2013 Annual Report on Food Facilities, Food Imports, and FDA Foreign Offices

November 2013

The Food Safety Modernization Act (FSMA) requires many deliverables from FDA, among them special reports and studies to be submitted to Congress.

Report to Congress
Annual Report to Congress on Food Facilities, Food Imports, and FDA Foreign Offices
Provisions of the FDA Food Safety Modernization Act
Submitted pursuant to Section 201 of P. L. 111-353
U.S. Department of Health and Human Services
Food and Drug Administration

Introduction

On January 4, 2011, President Obama signed into law the FDA Food Safety Modernization Act (FSMA) (Public Law 111-353). Section 201(b) of FSMA amends section 1003 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) by requiring the Secretary of Health and Human Services (HHS) to annually submit to Congress a report that includes the Food and Drug Administration's (FDA) efforts to coordinate and cooperate with other federal agencies with responsibilities for food inspections, regarding—(1) information about food facilities including—(A) the appropriations used to inspect facilities registered pursuant to section 415 of the FD&C Act in the previous fiscal year; (B) the average cost of both a non-high-risk food facility inspection and a high-risk food facility inspection, if such a difference exists, in the previous fiscal year; (C) the number of domestic facilities and the number of foreign facilities registered pursuant to section 415 of the FD&C Act that the Secretary inspected in the previous fiscal year; (D) the number of domestic facilities and the number of foreign facilities registered pursuant to section 415 of the FD&C Act that were scheduled for inspection in the previous fiscal year and which the Secretary did not inspect in such year; (E) the number of high-risk facilities identified pursuant to section 421 of the FD&C Act that the Secretary inspected in the previous fiscal year; and (F) the number of high-risk facilities identified pursuant to section 421 of the FD&C Act that were scheduled for inspection in the previous fiscal year and which the Secretary did not inspect in such year. Section 201(b) also requires (2) information about food imports including— (A) the number of lines of food imported into the United States that the Secretary physically inspected or sampled in the previous fiscal year; (B) the number of lines of food imported into the United States that the Secretary did not physically inspect or sample in the previous fiscal

year; and (C) the average cost of physically inspecting or sampling a line of food subject to the FD&C Act that is imported or offered for import into the United States. Lastly, the report should include (3) information on the foreign offices of FDA including— (A) the number of foreign offices established; and (B) the number of personnel permanently stationed in each foreign office.

The following report is the third annual report in response to this mandate since the signing of FSMA on January 4, 2011.

Background

FDA is responsible for protecting and promoting public health by, among other things, ensuring that the nation's food supply for human and animal consumption is safe, sanitary, wholesome, and properly labeled. FDA regulates $417 billion worth of domestic food and $49 billion worth of imported foods. FDA's responsibility in the food area generally covers all domestic and imported food except meat, poultry, and processed eggs, which are primarily the responsibility of the U.S. Department of Agriculture's (USDA) Food Safety and Inspection Service (FSIS). FDA oversees more than 377,000 domestic and foreign facilities registered with FDA as a result of the Public Health Security and Bioterrorism Preparedness and Response Act (BT Act) of 2002. FDA devotes more than 1,300[1] full-time staff years (known as full-time equivalents, or FTEs) to conducting field activities, primarily food and feed inspections and investigational activities.

Importers of food products intended for introduction into United States interstate commerce are responsible for ensuring that the products are safe, sanitary, wholesome, and labeled according to U.S. requirements. Foreign inspections are designed to identify potential food safety problems before products arrive in the United States, to determine the status of a firm's compliance with FDA's requirements and food safety standards, to help FDA make admissibility decisions when food products are offered for importation into the United States, and to help ensure that food products under FDA's jurisdiction meet U.S. requirements under the FD&C Act. Both imported and domestically-produced foods must meet the same food safety requirements.

Coordination and Cooperation with State and Local Agencies

In addition to executing its mission through its federal workforce, and in cooperation with other federal agencies, FDA works with its state, local, tribal, and territorial counterparts to further FDA's mission. FDA funds contracts, grants and cooperative agreements for states to conduct inspections on behalf of FDA and to build infrastructure and capacity in the funded programs. FDA provides training, guidance, and technical standards, including the model Food Code, the Manufactured Food Regulatory Program Standards (MFRPS), and the Voluntary National Retail Food Regulatory Program Standards (VNRFRPS), to regulatory and public health partners to support and promote uniform coverage of food establishments.

FDA has devoted significant time and resources to building a fully integrated national food safety system in collaboration with regulatory and public health partners. FSMA encourages and enables FDA to make further progress toward an integrated national food safety system. In 2011, FDA established several working groups to begin the process of implementing the provisions of FSMA that directly impact partnerships with state, local, tribal, and territorial partners. FDA continues to support the Partnership for Food Protection (PFP) workgroups. In 2012, FDA and PFP held a 50-state workshop to develop and implement key deliverables critical to an integrated food safety system. Both the FSMA and PFP work groups contain federal, state, and local government representatives. The mission of these work groups is to work on key deliverables to build and implement an integrated food safety system. In working to build a fully integrated national system, FDA places a priority on preventing foodborne illness, in both humans and animals, through uniform program standards, inspections, laboratory testing, and improved response. Implementation of uniform national standards will result in uniform inspectional coverage and sample collection and analysis to enable greater ability to utilize analyses and observations across jurisdictions to protect public health. In Fiscal Year (FY) 2012, there was an increase in implementation of the MFRPS and the VNRFRPS in state and local programs. FDA has also collaborated with the Association of American Feed Control Officials to develop the Animal Feed Regulatory Program Standards. In addition, FDA is working with its partners on the development of a national laboratory proficiency-testing program, which will result in consistent and meaningful data for compliance, surveillance, and environmental sampling. Further, FDA's integration of response efforts, including the use of cooperative agreements for multi-jurisdictional Rapid Response Teams and the Food Emergency Response Network of laboratories, will result in coordinated, faster, and more effective responses to food safety events. In addition, FDA has contracts and cooperative agreements in place to leverage state regulatory resources, enhance inspectional coverage of FDA-regulated food and feed establishments, and create positive working relationships with the states in both emergency and non-emergency situations.

Coordination and Cooperation with Other Federal Agencies with Food Safety-Related Responsibilities

FDA works closely with a number of federal agencies and over the past several years has increased efforts to improve coordination. In 2009, President Obama created the multiagency President's Food Safety Working Group (FSWG). In July 2009, FSWG issued its key findings on how to upgrade the food safety system for the 21st century. The FSWG's recommendation for a new public health-focused approach to food safety was based on three core principles: prioritizing prevention, strengthening surveillance and enforcement, and improving response and recovery. In December 2011, the FSWG issued a progress report and outlined its agenda for 2012 and beyond. Implementation of FSMA is one of the highest priorities for the working group.

FDA's long-standing cooperation with other federal agencies includes inspections, surveillance, outbreak investigations, capacity building to improve the safety of domestic and imported food, and the development of policies related to food safety.

Below are specific examples of how FDA works with other federal agencies. In many instances, FDA has Memoranda of Understanding (MOUs) and interagency agreements with those agencies to delineate how FDA and the other agencies will coordinate their respective responsibilities.

Centers for Disease Control and Prevention (CDC)

FDA works very closely with CDC to conduct surveillance; investigate outbreaks of foodborne illness; develop standards, protocols and guidelines; conduct studies and risk assessments; and educate and inform the public, consumer groups, public health partners, industry, and other stakeholders on food safety. FDA and CDC also collaborate with FSIS and state health and agriculture departments on these activities. For example, FDA, CDC, FSIS, and state and local representatives recently published guidelines on multi-state foodborne outbreak investigations to facilitate better coordination among jurisdictions affected by an outbreak. In addition, FDA, CDC, and FSIS have established protocols for a multiagency coordination group for foodborne illness outbreaks that can quickly convene during an outbreak of foodborne illness involving multiple federal agencies to share information, make decisions, and leverage resources. Response managers from FDA, CDC, and FSIS have been actively working together to improve communications and coordination during outbreaks. FSIS and FDA have embedded epidemiologists in CDC's foodborne outbreak detection and response section to improve information flow among the agencies. CDC has embedded an epidemiologist in FDA's Office of Foods and Veterinary Medicine to facilitate collaboration and communication with respect to FSMA, and other food safety initiatives, programs and activities.

Further, FDA partners with CDC and FSIS on the biennial update of the Food Code, a model ordinance developed since 1993 through the Conference for Food Protection. FDA issues a new Food Code every four years and works with the states to secure adoption of the Code as law regulating food safety in retail stores and food service facilities. The next complete revision of the Food Code will be published in 2013.

U.S. Department of Agriculture, Food Safety and Inspection Service (FSIS)

FDA's responsibility in the food area generally covers all domestic and imported food except meat, poultry, and processed eggs, which are primarily the responsibility of FSIS. Under a 2012 MOU, FDA and several USDA agencies, including FSIS, share information related to food safety; public health; and associated regulatory, marketing, trade and research activities substantially affecting the public health. FSIS and FDA work in a collaborative effort to perform recalls when

multi-ingredient products containing foods regulated by both agencies require joint efforts to protect the public health. In FY 2012, FSIS worked with FDA on nine Class I Recalls[2] of multi-ingredient products possibly contaminated with Listeria monocytogenes (8) and Salmonella (1).

FSIS also works with FDA when performing effectiveness checks. The effectiveness checks are used to verify that recalling firms have properly communicated their recall information to consignees regarding the status of the recalled product(s). As part of the effectiveness checks, the two agencies perform verification checks to ensure that the recalled product(s) has undergone proper disposition in accordance with regulatory requirements. These effectiveness checks are used to safeguard public health from products that may potentially have serious adverse health risks.

The agencies also worked together on responding to a European Union residue audit and finding ways to improve the National Antimicrobial Resistance Monitoring System (NARMS). NARMS is a national public health surveillance system that tracks antibiotic resistance in foodborne bacteria and monitors antimicrobial susceptibility among enteric bacteria from humans, retail meats, and food animals. This program was established in 1996 as a partnership between FDA, CDC, and USDA.

U.S. Department of Agriculture, Agricultural Marketing Service (AMS)

FDA cooperates with AMS on shell egg safety. FDA has regulatory authority over shell eggs and conducts inspections of egg farms. AMS is responsible for shell egg surveillance inspections at certain establishments, as mandated by the Egg Products Inspection Act (21 U.S.C. 1031 et seq). AMS also provides shell egg grading service at approximately 160 high-volume egg processing facilities packaging eggs for the ultimate consumer in accordance with the Regulations Governing the Voluntary Grading of Shell Eggs. These egg processing plants using AMS' shell egg grading service on a fee basis are inspected daily by AMS to meet good manufacturing practices and sanitary facility requirements. The AMS graders and surveillance inspection activities ensure proper disposition of cracked, dirty, or other loss-type eggs and identify contaminated or adulterated eggs. The surveillance inspections are conducted by AMS and cooperating state agencies at least once each calendar quarter.

In the wake of the Salmonella outbreak involving shell eggs in 2010, FDA is working with AMS on cross-training to enable AMS graders in FDA-regulated shell egg facilities to spot and report significant observations or other information relevant to FDA's safety and public health mission.

U.S. Department of Agriculture, Foreign Agricultural Service (FAS)

To improve food safety practices in countries exporting to the United States, FDA, FSIS, and FAS, along with the U.S. Codex office, created the International Policy Coordination Group (IPCG). The IPCG assesses ongoing U.S. Government international food safety technical assistance and capacity building activities in order to coordinate future activities and

approaches on selected food safety issues facing developing countries and emerging markets. For example, in FY 2012, FAS, FSIS, and FDA collaborated to support several international food defense outreach and training activities. Additionally, FAS has worked with FDA to assist in providing information on FSMA to trading partners. FAS, through its network of overseas offices and capacity building efforts, has engaged with foreign officials and the private sector to help keep them up-to-date on the status of FSMA implementation, and encourage their participation in the public comment process for the FSMA proposed rules published by FDA.

U.S. Department of Agriculture, Food and Nutrition Service (FNS)

In some instances, FDA investigations involve FDA-regulated products distributed via domestic nutrition assistance programs administered by FNS. Examples of such programs include the National School Lunch Program and the Emergency Food Assistance Program. In these situations, FDA shares information and updates on complaints, reports, product recalls, or events that may affect the health and safety of USDA nutrition assistance program recipients with FNS.

Environmental Protection Agency (EPA)

FDA, FSIS, and EPA meet regularly through both the Interagency Strategic Assessment Team and the Interagency Regulatory Coordinating Group to coordinate activities on establishing priorities and addressing other issues related to residues of animal drugs and pesticides in food animals, detecting illegal residues, and taking regulatory action against violators.

In addition, FDA, FSIS, and EPA have formed a Senior Executive Committee that meets regularly to develop standard operating procedures, and review and improve the protocols of the National Residue Program. The National Residue Program is charged with protecting the public from residual drugs, pesticides, and environmental contaminants that are sometimes found in meat and poultry. FSIS and FDA manage the Residue Violations Information System, which FSIS uses to inform FDA when it finds that an animal drug has been used illegally in meat or poultry.

U.S. Department of Homeland Security (DHS)

FDA works closely with DHS's U.S. Customs and Border Protection (CBP) regarding the import of FDA-regulated products. That cooperation reached a new level under the BT Act, which gave FDA new authorities to ensure the safety and security of imported food. In response to the BT Act, CBP personnel at many ports of entry around the country were formally commissioned and specially trained to conduct cargo and other examinations of FDA-regulated articles. CBP personnel have the authority to hold suspect shipments for further examination and sampling.

Under the Prior Notice Final Rule issued in accordance with the BT Act, articles of imported food that are refused for prior notice violations must be held at the port, or moved to a secure facility outside the port, and cannot be delivered to the importer, owner, or ultimate consignee (21 CFR 1.283). In addition, in accordance with the FDA Compliance Policy Guide for Prior Notice of Imported Food jointly issued with CBP, regulatory actions for violations of the prior notice or food facility registration requirements may include FDA-initiated refusals, holds, injunctions, prosecutions, and/or debarments, as well as result in CBP seizures or civil monetary penalties. CBP may assess civil monetary penalties against any person who directs, assists financially or otherwise, or is in any way involved in the importation of any merchandise contrary to law.

In 2003, FDA and CBP also streamlined the implementation of the prior notice requirements by allowing food importers to provide required information on food imports to both agencies using an integrated electronic process.

DHS, FDA, and FSIS also partner through the Food and Agriculture Sector Government Coordinating Council and Sector Coordinating Council (GCC/SCC). These councils serve to enable sharing of information and communicating mission needs with the food and agriculture community. The GCC and SCC have developed a web-portal to facilitate outreach and information sharing. Through the councils, FDA, FSIS, and DHS collaborated with the DHS Center of Excellence in Minnesota (also known as the National Center for Food Protection and Defense), to study economically motivated adulteration (EMA) of food products. Several potential EMA indicators were identified based on the information obtained through this collaboration. The workgroup is also developing quantitative measures to help identify potential EMA incidents.

U.S. Department of Commerce, National Oceanic and Atmospheric Administration, National Marine Fisheries Service (NMFS)

Although FDA is the primary organization responsible for ensuring that domestic and imported seafood products are safe, sanitary, wholesome, and properly labeled, NMFS conducts, on a fee-for-service basis, a voluntary seafood inspection and grading program that focuses on marketing and quality attributes of U.S. fish and shellfish. FDA provided training and other technical assistance to NMFS. Under this voluntary program, NMFS inspects about 20 percent of the seafood consumed annually in the United States. If industry contracts with NMFS to provide the service, NMFS personnel may inspect fishing vessels and processing plants to ensure that sanitary practices are in keeping with FDA standards. NMFS periodically may evaluate products at processing facilities for general condition, wholesomeness, and proper grading and labeling, and they may sample products for chemical and microbiological contamination, decomposition, and species identification.

In 2010, FDA and NMFS worked together to ensure that seafood from the Gulf of Mexico was safe to eat following the Deepwater Horizon oil spill. FDA and NMFS worked with the Gulf states' regulatory agencies to develop a multi-pronged strategy that included issuing precautionary closures, increasing seafood testing, developing protocols for reopening the Gulf waters, and conducting outreach and education to consumers and other key stakeholders.

Section 201(a) of FSMA created section 421 of the FD&C Act, which, in section 421(c)(2)(E), gave FDA authority to develop a process by which officers and employees of the National Oceanic and Atmospheric Administration may be duly designated to carry out seafood examinations and investigations under section 801 (Imports and Exports) of the FD&C Act or section 203 (Requirement of Information Regarding Allergenic Substances) of the Food Allergen Labeling and Consumer Protection Act of 2004.

U.S. Department of Defense (DOD)

FDA works with DOD to enhance information sharing and collaboration, promote the efficient use of resources, and build an interagency infrastructure and processes as they relate to food at DOD facilities. DOD and FDA have information sharing networks and processes on facility audits and inspections, recalls, import alerts, laboratory findings and methods, and other food protection procedures.

U.S. Department of Labor, Occupational Safety, and Health Administration (OSHA)

Although not technically responsible for performing food inspections, OSHA does inspect workplaces where food may be produced, processed, or held. FDA is working with OSHA to enable the agencies to share relevant information obtained during their respective inspections of facilities where food is produced, processed, or held. OSHA's role is to set and enforce standards that will ensure safe working conditions. While carrying out their respective roles, FDA investigators and OSHA compliance officers may observe conditions or obtain information relevant to the other agency's safety and health mission.

In 2011, OSHA and FDA signed an MOU to facilitate information sharing with respect to matters affecting the occupational safety and health of workers and the safety and security of our nation's food supply in facilities where food is produced, processed, or held.

Federal Trade Commission (FTC)

FDA works with FTC to further the common objective of preventing injury to, and deception of, consumers. Since 1958, FDA and FTC have had agreements in place to facilitate information sharing. The current MOU was signed in 1971 to facilitate coordination of programs and exchange of information and evidence. FDA, FTC, and the Department of Justice have monthly meetings to discuss current cases and enforcement strategies. For example, in 2011, FDA and

FTC issued seven jointly-signed warning letters to companies marketing over-the-counter weight loss products. In 2010, both FDA and FTC issued warning letters to POM Wonderful over marketing of their POM Wonderful 100 percent Pomegranate Juice due to statements that it is intended for use for the cure, mitigation, treatment, or prevention of disease.

FDA Data on Food Facilities, Food Imports, and FDA Foreign Offices

Food Facilities

Section 1003(h)(1)(A) - Appropriations used to inspect registered food facilities

For FY 2012, the appropriation used to inspect facilities registered pursuant to section 415 of the FD&C Act[3] was approximately $198.5 million. Of this amount, $145.2 million was used for FDA inspection of domestic facilities and $34.7 million for FDA inspection of foreign facilities. These amounts include appropriations used to inspect facilities that manufacture food for human consumption and post-market inspections conducted for FDA's Center for Veterinary Medicine (CVM), with the exception of veterinary drug inspections. In addition, of this total, $18.6 million was provided to state agencies, through contracts, to perform domestic inspections on behalf of FDA. These figures do not include the cost of inspections at the border (i.e., sampling and field examinations) since this function is not performed in registered facilities, nor does it include costs for functions such as laboratory analyses or criminal investigations.

Section 1003(h)(1)(B) - Average cost of inspections of non-high-risk food facilities and high-risk food facilities

The framework for identifying high-risk and non-high-risk facilities that was established by section 201 of FSMA, which created section 421 of the FD&C Act, contains additional risk factors that change FDA's historic categorization of facility inspections according to risk. In FY 2012, the average inspection costs of FDA-identified FSMA high-risk and non-high-risk domestic food facilities were: $15,500 (including attempted inspections)[4] per high-risk food facility inspection and $9,200 (including attempted inspections) per non-high-risk food facility inspection.[5] "Attempted inspections" are inspections where the investigators determine that the facility is out-of-business, no longer handles FDA regulated products, or is not operating at the time of the attempted inspection. Foreign high-risk food facility inspections averaged $23,600 per inspection. The high-risk and non-high-risk food facility inventories are not static and will change as new information informs the risk models.

As of June 2013, FDA has only categorized facilities manufacturing food for human consumption as high-risk and non-high-risk under the framework established by FSMA. CVM currently inspects approximately 1,000 high-risk firms per year between the FDA's Office of Regulatory Affairs (ORA) Contract Performance Goal for bovine spongiform encephalopathy (BSE) and the Licensed Medicated Feed Mills program area. The complete inventory of FSMA

high-risk firms under the purview of CVM, i.e. animal feed manufacturing firms, is estimated to be between 8,000 and 10,000 firms. The manufacturing facilities and processes used by many of these establishments are currently not subject to regulation and inspection with the exception of those required to comply with BSE or Medicated Feed Manufacturing compliance programs. CVM is currently working on developing a FSMA risk model that is more comprehensive in its approach and will consider risks beyond what the BSE and Medicated Feed risk models include.

Whether a facility is characterized as high-risk or non-high-risk does not alone determine the cost of inspection. It should be noted that the risk level is only one element of many that affects the cost of doing an inspection. Other factors include but are not limited to the size of the facility, both in terms of the number of people and square footage of the facility, the complexity or level of automation of the manufacturing process, and the volume of products, both in terms of the quantity produced and the number of different types of products produced.

Section 1003(h)(1)(C) - Number of registered facilities inspected

Prior to October 22, 2012, there were 172,969 active registered domestic food and feed facilities and 285,977 active registered foreign food and feed facilities, for a total of 458,946. FSMA's amendments to section 415 of the FD&C Act had not been fully implemented in FY 2012. The numbers above, therefore, reflect food facilities registered under the BT Act requirements, i.e., the section 415 requirements prior to FSMA. Due to data quality challenges, the Official Establishment Inventory (OEI), rather than the section 415 registration database, was used to determine which facilities were inspected in FY 2011-12 and which ones will be inspected in FY 2013. It is FDA's intent to use information from the section 415 registration database to determine which facilities to inspect for future work planning cycles.[6] In FY 2012, FDA and the states under contract with FDA inspected (or attempted to inspect) 24,462 domestic food facilities and FDA inspected 1,342 foreign food facilities.

Section 1003(h)(1)(D) - Number of registered domestic and foreign facilities scheduled for inspection in the previous fiscal year which the Secretary did not inspect

FDA is unable to answer this question at this time. FSMA was enacted in January 2011. In the months following enactment of the law, FDA developed a model for determining if a facility is a high-risk facility or a non-high-risk facility. FDA then assigned the known inventory from OEI to either the high-risk or the non-high-risk category in late FY 2011. FDA then looked at the firms inspected in FY 2011 retrospectively to determine the number of high-risk or non-high-risk facilities inspected. Therefore, the usual sequence of scheduling certain facilities for inspection and then striving to meet that benchmark did not take place. FDA is attempting to inspect all initially-identified high-risk facilities in 3 years (FY 2011-2013), 2 years earlier than directed by this legislation. Additionally, FDA is attempting to inspect all non-high-risk facilities

in 7 years (FY 2011-2017), as directed by this legislation. In next year's report, FDA should be able to report those food facilities, if any, that were scheduled for inspection in FY 2011-2013 but were not inspected during the 3-year cycle.

Section 1003(h)(1)(E) - Number of high-risk facilities inspected

During FY 2011, FDA's Center for Food Safety and Applied Nutrition (CFSAN) identified 22,325 domestic food firms as high-risk per section 421. Of this inventory, 11,007 were inspected in FY 2011. In FY 2012, another 8,023 facilities were inspected (or inspection was attempted), totaling 19,030 or 85 percent of this inventory. In addition, another 3,736 firms inspected in FY 2011 were re-inspected (or inspection was attempted) in FY 2012.

As of June 2013, FDA has only categorized facilities manufacturing food for human consumption as high-risk and non-high-risk under the framework established by FSMA. CVM currently inspects approximately 1,000 high-risk firms per year between the ORA Contract Performance Goal for BSE and the Licensed Medicated Feed Mills program area. The complete inventory of FSMA high-risk firms under the purview of CVM, i.e. animal feed manufacturing firms, is estimated to be between 8,000 and 10,000 firms. The manufacturing facilities and processes used by many of these establishments are currently not subject to regulation and inspection with the exception of those required to comply with BSE or Medicated Feed Manufacturing compliance programs. As stated above, CVM is currently working on developing a FSMA risk model that is more comprehensive in its approach and will consider risks beyond what the BSE and Medicated Feed risk models include.

Section 1003(h)(1)(F) – Number of high-risk facilities scheduled for inspection but not inspected

FDA is unable to answer this question at this time. FSMA was enacted in January 2011. In ensuing months, FDA developed a model for determining if a facility is a high-risk facility or a non-high-risk facility. FDA then assigned the known inventory from OEI to either the high-risk or non-high-risk category in late FY 2011. FDA then looked at the firms inspected in FY 2011 retrospectively to determine the number of high-risk or non-high-risk facilities inspected. Therefore, the usual sequence of scheduling certain facilities for inspection and then striving to meet that benchmark did not take place. FDA is attempting to inspect all initially-identified high-risk facilities in 3 years (FY 2011-2013), 2 years earlier than directed by this legislation. Additionally, FDA is attempting to inspect all non-high-risk facilities in 7 years (FY 2011-2017), as directed by this legislation. In next year's report, FDA should be able to report those high-risk facilities, if any, that were scheduled for inspection in FY 2011-2013 but were not inspected during the 3-year cycle.

Food Imports

Section 1003(h)(2)(A) - Number of import lines examined/sampled

FDA physically examined (conducted field exams or analyzed samples) 207,839 food and feed import lines in FY 2012.

Section 1003(h)(2)(B) - Number of import lines not examined/sampled

The total number of food import lines for FY 2012 was 11,136,599. FDA physically examined 1.9 percent, or 207,839, of the food import lines. It is important to note that while FDA is not able to physically inspect a large percentage of food entries, all import entries are electronically screened using an automated system, which helps field inspectors determine which products pose the greatest risk and, therefore, should be physically examined. FDA recently enhanced screening capability by implementing the Predictive Risk-based Evaluation for Dynamic Import Compliance Targeting (PREDICT) information technology system. PREDICT uses data analytics from the entire life cycle of a product to better identify and target high-risk products before they enter the country. In addition, when necessary, FDA can issue import bulletins which signal FDA inspectors to pay special attention to a particular product, or a range of products from a particular producer, shipper, or importer. Under import alerts, products that appear to be subject to refusal based on existing evidence (such as a history of violations) can be detained at the border and refused admission into U.S. commerce unless the importer is able to demonstrate that the products are in compliance.

Section 1003(h)(2)(C) - Average cost of import examination/sampling

The average cost of physically inspecting or sampling a line of food subject to the FD&C Act that is imported or offered for import into the United States is approximately $160 per field exam and approximately $3,100 per sample analyzed.

FDA Foreign Offices

Section 1003(h)(3) - Number of foreign offices and personnel

As of May 2013, FDA has established a total of 12 foreign posts. The posts have 30 U.S. direct hires (USDH) and 16 locally employed staff (LES) and are fully operational.

Foreign Post Established	USDH	LES	Comments
Beijing, China	4	2	
Shanghai, China	2	2	
Guangzhou, China	2	1	
New Delhi, India	7	2	
Mumbai, India	4	1	

Foreign Post Established	USDH	LES	Comments
San Jose, Costa Rica	3	2	
Santiago, Chile	1	2	
Mexico City, Mexico	2	2	
Brussels, Belgium	2	0	Staff re-deployed to post in 2012
London, England, UK	1	0	
Parma, Italy	0	0	Staff moved to Brussels in 2012
Pretoria, South Africa	1	1	
Amman, Jordan	1	1	
Totals	30	16	

Conclusion

This third annual report required by FSMA provides data for FY 2012. It outlines various food safety activities undertaken by FDA and in partnership with other agencies with responsibilities in the food safety arena.

FDA has long-standing and productive relationships with federal, state, local, tribal, and territorial public health officials on food safety issues.

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[1] This number only includes inspectional FTEs.

[2] A Class I Recall is a situation in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious adverse health consequences or death.

[3] Section 102 of FSMA modified section 415 of the FD&C Act. However, these modifications had not been fully implemented in FY 2012. The registration data in this report reflects facilities currently registered under the BT Act requirements, i.e., the section 415 requirements prior to FSMA.

[4] In FY11, the small proportion of attempted inspections to completed inspections had a minor effect on the cost per inspection calculation; whereas in FY12, the much larger proportion of attempted inspections to completed inspections had a much larger impact on the cost per inspection calculation.

[5] Inspection costs include payroll, benefits and operating costs (e.g. travel, training, and rent and rent-related costs), and information technology shared services. These costs also include Center-related costs and Office of Commissioner overhead.

[6] Section 102(a) of FSMA created section 415(a)(3) of the FD&C Act, which requires biennial registration renewal during the period beginning on October 1 and ending on December 31 of each even-numbered year. However, there was a delay in implementation of biennial registration renewal for the 2012 cycle, and registration renewal did not become available until October 22, 2012. FDA exercised enforcement discretion with respect to registration renewals submitted to FDA after December 31, 2012, for a period of 31 days, until January 31, 2013.