THE FDA FOOD SAFETY MODERNIZATION ACT: EXPANDING THE GOVERNMENT'S ABILITY TO PREVENT, DETECT, AND RESPOND TO FOODBORNE ILLNESS OUTBREAKS IN THE UNITED STATES

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On January 4, 2011, President Obama signed into law the FDA Food Safety Modernization Act ("FSMA"). This law is the first significant overhaul of the Federal Food, Drug, and Cosmetic Act ("FFDCA"), which Congress passed in 1938. The FSMA concentrates on three major goals for the nation's food safety program. The first goal is preventing the occurrence of national food hazards. The second goal is improving the detection of foodborne illness outbreaks and the government's response to such outbreaks when they do occur. The final goal is strengthening food safety requirements for imported foods. In order to effectuate these goals, the FSMA places new requirements on, and grants new authority to, the Department of Health and Human Services ("HHS") and the Food and Drug Administration ("FDA"). The legislation does not address the safety of food items regulated by the Department of Agriculture ("USDA"), such as meat, poultry, or processed eggs, which are subject to even more rigorous inspection and oversight than foods regulated by the FDA.

The FSMA had a tumultuous trip through Congress before it was passed. The legislation originated in the Senate, which initiated the food safety bill in its current form in November 2010. The Senate-originated bill, however, included fee provisions that violated the Origination Clause in the United States Constitution. To overcome this constitutional roadblock, the House attached the Senate's version of the food safety legislation to an omnibus appropriations bill. The Senate, however, refused to take up the omnibus bill, stalling the food safety legislation for weeks. Determined to pass the legislation, on December 19, 2010, the Senate amended a House shell bill to add the language of the Senate's food safety bill and sent the bill back to the House. The House voted to accept the changes to the House shell bill on December 21, 2010, finally clearing the bill for the White House.

Although the FSMA has now been signed into law, the legislation's efficacy is still uncertain. The Congressional Budget Office estimates that enforcement of the FSMA would require $1.4 billion annually, yet the FSMA does not include the required funding. Given the current budgetary issues, it is uncertain whether this Congress will allocate the funding necessary to implement the new law fully.

TITLE ONE: PREVENTING THE OCCURRENCE OF NATIONAL FOOD HAZARDS

Title One of the FSMA significantly expands the power of the government to establish preventive controls for national food safety. Perhaps the most significant preventive control provided in the legislation is the hazard analysis and control program. Under this program, owners, operators, or agents in charge of food facilities that manufacture, process, package, and handle food, such as factories and warehouses, are required to: (1) evaluate the hazards in their operations; (2) implement and monitor effective measures to prevent contamination; (3) reanalyze the hazards when necessary; and (4) have a plan in place to take corrective action if preventive controls have not been properly implemented or are found to be ineffective. Title One describes such hazards as "biological, chemical, physical, and radiological hazards, natural toxins, pesticides, drug residues, decomposition, parasites, allergens, and unapproved food and color additives," as well as those hazards "that occur naturally, or may be unintentionally introduced," and those "that may be intentionally introduced, including by acts of terrorism."

A hazard analysis and control program can be a formidable undertaking. For example, the FDA's Hazard Analysis Critical Control Points Program for Seafood ("Seafood HACCP") consists of more than 350 pages of detailed requirements and needed a substantial "mid-course correction."[1]

The requirements introduced by the hazard analysis and control program do not apply to numerous entities. For example, the following entities are exempt from the program:

- Farms
- Restaurants
- Other retail food establishments
- Nonprofit food establishments in which food is prepared for or served directly to the consumer
- Fishing vessels
- Entities that are determined to be "very small business[es]"
- Facilities that have average annual sales of less than $500,000
- Facilities that are required to comply with the Seafood HACCP, the Juice HACCP, and/or the government's standards for Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers

Title One places numerous requirements on HHS in an effort to prevent national food safety problems. For example, Title One requires the Secretary of HHS, in coordination with the Secretary of Agriculture, to review and evaluate relevant health data and other relevant information to determine the most significant foodborne contaminants. On the basis of this review and evaluation, the Secretary of HHS must issue contaminant-specific and science-based guidance documents prescribing action levels or regulations, when appropriate, to reduce the risk of serious illness or death, prevent food adulteration, or prevent the spread of communicable disease.

In response to the produce-related outbreaks that have occurred in recent years, Title One also requires the Secretary of HHS, in coordination with the Secretary of Agriculture and in consultation with the Secretary of Homeland Security, to publish a notice of proposed rulemaking setting minimum science-based standards for the produce industry. Intended to facilitate the safe production and harvesting of certain fruits and vegetables, these standards have been established for specific mixes or categories of foods comprising raw agricultural commodities and have been determined by the Secretary to minimize the risk of serious adverse health consequences or death.

The new legislation also requires the Secretary of HHS, in consultation with the Secretary of Education, to establish guidelines to be used on a voluntary basis to manage the risk of food allergies and anaphylaxis in schools and early-childhood education programs. The guidelines would address: (1) parental obligations to notify schools or early-childhood education programs of children's food allergies or risks of anaphylaxis; (2) food allergy education and management training of personnel in schools and early-childhood education programs; and (3) other elements that the Secretary determines necessary for the management of food allergies and anaphylaxis in schools and early-childhood education programs.

Title One further requires the Secretary of HHS to promulgate regulations to protect against the intentional adulteration of food. In doing so, the Secretary of HHS, in coordination with the Secretary of Homeland Security and in consultation with the Secretary of Agriculture, must conduct a vulnerability assessment of the food system; consider the uncertainties, risks, costs, and benefits associated with guarding food against intentional adulteration at vulnerable points; and determine the types of science-based mitigation strategies that are necessary to protect against adulteration. The regulations must establish appropriate mitigation strategies to protect food in the supply chain at specific vulnerable points and specify when implementation is required.

Finally, the new legislation requires the Secretary of HHS and the Secretary of Agriculture, in coordination with the Secretary of Homeland Security, to prepare a National Agriculture and Food Defense Strategy. In general, the National Agriculture and Food Defense Strategy must include a description of the process to be used by the various departments to achieve the following goals: (1) enhancement of the agriculture and food system; (2) improvement of the system's detection capabilities; (3) assurance of an efficient response to agriculture and food emergencies; and (4) security of agriculture and food production after an agriculture or food emergency. The National Agriculture and Food Defense Strategy must be made available to the relevant committees of Congress and to the public via the web sites maintained by HHS and the USDA.

Title One also gives the Secretary of HHS critical enforcement tools to prevent national food safety problems. First, the new legislation delineates a procedure by which the Secretary of HHS can gain access to records relating to an article of food that the Secretary reasonably believes will have serious adverse health consequences for humans or animals. Second, Title One provides the Secretary of HHS with the power to suspend the registration of a food facility if the Secretary determines that the facility packs, receives, or holds food that has a reasonable probability of having adverse health consequences for humans or animals and the facility was responsible for, and knew or should have known of, the potential hazard. Such a suspension would prohibit the facility from introducing food into interstate or intrastate commerce in the United States and from importing food into, or exporting food from, the United States. Finally, under the new legislation, the Secretary of HHS can assess and collect fees related to food facility reinspection, food recalls, the Voluntary Qualified Importer Program, and importer reinspection.

TITLE TWO: IMPROVING THE DETECTION OF FOODBORNE ILLNESS OUTBREAKS AND THE RESPONSE TO SUCH OUTBREAKS

Title Two of the FSMA significantly expands the power of the government to detect and respond to foodborne illness outbreaks. First, the legislation increases the FDA's inspection capabilities by requiring the number of inspections to be determined according to the level of risk posed by the facility. For example, Title Two requires the FDA to inspect domestic high-risk facilities at least once within the five-year period following the enactment of the law and at least every three years thereafter. In contrast, for domestic non-high-risk facilities, an inspection must be conducted at least once within the seven-year period following the enactment of the law and at least every five years thereafter. For foreign facilities, twice the number of inspections conducted during the previous year must be conducted each year for five years, beginning in 2011. Inspections of at least 600 foreign facilities must be conducted within the year following the enactment of the law.

Whether a domestic facility is determined to be high-risk under Title Two will depend on a number of factors, including but not limited to: (1) the known safety risks of the food manufactured, processed, packed, or held in the facility; (2) the compliance history at the facility; (3) the rigor and effectiveness of the facility's hazard analysis and risk-based preventive controls; (4) whether the food at the facility meets the criteria for a priority inspection under § 801(h)(1) of the FFDCA; (5) whether the food and/or the facility has received certification under § 801(q) and/or § 806 of the FFDCA; and (6) any other criteria deemed necessary and appropriate by the Secretary of HHS.

Title Two specifically addresses the need for coordinated and integrated laboratory methods to detect contaminants around the country. The new legislation requires the Secretary of HHS to establish a program for the testing of food by accredited laboratories, as well as a publicly available registry of accredited laboratories and accreditation bodies recognized by the Secretary. Also, as a condition of recognition or accreditation, recognized accredited bodies are required to report to the Secretary any changes that might affect accreditation.

In addition, the Secretary of Homeland Security, in conjunction with the Secretary of HHS, the Secretary of Agriculture, the Secretary of Commerce, and the Administrator of the Environmental Protection Agency, is required to establish and maintain an agreement whereby registered laboratories can decide on common laboratory methods in order to reduce the time required to detect and respond to foodborne illness outbreaks; facilitate the sharing of knowledge and information related to health and agriculture; and identify means by which the laboratories can work cooperatively.

Under Title Two, the Secretary of HHS is also tasked with improving the tracking of food as it flows through the supply chain. As a consequence, the legislation requires HHS to establish pilot projects to explore and evaluate methods to rapidly and effectively identify recipients of food, in order to prevent or mitigate a foodborne illness outbreak and to address credible threats of adverse health consequences or death as a result of the adulteration or misbranding of such food.

The pilot projects must reflect the diversity of the food supply and include at least three different types of foods that have been the subject of significant outbreaks during the five years preceding the enactment of the law. The pilot projects must be selected in order to develop and demonstrate methods for the rapid and effective tracing of food in a manner that is practicable for facilities of various sizes; develop and demonstrate technologies that enhance the tracking and

tracing of food; and assist in the promulgation of additional recordkeeping requirements for high-risk foods. In addition, the Secretary of HHS, in consultation with the Secretary of Agriculture, is required to establish a product-tracing system within the FDA in order to effectively and rapidly track and trace food that is in the United States or offered for import into the United States.

Title Two provides for states, localities, and tribes to work with the federal government in a coordinated fashion to prevent and respond to foodborne illness outbreaks; recommendations include training, grant programs, and the creation of resource centers. The law also requires foodborne illness surveillance systems to be established nationwide by the Secretary of HHS, acting through the Centers for Disease Control and Prevention, in order to improve the collection, analysis, reporting, and usefulness of data on foodborne illness. The Secretary of HHS must:

- Coordinate federal, state, and local foodborne illness surveillance systems.
- Facilitate the sharing of surveillance information among governmental agencies.
- Develop improved epidemiological tools for obtaining quality exposure data and microbiological methods for classifying cases.
- Improve the current capability to attribute a foodborne illness outbreak to a specific food.
- Publish current reports and findings from, and allow timely public access to, the surveillance systems.
- Facilitate scientific research by academic institutions.
- Integrate surveillance systems and data with other biosurveillance and public-health situational-awareness data.

Title Two gives the FDA mandatory recall authority for the first time. This recall authority allows the FDA to order a facility to stop distributing an article of food that has been adulterated or misbranded, threatening serious adverse health consequences, if the facility has refused to recall the product voluntarily and has had the opportunity for an expedited informal hearing. Once a food recall is in effect, the law requires the Secretary of HHS to publish a press release regarding the food recall in order to inform consumers and retailers. The press release shall, at the minimum, identify the food, the risk associated with the food, and similar foods that are not affected by the recall. Prior law, which allowed the FDA only to negotiate with businesses for voluntary recalls, sometimes impeded the expedited removal of contaminated food from the market.

TITLE THREE: STRENGTHENING FOOD SAFETY REQUIREMENTS FOR IMPORTED FOODS

Title Three significantly enhances the FDA's ability to oversee the millions of food products imported into the United States each year. Under Title Three, importers must verify, and sometimes even certify, the safety of food from their suppliers to ensure that the food meets the applicable requirements of the legislation. Verification activities may include monitoring records for shipment, lot-by-lot certification of compliance, annual on-site inspections, checking the hazard analysis and risk-based preventive control plan of the foreign supplier, and periodically testing and sampling shipments.

Title Three emphasizes the importance of direct collaboration with foreign governments to assess the safety of imported foods. First, the new legislation gives the U.S. government the power to aid foreign governments in improving their food safety programs. This aid is through government-to-government support and U.S. recognition of bodies that accredit third-party auditors of foreign food facilities. Second, Title Three gives the Secretary of HHS the ability to enter into arrangements and agreements with foreign governments to facilitate the inspection of registered foreign facilities, factories, warehouses, and other establishments. However, if U.S. inspectors or other individuals designated by the Secretary of HHS are refused the right to inspect such a foreign facility, the FSMA requires food from that foreign facility to be refused admission into the United States.

MISCELLANEOUS PROVISIONS IN THE FSMA

Numerous provisions in the FSMA advance goals other than those described in the preceding three sections. For example, the FSMA contains a food safety whistleblower provision, which prohibits discrimination against and discharge of an employee who identifies, reports, or refuses to participate in a violation of the above regulations by an entity involved in the manufacturing, processing, packing, transporting, distribution, reception, holding, or importation of food. While such provisions are intended to enhance compliance, they can lead to retaliatory reporting by disgruntled employees and hamper employment relations.

The FSMA exempts small businesses and agricultural producers from much of the new regulatory scheme. For example, "very small businesses" and "small businesses"—to be defined by HHS in subsequent regulations—either will be exempt from many of the new requirements or will not have to begin complying with a number of the new regulations until one to two years after promulgation. In addition, for a number of provisions, the Secretary of HHS is required to issue a guide to help small entities comply with the new requirements.

Similarly, farms and other establishments that sell food directly to consumers, such as roadside stands, farmers' markets, and participants in community-supported agricultural programs, are granted certain exemptions and flexibilities under the FSMA. For example, as a result of what is known as the Tester-Hagan Amendment, farms that make at least half of their profits from direct-to-consumer sales and earn $500,000 a year or less (adjusted for inflation) are exempt from most of the new regulations by the FSMA. The Secretary of HHS, however, has the ability to revoke these exemptions if the farm or small business is involved in an outbreak.

Some farms are also exempt from the recordkeeping requirements intended to help the government trace food as it flows through the supply chain. Food packaged and produced on a farm has only minimal recordkeeping requirements if "the packaging of the food maintains the integrity of the product and prevents subsequent contamination or adulteration" and if the labeling of the product includes complete business-contact information for the farm. If a farm sells food directly to a consumer, it does not have to maintain any records. If a farm sells food directly to a grocery store, the store must maintain records documenting that farm. In this context, "sale of food" occurs when "food is produced on a farm" and "sale is made by the owner, operator, or agent in charge."

CONCLUSION

The FSMA contemplates great strides in preventing, detecting, and responding to potential foodborne illness outbreaks in the United States. The legislation significantly expands the powers of the U.S. government to regulate the food industry, allowing the FDA to create new food safety standards, issue mandatory food recalls, and impose severe penalties on those entities that fail to comply with the new regulations. The FSMA also significantly enhances the FDA's ability to oversee the millions of food products coming into the United States from other countries each year.

In addition, the FSMA imposes substantial new financial burdens and regulatory uncertainties on larger food producers while vaguely referring to new requirements and standards that will not be defined until the FDA issues the regulations required under the new law. Therefore, producers may not know the true extent of their responsibilities and costs under the new law until the regulations are finally promulgated—a matter of months or even years. Moreover, timely implementation and enforcement depend upon whether Congress provides the funding necessary to achieve the ambitious programs envisioned by the FSMA. ■

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[1] For more information on the Seafood HACCP, see the following web site maintained by the FDA: http://www.fda.gov/Food/FoodSafety/HazardAnalysisCriticalControlPointsHACCP/SeafoodHACCP/default.htm (web site last visited May 20, 2011).