SPECIAL INTEREST PAPER

The Food Safety Modernization Act –

A Series on What is Essential for a Food Professional to Know

[*Article 6. Imported Food*]

CAROLINE SMITH DEWAAL* AND DAVID W. PLUNKETT

Center for Science in the Public Interest, 1220 L St. NW, Washington, D.C. 20005, USA

ABSTRACT

The FDA Food Safety Modernization Act (FSMA) is a significant and far reaching update of the laws and subsequent regulations that affect the safety of domestically produced and imported foods regulated by the Food and Drug Administration (FDA). Through FSMA, the U.S. Congress provides FDA with greater powers and directs it to develop regulations that will focus the food industry on the prevention of foodborne illness. This series of articles describes the legal "basics" for the readers of *Food Protection Trends*. This sixth article focuses on FSMA's provisions that apply to imported food. Past articles have reviewed FSMA's provisions on preventive controls, food defense, produce safety standards, and foodborne illness surveillance. A future article will conclude the series by discussing the provisions of FSMA that govern lab accreditation.

INTRODUCTION

Many aspects of the FDA Food Safety Modernization Act (FSMA), like registration of food facilities and preventive controls, build on a foundation already in place through previous regulatory or legislative initiatives, but the elements of the law covering imported foods are largely new constructions. Through FSMA, FDA will extend its reach to the foreign growers and manufacturers who ship 10 million line items of food to the United States annually. It does this with a comprehensive program to verify that the preventive controls requirements covering food processors and the produce safety standards covering many high risk agriculture products are being complied with by companies that import food to U.S. markets. These new programs for importers are further verified by improvements to foreign and border inspections and a more systematic approach to working with foreign governments. FDA can reward companies that demonstrate good practices with an expedited entry program, and FSMA also establishes a risk-based inspection program that allows the agency to compel certification of high-risk imports or those coming from high-risk countries.

Title III of FSMA contains the imported food provisions, but foreign producers must be aware of the full contents of the statute and the regulations that will implement it. Cross-cutting provisions, like Section 101 on records access and Section 306 on foreign inspections, must be understood together. Registration and suspension under Section 102 has consequences for the Foreign Supplier Verification Program. Section 103 applies preventive controls to any covered food facility, whether foreign or domestic. Importers in Title III are covered by the mandatory recall provisions in Section 206 of Title II. FDA has the ability to recover certain costs associated with enforcement actions from importers under a provision in Section 107 of Title I. This interweaving of parts means that businesses which rely on foreign suppliers, and regulators who oversee the import system must be aware of the full scope of FSMA's provisions.

This is the sixth of seven articles that analyze the text of the relevant FSMA provisions. This article covers seven FSMA provisions affecting imports:

1. Requirements on foreign suppliers,
2. Importer verification requirements,
3. Certification of high-risk imports,
4. Expedited entry under VQIP,
5. International capacity building,
6. Accreditation of third party auditors, and
7. FDA's oversight role.

***Author for correspondence: Phone: +1 202.777.8366; Fax: +1 202.265.4954; E-mail: csmithdewaal@cspinet.org**

TABLE 1. Location of Imported Food Provisions in the Food Safety Modernization Act (FSMA), the Food, Drug, and Cosmetic Act (FDCA), and the U.S. Code

DESCRIPTION	LOCATION		
	FSMA	FDCA	U.S. CODE
INSPECTION OF RECORDS.	§ 101	§ 414	21 U.S.C. § 350c
REGISTRATION.			
United States agent and biennial registration.	§ 102(a)	§ 415(a)	21 U.S.C. § 350d(a)
Suspension of registration.	§ 102(b)	§ 415(b)	21 U.S.C. § 350d(b)
Effect of suspension on imported food.	§ 102(b)(3)	§ 801(l)	21 U.S.C. § 381(l)
PREVENTIVE CONTROLS REQUIREMENTS APPLY TO FOREIGN FOOD FACILITIES.	§ 103(a)	§ 418(o)(2)	21 U.S.C. § 350g(o)(2)
PRODUCE SAFETY STANDARDS			
Process for requesting variances from produce safety standards.	§ 105(a)	§§ 419(c)(1)(F) & (2)	21 U.S.C. §§ 350h(c)(1)(F) & (2)
Requirement to issue guidance for importers (and others).	§ 105(a)	§ 419(e)	21 U.S.C. § 350h(e)
FEES			
Cost recovery fees for reinspection and mandatory recall apply to importers.	§ 107	§ 743(a)	21 U.S.C. § 379j-31(a)
Voluntary Qualified Importer Program.	§ 107	§§ 743(a)(1)(C) & (b)(2)(B)	21 U.S.C. §§ 379j-31(a)(1)(C) & (b)(2)(B)
NOTIFICATION REGARDING "PORT SHOPPING."	§ 115		21 U.S.C. § 381(note)
EXEMPTIONS FOR ALCOHOLIC BEVERAGE IMPORTERS.	§ 116		21 U.S.C. § 2206
RISK-BASED TARGETING OF FOREIGN FACILITY AND BORDER INSPECTIONS.	§ 201	§ 421	21 U.S.C. § 350j
ACCREDITATION OF FOREIGN LABORATORIES.	§ 202	§ 422(a)(5)	21 U.S.C. § 350k(a)(5)
ACCREDITED LABORATORY REQUIRED FOR TESTING IMPORTED FOOD IN SUPPORT OF ADMISSION UNDER SECTION 801(A).	§ 202	§ 422(b)	21 U.S.C. § 350k(b)
ENHANCED TRACKING AND TRACING OF IMPORTED FOOD.			
Traceability system applies to imported food.	§ 204(c)		21 U.S.C. § 2223(c)
Importing food without traceability information prohibited.	§ 204(j)(2)	§ 801(a)	21 U.S.C. § 381(a)
MANDATORY RECALL APPLIES TO IMPORTED FOOD.	§ 206	§ 423(b)(1)(B)	21 U.S.C. § 350l(b)(1)(B)
FOREIGN SUPPLIER VERIFICATION PROGRAM.	§ 301	§ 805	21 U.S.C. § 384a

TABLE 1. Location of Imported Food Provisions in the Food Safety Modernization Act (FSMA), the Food, Drug, and Cosmetic Act (FDCA), and the U.S. Code (cont.)

DESCRIPTION	LOCATION		
	FSMA	FDCA	U.S. CODE
VOLUNTARY QUALIFIED IMPORTER PROGRAM.	§ 302	§ 806	21 U.S.C. § 384b
AUTHORITY TO REQUIRE IMPORT CERTIFICATIONS.	§ 303	§ 801(q)	21 U.S.C. § 381(q)
PRIOR NOTICE OF IMPORTED FOOD SHIPMENTS.	§ 304	§ 801(m)(1)	21 U.S.C. § 381(m)(1)
BUILDING CAPACITY OF FOREIGN GOVERNMENTS WITH RESPECT TO FOOD SAFETY.	§ 305		
INSPECTION OF FOREIGN FACILITIES.	§ 306	§ 807	21 U.S.C. § 384c
ACCREDITATION OF THIRD-PARTY AUDITORS.	§ 307	§ 808	21 U.S.C. § 384d
FOREIGN OFFICES.	§ 308		21 U.S.C. § 2242
SMUGGLED FOOD.	§ 309		21 U.S.C. § 2243
COMPLIANCE WITH INTERNATIONAL AGREEMENTS.	§ 404		21 U.S.C. § 2252.

FSMA Requirements Apply to Foreign Food Suppliers

All laws that cover food safety for domestic growers or food processors apply to foreign growers and processors who want to import food to the United States. This includes registration requirements under § 102; produce safety standards under § 105; and process control standards under § 103.

Verification: The Importer's Essential Role

Under § 301, FSMA establishes a mandatory requirement for importers to ensure that the food they bring into the U.S. market meets the requirements of the Act. This means that importers conduct "verification activities" to confirm that food is subject to preventive control systems and meets produce safety standards. Further, importers must verify that the food is not adulterated or misbranded. FSMA defines importers of food as either the owner (or consignee) of the food when it enters the U.S. or the agent or representative of the foreign owner (or consignee) of the food at the time it enters the U.S.

To implement this provision, FDA is required to develop regulations describing the types of activities importers can use to assure imported food meets the same level of public health protection required under the Act, and to verify that "food imported into the United States is as safe as food produced and sold within the United States." In contrast to several sections of FSMA that limit FDA's ability to regulate, when it comes to food imports, FDA has a great deal of latitude.

FDA must consider differences in importers and types of imported foods, including the level of risk posed by the food. Verification activities prescribed by the regulation may include monitoring records for shipments, 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. FSMA requires that importers maintain records to document these activities for at least two years. These records are subject to inspection by FDA on request.

There are exemptions from the Foreign Supplier Verification Program for several industries that have been operating under preventive controls regulations for some time. These include seafood, juice and low-acid canned foods processors that are in compliance with Hazard Analysis Critical Control Points (HACCP) regulations for those sectors. Food imported in small quantities for research, evaluation or personal consumption is also exempt as long as it is not sold or distributed to the public.

A list of importers participating under the Foreign Supplier Verification Program is to be published on a website for the public and failure to participate is considered a prohibited act under the Federal Food, Drug and Cosmetic Act. While Congress prescribed that this section of FSMA should become effective two years after the date of enactment, it has not yet been implemented; regulations to implement this section were released for public comment in July 2013.

Certification of Imports

While the Foreign Supplier Verification Program establishes a mandatory requirement on importers, FSMA gives FDA and importers other tools to help assess the safety of imports. Import certification is an important innovation contained in § 303 and § 307 of FSMA. Certification is the concept of using a third party, specifically a foreign government or third party auditor, to provide assurance that the requirements of the law have been met. It was added to FSMA to respond to concerns that FDA did not have the capacity to inspect the large number of foreign companies that registered as importers after registration became required in 2003.

Under FSMA, certification is recognized in two contexts. First, under § 303, FDA can mandate certification for imported foods based on the "risk of the food." This is determined by analysis of the known food safety risks associated with the food or the country, territory, or region where the food originates. FDA can also require certification if it finds that the food safety programs in the country of origin are not adequate to ensure that the food is as safe as a similar product produced domestically, and that the certification would assist the Secretary in either admitting or refusing entry of the food. When the food safety programs in a specific country are found to be deficient, FDA must establish a system to allow the foreign government to inform the agency when improvements are implemented, and to demonstrate that they are adequate to ensure the food "is as safe as a similar article of food that is manufactured . . . in the United States in accordance with this Act."

Voluntary Qualified Importer Program

Under § 302, FSMA also allows for the use of certification in the Voluntary Qualified Importer Program (VQIP). This program provides for expedited review and importation of food by importers who opt to participate. Participation in the program follows an application to the FDA, and must be consistent with requirements of the certification section of the Act, as each facility that qualifies must have certification. FDA can manage the program under a guidance that controls the participation of companies, and sets out the standards for compliance with the program, together with revocation and reinstatement in the program, where necessary. Imported food that comes in under the VQIP program must have proof that it is from a certified facility.

FDA reviews applications to VQIP and makes determinations based on criteria outlined in FSMA, such as (1) the known food safety risks of the food; (2) the compliance history of foreign suppliers; (3) the capability of the regulatory system of the country of export; (4) the importers' compliance with the Foreign Supplier Verification Program; (5) practices of the importer, including recordkeeping, testing, inspection and audits of the facilities, traceability of the food, temperature controls, and sourcing practices; (6) the potential risk for intentional adulteration; and (7) any other factor the Secretary determines is appropriate. Reevaluation of the company's fitness for VQIP is done at least once every three years.

Cooperation: International Capacity Building and Cooperation

Under § 305, FSMA requires FDA to establish a plan for building the food safety capacity of foreign governments, including the technical, scientific, and regulatory capacity of governments that export food to the U.S. The plan should outline FDA's recommendations for bilateral and multilateral arrangements; provisions for secure electronic data collection and mutual recognition of inspection reports; training for foreign governments and food producers; recommendations for harmonization with Codex Alimentarius requirements; and international acceptance of laboratory methods, testing and detection techniques.

Accreditation of Third-Party Auditors

Under § 307, FSMA recognizes in statute the role of auditors as part of the regulatory system. This is a significant departure from the normal regulatory approach that accepts findings following an on-site U.S. government inspection. Importantly, "third-party auditors" can be foreign governments, agencies of a foreign government, foreign cooperatives or other third parties that the FDA determines are appropriate in this context. Audits permitted under this section must be performed by an auditor that is accredited by FDA or an accrediting body it has recognized for that purpose. They also should be unannounced and conducted in a manner to minimize conflicts of interest.

To be accredited under FSMA, an auditor must be capable of conducting food safety audits to certify that the company or facility is in compliance with the requirements of FSMA, and be willing to certify to that compliance, either for the purposes of mandatory certification or VQIP. If an auditor discovers a condition that could lead to a risk to public health, the law obligates the auditor to notify FDA. The law also prescribes a number of limitations and conflicts of interest for third party auditors.

Auditors must be able to issue a written and electronic food certification, as needed, or a facility certification to accompany each food import shipment. Certificates can only be issued after conducting a regulatory audit and such other activities as are needed to establish compliance. The Act describes the purpose of certification as both to approve specific food shipments and also to determine if the facility meets eligibility for the VQIP.

Auditors can lose their accreditation if the food they certify is linked to an outbreak of foodborne illness that can cause serious illness or death in humans or animals or if FDA finds that the auditor no longer meets the requirements. Accreditation also is contingent on FDA's ability to review audits or investigations of the auditor.

FDA has the authority to recognize accreditation bodies to assist the agency in identifying qualified auditors and the authority to both revoke and reinstate that recognition. FSMA gives FDA the authority to prescribe the type of audit reports that meet the requirements of the Act, including the date and scope of the audit, and name of the person at the facility responsible for meeting the requirements of the Act. Regulatory audit reports are accessible to FDA at any time. FSMA also sets out specific requirements for different types of recognized auditors, including foreign governments, foreign cooperatives and other third parties. FDA must maintain a public registry of accredited auditors and accreditation bodies approved by the agency and periodically (no less than once in 4 years) reevaluate those approvals.

Oversight: FDA's Role

In addition to FDA's role in designing and administering the import programs described above, the agency also has responsibilities to improve foreign and border inspections, and establish a presence in

regions from which much of our imported food comes. In § 201 of FSMA, the agency is required to double the number of foreign inspections each year for five years. While meeting this mandate will be dependent on annual funding levels approved by Congress, it establishes a clear direction for the agency to more closely monitor conditions in exporting countries. FDA inspected 995 foreign facilities in fiscal year 2011 *(1)* a significant increase over its lowest point of 96 foreign inspections conducted in 2007 *(2)*. At the border, FDA is required to conduct risk-based inspections. In addition to the known risk of the food item, it also must evaluate the country or region it originates from, the compliance history of the importer, and any certification provided under the VQIP or mandatory certification program.

FSMA also authorizes establishment of foreign offices to assist foreign governments with measures to provide for the safety of foods they export, and to conduct direct inspections. FDA had begun setting up these offices prior to FSMA's passage. Consistent with § 308, the agency expanded the program and now has 13 offices in 10 countries *(1)*.

CONCLUSION

The imported food program under FSMA makes major changes to the way FDA regulates imported food. It places new responsibilities on importers to make sure their suppliers are complying with U.S. food safety standards. In the case of high-risk foods, it establishes a new program for accredited auditors to certify the safety of the product before it leaves the country where it was manufactured. These two provisions ease pressure on the border inspection system by moving safety assurances back to the exporting country. Together, the new provisions provide a comprehensive system that emphasizes prevention, supported by more frequent foreign inspections and border checks to verify FSMA is working to protect consumers.

ACKNOWLEDGMENTS

The authors are grateful for the advice, assistance and contributions of our fellow IAFP Food Law Professional Development Group members, and for the assistance of our law intern Christina Hatano.

REFERENCES

1. FDA. 2013. 2012 Annual Report on Food Facilities, Food Imports, and FDA Foreign Offices. Available at: http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm315486.htm#food_imports. Accessed 22 August 2013.
2. FDA. 2008. FDA FY 2009 Congressional Justification: Foods. Available at: http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/BudgetReports/2009FDABudgetSummary/ucm116140.pdf. Accessed 22 August 2013.

ABOUT THE **AUTHORS**

Caroline Smith DeWaal *is the Director of the Food Safety Program at the Center for Science in the Public Interest.*

David W. Plunkett, JD, JM *is Senior Staff Attorney for the Food Safety Program at the Center for Science in the Public Interest.*

In Memory

John H. Fritz

Silver Springs, MD

IAFP would like to extend our deepest sympathy to the family of John H. (Jack) Fritz who recently passed away. IAFP will always have sincere gratitude for his contribution to the Association and the profession. Mr. Fritz was President of the Association in 1964.