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New Food Safety Law: Effectiveness on the Ground

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New Food Safety Law: Effectiveness on the Ground

FINAL

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Abstract

The demand for safety in the U.S. food supply from production to consumption necessitates a scientific, risk-based strategy for the management of microbiological, chemical, and physical hazards in food. The key to successful management is an increase in systematic collaboration and communication and in enforceable procedures with all domestic and international stakeholders. The enactment of the Food Safety Modernization Act aims to prevent or reduce large-scale food borne illness outbreaks through stricter facility registration and records standards, mandatory prevention-based controls, increased facility inspections in the United States and internationally, mandatory recall authority, import controls, and increased consumer communication. The bill provisions are expected to cost $1.4 billion over the next four years. Effective implementation of the Food Safety Modernization Act's fifty rules, reports, studies, and guidance documents in addition to an increased inspection burden requires further funding

appropriations. Additional full-time inspectors and unprecedented foreign compliance is necessary for the full and effective implementation of the Food Safety Modernization Act.

Keywords Food Safety Modernization Act, FSMA, Food and Drug Administration, FDA HACCP, risk

Introduction

In the United States, total food expenditures in 2009 were $1,182 billion with 48.6 percent spent on food away from home and the remaining 51.4 percent spent on food for home (USDA, 2011). Food safety is fundamentally a public health concern that at times causes significant human suffering and economic loss (WHO and FAO, 2006). Growing concern about the safety of the U.S. food supply unites members of the five primary stakeholder groups: consumer population; government regulatory agencies; private industry; academia and research institutions; and inter-governmental organizations (Institute of Medicine, 2009). The Center for Disease Control and Prevention estimates that one in six people in the United States- 48 million people- contract a food borne illness each year at an annual total cost of $152 billion (CDC, 2011; Scharff, 2010). It is estimated that food transmits more then 200 diseases (Bryant, 1982). Disease decreases the public's trust in the food supply and diminishes the credibility of the government regulatory agencies. The *Salmonella* outbreak traced to peanuts from the Peanut

Corporation of American in 2009 ultimately cost that company their business and decreased peanut butter sales by 25 percent across the industry (Wall Street Journal, 2009). The Food and Drug Administration, responsible for the oversight of 80 percent of the food supply yet operating with limited resources and authority, is the historic and modern focal point for accountability (Becker, 2010; GAO, 2009). One-third of adult Americans (31 percent) surveyed view food safety as a shared responsibility among five or more stakeholder groups including farmers/producers, retailers, and themselves (IFIC Foundation, 2010).

Questions about who is responsible for the safety of the food system and whether it is possible to have a completely safe food supply remain at the heart of the dialogue regarding the U.S. food supply. The recognition that no single company or country is entirely responsible for the food system presents a significant challenge and raises questions about what sector or area can most effectively address the need for food safety (IOM, 2009). In a 2009 White House Address, President Barack Obama stated, “There are certain things only a government can do. And one of those things is ensuring the foods we eat are safe and do not cause us harm” (Obama, 2009). The belief that the U.S. government can and will control risk in the food supply has been predominant since the inception of the Food and Drug Administration in 1906. Regulation and inspection have been the foundation of the food safety approach in the United States since the early twentieth century (Williams et al, 2010). Subsequently, significant changes to food production through expansion and increased complexity of distribution facilities and the enhanced tracking of food borne illness to its origin have dramatically shifted the food landscape in the U.S. (Williams et al, 2010). The FDA is responsible for the oversight of an estimated 167,033 active registered domestic food facilities plus an additional 254,088 active registered

foreign facilities (FDA, April 6, 2011). Diversification of the American food supply, driven by consumer demand for more diet variety and increased access to healthful products, now drives a $78 billion import market with foods arriving from more than 150 countries (Brooks et al, 2009; Wolters Kluwer Law & Business, 2011). Despite significant developments in risk analysis and performance standards, international standards still do not exist for all aspects of the food supply and data recording is often sporadic. Making informed comparisons or empirical commentary on the effect of changes in regulation is therefore difficult.

This paper focuses on the U.S. historical and modern food safety climate and approaches and on the 2010 enactment of the Food Safety Modernization Act (FSMA), the first major bill purported to enhance food safety since the 1938 Federal Food, Drug, and Cosmetic Act. The historic passage of this legislation is evidence of both the current need and complexity of policy-making. Key industry leaders and consumer groups collaborated to unite food manufacturers and food safety advocates in persuading U.S. policymakers to enact FSMA. The requisite leadership support, internal capacity, and external constituency all came into satisfactory alignment, gaining bipartisan support for a final affirmative vote of 215-144. On January 4, 2011 President Barack Obama signed the Food Safety Modernization Act making it Public Law 111-353. The bill's projected effectiveness is assessed through examination of its provisions as well as expected costs and available resources.

Food Safety in the United States (Background)

The Food and Drug Administration was largely established in response to public pressure regarding increased reports of food adulteration, poor

sanitary conditions, and food related illness and death. American consumers continue to demand resources and effective structural organization to protect them from hazards. Recent research indicates increased concern and disapproval. According to the 2010 Food & Healthy Survey from the International Food Information Council Foundation, 47% of the 1,024 Americans surveyed expressed confidence in the U.S. food supply (IFIC Foundation, 2010). When these Americans were asked who they believe is responsible for food safety in the U.S they cited the following stakeholders: government (74%); food industry (70%); famers/producers (56%); retailers/food service (49%); and consumers/individuals (41%) (IFIC Foundation, 2010). Sixty-five percent of the 1,102 American consumers surveyed by Deloitte, an independent research company, via the online 2010 Food Safety Survey, expressed concern about the quality of the food they eat, a 17 percent increase from 2008 (Deloitte, 2010). This American population felt the following food system stakeholders were responsible for communicating food hazards and recall information: manufactures/food companies (75%); government organizations such as the Food and Drug Administration (73%); and then retailers (53%); and media (51%) (Deloitte, 2010). These surveys both indicate that Americans consumers believe that the

U.S. government and the food manufactures and companies hold primary responsibility for a "safe" food supply. In contrast, in the United Kingdom (UK), a 2010 UK Food Standards Agency consumer tracker survey indicated that only 29 percent of the 2015 respondents were concerned about food poisoning and 62 percent of respondents trust the Agency to do its job (Food Standards Agency, November 2010). American consumers' growing concern about food safety is largely rooted in the vast media coverage given to the increasing number of food recalls initiated by the FDA and the increased ability of CDC to track the prevalence of food borne illness.

Food Borne Disease Prevalence

Of the estimated 48 million food borne disease cases annually, about 128,000 of the people are hospitalized and 3,000 die (CDC, 2011). The CDC strives to identify which of the 31 known food borne virus, bacteria, or microbes ("pathogens") are causing the most illnesses and how many cases do not have a known cause or an "unspecified agent" (CDC, 2011). *Salmonella* is the leading pathogen known to cause hospitalization and death from food borne illness (CDC, 2011). However, it is not the only contributing factor and the extent of food borne illness is becoming an increasing worrisome fact for populations throughout the food system. Overall only 20 percent of the cases have an identifiable cause with eight pathogens primarily contributing to food borne illness, hospitalization, or death (CDC, 2011). The other 80 percent of the "unspecified agents" are unidentifiable and therefore cannot be tracked, further complicating measures for prevention and elimination (CDC, 2011).

Robert Scharff, a former economist with the FDA, estimated the economic impact of food-related illness is a cost of $152 billion to the United States each year (Scharff, 2010). Despite the prevalence of food borne illness and the high cost per case, the CDC does not currently track the age and health status of the individuals who develop confirmed cases of food borne illness. One can assume that members of vulnerable population such as elderly and pregnant women may be more susceptible to the food-related illnesses however data is lacking. The scientific rigor of the CDC methodology used to collect and collate evidence from an estimated ten different surveillance systems and to then infer estimates of illnesses, hospitalizations, and deaths are questionable (World Apple Report, February 2011). While there are limitations and gaps in data, despite ongoing scientific advancements, at times the translation of scientific results and systems into government activity can also be deficient.

Improvements and expansions to food supply surveillance systems are prompting an increase in reported outbreaks. According to Williams et al, the Centers for Disease Control and Prevention's (CDC) two primary surveillance systems, Food-Net and PulseNet, enable the better identification of individual and smaller outbreak cases, which all contributes to an increase in the amount of reports (Williams et al, 2010) and better tracking of outbreaks and causality. In addition, the increased availability of information on the Internet and via greater media coverage highlights food safety concerns at an amplified rate (Williams et al, 2010). However, a nationally representative survey of over 2,000 American adults revealed that only one-fifth "were aware of having purchased food, medication, or a product (other than a car) that was recalled in the past three years" and that "they are not confident that they are getting adequate information delivered to them" (Consumers Union, 2010). These presence of food borne illness and death, hazard such

as pesticides and other substances in food and the limited efficacy of food recalls are shared concerns of the American public and government officials.

In December 2010, FDA Commissioner Margaret A. Hamburg, M.D. spoke in support of the passage of new food safety legislation stating that "Food borne illnesses and deaths are preventable, and as such, are unacceptable. We must, and can, do better by intensifying our efforts to implement measures that are prevention-oriented and science-based " (Hamburg, 2011). The sentiment of Hamburg's message resonated with many proponents of the FSMA who became unlikely partners in legislative advocacy efforts. Realizing a safe food supply is a complex challenge that requires extensive, transparent, and consistent collaboration between all food system stakeholders. The safety of the U.S. food supply relies heavily on industry self-regulation "At one level, an industry and its regulation agency are adversaries…at another level, though, regulators and the regulated always have a symbiotic relationship. They depend on each other" (Stone, 2002). Food safety is often the number one priority for food producers such as the American Frozen Food Institute (AFFI, 2011). Limited FDA resources are insufficient to monitor all of the active registered domestic and foreign facilities, totaling 421,121, on a regular basis (FDA, April 6, 2011). Additionally, industry science and innovation are responsible for the development of many, if not most, of the microbial test methods and notably for the peanut aflatoxin detection and decontamination controls (Whitaker et al, 2004). Industry-funded research to address issues such as *e. coli* and *Salmonella* has led to most of the current food safely knowledge and technologies. According to former USDA Under Secretary for Food Safety Elsa Murano, "We (United States) are the model for the whole world and I think it's the leadership displayed by the industry that has gotten us to this point" (Murano, unknown).

Extensive and multi-sectoral collaboration underpins the overall safety of the U.S. food supply. However, strict regulation is still necessary. The history of U.S. food safety and the regulatory environment and system operating prior to the enactment of the Food Safety Modernization Act provide relevant context for understanding its provisions and potential effectiveness.

History of the U.S. Food Safety and Regulatory Environment

On June 30, 1906 United States President Theodore Roosevelt signed the Pure Food and Drugs Act and charged the Bureau of Chemistry, under Harvey W. Wiley, MD, with its administration. This statute and bureau later became the Food and Drug Administration (FDA). The FDA became one of the earliest, and arguable most powerful federal regulatory agencies, established "to prohibit interstate commerce of adulterated foods" (Borchers et al, 2007). In the past 100 years the scope of the FDA's responsibilities has increased. Today the Food and Drug Administration is part of the U.S. Department of Health and Human Services and is charged with providing oversight for "protecting the public health by assuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, our nation's food supply, cosmetics, and products that emit radiation. The FDA is also responsible for advancing the public health by helping to speed innovations that make medicines and foods more effective, safer, and more affordable; and by helping the public get the accurate, science-based information they need to use medicines and foods to improve their health (U.S. Department of Health and Human Services, 2011). The FDA has responsibility for about 80 percent of all the food

consumed in the U.S., including seafood, dairy and produce with a budget of $649 million (Becker, 2010).

> "Source for the food supply proportions is GAO, "Revamping Oversight of Food Safety," urgent issues prepared for the 2009 Congressional and Presidential Transition, accessed December 2008 at http://www.gao.gov/transition_2009/urgent/food-safety.php. GAO here does not provide a basis for its calculations, although they appear to represent proportions of total spending for food consumed at home. Examined another way, meat and poultry could account for as little as 10% of U.S. per capita food consumption, according to data maintained by USDA's Economic Research Service (ERS); these per capita data adjust food availability for spoilage, plate waste, and other losses. Source: ERS Food Availability (Per Capita) Data System, accessed December 29, 2008, at http://www.ers.usda.gov/data/foodconsumption/." (Becker, 2010)

In 1906 Roosevelt's legislative initiative came in response to growing publicity about the conditions for and products of the commercial food supply and the public's growing outrage. Harvey W. Wiley's 1887 publication, "Foods and Food Adulterants" further documented practices of flour containing plaster of paris or chalk and chocolate that contained pieces of soap and beans as well as red oxide of mercury for coloration (Hilts, 2003). His famed "Poison Squad" conducted extensive human experiments with the chemical preservatives in food, previously thought to be harmless (Hilts, 2003). The outcomes of these studies, although lacking integrity by modern standards, were the first introduction of science in policy making (Borchers et al, 2007). Wiley's commitment to food safety included writing poems and songs that rose to popularity through the media. Additionally, Upton Sinclair's prominent and historic book, *The*

Jungle, exposed the nature and extent of adulteration of meat in Chicago in 1906. It was in this environment that nearly 100 food and drug bills were both introduced and rejected by Congress during the years of 1879 through 1905 (Borchers et al, 2007). When Roosevelt signed the 1906 Pure Food and Drugs Act, and the Meat Inspection Act on the same day, he enacted the federal government's responsibility of consumer protection.

A shared belief in the government's responsibility to protect food and medicine is not the only commonality between President Roosevelt and President Obama and their respective years in office. The specificity of food and drug regulation and the funds for adequate enforcement were dubious both then and now. The 1906 Pure Food & Drug Act deemed it unlawful to manufacture adulterated foods or drugs, prohibited interstate commerce of adulterated goods, introduced inspections of imported goods and the chemical composition of goods by the Bureau of Chemistry (now FDA), prohibited false or misleading branding of foods and drugs, mandated a manufacturers guarantee, and provided the FDA with legal jurisdiction for enforcement (U.S. Department of Health and Human Services, 2011).

Excluded from the 1906 law were regulations regarding misleading ingredient or statement information in advertising and provisions for food quality (Borchers et al, 2007). Wiley and his supporters had sought inclusion of these regulations but were unsuccessful. The Pure Food & Drug Act did not receive a funding allocation, which made enforcement particularly challenging. These challenges were remedied, in part, through subsequent amendments (Borchers et al, 2007).

In 1938 the Federal Food, Drug and Cosmetic Act finally established food standards 'to promote honesty and fair dealing in the interest of the consumer', authorized factory inspections,

and prohibited the addition of poisonous substances to food "except when required in production or otherwise unavoidable" as well as laws to oversee the safety of cosmetics and drugs (Borchers et al, 2007). Again it was media coverage, public opinion and pressure, and the presence of a crisis that were vital aspects of the 1938 bill signing (Borchers et al, 2007).

In the past one hundred years the scope of the FDA's responsibilities has increased despite reports that highlight disjointed federal food safety oversight, inadequate science capability and information technology infrastructure, and insufficient funds and resources to effectively ensure a safe US food supply. The *H.R. 2751* Food Safety and Modernization Act is considered an amendment to the Federal Food, Drug and Cosmetic Act and necessitated the same level of public and political will for passage. The structure and challenges within the U.S. food safety regulatory environment and the preferred food safely approaches are important for understanding the evolution and content of the FSMA.

Current U.S. Federal Food Safety Regulatory Environment

In the United States as many as fifteen federal agencies are responsible for food safety through administering about thirty food safety laws (Government Accountability Office, 2009). The majority of the oversight responsibility lies with the Food and Drug Administration (FDA), within the U.S. Department of Health and Human Services, and the Food Safety Inspection Service (FSIS), which is part of the United States Department of Agriculture (Becker, 2010). The FSIS regulates major meat and poultry and their products, domestic and imported, as well as

catfish products and processed egg products (Becker, 2010). The FDA is responsible for the remainder of the domestic and imported foods as well as animal feed and drugs. The Center for Food Safety and Applied Nutrition (CFSAN) is the branch of the FDA that, in conjunction with the Agency's field staff, is primarily responsible for the regulation of food and has a mission, in part, of, "promoting and protecting the public's health by ensuring that the nation's food supply is safe, sanitary, wholesome, and honestly labeled" (FDA, CFSAN, 2011).

Funding appropriation for the FY2009 for FSIS was $972 million and $649 million for FDA with a staff of 8,000 to 1,900, respectively (Becker, 2010). The jurisdiction of the FDA includes about eighty percent of the at-home U.S. food spending while for FSIS the products total about twenty percent of at-home spending (Becker, 2010). The approach to imports and inspections differs as well as the scope of authority (Becker, 2010). Most drastically, the amount of domestic facilities where each agency must provide oversight is 6,300 for FSIS and 68,000 for FDA (Becker, 2010). The FSIS is responsible for "ensuring that the nation's commercial supply of meat (excluding game meats, such as venison), poultry, and egg product is safe, wholesome, and correctly labeled and packaged" but their authority does not extend to the farm (USDA, 2011). The FDA has responsibility for the rest of the foods and does inspect dairy farms. The Environmental Protection Agency, National Marine Fisheries Service, and Center for Disease Control and Prevention all play additional smaller federal roles in ensuring a safe and wholesome U.S. food supply (Becker, 2010). The role of the states has not been mentioned due to the federal focus of this paper. However, the states could arguably be highlighted as having one of the largest roles in regulation.

This fragmentation of food safety oversight during a time of increased importation of foods, greater reports of food borne illness outbreaks, and new and emerging technology prompted the Government Accountability Office (GAO) to include "Revamping Federal Oversight of Food Safety" in their 2007 High-Risk List. The "high-risk list" identifies areas of the U.S. federal government that require the attention of the executive branch and Congress (GAO, 2009). The 2007 listing noted that "comprehensive, uniform and risk-based food safety legislation" was likely to be necessary after the completion of an expert, thorough analysis of alternative organization structures (GAO, 2009). Between April 2007 and November 2008 the GAO generated ten reports related to the 2007 high-risk area of "Revamping Federal Oversight of Food Safety" (GAO, 2009). Subsequently in the 2009 GAO *High-Risk Series* report, disjointed federal food safety oversight was blamed as the source of "inconsistent oversight, ineffective coordination, and inefficient use of resources" (GAO, 2009). This report detailed why federal oversight of food safety is a high-risk area and provided recommendations (GAO, 2009). Because the Food and Drug Administration is responsible for the safety of about 80 percent of the U.S. food supply it became the focus of the GAO assessment and recommendations (GAO, 2009).

At the same time that federal oversight of food safety made the GAO "high-risk list", FDA Commissioner Andrew von Eschenbach requested an assessment by the FDA Science Board Subcommittee on Science and Technology on the status of the science and technology at the FDA (Report of the Science Board Subcommittee on Science and Technology, 2007). In response the FDA Science Board Subcommittee on Science and Technology formed and released a report entitled *FDA Science and Mission at Risk* in November 2007 (Report of the

Subcommittee on Science and Technology, 2007). The report outlines major findings and recommendations regarding its scientific expertise and technology and also assesses resources, concluding that the two are too intertwined to separate (Report of the Subcommittee on Science and Technology, 2007). The gravity of the report findings are framed by the report's Executive Summary, which states FDA's regulatory activities are designed to protect 80 percent of the food consumed in the United States and that it is "integral to the nation's economy and its security" (Report of the Subcommittee on Science and Technology, 2007). The *FDA Science and Mission at Risk* report highlights "substantial weaknesses across the Agency" and states, "the nation's food supply is at risk" (Report of the Subcommittee on Science and Technology, 2007). The report's major findings include statements that the FDA cannot fulfill its mission because the "scientific base has eroded and its scientific organizational structure is weak…its scientific workforce does not have sufficient capacity and capability...its information technology (IT) infrastructure is inadequate" (Report of the Subcommittee on Science and Technology, 2007). These conclusions were combined with prior reports that focused on the danger of a decline in FDA resources coupled with an increase in responsibilities (Report of the Subcommittee on Science and Technology, 2007). The 2007 report concluded, "that some of those crises are now realities and American lives are at risk" (Report of the Subcommittee on Science and Technology, 2007). Ironically the risk to the American public in the early 1900s served as an impetus for the establishment of the Federal Drug Administration. These reports indicate that the effectiveness of the agency's prime directive is failed.

More recently, the FDA Science Board charged a team of experts from the fields of food science, food safety, food processing, nutrition, and consumer communications to serve as the

Center for Food Safety and Nutrition (CFSAN) Research Review Subcommittee (CRRS). The CRRS was charged with providing a review of "CFSAN's research, support programs, and alignment with regulatory responsibilities" (CRRS, 2010). The collective goal of CRRS was to conduct a review and generate a report that could be used to assist and improve CFSAN as an organization (CRRS, 2010). Before, during, and after a two-day site visit at CFSAN on January 14-15, 2010, the CRRS conducted extensive reviews, engaged in meetings and observation, and facilitated weekly conference calls and electronic communication (CRRS, 2010). Submitted on August 11, 2010, the final report from the CRRS, *Center for Food Safety and Applied Nutrition: Research, Support Programs, and Alignment with Regulatory Responsibilities*, provides a comprehensive analysis and evaluation of the status of CFSAN. Key findings and recommendations from the report reveal that administrative and technical staffing is insufficient and that more succession planning to ensure the subsequent recruitment and retention of highly skilled experts is necessary (CRRS, 2010). Laboratory and non-laboratory research needs expansion and more equal and integrated attention (CRRS, 2010). Additional clarity for research prioritization, especially related to regulatory science, prompts a recommendation to establish a formalized process to identify and prioritize research topics and for project management (CRRS, 2010). The full value of CFSAN's efforts in public health are not always clearly communicated therefore developing a more "public face" would be beneficial. Similarly, the report recommends that CFSAN create more opportunities to engage in scientific exchanges and collaborations with international counterparts (CRRS, 2010). Increased capacity to engage with leading scientists in academia and industry as well as additional depth for CFSAN's subject matter experts and critical leadership positions would address the report's concerns about the Center's vulnerability

moving forward (CRRS, 2010). To this point, the CRRS recommends the use of the best expertise and scientific evidence to meet CFSAN's mission as well as a systematic approach to emerging risk issues using maps, environmental scans, and the counsel of internal and external advisory boards (CRRS, 2010). The inherent and inevitable risk of such an expansive and diverse food system is a paramount factor in food safety.

Risk

The concept of risk has long been a pillar of the food safety conversation. According to the World Health Organization, risk is defined as, "a function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard(s) in food" (WHO and FAO, 2008). There are three main categories of risk associated with food: microbiological; chemical; and physical (IOM, Brackett, 2010). Microbiological risks are most evident via "outbreaks" such as the 2008 discovery of *Salmonella* linked to jalapeno peppers and the case of *Cyclospora* in raspberries in 2000 (Ho et al, 2002; CDC, 2008). The Center for Disease Control and Prevention (CDC) provides surveillance of these outbreaks and the U.S. media provides extensive coverage. Regulatory agencies seek to trace the origin of the contaminated food(s). Chemical risks may include "undeclared allergens", unapproved pesticides, and heavy metals such as lead in candy or mercury in fish (IOM, Brackett, 2010). Physical risk typically refers to objects like glass or rocks being present in the food system in a way that is potentially harmful if consumed. (IOM, Brackett, 2010). Each of these types of risk can have potentially adverse health effects, prompting the establishment and sustainability of a robust risk analysis program in the United States.

According to the World Health Organization and Food and Agriculture Organization of the United Nations, risk analysis is the preferred approach to assessing "possible links between hazards in the food chain and actual risk to human health, and takes into account a wide range of inputs to decision-making on appropriate control measures" (WHO and FAO, 2006). The risk analysis process has evolved over the past several decades and now includes the assessment, management and communication of risk (WHO and FAO, 2008). According to the WHO and FAO, risk assessment is the "science-based component that includes the following steps: i) hazard identification; ii) hazard characterization; iii) exposure assessment; and iv) risk characterization" (WHO and FAO, 2008). The risk management process weighs policy alternatives and values while the communication occurs throughout the entire risk analysis process with all stakeholders regarding the "risk, risk-related factors and risk perceptions" (WHO and FAO, 2008). Although the approach is structured and grounded in the best scientific evidence, it is also iterative and ongoing with an emphasis on consistency, transparency, inclusivity and clarity "in its treatment of uncertainty and variability" (WHO and FAO, 2008). When the risk analysis framework is used appropriately, it enables "laws, policies, regulations and standards" that collectively establish food safety control measures (WHO and FAO, 2008). Risk analysis is the preferred approach in the United States and contributes the increasingly favored plans to identify and control risks through the Hazard Analysis and Critical Control Point approach.

Hazard Analysis and Critical Control Point (HACCP)

Hazard Analysis and Critical Control Point (HACCP) is the predominant and

recommended risk and science-based approach. As a system of preventative controls, HACCP reduces risk of foodborne illness and injury and through that role may assist with food safety inspections and engendering confidence in the food supply. HACCP was officially added to the Codex Alimenatrius Recommended International Code of Practice-General Principles of Food Hygiene in 1997 and revised in 1999 and 2003 (FAO and WHO, 2003). The HACCP system was initially implemented to identify and reduce risk of food borne illness for astronauts while in space (IOM, 2003). Today it is the prevailing system to identify, evaluate, and controls hazards that are significant for the entire food chain from initial production through consumer consumption (FAO and WHO, 2003). HACCP is a plan for prevention rather then a finished product inspection system and is used throughout food production and preparation, including packaging and distribution. Food processors are encouraged to identify and document mistakes and to also document the corrective action taken. According to FDA Consumer Safety Officer Rick Licari, "in the past there was an incentive to conceal mistakes for fear of regulatory action" but with HACCP the focus "shifts from occasions when problems occur to occasions when a processor fails to take corrective action when a problem occurs (Licari, 1997).

Food safety problems still occur despite HACCP's seven systematic principles: hazard analysis; identification of critical control points (CCPS); establishment of critical control limits for each CCP; establishment of monitoring procedures for each CCP; establishment of corrective actions; establishment of record-keeping procedures; and the establishment of verification procedures; along with sound scientific knowledge and practice (IOM, 2003). It is also essential for processers to have a traceability program that includes all relevant records on incoming materials and labeling as well as a recall program in the event a product origin is traced and the

need to remove it from the marketplace is determined (FAO, 2008). This necessity to enforce the presence of recall plans is evidence that complete "safety" of the food system, as consumers may wish, is not realistic.

In general food safety criteria contribute toward a shared goal of protecting or improving public health. As scientific knowledge advances and the nature and diversity of the food supply evolves, the need for changes in the criteria arise (IOM, 2003). Current and appropriate updates of the criteria upon which the regulations are based are time-consuming and cumbersome within the present administrative system, enabling regulation to be outpaced by science (IOM, 2003). This inefficiency inhibits effective implementation of the defined food safety objectives and the meeting of those objectives (IOM, 2003). The food safety objective is defined as, " a statement of the maximum frequency and/or concentration of a hazard in a food at the time of consumption that is considered tolerable to consumers" (IOM, 2003). Objectives are an acknowledgement that there are tolerable amounts or frequency of "hazards" in food. This approach is very important for consumers to understand as there is an often-held public perception that effective U.S. food safety will enforce "zero tolerance" policy, or the absence of hazards in the food supply (IOM, 2003). In reality, the absence of a hazard, such as a pathogen or contaminant, "cannot be scientifically assured" (IOM, 2003). The term "zero tolerance" is often used by the media in reference to food safety and to other topics such as drug-law enforcement or offensive behavior (IOM, 2003). In areas other than food "zero" may equate to the true absence of the undesirable characteristic however when related to food, "zero" really means the lack of detection under a prescribed set of conditions such as specific methods, which may include new instrumentation, data management, visual observation, or sample size, etc. Because this reality may not be know

to the general public, "zero" is presumed attainable. Scientists and regulators know that the presence of hazards in the food supply is inevitable and that detection has limitations. In addition, the scope of regulatory oversight is limited and varies across different countries, many of which are contributing ingredients and products to the US food supply. As mentioned previously, the prevalence, or perceived prevalence, of human food borne illness coupled with publicity about the decline of FDA's effectiveness greatly contributed to the creation of the "policy window" which helped to enable the enactment of the Food Safety Modernization Act.

Good manufacturing practices (GMPs) are mandatory (FD&C, § 110). Enforcement of good manufacturing practices (GMPs) and effective implementation of HACCP systems at some domestic and foreign facilities was challenging prior to the passage of the FSMA. Inspection frequency has not been explicitly required with estimates of actual FDA inspections per facility at once for every five to ten years plus annually for "high risk facilities" (Becker, 2010). At the FSIS the inspections occurs at all time of operation at slaughter plants and one a day at, at least, at processing plants (Becker, 2010). The Health and Human Service's Office of Inspector General conducted a five year study regarding domestic food facility inspections and learned that the notifications from other external federal, industry or state personnel requesting FDA facility inspections increased by 9,000 between 2004 and 2008 (HHS OIG, 2010). During the same time period, the number of facility inspections conducted by the FDA declined from 17,000 (29%) to 15,000 per year (22%) (HHS OIG, 2010). The FDA was already reliant on the cooperation of over 400 state inspectors to conduct inspections as well as external notifications about facilities that were deemed "high-risk" and in need of inspection (Becker, 2010). This report further highlighted the resource and staffing deficit inhibiting the FDA's ability to adequately perform

its duties. If the FDA did conduct an inspection and identified a violation they would issue notice of a violation and potentially follow up with an injunction, seizure action, or warning letter. The authority to mandate a recall fell outside the FDA's authority however. With the quality and efficacy of the food regulatory system in the United States in question, Senate and House legislators both began to draft amendments.

Evolution and Provisions of the Food and Drug Safety Modernization Act (FSMA)

In July of 2009 the House passed a food safety bill that was then followed by the Senate's version of the bill, *S. 510:* FDA Food Safety Modernization Act of 2010*,* which passed with a vote of 73 "Aye" votes to 25 "Nay" votes on November 30, 2010. This bill was presented as*,"* a bill to amend the Federal Food, Drug, and Cosmetic Act with respect to the safety of the food supply" (S.510-Summary, 2010). Prior to full implementation, the need for the bill to pass as a revenue-raising bill mandated that the *S.510* version was made obsolete and the text was transferred to *H.R. 2751*. On December 21, 2010, an affirmative vote of 215-144 confirmed the passage of *H.R. 2751.* This Food Safety Modernization Act (FSMA) was signed into law on January 4, 2011 by President Barack Obama and became Public Law No: 111-35. The Commissioner of Food and Drugs, Margaret A. Hamburg, M.D., heralded the new law "a sea change for food safety in America, bringing new focus on prevention" with the expectation that it will "have a dramatic and positive effect on the safety of the food supply" (Hamburg, 2011).

The *H.R. 2751:* Food Safety Modernization Act (FSMA) includes many revisions to the U.S. food safety laws, some of which are rather significant (Covington & Burling, 2010). The FSMA has four primary "Titles" or parts. The Titles in FSMA include; Improving Capacity to Prevent Food Safety Problems, Improving Capacity to Detect and Respond to Food Safety Problems, Improving the Safety of Imported Food, and Miscellaneous Provisions (H.R. 2751, 2011). According to Stewart and Gostin, the Food Safety Modernization Act the regulatory powers of these four primary provisions are summarized by the categories; prevention, response, recall and import safety (Stewart and Gostin, 2011). Specifically, key provisions poised to affect food facilities include facility registration, maintenance of records, inspections, and written hazard analysis and control points plans and execution. All food-related facilities, with the exception of farms, retail facilities, and restaurants, must register with FDA starting 180 days after enactment of FSMA and update that registration on even numbered years, every two years (FSMA, § 102). An increase in inspections aimed at preventative identification and correction of food safety problems is a significant focus of FSMA. A facility re-inspection also incurs a fee. The hazard evaluation plan must be available to inspectors upon arrival at a registered facility and documents must indicate compliance with the FDA's produce safety standards and tracking and tracing requirements (FSMA, § 103; FSMA, § 105; FSMA, § 204). Within two years, FDA must propose tracing procedures and regulations for facilities to follow (FSMA, § 204). FSMA also mandates that the FDA establish produce production and harvesting standards as well as create and publish a list of high-risk foods (FSMA, § 105). The standards and list will be made available within the first year of enactment of FSMA (FSMA, § 105).

High-risk facilities are the target for the inspections with one required visit in the first five years of enactment and at least one in every three year thereafter (FSMA, § 201). The non-high risk facilities are subject to inspection once in the first seven years after FSMA is enacted and afterwards once per every five years (FSMA, § 201). Additionally, the FDA is charged with inspecting at least 600 foreign facilitates within the first year of enactment and doubling that number in comparison with the previous year for each of the subsequent years in the next five (FSMA, § 201). All foreign suppliers that refuse inspection will have their food denied entry into the U.S. and the FDA is charged with creating a plan to "expand the technical, scientific, and regulatory capacity of food governments and food industries from which foods are exported to the United States" (FSMA, § 306). Within one year, American importers of food will be required to implement a program to verify that the imported food meets the U.S. requirements which will be set forth in FDA regulations within a year of the FSMA enactment (FSMA, § 301).

In addition to the increased enforcement mechanism gained from the increased access to records, the FSMA contains some other enforcement provisions intended to enable FDA to better respond to Food, Drug, and Cosmetic Act (FDCA) violations and to enhance the overall "authority" of the agency. The three other primary enforcement mechanisms are the suspension of facility registration, "lowering the standard for administrative detention of food", and protection for whistleblowers. If a FDA inspector finds evidence of food adulteration that could cause harmful health consequences or death then it may suspend a facility's registration until a corrective action plan is developed and submitted to FDA (FSMA, § 102). Lowering the standards for detention of food means that "reason to believe" rather then "credible evidence" of "adulterated or misbranded" food is sufficient for the suspension of a facility's registration if the

safety findings are problematic (FSMA, § 102; Covington & Burling, 2010). Whistleblower protection will be granted to anyone who notifies the FDA of a suspected food safety infraction, especially in conjunction with the increased emphasis on the detection and prevention of adulterated or smuggled foods entering the market and potentially causing widespread physical harm to American consumers.

The FSMA provides FDA with the authority to issue mandatory recall of food when there is "reasonable probability" of adulteration or misbranding that may cause "serious adverse health consequences or death to humans or animals" (FSMA, § 206; Covington & Burling, 2010). Previously only an activity of state authorities, the FDA can now follow a cease distribution order with a maximum $50,000 fine for an individual or $250,000 for other entities in cases where there is failure to comply with the FDA authority (Covington & Burling, 2010). In addition, section 211 in FSMA provides specific guidelines to large grocery store chains to post "consumer-orientated information" from the responsible parties in a conspicuous location within stores (FSMA, § 211).

Highlights and Concerns

The FSMA requires the implementation of more than fifty rules, reports, studies, and guidance documents (Taylor, 2011). Taken in its entirety the FSMA focuses on prevention of food borne illness outbreaks and the exclusion of adulterated foods to maintain a safe food supply from farm to market. However, certain FSMA provisions have gained considerable attention and need to be examined when considering its potential effectiveness.

Although the FSMA gained bipartisan support, its passage also marked a milestone in, "a ferocious two-year battle that has pitted the small-farm, locavore food movement against large

growers and food safety interest groups" (Lochhead, 2010). Some of the interests in support of the bill included livestock, environmental, health and welfare, consumer, non-profits, farmers, bipartisan, beverages, and non-profits while farm organizations and cooperatives, food wholesalers, biotech research and products, and pro-business associations and vegetables, fruits and tree nut interests opposed the bill (Open Congress, 2010). Perhaps the most controversial section of the FSMA during the two-year period preceding its enactment is Section 103, Hazard Analysis and Risk Based Preventative Controls, located within Title I, Improving the Capacity to Detect Food Safety Problems. The content of this section, included below, is at the crux of the U.S. risk-based approach for maintaining a safe food supply.

> In General--The owner, operator, or agent in charge of a facility shall, in accordance with this section, evaluate the hazards that could affect food manufactured, processed, packed, or held by such facility, identify and implement preventive controls to significantly minimize or prevent the occurrence of such hazards and provide assurances that such food is not adulterated under section 402 or misbranded under section 403(w), monitor the performance of those controls, and maintain records of this monitoring as a matter of routine practice (FSMA, § 103).

Small farmers expressed concerns that they were not to blame for the mass food poisoning outbreaks and the new safety protocols were designed to regulate industrial agriculture and therefore would be so cost burdensome that it would put them out of business (Lochhead, 2010). On the other side, food safety activists and owners of large farms and production argued

that, "bacteria do not discriminate by farm size" (Lochhead, 2010). To address the concerns of small, local food processors and producers, Senator Jon Tester (D-Mont.), who owns a small organic farm, sponsored a bill amendment to provide them exemption from implementing preventative controls. The food facilities that qualify for exemption are those with food sale averages less then $500,000 sold directly to grocery stores, restaurants, and consumers within 275 miles during the three previous years and "very small businesses" as defined by the FDA (Wolters Kluwer Law & Business, 2011). The FDA needs to conduct a study to generate a definition for "very small business" in this context (Wolters Kluwer Law & Business, 2011). It is unlikely they will address the fact that many larger food retailers like Whole Foods often buy from smaller, often organic producers and yet are still involved in numerous food recalls (Whole Foods Market, 2011). Ideology and speculation rather then science is at the root of the exemption for small farms and business operations from federal food safety requirements to protect American consumers.

In late December 2010 nearly one hundred people reported symptoms of illness in about seven states and the Canadian provinces Ontario and Quebec. It was determined these people were sickened from consumption of certain alfalfa sprouts and spicy sprouts (alfalfa mixed with radish and clover spouts) contaminated with *Salmonella* (FDA, December 29, 2010). This multistate outbreak was traced back to a 30-acre, organic farm located in central Illinois called Tiny Greens (FDA, December 29, 2010). Alternative technologies and eco-friendly practices are integral to the growth and distribution of this small farm's micro-greens. However, as this 2010 *Salmonella* outbreak demonstrates, this unique and independent farm is not immune to product

contamination, which is often portrayed in the media as a byproduct of large production facilities.

In addition to the disputes about the Tester Amendments, another area of prime interest within FSMA is whether or not the bill will be successful in its efforts to increase the safety of foods imported to the United States. The United States imports from an estimated 150 countries and concerns about safety are increasing in accordance with the expansion of the globalization of food (Hamburg, March 15, 2011). In the Improving the Safety of Imported Food title of FSMA new tools and additional FDA authority are outlined. Several sections address the requirement for U.S. importers to "perform risk-based foreign supplier verification activities to verify that imported food is produced in compliance with applicable requirements related to hazard analysis and standards" (FSMA, § 301). In addition, the FSMA includes provisions that require the FDA to "enter into arrangements and agreements with foreign governments to facilitate the inspection of foreign facilities" and to "direct resources" to these inspections (FSMA, § 306). Critics of the bill raise concerns about the appropriateness and probability of the FDA implementing extensive foreign inspections. Resources are already limited with the current number of federal inspectors unable to meet the demand for domestic inspections alone. FDA efforts to lead global food safety harmonization are also questioned.

A key approach for improving the safety of imported foods includes developing, implementing, and enforcing traceability systems. According to the 2009 Global Traceability Standard, traceability is defined as the "ability to track forward the movement through specified stage(s) of the extended supply chain and trace backward the history, application or location of that which is under consideration" (GSI Standards Document, 2009). Industry standards and

assurance that all parties involved in the food supply chain will be in compliance with product identification and information sharing is critical (GSI Standards Document, 2009). The FSMA legislation seeks to strengthen and synchronize these traceability systems that will ideally allow the identification of the source of a food-borne illness outbreak to occur much more quickly. However, due to the fragmented natures of the U.S. food safety oversight, not all food falls under FDA jurisdiction. For example, FDA is responsible for regulating shell eggs while egg products such as Egg Beaters are the responsibility of the USDA. When the *Salmonella enteritidis* outbreak occurred in the summer of 2010, it took three months to trace the illness back to Wright County Egg in Iowa (CDC, 2010). While this timeframe for a traceback is considered reasonable by regulators, it stimulated consumer concern as the illness symptoms spread. Consumers began to demand greater food safety traceability and accountability in the United States. The globalized nature of the food system will however bring to question whether there will be significant international willpower, technology, and resources to implement all of the FSMA import safety provisions in a way that makes a meaningful difference in traceability and overall safety of the U.S. food supply.

Although making changes to standards is typically presented favorably there are potential drawbacks. As standards change, such as the maximum limits of foreign material in peanuts, shellers, for example, will need to have the resources and technology to estimate the actual amount of foreign material and when necessary to remove it from the lot (Whitaker, 2008). This high degree of science availability and other resources are increasingly required for most members of the food industry. When conducting risk analysis on products, the probable variability among replicated sample concentrations poses a significant time and cost burden to

producers (Whitaker, 2004). Also, unfortunate problems with detection technology sometimes result in false positives. Although theoretically tempting for small producers to underreport false positives, they must be reported to the Reportable Food Registry or face a violation of the law.

The 2007 establishment of the FDA Reportable Food Registry (RFR), where adulterated food ingredients or products are reported to FDA, initially stimulated confusion and numerous reports (Brackett, 2011). While the FDA has addressed many of the concerns of the industry, prior to the FSMA unresolved issues remained such as "the need for better lot definition on the part of the industry, impact of reports on prompting recalls, potential impact of new records access by FDA, and the impact or utility of product testing" (Brackett, 2011). These issues in addition to an overall erosion of science that at times favors trends toward the precautionary principle and pressing the use of less studied foods rather then some that are more highly studied are added challenges for the food industry (Brackett, 2010). The enactment of the FSMA will likely affect the food industry in both anticipated and unexpected ways as the regulations continue to be drafted and provisions are implemented.

The final aspect of concern relates to the mandate for the Secretary of Health and Human Services to increase the number of field staff to effectively implement all the provisions of the FSMA. The FSMA outlines that the field staff of the responsible Centers shall increase with a goal of not fewer than: 4,000 staff members in fiscal year 2011; 4,200 staff members in fiscal year 2012; 4,600 staff members in fiscal year 2013; and 5,000 staff members in fiscal year 2014 (FSMA, § 401). In order to adequately identify and respond to food defense threats and "to detect, track and remove smuggled food", the field staff "shall include an increase of 150 employees by fiscal year 2011" (FSMA, § 401). These staff increases will require funding

appropriations that seem somewhat ominous in the current fiscal climate. On January 3, 2011, Commissioner Margaret Hamburg released a statement regarding the FSMA. In addition to highlighting the need for continued involvement from stakeholders throughout the food system and referencing some of the FSMA provisions, Dr. Hamburg wrote about the FDA and its actual implementation of FSMA. A key aspect of her statement fuels concern about its potential effectiveness, "already we know that the legislation did not include sufficient fee resources to cover the costs of the new requirements" (Hamburg, 2011). On January 27, 2011, FDA Deputy Commissioner for Foods, Michael Taylor, stated that the FSMA implementation "will require new resources and investment" (Taylor, 2011). The anticipated cost of FSMA is a significant issue to explore.

Cost

The estimated minimum cost for the Food Safety Modernization Act (FSMA) is $1.4 to $1.6 billion over five years plus an additional $230 million in expenditures that would be offset by fees gathered through domestic facility and importer re-inspections, food recalls, and the voluntary qualified importer program (Johnson et al, 2010; FSMA, § 107). The bill also contains a proposed $335 million in discretionary spending for non-FDA programs such as school-based allergy and anaphylaxis management grants, grants for food safety training, education, outreach and technical assistance for small farms, producers, and fruit and vegetable merchant wholesalers as well as food safety participation grants for Indian tribes (Johnson et al, 2010). The estimated $1.4 to $1.6 billion is not offset by other cuts in budgetary spending and therefore may increase food prices that the consumers bear, according to opponents of FSMA.

After the official enactment of the Food Safety Modernization Act, the Congressional

Budget Office released an estimate of the statutory Pay-As-You-Go Effects with an aim to estimate a net increase or decrease in the federal deficit, by fiscal year, as calculated in the millions of dollars. For the years 2011 through 2020 neither an increase nor decrease is anticipated, as indicated by a "zero" under each year. The following statement accompanied the visual estimate,

> H.R. 2751 would increase federal efforts to ensure the safety of commercially distributed food. H.R. 2751 would stipulate that the failure to comply with new requirements, such as mandatory recalls and risk-based preventive controls, could result in the assessment of civil or criminal penalties. Criminal fines are recorded as revenues, then deposited in the Crime Victims Fund, and later spent. Enacting H.R. 2751 could increase revenues and direct spending, but CBO estimates that the net budget impact would be negligible for each year (Congressional Budget Office, December 20, 2010).

Many of the FSMA mandates are unfunded and will require appropriations from future Congress. Given the current fiscal austerity, the funding may prove insufficient to effectively implement many of the provisions. The increased inspection schedule is an area of particular concern with the increased amount of FDA inspectors necessary to meet the additional burden.

The inadequacy of inspection resources has been a persistent concern in many reports and proposals submitted during previous Congress sessions. Prior to FSMA, FDA already collaborated with more then 400 state agencies to execute a variety of food safety regulatory activities (Becker, 2010). Many state food safety inspectors are under contract to perform field inspections that are federally required of the FDA (Becker, 2010). Despite the fact that some

FSMA critics believe the new inspection requirements are still too sparse, state inspectors may now require additional training and have to be further engaged in more inspections to help the FDA meet the additional burden. Moreover, the states have varying standards for food establishments and commodities and are likely to be further disparate from foreign importer standards. Increased emphasis on science-based standards and preventative approaches such as facility inspections, mandatory hazard assessments and preventative controls, and all of the other FSMA provisions within the United States already requires extensive investment and new resources.

Additional efforts to improve the safety of imported food, including FDA personnel traveling to foreign countries for inspections and to assist with scientific and regulatory infrastructure, will further strain the limited FDA resources. As of January 2011 there are thirteen fully operational, FDA-established foreign posts with eleven of the posts staffed by thirty U.S. direct hires and fourteen locally employed staff (FDA, April 6, 2011). The reality of globalization continues to affect all of the FDA activities, providing new risks that require ongoing attention and innovation (Hamburg, March 17, 2011).

The overall cost of full implementation of all of the FDA provisions will necessitate additional funding or other key functions may be compromised (FDA, 2011). Favorable Congressional budget appropriations are one approach toward funding the FSMA provisions. President Obama's fiscal year (FY) 2012 budget includes a proposal to impose a new food tax on food companies and consumers to offset FSMA implementation costs. A coalition of sixteen food group allies, led by the American Frozen Food Institute (AFFI), and including the National Meat Association, United Fresh Produce Association, Snack Food Association and the National

Chicken Council, to name a few, are already stating opposition to the potential new user fees (AFFI, 2011).

Conclusion

The authors strongly believe that scientific research, evidence and interpretation should be the basis for food safety policy and regulation. To a large degree U.S. federal agencies have provided science-based guidance, oversight, and policy during the seventy-two years since the signing of the 1938 Federal Food, Drug and Cosmetic Act. However, care must always be taken to ensure that this remains the case as the U.S. strives to maintain the safest food system in the world. It is also an absolute necessity to make sure the FSMA regulations do not stifle new innovation to continue to produce food to increase human health at lower cost for consumers. It is imperative to work with members of the food industry at all time to avoid regulations that create disincentives.

Generally, industry and consumer groups have supported the systematic, preventative Hazard Analysis and Critical Control Point (HACCP) system utilized in the United States. Ongoing communication of relevant and emerging information to the industries supports FDA's mission to "promote and protect the public health". When it became increasingly evident to multiple stakeholders that the U.S. was "struggling to find the political will to rationalize a fragmented and somewhat under-funded system of multi-agency control" (Hoffmann, 2010), the

enactment of the Food Safety Modernization Act became possible. Regulation of the entire food system has become increasing complicated and concerns about who is ultimately accountable continue to rise. The FSMA aims to increase the regulatory power of the Food and Drug Administration to influence practices that decrease the levels of risk and frequency of food-borne illness outbreaks in the U.S. food supply. Although the FDA is responsible for the safety of 80 percent of the U.S. food supply, it is still only one of the many federal agencies involved in regulation in addition to the extensive collaboration with and compliance from members of the food industry, state governments, consumers and other stakeholders.

The scope of intended oversight to both domestic and imported foods is extensive, extending far beyond the capacity of the current staff of inspectors, the current level of funding, and potentially the collaboration of other countries. Such a pronounced increase in federal regulation bears a cost, one that is likely to be borne by food producers, industry, and consumers. Consumers are likely to experience higher food prices when there are changes in standards or if industry members are required to pay a "food safety fee". The economic viability and sustainability, for all stakeholders in the U.S. food system, is a significant concern regarding the potential effectiveness of the FSMA. The legislation explicitly acknowledges the importance of increased collaboration with and training for all food safety agencies at the U.S. federal, foreign, state, local, tribal, and territorial levels. However, the economic crisis is widespread and available resources for members of all the food safety agencies outside of the FDA are also scarce. If the effectiveness of the FSMA heavily relies upon external contributions and support, as is the indication, then the efficacy seems uncertain.

The prevention-based focus of the FSMA is one rooted in proven scientific approaches. Additional authority and enforcement provisions are touted as closing "significant and longstanding gaps" in FDA activity (Hamburg, March 17, 2011). At a time when the FDA has already been struggling to fulfill its responsibilities, the additional fifty new rules, reports, studies, and guidance documents that are mandated by the FSMA, are a daunting and potentially unrealistic task. Furthermore, Congress may elect to "significantly roll back funding for the federal agencies next year" which would render the ambitious scope of FSMA impossible (Covington & Burling, 2011). The effectiveness of the Food and Safety Modernization Act is dubious, leaving critics to still wonder if the establishment of a new, independent food safety agency is preferable (Becker, 2010). As recommended by the Government Accountability Office High-Risk Series report in January 2009, now may also be the time to consider alternative organizational structures for the oversight of food safety in the U.S. food supply (GAO, 2009).

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