



Report to the Chairman, Subcommittee
on Europe, Eurasia, and Emerging
Threats, Committee on Foreign Affairs,
House of Representatives

January 2015

FOOD SAFETY

Additional Actions Needed to Help FDA's Foreign Offices Ensure Safety of Imported Food

Accessible Version

GAO Highlights

Highlights of [GAO-15-183](#), a report to the Chairman, Subcommittee on Europe, Eurasia, and Emerging Threats, Committee on Foreign Affairs, House of Representatives

Why GAO Did This Study

FDA has responsibility for ensuring the safety and proper labeling of more than 80 percent of the U.S. food supply, including an increased volume of imported food. Beginning in 2008, FDA established foreign offices to help prevent unsafe products from reaching U.S. borders. In 2010, GAO examined FDA's foreign offices and found that they engaged in a variety of activities relating to food safety but faced challenges due to an increasing workload and other factors. GAO was asked to follow up that report.

This study examines (1) the activities FDA foreign offices have engaged in since 2010 to help ensure the safety of imported food, (2) the extent of the foreign offices' contributions to the safety of imported food, and (3) the extent to which FDA has engaged in workforce planning for its foreign offices. GAO reviewed documentation of foreign office activities and plans, visited offices in China and Mexico, and interviewed agency officials, foreign regulators, and other stakeholders.

What GAO Recommends

GAO recommends that FDA complete an analysis to determine the annual number of foreign food inspections that is sufficient to ensure comparable safety of imported and domestic food. FDA agreed with GAO's recommendation.

View [GAO-15-183](#). For more information, contact J. Alfredo Gómez at (202) 512-3841 or gomezj@gao.gov.

January 2015

FOOD SAFETY

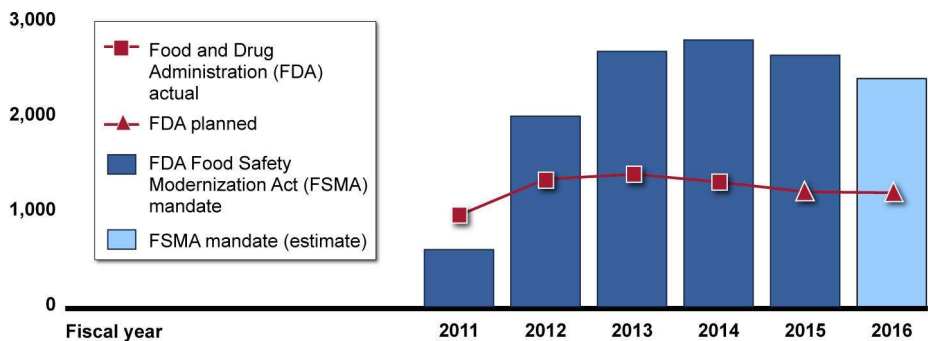
Additional Actions Needed to Help FDA's Foreign Offices Ensure Safety of Imported Food

What GAO Found

The Food and Drug Administration's (FDA) foreign offices have engaged in a variety of activities since 2010 to help ensure that imported food is safe. Foreign offices reported that building relationships with foreign counterparts and gathering and assessing information were among their top priorities. As directed by the FDA Food Safety Modernization Act (FSMA), foreign offices also inspected foreign food facilities. Under FSMA, FDA is to inspect at least 600 foreign food facilities in 2011 and, for each of the next 5 years, inspect at least twice the number of facilities inspected during the previous year. As shown in the figure below, FDA is not currently keeping pace with the FSMA mandate. FDA officials told GAO that they do not plan to meet the FSMA mandate because of funding, and they question the usefulness of conducting that many inspections. However, FDA has not conducted an analysis to determine whether the number of inspections in the FSMA mandate or the lower number of inspections it is conducting is sufficient to ensure comparable safety of imported and domestic food. Without such an analysis, FDA is not in a position to know what is a sufficient number of foreign inspections and, if appropriate, request a change in the mandate.

FDA Inspections of Foreign Food Facilities Compared with FSMA Mandate

Number of inspections of foreign food facilities



Sources: GAO analysis of FDA (data) and FSMA. | GAO-15-183

FDA foreign offices cite their contributions to the safety of imported food, but the agency's performance measures do not fully capture these contributions. GAO recommended in 2010 that FDA develop performance measures that can be used to demonstrate the offices' contributions to imported food safety. This recommendation remains valid. FDA has initiated a review to determine how to better reflect the value of the foreign offices in the agency-wide performance systems. Until the offices' contributions are captured, FDA will have less information to effectively measure their progress toward meeting agency goals.

FDA has taken some steps to address recruitment challenges since GAO last reported, but it still does not have a strategic workforce plan. In 2010, GAO recommended that FDA develop such a plan for the foreign offices to help ensure that it recruits and retains staff with the necessary experience and skills. GAO continues to believe that such a plan for the foreign offices is critical to FDA's ability to address staffing challenges, especially since 44 percent of foreign office positions were vacant as of October 2014.

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Abbreviations

CBO	Congressional Budget Office
CDC	Centers for Disease Control and Prevention
EFSA	European Food Safety Authority
EPA	Environmental Protection Agency
FDA	Food and Drug Administration
FSIS	Food Safety and Inspection Service
FSMA	FDA Food Safety Modernization Act
OIP	Office of International Programs
ORA	Office of Regulatory Affairs
USDA	United States Department of Agriculture

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Letter

U.S. GOVERNMENT ACCOUNTABILITY OFFICE

441 G St. N.W.
Washington, DC 20548

January 30, 2015

The Honorable Dana Rohrabacher
Chairman
Subcommittee on Europe, Eurasia, and Emerging Threats
Committee on Foreign Affairs
House of Representatives

Dear Mr. Chairman:

Globalization has increased the volume of food imported into the United States and introduced a higher level of complexity for ensuring the safety of food. For example, melamine- and cyanuric acid-contaminated pet food imported from China sickened and killed U.S. cats and dogs in 2007 and raised concerns about the safety of imported human and animal food. Melamine, an industrial chemical that is not approved for use in food in the United States, was used by a Chinese manufacturer to mimic increased protein levels in food ingredients. The U.S. reliance on imported food as a percentage of all food consumed has grown from about 9 percent in 2000 to more than 16 percent in 2011. Some food categories are now more likely to come from foreign sources than domestic ones. For example, about 91 percent of seafood consumed in the United States was imported in 2011, according to the National Marine Fisheries Service. The United States also imported \$4.6 billion in fresh vegetables and \$3.1 billion in fresh fruit (excluding bananas) from Mexico in 2013, according to the Office of the U.S. Trade Representative. GAO's 2013 High Risk List included the need to revamp federal oversight of food safety and cited, as a major food safety challenge, the substantial and increasing portion of the U.S. food supply that is imported.¹

The Food and Drug Administration (FDA) has responsibility for helping to ensure the safety and proper labeling of more than 80 percent of the U.S. food supply, including the increased volume of food imports. In response to the challenge of globalization, beginning in 2008, FDA established a total of seven foreign offices, each with responsibility for a different area of the world. According to FDA, the mission of the foreign offices is to engage with stakeholders in strategic areas abroad to help prevent

¹GAO, *High-Risk Series: An Update*, [GAO-13-283](#) (Washington, D.C.: February 2013).

unsafe products, such as food, drugs, and medical devices, from reaching U.S. borders and to help FDA make informed decisions about product entry into the United States. In 2010, we examined the activities of FDA's foreign offices and found that they engaged in a variety of activities to help ensure the safety of imported products, but FDA faced challenges due to an increasing workload and other factors.² You asked us to follow up on that report and review issues related to FDA's foreign offices and the safety of imported food. This report examines (1) the activities FDA foreign offices have engaged in since 2010 to help ensure the safety of imported food, (2) the extent of the foreign offices' contributions to the safety of imported food, and (3) the extent to which FDA has engaged in workforce planning for its foreign offices. For the purposes of this report, "food" refers to food and dietary supplements for humans and food for animals, unless otherwise specified.

To address all three objectives, we conducted an in-depth review of foreign office operations in Canada, China, and Mexico. We selected these locations based on an analysis of the volume of food imports, the percentage of food imports refused at the border, and the number of food facility inspections for fiscal year 2013, among other factors. Our review included site visits to FDA's locations in Beijing and Guangzhou, China, and Mexico City, Mexico, to interview key FDA and U.S. embassy officials, as well as foreign food safety regulatory authorities. We selected those locations because they conduct food inspections, among other reasons. We also accompanied foreign office staff on site visits to food facilities to learn how inspections are conducted in other countries. To examine the activities FDA's foreign offices have engaged in since our 2010 report, we evaluated answers the foreign offices submitted to questions about their activities, conducted structured interviews with officials from the foreign offices, and compared the numbers of food inspections completed by FDA investigators with targets mandated in the FDA Food Safety Modernization Act (FSMA).³ To examine the extent of the foreign offices' contributions to the safety of imported food, we analyzed documents describing outcomes of the foreign offices' activities—including inspection reports and import alerts—and interviewed

²GAO, *Food and Drug Administration: Overseas Offices Have Taken Steps to Help Ensure Import Safety, but More Long-Term Planning Is Needed*, [GAO-10-960](#) (Washington, D.C.: Sept. 30, 2010).

³FDA Food Safety Modernization Act, Pub. L. No.111-353, 124 Stat. 3885 (2011).

officials. We analyzed performance planning and management documentation to determine the extent that FDA had performance measures that were outcome oriented and captured the activities of the foreign offices, based on leading practices that we have previously identified.⁴ To examine the extent to which FDA has engaged in workforce planning for its foreign offices, we evaluated staffing numbers, interviewed officials, and reviewed workforce planning documents. We also reviewed leading practices for workforce planning that we have previously identified.⁵ Through interviews with FDA officials knowledgeable about inspection, performance, and staffing data, we determined that the data were sufficiently reliable for use in our review. Appendix I provides details about our objectives, scope, and methodology.

We conducted this performance audit from November 2013 to January 2015 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Background

FDA is responsible for helping to ensure that food products marketed in the United States meet the same statutory and regulatory requirements, whether they are produced in the United States or another country. FDA shares responsibility for the oversight of food safety with the United States Department of Agriculture's (USDA) Food Safety and Inspection Service (FSIS). FSIS oversees the safety of domestic and imported meat, poultry, and processed egg products, while FDA is responsible for the safety of virtually all other foods, including milk, seafood, fruits, and vegetables. FDA's responsibilities for overseeing the safety of imported products are divided among its product centers and program offices. FDA's six centers are each responsible for the regulation of specific types

⁴GAO, *Agency Performance Plans: Examples of Practices That Can Improve Usefulness to Decisionmakers*, [GAO/GGD/AIMD-99-69](#) (Washington, D.C.: Feb. 26, 1999) and *Managing for Results: Critical Issues for Improving Federal Agencies' Strategic Plans*, [GAO/GGD-97-180](#) (Washington, D.C.: Sept. 16, 1997).

⁵GAO, *Human Capital: Key Principles for Effective Strategic Workforce Planning*, [GAO-04-39](#) (Washington, D.C.: Dec. 11, 2003).

of products, whether manufactured in the United States or another country. For example, the Center for Food Safety and Applied Nutrition is responsible for ensuring that the nation's food supply is safe, sanitary, wholesome, and honestly labeled, and that cosmetic products are safe and properly labeled.⁶ FDA's Office of International Programs (OIP) has responsibility for leading, managing, and coordinating all of the agency's international activities, including its foreign offices. OIP, which is part of FDA's Office of Global Regulatory Operations and Policy, collaborates with the international affairs staff in FDA's centers and the Office of Regulatory Affairs (ORA). ORA—also part of the Office of Global Regulatory Operations and Policy—performs fieldwork to promote compliance with FDA requirements and the applicable laws, such as inspecting foreign facilities and examining products at the U.S. border.

FDA's foreign offices function within the embassy or consulate for the country or region under the auspices of the Department of State, along with other federal agencies that operate abroad, such as the USDA's Foreign Agricultural Service, USDA's Animal and Plant Health Inspection Service, and the Department of Commerce's U.S. Commercial Service.⁷ FDA also works on related issues with other U.S. agencies, including USDA's Food Safety Inspection Service to share food safety information, the Centers for Disease Control and Prevention (CDC) during foodborne outbreaks, and the Environmental Protection Agency (EPA) to enforce pesticide residue tolerances in foods that are established by EPA.

FDA's foreign offices have a director or deputy director to whom staff members report. The offices also may have food investigators that conduct inspections, as well as senior regional specialists, technical experts, and program support specialists who are responsible for engaging with foreign stakeholders and gathering information. Some offices also may have investigators responsible for inspecting other FDA-regulated products, such as drugs and medical devices, and locally

⁶FDA's other centers are the Center for Veterinary Medicine, Center for Biologics Evaluation and Research, Center for Devices and Radiological Health, Center for Drug Evaluation and Research, and the Center for Tobacco Products.

⁷The Foreign Agricultural Service promotes U.S. agriculture overseas and provides food aid and technical assistance to foreign countries; the Animal and Plant Health Inspection Service protects and promotes U.S. agricultural health; and the U.S. Commercial Service helps U.S. companies export or increase sales to new global markets.

employed staff, also known as Foreign Service Nationals, who are non-U.S. citizens employed at U.S. missions abroad.

In 2011, FSMA expanded and modified FDA's authorities and responsibilities, enhancing the agency's oversight of imported food by, among other things, including provisions that might better ensure the comparable safety of imported and domestic food. For example, FSMA gave FDA express authority to hold imported foods to the same standards as domestic foods. FSMA directed the establishment of offices in foreign countries and specified that the offices (1) assist governments in those countries in ensuring the safety of food and other FDA-regulated products and (2) conduct risk-based inspections of food and other products and support such inspections by foreign governments. With respect to foreign facilities that are sources of food imported to the United States, the law directs FDA to inspect at least 600 foreign facilities within 1 year of enactment of FSMA and, in each of the 5 years following that period, to inspect at least twice the number it inspected during the previous year. In addition, FDA can refuse entry into the United States of food from a foreign facility if FDA is denied access for inspections by the foreign facility or the country in which the facility is located.

FDA Foreign Offices Have Engaged in a Variety of Activities Since 2010 to Help Ensure the Safety of Imported Food

FDA's foreign offices have engaged in a variety of activities intended to help ensure the safety of imported food; building relationships with foreign counterparts has been a top-priority activity. Foreign offices have conducted inspections of foreign food facilities, but FDA is not keeping pace with FSMA's mandate for increasing the number of these inspections.

Foreign Offices Vary in Their Focus on Different Activities; Building Relationships with Foreign Counterparts Has Been a Top Priority

FDA reported to Congress in 2012 that the primary purpose of posting staff in other countries is to engage more proactively and consistently with various stakeholders to help prevent unsafe products from reaching U.S. borders.⁸ To accomplish that purpose, the foreign offices have engaged in various types of activities, including (1) building collaborative and cooperative working relationships with foreign regulatory authorities and U.S. federal agencies located in other countries, (2) gathering and assessing information to increase FDA’s knowledge of the regulatory landscape, such as conditions in other countries that could affect the safety of food, and (3) conducting inspections to help identify high-risk facilities and determine the risks from imported products. Table 1 explains these and other types of activities conducted by FDA’s foreign offices.

Table 1: Food and Drug Administration (FDA) Foreign Office Activities Related to Food Safety

Activity	Explanation
Conducting inspections and investigations	Conduct inspections of a routine, priority, or emergency nature and collect information about the manufacture of FDA-regulated products exported to the United States, as directed by the Office of Regulatory Affairs (ORA). For example, FDA investigators posted in the India Office completed a total of 67 food facility inspections in 2014. Information gathered from inspections and investigations is used to better target inspections of high-risk facilities and high-risk products and better analyze risks from imported products.
Collecting samples	Collect samples of, and examine, FDA-regulated products destined for the United States. For example, as part of an outbreak investigation involving fresh produce, the Latin America Office location in Mexico City collected water samples to send to the United States for testing.
Managing recalls	Engage in the recall of, or track an outbreak related to, FDA-regulated products destined for the United States that are manufactured in the office’s area. For example, the Europe Office helped link a 2012 outbreak of listeriosis, which sickened 22 people and resulted in four deaths in the United States, to ricotta cheese imported from Italy. As a result, some ricotta cheese from Italy was recalled, ending instances of illness and death in the United States.
Gathering and assessing information	Increase FDA’s knowledge of a country’s or region’s regulatory landscape by assessing conditions and events that might affect the safety, quality, efficacy, security, and availability of FDA-regulated products exported to the United States. For example, the Europe Office “scans” the environment within their geographic locales to obtain information that may be helpful to the FDA centers, ORA and other FDA offices, and senior executive leadership in their decision making, and compiles that information into “country profiles.” This information is to help FDA’s centers and border officials make informed decisions about allowing a product into the United States.
Providing information on FDA policies, laws, regulations, standards, and expectations	Work with the regulated industries to help increase their understanding of FDA’s requirements and expectations regarding regulated products. For example, the China Office location in Beijing conducts workshops and serves as a resource for industry and local governments.

⁸U.S. Department of Health and Human Services, Food and Drug Administration, *Report to Congress on the FDA Foreign Offices, Submitted pursuant to Section 308 (c) of the FDA Food Safety Modernization Act (P. L. 111-353)*, Feb. 3, 2012.

Activity	Explanation
Building relationships	Engage with foreign counterpart regulatory authorities to establish and maintain collaborative and cooperative working relationships that help to ensure timely exchange of information regarding the manufacturing and distribution of food products that are exported to the United States. For example, the Latin America Office location in Mexico City regularly meets with its in-country regulatory counterparts.
Engaging in technical cooperation and capacity-building	Partner with foreign regulatory counterparts to address regulatory issues of mutual concern and priority, and to leverage each others' information and activities, as appropriate. Capacity-building, in turn, supports a data-driven approach to FDA decision making. For example, FDA, including the Asia-Pacific Office, is negotiating an agreement with Canada that includes regulatory cooperation and opportunities to strengthen regulatory data and systems to help ensure the safety and quality of FDA-regulated products. ^a
Cooperating with other U.S. government agencies	Coordinate and collaborate routinely on product quality and safety issues with other U.S. government agencies in-country that have complementary missions. For example, the China Office location in Beijing interacts with the U.S. Departments of State, Agriculture, Commerce, and the United States Trade Representative on food-safety issues as they arise.

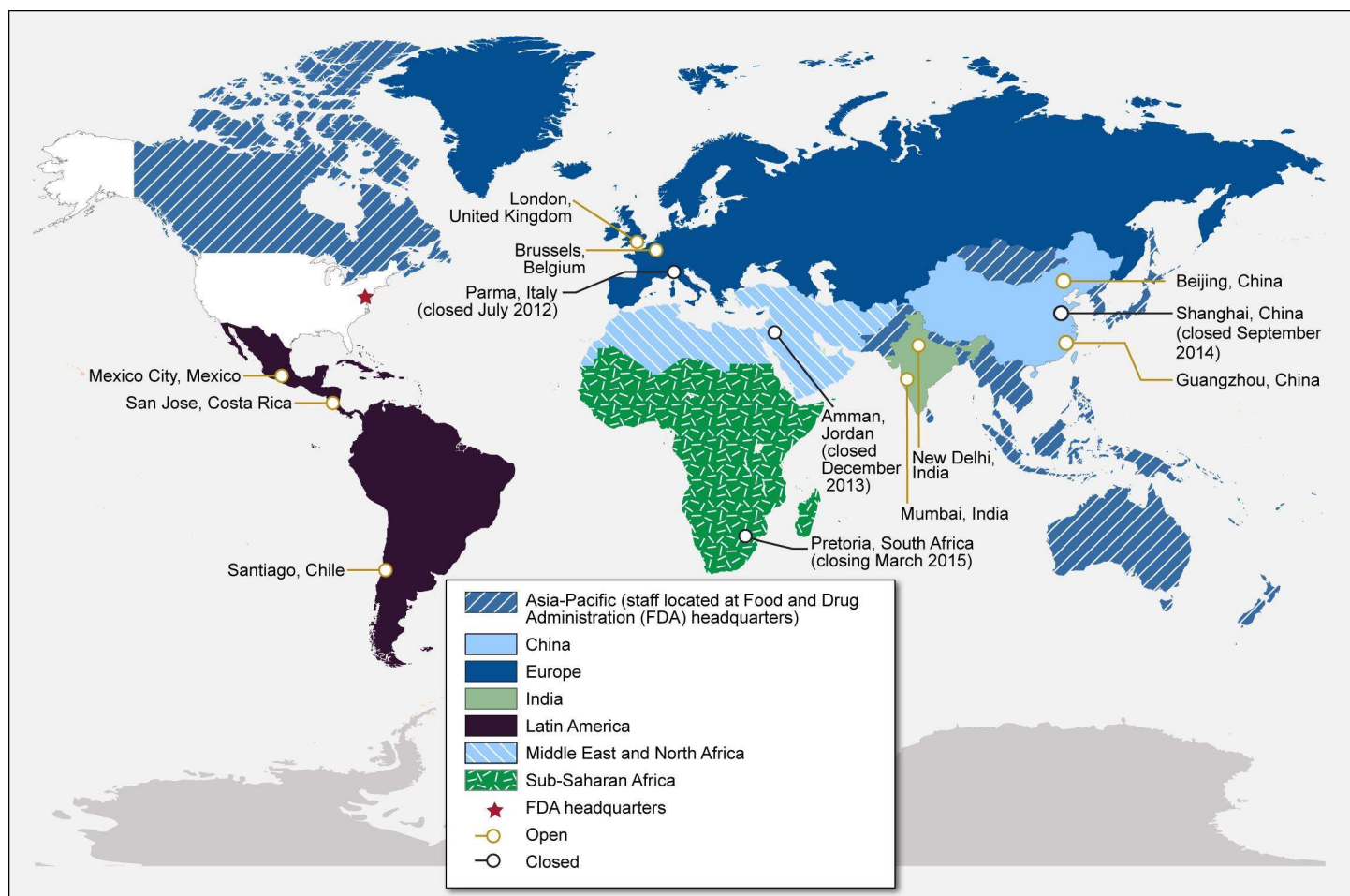
Source: GAO summary of FDA documents. | GAO-15-183

^aIn December 2014, FDA changed the name of its Asia-Pacific Office to the Office of Regional and Country Affairs.

These activities are carried out by FDA's foreign offices—some of which have multiple locations—that divide up responsibilities for different parts of the world. As shown in figure 1, all offices are located in other countries except the Asia-Pacific Office, which is located at FDA headquarters in the United States.⁹ As illustrated in the figure, FDA has closed, or plans to close, some of its foreign office locations. FDA has closed these offices for a variety of reasons. For example, the location in Parma, Italy—where the European Food Safety Authority (EFSA) is headquartered—was closed, and FDA staff relocated to the United States Mission to the European Union in Brussels, Belgium, as a more efficient use of resources to ensure coverage for FDA-related activities within the European Union while maintaining the liaison with EFSA through temporary duty assignments. As part of these closures, the Asia-Pacific Office—which covers Canada, Australia, New Zealand, and countries in Asia other than China and India—has absorbed responsibilities for countries previously covered by the Middle East and North Africa Office and the Sub-Saharan Africa Office.

⁹On December 17, 2014, FDA changed the name of its Asia-Pacific Office to the Office of Regional and Country Affairs. For the purpose of this report, we use the former name of the office.

Figure 1: Food and Drug Administration (FDA) Foreign Office Locations



Sources: GAO analysis of FDA information; Map Resources (map). | GAO-15-183

Note: In December 2014, FDA changed the name of its Asia-Pacific Office to the Office of Regional and Country Affairs.

We questioned the foreign offices to determine the extent to which they performed these activities and which three activities were a top priority in 2014. The foreign offices reported similarities and differences in the types of activities they conducted. For example, all offices similarly reported conducting activities related to (1) gathering and assessing information, (2) providing information on FDA standards, and (3) building relationships. As shown in figure 2, we found differences in top-priority activities across the foreign offices.

Figure 2: Top-priority Food Safety Activities, as Reported by Food and Drug Administration (FDA) Foreign Offices in 2014

Foreign office	Conducting inspections	Collecting samples	Managing recalls	Gathering and assessing information	Providing information about Food and Drug Administration (FDA)	Building relationships	Engaging in technical cooperation	Cooperating with other U.S. agencies
Asia-Pacific					✓	✓	✓	
China (Beijing)	✓			✓			✓	
China (Guangzhou)	✓			✓	✓			
Europe (Brussels)				✓	✓	✓		
Europe (London)				✓	✓	✓		
India (Mumbai)	✓			✓		✓		
India (New Delhi)	✓			✓		✓		
Latin America (Costa Rica)					✓	✓	✓	
Latin America (Mexico)					✓	✓	✓	

✓ Top-priority activity

Source: GAO analysis of FDA information. | GAO-15-183

Notes: The foreign offices each identified their three top priority activities.

In December 2014, FDA changed the name of its Asia-Pacific Office to the Office of Regional and Country Affairs.

Foreign Offices Have Conducted Food Inspections, but FDA Is Not Keeping Pace with Mandated Targets

As noted earlier, FSMA directed, among other things, the establishment of foreign offices to conduct risk-based inspections of food and other products. The foreign offices that conduct inspections of food facilities use investigators that are either assigned to a foreign office for at least a 2-year rotation (in-house) or assigned to a foreign office on temporary duty for 60, 90, or 120 days from ORA.¹⁰ FDA's China Office, India Office, and Latin America Office are the only foreign offices that conducted inspections of food facilities in 2014.

Our analysis showed that the number of inspections performed by the foreign offices has increased since we reported in 2010 but remains a small part of FDA's total number of foreign food inspections.¹¹ In 2010, FDA's China Office completed 13 food inspections, and the India Office completed none. By 2013, the China Office completed 45 of FDA's total 59 food inspections in China (about 76 percent), and the India Office completed all 20 FDA food inspections in India—about 5 percent of FDA's total 1,415 inspections of foreign food facilities.¹² In 2014, FDA added food investigators to its Latin America Office to conduct inspections, and the agency anticipates conducting more inspections of foreign food facilities in the future. During 2014, the foreign offices completed 140 of FDA's total 1,323 inspections of foreign food facilities—66 in China, 67 in India, and 7 in Latin America—a 10-fold increase in the 4 years since 2010.

The foreign offices also have begun providing in-country information to U.S.-based ORA investigators to help them complete their assigned foreign food inspections. Figure 3 shows the locations where FDA investigators conducted inspections of foreign food facilities in fiscal year 2014. These numbers include food inspections performed by FDA investigators, whether they were assigned to a specific foreign office, on

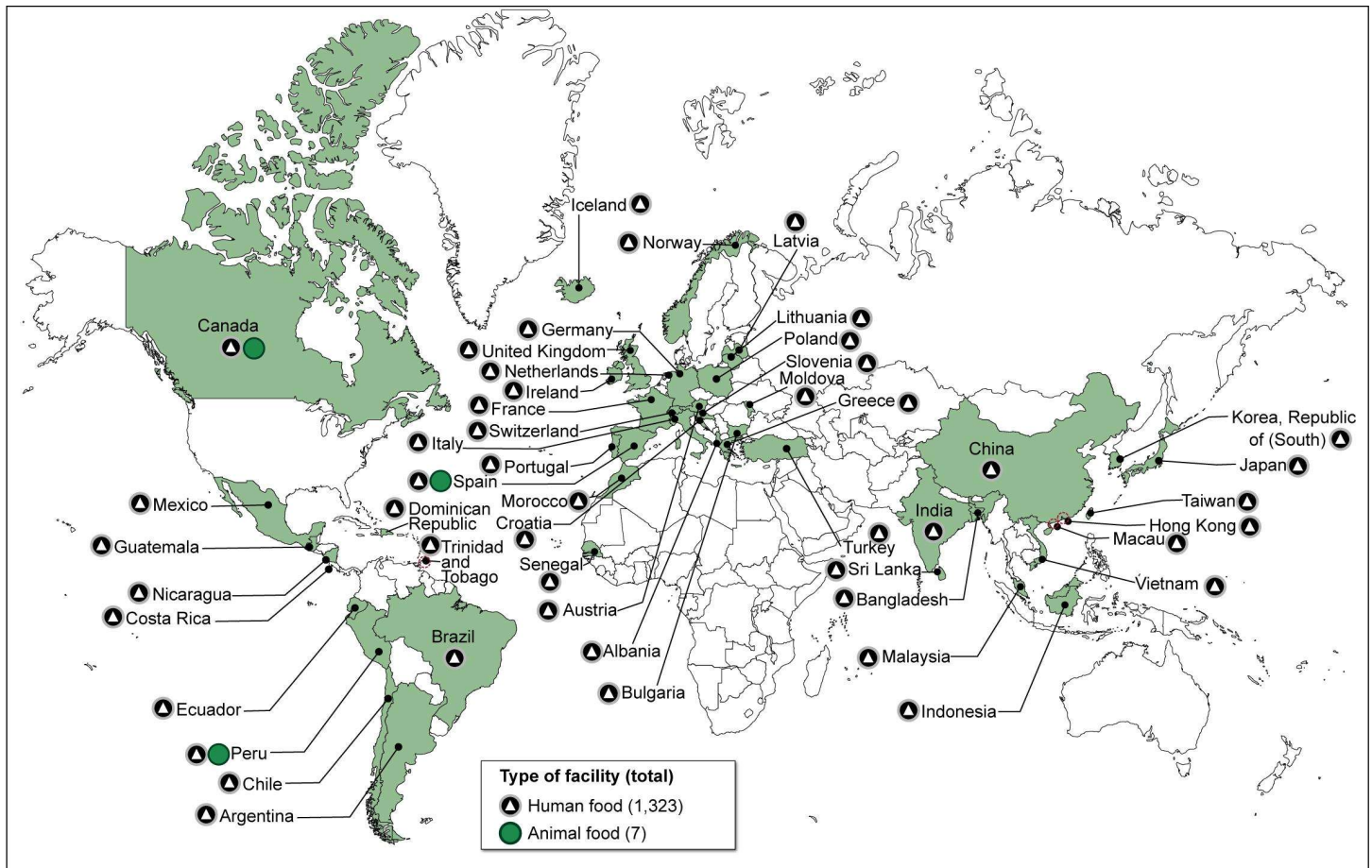
¹⁰FDA inspections of foreign food facilities are also conducted by investigators assigned to an ORA location in the United States who travel to other countries for a few weeks at a time.

¹¹FDA tracks its completed inspections by fiscal year. As a result, the annual inspection data presented in this report are for the given fiscal year. For example, inspections listed as occurring in year 2014 were completed from October 1, 2013, through September 30, 2014.

¹²The 1,403 inspections in 2013 included inspections of foreign facilities producing food for human consumption and 12 of foreign facilities producing food for animals.

temporary duty from ORA, or based with ORA in the United States and assigned to travel for a few weeks at a time to inspect foreign facilities.

Figure 3: Food and Drug Administration (FDA) Inspections of Foreign Food Facilities in 2014



Country	Human Food	Animal Food	Country	Human Food	Animal Food	Country	Human Food	Animal Food	Country	Human Food	Animal Food	Country	Human Food	Animal Food
Albania	4		Croatia	12		India	108		Malaysia	15		Senegal	5	
Argentina	38		Dominican Republic	5		Indonesia	17		Mexico	13		Slovenia	9	
Austria	1		Ecuador	24		Ireland	1		Moldova	5		Spain	72	1
Bangladesh	10		France	42		Italy	82		Morocco	6		Sri Lanka	22	
Brazil	45		Germany	1		Korea, Republic of (South)	49		Netherlands	1		Switzerland	8	
Bulgaria	23		Greece	32		Japan	114		Nicaragua	11		Taiwan	51	
Canada	7	5	Guatemala	22		Latvia	10		Norway	19		Trinidad & Tobago	19	
Chile	32		Hong Kong	7		Lithuania	9		Peru	47	1	Turkey	28	
China	145		Iceland	23		Macau	2		Poland	22		United Kingdom	7	
Costa Rica	26								Portugal	53		Vietnam	19	

Source: GAO analysis of FDA data; Map Resources (map). | GAO-15-183

Note: The Food and Drug Administration's year 2014 inspections were completed from October 1, 2013, through September 30, 2014.

The increase in inspections completed by the foreign offices notwithstanding, FDA is not keeping pace with the targets for foreign food inspections set by Congress in FSMA. The act mandated that FDA inspect at least 600 foreign food facilities in the 1-year period following the enactment of FSMA. For each of the 5 following years, FSMA mandated that FDA inspect at least twice the number of facilities inspected during the previous year.¹³ Figure 4 shows the number of inspections FDA actually completed (or has planned to complete), along with two possible scenarios in response to FSMA. The first scenario has FDA inspecting twice the actual (or planned) number of foreign food facilities compared with the previous year, starting with the 1,002 inspections FDA completed in 2011 (see shaded bars labeled “FSMA mandate”). For example, as highlighted in the figure data, the FSMA mandate set a target of at least twice as many inspections—2,004—in 2012 as FDA actually inspected in 2011. The second scenario shows FDA inspecting 600 facilities—the FSMA minimum—in 2011, then doubling that number each of the 5 following years (see white bars labeled “Doubling each year”). The first scenario would yield a target of at least 2,646 foreign inspections in 2015 and an estimated target of at least 2,400 foreign inspections in 2016, the final year of the mandate.¹⁴ The second scenario, as FDA has reported to Congress, would yield a target of 19,200 foreign inspections in 2016.¹⁵

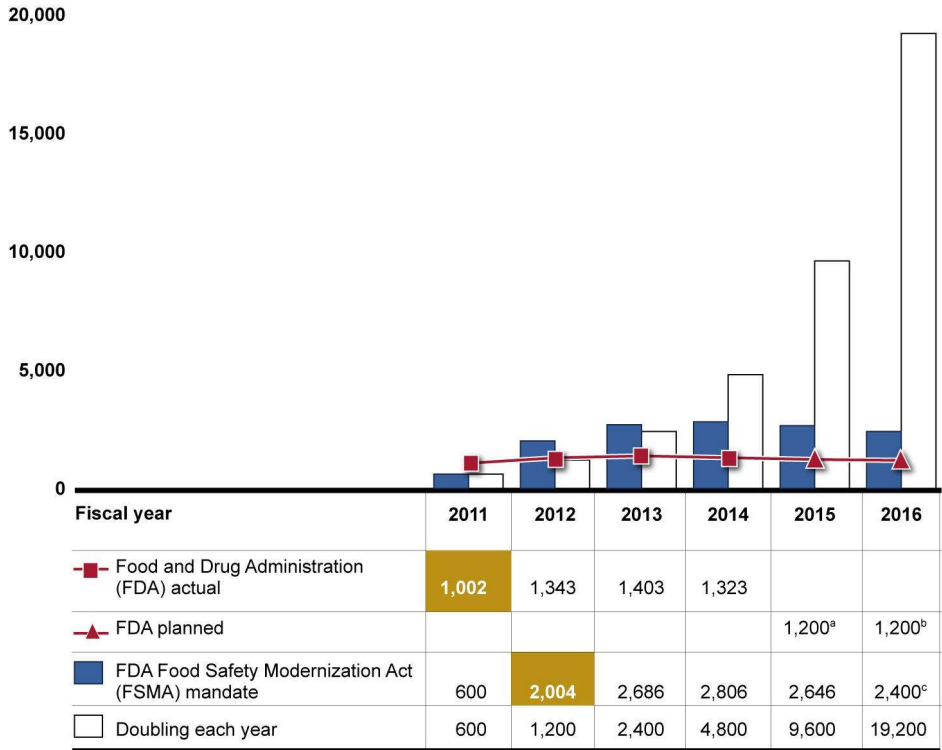
¹³FSMA links the mandate to a 1-year period from January of each year to January of the following year. FDA plans, conducts, and reports its inspections by fiscal year. Therefore, we have reported the inspection numbers by fiscal year. For the purpose of this report, the first year of the FSMA mandate is shown as fiscal year 2011.

¹⁴This number assumes that FDA completes 1,200 inspections in 2015, as it projects, and follows the language of the statute and completes twice that number of inspections in 2016.

¹⁵FDA, *Ensuring a Safe Food Supply: A Report to Congress Under the FDA Food Safety Modernization Act Section 110(a)(1)*, April 2013.

Figure 4: Food and Drug Administration (FDA) Inspections of Foreign Food Facilities Compared with FDA Food Safety Modernization Act (FSMA) Scenarios

Number of inspections of foreign food facilities



Sources: GAO analysis of FSMA and FDA data. | GAO-15-183

^aEstimate based on the Food and Drug Administration's (FDA) plans for 2015.

^bFDA has not completed plans for 2016, but officials expect the agency to complete about 1,200 foreign food inspections a year for the foreseeable future.

^cFSMA mandate (estimate) based on FDA plans for 2015.

FDA is not currently keeping pace with the FSMA mandate for increased foreign food inspections under either scenario's targets. As the figure shows, FDA completed 1,002 foreign food inspections in 2011, 167 percent of the FSMA mandate. In 2012, FDA completed 1,343 such inspections, a 34 percent increase from, but not twice, the previous year's number. During 2013, FDA completed 1,403 such inspections, a 4 percent increase from the previous year but also less than twice the previous year's number. Thus far, the agency has completed 1,323

inspections in 2014, which is more than planned but an overall decrease compared with the previous 2 years.¹⁶ FDA officials told us that the agency has not met—and is not planning to meet—the FSMA mandate. They questioned the usefulness of conducting the number of inspections mandated by FSMA.

According to FDA officials, the cost of inspections is the main reason that the agency is not keeping pace with the FSMA mandate for foreign food facility inspections. In its most recent report to Congress on food imports and foreign offices, FDA estimated that the average cost of a foreign inspection was \$23,600, compared with \$15,500 for a comparable domestic one.¹⁷ By that estimate, FDA would have needed at least \$113 million to complete the 4,800 foreign inspections that it has reported were required in fiscal year 2014 to meet the FSMA mandate. For 2014 and 2015, FDA requested funding for 1,200 foreign food inspections for each year. For fiscal year 2014, FDA received a total of about \$138 million to implement all provisions of FSMA, including training, rulemaking, and foreign inspections.¹⁸ FDA officials told us that, given limited funding, the agency determined that additional foreign inspections were not the best use of FSMA-related funds. FDA officials said they were focusing resources instead on technical assistance to the domestic and foreign food industry to help manufacturers comply with new FSMA rules, as well as training for FDA investigators and other agency staff to modernize FDA's food inspection program. However, FDA has not conducted an analysis to determine whether either the required number of inspections

¹⁶FDA updates annual inspection counts as inspections are completed and reviewed based on the date that an inspection is completed. Therefore, the number of inspections reported as completed in 2014 may change.

¹⁷U.S. Department of Health and Human Services, Food and Drug Administration, *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 Pub. L. No. 111-353 (November 2013). FDA reported that the appropriation used to inspect facilities registered pursuant to section 415 of the Federal Food Drug and Cosmetic Act was approximately \$198.5 million for fiscal year 2012. Of this amount, \$145.2 million was used for FDA inspections of domestic facilities and \$34.7 million for FDA inspections of foreign facilities.

¹⁸The Congressional Budget Office (CBO) estimated an additional cost for the first 5 years of FSMA implementation of \$1.1 billion dollars, including \$583 million in fiscal year 2015. CBO's estimate did not account for the cost of doubling foreign inspections in fiscal year 2016, the final year of the mandate (see CBO, *Congressional Budget Office Cost Estimate: S. 510 Food Safety Modernization Act*, Aug. 12, 2010).

in the FSMA mandate or the lower number of inspections it is conducting is sufficient to ensure comparable safety of imported and domestic food. Without such an analysis, FDA is not in a position to know what is a sufficient number of foreign inspections and, if appropriate, request a change in the mandate regarding the number of foreign inspections to be conducted.

FDA Foreign Offices Cited Contributions to the Safety of Imported Food, but the Extent of These Contributions Has Not Been Fully Measured

FDA foreign office officials cited a variety of contributions to improving the safety of food imported from other countries to the United States. However, the extent of the contributions is unknown because FDA's performance measures have not fully captured these contributions.

FDA Foreign Office Officials Cited Contributions to the Safety of Imported Food

Officials from the foreign offices cited instances when they had made significant contributions to determining the cause of outbreaks that led to illnesses and deaths in the United States. Among them:

- The Europe Office credited new relationships with their Italian counterparts for providing information that helped link a 2012 outbreak of listeriosis, which sickened 22 people and resulted in four deaths in the United States, to ricotta cheese imported from Italy.¹⁹ According to FDA officials, the office staff worked with Italian food safety authorities to investigate firms that could have caused the outbreak. The result of these efforts was a recall of some ricotta cheese, ending instances of illness and death in the United States.
- In 2012, the India Office's in-country investigators were able to rapidly conduct inspections of tuna processing facilities that were identified as

¹⁹Listeriosis is a serious infection usually caused by eating food contaminated with the bacterium *Listeria monocytogenes* and, according to CDC, is an important public health problem in the United States. CDC, Multistate Outbreak of Listeriosis Linked to Imported Frescolina Marte Brand Ricotta Salata Cheese (Final Update), accessed January 21, 2015, <http://www.cdc.gov/listeria/outbreaks/cheese-09-12/>.

potential sources of an outbreak of Salmonella in tuna products, which sickened 425 people in the United States.²⁰ FDA and other agencies were then able to quickly take action on the inspection findings, including FDA issuing an import alert for the tuna products.

Examples of Potential Foodborne Illnesses

Listeriosis. The Centers for Disease Control and Prevention (CDC) estimated that approximately 1,600 illnesses and 260 deaths due to listeriosis occur annually in the United States. Listeriosis is a serious infection with symptoms that can include headache, stiff neck, confusion, loss of balance, and convulsions in addition to fever and muscle aches. Infection during pregnancy can lead to miscarriage, stillbirth, premature delivery, or life-threatening infection of the newborn.

Salmonellosis. According to the CDC, *Salmonella* is estimated to cause more than 1 million illnesses annually in the United States, with 19,000 hospitalizations and 380 deaths. Most persons infected with *Salmonella* develop diarrhea, fever, and abdominal cramps 12 to 72 hours after infection.

Cyclosporiasis. Cyclosporiasis is an intestinal infection that can be caused by people ingesting food or water contaminated with feces. In the United States, outbreaks since the mid-1990s have been linked to various types of imported fresh produce such as raspberries, basil, and mesclun lettuce.

Sources: GAO and CDC. | GAO-15-183

- The Latin America Office in Mexico City was able to capitalize on its relationship with the Mexican government's food regulatory authorities to narrow down the source of a Cyclospora outbreak in 2013 that sickened 631 people in the United States.²¹ This office coordinated investigations at the facilities that handled the leafy greens identified as the potential source of the outbreak and certified the facilities as free of Cyclospora so the shipment of the products could resume.

The foreign office officials also provided examples of additional actions that stopped the importation of food products that were potentially harmful to humans. For example, in 2012, the Latin America Office in Mexico City helped stop the importation of a fraudulent dietary supplement into the United States because the officials discovered that the supplement did not contain the ingredients it claimed to include. Also, in 2012, this office helped test shipments of orange juice products from all foreign sources for a pesticide residue, carbendazim, and found that 31 of 166 shipments had carbendazim.²² EPA has not registered carbendazim for use as a fungicide on oranges or established a tolerance or an exemption from a tolerance for carbendazim in orange juice. As a result of the testing, several facilities were stopped from exporting orange juice containing carbendazim residues to the United States, and the occurrence of carbendazim in imported orange juice declined.

FDA also provided an example of a foreign office's contribution to the safety of imported animal food. Specifically, in 2012, in-country investigators in the China Office conducted inspections of five facilities that made jerky pet treats to determine if they were the cause of ongoing illnesses and deaths in pets in the United States. As of May 2014, FDA

²⁰Salmonellosis is an infection usually caused by eating food contaminated with the bacterium *Salmonella*.

²¹Cyclosporiasis is an intestinal infection that can be caused by people ingesting food or water contaminated with the microscopic parasite *Cyclospora cayetanensis*.

²²This testing is done in conjunction with the EPA, which determines approved pesticides for use in agriculture.

had received reports of illness involving more than 5,600 dogs and 24 cats, and the deaths of more than 1,000 dogs, which may be related to consumption of jerky pet treats. In addition, FDA received three reports of human illness after exposure to jerky pet treats.²³ The China Office has assisted with the ongoing investigation into the illnesses; however, as of October 2014, the cause has not been found.²⁴ FDA investigators were not permitted to take samples of the pet treats or their ingredients inside the facilities and have them tested in an FDA laboratory in the United States. Foreign office officials told us that FDA investigators do not typically take samples during foreign inspections, but they have taken samples in Mexico and sent them to an FDA laboratory in the United States to assist in a food outbreak investigation. FDA's Center for Veterinary Medicine continues to work on finding the cause for illnesses and deaths linked to jerky pet treats.

FDA Performance Measures Do Not Fully Capture the Contributions of Foreign Offices

The extent of the foreign offices' contributions to food safety is unknown because FDA does not fully capture the foreign offices' contributions through performance measures that are either agency-wide or specifically developed by OIP for the foreign offices. In our 2010 report, we recommended that, as the agency completed its strategic planning process for the foreign offices, it develop performance goals and measures that can be used to demonstrate the offices' contributions to long-term outcomes related to imported FDA-regulated products.

FDA's agency-wide performance measures for the foreign offices provide counts from each foreign office on how many inspections were conducted within each country and the number of completed country profiles—reports and papers on the food safety conditions in a given country.²⁵ These measures do provide important output information, but they do not provide outcome-oriented information on how a specific action by a foreign office contributed to food safety. For example, an output measure, such as a number count of inspections, does not show how the

²³Two of the cases reported exposure to product produced in China, and the other case reported exposure to a domestically produced jerky product.

²⁴FDA, Jerky Pet Treats, accessed January 26, 2015, <http://www.fda.gov/AnimalVeterinary/SafetyHealth/ProductSafetyInformation/ucm360951.htm>.

²⁵FDA's agency-wide performance management system is called FDA-TRACK.

inspections and reports contribute to broader food safety goals. OIP does have one measure that is outcome oriented—a measure of collaborative actions by each foreign office that led to improved public health outcomes. However, neither FDA’s agency-wide performance measures nor OIP’s measure fully captures the foreign offices’ activities to help improve food safety. See table 2 for a list of FDA agency-wide and OIP performance measures for the foreign offices in fiscal year 2014.

Table 2: Food and Drug Administration (FDA) Performance Measures for Foreign Offices for Fiscal Year 2014

Performance measure	Information collected and reported	Reported numbers
Inspection counts	Number of high priority or routine food and dietary supplement inspections completed	140
	Number of new or updated country profiles	32
Country profiles	Number of times country profiles were viewed within FDA	121
	Collaborative actions ^a	Number of collaborative actions taken that led to improved public health outcomes

Source: GAO analysis of FDA data. | GAO-15-183

^aCollaborative actions data are for fiscal year 2013. Data for 2014 were not yet available.

In our 2010 report, we acknowledged that some measures are difficult to develop because results for some activities are not easy to quantify and that it can be difficult to attribute results to programs that involve multiple organizations within FDA. However, performance measures are important management tools for agencies.²⁶ The agency has initiated a review to determine how to better reflect the value of the foreign offices in the agency-wide performance system. The initial phase of this review has been completed, and FDA could not provide a date when the full review would be completed or when new performance measures would be implemented. OIP has developed a strategic map that aligns the activities of the foreign offices with strategic outcomes. OIP is also collecting information from its foreign offices by means of annual operational plans that track each office’s progress toward completing a specific project, such as organizing a conference to help foreign regulatory counterparts and industry officials better understand FSMA. These are potentially useful performance planning and management tools; however, they are

²⁶[GAO/GGD-97-180](#).

not performance measures. Leading practices indicate that results-oriented performance measures focus on expected results to show progress toward, or contributions to, intended results.²⁷ We believe our previous recommendation that FDA develop performance goals and measures for the foreign offices that are outcome-oriented is still valid. Without performance measures that can be used to demonstrate the offices' contributions to long-term outcomes related to imported FDA-regulated products, FDA has less information available to effectively measure the foreign offices' progress toward meeting the agency's goals.

FDA Has Not Completed a Strategic Workforce Plan for Its Foreign Offices

Since we last reported, FDA has continued to experience recruitment challenges in the foreign offices. FDA has taken some steps to address those challenges, but it has not completed a strategic workforce plan.

FDA Continues to Experience Recruitment Challenges in the Foreign Offices

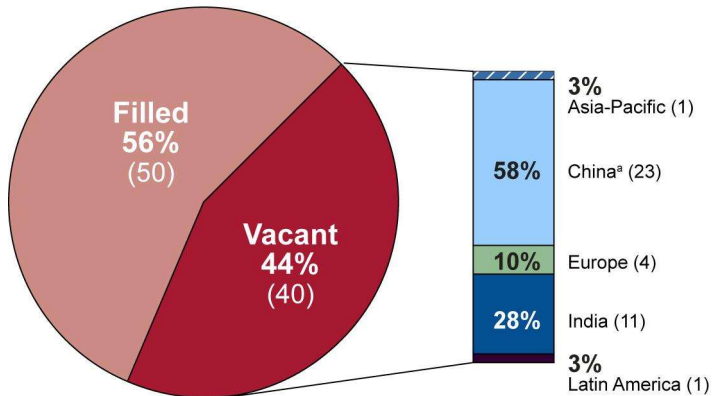
In 2010, we found that FDA had experienced challenges in staffing some of the foreign offices. For example, at that time, FDA had 2 vacant staff positions in the Latin America Office out of a total of 14 positions, and 4 vacancies in the India Office out of a total of 15 positions. In subsequent years, the number of vacancies in the foreign offices has increased as these offices have expanded. There are fewer staff members in the foreign offices now than in 2010, and the percentage of vacant positions has increased because the number of approved staff positions is larger.²⁸ As shown in figure 5, 44 percent of FDA's approved foreign office positions were vacant as of October 2014, and most of these vacancies were in the China Office.

²⁷ [GAO/GGD/AIMD-99-69](#).

²⁸ The number of filled positions increased in the India Office from 11 to 12, and in the Latin America Office from 12 to 14. The number of filled positions decreased in the China Office from 13 in 2010 to 10 in 2014, and in the Europe Office from 6.5 in 2010 to 4 in 2014.

Figure 5: Filled and Vacant Staff Positions Approved by the Food and Drug Administration (FDA) for the Foreign Offices, as of October 2014

Percentage of approved positions (number of positions)



Source: GAO analysis of FDA data. | GAO-15-183

Notes: The percentages do not add up to 100 because of rounding.

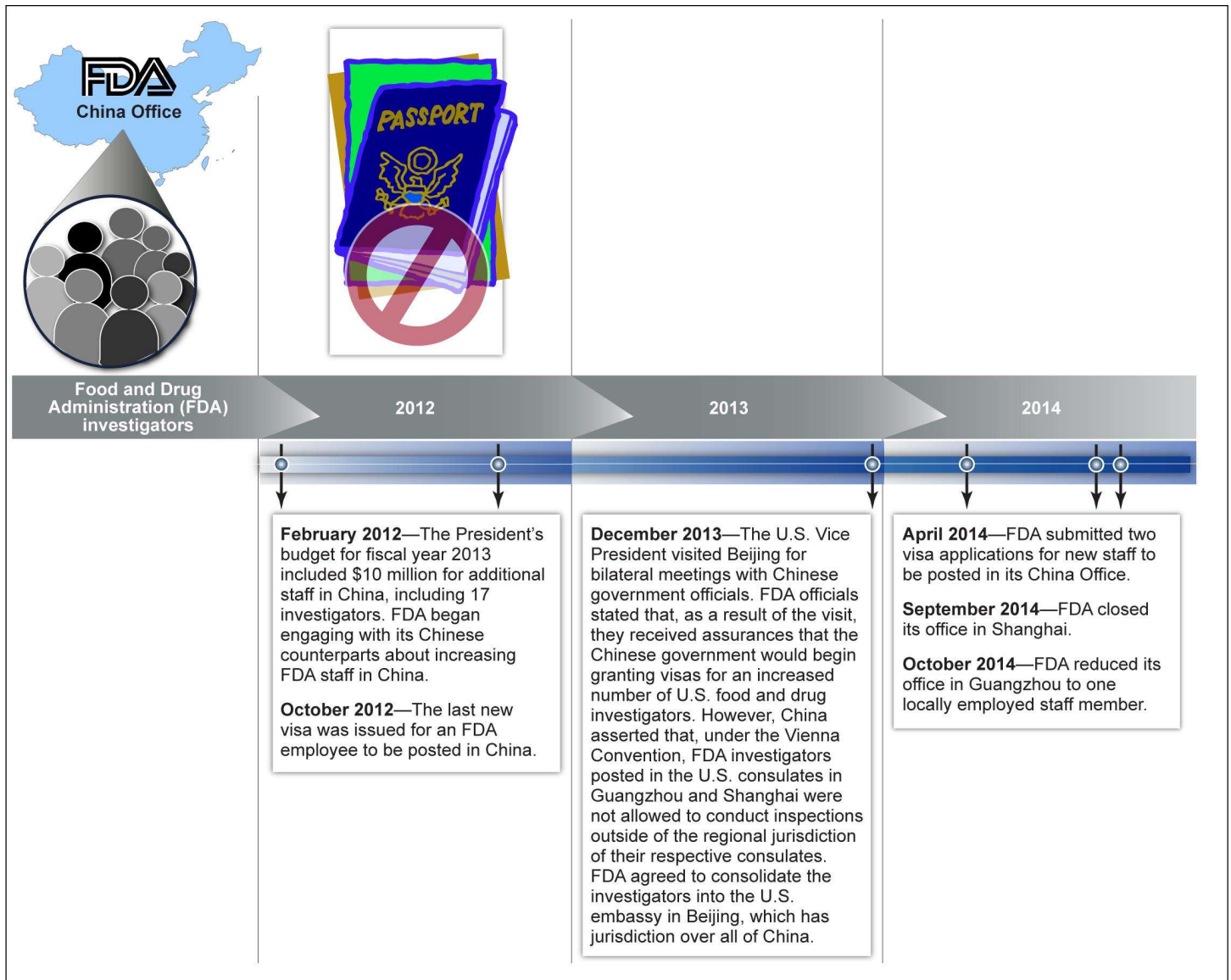
In December 2014, FDA changed the name of its Asia-Pacific Office to the Office of Regional and Country Affairs.

^aIncluded in the 23 vacancies listed for the China Office are nine U.S. government employees who have been hired but are unable to deploy to China because of the Chinese government's delay in issuing new visas for Food and Drug Administration employees to be posted in China.

These vacancies shown in the figure above include both U.S. government and locally employed staff positions. Locally employed staff account for 17 out of the 50, or 34 percent of the total staff working in FDA's foreign offices, as of October 2014. Appendix II provides additional information about the staffing composition of the foreign offices and the contributions of locally employed staff.

A number of factors have contributed to vacancies in the foreign offices, including delays in obtaining visas from the Chinese government. According to FDA officials, the last visa for a new FDA staff member to be posted in the China Office was issued in October 2012; there are nine U.S. government staff who have been hired by FDA for the China Office, but they cannot deploy because of the Chinese government's delay in issuing new visas for FDA employees. OIP officials told us that they began discussions with Chinese government officials in February 2012 about increasing the number of investigators in the China Office. As of October 2014, FDA's discussions with the Chinese government were ongoing. Figure 6 shows a timeline of developments, including White House involvement, related to FDA's efforts to obtain visas for new staff in the China Office.

Figure 6: Timeline of the Food and Drug Administration’s (FDA) Efforts to Obtain Visas for New FDA Investigators in China



Sources: FDA (information); Art Explosion (images). | GAO-15-183

In an effort to facilitate the granting of visas for new staff, FDA agreed to close its locations in Guangzhou and Shanghai and consolidate all China Office staff in Beijing. However, officials in the China Office expressed concern that they will lose a valuable resource because one of the two locally employed staff members in Guangzhou will not be able to relocate

to Beijing. The language skills of the locally employed staff are especially important in China, where the investigators do not typically speak the local language. OIP officials told us that, in the absence of locally employed staff available to translate, investigators in China rely on translators provided by the firms that are being inspected.²⁹ Consolidating all China Office staff in Beijing also poses challenges in providing enough office space within the embassy. OIP officials told us that when adding investigators to the China Office was first proposed in February 2012, they knew that they might face space constraints regardless of whether staff were placed in the China Office's locations in Shanghai, Guangzhou, or Beijing. There is not enough space in the U.S. embassy in Beijing to house additional FDA staff, so FDA will be one of the occupants in a new annex building that the Department of State is currently constructing. FDA anticipates moving into that space in October 2015.

Other factors that have affected the recruitment of staff for the foreign offices include issues that are directly affected by FDA personnel policies, such as reintegration of staff who have returned from assignments at a foreign office location. In the past, FDA handled reintegration on a case-by-case basis. Foreign office officials told us that not having a reintegration policy for staff members who have completed foreign assignments had hampered their ability to recruit staff to work in the foreign offices. Foreign office officials said U.S.-based ORA investigators have been hesitant to transfer to foreign offices because they were concerned about whether they would be able to return to their previous geographic location once they completed their posting abroad. They have also been concerned about whether FDA would value the experiences they gained while abroad. To address the uncertainty surrounding reintegration, FDA adopted a set of standard operating procedures, which were finalized in November 2014. OIP officials said they, in conjunction with the Office of Human Resources, have been engaging in outreach efforts to help managers understand the reintegration process.

Foreign office officials told us that lengthy hiring processes also have affected FDA's ability to staff its foreign offices. According to information

²⁹According to FDA officials, it is standard practice to ask firms being inspected if they have either an English speaker or a translator on the premises. If the firm says yes to either of those, FDA would use the firm's services, if needed. If the firm does not have an English speaker or a translator on the premises, FDA would obtain one through its translation services contract.

published by the Office of Management and Budget, in 2009 it took federal agencies an average of 122 days to fill an open position.³⁰ According to the most recent data available, that time dropped to an average of 93 days for fiscal year 2011 and 87 days for fiscal year 2012. For FDA, during fiscal years 2013 and 2014, it took an average of 121 days to fill staff positions in the Asia-Pacific Office, 140 days in the China Office, 172 days in the Europe Office, 200 days in the India Office, and 104 days in the Latin America Office.³¹ FDA has recently implemented an agency-wide initiative known as FDA's Accelerated Staffing Track to reduce the time it takes to hire a candidate to 80 calendar days.³²

FDA Has Taken Some Steps to Address Workforce Challenges in Its Foreign Offices

OIP has undertaken initiatives to help recruit and develop staff. According to OIP officials, one successful initiative was to implement temporary duty assignments of investigators for 60, 90, or 120 days to meet immediate resource needs of the foreign offices. Officials in the foreign offices told us that the investigators assigned on temporary duty were a staffing resource that helped the offices conduct inspections. Temporary duty assignments also served as an important recruiting tool since investigators returning from a temporary overseas assignment can provide a firsthand account of their foreign office experiences to their U.S. colleagues. In addition, OIP officials told us that they were able to use information from a draft workforce gap analysis to implement some learning and development initiatives to help ensure that the foreign office

³⁰Time to fill an open position is calculated from the date the agency validates the need for the position to a candidate's entrance on duty date.

³¹These time frames are calculated from the date the vacancy announcements were posted to the candidate's entrance on duty date. They are based on four positions in the Asia-Pacific Office, eight positions in the China Office, one position in the Europe Office, seven positions in the India Office, and three positions in the Latin America Office. It does not include positions in the India Office and Latin America Office where a 6-month continuous advertisement was used. Staff members hired for the China Office have not been able to deploy to China because of the inability to obtain visas from the Chinese government.

³²FDA's Accelerated Staffing Track is FDA's response to the President's May 2010 memorandum on improving the Federal Recruitment and Hiring Model and was implemented on September 2, 2014.

staff had the necessary skills to perform their job duties.³³ OIP identified “diplomacy” and “global awareness” as training topics for foreign office staff. OIP also sought to strengthen staff members’ foreign language skills by offering language training.

However, OIP does not have a formalized staffing mechanism through which it can decide on strategic resource allocations based on a targeted analysis of the specific staffing needs of its various foreign offices. Such a staffing mechanism would be included in a strategic workforce plan. Currently, the foreign offices provide input into staffing decisions through office-level staffing proposals, but some of the needs identified in their proposals have not been met. For example, officials from one foreign office expressed a need to have a staff member located in headquarters to represent them in real time during face-to-face discussions of policy matters. That office also identified a need for additional information technology support because of the challenges created by operating in a time zone when headquarters staff are not typically working and the security requirements for accessing FDA computer systems in an embassy setting.

OIP officials told us that they are developing a strategic workforce plan that requires an FDA-wide perspective and approach that recognizes the broad role of FDA’s centers and ORA in its international activities. To that end, OIP has developed a strategic workforce planning framework, and officials told us that, over the next year, they will develop the first phase of a forward-looking strategic workforce plan for the foreign offices. However, OIP has yet to define what the workforce plan will entail, and there are no time frames for completion. Strategic workforce planning is an essential tool to help agencies align their workforces with their current and emerging missions and develop long-term strategies for acquiring, developing, and retaining staff.³⁴ In our 2010 report on FDA’s foreign

³³OIP officials told us that, in 2011, FDA hired a contractor to develop a strategic workforce plan for the foreign offices. The contractor produced a draft workforce gap analysis; however, FDA officials stated that, because of dissatisfaction with the contractor’s performance, they declined to finalize the draft analysis produced by the contractor. FDA initiated a reduction in scope that eliminated the later phases of the contract and declined to extend the contract.

³⁴GAO, *Workforce Planning: Interior, EPA, and the Forest Service Should Strengthen Linkages to Their Strategic Plans and Improve Evaluation*, [GAO-10-413](#) (Washington, D.C.: Mar. 31, 2010).

offices, we recommended that FDA develop a strategic workforce plan for the foreign offices to help ensure that the agency is able to recruit and retain staff with the necessary experience and skills. We continue to believe that completing a strategic workforce plan for the foreign offices is critical to FDA's ability to address staffing challenges.

Conclusions

FDA established foreign offices to help prevent unsafe products from entering the United States. Through their activities, FDA's foreign offices have helped the agency to increase the total number of foreign food inspections conducted annually. Nonetheless, FDA has not kept pace with FSMA's inspection mandate since 2011. FDA is planning to conduct 1,200 foreign food inspections through the end of the mandate—well below either scenario that might satisfy the FSMA mandate to increase inspections each year through 2016. FDA officials cited limited resources as the primary reason they are not conducting more foreign food inspections. FDA officials also questioned the usefulness of conducting the number of inspections mandated by FSMA. However, FDA has not conducted an analysis to determine whether the number of inspections mandated by FSMA or the number of inspections it is now conducting is sufficient to ensure comparable safety of imported and domestic food. Without such an analysis, FDA is not in a position to know what is a sufficient number of foreign inspections and, if appropriate, request a change in the mandate regarding the number of foreign inspections to be conducted.

In addition, in 2010, we recommended that FDA develop performance goals and measures that can be used to demonstrate the foreign offices' contributions to long-term outcomes related to improving the safety of imported food products. According to FDA officials, the agency has initiated a review to determine how to better reflect the value of the foreign offices in the agency-wide performance system. However, FDA has not yet implemented new performance measures or determined when its review would be completed. We continue to believe that performance measures that demonstrate the foreign offices' contributions to long-term outcomes for the safety of imported food are important to provide information to help the agency track progress toward meeting its goals and to provide managers with crucial information on which to base funding decisions. We also recommended that FDA develop a strategic workforce plan for the foreign offices to help ensure that the agency is able to recruit and retain staff with the necessary experience and skills. FDA has taken some steps to address recruitment challenges, but the agency has not yet completed a strategic workforce plan. We continue to

believe that a strategic workforce plan for the foreign offices is critical to FDA's ability to address staffing challenges, especially given the number of vacancies abroad. There are other challenges affecting the foreign offices, such as problems obtaining visas for the China Office staff. However, a strategic workforce plan would provide FDA some assurance that it has placed the right people in the right positions at the right time and can carry out its mission to protect public health in an increasingly complex and globalized world.

Recommendation for Executive Action

To help ensure the safety of food imported into the United States, we recommend that the Commissioner of Food and Drugs complete an analysis to determine the annual number of foreign food inspections that is sufficient to ensure comparable safety of imported and domestic food. If the inspection numbers from that evaluation are different from the inspection targets mandated in FSMA, FDA should report the results to Congress and recommend appropriate legislative changes.

Agency Comments and Our Evaluation

We provided a draft of this report to FDA for comment. In its written comments, which are reprinted in appendix III, FDA concurred with the recommendation, pending the necessary resources to conduct the analysis, as part of a larger FSMA-implementation strategy to improve the safety of imported food that will, among other things, reconsider the number of inspections conducted in other countries. FDA said that foreign inspections are an important part of FSMA, providing accountability for inspected foreign firms, incentives for them to comply with U.S. import requirements, and intelligence about foreign food safety practices. FDA added that foreign inspections will not, in themselves, ensure comparable safety of imported and domestic food, and the agency is expanding its collaborations with foreign governments to assist in ensuring the safety of imported food. As noted in its comments, FDA is optimistic that additional visas will be approved to expand its presence in China, which would help reduce the number of vacant staff positions that we cite in this report. FDA also provided technical comments that were incorporated, as appropriate.

As agreed with your office, unless you publicly announce the contents of this report earlier, we plan no further distribution until 30 days from the report date. At that time, we will send copies to the appropriate congressional committees, the Commissioner of Food and Drugs, the Secretary of Health and Human Services, and other interested parties. In

addition, the report will be available at no charge on the GAO website at <http://www.gao.gov>.

If you or your staff members have any questions about this report, please contact me at (202) 512-3841 or gomezj@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this report. GAO staff who made key contributions to this report are listed in appendix IV.

Sincerely yours,

A handwritten signature in black ink that reads "Alfredo Gómez". The signature is written in a cursive style with a large initial "A" and a stylized "G".

J. Alfredo Gómez, Director
Natural Resources and Environment

Appendix I: Objectives, Scope, and Methodology

This report responds to your request that we examine the progress of Food and Drug Administration (FDA) foreign offices since we last reported in 2010 for helping to ensure the safety of imported food. Our objectives of this report were to examine (1) the activities the FDA foreign offices have engaged in since 2010 to help ensure the safety of imported food, (2) the extent of the foreign offices' contributions to the safety of imported food, and (3) the extent to which FDA has engaged in workforce planning for its foreign offices. For the purposes of this report, imported food refers to food for human or animal consumption, unless otherwise specified.

To examine the activities of FDA's foreign offices, we reviewed and analyzed documents including FDA reports to Congress that were mandated by the FDA Food Safety Modernization Act (FSMA) that describe the activities of all foreign offices, evaluated written answers to questions about their activities since the 2010 report, and conducted structured interviews with FDA officials in the foreign offices, and analyzed counts of foreign food facility inspections for each year of the FSMA mandate. We questioned all FDA offices that reported conducting food safety activities at the time of our review. The Sub-Saharan Africa post was vacant and, therefore, was not included in the structured interview. Based on conversations with officials from the China Office and Latin America Office, the Chile post and Shanghai post were not included in the structured interview because the posts did not focus on food. As part of our questions, we asked the officials to identify their three top priority activities. In addition, we analyzed food inspections conducted by the foreign offices compared with targets mandated in FSMA between 2011 and 2016.¹ We cross-checked FDA's foreign inspection numbers, as provided by the Office of Regulatory Affairs through its FACTS database, with information in FDA reports to Congress and additional information obtained during our site visits to locations in Beijing and Guangzhou, China, and Mexico City, Mexico. We selected those offices, in part, because they conducted food inspections. Through this examination of the data and interviews with FDA officials who were knowledgeable about foreign food inspections, we determined that the inspection counts provided by the agency were sufficiently reliable for use in our review.

¹FDA Food Safety Modernization Act, Pub. L. No.111-353, 124 Stat. 3885 (2011).

To examine how FDA foreign offices have contributed to imported food safety, we reviewed and analyzed documents and data that described the outcomes of the foreign offices' activities, including inspection reports and import alerts. We conducted structured interviews with FDA officials from the foreign offices, including the Asia-Pacific Office, China Office, Europe Office, India Office, and Latin America Office to determine the outcomes of the foreign offices' activities. We also discussed the outcomes of the foreign offices with FDA's Center for Food Safety and Applied Nutrition and Center for Veterinary Medicine. We analyzed performance planning and management planning documentation to determine the extent that FDA had performance measures that were outcome oriented and captured the activities of the foreign offices, based on leading practices that we have previously identified.² We interviewed FDA officials in the Office of International Programs (OIP) and the Office of Strategic Planning and Analytics to understand how FDA is measuring the performance of the foreign offices. Through interviews with FDA officials knowledgeable about performance measures for the foreign offices, we determined that the performance measure data were sufficiently reliable for use in our review.

To examine the extent to which FDA has engaged in workforce planning for its foreign offices, we reviewed workforce planning documents, including descriptions of recruitment and retention and learning and development initiatives, FDA's 80-day hiring model and draft reintegration policy, and draft analyses from a contractor hired to develop a workforce plan for the foreign offices. We also reviewed leading practices for workforce planning that we have previously identified.³ We also analyzed staffing data from the foreign offices, and we interviewed officials from the OIP, the Office of Operations, the Office of Planning, and the Office of Human Resources. We cross-checked the staffing counts provided by the OIP with information we obtained during our site visits to locations in Beijing and Guangzhou, China, and Mexico City, Mexico. Through this examination of the data and interviews with FDA officials knowledgeable about staffing for the foreign offices, we determined that the data were sufficiently reliable for use in our review.

²[GAO/GGD/AIMD-99-69](#) and [GAO/GGD-97-180](#).

³[GAO-10-413](#) and [GAO-04-39](#).

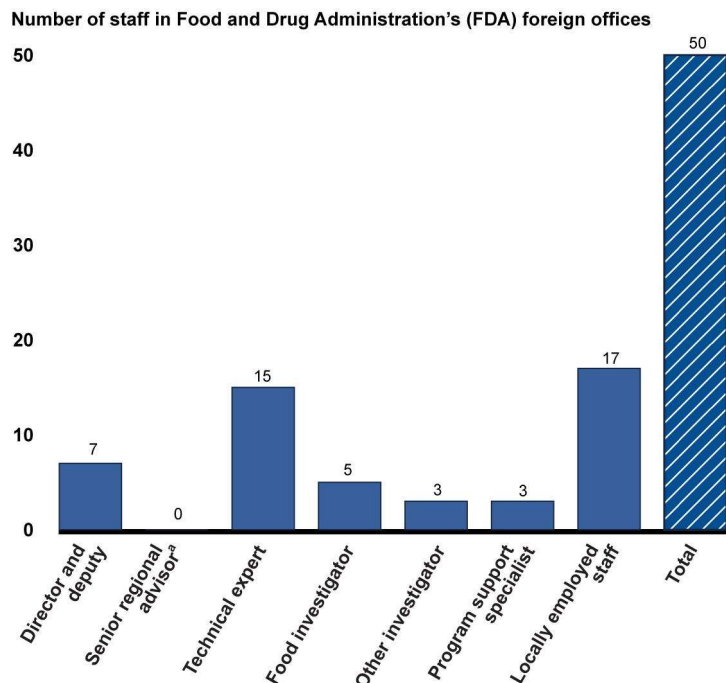
In addition, to address all three objectives, we conducted an in-depth review of FDA operations in Canada, China, and Mexico. We selected these locations based on an analysis of the volume of food imports, the percentage of food imports refused at the border, and the number of food facility inspections for fiscal year 2013. We also considered the number of active import alerts (i.e., warnings about particular products, manufacturers, and countries based on FDA experience or information that triggers a more intensive inspection at the U.S. border). We visited FDA's offices in Beijing and Guangzhou, China, and Mexico City, Mexico. We interviewed all FDA staff at those locations, as well as the regional director for the Latin America Office who was present in Mexico City during our visit. We also met with officials from U.S. government agencies in those locations, including the United States Department of Agriculture's (USDA) Foreign Agricultural Service and USDA's Animal and Plant Health Inspection Service, the Centers for Disease Control and Prevention, the Department of Commerce's Foreign Commercial Service and the Department of State's Environment, Science, Technology, and Health Officers. We also accompanied FDA foreign office staff on site visits to food facilities. During our visit to Mexico City, we visited the world's largest greenhouse, which grows and packs hydroponic tomatoes and peppers for export to the United States. During our visit to Guangzhou, we visited a large facility that produces farm-raised seafood for export to the U.S. market. Additionally, we spoke with food safety regulatory authorities in Canada, China, and Mexico, including the Canadian Food Inspection Agency; the China Food and Drug Administration; the China Center for Food Safety Risk Assessment; the General Administration of Quality Supervision, Inspection, and Quarantine of the People's Republic of China; the Guangdong Entry-Exit Inspection and Quarantine Bureau of the People's Republic of China; the Mexico Federal Commission for the Protection against Sanitary Risk; and the Mexico National Service of Agro Alimentary Health, Safety and Quality.

We conducted this performance audit from November 2013 to January 2015 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Appendix II: Additional Information about Staffing of Foreign Offices

The Food and Drug Administration's (FDA) foreign offices comprise both U.S. government staff and locally employed staff who are non-U.S. citizens employed at U.S. missions abroad. Figure 7 below shows staff numbers for each foreign office position, as of October 2014.

Figure 7: Number of Staff Working in Food and Drug Administration (FDA) Foreign Offices by Position, as of October 2014

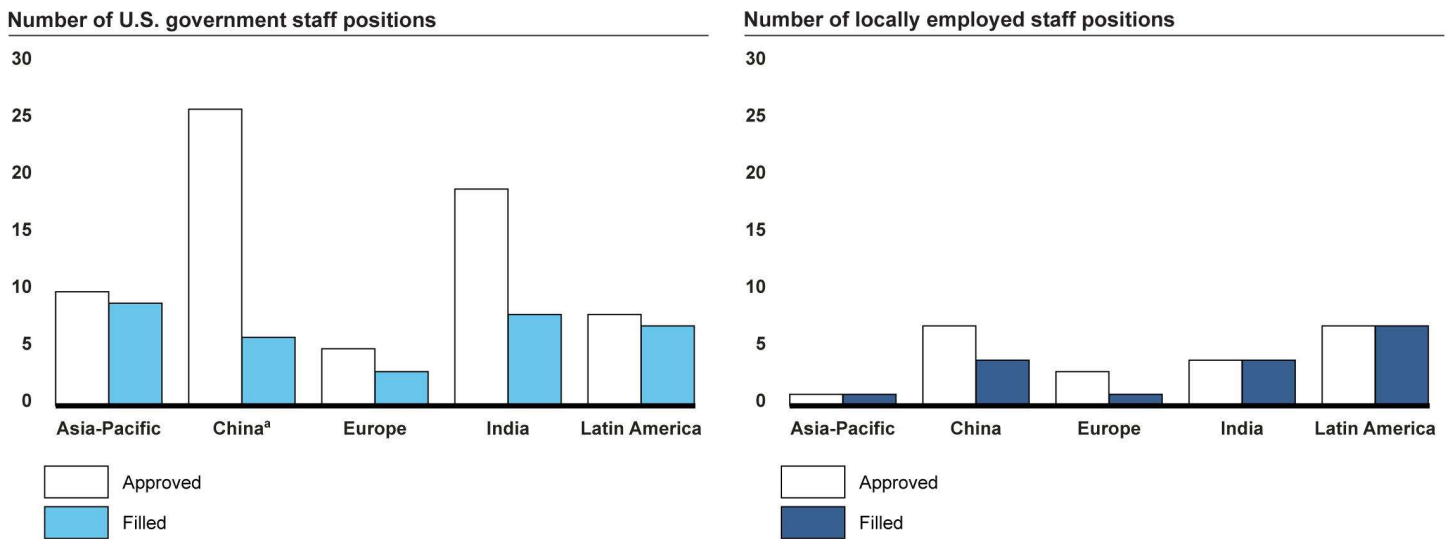


Source: GAO analysis of FDA data. | GAO-15-183

^aThe senior regional advisor position in Pretoria, South Africa, which provides supervision for the locally employed staff there, is being filled by an extended temporary duty assignment.

Figure 8 shows the approved and filled staff positions by foreign office, as of October 2014.

Figure 8: Approved and Filled Staff Positions by Food and Drug Administration (FDA) Foreign Office, as of October 2014



Source: GAO analysis of Food and Drug Administration data. | GAO-15-183

Notes: In December 2014, FDA changed the name of its Asia-Pacific Office to the Office of Regional and Country Affairs.

^aIn addition to the six filled U.S. government staff positions listed for the China Office, there are nine U.S. government employees who have been hired but are unable to deploy to China because of the Chinese government's delay in issuing new visas for Food and Drug Administration employees to be posted in China.

Foreign office officials told us that locally employed staff provide valuable contributions toward the activities of the foreign offices. Locally employed staff speak the local language and help foreign office staff better understand local regulations. Foreign office officials said that the locally employed staff also are knowledgeable about FDA standards and inspection protocols and are helpful to FDA investigators.

Table 3 shows the number of staff in each foreign office by location and position as of October 2014.

**Appendix II: Additional Information about
Staffing of Foreign Offices**

Table 3: Number of Staff Working in Each Food and Drug Administration (FDA) Foreign Office, as of October 2014

Foreign office	Director and deputy	Senior regional advisor	Technical expert	Food investigator	Other investigator	Program support specialist	Locally employed staff	Total
Asia-Pacific								10
Pretoria, South Africa ^a	0	0	0	0	0	0	1	1
Headquarters	2	0	5	0	0	2	0	9
China								10
Beijing	2	0	3	0	0	0	2	7
Guangzhou	0	0	0	1	0	0	1	2
Shanghai	0	0	0	0	0	0	1	1
Europe								4
Brussels, Belgium	1	0	0	0	0	0	1	2
London, England	0	0	0	0	0	0	0	0
Headquarters	0	0	1	0	0	1	0	2
India								12
Mumbai	0	0	0	0	2	0	2	4
New Delhi	0	0	3	2	1	0	2	8
Latin America								14
Mexico City, Mexico	1	0	2	1	0	0	3	7
San Jose, Costa Rica	1	0	1	0	0	0	2	4
Santiago, Chile ^b	0	0	0	1	0	0	2	3

Source: GAO analysis of FDA data. | GAO-15-183

Notes: This list excludes employees on temporary duty assignment.

In December 2014, FDA changed the name of its Asia-Pacific Office to the Office of Regional and Country Affairs.

^aThe senior regional advisor position in Pretoria, South Africa, which provides supervision for the locally employed staff there, is being filled by an extended temporary duty assignment.

^bThe food investigator position shown in Santiago, Chile, is a hybrid position, with 50 percent time as a food investigator and 50 percent time as a technical expert.

Appendix III: Comments from the Department of Health and Human Services



DEPARTMENT OF HEALTH & HUMAN SERVICES

OFFICE OF THE SECRETARY

Assistant Secretary for Legislation
Washington, DC 20201

JAN 15 2015

J. Alfredo Gomez
Director, Natural Resources and Environment
U.S. Government Accountability Office
441 G Street NW
Washington, DC 20548

Dear Mr. Gomez:

Attached are comments on the U.S. Government Accountability Office's (GAO) report entitled, "Food Safety: Additional Actions Needed to Help FDA's Foreign Offices Ensure Safety of Imported Food" (GAO-15-183).

The Department appreciates the opportunity to review this report prior to publication.

Sincerely,

A handwritten signature in black ink that reads "Jim R. Esquea".

Jim R. Esquea
Assistant Secretary for Legislation

Attachment

**GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES
(HHS) ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S (GAO) DRAFT REPORT
ENTITLED: FOOD SAFETY: ADDITIONAL ACTIONS NEEDED TO HELP FDA'S
FOREIGN OFFICES ENSURE SAFETY OF IMPORTED FOOD (GAO-15-183)**

The U.S. Department of Health and Human Services (HHS) appreciates the Government Accountability Office (GAO) for the opportunity to review and comment on this draft report.

GAO Recommendation

To help ensure the safety of the food imported into the United States, we recommend that the Commissioner of Food and Drugs complete an analysis to determine the annual number of foreign food inspections that is sufficient to ensure comparable safety of imported and domestic food. If the inspection numbers from that evaluation are different than the inspection targets mandated in Food Safety Modernization Act (FSMA), the U.S. Food and Drug Administration (FDA) should report the results to Congress and recommend appropriate legislative changes.

HHS Response

FDA concurs with this recommendation, pending the necessary resources to conduct the analysis, as part of a larger post-FSMA strategy to improve the safety of imported food. GAO notes that, under the FDA FSMA, FDA is directed to inspect at least 600 foreign food facilities in 2011 and, for each of the next 5 years, inspect twice the number of facilities inspected during the previous year. GAO noted that FDA is not keeping pace with the FSMA mandate and recommends that the FDA complete an analysis to determine the annual number of foreign inspections that is sufficient to ensure comparable safety of imported and domestic food.

FSMA provides FDA a multi-faceted toolkit to better ensure the safety of imported food. This toolkit includes increased foreign inspections, as foreign inspections provide direct accountability for inspected firms, incentives for all foreign firms exporting to the U.S. to comply with U.S. requirements, and critical intelligence for FDA concerning foreign food safety practices. The toolkit also includes sharpening private sector accountability for import safety, leveraging private sector resources, and taking advantage of what foreign governments can do to elevate assurances that food coming into the United States meets FSMA's prevention-oriented standards.

Foreign inspections are an important part of the new import safety system mandated by FSMA, but they will not, in themselves, ensure comparable safety of imported and domestic food. FDA has been clear in its report to Congress under section 110(a)(1) of FSMA (a report referenced on page 11, reference 14, in GAO's report) that the Agency does not anticipate going significantly beyond 1200 foreign food facility inspections per year in the foreseeable future. FDA's position is based on the enormity of the additional funding that would be needed to meet FSMA's foreign inspection goals, coupled with FDA's view that additional resources would be better spent on implementing tools in the FSMA import safety toolkit that leverage both FDA and private sector resources more effectively to ensure the safety of foods exported to the U.S. by foreign firms. In other words, FDA is committed to using its resources in a risk-based way to protect the safety of the U.S. food supply.

For example, the foreign supplier verification programs mandated by FSMA will be the foundation of a new system under which importers will take greater responsibility for ensuring that foreign manufacturers produce food in compliance with U.S. safety requirements. Another import-related program, the Voluntary Qualified Importer Program, will make it easier for participants in the program to import items into the U.S., based on demonstrated high-performance on food safety, and enable FDA to better focus its resources on potentially higher risk imports. FSMA also directs FDA to establish an accredited third party audit program, under which third party auditors can assure importers and FDA that foreign producers are using effective preventive controls. Final rules requiring foreign supplier verification programs and establishing the accredited third party audit program will publish this year.

The Agency is expanding its collaborations with foreign governments so that FDA can rely as appropriate on foreign government food safety programs and gain knowledge about the safety of foreign exports. This allows

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FDA to focus its own resources more efficiently. One way the Agency can ensure a foreign government's food safety programs and information are reliable is through a formal assessment of the foreign food safety system to determine if it offers a comparable level of public health protection. FDA is currently pursuing such systems recognition assessments. Finally, FDA will continue to engage in capacity building to help foreign governments and facilities meet FDA standards, in part through FDA's foreign offices.

FDA's current focus with respect to foreign facility inspections is targeting them to achieve the greatest public health benefit. FDA's selection of foreign food facilities for inspection is based on an overall, cross-cutting risk profile. The primary factors contributing to a facility's risk profile include: (1) the food safety risk associated with the commodity (the type of food), (2) the manufacturing process, and (3) the compliance history of the facility, such as refusal rates for products that were denied entry into the United States. In addition, section 201 of FSMA requires FDA to identify high-risk facilities and allocate resources to inspect facilities according to the known safety risks, and includes several other factors to consider when developing a facility's risk profile.

Looking ahead, as part of FDA's Operational Strategy for the Implementation of FSMA (see <http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm395105.htm>), FDA is committed to reconfiguring import screening and field exam activities to ensure that FDA is making strategic, risk-based use of its import oversight resources. FDA is also committed to building data integration and analysis systems to strengthen risk-based targeting of resources. As FDA moves forward with implementing the new FSMA toolkit for imports, FDA intends to monitor, analyze, and reconsider a host of factors, including the number of foreign inspections we conduct and how we target them, and adjust as necessary and as funding permits, to further our public health mission. All of these activities will contribute to FDA's ability to ensure comparable safety of imported and domestic food and rely on FDA receiving sufficient resources.

FDA's Progress on 2010 Recommendations

Since this GAO report provides an assessment of FDA's foreign offices, the Agency would also like to comment on some observations within this report specific to FDA's Office of International Programs, and provide additional information on FDA's activities since the 2010 GAO study on FDA's foreign offices.

As of January 2015, FDA maintains eight foreign posts, in addition to the Office of Regional and Country Affairs (ORCA),¹ based at headquarters. Specifically, FDA has a presence in China, India (New Delhi and Mumbai), Belgium, the United Kingdom, Mexico, Costa Rica, and Chile.² FDA's foreign offices are essential to ensuring accessibility to and strengthening relationships with regulatory counterparts. The collaborative work and regulatory systems strengthening activities undertaken by FDA's foreign offices directly contribute to the safety of imported foods. For example, following concerns in the U.S. regarding the safety of food imported from China, FDA's regulatory counterparts in China expressed significant interest in learning about topics such as FDA's risk-based inspections models, risk communication, strong supply chains, food defense, and professionalized inspectors. Having a presence in China has allowed our FDA staff to be accessible to our Chinese regulatory counterparts and maintain regular interactions on subjects that help strengthen China's food safety systems.

In 2010, GAO examined FDA's newly established foreign offices and recommended that FDA take steps to enhance strategic planning by developing a set of performance goals and measures to demonstrate the foreign

¹ Previously known as the Asia-Pacific Office, this Office covers countries and regions not covered by FDA's Foreign Offices.

² FDA is closing its post in South Africa in January 2015. Responsibilities for FDA activities in this region have been transferred to the Office of Regional and Country Affairs, within FDA's Office of International Programs.

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offices' contributions. GAO also recommended that FDA develop a workforce plan to help recruit and retain overseas staff. FDA concurred with these recommendations, and since 2010 has made significant progress in these areas.

Steps to Enhance Strategic Planning

OIP has enhanced strategic planning efforts as demonstrated by the following key accomplishments: (1) developed an updated OIP Strategic Plan and OIP Strategy Map; (2) established six OIP Strategic Priorities that align with the Agency's overarching strategy; and (3) implemented a number of performance and accomplishment metrics to demonstrate contributions of FDA's foreign offices. Through the Agency-wide FDA-TRACK performance management system, we monitor accomplishments such as inspections completed by in-country investigators and detailees, and track these figures by commodity. These metrics are reported quarterly on the FDA Website.

In its current report, GAO acknowledges an additional metric that OIP utilizes to assess its performance: collaborative actions based upon meaningful analyses of the global regulatory landscape. We believe that this performance metric does capture the activities and outcomes of FDA's foreign offices that align with OIP's strategic approaches. By tracking collaborative actions, FDA is able to monitor engagement with regulatory counterparts and international agreements entered into with key stakeholders. For example, in February 2014, FDA signed the first-ever Statement of Intent with Indian regulatory authorities to facilitate collaboration and further enhance lines of communication to ensure products exported from India to the U.S. are safe and of high quality. Five months later, in July 2014, the Commissioner signed a Statement of Intent announcing the FDA-Mexico Produce Safety Partnership, which focuses on preventive practices and verification measures supporting compliance with produce safety standards, guidelines and best practices. With this new partnership in place, FDA expects to help improve the safety of fruits and vegetables for consumers on both sides of the border. FDA will closely monitor the outcomes of this partnership through regular reports that will contribute to the Agency's collaborative actions metric.

Since FDA's foreign offices first opened, they have continued to refine, review and evaluate these metrics to align with OIP's strategic and operational planning efforts. While the FDA believes its current measurement tools capture the contributions of the foreign offices to the safety of imported food and other FDA-regulated products, we recognize these efforts can be improved. Therefore, OIP continues to explore options to measure results-oriented goals and the impact achieved by FDA's foreign offices.

Development of Workforce Plan to Recruit and Retain Overseas Staff

During the past few years, OIP has focused on workforce planning efforts in four areas: recruitment and retention, learning and development, succession planning, and performance management. Agency-level and activities within the Office of Regulatory Affairs (ORA) have supplemented OIP's workforce planning initiatives. Highlights of key accomplishments include: posting open continuous vacancy announcements as a recruitment tool for would-be investigators overseas; utilizing OIP's tour renewal and extension program to renew deployments abroad, with input from ORA and Centers; and providing short-term temporary duty (TDY) deployments to meet the Agency's immediate workforce needs. Feeding into these efforts are long-term planning and staffing. OIP continues to actively recruit for and expand staff at FDA's foreign offices. Because of the fluctuations in staffing abroad, the staffing figures discussed throughout the GAO report present a snapshot in time and are expected to change as staffing priorities shift over time. Although OIP has instituted numerous workforce planning processes, including a recently finalized reintegration process that provides a more predictable and transparent process for FDA employees once they complete a foreign assignment, OIP recognizes the value in having a more formal strategic workforce plan. Workforce planning, however, is an Agency-wide responsibility, and any plan for FDA's foreign offices must integrate with the broader Agency

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strategy including the product Centers and the Office of Regulatory Affairs (ORA), among others. In 2015, OIP, in collaboration with ORA and the Office of Human Resources, will develop the first phase of this forward-looking strategic workforce plan for FDA's foreign offices. To facilitate the process, OIP already has developed a preliminary strategic workforce planning framework based on the workforce planning model and best practices recommended by the U.S. Office of Personnel Management.

As noted in the GAO report, FDA has undertaken efforts to improve staffing in its foreign posts but has experienced some challenges. For example, following expanded funding under the China Safety Initiative, FDA's China Office has been working extensively with Chinese counterparts to obtain visas for an increased number of FDA staff to be based in China. In a positive development, the FDA signed two Implementing Arrangements (IAs) with its Chinese counterparts in November and December 2014. The documents, signed with China's General Administration of Quality Supervision, Inspection and Quarantine (AQSIQ) and China's Food and Drug Administration (CFDA), frame the work of regulatory personnel posted in each country, outline commitments from FDA and AQSIQ regarding inspections of food facilities, and detail commitments from FDA and CFDA regarding inspections of drug facilities. With these developments, FDA is optimistic that additional visas will be approved to expand FDA's presence in China.

Despite some challenges to recruit highly qualified investigators to our foreign offices, OIP has been successful in strengthening inspection capabilities in FDA's offices overseas. In the past year alone, FDA's foreign offices have increased the total number of inspections and expanded the countries in which foreign inspections are being conducted by in-country investigators and investigators on 60-120 day detail assignments to foreign offices.

Additional Activities of Foreign Offices in Food Safety

The mandates of the foreign offices extend beyond inspections in accordance with section 308 of the FDA Food Safety Modernization Act (FSMA) (P.L. 111-353). Section 308 specifically authorizes FDA's foreign offices to provide assistance to governmental entities to provide for the safety of food and other FDA-regulated products. Toward that end, FDA's foreign offices have been heavily engaged in conducting in-country analysis and information gathering, strengthening relationships with regulatory counterparts, and sharing information.

FDA notes that Figure 2 presented in GAO's current report does not accurately characterize the work of the foreign offices. During discussions with GAO, FDA's foreign offices were asked to identify their top three activities; however, priority activities in each foreign office are cyclical and depend entirely on current issues and activities in the regions where the offices are located. By limiting the figure to only three activities, the report does not provide a comprehensive portrayal of the key activities of the foreign offices. Below FDA has included a few examples where the actions of our foreign offices go beyond three key activities.

FDA's foreign offices are providing invaluable in-country analysis and intelligence to FDA Centers and ORA. For example, they provide critical intelligence to ORA and the Centers that issue the inspection assignments. They also contribute toward identifying higher risk firms and identifying commodities and hazards that may present increased risks to U.S. imports.

FDA has expanded upon its efforts to regulate the quality and safety of products coming into the U.S. from China through the China Safety Initiative (CSI). The primary activity of the CSI is to expand investigators in China. While the China Office has struggled to expand the number of full-time investigators in China due to delays in obtaining visas, the Office has continued to increase the number of inspections completed by in-country investigators by offering U.S.-based investigators on detail assignments of 60 to 120 days. In 2014, AQSIQ and the Certification and Accreditation Administration of the People's Republic of China (CNCA)

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engaged with FDA for the first time on issues related to data falsification. An investigator from the China Office and one of FDA's locally employed staff met with senior Chinese officials to describe FDA inspectional findings concerning falsified documentation and why accurate documentation is important to overall quality and safety. Following this meeting, the top inspectors from several Chinese provinces attended training provided by the FDA that included a review of the regulatory requirements for low acid canned food production, identification of falsified documentation and how accurate documentation is related to the overall quality and safety of food. Additionally, the CSI is funding a project to verify 1150 manufacturing and production sites of FDA-regulated commodities in China to better assess inspection prioritization needs. This is in addition to other projects that utilize innovative methodologies and monitoring of publicly available private sector and social media data sources that have not been used by FDA traditionally, to provide early signal detection of foodborne illness outbreaks or adverse events in order to better inform Agency decision-making regarding product safety and quality.

FDA's China, India, and Latin America Offices offer regulatory counterparts the opportunity to observe FDA inspections. This affords our regulatory counterparts the opportunity to learn about FDA's systems-based inspection approaches with a future goal of regulatory inspectors worldwide that adhere to FDA standards.

Through these past and ongoing inspectional and non-inspectional efforts, the FDA's foreign offices are well positioned to assist the Agency in responding to FSMA and other Agency mandates, particularly in countries and regions where FDA already has a strong physical presence. We look forward to working with GAO as we further develop FDA's Foreign Offices and engage in the FDA's global mission.

Appendix IV: GAO Contact and Staff Acknowledgments

GAO Contact

J. Alfredo Gómez, (202) 512-3841 or gomezj@gao.gov

Staff Acknowledgments

In addition to the individual named above, Mary Denigan-Macauley (Assistant Director), Darnita Akers, Cheryl Arvidson, Kevin Bray, Michele Fejfar, Jennifer Gould, and Terrance Horner Jr. made key contributions to this report. Other contributors included Adam Cowles, Marcia Crosse, Elizabeth Curda, Joyce Evans, Kimberly Gianopoulos, Armetha Liles, Cynthia Norris, Ifunanya Nwokedi, and Geri Redican-Bigott.

Appendix V: Accessible Data

Data Table for chart on Highlights page, Figure: FDA Inspections of Foreign Food Facilities Compared with FSMA Mandate

Year	Food and Drug Administration (FDA) actual	FDA planned	FDA Food Safety Modernization Act (FSMA) mandate	FSMA mandate (estimate)
2011	1002		600	
2012	1343		2004	
2013	1403		2686	
2014	1323		2806	
2015		1200	2646	
2016		1200		2400

Data Table for Figure 1: Food and Drug Administration (FDA) Foreign Office Locations

Status	Asia-Pacific (staff located at Food and Drug Administration (FDA) headquarters)	China	Europe	India	Latin America	Middle East and North Africa	Sub-Saharan Africa	FDA headquarters
Open		Beijing, China	Brussels, Belgium London, United	New Delhi, India Mumbai, India	Mexico City, Mexico Santiago, Chile San Jose, Costa Rica			
		Guangzhou, China (open)						
Closed	Pretoria, South Africa (closing March 2015)	closed September 2014)	Parma, Italy (closed July 2012)			Amman, Jordan (closed December 2013)		

Data Table for Figure 2: Top-priority Food Safety Activities, as Reported by Food and Drug Administration (FDA) Foreign Offices in 2014

Foreign office	Conducting inspections	Collecting sample	Managing recalls	Gathering and assessing information	Providing information about Food and Drug Administration (FDA)	Building relationships	Engaging in technical cooperation	Cooperating with other U.S. agencies
Asia-Pacific					yes	yes	yes	

Appendix V: Accessible Data

Foreign office	Conducting inspections	Collecting sample	Managing recalls	Gathering and assessing information	Providing information about Food and Drug Administration (FDA)	Building relationships	Engaging in technical cooperation	Cooperating with other U.S. agencies
China (Beijing)	yes			yes			yes	
China (Guangzhou)	yes			yes	yes			
Europe (Brussels)				yes	yes	yes		
Europe (London)				yes	yes	yes		
India (Mumbai)	yes			yes		yes		
India-New Delhi	yes			yes		yes		
Latin America (Costa Rica)					yes	yes	yes	
Latin America (Mexico)					yes	yes	yes	

Data Table for Figure 3: Food and Drug Administration (FDA) Inspections of Foreign Food Facilities in 2014

Country	Type of inspection (total)	
	Human food (1,323)	Animal food (7)
Albania	4	
Argentina	38	
Austria	1	
Bangladesh	10	
Brazil	45	
Bulgaria	23	
Canada	7	5
Chile	32	
China	145	
Costa Rica	26	
Croatia	12	
Dominican Republic	5	
Ecuador	24	
France	42	

Country	Type of inspection (total)	
	Human food (1,323)	Animal food (7)
Germany	1	
Greece	32	
Guatemala	22	
Hong Kong	7	
Iceland	23	
India	108	
Indonesia	17	
Ireland	1	
Italy	82	
Korea, Republic of (South)	49	
Japan	114	
Latvia	10	
Lithuania	9	
Macau SAR	2	
Malaysia	15	
Mexico	13	
Moldova	5	
Morocco	6	
Netherlands	1	
Nicaragua	11	
Norway	19	
Peru	47	1
Poland	22	
Portugal	53	
Senegal	5	
Slovenia	9	
Spain	72	1
Sri Lanka	22	
Switzerland	8	
Taiwan	51	
Trinidad & Tobago	19	
Turkey	28	
United Kingdom	7	
Vietnam	19	

Data Table for Figure 4: Food and Drug Administration (FDA) Inspections of Foreign Food Facilities Compared with FDA Food Safety Modernization Act (FSMA) Scenarios

Year	Food and Drug Administration_(FDA) actual	Planned FDA	FDA Food Safety Modernization Act (FSMA) mandate	Doubling each year
2011	1002		600	600
2012	1343		2004	1200
2013	1403		2686	2400
2014	1323		2806	4800
2015		1200a	2646	9600
2016		1200b	2400a	19200

Data Table for Figure 5: Filled and Vacant Staff Positions Approved by the Food and Drug Administration (FDA) for the Foreign Offices, as of October 2014

Number of positions				
Vacant	Filled	Foreign office	Total	Percentage
44 (40)	56 (50)	Asia-Pacific	1	3
		China ^a	23	28
		Europe	4	10
		India	11	58
		Latin America	1	3

Figure 6: Timeline of the Food and Drug Administration’s (FDA) Efforts to Obtain Visas for New FDA Investigators in China

2012	2013	2014
<p>February 2012—The President’s budget for fiscal year 2013 included \$10 million for additional staff in China, including 17 investigators. FDA began engaging with its Chinese counterparts about increasing FDA staff in China.</p> <p>October 2012—The last new visa was issued for an FDA employee to be posted in China.</p>	<p>President visited Beijing for bilateral meetings with Chinese government officials. FDA officials stated that, as a result of the visit, they received assurances that the Chinese government would begin granting visas for an increased number of U.S. food and drug investigators. However, China asserted that, under the Vienna Convention, FDA investigators posted in the U.S. consulates in Guangzhou and Shanghai were not allowed to conduct inspections outside of the regional jurisdiction of their respective consulates. FDA agreed to consolidate the investigators into the U.S. embassy in Beijing, which has jurisdiction over all of China.</p>	<p>April 2014—FDA submitted two visa applications for new staff to be posted in its China Office.</p> <p>September 2014—FDA closed its office in Shanghai.</p> <p>October 2014—FDA reduced its office in Guangzhou to one locally employed staff member.</p>

Figure 7: Number of Staff Working in Food and Drug Administration (FDA) Foreign Offices by Position, as of October 2014

Staff Role	Number of Staff
Director and deputy	7
Senior regional advisor ^a	0
Technical expert	15
Food investigator	5
Other investigator	3
Program support specialist	3
Locally employed staff	17
Total	50

Figure 8: Approved and Filled Staff Positions by Food and Drug Administration (FDA) Foreign Office, as of October 2014 (two bar charts)

Number of U.S. government staff positions

Region	Approved	Filled
Asia-Pacific	10	9
China	26	6
Europe	5	3

Region	Approved	Filled
India	19	8
Latin America	8	7

Number of locally employed staff positions

Region	Approved	Filled
Asia-Pacific	1	1
China	7	4
Europe	3	1
India	4	4
Latin America	7	7

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