Chapter 10

Food Regulation, Safety Systems, and Security

Food and Packaging Regulation History

The history of food regulation dates beyond recorded history – The Code of Hammurabi (ca. 1760 BC), one of the earliest western legal documents, contained sections on fair pricing of drink at taverns, Chinese case law records food contamination litigation as early as 200 BCE, and the Magna Carta, as described in Chapter 2, addressed grain and wine measurement [1]. Archaeological and more modern records indicate that standardization of weights and measures of precious metals in currency, as well as guilds of food-related craftsmen such as brewers, millers, and bakers were among the first to apply standards of production and to be held responsible for consistency of product quantity or quality. These systems, as well as consumers' skeptical self-reliance while purchasing goods from doubtful sources, persisted well into the era of food mass production. With the advent of large-scale, mass-produced package foods and drugs, the producer and contents of products were obscured to the point where large-scale adulteration and contamination of foods became a substantial problem. In parallel with this trend, understanding of both the microbiology, chemistry, and, to some extent, toxicology of food-borne illness grew to contribute understanding of the sources of the problems that were occurring.

During the 1800s, armies began to experiment with the replacement of unpalatable dried meats with heat-sterilized jars and then sealed metal cans of "bully beef" (from the French, "boulli" meaning "boiled" after the method of sterilization in use at the time) to extend their capacity to travel without depending on local rations. Although canned goods were hand-produced at that point and production proved to be too slow and expensive to make a large impact in the Napoleonic era, later campaigns in the American Civil War and Spanish-American war, Britain's Crimean War, and the Franco-Prussian wars motivated high-volume mass-production of canned goods.

In the United States, the food supply was changing rapidly as well. From a barter and self-sufficiency food distribution system to the doubtful products carried in local general stores, the nature of the retail markets was beginning to change at an accelerating rate. P. T. Barnum, recalling his days as a clerk bartering doubtful goods for dubious furs in a "country barter store," wrote: "Nearly everything was different from what it was represented. Our ground coffee was as good as burned peas, beans and corn could make, and our ginger was tolerable, considering the price of cornmeal." [2]

The advent of packaged and pre-prepared food goods and the expansion of rail infrastructure across an enormous continent began to demand that the consumer trust a producer that they did not know. Indeed, the producer could not know many of the early manufacturers as there was no requirement that the producers identify themselves, the actual contents of the product, or the

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actual weight or volume of product. This distrust produced a tremendous marketing opportunity for early packaged foods producers, most notably Ferdinand Schumacher and the American Cereal Company (which later became Quaker Oats) in Akron, Ohio [3]. He turned consumer mistrust into a sales tool by carefully identifying the manufacturer and contents, offering a money-back guarantee, and tying them into some of the first national food marketing campaigns based on panacean health claims. This latter marketing twist was the start of campaigns that have continued unabated by most manufacturers to this day, and which have prompted both a continuing escalation of regulations and their continuing circumvention.

The Pure Food and Drug Act of 1906

The first US federal legislation broadly regulating food in the nation, the Pure Food and Drug Act of 1906, was the result of a long history of regulation at the state and federal level of smaller issues such as contaminated drugs and the various foods, both toxic and otherwise, made from the output of a burgeoning chemical industry that created synthetic food materials that often drove more wholesome, naturally produced foods out of the marketplace. This is a debate that continues into the present, with issues like the escalating use of high fructose corn syrup and various additives, preservatives, and packaging materials' extracts in foods, as well as dietary supplements [4].

The tipping point was reached by a military inquiry ordered by General Nelson Miles into "embalmed" beef rations that were contracted by the Secretary of War, Russell Alger, from Chicago meat packers for use in the Spanish-American War in spite of recommendations to purchase local beef near army camps in the field. Allegations of the use of preservatives that were suspected to include borates and salcylates in the canned meat were dismissed by a military court in a controversial inquiry that eventually censured Miles, but questioned the safety and methods of the meat packers and the contracting practices of the Secretary of War [5, 6, 7].

In the interim, enough questions had been raised to motivate the sponsorship of the author Upton Sinclair to write an exposé of the anti-labor operations of the beef-packing "trust" (cartel) in Chicago in the early 1900s. The "Army Meat Scandal" and Sinclair's exposé of the unsanitary practices of Chicago's meat-packing industry that became the bestselling book *The Jungle* prompted inquiries by European governments and their rejection of imported meat products, both because of the use of boric acid and other chemicals as preservatives, and because of inspection policies that favored the Chicago beef producers [8]. The absence of a comprehensive food purity bill in the United States, and the loss of business by producers exporting products to Europe (and particularly Britain), which already had such legislation in place, added urgency to the legislation. Although much of the objection could be seen as protectionist trade policy by the countries involved, a comprehensive bill protecting consumers in the United States (and its foreign trade markets) was long overdue by the time of its passage. A pure-foods bill was initially submitted (and patterned) after the 1875 British Pure Foods and Drugs Act but was stalled in Congress for decades because of industry influence and debate over the constitutionality of the legislation.

When the Pure Food and Drug Act of 1906 was finally passed, it provided the basic requirements for the listing of manufacturer, weight or volume of contents, and ingredients for any food or drug produced for sale in the United States, and implemented penalties for the production of unfit, mislabeled, or contaminated foods both for domestic consumption and for export [9]. It also contained the "Beveridge Bill" (named for Indiana senator Albert J. Beveridge), strictly regulating practices in the beef industry that was passed under the threat of making public a

report conducted by Commissioner of the Labor Bureau Charles P. Neill, and Assistant Secretary of the Treasury James B. Reynolds into practices Chicago's beef-packing operations [10]. Intriguingly, the Congress also approved boric acid as a meat preservative almost immediately after adopting the Act, thereby approving one of the pivotal alleged contaminants for further use. These regulations have been periodically updated and expanded as the industry and science have evolved to include food, drugs, cosmetics, medical devices, and many other items.

Whereas original legislation was concerned with simply eliminating harmful contaminants, and considered food as adulterated or unfit "if it contain any added poisonous or other added deleterious ingredient which may render such article injurious to health," it did not set specific levels for contamination or trace materials, most of which were below the detection limits of the analytical methods of the era. As analytical techniques improved, the concept of "any added poisonous or other added deleterious ingredient" inevitably collided with modern analytical techniques and equipment sensitive enough to detect trace contaminants into the parts-per-trillion range. This has required making decisions about the minimum acceptable level of contamination for both direct and indirect food additives. These levels have been subject to occasional changes and a good deal of debate as analytical techniques, medical knowledge of the substance's effects, and considerations of total dietary intake have shifted. As a part of most country's regulatory policies, food packaging must not represent a source of "contamination" of the food, and in most cases may not be used as a means of adding a food component that is not properly represented in the label statement. It remains to be seen what sort of labeling requirement will emerge for active packaging materials that become an integral part of the food production process, such as those which react with foods during storage to remove lactose or perform other functions, as described in Chapter 8.

Further regulations by other government agencies have been implemented to regulate toxic materials that may be released into the environment. Packaging materials are also regulated because they are food contact substances and can release *indirect additives* – materials that will contaminate food after it is processed and packaged – into a food product. This may be a beneficial effect, such as the antioxidants that are incorporated into butter and margarine overwraps to reduce oxidation of fats, but the largest concern is with harmful contaminants such as lead from soldered can seams, carcinogenic monomers from plastic materials, and organic solvents from printing inks. More modern, contentious issues such as the issue of correlation of teratogenic effects (teratogenic substances interfere with normal fetal development, and may cause birth defects or later problems in maturation and sexual differentiation) and endocrine disruption with low-level chemical exposure to plasticizers contained in polymeric packaging components continue to be a source of debate.

Food and Packaging Laws and Their Related Agencies

Although food or packaging law can (and has) become an entire professional specialization, this chapter will attempt to outline some of the more consistent requirements of packaging legislation in the United States' laws without belaboring the minutiae of any of them considering that they represent a mountainous volume of material, some of which will inevitably be subject to periodic change. Rather, the intent is to outline the general intent of the legislation and technical requirements to illustrate the legal framework within which the food processing and packaging operates. European Union regulations rely more on a coordinated panoply of member country's internal regulations, overseen by the European Food Safety Authority for food hazards, as well as specific acts of EU legislation such as the European Parliament and

Table 10.1. Food Production Laws and Standards of Selected Countries

Country/Region	Document	Access
Australia & New Zealand	Australia New Zealand Food Standards Code	http://www.foodstandards.gov.au/thecode/foodstandardscode.cfm
People's Republic of China	PRC Food Safety Law (2008)	http://www.euchinawto.org/index.php?option=com_docman&task=doc_download&gid=449
EEU	EU – Food Safety From The Farm To The Fork	http://ec.europa.eu/food/index_en.htm
EEU*	Product Labelling and Packaging	http://europa.eu/scadplus/leg/en/s16600.htm
India	The Food Safety and Standards Bill (2005)	http://mofpi.nic.in/foodsfty.pdf
Japan	The Food Safety Basic Law (Tentative Translation)	http://www.fsc.go.jp/sonota/fsb_law160330.pdf

*Also recommended: Heckman, Jerome H. (2005), "Food Packaging Regulation in the United States and the European Union." *Regulatory Toxicology and Pharmacology* 42: 96–122.

Council Directive 94/62/EC of 20 December 1994 on packaging and packaging waste [11]. A strict correlation of function between US agencies and EU or other countries' similar entities would be the subject of several more chapters, if not several books. A table of Web-accessible English-language references to other countries' food safety and packaging regulations is listed in Table 10.1.

Whereas the usual description of food packaging regulations goes into excruciating detail about labeling requirements for food packaging, it is also instructive to see how many systems of regulation can affect packaging in various ways. Because packaging is a globally integrated field, drawing from nearly every segment of both science and commercial practice, the list of involved agencies is enormous and can be described here only briefly.

National Institutes of Standards and Technology (NIST)

The general principle that predominates with most products is that protection of the consumer means that measurement error must be minimized during filling. The method used by all US agencies (unless otherwise specified by special circumstances) for checking the net contents of all types of packaged goods is given in NIST Handbook 133 [12]. Additionally, NIST publishes or is involved in nearly all standards of measurement and purity at some level, from weights and measures to standardized test substances and the traceability of measurement back to known standards.

Federal Trade Commission (FTC)

The Federal Trade Commission regulates deceptive packaging and unfair trade practices in non-food products and may be involved in food products that are mislabeled in terms of quantity or package type. Additionally, the FTC is responsible for marketing claims such as "Sale" or "Economy-Sized," as well as environmental claims such as "Biodegradable" and "Ozone Friendly." In general, this means that the size of the package relative to its contents, as well as many of the label statements, is covered by the FTC. Excessive headspace, false bottoms, and "outage" (loss or reduction of product during transportation and storage) are typical concerns

in terms of package size and are the reason that a disclaimer such as "product is sold by weight not volume – some settling may occur" is often put on products that settle in shipping, such as breakfast cereals. Under-filled packages that exceed the limits of filling error as well as intentional deception can be the cause for product recalls or consumer reimbursement.

United States Department of Agriculture (USDA)

The USDA regulates production, labeling, and packaging of fruit, vegetables, meat, and poultry products that are not subject to the Pure Food and Drug Act. The typical label must contain: a statement identifying the product, net content weight, list of ingredients in descending order of predominance (this is not required for whole-muscle products such as chicken breasts), and the name and place of business of the producer, as well as the inspection legend and establishment number, if applicable, and safe handling instructions. Nutrition labeling is voluntary for single-ingredient products such as steak or chicken breasts and may be provided as point-of-purchase information. Nutrition labeling is mandatory for those other products that are supplemented (have additional added ingredients). As of March 16, 2009, Country of Origin Labeling (COOL) is required of retailers of meat and poultry and retailers of fresh and frozen fruits and vegetables with an invoice value over $230,000 annually [13]. COOL is required on:

- Muscle cuts and ground meat of beef, lamb, chicken, goat, and pork
- Fish and shellfish
- Perishable agricultural commodities (fresh and frozen fruits and vegetables)
- Peanuts, pecans, macadamia nuts, and ginseng

Retail establishments such as restaurants, delicatessens, salad bars, and the like are excluded, as are many processed foods and game meats [14].

United States Food and Drug Administration (FDA)

The Food and Drug Administration is the agency with the primary responsibility of enforcing the current version of the original Pure Food Act, now the Federal Food Drug and Cosmetics Act (FFDCA). This has been amended frequently as the agency contends with more issues and as the technology and level of scientific knowledge changes.

The FDA currently regulates biologics, cosmetics, drugs, foods and beverages, medical devices and materials, radiation-emitting electronics, and veterinary products and devices. For food and beverage products, there are some exemptions, many of which are intended to reduce regulatory burdens on small businesses, which are often overseen by state agencies. Small businesses with fewer than 100 employees and fewer than 100,000 units/year sold are typically exempt from federal oversight, although they may be overseen by state agencies. Facilities that produce food for immediate consumption, such as restaurants and delicatessens, are also not regulated by the FDA, although they are usually under the scrutiny of state and local food service inspection systems.

In grossly oversimplified terms, FDA regulations are concerned with the safety of the food formulation, the proper labeling of the product in terms of its nutrition and health effects, and the longer-term interactions between the product and food contact substances, including the package. Additionally, it requires that the producer (or, more commonly, the distributor) of the product is identified on the package. In order to eliminate pointless testing to ensure that every commonplace ingredient and material such as clean water and properly prepared grains are safe

even though they have been used since prehistoric times, the agency lists "Generally Recognized As Safe" (GRAS) ingredients and food contact materials for exclusion from approval. As new or previously unlisted ingredients and materials are developed for use with food products, they must be proven safe by the manufacturer, often after extensive testing, usually in animal-model studies. For an ingredient that is likely to see large-scale use, such as a new artificial sweetener, these tests may be extensive if it is a synthetic product such as cyclamates, or less stringent for a plant-extract material such as rebaudioside A, a purified stevia plant extract. Obviously these tests may be expensive and have historically been time consuming – an issue that the FDA contends with on a continuing basis.

For packaging materials, the major concern is the extraction of packaging materials into the product, which often presents a much smaller hazard. The approval process for new packaging materials and some additives has several faster options available, provided that the dietary exposure to the extracted material is small and the material is non-carcinogenic. These approval paths, the Threshold of Regulation and Food Contact Notification, are outlined later in this chapter.

The food labeling originally begun with the Pure Food and Drug Act of 1906 required the identification of a product, its net weight, the manufacturer's name and address, and an ingredients list in descending "order of predominance." The subsequent 1938 Federal Food Drug and Cosmetic Act added the regulation of production and distribution of food, set food Standards of Identity for common items such as catchup and orange juice, and set quality standards and acceptable levels of fill-in containers. Standards of identity were developed to promote a minimum standard of manufacture for particular items that were commonly produced by many manufacturers in order to ensure that consumers received acceptable products regardless of the source. This has had some interesting side effects, in that one of the compromises agreed to in the legislation was that if a product met the minimum Standard of Identity, it was allowed much more leeway in making advertising claims. The predictable result of this is that although many essentially identical Standard of Identity products such as ketchup are on the shelf, they compete for the consumer's dollar with claims of "better" or "thicker" or "more flavorful" without verification [15]. Another sometimes contentious effect is that certain foods such as children's breakfast cereal hover just below the requirement for labeling as "candy" because of the extraordinarily high sugar content.

Amendments such as the 1973 Nutrition Labeling Regulations, which began listing nutrients on a voluntary basis, were later supplemented with the requirement for sodium labeling and the revisionary 1990 National Labeling and Education Act (NLEA) that required nutritional labeling for most foods (those that neither make a nutritional claim nor have an added nutrient are often exempt), and was quite specific about how and where the labels were to be presented. It additionally clarified the requirements for making claims about the foods both in terms of health benefits and other more consumer-oriented statements such as "light" or "fat free."

The NLEA also prohibited states from enacting laws that differ from federal laws regarding items such as standards of identity, labeling, and packaging, but in turn allowed states to bring action under federal statutes in an attempt to unify the regulation of food manufacturing.

Current food labels describe "serving sizes" (which seemingly have little bearing on the amount that consumers typically eat or the calories they consume) and is based on "typical portion sizes (from food consumption surveys), ease of use, nutrient content, and tradition (of use in previous food guides)" [16]. The labels must bear ingredients in descending order of percentage of content. The nutrition information panel contains both mandatory components and voluntary components, as shown in Table 10.2. Voluntary components become mandatory

Table 10.2. NLEA Required Food Package Label Components

NLEA Nutrition Information Panel Components[i]	
Mandatory	Voluntary
Total Calories	Calories from Saturated Fat
Calories from Fat	Polyunsaturated Fat
Total Fat (g)	Monounsaturated Fat
Saturated Fat (g)	Potassium
Cholesterol (mg)	Soluble Fiber
Sodium (mg)	Insoluble Fiber
Total Carbohydrate (g)	Sugar Alcohol – usually a sugar substitute such as sorbitol or xylitol
Dietary Fiber (g)	Percent of Vitamin A as Beta Carotene
Sugars (g)	Other Essential Vitamins and Minerals
Protein (g)	
Vitamin A	
Vitamin C	
Calcium	
Iron	

[i] *Source*: The Food Label. http://www.cfsan.fda.gov/~dms/fdnewlab.html

if a claim is made about any of the optional components or if a food is fortified or enriched with a component.

NLEA and Health Claims

In July 2003, the FDA issued two guidance documents regarding "qualified health claims" on food labels. A qualified health claim is one that is accompanied by a qualifying statement to indicate that there is some degree of uncertainty regarding the scientific validity of the claim.

The FDA will approve qualified health claims in situations where the scientific evidence supporting the claim falls short of that required for an unqualified health claim under the Nutrition Labeling and Education Act of 1990 (NLEA). Under NLEA, for an "unqualified" health claim to receive authorization, it must be supported by the totality of publicly available scientific evidence. There must be "significant scientific agreement" (SSA) among qualified experts that the claim is supported by such evidence. One example is that of soluble fiber and reduction of heart disease. The Food and Drug Administration Modernization Act of 1997 (FDAMA) provides a second way for the use of a health claim on foods to be authorized. FDAMA allows certain health claims to be made as a result of a successful notification to FDA of a health claim based on an "authoritative statement" from a scientific body of the United States, such as the US or other credible government source, or the National Academy of Sciences, among others. Dietary supplements, a distinct class of edible materials in the eyes of the FDA, are subject to a great deal less scrutiny and are allowed a great deal of latitude in poorly substantiated claims of health benefits. Because of the low level of required scientific evidence and regulatory compliance, and often enormous profitability, both food and drug manufacturers continue to explore this area in many markets. EU regulators have taken steps to enforce the 2006 Nutrition and Health Claims Regulation on many of these products that are sold based on dubious or unproven health claims, much as British Parliament led pure food regulation in the United States by several decades.

Structure-Function Claims

Structure-function claims have historically appeared on the labels of conventional foods and dietary supplements as well as drugs. These claims describe the role of a nutrient or dietary ingredient intended to affect normal structure or function in humans, for example, "calcium builds strong bones." For a structure-function claim, the manufacturer is responsible for ensuring the accuracy and truthfulness of these claims. Structure-function claims are not pre-approved by the FDA but must be truthful and not misleading. If a dietary supplement label includes such a structure-function claim, it must be labeled with an often-seen disclaimer: "This statement has not been evaluated by the FDA. This product is not intended to diagnose, treat, cure, or prevent any disease".

Food Additive Petitions

Food additive petitions are the oldest and most difficult means of getting a new material approved. This can be an extremely arduous process for a new food ingredient such as a synthetic sweetener or fat substitute, and may require years of testing before approval is granted.

For packaging materials, the regulations hold that "[a]ny substance used as a component of articles that contact food shall be of a purity suitable for its intended use," as well as:

> "Food-contact material must not transfer substances to food that may render the food injurious to health and, therefore, adulterated within the terms of Section 402 (a) (3) of the Federal Food, Drug, and Cosmetic Act (FFDCA) The food-contact material must not impart a taste or odor to the food that causes it to be unfit for consumption and, therefore, adulterated within the terms of Section 402 (a) (3) of the FFDCA."

Because of this, it is incumbent on the manufacturer to prove that new materials are safe for their intended use, and this must be accompanied by a substantial amount of scientific data demonstrating that no contaminants will be extracted from the packaging material into the product. Thus, to file a petition for the use of an indirect food additive, extractability studies usually must be performed. For packaging materials, this usually involves exposure of materials to food simulant, a solvent that approximates the type of product the packaging material will be exposed to. To simplify testing somewhat, simulants are broken into several simple categories generally outlined in Table 10.3 [17]. There are many exceptions and variations on this general protocol depending on the food type, toxicity of the material involved, dietary exposure, and intended use. If new data indicate a lower level of acceptable exposure to a substance, that

Table 10.3. List of Food Simulants for Extractability Studies

Food Type	Recommended Solvent
Fatty Foods Meats, High Oil Content Foods	Food Oil (Corn Oil, Fatty Triglycerides, or coconut oil)
Aqueous or Acidic Foods Pickles, Sauces, Fermented Products	10% Ethanol (EOH) solution in water
Low Alcohol Products (EOH < 15%) Beer, Wine, Fermented Alcoholic Beverages	10% or actual EOH concentration in water
High Alcohol Products (EOH > 15%) Distilled Spirits, Flavor Extracts	50% or actual EOH concentration in water
Exposure time is most often 10 days at 40°C	

also needs to be taken into consideration even in evaluating a material with long-standing FDA regulatory clearance.

Because of the extraordinarily long approval period and expense of testing, the FDA has created two alternate systems that may apply to low-level, non-carcinogenic extractables: the Threshold of Regulation Request and the Food Contact Notification.

Threshold of Regulation (TOR) – 21 CFR 170.39

Requests are made through the Threshold of Regulation Program of the FDA to allow an exemption for food contact substances if it is determined that the consumer will not ingest a large amount of the product or migrating compound. A dietary concentration of 0.5 parts per billion (ppb) is a typical upper level for TOR approval, and 0.5 ppb is the dietary concentration threshold for most food contact substances, provided that the substance is not carcinogenic. If no new data is necessary (usually because of previously published studies) the approval process can be very fast, often less than 120 days. Dietary concentration is calculated by applying appropriate reduction factors (i.e., food-type distribution and consumption patterns) to the measured or calculated worst-case migration values. Thus, the threshold of regulation can be met even if the migration level is much higher than 0.5 ppb. The Threshold of Regulation exemption, once granted, does not grant any proprietary rights to the filers and effectively provides clearance for all manufacturers of a particular material.

Food Contact Notification (FCN) Sec. 409 [21 USC §348]

Food Contact Notification filings can be submitted for any substance that is properly classified as a "food-contact substance" and has largely superseded the TOR program. There are exceptions for some substances for which the calculated dietary exposure exceeds 1 part per million (ppm), but generally speaking, for substances whose dietary intake exceeds 0.5 ppb, some amount of toxicity data will be needed to demonstrate the safety of this level of exposure. For low dietary intakes – up to 50 ppb in the diet – this means submitting reports of *in vitro* genotoxicity assays such as an Ames test, mouse lymphoma, or chromosome aberration study. These can be studies performed by the notifier or obtained from the public literature. Of course, if these studies do not provide uniformly negative results, this will complicate the review process. If the dietary exposure is higher than 50 ppb, it may be necessary to submit more extensive toxicity data such as oral sub-chronic study in rats/dogs. These studies must demonstrate a clear No Observed Adverse Effect Level (NOAEL), and the NOAEL must exceed the calculated dietary exposure by a safe margin, usually 1,000 times. The advantages to the filing entity are that the FDA has only 120 days to complete its review of the notification, and in the absence of an explicit FDA objection by day 120, the notification automatically becomes effective. Additionally, the notification only approves the food-contact substance of the manufacturer/supplier listed in the FCN, which may offer an incentive for filing for approval in a competitive market. Of course, this does not prevent others from submitting their own notifications to get approval of similar, competitive products.

National Marine Fisheries Service (NMFS)

Although the FDA and USDA are the primary sources of regulation for seafood, the NMFS offers inspection services and legally recognized certification of seafood and related processing operations [18].

Bureau of Alcohol, Tobacco, Firearms and Explosives (ATF)

The Bureau of Alcohol, Tobacco, Firearms and Explosives (the acronym omits the "E" for recently added responsibilities with regard to explosives), which is administered by the US Justice Department, regulates – as its name implies – the manufacture, labeling, transportation, and packaging of alcoholic beverages, tobacco products, firearms, explosives and related materials, as well as some aspects of advertising for wine, distilled spirits, and malt beverages. Tobacco products and alcoholic beverages are subject to a variety of regulations in terms of specific labeling about the type and number or volume of product as well as health warnings about their use. Although the interstate transportation of explosives and ammunition is outside the purview of this book, it is useful to remember that high-proof alcoholic beverages may be quite flammable and require specific marking of containers and placarding on vehicles that transport them.

Department of Transportation (DOT)

The Department of Transportation oversees the transportation of goods in nearly every mode of conveyance imaginable. Because of the differing modes of transportation for different types of materials, the responsibilities for enforcement of these regulations are further delegated to the Federal Highway Administration, the Federal Railroad Administration, and the Federal Aviation Administration. Marine shipping is the responsibility of the DOT's Maritime Administration as well as the Federal Maritime Commission, under the Department of Commerce. With the Surface Transportation Board (STB) of the DOT replacing the previous Interstate Commerce Commission in 1996, and taking over the regulation of certain parts of the truck, rail, bus, and pipeline transportation of goods, many of the rate and classification systems for non-hazardous freight have been left to several industry groups discussed subsequently.

The most familiar face of DOT regulations in packaging are the distinctive system of hazardous materials markings illustrated in Figure 10.1.

Figure 10.1. Hazardous Material Placard

The Department of Transportation oversees the transportation of goods, and particularly hazardous goods, as specified in 49 CFR§172 [19]. The Hazardous Materials Table contained in 48 CFR§ 172.101 specifies the type of packaging, marking, documentation, and surface vehicle placarding used for an extensive list of various types of hazardous chemicals.

Air shipments of hazardous materials are regulated by the Federal Aviation Administration (FAA), which is concerned with the safety of the aircraft involved as well as the passengers, considering that most airlines fly mixed freight/passenger routes. Further shipping rules are put forth by the Air Transport Association in the United States and by the International Air Transport Association internationally. Thus, the shipment of particular materials that are generally detrimental to airframes (such as strong bases and mercury) and flammable, explosive, or other destructive materials may be prohibited or strongly regulated by the FAA; other less hazardous materials may covered be under the rules put forth by the respective industry groups.

Shipments of materials into space, although certainly a specialty market at this point (typically, 20–25 commercial launches per year worldwide), are also controlled in the United States by the FAA, who licenses commercial space transportation [20]. Given the extraordinary costs involved in getting material into low suborbital flight, there is always an enormous premium placed on the weight and material efficiency of payload design and resistance to the acceleration and vibration encountered during launch (and re-entry for missions that return material rather than leaving it in orbit). There is little need for extensive packaging regulation at this point considering how few commodity-level goods are shipped in this manner so far.

The Environmental Protection Agency (EPA)

While the FDA and USDA concerns about food packaging have to do with the effect on the product and the consumer, EPA regulations address concerns about the package and its contents' effect on the environment. Thus, concerns about post-consumer effects of packaging on the environment have lead to such things as the prohibition of many toxic metals, particularly those used in printing and polymer production and stabilization in significant concentrations, that may leach into groundwater supplies or otherwise affect public health.

Because the EPA is generally responsible for pesticide and antimicrobial environmental regulation, and some types of food packaging have been developed with antimicrobial and insecticidal properties as well as antimicrobial additives to foods themselves, an agreement was reached in the Food Quality Protection Act of 1996 giving the Food and Drug Agency jurisdiction over antimicrobials in food packaging, which would otherwise be considered as pesticides and be under the jurisdiction of the EPA, as shown in Figure 10.2.

Additionally, state regulations in nineteen states (California, New Hampshire, Connecticut, New Jersey, Florida, New York, Georgia, Pennsylvania, Illinois, Rhode Island, Iowa, Vermont, Maine, Virginia, Maryland, Washington, Minnesota, Wisconsin, and Missouri) prohibit the intentional use of lead, cadmium, mercury, and hexavalent chromium in packaging or individual packaging components, such as coatings, inks, adhesives, or labels above a level of 100 ppm, with some exceptions for recycled-content, reusable containers, and recycled packages [21]. Because these prohibitions affect a very large percentage of the national market, they have driven a national effort to reduce these metals in packaging materials that are used in national distribution.

Additionally, the EPA regulates permissible discharges from processing operations, which may be a concern with residual processing chemicals, as well as biological oxygen demand

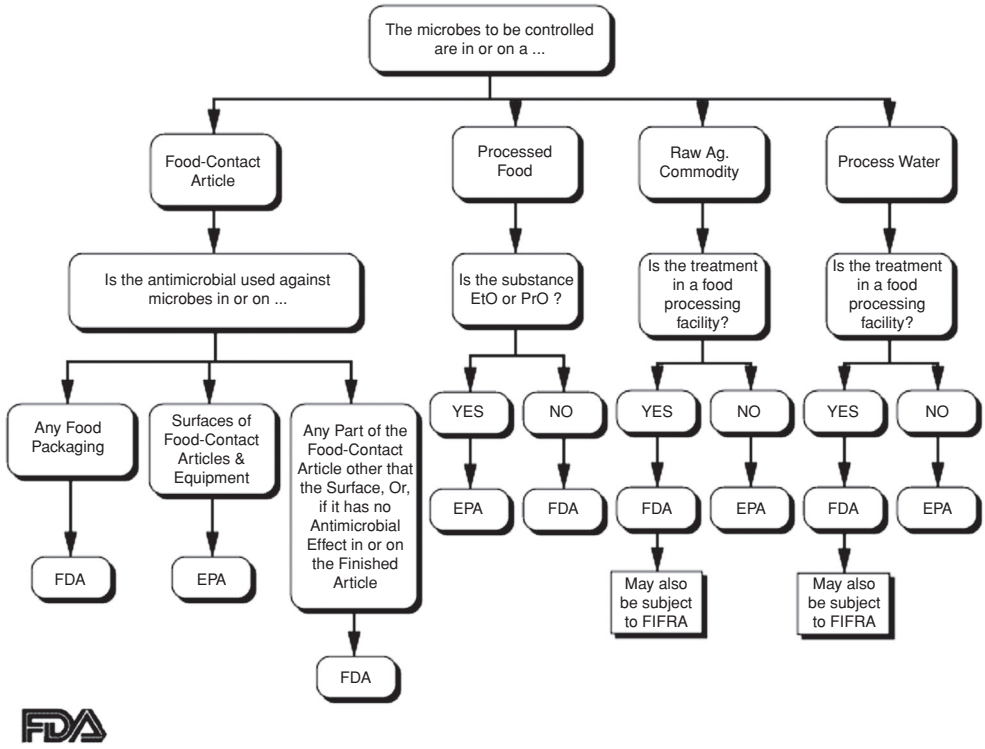

Figure 10.2. FDA Antimicrobial Flowchart
Source: FDA

(BOD) from food-processing waste and large-scale animal processing facilities, among other concerns.

Department of Homeland Security (DHS)

DHS was established to coordinate and assimilate functions from many pre-existing departments of the federal government, as well as to create a unified security structure for national defense. Although the general requirements for security will be discussed in a subsequent part of the chapter, in general, DHS oversees most of the concerns regarding bioterrorism, product and package tampering, and disruption of the food supply in coordination with the USDA, FDA, and Health and Human Services' Centers for Disease Control, among others. Although best known for luggage screening at airports, the DHS has been assigned the task of overseeing both commercial and private activities that might constitute a threat to the security of the country, including the food processing and packaging industries. This has led to increased security surrounding food processing facilities, among other changes.

Department of Defense (DOD)

The Department of Defense oversees military and related operations in the United States. As such, it is also responsible for the large-scale purchasing of materials and supplies for

use by the military. The requirements for these are often much more stringent in terms of safety, damage prevention, and, for food and medical supplies, shelf life and quality extension. The Meals Ready to Eat (MRE) rations that have replaced canned rations must survive for three years of storage (and are often stockpiled beyond that) as well as being air-dropped without a parachute. Ordnance, instrumentation, and communications gear must often survive shipping and deployment conditions far in excess of that seen by consumer items, with the result being that the DOD and its agencies may have distinct and stringent requirements for processing and packaging of products, and sub-industries have sprung up to assist in both understanding and fulfilling these requirements. Packaging requirement codes are given by MIL-STD-2073-1E in a standardized form that may describe wrapping material, unit container levels, and other requirements, with other requirements and standards used on a contractual basis, although specialized items and devices may also carry specifications for specialized packaging for deployment.

United States Post Office (USPS)

The United States Post Office led the way to the mass-distribution of goods in the United States that barely had a transportation infrastructure by implementing the Rural Free Delivery system. This allowed the creation and explosive growth of "modern" catalogue-order retailing operations that have since metamorphosed into our current online ordering and rapid delivery industry. It remains the major conduit for written communications and carries a staggering number of goods and documents, although it competes with private carriers for the latter. For obvious reasons, the post office sets both limits on what can be sent and the manner in which it must be packaged. There are substantial limitations on hazardous, restricted, and perishable materials, as given in USPS Publication 52, and maximum weight, labeling, and sealing are all subject to minimal strength and integrity standards [22, 23].

For large quantities of materials to be handled by the Postal Service, such as a mail-order operation, the local USPS station may work with the customer to provide approved bins, trays, or other means by which goods can be presorted or otherwise fitted into the facility's workflow.

United States Patent and Trademark Office (USPTO)

The USPTO, a unit of the Department of Commerce (DOC), is the office in charge of documenting and regulating patents, trademarks, and copyrights, which puts it squarely in the midst of most of the modern media-usage debates and any number of other contentious intellectual property disputes. Patents typically protect the inventor for an initial period of 17 years, and extensions can be filed. There is a substantial risk, however, because filing a patent requires public disclosure of the nature and method of the invention. Much industrial research is concerned with *patent breaking* – creating a similar product without violating the exact terms of the patent, and often using the disclosure inherent in the patent filing. Because of this, many businesses do not file patents, preferring to rely on their own internal security measures as well as contractual non-disclosure agreements and confidentiality agreements for protection.

Trademarks and service marks are marks, logos, or other content used to distinguish a product. A *trademark* is a word, phrase, symbol, or design, or a combination of words, phrases, symbols or designs, that identifies and distinguishes the source of the goods of one party from those of others. A *service mark* is the same as a trademark, except that it identifies and distinguishes the source of a service rather than a product.

For goods: the mark must appear on the goods, the container for the goods, or displays associated with the goods, and the goods must be sold or transported in commerce.

For services: the mark must be used or displayed in the sale or advertising of the services and the services must be rendered in commerce [24].

The "in commerce" stipulation requires that the trade or service mark is actually used rather than simply being pre-emptively filed in order to prevent others from acquiring it and preventing further use, as has often been done with Internet domain names.

Trademarks and service marks offer the benefits of constructive notice nationwide of the trademark owners' claim, and the legal use of the® and SM symbols, respectively. The jurisdiction of federal courts can be invoked in disputes over trademark and service mark issues and the ownership can be used both as the basis of filings for foreign equivalents and of registration filed with U.S. Customs Service to prevent importation of infringing foreign goods. Trade and service marks have a ten-year renewal cycle and typically may be used as long as they are for products or services rendered in commerce.

Library of Congress – Copyright Registration

Copyright filing with the Library of Congress will regulate "Rights to Copy" of media. These are effectively the right to use, distribute, sell, and make derivative works from original "material," which may be any type of idea, information, or media content that can be kept in any kind of substantial form [25]. Traditionally thought of as protecting written works and music, copyrights also cover many other types of intellectual property such as architectural designs, boat hull designs, and even choreography. Whereas copyright law is at the heart of much of the controversy around the disruption of traditional media distribution (such as digital online music sales), for commercial applications such as food manufacturing and packaging, the concern is more often with the marketing information that is part of the overall brand identity and sales campaign.

Copyrights usually extend for the life of the original author(s) and can be renewed for very long periods of time (often 50–100 years). Increasingly stringent enforcement provisions such as the Digital Millennium Copyright Act and the 1996 treaties of the World Intellectual Properties Organization have criminalized the act of distributing some types of copyrighted material, particularly those related to mass media and software. This has led to some ludicrous enforcement actions against individuals who copy purchased music for their own use or perform live copyrighted music in small, nonprofit venues, but it is also a necessary part of preventing fraud and counterfeit goods production and distribution.

Consumer Product Safety Commission (CPSC)

Most often thought of in its role of recalling defective and unsafe consumer products, the CPSC regulates many different types of products that are not under the jurisdiction of other government agencies. It also has issued the Poison Prevention Packaging Act in 1970, subsequently amended, which requires child-resistant packaging for household substances that it deems hazardous (including foods, drugs, cosmetics, and fuels) [26]. The technical testing specifics are more fully discussed in Chapter 4, and the original provisions of the bill have been amended to include some requirements for certificate of manufacture, which are a matter of some controversy. There are exemptions based on whether the product is expected to be used in the house, is a pharmaceutical to be repackaged by a pharmacist, and similar occurrences, but the end result is

that thousands of household poisonings of children are prevented each year. While child-proof packaging is the butt of many jokes (and is claimed to be adult-proof as well), and there have been concerns about adults leaving them off at the risk of poisoning children, the benefits are substantial [27]. The CPSC also tracks the approximately 6,000 emergency room visits for lacerations and punctures caused by trying to open obstinate packages with sharp tools [28].

Occupational Safety and Health Administration (OSHA)

OSHA, under the Department of Labor, has been mentioned in conjunction with several other particular aspects of packaging and food processing, but in general is concerned with preventing workplace-related injuries and health problems, and ensuring compliance with the Occupational Safety and Health Act of 1970. The more general involvement in the packaging and food processing industries have to do with OSHA regulations requiring proper safety equipment and training as well as adequate safeguards on operating machinery. Printing equipment and packaging machinery can be particularly dangerous if the operating mechanisms are left unprotected, and requirements demand guards on nearly any accessible part where contact with moving or dangerous equipment may occur.

Personal protective equipment, permissible exposure limits (PEL) to a substantial list of chemicals, "Right to Know" communications about chemical products, and process safety management standards may also come into play, although many of the latter are targeted at the chemical and petroleum industries. Because many of the hazards are made known by employees or other non-management personnel, there are also whistleblower protection provisions as well as authorization to access information, particularly where an accident has occurred [29].

The National Institute for Occupational Safety and Health (NIOSH), which develops safety procedures and ergonomic standards, is not administered by OSHA but by the Department of Health and Human Services. Even though the two institutions have approximately the same mission, and OSHA makes use of NIOSH information, the latter is considered to be more research-related and deals with a variety of unusual issues, from Alaskan aviation to "body art" [30].

Private Carriers

The National Motor Freight Classification dictates the type of packaging to be used for truck transport, and is a set of tariffs originated by the now-defunct Interstate Commerce Commission (predecessor of the DOT) and now managed by the American Trucking Association's National Motor Freight Traffic Association [31]. Item 222 of the National Motor Freight Classification (NMFC) lists the specifics of packaging mandated by the tariffs both by box type and by corrugated board type and strength. Additionally, the NMFC lists "general packaging definitions and specifications, specifications for packages that have been approved expressly for the transportation of certain commodities, and performance-based packaging criteria."

The National Railroad Freight Committee's Uniform Freight Classification (UFC) Rule 41 provides similar (and often identical) tariffs for rail freight in the same manner. Although this may seem restrictive, the requirements are minimums that allow a good deal of latitude for packaging design, and may avoid problems with accusations of insufficient packaging in the event of damage claims being filed on a shipment.

Private delivery carriers such as United Parcel Service and FedEx require compliance with Rule 222 for most commercial manufacturers and may have additional requirements in their tariffs if the shipment is to be transported by air. For small consumer shipments, the requirements

may be simply to be well packed as assessed by the counter personnel, and to not be carrying a list of proscribed materials such as explosives, biohazards, or dangerous chemicals. These may have some additional latitude in "Surface Only" shipments that avoid the more stringent air carrier safety standards, but will take longer to arrive.

Food Safety and Security Systems

Although food safety has always been a concern with fresh and preserved food products, recent political concerns with the security of food, particularly imported food, that travels large distances very quickly has generated another layer of complication that may force information technologies to stretch in order to trace and account for shipments. Additionally, food processing facilities have quietly become much more secure, limiting unsupervised access because the introduction of a dangerous component into a centrally located food facility could have far-reaching consequences, as recent instances of contaminated imported and domestic food ingredients has shown.

Food safety, defined here as the unintentional contamination of food, has been a concern throughout history, considering that nature has all sorts of microscopic organisms, vermin, and toxins that are capable of rendering food inedible or poisonous. The commercial agricultural and food distribution system has been dealing with these issues for some time with a high degree of success, as have the agrarian societies that preceded them. Current political developments have prompted a great deal of concern about the food security, which refers to both to the intentional contamination or destruction of a food supply via asymmetric warfare, terrorism, or hostility, and also refers to ensuring that a population has a sufficient food supply in the face of natural hazards or geopolitical conflicts.

Because of the nature of agriculture, the food supply is very accessible to external environmental inputs from any conceivable direction. Insect or chemical contamination can occur very easily, and it is difficult to provide any sort of meaningful security for vast expanses of farmlands. In tandem with this, the effect of a small contamination or infestation incident, if detected, will be easily contained and quarantined. As crops are concentrated and processed, the stakes of such actions begin to increase and the concern with safety increases as well. Finally, there is an "hourglass effect" for contamination incidents, with crops and retail distribution having the lowest effect and ingredient-level contamination being the most hazardous.

The hourglass diagram in Figure 10.3 illustrates that the most concentrated point of influence in the food production and distribution system would be located where operations and materials

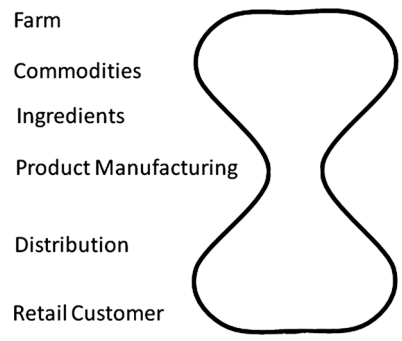

Figure 10.3. Security Hourglass

are concentrated, and then widely redistributed. Because of this, food production and distribution operations are being subjected to more intense security requirements, and producers and distributors themselves are faced with larger concerns about the products that they manufacture and distribute. Food ingredients have also become a matter of great concern because of the broad influence that a food additive that was used in a large number of products could have. Additionally, increased outsourcing of food ingredients to international suppliers can result in the complication of validating the received material as being genuine and safe.

HACCP

Current manufacturing practice usually involves the development of a Hazard Analysis and Critical Control Points (HACCP) plan to prevent hazards and contamination during the manufacturing process and to efficiently use resources rather than simply inspecting the final product for quality conformance. HACCP plans may be effective if designed and implemented correctly, and can save the manufacturer from serious processing failures, but there have been objections that some manufacturers are simply repackaging their existing hygiene programs as a HACCP plan for the appearance of conforming with requirements [32].

HACCP systems usually involve at least seven basic components [33]:

1. Hazard Analysis
   Potential biological, chemical, or physical hazards associated with a food and measures to control those hazards are identified.
2. Critical Control Point Identification
   Identification of the points the production system from raw materials to packaged product where the potential hazard can be detected, controlled, or eliminated.
3. Prevention
   Development of preventative methods with critical control limits to relevant specifications (such as temperature, pressure, and water content) for each control point.
4. Monitoring
   Development and implementation of monitoring procedures for each of the critical control points.
5. Remediation
   Development of remedial actions to be taken when a critical measure has not been achieved, such as under-cooking or over-dehydration of the product.
6. Validation
   Develop a system to verify that monitoring equipment is functional, accurate, and is being properly used as required.
7. Recording
   Implement archival records that document operation of the HACCP system. This should include records of hazards and their control methods, the results of monitoring of safety requirements, and any corrective action taken.

Product Recalls

For the food manufacturing and distribution system in most economies, there is usually some tracking and identification system in place to identify particular batches of processed product that may be contaminated or defective. Recently, contamination incidents with products such as ground beef and fresh spinach have highlighted a more "brittle" response – the kind that paralyzes a whole segment of the market – when grocers removed that entire particular product

category from sale as a safety margin. This often has much more to do with the maintenance of consumer confidence than it does with a strategic elimination of hazardous products, and as such is inefficient and extremely costly in the long run. In any event, the ability to track individual batches of product using either open or closed coding types, as well as other means such as flagging particular UPC codes, indicates that the infrastructure already supports a moderately flexible response system. For a food product, regulatory agencies such as the Food and Drug Administration in the United States have a mechanism for issuing recalls, usually with a multistep approach [34]:

Class I recalls for dangerous or defective products that predictably could cause serious health problems or death. Examples of products that could fall into this category are food items found to contain botulism toxin, food with undeclared allergens, a label mix-up on a life-saving drug, or a defective artificial heart valve.

Class II recalls for products that might cause a temporary health problem or pose only a slight threat of creating a more serious problem. One example is a drug that is under-strength but that is not used to treat life-threatening situations.

Class III recalls for products that are unlikely to cause any adverse health reaction, but that violate FDA labeling or manufacturing regulations. Examples might be a container defect (plastic material delaminating or a lid that does not seal); off-taste, color, or leaks in a bottled drink, and lack of English labeling on a retail food item.

Recall management systems are a common feature in many operations, particularly in the food and pharmaceutical industries, and there are consulting firms that can assist smaller operations when needed. For manufacturing or processing defect issues, the response-and-recall system has been shown to be most effective when the companies involved are willing to immediately and effectively take ownership of the issue and then proactively drive the process. Delaying or denying the problem can result in an enormous illness or death, loss of consumer confidence, and the resulting loss of sales. In general, the four basic steps for managing product recall are [35]:

Planning

A recall plan and necessary acceptance infrastructure should be in place before any actual incident occurs. Simulated and test recalls can help highlight problems in the system before an actual recall occurs.

Response Time

A rapid response aids in dealing with the actual problem and will minimize any loss of consumer confidence in the product and the company. Additionally, a rapid response may reduce liability by restricting the infiltration of the contaminated product into the marketplace by holding them during distribution or at the retail level.

Effective Communication

Immediate and effective communication to all concerned parties is critical in a product recall. Communicating of the necessary identification and remediation instructions to the actual handlers, sellers, and customers of the product is of the utmost importance. Communication of the company's response to the problem is also critical in maintaining (and in some cases increasing) consumer confidence in the company and product line.

Follow-Up

Following up a recall event with analysis of the problems (and successes) of the response system will highlight any potential problems or areas that need to be addressed in the response strategy. Additional follow-up in re-marketing a product that has suffered a catastrophic loss of market position because of the effects of a recall may be required as well.

The actual steps to be taken in the event of a recall will vary considerably with the product. In the computer software industry, current problems are usually handled by "patch" downloads, arguably the most cost-effective means possible considering that the distribution is automatic and the installation is handled by the consumer. For other consumer products, the solutions will vary widely, ranging from additional repair parts being sent from the manufacturer allowing service personnel to remedy the problem and service recalls in the automobile industry, to food recalls where the product is removed from sale and the consumer is urged to not use that product for a short period. This last method is often catastrophic to a particular product or type of product and it may require careful management to re-establish consumer confidence in a useful time frame.

Food Security

All of the scenarios discussed so far have been those developed for use in response to a defective product that has unintentionally created a hazard, either through a fault of design or an oversight in manufacture and processing. The intentional hazards that make up food security issues have the additional factor of careful forethought and a degree of planning, but the same mechanisms that assist in "accidentally" contaminated product recalls can assist in providing a flexible response to an intentionally contaminated product, because there is little difference between the two events. The complete prevention of product problems by a clever and determined party may be nearly impossible, but an acceptable level of security can be provided by quality control checks and the understanding of the influence of a single contaminated ingredient at the "pinch point" of the hourglass. Paradoxically, for food products, the most influential contamination ingredients would be those used in the largest number of products, such as high fructose corn syrup and vegetable oil, but the large quantity used would mean that creating a broad contamination would be very difficult because of the large volume and number of suppliers. In the instance of manufacturers knowingly shipping contaminated product, there is little difference in final effect between that action and a politically motivated malicious attack. Recent problems with peanut butter contamination highlight the extraordinary delay, negligence, and lack of response by inspectors and local health officials, even though similar problems had occurred in nearby operations and had caused widespread illnesses [36]. This creates a system ripe for abuse, with the potential (as was shown) for widespread illnesses and several deaths.

Security Concepts

While the security industry utilizes a large number of increasingly technical solutions for both real and perceived potential threats, some basic concepts and questions underlie most of the solutions and policies. Assets to be protected are effectively "something you value." This can range from personal property and bodily safety to something a good deal more abstract such as a computer password or the goodwill of a brand line [37]. Threats to these assets can result in actual "attacks" that can be foiled, mitigated, or recovered from. For any security measure

that is to be implemented, as with any change in technology, one must consider what the actual threat is, what the costs of prevention are, and what further problems may be propagated by implementing those solutions [38]. The unintended consequences of many types of security changes can be significant, ranging from consumer inconvenience removing the inner seal from a bottle of ketchup to being arrested as the result of false identification by a criminal database. Additionally, security systems exhibit *emergent properties* – characteristics that occur as complex systems interact in unexpected ways.

Asymmetric warfare refers to conflict between parties where their power, numerically, technologically, or strategically, differs by a significant amount. This term has been adapted to refer to asymmetry of strategy or tactics, and currently the term often describes a military or civil-conflict situation in which parties of unequal power interact and attempt to take advantage of their opponents' weaknesses using widely differing tactics [39].

One of these tactics would theoretically include sabotage of infrastructure and the creation of distrust and fear within one of the parties' civilian population. Interestingly, this is often less of a concern in modern conflicts that are symmetrical in more conventional ways – the Cold War of the late 20th century saw little ongoing concern for the integrity of the food supply.

The popular impact of food contamination fear has been extensively shaped by previous incidents in the United States with product tampering, most notoriously the Tylenol poisonings in the 1970s. More recent problems with so-called *counterfeit goods* have highlighted the susceptibility of the supply chain to goods that have been counterfeited for financial gain. Unfortunately, it would be relatively difficult for each farm and each retail store to have the sorts of security that one typically faces at an airport, and the costs would be enormous. So a trade-off has been made in favor of increased security at the "pinch points" of the system – in the production facilities rather than in retail outlets, farms, restaurants, or fishing vessels.

In general, bioterrorism requires an infectious or poisonous agent, a means of dispersal (*vector*), whether it be insect transport or physical distribution, and a host that the agent can infect or poison. Usual bioterrorism controls seek to sequester the infectious agents before they can be dispersed, and will occasionally address the host directly with protective vaccines or other measures. Although the risk of bioterrorist attack is very low – the largest incident in the United States so far being the intentional contamination by the members of a religious cult in Oregon who were seeking to influence a city election, and the most deadly apparently being from a single person distributing anthrax through the mail – the potential for actual harm and general panic is enormous [40, 41].

The Bioterrorism Act of 2002 and subsequent amendments and modifications have added a significant amount of registration and oversight to the food production system which was, by comparison, very lax in its ability to import process and distribute food. Prior to the act, the chief concern was with the final product, and this has shifted somewhat by requiring registration of facilities, safeguards, and identification within production facilities, prior notice of imported materials, and allowing detention of raw and intermediate products before they are distributed [42].

The Role of Identification and Information Technologies in Food Security

The basic terminology of identification when used in a security context is important as many of the concepts are used interchangeably when they have distinct meanings. Identification is usually based on something that an item or person intrinsically has (a fingerprint, for example),

something it is assigned (such as a name), something that it "knows" (such as a password), and something it might extrinsically carry (generically referred to as a "token," such as an identification card) [43].

Authentication of an identity occurs when the verifier compares an identifier against a different knowledge set looking for a match. Authentication allows a process to go forward, whether it be admittance to a work area or the acceptance of a shipment of materials. A good example of this would be the examination of the identification card of a student trying to get into a college bar. Comparing the picture on the identity card against the person attempting to identify themselves with it gives a rough means of verification and admittance to the establishment, although this is obviously circumvented on a regular basis.

With all types of identification used for authorization, the risk of both fraudulent and mistaken misidentification can be matched to the rewards from doing so. State drivers' licensing offices are frequently the subject of investigation as the sale of drivers' licenses can be worth several thousand dollars apiece, and an inattentive examiner can similarly mistakenly authenticate an identity document.

Counterfeit goods that have been produced to intentionally misrepresent themselves, either as a known commercial product or as having an inflated quality or safety level, are a profitable item for the sake of commercial gain, and have always existed. A good deal of ancient trade was based on the value of the quality of a product, and so misrepresented, sub-standard products always represented a chance at profitability. Recently, because of the inordinately high value of some items – pharmaceuticals and aircraft parts, for example – counterfeiting has been of great concern. Similarly, counterfeiting has been used to encompass intellectual property such as illegally copied music and software that is easily reproduced and distributed without paying fees and royalties.

Counterfeiting the identification of a particular food ingredient may be similarly desirable considering that misrepresenting the quality or safety of a particular item can bring enormous increases in financial gain. This is particularly true for items that are difficult for the average user to distinguish, and which vary widely in price. Ordinary seafood is routinely sold as more expensive species because it is hard to discern one fish from the next after processing. Misrepresentation of vintage wines is a relatively common occurrence, and more usual consumer items that have a high markup value based on quality attributes, such as extra virgin olive oil, are regularly the subject of fraud, often on a shipload scale [44,45,46]. With this in mind, a lot of the security features that are commonly advocated to safeguard the food supply are little more than window dressing in the face of an entity that is determined to gain access. Further, these offer the potential of allowing reliance on gadgetry rather than observation and common sense. Because of the highly developed distribution network for food products, in theory it should be possible to track shipments and to verify whether these are legitimate or not. What is not so certain is whether the system, already optimized for extreme low cost, will be willing to bear the expense of doing so.

Transparency is a critical component of safety as well, and one that is currently not required of food producers. The Heinrich Accident Triangle holds that each major harmful occurrence follows a certain number of minor occurrences – a principle that can hold true in nearly every security scenario, although unfortunately too often done in hindsight. With current food safety regulations, many of these incidents are never revealed by manufacturers because they are not required to do so (and are allowed to refuse inspector's requests for information). This has the effect of compounding the extent of safety and security problems because they can be well into distribution and incorporation into other products before a response even begins. In the event

of malicious or intentionally fraudulent production of dangerous ingredients, the results can be a widespread event of sickness and even deaths before a response even begins, and the results can be destructive both to consumers and to the other, legitimate producers of similar items.

Information-Based Security Systems

The technological basis for an information-based security system has its roots in the cryptography sector that has been working to develop secure information transmission systems. In essence, many of these systems depend on a validation system where the information carried has no meaning to the casual (or intrusive) observer, but that can be unlocked with a key and mathematical algorithm to yield the validation code or message. This is the basis for the critical security features of nearly all electronic commerce, banking, Web-based purchasing, and credit card data transfer, and is often used to encrypt software and media files.

In essence, most security and encryption schemes rely on a linked two-part system: encryption and decryption (Figure 10.4). Historical methods required that these methods have the same method or algorithm, and the same *keys* for encryption and decryption. These keys are sequences used to scramble the *plaintext* message into apparently random characters, signals, or numbers termed *ciphertext* that have no apparent meaning or even pattern of information.

Recent developments have resulted in two-part keys based on large prime numbers, which produce so-called *public key* systems that allow encryption with one key and decryption with another. The most famous of these is the RSA algorithm based on modulo encoding using very large prime numbers, and which derives security from the computational difficulty of factoring these. In essence, the sender and receiver of information do not have the same key, and the use of one key does not make the other vulnerable, though the decryption key obviously must be kept private. Moreover, intercepting the ciphertext, whether it is electronic data, a printed label, or some other communications means, is useless without the ability to decrypt it.

The application to a food security system can involve validation at various points in the distribution system, verifying products' information against a validation key carried in a scanner, or other separate means. Because of the increased amount of information that can be carried in systems such as data-matrix optical coding schemes and RFID systems, the potential for a moderately secure, fairly complex, yet easily translated validation system has emerged.

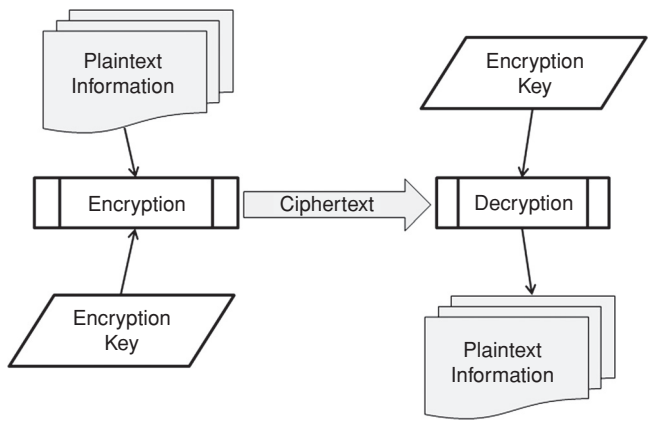

Figure 10.4. Encryption Flowchart

Other types of validation have been proposed, using printed interferometric methods, holographic validation seals, and other methods such as the inclusion of inert "validating" materials – even DNA fragments – in foods as a means of ascertaining whether they are genuine or not. Concerns about complexity, safety, and cost will often make these methods less attractive, and the time and the fragility of many validation systems as well as their susceptibility to *lifting* – removing the validation token from a legitimate item and transferring it to a counterfeit one – can render these only marginally useful for large-scale commodities such as food items.

Food System Response to Threats

Regardless of the identification, verification, and tracking systems used, once a problem, intentional or unintentional problem is identified, the food distribution and retail must respond in a rapid, appropriate, and flexible manner. Workers in systems security consider many response scenarios to be *brittle* – that is, when a system has a credible threat, the response requires the entire system to stop functioning or to be extraordinarily restrictive. A good example of this is current airport security system that often closes an entire airport's operation if an uninspected passenger enters a secured boarding area. The problem is not that this is an inappropriate response to an actual threat; rather, it is an inappropriate response to the perception of a threat. If the entire food distribution system of a country shuts down upon the detection of a single product tampering or contamination threat, every false alarm would be disrupting and expensive, and would result in a system that was completely dysfunctional. Worse, this kind of exaggerated response can be used to create a *denial-of-service* attack, which is the equivalent of setting off all the fire alarms in a building in order to keep legitimate users out, and might prove more harmful than more direct attacks.

As discussed in Chapter 8, the base-rate fallacy problem continues to apply: In a system with a large population (in this case, a large volume and diversity of products) that has a very low level of actual occurrences of some hazard, even a moderate number of false alarms can result in a maddening number of delays and shutdowns if the system is not adequately prepared to respond flexibly to varying levels of threat. Because of biological hazards that the food preservation systems were originally intended to defeat, and chemical contamination that occurs periodically, the threat of food safety problems have already created a fairly good system for responding to problems with particular food products.

More useful is the careful design of flexible response, where small segments of a particular system are shut down to contain a potential threat. Additional, judicious safeguards on the quality of the food supply both with regard to intentional and criminal contamination, as well as accidental errors in processing or formulation, when coupled with rapid methods of detection of contamination and a rapid response by the distribution chain, will probably justify the additional cost and complexity required to achieve these results.

As previously discussed, the current recall system is already a selective and responsive means to that end if used promptly and properly. Accurate, transparent, and responsive safety system allows the rapid containment of emerging threats before substantial harm is done and without paralyzing whole segments of the economy.

Additional Resources

1. "Hair and Grass in the Lord's Food," contained in "Zouyan Shu" (record of doubtful cases), recovered from a tomb at Zhangjiashan (Hubei Province), under translation by ABarbieri-Low. http://www. history.ucsb.edu/faculty/barbierilow/Research/research.html

2. Barnum, Phineas Taylor (1855), *The Life of P. T. Barnum*. New York: Redfield Publishing, p. 99.
3. "The Quaker's Oats." The Cleveland Memory Project, Chapter 17. http://www.clevelandmemory.org/ellis/chap17.html
4. Center for Science in the Public Interest (1999), "CSPI's Petition to the FDA to Require Better Sugar Labeling on Foods." www.cspinet.org/reports/sugar/sugarpet1.pdf
5. "Merritt's 'Embalmed' Beef." *New York Times* (December 28, 1898).
6. "The Army Meat Scandal." *New York Times* (February 21, 1899).
7. "Army Beef Scandal Made Public." *New York Times* (May 8, 1899).
8. "Our Beef Scandal Abroad; Question of Protecting British Public to be Raised in the Commons." *New York Times* (May 30, 1906).
9. United States Congress. " Pure Food and Drug Act of 1906." 59th Cong., Sess. I, Chp. 3915, pp. 768–772.
10. "Meat Inspection Bill Passes the Senate." *New York Times* (May 26, 1906).
11. European Parliament and Council Directive 94/62/EC of 20 December 1994 on packaging and packaging waste. http://europa.eu/scadplus/leg/en/lvb/l21207.htm.
12. "NIST Handbook 133: Checking the Net Contents of Packaged Goods as Adopted by the 89th National Conference on Weights and Measures 2004." http://ts.nist.gov/WeightsAndMeasures/upload/All-H133-05-Z-2.pdf.
13. US Department of Agriculture, Agricultural Marketing Service. "Country of Origin Labeling." http://www.ams.usda.gov/AMSv1.0/cool
14. US Department of Agriculture, Agricultural Marketing Service (2009), "Mandatory Country of Origin Labeling – Final Rule." http://www.ams. usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5074847
15. Lutz, W. (1997), *The New Doublespeak: Why No One Knows What Anyone's Saying Anymore*. New York: Harper Perennial.
16. "Serving Sizes in the Food Guide Pyramid and on the Nutrition Facts Label: What's Different and Why?" USDA Center for Nutrition Policy and Promotion, Insight 22, December 2000. http://www.cnpp.usda.gov/Publications/NutritionInsights/Insight22.pdf
17. US Code of Federal Regulations, 21 CFR §174.5 and §175–179. These and other federal regulations can be accessed online at http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&tpl=%2Findex.tpl
18. "NOAA Seafood Inspection Program: Protection through Inspection." http://www.seafood.nmfs.noaa.gov
19. US Code of Federal Regulations, 49 CFR§172.
20. United States Federal Aviation Administration (2008), "FAA Aerospace Forecast Fiscal Years 2009–2025." http://www.faa.gov/data_research/aviation/aerospace_forecasts/2009-2025/media/Forecast%20Highlights.pdf
21. Northeast Recycling Council. "Fact Sheet, Toxics in Packaging Clearinghouse." http://www.toxicsinpackaging.org
22. US Postal Service (1999), "Hazardous, Restricted, and Perishable Mail." Publication 52. http://www.usps.com/cpim/ftp/pubs/pub52.pdf
23. US Postal Service (2002), "Packaging for Mailing." Publication 2. http://pe.usps.com/text/pub2/welcome.htm
24. The United States Patent and Trademark Office. "Who We Are." http://www.uspto.gov/about/index.jsp
25. "United States Copyright Office: A Brief Introduction and History." http://www.copyright.gov/circs/circ1a.html
26. Poison Prevention Packaging Act. October 14, 2008. Version (Codified at 15 U.S.C. §§ 1471−1477), (Public Law 91-601, 84 Stat. 1670, December 30, 1970, as amended). http://www.cpsc.gov/businfo/pppa.pdf
27. Viscusi, W. Kip (1984), "The Lulling Effect: The Impact of Child-Resistant Packaging on Aspirin and Analgesic Ingestions." *The American Economic Review* 74 (2): 324–327.
28. "Ho Ho Woes: Wrap Rage Results in Lacerations and Bad Tempers." *American Medical News* (December 22, 2008). www.ama-assn.org/amednews/2008/12/22/hll21222.htm
29. US Department of Labor, Occupational Safety and Health Administration. "Information for Workers." http://www.osha.gov/workers.html
30. "NIOSH Workplace Safety and Health Topics; Industries & Occupations." http://www.cdc.gov/NIOSH/topics/industries.html
31. National Motor Freight Traffic Association. "Packaging." http://www.nmfta.org/Pages/NMFCPackaging.aspx
32. Unterman, F. (2000), "Food Safety Management and Misinterpretation of HACCP." *Food Control* 10: 161–167.
33. US Food and Drug Administration. "Hazard Analysis and Critical Control Points." http://www.cfsan.fda.gov/∼lrd/bghaccp.html
34. US Food and Drug Administration Center for Food Safety and Applied Nutrition. "Industry Affairs Staff Brochure." June 2002. http://www.cfsan.fda.gov/∼lrd/recall2.html
35. Kaletunç, Gönül and Özadali, Ferhan. "Understanding the Recall Concept in the Food Industry." Ohio State University Extension Fact Sheet AEX-251-02. http://ohioline.osu.edu/aex-fact/0251.html

36. Morris, S. A. (2010), " Processing and Packaging That Protects the Food Supply Against Intentional Contamination." In *Wiley Handbook of Science and Technology for Homeland Security*. New York: John Wiley & Sons.
37. Harper, Jim (2006), *Identity Crisis: How Identification Is Overused and Misunderstood*. Washington, DC: Cato Institute Press.
38. Schneier, Bruce (2003), *Beyond Fear: Thinking Sensibly about Security in an Uncertain World*. New York: Springer.
39. Ancker, Col. C. J. III (2003), "Doctrine for Asymmetric Warfare." *Military Review* (July–August): 18–25.
40. Tonsfeldt, W. and Claeyssens, P. G. "The Oregon History Project, Subtopic: Post-Industrial Years: 1970-Present: Communities in the Post-Industrial Period, Themes: Social Relations." http://www.ohs.org/education/oregonhistory/narratives/subtopic.cfm?subtopic_ID=414
41. "Anthrax Scientist – and Top Suspect – Dead in Apparent Suicide." Christian Science Monitor (August 2, 2008). http://www.csmonitor.com/2008/0802/p99s01-duts.html
42. "Summary of Title III, Subtitle A of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, Title III – Protecting Safety and Security of Food and Drug Supply, Subtitle A – Protection of Food Supply." http://www.cfsan.fda.gov/~dms/sec-ltr.html#attach-a
43. Harper, Jim (2006), *Identity Crisis: How Identification Is Overused and Misunderstood*. Washington, DC: Cato Institute Press. Op cit.
44. US General Accounting Office (2009), "Seafood Fraud FDA Program Changes and Better Collaboration among Key Federal Agencies Could Improve Detection and Prevention: Report to the Ranking Member, Subcommittee on Oceans, Atmosphere, Fisheries, and Coast Guard, Committee on Commerce, Science, and Transportation, U.S. Senate." http://www.gao.gov/new.items/d09258.pdf
45. "Letter from Italy: Slippery Business – The Trade in Adulterated Olive Oil." *New Yorker Magazine* (August 13, 2007). http://www.newyorker.com/reporting/2007/08/13/070813fa_fact_mueller
46. "Countering Counterfeit Wines." *New York Sun* (October 24, 2007). http://www.nysun.com/food-drink/countering-counterfeit-wines/65159/?print=1787137321