12.1 Introduction

Food regulation in the US will be dramatically transformed by the Food Safety Modernization Act (FSMA) signed into law January 2011 (Public Law 111-353). The Food and Drug Administration (FDA) regulates about 80% of the food we eat, and requirements for a food protection plan with suitable preventive controls to guard food from intentional and unintentional contamination advancing global food safety are now a requirement for all food, domestically produced or imported, in the US. Provisions of the new law will be adopted either formally or through market-induced changes to business practices globally and at a substantial cost. Many are hopeful this new law will improve food safety, but it is likely to come at the cost of further consolidation throughout the industry as regulatory compliance costs drive marginal producers, particularly of “high-risk foods” and potentially fresh produce and aquatic foods, out of the market due to the high cost of regulatory compliance associated with the provisions of this new law. The federal government has consolidated its control over food safety programs within the US over the past six decades, most recently through the expansion of federal jurisdiction under this and other recent Acts, and the regulatory strategies by which the agencies choose to implement them.1

Changes in the regulations and practice of the United States Department of Agriculture Food Safety and Inspection Service (USDAFSIS), which subsumed state programs in recent decades, have further expanded federal authority. With 10–15% of all foods consumed in the US now imported, an increased focus is being placed upon the safety and quality of imported foods and ingredients along with the strategies to regulate their safety. Import product safety is prominent in the FSMA and in USDA programs, and with this will come the evolution of additional testing and certification programs. Many companies outsource testing services and inspections to third parties due to a lack of in-house expertise or because requirements of their retail customers specify that third-party audits or certifications be conducted to one of a variety of different standards. The proliferation of audit programs with the inherent conflict of interest that inevitably accompanies them will be exacerbated under FSMA and will increase food costs.

As a food technologist employed in the private sector, your responsibility will include assisting the company to develop strategies to support business operations by successfully implementing and managing an effective food protection program compliant with myriad government and external certification requirements that could lead to reduced litigation exposure. User fees, costs of testing, and third-party inspections will continue to increase the cost of food for consumers across the world, exacerbating the global food security crisis. Resources are limited in both economically developed and developing countries, and unfortunately, resources dedicated to overly stringent food safety and compliance programs are taken directly from food production and processing that could be used to make more food for more people, following the law of diminishing returns.

This chapter will outline some of the legal issues of which a food technologist should be cognizant and which will

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1 LM Lewis (2011) Informal guidance and FDA. Food and Drug Law Journal 66(4): 507–550 provides a historical overview of how the FDA develops regulations and guidance documents and raises recent examples of how the FDA has attempted to pre-empt state law and expand the scope of statutory authority through the issuance of informal guidance. Lewis notes that the FDA is very unlikely to change its position or incorporate any substantive stakeholder feedback into a guidance or a final rule. He further states that there is essentially no recourse to challenge FDA guidance in court, through a process known as judicial review.
likely impact his/her professional life. This chapter is not an exposition on civics and will not cover in detail information on food safety plans and programs such as HACCP, GAP, cGMPs, SSOPs, product labeling, etc, which are covered in other chapters. Instead, the objective is to provide an overview of newer legal trends and requirements, with an emphasis on issues that impact international trade.

### 12.2 The regulatory status of food ingredients and additives

Many useful substances are added to processed foods. The FDA determines the regulatory status of substances added to food, including any food ingredient or other substance that might become a component of the food, such as from a food contact surface or from packaging, under Section 409 of the Food Drug and Cosmetic Act. Companies are legally responsible for the safety of a new food or an additive. Common ingredients added to foods such as food acids, salt, and sugar are “generally recognized as safe” (GRAS) because of a long history of safe use as a food additive. However, if a food additive is not “generally recognized as safe” by experts or previously approved informally by the federal government for the described use” the FDA will review safety and issue a decision (premarket approval) on if and how the additive can be used. One class of additives that receives special scrutiny is artificial colorants; these are subjected to pretesting and safety clearance by the FDA. The Center for Food Safety and Applied Nutrition reviews petitions for food and color additives along with notices submitted for the use of materials added to food that may be potentially harmful, such as food or ingredients made using modern genetic technologies. Any new food additives that are not GRAS are required to undergo premarket approval regardless of the type of method used to produce them.

### 12.3 Adulteration and misbranding

It is illegal to sell foods that are either adulterated or misbranded, and the FDA has a number of regulatory tools to force removal of foods that pose a risk to public health, are not wholesome, or mislead consumers about the quality, quantity or marketable features of the food. A food is adulterated if it bears or contains any added poisonous or deleterious substance that may render it injurious to health, pathogenic microorganisms included. Under the Food Drug and Cosmetic Act (Section 402), a food is also deemed adulterated if:

1. any valuable constituent has been omitted in whole or in part
2. any substance has been substituted in whole or in part
3. damage or inferiority has been concealed in any manner, or
4. any substance has been added so as to increase its bulk or weight, or reduce its quality or strength, or make it appear better or of greater value than it is.

Food is adulterated if it is unwholesome or otherwise unfit for consumption.

A food is misbranded under the Act (Section 403) if its labeling is false or misleading in any particular aspect. To determine if a label is misleading, the FDA considers representations made about the product on the label, and the extent to which the labeling fails to reveal material facts in light of such representations made or suggested in the labeling or accompanying material. Its review emphasizes safety (and may not pay as much attention to issues that would be called “economic adulteration”), of a GMO Atlantic salmon, that grows more rapidly because of the incorporation of a king (Chinook) salmon growth hormone gene, has languished for 15 years after hopes in 2010 that FDA approval was pending following a series of high-level hearings. Foods from cloned animals have received approval because the animals do not contain foreign genes.

An omission in the Food Safety Modernization Act is failure to define “economic adulteration” or “economically motivated adulteration” but it does retain the definition under the Food Drug and Cosmetic Act. This is a problem because economic fraud has been the basis for a number of recent high-profile food adulteration incidents that have resulted in numerous illnesses and deaths, the most notorious being the series of melamine contaminations of plant proteins, wheat, and milk powder in China (2007–2010).
and label reviews are conducted with an eye towards determining consequences that may result if a consumer uses the food as per the instructions provided or under conditions of customary or usual use. The omission of certain material facts from the label or labeling of a food is a form of misbranding. Product information, claims, package inserts, and accompanying literature are covered by similar provision to protect against consumer deception.\(^4\)

Food must be labeled truthfully and provide information that will not mislead consumers. A summary of information to be provided on a food label is presented in Box 12.1. A misbranded food has one or more of the following features.

1. **A false or misleading label.** If the label is false or misleading in any particular, or if its advertising is false or misleading in a material aspect or if it is offered for sale under the name of another food.

2. **Imitation of another food.** If it is an imitation, then the label must contain in type, print size, and prominence the word “imitation” immediately before the name of the food. A food is an imitation if it lacks or is deficient in one or more characteristics considered to be important for the food, for example, low fat or vitamin content.

3. **Misleading container.** Containers cannot be formed, made, or filled to be misleading.

4. **Improper package form.** The package must contain a label with (1) the name and address of business of the manufacturer, packer or distributor, and (2) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count.

5. **Lack of prominence of information on the label.** If any word, statement or other information is required to appear on the label, this must be conspicuous and readable, and likely to be read and understood by ordinary individuals under customary conditions of purchase and use.

6. **Lack of representation as to definition and standard of identity.** If the food has a standard of identity it must conform to the compositional standards, ingredient statement, and be labeled in accordance with the standard.

7. **Lack of representation as to standards of quality and fill of container.** Requirements for foods with a standard of identity must meet requirements for fill or be marked that they do not meet these requirements.

8. **Lack of labels for foods with no standard of identity.** Foods and beverages must contain the common or usual name of the food/beverage and the common name of ingredients. Ingredients must be listed in decreasing order. In a beverage claiming to be a vegetable or fruit juice, the quantity of juice (total percentage) must be labeled prominently.

9. **Lack of representation for special dietary use.** Label must contain information about vitamins, minerals and dietary properties necessary to inform purchasers about the value of the product for such uses.

10. **List of artificial flavoring, artificial coloring, or chemical preservatives missing or misleading.** Foods with these components must have them listed on the label. There are special requirements for artificial coloring in butter, cheese, and ice cream. Labeling of pesticide chemicals on raw agricultural products (produce of the soil) is exempt (see 11).

11. **List of pesticide chemicals on raw agricultural commodities missing or misleading.** If a food is a raw agricultural commodity that is the produce of the soil, bearing or containing a pesticide chemical applied after harvest, the shipping container must be labeled with the common or usual name of the pesticide chemical(s) and its function.

12. **Color additive list missing or misleading.** Color additive packaging and labeling must conform to requirements. Certain colors, for example yellow 5, must be separately labeled.

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\(^4\)The Federal Trade Commission regulates food advertising and applies the same legal standards as the FDA when determining whether advertising is “misleading” to a reasonable consumer under the circumstances, and whether it is “material”, in the sense that it will likely affect a consumer’s conduct or decision to purchase a product.
13. Misleading nutrition information. Label must contain nutritional information as follows.

a. Serving size in amount customarily consumed. This must be expressed in a common household measure, and by weight.

b. Number of servings per container.

c. Total calories and calories from fat on a per serving basis.

d. The amount of the following nutrients: macro-nutrients [(total fat, saturated fat, trans fat (trans-esterified fatty acids)) total carbohydrate, complex carbohydrate (optional), sugars, total dietary fiber (required), soluble and insoluble fiber (optional) and total protein], cholesterol, sodium, vitamins (A, C), and minerals (calcium, iron). Labeling of other constituents is permissible. The labeling is factual, is not misleading or not otherwise prohibited by regulation. If a food has been fortified with added nutrients, this should be noted. The FDA may permit certain nutrients to be highlighted on the label if this will help consumers maintain healthy dietary practices.

e. Bulk foods and popular unpackaged fruits vegetable and seafood items should have nutritional information provided for consumers at point of retail sale.

14. Misleading nutrition levels and health-related claims. Express or implied claims on the label that characterize the level of any nutrient or the relationship of any nutrient with a disease or health-related condition must comply with FDA guidelines.

a. May not state the absence of a nutrient unless the nutrient is usually present in the food (or in a food which substitutes for the food in question) and the nutrient level or health-related claims are permitted by the FDA on the basis of a finding that such a statement would assist consumers to maintain healthy dietary practices. Claims for foods containing cholesterol must not contain fat or saturated fat in an amount that could increase the risk of a disease or a diet-related health-related condition unless the cholesterol level is substantially less than normally present in the food (or a substitute), or cholesterol is not normally present in the food and a statement would assist consumers to maintain healthy dietary practices. The level of saturated fat and total fat must be prominent and in immediate proximity to the cholesterol claim on the label.

b. May not state that a food is high in dietary fiber unless the food is also low in total fat. Total fat must be disclosed on the label prominently and in close proximity to fiber claim on the label.

c. Claims may not be made if they are prohibited by regulation or if the FDA determines that the claim is misleading in the light of the level of another nutrient in the food.

d. If a nutrient claim is made for a food containing a nutrient at a level that increases the risk of a diet-related disease or a health-related condition to persons in the general population, the food shall prominently place the statement “See nutrition information for ---- content” in immediate proximity to the nutrient claim.

e. Claims for which there are no regulations may be made if a scientific body of the US government has published an authoritative statement regarding the nutrient; notice and claims approval provisions apply.5

5 Dietary supplements, from a safety standpoint, are regulated in the same ways as foods and not like over-the-counter drugs, which might be more appropriate because these items are consumed, not as a food is consumed, but instead in small quantities as a pill, capsule, or as a small volume in liquid or solid form. However, labeling of nutrient supplements has significantly more leeway and more liberal labeling provisions than those permitted for food and are outlined in the Dietary Supplement Health and Education Act and its accompanying regulations. Nutrient label claims for dietary supplements composed of vitamins, minerals, or other similar nutritional substances and more provisions are allowed. For example, a supplement can have claims highlighting a benefit of consumption for alleviating a classic nutrient deficiency (e.g. iron deficient anemia), role of nutrient or dietary ingredients on the structure or function of the human body, characterization of a documented mechanism by which the nutrient acts, or describes the general well-being from consumption are permissible if such statements are truthful and not misleading. However, the statement: “This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease” must be prominently displayed on packages upon which nutrient claims are made. See Pearson v Shalala (1999) (164 F.3d 650, 334 U.S. App. D.C. 71) in which the appellate court declared that FDA regulations for evaluating health claims for dietary supplements violated first amendment rights of commercial free speech when the agency refused to authorize supplement health claims accompanied by a “reasonable disclaimer.” The court also invalidated the manner in which the FDA conducted reviews for supplement labeling. Because of this ruling, for supplements, but not for foods, the FDA has the burden of proving that a claim is inherently misleading and that this cannot be “neutralized” by including a disclaimer on the product packaging. A common disclaimer is: “These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.”
f. An implied claim made within a brand name may be made following a petition to the FDA for its use; claim cannot be misleading.

15. Lack of proper allergen labeling. The common or usual name of each of the major food allergens the product contains is required on the product label or in the ingredient statement if the ingredient name includes the name of the allergenic food source. Allergen labeling is required for foods containing: tree nuts, peanuts, fish, crustaceans, milk, eggs, wheat, and soybeans or ingredients obtained from them. Flavorings, colorings or incidental additives that contain a major food allergen are subject to labeling; some highly refined foods, such as oils, may be exempt from allergen labeling because the levels of allergenic components would be very low. There are specific provisions for “gluten free” labeling.

12.4 The global food trade: risk from adulterated and misbranded foods

Economic fraud poses one of the greatest risks to our food supply. Adulteration is rampant in developing countries, with at least 30 identified adulterants added to milk to improve shelf life or increase apparent protein, solids or fat content. The melamine scandal in China made international headlines in 2007 after the death of domestic animals in the USA, Europe, South Africa, Canada and throughout Asia resulting from addition of melamine to increase the apparent protein content of plant protein ingredients that were used in animal feed. In 2008, milk powder containing melamine led to a global recall of milk powder and thousands of food products containing milk powder from China. Hundreds of thousands of children were affected in China alone, and untold numbers of others in countries in which this melamine-tainted milk powder was sold and consumed. Many of these children will likely suffer from chronic kidney problems from this exposure.

This disastrous failure of our food safety systems finally focused worldwide attention on the problem of intentional contamination in which the motivation is economic fraud. Several provisions of the FSMA are directed at economic fraud, in the sense that this is a form of intentional contamination that can potentially cause serious adverse health consequences or death. However, addressing this form of insidious and clever adulteration in a preventive measure program is difficult. The FDA recognizes this dilemma and has recharacterized itself as a global agency that must prepare itself to “regulate in an environment in which product safety and quality know no borders.”

The US Government Accounting Office, in a review of FDA efforts in this area, offers a definition of economic adulteration: economic adulteration is fraudulent, intentional substitution or addition of a substance in a product for the purpose of increasing the apparent value of the product or reducing the cost of its production, for economic gain (GAO, 2011). Examples of economic adulteration include the dilution of products with increased quantities of an already present substance (e.g. increasing inactive ingredients of a drug with a resulting reduction in the strength of the finished product, or watering down milk or juice), as well as the addition or substitution of substances in order to mask dilution. This definition is the same as the working definition of “economically motivated adulteration” that the FDA developed in 2009, but which is likely to be included in regulation or guidance.

The FDA should build criminal cases against companies engaged in economic fraud and prosecute such cases vigorously (GAO, 2011). This would provide a strategy for keeping adulterated ingredients out of the food supply. Industry self-policing with market sanctions is critical for curtailing economic fraud and often brings fraud to the attention of governmental authorities.

Traceability will be the key to managing the impact of economic fraud along a complex value chain, although the technologies that are available to address this problem remain inadequate. Provisions for country of origin labeling will not be effective for monitoring the source of ingredients in a food that changes hands several times during processing and distribution if the initial source of the food is not disclosed. Similarly, ingredients are sourced from numerous regions and countries, depending upon season, demand, and price, making tracking difficult further down the supply chain. Provisions in the FSMA require companies to track the immediate previous source of an ingredient and then track the ingredient into the production lot(s) in which it is used. This information will help the company, as well as the FDA, to locate foods affected by a recall if ingredients are deemed to be unsafe or if other problems arise with a product. Still, because multiple parties are involved along the supply chain for the manufacture and distribution of foods containing multiple components from multiple sources, and with increasing numbers of transfers of components between parties in different countries, opportunities for adulteration are widespread.
for each party further down the distribution chain. The FDA lacks the expertise in forensic investigation and analytical capacity to scratch the surface of this problem, but passing the burden to companies is irresponsible, since companies, particularly smaller ones, often have few resources for this activity. Regardless, traceability programs need to be implemented and continually improved since effective tracking reduces the public health and market impact of an adulteration incident. The FDA is seeking assistance from the private sector regarding traceability systems and will likely be issuing guidance in this area.

The FDA has required registration of food facilities for the past 10 years under provisions of the Bioterrorism Act of 2002 and has incorporated these requirements into the FSMA, as will be discussed in detail later in this chapter. The registration requirements cover both domestic and foreign producers and directly affects over 700,000 entities as of this writing. Foods regulated by the FDA cannot be sold unless the firm is registered. If food fails to meet certain regulatory requirements, the agency can pull the registration, meaning that it will not be possible for the food to be sold. This registration provision was devised to provide a means of tracking food to its source and is tied into traceability provisions under the law.

A major complication in the current regulatory scheme is that the US does not have the legal authority to inspect foreign operations or to accredit third parties in foreign countries unless this is voluntarily granted by the foreign entity. Despite the lack of jurisdiction, Congress has placed an obligation upon the agency to inspect foreign facilities and establish overseas office(s) as a means of increasing oversight of imported foods. Some of this enhanced oversight will be through third-party certifiers. Unfortunately, corruption within the third-party inspection process and accreditation process is common and the burden to protect our food supply from adulteration, economic or otherwise, will fall upon the importing country and border control programs to prevent entry of adulterated food.

12.5 US Department of Agriculture programs

The USDA is engaged in numerous activities that promote agriculture and, since the 1960s, an expanded mission for food security. The USDA engages in market support and market and economic research, promotion of international agricultural trade and market grades and standards, plant and animal health, food safety, and research on many aspects of agriculture, with a recently expanded emphasis on resource conservation, including water and soil management and climate change.

12.5.1 Food safety: the Food Safety and Inspection Service

Food safety within the USDA is within the purview of the Food Safety and Inspection Service (FSIS). The FSIS inspects and monitors all meat, poultry, and liquid egg products sold in interstate and foreign commerce. The Federal Meat, Poultry and Egg Products Inspection Acts ensure compliance with mandatory US food safety standards. The Federal Meat Inspection Act provides for inspection of all meat products, with the exception of custom-processed meat covered by state programs, and reinspection of imported meat products. The Poultry Products Inspection Act similarly gives the FSIS authority for all poultry products sold in interstate commerce. The Egg Products Inspection Act provides for inspection of domestically produced liquid eggs and reinspection of imported liquid eggs. (Eggs in the shell are inspected by the FDA.) For processed eggs, eggs are examined before and after breaking. The Humane Methods of Livestock Slaughter Act mandates that livestock slaughter must be conducted humanely.

Procedures for obtaining meat or poultry inspection are straightforward and outlined in the Federal Grant of Inspection Guide found on the USDA website (USDA, 2012). A company applies for a grant of inspection and with this must show that the facility can meet performance standards for the products in question, develop a sanitation plan (sanitation SOPs), and Hazard Analysis Critical Control Point (HACCP) program that meets FSIS criteria, have approval of a potable water source (a report from a municipal water authority showing water is potable) and a sewage discharge system that prevents back-up of sewage into areas where food is processed, handled or stored. Model plans are provided for different facilities, including small and very small processing facilities. Agency label review is mandatory and guidance is provided. Once a grant of inspection is made, a facility will be provided with an establishment number and mark that is affixed to the FSIS inspected and passed product. The FSIS can withdraw inspection and this will prevent sale of food until the facility is back in compliance.

Withdrawing inspection of a facility by the FSIS can occur under the following circumstances.
1. An establishment produced and shipped adulterated product.
2. An establishment did not have or maintain a HACCP plan.
3. An establishment did not have or maintain sanitation SOPs.
4. An establishment did not maintain sanitary conditions.
5. An establishment did not collect and analyze samples of *Escherichia coli* biotype I and record results as required.
6. An establishment did not comply with *Salmonella* spp. performance standards.
7. An establishment did not slaughter or handle livestock humanely.
8. An establishment operator, officer, employee or agent assaulted, threatened to assault, intimidated or interfered with an FSIS program employee.
9. A recipient of inspection or anyone responsibly connected to the recipient is unfit to engage in any business requiring inspection.

### 12.5.2 Food safety: the Animal and Plant Health Inspection Service

The Animal and Plant Health Inspection Service (APHIS) is charged with protecting the health of agricultural animals and plants, regulating genetically engineered organisms, administering the Animal Welfare Act and managing certain wildlife activities. One of the most important roles the APHIS plays is to guard against the introduction of agricultural insect pests and diseases into domestic food production. The APHIS plays a role in import inspections and manages quarantine programs for animals and plants, including emergency protocols to manage and eradicate an outbreak conducted in conjunction with state and international partners. The agency develops sanitary and phytosanitary standards to promote international trade and prevent unjustified trade restrictions or non-tariff trade barriers.

### 12.5.3 International trade

#### 12.5.3.1 Marketing and regulatory programs

The USDA has a number of marketing and regulatory programs to promote and facilitate domestic and international marketing of US agricultural products. USDA employees are actively involved in setting national and international market and trade standards for agricultural products. These include health and care of animals and plants, import requirements and harmonization of international standards to encourage global trade, and a number of market promotion programs.

#### 12.5.3.1.1 Agricultural Marketing Service

The Agricultural Marketing Service (AMS) provides quality grade standards, grading programs, certification, audit and accreditation programs, and laboratory analysis and approval, and equipment review as part of a voluntary program to promote trade and promote quality to customers domestically and internationally. Companies pay for these services.

The USDA quality grade marks are seen in the marketplace for beef, lamb, chicken, turkey, dairy products, and eggs. The grading service is used by wholesalers. Depending on how wholesalers want to market their products, they may include a quality grade mark on fresh or processed fruits or vegetables. Quality grades make business transactions easier since product attributes are clearly defined and understood by market actors. A number of countries have adopted US grade standards for commerce.

Quality standards are based on measurable attributes that describe the value and utility of the product. For example, beef quality standards are based on attributes such as marbling (the amount of fat interspersed with lean meat), color, firmness, texture, and age of the animal, for each grade. Quality grade standards describe a range of attributes for which there is a standard for a product, and the number of grades varies by commodity. These include yield, size, level of defects, factors associated with functional properties, cosmetic appearance, and sensory characteristics. There are eight grades for beef and three each for chickens, eggs, and turkeys. Thirty eight grades exist for cotton, and more than 312 for fruit, vegetables, and specialty product standards (www.usda.ams.gov).

The AMS also provides audit and accreditation programs based on International Organization for Standardization (ISO) standards and/or HACCP principles and guidelines, and verifies these documented programs through their provision of independent, third-party audits. AMS audit and accreditation programs are voluntary and paid through hourly user-fees (www.usda.gov).

#### 12.5.3.1.2 Country of origin labeling (COOL)

Country of origin labeling (7 CFR Part 60 et seq) is a retail-level requirement that provides consumers with notification about the geographic origin of foods they
buy. Manufacturers provide country of origin on packaged foods under this mandatory program and voluntarily on other items. This label is required for muscle cut and ground meats: beef, veal, pork, lamb, goat, and chicken; wild and farm-raised fish and shellfish; fresh and frozen fruits and vegetables; peanuts, pecans, and macadamia nuts; and ginseng. For meat, poultry and seafood items, a "United States country of origin" label can only be used for animals born, raised, and slaughtered in the US, and for aquatic foods harvested from US waters or by a US-flagged vessel. For peanuts, pecans, ginseng, and macadamia nuts, these must be exclusively produced in the US in order to receive a US country of origin designation. Any of the food items covered under this regulation must retain their original country designation unless they have undergone "substantial transformation" following import into the US. As an example, in the case of seafood, the food would be labeled: "From [country X], processed in the United States.” Alternatively, the food could be labeled: "Product of country X and the United States.” Aquatic foods must also have a designation as to whether they are cultivated or wild harvested.

A food can have multiple countries of origin if the raw materials from a number of countries have commingled in a production lot; for example, a label on ground beef might read: "Product of country X, Y and Z.” However, to reduce consumer confusion, “or” and “and/or” in the country of origin designation declaration are not allowed; for example, retailers would not be allowed to put: "Product of the US, Canada, and/or Mexico.”

Processed foods are exempt under COOL, but may require country of origin labeling under the Tariff Act of 1930 (Tariff Act). One example is for frozen mixed vegetables containing items from a number of countries blended together in the US which must have the separate countries listed on the retail package. Another example where origin of the raw material is required is a container of roast nuts consisting of peanuts of foreign origin roasted in the US; similarly canned salmon made from imported Chilean salmon. An example of where such a label is not required is for a candy bar or trail mix containing peanuts because of the presence of other “substantive food ingredients,” and processing to the extent that the character of the peanuts is transformed into a completely different food item.

12.5.3.2 Organic foods

The USDA manages one of the most widely recognized organic programs in the world. The USDA and Washington, Oregon and California states are international leaders in the development of organic food requirements and over a period of years have led efforts to build a comprehensive organic certification program for foods, consumer products, and fabrics. The USDA defines organic as:

labeling term signifying that the food or other agricultural product has been produced using approved methods that integrate cultural, biological, and mechanical practices that foster cycling of resources, promote ecological balance, and conserve biodiversity. Use of synthetic fertilizers, prohibited pesticides, sewage sludge, irradiation, and genetic engineering is prohibited.

Development of rigorous organic standards arose in response to consumer pressure in the US in the 1990s to label foods containing ingredients from genetically modified organisms and in response to scares associated with pesticide and agricultural chemical use. The National Organics Program regulates all products certified in the US to the USDA standards through organic certifiers. Agricultural products in international markets can be certified to USDA standards and the USDA seal is found on a variety of foods around the world. The USDA conducts investigations and enforcement activities to ensure compliance with products on which its organic seal or

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6 Substantial transformation is defined by Customs and Border Protection (CBP) and is a designation assigned for collections of duties and tariffs, a food item is substantially transformed if it has been processed. CBP does not consider blanching, cutting, freezing, and combining and packaging different vegetables to exclude them from CBP marking requirements.

Here is an example of a definition of processed foods for country of origin labeling (see 7 CFR Sec. 65.220). A processed food item means a retail item derived from a covered commodity that has undergone specific processing resulting in a change in the character of the covered commodity, or that has been combined with at least one other covered commodity or other substantive food component (e.g. chocolate, breading, tomato sauce), except that the addition of a component (such as water, salt, or sugar) that enhances or represents a further step in the preparation of the product for consumption, would not in itself result in a processed food item. Specific processing that results in a change in the character of the covered commodity includes cooking (e.g. frying, broiling, grilling, boiling, steaming, baking, roasting), curing (e.g. salt curing, sugar curing, drying), smoking (hot or cold), and restructuring (e.g. emulsifying and extruding). Examples of items excluded include teriyaki flavored pork loin, roasted peanuts, breaded chicken tenders, and fruit medley.
The United States Environmental Protection Agency (EPA) regulates many aspects of agricultural and food production, including fertilizer and pesticide/herbicide usage; discharge of solid, liquid and gaseous materials into water and air; management of solid waste and transport storage and disposal of hazardous materials; and environmental management of concentrated animal feeding establishments. Many of these programs are managed by complicated permitting processes, along with compliance with industry-specific discharge requirements. State and local authorities also play a role in setting requirements for food processing operations for air and water; management of solid waste and transport; and various zoning/building requirements. A list of laws directed at or including agricultural, food, or environment along with the cost and delays associated with obtaining these permits has caused many companies to curtail or abandon their US operations, jeopardizing our ability as a nation to provide sufficient food to feed ourselves. Violations of federal laws often lead to prosecution under similar state laws and vice versa and liability in multiple jurisdictions for the same activity.

12.7 The Food Safety Modernization Act

In the past decade, the jurisdiction of the US FDA has been greatly expanded through new provisions of the FSMA and the incorporation within it of some of the earlier provisions in PL 107-188 The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act), requiring registration of food processing facilities, prior notice to the agency for imported foods and ingredients entering the US, new provisions for traceability, and delegation to the FDA of a new authority to administratively detain food.

From a food processing perspective, provisions in the FSMA for Preventative Control Plan (similar to HACCP)-based food protection programs, and stricter traceability requirements are the parts of the law likely to impact food technologists to the greatest extent from in error and none of the allegedly out of compliance containers had left company custody. The company challenged the fine and it was reversed because the company was not only in compliance but had also passed a number of recent inspections in which the same labeling scheme had been used. The inspector was educated as to the difference between a primary and secondary container and hopefully reassigned. A disconcerting aspect of this incident was that if the fine had been 1 million dollars, the company would have paid it just to prevent damage to its reputation.

Reporting requirements for minor discharges have to be made within a short period, normally 48 h or less regardless of staffing, size of the company, or hours of operations, making a minor 5 gallon (18.9 L) ammonia discharge on a weekend from a refrigeration system into a $50,000 proposition if paperwork is not filed in a timely fashion by 9 am Monday morning.

Good faith efforts on the part of companies in their attempt to interpret ambiguous and confusing permitting requirements are not recognized. One small firm was fined tens of thousands of dollars for failing to properly transfer a water discharge permit after closely following instructions of district and regional offices on how to conduct the transfer.

12.6 Environmental Protection Agency programs

The United States Environmental Protection Agency (EPA) is primarily funded by user fees and civil penalties. This provides an incentive to maximize fees. Under various mandates, the EPA can assess civil penalties on a daily basis or on a per container basis. Incidents from the past year coming to the author’s attention include the following. Hundreds of boxes of a pesticide chemical in a warehouse were considered by an EPA inspector to be out of compliance because a required label on the primary package had not additionally been placed upon the outside carton. This inspector treated each box as a separate violation and levied a fine of around 100 million dollars. The company’s labeling was not paperwork filings, and for small but environmentally insignificant discharges of pollutants. Discharge permit requirements by the EPA or state departments of ecology or environment along with the cost and delays associated with obtaining these permits have caused many companies to curtail or abandon their US operations, jeopardizing our ability as a nation to provide sufficient food to feed ourselves. Violations of federal laws often lead to prosecution under similar state laws and vice versa and liability in multiple jurisdictions for the same activity.
the passage of this new law. Specific provisions in the FMSA are outlined in Box 12.3.8.

The FSMA incorporates many of the provisions of the Bioterrorism Act. The most important of these for a food technologist is the addition to conventional HACCP-based food safety plans that require a food producer to address intentional adulteration risk (vulnerability assessment) along with the development of mitigation strategies to control intentional contamination risks, including those from biological, chemical, and radiological hazards.

The FSMA is the greatest expansion of federal authority over food production and sales since implementation of the Food Drug and Cosmetic Act of 1938 (FDCA). The FDCA provided direct federal authority over foods by statute and provided enhanced enforcement authority and control over the food industry by prohibiting the sale of adulterated or misbranded foods through an enforcement system based upon periodic inspections of food facilities, federal checks for compliance with good manufacturing practices, and records-based reviews. The FDCA followed about 30 years after the adoption of the Federal Meat Inspection Act (1906) and Poultry Products Inspection Act (1906) that mandated in-plant inspection programs, including continuous presence of USDA employees in meat and poultry plants to conduct veterinary inspections of animals prior to slaughter, carcass inspections after slaughter, and later adoption of microbial sampling and HACCP-based food safety programs.

The strategies used by both the FDA and FSIS are converging. The FDA was first to adopt HACCP-based programs with the first programs being with seafood products (1995) (Procedures for the Safe and Sanitary Processing and Importing of Fish and Fishery Products, 60 Federal Register 65096, December 18, 1995), followed by FSIS HACCP programs in 1996 (Pathogen Reduction: Hazard Analysis and Critical Control Point (HACCP) System, 61 Federal Register 38806, July 25, 1996). Meat and poultry products have been labeled as passing inspection since the beginning of in-plant meat and poultry inspection programs, with slaughtering and processing facilities for meat- or poultry-containing foods receiving an establishment mark that permits them to sell the products they make. Facilities out of compliance will lose the right to use their mark, and will not be able to sell food until the facility is back in compliance and use of the mark restored by the FSIS.

The FDA, through the new FSMA law, has adopted a similar strategy by requiring registration of food processing and warehousing facilities domestically and internationally as previously mentioned. If the FDA believes that a food has “a reasonable probability of causing serious adverse health
Box 12.3 Provisions of the Food Safety Modernization Act (www.fda.gov/Food/GuidanceRegulation/FSMA/ucm247548.htm)

TITLE I – IMPROVING CAPACITY TO PREVENT FOOD SAFETY PROBLEMS
Sec. 101. Inspections of records.
Sec. 102. Registration of food facilities.
Sec. 103. Hazard analysis and risk-based preventive controls.
Sec. 104. Performance standards.
Sec. 105. Standards for produce safety.
Sec. 106. Protection against intentional adulteration.
Sec. 107. Authority to collect fees.
Sec. 108. National agriculture and food defense strategy.
Sec. 109. Food and Agriculture Coordinating Councils.
Sec. 110. Building domestic capacity.
Sec. 111. Sanitary transportation of food.
Sec. 112. Food allergy and anaphylaxis management.
Sec. 113. New dietary ingredients.
Sec. 114. Requirement for guidance relating to post harvest processing of raw oysters.
Sec. 115. Port shopping.
Sec. 116. Alcohol-related facilities.

TITLE II – IMPROVING CAPACITY TO DETECT AND RESPOND TO FOOD SAFETY PROBLEMS
Sec. 201. Targeting of inspection resources for domestic facilities, foreign facilities, and ports of entry; annual report.
Sec. 202. Laboratory accreditation for analyses of foods.
Sec. 203. Integrated consortium of laboratory networks.
Sec. 204. Enhancing tracking and tracing of food and recordkeeping.
Sec. 205. Surveillance.
Sec. 206. Mandatory recall authority.
Sec. 207. Administrative detention of food.
Sec. 208. Decontamination and disposal standards and plans.
Sec. 209. Improving the training of state, local, territorial, and tribal food safety officials.
Sec. 210. Enhancing food safety.
Sec. 211. Improving the reportable food registry.

TITLE III – IMPROVING THE SAFETY OF IMPORTED FOOD
Sec. 301. Foreign supplier verification program.
Sec. 302. Voluntary qualified importer program.
Sec. 303. Authority to require import certifications for food.
Sec. 304. Prior notice of imported food shipments.
Sec. 305. Building capacity of foreign governments with respect to food safety.
Sec. 306. Inspection of foreign food facilities.
Sec. 307. Accreditation of third-party auditors.
Sec. 308. Foreign offices of the Food and Drug Administration.
Sec. 309. Smuggled food.

TITLE IV – MISCELLANEOUS PROVISIONS
Sec. 401. Funding for food safety.
Sec. 402. Employee protections.
Sec. 403. Jurisdiction; authorities.
Sec. 404. Compliance with international agreements.
Sec. 405. Determination of budgetary effects.
consequences or death to humans or animals,” a registration can be “suspended” and food cannot be sold. Registration can be restored when the FDA is satisfied that the facility is back in compliance.

The FSMA provides for mandatory recalls without having hard evidence that the food is contaminated but instead, only that there is a “reasonable probability” that the food is contaminated. The mandatory HACCP-based food protection program requires that allergens and decomposition that could make a food unsafe be addressed in addition to the more conventional biological, chemical, and physical hazards. Relatively rigid record-keeping requirements are envisioned for high-risk foods. There are provisions in the FSMA for new rules on fresh keeping requirements are envisioned for high-risk foods. There are provisions for postproduction handling of oysters, allergens in foods served in schools, and anabolic steroid-containing dietary ingredients.

9 Along with politically motivated inclusions, somewhat unrelated, are provisions for postproduction handling of oysters, allergens in foods served in schools, and anabolic steroid-containing dietary ingredients.

inspected. Only registered facilities can sell food in the US. The registration stipulates that the FDA can inspect the facility. Registration is suspended if the FDA “determines that food manufactured, processed, packed, received, or held by a registered facility has a reasonable probability of causing serious adverse health consequences or death to humans or animals.”10 The company can request an informal hearing not later than 2 business days after suspension about the actions that it needs to take to have its registration reinstated and to propose a corrective action plan to correct conditions. Reinstatement is solely at the agency’s discretion.

SEC. 103. Hazard analysis and risk-based preventive controls. The individual in charge of a food facility that processes, packs, or holds foods must identify and implement preventive measures to “significantly minimize or prevent the occurrence” of certain hazards and also ensure that food is not adulterated or misbranded. This is an expansion of HACCP as it is currently implemented in the industry which addresses food safety hazards that are “reasonably likely to occur” and have the potential to cause serious injury or death, with preventive measures to eliminate the hazard or reduce it to an acceptable level.

Under the FSMA, a facility is now required to:

1. identify and evaluate known or reasonably foreseeable hazards that may be associated with the facility, including:
   a. biological, chemical, physical, and radiological hazards, natural toxins, pesticides, drug residues, decomposition, parasites, allergens, and unapproved food and color additives; and
   b. hazards that occur naturally, or may be unintentionally introduced; and

2. identify and evaluate hazards that may be intentionally introduced, including by acts of terrorism; and

3. develop a written analysis of the hazards.

Preventive controls include measures to significantly minimize or prevent the identified hazards and assure that the food is not adulterated or misbranded. These need to be monitored as part of a written plan, either as a critical control point or control point, if most appropriate, or as part of good manufacturing practices (GMPs) or as part of a sanitation program (SOP). If preventive controls fail, any affected food has to be segregated and not sold, and activities taken to correct the problem so that it is not likely to reoccur. The preventive measures have

10 A registration may be suspended if it created, caused, or was otherwise responsible for such reasonable probability; knew of, or had reason to know of such reasonable probability; and packed, received, or held such food.
to be verified to show that they are adequate to control the hazards identified, with recommendations for environmental and product testing programs. A written plan with monitoring and corrective actions is required. Facilities must conduct a new hazard analysis at least every 3 years or when there is a significant change in the operation of the facility, including type and sourcing of ingredients that could either introduce a new hazard or remove an old one. Records must be retained for 2 years for review by the FDA on either a written or oral request and include monitoring records, documentation of non-conformance critical to food safety along with corrective actions, verification activities including test results. Needless to say, care must be taken as part of this new HACCP-based program to ensure the completeness of records; equally critical is protection of intellectual property, specifically formulations and proprietary processes, so that these are not released to the agency without appropriate actions taken to protect confidential information.

SEC. 105. Standards for produce safety. Science-based minimum standards for the safe production and harvesting of raw fruits and vegetables to minimize the risk of serious adverse health consequences or death are being established with proposed rules for produce safety slated for 2014.

SEC. 106. Protection against intentional adulteration. The FDA will conduct a vulnerability assessment of the overall food system considering Department of Homeland Security biological, chemical, radiological, or other terrorism risk assessments to better understand the uncertainties, risks, costs, and benefits associated with guarding against intentional adulteration of food at vulnerable points, and determine the types of science-based mitigation strategies or measures that are necessary to protect against the intentional adulteration of food. A series of regulations were proposed in 2013 to protect against the intentional adulteration of food, specifying how a person shall assess such risks and implement mitigation strategies intended to protect against the intentional adulteration of food. These regulations would apply only to foods for which there is a high risk of intentional contamination, and could cause serious adverse health consequences or death to humans or animals and shall include those foods with clearly identified vulnerabilities such as a short shelf life or susceptibility to intentional contamination at critical control points, and are in bulk or batch form (such as milk), prior to being packaged for the final consumer. It is uncertain given the lack of technical information available whether the target date for these regulations is realistic.

SEC. 107. Authority to collect fees. The FDA will institute new fees for food facility reinspection (domestic and foreign), certain recall activities and import activities, such as the voluntary qualified importer program, and is authorized to recover the full cost including administrative fees associated with these activities. The total fee assessed will depend on the number of hours the FDA spends directly on the reinspection-related activities or food recall activities associated with a recall order.

SEC. 108. National agriculture and food defense strategy. Part of this program is for the agency to work with the private sector to develop business recovery plans to rapidly resume agriculture, food production, and international trade following a food safety disaster. This would involve conducting exercises of the plans with the goal of long-term recovery results; rapidly removing and effectively disposing of contaminated agriculture and food products, and infected plants and animals; and decontaminating and restoring areas affected by an agriculture or food emergency.

SEC. 111. Sanitary transportation of food. The FDA will conduct a study of food transportation systems, including air transport, and evaluate the unique needs of safe and sanitary food delivery to rural communities. Guidance will be provided on how to properly sanitize containers and vehicles used for food transportation to minimize cross-contamination.

SEC. 113. New dietary ingredients. This particular provision relates only to the safety of dietary ingredients and supplements containing anabolic steroids or their analogs.

SEC. 114. Requirement for guidance relating to postharvest processing of raw oysters. Certain individuals within the agency have targeted the consumption of raw molluscan shellfish for years, with the intent to ban sales. This provision reflects a compromise relating to postharvest processing for raw oysters and controls that could improve product safety. It applies to both domestic and foreign producers. Depuration (purification) is likely the most appropriate control and is not excluded in the text of the statute.

SEC. 115. Port shopping. Port shopping is when an importer attempts to select a port that will provide less scrutiny to incoming shipments. Prior notice provisions will make port shopping more difficult, and with this provision will provide notice to other ports that a certain shipment has been denied entry so that it will not be admitted at another location.
SEC. 201. Targeting of inspection resources for domestic facilities, foreign facilities, and ports of entry; annual report. The emphasis of inspections will be upon high-risk facilities and products based upon the following factors.

1. Known safety risks of the food.
2. Compliance history of a facility including recalls, food-borne illness outbreaks, and food safety violations.
3. Rigor and effectiveness of the facility’s hazard analysis and preventive controls plan.
4. For imports, these additional criteria apply: known risks with the imported food, known food safety risks of the country or regions of origin and countries through which the food may be transported, compliance history of the importer, rigor of the importer’s food safety program including compliance with the foreign supplier verification program and their participation in the voluntary qualified importer program, current physical inspection rate, number of line items for the food imported, and FDA experience in the exporting country.

Domestic facilities will be inspected at least every 5 years initially and every 3 years thereafter, and for lower risk foods, not less than every 7 years initially and every 5 years thereafter. Inspection of foreign facilities will increase from 600 during the first year (2012) to more than 19,000 by 2018. Reliance will be placed upon state and local inspectors and those of foreign governments and third parties since the FDA will not have the resources to conduct this task. How the FDA will coordinate these activities to assure consistency is not clear at this time.

SEC. 202. Laboratory accreditation for analyses of foods. By 2015, any laboratory testing that is to be conducted with regard to a food safety investigation will have to be conducted in an “accredited laboratory” approved by an “accrediting body.” This expensive and tedious process, applicable not just to the laboratory but for any sampling program and analytical testing protocol conducted within it, will substantially increase the cost of laboratory testing and may place it out of reach of many small businesses. The process will not necessarily increase the reliability of the testing, just its expense, and will undermine the ability to establish in-house laboratories within small and medium-sized food businesses because of the accreditation expense. The FDA would establish a registry of accreditation bodies that will determine if a laboratory has “demonstrated capability to conduct one or more sampling and analytical testing methodologies for food.” Foreign laboratories would also require accreditation and will be required to meet the same standards as domestic laboratories. The FDA “shall develop model standards that a laboratory shall meet to be accredited by a recognized accreditation body for a specified sampling or analytical testing methodology and included in the registry” and will review accreditation bodies every 5 years.

SEC. 204. Enhancing tracking and tracing of food and record keeping. The requirement for one-step-forward one-step-back traceability remains a technical challenge. In response to this requirement the FDA will be spearheading a pilot project “in co-ordination with the food industry to explore and evaluate methods to rapidly and effectively identify recipients of food to prevent or mitigate a food-borne illness outbreak and to address credible threats of serious adverse health consequences or death to humans or animals as a result of such food being adulterated or misbranded,” with studies on the processed food sector, raw fruits and vegetables, foods that have been the subject of significant outbreaks in the past 5 years and a diversity of other foods, including imports. The objectives are to build a tracking system that the agency can effectively implement and to develop and demonstrate methods and appropriate technologies for rapid and effective tracking of foods that is practicable for facilities of varying sizes, including small businesses.

SEC. 206. Mandatory recall authority. The FDA has mandatory recall authority, although many question whether this provision is necessary for domestic food producers, and consider the checks upon agency action through involvement of the individual states or the Justice Department to have been perfectly adequate to ensure that the US food supply remains safe. It is rare for a company not to initiate a food recall voluntarily once it is put on notice that its food may pose a risk to consumers.

A company may be notified of a “reasonable probability” that its food is adulterated or misbranded from an
SEC. 207. Administrative detention of food. The FDA may order the detention of any article of food that is found during an inspection, examination, or investigation in a secure facility if it has reason to believe that the article of food is adulterated or misbranded. This was written into the Act to ensure that rejected product from other countries did not enter into the US. Food that is regulated exclusively by the USDA under the Federal Meat Inspection Act, the Poultry Products Inspection Act, or the Egg Products Inspection Act is not subject to administrative detention. All other food is subject to this regulation, when it enters interstate commerce. Import detention applies to food offered for import into the US and that may be subject to refusal of admission. Perishable food can be detained for 7 days with recommendations to the Department of Justice for seizure within 4 days and other food, 20 days. Detention can be appealed. Administrative detention is likely to be less costly to the agency than other enforcement actions. The cost to the private sector is another matter, and the fact that 65% of seizure actions are challenged and half of these reversed indicates that the process is far from foolproof.

SEC. 208. Decontamination and disposal standards and plans. The EPA, in co-ordination with Health and Human Services, Homeland Security, and the Department of Agriculture, shall provide support and technical assistance to state, local, and tribal governments to prepare for, assess, decontaminate, and recover from an agriculture or food emergency. This will involve conducting annual exercises and the development of specific standards and protocols and model plans to clean up, clear, and conduct recovery activities following decontamination of people, equipment and facilities, and disposal of specific threat agents and foreign animal diseases, and disposal of contaminated animals and crops.

SEC. 211. Reportable Food Registry. Retail food stores are required to provide a means for notifying customers at the register and at other prominent locations in the store providing targeted recall information for consumers.

SEC. 301. Foreign supplier verification program. Importers are now required to perform risk-based foreign supplier verification activities to show that their foods are neither adulterated nor misbranded. This requires verification that the processors they represent have appropriate risk-based preventive controls in place and that imported foods are as safe as those produced in the US. Verification activities may include monitoring records for shipments, lot-by-lot certification of compliance, annual on-site inspections, checking the hazard analysis and risk-based preventive control plan of the foreign supplier, and periodically testing and sampling shipments. Importer records must be held for 2 years.

SEC. 302. Voluntary qualified importer program. The Voluntary Qualified Importer Program provides importers with expedited entry of food into the US if certain provisions are met. An importer must request participation and may be accepted to participate for a 3-year period, subject to renewal. Various factors are considered.

1. The known safety risks of the food to be imported.
2. The compliance history of foreign suppliers used by the importer, as appropriate.
3. The capability of the regulatory system of the country of export to ensure compliance with United States food safety standards for a designated food.
4. The compliance of the importer with the other requirements (section 805).
5. The record keeping, testing, inspections and audits of facilities, traceability of articles of food, temperature controls, and sourcing practices of the importer.
6. The potential risk for intentional adulteration of the food.
7. Any other factor that the Secretary determines appropriate.

SEC. 303. Authority to require import certifications for food. Imported food must be accompanied by a certificate or other assurance that the food meets applicable requirements of the FSMA in the form of shipment-specific certificates, a listing of certified facilities that manufacture, process, pack, or hold such food, or in some other manner. Certification requirements track the criteria listed above in SEC. 302. An agency or a representative of the government of the country from which the article of food at issue originated could issue a certificate as could other entities recognized by the FDA as reliable certifiers. If the FDA determines that the food safety programs, systems, and standards in a foreign region, country, or territory are inadequate to ensure that an article of food is as safe as a similar article of food that is manufactured, processed, packed, or held in the US, it shall identify such inadequacies and establish a process by which the foreign region, country, or territory may inform the Secretary of improvements made to the food safety program, system, or standard and demonstrate that those controls are adequate to ensure that an article of food is safe.

SEC. 304. Prior notice of imported food shipments. Prior notice provides the FDA with the opportunity to schedule inspections of food before it arrives in port. These must be submitted electronically. Much detailed information is required on these notices; for example, there is a requirement to identify each article of food in a shipment, not just to provide a general description of the cargo. Failure to comply with prior notice provisions, including reporting the name of any country to which food or animal feed within the shipment has been denied entry, could lead to bars to further shipments.

SEC. 305. Inspection of foreign food facilities. The FDA intends to enter into agreements with foreign governments to facilitate their inspection of registered foreign facilities, directing resources to high-risk foods. Food will be “refused admission into the United States if it is from a foreign factory, warehouse, or other establishment of which the owner, operator, or agent in charge, or the government of the foreign country, refuses to permit entry of United States inspectors or other individuals duly designated by the Secretary, upon request, to inspect such factory, warehouse, or other establishment.”

SEC. 306. Accreditation of third-party auditors. The FDA is developing a process for accreditation of third-party food safety auditors (audit agents) because they lack the resources to conduct the mandated inspections. An “audit agent” is an individual who is an employee or agent of an accredited third-party auditor and, although not individually accredited, qualified to conduct food safety audits on behalf of an accredited third-party auditor. This auditor is required to be recognized by an “accreditation body” which is an authority that performs accreditation of third-party auditors and will most likely be an agency of a foreign government. A third-party auditor may be a single individual or an employer of others who would conduct audits to determine if a firm is in compliance with the FSMA and applicable industry standards (a consultative audit) or if a food can be certified for export (regulatory audit) if the firm is in compliance with the provisions of this Act, and the results of which determine whether food manufactured, processed, packed, or held the entity is eligible to receive a food certification.

SEC. 307. Accreditation of third-party auditors. This auditor is required to be recognized by an “accreditation body” which is an authority that performs accreditation of third-party auditors and will most likely be an agency of a foreign government. A third-party auditor may be a single individual or an employer of others who would conduct audits to determine if a firm is in compliance with the FSMA and applicable industry standards (a consultative audit) or if a food can be certified for export (regulatory audit) if the firm is in compliance with the provisions of this Act, and the results of which determine whether food manufactured, processed, packed, or held the entity is eligible to receive a food certification.

SEC. 308. Foreign offices of the Food and Drug Administration. The FDA is intent upon establishing foreign offices to provide assistance to the appropriate governmental entities to improve the safety of exported food, including directly conducting risk-based inspections of foreign food facilities and supporting foreign government inspection programs.

SEC. 402. Employee protections. Companies that produce, distribute, transport or sell food may not discharge an employee or otherwise discriminate against an employee with respect to compensation, terms, conditions, or privileges of employment because the employee, whether at the employee’s initiative or in the ordinary course of employment:

1. provided, caused to be provided, or is about to provide or cause to be provided to the employer, the Federal Government, or the attorney general of a State information relating to any violation of, or any act or omission the employee reasonably believes to be a violation of any provision of this Act;
2. testified or is about to testify in a proceeding concerning such violation;
3. assisted or participated or is about to assist or participate in such a proceeding; or
4. objected to, or refused to participate in, any activity, policy, practice, or assigned task that the employee (or other such person) reasonably believed to be in violation of any provision of this Act. A person who believes that he or she has been discharged or otherwise discriminated against may file a complaint with the Secretary of Labor alleging unfair discharge or discrimination and identifying the person responsible and an investigation will ensue with a finding in 60 days and a final order in 120 days.
An employer must show by clear and convincing evidence that it would have otherwise taken the same unfavorable personnel action against the employee. If the finding is in favor of the employee, relief necessary to make the employee whole can be granted, including injunctive relief and compensatory damages, including: reinstatement with the same seniority status that the employee would have had, but for the discharge or discrimination; the amount of back pay, with interest; and compensation for any special damages sustained as a result of the discharge or discrimination, including litigation costs, expert witness fees, and reasonable attorney’s fees. In contrast, sanctions for a bad faith claim are reasonable attorneys’ fee, not exceeding $1000, to be paid by the complainant. The final order is not subject to judicial review.

12.8 Summary

The food regulatory environment, with its safety, record-keeping and labeling requirements, is becoming increasingly complicated and increasingly global. The international market impact of potential new products must be considered now more than ever, before the development cycle begins. Managing a global supply chain and the associated regulatory requirements are issues that had limited impact on food technologists a few years ago but which now play a major role in their professional lives. Having an understanding of the Food Safety Modernization Act and examples of some of the common labeling requirements and agricultural marketing programs as outlined here should provide a basis upon which to build a stronger understanding of the basic legal requirements surrounding the manufacture and sale of foods. Most nations are moving to science-based risk assessment, coupled with HACCP-based preventive controls for food safety, with varying degrees of rigidity regarding monitoring, records, and testing.

References

Citations are included in the body of the text. The other documents listed here are general references besides statutes and regulations.


