The FDA Food Safety Modernization Act: 
The Key New Requirements

Executive Summary

The FDA Food Safety Modernization Act (FSMA) was signed into law by President Obama on January 4, 2011. The law amends the Federal Food, Drug, and Cosmetic Act (FDC Act) to shift the focus of the United States Food and Drug Administration (FDA) from primarily reacting to food safety problems to prevention. The law also provides FDA with new enforcement authorities designed to (1) achieve higher rates of compliance with prevention and risk-based food safety standards; (2) give FDA authority to require that food manufacturers employ preventative food safety systems; (3) augment FDA’s ability to police those food safety systems; and (4) enhance FDA’s ability to detect, respond to, and contain problems when they do occur. The law also grants FDA new tools to hold imported foods to the domestic food standards. Moreover, the law directs FDA to build an integrated national food safety system in partnership with state and local authorities and expands the potential international collaboration.

Some of the law’s new authorities went into effect immediately, such as FDA’s authority to order companies to recall food. Other authorities require FDA to prepare and issue regulations and guidance documents. The funding the Agency receives from Congress will affect how quickly FDA carries out these tasks. FDA has expressed commitment to implement the requirements through an open process with opportunity for input from all stakeholders. Although many requirements will not take place immediately, domestic and foreign food producers need to begin taking steps now to avoid the potentially harsh consequences of failure to comply.

The following summary focuses on key new provisions and their impact.
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Prevention

For the first time, FDA has a legislative mandate to require comprehensive, science-based preventive controls across the food supply. This mandate includes:

**Mandatory Hazard Analysis and Risk-Based Preventive Controls**

Section 418 requires that food facilities implement a written hazard analysis and preventive control plan.\(^1\) What is required is essentially a Hazard Analysis and Critical Control Point (HACCP) system.\(^2\) The “operator, or agent in charge of a facility” must (1) identify and evaluate known or reasonably foreseeable hazards, (2) develop a written analysis of the hazards, (3) implement preventive controls for significantly minimizing or preventing the identified hazards (including hazards intentionally introduced, such as terrorism), (4) monitor these controls to ensure they are working, (5) establish procedures for corrective actions, (6) verify the plan is carried out and effective, (7) maintain records for two years. In addition, there is a provision requiring re-analysis of the preventive controls whenever a change at the facility creates a reasonable potential for a new hazard or significantly increases the potential of a previously identified hazard. If there are no changes, re-analysis must be conducted not less than every three years.

Importers must verify that their foreign suppliers have instituted the required Section 418 hazard analysis and preventive control plan. Seafood, juice, and low-acid canning facilities are already subject to Hazard Analysis and Critical Control Point (HACCP), and so they are exempt from this new requirement. There also is a small business exemption available.

FDA is required to promulgate rules establishing “science-based minimum standards” for hazard analysis and preventive control plan (HAPCP) compliance by July 4, 2012. FDA also must issue a guidance document explaining the hazard analysis and preventive control principles and requirements.

**Mandatory Produce Safety Standards**

FDA historically has had little involvement in raw produce safety. Now, FDA must work with the U.S. Department of Agriculture (USDA) to propose “science-based minimum standards for the safe production and harvesting” of fruits and vegetables

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1. FSMA § 103 amending the Food, Drug, and Cosmetic Act (FDC Act) by adding § 418 [21 U.S.C. 350g].
2. The difference between the FSMA hazard analysis and preventive control plan (HAPCP) is that the law is broader in that it requires identification and control of hazards generally, not just critical control points (CCPs). How this works out in practice will depend upon the regulations and guidance that FDA writes.
that are raw agricultural commodities and that FDA has determined such standards will minimize the risk of “serious adverse health consequences.” The rules must consider naturally occurring hazards, as well as those that may be introduced either unintentionally or intentionally, and must address soil amendments (such as compost), hygiene, packaging, temperature controls, animals in the growing area and water.

Due to inherent difficulties in regulating raw agricultural commodities, the law requires that any proposed rule “provide sufficient flexibility to be applicable to various types of entities engaged in the production and harvesting of fruits and vegetables.” In addition, Section 419 requires FDA prioritize the implementation of regulations based on the known risks accompanying raw agricultural commodities. Past foodborne illness outbreaks are likely to outline FDA’s prioritization.

The proposed rule is due by January 4, 2012. The effective date of the final rule is to be delayed for “small businesses” and “very small businesses” (terms to be defined by FDA by regulation) by one year and two years, respectively. A state or foreign country from which food is imported may request a variance from FDA from any of the requirements in a regulation under this section. The request for a variance must present information demonstrating that the variance does not increase the likelihood that the food for which the variance is requested will be adulterated under Section 402 and whether the variance provides the same level of public health protection as the requirements of the regulations adopted under Section 419.

Protection against intentional contamination
Section 420 requires that FDA issue regulations to protect against the intentional adulteration of food, including the establishment of science-based mitigation strategies to prepare and protect the food supply chain at specific vulnerable points. The regulations are only to apply to that food the FDA determines carries a “high risk” of “intentional contamination” that could cause “serious adverse health consequences.” FDA must also develop guidance documents related to protecting consumers against the intentional adulteration of food and develop mitigation strategies or measures to guard against such adulteration.

Inspection and Compliance
Preventive control standards improve food safety only to the extent that producers and processors comply with them. Therefore, FSMA increases FDA oversight for

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3 FSMA § 105 amending FDC Act § 419 [21 USC 350h]
compliance with these requirements and provides FDA with new tools to respond effectively when problems emerge, including the following:

**Mandated inspection frequency**
The FSMA establishes a mandated inspection frequency, based on risk, for food facilities and requires the frequency of inspection to increase immediately. All high-risk domestic facilities must be inspected within five years of enactment and no less than every three years thereafter.

The mandate with respect to foreign facilities is more remarkable. FDA must inspect no fewer than 600 facilities in the first year following enactment of FSMA. In each of the subsequent five years, the law directs FDA to double the number of foreign facilities inspected during the previous year. This means in 2016, FDA should be inspecting 19,200 foreign facilities. In comparison, FDA only inspected 153 foreign food facilities in 2007.

**Records access**
FDA will have access to records of the required food safety plans and the records firms will be required to keep documenting implementation of their plans. FDA also has expanded authority to access records for foods where there is a reasonable belief that the food is adulterated and may cause serious adverse health consequences. An importer must keep records of importer verification for not less than two years. The records must be made available “promptly” to a duly authorized agent of FDA.

**Testing by accredited laboratories**
The FSMA requires certain food testing to be carried out by accredited laboratories and directs FDA to establish a program for laboratory accreditation. This is to be accomplished by January 4, 2013.

**Regulatory Response**
The FSMA grants FDA new tools to respond effectively when food safety problems emerge despite preventive controls. These new authorities include:

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4 FSMA § 201.
5 FSMA § 101 amending FDC Act § 414(a) [21 U.S.C. 350c(a)].
Mandatory recall
For the first time, FDA has the authority to issue a mandatory recall when a company fails to voluntarily recall unsafe food after being asked to by the FDA. In the past nearly all companies complied with an FDA request for a voluntary recall, so this provision will have little effect on most companies. However, it will change the dynamic between FDA and companies that face requests for voluntary recalls, especially companies reluctant to agree to a voluntary recall. If a mandatory recall is issued, failure to comply is a prohibited act and also subjects a person to civil penalty. In addition, anyone who does not comply with a recall order will pay the FDA’s costs associated with the recall order, including technical assistance, follow-up effectiveness checks, and public notifications.

Larger grocery store chains will be required to post certain consumer-oriented information regarding food recalls.

Expanded administrative detention
The FSMA provides FDA with a more flexible standard for administratively detaining products that are potentially in violation of the law (administrative detention is the procedure FDA uses to keep suspect food from being moved).

Registration renewal and suspension of registration
Section 415 requires facility registration renewal every two years. FDA can suspend a registration of a facility if the agency concludes that the food carries, to a “reasonable probability,” the potential of causing “serious adverse health consequences or death.” Food from a facility whose registration has been suspended cannot be introduced into interstate or intrastate commerce and cannot be imported or exported. This authority is effective beginning July 4, 2011.

Enhanced tracking and tracing of food
FDA is directed to establish a system that will enhance the agency’s ability to track and trace both domestic and imported foods. In addition, FDA is directed to establish

7 FDC Act § 301(xx) (21 U.S.C. 331’’(xx)).
9 FSMA § 107 adding FDC Act § 743(b).
10 FSMA § 102 amending FDC Act § 415(a) [21 U.S.C. 350d(a)].
11 FDC Act § 415(b) [21 U.S.C. 350d(b)].
12 FDC Act § 415(b)(4).
13 FSMA § 204.
pilot projects to explore and evaluate methods to rapidly and effectively identify recipients of food to prevent or mitigate a foodborne illness outbreak.

Failure to abide by any recordkeeping requirement established under FSMA Section 204 is a prohibited act, and also FDA will refuse admission of imported food produced at such facility without the required recordkeeping.\(^{14}\)

**Additional recordkeeping for high-risk foods**
FDA is directed to issue proposed rulemaking to establish additional recordkeeping requirements for facilities that manufacture, process, pack, or hold foods that the Secretary designates as high-risk foods.\(^{15}\) FDA is directed to propose the new rule by January 4, 2013.

**Imports**
FDA estimates that 15 percent of the U.S. food supply is imported. The FSMA gives FDA enhanced authority to ensure that imported products meet U.S. standards and are safe. Failure to comply with any of the previously mentioned requirements would be reason to deny admission of the food to the U.S.

**Foreign Supplier Verification Program—Importer Accountability**
A new FDC Act Section 805 requires that importers verify that their foreign suppliers have adequate preventive controls in place to ensure that the food they produce is safe and in compliance with U.S. food safety standards.\(^{16}\) Importers will need to institute risk-based foreign supplier verification programs to assure that imported food is in compliance with the new Section 418 or 419, not adulterated under Section 402, and is labeled in compliance with Section 403(w) on allergens. It is a prohibited act to import and “offer” for import a food for which an importer does not have a compliant foreign supplier verification program in place.

Section 805 becomes effective January 4, 2013. FDA is required to promulgate a final regulation and guidance on foreign supplier verification by January 4, 2012. FDA is unlikely to make this deadline. However, importers should not wait for the FDA rules and guidance, and should begin to develop verification programs now. An importer with varied suppliers and varied products will likely have to implement multiple import verification programs as varied as the range of imported products. A cookie

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\(^{14}\) FDC Act §§ 301(e) [21 U.S.C. 331(e)] & 801(a) (4) [21 U.S.C. § 381(a)(4)].
\(^{15}\) FSMA § 204(d).
\(^{16}\) FSMA § 301 adding FDC Act § 805 [21 U.S.C. § 384a].
cutter approach to developing verification programs is unlikely to comply. Therefore, an importer with many suppliers and products faces a corresponding increase in the task ahead. FDA is likely to issue proposed rules within the next 12 to 18 months. Importers and other interested parties should be alert and ready to review the proposed rules and to comment. One important area to watch is specification of who is an “importer” for purposes of Section 805. The FSMA language designates the “importer” as the owner or consignee of the article of food at the time of entry of the article into the U.S. Thus, companies purchasing foreign food or ingredients through import companies could in some circumstance become “importers” for purposes of Section 805. If an importer is unable to provide records confirming the importer’s foreign supplier verification program, the imported food will be refused admission into the U.S.

**Third Party Certification**

FSMA establishes a program through which qualified third parties can certify that foreign food facilities comply with U.S. food safety standards. This certification may be used to facilitate the entry of imports. FDA is directed to establish a system to recognize accreditation bodies by 2013. Only accredited auditors will be recognized for the purpose of the inspections and audits necessary to received certification of compliance with U.S. food safety requirements. If the auditor determines that a food or a facility is not in compliance with U.S. requirements, the auditor must notify FDA or risk losing accreditation.

**Importer certification for high-risk foods**

FDA has the authority to require that high-risk imported foods be accompanied by a credible third-party certification or other assurance of compliance as a condition of entry into the U.S. This authority would be exercised where FDA concludes that the imported food is high-risk or that the food safety programs in a country or territory are inadequate to ensure that the food at issue is as safe and meets the food safety requirements of the U.S. Such certification may be obtained from either (1) an agency or representative of the government of the country from which the food is being imported or (2) an accredited third-party auditor.

**Port shopping**

Section 304 of the FSMA requires that FDA be notified prior to import of any food, if the food has been refused entry into any other country and, in such a case, FDA be informed of the identity of the country refusing entry.
Voluntary qualified importer program

FDA must establish a voluntary program for importers that provides for expedited review and entry of foods from participating importers. This program applies to importers offering food from certified facilities. Once implemented, this program will allow importers to seek expedited review and importation of certain foods from qualified foreign facilities. Some have referred to this as a “fast track program” or “green-laning.” To determine if a foreign facility is qualified, FDA will look to a number of factors including the risks associated with a particular type of food, the importer’s compliance history, the exporting country’s food safety system, the importer’s record-keeping practices, and the risk of adulteration. FDA is directed to implement the voluntary qualified importer program by July 4, 2012.

Inspection of foreign food facilities required for import entry

FDA can refuse entry of food into the U.S. from a foreign facility if FDA’s inspectors or agents are denied access to inspect the facility. This authority applies both if FDA is denied access by the facility and denied access by the country in which the facility is located.

Enhanced Partnerships

The FSMA builds a formal system of collaboration with other government agencies, both domestic and foreign. In doing so, the statute explicitly recognizes that all food safety agencies need to work together in an integrated way to achieve our public health goals. The following are examples of enhanced collaboration:

State and local capacity building

FDA must develop and implement strategies to leverage and enhance the food safety and defense capacities of state and local agencies. The FSMA provides FDA with a new multi-year grant mechanism to facilitate investment in state capacity to more efficiently achieve national food safety goals.

Section 306 of FSMA authorizes FDA to enter into “arrangements” or “agreements” with foreign governments in an effort to facilitate the inspection of foreign facilities registered under Section 415 of the FDC Act.

Foreign capacity building

The law directs FDA to develop a comprehensive plan to expand the capacity of foreign governments and their industries. One component of the plan is to address training of foreign governments and food producers on U.S. food safety requirements.

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17 FSMA § 302 adding FDC Act § 806 [21 U.S.C. § 384b].
18 FDC Act §807(b).
Reliance on inspections by other agencies
FDA is explicitly authorized to rely on inspections of other federal, state and local agencies to meet its increased inspection mandate for domestic facilities. The FSMA also allows FDA to enter into interagency agreements to leverage resources with respect to the inspection of seafood facilities, both domestic and foreign, as well as seafood imports.

Additional partnerships are required to develop and implement a national agriculture and food defense strategy, to establish an integrated consortium of laboratory networks, and to improve foodborne illness surveillance.

Resources

Text of the FSMA
The complete text of the FSMA may be found on the FDA website at:
http://www.fda.gov/Food/FoodSafety/FSMA/ucm247548.htm

Translations of Key FSMA Resources
Key information concerning the Food Safety Modernization Act (FSMA) is provided in several languages for the international community at:
http://www.fda.gov/Food/FoodSafety/FSMA/ucm242834.htm.

Sincerely,
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This paper provides a general summary of recent developments for educational purposes. It is not intended to be and should not be relied on as legal advice.