

FSMA: Regulating Prevention, Detection and Response, and Imported Foods

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The U.S. Food Safety Modernization Act (FSMA) was signed into law on January 4, 2011 (www.fda.gov/Food/FoodSafety/FSMA/ucm247548.htm). There is little disagreement that the act was past due, as the complexity and increasing challenges of food production and distribution have accelerated rapidly in recent years. Highly publicized food-related disease outbreaks have caused pain and suffering for some consumers and a subsequent loss of faith in those who manufacture and oversee the safety assurance of the foods we eat.

For the majority of today's consumers, a trip to the local grocery store is anything but local. Fresh produce of all types is available year-round, sourcing of the ingredients used in many processed foods is a multinational effort, and comingling of foods as they are shipped from farm to retailers located around the world can mean that contamination from one location is spread to many. Use of the term complicated would be a gross understatement in trying to explain the complexities associated with the sourcing and distribution chain of foods sold in today's markets.

The supply chain of foods consumed in the United States encompasses every stage of production from farmers (e.g., cereal grains, blueberries, oranges, peanuts, tree nuts, etc.), miners (e.g., salt, chemical leavening agents, etc.), and chemists (e.g., enzymes, vitamins, etc.) to consumers. Procurers and brokers source and mingle ingredients to maximize availability and minimize costs, while distributors transport goods by truck (farm, multiuse semi, and company-owned dedicated trucks), railcar, maritime shipping, and

air and sometimes even by oxen-hauled trailers used to convey fresh products from farms to more central shipping or processing locations in remote locations such as rural China. Storage and warehousing facilities are used to collect and store a wide variety of goods, including refrigerated, dry, liquid, bulk, and bagged products. Production encompasses intermediate ingredient production for further processing, production of ingredients for consumer use, and foods that are ready for the consumer to prepare or eat as-is. Packaging materials vary from 1,000 lb totes to 3 oz single-serving packets and pizza delivery boxes. Retailers stock an array of products (e.g., dry goods, prepared deli-style meals, etc.). Finally, the food product is purchased and eaten by the consumer. This list is not exhaustive, and there is a temptation not to enter into this chasm of information, but to understand the challenge the FDA is facing and why FSMA is so complex, one must first have at least a rudimentary understanding of what the term "food industry" entails.

As the FDA contemplates better ways to ensure the safety of the foods we eat, the ways in which a food product may become unsafe to eat must be considered. At a very simplistic level, although the distinction is critically important, food can be contaminated accidentally or intentionally. In both cases, the reasons behind the contamination must be studied, evaluated, and managed to eliminate a recurrence. The focus on this distinction and its addition to the way in which the FDA views food safety management requirements is an important addition to FDA regulations introduced by FSMA. Following the signing of FSMA into law, FDA Commissioner Margaret Hamburg wrote a response



stating her perspective on what the major impact of the new regulation will be:

- Issuing recalls will no longer be voluntary
- More frequent inspection of food facilities will be conducted based on risk
- Significant enhancements will be made to inspection of foods imported into the United States and to the ability to prevent foods from entering the country if inspection is refused
- Food production facilities will be required to have written plans documenting preventive control methods
- Science-based standards will be established for the safe production and harvest of fruits and vegetables
- The role of small businesses and farms will be respected by providing flexibility in regulations, such as exemptions for small farms that sell directly to consumers

Hamburg's list hits on some of the major highlights of the program contained in FSMA's three main categories: prevention, detection and response, and imported foods.

Prevention

Title I of FSMA, "Improving Capacity to Prevent Food Safety Problems," focuses on prevention. Clearly, prevention is the

first priority and the most sought after element of any food safety program. This is true from the perspective of the company working to protect its customers and brand, as well as the regulator defining ways to ensure the safety of the consumer. FSMA contains 16 sections under Title I, 5 of which were implemented upon the enactment of FSMA or within the first six months. Of these five sections, those that have the most wide-ranging impact on the cereal grains-based industry include

Section 101 Inspection of Records.

The FDA is given additional access to all records if it is believed that there is a reasonable probability that the use of or exposure to an article of food related to the manufacturing, processing, packaging, transportation, distribution, receipt, holding, or importation of an article of food will cause serious adverse health consequences or death in humans or animals. The key change from past regulation is that historically the FDA could only access records for a specific food if it had reason to believe the food was adulterated.

Section 102 Registration of Food Facilities. Food facilities are now required to register with the FDA biannually on even-numbered years. Registration is a requirement of doing business. Additionally, the FDA has the authority to suspend registration and ultimately stop a facility from producing food until corrective action has been taken and registration has been reinstated.

Section 107 Authority to Collect Fees.

The FDA has been given the ability to charge fees for facilities that require reinspections due to nonconformance with FSMA requirements and follow-up on corrective actions identified in initial inspections. Also included in the purview of fee requirements are peripheral activities, including administrative costs for importers participating in the voluntary qualified importer program. These fees will be charged for both domestic and foreign facilities. The FDA will publish fee schedules 60 days prior to the beginning of each year.

One of the activities that is central in preventing food-related hazards is the mandated requirement for hazard analysis and preventive controls (HAPC). For years the food industry has policed itself by requiring suppliers to have and devel-

op their own internal hazard analysis and critical control programs (HACCP). With the implementation of FSMA, a slight twist on the theme is now required. The requirement is similar in many respects to HACCP; however, elements required for monitoring the source of contamination have expanded to include areas not previously noted.

Section 103 Hazard Analysis and Risk-based Preventive Controls (HAPC).

A facility must identify and evaluate all known or reasonably foreseeable hazards that may be associated with the facility (including biological, chemical, physical, and radiological hazards, as well as natural toxins, pesticides, drug residues, decomposition, parasites, allergens, and unapproved food and color additives) and prepare a written hazard analysis. The facility must also identify and implement preventive controls (including critical control points, if any) to provide assurances that 1) hazards identified in the hazard analysis are significantly minimized or prevented; 2) hazards that may be intentionally introduced are significantly minimized or prevented; and 3) the food manufactured, processed, packed, or held by the facility will not be adulterated or misbranded. The FDA is tasked with the development of a science-based standard for conducting a hazard analysis, implementing preventive controls, and documenting implementation of preventive controls. A proposed rule for this section is due in July 2012. Preventive controls may include

- Sanitation procedures for food contact surfaces and utensils
- Supervisor, manager, and employee hygiene training
- An environmental monitoring program to verify the effectiveness of pathogen controls in processes where food is exposed to a potential contaminant in the environment
- A food allergen control program
- A recall plan
- Current Good Manufacturing Practices (GMP)
- Supplier verification activities related to food safety

Development of these programs is important to the overall sustainability of HAPC programs. All documentation established for conformance with this

section of FSMA must be made available to the FDA during inspections. The FDA is tasked with establishing science-based standards to be used in conducting hazard analyses.

Facilities must not lose sight of the critical need for “on the floor” inspections to maintain control over the production process, including internal inspections. Development and maintenance of records have been found to help improve food safety systems. However, these activities must be teamed with physical inspections of the production area to ensure control of potential product contamination.

To stay current with advances in science and improvements in industry best practices, the FDA is required to review and evaluate toxicological and epidemiological studies every two years to determine changes and identify new or significant food-borne contaminants. This requirement is outlined in Section 104, and information developed in these reviews will be used as the basis of new regulations or guidance documents and/or contaminant-specific performance standards.

Section 106 Protection Against Intentional Adulteration. This section specifically addresses the element of intentional contamination or adulteration and requires the “FDA to conduct a vulnerability assessment of the food system and determine the types of mitigation strategies necessary to protect against intentional adulteration of food.” Elements of this focus are also described in Section 108 National Agriculture and Food Defense Strategy and Section 109 Food and Agriculture Coordinating Councils.

These sections require that at least every four years the FDA and U.S. Department of Agriculture, in coordination with the U.S. Department of Homeland Security, develop a national agricultural food defense strategy and make it available on the Internet.

Three other sections also impact cereals producers: Section 111 Sanitary Transportation of Food, Section 113 New Dietary Ingredients, and Section 112 Food Allergy and Anaphylaxis Voluntary Guidelines. Under Section 111 the FDA is required to conduct a study on food transportation and examine the unique needs of the industry, from commercial transportation to rural and frontier areas. Allergens (Section 112) are clearly included in the HAPC programs; however,

oversight through FSMA has extended to voluntary guidelines for use in classrooms and cafeterias.

Detection and Response

Detection and response is the second major category referred to in FSMA under Title II, “Improving Capacity to Detect and Respond to Food Safety Problems.” This section of FSMA focuses on activities that will help authorities to identify and manage food safety-related issues before they cause harm to humans. One of the most commonly used methods of detecting problems is inspections.

Section 201 Targeting of Inspection Resources for Domestic Facilities, Foreign Facilities, and Ports of Entry, Annual Report. The FDA requires an increase in the number of inspections in facilities in the United States and internationally. In this section, it is mandated that the FDA will identify “high risk” facilities and allocate resources in inspections according to the level of risk. A high-risk profile can be based on several factors that may include the known safety risks of the food produced, packaged, or held in the facility or the facility’s compliance history, including outbreaks, and other potential safety factors. Due to the potential for contamination of cereal grains during harvest and storage, there remains the possibility of grains being listed as high-risk foods if the product containing the raw material could be eaten without further kill-step processing.

The required frequency of inspection by the FDA or an FDA designee is once in the first five years for high-risk products in domestic food facilities and once every three years thereafter. For food facilities that are not high risk, the inspection rate is once in the first seven years and then every five years thereafter. For international facilities importing food into the United States, the FDA is required to audit 600 foreign facilities and must double the number of inspections every year compared with the previous year for the next five years.

With the current funding situation and little potential for future funding increases for this activity, it is highly unlikely that the FDA will have the resources needed to meet these requirements. For domestic facilities, the FDA will likely be looking for help at the state and local levels. For imported products, the FDA is in the

midst of discussing the use of third-party certification, as well as the designation of approved government programs, to fulfill the audit requirements outlined in FSMA. This process is ongoing, and third-party auditing organizations such as AIB, citizen support groups, and food industry representatives are working with the FDA to identify auditing activities that would help provide the level of assurance that international processors sending food into the United States follow practices that are in line with U.S. requirements.

Section 202 Laboratory Accreditation for Analysis of Foods. Laboratories that perform product and environmental testing must be accredited under the new law. The FDA will provide model standards that include sampling, analytical procedures, and training for those performing the tests. Environmental testing is clearly on the rise and will likely be a required activity and be included in records that provide the FDA with information during onsite inspections.

Section 204 Enhancing Tracking and Tracing of Food and Recordkeeping. FSMA provides the FDA with enhanced access to records based on a facility’s ability to trace products and ingredients. Improvements in the effectiveness of tracing materials, the cost impact of implementing this activity, inclusion of new potentially useful technologies, and identification of those materials considered high risk are being reviewed, and a process will be tested in pilot studies over the next several months.

A pilot study has been initiated in cooperation with IFT (Institute of Food Technologists). IFT will conduct one pilot study in coordination with the produce sector to “explore and demonstrate” tracking and tracing of selected fruits and vegetables and mock tracebacks with the goal of identifying a common source in the supply chain. The intent is to include various food safety-based organizations for input that will help to cover a variety of interests.

Section 206 Mandatory Recall Authority. This section is a very highly touted addition to the act and a good add. In reality, however, it will probably result in little change in current industry activities. Although the FDA

did not have the authority in the past to require a company to recall products that were misbranded or adulterated or that would cause serious adverse health consequences or death, there is little evidence that if an issue is identified a company would not immediately recall the product on its own. The new law does, however, ensure the FDA has the authority to force a product recall if it deems a product to be potentially harmful to consumers.

Section 207 Administrative Detention of Food. This section significantly expands the FDA’s power to detain foods. Under current law, the FDA must have “credible evidence or information” that an article of food “presents a threat of serious adverse health consequences or death to humans or animals” in order to detain a food. The new regulation gives the FDA the authority to detain a food if the FDA has “reason to believe” that the food is adulterated or misbranded. The difference between “credible evidence” and “reason to believe” is substantial and will impact the authority the FDA has over inspected food products.

Imported Foods

Title III, “A New Paradigm for Importers,” of FSMA deals with the third major category of the act—imported foods.

Section 301 Foreign Supplier Verification Program. This section places the burden of safety assurance squarely on the importer. The FDA has been tasked with issuing guidance to help in development of verification programs for use by importers. It is now the responsibility of importers to assure that they are bringing food to market that has been produced, packaged, and held under conditions that are in compliance with U.S. food laws. Additionally, importers must be fully aware of and understand the safety of the supply chain to its point of purchase. The impact of this section can be linked to some extent to the provision in Section 302.

Section 302 Voluntary Qualified Importer Program. This section provides importers with the means to speed the process of assuring import safety. The FDA is again tasked with establishing a program based on requirements that have yet to be fully outlined. It is anticipated that to comply importers

must show that an imported product was produced in a facility that has been certified by an accredited third-party auditor. "Certification" has not yet been defined, but it is anticipated that the requirements will encompass GMP, prerequisites, HACCP, and industry best practices. This will be a fee-driven program and may have far-reaching implications for importers and third-party auditors.

Section 303 Authority to Require Import Certifications for Food and Section 307 Accreditation of Third-Party Auditors. Both sections deal with identification of what "certification" means in the eyes of the FDA, how that activity will be carried out, and what process will be put in place to establish requirements for FDA-designated third-party auditors.

Timelines placed on the FDA by FSMA generally have been followed and completed to date. The FDA has issued interim final rules on criteria for administrative detention and on prior notice of imported food. Additionally, the FDA has held many stakeholder meetings to gather information on ideas, challenges, and best practices pertaining to major sections of FSMA.

Some of the timelines will be difficult to meet, however. Michael Landa, director of the FDA Center for Food Safety and Applied Nutrition, outlined some of the potential delays in a recent presentation. Even though the FDA completed proposed rules for several areas, including Section 103 Preventive Controls and Section 301 Foreign Supplier Verification Program, Landa's comments indicate that some areas may take several months

longer than required by FSMA due to pending review by the Office of Management and Budget (OMB). It is difficult to establish a timeline based on OMB's ability to respond.

Conclusions

Although there are movements around the world encouraging people to consume foods produced close to where they live, to consume foods produced and handled using more environmentally friendly methods, or to simply be aware of where their food comes from, the reality is that we will continue to experience the complexities involved in accessing ingredients and producing and shipping foods described here and will continue to encounter food safety-related complications and challenges not yet identified. The food industry has made major changes in recent years to improve the culture of food safety within its organizations through greater focus on education, expanded systems approaches, and a real shift in food safety behavior from the top down.

FSMA was established to improve governmental oversight of this complex system and help provide assurance that the foods eaten by U.S. consumers are safe. The challenge to the FDA to review and evaluate current practices and move toward improved programs has been met in many instances, and the agency seems to be moving quickly to complete its charge. Clearly, some of the hurdles inherent in government bureaucracy are slowing progress, but the ultimate focus on advancing food safety is one that the industry and regulatory bodies must continue to perfect.

More information about the Food Safety Modernization Act is available at www.aibonline.org/knowledgecenter.html.



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