Chapter 19
Government Regulatory

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Government regulation of food products, food processing, and food preparation is imperative in bringing an unadulterated, non-misleading, and safe food product to market and is relevant to all areas of food science, including engineering, processing, chemistry, and microbiology. The liability associated with providing consumers with an adulterated or substandard product cannot only tarnish a company's name and reputation but also impose substantial financial repercussions on the company and those individuals who play an active role in the violation. In order for a company to fully comply with the relevant food laws (both federal and state), an intimate knowledge of food science is required. Individuals knowledgeable in food science play an integral role not only in implementing and counseling food companies/processors to ensure compliance with government regulations, but these individuals are also necessary to the state and federal governments that make and enforce the relevant laws and regulators. For these reasons and more, to be further explained below, government regulation of food protection and processing presents many diverse career options for a food scientist.

Federal Regulations

Food regulatory law encompasses many areas of study including food science, business, and law. The primary reasons for enacting food laws include prevention of foodborne illness and preventing consumers from receiving

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illegitimate or adulterated products. The two main government agencies that regulate foods are the Food and Drug Administration (FDA) and the United States Department of Agriculture (USDA). The FDA is responsible for enacting and enforcing laws including, but not limited to, the labeling of foods, setting standards of identity for food products, and approving and regulating food additives and GRAS (generally recognized as safe) substances. The FDA also enforces and regulates its laws in the following areas: misleading products, mislabeling of products, the contents of a food label, and nutrition facts and claims (i.e., health claims, nutrition claims, and qualified health claims). The two major roles the FDA plays are to administer inspections of food plants (and thereby protect the health of the public) and to test and set standards for products. Furthermore, the counterpart of the FDA, the USDA, concentrates its regulatory efforts on compliance in the meat and poultry industry.

With innovation at its height, as many new ingredients, additives, and new technologies (e.g., implementing nanoscience into foods and food processing) are being developed daily, food regulatory requirements are at elevated levels of importance. Labeling issues, evaluation of GRAS status for packaging components and food ingredients, developing and implementing FDA compliance procedures, and implementing responses to government inspections (i.e., recalls) are taking a front seat following threats of bioterrorism in the food supply, highly publicized and nationalized foodborne disease outbreaks, and new food products and ingredients being developed at rapid-fire pace.

One technology in particular, application of nanotechnology in foods, will pose many challenges for the FDA and will require the knowledge and expertise of food scientists to assist the government in regulating this emerging technology. In particular, areas of interest in food nanotechnology include: nanoparticles in edible coatings and barriers, preservatives, antimicrobials, and mineral supplements. With the possibility and probability of applying nanoscience in food packaging and processing and ingredient technology, interest in this emerging technology is especially prevalent to food companies and is also resulting in increased private funding in this area. In order for food nanotechnology to be approved, accepted, and implemented into food-related applications, the involvement of food scientists in obtaining the requisite government approval is necessary.

The most prominent statute enacted and enforced by the FDA is the Food, Drug and Cosmetics Act (FDCA). The FDCA is a strict liability statute which imposes criminal penalties, seizures, and injunctions on individuals or corporations who violate the Act. Products also may be recalled either voluntarily (by the company) or by an order from the judge (court order).

In addition to lawmakers, attorneys, and lobbyists, scientists also play a pivotal role in the government/regulatory realm. Job opportunities for food scientists in the government/regulatory arena incorporate many facets of the field of food science and include, but are not limited to:

- Food analysis (studying the biological effects of various agents commonly found in foods, such as additives or contaminants)
- Food chemistry (conducting research projects that study the effects of food components and dietary supplements on utilizing essential and toxic minerals in the diet)
- Food process engineering (presenting reviews, conclusions, opinions, and recommendations to appropriate scientific review panel on premarket approval applications, product development protocols, and petitions for reclassification)
- Food microbiology (conducting research on the development of media and procedures for isolating and identifying pathogens from foods and on the definition of the kinetics of growth, survival, or destruction of foodborne pathogens under the environmental conditions occurring during food processing and storage)

Even though the FDA is headquartered in Washington, DC, it has district offices scattered throughout the nation, including Chicago, Dallas, Baltimore, and Minneapolis.

If an individual is interested in not only the laws themselves but the science behind the laws, a career in food regulation will likely be a suitable fit. Analyzing, interpreting, and implementing laws is also crucial in the food regulatory arena. Therefore, if an individual is interested in food science (processing, engineering, chemistry, microbiology, etc.) but would like to use their food science knowledge in contributing to and/or analyzing and implementing food laws and explore a career outside of the well-recognized food science careers (i.e., research and development and quality control/assurance), the career and internship opportunities in food regulation should be considered.

As mentioned previously, the USDA regulates meat and poultry products and processing. Opportunities for food scientists in the USDA include: meat and poultry plant inspectors, food microbiologists, and the like. Similar to the FDA, the USDA also creates and enforces laws and regulations in the meat and poultry industry, with respect to labeling, packaging materials, additives (traditional additives in addition to radiation used to reduce microorganisms in meat and poultry products), and allergens, in addition to performing safety inspections of facilities. Inspectors for the USDA must be knowledgeable in food science applications such as food processing,

engineering, and microbiology to ensure that meat and poultry facilities are functioning in conjunction with the standards set forth by the USDA.

Although the USDA is best known for its regulation of meat and poultry products and processing, it has carved out a niche for its technology and intellectual property management (e.g., patenting new and emerging technologies in the meat and poultry industry). The USDA partners with commercial firms to transfer its technology to American farmers, businesses, and consumers. The USDA offers private sector businesses, state and local governments, and universities the opportunity to license federally owned inventions. In the words of the USDA, these partnerships are designed to "expedite research results to the private sector, exchange information and knowledge, stimulate new business and economic development, enhance trade, preserve the environment, and improve the quality of life for all Americans." Some patent applications and issued patents available for licensing through the USDA are as follows: "Sweet-N-Up" A New Distinct Peach Variety; Gene That Extends Fruit Shelf Life; New Technique to Eliminate Bitter Compounds in Potatoes; and New Edible Food Coatings. The USDA is also responsible for the National Organic Program and Organic Foods Production Act, for certifying foods as organic, "to assure consumers that the organic foods they purchase are produced, processed, and certified to be consistent with national organic standards."

Many subsections and specialties exist within the umbrella of food law. For example, some practitioners specialize in packaging law, compliance, GRAS approval petitions, and litigation surrounding violations and/or foodborne disease outbreaks. Packaging law relates to the regulation surrounding both the packaging and labeling of food products in conformity with FDA regulations, whereas compliance refers to counseling food manufacturers and processors to ensure compliance with the relevant foods laws. .Additionally, GRAS approval petitions require not only legal counseling but also counseling by a food scientist in order to perform the relevant testing and research and opine as to the safety of a substance in a food product in order to obtain government approval for using the substance in a food product. The knowledge and experience of a food scientist, in litigation surrounding violations and/or foodborne disease outbreaks, is also necessary, as food scientists are used as expert witnesses and are needed to build both sides of the case.

State Regulation

The states also play an important role in regulating food products and the food industry. For example, in Wisconsin, the two enforcement bodies of the state government are the Department of Health and Human Services along

with the Department of Agriculture, Trade, and Consumer Protection. It should be noted that the state laws that regulate in the same area as federal laws cannot be more lenient than the existing federal law; however, they may impose stricter guidelines. Additionally, states have embargo type power which allows them to halt a product's movement in interstate commerce; however, the FDA doesn't have the power to go into a food plant and seize/embargo it. Yet, the FDA can take action against anyone in the chain of the product's movement, including production, distribution, and retail.

In recent years, there has been a push on the part of the FDA to streamline states' regulations. As stated in the September 2007 issue of the *Journal of Food Technology*, in order to achieve consistency throughout the states, the FDA is urging states to adopt the Manufactured Food Regulatory Program Standards "for measuring and improving the performance of state programs for regulating manufactured food and help the state and federal authorities reduce foodborne illness hazards in food facilities." These Standards define best practices for the critical elements of state regulatory programs and include: staff training, inspection, quality assurance, incident investigation, enforcement, etc.

In addition to federal and state regulations, if products are marketed abroad, they are also subject to international regulations. International regulatory groups include the Food and Agriculture Organization and the Codex Alimentarius Commission.

My Experiences

Due to the variety of disciplines encompassed in food regulation, this career path sparked my interest. As an undergraduate majoring in food science, I was particularly interested in the laws surrounding the processing, distribution, and sale of food products. Following graduation with a BS in food science, I interviewed with and obtained an internship through the Wisconsin Department of Health and Family Services (DHFS) in the Food Safety and Recreational Licensing Division.

During my time at DHFS, I evaluated the efficacy of the Wisconsin Food Manager Certification Program, a program included in the Wisconsin Food Code and enforced by DHFS. This program requires that at least one certified food manager is employed in the particular eating establishment and is based on the establishment's size and/or type of food being served. This research was supported by a grant from the Centers for Disease Control (CDC).

In evaluating the Wisconsin program, I met with interested parties, such as the Wisconsin Restaurant Association to obtain their feedback and

opinions on the program. Additionally, I researched and contacted other states with certification programs and attempted to correlate the type of certification program implemented to the number of instances of foodborne illness complaints in that state during a specified period. I also met with representatives from the Department of Agriculture, Trade, and Consumer Protection (DATCP) and the Environmental Protection Division of DHFS regarding the Food Manager Certification Program. An additional duty of my position entailed digitizing a database including policies passed by the Division.

In addition to internships with state regulatory agencies, an undergraduate can gain experience in the governmental regulatory arena by taking food law courses and interning with a food manufacturer or processor. Internships with the FDA and USDA (in both the national headquarters and district offices) are also ways for an undergraduate to gain invaluable experience in this field.

After working at DHFS for a year, I attended law school, planning to specialize in food law and/or intellectual property law (in food science and the chemical arts). During my undergraduate studies, I took a food law course which sparked my interest in the regulatory arena of food law and also took a food and drug law course during law school. However, although many law schools do not offer extensive food and drug law electives, the food-related agencies, such as the FDA, are discussed in a variety of courses offered by law schools, such as legislative process and administrative law. Food science-related issues are raised in many intellectual property law classes, such as trademark law, trade secret law, and patent law.

During law school, I clerked at one of the largest food and beverage corporations. In clerking for this corporation, I experienced firsthand how the FDA regulations governed many aspects of the legal department and the corporation as a whole. Any food corporation needs to keep abreast of any labeling laws and all other pertinent regulations, to ensure compliance with these laws. The federal laws that are most integral to most food corporations include labeling, including ingredient labels and claims, in addition to standards of identity, certifications, and the like.

While in law school, I found that my food science background was an invaluable asset to my legal education. The technical writing required in many of my food science courses helped me to seamlessly transition into legal writing. In addition, the time spent researching in preparation to write technical papers and perform experiments and independent study projects also proved advantageous in helping me excel at legal research. Additionally, a technical science background, such as food science, is required in order to sit for the patent examination to practice before the United States Patent and Trademark Office.

Summary

Many diverse and exciting opportunities are available for food scientists in the government regulatory arena. Opportunities arise not only in the federal government but also in state governments and private food companies. The federal and state governments conduct the research behind, implement, and enforce the laws, whereas an industry must ensure its compliance with these laws. Whether your interest lies in bacteriology, chemistry, engineering, processing, etc., the state and federal governments in addition to private food companies provide a wide and interesting array of career options for the food scientists.

Katie Becker joined the food science program at UW–Madison in 1999 due to her interest in food technology and laws and regulations pertinent to the food industry. While at UW–Madison, she worked as a lab assistant in a food safety research lab on campus, joined the Food Science Club and the Badger Student Fan Club, and was a member of the UW–Madison fishing team. After graduating in 2003, Katie spent a year with the State of Wisconsin Health and Family Services Department working on food safety compliance programs. She then attended law school and has worked as a private practitioner at an intellectual property law firm in Chicago, Illinois, since graduating from law school. Her practice focuses on patent procurement and enforcement, representing clients ranging from start-ups to Fortune 50 corporations. While she finds all of her work exciting, she has a soft spot for representing clients and innovations in the food technology space.