PART I

INTRODUCTORY CHAPTERS

1

INTRODUCTION TO FOOD REGULATION IN THE UNITED STATES

1.1 INTRODUCTION

This chapter provides basic information for students with greatly varied backgrounds. Necessarily, this information may be repetitive or elementary for some readers. Those readers are encouraged to treat this material as a review and refresher. Most of the topics provided in overview in this chapter will be covered later in more depth.

This introduction also provides a historical background that gives insight into the public policy decisions in food regulation. A general explanation of the legal system, regulatory law in general, and the legal basis of food regulation in the United States are included. To enhance an understanding of the legal structures and to simplify its otherwise mysteriousness, this chapter provides an overview of the history of food regulation in the United States. This history accounts for and explains much of the current organization of federal and state regulatory agencies.

This chapter further presents an overview of the major food statutes, regulations, and the jurisdictions of various agencies. This knowledge will allow you to enhance your communication and functioning within this legal framework. In addition, a better understanding of the functions, authority, and interrelationship of various regulatory agencies promotes improved relations with those agencies. This understanding will also improve your ability to function within the regulatory system.

1.2 A SHORT HISTORY OF FOOD REGULATION IN THE UNITED STATES

1.2.1 Why Do We Have Food Laws?

From the beginnings of civilization, people have been concerned about food quality and safety. The focus of governmental protection originated to protect against economic fraud and to prevent against the sale of unsafe food. As early as the fourth century BCE, Theophrastus (372–287 BCE) in his ten-volume treatise, *Enquiry into Plants*, reported on the use of food adulterants for economic reasons. Pliny the Elder's (CE 23–79) *Natural History* provides evidence of widespread adulteration, such as bread with chalk, pepper with juniper berries, and even adulteration with cattle fodder.[1] Ancient Roman law reflected this concern for adulteration of food with punishment that could result in condemnation to the mines or temporary exile.[2]

Starting in the thirteenth century, the trade guilds advanced higher food standards. The trade guilds, which included bakers, butchers, cooks, and fruiters among the many tradecrafts, held the power to search for and seize unwholesome products.

[1] Peter Barton Hutt, *Government Regulation of the Integrity of the Food Supply*, 4 ANNUAL REVIEW OF NUTRITION 1 (1984).
[2] *Id.*

Food Regulation: Law, Science, Policy, and Practice, Second Edition. Neal D. Fortin.

Indeed, as the guilds policed the marketplace, they were most interested to ensure continued and strong markets for their goods. Nonetheless, the guilds provide an early demonstration how stringent product quality and safety standards can bring a competitive economic advantage to industries and nations. Trust in food's safety and wholesomeness is necessary for the market to prosper. A number of commentators have noted the commonality of interest between business self-interest and stringent product safety standards.[3]

Regulation of food in the United States dates back to the colonial era, but the early food laws were nearly all state and local regulations. Federal activity was limited to imported foods. The first federal food protection law was enacted by Congress in 1883 to prevent the importation of adulterated tea. This was followed in 1896 by the oleomargarine statute, which was passed because dairy farmers and the dairy industry objected to the sale of adulterated butter and fats colored to look like butter.

* * * * *

An Early Massachusetts Food Law[4]

Passed March 8, 1785

An Act Against Selling Unwholesome Provisions

> *Whereas some evilly disposed persons, from motives of avarice and filthy lucre, have been induced to sell diseased, corrupted, contagious, or unwholesome provisions, to the great nuisance of public health and peace:*
>
> *Be it therefore enacted by the Senate and House of Representatives, in General Court assembled, and by the authority of the same, That if any person shall sell any such diseased, corrupted, contagious or unwholesome provisions, whether for meat or drink, knowing the same without making it known to the buyer, and being thereof convicted before the Justices of the General Sessions of the Peace, in the county where such offence shall be committed, or the Justices of the Supreme Judicial Court, he shall be punished by fine, imprisonment, standing in the pillory, and binding to the good behaviour, or one or more of these punishments, to be inflicted according to the degree and aggravation of the offence.*

* * * * *

Although adulteration and mislabeling of food had been a centuries-old concern, the magnitude of the problems increased in the last half of the nineteenth century. This was an era of rapid development in chemistry, bringing advancements in food science, new food additives and colorings, and new means of adulteration. Fortunately, these scientific advances also provided the tools for detecting adulteration.

> We face a new situation in history. Ingenuity, striking hands with cunning trickery, compounds a substance to counterfeit an article of food. It is made to look like something it is not; to taste and smell like something it is not; to sell like something it is not, and so deceive the purchaser.
>
> Congressional Record, 49 Congress I Session 1886

In this era, food production began shifting from the home to the factory, from consumers buying basic ingredients from neighbors in their community to food processors and manufacturers more often at a distance. With this trend, consumers found it harder to determine the safety and quality of their food. Inevitably, the responsibility for ensuring the safety of foods only shifted from local to state government, and the demand for federal oversight increased. As national markets grew, legitimate manufacturers became concerned that their markets were being harmed by the dishonest and unsafe goods.

1.2.2 The 1906 Pure Food and Drug Act

In 1883, Dr. Harvey Wiley became the chief chemist of the U.S. Bureau of Chemistry (at that time part of the Department of Agriculture). Dr. Wiley expanded research and testing of food and documented widespread adulteration.[5] He helped spur public indignation by his publications and by campaigning for a national food and drug law. Wiley dramatically focused concern about chemical preservatives as adulterants through his highly publicized "Poison Squad."

The Poison Squad consisted of live volunteers who consumed questionable food additives, such as boric acid and formaldehyde, to determine the impact on health. Observation and documentation of the ill effects and symptoms of the volunteers provided an appalling crude gauge of food additive safety.[6] However crude by today's standards, Wiley's leadership with the tools of the day helped galvanize public awareness and advanced food safety.

Public support for passage of a federal food and drug law grew as muckraking journalists exposed in shocking detail the frauds and dangers of the food and drug trades, such as the use of poisonous preservatives and dyes in food and deadly opiate-laced syrups for children.[7] A final catalyst for change was the 1905 publication of Upton Sinclair's *The Jungle*. Sinclair portrayed nauseating practices and unsanitary conditions in the meat-packing industry, such as food handlers sick with tuberculosis and carcasses covered

[3] *See, e.g.,* MICHAEL E. PORTER, THE COMPETITIVE ADVANTAGE OF NATIONS, 648–649 (1990).

[4] JOHN P. SWANN, HISTORY OF THE FDA, FDA History Office (Dec. 17, 2001).

[5] FDA, FDA BACKGROUNDER: MILESTONES IN U.S. FOOD AND DRUG LAW HISTORY (updated May 5, 2012).

[6] The data is collected in the USDA, Bureau of Chemistry, bulletin no. 84 (1902–1908).

[7] Philip J. Hilts, *The FDA at Work: Cutting-Edge Science Promoting Public Health*, FDA CONSUMER MAGAZINE (Jan.–Feb. 2006).

in rat droppings being made into sausage. The book was a best seller, and meat sales dropped by half.[8]

Outraged at the conditions described in *The Jungle*, President Theodore Roosevelt sent his own investigators to the Chicago packinghouses. They found the situation as revolting as Sinclair had described, including witnessing a carcass falling into a latrine, being hauled back out, and put back uncleaned with the other meat.[9] Even though leaders within the meat industry were ready for new rules, Congress refused to pass a bill. President Roosevelt had held back his investigators' report, but when Congress would not act, he released the report to the newspapers. Soon Roosevelt had his bill.[10]

On June 30, 1906, President Theodore Roosevelt signed both the Pure Food and Drug Act[11] and the Meat Inspection Act[12] into law. Passage of these two statutes began the modern era of U.S. food regulation. While neither act could be considered comprehensive, both responded to the concerns of the day.

The Pure Food and Drug Act added regulatory functions to the U.S. Bureau of Chemistry. The Meat Inspection Act of 1906 required the U.S. Department of Agriculture to inspect all cattle, sheep, swine, goats, and horses when slaughtered and processed into products for human consumption. The primary goals of the Meat Inspection Act were to prevent adulterated livestock from being processed into food and to ensure that meat was slaughtered and processed under sanitary conditions.

1.2.3 Evolution of the Food Statutes

Not long after passage of the Pure Food and Drug Act, legislative battles began to expand and strengthen the law. For instance, the act did not prohibit false therapeutic claims, but only false and misleading statements about the ingredients or identity of a drug. Therefore, the Food and Drug Administration (FDA) could take no action against snake oil with an illegitimate claim to cure cancer so long as the product actually was oil from snakes. In addition, leaders in the food industry called for more stringent product quality standards to create a level playing field. Members of Congress called for better safety standards and fair dealing.

However, major revision of the food law stalled until a precipitous event fell while a significant segment of the public was paying attention. Sulfanilamide, one of the new sulfa drugs, was being used effectively to treat strep throat and other bacterial diseases (Figure 1.1). To increase the palatability of the bad tasting drug, a drug company mixed the antibiotic with diethylene glycol, a sweet tasting

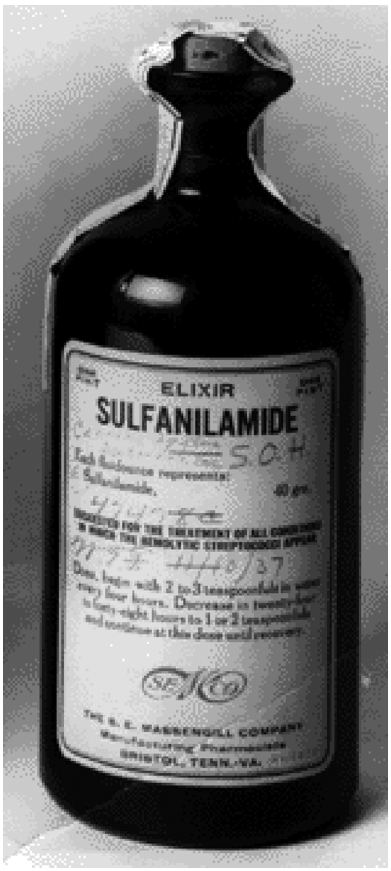

FIGURE 1.1 Elixir of sulfanilamide. (Image courtesy of FDA.)

liquid. The mixture was called elixir of sulfanilamide and shipped in the fall of 1937. Within weeks, deaths were reported to FDA. The manufacturer admitted they performed no safety tests. None were required. At least 107 died in an often agonizing death. Many of the dead were children who received the elixir for strep throat.[13]

The tragedy spurred legislative action, and in 1938, the Food, Drug, and Cosmetic (FD&C) Act was enacted. The FD&C Act required premarketing approval and proof of the safety of drugs. The act also:

- extended government control to cosmetics and therapeutic devices,
- provided that safe tolerances be set for unavoidable poisonous substances in food,
- authorized standards of identity, quality, and fill-of-container for foods,
- authorized factory inspections, and
- added court injunctions to the previous penalties of seizures and prosecutions.

The food laws continued to evolve based on the concerns and issues of the times. In the 1950s, concerns over synthetic food

[8] *Id.*
[9] *Id.*
[10] *Id.*
[11] 21 U.S.C. § 1 *et seq.*
[12] 21 U.S.C. § 601 *et seq.*
[13] PHILIP J. HILTS, PROTECTING AMERICA'S HEALTH: THE FDA, BUSINESS, AND ONE HUNDRED YEARS OF REGULATION 89–92 (2003).

additives, pesticides, and cancer were high. Consequently, in 1958, the Food Additives Amendment to the FD&C Act was enacted, requiring the evaluation of food additives to establish safety. The Delaney Clause forbade the use of any food additive that was found to cause cancer in humans or animals. In 1960, the Color Additive Amendment to the FD&C Act was enacted, which required manufacturers to establish the safety of color additives in foods, drugs, and cosmetics.

After a number of well-publicized outbreaks of botulism food poisoning from canned foods, the FDA issued Low-Acid Food Processing Regulations in 1973. After deaths from cyanide placed in Tylenol capsules, FDA issued the Tamper-Resistant Packaging Regulations in 1982. In 1983, Congress passed the Federal Anti-Tampering Act, which makes it a federal crime to tamper with packaged consumer products.

Throughout the 1980s, there was a growing interest in the effect of nutrition on health along with increased marketing of foods to fulfill health concerns. At the same time, food processing continued a trend toward becoming nationally distributed rather than local. Various states implemented nonuniform laws to regulate health and nutrition claims, which the national industry found hindered interstate commerce. In 1990, Congress enacted the Nutritional Labeling and Education Act (NLEA), which requires nearly all packaged foods to bear nutritional labeling. The act also requires nutritional and health claims for foods to be consistent with terms defined by the FDA.

Then impetus grew for enhanced food safety regulation over several years of high-profile food recalls, foodborne illness outbreaks, and consumer advisories. In 2006, fresh spinach sickened over 200, and the fresh greens industry suffered huge losses. In 2007, nearly 2,000 pet food products were recalled due to melamine adulteration of gluten. In 2007, more than 600 people became ill from contaminated peanut butter. In 2008, imported peppers sickened over 1,400, but not before tomatoes were misidentified, causing huge losses to the tomato industry. In 2009—in what may have been the precipitating event—nine deaths and hundreds of illnesses were traced back to peanut paste from the Peanut Corporation of America. In the end, nearly 4,000 consumer products were recalled with an unusually long recall span of over a year. Finally, in 2010, nearly 2,000 cases of illness were linked to eggs from two farms in Iowa, and more than 500 million eggs were recalled.

On January 4, 2011, President Barack Obama signed the FDA Food Safety Modernization Act (FSMA) into law.[14] This amendment of the FD&C Act is the most significant revision of U.S. food law since 1938 when the Food, Drug, and Cosmetic Act replaced the Food and Drug Act of 1906. The law is historic both in breadth and depth of it coverage.

With this background, it is time to review some aspects of the U.S. legal system.

[14] The FDA Food Safety Modernization Act, Pub. L. 111-353 (2011).

1.3 THE U.S. LEGAL SYSTEM

To understand the legal basis of food regulation in the United States, it is necessary to have an overall understanding of the U.S. legal system and some of the key concepts in American jurisprudence. First, let us look at the basic terminology.

Law: (1) a binding custom of a community; (2) a rule of conduct or action prescribed or enforced by a controlling authority; (3) the whole body of such rules; (4) the control brought about by the enforcement of such law; (5) the legal process; and (6) the whole body of laws relating to one subject.

As you can quickly see, even defining the term "law" is not a simple proposition. To simplify the terminology, this text follows the predominant American meanings for the term "law" and its synonyms:

Law implies imposition by a sovereign authority. Law commonly refers to the entire body of law on the subject, but also is a synonym for "statute."

Statute means a law enacted by a legislative body.

Regulation implies prescription by administrative agency to carry out their statutory responsibilities. Federal regulations are first published in the *Federal Register*, which is published daily and organized by date and page number. Later the regulations are codified in the Code of Federal Regulations.[15]

Rule applies to more restricted or more specific laws than statutes. "Rule" often is an abbreviated form of the term "administrative rule," which is a law promulgated by an administrative agency. Administrative rules are also called regulations. However, administrative rules are only one form of rules. Some administrative orders, resolutions, and formal opinions are also "rules."

Guideline suggests something advisory rather than binding.

Ordinance applies to an order enforced by a local unit of government, such as a city.

The system of U.S. laws can be divided into four parts:

- Constitution
- Statutes
- Regulations
- Common law and case law

These four types of laws are described below in reference to the federal law. However, a similar system of laws occurs within the various states.

[15] "Codification" is the arrangement of the laws (statutes or regulations) into an organized code. The volumes of the Code of Federal Regulations are organized by subject matter.

1.3.1 The Constitution[16]

The U.S. Constitution provides the framework for the U.S. legal system. The Constitution both empowers and limits government. The Constitution provides the supreme law of the land, and it is, by design, difficult to alter as a way of protecting long-standing values.

The U.S. Constitution creates the federal government and divides the power into the three branches, legislative, executive, and judicial. The legislative power is vested in the U.S. Congress (Article I). (However, additional laws can be created by the executive and judicial branches.) The executive power is placed in the President (Article II). The judicial power is vested in the courts (Article III). This "separation of powers" was designed to create checks and balances to protect against tyrannical rule. Each of the three branches is considered separate but equal.

This caution over the concentration of power is a theme that runs throughout U.S. law. The Constitution, in addition to granting powers to government, also limits government's powers and functions, particularly of the federal government. The first ten amendments of the Constitution are known as the Bill of Rights,[17] and they protect individual rights by setting restrictions on the activities of the federal government.

1.3.2 Statutes

Within their power granted by the U.S. and state constitutions respectively, Congress and state legislatures enact public acts, also called statutes. (Cities and other municipalities generally call their enactments of law "ordinances.") All statutes must be consistent with the U.S. Constitution. State and local laws must also be consistent with the applicable state constitution.

1.3.3 Regulations

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

In theory, the administrative agencies merely execute the laws enacted by the legislature. However—because the legislatures often provide only a broad mandate—the agencies have considerable leeway in interpreting and applying their mandate. Typically, an administrative agency promulgates the detailed regulations that are necessary to translate the legislative mandate into operating standards. The regulations must fall under the scope of authority delegated by the legislature in statute. Regulations must also be consistent with other relevant constitutional and statutory requirements. Generally, regulations have the full force of law found in the enabling statute.

The executive branch agencies have increased in number, size, and importance since the 1930s. However, it is important to remember that the agencies can only carry out that, which they are authorized to do by the legislature. In addition, the legislature determines the amount of funding the agencies receive. It is common for legislatures to grant enact popular statutes with noble sounding mandates but then fail to provide the necessary funds to agencies to carry out the new legislative mandate.

1.3.4 Case Law and Common Law

Both case law and common law are based on judicial decisions. Case law is the law established by the precedents of judicial decisions in cases (as distinguished from laws created by legislatures). Case law is important because of the tradition of following precedents. When a court addresses a legal dispute, it is usually guided by what has been decided previously in similar cases. These precedents become the case law. The general concept is that judges should follow the principles of law set down in prior decisions, unless it would violate justice or fair play to do so. Reliance on precedent serves to promote uniformity, predictability, and foster trust in a rule by law, not by person. Case law precedence is only set by the appellate courts.

Common law is the body of law based on legal tradition, custom, and general principles. Common law is embodied in case law and that serves as precedent or is applied to situations not covered by statute. U.S. common law was originally derived from English legal principles and traditions, but now includes the precedents that have developed over time from the decisions of U.S. courts.

Common law generally applies only to areas of law where there is no statutory law. For example, if a firm discharges food processing waste on a field, and a foul smell permeates nearby homes, this may violate the common law of nuisance. Private nuisance common law might allow individuals to sue the processing plant. Public nuisance common law might allow a government official to take action. However, if a statute regulates acceptable waste-handling methods for processing plants, then the legislative law can override the common law.

1.3.5 Federalism

To understand how the U.S. system of law interrelates, one needs to understand federalism. The Constitution divides the power of government vertically between federal and state

[16] Although the U.S. Constitution is at the root of all American law, nonlawyers seldom read the document. Do not be intimidated by the document's importance. Its language is surprisingly simple to understand.
[17] See the appendix to this chapter.

governments. Federalism is the term used to refer to this division of power. Federalism also limits the ability of a state to interfere or burden other states. An important 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.[18] This provision, as a general matter, means that the federal laws preempt state and local laws if they conflict.[19] However, federal law can only preempt state law where there is authorization by the Constitution. The federal government only holds the powers delegated to it by the Constitution; other powers are reserved to the states or to the people.[20]

This division of power has been a great debate throughout U.S. history. However, the growth of national and international commerce and the problems of the modern age have led to a very expansive interpretation of the federal power. The Commerce Clause of the Constitution grants Congress plenary power to regulate commerce.[21] Commerce covers a wide range of activities, not just direct interstate commerce, but any activities indirectly affecting interstate commerce. Today, given the nationally integrated economy of the United States, nearly all commerce is interstate or has an interstate impact, thus it is under federal purview.

However, states retain control over all matters not specifically delegated to the federal government.[22] The key area here is that *only* the states possess the power to regulate specifically for the health and welfare of the people.[23] Police power is the term used to refer to this exclusive state power, the broad powers traditionally possessed by governments and exercised to protect the health, safety, welfare, and general well being of the citizenry.[24] Authority to make food inspection laws and health laws are part of the traditional police powers.

Nevertheless, often the federal government may regulate an activity that falls under the police power category, because it also falls under federal authority via another power, such as the power to regulate interstate commerce. For example, the federal government could not regulate the minimum cold-holding temperatures of foods for health and safety reasons, but it may do so for the purpose of regulating interstate commerce.

In theory, this limitation on the federal government reach is considerable. In practice due to the interconnected nature of the food supply, most food businesses would be considered to have an effect on interstate commerce. For instance, use of a single ingredient that was shipped in interstate commerce in a multi-ingredient food would create federal jurisdiction and fall within the scope of the FD&C Act.[25]

The end result of federalism is the states' independent power creates more regional differences in the law and regulation than would occur if there were a single national legal standard. In addition, states are free to legislate and regulate any arena that has not been preempted by federal law.[26] However, any additional restriction passed by a state must not place an unreasonable burden on interstate commerce.

Accordingly, firms shipping into various states must be careful that they meet both federal and state requirements. This patchwork of different laws has been criticized as being of burden to firms shipping to several states.

While troublesome from a commercial standpoint, this decentralization of power was intentional to prevent against tyranny. There is also the benefit of different localities having the opportunity to propose laws that best serve the needs of their community. For instance, coastal states often have closer scrutiny for seafood harvests than states without fisheries.[27]

The experience of trying out new ideas and conducting these regulatory experiments in local settings may yield useful information for future efforts to solve problems that face all communities.[28] For example, because sulfites can be dangerous to sensitive individuals, Michigan requires the

[18] The U.S. Constitution provides that the Constitution, and the Laws of the United States which shall be made in pursuance thereof; and all Treaties made, or which shall be made, under the Authority of the United States, shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, anything in the Constitution or Laws of any State to the Contrary notwithstanding. U.S. CONST. art.VI.

[19] Of course, state and federal laws may be different without direct conflict. Generally, states may pass more restrictive or stringent food safety laws (or weaker laws) than those promulgated at the federal level, so long as there is no direct conflict in the specifics of the laws.

[20] "The powers not delegated to the United States by the Constitution, nor prohibited by it to the States, are reserved to the States respectively or to the people." U.S. CONST. amend. X.

[21] Article I of the Constitution authorizes Congress to make all laws which shall be necessary and proper for carrying into execution the government's constitutional powers. The "Commerce Clause," in article I, section 8, clause 3 of the Constitution, authorizes Congress to regulate commerce with foreign nations, among the several States and with the Indian tribes.

[22] "The powers not delegated to the United States by the Constitution, nor prohibited by it to the States, are reserved to the States respectively or to the people." U.S. CONST. amend. X.

[23] United States v. Lopez, 514 U.S. 549 (1995).

[24] Gibbons v. Ogden, 22 U.S. 1 (1824) (Police powers "form a portion of that immense mass of legislation which embraces everything within the territory of the state, not surrendered to the general government; all of which can advantageously be exercised by the states themselves. Inspection laws, quarantine laws, health laws of every description . . . are component parts of this mass.")

[25] See Chapter 15 for greater details and *United States v. 40 Cases . . . "Pinocchio Brand . . . Blended . . . Oil,"* 289 F.2d 343 (2nd Cir. 1961).

[26] Alden v. Maine, 527 U.S. 706 (1999).

[27] At least 16 states have shellfish safety laws.

[28] New Ice Co. v. Liebman, 285 U.S. 262, 311 (1932); United States v. Lopez, 514 U.S. 549, 581 (1995).

labeling of sulfite use on salad bars.[29] California, a major producer of canned food, adopted the first regulation for mandated thermal processing controls for canned food in 1920.[30] California's updated low-acid canning regulation eventually served as the model for the FDA low-acid canning regulation promulgated in 1973.

At the beginning of the twentieth century, increased distribution of milk to growing population centers resulted in outbreaks of milk-borne diseases. The city of Chicago passed the first mandatory milk pasteurization law in 1908. In 1947, Michigan became the first state to require milk pasteurization.[31] Other states soon followed, but federal regulation did not prohibit unpasteurized milk until 1987.[32]

Consistent with the principles of federalism and of state's rights, courts have generally held that states may enact and enforce food laws that are different from the federal law so long as the state laws are not inconsistent with the federal law, and do not unreasonably burden interstate commerce. "Inconsistent" generally means direct or indirect conflict between the state and federal law.[33]

To prevent the problems from inconsistency, cooperative and educational efforts at uniformity have been an important part of the legal landscape in food law. For example, the FDA issues a model Food Code for retail food establishment, and the Association of Food and Drug Officials issues a model Food, Drug, and Cosmetic Act. When the models or the federal laws are perceived as adequate by state governments, usually the states will adopt the model or federal regulations essentially word for word into state law.

1.4 AGENCY PROCEDURAL REGULATION

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.

In addition to following the requirements of the Constitution and the enabling statutes, administrative agencies must comply with a number of procedural statutes. Following three are the most important:

Administrative Procedure Act (APA), which specifies requirements for rulemaking (the process by which federal agencies make regulations) and agency adjudication.

Federal Advisory Committee Act (FACA), which requires that certain kinds of groups whose advice is relied upon by the government be chartered as advisory committees, that they be constituted to provide balance, to avoid a conflict of interest, and to hold committee meetings in public with an opportunity for comment from those outside the committee.

Freedom of Information Act (FOIA), which provides the public with a right to access agency information.

1.4.1 The Administrative Procedure Act

The federal Administrative Procedure Act (5 U.S.C. § 551 *et seq*.) provides for basic procedural safeguards in the federal regulatory system, and establishes and defines judicial review authority over the federal regulatory agencies. A major thrust of the APA is to ensure due process in the rulemaking and adjudication by administrative agencies.

In simplest terms, due process means fairness. The three most basic elements of due process are that those affected by the regulatory process are guaranteed notice, an opportunity to be heard, and a record for use in judicial appeals. The major statutory requirements of procedural fairness in the federal Administrative Procedure Act are paralleled in state administrative procedure acts.

1.4.2 Rulemaking

Rulemaking involves the development of administrative rules or regulations for future enforcement. Generally, regulations specify the technical details that are necessary to comply with a law's much broader requirements. For example, the FD&C Act, section 403, states in part, "A food shall be deemed to be misbranded (a) If (1) its labeling is false or misleading in any particular. . . . " Regulations are promulgated by the FDA to define specific information required on a label to avoid being false or misleading in any particular.

The APA specifies minimum procedural safeguards that agencies must follow when engaged in rulemaking. Notice of any proposed rule must be published by the proposing agency in the *Federal Register*. The agency must allow interested parties time to submit comments. In some instances, public hearings must be conducted with an official record and formal rules. Public comments must be reviewed and considered by the agency before final adoption of a regulation. The agency must explain why it did or did not incorporate suggestions in the final regulation. Final regulations must be published at least 30 days before they are to take effect, so as to allow an opportunity both for legal challenge and for adjustments necessary for compliance with the regulation. Note, however, that unless Congress specifies

[29] MCL §289.8103; for background on sulfites, *see* Ruth Papazian, *Sulfites: Safe for Most, Dangerous for Some*, FDA Consumer (Dec. 1996).
[30] Food and Drug Branch, California Department of Public Health, *History of the California Cannery Inspection Program* (2008) ("From 1899 to 1949, there were 483 outbreaks of botulism reported in North America (the United States and Canada) involving 1319 cases and 851 deaths.")
[31] Cornell University, *Heat Treatments and Pasteurization* (Apr. 2, 2008).
[32] 21 C.F.R. § 1240.61.
[33] See Chapter 14 for greater details.

otherwise, federal agencies have some discretion under these procedural rules.

1.4.3 Adjudication

Judging noncompliance and imposing penalties for violation of regulations may also be a part of an agency's responsibility (if so authorized by statute). Agency adjudication is an agency hearing, somewhat similar to a judicial proceeding, but typically conducted before an agency official acting in the capacity of an administrative law judge (or hearing referee). Agency adjudication is less formal than most judicial proceedings. An adjudicatory hearing deals with specific parties and facts; it establishes what happened and prescribes what is to be done, including determining penalties. For example, a state agriculture department might conduct an adjudication proceeding in which it first establishes the facts as to whether a food establishment violated applicable sanitation standards and then whether revocation of the establishment's license is warranted.

Thus, an administrative agency can serve as the lawmaker, the prosecutor, and the judge, all rolled into one. This does not necessarily violate the principle of separation of powers. The rationale is that administrative agencies have narrow areas of technical expertise, they are controlled by numerous procedural requirements, and these decisions always may be appealed to the court system. Due process and the APA specify that agencies, when engaged in adjudication, must provide a person notice of the case against him or her, and a meaningful opportunity to present their case. In some cases the determination must be made by trial-type proceeding.[34]

While court challenges of agency adjudications are not uncommon, it should be noted that those challenges are usually based on procedural, rather than substantive grounds. The courts are enormously deferential to an agency's expertise and are unlikely to interfere with the substantive decisions made by an agency.[35] Procedural challenges are much more likely to be successful, and also provide greater advantage for negotiated settlements or delays in the implementation of the agency's decision. For example, a grocery store may challenge an agency's decision to revoke their license due to insanitary conditions. However, the challenge is far less likely to be successful on the basis that the agency was incorrect in its professional judgment that the store was insanitary (a substantive challenge), as opposed to the challenge that the agency failed to consider all pertinent evidence in the record because it failed to properly notify the establishment (procedural challenges). A court is far less likely to overturn the agency's decision on the seriousness of the insanitation than to find there a procedural deficiency.

1.4.4 Judicial Review

Administrative agency activity must also be consistent with the Constitution and relevant statutes. Judicial review of administrative agency activity oversees this consistency. Standards for judicial review of agency actions are outlined in the Administrative Procedure Act, which defines the basis and scope of judicial intervention and review. Generally, the courts will *not* consider whether an agency acted wisely, but only whether the agency acted as follows:

- Stayed within its constitutional and statutory authority.
- Properly interpreted the applicable law.
- Conducted a fair proceeding.
- Avoided arbitrary or capricious action.
- Reached a decision supported by substantial evidence in the record.

However, the Supreme Court has also ruled that the courts are to review agency decisions with a searching and careful inquiry to determine "whether the decision was based on consideration of the relevant factors and whether there has been a clear error of judgment."[36] This "Hard Look" doctrine leaves reviewing courts with considerable latitude for overseeing the actions of administrative agencies.

1.4.5 Federal Advisory Committee Act (FACA)

FACA requires that certain kinds of groups whose advice is relied upon by the government be chartered as advisory committees. Advisory committees must be constituted to provide balance and to avoid a conflict of interest. Committee meetings must also be held in public with an opportunity for comment from those outside the committee.

As science-based programs, the food-regulation agencies often rely on committees for scientific advice. Therefore, affected parties may find it important to have a say in the deliberations and recommendations of these advisory committees. For example, the U.S. Department of Agriculture (USDA) and HHS select members for the Dietary Guidelines Advisory Committee, which issues the nation's nutritional and dietary guidelines. These recommendations are the foundation for the nutritional standards in all federal food assistance programs, including school lunches and food stamps, and are used in developing the food guides and nutritional classes. Various groups have contested the makeup of the committee for lack of balance and for

[34] Mathews v. Eldridge, 424 U.S. 319; 96 S.Ct. 893 (1976).

[35] Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc., 467 U.S. 837 (1984).

[36] Citizens to Preserve Overton Park, Inc. v. Volpe, 401 U.S. 402 (1971).

conflicts of interest. Because food companies are regular sponsors for educational activities of nutrition professional associations as well as nutrition research, finding nutrition academics without some connection to the food industry is difficult.[37]

NOTES AND QUESTIONS

1.1. FACA. Why would the composition of the various advisory committees be so important that Congress would write a law requiring balance?

1.2. Conflicts of interest. What type of conflicts of interest might arise in the composition of the Dietary Guidelines Advisory Committee?

1.3. Advisory Committees. The FDA relies on expert advisory committees heavily for therapeutic products approval. To a lesser extent they are used for food. The FD&C Act § 721(b)(5)(D) & (D) mandates an advisory committee for color additives, but that is an exception and most advisory committees are established at FDA's discretion.

1.4.6 Freedom of Information Act (FOIA)

> A popular Government without popular information or the means of acquiring it, is but a Prologue to a Farce or a Tragedy or perhaps both. Knowledge will forever govern ignorance, and a people who mean to be their own Governors, must arm themselves with the power knowledge gives.
>
> James Madison

Federal executive branch agencies are required under the Freedom of Information Act (FOIA) to disclose most records requested in writing by any person. Agencies may withhold information under nine exemptions and three exclusions in the statute.

FOIA litigation is a complex area of law with thousands of court decisions interpreting the act. However, this should not intimidate you from understanding the fundamentals of the law or from making a request yourself. More information on FOIA is found in Chapter 20 *infra*.

1.4.7 Constitutional Limitations on Agency Power

Police power, specifically the power of state governments to regulate for the health and welfare of the people, has been upheld to be quite broad in reach and impact. Generally, these laws will be upheld if they are at all rational attempts to protect and promote the public's health, safety, or general welfare. The courts will not review whether the laws are the best option or even whether they are "good" laws, but merely whether they avoid being arbitrary or capricious.

State authority to regulate health, safety, and general welfare has been sustained not only for laws aimed at protecting the public in general but also protecting individuals. Such laws have been upheld even when restricting property rights and individual autonomy. The U.S. Supreme Court made it clear that "the police power is one of the least limitable of governmental powers . . . ," and that the states possess extensive authority to protect public health and safety.[38]

Although the courts have interpreted the state police power broadly, governmental authorities do have limits placed on their powers. Limitations on state and federal powers are mainly found in the following documents:

- The U.S. Constitution.
- The constitutions of individual states.
- Federal and state laws.

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 it is a matter beyond the constitutional reach of government altogether. For example, Congress passed a law that required states to provide a disposal site for low-level radioactive waste by a specific date. Any state that failed to meet that deadline was required to take title to and be responsible for all low-level radioactive waste produced in the state. New York State contested the "take title" provision on the ground that it went beyond the enumerated powers of the federal government. The U.S. Supreme Court agreed that the act violated the Tenth Amendment of the U.S. Constitution.[39]

Food laws are sometimes challenged as infringing upon constitutionally protected individual rights. The first ten amendments to the Constitution, the Bill of Rights, define those things that government cannot do to the individual. If Congress or a state legislature enacts a law inconsistent with any of these constitutional provisions, the courts may be asked to invalidate the law as being "repugnant to the Constitution."

In the area of food safety, however, the courts historically have been hesitant to invalidate these laws, even for the sake of protecting individual rights. Nonetheless, food laws have been challenged on this basis, and some important aspects highlighted below foreshadow issues that will rise in later chapters. The cases illustrate how an individual's rights are balanced against society's need for protection from preventable harms.

[37] Marion Nestle, Food Politics 112 (2002).

[38] Queenside Hills Realty Co., Inc. v. Saxl, Commissioner of Housing and Buildings of the City of New York, 328 U.S. 80 (1946).

[39] New York v. United States, 505 U.S. 144 (1992).

The Bill of Rights is generally applicable to the states through the Fourteenth Amendment. Right by right, the Supreme Court has applied most, but not all, of the Bill of Rights' restrictions to the state governments through the Fourteenth Amendment. For example, the states may not pass laws that abridge the freedom of speech, press, or assembly. Technically, the state law would be in violation of the Fourteenth Amendment, but for ease of reference, this chapter will refer to the underlying Bill of Rights amendment (in this example the First Amendment's protections of the freedom of speech, press, and assembly).

Free Speech Laws may be invalidated because they conflict with the part of the First Amendment that protects the free communication of ideas: "Congress shall make no law . . . abridging the freedom of speech or of the press. . . . " As with all the Bill of Rights, the First Amendment rights are not absolute and may be abridged under certain circumstances. Justice Holmes famously noted that the First Amendment does not afford a right to cry "fire" in a crowded theater.

In *Cox v. New Hampshire*, 312 U.S. 569 (1941), the U.S. Supreme Court upheld an ordinance that required parade permits, although a group who challenged the law argued that it abridged their First Amendment rights of assembly and communication. The Court concluded

> The authority of a municipality to impose regulations in order to assure the safety and convenience of the people in the use of public highways has never been regarded as inconsistent with civil liberties, but rather as one of the means of safe-guarding the good order upon which they ultimately depend. . . . The question in a particular case is whether that control is exerted so as not to deny or unwarrantedly abridge the right of assembly and the opportunities for the communication of thought and the discussion of public questions immemorially associated with resort to public places.

First Amendment issues will be discussed in later chapters regarding the right of free expression of commercial speech in conjunction with food advertising and claims.

Searches The Fourth Amendment to the U.S. Constitution provides that

> The right of the people to be secure in their persons, houses, papers, and effects, against unreasonable searches and seizures, shall not be violated, and no Warrants shall issue but upon probable cause supported by Oath or affirmation and particularly describing the place to be searched and the persons or things to be seized.

This is particularly relevant to how agencies conduct inspections. The courts have generally upheld the validity of laws granting government agencies the right to inspect food establishments; however, the scope of inspections is more controversial. The right to take photographs and the right to access records, such as complaint files, formulation files, and personnel files, will be discussed in later chapters.

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 himself 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.

Self-Incrimination Under the Fifth Amendment's protection that no person shall be compelled to be a witness against himself in a criminal case, a person may refuse to answer official questions if the answers could be used as evidence against him in a criminal prosecution. This right applies not only to questioning by the federal government, but also through application of the Fourteenth Amendment, to questioning by state and local governmental agencies.

However, the Fifth Amendment protection against self-incrimination has limited applicability to agency authority to see records or require the production of documents kept by a food establishment. Largely this is because the privilege against self-incrimination is a personal one and does not extend to corporations and similar unincorporated collective entities or associations.[40] In addition, this privilege does not extend to the agents or custodian of the records of corporations and other collective entities.[41] Nor does the privilege extend to the sole proprietor of a business to withhold records kept under a legitimate regulatory program.[42] For example, the Fifth Amendment provides no privilege to withhold the time and temperature records a company is required to keep under food safety regulations.

On the other hand, the privilege against self-incrimination could apply a law requiring documentation of criminal activity. For example, bookies (those running an illegal gambling operation, or "bookmaking") cannot be compelled to register their occupation because it would be compelled self-incrimination.[43] The difference here is the requirement concerns inherently criminal activity, while required food establishment records are essentially noncriminal and regulatory in nature.

[40] *See, e.g.*, Hale v. Henkel, 201 U.S. 43 at 74-75 (1906) (a corporation is a creation of the state, and there is a reserved right to unimpaired access to records to ensure compliance with the regulatory limits of the state).
[41] *See*, Braswell v. United States, 487 U.S. 99 (1988).
[42] *See*, Shapiro v. United States, 335 U.S. 1 (1948).
[43] Marchetti v. United States, 390 U.S. 39 (1968).

Nonetheless, when the records and reports required to be produced by food establishments and supplied to regulatory agencies could conceivably lead to criminal prosecution, there can be a concern over the reluctance to create incriminatory records. This reluctance for candor in the records can inhibit the purpose of certain self-regulatory measures. For instance, the requirement to document deviations from time or temperature controls and correspondingly take corrective actions is an important preventative means in keeping safety issues from reaching the consumers. If the concern over self-incrimination prevents the effectiveness of such controls, this potential conflict has been avoided by making it a criminal offense to fail to maintain and report such records, but forbidding their use for criminal prosecution.[44]

Due Process The Fifth Amendment due process provision provides that "no person shall be deprived of life, liberty, or property without due process of law." This clause, along with a similar provision in the Fourteenth Amendment applying due process to state governmental actions, establishes the principle that government must act fairly, according to clear procedures. In its most straightforward sense, due process means fairness in the procedural application of the law. The most basic components of due process fairness are notice and an opportunity to be heard, which were also discussed above regarding the Administrative Procedures Act.

Additionally, 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 those subject to the law can understand what the law requires. A law that is so vague that reasonable people may not understand its meaning lacks basic fairness and violates due process. Such statutory or regulatory language could be invalidated by the courts as "void for vagueness" under the Due Process clause.

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 agency may unilaterally revoke a license, but the agency must then give the owner an opportunity to challenge the revocation in a later hearing.

Just Compensation for the Taking of Private Property The Fifth Amendment provides that no private property shall be taken for public use without just compensation. Agencies may seize or embargo food for being adulterated or misbranded. Is such a seizure a "taking" under the Fifth Amendment? If it is, then the government would be constitutionally required to compensate those persons whose private property rights were affected.

Adulterated food with no commercial value presents an easy answer, because with no value there can be no takings. However, the state is not required to compensate the seller of adulterated meat for the salvage value of the protein.

Seizures clearly interfere with people's use and enjoyment of their property. However, foods under seizure are not taken for the public use. The purpose of the seizures is protection of the public's health and welfare. However, in keeping with the broad authority the Constitution extends to government as the protector of public health and safety, the general rule is that government seizure of private property to prevent harm does not require compensation.

The Supreme Court balances the public interest involved against the reasonableness of the infringement on individual private interests. In *Mulger v. Kansas,* 123 U.S. 623 (1887), the U.S. Supreme Court noted

> The power which the States have of prohibiting such use by individuals of their property as will be prejudicial to the health, the morals, or the safety of the public, is not – and, consistently with the existence and safety of organized society, cannot be – burdened with the condition that the State must compensate such individual owners for pecuniary losses they may sustain. The exercise of the police power by the destruction of property which is itself a public nuisance, or the prohibition of its use in a particular way, whereby its value becomes depreciated, is very different from taking property for public use, or from depriving a person of his property without due process of law. In the one case, a nuisance only is abated; in the other, unoffending property is taken away from an innocent owner.

The courts have routinely upheld the exercise of the police power even when property will be confiscated or destroyed.

Equal Protection The U.S. Supreme Court has also interpreted due process to mean that no person shall be denied equal protection of the laws. This guarantee is provided explicitly in the Fourteenth Amendment, applicable to the states, and implicitly in the Fifth Amendment Due Process clause, applicable to the federal government. Equal protection of the law refers to an even-handed application of law. In its most basic sense this means

[44] Frank P. Grad, The Public Health Law Manual, 2nd ed., 272-278, Washington, D.C.: American Public Health Association (1990) (New York City took this approach in its self-inspection program for food establishments. N.Y.C. Health Code §§ 81.39(a), 131.03(d), 131.05(b)).

that government and the legal system cannot arbitrarily discriminate. Equal protection may be violated in two ways: directly by the words of the law or by the application of the law.

Equality before the law applies not only to the specifics of a law but also to how agencies implement the law. For example, under a local ordinance, which prohibited the construction of wooden laundries without a license, almost all Chinese applicants were denied licenses, while non-Chinese applicants routinely received them. Although the ordinance was a valid safety measure on its face, the implementation violated the equal protection clause of the Fourteenth Amendment.[45]

Nonetheless, equal protection does not require identical treatment. Government may classify people into groups and treat these groups differently. For example, regarding 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 it has good reason to do so. The critical question is what is an acceptable reason for applying the law differently to persons in similar situations.

Privacy Rights Although privacy right objections are frequently made against public health laws—such as immunization, fluoridation, and compulsory HIV testing—the argument is less common against food laws. The seminal case on privacy rights is *Griswold v. Connecticut,* 381 U.S. 479 (1965), where a Connecticut law prohibited the prescribing of contraceptives and their use by any person, including married couples. The U.S. Supreme Court declared the Connecticut statute unconstitutional. In the main opinion, Justice William O. Douglas laid out the basis of a constitutional right to privacy. 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. Efforts to expand the right of privacy to less intimate areas as a basis for invalidating public health and safety laws have not succeeded.

1.5 AGENCY JURISDICTION

Federal responsibility for the direct regulation of food in the United States has primarily been delegated to the FDA and the USDA. However, a number of other federal agencies become involved, depending on the type of food and the type of activity to be regulated. Although the involvement of food with some of these agencies is less direct than that of FDA and USDA, their roles are neither unimportant nor necessarily small.

THUMBNAIL COMPARISON OF AGENCY RESPONSIBILITIES FOR FOOD

Agency	*Responsibility*
Environmental Protection Agency (EPA)	• Drinking water • Pesticide residues
FDA	• Food (but not meat) • Drug (OTC and prescriptions) • Dietary supplements • Cosmetics • Medical devices • Bottled water • Seafood • Wild game (“exotic” meat) • Eggs in the shell
Federal Trade Commission (FTC)	• Advertising
Alcohol and Tobacco Tax and Trade Bureau (TTB)	• Alcohol
USDA	• Raw vegetables grading • Raw fruit grading • Meats • Poultry • Eggs, processing, and grading

The remainder of this chapter presents an overview of principal federal regulatory organizations responsible for food regulation[46] along with a summary of the major federal statutes.

1.5.1 Food and Drug Administration[47] (FDA)

Oversees

- All domestic and imported food sold in interstate commerce, including shell eggs, but not meat and poultry.
- Bottled water.
- Wine beverages with less than 7 percent alcohol.

[45] Yick Wo v. Hopkins, 118 U.S. 356 (1886).

[46] *Derived from* FDA, FDA BACKGROUNDER: FOOD SAFETY: A TEAM APPROACH (Sept. 24, 1998).

[47] For a listing of the statutory responsibilities of the FDA, *see* 21 C.F.R. § 5.10.

- Shell eggs and egg containing products that do not meet USDA's definition of "egg product." Egg washing, sorting, and packing.[48]

Food Safety Role Food safety laws governing domestic and imported food, except meat and poultry, are enforced by the following ways:

- Inspecting food production establishments and food warehouses.
- Collecting and analyzing samples for physical, chemical, and microbial contamination.
- Reviewing safety of food and color additives before marketing.
- Reviewing animal drugs for safety to animals that receive them, and humans who eat food produced from the animals.
- Monitoring safety of animal feeds used in food-producing animals.
- Developing model codes and ordinances, guidelines and interpretations, and working with states to implement them.
- Establishing good food manufacturing practices and other production standards such as plant sanitation, packaging requirements, and hazard analysis and critical control point programs.
- Working with foreign governments to ensure safety of certain imported food products.
- Requesting manufacturers to recall unsafe food products and monitoring those recalls.
- Taking appropriate enforcement actions.
- Educating industry and consumers on safe food-handling practices.

1.5.2 Centers for Disease Control and Prevention (CDC)

Food Safety Role

- Investigates with local, state, and other federal official sources of foodborne disease outbreaks.
- Maintains a nationwide system of foodborne disease surveillance.
- Develops and advocates public health policies to prevent foodborne diseases.
- Conducts research to help prevent foodborne illness.

For more information: www.cdc.gov

1.5.3 USDA Food Safety and Inspection Service (FSIS)

Oversees

- Domestic and imported meat and poultry, and related products such as meat- or poultry-containing stews, pizzas, and frozen foods.
- Processed egg products (generally liquid, frozen, and dried pasteurized egg products).

Food Safety Role The Federal Meat Inspection Act, the Poultry Products Inspection Act, and the Egg Products Inspection Act, which regulate meat, poultry, and egg products, are enforced by the following:

- Inspecting food animals for diseases before and after slaughter.
- Inspecting meat and poultry slaughter and processing plants.
- Inspecting "egg product" processing plants (egg breaking and pasteurizing operations).[49]
- With USDA's Agricultural Marketing Service, monitoring and inspecting processed egg products.
- Collecting and analyzing samples of food products for microbial and chemical contaminants and infectious and toxic agents.
- Establishing production standards for use of food additives and other ingredients in preparing and packaging meat and poultry products, and for plant sanitation, thermal processing, and other processes.
- Ensuring all foreign meat and poultry processing plants exporting to the United States meet U.S. standards.
- Seeking voluntary recalls by meat and poultry processors of unsafe products.
- Educating industry and consumers on safe food-handling practices.

For more information: www.fsis.usda.gov

1.5.4 U.S. Environmental Protection Agency (EPA)

Oversees

- Drinking water
- Pesticide safety

[48] FDA-regulated egg products include hard boiled eggs, cooked omelets, frozen egg patties, imitation egg products, egg substitutes, noodles, cake mixes, freeze-dried products, dietary foods, dried no-bake custard mixes, egg nog mixes, acidic dressings, mayonnaise, milk and egg dip, foods containing egg extracts, French toast, sandwiches containing eggs or egg products, and balut and other similar ethnic delicacies. FDA also has jurisdiction in establishments not covered by USDA; e.g. restaurants, bakeries, and cake mix plants.

[49] The definition of "egg product" includes dried, frozen, or liquid eggs, with or without added ingredients, but contains many exceptions. Exemptions include freeze-dried products, egg substitutes, egg nog, etc.

Food Safety Role

- Establishes safe drinking water standards.
- Regulates toxic substances and wastes to prevent their entry into the environment and food chain.
- Determines safety of new pesticides, sets tolerance levels for pesticide residues in foods, and publishes directions on safe use of pesticides.

For more information: www.epa.gov

1.5.5 National Marine Fisheries Service (NMFS)

Oversees

- Fish and seafood products (through a voluntary, fee-for-service system).

Food Safety Role

- The Seafood Inspection Program inspects and certifies fishing vessels, seafood processing plants, and retail facilities for federal sanitation standards.

For more information: www.nmfs.noaa.gov

1.5.6 Alcohol and Tobacco Tax and Trade Bureau (TTB)

The Alcohol and Tobacco Tax and Trade Bureau (TTB) of the U.S. Department of Treasury has jurisdiction over the labeling of alcoholic beverages under the Federal Alcohol Administration Act, 27 USC § 201 *et seq.*

Oversees

- Alcoholic beverages except nonmalt beverages containing less than 7 percent alcohol.

Food Safety Role

- Enforces food safety laws governing alcoholic beverages.
- Investigates adulteration alcoholic products, sometimes with help from FDA.

For more information: www.ttb.gov

1.5.7 U.S. Customs and Border Protection (CBP)

Oversees

- Imported foods.

Food Safety Role

- Works with federal regulatory agencies to ensure that all goods entering and exiting the United States do so according to U.S. laws and regulations.

For more information: www.cbp.gov

1.5.8 U.S. Department of Justice (DOJ)

Food Safety Role

- Prosecutes companies and individuals suspected of violating food safety laws.
- Through U.S. Marshals Service, seizes unsafe food products not yet in the marketplace, as ordered by courts.

For more information: www.usdoj.gov

1.5.9 Federal Trade Commission (FTC)

Oversees

- Advertising

Food Safety Role

- Enforces a variety of laws that protect consumers from unfair, deceptive, or fraudulent practices, including deceptive and unsubstantiated advertising.

For more information: www.ftc.gov

Other agencies and units become involved with food in some way as well. For example, the USDA has a number of programs that, while nonregulatory by nature, can effect food regulation. The USDA Agricultural Marketing Service (AMS) provides voluntary standardization, grading, and market news services for specific agricultural commodities. The Agricultural Research Service (ARS) is the main scientific research arm of USDA. The USDA Economic Research Service (ERS) provides economic analysis relating to agriculture, food, environment, and rural development. The USDA Grain Inspection, Packers, and Stockyards Administration (GIPSA) provides grading and standardization programs for grains and related products, and regulates and maintains fair trade practices in the marketing of livestock.

The U.S. Codex Office is the point of contact in the United States for the Codex Alimentarius Commission and its activities. The Department of Commerce, National Marine Fisheries Service (NMFS), provides voluntary inspection and certification of fish operations, and administers grades and standards for fish and fish products (similar to the AMS grading and standards programs).

These food regulatory agencies also work with other government agencies when there are crossover responsibilities. For example, FDA works with the Consumer Product Safety Commission to enforce the Poison Prevention Packaging Act. FDA and USDA work with the FBI to enforce the Federal Anti-Tampering Act, the Department of Transportation to enforce the Sanitary Food Transportation Act, and the U.S. Postal Service to enforce laws against mail fraud.

This federal delegation and organization of responsibilities is somewhat a haphazard patchwork. Just as the statutes were written to address specific problems at particular points in history, the delegation of food regulation was developed to address specific concerns. The delegation, therefore, represents an evolution rather than an organization by design.

A number of authors have called for an end to this patchwork system by creation of a unified food safety agency with paramount responsibility for the safety of the U.S. food supply.[50] Similarly, when large outbreaks of foodborne illnesses become public concerns, attention focuses on the organization of food safety regulation.

1.5.10 State and Local Governments

Allocation of resources is an additional reason state and local governments play a prominent role in food safety regulation in the United States. The combined food-related budget of the above-mentioned federal agencies amounts to only a small fraction of the total federal government budget. The combined total of state and local officials far outnumbers the federal food regulatory staff.

State and local governments employ food inspectors, sanitarians, microbiologists, epidemiologists, food scientists, and more. Their precise duties are dictated by state and local laws. Some of these officials monitor only one kind of food such as milk or seafood. Many work within a specified geographical area, such as a county or a city. Others regulate only one type of food establishment, such as restaurants or meat packing plants.

State meat and poultry inspection programs must be assessed by the USDA FSIS to determine whether the state inspection programs are at least equal to the federal program. FSIS assumes responsibility for inspection in a state that chooses to end its inspection program or cannot maintain the equivalent standard.

DISCUSSION QUESTION

1.4. A single food safety agency. The present U.S. food safety system is a patchwork of a dozen different federal agencies. In 1998, the National Academy of Sciences urged Congress to establish a "unified, central framework for managing food safety programs" headed by a single individual. What are some of the pros and cons of creating a single federal food safety agency?

1.6 MAJOR FEDERAL LAWS

1.6.1 The Main Statutes

All statutes in force in the United States are codified in the United States Code (U.S.C.). The U.S.C. is organized into subject matter titles with numbering that is unique from the section numbering in the statutes as they were enacted into the public acts. For example, section 1 of the Food, Drug, and Cosmetic Act is codified as 21 U.S.C. § 301. Thus, this section may be cited with one or the other or both reference numbers, such as "Sec. 1. [301]."

Food, Drug, and Cosmetic Act (FD&C Act) The Federal Food, Drug, and Cosmetic Act of 1938 gives FDA authority over cosmetics and medical devices as well as food and drugs. The 1938 Act was adopted to correct the imperfections of the 1906 Act and to respond to change in technology and in societal demands from consumers who demanded ever-increasing information about food products. In particular, the 1938 act enacted a comprehensive set of standards by which food safety could be regulated.

Further amendments and revisions to the act after 1938 extended the coverage of the FD&C Act or enlarged FDA's authority over certain products. However, a few amendments have narrowed FDA's authority.

Many states have adopted the Uniform State Food, Drug, and Cosmetics Bill recommended by the Association of Food and Drug Officials, which bears many similarities to the federal FD&C Act. Adoption of this model law is voluntary, but most states have primary food laws that are largely the same as the federal law.

Federal Meat Inspection Act (FMIA) Federal Meat Inspection Act of 1906 was substantially amended by the Wholesome Meat Act of 1967.[51] The FMIA requires USDA to inspect all cattle, sheep, swine, goats, and horses when slaughtered and processed into products for human consumption. The primary goals of the law are to prevent adulterated or misbranded livestock and products from being sold as food, and to ensure that meat and meat products are slaughtered and processed under sanitary conditions.

These requirements apply to animals and their products produced and sold within states as well as to imports, which must be inspected under equivalent foreign standards. The Food

[50] *See, e.g.,* U.S. General Accounting Office (GAO), U.S. Needs a Single Agency to Administer a Unified, Risk-Based Inspection System, GAO/T-RCED-99-256 (Aug. 4, 1999).

[51] Pub. L. 90-201 (1967).

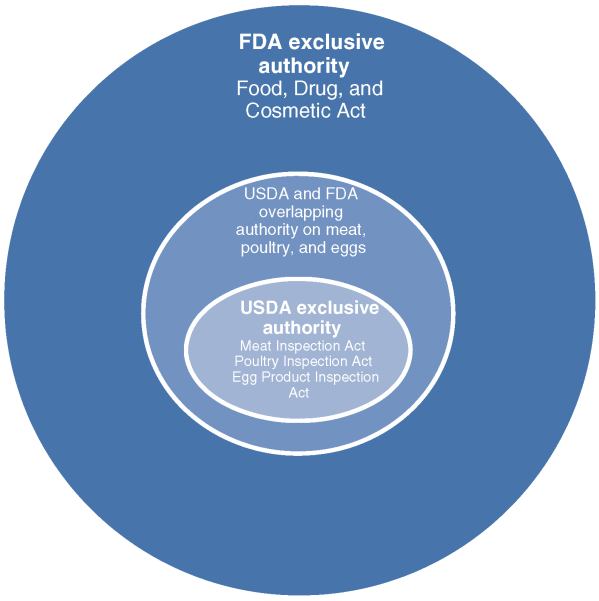

FIGURE 1.2 Overlapping statutory authorities.

and Drug Administration is responsible for all meats considered "exotic," including venison and buffalo (see Figure 1.2).

Poultry Products Inspection Act (PPIA) PPIA provides for the inspection of poultry and poultry products, and regulates the processing and distribution poultry to prevent the movement or sale of poultry products that are adulterated or misbranded.

Egg Products Inspection Act (EPIA) EPIA provides for the inspection of certain egg products, restrictions on the certain qualities of eggs, and uniform standards for eggs. EPIA otherwise regulates the processing and distribution of eggs and egg products.

1.6.2 Other Statutes

The FD&C Act has been amended over 100 times. Usually the amending statute is no longer named and reference is made to the FD&C Act directly. For instance, the Food Safety Modernization Act may not be mentioned but rather the amended powers added into the FD&C Act will be referenced.

A few significant statutes in the food laws of the United States that are notable include the following.

The Food Additive Amendment of 1958 The Food Additive Amendment requires manufacturers of new food additives to establish safety before use in food. The Delaney clause prohibits the approval of any food additive shown to induce cancer in humans or other animals.

The Color Additive Amendment of 1960 The Color Additive Amendment requires manufacturers to establish the safety of color additives in foods, drugs, and cosmetics. The Color Additive Amendment is more stringent than the law for other additives and includes its own Delaney clause.

Food Quality Protection Act (FQPA) in 1996 The FQPA amended prior pesticide legislation to establish a more consistent regulatory scheme based on current science. It mandates a single, health-based standard for all pesticides in all foods, and provides special protections for infants and children, among other provisions. It also requires periodic reevaluation of pesticide registrations and tolerances to ensure that the scientific data supporting pesticide registrations will remain up to date in the future.

FDA Modernization Act of 1997 The FDA Modernization Act reformed many aspects of the regulation of food, medical products, and cosmetics. The most important food regulation aspect is that the act eliminated the requirement for FDA's premarket approval for most packaging and other substances that come in contact with food and may migrate into it. The act also expanded the procedures under which FDA can authorize health claims and nutrient content claims on foods.

Food Safety Modernization Act (FSMA) in 2011 FSMA may be the most significant amendment of the United States food law in history. The 1938 Food, Drug, and Cosmetic Act was broad in scope in amending the 1906 Pure Food and Drug Act. The 1958 Food Additive Amendment was detailed in its provisions. In comparison the Food Safety Modernization Act is broader in scope than the 1938 act and more detailed than the 1958 amendment.

FSMA shifts the focus of the U.S. FDA from primarily reacting to food safety problems to prevention. FSMA empowers the FDA to order recalls, implement new standards on domestic producers, and to place restrictions on importers of food to make sure that imports meet these new standards.

1.6.3 The Regulations

Regulations are promulgated by federal agencies to implement and interpret the statutes that are passed by Congress. Regulations are codified in the Code of Federal Regulations (C.F.R.). Regulation typically have the same or similar title number as their corresponding enabling statute in the U.S. C. For example, the regulations which have been promulgated to interpret and implement Title 21 of the United States Code are, for the most part, located in Title 21 of the C.F.R..

Regulations are first published in the *Federal Register* to order to comply with the requirement for notice and comment of the Administration Procedure Act. Titles 7, 9, and 21 contain most of the laws regulating foods. However, Titles 5,

15, 16, 19, 27, 42, and 49 contain other matters that may relate to food in a less direct manner.

Title 5	Governmental organizations and employees
Title 7	Agriculture
Title 9	Animal and animal products
Title 15	Commerce and trade
Title 16	Conservation
Title 19	Customs
Title 21	Food and drugs
Title 27	Alcohol, tobacco products, and firearms
Title 42	Public health and welfare
Title 49	Transportation

1.7 INFORMATIONAL RESOURCES

1.7.1 Government Agencies

The government agencies provide a wealth of information on food regulations. Examples of gateway sites are as follows:

- The Food and Drug Administration welcome page: www.fda.gov
- Government food safety information: www.foodsafety.gov
- USDA FSIS web site: www.fsis.usda.gov

1.7.2 Associations and Trade Groups

Trade and professional associations can provide important sources of information, particularly on law and policy issues. Some examples are as follows:

- Association of Food and Drug Officials (AFDO): www.afdo.org
- Biotechnology Industry Organization (BIO): www.bio.org
- The Association of Food, Beverage and Consumer Products companies (previously the Grocery Manufacturers Association (GMA)): www.gmaonline.org
- Institute of Food Technologists (IFT): www.ift.org

1.7.3 Other Sources

As you have learned, the local food laws and regulations can vary from state to state and even city to city. Therefore, you need develop skill at accessing this information. In particular, do not overlook your contacts and acquaintances. The Internet is a growing source of information, but some more traditional sources of information should not be forgotten:

- Colleagues
- Contacts and acquaintances
- Elected and nonelected officials
- Public interest groups
- Trade groups
- Public records
- State registers (similar to the *Federal Register*)

APPENDIX: CONSTITUTIONAL AMENDMENTS I THROUGH X (THE BILL OF RIGHTS)

Amendment I

Congress shall make no law respecting an establishment of religion, or prohibiting the free exercise thereof; or abridging the freedom of speech, or of the press; or the right of the people peaceably to assemble, and to petition the Government for a redress of grievances.

Amendment II

A well regulated Militia, being necessary to the security of a free State, the right of the people to keep and bear Arms, shall not be infringed.

Amendment III

No Soldier shall, in time of peace be quartered in any house, without the consent of the Owner, nor in time of war, but in a manner to be prescribed by law.

Amendment IV

The right of the people to be secure in their persons, houses, papers, and effects, against unreasonable searches and seizures, shall not be violated, and no Warrants shall issue, but upon probable cause, supported by Oath or affirmation, and particularly describing the place to be searched, and the persons or things to be seized.

Amendment V

No person shall be held to answer for a capital, or otherwise infamous crime, unless on a presentment or indictment of a Grand Jury, except in cases arising in the land or naval forces, or in the Militia, when in actual service in time of War or public danger; nor shall any person be subject for the same offence to be twice put in jeopardy of life or limb; nor shall be compelled in any criminal case to be a witness against himself, nor be deprived of life, liberty, or property, without due process of law; nor shall private property be taken for public use, without just compensation.

Amendment VI

In all criminal prosecutions, the accused shall enjoy the right to a speedy and public trial, by an impartial jury of the State and district wherein the crime shall have been committed, which district shall have been previously ascertained by law, and to be informed of the nature and cause of the accusation; to be confronted with the witnesses against him; to have compulsory process for obtaining witnesses in his favor, and to have the Assistance of Counsel for his defense.

Amendment VII

In suits at common law, where the value in controversy shall exceed twenty dollars, the right of trial by jury shall be preserved, and no fact tried by a jury, shall be otherwise reexamined in any Court of the United States, than according to the rules of the common law.

Amendment VIII

Excessive bail shall not be required, nor excessive fines imposed, nor cruel and unusual punishments inflicted.

Amendment IX

The enumeration in the Constitution, of certain rights, shall not be construed to deny or disparage others retained by the people.

Amendment X

The powers not delegated to the United States by the Constitution, nor prohibited by it to the States, are reserved to the States respectively, or to the people.