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GAO

Report to Congressional Requesters

April 2011

SEAFOOD SAFETY

FDA Needs to Improve Oversight of Imported Seafood and Better Leverage Limited Resources

GAO-11-286

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Highlights

Highlights of GAO-11-286, a report to congressional requesters

Why GAO Did This Study

About half of the seafood imported into the U.S. comes from farmed fish (aquaculture). Fish grown in confined aquacultured areas can have bacterial infections, which may require farmers to use drugs like antibiotics. The residues of some drugs can cause cancer and antibiotic resistance. The Department of Health and Human Services' (HHS) Food and Drug Administration (FDA) is charged with ensuring the safety of seafood against residues from unapproved drugs, and the Department of Commerce's National Marine Fisheries Service (NMFS) provides inspection services on request. In 2009, these agencies signed a memorandum of understanding (MOU) to enhance seafood oversight and leverage inspection resources. GAO was asked to assess the extent to which (1) FDA's program is able to ensure the safety of seafood imports against residues from unapproved drugs and (2) FDA and NMFS have implemented the 2009 MOU. GAO reviewed data and documents from each agency and interviewed agency officials and other key stakeholders.

What GAO Recommends

GAO recommends that FDA study the feasibility of adopting practices used by other entities to better ensure the safety of imported seafood, enhance its import sampling program, and develop a strategic approach for enhancing collaboration with NMFS and better leveraging resources. HHS neither agreed nor disagreed with GAO's recommendations but cited actions in process or planned that are generally responsive to them.

View GAO-11-286 or key components.
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What GAO Found

FDA's oversight program to ensure the safety of imported seafood from residues of unapproved drugs is limited, especially as compared with the European Union (EU). FDA's program is generally limited to enforcing the Hazard Analysis and Critical Control Point—the internationally recognized food safety management system—by conducting inspections of foreign seafood processors and importers each year. These inspections involve FDA inspectors reviewing records to ensure the processors and importers considered significant hazards, including those resulting from drug residues if the seafood they receive are from fish farms. The inspectors generally do not visit the farms to evaluate drug use or the capabilities, competence, and quality control of laboratories that analyze the seafood. In addition, FDA has conducted foreign country assessments in five countries to gather information about those countries' aquaculture programs. However, these assessments have been limited by FDA's lack of procedures, criteria, and standards. In contrast, the EU reviews foreign government structures, food safety legislation, the foreign country's fish farm inspection program, and visits farms to ensure that imported seafood products come from countries with seafood safety systems equivalent to that of the EU. In addition, the scope of FDA's sampling program, which supplements its oversight program, is limited. Specifically, the sampling program does not generally test for drugs that some countries and the EU have approved for use in aquaculture. Consequently, seafood containing residues of drugs not approved for use in the United States may be entering U.S. commerce. Further, FDA's sampling program is ineffectively implemented. For example, for fiscal years 2006 through 2009, FDA missed its assignment plan goal for collecting import samples by about 30 percent. In addition, in fiscal year 2009, FDA tested about 0.1 percent of all imported seafood products for drug residues. Moreover, FDA's reliance on 7 of its 13 laboratories to conduct all its aquaculture drug residue testing raises questions about the agency's use of resources.

FDA and NMFS have made limited progress in implementing their 2009 MOU. The agencies have developed procedures for certain MOU activities, such as notifying NMFS of pending FDA regulatory actions. However, because FDA believes NMFS inspectors need training to conduct inspections according to FDA standards, it has not utilized NMFS' inspection resources or results in a systematic manner. Better leveraging available resources is critical, especially in places like China, where FDA has inspected 1.5 percent of Chinese seafood processing facilities in the last 6 years.

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Abbreviations

EU	European Union
FDA	Food and Drug Administration
FSIS	Food Safety and Inspection Service
HACCP	Hazard Analysis and Critical Control Point
HHS	Department of Health and Human Services
MOU	memorandum of understanding
NMFS	National Marine Fisheries Service

GAO
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United States Government Accountability Office
Washington, DC 20548

April 14, 2011

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
The Honorable Daniel K. Inouye
United States Senate

The United States has increased the amount of seafood it imports over the past 10 years, currently importing seafood from approximately 130 countries. According to estimates from the Department of Commerce's National Oceanic and Atmospheric Administration, in 2010 more than 80 percent of seafood consumed in the United States—such as shrimp, salmon, and tilapia—was imported, with about half coming from aquaculture (fish farming). Because fish grown in confined aquacultured areas can have high rates of bacterial infections, farmers may treat them with drugs, such as antibiotics and antifungal agents, to increase their survival rates. Once drugs are introduced, their residue can remain in the fish through harvesting, processing, and consumption. According to the Department of Health and Human Services' Food and Drug Administration's (FDA) 2008 Report to Congress,[1] the residues of some drugs can cause cancer, allergic reactions, and antibiotic resistance when consumed by humans. As imports of aquacultured seafood products increase, so too do the concerns over the presence of drug residues.

Under the Federal Food, Drug, and Cosmetic Act, FDA is responsible for ensuring that the nation's food supply, including imported seafood, is safe,

[1]FDA, *Enhanced Aquaculture and Seafood Inspection–Report to Congress* (Washington, D.C., Nov. 20, 2008).

wholesome, sanitary, and properly labeled.[2] Since 1997, when imported seafood first accounted for more than 60 percent of the seafood consumed in the United States, FDA has used the internationally recognized Hazard Analysis and Critical Control Point (HACCP) system as its main safety oversight program for imported seafood. Under HACCP requirements, seafood processing firms, including firms that manufacture, pack, or label, are responsible for conducting a hazard analysis and for developing and implementing HACCP plans whenever an analysis shows that one or more hazards are reasonably likely to occur. Food safety hazards may result from, among other things, drug residues, pesticides, parasites, and decomposition. HACCP requires (1) food processors to identify and develop strategies to prevent, eliminate, or reduce to an acceptable level the hazard and (2) importers to ensure that the products they import have been processed in accordance with HACCP requirements or that the products have been obtained from a country with an active agreement with FDA covering the product that documents equivalence or compliance with the U.S. system. FDA enforces HACCP requirements related to drug residues in imported seafood in two main ways. First, FDA inspects a number of foreign seafood processing facilities each year to ensure they comply with HACCP requirements. If a processor fails to have and effectively implement a HACCP plan, its products are considered adulterated and may be refused entry into U.S. commerce. Second, FDA conducts inspections at a designated number of U.S. importers each year to determine if they have maintained the appropriate documents to prove that the processors from whom they import seafood meet HACCP requirements. If importers cannot provide assurance that the seafood products they import have been processed under conditions established by HACCP requirements, the products are considered adulterated and can be refused entry into the United States. FDA is not required to preapprove HACCP plans; however, FDA, not the processors or importers, is responsible for determining whether processors and importers adequately comply with seafood HACCP requirements. During facility inspections for HACCP compliance, inspectors review HACCP plans and according to FDA officials, determine if the plans are implemented. Supplementing its HACCP oversight activities, FDA has an import sampling program that tests imported seafood products at ports of entry to, among other things, ensure that they do not contain certain targeted drug residues, including

[2]The 2008 Farm Bill amended the Federal Meat Inspection Act to give the Department of Agriculture responsibility for the mandatory inspection of catfish and catfish products. On February 24, 2011, the department published a proposed rule on this matter. The Farm Bill amendments specified that they would not apply until final regulations are issued.

residues of drugs that are unapproved for use in the United States and render the seafood adulterated under the Federal Food, Drug, and Cosmetic Act.

In addition to FDA's seafood safety activities, the National Oceanic and Atmospheric Administration's National Marine Fisheries Service (NMFS) Seafood Inspection Program provides fee-for-service inspection services, on request to the seafood industry—including domestic and foreign processors, distributors, and other firms—to, among other things, certify that these seafood firms comply with HACCP and other federal food safety standards. Some retailers require this certification as a condition for purchasing the seafood products.

In 1974, FDA and NMFS signed a memorandum of understanding (MOU), in part, to improve the efficient use of FDA's inspection resources by minimizing the number of FDA inspections at establishments already inspected by NMFS. We reported in 2005 that FDA had not fully met its responsibilities under the MOU and that, in some cases, the agency was continuing to duplicate NMFS inspections. We recommended in that report that FDA fully meet its responsibilities under the MOU.[3] In that same year, we identified promising practices for collaboration among federal agencies, stating that collaboration can occur when they (1) establish procedures and policies for working together systematically across agency lines and (2) identify ways to leverage their resources to maximize their effectiveness, among other things.[4] In 2007, we added the federal oversight of food safety to our list of high-risk areas needing broad-based transformation, largely because of continued ineffective coordination and inefficient use of resources.[5] In February 2009, we reported that FDA and NMFS had not yet begun to work together and recommended that the agencies collaborate to more effectively and efficiently share information and leverage their inspection resources to

[3]GAO, *Oversight of Food Safety Activities: Federal Agencies Should Pursue Opportunities to Reduce Overlap and Better Leverage Resources*, GAO-05-213 (Washington, D.C.: Mar. 30, 2005).

[4]GAO, *Results Oriented Government: Practices That Can Help Enhance and Sustain Collaboration among Federal Agencies*, GAO-06-15 (Washington, D.C.: Oct. 21, 2005).

[5]See our most recent series, see GAO, *High-Risk Series: An Update*, GAO-11-278 (Washington, D.C.: February 2011). Also see GAO, *High-Risk Series: An Update*, GAO-07-310 (Washington, D.C.: January 2007).

enhance federal oversight of seafood.[6] In October 2009, FDA and NMFS finalized a new MOU that updated the 1974 MOU—the agencies agreed, in part, to maximize the use of their resources, when appropriate and as resources permit, by taking advantage of each others' inspection capabilities.

In this context, you asked us to examine how federal agencies ensure the safety of seafood, in particular imported seafood, from drug residues. Specifically, this report addresses the extent to which (1) FDA's program is able to ensure the safety of seafood imports against residues from unapproved drugs and (2) FDA and NMFS have implemented the 2009 MOU to enhance federal oversight of seafood and leverage federal resources.

To assess the extent to which FDA's program is able to ensure the safety of seafood imports against residues from unapproved drugs, we analyzed information on FDA's oversight mechanism for seafood imports—importer and foreign country processing facilities inspections—and its seafood import sampling program. In particular, we analyzed information on the major components and requirements of FDA's importer and foreign facility HACCP inspections. We analyzed fiscal years 2006 through 2009 data on FDA's import sampling test results and determined that the data were sufficiently reliable for our purposes. In addition, we reviewed the European Union's (EU) seafood importing program to determine if its practices for ensuring the safety of seafood imports have the potential for enhancing our own practices. We also reviewed the imported seafood sampling programs of the EU, the largest importer of seafood worldwide; Japan, the second largest importer; and Canada, a major provider of seafood to the United States, to determine if their sampling practices had the potential for enhancing our own practices as well. Furthermore, we reviewed oversight practices the Department of Agriculture's Food Safety and Inspection Service (FSIS) uses to ensure the safety of imported meat and poultry products for the same purpose. We interviewed knowledgeable FDA, FSIS, EU, Canadian, and Japanese officials to obtain more information on how their respective programs function. We analyzed relevant documents to assess the extent to which FDA and NMFS have implemented the 2009 MOU to enhance federal oversight of seafood. We

[6]GAO, *Seafood Fraud: FDA Program Changes and Better Collaboration among Key Federal Agencies Could Improve Detection and Prevention*, GAO-09-258 (Washington, D.C.: Feb. 19, 2009).

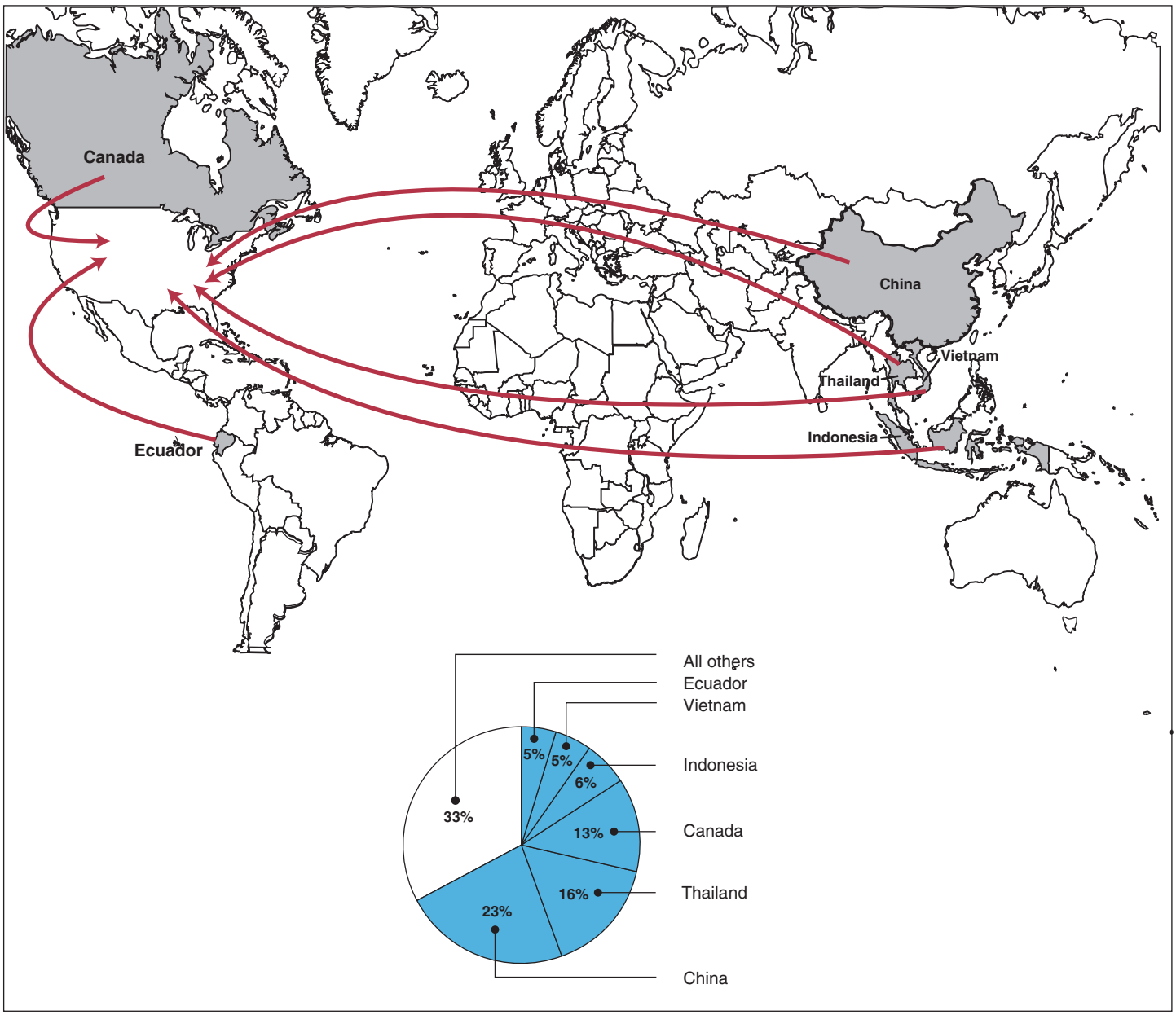
also interviewed knowledgeable FDA and NMFS officials to determine their progress in implementing the 2009 MOU. (See app. I for additional information on our scope and methodology.)

We conducted this performance audit from April 2010 to April 2011 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

Fishery products, including wild catch, aquaculture, and processed fish products, are one of the most traded commodities in the world today. More than half of this commodity originates in developing countries, and almost 75 percent of it ends up either in the EU, Japan, or the United States. Not only is the United States importing more of the seafood it consumes today than it did 10 years ago, but more of those imports are from fish farms. Currently the United States imports 84 percent of the seafood consumed, and about 50 percent of it is from aquaculture. Figure 1 shows the proportion of imports to the United States from the top six countries exporting seafood to the United States.

Figure 1: Top Six U.S. Seafood Import Sources in 2009



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

Note: Percentages do not add up to 100 percent due to rounding.

Concerns regarding the use in aquaculture operations of veterinary drugs that are unapproved in the United States and the misuse of approved drugs have increased substantially as the aquaculture industry has grown, according to FDA documents. While antimicrobials, including antibiotics, are used to treat diseases in animals, including seafood, the use of unapproved antibiotics in aquaculture has raised significant public health concerns. For example, nitrofurans are specifically not allowed for use in seafood, among other foods, by the United States because they have been shown to have a carcinogenic effect after prolonged exposure. However, some drugs that remain unapproved by FDA, such as emamectin benzoate and oxolinic acid, may be used in aquaculture by other countries. Another concern associated with the use of drugs in animals used for food, including seafood, is the extent of their contribution to antimicrobial resistance.

Processing Facilities and Importer Inspections

HACCP regulations require seafood processors to conduct a hazard analysis and to develop and implement HACCP plans for hazards whenever an analysis shows that one or more hazards are reasonably likely to occur, including hazards resulting from drug residues. Processors must verify that their HACCP plans are adequate to control the identified significant hazards and are being effectively implemented. This verification must include, at a minimum, a periodic reassessment of the plan as well as ongoing verification activities, such as regular testing of the product. Processors are responsible for addressing hazards that may have been introduced into the products before they reach the processors, which could include hazards resulting from drugs unapproved by FDA for use in aquaculture. According to FDA documents, the agency targets countries for inspection based on the volume of imports from that country, the nature of the product (high- or low-risk potential), and violation history, among other things. According to FDA officials, the agency also targets facilities for inspection based on, among other things, their history of violations and seafood products refused entry into the United States. FDA has guidance that provides instructions on the inspection of foreign seafood processing facilities and products. From fiscal years 2005 through 2010, FDA inspected, on average, 84 foreign processing facilities annually out of an estimated 17,000 worldwide. (See app. II for additional information on the foreign facilities FDA inspected.)

In addition, FDA inspects importers of seafood products to ensure their compliance with HACCP requirements. HACCP regulations require importers to demonstrate, through documentation, that the seafood they import into the United States complies with HACCP requirements. Under

HACCP, every importer of seafood products must 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) maintain written verification procedures that 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. We discuss the most commonly used affirmative steps later in this report. According to FDA officials, the agency currently has no such agreements with any foreign countries. FDA has guidance that provides direction on the inspection of seafood importers. From fiscal years 2005 through 2010, FDA inspected, on average, 217 importers annually out of about 3,900 importers registered with the FDA.

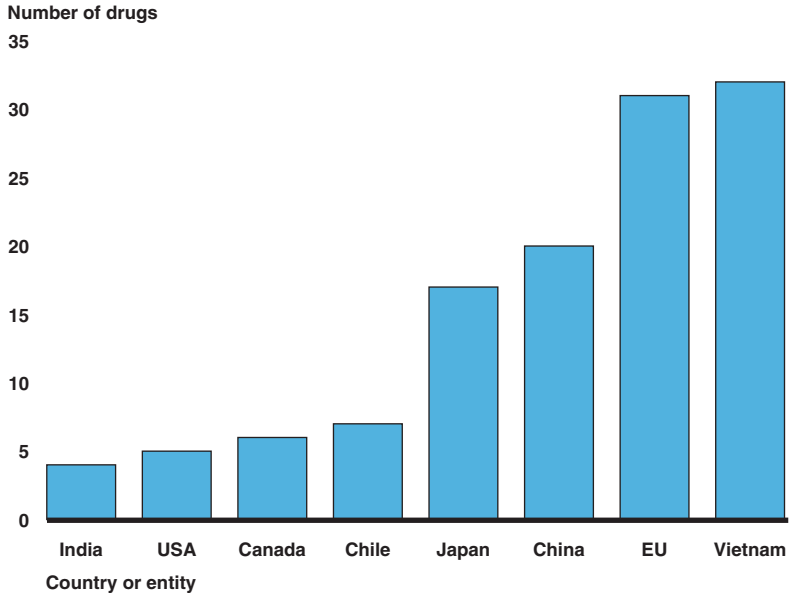
FDA's Sampling Program

In the United States, drugs used in animals that are used for food, including seafood, generally must be approved by FDA. According to FDA officials, the process for obtaining a new drug approval, including drugs for aquaculture, originates with an entity or individual (sponsor) submitting an application for review. FDA may approve a drug for, among other things, specific species and certain disease conditions. When FDA approves a drug, it may establish a maximum residue level for the safe use of the drug—known as a tolerance level. If residues of the approved drug are detected in an animal product above the tolerance level, then the product is considered noncompliant. FDA may take regulatory action when the residues are confirmed at or above a drug tolerance level, which can vary by species and residue. Likewise, if any residue of a drug unapproved by FDA is detected, then the product is also considered noncompliant. Similar to the United States, the EU and other countries also set maximum residue limits for the drugs approved for use in aquaculture. FDA has approved five different drugs for use in aquaculture that have a maximum residue limit, but one approved drug (sulfamerazine) is no longer marketed.[7] In addition, FDA has approved two drugs—formalin and hydrogen peroxide—for which it has not set a tolerance level

[7]The five drugs include: florfenicol, sulfamerazine, chorionic gonadotropin, oxytetracycline dihydrate, oxytetracycline hydrochloride, and a drug combination of sulfadimethoxine and ormetoprim. For the purpose of our report, we counted products (such as oxytetracycline dihydrate and oxytetracycline hydrochloride) that contain the same regulated ingredient (oxytetracycline) as one drug to ensure the total number of different drugs approved across countries is comparable.

because the drugs are generally not absorbed into fish. FDA has also approved tricaine methanesulfonate but has not set a tolerance level because according to agency officials, this drug is approved for research purposes only. In contrast, certain other countries and the EU have approved more drugs, ranging from 7 to 32 (see fig. 2). Three of the drugs FDA has approved have also been approved for use in aquaculture by some of the countries listed in figure 2.

Figure 2: Drugs Approved for Aquaculture by Selected Countries and the EU That Have a Maximum Residue Limit



Source: GAO analysis based on data from various countries and the EU.

Note: Information on the number of drugs approved by the various countries and entity are from reports with different dates.

FDA has an import sampling program to guide its sampling of imported seafood products for drug residues. FDA does not sample for the drugs it has approved. According to FDA officials, its compliance program guidance takes a risk-based approach to identify types of products to sample, countries of interest, and specific drugs to look for. For example, the current work plan for collecting samples of seafood imports states that samples of shrimp products should be tested for residues of nitrofurans. Additionally, every year FDA determines the total number of import samples to collect for each product based on an annual evaluation of the program's accomplishments and availability of resources. When FDA detects a pattern of products in noncompliance—when residues of drugs

unapproved by FDA are present or approved drugs exceed the tolerance levels—the agency can place the relevant firm and product on import alert, which, among other things, places the sampling and testing burden on the importer. On the basis of the agency's compliance program guidance, FDA's sampling program has targeted 16 drugs that may not be used in U.S. aquaculture, including three antibiotic classes: fluoroquinolones (ciprofloxacin, difloxacin, enrofloxacin, and sarafloxacin), nitrofurans (nitrofurantoin, furazolidone, nitrofurazone, and furaltadone), and quinolones (flumequine, nalidixic acid, and oxolinic acid); one antibiotic: chloramphenicol; one antiparasitic: ivermectin; two antifungals: gentian violet (also called crystal violet) and malachite green; and one steroid: methyltestosterone. According to FDA officials, the agency generally collects samples for drug residue testing at either the domestic seafood processors or the ports of entry for imported seafood products. Although there are numerous other drugs unapproved for use in aquaculture in the United States, FDA targets these drugs due to the potential human health consequences of consuming residues of these drugs, which can cause cancer, allergic reactions, and antibiotic resistance when consumed by humans, according to FDA. FDA's sampling program emphasizes seafood products originating from countries whose products have repeatedly been found to contain at least one of these 16 drugs.

FDA can take several actions if it identifies HACCP violations or adulterated seafood products. FDA may issue a warning letter—a notice that enforcement actions may be forthcoming if corrections are not made—to firms for serious violations of regulatory significance, such as producing seafood products without a HACCP plan. FDA also may issue import alerts, which are notifications to FDA staff that certain products may be detained at the border without a physical examination. Import alerts are designed to ensure that imported products covered by the alert are detained and refused entry into the United States unless the importer can overcome the appearance of the violation, such as by providing FDA with the results of third-party laboratory analysis or by passing an inspection that is appropriate to the violation that demonstrates the imported product is safe and complies with all applicable regulations. FDA currently has six seafood import alerts in place: four related to the presence of drug residues and two associated with HACCP violations. HACCP violations resulting in the placement of a facility on an import alert may be related to drug residue problems or other issues such as problems with sanitation controls. According to FDA, the number of facilities and products under import alerts changes as the facilities and products comply with FDA regulations. (See app. III for information on the six import alerts as of March 2011.)

MOU between FDA and NMFS

The Department of Commerce's NMFS also has a role in promoting seafood safety and quality. Under the Federal Agricultural Marketing Act of 1946, as amended, NMFS' Seafood Inspection Program provides inspection services on a fee-for-service basis to assist in marketing seafood products. NMFS services include inspections for safety, wholesomeness, and proper handling, as well as seafood grading, laboratory analysis, training, and product inspection and certification. In 2010, NMFS had contracts with 123 domestic processing facilities under its HACCP Quality Management Program, which requires NMFS to provide, at a minimum, quarterly HACCP-based inspections. NMFS also had contracts with 37 foreign seafood processing facilities to provide HACCP inspections. According to NMFS officials, it inspects about one-third of all seafood consumed in the United States.

The 1974 MOU outlined actions for each agency regarding, among other things, FDA's agreement to notify NMFS before taking regulatory action and to conduct periodic joint meetings to develop collaboration efforts. Despite the MOU, however, FDA did not take advantage of NMFS inspection services or results to reduce its own inspection workload. In particular, from fiscal years 2005 through 2009, we found that FDA inspected 315 facilities that NMFS also inspected. In addition, in 2005, FDA considered taking legal action against NMFS officials because FDA believed NMFS was interfering with its responsibilities, according to senior NMFS officials. In the end, FDA did not pursue this course of action. According to NMFS officials, as a result of this incident, FDA and NMFS began negotiating an update of the 1974 MOU that was finalized in October 2009. According to NMFS officials, since the signing of the 2009 MOU, there have been instances where NOAA and FDA have worked closely together to address safety issues that arose from the Gulf of Mexico oil spill as well as coordinate on FDA regulatory actions.

FDA Food Safety Modernization Act

Provisions included in the FDA Food Safety Modernization Act, enacted in January 2011, may impact FDA's role in ensuring the safety of seafood. For example, the act requires FDA to increase every year the number of inspections of foreign food facilities. This may include additional inspections of foreign seafood processing facilities. In addition, the act includes provisions to encourage interagency cooperation in regards to seafood inspections. This includes FDA coordinating with the Secretary of Commerce on the inspections of foreign seafood facilities and using Department of Commerce employees to conduct inspections for FDA. The act's provisions also give FDA the authority, as part of a third party accreditation program, to review a foreign country's food safety programs,

systems, and standards to determine that the foreign government is capable of ensuring foods certified for export to the United States meet the requirements of the Federal Food, Drug, and Cosmetic Act. In addition, the act requires the Secretary of Health and Human Services to issue guidance to assist importers in developing a foreign supplier verification program to help importers perform risk-based activities to verify that imported goods comply with U.S. requirements. Facilities that are required to comply with seafood HACCP regulations are exempt from the supplier verification program. FDA also noted that the act gives the agency important new tools, such as suspension of a facility's registration, to ensure that imported seafood is as safe as domestic seafood (See app. IV, where the Department of Health and Human Services provides details on these tools in its comments on our report.)

FDA's Program to Ensure the Safety of Imported Seafood from Residues of Unapproved Drugs Is Limited, Especially as Compared with the EU

FDA's program to ensure the safety of imported seafood from residues of unapproved drugs is limited, because the agency's primary oversight program generally involves reviews of documents at individual foreign processing facilities and importers for HACCP compliance. In contrast, the EU reviews foreign government structures, food safety legislation, and the foreign country's fish farm inspection program to ensure imported seafood products come from countries with seafood safety systems equivalent to that of the EU. Moreover, FDA's sampling program is limited in scope, is not effectively implemented, and does not fully use the capabilities of FDA's laboratories.

FDA HACCP Inspections Are Limited When Compared to More Comprehensive Reviews of Food Safety Systems Conducted by the EU and the Department of Agriculture's FSIS

FDA's program to ensure the safety of imported seafood against unapproved drugs is generally limited to the HACCP regulations it enforces. While the EU also requires compliance with HACCP, it also takes a wide-ranging review of the food safety system of the foreign country that wants to export its seafood products to the EU. In order to export seafood to the United States, foreign processors must meet the same HACCP regulations as domestic processors and FDA inspects some foreign seafood processors each year to ensure compliance. These inspections involve reviewing the processors' HACCP plans and other records to ensure the processors have considered drug residues as a hazard that is reasonably likely to occur if the seafood products it receives are from fish farms. In general, as part of foreign HACCP inspections, FDA inspectors do not visit fish farms to evaluate drug use or controls. FDA inspectors also do not evaluate the capability, competence, and quality controls of

laboratories used to sample seafood from fish farms to determine if they contain unapproved drugs because these facilities are not considered processors under the regulations and are therefore not covered by HACCP. We reviewed the 15 FDA inspection reports for seafood processing facilities from fiscal years 2007 through 2009 from countries exporting seafood to the United States—Bangladesh, Chile, China, and Thailand. According to the reports, we found that during their visits to these processing facilities, the inspectors generally conducted these inspections as described above. In contrast, the EU includes inspection visits to farms and other pertinent areas, such as laboratories, to undertake a more comprehensive review of a foreign country's food safety system. The EU conducts a review of the country's relevant legislation; the government's structure for implementing it; and the country's implementation of its national residues monitoring plan, which the EU directs its trading partners to submit. Foreign countries that trade with the EU are directed to implement the monitoring plan and sample for drugs of specific concern to the EU. Once implemented, these foreign countries are to provide an annual report on the sampling results.[8] In addition, the EU also reviews a sample of farms and processing facilities, and the capabilities and quality of the country's laboratories. The EU also requires that foreign countries exporting seafood to the EU maintain seafood safety systems that meet EU requirements or equivalent conditions, or meet specific requirements provided in an agreement between the EU and the foreign country.

In addition to FDA's HACCP inspections, the agency conducts foreign country assessments to gather information about other countries' aquaculture programs including the country's competent authority and regulatory infrastructure. During these assessments, FDA officials visited some farms where aquaculture products originated to evaluate veterinary drug use and reviewed some laboratories that analyzed the seafood products for drug residues for processors, among other places. FDA officials stated that these visits are planned and tailored for each country and conducted in a systematic and consistent manner. The information the agency collects during these assessments results in a written report and can be used to direct future foreign facility HACCP inspections and FDA's sampling program for imported seafood. However, according to FDA

[8]The monitoring plan includes information on the structure of the foreign government agency responsible for developing and implementing the plan, a list of approved laboratories responsible for residue testing and the status of their accreditation, the rules covering the collection of the official samples, and the sampling levels, among other things.

officials, the agency does not have any written operating procedures or any criteria or standards that it uses for these assessments to evaluate a country's regulatory infrastructure; farms; or the capabilities, competence, and quality controls of foreign laboratories. Without policies and procedures or guidance to direct the implementation of these assessments and criteria or standards to evaluate foreign systems, it may be difficult for FDA to conduct foreign country assessments that are either systematic or consistent and that result in valid findings. By systematically and consistently conducting its foreign country assessments, FDA can better assure that it is using its resources effectively and efficiently. FDA has conducted such foreign country assessments in five countries: Chile, China, India, Indonesia, and Vietnam. FDA conducted its first foreign country assessment in April 2006 and according to FDA officials, each assessment cost about $45,000. About a week after our closing meeting, FDA provided us with newly prepared standard operating procedures for conducting its foreign country assessments. FDA prepared these procedures almost 5 years after conducting its first assessment in Vietnam. These new procedures include the purpose of the assessments, country selection process, provisions on conducting these assessments, and structure of the assessment reports, among other things. We did not evaluate the newly prepared procedures. Still, FDA has not documented (1) the assessments on its Web site, including any program guidance manuals, and (2) the link between these assessments and its HACCP inspections of foreign facilities or its imported seafood sampling program.

The following are examples of some of the limitations of FDA's oversight approach of reviewing records and other documentation of foreign processors as required by HACCP and limited effectiveness of its foreign country assessments.

- As described in FDA's inspection reports for three Chilean salmon processing facilities in 2008, FDA's review of their records during the inspectors' visits to these facilities revealed that, contrary to HACCP regulations, they had received fish farm products that had been treated with oxolinic acid, flumequine, or emamectin benzoate—drugs unapproved for use in aquaculture in the United States. According to FDA documents, the agency placed all three facilities on an import alert for failing to comply with HACCP. FDA removed one of these facilities from the import alert 14 days later and the other two facilities several weeks later after they made changes to their respective HACCP plans. FDA, however, could not provide documents detailing the changes these facilities made in order for FDA to remove them from the import alert. Two of the facilities then shipped salmon to the United States, where it

was accepted for import. While this approach is in concert with FDA's routine inspection process, FDA had no assurance that the changes the facilities made to their HACCP plans were implemented, since it did not reinspect the facilities to conduct follow-up reviews of their records. In March and April of 2009, FDA officials conducting a foreign country assessment visited Chile to gather information about Chile's measures to control drug residues in aquaculture seafood products it exported to the United States. These officials found that the same unapproved drugs were still in use in the country. According to these officials, Chilean officials told them that the Chilean government could not prohibit the export of products containing residues of drugs approved for use in Chile without a special agreement with the importing country. According to FDA officials, the agency has not taken steps to develop such an agreement. Chile represents about 4 percent of seafood imported into the United States and in 2009, it was the largest source of farmed salmon imports into the United States.

- In addition to the 15 inspection reports, FDA documented the results of its officials' visit, part of a foreign country assessment, in September 2008 to Vietnam to gather information about the country's drug residues control program. The documentation indicated that all processing facilities' HACCP plans stated if a drug unapproved by the EU is found in a seafood product, that product should be diverted to another market. The FDA officials concluded that this HACCP plan requirement could result in such products being imported into the United States. In addition, the documentation indicates these FDA officials found that Vietnam permitted 38 drugs, most of which are unapproved by the United States, to be used in aquaculture. For example, FDA's documentation on this visit stated that fish farms were likely using fluoroquinolones. FDA officials asked that the Vietnamese government notify processors that seafood products purchased from farms using this drug could not be exported to the United States. FDA also asked the government to test 100 percent of seafood products destined for the United States for unapproved drugs such as nitrofurans and chloramphenicol. The Vietnamese government responded that it performed 100 percent testing only for products intended for countries with which it had a bilateral agreement, of which the United States was not one. The government stated, however, that it was taking other actions that would preclude the need for this level of testing, such as disseminating information on unapproved drugs, providing training to local authorities, and disciplining violators. According to FDA officials, the agency has not taken steps to develop such an agreement. Vietnam represents about 5 percent of the seafood imported into the United States. In 2009, Vietnam was the largest source of farmed catfish-pangasius

imports and the third largest source of farmed shrimp imports into the United States.

In addition to foreign processors, FDA also inspects the records of importers that bring seafood products into the United States to make sure they follow HACCP regulations, which includes requirements that importers maintain documents showing that the imported products are from foreign suppliers that have themselves complied with HACCP regulations or that the product is obtained from a country with an active agreement with FDA covering the product that documents equivalence or compliance with the U.S. system. We found limitations with this aspect of FDA's program as well. According to FDA officials, importers most frequently comply with this regulation in one of the three following ways:

- Importers obtain a copy of a foreign processor's HACCP plan and an attestation that the foreign firm processes its seafood products in compliance with HACCP regulations. Importers review the HACCP plan they get from their foreign suppliers and determine if all of the hazards the importers identified in their specifications are controlled in the HACCP plan. However, according to a senior FDA official, foreign processors can obtain a HACCP plan that is not associated with its own operation, thus defeating the purpose of importers' acquiring a copy of the plan unless the importers also visit the foreign processor to validate the information in the plan and that it is being implemented. FDA does not require importers to visit the foreign processors to ensure they effectively implement their HACCP plans.

- Importers obtain inspection certificates from what FDA calls a "competent authority," such as the Canadian Food Inspection Agency, that attests to the safety of the seafood product. However, FDA has not made any formal judgments about any entity's capability to declare that any foreign seafood products meet U.S. safety standards or concluded any agreements on a foreign certification program.

- Importers obtain seafood products from Canada or Japan from firms that those governments stated both are in "good standing" and are listed on an FDA Web site as processing seafood in accordance with HACCP regulations. However, FDA has neither evaluated the Canadian or Japanese seafood safety systems to determine the extent to which these countries' systems meet U.S. standards nor verified the lists or the information on them. For example, FDA has inspected for HACCP compliance, 4 Canadian and 22 Japanese seafood processing facilities out

of an estimated total of 944 and 2,697 facilities in each country, respectively, from fiscal years 2005 through 2010.

The EU not only requires individual processors to meet HACCP requirements, but also requires the foreign countries that want to export farmed seafood to the EU to demonstrate that their seafood safety systems meet EU or equivalent requirements, or meet requirements specified in an agreement between the EU and the exporting country. The EU Web site provides information for foreign countries on the EU standards for food products, including seafood, destined for the EU. These standards are used to evaluate foreign food safety systems. The EU publishes its foreign country inspection reports on its Web site, along with the foreign country's comments and their plan to address the inspection report's recommendations. To ensure continuous compliance with EU requirements, EU inspectors periodically conduct follow-up reviews of foreign countries' seafood safety systems. If inspectors identify deficiencies, they recommend solutions and ask the government in question to develop an action plan to address the recommendations. Using this approach, the EU has been able to persuade foreign governments to take appropriate action to address recommendations. For example:

- The EU inspected Indonesia in November 2009 to evaluate, in part, the country's measures to control drug residues in animal products including seafood. The inspectors concluded that the effectiveness of the system to control drug residues was compromised by failings in the planning and implementation of Indonesia's national residue control plan and problems in laboratory performance, including questionable validation of methods to detect drug residues in aquaculture products. According to the EU inspectors, the system to control drug residues did not provide guarantees equal to those required by EU regulations. The EU inspectors made specific recommendations to resolve the problems, including aligning the Indonesian limits for drug residues with those of the EU and ensuring that government controls on the distribution and use of veterinary medicinal products were carried out throughout the distribution chain. The Indonesian government developed an action plan to address all the recommendations. Nevertheless, as a result of the inspection report findings, the EU imposed a 20 percent sampling requirement at the EU ports of entry for all farmed fish imports because it believed that there was a risk that imported farmed products from Indonesia contained residues of chloramphenicol, nitrofurans, and tetracyclines.

- In November 2008, the EU inspected Bangladesh, in part, to evaluate the country's programs to control drug residues in seafood and review the

implementation of corrective actions promised by the Bangladesh government to address previous EU recommendations. EU inspectors found that Bangladesh was making changes to its sampling and laboratory analysis, among other things. Nevertheless, the inspectors concluded that despite the steps taken by the Bangladesh government to eliminate all sources of nitrofurans and chloramphenicol from farmed fish, the high detection rate of these drugs identified by Bangladesh's own national monitoring program suggested that fish farms were still using these drugs. According to the EU inspectors, the Bangladesh system to control residues did not provide assurances equal to those required by EU regulations, among other things. In part because of the findings of this inspection, the Bangladesh government imposed a voluntary ban on the export of freshwater shrimp to the EU from May 2009 until January 2010. The Bangladesh government recognized that it had a problem with nitrofurans in freshwater shrimp and took this action to avert any potential ban by the EU. The EU placed Bangladesh on special import conditions in 2008, which required 100 percent testing of all shrimp bound for the EU for chloramphenicol, tetracycline, nitrofurans, malachite green, and crystal violet in Bangladesh prior to export. In addition, 20 percent of all shrimp imports must also be tested at EU ports of entry at the importers' expense.

In contrast, FDA inspected five Bangladesh seafood processing facilities in February 2009, and a review of the inspection reports indicated that FDA inspectors did not identify the continued use of nitrofurans and chloramphenicol by the fish farms. Because FDA's focus was on HACCP compliance—which required the review of documents to ensure consideration was given to whether potential hazards were reasonably likely to occur as a result of drug residues, among other things—rather than the review of elements of the Bangladesh seafood safety system, FDA was unable to identify this issue. Although the Bangladesh government considered the EU findings from 2008 significant enough to impose a ban of shipments of freshwater shrimp to the EU about 3 months after the FDA inspections, Bangladesh officials present at FDA's inspections did not provide information on the EU findings of the continued use of unapproved drugs by fish farms to FDA. Moreover, Bangladesh did not impose a similar ban on shipments to the United States, and according to FDA officials, the agency, at the time, had no knowledge of the Bangladesh ban on shipments to the EU.[9] Had the FDA inspectors had this

[9]According to FDA, agency officials became aware of the ban when Bangladesh scientists discussed it during a training session in Bangladesh that took place about 5 months after the ban began.

information, they could have more effectively scrutinized the methods processors used to ensure the safety of the seafood products they received from fish farms. FDA inspectors could have also discussed Bangladesh government efforts to eradicate the use of unapproved drugs by the fish farms. With information on the use of nitrofurans by Bangladesh shrimp farms, FDA inspectors could have helped direct FDA's import sampling program to target these products. Because it lacked this information, FDA did not adjust its sampling program to take into account the likelihood that shrimp exports from Bangladesh would be contaminated. In fact, from June through December 2009—the period of the ban—FDA analyzed four shrimp samples from Bangladesh for nitrofurans. Finally, equipped with this information, the United States could have potentially received similar consideration as was given to the EU in regards to the ban by the Bangladesh government.

Like the EU, the Department of Agriculture's FSIS regulations place greater responsibility on the foreign country that wants to export meat, poultry, or processed egg products to the United States. More specifically, 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. The FSIS Web site provides information on its equivalence process and on the standard for eligibility of foreign countries to export FSIS regulated products to the United States. FSIS audit reports also provide information on the criteria used for its audits. In addition, FSIS publishes its foreign country audit reports on its Web site. FSIS staff not only review documents provided by foreign governments to ensure their food safety regulations and oversight are adequate and that processors implement HACCP, among other things, but also conduct onsite evaluations of the governments' inspections of slaughter processing facilities and their audits of laboratories and controls over, among other things, drug residues, sanitation, and animal disease of public health concern. In addition to the reviews and onsite evaluations, FSIS also conducts drug residue sampling, microbiological sampling, and labeling verification, among other things, at U.S. ports of entry to promote compliance. FSIS' program and the requirements it places on foreign governments wishing to export food products to the United States may have an effect on how countries react to problems that FSIS identifies with their products.

The potential effect that the FSIS' oversight approach can have on the food safety actions of other countries can be illustrated in the situation that occurred with Brazilian beef. In May 2010, as part of FSIS' port-of-entry inspection program, the agency analyzed samples of cooked beef

products from a Brazilian plant and identified levels of ivermectin, an antiparasitic agent, above allowed limits. FSIS increased its testing of cooked beef products from this plant and continued to find drug residue problems. Consequently, FSIS refused entry of cooked beef products into the United States from this plant and expanded its sampling effort to include Brazilian cooked beef products already in commerce and cooked beef products from other Brazilian plants. The testing data indicated that cooked beef products from other Brazilian plants also had levels of ivermectin above allowed limits. Given the consistency of the data, FSIS concluded that the Brazilian government's oversight program—including its residue sampling and control programs—had broken down. The U.S. government communicated its findings to the Brazilian government and asked that it resolve this violation of U.S. regulations. Although FSIS had the authority to deny entry into the United States of the products of all of these Brazilian plants if this issue had not been resolved appropriately, the Brazilian government voluntarily stopped exporting cooked beef products from 24 plants and prepared and submitted a plan to FSIS for how it intended to address this issue. According to FSIS, on December 28, 2010, FSIS accepted Brazil's corrective action plan, resulting in Brazil removing its voluntary suspension to allow 12 of the 24 plants to export cooked beef products to the United States. In addition, to verify that Brazil's corrective actions are adequate and effective in preventing a recurrence of this situation, FSIS will request Brazil to provide documentation demonstrating that its residue plan is working.

FDA's Sampling Program Is Limited in Scope, Not Effectively Implemented, and Does Not Fully Use Its Laboratories' Capabilities

FDA's sampling program for detecting residues from unapproved drugs in imported seafood products is limited in scope. Although FDA tests for residues of 16 unapproved drugs, some other countries importing from the same countries as the United States test for up to 57 drugs. In addition, although the 16 drugs include drugs such as flumequine and oxolinic acid, which are approved in certain other countries, FDA is not testing for residues of other drugs, such as emamectin benzoate or tetracycline, that are approved in other countries but unapproved in the United States. Thus, FDA does not generally test for drugs that some countries and the EU have approved for use in aquaculture. Because these drugs may be used in countries with which the United States conducts considerable trade, seafood products containing these unapproved drugs may be entering the country. For example, China, a major seafood exporter to the United States, approves the use of tetracycline in aquaculture although the United States does not. Vietnam, also a major seafood exporter to the United States, approves the use of neomycin in aquaculture but the United States does not. Both tetracycline and neomycin have been determined to be

highly important antimicrobials in humans; according to the World Health Organization, however, the overuse of these drugs in food animals could contribute to increasing the risk of antibiotic resistant bacterial infections in humans. In 2007, Japan detected excessive levels of tetracycline residues in the shrimp products it imported from China and in 2010, the EU detected excessive levels of neomycin in imported catfish from Vietnam. Because FDA does not include tetracycline and neomycin in its sampling program, it has no assurance that seafood containing these drug residues has not entered the United States.

In addition, FDA does not effectively implement its limited sampling program. According to FDA officials, the equipment and personnel the agency dedicates to its sampling program are sufficient to complete its assignment plan in its entirety. However, FDA did not meet the performance goals it set for its targeted unapproved drugs for fiscal years 2006 through 2009: the agency planned to collect on average 975 import samples annually for testing but collected an average of about 680 samples (or about 70 percent). According to FDA officials, the agency may not achieve its goals because a specific seafood product may not come into the country as anticipated or there may be a need to shift laboratory resources to handle other urgent tasks, such as testing imported honey for chloramphenicol. Moreover, FDA's planned number of import samples to collect represents a small portion of the annual seafood imports into the United States. Thus, in fiscal year 2009, the seafood samples FDA reported it collected for drug residue testing amounted to 0.1 percent of all the seafood products imported into the United States. In addition, although FDA's import sampling program states that it prioritizes the testing of all shrimp and all catfish and catfish-related species for residues of nitrofurans, during fiscal years 2006 through 2009 FDA analyzed 279 shrimp samples out of the 1,060 shrimp samples collected for residues of nitrofurans and did not analyze any catfish samples for nitrofurans. In fiscal year 2008, according to its annual work plan, FDA planned to collect 125 shrimp samples for nitrofurans analysis. Although FDA collected a total of 349 shrimp samples, it tested only 34 for residues of nitrofurans, and 6 (18 percent) of these samples were found to contain nitrofurans. Because of FDA's limited sampling, some of the more than 2.5 million metric tons of shrimp and 156,000 metric tons of catfish imports that entered the United States during fiscal years 2006 through 2009 could have contained residues of nitrofurans.

In addition to the limitations of FDA's sampling program for drug residues, the agency does not effectively use its laboratory resources. For example, while some other countries have increased their laboratory capabilities

through programs to accredit commercial laboratories, FDA relies on 7 of its 13 laboratories to conduct all of its aquaculture drug residue testing.[10] According to FDA officials, the number of laboratories participating in the sampling program is not important because sufficient laboratory capacity and capabilities are developed to meet obligations. However, as discussed above, FDA has not met its sampling performance goals during the past years and the number of laboratories participating in the sampling program may play a part in this. In terms of the laboratories that FDA uses for its sampling program, not all seven have the capability to test for all of the drugs included in FDA's sampling program. For example, one laboratory is capable of testing for residues of chloramphenicol, and four laboratories are capable of testing for nitrofurans, three of which have the capability to test for malachite green, gentian violet, fluoroquinolones, and quinolones. Further, FDA lacks some of the analytical methods that its laboratories need to test for specific drugs in aquaculture. For example, FDA has no method to detect residues of emamectin benzoate, a drug unapproved for use in U.S. aquaculture but used in Chile, as noted above, and approved for use in other countries as well. Moreover, although FDA can test for nitrofurans in four of its laboratories, it has only one method for testing nitrofurans in catfish samples.[11] FDA's laboratory capabilities are also limited by the personnel available to perform the tests. Although FDA has assigned personnel to its sampling program, these resources can be shared across FDA's food programs. Consequently, FDA can divert personnel to other programs that it may consider higher priority when the need arises, which could result in a lag in the turnaround time for drug residue testing. For example, according to FDA officials, FDA allows 14 calendar days to test a sample for drug residues. In addition, time frames for the completion of analyses under the sampling program will vary by residue and species. We found that the average time between sample collection and testing was about 22 calendar days. In one instance, testing for one sample was completed 154 calendar days after it was collected; in another instance, FDA took 56 days to complete the analysis of two separate samples—both of which turned out to contain residues of unapproved drugs.

[10]FDA just recently added the seventh laboratory in fiscal year 2010. The seven are the Denver District, Kansas City District, Northeast Regional, Pacific Southwest Regional, Pacific Northwest Regional, Southeast Regional, and Arkansas Regional laboratories. According to FDA officials, the other six laboratories not conducting food work are dedicated to pharmaceuticals and devices, among other things.

[11]According to FDA officials, the agency is working to develop and validate new methods to detect other drug residues including emamectin benzoate.

In contrast with FDA's import sampling program, the sampling programs of Canada, the EU, and Japan test for significantly more drugs: Canada tests its imported seafood products for more than 40 different drugs, select EU member countries test for 50 drugs, and Japan tests for 57. In addition, Canada and Japan test for levels of drugs they have approved for use in aquaculture as well as for drugs that are unapproved in their own country but approved in other countries. Moreover, Canada, the EU, and Japan generally test more samples of seafood and have more extensive laboratory capabilities than FDA. For example, Canada routinely tests at least 5 percent of all seafood imports, and Japan tested about 11 percent of seafood imports in fiscal year 2009. Select EU member countries test for as much as 4 percent of their seafood imports. In addition, the EU requires more testing for countries that produce larger quantities of seafood because of the increased risk of more adulterated products. Further, unlike FDA, which relies only on its own laboratory capabilities, Canada, the EU, and Japan have systems in place to accredit commercial laboratories which may be involved in the testing for drug residues in seafood products. For example, Belgium has 8 national laboratories as well as a network of 62 EU member state and commercial laboratories to assist with drug residue testing.

FDA and NMFS Have Made Limited Progress to Implement the 2009 MOU, and FDA Has Not Leveraged NMFS Inspection Resources

FDA and NMFS have made limited progress in implementing the 2009 MOU, resulting in a lack of systematic collaboration between the agencies. Since March 2010, the agencies have collaborated to some extent in developing procedures for certain MOU responsibilities, specifically FDA notification of regulatory action. In addition, while FDA and NMFS effectively collaborated and successfully leveraged each others' resources during the 2010 emergency Gulf of Mexico oil spill, FDA has not yet fully met its MOU responsibility to utilize NMFS' foreign and domestic inspection resources in a systematic manner. NMFS Seafood Inspection Program describes its mission as ensuring the safety and quality of the seafood it inspects. FDA officials stated that training NMFS inspectors would bring them to a level commensurate with the level that FDA requires of its own inspectors. By effectively utilizing NMFS inspections resources to help minimize its own inspection responsibilities, FDA could inspect other facilities that have not yet been inspected.

FDA and NMFS Have Made Limited Progress in Implementing Specific MOU Responsibilities

During a meeting to discuss the MOU in March 2010, the agencies agreed to create standard operating procedures for certain MOU responsibilities. FDA officials told us that in September 2010 they sent NMFS a letter notifying them of an FDA regulatory action, which is one of the MOU responsibilities. According to NMFS officials, this letter was the first prior notification of regulatory action FDA had ever provided. NMFS officials added that communication between the agencies has consisted of periodic conference calls that included discussions of the oil spill. Frequent communication among collaborating agencies is a means to facilitate working across agency boundaries and prevent misunderstanding; without such communication, enhanced collaboration may not be sustained.[12] According to NMFS officials, NMFS has developed guidance for its staff regarding its 2009 MOU responsibilities. Similarly, according to FDA officials, the agency has developed some guidance like the notification letter template. However, the agencies have not developed guidance for items of mutual responsibility. As we previously reported, agencies need to address the compatibility of standards, policies, and procedures in order to facilitate collaboration.[13] The agencies have agreed to develop standard operating procedures for information sharing and cross training of personnel, but they have not yet done so.

Success in Leveraging Resources for the Gulf of Mexico Oil Spill Has Not Translated to FDA Leveraging NMFS Inspection Resources or Results in a Systematic Manner

Even with FDA's and NMFS' success in leveraging each other's resources in the 2010 Gulf of Mexico oil spill, FDA has yet to fully meet its responsibility under the MOU to utilize NMFS inspection resources or results in a systematic manner. While NMFS describes its mission as ensuring the safety and quality of the seafood it inspects, FDA officials stated that training NMFS inspectors would bring them to a level commensurate with the level that FDA requires of its own inspectors.

The leveraging of resources played a crucial role in FDA and NMFS' ability to address the effects of the Gulf of Mexico oil spill. Using guidance developed from previous oil spills, the agencies quickly and jointly developed a protocol to reopen oil-impacted areas closed to seafood harvesting. The emergency nature of the spill meant that implementing the protocol required timely collaboration between FDA and NMFS. The agencies successfully implemented their reopening protocol by, among other things, sharing staff and laboratory resources and cooperating

[12]GAO-06-15.

[13]GAO-06-15.

efficiently. In accordance with the reopening protocol, the agencies jointly organized the seafood sampling plan and agreed upon the use of NMFS' sensory testing protocol following FDA review. The agencies successfully coordinated the chemical testing of samples for oil residue among their respective laboratories. As agreed upon in their reopening protocol, both agencies reviewed all sample results and consulted with each other before NMFS communicated the results to the states.

Going forward, FDA has not developed a process to leverage NMFS' domestic and foreign inspections or results in order to maximize its limited resources and inspect other facilities that have not yet been inspected. Both the 1974 and 2009 MOUs address the leveraging of NMFS' inspections by FDA in order to maximize the use of available resources. As we stated in our October 2005 report, collaborating agencies bring different levels of resources and capacities to the collaborative effort and can leverage each others' resources to obtain additional benefits that would not be available if they were working separately.[14] FDA's inspection work plan does not consider establishments under contract with NMFS in determining the facilities FDA plans to inspect in any given year. In addition, by not effectively utilizing NMFS inspection resources or results, FDA has allowed some processing facilities to go without an inspection. A 2010 audit by the Department of Health and Human Services' Office of Inspector General found that 56 percent of domestic food facilities had gone 5 years or more without an FDA inspection. The audit report pointed out that FDA cannot ensure that these facilities are complying with applicable laws and regulations if it does not routinely inspect them.[15] The need to leverage NMFS inspection resources or results was especially critical in China, which accounts for 23 percent of seafood imports into the United States. FDA has inspected 41 of 2,744 (or 1.5 percent) Chinese seafood processing facilities in the last 6 years.

FDA officials provided new information during our closing meeting concerning the agency's plans to use NMFS inspections results. According to these officials, the agency needs to first increase the level of training of NMFS inspectors. Towards that goal, FDA has begun to train NMFS inspectors using an advanced FDA course to increase the inspection capabilities of NMFS inspectors to a level commensurate with the level

[14]GAO-06-15.

[15]Department of Health and Human Services, Office of Inspector General, *FDA Inspections of Domestic Food Facilities* (Washington, D.C., April 2010).

that FDA requires of its own inspectors. For example, FDA plans to train at least 16 NMFS inspectors during fiscal year 2011. NMFS officials confirmed that NMFS inspectors are attending FDA's training in order to meet FDA's training requirement and advance the MOU's provision of leveraging resources. In addition, these NMFS inspectors who completed the training and took the FDA exam, passed. However, according to NMFS officials, NMFS training and its inspectors' capabilities are already equivalent to those of FDA inspectors. According to FDA officials, once NMFS inspectors are trained, the agency plans to inspect some Chinese seafood processing facilities jointly with NMFS to evaluate the NMFS inspectors' capabilities. FDA officials also noted that once NMFS inspection capabilities reach FDA's required level, the agency will consider using NMFS inspection results as another source of information that will feed into FDA's risk analysis process for determining the facilities to inspect in any given year. However, FDA has yet to fully develop this risk approach and no time frames or documentation exists for its full development. FDA noted that the use of NMFS inspection results would be part of FDA's implementation of any third-party certification program, which is mandated by the FDA Food Safety Modernization Act. Therefore, at this point, FDA has not documented how it plans to use NMFS inspection results.

FDA has previously provided other reasons for not using NMFS inspection resources or results. In 2005, we recommended that FDA recognize the results of NMFS inspections when the agency determined the frequency of its seafood inspections. In response, FDA stated that it would assess this issue. However, FDA officials also stated that the agency did not rely on NMFS's inspection information because NMFS could have conflicts of interest due to its fee-for-service inspection approach and because FDA did not know what facilities NMFS was inspecting.[16] A year earlier, we recommended that FDA and NMFS develop a MOU so that FDA, in part, would use and leverage NMFS inspection services to more efficiently and effectively monitor the safety of imported seafood. In response, FDA stated that it would explore additional opportunities to better leverage NMFS inspection resources and more efficiently and effectively protect the public health. We also noted that an FDA official raised concerns

[16]GAO-05-213.

about potential conflicts of interest with NMFS inspections, but that other officials thought that these concerns could be addressed in an agreement.[17]

Conclusions

With about a 20 percent increase in the consumption of imported seafood in the last 10 years, FDA's responsibility has also increased for ensuring the safety of the nation's food supply, including imported seafood. However, FDA still uses the same approach it developed more than 10 years ago to ensure the safety of imported seafood, even though the United States' reliance on imported seafood has increased and aquaculture has emerged as a major source of those imports. FDA's approach is generally focused on reviewing records of foreign processors and importers and does not consider other pertinent areas of a foreign country's food safety system. Its foreign country assessments have been limited by the lack of formal structure and necessary policies, guidance, and criteria. In addition, FDA's sampling program does not give appropriate consideration to testing for the drugs approved for use in aquaculture by major U.S. seafood trading partners but unapproved by the United States and does not effectively use its laboratory resources. There are practices employed by other entities with similar regulatory responsibilities as FDA, including another U.S. government agency, which show potentially more effective alternatives to the current FDA approach. The recently enacted food safety legislation provides FDA with new authorities that may enable it to more comprehensively review a foreign country's seafood safety system and implement the practices that other entities employ to ensure the safety of imported food products. For example, the EU requires foreign countries with which it trades to maintain seafood safety systems that meet EU requirements or equivalent conditions, or meet specific requirements provided in an agreement between the EU and the foreign country before the EU will accept seafood imports from that country. Also, the EU specifically directs that the foreign country submit a national residues monitoring plan, which provides information on the sampling for drugs of concern to the EU for seafood products destined to the EU. That monitoring plan must have an effect at least equivalent to those required within the EU. To facilitate consideration and implementation of a different oversight approach to ensure the safety of imported seafood, FDA must utilize its current resources in the most efficient manner. However, FDA is not efficiently

[17]GAO, *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).

using its resources when it does not effectively implement the 2009 MOU with NMFS and fully utilize the resources of NMFS' Seafood Inspection Program, an agency dedicated specifically and solely to ensuring the quality and safety of seafood. According to FDA officials, training NMFS inspectors would bring their capabilities to a level commensurate with FDA requirements. Furthermore, although FDA worked effectively with NMFS in ensuring the safety of domestic seafood during the Gulf of Mexico oil spill, it lacks systematic collaboration with that agency. Provisions in the new food safety legislation also provide FDA with more specific direction and opportunity for greater collaboration with NMFS through, in part, more effective use of its inspection resources or results.

Recommendations for Executive Action

To better ensure the safety of seafood imports, we recommend that the Secretary of Health and Human Services direct the Commissioner of FDA to take the following three actions:

- study the feasibility of adopting other practices used by other entities, such as requiring foreign countries that want to export seafood to the United States to develop a national residues monitoring plan to control the use of aquaculture drugs, to more efficiently ensure the safety of imported seafood and report its findings to the Secretary;
- develop a more comprehensive import sampling program for seafood by more effectively using its laboratory resources and taking into account the imported seafood sampling programs of other entities and countries; and
- develop a strategic approach with specific time frames for enhancing collaborative efforts with NMFS and better leveraging NMFS inspection resources.

Agency Comments and Our Evaluation

We provided the Departments of Agriculture, Commerce, and Health and Human Services (HHS) 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 Homeland Security, the Department of State, and the Office of the United States Trade Representative. On March 23, 2011, we received written comments from HHS, which are reproduced in appendix IV; HHS neither agreed nor disagreed with the findings and recommendations in the report. The Departments of Agriculture and Commerce did not provide written comments.

HHS notes that our report represents a baseline against which FDA can measure its ongoing progress. The department also states, however, that

reading our report may not result in a full understanding of FDA's multifaceted and risk-informed seafood safety program that relies on information from various sources and provided additional information in this regard. (See app. IV for our response to this and other general comments.) In addition, while HHS did not explicitly agree or disagree with our recommendations, the department provided information in its written comments on actions in process or planned related to each of the recommendations we made in our draft report. The additional information related to each of our three recommendations follows:

- *Study the feasibility of adopting other practices used by other entities, such as requiring foreign countries that want to export seafood to the United States to develop a national residues monitoring plan to control the use of aquaculture drugs, to more efficiently ensure the safety of imported seafood and report its findings to the Secretary*: HHS stated that as part of implementing the Food Safety Modernization Act, FDA will determine whether the legislation supports the kind of precondition for export to the United States that the FDA stated our recommendation envisioned.

- *Develop a more comprehensive import sampling program for seafood by more effectively using its laboratory resources and taking into account the imported seafood sampling programs of other entities and countries*: HHS stated that FDA agrees that effective use of laboratory resources and import sampling programs are important facets of a comprehensive and risk-informed program to ensure seafood safety. HHS stated that FDA is evaluating proposed research to further expand residue and species coverage and identify areas for improved laboratory testing efficiencies.

- *Develop a strategic approach with specific time frames for enhancing collaborative efforts with NMFS and better leveraging NMFS inspection resources*: HHS stated that FDA agrees that it is important for the agency to maintain and foster this collaborative and effective working relationship with NMFS. Further, FDA will work with NMFS to develop strategic approaches for enhancing collaboration and better leveraging seafood inspection resources. However, the agency did not comment on its intent to establish specific time frames for this enhanced collaboration, which we believe remains essential to help ensure accountability for and expeditious implementation of this strategic approach.

HHS and the Department of Commerce also provided technical comments, which we incorporated as appropriate.

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 United States Trade Representative; and other interested parties. In addition, the report will be available at no charge on the GAO Web site at http://www.gao.gov.

If you or your staff 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 V.

Lisa Shames
Director, Natural Resources and Environment

Appendix I: Scope and Methodology

The Department of Health and Human Services' Food and Drug Administration (FDA) has responsibility for ensuring the safety of seafood imports. The Department of Commerce's National Marine Fisheries Service (NMFS) provides voluntary fee-for-service inspections to ensure compliance with FDA's Hazard Analysis and Critical Control Point (HACCP) regulations, among other things. To assess the extent to which FDA ensures the safety of seafood imports against residues from unapproved drugs, we analyzed information on FDA's oversight mechanism for seafood imports—importer and foreign country processing facilities inspections—and its seafood import sampling program. In particular, we analyzed information on the major components and requirements of FDA's importer and foreign facility HACCP inspections. Specifically, we reviewed FDA's inspection reports for seafood processing facilities from major seafood exporting countries to the United States—Bangladesh, Chile, China, and Thailand—and focused our review on 15 FDA inspection reports for facilities that processed aquaculture seafood products during fiscal years 2007 through 2009. We analyzed fiscal years 2006 through 2009 data on FDA's import sampling program's test results to determine the magnitude and scope of the program. As part of our data request, we asked FDA to provide the drug residue being tested for in each analysis. However, information on drug residue, country of origin, and type of seafood was in data fields combined with other information and not easily analyzable. Consequently, we used a statistical program searching for key words to analyze the data. After this preliminary identification of the drug being analyzed, country, and seafood type, we independently verified that the information was correct. In addition, we conducted several data checks, including reviewing the data for missing or incomplete information and testing for obvious errors in accuracy and completeness, to ensure the reliability of the data. Furthermore, we interviewed knowledgeable FDA officials to discuss the database's internal controls and other measures used to ensure the reliability of the data. We determined that the data were sufficiently reliable for our purposes.

We reviewed documents regarding the seafood importing programs of the European Union (EU), the largest importer of seafood worldwide; Japan, the second largest importer of seafood worldwide; and Canada, a major provider of seafood to the United States. We reviewed the EU's importing program to determine if its practices for ensuring the safety of seafood imports have the potential for enhancing our own practices. As part of this effort, we reviewed the EU's inspection reports of select foreign countries that are the major providers of seafood products. We reviewed the imported seafood sampling programs of Canada, the EU, and Japan to determine if their sampling practices had the potential for enhancing our

own practices as well. We reviewed information on import refusals and alerts identified by Canada, the EU, and Japan's to determine the types of drug residues identified in these countries' seafood imports. In addition, we reviewed the approach the Department of Agriculture's Food Safety and Inspection Service (FSIS) uses to ensure the safety of imported meat and poultry products to identify promising practices used by another federal agency responsible for the safety of imported food products. We visited the European Commission (Brussels, Belgium) and its inspection office—the Food and Veterinary Office (Grange, Ireland)—to gain a better understanding of its programs and oversight controls for seafood imports. During the visit, we met with officials from the Belgian and Irish governments to learn about their drug residue testing programs for seafood imports. In addition, we visited a government laboratory in Ghent, Belgium, and Rinville, Ireland, each to learn about the analytical methods available to detect drug residues in seafood products. We also visited the Port of Antwerp (Antwerp, Belgium), the largest port of entry for seafood products in the EU, to learn about oversight controls for seafood imports.

We visited the Port of New York/Newark in Newark, New Jersey, the largest port of entry for seafood products on the East Coast, and met with Customs and Border Protection to learn about its activities related to ensuring the safety of seafood imports. We also visited a cold storage facility—in close vicinity to the New York/Newark port and where FSIS inspectors are stationed—to learn about the measures FSIS uses to ensure the safety of imported meat and poultry products. During the same trip, we visited FDA's Northeast laboratory in Jamaica, New York, and a Customs and Border Protection's laboratory in Newark to learn about the analytical methods available to detect drug residues in seafood products.

We visited FDA's and NMFS' laboratories that specialize in seafood research—FDA's Gulf Coast Seafood Laboratory (Dauphin Island, Alabama) and NMFS's National Seafood Inspection Laboratory (Pascagoula, Mississippi)—to learn about the research the agencies are conducting on drug residues in seafood products. We visited a state actively involved in testing seafood imports—Florida's Department of Agriculture's laboratory (Tallahassee, Florida) and the Florida Agricultural and Mechanical University's Research and Extension facility (Quincy, Florida)—to learn about fish farming practices.

We interviewed knowledgeable officials from Canada; FDA's Center for Food Safety and Applied Nutrition, Office of Regulatory Affairs, and Center for Veterinary Medicine; FSIS; and Japan to better understand how their respective programs function. For informational purposes, we spoke

with representatives from the states of Alabama and Mississippi because of their testing program for imported seafood and proximity to the Gulf of Mexico. To gain various stakeholders' perspectives on the safety of seafood imports, we also spoke with representatives from

- industry (Charm Sciences, Inc.; Costco; Darden; and SGS—a third party entity that certifies seafood farms and processors),
- trade associations (the Catfish Farmers of America; National Aquaculture Association, National Fisheries Institute; and Southeastern Fisheries Association, Inc.), and
- consumer advocacy groups (the Center for Science in the Public Interest and Food and Water Watch).

To assess the extent to which FDA and NMFS have implemented the 2009 memorandum of understanding (MOU) to enhance federal oversight of seafood, we analyzed relevant agency documents on its implementation. Specifically, we obtained and reviewed the 1974 MOU, letters of notification between the agencies, and MOU guidance provided by each agency to their respective field offices. We focused on two of the eight practices identified in our previous work to enhance cooperation between federal agencies in order to determine the extent that a collaborative working relationship exists between FDA and NMFS: (1) establish policies and procedures to facilitate systematic collaboration across agency lines and (2) identify potential ways to leverage resources to maximize and sustain collaborative effort. We did not address the remaining practices: (1) define and articulate a common outcome; (2) establish mutually reinforcing or joint strategies; (3) agree on roles and responsibilities; (4) develop mechanisms to monitor, evaluate, and report on results; (5) reinforce agency accountability for collaborative efforts; and (6) reinforce individual accountability for collaborative efforts.[1] We did not address the first three practices because the agencies have already implemented them; additionally, due to the lack of compatible policies and leveraging of resources, we did not expect the agencies to have developed mechanisms for evaluation or agency and individual accountability. We obtained and reviewed the 2009 MOU implementation plan as well as compared lists of establishments that received FDA or NMFS inspections for fiscal years 2005 through 2009 to determine the extent of inspection duplication. In

[1]GAO-06-15.

order to present information on possible duplication for background purposes, we matched facility names and addresses using a statistical program; for any potential but nonexact matches, we independently verified the matches to determine whether they were correct. We determined that the inspection data were sufficiently reliable for our purposes. We interviewed knowledgeable FDA and NMFS headquarters officials to determine their progress in implementing the 2009 MOU. We reviewed the National Oceanic and Atmospheric Administration's report on ensuring seafood safety after an oil spill and the jointly written 2010 protocol for reopening oil-impacted areas to assess the cooperation between FDA and NMFS in response to the oil spill in the Gulf of Mexico. We interviewed officials at NMFS' laboratory in Pascagoula, Mississippi, as well as FDA's mobile laboratory in Tallahassee, Florida, and Gulf Coast Seafood Laboratory in Dauphin Island, Alabama, to determine the extent to which the agencies coordinated efforts and leveraged resources during this emergency situation.

We conducted this performance audit from April 2010 to April 2011 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: FDA Foreign Facility Inspections and Number of Processing Facilities in the Country

Country	Fiscal year 2005	2006	2007	2008	2009	2010	Total inspections	Number of facilities
Argentina			9				9	340
Bangladesh					5		5	108
Belize				4			4	11
Brazil	9						9	192
Canada						4	4	944
Chile		11		5	6		22	348
China	6			13	2	20	41	2,744
Colombia	3				3		6	61
Costa Rica	5			7			12	38
Ecuador		11	10		17	10	48	184
Fiji			13		5		18	46
Guatemala	6			4	5		15	101
India		7			1		8	477
Indonesia				3			3	361
Italy						3	3	214
Japan						22	22	2,697
Korea Republic of (South)	7		6		11		24	1,017
Malaysia	9			6		5	20	164
Mexico	6	5	14	10	9	4	48	689
Morocco					1	3	4	38
Panama				9			9	80
Peru			9	3	6		18	297
Philippines					11		11	303
Singapore				3			3	38
South Africa					2	4	6	71
Spain						10	10	279
Surinam	10				3		13	17
Taiwan		7		7	3		17	208

	Fiscal year							
Country	**2005**	**2006**	**2007**	**2008**	**2009**	**2010**	**Total inspections**	**Number of facilities**
Thailand		12		12		38	62	456
Trinidad & Tobago				5			5	35
Venezuela	7						7	100
Vietnam	8			4		5	17	801
Total	**76**	**53**	**61**	**95**	**90**	**128**	**503**	**13,459**

Source: GAO analysis of FDA data.

Note: The total for the number of facilities represents only those facilities out of an estimated 17,000 worldwide that FDA inspected from fiscal years 2005 through 2010.

Appendix III: FDA Import Alerts Related to Drug Residue or HACCP Violations

Import alert	Purpose	Number of facilities covered and countries
16-119	detention without physical examination of fish and fishery products for importer and foreign processor combinations not in compliance with HACCP	95 from 29 countries
16-120	detention without physical examination of fish and fishery products for foreign processors not in compliance with HACCP	69 from 28 countries
16-124	detention without physical examination of aquaculture seafood products due to unapproved drugs	41 from 7 countries
16-127	detention without physical examination of crabmeat due to chloramphenicol	29 from 4 countries
16-129	detention without physical examination of seafood products due to nitrofurans	7 from 4 countries
16-131	detention without physical examination of aquacultured catfish, basa, shrimp, dace, and eel from China for the presence of new animal drugs or unsafe food additives	all facilities except 12

Source: GAO analysis of FDA data.

Note: HACCP violations may be related to drug residue problems or other issues such as sanitation controls.

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

Note: GAO comments supplementing those in the report text appear at the end of this appendix.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Assistant Secretary for Legislation

Washington, D.C. 20201

MAR 23 2011

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

Dear Ms. Shames:

Attached are comments on the U.S. Government Accountability Office's (GAO) draft report entitled: "SEAFOOD SAFETY: FDA Needs to Improve Oversight of Imported Seafood and Better Leverage Limited Resources" (GAO-11-286).

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

Sincerely,

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, "SEAFOOD SAFETY: FDA NEEDS TO IMPROVE OVERSIGHT OF IMPORTED SEAFOOD AND BETTER LEVERAGE LIMITED RESOURCES" (GAO-11-286)

The Department appreciates the opportunity to review and comment on this draft report.

The draft report represents a baseline against which the Food and Drug Administration (FDA or the Agency) can measure its ongoing progress, given the Government Accountability Office (GAO) study's focus on past strategies, authorities, and practices, and the opportunities presented to FDA by the newly enacted Food Safety Modernization Act of 2010 (FSMA).

See comment 1.

Reading the GAO report may not result in a full understanding of FDA's multifaceted and risk-informed seafood safety program, which relies on various measures of compliance with its seafood Hazard Analysis and Critical Control Points (HACCP) regulations. For imported seafood, these measures include:

- inspections of foreign processing facilities,
- sampling of seafood offered for import into the United States,
- domestic surveillance sampling of imported products,
- inspections of seafood importers,
- evaluations of filers of seafood products,
- foreign country program assessments, and
- relevant information from our foreign partners and FDA overseas offices.

See comment 2.

FDA has increased the number of foreign site inspections in recent years. FDA is also implementing the Predictive Risk-based Evaluation for Dynamic Import Compliance Targeting (PREDICT), which will improve on our current electronic screening system by targeting higher risk products for exam and sampling and minimizing the delays of shipments of lower risk products. PREDICT will improve our ability to detect trends and investigate patterns. This, in turn, will help to make more efficient use of FDA's import resources and allow FDA to adjust its import sampling level for seafood products over time and as appropriate.

See comment 3.

In addition, FDA conducts foreign country assessments to evaluate a country's aquaculture systems and controls and to assess products. FDA also assesses the country's laws for, and implementation of, control of animal drug residues in the aquaculture products it ships to the United States. In this respect, FDA's assessments are similar to the European Union country audits that GAO references in the draft report.

Whereas a facility inspection offers a snapshot of an individual facility's compliance with HACCP regulations, a country assessment is a systems review that collects information that an investigator cannot collect during a facility inspection. A country assessment offers FDA a broad view of the ability of the country's industry and regulatory infrastructure to control aquaculture drugs. During a country assessment, FDA interviews the country's competent authority officials—at headquarters and regional/local

1

GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S (GAO) DRAFT REPORT ENTITLED, "SEAFOOD SAFETY: FDA NEEDS TO IMPROVE OVERSIGHT OF IMPORTED SEAFOOD AND BETTER LEVERAGE LIMITED RESOURCES" (GAO-11-286)

offices and drug residue testing laboratories—and industry—during visits to farms, processing plants, animal drug and fish feed selling centers and stores, and trade associations. An assessment allows FDA to become familiar with the controls that a country's competent authority is implementing for the distribution, availability, and use of animal drugs, which serves as the foundation for the country's processors to meet the requirements of FDA's HACCP regulation and other laws and regulations relevant to the safety of aquaculture products intended for the U.S. market.

FDA uses information from country assessments to better target (i.e., increase or decrease) surveillance sampling of imported aquaculture products; to inform its decisions on what new analytical methods it needs to develop and what drugs or chemicals it should target for surveillance sampling; to inform its planning of foreign seafood HACCP inspections; to provide additional evidence for potential regulatory actions, such as an import alert; to improve collaboration with foreign government and industry contacts to achieve better compliance with FDA's regulatory requirements; and to better understand the causes for significant changes in a country's drug residue problem, such as a sudden spike in noncompliant samples. FDA provided GAO with several examples of the value and utility of the country assessment program, including the following:

- The assessment trip to China in 2006 was a key consideration in issuance of the country-wide Import Alerts for specific aquaculture products from China in 2007.
- The country assessments for China in 2006, Chile in 2008, and India in 2010 were considered and resulted in increased sampling and testing under the compliance program and special assignments for aquaculture products from these countries (e.g., eel from China, salmon from Chile, and shrimp from India).

The country assessment program helps FDA direct its foreign inspection and border surveillance resources more effectively and efficiently and allows FDA to work directly with countries to resolve drug residue problems.

FDA conducts its seafood safety oversight activities in conformance with its statutory authorities, which have recently been expanded by FSMA. FSMA represents the first major overhaul of FDA's food safety law in more than 70 years and will transform FDA's food safety program. FSMA closes significant and longstanding gaps in FDA's food safety authority, with new safeguards to prevent, rather than react, to food safety problems. Most significantly for purposes of this study, FSMA gives FDA important new tools to ensure that imported seafood is as safe as domestic seafood:

- Suspension of registration: FDA can suspend registration of a facility if it determines that the food poses a reasonable probability of serious adverse

2

GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S (GAO) DRAFT REPORT ENTITLED, "SEAFOOD SAFETY: FDA NEEDS TO IMPROVE OVERSIGHT OF IMPORTED SEAFOOD AND BETTER LEVERAGE LIMITED RESOURCES" (GAO-11-286)

health consequences or death. If the registration of a facility is suspended, food from that facility cannot be imported or exported into the United States, among other things. [See section 102 of FSMA.]

- Enhanced product tracing abilities: FDA is directed to establish a system that will enhance its ability to track and trace both domestic and imported foods. [See section 204 of FSMA.]
- Reliance on inspections by other agencies: FDA is explicitly authorized to rely on inspections by other federal, state and local agencies to meet its increased inspection mandate. FSMA also allows FDA to enter into agreements with state and local governments to leverage resources with respect to the inspection of facilities, both domestic and foreign, as well as imports. [See section 201 and 209 of FSMA.]
- Voluntary Qualified Importer Program: FSMA requires FDA to establish within 18 months a program for expedited review and importation of products from importers voluntarily participating in a qualified importer program. [See section 301 of FSMA.]
- Inspection of foreign food facilities: FSMA authorizes FDA to enter into agreements with foreign countries to facilitate the inspection of registered foreign facilities and require the inspection resources be directed to those facilities, suppliers, and food types that present a high risk. FSMA also prohibits the importation of food from foreign facilities that refuse to permit, limit, or unduly delay U.S. inspections. [See section 306 of FSMA.]

FDA's country assessment program will be useful in developing the program for accredited third-parties called for under FSMA, which may include foreign governments and agencies of foreign governments that meet FDA model standards to certify food imports.

In addition to implementing these new FSMA authorities, FDA will continue the national residue monitoring program and recognizes the benefit of such a program to ensure that foods are not contaminated with illegal animal drug residues. In earlier reports, GAO has called on FDA to consider accrediting private laboratories to test seafood. FSMA directs FDA to establish a program for testing of food by accredited laboratories and will require that food be tested by accredited laboratories in some circumstances, such as in support of admission of imported food. FDA is developing the laboratory accreditation program as part of its FSMA implementation efforts.

3

GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S (GAO) DRAFT REPORT ENTITLED, "SEAFOOD SAFETY: FDA NEEDS TO IMPROVE OVERSIGHT OF IMPORTED SEAFOOD AND BETTER LEVERAGE LIMITED RESOURCES" (GAO-11-286)

Response to GAO's 3 Recommendations for Executive Action

No. 1 - Studying the Feasibility of Adopting Other Practices Used by Other Entities

GAO recommends that FDA *study the feasibility of adopting practices used by other entities, such as requiring foreign countries that want to export seafood to the United States to develop a national residues monitoring plan to control the use of aquaculture drugs, to more efficiently ensure the safety of imported seafood, and report its findings to the Secretary of Health and Human Services.*

This GAO recommendation appears to envision FDA requiring, as a condition of entry into the United States, a national residue monitoring program in the source country for all aquaculture fish. Prior to the passage of FSMA, FDA lacked the authority to demand foreign governmental controls for food as a condition of entry into the United States.

As part of implementing FSMA, FDA will determine whether the legislation supports the kind of precondition envisioned by GAO for entry of aquacultured fish from some or all countries that export to the United States.

No. 2 - Import Sampling Program

GAO recommends that FDA *develop a more comprehensive import sampling program for seafood by more effectively using its laboratory resources and taking into account the imported seafood sampling programs of other entities and countries.*

FDA agrees that effective use of laboratory resources and import sampling programs are important facets of a comprehensive and risk-informed program to assure seafood safety. FDA regulatory testing of residues in seafood, to serve the Agency's regulatory purposes, must be rigorous and confirmatory. Such testing requires a high degree of analytic proficiency, relies on the most advanced laboratory instrumentation, and is supported by significant research efforts. The regulatory tests that FDA must conduct are not comparable to the less rigorous and non-confirmatory screening methods used in Canada, the European Union (EU), and Japan, as referenced by GAO.

FDA offers the following example to illustrate this point. In 2008, the EU found nitrofuran in over 50 fresh water shrimp (Macrobrachium) samples. The positive results came from one laboratory in Belgium that, over a six week period, found positive results in 41 of these samples. During extensive sampling elsewhere over the same six week period, only four samples were found to be positive in the United Kingdom and one each in New Zealand and Germany. The Bangladesh industry did voluntarily stop shipments to the EU based on these results. However, a closer look at the EU test results revealed

GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S (GAO) DRAFT REPORT ENTITLED, "SEAFOOD SAFETY: FDA NEEDS TO IMPROVE OVERSIGHT OF IMPORTED SEAFOOD AND BETTER LEVERAGE LIMITED RESOURCES" (GAO-11-286)

that the laboratory in Belgium that found the 41 positive samples had altered the analytical procedure to include whole body shrimp with the shell on. Two studies conducted independently by Dr. Christof van Poucke of Ghent University in Belgium and Dr. Glenn Kennedy of the Agri-Food & Biosciences Institute in Belfast, United Kingdom, concluded that semicarbazide, the marker used to detect nitrofurazone, occurs naturally in the shell of crustaceans[1]

FDA is evaluating proposed research to further expand residue and species coverage and identify areas for improved laboratory testing efficiencies. Many of FDA's current methods describe the testing of one or two species of fish for one residue, or of one or two species of fish for a class of compounds. FDA is working to develop methods that address multiple species and/or multiple classes of drugs in one method. For example, FDA is attempting to implement a method for shrimp that tests for 15 compounds and a finfish method for multiple classes of compounds. These multiple species/multiple drug class methods would reduce the number of methods FDA must support and will permit greater screening volume.

No. 3 - Enhancing Collaboration with NMFS

GAO recommends that FDA *develop a strategic approach with specific timeframes for enhancing collaborative efforts with the National Oceanic and Atmospheric Administration's (NOAA) National Marine Fisheries Service (NMFS) and better leveraging NMFS inspection resources.*

FDA's current collaboration with NMFS is strong, as illustrated by the multi-agency cooperation on the Deep Water Horizon Oil Spill Response and two recent FDA regulatory actions wherein NOAA worked with FDA, under the 2009 FDA-NMFS Memorandum of Understanding, to coordinate agency efforts and effect food safety compliance.

Moreover, FDA agrees that it is important to maintain and foster this collaborative and effective working relationship with NMFS. FDA will work with NMFS to develop strategic approaches for enhancing collaboration and better leveraging seafood inspection resources. Efforts made to date by FDA and NMFS to train and ultimately certify NMFS inspectors on FDA regulatory procedures and FDA's expectations under the seafood HACCP regulation represent significant investments by both agencies in a program where FDA can take maximum benefit from NMFS inspection activities in the United States and abroad. This work remains a priority and will continue to evolve and develop as resources permit.

[1] For more information, see press release from Seafood Importers and Processors Alliance at following URL: http://www.asemaquaculture.org/files/sipa/sipa_press_release.pdf

5

GAO Comments

The following are GAO's comments on the Department of Health and Human Services' (HHS) letter dated March 23, 2011.

1. We acknowledge that FDA has a multifaceted seafood safety program, and our report discusses various measures that the agency uses to ensure the safety of imported seafood. For example, our report discusses facility and importer HACCP inspections, FDA's drug residue sampling program, and foreign country assessments. As we note in the report, these measures are limited when compared to more comprehensive reviews conducted by the EU and the Department of Agriculture's FSIS. FDA notes that another measure is information from its overseas offices. In our September 2010 report on FDA's overseas offices, however, we found that although the offices have engaged in a variety of activities to help ensure the safety of all FDA imported products, overseas FDA officials report facing a variety of challenges that may limit their ability to enhance agency oversight.[1]

2. HHS notes that FDA is also implementing the Predictive Risk-based Evaluation for Dynamic Import Compliance Targeting (PREDICT), which the department states will improve its current electronic screening system by targeting higher risk products for exam and sampling. The department notes that PREDICT will make more efficient use of FDA's import resources and allow the agency to adjust its import sampling level for seafood products over time. In our April 2010 report, we found that according to FDA officials, the agency had delayed a nationwide rollout of PREDICT due primarily to information technology infrastructure problems, such as server crashes and overloads.[2]

3. HHS describes the role of FDA's foreign country assessments in ensuring the safety of imported seafood by evaluating a foreign country's aquaculture systems and controls and to assess products. We state in our report, however, that until recently, FDA had not developed written standard operating procedures for conducting its foreign country assessments. In its comments, HHS states that, during a foreign country assessment, FDA assesses a foreign country's laws

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

[2]GAO, *Food Safety: FDA has Begun to Take Action to Address Weaknesses in Food Safety Research, but Gaps Remain*, GAO-10-182R (Washington, D.C.: Apr. 23, 2010).

and their implementation for the control of animal drug residues in the aquaculture products it ships to the United States. However, in the absence of written criteria, standards, and program policies, it may be difficult for FDA to carry on such an effort in a systematic or consistent manner. In its comments, HHS describes the breadth and value of FDA's foreign country assessments as part of its import oversight program, but these assessments are not identified in FDA's publicly available information as is its HACCP inspection program. FDA also has not documented that these assessments are linked to any inspection or sampling program.

Appendix V: GAO Contact and Staff Acknowledgments

GAO Contact

Lisa Shames, (202) 512-3841 or shamesl@gao.gov

Staff Acknowledgments

In addition to the individual named above, Jose Alfredo Gomez (Assistant Director), David Moreno (Analyst-in-Charge), David Adams, Nancy Crothers, Diana Goody, Christine Ramos, and Kiki Theodoropoulos made key contributions to this report. Important contributions were also made by Kevin Bray, Michele Fejfar, and Catherine Hurley.

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