

The Very Real Impact of the Food Safety Modernization Act: A Roundtable Symposium Addressing FSMA's Effect on Academia and Industry

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SUMMARY

The Food Safety Modernization Act (FSMA), which was signed into United States (U.S.) law in 2011, outlines new requirements for the food industry and how food safety authorities will enforce these requirements. FSMA affects every entity that produces, imports, distributes, manufactures and transports food, not only for U.S. food industry members but also for foreign suppliers. In this article we present a collection of testimonials from food safety experts in governmental agencies, academia and industry who participated in a roundtable symposium held during the 2017 Institute of Food Technologists (IFT) Annual Meeting. The food safety experts discussed the complexities of the FSMA and reported on the impact this regulation has had on their daily professional lives.

OVERVIEW

The Food Safety Modernization Act (FSMA) was enacted in 2011 as an integrated nationwide system tasked with the prevention of food contamination (9). The FSMA was created for restructuring the existing governmental approach to food safety by enabling stakeholders in the food safety chain to focus on prevention. In this new regulatory scenario, the emphasis is shifted from reacting to food safety events to preventing them (6).

FSMA is divided into distinct parts designed to improve the capacity to prevent, detect and respond to food safety problems as well as to improve the safety of imported food, while advocating for collaboration with industry-wide partners and other stakeholders (5). The first part of the law defines the requirements for businesses to implement Hazard Analysis and Risk Based Preventive Controls (HARPC), which builds upon current food safety protocols such as Hazard Analysis Critical Control Point (HACCP) by mandating a pre-assessment of food-safety hazards (6). Although FSMA was originally enacted seven years ago, its impacts are just now being felt, as the law has been transitioning from the rulemaking phase to implementation.

Implementation of FSMA affects every link in the nation's food supply chain, including producers, manufacturers and transporters. Furthermore, because the nation's food supply

is global, with a significant proportion of our food coming from abroad, FSMA also governs importers and distributors. For registered food facilities, FSMA requires owners or operators to evaluate food safety hazards, implement and validate preventive controls, monitor the effectiveness of these controls, and document all of these efforts (7). The Food and Drug Administration (FDA), in turn, is required to enact science-based regulations and monitoring tools to implement the law (5), as the FSMA addresses the safety of FDA-regulated food products (9). This differs from previous regulations in that it "mandates a logical pre-assessment of food safety hazards" (6). The deadlines for small businesses to comply with FSMA regulations began in 2017 and will continue through 2020 (4). This places company owners and operators under substantial pressure to understand and implement these complicated regulations within the stipulated time limit. Challenges with implementing FSMA exist for all food industry members, and concerns persist regarding feasibility, especially for small food facilities with limited resources. Some research indicates that small food facilities worldwide cited difficulties implementing HACCP (6). Therefore, small FDA-regulated facilities may experience the same problems implementing HARPC; similarly, small farmers may also struggle with meeting the requirements outlined in the produce safety rule of the FSMA.

At the Institute of Food Technologists Annual Meeting in Las Vegas, which convened July 25–28 of 2017, a roundtable symposium was held to discuss these types of challenges and the FSMA's effects on food industry companies. The symposium consisted of two segments; the first allowed the four invited speakers to discuss the different training possibilities offered by academia as well as the actual changes FSMA has initiated in the food industry, and the second provided session attendees with the opportunity to ask questions. The invited speakers represented the Grocery Manufacturer's Association (GMA), The Acheson Group (TAG), the Food Science Institute at Kansas State University, and the Southern Center for FSMA training, a part of the Institute of Food and Agricultural Sciences at the University of Florida. The presenters shared information on associated topics, provided information about how

the complex FSMA regulations have affected their daily professional lives, and led the discussion.

FSMA: The regulatory evolution of global food safety

Dr. Kristen Spotz, Senior Manager for Food Safety and Quality Assurance at the Grocery Manufacturer’s Association, which represents more than 250 leading food, beverage and consumer product companies, presented an overview of the new regulatory changes associated with the FSMA and their impact on global food safety. The speaker described GMA’s role as an active partner of FDA in providing both technical and scientific assistance to successfully implement FSMA. Because of the complexity and global scale of today’s food chains, the FDA is in the process of developing new strategies to successfully implement all facets of FSMA (8). Long-term outcomes of FSMA are expected to enable the food industry to be proactive in ensuring food safety at every step of the food chain from farm to table (8). For FDA’s food safety program, this new approach means the creation of an operational strategy that advances public health, leverages partner resources, collaborates with industry and government organizations, and creates strategic and risk-based industry oversight (8). Moreover, science-based measures should be utilized at every appropriate step of food production, and careful management on the part of the food industry should be practiced by maintaining documentation of “appropriate preventive measures as a matter of routine

practice every day” (8). Dr. Spotz also presented a very helpful list of the most relevant compliance deadlines for businesses categorized as General, Small Business, and Very Small Business (Table 1). GMA is “actively involved” with training and enforcing issues stemming from FSMA, as well as providing FDA with the technical support and scientific expertise necessary for adjusting to prevention-oriented food safety standards (8).

The role of academia in FSMA training

Although academia does not play an active role in FSMA enforcement, Dr. Fadi Aramouni, a professor and extension specialist in food science at Kansas State University’s Food Science Institute, highlighted the key role of universities in FSMA implementation. In his presentation, Dr. Aramouni postulated that researchers can affect both industry and consumers through the education of future food scientists who will assume roles in the food industry of the future. He explained that providing learning experiences for students preparing for careers in food science will help to ensure that the next generation of food safety workers are prepared to comply with the FSMA regulations. As a professor at one of the nation’s land-grant universities, Dr. Aramouni believes that coursework at Kansas State prepares students to understand the principles of HACCP, as well as the place of hazard prevention practices in HARPC. His course objectives guide food science students through the steps of developing HACCP and Preventive Controls (PC) for

TABLE 1. FSMA Compliance Dates (Simplified from GMA, 2016)

Final Rule	General Compliance	Small Business Compliance	Very Small Business Compliance
Preventive Controls for Human Food	19 September 2016	18 September 2017	17 September 2018
Preventive Controls for Animal Feed	19 September 2016 (cGMP*) 18 September 2017 (PC#)	18 September 2017 (cGMP) 17 September 2018 (PC)	17 September 2018 (cGMP) 17 September 2019 (PC)
Produce Safety	26 January 2018	26 January 2019	26 January 2020
Foreign Supplier Verification Program (FSVP)	30 May 2017	30 May 2017	30 May 2017
Third Party Accreditation and Certification	N/A	N/A	N/A
Sanitary Transportation	6 April 2017	6 April 2018	N/A
Food Defense	26 July 2019	26 July 2020	26 July 2021

*GMP: Good Manufacturing Practices

PC: Preventative Controls

N/A: not applicable

human food plans. He described how teams of students develop a “systematic, logical protocol” for their HACCP and PC plans and evaluate those plans in terms of mandatory requirements and scientific credibility (1).

The classroom discussions and individual assignments are not based on hypothetical scenarios. Rather, students are matched to small- and medium-sized processors from the Midwest region that have requested help with their HACCP/PC plans. As part of their coursework, student teams make site visits and meet with industry professionals, and many of them are subsequently hired on as summer interns or as consultants after completing their studies (1).

Implementing FSMA: Food industry challenges

Dr. Peyman Fatemi is Vice President of Scientific Affairs for TAG, a global food and beverage safety consulting company. He presented the industry perspective on how the FSMA rule for human food preventive controls has transformed hazard prevention within the food industry. The FSMA preventive control rules for human and animal foods represent the basic regulatory requirements of the overall FSMA law. Within these rules, there is a specific focus on suppliers of imported foods, which Dr. Fatemi identified as one of the greater challenges for organizations working toward FSMA compliance (5).

The philosophy of ensuring food safety through prevention is essentially the core of FSMA, which mandates that all companies create a food safety plan to mitigate hazards (5). In his presentation, Dr. Fatemi illustrated how a proper food safety plan works within an organization, beginning with training personnel how to identify and analyze hazards. Once potential hazards are identified, his sample plan moved to preventive controls, including supplier controls, followed by monitoring, corrective actions, verification and then reanalysis. FSMA requires facilities to maintain records and make them available upon request. Recording each part of an operation’s food safety strategy, and reviewing it regularly, is truly at the center of any successful food safety plan.

Dr. Fatemi illustrated how facilities could structure their operations to ensure food safety. Operations first must prevent contaminants from entering the facility, through control of raw materials and pests, as well as construction and visitor procedures. The second step consists of removing contaminants through cleaning, sanitization, and use of sanitary design for equipment and facilities. Following this step, the control of water, time and temperature, using sanitary design for facilities and equipment, and controlling contamination through adequate frequency of cleaning and sanitation, is key for successful compliance. His final recommendation was with regard to controlling food contaminant transfer, which is achieved through the control of vectors (air, contact surfaces and water), sources (niches), and raw material and personnel traffic patterns (3).

FSMA requires that suppliers of the food industry verify that risks are controlled. To meet this mandate, the use of approved suppliers, as well as verification that suppliers control risks, was suggested. Documenting supply chain risks by combining ingredient and supplier risks into a combined metric to determine an overall material risk score was also illustrated. Operators can use this risk score to document their decisions about suppliers and their products and include the score as part of their overall preventive controls plan. The presenter concluded his presentation by stating that compliance with FSMA rules would lead to industries’ reduction of their brand risk (3).

The voice of the stakeholder in the new regulatory framework

Dr. Michelle Danyluk is the Principal Investigator for the Southern Center for Training, Education, Extension, Outreach and Technical Assistance to Enhance Produce Safety. This center, a part of the Institute of Food and Agricultural Sciences at the University of Florida, works to build a collaborative infrastructure in the southern region of the country to support FSMA training, especially for the produce industry. Her presentation reported on the stakeholder perspective and commitment to FSMA rules for produce safety, foreign supplier verification, and third-party accreditation.

To obtain data relative to stakeholder perspectives and commitments, Dr. Danyluk and her team identified regional stakeholders and provided them with specific technical assistance and FSMA training information. By doing so, the Southern Center hoped to forge strong partnerships within the region to improve capacity building and to increase the potential for future FSMA trainings. A questionnaire was administered to stakeholders to identify their perceptions of challenges to FSMA compliance. The results of the questionnaire identified challenges as cost of compliance, current knowledge of FSMA, and participation in FSMA trainings. It also addressed producers’ perceptions of, and attitudes toward, the FSMA and the availability of information about the FSMA. About 80 percent of the stakeholders surveyed were industry members, while the remaining 20 percent consisted of extension agents, specialists and consultants (2).

Of those responding to the questionnaire, one-third had attended no food safety training during the previous year. Another 49 percent had attended one or two trainings. Respondents noted that their most common perceived challenges to FSMA compliance were producers’ current knowledge of FSMA, as well as costs of compliance to producers. According to the presentation, 80 percent of respondents said that extension’s ability to provide training on FSMA was not a significant challenge.

Dr. Danyluk and her team also used the questionnaire to understand challenges associated with the FSMA within

each part of the produce industry – primary (growers), secondary (wholesale/retail) and processors. Her data demonstrate that the greatest challenge for primary respondents was the cost of compliance (61 percent), while the greatest challenge for secondary and processing was their current knowledge about the FSMA (68 and 58 percent, respectively). All three sectors of the produce industry indicated extension's ability to provide training as the least significant challenge.

With these things in mind, a qualitative evaluation was conducted with participants after they attended a Food Safety Preventive Controls Alliance (FSPCA) training at the Southern Center. As a result of this training, respondents indicated they possessed the competencies needed to conduct their own FSPCA trainings, and their knowledge of FSMA was improved. However, Dr. Danyluk reported that some respondents noted "implementation difficulties may exist in supply chain requirements, such as accountability at different points in the supply chain" and suggested the use of real-world examples in future FSPCA trainings (2).

CONCLUSION

This roundtable was intended to identify and illustrate both the challenges and opportunities associated with

FSMA implementation that have been encountered by food safety personnel in governmental agencies, academia, and industry. FSMA represents a legislative opportunity to build a preventive system to control foodborne illnesses and reduce their public health impact. Collaboration between academicians, the food industry, government, and consumers is required to maximize the positive impact that is intended by FSMA. In addition to sharing information and providing opportunity for discussion, this symposium offered an occasion for networking and building relationships, which is critical for ensuring that all impacted by FSMA are equipped with the necessary resources to fulfill all legislative requirements.

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