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The FDA Food Safety Modernization Act: What You Need to Know Now

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The FDA Food Safety Modernization Act (FSMA), which became law on January 4, 2011, makes significant amendments to the Federal Food, Drug & Cosmetic Act (FDCA) which are designed to strengthen food safety protections in ways that help minimize the risk that unsafe food will enter the U.S. market, and expedite the removal of food that is discovered to be unsafe after it has entered the market. The new FSMA requirements will have far-reaching implications for virtually all domestic and foreign companies that produce, manufacture, transport, import, or market food that is destined for the U.S. market.

The FSMA significantly expands FDA's authority to regulate the conditions under which food products are produced, manufactured, transported, imported, and marketed in the United States. The FSMA also expands the scope of FDA's discretion to prescribe standards, monitoring and testing requirements, and recordkeeping practices documenting the effectiveness of company practices in controlling food safety risks and substantiating compliance with FDA requirements. In addition, the FSMA expands the conditions under which FDA has access to company records containing sensitive product-related information, and publicize agency findings suggesting that particular products and companies may be linked to foodborne disease outbreaks or other public health risks.

The expansion of FDA authority in these areas is expected to increase the odds that regulatory compliance and product safety missteps will be exposed and result in adverse FDA findings, enforcement, publicity, litigation, and related liability. In addition, the FSMA raises important liability issues for responsible companies with a solid track record concerning FDCA compliance and food safety assurance. Like the previous amendments to the food-related provisions of the FDCA that have been enacted in the period since September 11, 2001, the FSMA expands FDA authority and enforcement discretion to promote food safety and food defense, but gives little attention to the need for clear and enforceable procedural safeguards to ensure that the agency is equipped to exercise its new authorities in ways that are lawful and appropriate, and at the same time do not put the legitimate legal and business interests of the affected companies or their employees in jeopardy.[1]

Beginning in 2011 and continuing over the next two years, the FSMA requires FDA to finish much of the work that will be required to implement and enforce the new law, and meet a series of interim deadlines as it completes each phase of the work. Many of the FSMA requirements will be fleshed out through new guidance documents and regulations, which FDA will publish for public comment. Affected companies are advised to evaluate the particular regulatory compliance burdens and liability risk management challenges they could confront as a result of the new FSMA requirements and to be engaged in FDA's program for implementing FSMA by bringing issues and concerns to the agency's attention early, including by responding to FDA requests for comment on proposed guidance documents and regulations.

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[1] Sarah Roller and Raqiyyah Pippins, *FDA's Expanding Postmarket Authority to Monitor and Publicize Food and Consumer Health Product Risks: The Need for Procedural Safeguards to Reduce "Transparency" Policy Harms in the Post-9/11 Regulatory Environment,* 64 Food and Drug Law Journal 3 (2009).

Under the FSMA, FDA has broad authority to:

- require companies to maintain records documenting the potential food safety hazards presented by a food and ongoing monitoring data which exposes whether the company has adopted an effective system for controlling these hazards on an ongoing basis;

- access and copy company records when investigating potential public health risks that may be linked to food products;

- order companies to suspend production and detain products that may pose a risk to public health;

- order companies to recall products from the market;

- publicize FDA findings that particular products and companies may be linked to potential food safety hazards.

In view of these issues, affected companies are advised to promptly evaluate the implications of the new FSMA requirements for existing regulatory compliance programs, and the legal and business risks associated with potential noncompliance under the new law in order to identify and characterize issues that should be considered by FDA and the Congress as guidelines, regulations, and enforcement policies implementing the FSMA are developed.

What specific actions can companies take now?

- Evaluate any current hazard analysis plans with respect to hazards, critical control points, auditing and documentation.

- Companies that do not have a hazard analysis plan in place should start evaluating the hazards present and prepare to implement a written plan. This may involve retention of outside consultants to fully evaluate the potential risks presented at a particular facility or designation of certain employees who are in charge of food safety plans at a particular facility.

- Evaluate records and capabilities regarding product tracing. Determine whether it is possible to trace forward and trace back each product movement.

- Determine whether facility records are inspection-ready.

- Companies that are importers should determine whether any current supplier qualification and audit methods are being used and whether they are sufficient. Also, determine if the product or ingredient testing methods are adequate to meet certification requirements.

- Be aware of the FDA's upcoming rulemaking activities and participate in those activities.

In the advisory below, we discuss the following changes to existing law:

- Hazard Analysis Requirements
- FDA Access to Records
- Facility Registration Requirements
- Safety Standards for Fresh Fruits and Vegetables
- Product Tracing
- Facility Inspections
- Reportable Food Registry
- Mandatory Recall Authority
- Requirements for Importers
- Exemptions for Small and Very Small Businesses

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I. Improving Capacity to Prevent Food Safety Problems

The new law includes several provisions designed to prevent and reduce the risk of food safety problems throughout the food production and supply chain. These provisions will affect food companies across numerous departments. Some of the main changes are highlighted below.

A. Companies Must Implement Written, Facility-Specific Hazard Analysis and Control Plans[2]

Owners, operators, or agents in charge of a facility where food is manufactured, packed, processed or held now will be required to create a written hazard analysis and prevention plan and to maintain documentation of the hazard analysis system for at least two years. Companies must ensure that their plans account for all reasonably foreseeable hazards, such as: "biological, chemical, physical and radiological hazards, natural toxins, pesticides, drug residues, decomposition, parasites, allergens, and unapproved food and color additives" and "…hazards that occur naturally, or may be unintentionally introduced". Additionally, companies' plans must account for "…hazards that may be intentionally introduced, including by acts of terrorism…."[3] Facility owners or operators will be required to produce the written plan upon FDA request and must update the plans whenever a significant change occurs that could introduce a new hazard or at least every three years. Not less than 18 months following enactment of the FSMA, the FDA is required to promulgate proposed regulations to establish science-based minimum standards for implementation of hazard analysis plans.

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2 H.R. 2751, 111th Cong. § 103 (2010).

3 *Id.* H.R. 2751 includes language recognizing that intentional hazards may not be foreseeable.

Facility owners or operators are also charged with developing and implementing preventive controls to minimize hazards, including hazards at critical control points to ensure that (1) hazards identified in the written hazard analysis will be minimized significantly or prevented and (2) that food manufactured, processed, packed or held in the facility will not be adulterated or misbranded in violation for the FDCA.

Additionally, the facilities must monitor preventive controls to verify their effectiveness and take corrective actions where the controls are found to be ineffective. Corrective actions include taking appropriate steps to reduce the likelihood of recurrence of preventive failure, ensuring that all affected food is evaluated for safety, and preventing any affected food from entering into commerce.

Facilities already subject to hazard analysis and critical control point (HACCP) requirements – such as facilities involved with seafood, juice, and low-acid canned foods in hermetically sealed containers (as to microbiological hazards only) – are exempt from the new requirements. Facilities that manufacture, process, pack, or hold dietary supplements also are exempt if such facilities are in compliance with FDA's 2007 Current Good Manufacturing Practices for dietary supplements. Further exemptions may be made for facilities that produce only animal feed or that store raw agricultural commodities intended for further processing prior to consumption.

Despite these exemptions, the seafood, juice and producers of low acid canned foods industry nevertheless may be affected by the new law. For example, the FSMA requires FDA to update its Fish and Fisheries Products Hazards and Control Guidance to account for changes in technology. FDA must do so within 180 days after enactment of the law. Changes to the Guidance will affect the Seafood HACCP and may impose new obligations to comply with in developing a Seafood HACCP. Those involved in the seafood industry will have to comply with the updated HACCP or be subject to the law's new evaluation standards. Further, nothing in the new law prevents the FDA from revising or enforcing existing HACCP requirements.

B. FDA Granted Expanded Access to Company Records to Determine Potential Health Risks

FSMA significantly expands FDA's access to view and copy records relating to an article of food where the FDA has a reasonable belief that an article of food is reasonably likely to cause serious adverse health consequences or death to humans or animals.[4] This provision applies to all records relating to the manufacture, processing, packing, distribution, receipt, or importation of such article by or on behalf of a person responsible for that article in any format and at any location. FDA also would have access to food safety plan information, including preventive controls, compliance and audit information.[5] This is a significant change from previous law, which allowed much more limited access to records.[6]

C. Companies Must Register Facilities Every Two Years; FDA Can Suspend Registration for Food Safety Violations

Companies are now required to renew their registration of domestic and foreign food facilities every two years.[7] The Secretary is required to provide an "abbreviated registration" process for those facilities whose information has not changed.[8]

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4 *Id*. at § 101.

5 *Id.* at § 204.

6 21 U.S.C. § 414.

7 *Id.* at § 102.

8 *Id*.

The Secretary may suspend the registration of facilities if the Secretary determines that food manufactured, processed, packed, received or held by a facility poses a reasonable probability of causing serious adverse health consequences or death to humans or animals and the facility (1) created, caused or was otherwise responsible for the probability; or (2) knew of or should have known of the probability; and (3) packed, received or held such food.[9]

Section 415 of the FDCA previously required only initial registration of domestic and foreign facilities. If registration information changes, for example, because of a change of ownership, current law requires an updated registration to be filed within 60 days.[10]

D. FDA to Promulgate New Safety Standards for Fruit and Vegetable Production and Harvesting[11]

Food companies involved in fruit and vegetable production and harvesting can expect new regulations designed to reduce the risks of foodborne illness associated with these products. The FSMA requires the FDA to examine food safety concerns associated with fruit and vegetable production and harvesting and then undertake rulemaking through notice and comment.

Within a year of passage, the law requires the FDA, in consultation with other agencies, to publish a proposed rule establishing science-based minimum standards pertaining to safe production and harvesting of those types of fruits and vegetables that FDA has determined pose a serious risk of adverse health consequences. The FDA regulations are required to account for the fruits, vegetables, and food safety incidents that have presented the most important risks to public health. Small produce operations may be exempt if it is determined that they do not pose a significant risk to public health. As part of the rulemaking process, the FDA is required to conduct at least three meetings in diverse geographic locations to solicit public comment.

Not later than one year after the close of the comment period for the proposed rule, the FDA would be required to propose a final rule that provides minimum science-based standards for those types of fruits and vegetables, including specific mixes or categories of fruits and vegetables, that are raw agricultural commodities, based on known safety risks, which may include a history of foodborne illness outbreaks. The final regulation must balance risk reduction with flexibility. For example, it must reduce the risk of serious harm or death and account for all types of unintentional and intentional hazards. Further, the final regulation must provide sufficient flexibility for small and very small businesses, which are required to comply on a rolling basis, provide for cooperation between state and local authorities, and provide a process for FDA to grant variances to foreign countries that import food into the U.S. At the same time, the regulation must not require a facility to hire a consultant or third party to assist with identifying requirements, implementation, or certification of compliance.

Not later than one year after enactment of the FSMA, the FDA is required to publish a guidance document regarding updated good agricultural practices and guidance for the safe production and harvesting of specific types of fresh produce. The FDA is also required to consult governmental and industry stakeholders as part of the guidance development process and conduct three meetings in diverse geographical areas to promote education and outreach.

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9 *Id*.

10 21 U.S.C. § 415.

11 H.R. 2751 at § 105.

E. FDA Granted Power to Assess and Collect New Fees

The FSMA also includes new fees to cover certain specific costs. They include the following:

- Recall fee for those facilities conducting recalls during the fiscal year: based on the cost of the recall to the FDA.[12]

- Facility re-inspection fee for facilities that do not pass an initial inspection: based on the cost of the re-inspection to the FDA.[13]

- User fees to fund the Qualified Importer Program[14] equivalent to the cost of the program to the FDA.[15]

F. FDA Required to Publish Guidance Regarding New Dietary Ingredients

Not later than 180 days after enactment of the FSMA, the FDA is required to publish guidance regarding when a dietary supplement ingredient is a new dietary ingredient, when the manufacturer or distributor should provide notice to the FDA, the evidence needed to document safety, and the appropriate methods for establishing the identity of the new dietary ingredient.[16] FDA also will be required to alert the Drug Enforcement Administration of any notices that are deemed inadequate because the substance for which the notice was made is an anabolic steroid or an analogue of an anabolic steroid. This provision follows a rash of FDA warning letters sent to companies selling products found to contain anabolic steroids or "designer" analogues meant to mimic anabolic steroids but evade drug laws.

II. Mitigating Food Safety Risks Presented by Products in the Marketplace

A. FDA Must Promulgate Product Tracing System for "High Risk" Foods[17]

Companies that produce foods that are deemed to be "high risk" will be subject to new record keeping requirements designed to facilitate tracing of foods through the production and supply chain as a means of identifying potential sources of contamination and thereby reducing the risks of foodborne illness. The tracing system will be limited to "high risk" foods and will not apply to "raw commingled agricultural commodities" defined as "any commodity that is combined or mixed after harvesting but before processing." Determination regarding whether a food is "high risk" would be based upon a number of factors, including the known safety risks of particular foods, the likelihood of microbiological or chemical contamination, the likelihood of foodborne illness and its likely severity.

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12 *Id.* at § 107.

13 *Id.*

14 FDA must establish a voluntary program for importers that provides for expedited review and entry of foods from participating importers. Eligibility is limited to, among other things, importers offering food from certified facilities.

15 *Id.*

16 *Id.* at § 113.

17 *Id*. at § 204.

To create this system, FDA must conduct pilot projects to test the traceability of both packaged food and raw agricultural commodities. The pilot projects must involve at least three different foods that were the subject of recent food outbreaks in the last five years. The FDA must also gather data on a number of areas, including: the costs and benefits associated with tracing technology, the feasibility/compatibility of such technology, and domestic and international tracing practices. Based upon these data, the FDA is required to establish a tracing system that can track and trace food offered for sale or imported into the U.S..

These new requirements also come with significant limitations, however. For example, the agency is limited in its determination of certain high risk foods. The new requirements will not apply to certain sales of farm foods, fishing vessels, raw commingled agricultural commodities, and the agency is not allowed to place restrictions on the commingling of food. Further, new requirements cannot require use of specific technologies, creation of duplicate records or a level of tracing detail beyond the immediate subsequent purchaser. In addition, the new requirements must be flexible enough to be suitable for businesses of varying sizes.

B. FDA Must Implement a Risk-Based Facility Inspection Program[18]

The FSMA requires the FDA to conduct facility inspections periodically, and to conduct inspections more frequently for facilities deemed "high risk." Domestic "high risk" facilities must be inspected once in the first five years after enactment and once every three years thereafter. "Non-high risk" facilities must be inspected every seven years after enactment and once every five years thereafter. The law requires inspection of foreign facilities. Specifically, the FDA must inspect 600 facilities in the first year following enactment and double the number of foreign inspections every year for five years thereafter.

Determination of whether a facility is high risk depends on a number of factors, including the known safety risks, compliance history of the facility, the rigor and effectiveness of the facility's hazard analysis plan, and, if imported food is involved, whether or not it is certified.

The FSMA also imposes certain new requirements relating to seafood safety. The FSMA allows for the FDA and other relevant agencies to enter into agreements to improve seafood safety. The scope of these potential agreements is quite broad, including testing of seafood imports, coordination of inspections, standardization of data to improve intra-agency cooperation, coordination to detect violations, and sharing of information regarding non-compliance both foreign and domestically to help improve the safety of imported seafood. Presently, the FDA conducts inspections at port facilities in conjunction with the Department of Homeland Security Customs and Border Protection, however, with the new import-related requirements, discussed below, these inspections are likely to focus on whether or not the new import requirements are met.

C. Businesses Must Submit Consumer-Friendly Information to the Reportable Food Registry[19]; Grocery Stores Required to Post Notices to Consumers

Companies that submit product information to the FDA's Reportable Food Registry will need to include information to allow a consumer to determine whether he or she possesses the reported food. Such information could include a description of the food or UPC/SKU numbers. The provision excludes fruits and vegetables that are raw agricultural commodities.

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[18] *Id*. at § 201.

[19] *Id.* at § 211.

The FDA must issue a release following company submission to the Reportable Food Registry. Based on this information, grocery stores that sold a reportable food are required to post a notice to consumers within 24 hours of the FDA's notice. This provision is limited to grocery stores with 15 or more physical locations.

D. FDA Granted Mandatory Recall Authority

One of the most significant changes to FDA's powers created by the FSMA is the grant of mandatory recall authority. The FSMA provides for the Secretary to request that a person voluntarily recall a potentially adulterated food item in addition to the power to order the person to cease and desist manufacturing, processing, packing, transporting or holding a food item where it is reasonably likely that the food may cause serious adverse health consequences or death to humans or animals.[20] Further, the FDA must establish an incident command center operation that would operate within 24 hours of initiation of a Class I recall, whether initiated voluntarily or mandated. The FDA will be required to provide an annual report to Congress indicating when the mandatory recall authority was used. The FSMA also grants the FDA administrative detention powers to be able to detain food that the agency "has reason to believe" is "adulterated or misbranded."[21]

III. Improving the Safety of Imported Foods

A. Companies that Import Food, Food Ingredients or Packaging Must Comply with New Import Requirements[22]

The FSMA requires importers to satisfy FDCA requirements before their products can enter the U.S. market. "Importer" is defined in Section 805(a)(2) of the FSMA as "(A) the U.S. owner or consignee of an article of food at the time of entry of such article into the U.S.; or (B) in the case where there is no U.S. owner or consignee as described in paragraph (A), the U.S. agent or representative of a foreign owner or consignee of the article of food at the time of entry of such article into the U.S." Under the FSMA, FDA must establish new programs that apply to importers and importers who must comply or risk losing the ability to import their products. An overview of these new programs and requirements is set forth below.

Foreign Supplier Verification Program and Certification. The FSMA requires importers, as defined above, to perform risk-based verification of foreign suppliers, the purpose of which is to ensure that imported food and food ingredients comply with FDCA standards. Not later than one year after enactment of the FSMA, the FDA must issue guidance to assist importers in establishing verification programs and must promulgate regulations to provide for the content of a foreign supplier verification program. Importers of products presently subject to HACCP, including seafood, juice and low-acid canned foods (as to microbiological hazards only) are exempt. Further, food imported in small quantities for research purposes may also be exempt. If a company imports a food without having the required supplier verification program in place, such conduct is deemed a "prohibited act" under the FSMA. These provisions take effect two years after the enactment of the FSMA.

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20 *Id.* at § 207.

21 *Id.*

22 *Id*. at § 301.

Expedited Entry. Within eighteen months after the enactment of the FSMA,[23] the FDA is to establish a program in consultation with the Department of Homeland Security for expedited entry of imported foods. Participation in the program would be voluntary for importers and would require third-party certification for any importer who wishes to participate in the program. Eligibility determinations would involve an analysis of the nature of the food, the risks of adulteration, the supplier's history of compliance, the exporting country's ability to ensure compliance, compliance with the foreign supplier verification program, the operational practices of the importer, and any other factor FDA considers appropriate.

Third-Party Certification. FDA may require importers, as a condition to granting admission of an article of food, to obtain third-party certifications for imported foods. Determination of whether certification will be required depends upon the risks presented by the food, including the known safety risks associated with the food, the country or region of origin, and the Secretary's concerns related to the adequacy, or lack thereof, of the food safety system in the country or region of origin. Importers would be required to obtain certification in order to participate in the expedited entry program.[24] The FSMA allows FDA to recognize certifications obtained from entities accredited by organizations other than FDA if those other accreditation bodies operate in accordance with established standards. If FDA requires certification, imported food not accompanied by certification or produced in a facility that is not certified would be misbranded.

Prior Notice. In addition to the identifying, manufacturing and shipping information that importers are already required to provide to FDA, under the FSMA, importers are also required to provide the name of any country that refused entry of the food.[25]

Foreign Inspectorate. FDA must establish offices in foreign countries and enter agreements with foreign countries to facilitate inspection of foreign facilities.

Building Capacity of Foreign Governments. FDA, in consultation with foreign and domestic governmental agencies, representatives of the food industry, and NGOs representing consumer interests, is required to create a plan to expand the ability of foreign countries exporting food to the U.S. to help manage food safety.[26] The plan would include recommendations for bilateral and multilateral agreements, provisions for data sharing and mutual recognition of inspection reports, and recommendations for harmonization with requirements of the Codex Alimentarius. Capacity building and harmonization efforts cannot interfere with how dietary supplements are currently regulated in the U.S. under the Dietary Supplement Health and Education Act of 1994. This law is largely unique to the U.S.

Review of Regulatory Authority of Foreign Countries. The FSMA authorizes the FDA to enter into agreements with foreign governments to facilitate inspections of foreign food facilities, particularly high risk facilities. FDA also has the power to refuse admission of food from a foreign factory, warehouse or facility where FDA was refused inspection access.

The FDA is also tasked with working in conjunction with the Secretary of Commerce to send one or more inspectors to a country or facility that imports seafood into the U.S. The purpose of these inspections is to assess practices and processes used in conjunction with farming, cultivation, harvesting, preparation for market or transportation of such seafood.

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23 *Id.* at § 302.

24 *Id*. at § 303.

25 *Id.* at § 304.

26 *Id.* at § 306.

Smuggled Foods. Within 180 days after enactment of the FSMA, the FDA must coordinate with the Department of Homeland Security to develop and implement a strategy to better identify smuggled food and prevent its entry into the U.S. "Smuggled food" is defined as "any food that a person introduces into the U.S. through fraudulent means or with the intent to defraud or mislead." FDA is required to notify DHS within 10 days of identifying a smuggled food that would cause serious adverse health consequences to humans or animals. If FDA believes such food has entered commerce and is likely to be consumed, FDA is required to issue a press release and take other emergency steps to alert consumers as to the dangers.[27]

V. Small and Very Small Business Amendment Exempts Some Producers from Preventive Control and Hazard Analysis Requirements

Senator John Tester (D-MT) championed the causes of those who supply food to the "locavore" food movement with a controversial amendment to the FSMA. Senator Tester's amendment exempts small and very small facilities and farmers from certain requirements in the bill and allows them to operate by meeting lower safety thresholds.

In order to qualify for the exemptions, facilities and farms must meet the definition of "very small business" – which will be defined during rulemaking – sell a certain threshold of food to qualified end users within the past three years and all food sold must have an average annual monetary value of less than $500,000. A "qualified end user" is defined as the consumer of a food or a restaurant or retail food establishment, located in the same state as a qualified facility or within 275 miles of the facility, that is purchasing the food for sale directly to consumers at a restaurant or retail food facility.

Exempt facilities would either have to document that they have identified the hazards associated with their facility and the food being produced there and have a monitoring program in place or demonstrate documented compliance with state and local requirements. Those facilities that rely on compliance with state and local requirements will also have to post a clear and conspicuous notice to consumers either on the label or at the point of purchase stating where the article was produced.

Farms that meet these thresholds would be required to display either on a label or a notice at the point of purchase the name and business address of the farm where the article was grown. The amendment specifically prohibits the FDA from requiring a new label for products produced at either facilities or farms that fall within the exemption. In the event that an exempt facility or farm is directly linked to an active investigation of foodborne illness or the Secretary determines that it is necessary to protect the public health and prevent or mitigate a foodborne illness outbreak based on conduct or conditions associated with a farm or facility, the Secretary may withdraw the exemption.

The Amendment also creates key limitations on the FDA's power with respect to inspection of small and very small businesses in two ways. First, it includes "direct sales," such as those conducted at a roadside stand or farmer's market typically by small or very small producers, within the definition of "retail food establishment" created in the 2002 Bioterrorism Act regulations. The effect is that retail food establishments, which now include direct sales, are not required to register with the FDA. Further, the Amendment specifically states that nothing in the section regarding farm exemptions shall be construed to increase the FDA's inspection authority. Although much has been made of the issue of inspectors having access to farms, given that farms and facilities would still have to demonstrate either documented hazard analysis or documented compliance with state and local laws, some kind of inspection is still allowed by these authorities.

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[27] *Id*. at § 309.

VI. Conclusion

Companies that produce, manufacture, import, distribute, store, or market food are advised to promptly evaluate the distinctive implications of the new law for their business activities, regulatory compliance programs, and related legal and business risk management programs. In addition, companies are advised to communicate issues and concerns regarding FSMA implementation to FDA and Congressional representatives beginning early in the implementation process; and develop regulatory compliance programs and implementation schedules that account for the varying effective dates of FSMA provisions and related compliance deadlines.

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