucumbers) present a greater contamination risk than plants where the edible portion of the fruit or vegetable is up off the ground (e.g., corn). Likewise, application of irrigation water via an overhead spray presents a greater contamination risk than drip or furrow irrigation systems, where water is distributed below the level of the edible portion of the plant.

Humans (i.e., workers and visitors) can be carriers of foodborne pathogens and, as a result, the source of produce contamination. Health and hygiene become increasingly significant issues as the number of workers employed to harvest or pack fresh produce increases. Contamination risks include worker health, hygiene, cleanliness of clothing (including shoes), and worker practices. Health and hygiene risks can be mitigated by providing adequate toilet and handwashing facilities, education about health and hygiene, and effective supervision. Similar to other food handling environments, ill workers must be excluded from activities that could cause contamination of fresh produce. Workers must wear clean clothing and, after handling animals or animal waste, must change or cover clothing before entering produce growing or packing areas. Properly-constructed and located toilets, handwashing facilities, and potable (safe) drinking water must be provided. The number and proximity of toilet and handwashing facilities is dependent on the number of workers and the size of the growing area. Because there may be language and cultural barriers to understanding expectations about health and hygiene, worker education, effective supervision, and modeling of expected behaviors are keys to establishing and reinforcing expectations about worker health and hygiene.

Both wild and domesticated animals pose a contamination risk for fresh produce. Domestic animals are more likely than wild animals to harbor zoonotic pathogens (e.g., *Salmonella*, *E. coli* O157:H7) due to their close proximity and interaction with humans. Animals contaminate fresh produce when pathogens contained in their feces contact the edible portion of the produce. Though animals cannot be completely excluded from the growing environment (or land adjacent to the growing environment), growers must monitor growing areas for the intrusion of wild animals, be aware of sources and potential routes of fecal material from domesticated

animals, and take action to minimize animal-related contamination risks. Produce found to be contaminated with animal feces or residue containing animal feces must not be harvested for use as human food.

Shell Eggs

Food safety risks associated with shell eggs are unique because environmental contaminants may contaminate shell eggs via a biological pathway as well as an environmental route. Shell eggs may be contaminated when pathogens present on the outside of the egg shell move or are drawn through the pores of the shell to the interior of the egg. Shell eggs may also be contaminated if pathogens are present in a hen's ovaries during formation of the egg. Egg contamination can occur during production, processing (washing, grading, and packing), storage, and preparation. The most common pathogen associated with shell eggs is *Salmonella* spp. In fact, Schroeder et al. (2005) estimated that 182,060 illnesses due to *Salmonella enteritidis*-contaminated egg shells occurred in the USA in 2000.

Rodents, flies, and other carriers of pathogens are difficult to keep out of egg-laying facilities. Microbial contamination, in caged layer production systems, is primarily on the surface of the egg and does not generally create a food safety issue if the egg is properly washed and sanitized. The current trend for "free range" and "cage free" production leads to more opportunities for not only shell surface microbial contamination, but contamination of the contents. Eggs in this type of production can be laid outside or on the ground where contamination can be caused by the eggs laying in wet manure, dirty water, or other filth, with microbes entering through pores in the egg shell and contaminating the albumen and yolk.

Subsequent to the egg-laying and collection processes, internal contamination of shell eggs can be caused by improper washing and sanitizing. Immersing the eggs in water can move pathogens into the egg through the pores. Spray-washing the eggs with water that is colder than the eggs causes the inner membranes to contract, pulling any bacteria in the water or on the shell surface through the pores and contaminating the albumen.

Regulation of shell eggs at the production level evolved to its current level over a period of more than 30 years. FDA, USDA, the states, and the egg industry have all been active participants in this evolution. Currently the responsibility for the regulation of shell eggs includes the FDA (for safety), the USDA (for quality), and the states who contract with one or both of these agencies to perform egg regulatory functions.

In the mid-1980s, there was a significant increase in egg-associated foodborne illness attributed to *Salmonella*. As a result, beginning in the late 1980s, state and federal food agencies began defining eggs as potentially-hazardous foods (i.e., foods requiring refrigeration for safety) and requiring shell eggs to be held at 45 °F or less after packing. In 2005, FDA implemented rules requiring a safe handling statement on all egg cartons ("To prevent illness from bacteria: keep eggs refrigerated, cook eggs until yolks are firm, and cook foods containing eggs thoroughly").

Eggs that are packed loose for food service use are required to have the safe handling statement on the case or an accompanying document such as an invoice. The 2005, 2009, and 2013 editions of the Retail Model Food Code (www.fda.gov/FoodCode/) contain additional safe-handling provisions for shell eggs sold in retail settings, including the requirement that undercooked eggs not be served to high-risk populations like nursing home residents.

The FDA has primary responsibility for the regulation of food safety risks associated with shell eggs. The FDA Egg Safety Rule (21 CFR Parts 16 and 18) was first proposed in 2004 and, after several comment periods, went into effect in 2009 (Egg Safety Center 2010). The rule was developed to help prevent egg-associated illness caused by *Salmonella*. Under the rule, egg producers at production sites with more than 3,000 chickens must maintain a written *Salmonella* enteritidis prevention plan, along with records documenting their compliance. Egg producers covered by the rule must also register with the FDA, which will develop guidance to help producers comply with the rule (FDA 2013).

The Egg Safety Rule contains provisions similar to those found in State Egg Quality Assurance Plans, including monitoring and controlling flies and rodents in layer hen production houses, environmental testing for *Salmonella*, holding eggs produced from environmentally-positive houses until the eggs are tested, diversion of eggs from flocks where eggs have tested positive, and cleaning and disinfecting layer houses between flocks.

The Egg Safety Rule is enforced by the FDA at all production sites with more than 3,000 chickens. Inspections are primarily conducted by the FDA and can be targeted and/or comprehensive. Targeted inspections are to verify the facility has implemented basic controls to comply with the rule and in some cases are conducted by state departments of agriculture through contracts with the FDA. Comprehensive inspections are conducted by the FDA investigators at higher-risk farms and include environmental testing. Some states under contract with the FDA have conducted shell egg inspections at production sites. Some states also visit sites as part of an investigation into egg-related *Salmonella* foodborne outbreaks.

Enforcement of the Egg Products Inspection Act (enacted in 1970) is conducted through the USDA Agricultural Marketing Service (AMS) (www.ams.usda.gov) and Food Safety and Inspection Service (FSIS, www.fsis.usda.gov). This law's implementing regulations prohibited the sale of cracked and dirty eggs to consumers and also implemented requirements for invoices documenting the date of delivery, name and address of the seller and buyer, grade, size, and quantity of the eggs (Musgrove 2011).

Quarterly inspections are conducted at all egg-grading stations and producer/packers with more than 3,000 chickens. The quarterly inspections are usually conducted by the state department of agriculture employees through cooperative agreements with AMS. The inspections are to verify disposition of restricted eggs, invoice information, labeling, and temperature compliance. Temperature violations are referred to FSIS for enforcement. FSIS also conducts inspections at wholesalers to verify compliance with temperature requirements, although the primary enforcement of this requirement is conducted by state departments of agriculture.

Shellfish

In 1925, the National Shellfish Sanitation Program (NSSP) was first developed by the US Public Health Service in cooperation with state and local public health officials. The creation of the NSSP was largely influenced by a series of typhoid fever outbreaks in New York, Chicago, and Washington, DC in the mid-1920s that were traced to oysters harvested from sewage-polluted waters. The NSSP is a federal/state cooperative program recognized by FDA and the Interstate Shellfish Sanitation Conference (ISSC, www.issc.org) for the sanitary control of shellfish produced and sold for human consumption (FDA 2014d). According to the ISSC, the term *shellfish* refers to oysters, clams, mussels, and scallops (ISSC 2009). Shellfish shippers that meet the requirements of the ISSC are certified by regulatory authorities and listed in the Interstate Certified Shellfish Shippers List.

The ISSC, which comprises state shellfish regulatory officials, is the vehicle recognized by FDA to provide guidance on issues related to the growing, harvesting, and production of shellfish. The ISSC meets biennially to review and update regulatory guidelines and procedures for states to follow to ensure uniformity in shellfish regulation. If FDA agrees with the ISSC recommendations, the guidelines are published as revisions to the NSSP Model Ordinance. The model ordinance includes requirements for sanitation, risk assessment, laboratory testing, shellstock growing areas, harvesting, transportation, and reshipping. States participating in the NSSP adopt and enforce the shellfish ordinance within their jurisdiction.

Shellfish are particularly susceptible to contaminants in their environment because they are filter feeders, i.e., they feed by filtering food and other nutrients out of the water in their habitat. In the process of filtering food, shellfish also retain microorganisms, including any pathogenic microorganisms that may be present. In many cases of shellfish-associated foodborne outbreaks, the cause was traced to pathogens from the harvest area. The pathogens found in shellfish come from naturally-occurring bacteria as well as bacteria and viruses associated with sewage. Pathogens of concern include *Vibrio parahaemolyticus*, *Vibrio vulnificus*, hepatitis A virus, norovirus, and *Campylobacter jejuni* (FDA 2014a).

Food safety risks posed by shellfish harvest waters are assessed using a variety of methods including sampling of water to determine the presence of fecal coliforms and biotoxins; shoreline surveys looking for potential sources of pollution; and monitoring of point sources of sewage discharge such as marinas, storm water discharge, and municipal sewerage systems. There are several processes approved that allow the industry to make labeling claims regarding the reduction of *V. vulnificus* or *V. parahaemolyticus*. These processes, called post-harvest processing (PHP), use a validated procedure to reduce pathogenic bacteria to a level below an FDA-established enforcement action level. Post-harvest processes that are currently approved and used by industry include high pressure processing (HPP), individual quick-frozen (IQF), low-temperature pasteurization, and irradiation.

Conclusion

Foods that are currently regulated at the production level as unprocessed foods present scientific, logistical, and culturally-related food safety challenges. Shellfish, shell eggs, and milk are nutrient-rich foods produced in agricultural environments. Because nutrients contained in these foods provide fuel for food pathogens as well as human nutrition, the food safety risks present in these production environments must be minimized, and the foods must be refrigerated beginning at harvest. Though milk, shell eggs, and shellfish are all normally processed to kill human food pathogens prior to sale and consumption, there are engrained cultural practices and evolving trends that may allow these foods to be consumed in an unprocessed or under-processed state. Though operational regulatory requirements for fresh produce are not yet in place, fresh produce presents a unique food safety challenge because fresh produce is not processed to kill pathogens. For this reason, the regulatory system for fresh produce must be almost entirely preventive in its approach.

Take-Home Message

Currently, only four categories of food are systematically regulated in an unprocessed form at the production level: milk, produce, shell eggs, and shellfish. These unprocessed foods are regulated in the raw form because during harvest, storage, or transportation, these foods are exposed to significant food safety risks that must be minimized or mitigated at the production level to ensure finished product safety and quality.

Activity

For each of the four types of unprocessed food covered in this chapter, give an example of a pathogen commonly associated with the food, a key food safety risk factor associated with the food, and an example of the how the unprocessed food is regulated.

	Regulated unprocessed food/food group			
	Milk	Shellfish	Shell eggs	Produce
Commonly-associated pathogens				
Key risk factors				
Legal/regulatory oversight				

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Answers

	Regulated unprocessed food/food group			
	Milk	Shellfish	Shell eggs	Produce
Commonly-associated pathogens	*Campylobacter jejuni*, *E. coli* O157:H7, *Listeria monocytogenes*, *Salmonella*	Norovirus, *Campylobacter jejuni*, *Vibrio vulnificus*, *Vibrio parahaemolyticus*, hepatitis A virus	*Salmonella* spp., *Salmonella Enteritidis*	*Clostridium botulinum*, *E. coli* O157:H7, *Salmonella*, *Shigella* spp., *Listeria monocytogenes*, *Cryptosporidium* spp., *Cyclospora* spp., hepatitis A virus
Key risk factors	Consuming unpasteurized milk, animal drug residues	Environmental (water)	Environmental (land)	Animal waste, water, animals (wild and domestic), humans
Legal/regulatory oversight	National Conference on Interstate Milk Shipments (NCIMS), Pasteurized Milk Ordinance (PMO)	National Shellfish Sanitation Program (NSSP), Interstate Shellfish Sanitation Conference (ISSC)	Egg Safety Rule, Egg Products Inspection Act	FSMA-directed Proposed Rule for Produce, Produce Safety Alliance, Sprout Safety Alliance, Good Agricultural Practices (GAPs)

Chapter 19
Manufactured Foundations

Katherine Simon, Catherine Martin, and Scott Gilliam

Learning Objectives

- Define manufactured (processed) food.
- Identify the acts and regulations associated with manufactured food.
- Explain the hazards associated with manufactured food, along with the factors that contribute to those hazards.
- Explain preventive controls associated with manufactured food.

Introduction

The manufacturing of processed foods in wholesale food plants is an important step in the food supply chain worldwide. New and innovative food products, sometimes in large quantities, are created on a daily basis due to advances in science and technology, as well as consumer market demands. A collection of regulations exist to ensure food manufacturers actively apply food safety controls, and oversight by food protection professionals provides critical verification of these controls to address hazards.

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Biological, chemical, and physical hazards can originate from incoming raw ingredients and can occur during manufacturing and distribution. The effects of these hazards can be amplified due to food supply chain systems, process techniques, and recent developments related to an increasingly global economy and culture. Due to the complexity of hazards related to food manufacturing, a conscientious food processor should have in place a comprehensive food safety system consisting of foundational programs such as good manufacturing practices (GMPs) and preventive controls.

Manufactured (Processed) Food

Section 201 of the Food, Drug, and Cosmetic Act (FD & C Act) defines *processed food* as any food other than a raw agricultural commodity and includes any raw agricultural commodity that has been subject to various *processes*. Manufactured food represents a wide spectrum, ranging from single ingredient items that undergo limited processing to complex multi-ingredient items that undergo multiple processes. Examples of food manufacturing processes include milling flour, roasting coffee, cutting and peeling fresh produce, grinding and cutting fresh meat (Fig. 19.1), baking breads (Fig. 19.2), preparing refrigerated ready-to-eat meals, smoking fish or meats, preparing partially-cooked frozen dinners, freezing fresh fruits and vegetables, and canning fruit, vegetables, and soups.

Scientific principles have resulted in processes and techniques that not only make foods last longer, i.e., preservation techniques, but also "add value" to foods by making them more palatable, storable, portable, useful, shelf-stable, waste-free, and convenient. In other words, food processors utilize factory systems to add economic value by transforming raw materials grown on farms or fished from the sea into

Fig. 19.1 Grinding fresh meat

Fig. 19.2 Baking bread

useful products. Steers become meat; wheat becomes flour; corn becomes fructose; and tuna becomes canned goods (Brody et al. 1999). Food processing facilities sell primarily on the wholesale market, which allows for their food products to be sold and consumed on a regional, national, or worldwide basis. Processing also occurs at retail food establishments and is subject to different requirements than wholesalers. Processing at retail is covered in Chap. 20, Retail Food Establishments.

Some preservation processes have been around for hundreds, if not thousands, of years. Individuals discovered early on that these processes allowed food to stay in an edible state for much longer periods of time. For example, fermentation is one of the oldest methods of food preservation known, involving the use of certain bacteria, yeasts, or other ingredients to create a chemical reaction that converts sugars to acids, gases, and/or alcohol. This conversion inhibits the growth of harmful bacteria. Fermentation is used to make products such as wine, yogurt, sauerkraut, and kimchi.

Other very old methods of preservation include *drying preservation*, in which water is removed from a food product, eliminating the amount of free water, which is necessary for pathogens to persist and grow. Many foods can be dried, but the process will typically change the character of the food from its original form, e.g., drying lean meat to make jerky or drying fruit. *Curing* is a process by which curing agents like salt, sugar, and nitrites are applied to the outside of a meat product. Curing agents retard spoilage and pathogen growth, thereby allowing the food to be safely consumed for weeks or months after the animal was harvested. Using salt alone or brined is called "corning," e.g., corned beef. *Smoking* is another method of curing, by which the amount of free water in a product is reduced, making the product (typically fish) stable against spoilage and pathogen growth.

Cooking, *refrigeration*, and *pasteurization* are methods of preservation that focus on raising and/or lowering the temperature of a food product. Bacteria grow best in certain temperatures, typically the "danger zone" between 40 °F and 140 °F (USDA 2013). As a result, some food needs to be cooked at a temperature of 140 °F or above (or microwaved at 165 °F or above) (Foodsafety.gov 2014a), while other

types of food such as meat, poultry, and casseroles need to be cooked at a higher temperature such as 160 °F or 165 °F (Foodsafety.gov 2014b). Hot foods need to be held at a temperature of 135 °F or above, while cold foods need to be held at a temperature of 41 °F or below (San Bernardino County 2012). The process of *refrigeration* involves moving heat from one location to another. "Cold" cannot be added into food; however, heat can be removed, which limits pathogen growth. Some of the first practical applications of refrigeration included providing beer breweries with a constant source of "cold" and refrigerated railcars for the transport of their brewed beverages. *Pasteurization* is a process of heating a food to a specific temperature for a predetermined amount of time and then immediately cooling the product to refrigeration temperatures. This process is most commonly conducted on liquid foods, like milk and juice, to reduce or slow the growth of organisms that spoil food. The food item will normally have a sell by date, since not all microorganisms have been destroyed and the product will begin to spoil at some point.

Some of the more recently developed preservation methods include *acidification*, *commercial sterility*, and *irradiation.* Foods with a pH (acidity) level at or below 4.6 are naturally acidic (or called acid foods), do not support growth of the deadly botulism organism, and are far less frequently the source of foodborne illness. Examples of acid foods include apples, oranges, food dressings, and condiment sauces. However, the pH level of a food can be lowered to 4.6 or below through the process of *acidification*, which typically involves treating the food product with vinegar or acid brine, or the process of fermentation. Examples of foods that can be acidified include beets, cocktail onions, cherry peppers, and some kinds of cabbage, cucumbers, and green olives (FDA 2010).

Commercial sterility involves the application of heat or chemical sterilants to equipment (e.g., a vat or bulk tank) and sealed containers of food. This application renders the equipment and containers free of viable microorganisms that have public health significance and that are capable of reproducing in the food under normal non-refrigerated conditions of storage and distribution, i.e., the legal definition of a typical canned or aseptically-packaged food product (21 CFR Part 113.3 (e)). There are significant measures that must be in place pertaining to commercial sterility, including specific employee training, filing of the scheduled process specifications with FDA, and approval by a recognized independent scientific expert hired by the company and legally referred to as a "process authority."

Finally, *irradiation* is the process whereby food is exposed to ionizing radiation for a specified amount of time to sterilize or minimize the presence of pathogens. Spices and some fruit products have routinely been irradiated to control pests as well as pathogens, and irradiation has been used for many years in the medical field; however, the method is not widely used in the food supply due to the lack of public acceptance, along with the fact that some foods are not suited for the method.

As long as there is increasing demand for longer-lasting and better quality food products, innovations in processing techniques will continue to be made. For example, today's technology allows curing agents to be injected directly into muscle mass, which provides a much more effective method of curing.

Acts and Regulations Associated with Manufactured Food

Good Manufacturing Practices (GMPs)

In the USA, all food processors that engage in interstate or international commerce must comply with the good manufacturing practices (GMPs) found in a regulation (21 CFR Part 110) under the FD & C Act. The GMP regulation is broad in scope and is designed to outline the basic environmental and operating conditions needed to produce food under safe, sanitary conditions. Interstate and international commerce is determined on the basis of the source of ingredients and/or the sale of the final food product.

The GMPs outline the regulatory requirements under six main headings: (1) plants and grounds, (2) sanitary operations, (3) sanitary facilities and controls, (4) equipment and utensils, (5) warehousing and distribution, and (6) natural defects in food that present no hazard. Due to the significant variations in manufactured food operations, there is no single approach that can ensure compliance with the GMPs. Choices in how, when, where, and what to produce all determine good manufacturing practices within each specific food manufacturing setting. These choices can also alter the potential for hazards that will require additional control measures (e.g., frozen vs. refrigerated distribution, timing of processes, equipment in use, product formulation, packaging). However, the manufactured food operator is ultimately responsible for ensuring compliance with all applicable regulations and should continually review facilities and processes, as well as stay current with emerging food science and food safety issues. Periodic audits conducted by manufactured food operators, independent third-party auditors, and regulatory personnel can help ensure compliance with GMPs.

Food Safety and Modernization Act

High-profile outbreaks of foodborne illness over the last decade, along with data showing that such illnesses strike one in six Americans each year (CDC 2014), have caused a widespread recognition of the need for new, modern food safety system approaches. The Food Safety Modernization Act (FSMA, signed into law in 2011) called on the US Food and Drug Administration (FDA) to propose a preventive controls for human food rule that focuses on *preventing* food safety problems as opposed to *reacting* to food safety problems (i.e., foodborne illness outbreaks) once the problems occur. Part of the proposed rule would require facilities to evaluate hazards, identify and implement preventive controls to address the hazards, verify that the preventive controls are adequate to control the hazards identified, take corrective action when needed, and maintain written plans and records (FDA 2014a). Prior to FSMA, only processors of specific food products such as low-acid and acidified canned foods, meat, poultry, seafood, dairy, and juice were mandated by

the Code of Federal Regulations (CFRs) to have preventive control programs related to monitoring, recordkeeping, verification of monitoring practices, and corrective actions. Once the final preventive controls rule is published in the Federal Register, large firms will have 1 year to comply with the rule, while small and very small firms will be allowed a longer time frame for compliance (FDA 2014a).

FSMA has also given the FDA the authority to create regulations that will apply to the food manufacturers. The preventive controls rule revises the existing GMP requirements with provisions requiring (1) hazard analysis and (2) risk-based preventive controls. Both of these requirements are to be placed into a new CFR Part 117 (21 CFR 117) "Current Good Manufacturing Practice and Hazard Analysis Risk-Based Preventive Controls for Human Food." This rule has yet to be published in the Federal Register, as of this writing.

The FDA has comprehensive information regarding FSMA and the proposed rule on preventive controls for human food here on its website: http://www.fda.gov/Food/GuidanceRegulation/FSMA/.

Hazards Associated with Manufactured Foods

Suitable controls during food processing are necessary due to the inherent hazards associated with the manufacture of food products. The FDA defines *hazard* as any biological, chemical, radiological to the list, or physical agent that is reasonably likely to cause illness or injury in the absence of its control (FDA 2013). These hazards need to be evaluated during all phases of manufacturing, including incoming raw ingredients, all processing activities, and distribution.

Hazards can be identified at different processing steps. Raw ingredients can have naturally-occurring hazards such as pathogenic bacteria, viruses, allergens, toxins, and environmental contaminants such as pesticides. Hazards can also be introduced into raw and partially-processed ingredients, or increased in number through the growing, harvesting, storage, and distribution conditions that unprocessed or partially-processed food materials undergo prior to food manufacturing. For example, a peppercorn may not have been sterilized for *Salmonella* by the primary processor, or a pathogen may grow in a ready-to-eat food during transit to the secondary manufacturing facility. Hazards in manufactured food can also be introduced or be exacerbated by the manufacturing environment and the manufacturing process, i.e., the manner in which a product moves through the facility and interacts with machinery and/or employees.

An accurate hazard analysis must be specific to both the product and the manufacturing process. Conducting the hazard analysis also involves an understanding of the methods of storage and distribution, the specific conditions within the facility, and sound scientific information regarding the likelihood of the hazard occurring. Many factors influence the likelihood of hazards occurring, including the type of raw ingredient, the length of time at a processing step, the processing conditions and equipment, handling by employees, and inherent variations within processes or ingredients.

The increasingly complex and globalized food supply system places additional burden on food processors concerning identification, tracking, and evaluation of food ingredients and potential hazards from sources outside of the USA. Manufacturers in the USA must understand *how* the food products or ingredients were manufactured in other counties where ingredients are sourced. At this time, importers of food ingredients or food products are responsible for verifying that the ingredient or food being imported is from a safe source, i.e., supplier verification.

To ensure product safety, many large food processors require inspection of their suppliers, whether national or international, either through an in-house inspection process or from a third-party auditing company. Agreements such as Certificates of Analysis between the supplier and manufacturer concerning hazard analysis and preventive controls are also quite common. Additionally, the FDA creates memorandums of understanding (MOUs) with countries that wish to export certain types of food items to the USA. These MOUs, which generally relate to acidified and low-acid canned foods, juice, and seafood, generally state that the country in question will follow specific CFRs that apply to these types of food items.

Finished product form and intended use can also impact the hazard analysis. For example, the sale of raw unprocessed peas that may be ready to eat, canned shelled peas, and frozen shelled peas may all have the same hazard identified in the raw ingredient such as pesticides. If these same raw peas are processed in a different manner, however (such as canning), then other hazards, mainly *Clostridium botulinum*, now become significant and must have a preventive control in place. Thus, a hazard analysis will differ depending on the process involved to manufacture the food item and the intended use of the product, such as whether the product is ready-to-eat or requires further cooking by the consumer.

Food technology can also have a significant impact on applicable hazards within a process due to risks associated with the problems the technology was designed to solve. For example, reduced or modified atmosphere packaging increases shelf-life and improves the appearance of specific products such as smoked fish. However, by reducing oxygen in the package, the environment inside increases the potential concern for the growth of anaerobic pathogens due to the reduction in competitive organisms and the creation of a positive growth atmosphere if the product is temperature abused. Advances in technology have also increased the use of rework within the food manufacturing industry. The Code of Federal Regulations (Title 21, Chap. 229, Appendix B) defines rework as clean, unadulterated food that has been removed from processing for reasons other than insanitary conditions or that has been successfully reconditioned by reprocessing and that is suitable for use as food. An example is chocolate covering that overflows as candy is enrobed, and the overflow is remelted and reused. The incorporation of rework can solve economic issues related to food waste, but may introduce new challenges, namely, the ability to track the use of reworked product and/or ensure additional hazards are not introduced into the system or allowed to increase in intensity. So a new allergen hazard should be considered if the chocolate rework in the example above originally came into contact with peanuts in the candy and then was used on candy without peanuts.

Complex food distribution networks may increase the potential for abuse and system failures. Due to the increase in demand and distribution of ready-to-eat

refrigerated and/or frozen food items, many manufacturers rely on temperature as a control for both perishability and pathogen growth. Emphasis has increased on the cold distribution chain as a system for food safety control, which places the food manufacturer in the unique and challenging position of relying on the distribution and retail sectors to ensure proper temperature controls are in place and maintained when the product is no longer in the possession of the manufacturer.

Preventive Controls Associated with Manufactured Foods

A food safety system for food manufacturers must be built on a foundation of prerequisite programs, preventive control programs for identified significant hazards, and recall plans. These programs work together in harmony, although there is some overlap of program components.

Prerequisite Programs

Prerequisite programs are procedural measures that, when implemented, reduce the likelihood of a food safety hazard, but which may not be directly related to activities taking place during production (SQF 2009). Prerequisite programs are needed to sustain a hygienic environment and minimize hazards throughout the food chain. Additionally, prerequisite programs address the operational conditions that provide the foundation for the hazard analysis and critical control points (HACCP) system (FDA 1997).

Prerequisite programs generally pertain to standard operating procedures (SOPs), sanitation standard operation procedures (SSOPs), preventive maintenance programs, and employee training programs. SOPs and SSOPs are procedures used by food processors to help meet the requirements in the GMPs. The procedures are effective in controlling food safety hazards that might be associated with the processing environment but do not reach the level of risk necessary to be part of the preventive controls program. These prerequisite programs are seen as necessary and must be maintained at all times to actively limit the likelihood of hazards or contamination occurring within a facility. Additionally, a lack of solid prerequisite programs will consistently undermine the effectiveness of further preventive controls programs or HACCP-based systems.

FSMA has given the FDA the authority to propose a preventive controls regulation requiring manufacturers to have comprehensive, science-based preventive controls in place for all types of food manufacturing. The proposed rule, 21 CFR 117, will require food facilities to implement a written preventive controls plan that involves the following: (1) evaluating the hazards that could affect food safety; (2) specifying what preventive steps, or controls, will be put in place to significantly minimize or prevent the hazards; (3) specifying how the facility will monitor these

controls to ensure the controls are working; (4) maintaining routine records of the monitoring; and (5) specifying what actions the facility will take to correct problems that arise (FDA 2014b). Preventive controls under the proposed rule, 21 CFR 117, would include, as appropriate, (1) process controls, (2) food allergen controls, (3) sanitation controls, and (4) a recall plan. However, the preventive controls required would depend on which, if any, hazards are reasonably likely to occur given the type of food being processed along with the processing facility.

Process-related controls are designed to prevent, reduce, or eliminate all identified significant hazards during critical points within the production process and can be identified by measureable activities such as cooking/cooling time and temperature and pH/water activity monitoring. HACCP plans, whether currently mandated or voluntary, follow these same principles. Allergen controls are specifically designed to control or prevent cross-contamination of common allergens such as peanuts, tree nuts, milk, soy, wheat, eggs, fish, and crustacean shellfish and are often included within sanitation controls and process-related controls.

Sanitation controls are designed to control the sanitary condition of equipment and facilities within the food manufacturing environment where a biological or chemical hazard that affects the safety of a ready-to-eat product can occur.

Recall plans must be adequate and effective in order to remove potentially hazardous food items from the marketplace. Deviations in process controls, along with human error, contribute to the need to recall an unsafe food item. Traceability of incoming ingredients, along with traceability of a product once the product leaves the manufacturing facility, plays a critical role in an effective recall plan. The FDA Reportable Food Registry (RFR) is a regulatory tool designed to increase the efficiency of response to contamination incidents and to ensure that appropriate notifications are sent and that appropriate actions are taken throughout the distribution chain when there is a recall. The RFR requires processors that initiate a recall to contact the FDA within 24 h of the event. This requirement includes a recall based on an ingredient that was used in a finished food product, but was then recalled by the original ingredient supplier. More information about the RFR can be found on the FDA website: http://www.fda.gov/Food/ComplianceEnforcement/RFR/default.htm.

RecordKeeping

Currently, record keeping is only mandated in a few areas of the food processing world: seafood, meat, juice, acidified foods, and low-acid foods. Although not required, manufacturers not subject to a record keeping requirement generally maintain process records on a voluntary basis. FSMA proposes that an owner, operator, or agent of a facility must keep records related to the monitoring of preventive controls, corrective actions, verification, and training for qualified individuals. These records are the "proof" that identified hazards have been eliminated, prevented, or controlled. The food protection professional performs verification activities during an inspection by reviewing the facility's records.

Conclusion

Thorough product and process hazard analysis is critical to ensure that adequate preventive controls are in place that prevent unsafe food from entering into the market. The hazards involved in the manufacture of food can originate from many different sources including the raw ingredients, manufacturing processes being utilized, finished product, or methods of storage and distribution. Food safety hazards can be biological, chemical, radiological to list, or physical and should be evaluated based on the likelihood of significant occurrence and the severity of any resulting illness or injury. Common controls used in the manufacture of food include many overlapping elements of food safety systems including GMPs, prerequisite programs, preventive controls programs, and HACCP programs. Food safety preventive controls programs should ensure adequate monitoring activities, appropriate corrective actions, and effective recordkeeping and recall procedures.

Take-Home Message

Many different biological, chemical, radiological to list, and physical hazards exist in manufactured foods. Food safety hazards must be evaluated based on risk, severity, and likelihood within a specific food processing operation. Food protection professionals must take into account factors related to the globalization of our food supply, along with changes in technology, manufacturing methods, and trends in human consumption. The development of an effective food safety system takes into account GMPs, prerequisite programs, hazard analysis, and science-based preventive controls programs.

Activity

Chapter review questions.

1. Preventive controls are required by all food processors in the USA.

   (a) True
   (b) False

2. What are GMPs?

   (a) General manufacturing procedures
   (b) Good monitoring practices
   (c) Good manufacturing practices
   (d) Generic manufacturing policies

3. List the four items that are to be included in preventive controls as per FSMA:

4. Recordkeeping is mandatory for juice and acidified foods.

   (a) True
   (b) False

5. Preventive controls are designed to do what with significant hazards?

   (a) Prevent
   (b) Eliminate
   (c) Control
   (d) All of the above

6. Once harvested from a field, intact raw agricultural commodities are considered a manufactured or processed food.

   (a) True
   (b) False

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U.S. Food and Drug Administration (2014b) Background on the FDA Food Safety Modernization Act (FSMA). http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm239907.htm. Accessed 30 July 2014

Additional Resources

Food Safety Preventive Controls Alliance, part of the Institute for Food Safety and Health, Illinois Institute of Technology. http://www.iit.edu/ifsh/alliance/

FDA Fish and Fisheries Hazards and Controls Guidance – Fourth Edition (2011) http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Seafood/ucm2018426.htm

FDA Guidance for Industry Juice HACCP Hazards and Controls Guidance – First Edition (2004) http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Juice/ucm072557.htm

FDA Hazards and Controls Guide for Dairy Foods HACCP: http://www.fda.gov/downloads/food/guidanceregulation/haccp/ucm292647.pdf

USDA: FSIS Meat and Poultry Hazards and Controls Guide: http://www.fsis.usda.gov/OPPDE/rdad/FSISDirectives/5100.2/Meat_and_Poultry_Hazards_Controls_Guide_10042005.pdf

FDA Preventive Control Measures for Fresh & Fresh Cut Produce: http://www.fda.gov/Food/FoodScienceResearch/SafePracticesforFoodProcesses/ucm090977.htm

Answer Key

1. False
2. Good manufacturing practices
3. Process controls, food allergen controls, sanitation controls, and recall plans
4. True
5. All of the above
6. False

Chapter 20
Retail Foundations

Catherine Martin

Learning Objectives
- Define retail food establishment.
- Discuss the FDA Model Food Code.
- Identify the 5 CDC risk factors related to foodborne illness.
- Define active managerial control and associated activities.
- Identify the hazards and preventive controls that may be found at retail establishments.
- Discuss processing activities that occur in retail establishments, along with variance requirements.

Introduction

Inspections are conducted in food manufacturing facilities and retail food facilities on a daily basis by agencies across the US. While the approach to conducting an evaluation of a retail establishment is slightly different from the approach taken at a manufacturing facility, the end goal is still the same: ensuring a safe food supply. This chapter will explore the characteristics of a retail food establishment, the guidance and resources that can help a food protection professional (FPP) identify deficiencies within a retail establishment, the risk factors associated with retail establishments as determined by the Centers for Disease Control and Prevention (CDC), and the preventive controls that can be utilized by retail establishments to address those hazards. The chapter will also address various processes within a

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retail food establishment that may require a variance or Hazard Analysis and Critical Control Points (HACCP) plan.

Considering that there are over 1 million retail food establishments within the US (FDA 2014), there is a definitive role played by FPPs that help ensure the prevention of foodborne illness. To do this, there are approximately 3,000 agencies at the state, local, tribal, and territorial levels that have the jurisdiction and responsibility to evaluate retail establishments as regulatory entities (FDA 2014). This number does not include the FPPs at the industry and third-party level who also perform evaluations of retail facilities. Providing a safe food supply that is unadulterated, prepared in a clean environment, and not a contributing factor in disease outbreak is a shared responsibility of food industry members and regulatory agencies (FDA 2013a). This shared responsibility ensures that the consumer is provided a safe food supply that does not become a contributing factor in disease outbreak or in the transmission of a communicable disease.

With FPPs from the different sectors—regulatory and industry—working in the same retail environment, there is a need for consistent training and guidance for all FPPs in order to correctly identify the factors that control the safety of the food supply. This need for consistency is the primary reason for efforts toward implementing the Integrated Food Safety System (IFSS) here in the US including program standards for both manufacturing and retail food regulatory programs.

Retail Establishments

The 2013 US Food and Drug Administration (FDA) Model Food Code is the primary reference document applied to retail food establishments. The Food Code defines a retail food establishment as an operation that:

(a) Stores, prepares, packages, serves, and vends food directly to the consumer
(b) Relinquishes possession of food to a consumer directly or indirectly through a delivery service

Retail establishments include restaurants, catering operations, markets, grocery and convenience stores, vending machines, food banks, mobile carts and trucks, cafeterias, commissaries, and institutions with kitchens such as correctional facilities, health care facilities, and schools. Retail establishments may also include certain elements of the operation such as a transportation/delivery vehicle. Under the definitions in the 2013 Food Code, retail establishments do *not* include establishments that offer only prepackaged foods that are not time- or temperature-controlled (e.g., individual servings of dry snack food, cans of soft drinks, candy); food processing facilities; produce stands that only offer whole, uncut fresh fruits and vegetables; and certain types of kitchens in private homes, such as small family day-care providers or bed-and-breakfast operations (FDA 2013b).

The Food Code

At the turn of the twentieth century, scientists began to study the spread of disease related to milk products. These studies led to the conclusion that to prevent the spread of disease, food sanitation measures were needed from production to consumption. As a result, in 1924, the Grade A Pasteurized Milk Ordinance was published, which outlined acceptable sanitation and pasteurization practices that would help prevent foodborne illness in relation to the consumption of dairy products. Subsequently, the US Public Health Service published recommended model codes addressing various components of the retail food industry (FDA 2013c) such as restaurants, food and drink establishments, vending machines, foodservice operations, and retail food stores.

The first Model Food Code was published in 1993 and has been updated periodically based on advances in science and technology, most recently in 2013. The Food Code serves as a guidance document for FPPs in regulatory and industry that evaluate or work in retail food establishments. The Code provides practical, science-based guidance for controlling risks known to cause or contribute to foodborne illness outbreaks associated with retail and foodservice establishments and helps establishments develop/enhance employee training and quality assurance. As of 2012, all 50 states and 3 of 6 territories reported having retail codes patterned after the Food Code (FDA 2013d). Many states and territories have adopted various editions of the Food Code, while other states and territories have adopted only sections of different editions. A copy of the 2013 Food Code, along with all prior versions of the Code, can be downloaded from the FDA website: http://www.fda.gov/Food/GuidanceRegulation/RetailFoodProtection/FoodCode/ucm391534.htm.

The Food Code is not a federal law or regulation and is not preemptive. Rather, the Code represents FDA guidance for ensuring the safety of food at retail (FDA 2013c). Only by adoption by a state legislature, local agency, or tribal council does the Food Code become a law or regulation that all retail food industry participants within the particular state, local, territorial, or tribal jurisdiction must follow. However, jurisdictions may modify the Model Food Code language or may not include all of its components during the adoption process. In fact, some jurisdictions may have their own ordinances/regulations that are stricter than the provisions of the Model Food Code; as a result, FPPs need to be aware of the role played by the Model Food Code in the FPP's particular jurisdiction.

The content of the 2013 Food Code is laid out in specific, defined chapters. Annexes to the Code offer additional, more in-depth information to help the FPP. The contents of the 2013 Code are as follows:

- Chapter 1: Purpose and Definitions
- Chapter 2: Management and Personnel
- Chapter 3: Food
- Chapter 4: Equipment, Utensils, and Linens
- Chapter 5: Water, Plumbing, and Waste

- Chapter 6: Physical Facilities
- Chapter 7: Poisonous or Toxic Materials
- Chapter 8: Compliance and Enforcement
- Annex 1: Compliance and Enforcement
- Annex 2: References
- Annex 3: Public Health Reasons/Administrative Guidelines
- Annex 4: Management of Food Safety Practices—Achieving Active Managerial Control of Foodborne Illness Risk Factors
- Annex 5: Conducting Risk-Based Inspections
- Annex 6: Food Processing Criteria
- Annex 7: Model Forms, Guides, and Other Aids
- Summary: Summary of Changes in the FDA Food Code

All items noted in the Food Code are given a "rating" as to how that item relates to food safety. The type of rating applied is dependent on the version of the Code that the various agencies have adopted or used as a foundation for food safety laws. In versions of the Food Code prior to the 2009 edition, violations were designated as either *critical (C)* or *noncritical (NC)* depending upon the nature of the violation. A *critical* item was considered to be more likely to contribute to foodborne illness or pose an environmental health hazard as compared with a *noncritical* item, which usually pertained to the facilities and how the facilities were maintained. The *critical* items within the Food Code were marked with an asterisk (FDA 2005).

The 2009 edition of the Food Code changed the designation of violations from critical/noncritical to *priority* (*P*), *priority foundation* (*Pf*), and *core*. A *priority* item is directly related to eliminating, preventing, or reducing to an acceptable level hazards associated with foodborne illness or injury. *Priority* items have a measurable aspect, such as time and/or temperature, to control hazards. Cooking, reheating, cooling, and handwashing are examples of items that are designated *priority.* A *priority foundation* item is one that supports, facilitates, or enables one or more *priority* items. Through the use of the *priority foundation* items, the establishment attempts to control risk factors that contribute to foodborne illness. Included under *priority foundation* items are HACCP plans, recordkeeping, personnel training, infrastructure or necessary equipment, and labeling. *Core* items generally relate to general sanitation, operational controls, sanitation standard operating procedures (SSOPs), facilities or structures, equipment design, or general maintenance (FDA 2013b).

CDC Risk Factors

The Centers for Disease Control and Prevention (CDC) has identified five broad risk factors related to employee behaviors and preparation practices in retail and foodservice establishments. Epidemiological data on foodborne illness outbreaks

repeatedly show that these five major risk factors contribute to foodborne illness. The five factors include:

1. Food from unsafe sources
2. Inadequate cooking
3. Improper holding temperatures
4. Contaminated equipment
5. Poor personal hygiene (FDA 2013e)

Surveys conducted by FDA in 1998, 2003, and 2008 within retail food establishments helped confirm that reducing these five risk factors helped reduce the incidence of foodborne illness. The studies also showed that if retail establishments are *proactive* and implement food safety management systems, the establishments will prevent, eliminate, or reduce the risk factors (FDA 2013e).

The Food Code establishes five key public health interventions to control these risk factors. These interventions, which are covered in Chaps. 2 and 3 of the Code, include employee health controls, employee training, time and temperature parameters, and consumer advisories (FDA 2013e).

Active Managerial Control

Usually during inspections, violations are noted on an inspection/evaluation report, a time frame for correction is provided, and reinspections are conducted to verify compliance with existing codes and regulations. If recurring violations are present, the violations may be handled through enforcement activities such as fines, hearings, suspension of permits, or even closure of the establishment. This approach has been the traditional method of inspections by regulatory agencies and represents a reactive rather than a proactive approach to prevent violations from occurring in the first place. However, one way for operators to be proactive is to use a*ctive managerial control*, which is the purposeful incorporation of specific actions or procedures by industry management to attain control over foodborne illness risk factors. Active control embodies a *preventive*, rather than reactive, approach to food safety and involves a continuous system of monitoring and verification (FDA 2013e).

Elements of active managerial control may include the following:

- Certified food protection managers who have shown a proficiency in required information by passing a test that is part of an accredited program
- Standard operating procedures (SOPs) for critical operational steps in a food preparation process, such as cooling
- Recipe cards that contain the specific steps for preparing a food item and the food safety critical limits, such as final cooking temperatures, that need to be monitored and verified
- Purchasing specifications
- Equipment and facility design and maintenance

- Monitoring procedures
- Recordkeeping
- Employee health policies for restricting or excluding ill employees
- Manager and employee training
- Ongoing quality control and assurance
- Specific goal-oriented plans, like Risk Control Plans that outline procedures for controlling foodborne illness risk factors (FDA 2013e)

Hazards and Preventive Controls

Hazards must be identified in the retail food establishment in order to understand how to determine appropriate control measures for the hazard. There are over two hundred foodborne hazards known to cause foodborne illness, and these hazards are generally classified as either biological, chemical, radiological, or physical. Biological hazards including bacteria, viruses, and parasites and associated poisonous toxins are the cause of most foodborne illnesses. Chemical hazards can include cleaning solutions, pesticides, and major food allergens. Physical hazards are dangers posed by the presence of particles that are not supposed to be present in food, including glass, metal, bone, and hair (Linton 2014). Appendix A identifies some of the common biological hazards found at retail food establishments, the foods associated with the hazards, appropriate control measures, and the onset time, duration, and symptoms associated with the hazards. Appendix B displays common chemical hazards at retail (both naturally occurring and added), along with associated foods and control measures. Appendix C identifies the main physical hazards, along with their common sources.

Processing at Retail

Food prepared at retail used to be defined as consumer-sized portions created by the retail food establishment and sold to the consumer for immediate consumption either on-site or off-site such as in the consumer's home. However, advances in food technology have increased value to food products through special manufacturing/processing, and specialized food processing is now occurring at the retail level. Some of these processes now seen or being considered at retail include, but are not limited to:

- Cook-chill
- Vacuum packaging
- Sous vide—a process by which raw or partially-cooked food is vacuum packaged, cooked in the bag, rapidly chilled, and then refrigerated (FDA 2013f)
- Smoking and curing

- Canning-acid, acidified, and low-acid foods in hermetically-sealed containers that are shelf-stable
- Brewing, processing, and bottling alcoholic beverages, carbonated beverages, or drinking water
- Custom processing of animals (FDA 2013f)

Since there is now crossover occurring with retail establishments also performing activities that used to be delegated to food processing facilities, there is a need for guidance as to how this processing can be accomplished in a safe manner. Chapter 3 (Sect. 502.11) of the 2013 Food Code states that, in some cases, a retail establishment must obtain a *variance* in order to conduct certain activities. The Food Code defines a variance as a written document issued by the REGULATORY AUTHORITY that authorizes a modification or waiver of one or more requirements of this Code if, in the opinion of the REGULATORY AUTHORITY, a health HAZARD or nuisance will not result from the modification or waiver (FDA 2013b). According to Sect. 502.11, activities requiring a variance include, but are not limited to:

- Smoking food as a method of food preservation rather than as a method of flavor enhancement
- Curing food
- Using food additives or adding components such as vinegar as a method of food preservation rather than as a method of flavor enhancement or to render a food that the food is not so potentially hazardous (time/temperature control of safety food)
- Packaging time/temperature control for safety food using a reduced oxygen packaging method (except in specific instances as spelled out in the Code)
- Operating a life-support display tank to store or display shellfish offered for human consumption
- Custom processing animals that are for personal use as food, such as rabbit, duck, livestock, or wild animals taken via hunting or trapping that are not intended for retail sale
- Sprouting seeds or beans

Chapter 3 (Sect. 502.12) of the Food Code adds a requirement for an acceptable HACCP plan in place to control the biological hazards associated with reduced oxygen packaging. In many instances, a regulatory agency will require a retail food establishment to have in place a HACCP plan for all products produced before a variance will be granted.

In retail establishments, many products have been identified as a high-risk food due to the processing method or hazard associated with the food. In the case of these high-risk foods, special requirements or regulations, such as the Code of Federal Regulations (CFRs), must be met. Food items that fall under the purview of the CFRs include:

- Shelf-stable-acidified and low-acid food items in hermetically-sealed containers (21 CFR 114 & 21 CFR 113)
- Wholesale seafood and juice manufacturing (21 CFR 123 & 21 CFR 120)
- Wholesale meat production (Title 21 Food & Drugs, Chapter 12-Meat Inspection)

The wholesale seafood, juice, and meat items *require* HACCP plans, not just variances, as mandated by the various CFRs regulating this type of food production, no matter where the food item is produced.

Conclusion

The Food Code, which has been adopted in some part or in totality, in all 50 states and 3 of 6 territories, provides a scientifically-sound foundation for evaluating the retail segment of the food industry, and the Code is updated on a regular basis. With the identification of the 5 CDC Risk Factors, and the studies that show a reduction in foodborne illnesses when the risk factors are controlled, the FPP can help to prevent foodborne illness involving retail establishments. By identifying hazards and understanding how to control, eliminate, or reduce these hazards, foodborne illness or injury can be reduced or prevented. At the retail level, specialized processing is becoming more frequent. Obtaining a variance and having a HACCP plan are measures that help retail establishments address potential hazards and implement acceptable control measures associated with these specialized processes.

Take-Home Message

With the guidance provided by the scientifically-based Food Code, the FFP should be able to:

1. Identify the CDC risks factors and hazards associated with retail food establishments.
2. Understand control measures that help ensure food safety in the retail food environment.
3. Know when a specialized process requires a variance or HACCP plan to control potential hazards.

Activity

Select the designation that best applies to items 1–20.

A = Active managerial control
FC = Food Code
H = Hazard

R = Retail
RF = Risk factor
V = Variance

1. Piece of metal in food item
2. Commissary
3. Poor personal hygiene
4. Vacuum-packaged smoked fish
5. SOPs and SSOPs
6. Contaminated equipment
7. Adopted in some form by all 50 states and 3 of the 6 territories
8. Guidance
9. Grocery store
10. Norovirus
11. Improper holding temperatures
12. Food sold directly to consumer
13. Critical/noncritical
14. Firm being proactive versus reactive
15. Employee health policies
16. Vending machine
17. Food from unsafe food sources
18. Certified food safety manager
19. Allergens
20. Restaurant

Appendix A: Biological and chemical hazards found at retail

Hazard	Associated foods	Control measures	Onset time	Duration	Symptoms
Bacillus cereus (diarrheal)	Wide variety including milk, meats, vegetables, and fish	Cooking, cooling, cold holding, hot holding	6–15 h	24 h	Abdominal pain, watery stool
Bacillus cereus (emetic)	Rice products and starchy foods, such as potatoes, pasta, cheese, soups, sauces, casseroles, pastries, puddings, and salads	Cooking, cooling, cold holding, hot holding	0.5–6 h	<24 h	Nausea, vomiting and/or diarrhea
Campylobacter jejuni	Poultry, raw milk	Cooking, handwashing, prevention of cross-contamination	2–5 Days	2–10 Days	Watery or bloody diarrhea, fever, abdominal pain, nausea, headache, and muscle pain
Clostridium botulinum	Vacuum-packed foods, reduced oxygen packaged foods, under-processed canned foods, garlic-in-oil mixtures, time/temperature-abused baked potatoes/sautéed onions	Thermal processing (time + pressure), cooling, cold holding, hot holding, acidification and drying, etc.	18–36 h	Days to months (possibly fatal)	Weakness, vertigo, followed by double vision and progressive difficulty speaking and swallowing. May include difficulty breathing, muscle weakness, abdominal distention, and constipation
Clostridium perfringens	Cooked meat and poultry, cooked meat and poultry products including casseroles and gravies	Cooling, cold holding, reheating, hot holding	8–22 h	24–48 h	Diarrhea and intense abdominal pain
E. coli O157:H7 (shiga-toxin producing)	Raw ground beef, raw seed sprouts, raw milk, unpasteurized juice, foods contaminated by infected food workers via fecal-oral route	Cooking, no bare hand contact with ready-to-eat foods, employee health policy, handwashing, prevention of cross-contamination, pasteurization, or treatment of juice	2–9 Days	5–10 Days	Diarrhea, severe abdominal pain, bloody diarrhea, and hemolytic uremic syndrome

Listeria monocytogenes	Raw meat and poultry, fresh soft cheese, pate, smoked seafood, deli meats, deli salads	Cooking date marking, cold holding, handwashing, prevention of cross-contamination	Unknown, probably greater than 12 h for enteric phase, 3–21 days for septic phase	Weeks	Sepsis (nonspecific flu) may have gastrointestinal symptoms of nausea, vomiting and diarrhea, pregnancy infections
Salmonella spp.	Meat and poultry, seafood, eggs, raw seed sprouts, raw vegetables, raw milk, unpasteurized juice	Cooking, use of pasteurized eggs, employee health policy, no bare hand contact with ready-to-eat foods, handwashing, pasteurization or treatment of juice	6–48 h	4–7 Days	Abdominal pain, headache, nausea, vomiting, fever, diarrhea
Shigella spp.	Raw vegetables and herbs, other foods contaminated by infected workers via fecal-oral route	Cooking, no bare hand contact with ready-to-eat foods, handwashing, employee health policy	12–50 h	4–7 Days	Abdominal pain, cramps, diarrhea, fever, vomiting, blood, and pus or mucus in stool
Staphylococcus aureus	Ready-to-eat foods touched by bare hands after cooking and further time/temperature-abused	Cooling, cold holding, hot holding, no bare hand contact with ready-to-eat foods, handwashing	1–6 h	24–48 h	Nausea, vomiting, retching, abdominal cramping, changes in blood pressure and pulse, prostration
Vibrio vulnificus	Seafood, shellfish	Cooking, approved source, prevention of cross-contamination	1–7 Days	2–8 Days	Gastroenteritis; individuals with diabetes, cirrhosis, or leukemia, or those who take immunosuppressive drugs or steroids are particularly susceptible to primary septicemia

(continued)

Appendix A (continued)

Hazard	Associated foods	Control measures	Onset time	Duration	Symptoms
Yersinia enterocolitica	Raw milk and unchlorinated water	Follow proper handwashing procedures; use proper cooling, cooking, and reheating temperatures; and avoid cross-contamination. Pasteurization will eliminate *Yersinia*	24–48 h	1–3 Weeks	Diarrhea and/or vomiting, fever, and abdominal pain, which mimics appendicitis
Hepatitis A	Shellfish, any food contaminated by infected worker via fecal-oral route	Approved source, no bare hand contact with ready-to- eat foods, handwashing, employee health policy, minimizing bare hand contact with food that is not ready to eat	10–50 Days (mean of 30 days)	Weeks to months	Fever, nausea, anorexia, abdominal discomfort, jaundice
Hepatitis E	Shellfish, any food contaminated by infected worker via fecal-oral route	Approved source, no bare hand contact with ready-to-eat foods, handwashing, employee health policy, minimizing bare hand contact with food that is not ready to eat	15–65 Days	Weeks to months	Fever, nausea, anorexia, abdominal discomfort

Rotaviruses, noroviruses, reoviruses	Any food contaminated by infected worker via fecal-oral route	No bare hand contact with ready-to-eat foods, handwashing, employee health policy, minimizing bare hand contact with food that is not ready to eat	24–48 h	24–60 h	Nausea, vomiting, diarrhea, malaise, abdominal pain, headache, and fever
Trichinella spiralis (parasite)	Pork, bear, and seal meat	Cooking	1–2 Days/2–8 weeks	Months	Nausea, diarrhea, vomiting, fatigue, fever, abdominal discomfort, headaches, fevers, chills, cough, eye swelling, aching joints and muscle pains, itchy skin, diarrhea, or constipation
Anisakis simplex (parasite)	Various fish (cod, haddock, fluke, pacific salmon, herring, flounder, monkfish)	Cooking, freezing	~2 Weeks	3 Weeks	Extreme pain

Source: North Carolina Department of Health and Human Services, Environmental Health Section, Division of Public Health. http://ehs.ncpublichealth.com/faf/food/fd/docs/BiologicalandChemicalHazardsFoundatRetail.pdf

Appendix B: Common chemical hazards at retail (naturally-occurring and added), along with their associated foods and control measures (FDA 2013e)

Naturally-occurring chemical hazard	Associated foods	Control measures
Scombrotoxin	Tuna fish, mahi-mahi, bluefish, anchovies bonito, mackerel; also found in cheese	Check temperatures at receiving; store at proper cold holding temperatures; buyer specifications: obtain verification from supplier that product has not been temperature-abused prior to arrival in facility
Ciguatoxin	Reef finfish from the extreme southeast USA, Hawaii, and tropical areas; barracuda, jacks, king mackerel, large groupers, snappers	Ensure finfish have not been caught: • Purchase fish from approved sources • Fish should not be harvested from an area that is subject to an adverse advisory
Tetrodotoxin	Puffer fish (fugu, blowfish)	Do not consume these fish
Mycotoxins Aflatoxin Patulin	Corn and corn products, peanuts and peanut products, cottonseed, milk, tree nuts such as Brazil nuts, pecans, pistachio nuts, and walnuts; other grains are susceptible but less prone to contamination Apple juice products	Check condition at receiving; do not use moldy or decomposed food Buyer specification: obtain verification from supplier or avoid the use of rotten apples in juice manufacturing
Toxic mushroom species	Numerous varieties of wild mushrooms	Do not eat unknown varieties or mushrooms from unapproved sources
Shellfish toxins Paralytic shellfish poisoning Diarrhetic shellfish poisoning Neurotoxin shellfish poisoning Amnesic shellfish poisoning	Molluscan shellfish from northeast US coastal regions; mackerel, viscera of lobsters and Dungeness, tanner, and red rock crabs Molluscan shellfish in Japan, western Europe, Chile, New Zealand, eastern Canada Molluscan shellfish from the Gulf of Mexico Molluscan shellfish from the northeast and northwest coasts of North America; viscera of Dungeness, tanner, and red rock crabs and anchovies	Ensure that molluscan shellfish are from an approved source and properly tagged and labeled

Pyrrolizidine alkaloids	Plant food containing these alkaloids. Most commonly found in members of the Boraginaceae, Compositae, and Leguminosae families	Do not consume food or medicinals contaminated with these alkaloids
Phytohaemagglutinin	Raw red kidney beans (undersoaked beans may be more toxic than raw beans)	Soak in water for at least 5 h. Pour away the water. Boil briskly in freshwater, with occasional stirring, for at least 10 min
Allergens	Foods containing or contacted by milk, egg, fish, crustacean shellfish, tree nuts, peanuts, soybeans, or wheat	Use a rigorous sanitation regime to prevent cross-contact between allergenic and nonallergenic ingredients

Added chemical hazard	Associated foods	Control measures
Environmental contaminants: pesticides, fungicides, fertilizers, insecticides, antibiotics, growth hormones	Any food may become contaminated	Follow label instructions for use of environmental chemicals. Soil or water analysis may be used to verify safety
PCBs	Fish	Comply with fish advisories
Prohibited substances (under 21 CFR 189)	Numerous substances are prohibited from use in human food; no substance may be used in human food unless it meets all applicable requirements of the FD&C Act	Do not use chemical substances that are not approved for use in human food
Toxic elements/compounds, mercury	Fish exposed to organic mercury: shark, tilefish, king mackerel, and swordfish. Grains treated with mercury-based fungicides	Pregnant women/women of childbearing age/ nursing mothers and young children should not eat shark, swordfish, king mackerel, or tilefish because they contain high levels of mercury. Do not use mercury-containing fungicides on grains or animals
Copper	High-acid food and beverages	Do not store high-acid foods in copper utensils; use backflow prevention device on beverage vending machines
Lead	High-acid food and beverages	Do not use vessels containing lead

(continued)

Appendix B (continued)

Added chemical hazard	Associated foods	Control measures
Preservatives and food additives Sulfiting agents (sulfur dioxide, sodium and potassium bisulfite, sodium and potassium metabisulfite	Fresh fruits and vegetables, shrimp, lobster, wine	Sulfiting agents added to a product in a processing plant must be declared on labeling Do not use on raw produce in food establishments
Nitrites/nitrates Niacin	Cured meats, fish, any food exposed to accidental contamination, spinach Meat and other foods to which sodium nicotinate is added	Do not use more than the prescribed amount of curing compound according to labeling instructions. Sodium nicotinate (niacin) is not currently approved for use in meat or poultry with or without nitrates or nitrites
Flavor enhancers (monosodium glutamate, or MSG)	Asian or Latin American food	Avoid using excessive amounts
Chemicals used in retail establishments (lubricants, cleaners, sanitizers, cleaning compounds, and paints)	Any food could become contaminated	Address through SOPs for proper labeling, storage, handling, and use of chemicals; retain Material Safety Data Sheets for all chemicals

Appendix C: Main materials of concern as physical hazards and common sources (Source: FDA 2013e)

Physical hazard	Injury potential	Sources
Glass fixtures	Cuts, bleeding; may require surgery to find or remove	Bottles, jars, lights, utensils, gauge covers
Wood	Cuts, infection, choking; may require surgery to remove	Fields, pallets, boxes, buildings
Stones, metal fragments	Choking, broken teeth, cuts, infection; may require surgery to remove	Fields, buildings, machinery, wire, employees
Insulation	Choking; long-term if asbestos	Building materials
Bone	Choking, trauma	Fields, improper plant processing
Plastic	Choking, cuts, infection; may require surgery to remove	Fields, plant packaging materials, pallets, employees
Personal effects	Choking, cuts, broken teeth; may require surgery to remove	Employees

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Answer Key

1. H
2. R
3. RF
4. V
5. A
6. RF
7. FC
8. FC
9. R
10. H
11. RF
12. R
13. FC
14. A
15. A
16. R
17. RF
18. A
19. H
20. R

Chapter 21
Food Defense Awareness

Art Johnstone, Ron Klein, Steven Wells, Ned Mitenius, and Sharon Thompson

Learning Objectives

- Provide examples of intentional contamination of the food supply.
- Examine vulnerabilities inherent in the food supply that could be exploited by terrorists or criminals.
- Define risk and threat with regards to intentional acts of contamination.
- Review major actions by government and industry to reduce risk from intentional contamination.
- Discuss tools available to help facilities create a Food Defense Plan.

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Introduction

In 2003, the Department of Homeland Security (DHS) issued a Presidential Directive (HSPD-7), which categorized the assets and systems most important to the social and economic viability of the USA into a list of critical infrastructure and key resource sectors (Bush 2003). Both the food and agriculture sectors, which produce an abundance of products for the national and global markets, were identified as part of this critical infrastructure. The US restaurant industry alone is projected to generate close to $700 billion in sales in 2014 or 4 % of the US gross domestic product (NRA 2014); farm assets in 2012 were valued at $2.8 trillion (USDA ERS 2014a), and the $141.3 billion of agricultural exports in 2012 produced a total domestic economic output of more than $320 billion and required 929,000 full-time civilian jobs (USDA ERS 2014b). These statistics indicate that a successful, wide-ranging terrorist attack against a high-profile target within the food and agriculture sector could have a significant impact on the US economy and public health. This chapter will explore how the food and agriculture sector may be vulnerable to terrorist attacks, the types of attacks possible, and preventive actions that can be considered.

Attacks on the Food Supply

1984, The Dalles, Oregon

In 1981, in a rural area of the Pacific Northwest called The Dalles, Oregon, a religious group known as the Rajneeshees purchased a 64,000-acre ranch. The leader of the group, the Bhagwan Shree Rajneesh, had assembled a significant following of 7,000 members (Snow 2003). By 1984, the religious commune had grown to almost 15,000 people and conflicts with local residents reached a high level, overloading the community's infrastructure and leading to clashes over building permits, zoning issues, and other government functions (FitzGerald 1987).

Within the Rajneeshee community, some of the group leaders began formulating a plan to gain control of the local government, thus removing the growth restrictions they had been facing. A plan led by two nurses running the group's health clinic was put in place to contaminate the local food supply with a pathogen just before an upcoming election, with the intent to cause local residents to become ill and prevent the residents from voting. This approach would give the Rajnees hees the opportunity to win enough seats to control the local government.

Using their public health credentials, the two nurses ordered several pathogens from a biological supply company (Miller et al. 2002). The nurses decided to use *Salmonella typhimurium*, a pathogen that could survive and reproduce in many different food mediums and cause widespread illness, but was unlikely to cause fatalities.

In September 1984, as a trial run for an upcoming election, the pathogen was introduced into the salad bars of ten local restaurants, allegedly through spraying the pathogen onto salad bar items and mixing the pathogen into salad dressings. Isolated instances of illness quickly became a mass epidemic affecting more than 750 individuals in the small community. The initial investigation concluded that the outbreak was naturally occurring (no human intent). However, the increased scrutiny prevented the group from intentionally introducing pathogens to impact the upcoming election (Urbano 2006).

In October 1985, federal officials entered the compound and discovered vials of *Salmonella* bacteria. Analysis confirmed the bacteria as the same strain found in the 1984 outbreak (Miller et al. 2002). Later that month, the two nurses were arrested in Germany, extradited, and eventually convicted of attempted murder, assault, and other crimes (Carter 1990).

In an age before increased fears of terrorism, there was virtually no national media coverage of this event, which is now considered by many experts as the first significant bioterrorism attack on American soil and the largest in US history. State and federal officials requested that details of the incident not be published in the Journal of the American Medical Association (JAMA) for 12 years due to fears of copycat crimes, and JAMA complied (Garrett 2000).

The implications of The Dalles event are now clear. Using readily available pathogens and without a great deal of sophistication, a group was able to enter several restaurants, contaminate the food, leave without being detected, and sicken hundreds of people. Alarmingly, the nurses behind the Rajneeshee attack had purchased several more dangerous infectious agents, including those for typhoid fever, tularemia, and *Shigella*, but had decided not to use these agents since fatalities may have attracted unnecessary attention (Miller et al. 2002).

In the three decades since The Dalles incident, little has changed that would prevent a determined individual or group from initiating a similar attack. Although our government would likely be more prepared to respond to a suspected intentional act and perhaps would be quicker at tracing the source and perpetrators, the government would likely not be able to prevent such an attack from being carried out. Dangerous pathogens, many of which can be obtained and cultured from natural sources, are still widely available. Our food supply, especially in retail environments, is still largely unprotected. Workers in the food industry are often transitory, with little or no significant vetting before employment. Additionally, the public would likely not be aware of an intentional attack on the food supply until innocent people began showing signs of illness and the foodborne illness was confirmed by investigators through laboratory results.

The list of biological agents, chemicals, or radiological agents that could be used for terrorist purposes is extensive, and many of these agents can be purchased or formulated with minimal effort or skill. There are reference guides readily available on the Internet that provide information on the acquisition, preparation, and dissemination of biological and chemical agents. Examples include readily-available commodity chemicals obtained through a chemical supply house such as nitric acid, ethanol, and sulfuric acid; chemical warfare agents such as choking agents (chlorine

and phosgene gas); blister agents (sulfur mustard and nitrogen mustard); nerve agents; incapacitating agents (mace and tear gas); toxic industrial chemicals such as organophosphate pesticides; and biological agents and toxins (poisonous substances produced from a living animal, plant, or microbe and, in some cases, altered to have a greater toxic effect, such as ricin extracted from castor beans) (Department of Justice 2014).

Additional examples of attacks upon the food supply in the US include an incident in 2011 where a woman in Kansas was sentenced to federal prison for putting poison in salsa served to patrons while working as a waitress at a Mexican restaurant. Approximately 50 patrons, ranging from young children to senior citizens, suffered illness from the salsa (Department of Justice 2011). In December 2002, a Michigan supermarket employee poured a container of pesticide containing nicotine sulfate into a grinder full of approximately 250 pounds of ground beef. Soon afterward, reports of ill consumers associated with the purchase of the ground beef were identified (Dasenbrock et al. 2005).

Attacks on the food supply are also an international issue. In January 2003, militants were arrested in Britain for plotting to lace the food supply with ricin on at least one British military base (Risen and Van Natta 2003). In September 2002, a snack shop owner in China poisoned food in a competitor's shop with a rodenticide, causing dozens of deaths (CDC 2003).

Vulnerabilities Inherent in the Food Supply that Could Be Exploited by Terrorists or Criminals

The food supply in the USA, as in most parts of the world, has many characteristics that could be targeted or exploited by a terrorist or a criminal. These potential vulnerabilities include the following:

- Traditionally open and unsecured agricultural and manufacturing operations
- Modern manufacturing methods based on large batches and homogenous mixing
- Modern distribution methods including rapid, just-in-time, national, and international distribution
- The global and domestic food transportation system that is inter-connected and relatively unsecure
- A complex, interconnected, global food supply
- Many fresh products that are rapidly consumed
- A relatively high background level of foodborne illnesses that could mask an intentional attack
- The likelihood of a time lag between a contamination event and incident reporting
- Difficulty detecting non-naturally occurring agents in various foods
- Small events that can have a disproportionate psychological and economic impact

Traditionally Open and Unsecured Agricultural and Manufacturing Operations

In our agrarian past, small family farms, while not well guarded, could at least be watched from the farmhouse. As farms grew in size, the ability to fence the farm or keep the farm under observation became increasingly difficult. Modern manufacturing operations can range from the size of a garage or a small kitchen operation to huge industrial campuses that cover thousands of acres. As these operations have grown, however, the focus has been on the efficient flow of materials and people rather than on restricting access. Even today, employees are commonly able to access all portions of a facility.

Modern Manufacturing Methods Based on Large Batches and Homogenous Mixing

In the quest for a uniform and desirable consumer experience, modern food manufacturing typically uses homogenous mixing. Large batch sizes have also become common to improve operating efficiency. A criminal or terrorist could successfully contaminate a large quantity of food products with a single contamination event by taking advantage of these characteristics of modern food production.

Modern Distribution Methods Including Rapid, Just-In-Time, National, and International Distribution

Many food manufacturers have consolidated into regional or national centers to maximize operational efficiency. However, this consolidation can lead to a single contamination event spreading quickly across many states. For example, in 2009, peanut products from single locations in Georgia and Texas were implicated in a national outbreak of *Salmonellae* that impacted virtually every state in the USA. At least 714 individuals in 46 states were sickened by *Salmonella* linked to these peanut products (CDC 2012a).

Food Transportation System That Is Interconnected and Relatively Unsecure

Food chain vulnerability assessments conducted by the US Department of Agriculture Food Safety and Inspection Service (USDA FSIS) for meat and poultry highlighted food transportation as one of the key areas of vulnerability. Issues that have

been raised include the lack of a standard use of seals, a failure of the transportation industry to report suspected issues, and concerns related to personnel charged with handling and/or transporting food. In fact, the General Accounting Office has estimated that over 80 % of cargo theft at port facilities is perpetrated by personnel whose employment gives them direct access to the cargo.

A Complex, Interconnected, Global Food Supply

As our manufacturing operations have become more centralized, the operations have become less reliant on local ingredients and components. Increasingly, those ingredients and components are sourced globally to reduce costs and improve availability. The Institute of Medicine of the National Academies illustrates a "well-traveled salad" with vegetables, fruit, cheese, and dressing sourced all over the world. As the source of ingredients moves further around the globe, assurance of the safety of these ingredients by the end food product manufacturer becomes more difficult to achieve (Institute of Medicine 2014). For example, a 2009 outbreak of *Salmonella* Montevideo caused by contaminated imported black and red pepper used in the production of Italian-style meats in the US caused 272 people in 44 states to become ill (CDC 2012b).

Many Fresh Products that Are Rapidly Consumed

Rapid consumption of some products, either due to short shelf-life or high turnover, can increase the impact of an intentional contamination. In this case, the contaminated product is largely consumed before any contamination can be detected and prior to any remaining product being removed from distribution channels. Value-added produce and milk are examples of short shelf-life products. Bottled water, while it does not have a short shelf-life, is rapidly consumed and therefore similarly vulnerable. In Italy in 2003, bottled water was injected with bleach or acetone, which resulted in copycat contaminations in 20 different cities (CNN 2003). The perpetrators of this act have still not been identified.

Relatively High Background Level of Foodborne Illnesses

There are a number of naturally-occurring agents that cause unintentional food contamination events, like *E. coli, Salmonella*, and *Listeria*. In fact, CDC estimates that each year in the US 48 million people get sick, 128,000 are hospitalized, and 3,000

die due to foodborne illness (CDC 2014). These numbers show how a naturally-occurring contamination can easily "mask" an intentional event, at least until a detailed investigation is conducted.

The Likelihood of a Time Lag Between a Contamination Event and Incident Determination and Reporting

Unless someone is caught in the act of contaminating food, there can be a considerable time lag before an intentional contamination becomes evident. The contaminated food must be distributed and consumed, and generally enough people need to become ill in order to suspect a possible contamination. Finally, an investigation to determine the cause of the contamination could take weeks or even months to complete, which could allow terrorists or criminals to disappear.

Difficulty Detecting Non-Naturally Occurring Agents in Various Food Matrices

Unfortunately, there are many agents that could be used to intentionally contaminate the food supply for which food is not normally tested. Testing for even one agent would involve differing sets of protocols depending on the food item (milk, ground meat, cooked vegetables, etc.); in fact, testing protocols for many types of food items have not yet been established. The fact that reliable and cost effective testing methodology for the majority of these agents is not available for food products can make the food supply a desirable target for intentional contamination.

Small Events that Can Have Disproportionate Psychological and Economic Impact

A small contamination of the food supply can have a large economic impact, even if the health impact is modest. This effect is based partly on public fear that if one product can be contaminated, any product can be contaminated. To illustrate, in September of 1982, Extra-Strength Tylenol capsules containing potassium cyanide killed seven people, including a 12-year-old child. Tampered bottles were discovered at six stores in the Chicago area (Saltzman 2009). The media attention was intense, leading to nationwide panic and fear, and resulted in the product being pulled from store shelves and a drop in sales. In 1989, the *threat* of cyanide in Chilean grapes stopped imports into the USA. Some reports indicate that inspectors found only three suspicious grapes: two had puncture marks and white rings, and a third was slashed. The incident cost Chile $300 million in lost revenue (Volokh 1996).

Risk and Threat With Regard to Intentional Acts of Contamination

A major intentional food contamination event is generally considered a low or very-low probability and a high or very-high consequence scenario. *Low probability* means the event probably will not happen in any given city or state or affect any given company or industry. However, if a major intentional food contamination event does occur, *high consequences* can be expected, including illnesses or deaths. Such an event could cause high levels of fear and uncertainty, significant economic damage, and loss of confidence in the food supply and government.

A number of approaches are used to evaluate "relative risk," without universal understanding and consensus definitions. A government or multinational organization may wish to evaluate relative risk by comparing different food commodities, ingredients, or supply chains, while an individual manufacturing facility may wish to evaluate relative risk by examining all components within the entire production facility. The purpose of any of these approaches is to understand "relative risk" so that preventive and mitigation measures can focus on the areas of highest priority.

One assessment tool associated with determining risk is CARVER + Shock, which addresses the following elements:

- *Criticality*: the economic and public health impact of an attack
- *Accessibility*: the ease by which someone with harmful intent can get into a facility
- *Recuperability*: the ability of a system to recover from an attack
- *Vulnerability*: the ease of carrying out an attack
- *Effect*: the amount of direct loss from an attack as measured by loss of production
- *Risk*: the ease of identifying a target

The CARVER tool also evaluates another attribute—the combined health, economic, and psychological impact of an attack, or its *shock* (FDA 2007). The psychological impact of an attack tends to be greater if a number of deaths are involved or if the target has cultural or historical importance. The Food Defense Plan Builder software (discussed in more detail later in this chapter) uses a light version of the CARVER attributes, *accessibility* and *vulnerability,* to assess risk. Additionally, some practitioners utilize the Hazard Analysis and Critical Control Points (HACCP) concepts of hazard, probability, and severity to assess risk.

Another way to assess relative risk is to look at the *vulnerability* of industry to be the target of an attack, along with the *threat* of an intentional act of contamination. *Vulnerability* can be further understood by looking at the factors that can contribute to a successful contamination (without being detected) and the relative impact of that contamination. Many of the vulnerabilities described in the previous section can be considered at either the commodity level or the unit operation level, including large batch sizes, uniform mixing, and rapid consumption. Additional factors

such as the ease of gaining access to a specific target can also increase vulnerability. A manufacturer can have the most impact by reducing its *vulnerability*, thereby making the manufacturing operations a less desirable target.

Threat can be defined as *capability* multiplied by *intent. Capability* can vary depending on the perpetrator. A disgruntled employee will have a different capability than a well-organized terrorist cell. Intelligence, military, and police organizations can reduce the capability of individuals to carry out an attack. *Intent* can vary with the goals of the perpetrator and also certain aspects of the food operation. A nationally-recognized brand or food for a specific population might warrant heightened attention and intent from a potential perpetrator. Foreign and economic policies may be able to impact *intent*, at least over time, while good company policies can reduce the *intent* of employees to do harm (i.e., no disgruntled employees).

Major Actions by Government and Industry to Reduce Risk and Protect Consumers, Industry, and Economic Stability

There have been a number of major actions taken by government and industry—largely in response to September 11, 2001—to reduce the risk of intentional contamination of the food supply. The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act) directed the US Food and Drug Administration (FDA) to take steps to protect the public from a threatened or actual terrorist attack on the US food supply and other food-related emergencies. To carry out certain provisions of the Bioterrorism Act, the FDA established regulations requiring that (1) food facilities register with FDA and (2) the FDA be given advance notice on shipments of imported food (before arriving at port). These regulations became effective in December, 2003.

In January of 2004, Homeland Security Presidential Directive 9 (HSPD-9) created a policy to defend the food and agriculture sectors against terrorist attacks, disasters, and emergencies. Specific provisions of HSPD-9 include:

- Developing awareness and early warning capabilities to recognize threats
- Mitigating vulnerabilities at critical production and processing points
- Enhancing screening procedures for domestic and imported products
- Enhancing response and recovery procedures

HSPD-9 also increased funding for the creation of the Food Emergency Response Network (FERN), a national interconnected laboratory network for food that integrates existing federal, state, and local laboratory resources, utilizes standardized diagnostic protocols and procedures, and is able to respond to emergencies involving biological, chemical, or radiological contamination of food. The FERN structure is organized to ensure interagency participation and cooperation.

In August of 2005, the Strategic Partnership Program Agroterrorism (SPPA, http://www.fda.gov/Food/FoodDefense/FoodDefensePrograms/ucm080836.htm) was created involving DHS, USDA, FDA, the Federal Bureau of Investigation (FBI), private industry, trade associations, and states. Efforts of the SPPA initiative from 2005 to 2008 included:

- Identifying indicators of planning for an attack
- Developing mitigation strategies to reduce the threat of or prevent an attack
- Validating US government assessments of the food and agriculture sectors
- Gathering information to enhance existing tools used by both industry and government

The 2011 Food Safety Modernization Act (FSMA) contains various provisions that impact food defense. Section 108 of the new law addresses a series of national agriculture and food defense goals (preparedness, detection, emergency response, and recovery). FSMA adds a new Section 418 to the Food, Drug, and Cosmetic Act requiring facilities to perform a hazard analysis and implement a preventive controls plan. FSMA requires the owner, operator, or agent in charge of a facility to identify and implement preventive controls to provide assurances that (1) hazards identified in the hazard analysis are significantly minimized or prevented and (2) hazards that may be intentionally introduced are significantly minimized or prevented. FSMA also contains a requirement that domestic and foreign facilities that manufacture, process, pack, or hold food have a written defense plan that addresses significant vulnerabilities in the facility's food operations (FDA 2014a). Proposed rules to implement these requirements are still under consideration by FDA. Additionally, FSMA calls on FDA to carry out a vulnerability assessment of the food system, determine the mitigation strategies related to intentional adulteration, and enact appropriate regulations. These regulations are to specify appropriate science-based mitigation efforts to protect the food supply and will only apply to food at a high risk for intentional adulteration, as determined by the FDA and DHS. With the exception of dairies, these requirements will not apply to farms.

In compliance with Section 106 of FSMA, FDA released an analysis of 25 completed Food Defense Vulnerability Assessments. This analysis classified food-processing steps into the following activity types: (1) coating/mixing/grinding/rework, (2) ingredient staging/prep/addition, (3) liquid receiving/loading, and (4) liquid storage/hold/surge tanks. This information was released so that industry could map processing steps into activity types, identify any mitigation strategies associated with those activity types, and then conduct audits of those strategies.

Tools Available to Help Build a Food Defense Plan

The overall goal of food defense is to reduce the possibility of an attack on any farm, wholesale or retail food establishment, means of transportation, storage facility, etc., to the lowest level possible. Therefore, having a plan in place that

promotes early detection of a terrorist attack, rapid response, quick resolution, and rapid recovery is vital. Accomplishing this goal includes the following steps: assessment of vulnerabilities, prioritization of vulnerabilities, and development of a defense plan and mitigation strategy.

An in-depth assessment of vulnerabilities can be aided by a process or operational flow diagram of all steps involved in producing the end product. Food protection professionals (FPPs) should rely on trusted employees with a thorough knowledge of all aspects of production—from receiving to storage to shipping. Vulnerabilities can be prioritized through a scoring system based on the CARVER + Shock analytical tool. Once the vulnerability assessment is completed, a mitigation plan can be developed to address the findings, based on availability of time and resources.

Food and Agriculture Sector Criticality Assessment Tool (FASCAT) and CARVER + Shock

The FASCAT methodology was developed by the National Center for Food Protection and Defense for use in the food and agriculture sector and shares similar principles with CARVER + Shock in evaluating vulnerabilities or risks related to a potential attack or other catastrophic event. The project objective was to conduct statewide risk assessments for the purpose of identifying critical infrastructure and key resources in the food and agriculture sectors of each state. The project emphasized the identification, prevention, protection, and recovery of resources from potential terrorist attacks or wide-ranging natural disasters such as hurricanes and floods. The assessment process includes the consideration that terrorists could use agriculture and food assets as either targets or weapons with the potential goal(s) of disrupting the food supply, causing economic ruin, and/or human death/illness. DHS, however, has currently discontinued the FASCAT project.

The CARVER + Shock tool evaluates individual facilities or assets for vulnerabilities and prioritizes these vulnerabilities using a scoring system. In fact, FDA currently uses CARVER + Shock as the agency's vulnerability assessment tool (FDA 2014b). The scoring system for each attribute (criticality, accessibility, recuperability, vulnerability, effect, recognizability and shock) is from one (1) to ten (10), with one (1) being the least severe and ten (10) the most severe. The lower the score, the less attractive a target is to attack.

The major difference between FASCAT and CARVER + Shock is that the former is designed to assess risks, threats, and consequences associated with commodities/systems on a statewide level basis (e.g., statewide dairy, swine, beef cattle, slaughter, food processing, etc.) and cannot be used for individual facility analysis, while CARVER + Shock can be used effectively to evaluate specific facility or operation vulnerabilities.

Other Assessment Tools

A Hazard Analysis and Critical Control Points (HACCP) system—the topic of Chap. 11 of this book—is used primarily by the food industry to identify and prevent the accidental contamination/adulteration of specific food products by biological, chemical, radiological, and physical hazards. HACCP plans are required in all wholesale meat, poultry, and egg processing facilities that are regulated by USDA FSIS. Likewise, the FDA mandates the use of HACCP principles in the preparation/packaging of fish, seafood, and juice products. However, HACCP is designed to prevent *accidental* contamination, as opposed to *intentional* contamination or adulteration of food products. As a result, HACCP is not recommended for use in developing a Food Defense Plan.

Operational Risk Management (ORM) assesses risk through a process-based approach.

Users of ORM understand that operational mistakes and errors have their origins in the design of the system (i.e., people, machines, plant environment, and management). The first step when conducting ORM is to identify the risks for each activity or step in the process of food preparation. Facilities generally list the sequence for food preparation to understand the flow of events in food production (FDA 2001).

In general, the ORM process involves the following steps:

- Identify the hazards in operation.
- Assess the risks.
- Analyze risk control measures.
- Make risk control decisions.
- Implement risk controls (FDA 2001).

Building a Food Defense Plan

There are several benefits to an effective Food Defense Plan. The plan can protect public health, employee health, and business health by:

- Reducing the risk of an unsafe product, thereby reducing the potential for significant economic loss
- Reducing the potential for theft of product and/or supplies
- Reducing the need for additional regulations relating to food defense
- Reducing company liability, potentially reducing insurance premiums/costs

Prior to developing a Food Defense Plan, a thorough assessment of all risks associated with the facility should be conducted. The tools mentioned in the preceding section can help with this assessment, along with the Food Defense Tools and Educational Materials section of the FDA website, http://www.fda.gov/Food/FoodDefense/ToolsEducationalMaterials/. One of the FDA tools is called the Food Defense Plan Builder (Figs. 21.1, 21.2, 21.3, 21.4, and 21.5), a software tool designed

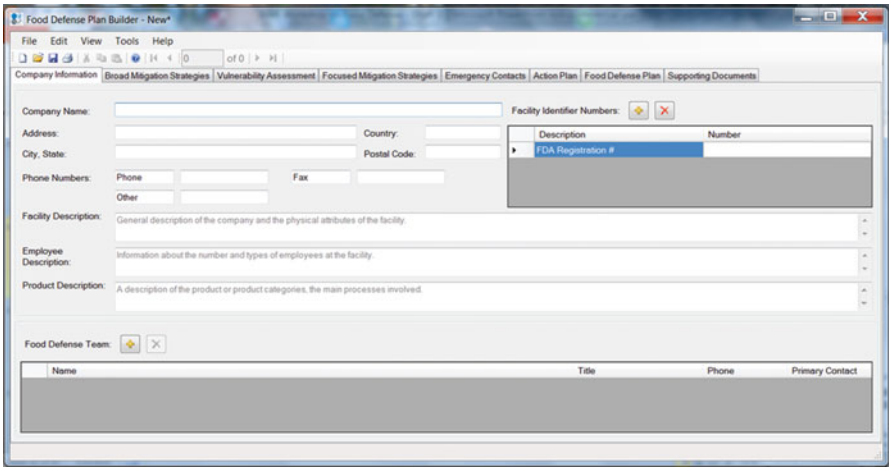

Fig. 21.1 FDA food defense plan builder screen shots

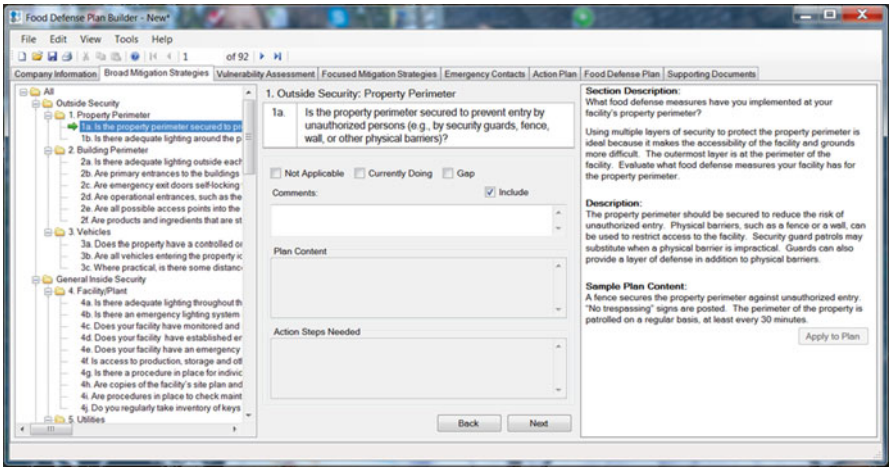

Fig. 21.2 FDA food defense plan builder screen shots

to assist owners/operators of food facilities with developing Food Defense Plans specific to their operations. The USDA FSIS also provides information on developing a Food Defense Plan at: http://www.fsis.usda.gov/wps/wcm/connect/99f95182-0c9e-4214-9762-e98197f54ebf/General-Food-Defense-Plan.pdf?MOD=AJPERES.

There are numerous categories of security measures that need to be taken into account when developing a Food Defense Plan. Outside security measures should prevent access to a facility by unauthorized individuals (especially those who might harbor harmful intentions) and prevent acceptance of unapproved materials or

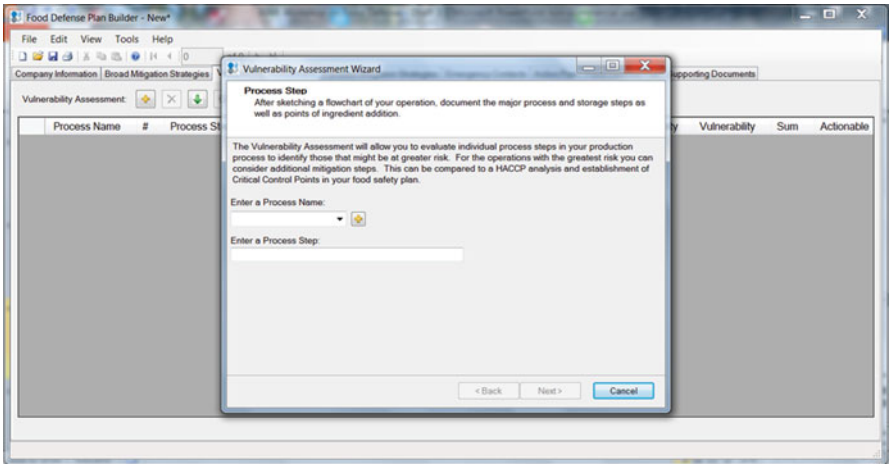

Fig. 21.3 FDA food defense plan builder screen shots

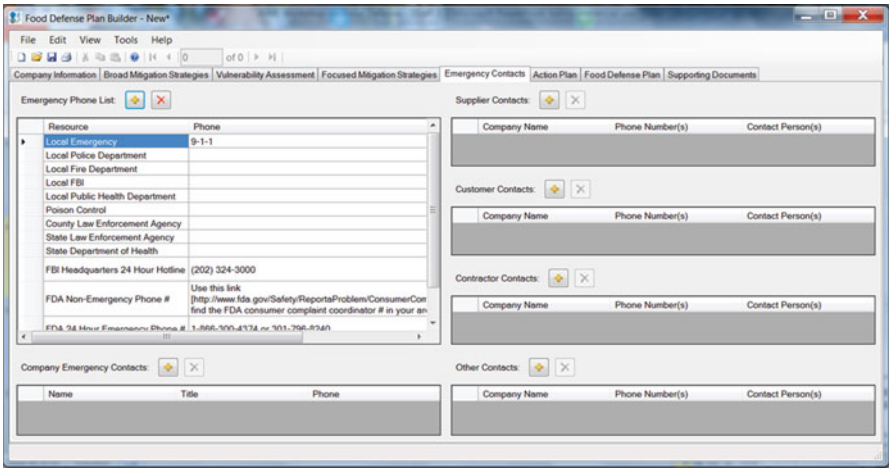

Fig. 21.4 FDA food defense plan builder screen shots

ingredients that could contaminate a product or have an adverse effect on production. Physical security measures include perimeter fencing, outside lighting, locked entrances, security passes, and security cameras. Shipping and receiving security measures involve the sealing/locking of transportation vehicles, examining vehicles and drivers, receiving and opening mail, the scheduling of loading and unloading activities, monitoring and surveillance of loading/unloading areas, and the sealing/locking of outgoing shipments.

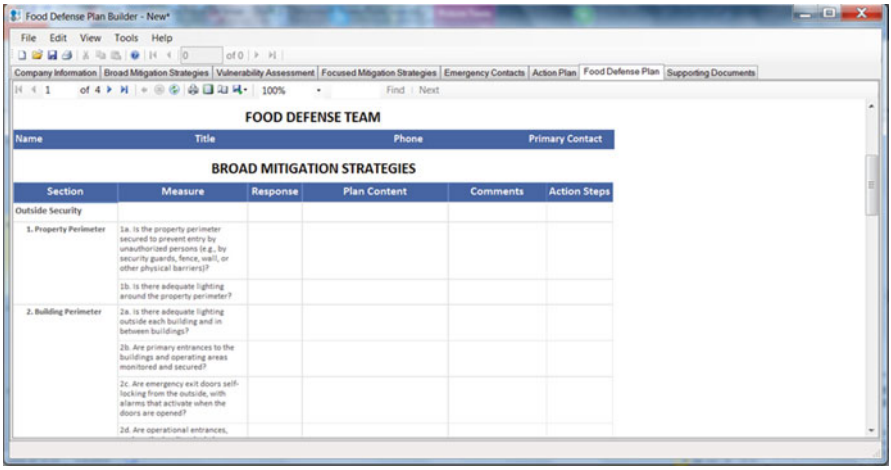

Fig. 21.5 FDA food defense plan builder screen shots

Inside security measures include activities such as identifying restricted areas with appropriate signage, maintaining adequate emergency lighting, instructing employees not to leave ingredients/containers unattended or open, educating personnel on how to respond to an emergency alert, performing background checks on employees and/or scheduled visitors, limiting computer access to trusted employees, and equipping computers with appropriate firewall and virus protection systems.

Ingredients and containers should be examined for any evidence of tampering and to help maintain an accurate record system that documents lot numbers, product and ingredient information, and supplier information. For restricted ingredients such as sodium nitrite or nitrate, a usage log should be utilized, and access should be restricted to trusted personnel. All water or ice supplies should be strictly controlled and monitored (i.e., checked at a regular frequency to make sure controls are working). Any water sources such as wells located outside of the facility/establishment should be secured in some manner to prevent unauthorized access. Items such as pesticides, cleaning agents, and sanitizers should be secured in a location away from any processing areas, and an inventory of any chemical or hazardous material should be maintained. Additional security measures related to storage include rotating stock, protecting product labels from theft or misuse, and restricting access to storage areas to appropriate personnel.

Once a Food Defense Plan has been developed and implemented, the Plan should be audited, i.e., doors are kept locked, surveillance cameras are working, the visitor log is being properly maintained, etc. The Plan should also be evaluated at least annually or more often in the face of threats or significant procedural changes.

Table 21.1 Percent of FSIS-regulated establishments with a food defense plan, 2006–2013

Establishment size	Aug 2006 (%)	Nov 2007 (%)	Aug 2008 (%)	Dec 2009 (%)	Jul 2010 (%)	Jul 2011 (%)	Aug 2012 (%)	Sept 2013 (%)
Large	88	91	96	97	97	96	99	98
Small	48	53	64	72	82	84	87	91
Very small	18	21	25	49	64	65	67	75
Total	34	39	46	62	74	75	77	83

The USDA FSIS began measuring the voluntary adoption of Food Defense Plans via annual surveys beginning in 2006, and the FSIS included the voluntary adoption of a Food Defense Plan as a performance measure in its FY 2010–2015 Strategic Plan. The eighth annual FSIS Food Defense Plan survey, completed in September of 2013, revealed that 83 % of all FSIS-regulated establishments surveyed had a functional Food Defense Plan, up from 77 % in 2012. In fact, the adoption of Food Defense Plans has consistently increased since the initial 2006 survey, as shown in Table 21.1 (USDA 2014c). Similar data for FDA-regulated establishments is not available.

Conclusion

Although government and industry have been proactive in identifying vulnerabilities and developing prevention and mitigation measures, there are still areas of our food supply that could be exploited by terrorists or other criminal elements. Additionally, as food technology improves, new vulnerabilities may emerge. Successful prevention of intentional contamination of our food and agriculture systems will require a continued partnership among government and industry and will require continued analysis of available resources.

Take-Home Message

The open nature of the US food and agriculture sectors naturally makes these sectors vulnerable to intentional contamination. Regardless of whether the source of such an attack originates from an international terrorist group or a single, disgruntled employee, the impact can be extensive and damaging to public health and to the local, national, or international economy. Recent attacks and threats of attacks against our country's food production demonstrate the wisdom of conducting vulnerability assessments to develop prevention and mitigation strategies for individual facilities (i.e., creating a Food Defense Plan).

Activity

Discussion Case Studies

Below are two case studies, based on actual events. What are some points to consider for each case?

Case 1

An employee at a fast-food restaurant at a highway rest stop was found guilty on a felony charge of food tampering and was imprisoned for up to 4 years. The employee had laced hamburgers with cleansers, degreasers, and spit and had sometimes "skated" on frozen hamburgers on the floor before broiling them. Unfortunately for the employee, an individual who became violently ill after eating one of the tainted burgers was a Sheriff's Deputy; another individual was a truck driver. The employee was acquitted on assault charges.

Case 2

A husband and wife were charged with tampering and petty larceny in connection with packages of pudding mix. The couple allegedly purchased boxes of the mix at four different stores, removed the contents, refilled the packages with a mix of salt and sand, and then returned the packages for refunds. There was no indication that the couple meant to harm anyone; they only wanted to get the pudding mixes without having to pay for them.

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Answer Key

Case 1: Points to consider: Restaurant management should consider the development of a Food Defense Plan for the restaurant. Some items that should be examined are securing chemicals such as cleansers and degreasers in an area separate from the food preparation or serving area. Additionally, maintenance of a log for these chemicals should be instituted. Another item to examine is employee procedures and protocols. Background checks should be considered on all employees. Protocols to ensure that other employees report any suspicious activity to restaurant management should be implemented. Other areas of vulnerability may be identified in a thorough vulnerability assessment conducted at the facility to support the development of a Food Defense Plan.

Case 2: Points to consider: A key issue would be evaluating what the store protocols are regarding returned items and evaluating returned products for product tampering before putting the products back out on the shelf for sale. This should be addressed under store policies and procedures and included in the stores Food Defense Plan.

Chapter 22
International Food Regulation Foundations

Neal Fortin and Cathy Weir

Learning Objectives

- Identify key international organizations related to food safety.
- Describe how the US government and US industry interact with the Codex Alimentarius to shape food safety policy at the national level.
- Identify the key regulatory authorities in the Food Safety Modernization Act that apply to imported food safety.
- Describe how inspection methods adapt in order to account for the globalization of the US food supply.

Introduction

Today, almost 15 % of all food consumed by Americans is imported (USDA Economic Research Service 2014). Food imports come from more than 150 countries and typically include seasonal fruits and vegetables, seafood, spices, and processed food ingredients (HHS 2013). Although international organizations such as the Codex Alimentarius have been established to protect the health of consumers and promote harmonized global standards, there remain differences in food safety

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measures around the world. Some of these differences occur because some countries may lack the resources and technical capacity to address food safety hazards, and in other cases what one country perceives as a risk may not be considered a risk in another. Globalization has rapidly increased the number of countries exporting food to the US, thus requiring the government to put in place new strategies to ensure safe food.

The recent enactment of the Food Safety Modernization Act (FSMA, Public Law 111-353) has provided US food systems new tools to ensure the safety of both domestic and imported foods. FSMA includes more emphasis for FDA to engage in international harmonization efforts, strengthen their communications with inspection agencies outside of the United States, and build partnerships with public and private sectors including industry. This chapter addresses key international organizations and how experts from the US government and industry are working together to improve food safety.

Key International Organizations Related to Food Safety

Key national and international organizations share common principles with respect to food safety. At the country level, national authorities have developed regulations to ensure safe and nutritious foods; they put in place standards of practice for food producers and processors and follow fair food trade practices established in the global community. Examples of national and supranational food safety authorities include the European Food Safety Authority (EFSA, www.efsa.europa.eu), mandated to identify and characterize emerging risks (i.e., risk assessments) in the fields of food and feed safety that apply to the European Union (EU) and its food and feed chain. The role of the US Food and Drug Administration (FDA) (www.fda.gov) is to provide the safety oversight of all domestic and imported food, medical devices, drugs, and cosmetics. Food Standards Australia New Zealand (FSANZ, www.foodstandards.gov.au) is a binational government agency that develops and administers a food code of practice for industry and coordinates assessment and surveillance of both domestic and imported foods. The national authority Health Canada is responsible for establishing food safety regulations and enforcing standards for food sold in Canada, as well as providing surveillance, prevention, control, and research of disease outbreaks (www.hc-sc.gc.ca).

The formulation of international food safety organizations grew from a recognized need to address global food safety problems and ensure fair trade practices. The United Nations (UN), Food and Agriculture Organization (FAO, www.fao.org), and World Health Organization (WHO, www.who.org) have taken on a significant role in actively addressing safe solutions to global food safety issues. WHO is a UN-specialized agency, established in 1948, to assist all people to attain a high level of health. The main function of WHO is to act as a directing and coordinating authority on public health. WHO is governed by 192 member states who meet annually at the World Health Assembly (WHA, www.who.int/mediacentre/events/

governance/wha/en/) to set international health regulations for its member nations. As a result, a core function of WHO is to strengthen national food safety systems by providing technical support, developing standards, and monitoring foodborne illness. WHO has established a food surveillance system and a food safety emergency network made up of national health department representatives. The International Food Safety Authorities Network (INFOSAN, www.who.int/foodsafety/fs_management/infosan/en/) is located at the WHO building in Geneva, Switzerland, and proactively exchanges food safety risk and information in six languages with governments around the globe.

The FAO and WHO work together to address various key food safety activities, including chemical risk assessments and provide capacity-building programs for developing countries (e.g., Food Quality and Standards Service, Economic and Social Development). Many food-related subjects–including scientific advice and training courses relevant to laboratory, inspection, and good manufacturing practices –are a key function of the joint work of FAO and WHO. The bodies providing independent scientific advice include the Joint Expert Committee on Food Additives (JECFA, http://www.Codexalimentarius.org/scientific-basis-for-Codex/jecfa/en/), Joint Meeting on Pesticide Residues (JMPR, http://www.Codexalimentarius.org/scientific-basis-for-Codex/jmpr/en/), and Joint Expert Meeting on Microbiological Risk Assessment (JEMRA, http://www.Codexalimentarius.org/scientific-basis-for-Codex/jmpr/en/). The outcomes of the expert meetings include identification of risk-based exposure concerns, factors that influence exposure to risk, analytical methods, and sampling plans. The expert opinions published by the FAO and WHO are used to set standards and guidelines in the Codex structure and for member states (i.e., national authorities) to establish their own national food standards. Specific areas of safety evaluation and risk assessment include:

- JECFA has evaluated more than 2500 food additives, approximately 40 contaminants and naturally-occurring toxicants, and residues of approximately 90 veterinary drugs. JECFA publications include specifications, analytical methods, and guidelines on conducing safety assessments of food additives and contaminants (FAO 2014a).
- JMPR reviews analytical aspects of pesticides, reviews toxicological data, and estimates acceptable daily intakes for humans (WHO 2014a).
- JEMRA provides microbiological risk assessment for pathogen and food combinations that are associated with foodborne illness. JEMRA has published risk assessment findings to provide guidance for hazard characterizations (FAO 2014b).

Codex Alimentarius

In 1962, the Codex Alimentarius Commission (Fig. 22.1) was established jointly by the FAO and the WHO and has become the single most important international reference for food standard development. The Codex Alimentarius (Latin for "food

Fig. 22.1 Codex Alimentarius plenary meeting, Rome, 2007 (Used with permission from Sepp Hasslberger. http://www.newmediaexplorer.org/sepp/2007/10/15/codex_alimentarius_will_eu_laws_become_world_standard.htm)

code") is a collection of internationally-adopted food standards covering all the principal foods traded (including raw and processed) and is supplemented with residue limits for pesticides and veterinary drugs in food, along with acceptable levels of food additives and contaminants.

The primary objective of Codex Committee meetings is to harmonize international food standards by bringing together scientists, technical experts, government regulators, and international consumer and industry groups. There are 186 Codex member countries, with each member country having one vote. Observer status of more than 200 organizations has been granted to industry and consumer representatives to participate in Codex meetings, although no observers may vote. The preparation of draft food standards takes place in Codex committees—taking into consideration member views and scientific advice from expert committees. The proposed Codex standard is reviewed by governments and interested parties, and if agreement is reached, the standard is endorsed by general Codex Committees and formally adopted by the Codex Commission. The standards, along with guidelines for food safety risk assessments and recommendations concerning sampling, analysis, and inspection, are available on the Codex website: www.Codexalimentarius.org. Although non-mandatory in nature, since 1995, the Codex standards have been a reference for international food trade under agreements of the World Trade Organization (WTO, www.wto.org).

International Plant Protection Convention (IPPC)

The International Plant Protection Convention (IPPC, www.ippc.int) is an international organization that facilitates trade agreements to protect plant health and prevent the spread of pests. Similar to the other international standard-setting bodies, the IPPC is made up of signatory members with an appointed national contact point to act as a liaison and foster information exchange between organizations. The primary function of the IPPC is to develop standards, enhance plant health inspection systems, and strengthen biological control.

World Organisation for Animal Health (OIE)

The World Organisation for Animal Health (OIE, www.oie.int), or Office International des Epizooties, was created to provide transparency of animal diseases around the world. The OIE collects data and makes the data available to appointed technical delegates (e.g., veterinarians) from each member country. The OIE develops standards for international trade of animal products and provides expertise and technical support to animal control. The international standards developed by the OIE are published in the Terrestrial Animal Health Code and the Manual of Standards for Diagnostic Tests and Vaccines.

World Trade Organization (WTO)

The World Trade Organization (WTO, www.wto.int) was established in 1995 around a system of rules aimed at governing international trade among countries. The WTO provides a forum to (1) allow governments to negotiate trade agreements, (2) notify members of draft food safety measures, and (3) raise an issue when members fail to comply. Key provisions of the WTO trade agreements are related to non-discrimination, scientific justification, consistency, and transparency. Two important food-related agreements include the Sanitary and Phytosanitary (SPS) Agreement, which ensures that nations may enact health and safety measures, but they must be based on sound science, and the Agreement on Technical Barriers to Trade (TBT), which ensures that national technical regulations do not create unnecessary barriers to international trade.

When WTO members fail to comply with international food standards, they can be challenged by another member state by requesting a dispute settlement with the SPS or TBT committee. Disputes generally involve the claim that a member state failed to base sanitary or phytosanitary measures on sound science or that the regulations are discriminatory.

How the US Government and US Industry Interact with Codex to Shape Food Safety Policy at the National Level

The US considers Codex as a key international organization to drive science-based standards. Therefore, in 2012, the US Codex Office developed a 5-year strategic plan to work with international experts and engage domestic stakeholders to collaboratively safeguard the food systems worldwide. The US Codex Office is based in Washington, DC, and is managed within the US Department of Agriculture (USDA) Food Safety and Inspection Service (FSIS). The US Codex Office holds policy and technical meetings to engage stakeholders across agencies, industry, and academia to develop the US response during Codex Committee meetings. Public meetings are regularly held to provide information and receive public comments on agenda items and draft US positions to be discussed at upcoming Codex meetings.

The Codex meeting attendees may include industry and trade organizations who serve as non-governmental organizations (NGOs) representing food companies around the world. The trade association representatives may monitor and participate in the work of Codex Committees and Codex task forces. Participation could include providing input to electronic working groups or providing data relevant to food safety issues. For example, to support the technological need for food additives, the food industry works with the JECFA experts to detail out processing systems.

Safe food benefits everyone. The technical and scientific data from industry is relevant to building safe food systems. Bringing together industry and government provides opportunity to develop strategic interventions and builds support to enforce food regulations.

Regulatory Authorities in the Food Safety Modernization Act (FSMA) That Apply to Imported Food Safety (by Neal Fortin)

FSMA and New, Science-Based, Preventive Controls

> *Prevention of foodborne illness, not reaction to problems, is now the guiding principle of our food safety law -- with the primary responsibility for prevention resting squarely on the shoulders of food producers and processors* (FDA 2011).

FSMA created a new paradigm for the regulation of imported foods regulated by FDA. FSMA shifts the focus of US food law from reacting to food safety problems to prevention. This preventive responsibility applies equally to foreign and domestic

food producers and processors. This preventive framework is built on risk-based preventive controls and produce safety standards.

Mandatory Risk-Based Preventive Controls

All FDA-regulated food companies must implement hazard analysis and preventive controls unless specifically exempt. Exemptions include juice and seafood whose suppliers are in compliance with HACCP regulations, food imported for research and evaluation purposes, food imported for personal consumption, alcoholic beverages, food imported for future export (outside of the United States), and products subject to low-acid canned food requirements. All food facilities, including foreign facilities for food imported into the United States, must implement a written hazard analysis and risk-based preventive control plan (21 U.S.C. 350g). The FSMA hazard analysis and preventive control plan (HAPCP) is essentially an enhanced HACCP system. FSMA HAPCP is slightly broader because the plan requires identification and control of hazards generally, not just critical control points (CCPs). In short, FSMA requires establishment of science-based mitigation strategies to prepare and protect the food supply chain against intentional contamination at vulnerable points (Food, Drug, and Cosmetic Act § 420).

Mandatory Produce Safety Standards

FSMA directs FDA to work with the USDA to create "science-based minimum standards for the safe production and harvesting" of fruits and vegetables for which FDA has determined such standards will minimize the risk of "serious adverse health consequences." The rules must consider naturally-occurring hazards, as well as those that may be introduced either unintentionally or intentionally, and must address soil amendments (such as compost), hygiene, packaging, temperature controls, animals in the growing area, and water (21 U.S.C. § 350h).

FDA's proposed produce rule covers all fruits and vegetables except those rarely consumed raw, produced for personal consumption, or destined for commercial processing that will reduce microorganisms of public health concern. The rule is based on science and risk analysis and therefore focuses on areas of risk, including but not limited to:

- Agricultural water
- Biological soil amendments
- Health and hygiene
- Domesticated and wild animals
- Equipment, tools, and buildings

The Regulatory "Tool Kit" for Imported Foods

The mandatory risk-based preventive controls and produce safety standards provide the preventive framework for the safety of imported (and domestic) food. To ensure implementation of these preventive standards, FSMA provides a new "regulatory tool kit" for imported foods, consisting of the following elements:

1. Foreign supplier verification programs (FSMA sec. 301)
2. Voluntary qualified importer program (sec. 302)
3. Mandatory certification (sec. 303)
4. Enhancements to prior notice (sec. 304)
5. Building capacity of foreign governments (sec. 305)
6. Improved enforcement authorities (sec. 306)
7. Accreditation of third-party auditors (sec. 307)

The scope of this chapter does not permit covering all of the above elements and is limited to salient points.

Definition of an Importer

The definition of an "importer" is important because the term determines responsibility and liability. The importer is a person in the United States who has purchased the food being offered for import. If there is no US owner at the time of entry, the importer is the US consignee. If there is no US owner or consignee at the time of entry, the importer is the US agent or representative of the foreign owner or consignee.

Foreign Supplier Verification Programs (FSVPs, FSMA sec. 301)

Importers are required to develop, maintain, and follow an FSVP for each food imported, unless an exemption applies. The requirements vary based on the type of food product, the category of importer (e.g., very small), the nature of the hazard identified in the food, and who is to control the hazard. Primarily, verification is based on controlling the hazards that are reasonably likely to occur.

Importers must perform certain risk-based activities to verify that food imported into the United States has been produced in a manner that provides the same level of public health protection as required of domestic food producers. In general, importers would need to conduct the following activities as part of their FSVPs:

- Compliance status review of foods and suppliers
- Hazard analysis

- Supplier verification activities
- Corrective actions (if necessary)
- Periodic reassessment of the FSVP
- Importer identification at entry
- Record/keeping

Compliance Status Review

The importer reviews the compliance status of the food and the potential foreign supplier before importing the food and follows up with periodic review afterward. At a minimum, the review needs to include any FDA warning letters, import alerts, and requirements for certification issued by FDA under sec. 801(q) of the Food, Drug, and Cosmetic Act (FD&C Act).

Hazard Analysis

The importer analyzes the hazards associated with each imported food. The hazard analysis is used to identify the hazards that are reasonably likely to occur for each type of food imported and evaluate the severity of the illness or injury if such a hazard were to occur.

Supplier Verification

The importer conducts activities that provide adequate assurances that the hazards identified as reasonably likely to occur are adequately controlled. Verification activities could include onsite auditing of foreign suppliers, periodic or lot-by-lot sampling and testing of food, periodic review of foreign supplier food safety records, or other appropriate risk-based procedures (Fig. 22.2). Verification activities applicable to all FSVPs, regardless of identified hazards, include maintaining a written list of foreign suppliers from which food is imported, as well as establishing—and following—adequate written procedures for conducting verification activities.

Corrective Actions

The importer reviews complaints he or she receives concerning the foods imported, investigates the cause or causes of adulteration or misbranding as needed, takes appropriate corrective actions, and revises the FSVPs when necessary.

Fig. 22.2 Consumer safety officers open refused boxes of bean curds at an FDA import destruction site in 2011 (*Source*: News21.com and Kyle Bruggerman, via Creative Commons) (http://www.flickr.com/photos/50436974@N04/6110870452/in/photolist-aiZNTo-aiX1WK-7HgKXW-aiX1uZ-aiZNQQ-aiZNLL-aiZPg5-ajyACx-aiZNVu-aiX1K8-aiZP6Y-ajyAvM-bXMhqj-82FPnZ-a7tfyd-9tVaWp-fqz4Nt-7K9h7F-7KdbHm-7KdbF1-7KdbKC-7KdbQw-em5cSx-hZz3tB-dCZoum-dCTYLe-7CpjSo-atsXky-d9prSQ-d9prVA-bmTwRa-7HcRnM-d9prML-d9prQL-d9prEU-d9prCb-d9prHL-kvHHMn-9rdUrg-fQgcA5-9Yo9Qd-ckiH2b-fpuZR5-8RuZxv-9JFMdT-9JJAc5-9JFLRr-85jVFH-9JFMiP-9JJA4Q-893TYD)

Periodic Reassessment

The importer must reassess the FSVPs within 3 years of establishing the FSVP or within 3 years of the last assessment. In addition, an importer must reassess the effectiveness of the FSVP sooner if the importer becomes aware of new information about potential hazards associated with the food.

Importer Identification

Importers would be required to obtain a Dun and Bradstreet Data Universal Numbering System (DUNS) number for their company and ensure that the DUNS number is provided electronically when filing for entry with Customs and Border Protection.

Record/Keeping

The importer must keep certain records, including those that document compliance status reviews, hazard analyses, foreign supplier verification activities, investigations and corrective actions, and FSVP reassessments.

Mandatory Certification (Sec. 303)

In certain circumstances, FDA may use certifications from accredited auditors in determining whether to admit imported food into the United States that the FDA has determined to pose a food safety risk. Certifications may also be used in determining whether an importer is eligible for expedited review and entry of food.

Capacity-Building (Sec. 305)

FSMA recognizes that domestic food safety depends in part on food safety in other countries. The statute directs FDA to develop a comprehensive plan to expand the technical, scientific, and regulatory food safety capacity of foreign governments and their food industries for countries that export food to the United States. Training of foreign governments and food producers on US requirements for safe food is a part of capacity-building. Other components may include data sharing, mutual recognition of inspection reports, and harmonization with requirements under Codex Alimentarius (FDA 2013).

The US government has already engaged in capacity-building around the world as part of its commitment to WTO. As part of WTO, "Members agree to facilitate the provision of technical assistance to other Members, especially developing country Members" (WTO 2014b).

Accreditation of Third-Party Auditors (Sec. 307)

FSMA directs FDA to establish a program for the accreditation of third-party auditors for foreign food facilities. Under this program, FDA would recognize accreditation bodies, which would in turn accredit third-party auditors to, among other things, conduct food safety audits and issue certifications for foreign facilities and food under specified programs. Accredited third-party audits and certification will be central to a global system for efficiently ensuring the safety of FDA-regulated food.

Certifications are issued by accredited third-party auditors for two purposes under FSMA. Section 302 of FSMA authorizes the voluntary qualified importer program (VQIP), which provides for expedited review and entry of food into the United States. In order to participate in VQIP, importers must import food from certified facilities. Section 303 of FSMA gives FDA authority to require certification as a condition of entry for certain foods that FDA has determined to pose a food safety risk under Sec. 801(q) of the FD&C Act. An accredited third-party auditor may provide such certifications.

Inspection and Compliance

Preventive control standards improve food safety only to the extent that producers and processors comply with the standards. Therefore, FSMA increases FDA oversight for compliance with these requirements. One of the foremost of these compliance tools is expanded records access. FDA will have authority to access the required written food safety plans, and the records firms are required to keep documenting implementation of their plans. These records are to be kept for not less than 2 years, and the records must be made available "promptly" to a duly authorized agent of FDA upon request (FD&C Act § 418(g) & (h)). FDA also has expanded authority to access records for foods where there is a reasonable belief that the food is adulterated and may cause serious adverse health consequences (FSMA § 101 amending FD&C Act § 414(a)). An importer must keep records of importer verification for not less than 2 years.

Some Points About Compliance

Food law in the United States puts the responsibility for food safety clearly on the shoulders of the manufacturer and seller of that food. Ultimately, this responsibility is the best reason for implementing a systematic risk-control plan. Complying mechanically with government regulations will not bring about the degree of confidence or safety that comes from a sincere commitment by management to systematically implement the highest degree of food safety.

Supervision must also ensure that records are properly maintained. "If it isn't documented, then it didn't happen" is a good refrain to remember. Documentation has never been more important for demonstrating compliance. This documentation can also be essential in any litigation involving injury from a food safety problem. Further, one of the best ways to prevent foodborne illness liability is to prevent the incidence of illness.

How Inspection Methods Adapt in Order to Account for the Globalization of the US Food Supply

Although the benefits are widely acknowledged, the adoption of HACCP was slow for many reasons (Fortin 2003). The benefits are real, but tend to be long-term benefits. On the other hand, the burden of responsibility is immediate and requires change. The change for industry is apparent, but changes in the philosophy and approach to inspections are also necessary.

Rather than a cat-and-mouse inspection for sanitation violations, the FPP performing inspections must seek to understand the risk-control *systems*, review the record/keeping documentation, and assess whether the food safety systems are functioning properly. This approach adds a new responsibility to both food facility managers and FPPs.

Regulatory policy must make enforcement a priority for cases involving incomplete, false, or deceptive records.

Conclusion

Due to significant changes in food technology and the globalization of food trade, there is a growing interest in governments working across national borders to ensure safe food. As a result, most countries are in the process of updating and/or modernizing their food systems by devoting more resources to prevention and capacity-building (i.e., laboratories, training inspectors). In the United States, domestic food safety must take into consideration the international context of food regulations, particularly Codex Alimentarius standards and World Trade Organization obligations. By working across international organizations and national agencies, it is possible to harmonize food safety systems and drive science-based regulations. There is a new regulatory "tool kit" for inspectors of importers and imported food. A key component is the foreign supplier verification programs (FSVPs). Importers are required to develop, maintain, and follow an FSVP for each food imported, unless an exemption applies. A new paradigm of regulation and inspection exists for US food importers. Importers must perform risk-based safety verification of each food imported and each supplier, including a hazard analysis of the food and record/keeping of the specific verification activities for each supplier.

Take-Home Message

Today's food industry and FPPs must be cognizant of the increasingly global nature of food supply chains. Fortunately, the new imported food paradigm provides powerful tools to ensure the safety of those supply chains. However, this approach will take a change in one's mindset of ensuring the effectiveness of systems and record/keeping for risk-based, preventive controls.

Activity

Fill in the Blank with the Appropriate Answer

1. The international standard for food safety regulation is the _____.
2. Independent scientific advisors to the UN FAO/WHO on food additives and contaminates specifications are provided by the _____.
3. Governments that belong to the _____ have a forum to learn of other governments' food safety measures and ensure that science-based regulations are being put into place.
4. Under FSMA, food importers have a responsibility to _____ that their foreign suppliers have adequate preventive controls in place to ensure that the food they produce is safe.

Discussion Question

5. How do HACCP-style inspection techniques apply to inspections of food importers?

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Additional Resources

Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. § 301 *et seq.*), Pub. L. No. 75-717, 52 Stat. 1040 (1938), as amended

Fortin ND (2009) Food regulation: law, science, policy, and practice. Wiley, Hoboken

Answers

1. Codex Alimentarius
2. Joint Expert Committee on Food Additives (JECFA)
3. World Trade Organization (WTO)
4. Verify
5. The participant should be able to explain how the HACCP inspection focuses on the risk-control systems via review of record/keeping and documentation, and, similarly, the inspector of a food importer must review record/keeping and documentation to assess the hazard analysis, foreign supplier verification activities, and so forth.

Chapter 23
Conclusion

Julia Bradsher, Gerald Wojtala, Craig Kaml, Christopher Weiss, and David Read

Regulatory Foundations for the Food Protection Professional is intended to provide a comprehensive introduction to the food protection content areas that entry-level food protection professionals (FPPs) will encounter during the course of their jobs. The volume was developed in accordance with the entry-level track of the IFPTI competency-based curriculum framework, which was developed to help in the creation of the integrated food safety system (IFSS).

The entire IFPTI framework, however, is career-spanning and contains tracks for FPPs at professional levels above the entry level i.e., journey level, technical specialist level, and leadership level. As a result, IFSS stakeholders can expect, over the coming years, companion volumes to be created by IFPTI for these additional professional levels, along with an updated, "second edition" volume for the entry-level FPP that reflects changes to laws, regulations, and agency authority, along with the increasingly global nature of the food supply system.

The editors hope that this volume inspires individuals to enter the important and challenging world of food protection, which is a key component in the overall government mission of protecting public health. Foodborne illness will undoubtedly continue to have significant impact on national health and economy; as a result, the roles of FPPs and food regulatory agencies will continue to be crucial.

The editors also hope this volume has demonstrated the challenges and complexity of the food protection profession. Even at the entry level, FPPs need to have a knowledge base that is much more expansive than merely knowing how to inspect a local kitchen for pests. First and foremost, the FPP must have a basic understanding of food regulatory authorities, their roles, their jurisdictions, their limitations, and the important role that these authorities play in protecting public health by preventing potentially-deadly foodborne illness.

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FPPs must also possess a foundational knowledge of scientific topics. As discussed in Chap. 6, knowledge of microbiology allows the FPP to identify potential harmful pathogens, food associated with those pathogens, the ways by which pathogens can end up causing illness and even death, and measures that can prevent pathogen growth. Knowledge of epidemiology, addressed in Chap. 8, enables the FPP to participate in a foodborne illness investigation in the hopes of identifying the source of the outbreak.

Additionally, the FPP must be cognizant of the personal safety risks that are present while the FPP performs his or her duties. As discussed in Chap. 16, FPPs performing their job duties can be exposed to dangerous equipment, harmful chemicals, hostile situations, falling items, and extreme weather conditions. In fact, personal protective equipment (PPE), such as bump caps and protective eyewear, is relatively common when conducting FPP activities within a manufactured food facility.

Finally, the editors hope that entry-level FPPs understand how conducting facility inspections helps further the mission of protecting public health. During inspections, FPPs can identify whether packaged food items are properly labeled (e.g., labeled for the presence of a major food allergen) as covered in Chap. 14, whether a manufacturing facility has an appropriate system in place to identify potential hazards along the production line (i.e., a HACCP plan, as discussed in Chap. 11), whether a facility has properly removed a dangerous food product from the marketplace (e.g., a product recalled by USDA or FDA, as mentioned in Chap. 12), and whether weaknesses in the food supply chain are targets for intentional contamination (i.e., terrorism or criminal activity, as addressed in Chap. 21).

Any questions or comments regarding *Regulatory Foundations for the Food Protection Professional* can be sent to IFPTI at support@ifpti.org.

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