

September 2012

FOOD SAFETY

FDA Can Better Oversee Food Imports by Assessing and Leveraging Other Countries' Oversight Resources



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Why GAO Did This Study

U.S. reliance on imported food increased from 2000 through 2011. For some products, imports make up a considerable share of the total amount consumed in the United States. FDA—responsible for ensuring the safety of most imported foods—received new authority under FSMA to enhance its oversight of food imports, including express authority to establish a system for accrediting third parties, which may include foreign governments and private auditing firms, to certify foreign food facilities' compliance with U.S. food safety requirements. FDA has also begun to assess selected foreign food safety systems to determine if these systems provide the same level of public health protection, among other things.

GAO was asked to (1) identify major actions FDA is to take to implement a system for accrediting third parties and challenges, if any, it and others report with these actions and (2) examine FDA's approach for using comparability assessments to leverage other countries' oversight capacity and enforcement authority. GAO reviewed FDA documents and interviewed officials from FDA and other agencies, and stakeholders, such as consumer groups and industry representatives.

What GAO Recommends

GAO recommends that FDA revise its comparability approach to one that also includes assessing foreign food safety systems for particular food products, such as seafood. FDA neither agreed nor disagreed with the recommendation.

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What GAO Found

We identified five major actions the Food and Drug Administration (FDA) is to complete under the FDA Food Safety Modernization Act (FSMA) to establish a reliable system that uses third-party audits conducted by foreign governments or other third parties to help ensure food safety. FDA officials and others report that each of these actions presents challenges that must be addressed. First, FDA is to develop new preventive controls and related guidance for all of the foods under its jurisdiction—such as produce, milk, cheese, spices, soft drinks, and processed foods—and will need to develop appropriate training, particularly for foreign producers and processors, which poses a challenge because FDA is responsible for a variety of food industries. Second, FDA is to establish a voluntary user fee program for importers that encourages the use of third-party certifications, and it faces a challenge in developing a program that encourages importers to participate. Third, FDA has to develop a system for recognizing accreditation bodies that can accredit third parties to certify foreign food facilities and is likely to face a challenge in addressing foreign governments' concerns about being evaluated by an entity other than FDA. Fourth, FDA is to develop model standards for accreditation bodies to use in evaluating and accrediting third parties and faces challenges in, among other things, determining third-party auditors' competency and deciding on how to avoid potential conflicts of interest. Fifth, FDA is to oversee the third-party accreditation system, including periodically evaluating accreditation bodies and third parties, and faces a challenge in deciding the level of oversight it will provide to the multiple parties involved in third-party certification.

FDA's approach for using comparability assessments can enable the agency to leverage other countries' oversight capacity and enforcement authority. This could result in some of the same advantages as the equivalence approach used by the U.S. Department of Agriculture's Food Safety Inspection Service (FSIS) and the European Union (EU) before specific food products can be imported. These advantages include having a foreign competent authority address any identified problems and take regulatory actions across the supply chain, as necessary. However, according to FDA officials, the agency expects few countries to seek comparability with the United States because, in part, most countries will not meet the FDA requirement that a foreign government's domestic and export food safety systems be comparable to the U.S. system for food products under FDA's jurisdiction. According to FDA documents, some countries have robust export certification programs for a specific food product, but their overall food safety systems, including domestic production systems, may not be comparable with those of the United States. Consequently, FDA would be unable to leverage the resources of countries with comparable systems for just one food product, such as seafood, which FDA has experience in assessing through its foreign country assessments. Representatives from major seafood exporting countries GAO interviewed stated that they would like to have agreements with FDA covering seafood that are similar to those they have with the EU, which uses a targeted approach through equivalence to determine whether certain exported food products are safe for domestic consumption.

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Abbreviations

AMS	Agriculture Marketing Service
ANSI	American National Standards Institute
CFIA	Canadian Food Inspection Agency
EU	European Union
FDA	Food and Drug Administration
FSMA	FDA Food Safety Modernization Act
FSIS	Food Safety and Inspection Service
GFSI	Global Food Safety Initiative
HACCP	Hazard Analysis and Critical Control Point
IAF	International Accreditation Forum
ISO	International Organization of Standardization
MOU	memorandum of understanding
SENASICA	Servicio Nacional de Sanidad, Inocuidad y Calidad Agroalimentaria
SIP	Seafood Inspection Program
USDA	U.S. Department of Agriculture
VQIP	Voluntary Qualified Importer Program

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United States Government Accountability Office
Washington, DC 20548

September 28, 2012

The Honorable John D. Rockefeller IV
Chairman
Committee on Commerce, Science,
and Transportation
United States Senate

The Honorable Olympia J. Snowe
Ranking Member
Subcommittee on Oceans, Atmosphere, Fisheries,
and Coast Guard
Committee on Commerce, Science, and Transportation
United States Senate

The Honorable Maria Cantwell
United States Senate

The Honorable Daniel K. Inouye
United States Senate

The U.S. reliance on imported food increased from 2000 through 2011. During this period, imported food as a percentage of all food consumed in the United States rose from about 9 percent to over 16 percent. Some food categories are more likely to come from foreign rather than domestic sources. For example, in 2009, we reported that 60 percent of fruits and vegetables and 80 percent of seafood in the U.S. food supply were imported. Some specific products are imported at an even higher rate. For instance, in 2010, over 90 percent of the U.S. shrimp supply consisted of imports. Imported foods can present food safety risks from the presence of pathogens, chemical contamination, and sanitary violations. The U.S. Department of Health and Human Services' Food and Drug Administration (FDA) has primary responsibility for ensuring the safety of about 80 percent of the U.S. food supply. The U.S. Department of Agriculture's (USDA) Food Safety and Inspection Service (FSIS) is responsible for meat, poultry, and processed egg products, while FDA is responsible for virtually all other foods, both domestic and imported, including produce and seafood. However, we have identified deficiencies in FDA's oversight of imported foods: in September 2009, we reported

that FDA, among other federal agencies responsible for food safety oversight, needs to address gaps in enforcement and collaboration to enhance the oversight of food imports.¹ In April 2011, we reported that imported seafood has been subject to limited U.S. oversight by FDA and that the agency needed to better leverage its resources.² FDA generally agreed with our recommendations in the 2009 report and neither agreed nor disagreed with the recommendations in our 2011 report. FDA has stated that it needs new approaches to improve its oversight of imported food that take into account the entire food supply chain and that it needs to push prevention of food safety risks offshore and leverage the efforts of others to avoid duplication and better target its food safety efforts.

The FDA Food Safety Modernization Act (FSMA) enacted in 2011 expands and modifies existing FDA authorities, among other things, giving FDA several new authorities that enhance the agency's oversight of imported food. Among other things, FSMA directed FDA to establish a system for recognizing accreditation bodies that would, in turn, accredit third-party auditors (third parties), which may include foreign governments and private auditing firms.³ These third parties would certify that food or eligible foreign entities, such as seafood processors, met applicable federal requirements. Third-party certifications would serve the following purposes: (1) certifications for a voluntary program that offers expedited entry for food products certified by accredited third parties and (2) certifications as a condition for entry into the United States of certain articles of food if FDA determines such certifications or assurances are necessary for the food based on, among other things, the known safety risks for foods.

Under its pre-FSMA authority, in early 2010, FDA began an effort to assess foreign food safety systems to determine if certain other countries have a regulatory system—food safety statutes, regulations, and an implementation strategy—that is comparable with the U.S. food safety

¹GAO, *Food Safety: Agencies Need to Address Gaps in Enforcement and Collaboration to Enhance Safety of Imported Food*, [GAO-09-873](#) (Washington, D.C.: Sept. 15, 2009).

²GAO, *Seafood Safety: FDA Needs to Improve Oversight of Imported Seafood and Better Leverage Limited Resources*, [GAO-11-286](#) (Washington, D.C.: Apr. 14, 2011).

³According to a February 2011 report by the Congressional Research Service, the use of third parties has been promoted as a method for helping FDA carry out its responsibilities and target enforcement and inspections while better using existing personnel.

system and that provides the same level of public health protection. FDA has stated that identifying countries with comparable food safety systems will, among other things, facilitate the agency's ability to develop closer regulatory partnerships, to exchange food safety-related information, and to leverage the work done by foreign competent food safety authorities. According to FDA officials, the agency envisions building a coalition of overseas regulators with which it can share information and leverage knowledge and resources to make more informed decisions on food imports. Under this effort, FDA, in 2010, developed a comparability tool to assess the overall food safety systems of foreign countries for foods under the agency's jurisdiction. FDA completed its on-site review for a comparability assessment pilot with New Zealand in late 2010 and is currently engaged in another such pilot with Canada. In May 2012, we reported that, by using third-party certifications and comparability assessments, FDA has the opportunity to enhance its oversight of imported catfish—and essentially all imported foods under FDA's oversight.⁴

In this context, you asked us to examine FDA's plans for improving its oversight of the safety of imported food under FDA's jurisdiction. Our objectives were to (1) identify the major actions FDA is to take to implement a system for accrediting third parties, as directed by FSMA, and the challenges, if any, FDA and others report will be associated with these actions and (2) examine FDA's approach for using its comparability assessments to leverage other countries' oversight capacity and enforcement authority.

To identify major actions FDA is to take to develop a system for accrediting third parties and any challenges FDA and others reported in taking these actions, we reviewed FDA's responsibilities for developing a system to accept third-party certification under FSMA, its plans for implementation, and the results of FDA's third-party certification pilot for imported shrimp, which it initiated in 2008. We interviewed FDA officials on the agency's plans to implement a system for accrediting third parties and on the challenges identified during the third-party certification pilot for imported shrimp. We interviewed third parties who participated in FDA's third-party certification pilot for imported shrimp, as well as industry and

⁴GAO, *Seafood Safety: Responsibility for Inspecting Catfish Should Not Be Assigned to USDA*, [GAO-12-411](#) (Washington, D.C.: May 10, 2012).

consumer groups, to obtain their perspectives on FDA's new authorities and requirements for accepting third-party certifications. We spoke with the American National Standards Institute, a U.S. based, not-for-profit accreditation organization that serves as the official U.S. representative to the International Organization for Standardization.⁵ We reviewed internationally recognized third-party accreditation systems and industry-based food safety certification systems that include those used by third parties in FDA's third-party certification pilot for imported shrimp, and we spoke with representatives of these industry systems. We reviewed USDA's policies and spoke with officials from the department's Agriculture Marketing Service about its management of the National Organics Program, which uses accredited third parties to complete certifications of organic operations that produce crops, livestock, and multi-ingredient foods domestically and overseas. We also reviewed policies and spoke with U.S. Customs and Border Protection officials about the agency's Customs-Trade Partnership Against Terrorism program and the results of its pilot using third parties. To examine FDA's approach for using its comparability assessment process, we reviewed the tool it is using in its comparability assessment pilots with Canada and New Zealand and reviewed FDA documents about the agency's approach for using comparability assessments. We spoke with (1) FDA officials about the agency's comparability assessment pilot and its plans for using comparability assessments and (2) New Zealand government officials about their experience with the pilot. We reviewed the approach used by FSIS and the European Union (EU) to determine if their practices for ensuring the safety of imported foods have the potential for enhancing FDA's practices, and we spoke with FSIS and EU officials. For both of our objectives, we reviewed policies and spoke with representatives of countries that are major seafood exporters to the United States—Canada, Ecuador, Indonesia, Thailand, and Vietnam—and a major trading partner, Mexico, about their perspectives on FDA's use of third-party certifications and approaches they use in supporting oversight of seafood exports to other countries. We chose to interview representatives of major seafood exporting countries, in part, because more seafood is imported than is produced domestically and because FDA has set internationally recognized Hazard Analysis and Critical Control Point (HACCP)

⁵The International Organization for Standardization publishes international standards covering almost all aspects of technology and business, including food safety and agriculture.

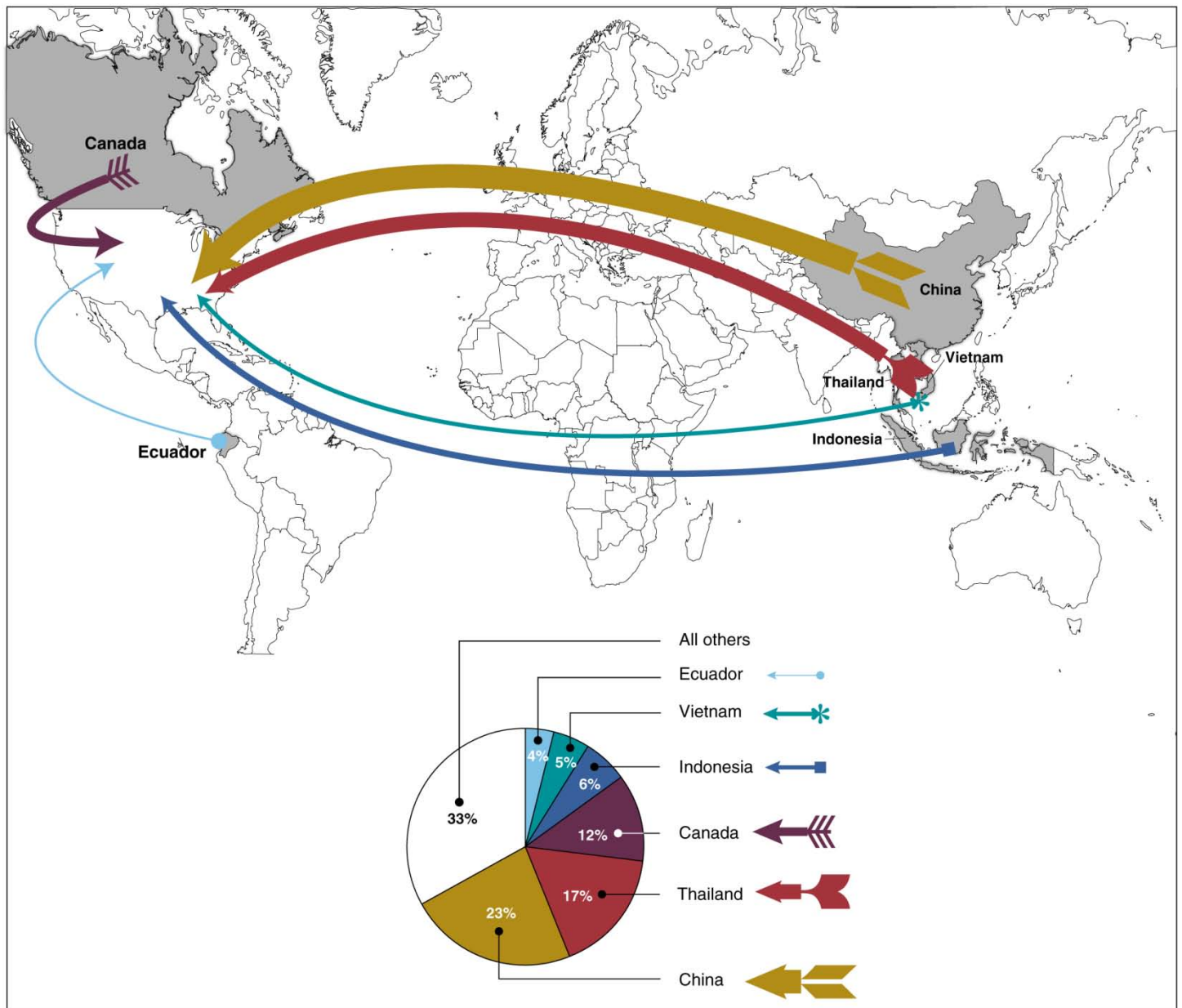
standards as its main oversight tool for seafood safety. Under HACCP, processors are primarily responsible for the safety of food, including seafood, they process and are required to implement preventive controls to address any identified hazards. Appendix I provides additional information on our scope and methodology.

We conducted this performance audit from June 2011 to September 2012 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

According to FDA documents, during the past 7 years, food imports have grown by an average of 10 percent each year, and over 16 percent of all food products now consumed in the United States are imported. Food imports are expected to continue to increase. According to FDA, from 2007 to 2015, it is estimated that imports under FDA's jurisdiction—including food—will triple, corresponding to a 15 percent growth rate. For some products, imports make up a considerable percentage of the total amount consumed in the United States. For example, in 2011, the United States imported 84 percent of the seafood consumed, and about half of such seafood was from aquacultured products. Figure 1 shows the proportion of seafood from the top six importing countries to the United States for 2010.

Figure 1: Top Six Seafood Importing Countries to the United States, 2010



Sources: GAO analysis of Department of Commerce and International Trade Commission data.

Under the Federal Food, Drug, and Cosmetic Act, FDA is responsible for ensuring that about 80 percent of the nation’s food supply—both domestic and imported—is safe, wholesome, sanitary, and properly labeled. Under

the act, any foreign company can export food products to the United States provided, among other things, that it first registers with the agency, if registration is required. FDA's approach to overseeing imported food safety encompasses (1) preventing food safety problems by promoting corporate responsibility; (2) intervening through targeted inspections, sampling, and surveillance; and (3) responding to food safety emergencies when they occur.

As part of its oversight activities, FDA inspects a targeted number of foreign food facilities that process foods under its jurisdiction to (1) identify potential food safety problems before products arrive in the United States, (2) help the agency make risk-based admissibility decisions when food products are offered for importation into the United States, and (3) help ensure that food products under FDA's jurisdiction meet U.S. requirements. In fiscal year 2011, FDA inspected 1,002 (about 0.4 percent) out of more than 270,000 registered foreign food facilities.

FDA supplements its inspection activities with examination and testing of select imported foods at ports of entry identified during a two-phase screening process of shipments' compliance with regulatory standards and requirements. First, before their arrival at a U.S. port, shipments are screened based on basic information required to be submitted to FDA as part of the Prior Notice requirements. Information that must be submitted includes the submitter's name and contact information; the article of food; the manufacturer or grower, if known; and the country from which the product was shipped. Second, shipments are subject to a separate assessment, called an admissibility review, which consists of screening the shipment for compliance with regulatory standards and requirements, as well as misbranding, adulteration, and safety. During the admissibility process, an FDA reviewer selects shipments for physical examination or testing, based on a review of shipment information, including, among other things, product type; manufacturer; and compliance history of manufacturers and importers. For example, for seafood, FDA conducts testing to identify the absence of residues of drugs that are unapproved for use in the United States and that would render the seafood adulterated under the Federal, Food, Drug, and Cosmetic Act. For fiscal year 2011, FDA reported that it examined about 2.2 percent of all food entry lines and specifically performed testing of samples from less than

0.5 percent of all food entry lines.⁶ Because items in an import entry having different tariff descriptions or FDA product codes must be listed separately, an entry line identifies each portion of an import shipment that is listed as a separate item on an entry document.

Some foods under FDA's jurisdiction, including seafood, are covered separately by specific regulations. Since regulations for enhancing seafood safety became effective in 1997, FDA has used the internationally recognized HACCP standards as its main oversight tool for seafood safety. FDA requires all seafood processing firms—those that, among other things, manufacture, pack, store, or label seafood products—to meet HACCP standards. Under HACCP standards, processors are primarily responsible for the safety of the seafood they process and are required to implement preventive controls to address any identified hazards. Food safety hazards in seafood may result from, among other things, microbial contamination, drug residues, pesticides, parasites, and decomposition. Processors are to lay out their hazard analysis and control procedures in HACCP plans whenever an analysis shows that one or more hazards are reasonably likely to occur. During inspections of seafood processing facilities, FDA verifies that seafood processors are in compliance with HACCP regulations and that controls are effectively implemented to minimize the food safety risk from identified hazards. In addition, FDA inspects importers of seafood products to ensure their compliance with HACCP requirements. Under FDA regulations, importers are to demonstrate, through documentation, that the seafood they import into the United States complies with HACCP requirements. FDA regulations require that every importer of seafood products either (1) obtain its seafood products from foreign firms in countries that have an agreement with FDA that documents the equivalency or compliance of the foreign inspection system with the U.S. system for imported products or (2) have and implement written verification procedures, which include product specifications designed to ensure that the product is not adulterated, and take at least one of six affirmative steps to document that the foreign firms supplying the seafood products comply with HACCP requirements. If importers cannot provide assurance that the seafood products they imported have been processed

⁶Examined food entry lines include lines that had an activity such as a field exam, label exam, or sample analysis performed.

under conditions established by HACCP requirements, the products are considered adulterated and can be refused entry into the United States.

USDA's FSIS is responsible for ensuring the safety of domestic and imported meat, poultry, and processed egg products. FSIS uses a three-part approach to overseeing the safety of imported food: (1) an equivalence system, whereby countries that wish to export meat and poultry products to the United States must demonstrate that their food safety systems for these food products are equivalent to those of the U.S. system; (2) periodic audits to verify that their system remains equivalent; and (3) reinspection of all imported shipments arriving at FSIS-approved import facilities located near about 30 U.S. ports of entry. Once FSIS determines equivalence, a single foreign government agency assumes responsibility for addressing any problems FSIS may identify with imported products, according to FSIS officials.

The EU likewise uses an equivalence approach to oversee all products of animal origin exported from foreign countries to the EU. As part of its equivalence determination process, countries must demonstrate that their food safety systems for a specified product, like seafood, meet EU or equivalent requirements or meet requirements specified in an agreement between the EU and the exporting country. The EU generally conducts an initial on-site inspection of the foreign country's food safety system for the food product the foreign country wants to export to the EU, as well as periodic follow-up reviews.

We and others have previously recommended that FDA take actions to both undertake equivalence determinations and use third parties. For example, in January 2001, to better ensure the safety of imported seafood, we recommended that FDA develop specific goals and time frames for establishing agreements with other countries to document that their seafood safety systems are equivalent to that of the United States.⁷ We stated that, without such equivalence agreements, FDA must rely principally on its reviews of importers' records to ascertain that imported seafood products are processed under an acceptable food safety system. FDA noted that foreign equivalencies was one of its priorities for fiscal year 2001 but added that a considerable exchange of data among the

⁷GAO, *Food Safety: Federal Oversight of Seafood Does Not Sufficiently Protect Consumers*, [GAO-01-204](#) (Washington, D.C.: Jan. 31, 2001).

countries involved had to take place before equivalence determinations could be made. In January 2004,⁸ we recommended, among other things, that FDA make it a priority to establish equivalence or other similar types of agreements with seafood-exporting countries, starting first with countries that have high-quality food safety systems. We further recommended that the agency explore the potential for implementing a certification program for third-party inspectors, which would involve reviewing FDA's legal authorities and considering the costs and benefits, including developing and implementing the standards, controls, and oversight necessary to provide FDA with reasonable assurance that third-party inspectors are qualified and independent. FDA did not agree with our recommendation on equivalence but generally agreed with our recommendation to explore the potential for implementing a certification program for third-party inspectors. Furthermore, in June 2010, a committee of experts convened by the Institute of Medicine and the National Research Council issued a report examining gaps in public health protection afforded by the farm-to-table food safety system under FDA's jurisdiction and identifying opportunities to fill those gaps. The report concluded that FDA needs to address barriers to improving the efficiency of inspections by, among other things, exploring third-party auditing of food facilities as an alternative model for measuring compliance.

FSMA

Enacted in January 2011, FSMA gives FDA new authorities to require comprehensive, prevention-based controls, among other things, for food under the agency's jurisdiction and enhances FDA's authority to oversee the safety of these imported foods. For example, the act requires FDA to develop a preventive controls rule for food facilities that manufacture, process, pack, or hold food within the agency's jurisdiction, with certain exceptions, such as seafood and juice facilities. Under the act, these food facilities are required to implement a written preventive control plan, provide in the plan for the monitoring of the performance of the controls, and specify the corrective actions the facility will take when necessary. In addition, under FSMA, FDA must develop produce safety standards for the safe production and harvesting of fruits and vegetables that will address soil amendments, hygiene, packaging, temperature controls, and water, among other issues.

⁸GAO *Food Safety: FDA's Imported Seafood Safety Program Shows Some Progress, but Further Improvements Are Needed*, [GAO-04-246](#) (Washington, D.C.: Jan. 30, 2004).

With regard to overseeing imported food under its jurisdiction, the act requires FDA to incrementally increase the number of FDA inspections of foreign food facilities over a period of 6 years. In addition, the act enables FDA to enter into agreements with foreign governments to facilitate the inspection of foreign facilities. Separate from FDA inspections of food facilities, the act's provisions give FDA the authority to require certifications or assurances issued by accredited third parties, which may include foreign governments or agencies of foreign governments that foods exported to the United States are in compliance with the Federal Food, Drug, and Cosmetics Act, including new preventive control requirements outlined in FSMA. The act also directs FDA to establish new regulations requiring importers to verify that imported foods are produced in compliance with processes and procedures that provide the same level of protection as U.S. food safety requirements (e.g., risk-based preventive controls), except certain imports, such as seafood, which has existing importer verification requirements. Furthermore, the act includes a provision directing FDA to develop a comprehensive plan to expand the food safety capacity of foreign governments. This plan must include recommendations for agreements with exporting countries to ensure the safety of food; approaches for mutual recognition of inspection reports; acceptance of laboratory methods and testing techniques; and training for foreign governments and food producers regarding U.S. requirements for safe foods, among other things.

According to FDA officials, the agency developed a structured implementation process to ensure clearly defined roles and responsibilities for meeting FSMA requirements. The structure consists of an implementation executive committee, as well as six implementation teams—including teams focused on preventive controls and imports that report directly to the senior leadership of FDA Foods Program and that are charged with developing related regulations and guidance.

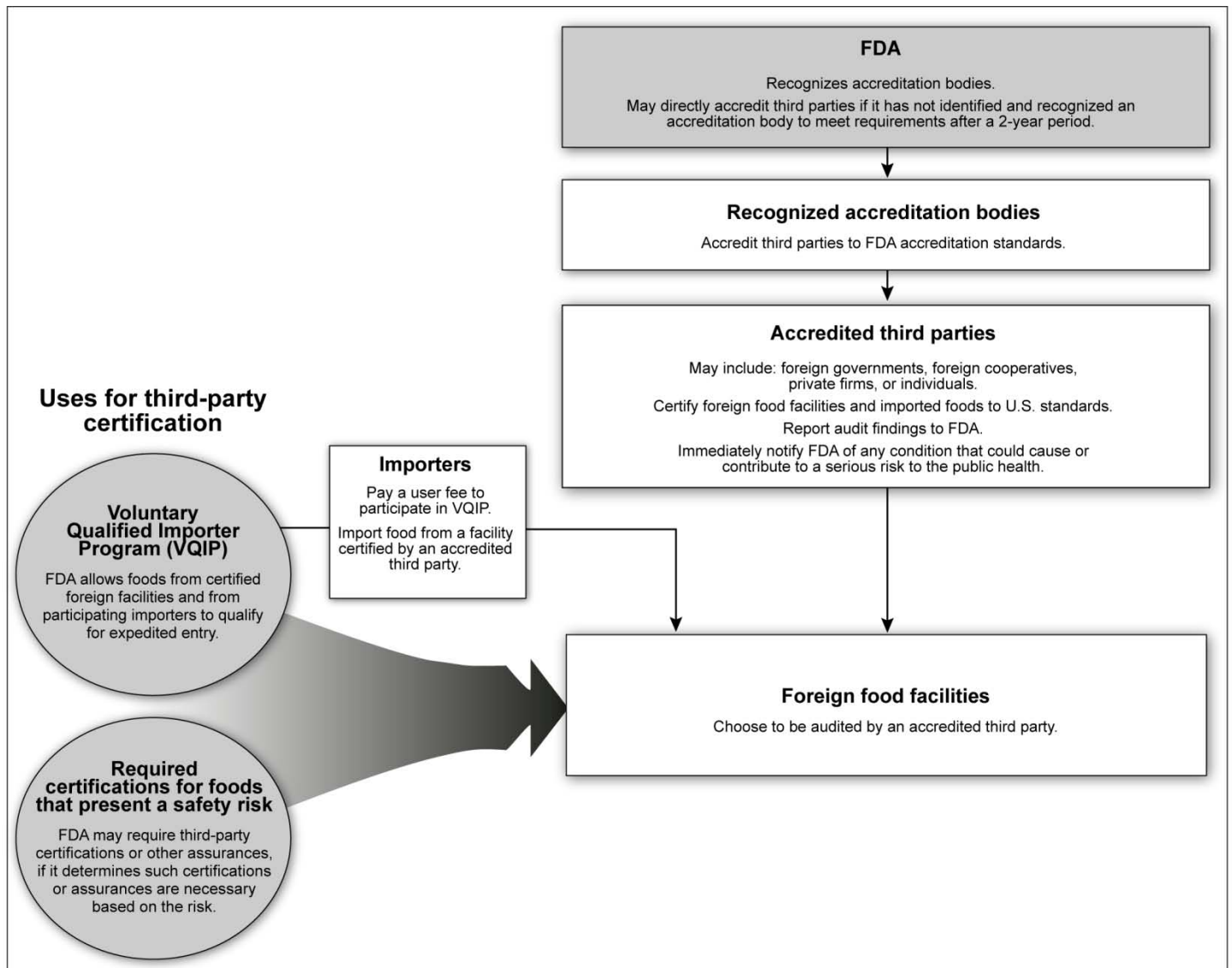
FDA Third-Party Accreditation System

FSMA requires FDA to establish a system for accrediting third parties that may certify foreign facilities or imported foods under the agency's jurisdiction. Under this system, accreditation bodies are responsible for accrediting third parties; third parties may conduct audits to certify that a foreign food product or facility complies with U.S. requirements, including new preventive control requirements. This system is to include model standards for accreditation bodies to use in evaluating and accrediting third parties. FDA may only directly accredit such third parties if it has not recognized an accreditation body within 2 years of establishing the accreditation system. Foreign governments, as well as foreign

cooperatives that market the products of growers or processors, private firms, and individuals may qualify as third parties. Under FSMA, FDA has the authority to withdraw accreditation from an accredited third party or revoke recognition of an accreditation body. FDA must also establish procedures to reaccredit third parties and reinstate the recognition of accreditation bodies.

According to FDA officials, third-party certifications may be used in two primary ways outlined in the act. First, FSMA requires FDA to establish a Voluntary Qualified Importer Program (VQIP) that allows FDA to offer expedited review and entry to participating importers who are importing foods from foreign facilities certified by accredited third parties. Second, FDA has the authority to require third-party certifications or other assurances as a condition of granting entry to imported foods based on a food safety risk. In addition, FSMA directs FDA to consider audits by accredited third parties in targeting FDA inspections of foreign facilities, as well as in targeting some imported foods for examination and testing at the ports of entry to ensure the products meet U.S. requirements. Moreover, FSMA directs FDA to operate the accreditation system as a revenue-neutral operation by developing a user fee to cover the cost of establishing and administering the system. Figure 2 shows how FDA may structure a system for recognizing third-party certification under FSMA, according to our review of FSMA and FDA documents.

Figure 2: Uses and Potential Structure of an FDA Third-Party Accreditation System



Sources: GAO analysis of FSMA and FDA documents.

FDA's Third-Party Certification Pilot for Aquacultured Shrimp

Before FSMA was enacted, FDA conducted a pilot of voluntary third-party certification of aquacultured shrimp (shrimp pilot) produced in foreign facilities and farms. In July 2008, FDA invited interested third parties to participate in the pilot and, by September 2009, FDA completed its assessment of third-party attributes and observations of third-parties' audit performance. FDA issued a report on its assessment of the shrimp

pilot in July 2011. This report raised a number of issues for FDA to consider as critical to the success of a full-scale third-party certification program, including the need for an appropriate infrastructure to be in place at FDA. According to this report, the goal of the shrimp pilot was for FDA to learn about third-party certifications and evaluate the feasibility of using these certifications to help make decisions, such as selecting foreign facilities for inspection or selecting imported foods for sampling. As part of the pilot, FDA (1) observed auditors from six third parties conducting actual audits of 28 foreign shrimp processors and 8 shrimp farms and (2) conducted audits of 11 laboratories in six countries. FDA chose to focus the pilot on aquacultured shrimp because HACCP safety standards for such shrimp have been in place since 1997; the industry was experienced in using third-party certifications; FDA had a record of finding microbial contamination and unapproved drug use in aquacultured shrimp; and the United States imports a high volume of shrimp. On the same day that FDA invited interested third parties to participate in the shrimp pilot, it also published draft guidance for industry on voluntary third-party certification for foods and animal feeds.

FDA Faces Challenges in Implementing a Third-Party Accreditation System to Help Ensure Imported Food Safety

We identified five major actions FDA is to complete under FSMA to establish a system that uses third parties to help ensure food safety, and FDA officials and others report that each of these actions presents challenges that must be addressed. First, FDA is to develop new preventive control requirements and supporting guidance for food products under its jurisdiction; the agency will also need to develop the appropriate training, particularly for foreign food producers and processors, which poses a challenge because FDA is responsible for ensuring the safety of a wide variety of food products, such as produce, milk, cheese, spices, bakery products, soft drinks, and processed foods. Second, FDA is to establish a voluntary user-fee program for importers that requires facility certification as a condition of VQIP eligibility. FDA may also require certification or other assurances as a condition for entry into the U.S. if it determines such certificates or assurances are necessary based on the known safety risks. However, the agency faces a challenge in laying out incentives for expediting imported food products under VQIP that will incur a fee and in establishing criteria to determine the risk of certain imported foods by, among other things, food product and country. Third, FDA has to develop a system for recognizing accreditation bodies and faces the challenge of addressing foreign governments' concerns about being reviewed by such bodies. Fourth, FDA is to develop model standards for accreditation bodies to use in evaluating and accrediting third parties and faces challenges in, among

other things, determining third-party auditors' competence and deciding how to avoid potential conflicts of interest. Fifth, FDA is to oversee the third-party accreditation system, including periodically evaluating accreditation bodies and third parties, and faces a challenge in deciding the level of oversight it will provide to the multiple parties involved in the process for third-party certification.

Developing Preventive Controls and Guidance for All Foods under Its Jurisdiction Requires FDA to Consider a Wide Variety of Food Industries

Under FSMA, FDA is required to develop minimum standards for implementing preventive controls and related guidance that consider the wide variety of foods under its jurisdiction. These controls are intended to minimize or prevent food safety hazards. Specifically, under FSMA, FDA was required to issue proposed produce safety standards by January 2012 and a final produce safety rule by 1 year after the close of the comment period for the proposed rule. In addition, FDA was required to issue a rule on minimum standards for the implementation of mandatory preventive controls for facilities that manufacture, process, pack, or hold food by July 2012. According to FDA officials, FDA has developed a proposed produce safety rule and has proposed preventive control rules for human food facilities and for pet food and animal feed facilities. As of August 2012, the Office of Management and Budget was reviewing these proposed rules. FDA officials stated that when the agency issues a final rule for preventive controls, it also plans to issue related guidance on how facilities are to implement the controls. Currently, facilities processing seafood and juice must comply with HACCP standards, which include preventive controls, and these facilities are exempt from the new preventive control requirements.

To support the development of training and guidance on preventive controls for industry and regulators, in November 2010, FDA helped fund the Produce Safety Alliance and, in December 2011, FDA funded the development of the Food Safety Preventive Controls Alliance. The Produce Safety Alliance is a collaborative project that includes FDA, Cornell University, and USDA and is to provide the produce industry and associated groups with training and educational opportunities related to current best practices and guidance, among other things. Similarly, the Food Safety Preventive Controls Alliance is a collaborative project between FDA and the Illinois Institute of Technology's Institute for Food Safety and Health to develop training courses and materials on preventing contamination for both human and animal food during production to help industry—particularly small- and medium-sized companies—comply with the new preventive control rule. These alliances are modeled after other FDA alliances, including the Seafood HACCP

National Organics Program

According to USDA Agriculture Marketing Service (AMS) officials who manage the National Organics Program, it is important to maintain clear written guidance and have a strategy for updating guidance to help ensure that third parties consistently apply standards. The National Organics Program uses third parties to certify that companies are eligible to use USDA labeling and meet USDA organic standards. A 2010 USDA Inspector General report found that third parties used differing criteria to evaluate organic operations in large part because AMS did not provide adequate guidance to third parties. Third parties indicated that guidance was not always clear or timely and noted that there was no centralized location for them to access existing guidance. Since then, according to AMS officials, AMS has provided program updates using a variety of means, such as increasing use of policy memos, which may be made available more quickly; an e-mail alert system for interested stakeholders including third parties, certified food companies, and consumers; and an enhanced website that serves as a central resource location for all relevant program information.

Alliance—a coalition of federal and state regulators and representatives from academia and industry that developed training for industry and regulators to support implementation of seafood HACCP standards. As of June 2012, the Produce Safety Alliance had held 89 focus groups with growers, and working committees of the alliance developed written recommendations on a training curriculum and training delivery. As of June 2012, the Food Safety Preventive Controls Alliance launched its website to maintain information on its activities; the alliance is in the process of forming work groups, according to its website.

Developing guidance with the necessary level of detail on each food industry under its jurisdiction could present a challenge for FDA. For example, a senior FDA official stated that it will be difficult to develop preventive controls for all produce that are sufficiently flexible to consider the diversity of the crops regulated, geographical areas involved, and growing and packing practices, among other things. With the need for this degree of flexibility, FDA officials told us that they do not expect the preventive controls guidance to be as detailed as the guidance for implementing seafood HACCP. To support implementation of HACCP standards for seafood, FDA published the *Fish and Fishery Products Hazards and Controls Guidance*. The guidance contains information to help industry (1) identify hazards associated with each fish species and product type and (2) formulate appropriate control strategies. It was also developed to serve as a tool for federal and state regulatory officials evaluating HACCP plans, according to the guidance document.

FDA may also face challenges in developing the necessary training and guidance, particularly for foreign food producers and processors, and it may take considerable time to achieve desired compliance levels at all facilities. For example, according to its evaluation reports of seafood HACCP implementation from 1998 to 2005, FDA expected HACCP implementation in developing countries to lag behind the domestic seafood industry, in part, because it was difficult for processors to obtain the necessary training and guidance. To help address this issue, FDA inspection teams for seafood focused on training both foreign seafood processors and foreign governments when they visited countries that were major seafood exporters to the United States, including China and Vietnam. Nevertheless, in fiscal year 2005, more than 8 years after HACCP requirements were put in place for seafood, FDA's evaluation of HACCP implementation indicated that of those seafood processors with required HACCP plans, 11 percent of domestic and 33 percent of foreign seafood processors did not adequately identify hazards in their plans.

FDA Faces Challenges in Laying Out the Incentives for Voluntary Third-Party Certifications and in Deciding on the Need for Mandatory Certifications for Certain Imported Foods

As directed by FSMA, FDA was to establish VQIP within 18 months of FSMA's enactment, or by July 2012. As part of program development, FDA is required to establish user fees for importers participating in VQIP. As outlined in FSMA, the fees will have to cover administrative costs, such as reviewing submitted applications for participation in the program. FDA officials told us they are in the process of developing VQIP, including establishing user fees. Some industry representatives we spoke with generally support the VQIP program, but according to a representative of an association of food importers, FDA faces a challenge in developing a voluntary program that provides sufficient incentives for expediting the import of food products to warrant the fee that importers will incur to participate in the program. For example, the representative told us that FDA will need to clearly articulate any benefits, including an explanation of what "expedited entry" will mean for importers so that importers can determine if the cost of participation is worthwhile. According to some industry representatives we spoke with, entry delays are largely related to detention times during FDA examinations and sampling of food imports at the port of entry and can take as long as a month or more. However, as noted earlier, only a small portion of all food entry lines—2.2 percent—were examined by FDA at ports of entry in fiscal year 2011. Industry representatives also stated that a VQIP user fee should be reasonable so that it is not perceived as a barrier to trade, especially for small businesses.

FSMA also gives FDA the authority to mandate third-party certifications or other assurances for imported products if the agency determines it is necessary based on the food safety risks. Under FSMA, FDA is to base the risk determination on: (1) known safety risks associated with the food; (2) known safety risks associated with the country, territory, or region of origin of the food; (3) a finding, supported by scientific risk-based evidence, that food safety systems in the country, territory, or region of origin where the food is produced are inadequate and that certification would assist FDA in determining whether to refuse or admit the imported food product; and (4) the information submitted to FDA regarding improvements to food safety systems are found by FDA to be inadequate.

FDA faces a challenge in deciding if it should use its authority to mandate third-party certifications. FDA's decisions could have an impact on whether a company, in turn, decides to export its food products to the United States, according to foreign government officials we spoke with from Thailand and Vietnam. For example, these officials told us that if FDA identifies seafood as a product that is considered a safety risk and requires third-party certification, companies may choose to reduce

seafood exports to the United States and sell their product to different markets if any required certifications are too costly.

FDA Is to Develop a System to Recognize Accreditation Bodies and Faces Challenges in Addressing Foreign Government Concerns

As directed by FSMA, by January 2013, FDA is required to establish a system for recognizing the accreditation bodies that can be responsible for accrediting third parties to certify foreign food facilities and imported food. According to FDA officials, FDA has gathered information on the number of accreditation bodies that might be interested in seeking recognition from FDA and participating in FDA's third-party accreditation system. Under the act, if FDA has not identified and recognized an accreditation body to meet the applicable requirements within 2 years of the establishment of the accreditation system, FDA can directly accredit third parties. Accreditation bodies are established in many countries with the primary purpose of ensuring that third parties are subject to oversight by an authoritative body and normally operate as not-for-profit organizations. For example, the American National Standards Institute (ANSI) is a not-for-profit accreditation organization in the United States. According to an ANSI official, the organization is the official U.S. representative at the International Organization of Standardization (ISO), which develops international standards. Founded in 1947, ISO has published more than 19,000 international standards covering almost all aspects of technology and business, including food safety and agriculture.

Under FSMA, accreditation bodies would also accredit any foreign countries that apply to be third parties and meet the model accreditation standards. However, country representatives we spoke with said that FDA is likely to face challenges in using accreditation bodies to accredit foreign countries. For example, foreign governments may be reluctant to apply for accreditation as a third party from a non-U.S. government agency, such as ANSI. Some foreign government officials we spoke with raised concerns about being evaluated by a private accreditation body, citing sovereignty issues as a concern. In addition, a foreign government official stated that, for seafood, his government preferred that FDA recognize the appropriate government agency as the accreditation body.

A majority of accreditation bodies are government-owned or quasi-governmental agencies, and some will not allow third parties to operate within their countries unless accredited by that country's accreditation body, according to ANSI officials. However, there is a potential conflict of interest in having a government accreditation body accrediting another government agency in its own country as a third party. According to ANSI officials, this type of an accreditation relationship makes it difficult to

consider the process unbiased. For example, all third parties operating in China, including a Chinese government agency, must be accredited by the China National Accreditation Service for Conformity Assessment, also a Chinese government agency. Moreover, ANSI officials told us that they are not aware of any accreditation body evaluating a foreign government system. FDA officials did not explain how they would address these challenges.

FDA Is to Develop Standards for Countries and Accrediting Private Organizations as Third Parties and Faces Challenges in Addressing Consumer Groups' Concerns

As required by FSMA, by July 2012, FDA was to develop model accreditation standards and conflict-of-interest regulations. The model accreditation standards must be used by accreditation bodies to evaluate third parties and include, for example, specific requirements for foreign governments that apply to serve as third parties in their own countries. In addition, conflict-of-interest regulations should protect against conflicts of interest between third parties and entities they audit by, among other things, including requirements on how audits are to be performed. Specifically, as directed by FSMA, FDA is to take the following actions:

- Develop standards foreign governments must meet before being accredited that involve review of their food safety programs, among other things. To develop these standards, FDA is drawing on different sources of information. According to FDA officials, these sources include (1) FDA's Manufactured Food Regulatory Program Standards,⁹ which were developed by FDA to establish a uniform foundation for design and management across state inspection programs they contract with to conduct food safety inspections; and (2) its International Comparability Assessment Tool, which is being piloted for use in evaluating the comparability of foreign government systems.
- Develop standards that other third parties, including private firms, must meet, which involves reviews and audits of third parties' training

⁹FDA's Manufactured Food Regulatory Program Standards establish critical elements of a regulatory program designed to protect the public from foodborne illness and injury and are being used on a voluntary basis by state regulatory programs that are providing contracted regulatory oversight of food facilities. The following 10 key elements are included in the program standards: (1) regulatory foundation, (2) training program, (3) inspection program, (4) inspection audit program, (5) food-related illness and outbreaks and response, (6) compliance and enforcement program, (7) industry and community relations, (8) program resources, (9) program assessment, and (10) laboratory support.

International Organization of Standardization (ISO)

According to some industry representatives we spoke with, the most efficient approach for developing standards to accredit foreign governments and private organizations as third parties would be for FDA to add its standards to existing ISO standards, such as the ISO product certification standard (ISO 65 -General Requirements for Bodies Operating Product Certification Systems). This ISO standard is commonly required of third parties focused on food safety, among other areas, according to industry representatives. The ISO product certification standard specifies requirements that a third party conducting certification activities for any product or process should meet if it is to be recognized as competent and reliable. Among other requirements, the ISO standard requires third parties to conduct periodic internal audits and management reviews, maintain a record system that demonstrates effectiveness of its certification program, and establishes minimum standards for auditors.

and qualifications, as well as reviews of internal systems and other investigations, as needed.

- Review standards already in place, such as industry-based and international accreditation standards, as part of the development of accreditation standards for evaluating both foreign governments and others. This review is intended to help avoid unnecessary duplication of effort and cost in developing accreditation standards. FDA officials told us that the agency has reviewed information from a number of sources in developing these standards, including voluntary international standards and information on other federal agency programs that share common issues relating to third-party auditing and use of accreditation standards.
- Issue audit reporting requirements as part of developing accreditation standards for third parties. In addition to meeting these audit reporting requirements, under FSMA, accredited third parties are required to notify FDA of any condition that could cause or contribute to a serious risk to the public health that they identify.
- Issue conflict-of-interest regulations that are to provide for unannounced audits, an approach to decreasing potential conflict of interest, including timing and public disclosure for audit fees paid by eligible entities to accredited third-party auditors, and for limits on financial affiliations between third parties and audited companies.

According to FDA officials, FDA is in the process of gathering information to develop these model accreditation standards and conflict-of-interest regulations; the agency was unable to provide a time frame when proposed standards and regulation would be available for the Office of Management and Budget and then public review.

FDA officials and industry representatives we spoke with identified the following three challenges associated with developing accreditation standards and conflict-of-interest regulations:

- *Develop standards for third parties.* A senior FDA official has publicly stated that the agency faces many challenges in developing standards for third parties that ensure competency of individual third-party auditors. These challenges include identifying the right level of training and experience for individual third-party auditors and determining the extent of specialized knowledge that they need to demonstrate. For example, in its assessment of its shrimp pilot, FDA reported that, in 79 percent of the 28 seafood processing audits FDA

observed, individual third-party auditors performing these audits did not demonstrate an understanding of how to identify, evaluate, and control food safety hazards with the product and process being audited to FDA standards. In addition, FDA reported a wide variation in third-party performance across participating companies and governments and less variation, although in some cases still significant, in the performance of individual auditors employed by a single third party. Moreover, FDA recognizes potential challenges in ensuring the capacity of qualified third parties to conduct third-party certifications. FDA stated that the agency will face challenges in determining how many qualified third parties will be needed, what expertise they need, what geographic areas they should cover, and how to attract and build a cadre of qualified auditors.

Industry representatives also recognize the need to address ongoing challenges with ensuring the competency of third parties to consistently apply standards. For example, Food Safety Services Providers, a trade association of accredited certification auditing companies, has a technical working group that is developing a best practices guide to address third-party auditor competency issues. There is already a program to have outside accreditation agencies observe audits to better ensure consistency. Similarly, the Global Food Safety Initiative (GFSI)—a collaboration that includes retailers and manufacturing and food service companies and that evaluates private food safety standards against GFSI-established criteria—also has a working group focused on addressing issues related to individual third-party auditor competency. Furthermore, one industry representative we spoke with expressed concerns about the number of qualified third parties available to conduct FDA certifications and described a lack of formal education and a career path as barriers to having qualified third-party auditors. According to this industry representative, there is currently a relatively small community of qualified third parties, in total about 200 entities worldwide.

- *Issue reporting and immediate notification requirements.* A senior FDA official stated that FDA will face challenges in determining the content for audit reports required for accredited third parties to submit to FDA. For example, FDA officials told us the level of detail that FDA may require is likely to depend on how it plans to use the information. In addition, according to FDA officials, the FSMA requirement for accredited third parties to notify FDA immediately of any observed condition that could cause or contribute to a serious risk to the public health provides a new role and new obligation for third parties. In audits conducted for private food safety standards, third parties

typically have not had to report their audit findings, including findings of a serious public health risk, to any government agency. According to some third parties we spoke with, FDA will need to develop guidance on what qualifies as a serious public health risk and how third parties should report such risks. In addition, some industry representatives also told us that required reporting of “immediate public health risks” could cause third parties to be viewed as an extension of FDA inspectors or a regulatory agent, thereby creating disincentives for food production and processing establishments to participate in an FDA third-party certification system or use industry-based systems in general. For example, some third parties told us that foreign food producers and processors are concerned that any voluntary audit conducted to meet market demands could lead to regulatory actions, such as an import alert, for their facilities.

Mexico Addresses Conflicts of Interest

Consumer groups we spoke with expressed concern about the conflicts of interest that may arise when the producer or food facility responsible for payment to the third party is the person or entity receiving the audit. A federal agency, the USDA Food Safety Inspection Service (FSIS), raised similar concerns regarding potential conflicts of interest in third-party certification systems. For example, FSIS made an equivalence determination for Mexico for the export of meat and processed poultry products. In conducting its periodic equivalence verification audit of Mexico’s inspection system for these products, the agency found that audited establishments directly paid third parties used by the Mexican government to support its oversight of food safety. FSIS saw this payment system as a potential conflict of interest. To address this problem, the Mexican government contracted with an outside agency to manage a centralized payment system.

- *Develop conflict-of-interest regulations.* In implementing conflict-of-interest regulations, FDA will face a challenge in developing regulations that sufficiently address consumer groups’ concerns about potential conflicts of interest in using private third parties and are still practical to implement, according to industry representatives we interviewed. For example, according to a trade association representing auditing companies, since most private certification systems require a detailed contract prior to the audit, typically these systems use announced audits because sites to be audited are aware that an audit is forthcoming. However, unannounced audits are an option in some programs. Under FSMA, FDA is required to issue regulations requiring third parties to conduct unannounced audits. Some third parties noted that unannounced audits present logistical challenges for planning a thorough audit and raised concerns about wasting time and resources if unannounced audits occur when facilities are not operating or when appropriate staff is unavailable to respond to questions. Other industry representatives we spoke with stated that, with a short notice period, unannounced audits may be reasonably conducted. In addition, regarding public disclosure of third-party audit fees, U.S. Customs and Border Protection reported that it had a disclosure requirement in its pilot using private third parties for its Customs Trade Partnership Against Terrorism program but could not enforce it. One industry representative we spoke with suggested a simple base fee for an FDA recognized audit could be disclosed, but this fee would not reflect the actual costs of the audit, which, according to third parties we spoke with, vary considerably and depend on many factors, including the location of the production or processing facility, the size of the facility, and the complexity of the operation. Representatives from some of these third parties told us

that the costs for audits by private firms may range from less than \$1,000 to more than \$10,000.

FDA Is to Monitor the Third-Party Accreditation System and Faces Challenges in Deciding on the Degree of Oversight

As part of overseeing the third-party accreditation system—which includes accreditation bodies responsible for accrediting third parties and third parties that conduct food safety audits of foreign food facilities—FSMA directs FDA to reevaluate accreditation bodies and to also evaluate the performance of each accredited third party at least every 4 years. FSMA does not specify how FDA would meet the requirement to reevaluate accreditation bodies; however, the act does provide direction on how FDA should evaluate third parties. For instance, FSMA states that FDA should at a minimum evaluate the performance of third parties by reviewing their audit reports and reviewing the compliance history of foreign food facilities the third parties have audited every 4 years. FSMA also authorizes FDA to conduct, at any time, site visits to any certified foreign facilities, with or without the third party present.

To provide the necessary level of oversight, FDA faces the challenge of determining how it will most effectively and efficiently work with accreditation bodies responsible for accrediting third parties. ANSI officials we spoke with identified more than 60 accreditation bodies with a food safety scope that follow relevant ISO standards and guides for accreditation processes and product certification systems.¹⁰ Some industry representatives have suggested that FDA require accreditation bodies be members of the International Accreditation Forum (IAF)—an international association of accreditation bodies established to help ensure accreditation bodies are following accreditation rules—and subject to its peer evaluation process. Under IAF’s peer evaluation process, members are regularly evaluated for conformance to ISO standards.¹¹ However, according to ANSI officials, peer reviews do not evaluate how accreditation bodies implement additional requirements, such as any that FDA might have, although these officials told us that IAF plans to be able to do such evaluations in the future. In addition, if FDA recognizes many

¹⁰Includes ISO/IEC Guide 65—General Requirements for Bodies Operating Product Certification Systems.

¹¹These standards are the ISO/IEC 17011, Conformity Assessment—General Requirements for Accreditation Bodies Accrediting Conformity Assessment Bodies and ISO/IEC Guide 65—General Requirements for Bodies Operating Product Certification Systems.

Third-Party Oversight Approaches

Federal agencies and private-sector organizations that use third-party certification employ varying approaches to oversee third parties. For example, USDA's Agriculture Marketing Service (AMS) directly accredits third parties to certify companies that meet USDA requirements for organics and conducts periodic on-site assessments of accredited third parties about every 2 to 3 years. In addition, to help facilitate communications regarding certification activities with over 90 accredited third parties, AMS assigns an accreditation manager to work with smaller groups of approximately 20 third parties. In the private sector, according to representatives of Global G.A.P.—an organization that sets voluntary certification standards for agricultural products—Global G.A.P. conducts its own oversight of third parties that complements the initial and periodic on-site reviews conducted by accreditation bodies. To track performance, Global G.A.P. conducts office assessments of accredited third parties at least every 2 years and also conducts reinspections of certified operations using its own assessors. As part of the third-party office assessment, Global G.A.P. is checking compliance with Global G.A.P. rules based on record review. During the reinspection, the Global G.A.P. assessor conducts a Global G.A.P. inspection of a recently inspected farm operation and compares his or her own findings with the third-party findings. A Global G.A.P. representative told us that new third parties are always entering the market, so there is a need for continual oversight. Some retailers we spoke with also have internal staff to conduct audits, in addition to third-party audits, to ensure that foreign suppliers meet their standards.

accreditation bodies, it may need to more formally oversee their work to ensure that these accreditation bodies are consistently evaluating third parties that they are responsible for accrediting. For example, Global G.A.P., a private food safety certification standards organization that issues among the largest number of food safety certifications, requires the more than 30 accreditation bodies recognized by Global G.A.P. to participate in IAF's peer evaluation program and attend an annual 2-day harmonization meeting to help ensure that they consistently apply accreditation standards. During the annual harmonization meeting, managers obtain input from the accreditation bodies, share information on activities, and provide input to Global G.A.P. on the accreditation process. In addition, Safe Quality Foods, a U.S.-based food safety standards organization, works closely with only two accreditation bodies that are also required to be members of IAF and meets at least 2 times a year.

FDA officials told us that they recognize that they will need to play an oversight role over all levels of the third-party accreditation system, including accredited third parties and their individual auditors. Specifically, these officials told us they face challenges in determining the extent of the oversight FDA will conduct. Using its authority to conduct oversight visits of accredited third parties presents FDA with cost and logistical challenges, as FDA reported in assessing its shrimp pilot. In addition, in its assessment of this pilot, FDA stated that it will be critical to provide robust formal training for agency personnel involved in on-site performance assessments of third parties to ensure consistent application of FDA criteria. Among the challenges related to oversight of third parties and individual auditors, a senior FDA official stated that the agency will need to determine the role of accreditation bodies in monitoring and ensuring the objectivity of accredited third parties and their individual auditors. In addition, it will be a challenge to determine the responsibilities of accredited third parties for ensuring the competence of auditors they employ. According to FDA officials, there is limited information available on the performance of third parties to date.

In addition to facing challenges in providing general oversight of accreditation bodies and accredited third parties, FDA faces the challenge of being responsible for conducting any follow up investigations or taking regulatory actions when compliance issues are identified by accredited third parties. According to FDA documents, accredited third parties will not be commissioned by FDA and will not otherwise serve as regulatory authorities acting on FDA's behalf—even if the accredited third party is itself a government agency. Follow-up investigative visits, similar to

oversight visits, present cost and logistical challenges for FDA, as identified in its shrimp pilot.

FDA officials also told us they will need to invest in an appropriate information technology system to be able to use information for targeting inspections and entry examinations. According to these officials, using this information technology to resolve data management issues can be costly, difficult to set up, and difficult to coordinate. In 2012, we identified challenges FDA is facing in implementing and managing efforts to modernize the agency's information technology systems, including initiatives to improve sharing data with other entities.¹² An FDA official stated that the agency also faces a challenge in determining what, if any, audit information will be made publicly available. Some industry and consumer representatives we spoke with said that transparency of the auditing process will be critical to building confidence in the third-party accreditation system.

Representatives of most consumer groups we spoke with raised concerns about FDA's reliance on third parties. They pointed to FDA's poor track record in overseeing inspections contracted to states as third parties as a reason for their concern. For example, in 2011, the Department of Health and Human Services' Inspector General reported that FDA did not complete 38 percent of the required oversight audits in one-third of states with contracts (14 of 41 states), citing lack of resources and limited trained FDA staff, and did not always follow up on identified systemic problems.¹³ According to FDA officials, the agency concurred with the report's findings and stated that it would develop processes and procedures to address them. The representatives of the consumer groups also told us that FDA will need to oversee all levels of the third-party accreditation system—the accreditation bodies, third parties, and individual third-party auditors. They also questioned the food safety assurances provided by private third parties that had issued certifications to facilities responsible for a 2011 *Listeria* outbreak in cantaloupes and the 2008 to 2009 *Salmonella* outbreak from processed peanuts.

¹²GAO, *Information Technology: FDA Needs to Fully Implement Key Management Practices to Lessen Modernization Risks*, [GAO-12-346](#) (Washington, D.C.: Apr. 14, 2011).

¹³U.S. Department of Health and Human Services, Office of the Inspector General, *Vulnerabilities in FDA's Oversight of State Food Facility Inspections* (Washington, D.C.: December 2011).

Consumer groups we spoke with told us that their order of preference for overseeing food safety is (1) FDA, (2) other federal agencies, (3) trusted foreign governments, and (4) private third parties.

In contrast, many industry representatives we spoke with—food retailers, manufacturers, and trade associations; organizations that developed private certification standards; and private third parties—viewed third-party certification as beneficial. Accredited third-party certifications are increasingly used by large-scale retailers and commercial companies as a way to require and verify the safety and quality of food they market. For example, more than 123,000 farm operations in over 100 countries are certified to Global G.A.P. standards, and nearly 14,000 food processing or packing operations in over 100 countries are certified to the British Research Consortium standard for food safety. In addition, retailers we spoke with indicated that they require third-party certification of their suppliers and expressed confidence in accredited third-party certification systems. For instance, the certification standards we reviewed require any deficiency identified during the audit—minor or major—to be corrected within a specified time frame as a condition of certification, and some industry representatives told us that audited food facilities have sufficient incentives to address identified problems. Furthermore, according to a 2011 document prepared for the United Kingdom’s Food Standards Agency to guide use of private certifications in setting priorities for inspecting domestic food facilities, most private certification standards for foods that researchers reviewed had well-established approaches to developing standards and conducting assessments, and clear requirements for auditor competency; many of these private certification standards met basic food safety laws for the United Kingdom.

FDA’s Comparability Assessment Approach Could Enable FDA to Leverage Other Countries’ Oversight Resources for Imported Foods

FDA’s approach for using comparability assessments, which is complemented by the use of third parties, could enable the agency to leverage other countries’ oversight capacity and enforcement authority. Using this approach could result in some of the same advantages of equivalence used by FSIS and the EU before certain foreign food products can be imported. According to FDA documents and officials, few countries are likely to meet requirements for comparability with the U.S. food safety system because the agency will require comparability of a foreign country’s entire food safety system. This involves a review of a foreign country’s domestic and export systems for all food products that are under FDA’s jurisdiction. However, FDA has already developed a process to assess a foreign country’s export systems for seafood, and foreign government officials we spoke with would like FDA to assess their

seafood safety systems for products exported to the United States. FSIS and the EU take a more targeted approach to determine the safety of imported food by examining whether a country's systems for ensuring the safety of a specific food product are equivalent to theirs.

FDA Plans to Use Comparability Assessments to Leverage Oversight Resources of Other Countries to More Efficiently Oversee Imported Foods

In a public hearing FDA held in March 2011 to discuss new initiatives for ensuring the safety of foods and animal feed imported into the United States, as well as in agency documents, FDA provided general information about how it plans to develop comparability assessments and how it may use these assessments to efficiently enhance the safety of all imported food products by leveraging the oversight resources of foreign countries. According to the information FDA officials provided, a comparability assessment is a review of a foreign country's regulatory system for food safety—statutes and regulations—to determine if that country's systems are comparable to the U.S. system and provide a comparable level of food safety protection. According to FDA documents, leveraging other countries' oversight resources could be accomplished through formal agreements. Thus, a result of an assessment may be an agreement between the United States and the foreign country, whereby the foreign country may assume greater responsibility for ensuring food products it exports to this country meet a comparable level of safety protection to that in United States, and these exports could move more expeditiously through U.S. ports of entry.

FDA has developed a comparability assessment tool, which serves as criteria for assessing a foreign government's domestic and export food safety systems for all its food products. Using the tool, FDA plans to review and compare the following elements of a foreign country's food safety system with the same elements in the U.S. food safety system: (1) laws, regulations, rules, ordinances, or other regulatory requirements that govern the operation of the foreign food safety control system; (2) a food safety training program for food safety personnel; (3) a food safety inspection program; (4) quality assurance program reviews; (5) surveillance, investigation, response, and subsequent review of alleged food-related incidents; (6) compliance and enforcement program; (7) industry and community relations; (8) program resources; (9) interacting and communicating with the international community on food safety standards; and (10) laboratory support.

According to FDA officials, the agency has used its assessment tool to conduct a comparability pilot with New Zealand, and it began another pilot with Canada in February 2012. The pilot with New Zealand took about 2

years, but the agency has not yet finalized the pilot project. FDA officials also told us that the agency does not have written procedures that it can use when assessing a foreign government's response to the assessment tool. Furthermore, FDA has not explained how it plans to integrate comparability assessments with the new authorities provided in FSMA, such as third-party certification or international capacity building. According to FDA officials, the agency expects to develop a plan for the use of comparability assessments once it concludes its pilot project with Canada in 2013.

Few Countries Are Likely to Meet Requirements for Comparability with the U.S. Food Safety System

According to FDA officials, the agency expects a limited number of countries to seek comparability with the United States because, in part, most countries will not meet the FDA requirement that the foreign government's domestic and export food safety systems be comparable with the U.S. system for all their food products. According to FDA documents, some countries have robust export certification programs for a specific food product, but their overall food safety systems, including domestic production systems, may not be comparable with those of the United States, and therefore, FDA would not find their food safety systems comparable. However, according to FDA officials, such countries would be more suited to apply for accreditation as a third party. In situations where a foreign country could not function as a third party, FDA documents show that private third parties could conduct the certifications. Under FDA's comparability assessment approach, the agency would leverage the oversight resources of foreign countries whose overall food safety systems were comparable with that of the United States.

FDA Has Experience in Conducting Focused Reviews of Foreign Seafood Safety Systems

According to FDA documents, the agency has developed a process for assessing a foreign country's aquaculture programs, including the agency responsible for overseeing aquaculture and the country's regulatory infrastructure. Specifically, FDA conducted foreign country assessments in five countries from 2006 to 2010: Chile, China, India, Indonesia, and Vietnam. According to FDA documents, these assessments were an integral part of its seafood safety program, and the agency used the assessment process to examine the other countries' laws for controlling drug residues in aquaculture products exported to the United States. For example, during these assessments, FDA officials visited some fish farms where aquaculture products originated to evaluate veterinary drug use and reviewed some laboratories that analyzed the seafood products for drug residues for processors. According to FDA officials, the agency is currently not conducting evaluations that focus only on seafood because

it is now devoting its resources to the broader comparability assessments. However, FDA's publicly available website includes information on foreign country assessments and describes them as one of several tools that the agency uses for its imported seafood safety program.

In addition to these reviews, FDA has entered into memorandums of understanding (MOU) with foreign governments and other parties when the agency determined that it needed to define lines of authority or responsibility or to clarify cooperative procedures, according to FDA documents. FDA has three active MOUs with Canada, Mexico, and New Zealand relating to molluscan shellfish. Only certified shippers from countries that have MOUs with FDA and have agreed to abide by the shellfish safety policies incorporated into the National Shellfish Sanitation Program—a federal/state cooperative program recognized by FDA for the sanitary control of shellfish produced and sold for human consumption—are permitted to export fresh or frozen uncooked shellfish into the United States. According to FDA, the agency used an audit process to establish these MOUs. The MOUs, however, are nonbinding agreements and were not developed as a result of an equivalence determination or a comparability assessment of the foreign country's capabilities for ensuring the safety of seafood.

**Foreign Country
Representatives We
Interviewed Want FDA to
Determine Comparability
Specifically for Their
Seafood Exports**

According to representatives of major seafood exporting countries we spoke with, they want FDA to evaluate their seafood export programs so that they can develop agreements similar to those they have with the EU. They added that having such agreements with the United States offers potential benefits. Specifically, they told us the following:

- *Thailand.* In 2010, the United States imported over 916 million pounds of edible seafood from Thailand, including catfish, shrimp, and tuna. For fiscal years 2005 through 2010, FDA had inspected about 14 percent of Thailand's seafood processing facilities. According to Thai officials we spoke with, when Thailand has a government-to-government agreement, as with the EU, the Thai government can better ensure that the seafood processing facilities meet the standards of the country to which the seafood products are exported and can address problems identified by the importing country in a timely manner. In addition, the officials said that the Thai government can address the issues that go beyond the facility level. For example, if an importing country identifies drug residues at unacceptable levels, the Thai government can track the product to the farm of origin, investigate the situation, and enforce any corrective actions in a timely

manner. As part of its oversight responsibilities, the Thai government sets standards and conducts inspections and certifications of the nearly 19,000 aquaculture operations, as well as registered processing facilities in the country. According to Thai officials, the government has about 300 inspectors and over 3,000 local officers in the 77 provinces that support inspection oversight. The Thai government has worked with FDA on the agency's best aquaculture practices program. However, Thai officials told us that because their government has no agreement with FDA on food safety and because no health certification is required for exports to the United States, the government cannot ensure the overall safety of the seafood products, particularly in the final processing stage. In addition, according to Thai officials, FDA and Thai officials do not formally communicate regarding the results of the inspections FDA conducts at processing facilities in Thailand and regarding examinations and testing at U.S. ports of entry. Instead, FDA contacts the Thai processing facilities, and the Thai government may not learn of the problem until 2 months later from those facilities.

- *Ecuador.* In 2010, the United States imported almost 243 million pounds of edible seafood from Ecuador, including shrimp, tilapia, and tuna. For fiscal years 2005 through 2010, FDA had inspected about 26 percent of Ecuador's seafood processing facilities. Ecuadoran officials stated that they have government staff who inspect and certify facilities that export seafood products to the EU, with which Ecuador has a formal agreement. Ecuadoran officials stated that the government developed a national control plan to address specific EU requirements and standards for seafood exports. This plan includes the rules for registering production facilities, verifying compliance with health regulations, and certifying compliance by issuing health certificates. For these facilities, Ecuadoran inspectors review controls over drugs and take samples during on-site visits. If a farm does not meet government standards, it can be decertified. Fish products from unapproved or decertified farms may not be delivered to registered and inspected processing facilities. According to Ecuadoran officials, if government inspectors identify a human health hazard, they will take steps to destroy the product. However, these farms can still sell their products to facilities not under government oversight, and these products can be exported to countries where Ecuadoran government certification is not required, such as the United States. In contrast, not all facilities exporting seafood products to the United States are registered and inspected by the Ecuadoran government. Because FDA has not entered into an agreement with Ecuador, Ecuadoran

officials cannot require exporting facilities to register and be subject to inspection.

- *Indonesia.* In 2010, the United States imported over 275 million pounds of edible seafood from Indonesia, including crabmeat, shrimp, and tuna. From fiscal years 2005 through 2010, FDA had inspected about 1 percent of Indonesia's seafood processing facilities. In addition, in 2007, FDA evaluated Indonesia's overall control of drug residues in aquaculture products exported to the United States, identified deficiencies in the country's program to control drug residues in these products, and made several recommendations to improve the program. According to Indonesian officials, their government wants to be assessed by FDA again. Indonesian officials said that they believe a reassessment could result in an agreement that could benefit the United States. For example, according to Indonesian officials, all processing facilities exporting to countries where there is a government-to-government agreement, as with the EU, must meet HACCP certification requirements and obtain a health certificate and meet any additional requirements of the country receiving the product. No such agreement exists between Indonesia and the United States. These additional requirements may result in fewer processing facilities exporting their products to the countries having these agreements with the Indonesian government. For example, of the 500 seafood processing facilities registered with the Indonesian government, 176 are approved to export to the EU. In contrast, 422 export to the United States. Under government-to-government agreements, importing countries can notify the competent authority of rejected products, which enables the Indonesian government to take timely regulatory action. According to Indonesian officials, their government has oversight of different parts of the aquaculture supply chain, including hatcheries, production, and processing. In addition, in 2008, the Indonesian government began certifying farms using good aquaculture practices. Indonesian officials told us that when they are notified of a rejected product, the affected processing plant is suspended from exporting additional seafood products until it takes the corrective action the government has determined is needed. If the processing plant does not take the corrective action, the government can revoke the plant's registration. According to Indonesian officials, FDA and the Indonesian government do not communicate on products that FDA has rejected for import. As a result, the Indonesian government does not learn that a product has been rejected for 2 or 3 months.

FSIS and the EU Use a Targeted Approach to Determine Whether Exported Food Is Safe for Domestic Consumption

For about 14 years, we have reported that FDA could enhance its oversight of imported food, including seafood, if it used an equivalence approach to place greater responsibility on exporting countries to ensure their food exports met U.S. requirements as follows:

- In 1998, we determined that FDA's approach to ensuring the safety of imported food was not effective and recommended that Congress require all food imported into the United States be produced under equivalent food safety systems.¹⁴ FDA stated that it had the authority to enter into equivalence agreements with other countries but did not require such agreements as a precondition of trade. In a 1997 federal notice, FDA stated that equivalence agreements would enable the agency to target its limited resources for imports on the products from countries without an agreement, and thus FDA would use its resources more efficiently and effectively.¹⁵ FDA added that it would enter into agreements that covered only certain food products, such as fish and fishery products, if a foreign country's regulatory system was designed to achieve, or was capable of achieving, equivalence for some food products but not for others.
- In 2001, we reviewed federal oversight of seafood safety and found that FDA still did not have seafood equivalence or compliance agreements with any foreign country.¹⁶ FDA noted that foreign equivalencies was one of its priorities for fiscal year 2001 but added that a considerable exchange of data among the countries involved had to take place before equivalence determinations could be made.
- In 2004, we reviewed FDA's imported seafood safety program and determined that the agency had made no progress in developing equivalence agreements with seafood exporting countries.¹⁷ FDA officials stated that developing these agreements was no longer a priority because the agency believed that equivalence agreements, as such, did not necessarily contribute to the enhanced safety of

¹⁴GAO, *Food Safety: Federal Efforts to Ensure the Safety of Imported Foods Are Inconsistent and Unreliable*, [GAO/RCED-98-103](#) (Washington, D.C.: Apr. 30, 1998).

¹⁵62 Fed. Reg. 30,593 (June 4, 1997).

¹⁶[GAO-01-204](#).

¹⁷[GAO-04-246](#).

imported seafood. We stated that FDA should view the creation of these agreements as a long-term investment in improving imported seafood safety and recommended that the agency strengthen its imported seafood program by making it a priority to establish equivalence or other similar types of agreements with seafood-exporting countries, starting first with countries that have high-quality food safety systems. FDA did not agree with our recommendation. In commenting on this recommendation, FDA said the agency was not currently positioned to assign high priority to negotiating equivalence or other types of agreements with numerous countries that export seafood to the United States in light of the pressing priorities associated with implementation of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002. FDA also said that establishing these agreements is extraordinarily resource intensive.

- In 2011, we reported that FDA was still using the same approach it developed more than 10 years earlier to ensure the safety of imported seafood, even though U.S. reliance on imported seafood had increased, and aquaculture had emerged as a major source of those imports.¹⁸ We determined that this approach was limited and, in some respects, ineffectively implemented. We recommended that the agency use a more broad-based approach to overseeing imported seafood and consider the feasibility of applying some of the practices employed by the EU and FSIS through their respective equivalence processes. The Department of Health and Human Services, responding for FDA, did not agree or disagree with our recommendations but provided information on the actions in progress or planned related to the recommendations we made. FDA does not currently have any equivalence agreements in place.

According to FDA officials, equivalence determinations generally entail an intensive, standard-by-standard review of a foreign country's food safety system, and it has been a challenge for the agency to conduct equivalence determinations or enter into such agreements. Still, FDA officials told us that the agency reviewed FSIS and EU equivalence models, among others, to examine their general approach and determine if the agency could use comparability assessments to acquire some of the same advantages realized by the FSIS and the EU through equivalence.

¹⁸[GAO-11-286](#).

As part of this review, FDA completed its on-site review for a comparability assessment pilot with New Zealand in late 2010 and is currently engaged in another such pilot with Canada.

Under FSIS's equivalence approach, imported meat, poultry, and processed egg products are not eligible for export to the United States unless FSIS has determined that the exporting country has a food safety system equivalent to that of the United States for one or all of these products. According to FSIS documents, FSIS determines that a foreign food safety system is equivalent if the sanitary measures applied in the foreign country, though different from those applied in the United States, achieve the same level of sanitary protection. As part of an equivalence determination, FSIS evaluates a foreign country's foreign meat and poultry food regulatory system through document analysis, on-site audit, and point-of-entry product reinspection. FSIS requires foreign countries to have an organizational structure and staffing to ensure uniform enforcement of the required laws and regulations throughout the system where products are prepared for export to the United States. FSIS staff review foreign governments' oversight of the food safety system, statutory authority and food safety regulations, sanitation standards, HACCP requirements, chemical residue control program, and microbiological testing program. According to FSIS documents, the agency's initial equivalence determinations can take from 3 to 5 years to complete. FSIS does not rely on third-party certifications because, under its equivalence approach, the foreign government becomes responsible for addressing any problems FSIS identifies.

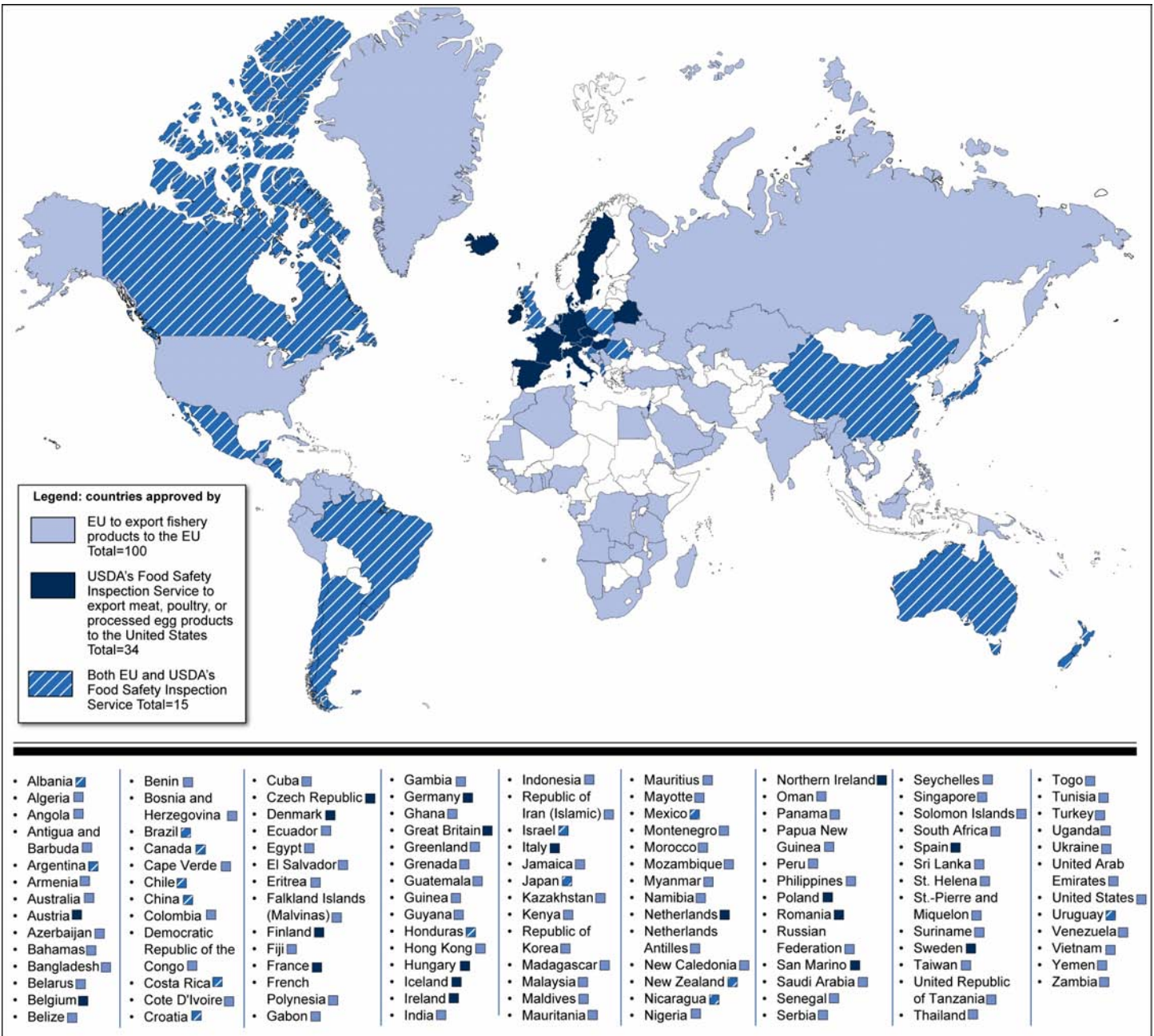
In 2008 and 2011, we reported that, in the EU, foreign countries that want to export all products of animal origin, including seafood, to EU countries must demonstrate that their food safety systems meet EU or equivalent requirements, or meet requirements specified in an agreement between the EU and the exporting country.¹⁹ According to EU regulations, foreign countries seeking EU equivalence for their food exports must provide information on their food safety laws; the organization of the competent authority, competent authority powers and independence, the supervision to which the competent authority is subject, and its enforcement authority;

¹⁹See GAO, *Food Safety: Selected Countries' Systems Can Offer Insights into Ensuring Import Safety and Responding to Foodborne Illness*, [GAO-08-794](#) (Washington, D.C.: June 10, 2008) and [GAO-11-286](#).

training of staff; resources, including diagnostic facilities; documented control procedures and control systems based on priorities; the situation regarding animal health, infectious diseases, and plant health; the extent and operation of official controls on imports of animals, plants, and animal or plant products; and the assurances the country can give regarding compliance with or equivalence to EU requirements. In our 2011 report, we stated that the EU generally conducts an on-site inspection of the foreign country's food safety system for a food product that the foreign country exports to the EU. These inspections include visits to farms and processing facilities and reviews of the capabilities and quality of the country's laboratories. To ensure continuous compliance with EU requirements, EU inspectors periodically conduct follow-up reviews of foreign countries' food safety systems for the specific food products, such as seafood. In addition, foreign countries that trade with the EU are directed to implement national residue monitoring plans and sample for drugs of specific concern to the EU for the food product exported to the EU.

According to FSIS and EU officials, when they have determined that a country has an equivalent food safety system for a particular food product, the foreign government becomes the competent and responsible authority for meeting FSIS and EU requirements. This competent authority becomes the single foreign government contact to address any identified problems and takes regulatory actions across the supply chain, from the farm to the processing facility, as necessary. For this reason, neither FSIS nor the EU needs to use third-party certifications. As a result, FSIS and the EU can leverage the oversight capacity and resources of many foreign governments determined to have equivalent export systems for specific food products. For example, FSIS has determined equivalence with 34 countries for the exportation of meat, poultry, or processed egg products; the EU has determined equivalence with 100 countries for the exportation of seafood products. See figure 3 for information on the countries that have been approved to export specific food products under the oversight of FSIS and the EU.

Figure 3: Countries Approved to Export Specific Products by USDA's FSIS and the European Union



Sources: GAO; Map Resources (map).

The equivalence approach has enabled both FSIS and the EU to review a foreign government's system for a particular food product and, in the opinion of officials from both entities, has allowed them to use their import oversight resources effectively and efficiently. In addition, both entities can monitor compliance by reviewing the residue monitoring test results that countries must submit annually. In April 2011, we reported that, using this approach, both FSIS and EU were able to get foreign governments to take appropriate actions to address identified deficiencies.²⁰

Other countries have also identified the effectiveness of leveraging the resources of the exporting country, including the United States. For example, according to the National Oceanic and Atmospheric Administration's Seafood Inspection Program (SIP) documents and the Director of SIP, Vietnam requires U.S. facilities that want to export seafood products to Vietnam to obtain an export health certificate. Under an MOU with FDA, the SIP will issue these certificates. The SIP will attest to the fact that the exported seafood products meet not only U.S. seafood safety requirements, but also Vietnam's requirements. In addition, the SIP may attest to the safety of the seafood exports through its inspections of the U.S. food facilities that want to export to Vietnam. Vietnamese government officials recently visited the United States to audit the SIP, among other programs. According to the SIP Director, the program will also provide this same service for seafood exports to China, and China may require the SIP to conduct inspections and laboratory testing. China also plans to review the SIP, including the relevant laws and regulations covered and their enforcement. In both of these cases, the SIP will serve as the point of contact for these certificates for Vietnam and China in the event that any issues arise with U.S. exported seafood products.

Conclusions

FDA, which is responsible for ensuring the safety of most imported foods, is in the process of developing programs to enhance the safety of imported food products, including seafood. FDA has stated that it needs new approaches to improve its oversight of imported food that take into account the entire food supply chain and that it needs to push prevention of food safety risks offshore and leverage the efforts of others to avoid duplication and better target its food safety efforts. Since 1998, we have reported on the need for FDA to enhance its oversight of imported food

²⁰[GAO-11-286](#).

products, including seafood, and have recommended that FDA use the tools available to it, such as equivalence, to leverage the resources of foreign countries to ensure exports meet U.S. requirements. Both FSIS and the EU have used equivalence as a tool to leverage exporting countries' resources by having the foreign governments ensure that certain foods imported into the United States and the EU meet their respective standards for safety. FDA has not used equivalence to leverage the oversight resources of foreign countries but has developed a new tool for conducting comparability assessments to assess a foreign country's entire food safety system, determine if it is comparable with the U.S. system, leverage the country's oversight resources, and place greater responsibility on the foreign government to ensure food products exported to this country meet a comparable level of safety protection to that in United States. Given the numerous challenges that FDA faces in developing and implementing a third-party accreditation system, the agency could reduce the need for accrediting and using third parties by using comparability assessments. However, FDA will find few countries that have systems comparable with the U.S. system because the agency would require comparability with a foreign government's entire domestic and export food safety systems for all food products. Consequently, FDA would be unable to leverage the resources of countries with comparable systems for just one food product. FDA can only take full advantage of comparability assessments if it modifies its approach for selecting comparable foreign countries and uses comparability assessments to identify countries that have similar food safety systems for targeted food products, such as seafood. This modification would be consistent with the approach FDA had originally envisioned in 1997 for the use of equivalence agreements—agreements that covered only certain food products that the foreign government's regulatory system was designed to achieve, or was capable of achieving equivalence. Representatives of major seafood exporting countries told us that they want FDA to evaluate their countries' food safety systems for seafood and obtain the benefits that accompany government-to-government agreements. Evaluating foreign countries on their seafood safety systems can be an effective and efficient approach to promoting the safety of imported seafood products because U.S. safety requirements for seafood have long been established and implemented and because FDA already has experience in assessing a foreign country's seafood safety system through its foreign country assessments. FDA officials told us that the agency will develop a written plan for developing and implementing comparability assessments when it completes its pilot with Canada. However, it is unclear whether this plan will clarify how FDA will integrate its new authorities under FSMA with the approach it plans for its comparability assessments. Furthermore,

this approach will still require full comparability of foreign countries' food safety systems, rather than comparability for particular food products.

Recommendation for Executive Action

To better leverage the oversight resources of foreign countries and ensure the safety of food imports, we recommend that the Secretary of Health and Human Services direct the Commissioner of FDA to revise FDA's comparability approach to one that allows for the flexibility of assessing foreign food safety systems for particular food products, such as seafood, when a full comparability assessment of foreign countries' food safety systems may not be feasible.

Agency Comments and Our Evaluation

We provided the departments of Health and Human Services, Agriculture, Commerce, and Homeland Security with a draft of this report for their review and comment. We also provided a draft of this report as a courtesy to the Department of State and the Office of the U.S. Trade Representative. The Department of Health and Human Services provided written comments in which it neither agreed nor disagreed with our recommendation, and its comments appear in appendix II. The remaining departments did not provide any comments on a draft of this report.

In commenting on a draft of this report, the Department of Health and Human Services stated that FDA believes that comparability is a more efficient and appropriate tool for it to use in assessing whether a country's entire food safety system provides adequate assurances of comparable public health outcomes, and third-party certification is a more appropriate approach for FDA to use when assessing a particular segment of a country's food safety system, such as export controls for one or more commodities. However, FDA also stated that it intends to seek public comment on its current comparability approach, and in that context, stakeholders will have an opportunity to comment on GAO's recommended approach.

We understand how comparability assessments and third-party certification can be complementary and noted this relationship in our report. We do not believe, however, that the use of third parties is preferable to comparability assessments to establish agreements with foreign governments. The role of third parties will be to certify that food or eligible foreign entities, such as seafood processors, meet the applicable federal requirements. However, comparability assessments, unlike third-party certifications, would enable FDA to use the outcome of a comparability assessment to gain the same advantages realized by FSIS

and the EU as part of their use of equivalence. In our opinion, the relationships that the EU has with foreign governments are more comprehensive than those that could be accomplished through a third-party accreditation arrangement. More specifically, if FDA had a comparability assessment agreement with a foreign country, similar to an EU equivalence agreement, a foreign competent authority would address any identified problems and take regulatory actions across the supply chain, as necessary.

Moreover, as we stated in our report, FDA faces multiple challenges in implementing a third-party accreditation program, and the use of comparability assessments could reduce the need for third parties. Specifically, foreign governments may be reluctant to apply for accreditation as a third party from a non-U.S. government agency, citing sovereignty issues as a concern. In addition, in some countries, third parties cannot operate in the territory unless accredited by that country's accreditation body. In these cases, there is a potential conflict of interest in having a government accreditation body accredit another government agency from the same country as a third party. This type of accreditation relationship may make it difficult to consider the process unbiased.

As agreed with your offices, 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 Secretaries of Health and Human Services, Agriculture, Commerce, Homeland Security, and State; the U.S. Trade Representative; 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 shamesl@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this report. Key contributors to this report are listed in appendix III.



Lisa Shames
Director, Natural Resources and Environment

Appendix I: Scope and Methodology

Our objectives were to (1) identify the major actions the Food and Drug Administration (FDA) is to take to implement a system for accrediting third parties, as directed by the FDA Food Safety Modernization Act (FSMA), and the challenges, if any, FDA and others report will be associated with these actions and (2) examine FDA's approach for using its comparability assessments to leverage other countries' oversight capacity and enforcement authority.

To address the first objective, we reviewed FDA's responsibilities for developing a system to accept third-party certification in FSMA; the agency's plans for implementing this system; the results of FDA's third-party certification pilot for imported shrimp, which it conducted in 2009; and reports evaluating implementation of FDA's Hazard Analysis and Critical Control Point (HACCP) program requirements for seafood. We also reviewed public comments from industry and consumer groups to FDA on the agency's plans to implement third-party accreditation and certification provisions under FSMA. We interviewed FDA officials on the agency's plans to implement a third-party accreditation system and on any challenges identified during the third-party certification pilot for imported shrimp. We interviewed third parties who participated in FDA's third-party certification pilot for imported shrimp. Specifically, we interviewed representatives of Bureau Veritas and SGS (formerly known as Société Générale de Surveillance)—both of which are private companies that offer inspection, verification, testing, and certification services—and officials from the Department of Commerce's National Marine Fisheries Service and the Global Aquaculture Alliance Best Aquaculture Practice, a standard-setting organization for aquaculture seafood. We also spoke with representatives involved in the shrimp pilot from the Inspectorate America Corporation, which is now a part of Bureau Veritas. We interviewed officials from the American National Standards Institute, a U.S. based not-for-profit accreditation organization that serves as the official U.S. representative to the International Organization for Standardization. We reviewed internationally recognized standards for third-party accreditation systems and industry food safety certification systems and spoke with representatives of these systems. Most of the certification systems were used by third parties in FDA's shrimp pilot or recognized by the Global Food Safety Initiative (GFSI)—a nonprofit foundation that resulted from the collaboration of retailers, manufacturing and food service companies and that compares private food safety certification systems against GFSI-established requirements. Specifically, we spoke with representatives of the British Research Consortium, Canada GAP, Global Aquaculture Alliance Best Aquaculture Practices, Global G.A.P., Mexico Calidad Suprema, and Safe Quality Foods. To

gain other stakeholder perspectives on FDA's new authorities and requirements for accepting third-party certifications, we spoke with representatives from

- industry (Costco, Darden, Walmart, Sogelco International);
- trade associations (the Association of Food Industries, Inc., Food Safety Services Providers, National Fisheries Institute, Grocery Manufacturers Association); and
- consumer advocacy groups (the Center for Science in the Public Interest, Consumer Federation of America, and Food and Water Watch).

We also visited two domestic seafood processors at their facilities in Massachusetts to get their perspectives on FDA's future use of third-party certifications. We reviewed policies and spoke with the U.S. Department of Agriculture's (USDA) Agriculture Marketing Service about its management of the National Organics Program, which uses accredited third parties to complete certifications overseas. We reviewed policies and spoke with U.S. Customs and Border Protection officials about its Customs-Trade Partnership Against Terrorism program and the results of its pilot using third parties.

To address the second objective, we reviewed the assessment tool FDA is using in its comparability assessment pilots with New Zealand and Canada. We reviewed FDA documents on the agency's plans and approach for the use of comparability assessments. We spoke with FDA officials about these pilots and the agency's plans for using comparability assessments and also spoke with New Zealand government officials about their experience with the pilot. We reviewed the approach used by USDA's Food Safety and Inspection Service (FSIS) and the European Union (EU) and compared their approach with FDA's to determine if their practices for ensuring the safety of imported foods have the potential for enhancing FDA's practices and spoke with FSIS and EU officials. We also reviewed the FSIS and EU approaches to their foreign equivalence determinations to learn about the time required for these determinations and the scope of their reviews. We reviewed past GAO reports relevant to this topic.

For both of our objectives, we reviewed policies and spoke with representatives of major seafood exporters to the United States—Canada, Ecuador, Indonesia, Thailand, and Vietnam—and a major

trading partner, Mexico, about their perspectives on FDA's third-party certification program and approaches they use in supporting oversight of seafood exports to the U.S. and other countries. We chose to interview representatives of major seafood exporting countries, in part, because more seafood is imported than produced domestically and because FDA has set HACCP standards for seafood. We visited the Canadian Food Inspection Agency (CFIA) in Ottawa, Canada, to learn about its seafood safety programs for both domestically produced seafood and imported seafood products. We visited Servicio Nacional de Sanidad, Inocuidad y Calidad Agroalimentaria (SENASICA), the primary food safety agency in Mexico for domestically produced food products, in Mexico City, to learn about its food safety oversight programs. We also toured SENASICA's food testing center in Tecamac, Mexico, to learn about their lab testing capabilities. During our visits with CFIA and SENASICA, we also learned about their programs using third parties to support oversight of food safety for domestically produced and processed products.

We visited the Port of Boston in Boston, Massachusetts, where seafood is among the major food products entering the port, and met with Customs and Border Protection officials to learn about the agency's activities related to ensuring the safety of seafood imports. We also visited a cold storage facility—in close vicinity to the Boston port and where FSIS inspectors conduct reinspections—to learn about measures FSIS uses to ensure the safety of imported meat and poultry products. During the same trip, we visited FDA's New England District Office in Stoneham, Massachusetts, to learn about FDA import entry review processes used to ensure the safety of imported foods under FDA's jurisdiction, and its laboratory in Winchester, Massachusetts, to learn about FDA food testing of imported foods.

We analyzed Department of Commerce data on imported seafood for 2010 and presented these data as background to illustrate the relative volume of imported seafood from top importing countries to the United States. For this data set, we reviewed existing documentation about the data and any limitations. In addition, we analyzed data on examination and testing rates for food and seafood entry lines in fiscal year 2011 as background and reported percentage of testing based on total import entry lines. We reviewed existing documentation on this data set. We found both of these data sets to be sufficiently reliable for the above-mentioned purposes. We also included data that we previously used in our 2011 report and presented it as background information to illustrate FDA's foreign facility inspection coverage for Ecuador, Indonesia, and

Thailand. As determined in our 2011 report, these data were sufficiently reliable for the purpose stated above.

We conducted this performance audit from June 2011 to September 2012 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: 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

SEP 17 2012

Lisa Shames, Director
Natural Resources and Environment
U.S. Government Accountability Office
441 G Street NW
Washington, DC 20548

Dear Ms. Shames:

Attached are comments on the U.S. Government Accountability Office's (GAO) report entitled: "Food Safety: FDA Can Better Oversee Food Imports by Assessing and Leveraging Other Countries' Oversight Resources" (GAO-12-933).

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: FDA CAN BETTER OVERSEE FOOD IMPORTS BY ASSESSING AND LEVERAGING OTHER COUNTRIES' OVERSIGHT RESOURCES" (GAO-12-933)

The Department appreciates the opportunity to review and comment on the findings in the Government Accountability Office's (GAO) draft report. Through the implementation of the FDA Food Safety Modernization Act (FSMA), FDA already has begun establishing additional processes and systems that will enhance the safety of food, including imported food.

GAO recommends that FDA revise its comparability approach to one that allows for the flexibility of assessing foreign food safety systems for particular food products, when a full comparability assessment of foreign countries' food safety systems may not be feasible.

To clarify, an FDA comparability assessment will involve a review of the country's food safety system and the ability of the food safety authority to oversee that system so as to ensure a comparable level of public health assurance as the U.S. System. An assessment for third party accreditation will involve a review of the food safety authority's ability to ensure that facilities or foods it certifies meet U.S. requirements. While the two programs fall along a spectrum, there is a clear distinction in the outcomes.

FDA believes that comparability is a more efficient and appropriate tool for FDA to use in assessing whether a country's entire food safety system provides adequate assurances of comparable public health outcomes, and third party certification is a more appropriate approach for FDA to use when assessing a particular segment of the food safety system—e.g., export controls for one or more commodities. FDA intends to seek public comment on FDA's current approach to comparability, and in that context, stakeholders will have an opportunity to comment on GAO's recommended approach.

FDA is developing the Accredited Third Party Program and the Comparability¹ program as complementary tools that FDA may use to assess countries' food safety systems, or parts thereof, specific to countries' particular capabilities, interests, and the maturity of their regulatory system.

¹ FDA has historically explored the use of equivalence programs and believes that, given the number and complexity of products for which FDA has oversight, using comparability assessments and third party certification will provide a better means to ensure the safety of imported products. The term "equivalence" is used principally in the context of the international trading regime established under the World Trade Organization and its associated agreements, including the Sanitary and Phytosanitary Measures (SPS) Agreement, as well as in other free trade agreements, such as the North American Free Trade Agreement. The SPS Agreement, for example, sets out basic rules governing the adoption and application of certain food safety and animal and plant health standards. To date, FDA has considered equivalence as most appropriately applied to the assessment of a foreign government's specific programs for certain high risk foods. This type of assessment provides a very detailed comparison of each measure that each country applies in controlling risks associated with the particular commodity under review. While this approach may be appropriate for assessing particular measures in specific commodity areas, the measure by measure approach is extremely burdensome when applied to entire food safety systems and is not required for the assessment of a system-wide level of protection.—In contrast, FDA will apply comparability to the assessment of a country's overall food safety system (both domestic and export), to determine whether the system as a whole offers a similar, though not identical, system of protections as does the FDA food safety system.

GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S (GAO) DRAFT REPORT ENTITLED, "FOOD SAFETY: FDA CAN BETTER OVERSEE FOOD IMPORTS BY ASSESSING AND LEVERAGING OTHER COUNTRIES' OVERSIGHT RESOURCES" (GAO-12-933)

Food safety authorities in other countries may wish FDA to assess their food safety systems as a whole through comparability or they may pursue assessments of the food safety controls and oversight in place for particular export products through accreditation as a third-party auditor. The selection of the most appropriate tool for a particular country will be made by FDA in consultation with the food safety authority of that country. We expect that countries with mature food safety systems that can ensure comparable levels of public health protection will likely seek an FDA system-wide determination of comparability—even those that currently rely on third-party auditors. Nevertheless, such countries could opt instead to seek accreditation as third-party auditors and would be assessed for their capabilities with respect to those standards.

In cases where a country's overall system is not comparable to that of the United States, but the competent authority has effective programs in place to meet FDA food safety requirements for certain commodities for export (including from a subset of producing firms in the country), the country may pursue an assessment under FDA's program currently under development for Third Party Accreditation. Indeed, the examples from GAO's report of Thailand, Ecuador, and Indonesia interaction with the E.U. is akin to FDA's Third Party Accreditation program, in that those countries ensure that they export seafood to the E.U. that meets the E.U.'s standards. A food safety authority that is accredited as a third party certification body for a particular product may, in the future, seek to complete a comparability determination for its full food safety system, once its food safety system matures into a system that can ensure a comparable level of public health protection as the U.S. system. As mentioned earlier, the Comparability and Third Party Programs provide a spectrum approach for countries to choose from, as appropriate. The result from both initiatives is that FDA will have additional high quality, credible information to help make risk based decisions on admissibility of food products.

In summary, while both programs are still in the formative stages, FDA intends that comparability and the third party program to be complementary tools suited to help enhance the safety of foods imported from countries with a wide range of food safety resources and capabilities. The Agency will look forward to comments on this approach from stakeholders as it moves forward.

Appendix III: GAO Contact and Staff Acknowledgments

GAO Contact

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Staff Acknowledgments

In addition to the individual named above, Anne K. Johnson, Assistant Director; David Moreno, Analyst-in-Charge; Carol Herrnstadt Shulman; Swati Sheladia Thomas; and Kiki Theodoropoulos made key contributions to this report. Important contributions were also made by Kevin Bray, Michele Fejfar, Armetha Liles, and Michelle Sahlhof.

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