2011 Annual Report on Food Facilities, Food Imports, and FDA Foreign Offices

April 2011

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

This first Annual Report on Food Facilities, Food Imports, and FDA Foreign Offices was submitted to Congress by HHS Secretary Sebelius on April 6, 2011, in response to Section 201 (b) of the Act. The report briefly describes the scope of FDA's responsibility and its activities in protecting the U.S. food supply under its jurisdiction. It also discusses how federal, state and local agencies cooperate with FDA in that effort. Baseline data are provided on the cost and number of domestic and foreign food facility inspections; the numbers of field samples analyzed to support FDA's compliance actions; and FDA's foreign posts and their staff who extend the international impact of FDA.

Submitted pursuant to Section 201 of P. L. 111-353
U.S. Department of Health and Human Services
Food and Drug Administration
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Introduction

On January 4, 2011, the President 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 ("the FD&C Act") by requiring, not later than February 1 of each year, that the Secretary of Health and Human Services (HHS) submit to Congress a report that describes the Food and Drug Administration's (FDA's) efforts to coordinate and cooperate with other Federal agencies with responsibilities for food inspections and regarding information about food facilities, food inspections, food imports, and FDA foreign offices.

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

Background

FDA is responsible for protecting and promoting the 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 420,000 registered domestic and foreign facilities. FDA devotes approximately 1,100 full-time staff years (known as full-time equivalents, or FTEs) to conducting food and feed inspection and investigational activities.

Importers of food products intended for introduction into U.S. 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 the agency 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 legal requirements.

Coordination and Cooperation with State and Local Agencies

Besides 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. FDA provides these authorities with training, guidance, model codes, and other technical assistance to provide support and promote uniform coverage of food establishments.

Recognizing the importance of a fully integrated national food safety system, FDA has devoted significant time and resources toward building such a system, in collaboration with all of these partners. The FSMA encourages and enables FDA to make further progress. The fully integrated national system will encompass inspections, laboratory testing, and response and will place priority on preventing foodborne illness, in both food for humans and animals. It will achieve the prevention goal through the new standard setting required by FSMA, more effective inspection and compliance activity by FDA, and partnership with the states supported by the adoption and uniform application of standards, such as the Manufactured Food and the Retail Food Regulatory Program Standards, that ensure state and local agencies on which FDA relies perform at a consistently high level. This collaboration will result in 1) better ability to assess potential risk at domestic food facilities; 2) greater and more consistent inspectional coverage of these facilities across the entire food supply chain; 3) greater food surveillance through integration of food facility inspection and testing information; and, 4) improved rapid response capacity and efficiency.

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), which in July 2009 issued its key findings on how to upgrade the food safety system for the 21st century. The Working Group 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. These core principles closely align with FSMA.

FDA's cooperation with other Federal agencies is long-standing and extends beyond inspections to other activities such as outbreak investigations and the development of policies related to food safety.

For example, FDA worked closely with USDA as it began work on a proposed rule that would establish standards for the production, harvesting, and packing of fresh produce. USDA's experience in working with the production community has been extremely useful during listening sessions and farm tours and in providing technical guidance to FDA.

Another example is FDA's continuing relationship with the Centers for Disease Control and Prevention (CDC) in investigating outbreaks of foodborne illness. The two agencies work closely together, and with the States and FSIS, and often form multidisciplinary teams to gather information during investigations. 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.

Another example of interagency cooperation relates to retail food safety. FDA partners with CDC and FSIS on each biennial issue of the Food Code, a model ordinance developed through the Conference for Food Protection. FDA works with the States to secure adoption of the Code as law regulating food safety in retail stores and food service facilities.

Another example involves residues of animal drugs in food. FDA, FSIS, and the Environmental Protection Agency (EPA) meet regularly through an Interagency Regulatory Coordinating Group to coordinate activities related to setting standards for residues of animal drugs in food animals, detecting illegal residues, and taking regulatory action against violators. FDA also works closely with the EPA, which sets pesticide tolerances that FDA enforces.

Below are examples of how FDA works with specific Federal agencies on inspections. 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 our respective responsibilities.

U.S. Department of Agriculture, FSIS

FDA's responsibility in the food area generally covers all domestic and imported food except meat, poultry, and frozen, dried and liquid egg products, which are the responsibility of USDA's FSIS.

FDA cooperates with FSIS on inspection in two major areas. First, FDA works with FSIS in dual-jurisdiction establishments, which are those establishments that produce and ship products regulated by FDA, as well as products regulated by FSIS. For example, a plant that produces and ships both a spaghetti sauce with meat and a spaghetti sauce without meat is a dual-jurisdiction establishment. While these are a small percentage of establishments, their oversight requires close coordination. FSIS and FDA communicate about findings of hazardous, contaminated, or mislabeled foods and about processes that may result in contamination, recalls, or evidence of tampering in these establishments. For example, FDA can use information from an FSIS inspection that might affect an FDA-regulated product. The two agencies are now discussing joint investigations, environmental assessments, evidence collection, and cross-training of staff as a way to further coordinate efforts. The agencies are also considering the implications of FSMA for these cooperative efforts.

Second, there are situations where an establishment regulated by one agency (not a dual jurisdiction establishment) produces a product using an ingredient regulated by the other. An example would be a sausage product with pepper as an ingredient. Although FSIS has regulatory authority over the establishment, FDA may be called in to assist with investigations in the event of an outbreak that might be linked to the pepper ingredient.

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 production facilities (e.g., 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.). The surveillance inspections ensure the proper disposition of eggs that are leaking or dirty, for example. These inspections by AMS and cooperating State agencies are conducted 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 that would 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 Homeland Security, Customs and Border Protection (CBP)

FDA works closely with CBP regarding imports of FDA-regulated products. That cooperation reached a new level under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Bioterrorism Act, or 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 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. 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.

U.S. Department of Commerce, National Marine Fisheries Service (NMFS)

Although FDA is the primary agency 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. 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; they 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.

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 OSHA is 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. The agencies would benefit in sharing this information.

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

Food Facilities

Section 421(h)(1)(A) - Appropriations used to inspect registered food facilities
For fiscal year 2010, the appropriations used to inspect facilities registered pursuant to section 415 of the FD&C Act was approximately $172 million. Of this amount, $129.6 million was used for FDA inspection of domestic facilities and $25.9 million for FDA inspection of foreign facilities. In addition, of this total, $16.5 million was provided to the States to perform domestic inspections for 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 421(h)(1)(B) - Average cost of inspections of non-high-risk food facilities and high-risk food facilities
FDA is unable to provide information at this time on the cost of inspecting facilities identified as high-risk or non high-risk under the framework established by FSMA. Specifically, the FD&C Act's new section 421 contains additional risk factors that change FDA's historic categorization of facility inspections according to risk. Historical data collection and analysis (e.g., FY 2010 and earlier years) were not structured to correspond to the new framework. Information on this point will be provided in future annual reports as it becomes available. 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 the size of the facility both in 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, just to name a few. Whether a facility is characterized as high or low risk does not alone determine the cost of inspection.

Section 421(h)(1)(C) - Number of registered facilities inspected
As of January 13, 2011, there were 167,033 active registered domestic facilities and 254,088 active registered foreign facilities, for a total of 421,121. In FY 2010, FDA and the States under contract with FDA inspected 25,214 domestic food facilities and
357 foreign food facilities.

Section 421(h)(1)(D) - Number of domestic and foreign facilities scheduled for inspection in the previous fiscal year which the Secretary did not inspect
We are unable to provide a response to this question since we do not plan our yearly inspections from a predetermined list of establishments.

Section 421(h)(1)(E) and (F) - Number of high-risk facilities inspected and not inspected
FDA is unable to provide information on inspections of high-risk facilities identified pursuant to section 421 at this time. As explained above, section 421, as added to the FD&C Act by section 201(a) of FSMA, did not exist in the previous fiscal year. New section 421 contains additional factors that would introduce a new framework for classifying facilities based on risk. We are unable to crosswalk historic categorization of facility inspections according to risk.

Food Imports

Section 421(h)(2)(A) - Number of line entries examined/sampled
FDA physically examined (conducted field exams or analyzed samples) 206,723 food import lines (shipments) in FY 2010.

Section 421(h)(2)(B) - Number of line entries not examined/sampled
The total number of food import lines (shipments) for FY 2010 was 9,974,958. FDA physically examined 2.1 percent, or 768,235, of the food import lines. However, it is important to note that FDA screens all import lines electronically against a variety of risk criteria.

Section 421(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 $390 per field exam and approximately $2,600 per sample analyzed.

FDA Foreign Offices

Section 421(h)(3) - Number of foreign offices and personnel
FDA has established a total of 13 foreign posts as of January 2011. Of the 13 posts, 11 posts have been staffed with a total of 30 U.S. direct hires (USDH) and 14 locally employed staff (LES) and are fully operational. The foreign posts and number of USDH and LES approved by the Department of State at each post are listed below.

Foreign Post Established	USDH	LES
Beijing, China	4	2
Shanghai, China	2	2
Guangzhou, China	2	0

Foreign Post Established	USDH	LES
New Delhi, India	7	2
Mumbai, India	5	1
San Jose, Costa Rica	4	2
Santiago, Chile	1	2
Mexico City, Mexico	2	2
Brussels, Belgium	1	1
London, England, UK	1	0
Parma, Italy	1	0
Totals	30	14

Conclusion

This first annual report required by the FSMA provides baseline data for FY2010 prior to enactment of the law. 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. We expect our collaborations and partnerships to be strengthened as we begin FSMA implementation.