

US Food Safety Modernization Act:

Overview and Impact for Importers and Exporters

August 2012

This paper covers important updates related to the US Food Safety Modernization Act (FSMA) and recent changes that will impact food shipments to the US. If your company exports food to the US or if you are a US importer of food, this document will contain valuable information for your business.

A publication of



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Who are Eurofins and Leavitt Partners and why are they working together?

Eurofins is a leading international group of laboratories providing an unparalleled range of testing and support services to the pharmaceutical, food, environmental and consumer products industries and to governments. With over 160 laboratories in 32 countries, Eurofins offers a portfolio of over 100,000 reliable analytical methods for characterizing the safety, identity, purity, composition, authenticity and origin of products and biological substances.

Leavitt Partners Global Food Safety Solution is comprised of an experienced team with regulatory, public health and scientific backgrounds that can use our network of global and domestic relationships to assist our clients in navigating the new challenges around producing and selling safe food in the context of managing risk in a cost conscious environment.

Together, Eurofins and Leavitt Partners believe that existing and prospective clients will find value in a new service that combines the expertise of both organizations to provide regulatory insight regarding new challenges around imported FDA regulated food into the U.S. along with expertise on validation and verification of preventive control programs that utilize robust testing strategies.

Introduction:

In the United States, lawmakers, regulators, consumers and the media are more focused on food safety than ever before. On January 4, 2011, President Obama signed the **Food Safety Modernization Act** into law, which represents the largest change of the food safety system since the passage for the Food, Drug, and Cosmetic Act in 1938. The new legislation will bring significant changes to an already shifting food safety landscape, especially in the area of imported foods and ingredients. This paper will outline **(1) the current food safety landscape that has impact on the way in which food imports are perceived in the U.S., (2) an overview of the key provisions of the new legislation of importance to importers and exporters, (3) additional considerations, and opportunities.**

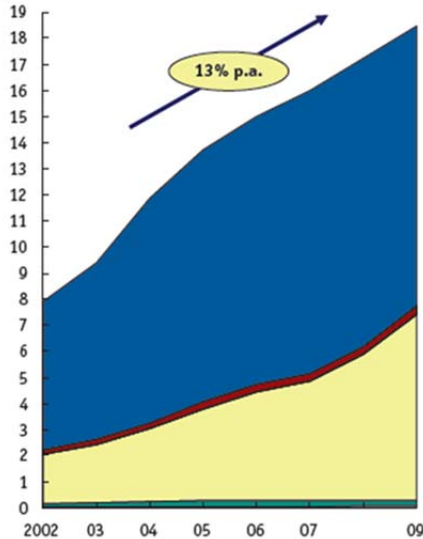
(1) Food Safety Landscape

Changing consumption patterns, large outbreaks of foodborne illness, new food safety science, and identification of new risks all contribute to the shifting food safety system. Consumer demand for fresh food year-round requires global sourcing of fresh food and ingredients. Currently, imports account for 15 percent of the U.S. food supply, including over 75 percent of seafood and 60 percent of fresh produce consumed in the U.S.¹ As **Figure 1** shows, the amount of food imported into the United States has greatly increased over the last 10 years.

¹ <http://www.ers.usda.gov>

Imported lines¹(millions)

Total = 7.9 MM in 2002; total = 18.5 MM in 2009



CAGR 2002-09		Explanation of center's products
Foods	9.5%	<ul style="list-style-type: none"> • Food products for human, animal, pet use, except meat and poultry • Articles for cleansing, beautifying, promoting attractiveness of body
Drugs	12.9%	<ul style="list-style-type: none"> • Prescription and OTC drugs for human
Devices	20.8%	<ul style="list-style-type: none"> • Medical devices for human use • Products that emit radiation (e.g., microwaves, lasers, x-ray machines)
Veterinary products	6.7%	<ul style="list-style-type: none"> • Drugs, devices, and food additives for animals and pets
Biologics	15.8%	<ul style="list-style-type: none"> • Blood products, vaccines, and tissues for transplantation

¹ An Import line represents the portion of a shipment listed as a separate item on an entry document. The number of units can vary.

Source: FDA

Figure 1: Imported Product Lines into US Commerce and Percentage Breakdown (2002 to 2009)

Numerous outbreaks over the past several years have made media, consumers, and the United States Congress keep a closer watch on food safety systems.

In response to the changing food safety landscape, United States regulatory agencies are cracking down on food safety violations which will result in faster, more frequent enforcement actions.

The expanding global food supply has resulted in an increased regulatory presence overseas, at the border, and domestically. FDA has opened foreign offices in China, India, Latin America, Europe, and the Middle East (currently based out of Washington, D.C.). FDA is implementing a predictive risk-based screening system at the border to better target field exams and speed up the importation of low-risk products. FDA is increasing inspections, both in the U.S. and overseas, and is leveraging with federal, state, local, tribal, and territorial partners to provide oversight of the U.S. food system.

New Foods Linked to Outbreaks of Foodborne Illness

- Bagged spinach
- Carrot juice
- Peanut butter
- Broccoli powder
- Dog food
- Pot pies
- Canned chili sauce
- Hot pepper
- White pepper
- Raw cookie dough

(2) Food Safety Modernization Act: Key Provisions

The Food Safety Modernization Act (FSMA) contains several provisions that give FDA new authority and place new requirements on those involved in the supply chain.

The primary aim of FSMA is to require food companies to implement preventive controls. In order to do that companies need to understand the risk both in their facility and in their supply chain and develop control systems to control that risk using validated systems, and document that those controls are working and maintain the records showing that the controls are working. One of the most important sections of FSMA is Section 103 that focusses on these preventive controls. Understanding this section is critical to meet the requirements that will be enacted with regard to imported foods.

Sec 103. Preventive Controls

One of the most anticipated sections of FSMA for all food manufacturers -whether inside or outside the United States - relates to the new requirement that all facilities that manufacture, process, pack or hold food products have documented preventive control programs in place. The preventive control requirements will go above and beyond a typical Hazard Analysis and Critical Control Point plan, and will include requirements related to recall plans, sanitation, employee hygiene training, environmental monitoring, allergen control program, current good manufacturing practices, supplier approval and verification activities, corrective actions, verification activities, and records. As we move beyond HACCP, preventative control programs should include training programs for managers and/or workers, audit programs, written records (e.g., batch records, sanitation records, etc.), validation of control measures, written sanitation standard operating procedures, food label review and control program, and testing of in-coming raw materials, in-process materials, finished products, and processing environment. Monitoring requirements must verify that controls are working correctly and are effectively and significantly minimizing or preventing the occurrence of identified hazards. Food safety plans (**Figure 2**) will need to be developed, and the next white paper in this series will provide additional details on how this can be approached.

This is one of the key rules that was expected to be released in January 2012 but has been delayed. All members of the food supply chain should pay close attention to these requirements and related guidance documents as soon as they become available.



Figure 2: Conceptual Example of a Food Safety Plan

Sec 105. Standards for Produce Safety

For the first time, FDA is requiring those who produce fruits and vegetables determined to be “high risk” based on their association with outbreaks to enact measures to ensure the safe production and harvesting of the produce. These requirements will apply to both domestic and imported produce and the measures include controls over soil amendments, hygiene, packaging, temperature controls, animals, and water, so as to reduce or eliminate the likelihood of both natural hazards as well as those that may be intentionally introduced from impacting the safety of the product. Like the preventive control rule, stakeholders are anxiously awaiting the release of this rule.

Sec. 301 Foreign Supplier Verification Program

FSMA is moving the burden of imported food safety onto importers. This section of FSMA lays out how importers are going to be held more accountable for the safety of food products and ingredients they import into the U.S. Importers will need to perform risk-based foreign supplier verifications activities to ensure that food entering the US has been produced by firms employing preventive controls (as described in Sec. 103) unless the food is already required to be manufactured using HACCP-based preventative controls (seafood, juice, low acid canned products).

This program, scheduled to be implemented in January 2013 but likely to be delayed, is dependent on the issuance of the preventive control rules that are currently delayed. This section of FSMA is significant for importers of foods and ingredients, as it makes them responsible for ensuring that the products they handle are safe. Thus, supply chain visibility will be crucial for compliance.

Sec. 302 Voluntary Qualified Importer Program (“Green Lane”)

FDA is required to establish a voluntary program that would provide expedited review of food and ingredients from participating importers. The program will be paid for by program participants (as specified in Section 207). Eligibility to participate in the program will depend, in part, on the known safety risk of the food product or ingredient to be imported; the compliance history of foreign suppliers used by an importer; the capability of the regulatory system of the country of export to ensure compliance with U.S. food-safety standards; recordkeeping, testing, inspection, and audits of facilities; traceability throughout the supply chain; proof of consistent temperature controls; and the potential risk for intentional adulteration of the food. The voluntary program will require the issuance of a facility certification to accompany products brought into the U.S. under this program.

Details emanating from FDA regarding this program have been substantially delayed, and it will likely be years until the program is fully implemented. However, for those exporting to the US, this should be an area of key interest.

(3) Food Safety Modernization Act: Additional Provisions

In addition to the key provisions described above, there are a number of provisions that impact importers. A summary of the key sections in the other titles is provided in **Table 1** and additional information can be found at <http://leavittpartners.com/global-food-solutions/>.

Table 1: Summary of Key Provisions Affecting US Importers as Defined in FSMA

Section	Key points	Timeline	Impact
101- Inspections of Records and Records Access	Increases FDAs access to records when there is a reasonable chance that exposure will cause serious adverse health consequences or death	Immediate	Firms will need to increase documentation and be ready to make it available to FDA
102- Registration of food facilities	Requires biennial facility registration renewal on even numbered years.	2012	Gives FDA authority to suspend registration, essentially meaning they cannot sell food in the US
104- Performance standards	FDA to review foodborne contaminants and issue guidance/regulations as necessary to reduce risks.	As Appropriate- every 2yrs min.	Companies will need to monitor this list in case their products are identified as needing to meet performance standards
105- Standards for produce safety	Establishes science-based minimum standards for the safe production and harvesting of produce	Delayed	Farms will need to ensure practices are aligned with this rule
106- Protection against intentional adulteration	Requires development of guidance and regulations to protect against intentional adulteration.		New mitigation strategies needed for high risk suppliers
107- Authority to collect fees	Gives authority to collect fees	October 2011	For reinspection, recalls, and voluntary qualified importer program
111- Sanitary transportation of food	Requires FDA to develop new regulations for the safe transportation of food.	Expected July 2012	
201- Targeting of inspection resources	inspectional resources targeted based on risk and outlines inspection frequency requirements	Immediate	New inspection mandate means FDA or their designee may visit you more frequently
202- Laboratory accreditation for analyses of foods	Requires FDA to establish a program for accrediting food laboratories.	July 2013	Increased number of qualified laboratories for product testing
203- Integrated consortium of laboratory networks	Requires FDA, USDA and EPA to form a consortium to identify common laboratory methods and provide surge capacity.	Immediate	
204- Enhancing tracking and tracing of food and recordkeeping	FDA to pilot tracing systems, consider establishing product tracing program, and expand recordkeeping requirements for high-risk foods.	January 2013 – proposed rule	
205- Surveillance	FDA and CDC shall enhance surveillance systems to improve collection, analysis and reporting.	Immediate	
206- Mandatory recall authority	Provides FDA mandatory recall authority.	Immediate	If you delay in recalling, FDA can recall it— and you will pay a fee for this service
207- Administrative detention of food	Expands FDA administrative detention of food	May 2011	FDA can more easily detain food if they have reasonable belief that the food is adulterated or misbranded
211- Improving the reportable food registry	Requires additional information to be submitted to the reportable food registry.	June 2012	
304- Prior notice of imported food shipments	Requires notification of any country to which food has been refused entry	immediate	
305- building capacity of foreign governments	Plan to expand the technical, scientific and regulatory food safety capacity of foreign governments, and their respective food industries	January 2013	
308- FDA foreign offices	Requires FDA to open offices worldwide	ongoing	Current offices in China, India, Mexico, Costa Rica, Chile, South Africa, Jordan, Italy, Belgium and the UK
309- Smuggled foods	With other government agencies, work to better identify countries of origin and food products at high risk for smuggling		The contamination of wheat gluten with melamine in 2007 could fall into this section

Sec. 104 Performance Standards

After periodic review of foodborne contaminant health data, including toxicological and epidemiological studies, FDA may issue guidance documents regarding action levels or regulations based on recommendations of advisory committees, including the Food Advisory Committee.

Sec. 115 Port Shopping

FDA has to provide notification to the Secretary of Homeland Security when refusing to admit food so that other US ports are aware that the food has previously been refused entry.

Sec. 303 Authority to Require Import Certifications for Food

Although unlikely to be required immediately, FDA now has the authority to require certificates issued by independent third parties or governments verifying that the food is in compliance with U.S. laws and regulations. FDA will use a risk-based approach to determine foods and ingredients for which a certificate will be required.

Sec. 306 Inspection of Foreign Food Facilities

The Secretary may enter into arrangements and agreements with foreign governments to fulfill FDA's mandate to conduct the 19,000 annual inspections required by 2016. Inspections will be targeted based on risk.

Sec. 307 Accreditation of Third-Party Auditors

The legislation requires FDA to establish a program to recognize accreditation bodies and third-party auditors including foreign governments, foreign cooperatives or a private entity. This audit will determine if a facility is eligible to offer food for import under the voluntary qualified importer program.

(4) Food Safety Modernization Act: Additional Considerations & Opportunities

Multiple drivers are currently impacting the food safety landscape and many changes are in motion, independent of the new legislation. The implementation of the new legislation will take time and is largely dependent on funding and how FDA drafts the regulations. The extent to which the U.S. Congress funds food safety will directly impact how much FDA can accomplish towards increasing inspections, and implementing new programs. However, the FDA will proceed with the writing of the regulations and thus set expectations and requirements.

With the implementation of the new legislation, there will be changes in the food safety landscape across the supply chain. It is important that every company stays informed on the implementation of the new law and ahead of changes to ensure a position as a food safety leader. The new legislation won't change the food safety landscape overnight, but there is a unique opportunity for industry leaders to



share best-practices with FDA, participate in shaping the new regulations and guidance, and position themselves to have the solutions to meet the needs created by the new requirements.

By following the developments in U.S. regulatory policy over the coming years and evaluating your business practices against current standards, when the time comes for FDA to open a new “Green Lane,” your company could be one of the first to gain expedited clearance for your products into the United States. Lining-up and working with leading independent third party auditors consultants, laboratories or foreign governments to accomplish this goal is critical to providing the necessary assurances to FDA that a protective and reliable food safety system is in place for your imported products. Eurofins and Leavitt Partners look forward to working with you to ensure that your company is properly aligned with all necessary requirements so that you maintain your firm’s leading edge. Please contact us to learn more about how we can help you meet the new requirements of FSMA. To help you ensure regulatory compliance we provide strategic analysis, customized updates, audits, and testing services that will help you protect your brands and expand your global market share.