



September 2017

IMPORTED SEAFOOD SAFETY

FDA and USDA Could Strengthen Efforts to Prevent Unsafe Drug Residues

GAO Highlights

Highlights of [GAO-17-443](#), a report to the Chairman, Committee on Appropriations, U.S. Senate.

Why GAO Did This Study

Most seafood consumed in the United States is imported, and about half of it is raised on fish farms. Because farmed seafood is raised in confined areas and susceptible to infections, farmers may use drugs like antibiotics. The use of unapproved drugs or the misuse of approved drugs may result in unsafe residues in seafood that can cause cancer or allergic reactions, according to FDA, which is charged with ensuring the safety of most seafood. Beginning in April 2016, FSIS became responsible for ensuring the safety of imported catfish.

This report examines (1) how FDA helps ensure the safety of imported seafood from unsafe drug residues and ways the agency could strengthen its efforts; (2) how FSIS helps ensure the safety of imported catfish from unsafe drug residues and ways the agency could strengthen its efforts; and (3) the extent to which FDA and FSIS coordinate their oversight efforts. GAO reviewed information from each agency and interviewed agency officials and other key stakeholders.

What GAO Recommends

GAO is making five recommendations, including that FDA pursue agreements with other countries to test seafood exported to the United States and that FSIS visit a sample of fish farms as part of foreign country on-site audits; and that FDA and FSIS coordinate in developing testing methods and corresponding residue levels for imported seafood. FDA agreed with or partially agreed with two; FSIS partially agreed with two and stated it already addresses a third. GAO disagrees and believes the recommendations should be implemented.

View [GAO-17-443](#). For more information, contact Steve Morris at (202) 512-3841 or morris@gao.gov.

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FDA and USDA Could Strengthen Efforts to Prevent Unsafe Drug Residues

What GAO Found

To help ensure the safety of imported seafood from unsafe drug residues, the Food and Drug Administration (FDA) generally depends on the actions of foreign processors and U.S. importers. FDA requires processors and importers to follow its Hazard Analysis and Critical Control Point (HACCP) regulations to identify hazards and the critical control points where the hazards, such as pathogen contamination, are likely to occur and take corrective action. FDA also performs a limited number of (1) inspections of processors and importers each year to ensure HACCP compliance, and (2) tests of imported seafood for contaminants, including unsafe drug residues. FDA could strengthen its efforts to ensure the safety of imported seafood from unsafe drug residues by pursuing agreements with other countries requiring that they test seafood exported to the United States for unsafe drug residues. Under an agency plan, FDA is to coordinate with other countries to increase their capabilities related to the safety of food exported to the United States and better leverage their resources. FDA has used country agreements with respect to pathogen hazards in molluscan shellfish intended for export to the United States. According to FDA officials, it might be worthwhile for the agency to pursue agreements with some countries, but FDA would have to carefully consider a number of factors in determining which countries would be appropriate, which it has not yet done.

In assuming responsibility for inspecting imported catfish, the U.S. Department of Agriculture's (USDA) Food Safety and Inspection Service (FSIS) provided foreign countries and others a transition period—March 1, 2016, through September 1, 2017—before full implementation of its catfish inspection program. Following the transition, countries seeking to continue exporting catfish to the United States are to request equivalence determinations by providing documentation showing that their catfish safety inspection systems are equivalent to the U.S. system. FSIS could strengthen its efforts to ensure the safety of imported catfish. The Agricultural Act of 2014 directs FSIS, in part, to consider the conditions under which catfish are raised, domestically and abroad, but FSIS has not made farm visits a routine part of an equivalence determination. It is not clear how FSIS could consider the conditions under which imported catfish are raised consistent with the act without visiting farms. In addition, during this determination, the agency will already have its inspectors in the foreign country for an on-site audit. FSIS officials generally visit government offices, commercial food processing facilities, and food testing laboratories in a foreign country. Without visiting a sample of farms whose catfish are exported to the United States, FSIS may be missing an opportunity to consider the conditions under which catfish are being raised.

FDA and FSIS took steps to accomplish the transfer of catfish oversight from FDA to FSIS, as called for in the 2014 memorandum of understanding (MOU) that both agencies signed. However, they generally have not coordinated on drug residue testing methods, resulting, in some cases, in differences in drug residue levels used to determine if seafood is unsafe—specifically for unapproved drugs—as called for in the 1984 MOU. Without this coordination, the agencies do not have reasonable assurance that they are consistently protecting consumers from unsafe drug residues.

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Abbreviations

2008 Farm Bill	Food, Conservation, and Energy Act of 2008
2014 Farm Bill	Agricultural Act of 2014
CBP	U.S. Customs and Border Protection
EU	European Union
FDA	Food and Drug Administration
FFDCA	Federal Food, Drug, and Cosmetic Act
FSIS	Food Safety and Inspection Service
FSMA	FDA Food Safety Modernization Act
HACCP	Hazard Analysis Critical Control Point
MOU	memorandum of understanding
MRL	maximum residue level
MRM	multi-residue method
NOAA	National Oceanic and Atmospheric Administration
PREDICT	Predictive Risk-based Evaluation for Dynamic Import Compliance Targeting
SRT	Self-Reporting Tool
USDA	U.S. Department of Agriculture

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September 15, 2017

The Honorable Thad Cochran
Chairman
Committee on Appropriations
United States Senate

Dear Mr. Chairman:

The United States has increased the amount of seafood it imports in recent years and is currently the world's second largest importer of seafood, importing from approximately 140 countries. These imports account for over 90 percent of the seafood consumed in the United States, with about half coming from aquaculture (fish farming). In 2015, the United States imported almost 6 billion pounds of seafood, including some of the most popular species with U.S. consumers, such as catfish (about 4 percent of all U.S. seafood imports).¹ Because fish grown in confined aquaculture 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 farmers introduce drugs, either in feed or water, drug residues can remain in the fish through harvesting, processing, and consumption. According to the Food and Drug Administration's (FDA) 2008 report to Congress and FDA officials, the residues of some drugs can cause cancer or allergic reactions.² In addition, some drugs administered to food-producing animal may cause bacteria of human health concern to become resistant to antibiotics used in humans. As imports of farmed seafood increase, so too do the concerns over the presence of drug residues.³ The potential use of unapproved drugs, or misuse of approved drugs, adds to these concerns.

¹Shrimp, salmon, tilapia, and catfish are among the most frequently consumed seafood species in the United States that come primarily from aquaculture. In 2015, the United States imported almost 1.3 billion pounds of shrimp, nearly 0.8 billion pounds of salmon, almost 0.5 billion pounds of tilapia, and over 0.2 billion pounds of catfish.

²Food and Drug Administration, *Enhanced Aquaculture and Seafood Inspection—Report to Congress* (Washington, D.C.: Nov. 20, 2008).

³Other potential hazards associated with fresh and farmed seafood include pathogens, parasites, decomposition, chemical contaminants, and pesticides. Thorough cooking can eliminate the hazards of pathogens, such as salmonella, and parasites, such as tapeworm.

Effective federal oversight is therefore important to help ensure that imported seafood is safe for U.S. consumers.

Historically, FDA has had the responsibility of ensuring the safety of all seafood consumed in the United States. More broadly, under the Federal Food, Drug, and Cosmetic Act (FFDCA), FDA is generally responsible for ensuring that the nation's food supply is safe, wholesome, sanitary, and properly labeled. All FDA-regulated food products imported into the United States must meet the same legal and regulatory requirements as food products produced domestically. The FDA Food Safety Modernization Act (FSMA) provided FDA with additional authorities, such as the authority to suspend the registration of a food facility when there is a reasonable probability of food from the facility causing serious adverse health consequences or death to humans or animals.⁴ With some exceptions, food facilities, including seafood facilities, must be registered with FDA to engage in the manufacturing, processing, packing, or holding of seafood for consumption in the United States.

The Food, Conservation, and Energy Act of 2008 (2008 Farm Bill) assigned regulatory responsibility, upon the issuance of final regulations, for the inspection of domestic and imported catfish to the U.S. Department of Agriculture (USDA). Within USDA, the Food Safety and Inspection Service (FSIS) carries out this responsibility. FSIS is also responsible for ensuring that meat, poultry, and processed egg products are safe, wholesome, and accurately labeled. In May 2012, we reported on the potential effects that FSIS's then-proposed catfish inspection program might have on other federal seafood safety inspection programs.⁵ We stated that FSIS's catfish inspection program would, in part, further fragment the responsibility for seafood safety and introduce

⁴Pub. L. No. 111-353, 124 Stat. 3885 (2011). Prior to FSMA, FDA focused on reacting to foodborne illnesses after they occurred. FSMA requires that FDA focus on preventing foodborne illnesses. The law also provides FDA with new enforcement authorities designed to achieve higher rates of compliance with prevention- and risk-based food safety standards and to better respond to and contain problems when they do occur. For example, FSMA required new preventive controls and food safety plans at some food processing facilities and farms, enhanced FDA's capacity to trace foodborne illness outbreaks within the nation's food distribution channels, and expanded FDA's authority to conduct a mandatory recall of contaminated food products.

⁵GAO, *Seafood Safety: Responsibility for Inspecting Catfish Should Not Be Assigned to USDA*, [GAO-12-411](#) (Washington, D.C.: May 10, 2012).

overlap.⁶ We also testified on this issue in December 2016.⁷ The Agricultural Act of 2014 (2014 Farm Bill), among other things, made all fish of the order *Siluriformes*,⁸ hereafter referred to as catfish, subject to FSIS inspection upon the issuance of final regulations. In addition, with the 2014 Farm Bill, Congress reaffirmed its commitment to assigning FSIS the responsibility for inspecting catfish. Prior to FSIS assuming this responsibility, FDA was responsible for ensuring the safety of catfish. In December 2015, FSIS issued a final rule for implementing a catfish inspection program, and in March 2016, FSIS assumed responsibility for inspecting domestic catfish processing facilities. In April 2016, FSIS assumed responsibility for inspecting imported catfish. FSIS considers its catfish program to be in a transitional period until September 1, 2017, at which time FSIS will begin analyzing whether countries exporting catfish to the United States have food safety systems for catfish that provide a similar level of public health protection as found in the United States.

You asked us to examine how FDA and FSIS ensure the safety of imported seafood from unsafe drug residues.⁹ This report examines (1) how FDA helps ensure the safety of imported seafood from unsafe drug residues and ways the agency could strengthen its efforts, (2) how FSIS helps ensure the safety of imported catfish from unsafe drug residues and ways the agency could strengthen its efforts, and (3) the extent to which FDA and FSIS coordinate their oversight efforts.¹⁰

To examine how FDA and FSIS help ensure the safety of imported seafood and catfish, respectively, from unsafe drug residues, we examined related legislation and regulations; relevant agency policies,

⁶Fragmentation refers to those circumstances in which more than one federal agency is involved in the same broad area of national need and opportunities exist to improve service delivery. Overlap occurs when multiple agencies or programs have similar goals, engage in similar activities or strategies to achieve them, or target similar beneficiaries.

⁷GAO, *Seafood Safety: Status of Issues Related to Catfish Inspection*, [GAO-17-289T](#) (Washington, D.C.: Dec. 7, 2016).

⁸The order *Siluriformes* includes the families of *Ictaluridae*, *Clariidae*, and *Pangasiidae*.

⁹Unsafe drug residues may include (1) residues from drugs unapproved for aquaculture use in the United States; (2) residues of approved drugs that exceed allowed levels; or (3) residues of drugs that are approved for use on one seafood species, but are being inappropriately used on another seafood species.

¹⁰For this report, we use “coordination” broadly to include interagency activities that others, and other GAO reports, have variously defined as “cooperation,” “collaboration,” “integration,” or “networking.”

manuals, directives, and guidance; and our past work on federal oversight of seafood safety. We also interviewed agency officials to gain a better understanding of their seafood safety programs. At FDA, we reviewed program data for fiscal years 2010 through 2015, including data on imported seafood sampling and testing and import refusals. We also reviewed a random sample of 74 foreign processor inspection reports out of a total of 318 reports prepared by FDA for fiscal years 2013 through 2015 to determine whether FDA's processor inspections included visiting farms and laboratories. In addition, we reviewed a random, non-generalizable sample of 9 FDA reports of importer inspections out of a total of 232 reports for fiscal year 2015. At FSIS, we reviewed similar data for catfish from May 1, 2016, when the agency began sampling catfish imports, through July 9, 2017. To assess the reliability of the agencies' data, we, among other things, reviewed controls for the systems that house these data and interviewed agency officials regarding these controls and found these FDA and FSIS data to be sufficiently reliable for the purposes of our reporting objectives. In addition, to gain a better understanding of the agencies' programs, we visited selected U.S. ports of entry in Otay Mesa, California; Long Beach, California; and Newark, New Jersey.¹¹ The Otay Mesa port is a land port of entry into California and in proximity to the Long Beach port. The New Jersey port is the largest port of entry for seafood products in the United States, and the Long Beach port is the second largest port of entry for seafood in the United States. We also visited an FDA laboratory and district office in Irvine, California, to discuss FDA testing of seafood imports for drug residues with laboratory officials. In addition, we interviewed representatives of the National Fisheries Institute,¹² whose members include more than 200 seafood processors, importers, and exporters. We also interviewed a representative from the Consumer Federation of America,¹³ whose members include nearly 300 consumer groups, to obtain their perspectives on the agencies' seafood safety programs. To examine ways, if any, that the agencies could strengthen their efforts, we compared FDA's and FSIS's efforts to help ensure the safety of imported

¹¹We selected the largest and second largest ports of entry for seafood into the United States and selected a land port that is in proximity to one of the sea ports.

¹²According to its website, the National Fisheries Institute is a non-profit organization dedicated to education about seafood safety and other issues.

¹³According to its website, the Consumer Federation of America is an association of non-profit consumer organizations that was established to advance the consumer interest through research, advocacy, and education.

seafood and catfish, respectively, to each other and to efforts of the European Union (EU) to determine if EU practices for ensuring the safety of imported foods have the potential for enhancing U.S. practices. We discussed the EU's practices with officials from the EU's Food and Veterinary Office (Grange, Ireland) to gain a better understanding of its programs and oversight controls for seafood imports.

To review the extent to which FDA and FSIS coordinate their oversight efforts, we reviewed memorandums of understanding on coordination signed by the agencies and coordination activities between the two agencies and also compared their coordination activities to key practices that can help enhance and sustain federal agencies' collaboration that we previously identified,¹⁴ particularly the practice of identifying and addressing needs by leveraging resources when responsibilities cut across more than one federal agency. We also interviewed FDA and FSIS officials to discuss information for all objectives, including obtaining their views on the opportunities to enhance their programs regarding unsafe drug residues in imported seafood. Appendix I provides additional information on our scope and methodology.

We conducted this performance audit from January 2016 to September 2017 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

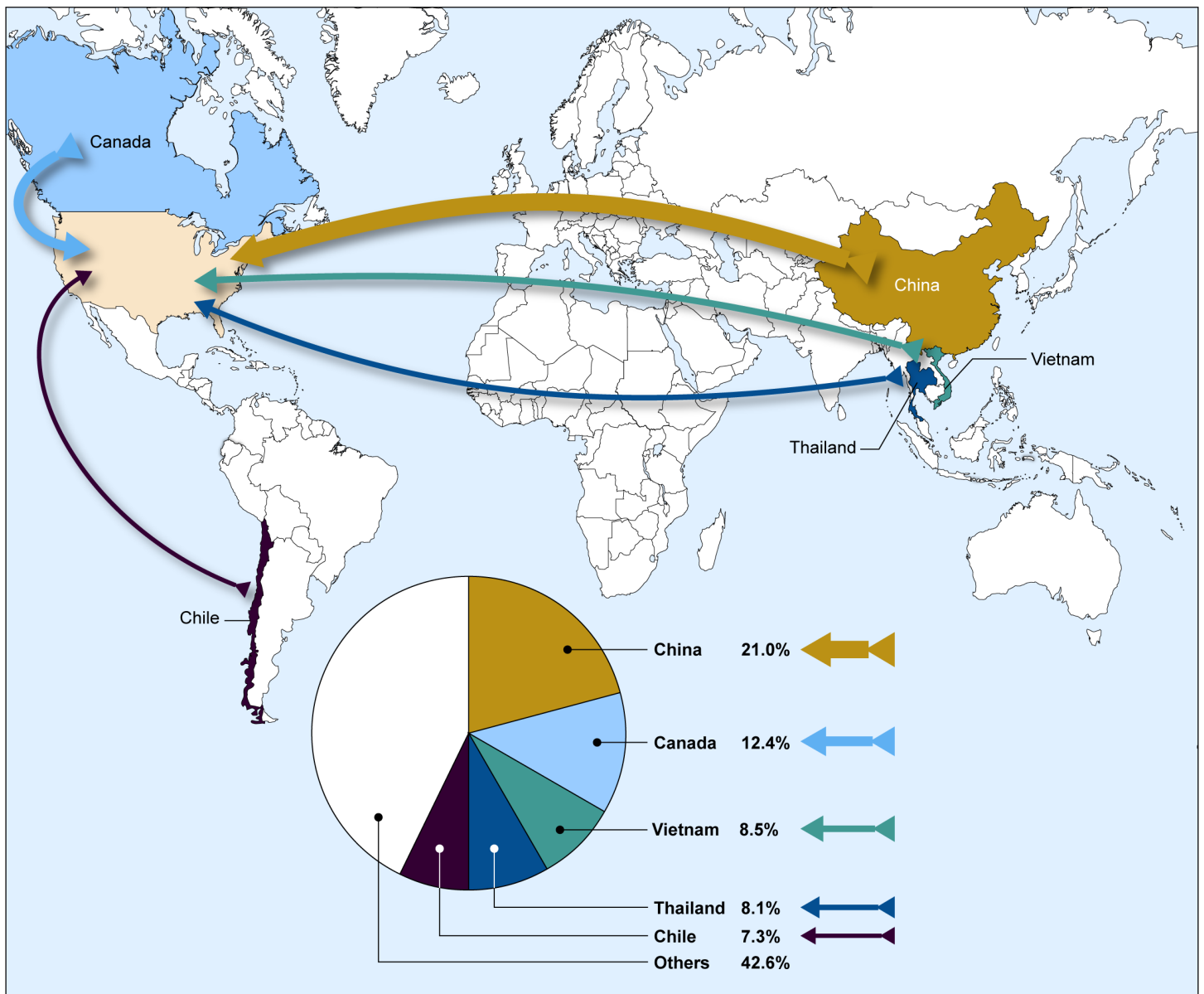
Fishery products (i.e., seafood), including wild catch, aquaculture, and processed fish products, are one of the most highly traded commodities in the world today, and more than half of this commodity originates in developing countries. The EU is the largest market for imported seafood, followed by the United States and Japan. Roughly 20 years ago, about 60 percent of the seafood consumed in the United States was imported. As of April 2016, over 90 percent of the seafood consumed in the United States was imported, about half of which was produced from aquaculture operations, also known as fish farms. In 2015, China was the overall

¹⁴GAO, *Results-Oriented Government: Practices That Can Help Enhance and Sustain Collaboration among Federal Agencies*, [GAO-06-15](#) (Washington, D.C.: Oct. 21, 2005).

leading exporter of seafood to the United States, India was the leading exporter of shrimp, and Vietnam was the leading exporter of catfish. Figure 1 shows the proportion of U.S. imports from the five countries exporting the most seafood to the United States in 2015. The “others” category represents 137 countries that also exported seafood to the United States in 2015.¹⁵ Figure 2 shows the countries that in 2015 were the major exporters of shrimp, salmon, tilapia, and catfish to the United States.

¹⁵These countries include Australia, Indonesia, and Mexico with seafood exports such as swordfish, shrimp, and snapper.

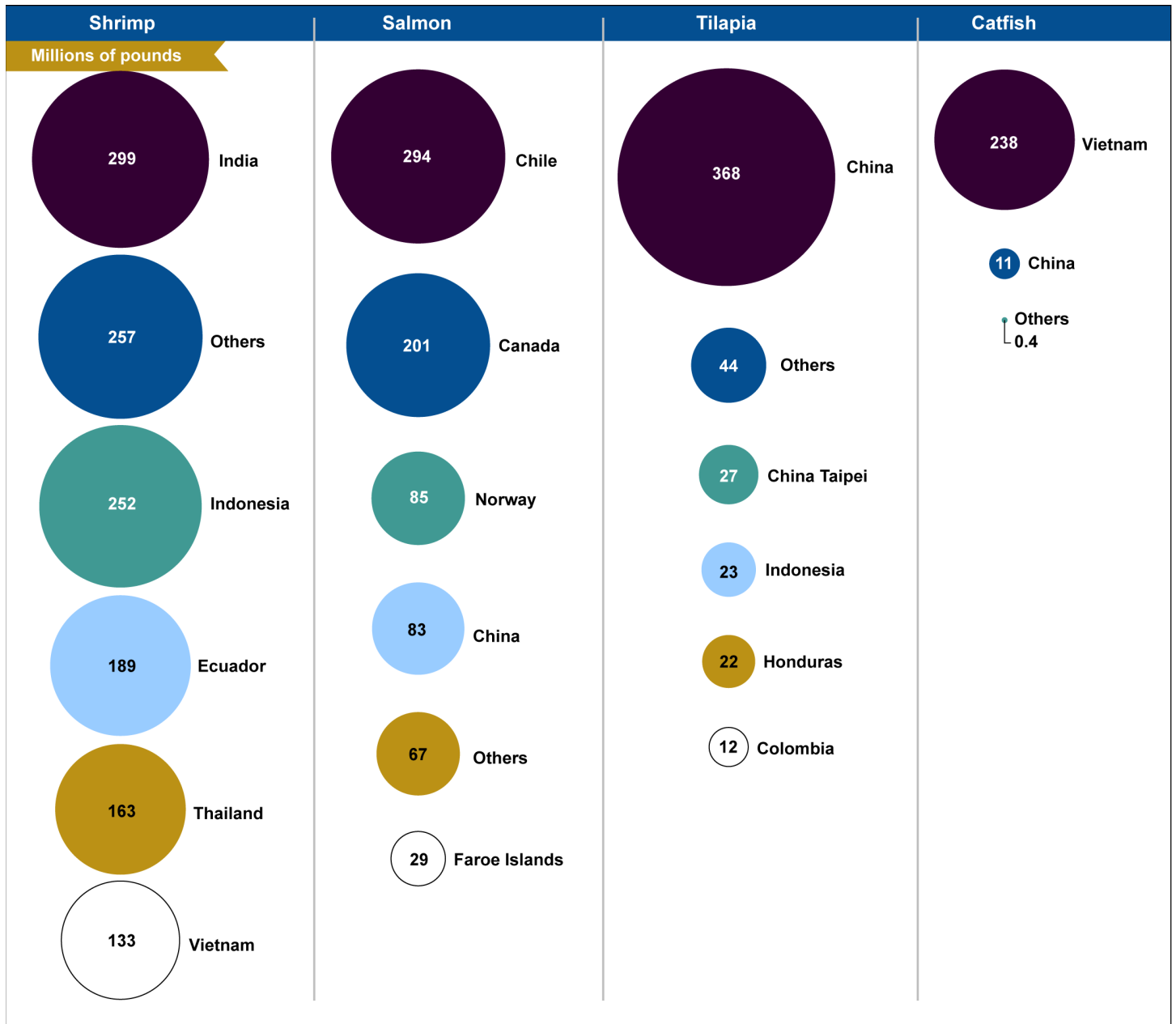
Figure 1: Seafood Imports to the United States in 2015 by Country of Origin



Source: GAO analysis of Department of Commerce and U.S. Customs and Border Protection data; Map Resources (map). | GAO-17-443

Note: The “Others” category represents 137 countries that also exported seafood to the United States in 2015. These countries include Australia, Indonesia, and Mexico with seafood exports such as swordfish, shrimp, and snapper.

Figure 2: Major Exporters of Shrimp, Salmon, Tilapia, and Catfish to the United States in 2015



Source: GAO analysis of Department of Commerce and U.S. Customs and Border Protection data. | GAO-17-443

As with seafood more generally, the volume of imported catfish has been increasing in recent years. In 2005, the United States imported over 30 million pounds of catfish. In 2010, the United States imported about 137 million pounds; the major catfish exporters were Vietnam, with 79 percent, and China, with 13 percent. By 2015, total catfish imports were almost 250 million pounds, with Vietnam alone accounting for over 95 percent of all such imports. Domestically, catfish production is concentrated in Alabama, Arkansas, Louisiana, and Mississippi. In general, according to USDA, domestic catfish production has trended downward in recent years, but data in this regard are incomplete. For example, data reported by USDA's National Agricultural Statistics Service showed a general decline in domestic catfish production from 2006 through 2012, including a 36 percent decline from 2010 to 2012, from about 472 million pounds in 2010 to about 300 million pounds in 2012.¹⁶ But this agency did not collect and report similar data for the period 2013 through 2016.

Before 2002, various fish in the order *Siluriformes* were commonly labeled and sold as "catfish." However, in 2002 Congress amended FFDCFA to allow only fish from the family *Ictaluridae* (in the order *Siluriformes*) to use the name catfish in labeling. All other fish, such as those from the *Pangasiidae* family (in the order *Siluriformes*) that had previously been labeled as catfish had to have other names on labels, such as basa, swai, or tra. However, as discussed, the 2014 Farm Bill made all fish in the order *Siluriformes* subject to FSIS inspection upon the issuance of final regulations. For purposes of this report, we refer to all fish potentially subject to FSIS regulations as "catfish," including fish in the family *Ictaluridae*, which are primarily of domestic origin, and *Pangasiidae*, which come primarily from Vietnam.

FDA's Approval of Drugs

In the United States, new animal drugs (veterinary 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 animal drug approval, including drugs used in aquaculture, originates with an entity or individual (sponsor) submitting an application for review. FDA may approve a drug for, among other things, certain disease conditions in specific species (e.g., catfish). When FDA approves a drug, it may

¹⁶The domestic volumes are based on "round weight". Round weight is the weight of the whole fish before processing or removal of any part.

establish a tolerance for the safe use of the drug. If residues of the approved drug are detected in a food product above the tolerance, the product is unsafe and therefore adulterated under FFDC. ¹⁷ Once residues are confirmed above a tolerance, which can vary by species and drug, FDA may take regulatory action. In addition, if any residue of a drug unapproved by FDA is detected, the food product is likewise unsafe and adulterated under FFDC. In general, drugs used in aquaculture may include anesthetics, antibiotics, disinfectants, hormones, parasiticides, and germicidal agents. Table 1 lists the drugs that FDA has approved for aquaculture use in the United States as of February 2017.

¹⁷Adulterated food is, among other things, food that contains a new animal drug (or conversion product thereof) that is unsafe.

Table 1: U.S. Food and Drug Administration (FDA) Approved Aquaculture Drugs and Examples of Their Intended Use in Seafood, as of February 2017.

FDA-approved aquaculture drugs	Examples of intended seafood
Anesthetics <ul style="list-style-type: none"> Tricaine-S (Tricaine methanesulfonate) 	Fish that includes catfish, perch, pike, and salmon
Antibiotics <ul style="list-style-type: none"> Aquaflor® (florfenicol) Terramycin® 200 for fish (oxytetracycline dihydrate) Oxymarine™, Pennox 343 Soluble Powder, Terramycin 343®, Tetroxy® 343 Soluble Powder, and Tetroxy® Aquatic (oxytetracycline hydrochloride) Romet-30® (sulfadimethoxine/ormetoprim) Sulfamerazine Fish Grade (sulfamerazine) 	Freshwater-reared finfish that includes salmon and catfish Includes salmon, catfish and lobster Finfish fry and fingerlings Fish that includes catfish and salmon Rainbow trout, brook trout, and brown trout
Disinfectants <ul style="list-style-type: none"> Halamid® Aqua (chloramine-T) 	Freshwater-reared fish that includes salmon and trout Walleye Freshwater-reared warmwater finfish that includes catfish and tilapia
Hormones <ul style="list-style-type: none"> Chorulon® (chorionic gonadotropin) 	Finfish
Parasiticides <ul style="list-style-type: none"> Formalin-F, Formacide-B, Parasite-S® (formalin) 	Finfish Finfish eggs Penaeid shrimp
Germicidal agents <ul style="list-style-type: none"> 35 percent Perox-aid® (hydrogen peroxide) 	Freshwater-reared finfish eggs Freshwater-reared fish that includes salmon and trout Freshwater-reared coolwater finfish Channel catfish

Source: GAO analysis of FDA data. | GAO-17-433

Note: Some FDA drug approvals are for specific subsets of these seafood types. For additional information on FDA-approved drugs and their use in seafood, see the following FDA links: <http://www.fda.gov/AnimalVeterinary/SafetyHealth/ProductSafetyInformation/ucm324048.htm> and <https://animaldrugatfda.fda.gov/adafda/views/#/search>.

For testing drug residues, FDA has established three types of maximum residue levels (MRL) for seafood intended for consumption in the United States. FDA applies two of these levels—the “tolerance” and “regulatory”

levels—to domestic and imported seafood. The third, “import tolerance” applies only to imported seafood. FDA regards the presence of drug residues above any of these levels to be potentially harmful to human health and may consider taking regulatory action, such as refusing a product’s entry into the United States if it contains drug residues above such levels. More specifically, the three levels are as follows:

- **Tolerance:** For drugs FDA has approved for use in aquaculture, the approval is often for specific species, disease conditions, and a maximum drug residue tolerance. A food product with a residue above the tolerance established for the drug in that food is adulterated under FFDCa. Tolerances for approved drugs are established in regulation and codified in the U.S. Code of Federal Regulations.¹⁸ FDA applies established tolerances for FDA approved drugs to imported and domestic seafood.
- **Regulatory level:** For certain unapproved drugs, FDA has also established maximum drug residue levels that for purposes of this report, we refer to as regulatory levels. In general, these levels correspond to the limits of detection achievable by the testing methods and equipment used by FDA laboratories. FDA does not generally publicly disclose regulatory levels for residues of unapproved drugs. According to agency officials, FDA is concerned that disclosing its regulatory levels for unapproved drugs may encourage some foreign fish farmers to use these drugs if they believe that they can do so in a manner that would result in residue levels below FDA’s regulatory levels.
- **Import tolerance:** For certain drugs that may be used by foreign fish farmers, FDA has established import tolerances. These drugs are not approved for use by domestic fish farmers. FDA has established import tolerances for three drugs¹⁹ that can be used in other countries on seafood, but none of them are for catfish.²⁰

The EU’s Equivalence Process

The EU, which is the largest importer of seafood worldwide, takes a wide-ranging review of the food safety systems of foreign countries that want to

¹⁸See Specific Tolerances for Residues of New Animal Drugs, 21 C.F.R. pt. 556, subpt. B.

¹⁹The three drugs for which FDA has developed import tolerances for seafood are lufenuron, azamethiphos, and teflubenzuron.

²⁰See <http://www.fda.gov/animalveterinary/products/importexports/ucm315830.htm> for additional information on import tolerances.

export their seafood products to it. Specifically, the EU requires that other countries seeking to export seafood to it demonstrate that their seafood safety systems meet its or equivalent requirements or comply with specific requirements established in an agreement between the EU and the exporting country. According to EU regulations, for other countries to demonstrate that their seafood safety systems meet EU or equivalent requirements, they must provide information on their food safety systems, including relevant laws, regulatory enforcement powers, and the laboratories that test seafood products. According to EU officials, once they determine that a country has an equivalent food safety system for a particular food product, the government of that country is then responsible for meeting the EU's safety requirements. Moreover, that government becomes the single point of contact to address any identified problems, such as seafood products with drug residues above the EU's accepted MRLs, and is expected to take regulatory actions across that country's supply chain, from farm to processing facility, as necessary.

The EU generally conducts an on-site audit of a country's food safety system governing the product that country seeks to export to the EU. The audit focuses on the ability of the competent government authority responsible for food safety to carry out its tasks and provide the necessary guarantees for the safety of food to be exported to the EU. The EU's on-site audits include visiting fish farms and processing facilities as well as reviewing the capabilities and quality of the country's food testing laboratories. In addition, to ensure continuous compliance with EU requirements, the EU periodically conducts follow-up audits of a country's food safety system for specific food products, such as seafood.

Countries that export food to the EU also are required to implement national residue monitoring plans, which include sampling and testing of food products for residues of specific drugs of concern to the EU. The EU must approve a country's residue monitoring plan as a prerequisite for export of food of animal origin, such as seafood, from that country to the EU. Countries exporting food to the EU must submit their residue monitoring plans to the EU for approval each year.²¹ The EU can prohibit a country from exporting seafood to the EU if drugs of concern to the EU are not included in the country's national residue monitoring plan or the country does not otherwise fully implement its plan.

²¹Once a country's residue monitoring plan is implemented, the country is to provide an annual report on the sampling results to the EU.

FDA Takes Steps to Help Ensure the Safety of Imported Seafood from Unsafe Drug Residues and Could Strengthen Its Efforts with Foreign Country Agreements

To help ensure the safety of imported seafood from unsafe drug residues, FDA generally depends on the actions of foreign processors and U.S. importers. Specifically, FDA requires processors and importers to follow its Hazard Analysis and Critical Control Point (HACCP) regulations to identify hazards and the critical control points where the hazards, such as pathogen contamination, are likely to occur and to take corrective action. FDA also performs a limited number of (1) inspections of processors and importers each year to ensure HACCP compliance, and (2) samples and tests of imported seafood for contaminants, including unsafe drug residues. However, FDA has not entered into agreements with other countries requiring that they test seafood exported to the United States for the specific drugs the agency tests for—drugs of concern to FDA.

FDA Requires Seafood Processors and Importers to Follow HACCP and Conducts a Limited Number of Inspections to Assess Compliance

Since 1997, FDA has used HACCP as its main safety oversight tool 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, such as pathogens or chemicals, are reasonably likely to occur.²² Under HACCP requirements, processors are also responsible for addressing hazards that may have been introduced before the seafood reached their facilities, including hazards from unsafe drug residues. FDA inspects a limited number of foreign seafood processing facilities each year to (1) identify potential seafood safety problems before seafood products arrive in the United States, (2) help the agency make admissibility decisions when seafood products are offered for importation into the United States,

²²A HACCP plan is a written plan that defines the procedures for maintaining control of potential food safety hazards at the critical control points of food preparation or processing. It includes information on the potential hazard associated with a specific food product; the measure that will be implemented to control the hazard; the critical control point to implement the measure; minimum or maximum values (critical control limit) at which a physical, chemical, or biological parameter must be controlled to minimize the risk that a potential food safety hazard may occur; the monitoring procedures to ensure that the hazard is controlled; and the corrective actions to be taken in response to deviations from critical control limits.

and (3) help ensure that imported seafood products under FDA's jurisdiction meet U.S. safety requirements, among other things.²³

In fiscal year 2016, FDA inspected 144 foreign seafood processor facilities for HACCP compliance, or nearly 2 percent of the 7,669 total processors that exported seafood to the United States that year.²⁴ According to FDA officials, limited resources dictate the number of inspections the agency can conduct. Similarly, in our January 2015 report, we found that FDA was not keeping pace with FSMA's mandate for increasing the number of these inspections of foreign food facilities.²⁵ According to FDA officials, the agency did not plan to meet this FSMA mandate because of limited funding. Regarding potential drug residues, FDA's inspections of foreign seafood processor facilities are limited. These inspections involve reviewing the processors' HACCP plans and other records to ensure that the processors considered drug residues as a hazard that is reasonably likely to occur if the seafood products it receives are from fish farms. However, the inspections do not include visiting the fish farms that supply the processor facilities to evaluate drug use or controls; it is at these farms where drugs are introduced. FDA's inspections also do not include visiting laboratories that may be asked by processors to test for unsafe drug residues in seafood to assess the laboratories capabilities and competence.

According to FDA officials, neither fish farms nor laboratories are subject to the HACCP regulations and therefore are not part of FDA's processor inspections. Our review of a random sample of 74 foreign processor inspection reports prepared by FDA for fiscal years 2013 through 2015 generally confirmed that FDA's processor inspections did not include visiting farms that supply the fish to the processor and laboratories that

²³According to FDA documents, inspections should focus on the implementation of the HACCP program for those targeted products. It also includes a review of monitoring, corrective action, and sanitation monitoring records. FDA may also conduct inspections to verify corrective actions have been implemented.

²⁴According to FDA officials, the agency only tracks the most recent number of registered processors and does not track the numbers that were registered in the past.

²⁵GAO, *Food Safety: Additional Actions Needed to Help FDA's Foreign Offices Ensure Safety of Imported Food*, [GAO-15-183](#) (Washington, D.C.: Jan. 30, 2015). We recommended that FDA complete an analysis to determine the annual number of foreign food inspections that is sufficient to ensure comparable safety of imported and domestic food. If the inspection numbers from that evaluation are different from the inspection targets mandated in FSMA, FDA should report the results to Congress and recommend appropriate legislative changes. FDA concurred with the recommendation.

conduct testing for the processor. From the 74 reports, we found only one case where the FDA inspectors also visited a fish farm supplying the processor. In that case, the farm was located near the processing facility.

FDA also requires U.S. importers to verify that foreign processing facilities are HACCP compliant. HACCP regulations require all importers of seafood to the United States to demonstrate that the seafood they import has been processed in accordance with HACCP requirements. For example, under HACCP requirements, importers of seafood products must (1) obtain seafood products from processing facilities in foreign countries that have an agreement with FDA documenting that the country's food safety system complies with or is equivalent to the U.S. system; or (2) maintain written verification procedures that include product specifications designed to ensure that products are not adulterated and take at least one of six affirmative steps to document that the foreign processing facilities supplying their seafood products comply with HACCP requirements. These steps may include, for example, maintaining on file a copy of the foreign processor's HACCP plan and a written guarantee from the processor that the imported seafood is processed in accordance with HACCP requirements, or obtaining a certificate from a foreign government inspection authority or competent third party certifying that the imported fish was processed in accordance with HACCP requirements.

As of June 2017, FDA had no equivalence agreements with other countries, according to FDA officials, precluding importers of seafood products from using the first of the two options noted above. Instead, according to FDA officials, U.S. seafood importers generally comply with HACCP regulations by obtaining (1) a copy of a foreign processor's HACCP plan and an attestation that the firm processes its seafood products in compliance with HACCP regulations and (2) lot-by-lot certifications from either a foreign government authority or third-party auditor attesting to the foreign processor's compliance with HACCP regulations.²⁶ However, according to FDA officials, under HACCP regulations, importers are not required to either visit foreign seafood processors to ensure that these processors implement their HACCP

²⁶According to an FDA document, how a lot is defined is largely up to the processor and the importer. For import shipments, FDA characterizes a lot as an entry, group of entries, or a portion of an entry of merchandise that can be clearly defined as a shipment for FDA sampling and examination purposes.

plans or assess the competence or ability of foreign governments or third-party auditors to issue lot-by-lot certifications.

Each year FDA inspects a small number of U.S. seafood importers to determine if they have obtained the appropriate documentation from foreign seafood processors indicating that the processors had met HACCP requirements. For fiscal years 2010 through 2015, FDA inspected, on average, 178 seafood importers annually, or about 4 percent of the average number of seafood importers (4,009) registered with FDA each year during that period. As with processing facility inspections, FDA officials stated that the number of importer inspections was affected by limited resources. Our review of nine random—a non-generalizable sample—FDA reports of importer inspections for fiscal year 2015 showed various problems with importer compliance with HACCP requirements. For example, of the nine reports, five noted that the importer inspected did not identify the affirmative step taken to document that the foreign processors supplying some or all of that importer’s seafood products were in compliance with HACCP requirements. In some cases, the inspection report also noted that an earlier FDA inspection had also found that the importer had failed to identify an affirmative step that was required in order to comply with HACCP regulations.

FDA Conducts a Limited Number of Port-of-Entry Examinations and Tests a Small Sample of Seafood Imports to Identify Unsafe Drug Residues

FDA uses a computerized tool for admissibility screening and to determine, in part, which seafood products to examine.²⁷ This tool is called the Predictive Risk-based Evaluation for Dynamic Import Compliance Targeting (PREDICT).²⁸ We previously reported on FDA's use of PREDICT in May 2016.²⁹ Examinations may include physical inspection (e.g., appearance and smell) of the seafood; inspection of the label; or sampling and laboratory testing of the seafood to identify any contaminants, including unsafe drug residues, that may render the seafood adulterated. FDA tests imported seafood for all drugs of concern to the agency and compares results to its corresponding MRL if one exists, according to FDA officials. FDA uses a multi-residue method (MRM) that tests for 26 drugs. FDA also uses other methods to test for drug residues. In cases in which the MRL is exceeded, the imported seafood is adulterated under FFDCa and subject to refusal.

If FDA finds adulterated seafood through testing or examination, the agency can refuse the shipment's entry into the United States. From fiscal years 2010 through 2015, FDA refused entry (import refusal) into the United States of 1,726 seafood products for drug-related violations. The majority of the refusals were of exports from four countries: China (37 percent), Malaysia (28 percent), Indonesia (12 percent), and Vietnam (11 percent). Shrimp represented 54 percent of all FDA refusals; other seafood, 32 percent; tilapia, 7 percent; catfish, 6 percent; and salmon, less than 1 percent. FDA officials said that import refusals may also occur based on FDA inspections of foreign processors but that they were not aware of a refusal based on FDA inspectional findings related to the use

²⁷Admissibility screening is intended to ensure that the food is admissible under FFDCa. Imported food products are generally considered admissible if they are in compliance with applicable FFDCa regulations that ensure food is not adulterated, misbranded, manufactured or packed under insanitary conditions, or restricted in sale in the country in which it was produced or from which it was exported, among other things.

²⁸PREDICT is designed to estimate the risk of imported products using information such as the history of the associated foreign processor facility; results of any FDA inspections of the facility, including any past problems with products from the facility; and the country of origin.

²⁹GAO, *Imported Food Safety: FDA's Targeting Tool Has Enhanced Screening, but Further Improvements Are Possible*, [GAO-16-399](#) (Washington, D.C.: May 26, 2016). We recommended that FDA take actions to improve the effectiveness of PREDICT by documenting the process by which FDA is to identify, obtain, and use open source data and establishing a timeline for implementing the remaining recommendations from FDA's 2013 evaluation of PREDICT. FDA generally agreed with these recommendations.

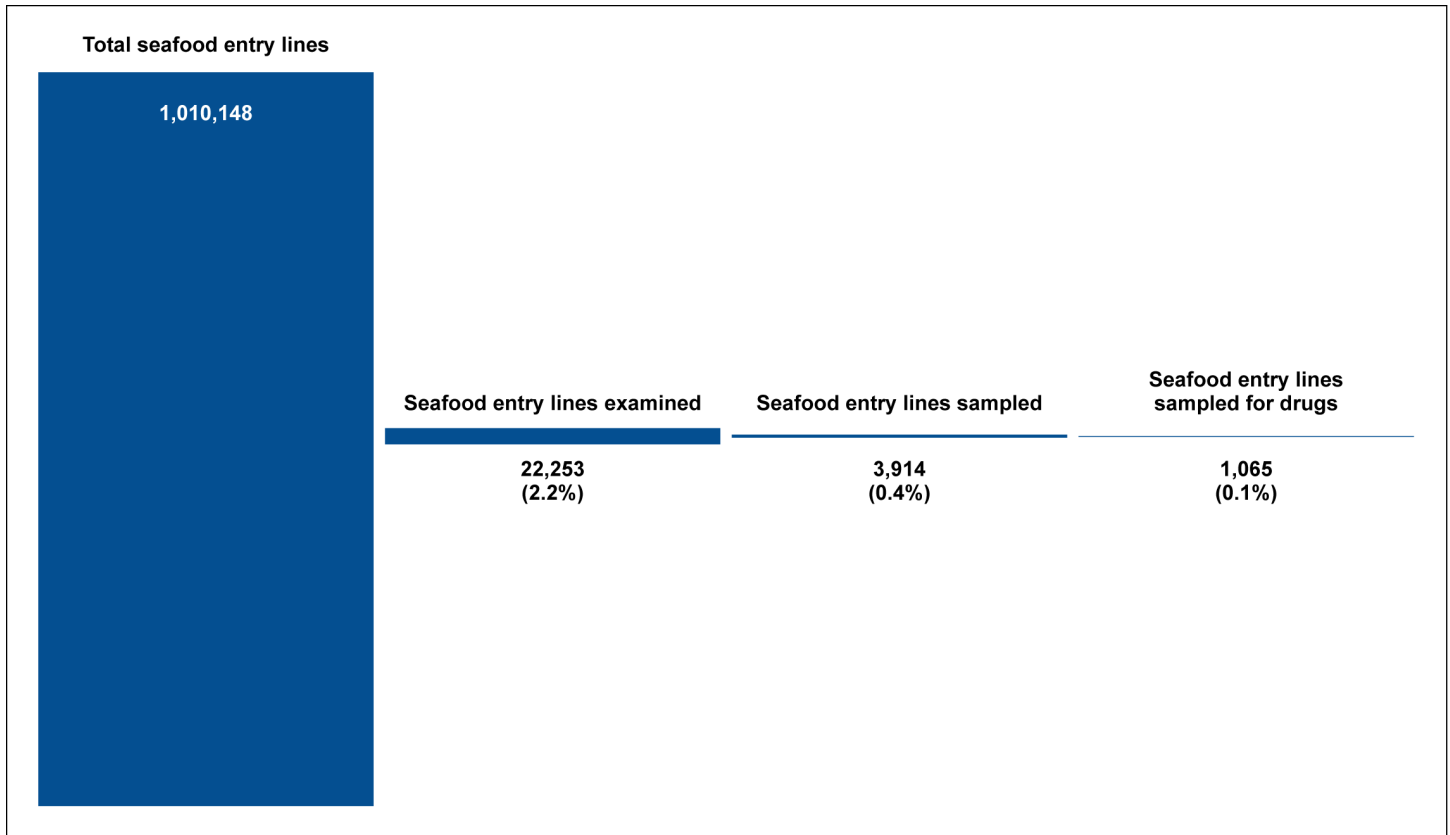
of an unsafe drug. Appendix II provides our analysis of FDA's drug testing results for fiscal years 2010 through 2015.

In fiscal year 2015, FDA examined 2.2 percent of all imported seafood entry lines for a variety of food safety issues.³⁰ The number of examinations is limited by available resources, according to FDA officials. Further, regarding drug residues, in fiscal year 2015 FDA tested 0.1 percent of about 1 million seafood entry lines for drugs of concern to FDA in an effort to detect unsafe residues. Of the imported seafood tested, the percentage that tested positive, by type of seafood was as follows: catfish, about 9 percent (3 of 33 samples); salmon, 0 (0 of 86); shrimp, about 12 percent (67 of 550); tilapia, about 11 percent (28 of 258); and "other" seafood, about 7 percent (14 of 213).³¹ Based on this level of testing, seafood shipments from a foreign processing facility would have a roughly 1 in 1,000 chance of being selected by FDA for drug residue testing, unless other information in PREDICT, such as the results of sampling of prior shipments, processing facility inspection records, and country of origin, among other factors, elevated or lowered that facility's risk score. According to FDA officials, the level of testing of seafood imports for drug residues is affected by the availability of resources. Figure 3 shows fiscal year 2015 data for FDA's examinations and sampling of imported seafood, including sampling specifically for drug residues.

³⁰An entry line is each portion of an import shipment that is listed as a separate item on an entry document offered for admission into U.S. commerce.

³¹The number of samples that FDA tested and the associated results are not intended to be statistically valid for projection purposes. Instead, FDA uses PREDICT for admissibility screening and for determining which products to examine and test based on various factors, such as past violations history and country of origin. In addition, some of these sample sizes are particularly small and the percentages may convey a level of precision that can be misleading because they can greatly change with minor changes in the data. The "other" seafood category includes, for example, crab, frog legs, and lobster.

Figure 3: Total Seafood Entry Lines, Lines Examined, Lines Sampled, and Lines Sampled for Drugs by the Food and Drug Administration (FDA), Fiscal Year 2015

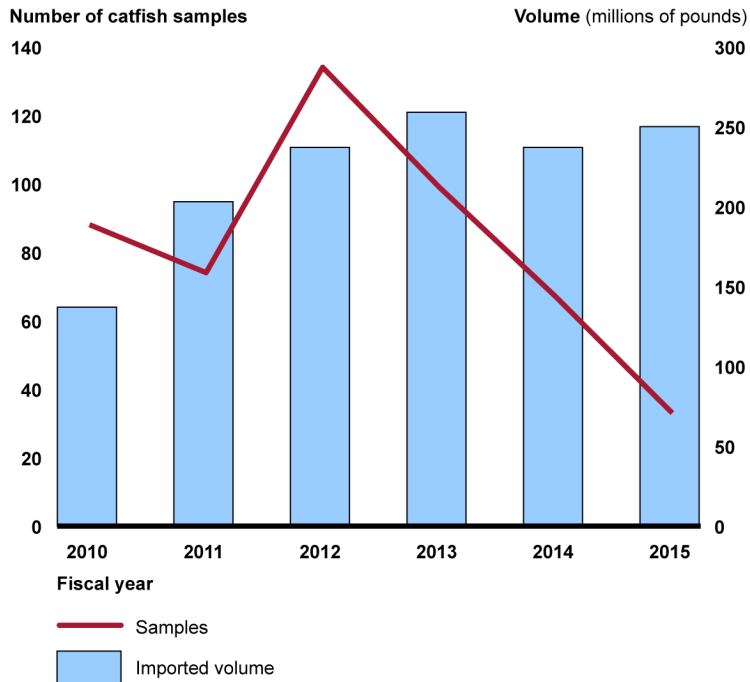


Source: GAO analysis of FDA data. | GAO-17-443

Notes: An entry line is a portion of an import shipment that is listed as a separate item on an entry document. An entry may include one imported item or hundreds; each item is identified as an entry line. Examined entry lines include those subject to physical inspection, label review, and sampling. FDA's selection of the seafood entry lines it sampled was not based solely on drug residue risk concerns but on a combination of risk variables, including potential pathogen hazards. The percentages are of the total seafood entry lines.

Regarding imported catfish specifically, FDA's sampling and testing for unsafe drug residues generally increased from fiscal years 2010 through 2012, but then dropped significantly in the following 3 fiscal years, even as the volume of catfish imports remained relatively the same. For example, as shown in figure 4, from fiscal years 2012 through 2015, FDA's sampling and testing of imported catfish for unsafe drug residues declined by 75 percent, even as the volume of catfish imports averaged about 250 million pounds annually during this period.

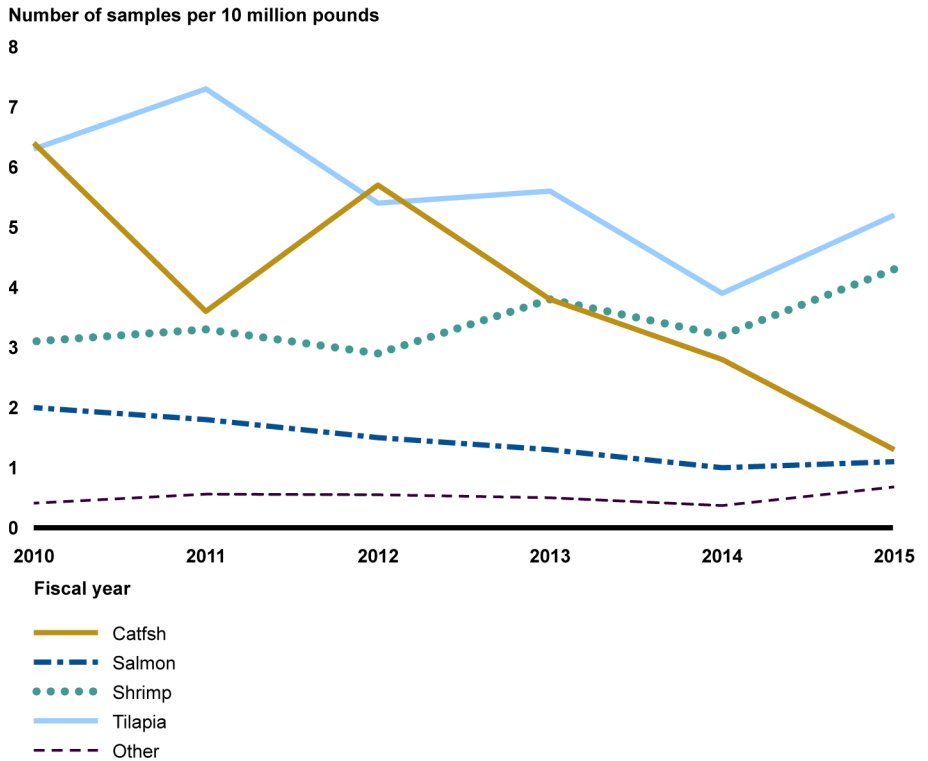
Figure 4: Number of Imported Catfish Samples Tested by the Food and Drug Administration (FDA) for Unsafe Drug Residues Compared to the Volume of Catfish Imported, Fiscal Years 2010 through 2015



Source: GAO analysis of FDA, Department of Commerce, and U.S. Customs and Border Protection data. GAO-17-443

Further, in comparison to FDA’s sampling and testing of other popular imported seafood species, such as salmon, shrimp, and tilapia, for unsafe drug residues, FDA’s sampling and testing of imported catfish showed the greatest drop relative to import volume for fiscal years 2010 through 2015. For example, as shown in figure 5, FDA’s sampling and testing of imported catfish experienced the greatest drop per 10 million pounds of imports, particularly from fiscal years 2012 through 2015. However, as shown in the figure, the level of sampling and testing per 10 million pounds of imports is limited for all of the seafood species depicted. Appendix II provides information on the total number of imported seafood samples, including for catfish, FDA tested for fiscal years 2010 through 2015.

Figure 5: Number of Imported Seafood Samples, by Type, Tested for Drug Residues by the Food and Drug Administration (FDA), per 10 Million Pounds of Imports, Fiscal Years 2010 through 2015



Source: GAO analysis of FDA, Department of Commerce, and U.S. Customs and Border Protection data. GAO-17-443

Note: Other includes, for example, crab, frog legs, and lobster.

The agency decreased its sampling and testing of imported catfish from fiscal years 2012 through 2015, as shown in figures 4 and 5. According to FDA officials, the agency reduced sampling and testing for fiscal years 2014 and 2015 because it anticipated that FSIS would soon assume this responsibility. As discussed, the 2008 Farm Bill assigned USDA this responsibility upon the issuance of regulations, and the 2014 Farm Bill reaffirmed this decision and gave USDA a timeline for implementing its catfish inspection program (within USDA, this responsibility is delegated to FSIS). FSIS began inspecting domestic catfish in March 2016 and imported catfish in April 2016. FDA officials said that the agency's ability to increase its sampling and testing of imported seafood for unsafe drug residues is constrained by resource limitations and competing priorities in other areas. For example, an E. coli outbreak in this country would

require FDA to address that outbreak and potentially reduce resources for drug residue testing.

FDA Could Strengthen Its Efforts by Pursuing Agreements with Other Countries Requiring That They Test Seafood Exported to the United States

FDA is not pursuing agreements with other countries requiring that they test seafood exported to the United States for unsafe drug residues, according to FDA officials, as the EU does. Establishing such agreements is a practice that we have previously recommended to FDA.³² FSMA requires FDA to develop a comprehensive plan to expand the technical, scientific, and regulatory capacity of foreign governments and their respective food industries in countries that export foods to the United States. To meet FSMA's requirement, in 2013 FDA developed its International Food Safety Capacity-Building Plan. This plan states, in part, that FDA will (1) coordinate with other countries to, among other things, increase their capabilities related to the safety of the food they export to the United States and (2) better leverage other countries' resources. Such leveraging may enable FDA to perform its work to ensure food safety more efficiently. Further, the plan states that agreements and other arrangements with foreign regulatory authorities or other entities are useful in ensuring the safety of food products and avoiding duplication of oversight efforts.

Even with the development of this plan in 2013, as of June 2017 FDA had not entered into any agreements or other arrangements to involve another country in ensuring the safety of the seafood it exports to the United States from unsafe drug residues, according to FDA officials. Further, as of that time, FDA was not actively pursuing such agreements or other arrangements. When asked why, agency officials said that it might be worthwhile for FDA to pursue agreements with some countries, but the agency would have to carefully consider a number of factors in determining which countries would be appropriate and has not done so. According to these FDA officials, some countries exporting seafood to the

³²In January 2001, to better ensure the safety of imported seafood, we recommended that FDA develop specific goals and time frames for establishing agreements with other countries to document that their seafood safety systems are equivalent to that of the United States. GAO, *Food Safety: Federal Oversight of Seafood Does Not Sufficiently Protect Consumers*, [GAO-01-204](#) (Washington, D.C.: Jan. 31, 2001). FDA disagreed that it should make it a priority to establish equivalence or other agreements. In a January 2004 report, we said that we continued to believe that such agreements are one of the most cost-effective methods for ensuring the safety of imported seafood. See 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).

United States might not be ready for such agreements. For example, they said that these countries may lack the laboratory infrastructure and capabilities needed to test for the drugs of concern to FDA, including at the corresponding MRLs that the agency established for these drugs, and their laboratory staff may need additional training and education.

According to EU officials, the foreign laboratories that test seafood products exported to the EU for drug residues should ideally be accredited and have the required methods included in the scope of accreditation. Further, these officials stated that those methods must be validated or the residue monitoring plan will not be approved by the EU. Countries seeking to export seafood to the EU must either demonstrate that their seafood safety systems meet EU or equivalent requirements or comply with specific requirements established in an agreement between the EU and the exporting country. The United States may still be a market for at least some seafood that did not meet the seafood safety standards of the EU because FDA does not have agreements with these countries.³³

Moreover, precedent exists for FDA's use of country agreements in another area. Specifically, the agency has used them with respect to pathogen hazards in molluscan shellfish intended for export to the United States. For example, FDA entered into an agreement with Mexico in 2012 in which Mexico committed that its sanitation program guidelines for harvesting, processing, transporting, and labeling molluscan shellfish would comply with U.S. requirements to reduce potential pathogen hazards. In addition, under the agreement, Mexico committed that its competent government authority would restrict the harvest of molluscan shellfish from unapproved growing areas and take enforcement action against persons or companies harvesting from unapproved areas.

In addition, in the course of doing work for our September 2012 report, officials from three major seafood exporting countries described the benefits of countries entering into agreements with them.³⁴ Noting that

³³In our 2011 report ([GAO-11-286](#)), we found that according to an FDA review of Vietnamese documents, all seafood processing facilities' HACCP plans stated that if a drug unapproved by the EU was found in a seafood product, that product should be diverted to another market. FDA officials concluded that this HACCP plan requirement could result in such products being exported to the United States.

³⁴GAO, *Food Safety: FDA Can Better Oversee Food Imports by Assessing and Leveraging Other Countries' Oversight Resources*, [GAO-12-933](#) (Washington, D.C.: Sept. 28, 2012).

they had such agreements with the EU, these officials said that their countries would be open to establishing similar agreements with the United States. For example, see the following:

- Thai officials said that because Thailand has a formal (government-to-government) agreement with the EU, the Thai government can better ensure that its seafood processing facilities meet the EU's safety standards for seafood exported to EU countries. These officials also said that, because of this agreement, their government can more efficiently address problems with Thai seafood exports identified by an EU country, including any drug residue problems.
- Noting that their country has a formal agreement with the EU, Ecuadoran officials said staff from their government inspect and certify processor facilities that export seafood products to the EU. Further, these officials said the Ecuadorian government developed a national control plan to address specific EU requirements and standards for seafood exports, including those related to drug residues.
- Noting that Indonesia has formal agreements with other countries, including the EU, Indonesian officials said that all Indonesian processing facilities that export seafood to those countries must meet HACCP certification requirements; obtain a health certificate; and meet any additional requirements of the importing country, which may include requirements related to drug residues.

Further, the results of FDA's "country assessments" of other countries exporting seafood to the United States point to the potential benefit of having formal agreements with these countries. FDA conducts these assessments to provide the agency with a broad view of a country's regulatory infrastructure and the capacity of its seafood industry to control unsafe drug residues. According to FDA guidance,³⁵ when the agency determines there is a significant risk that a country may be exporting seafood with unapproved drug residues to the United States, FDA may undertake an assessment of the country's drug residue control program. FDA has conducted 10 foreign country assessments focused on the use of drugs in aquaculture in eight countries from 2006 through December 2016. The most recent assessments of China and Indonesia, major exporters of seafood, were conducted in 2006 and 2007, respectively. According to the guidance, FDA's determination may be based on the

³⁵The guidance is found in FDA's *Standard Operating Procedures for Conducting Country Assessments for Animal Drug Residues in Aquacultured Products*.

results of its own sampling and testing of seafood exported from that country or on other information, such as a significant change in a country's competent government authority responsible for seafood safety oversight. As described in the guidance, in the course of doing an assessment, FDA officials may visit seafood processors, fish farms, drug testing laboratories, feed mills, and veterinary drug distributors and retailers in the country.

At the conclusion of a country assessment, FDA may offer suggestions or recommendations to government officials and seafood industry representatives for improving the country's seafood safety program. However, as noted in some of these assessments, the country involved reported that it could not act on these suggestions or recommendations in the absence of a formal agreement with the United States, or it was otherwise apparent that the absence of an agreement was likely an impediment. For example, see the following:

- In its 2012 assessment of Vietnam, FDA recommended that the Vietnamese government reinstate a requirement that its processors test all farmed seafood consignments intended for the U.S. market for unsafe drug residues until such testing showed that unsafe drug residues were no longer a problem. However, according to the assessment, Vietnam responded that under its new food safety law, it can only conduct mandatory consignment testing when required by a formal agreement with the receiving country. Vietnam noted that it has such agreements with other countries, such as Canada, the EU, Japan, and Korea, but does not have an agreement with the United States.
- In its 2013 assessment of Ecuador, FDA strongly suggests that the competent government authority require that seafood processors exporting to the United States meet all requirements in Ecuador's drug residue plan. However, according to the assessment, Ecuador responded that its plan is voluntary and thus the country cannot require that its processors comply with the plan's requirements except in cases where Ecuador has a formal agreement with another country. Ecuador noted that it has such agreements with Argentina, Brazil, China, the EU, and Russia but not with the United States. Those countries that have agreements with Ecuador are regulated by EU standards, according to the assessment. As a result, shrimp or tilapia that cannot be shipped to EU countries because of concerns about violative drug residues may be shipped to the United States.

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- In its 2011 assessment of Malaysia, FDA said that Malaysian testing of seafood exported to the United States was limited to three drugs and it was not possible to verify that this seafood met U.S. requirements and was free of unsafe drug residues. In response to FDA's concerns, the competent government authority declined to make changes in its testing, stating it is the responsibility of U.S. importers to ensure that seafood imports comply with U.S. requirements. In contrast, FDA determined that the Malaysian seafood safety control system underwent major changes in response to an EU audit, and the country is on the list of countries approved to export fishery products to the EU.
 - In its 2010 assessment of India, FDA noted that drug residue testing required by the Indian government for seafood exports to the EU and the United States differed. Specifically, a greater level of testing was required for seafood exports to the EU. According to FDA's assessment, the Indian government said the type of testing done on seafood intended for the EU would also be done on seafood intended for the U.S. market if FDA required that seafood exports be accompanied by a health certificate, as is required by the EU, Japan, and South Korea. However, FDA does not require health certificates and took no action to require them after completing this assessment, according to FDA officials.

As of June 2017, FDA had not entered into any agreements or other arrangements with any country for ensuring the safety of the seafood exported to the United States from unsafe drug residues.

In light of FDA's limited inspections of foreign seafood processors and U.S. importers, its limited sampling and testing of imported seafood for unsafe drug residues, and the limitations of FDA's country assessments to obtain other countries' voluntary cooperation in ensuring that their seafood exports to the United States are free of unsafe drug residues, FDA not pursuing formal country agreements is counter to the agency's International Food Safety Capacity-Building Plan. Under the plan, FDA is to coordinate with other countries to, among other things, increase their capabilities related to the safety of food exported to the United States and better leverage other countries' resources. Such leveraging may enable FDA to more efficiently perform its work to ensure food safety. However, FDA has not pursued formal agreements with countries exporting seafood to the United States that commit the countries to take actions, such as testing for drugs of concern to FDA and the corresponding MRLs, that would leverage those countries' resources, according to FDA officials. The EU and other countries have successfully pursued such agreements.

By pursuing formal agreements with countries exporting seafood to the United States that commit these countries to test for drugs of concern to FDA and the corresponding MRLs that the agency established for these drugs, FDA could strengthen its efforts toward ensuring that imported seafood does not contain unsafe drug residues. Further, such agreements would allow FDA to leverage other countries' resources to improve imported seafood safety and further protect U.S. consumers from unsafe drug residues. FDA officials acknowledged that such agreements would be helpful in protecting U.S. consumers from unsafe drug residues.

FSIS Takes Steps to Help Ensure the Safety of Imported Catfish from Unsafe Drug Residues and Could Strengthen Its Efforts

In assuming responsibility for inspecting imported catfish, FSIS provided for an 18-month transition period—March 1, 2016, through September 1, 2017—to provide foreign countries, importers, and other stakeholders time to transition to the full implementation of the agency's catfish inspection program for imports.³⁶ Following the transition period, a foreign country seeking to continue exporting catfish to the United States after September 1, 2017, is to request an equivalence determination and provide documentation showing that its catfish safety inspection system is equivalent to that of the United States. However, FSIS has not made farm visits a routine part of initial equivalence determination and verification on-site audits. FSIS also does not plan to require other countries to test catfish exported to the United States for the same drugs it tests for—the drugs of concern to FSIS—at the agency's MRLs.

Upon Assuming Responsibility for Catfish Oversight, FSIS Allowed an 18-Month Transition Period

As of March 1, 2016, countries exporting catfish to the United States and intending to continue those exports after September 1, 2017, were required to provide FSIS with documentation demonstrating that their food safety systems generally comply with U.S. requirements, including the use of HACCP.³⁷ In addition, by that date, these countries were to provide FSIS with a list of processors intending to continue exporting catfish to the United States. As of June 2017, 13 countries submitted the documentation required to continue exporting catfish to the United States during the transition period.

³⁶The transition period also provides time for domestic catfish processors to bring their operations into full compliance with FSIS regulations.

³⁷During the transition, FSIS required foreign countries to show that they had laws or other legal measures in place that ensure that their respective catfish processors comply with FDA HACCP regulations.

In April 2016, FSIS assumed responsibility for inspecting imported catfish at ports of entry. FSIS refers to this as re-inspection, and it generally included (1) physical examinations and (2) collecting samples for testing for unsafe drug residues or other contaminants. During the transition, FSIS targeted shipments for re-inspection on at least a quarterly basis.³⁸ As part of the re-inspection, FSIS tested for unsafe drug residues, including for all drugs of concern to the agency and their corresponding MRLs. FSIS used, in part, an MRM that tested for 61 drugs. In cases in which an MRL was exceeded, FSIS considered the imported catfish to be adulterated and subject to refusal. For drugs approved by FDA for use in catfish, FSIS's MRLs are based on FDA's tolerances for these drugs. For unapproved drugs, FSIS's MRLs are based on levels determined by the agency.³⁹

According to FSIS re-inspection data, from May 1, 2016, through July 9, 2017, the agency collected and tested 382 samples from 195 shipments of imported catfish for unsafe drug residues. Those shipments totaling over 4.4 million pounds came from 57 processors. FSIS found unsafe drug residues in 20 of the shipments and refused their entry into the United States. Together, these 20 shipments included about 422,000 pounds of catfish and came primarily from processors either in China or Vietnam. The drugs involved included dyes used as anti-fungal agents and antibiotics that are not approved for use in catfish in the United States.⁴⁰

³⁸According to FSIS documents, the criteria for selecting shipments for reinspection were based, in part, on the exporting country and volume of product exported by catfish processors in that country.

³⁹FSIS refers to these levels as minimum levels of applicability and any catfish with drug residues above these levels is considered adulterated.

⁴⁰The drugs found by FSIS included gentian violet, malachite green, nitrofurans, and enrofloxacin. Gentian violet and malachite green are dyes effective against fungal infections. Nitrofurans and enrofloxacin are antibiotics.

Through Its Equivalence Determination Process, FSIS Relies on Other Countries to Ensure the Safety of the Food They Export to the United States

As discussed, under FSIS's December 2015 final rule for its catfish inspection program,⁴¹ a country wanting to continue exporting catfish to the United States after September 1, 2017, is to submit specified documentation and information to FSIS by that date. According to an FSIS document, the agency will use a country's documentation and information to begin assessing whether the country's sanitary measures for catfish provide an equivalent level of public health protection as found in the United States. According to FSIS documents, a country is expected to provide information about its food safety laws and regulations; inspection procedures, including manuals and directives; enforcement and compliance programs and policies; and inspection training programs.⁴² According to FSIS documents, the equivalence determination process may take several years to complete.⁴³ During that time, FSIS may ask the country for additional information, as needed, and FSIS officials are to conduct an on-site (in-country) audit, and in many cases more than one to verify the information provided by the country. FSIS conducts an on-site audit at least once during an initial equivalence determination and again periodically during subsequent verification audits. According to agency officials, FSIS will conduct periodic on-site audits in countries with equivalence determinations to verify that their food safety systems remain equivalent. FSIS uses a data analysis tool, known as the Country Performance Algorithm, to prioritize the countries subject to these audits. The agency also publishes the related audit reports on its website. In the course of an on-site audit, FSIS officials generally visit government offices, commercial food processing facilities, and food testing laboratories in the country.

In essence, FSIS intends to use the same equivalence determination process for imported catfish that it currently uses for imported meat, poultry, and processed egg products, according to agency officials. As part of the equivalence determination, FSIS also requires a foreign country to develop a residue monitoring plan that includes testing for drug

⁴¹80 Fed. Reg. 75,590 (Dec. 2, 2015).

⁴²FSIS expects that the country's competent government authority for food safety will address the Self-Reporting Tool questions according to these documents.

⁴³The explanatory statement associated with the 2017 Consolidated Appropriations Act directs FSIS to complete an equivalence determination for the catfish inspection program in a foreign country that exports catfish and catfish products to the United States not later than 180 days after the end of the 18-month transition period specified in FSIS's final catfish inspection rule—March 1, 2018.

residues. According to FSIS documents, these plans must include, in part, random sampling of food products at slaughter and the use of approved sampling and testing analytical methods. We also discussed, in part, FSIS's equivalence determination process in an April 2017 report.⁴⁴

In October 2016, FSIS finalized its Self-Reporting Tool (SRT), a standardized questionnaire that the agency provides to countries that request an equivalence determination for catfish. The SRT describes the types of documentation and information that the country must provide to FSIS for the agency to initiate the equivalence determination process. In general, this documentation and information relates to the country's food safety system and regulatory infrastructure. For example, the SRT asks for documentation and information on the following six equivalence components of a country's food safety system

- government oversight,
- statutory authority for food safety and other consumer protection regulations,
- sanitation,
- HACCP compliance,⁴⁵
- chemical residue testing programs, and
- microbiological testing programs.

According to FSIS officials, as of May 2017, 10 countries had requested an equivalence determination and FSIS provided them with the SRT. These countries were Bangladesh, China, the Dominican Republic, El Salvador, Guyana, Jamaica, India, Nigeria, Thailand, and Vietnam. Furthermore, as of June 2017, Guyana and Thailand had provided

⁴⁴GAO, *Foot-and-Mouth Disease: USDA's Evaluations of Foreign Animal Health Systems Could Benefit from Better Guidance and Greater Transparency*, [GAO-17-373](#) (Washington, D.C.: Apr. 28, 2017). GAO recommended that USDA (1) clarify its guidance on how staff should document analysis of a foreign country's animal health system and the results of in-country visits to verify information; (2) complete its efforts to develop an information management system to better store, organize, and manage documentation gathered about a foreign country's animal health system; and (3) develop guidance promoting greater transparency in risk analysis reports in accordance with the quality information guidelines issued by USDA's Chief Information Officer and guidance from the Office of Management and Budget. USDA concurred with these recommendations.

⁴⁵According to FSIS documents, following the transition, foreign governments will have to show that they require their catfish processors to use a HACCP system comparable to FSIS's HACCP requirements as part of the equivalence determination process.

sufficient information for FSIS to begin the equivalence determination process.

According to FSIS documents, once it has completed its review and analysis of a country's documentation and information, including the results of its own on-site audits, if deemed satisfactory, FSIS is to then publish a proposed rule in the *Federal Register* indicating its intention to add the country to FSIS's list of countries eligible to export a particular food commodity to the United States. After receiving and reviewing any public comments on the proposed rule, FSIS will make a final equivalence determination decision and, as appropriate, publish a final rule in the *Federal Register* regarding the country's eligibility to export the commodity to the United States. As discussed, the equivalence determination process can take several years from the time a country completes and submits the SRT until FSIS makes its final determination. According to agency officials and FSIS documentation, FSIS will allow a country that submitted an SRT to continue exporting catfish to the United States pending completion of its equivalence determination as long as that country continues to respond to FSIS's requests for additional information within the timeframe indicated.

According to FSIS officials and documents, after an equivalence determination is completed, the country reviewed is authorized to export the related food product to the United States. Thereafter, on an annual basis, FSIS expects the country's government to review and update its SRT responses, as appropriate, and notify FSIS of any changes to the country's food safety system. SRT revisions may be necessary because of country-initiated changes, or revisions may be needed because of new policies adopted by the United States. FSIS will also require the country to submit, on an annual basis, specific documents, including an updated list of all certified food processing facilities eligible to export to the United States, and an updated description of the country's residue monitoring plan, including the previous year's test results and any actions taken in response to unsafe drug residue test results.

According to FSIS officials, after the transition period, all shipments of imported catfish from countries that the agency has determined to have an equivalent food safety system will have to be presented to FSIS inspectors for reinspection. In addition, a subset of reinspected shipments will be sampled. According to FSIS officials, after the 18-month transition period, the agency will update the sampling program based on sampling results and findings from the transition period. Furthermore, according to agency officials and FSIS documents, shipments of imported catfish may

be subject to the same three levels of sampling used for imported meat and poultry: (1) normal sampling, which is based on random sampling; (2) increased sampling, which is above-normal sampling resulting from an agency management decision; and (3) intensified sampling, which is additional sampling undertaken when a previous sample failed to meet U.S. requirements, such as drug residues that are above the corresponding MRL. According to FSIS officials and documents, after equivalence determinations have been done, the intent of the reinspection process is to verify the effectiveness of the foreign country's food safety system, not to evaluate the performance of individual catfish processing facilities or as the primary effort/point to identify unsafe drug residues in imported catfish.

FSIS Could Strengthen Its Efforts to Ensure the Safety of Imported of Catfish

As discussed, during FSIS's on-site audits, which the agency conducts at least once to verify the accuracy of the documentation and information a foreign country seeking an equivalence determination has provided in an SRT, FSIS generally visits government offices, commercial food processing facilities, and food testing laboratories in the foreign country. However, FSIS has not made farm visits—where catfish exported to the United States are grown and where drugs are potentially first introduced into catfish—a routine part of initial equivalence determination and verification on-site audits. In addition, although FSIS will require foreign countries to develop and implement residue monitoring plans, the agency will not require these countries to test for drugs of concern to FSIS. In contrast, the EU requires countries to test for drugs of concern to the EU.

The 2014 Farm Bill directs USDA to consider the conditions under which catfish are raised and transported to the processing establishment for examination and inspection. According to agency officials, this directive allows FSIS to visit catfish farms in exporting countries as part of its on-site audits related to an initial equivalence determination or a subsequent verification audit. However, these officials said FSIS has not made farm visits a routine part of initial equivalence determination and verification on-site audits, because the agency has not yet decided whether to make visits to fish farms routine like visits to foreign laboratories or processing facilities.

It is at the fish farms where drugs are first introduced and used. Other seafood regulators conduct such visits to fish farms, including FDA and the EU. For example, according to FDA's procedures for conducting country assessments, visiting fish farms is a critical element in evaluating a country's seafood safety oversight program because farms are where

the potential hazard of unsafe drug residues originates. At such farms, FDA officials said they review (1) preventive controls to guard against unapproved drug use; (2) water quality or other factors that may lead farmers to use drugs; (3) drug use records, including drug withdrawal times⁴⁶ (4) information on countries' fish farm oversight programs (e.g., registration, inspection, and sampling); (5) data that can be compared to seafood processor records to determine the accuracy and reliability of these records; and (6) biosecurity measures meant to prevent the spread of disease and keep fish healthy. According to FDA documents, FDA officials visit farms that supply the products to the seafood processing facilities scheduled to be visited by FDA during the assessment. This is done to verify the controls stated in the processors' seafood HACCP plans. Further, by visiting fish farms, FDA gathers useful information about any foreign government oversight of the farms, as well as the drugs that are actually being used on the farms in that country, according to agency documents. For example, as part of FDA's country assessment for Ecuador, FDA staff visiting two fish farms in that country discovered that the farms were using an antibiotic on shrimp that FDA had not approved for that product.⁴⁷

The EU also visits fish farms in foreign countries during its initial equivalence determinations and periodic verification audits. According to EU officials, by visiting these farms and other locations in a country, the EU audit team occasionally learns of drugs being used by farms that are not included in the country's residue monitoring plan. For example, during the EU's 2012 verification audit of Ecuador, EU inspectors visited fish farms and found them using a hormone that the Ecuadorian government could not verify it had approved for use in aquaculture. In addition, the information on the drug label did not indicate that it was authorized for use in Ecuador. Furthermore, one of the farms visited had barrels of an antibiotic that did not bear numbers or labels, indicating that the antibiotic was authorized for use in Ecuador.

It is not clear how FSIS could consider the conditions under which imported catfish are raised, as directed by the 2014 Farm Bill, without visiting foreign catfish farms. In addition, the agency will already have its

⁴⁶The withdrawal time is the period following the last treatment with a drug during which an animal may not be offered for slaughter and products from the animal, such as milk and eggs, may not be offered for sale.

⁴⁷However, Ecuador was not under any obligation or requirement to take any action on this matter because it does not have a formal agreement with the United States.

inspectors in the foreign country for an on-site audit. Without visiting at least a sample of farms whose catfish are exported to the United States, FSIS may be missing an opportunity to fully understand the conditions under which the catfish are being raised. For example, FSIS could choose to visit farms that supply catfish to seafood processing facilities that the agency plans to visit during its on-site audits, like FDA does.

FSIS also does not plan to require countries exporting catfish to the United States to test for drugs of concern to FSIS as part of a country's drug residue monitoring plan, according to agency officials. Instead, as part of an equivalence determination, FSIS will require a country to have a national residue monitoring plan. Further, the officials said that FSIS will expect this plan to include such information as the (1) chemicals, including drugs, that will be tested for; (2) proposed number of samples to be taken; (3) testing methods to be used for screening and confirming the presence of chemicals, including drugs; (4) MRLs to be used; (5) chemicals, including drugs, newly approved or banned in the past year; and (6) corrective actions to be taken when a residue violation is found. However, while agency officials said that FSIS expects another country to provide an overall level of sanitary protection similar to that in the United States, the country has flexibility regarding its regulatory practices, including the specific drugs included in its national residue monitoring plan.

Even if a country allows its catfish farmers to use drugs not approved for use in the United States, that country's catfish exports must still comply with FSIS's requirements (i.e., MRLs) for allowable drug residues.⁴⁸ As noted by agency officials, FSIS expects imported catfish to be subject to the same level of scrutiny as domestic catfish. However, while FSIS will test domestic catfish for at least 61 drugs using its MRM and other methods, it is not clear how many drugs or which drugs other countries will test for in catfish exported to the United States because FSIS will not have such specific requirements for a foreign country's residue monitoring plan after the transition period. Further, FSIS will assess the safety of drug residues found in domestic catfish against MRLs determined by the agency, although other countries may use their own MRLs in their drug residue monitoring plans. For example, Vietnam, the largest exporter of catfish to the United States, developed its drug residue monitoring plan

⁴⁸FDA has approved nine drugs for use in domestic catfish. Catfish farmers in other countries are able to use all drugs approved by their governments, regardless of whether those drugs are approved by FDA.

and MRLs to meet the EU's requirements. In comparing FSIS's MRLs to Vietnam's levels for 14 drugs that could be used in catfish, we found 9 drugs for which Vietnam had higher MRLs than FSIS's. For one antibiotic, the residue level that Vietnam considers a violation is 30 times greater than FSIS's level.

The first time imported catfish may be subject to drug residue testing similar to the testing done of domestic catfish, including the same 61 drugs and associated MRLs, is likely to be when, and if, the imported catfish is selected for sampling by FSIS in U.S. ports of entry. As a result, even after equivalence determinations are completed, FSIS's sampling and testing of imported catfish shipments will become the primary mechanism for identifying the potential presence of unsafe residues of drugs of concern to FSIS. According to FSIS officials, as of July 2017, the agency has not yet documented the size of the samples that it will test for during fiscal year 2018.

In contrast, the EU requires countries exporting seafood to the EU to include drugs of concern to the EU in their residue monitoring plans. Although FSIS officials said that the agency expects imported catfish to be subject to the same level of scrutiny as domestic catfish and that reinspection is to verify the effectiveness of the exporting country's food safety system, the agency is not requiring that the foreign countries test for the drugs of concern to FSIS and the corresponding MRLs, which would qualify as the initial foreign country inspection. By having countries exporting catfish to the United States include in their national residue monitoring plans the drugs of concern to FSIS and the corresponding MRLs, as a precondition for an equivalence determination, FSIS would have better assurance that U.S. food safety requirements were being met and that U.S. consumers were being protected.

FDA and FSIS Took Key Steps to Coordinate the Transfer of Catfish Oversight, but They Have Not Fully Coordinated on Drug Residue Testing Methods

FDA and FSIS took steps to accomplish the transfer of catfish oversight from FDA to FSIS, as called for in the 2014 memorandum of understanding (MOU) that both agencies signed. However, they generally have not coordinated on drug residue testing methods, resulting, in some cases, in differences in MRLs—specifically for unapproved drugs. FDA and FSIS agreed in their 1984 MOU to exchange information on their drug testing methods and ensure the comparability of their results.

FDA and FSIS Took a Number of Steps to Coordinate the Transfer of Catfish Oversight

In April 2014, FDA and FSIS entered into an MOU to improve interagency cooperation on food safety and fraud prevention and maximize the effectiveness of personnel and resources related to examination and inspection, and to plan for an orderly transition of catfish safety oversight from FDA to FSIS. The 2014 Farm Bill, which required the agencies to develop this MOU, directed that the MOU should build upon any prior agreements between the agencies to improve interagency cooperation. Pursuant to this MOU, FDA and FSIS took a number of steps to coordinate the transfer, including the following:

- According to FDA officials, in January 2015, FDA established an internal FDA work group that compiled a list of questions and answers for FDA and FSIS management officials on topics related to the transfer.
- According to FSIS officials, FDA and FSIS established a transition work group comprising of FDA and FSIS management officials and subject matter experts. According to FSIS officials, members of this workgroup met periodically to discuss issues pertaining to the transition of jurisdiction and regulatory oversight of catfish from FDA to FSIS. According to FDA officials, the first transition group conference call was held on May 19, 2015.
- According to FSIS officials, from May 2015 through June 2016, FDA and FSIS held three teleconferences to coordinate activities related to the transfer. Specifically, agency officials discussed inspection methodologies, sampling, and laboratory testing; FDA's previous strategy for regulatory oversight of imported catfish, including relevant

FDA import alerts; and sharing of FDA's knowledge of fish farms and processing facilities in the United States that handle catfish.

- According to FSIS officials, before publishing the final rule for its catfish oversight program in December 2015, FSIS provided a draft of this rule to FDA for its review and comment.
- FDA and FSIS agreed—as FSIS assumed responsibility for domestic catfish oversight on March 1, 2016, and imported catfish oversight on April 15, 2016—that there would be no duplication of the inspection and testing of catfish between the two agencies. Further, FDA agreed not to inspect domestic or foreign catfish processing facilities or test catfish products unless FSIS requested such inspections.

Further, after the agencies took these steps and the transfer was completed, in discussions with FDA and FSIS officials in January 2017, we mentioned that FDA appeared to have information that might be useful to FSIS in carrying out its catfish oversight program that FDA had not shared with FSIS. We suggested that FDA share with FSIS its past (1) drug residue testing data for catfish, (2) catfish processor inspection reports, and (3) foreign country assessments for catfish-exporting countries. For example, we suggested that information in FDA's foreign country assessments might be useful to FSIS in doing equivalence determinations for some of the same countries. After these meetings, FSIS requested, and FDA provided, this additional information.

FDA and FSIS Have Not Fully Coordinated on Drug Residue Testing Methods

Although FDA and FSIS took steps to implement the 2014 MOU and ensure the smooth transfer of catfish oversight responsibility from FDA to FSIS, the agencies have not fully coordinated on drug residue testing methods. For example, the agencies generally did not coordinate in developing drug residue testing methods and the corresponding MRLs—specifically, for unapproved drugs—that define unsafe drug residues in imported seafood, including catfish. As a result, the agencies are not leveraging each other's knowledge and resources to develop drug residue testing methods.

As discussed, FDA and FSIS staff held three teleconferences from May 2015 through June 2016 to discuss the transfer of catfish oversight to FSIS. According to agency officials, the sampling and testing of catfish for drug residues was among the topics discussed, including the drug testing methods being used by each agency. Nevertheless, during the course of our work, we found examples where FDA and FSIS officials, including program directors and laboratory officials, said that they were unaware of the other agency's development and use of more efficient methods to

detect drug residues in seafood, including catfish. These examples include the following:

- FDA officials first learned from us in May 2016 about an MRM used by FSIS that could identify a significantly greater number of drug residues present in food, including catfish, than the MRM being used by FDA for other seafood. Specifically, at that time, FSIS's MRM could identify 61 drug residues, and FDA's MRM could identify 26 residues.
- FDA had not informed FSIS that it was developing a new MRM for testing shrimp, although according to agency officials FDA also expected to adapt the MRM for use in other seafood, including finfish such as catfish. FSIS officials said that they became aware of FDA's work on this new MRM after hearing FDA officials discuss it at a public workshop (the North American Chemical Residue Workshop) in July 2016.
- At the time of our work, FDA was developing two new MRMs that would test for, among other drugs, the antibiotics flumequine, naladixic acid, and oxolinic acid—drugs that do not have FDA approval for use in aquaculture. Pending development of these MRMs, FDA had been using other methods—such as the MRM that tests for 26 drugs—to test for these drugs, including in catfish when FDA had this responsibility. According to FDA officials, the agency tested for these drugs because they were of high enforcement priority based on human food safety concerns and on the extent of use in the aquaculture industry. However, FSIS officials told us in May 2016 that FDA had not informed them of its efforts to develop these two new MRMs, and FSIS did not have its own method to test for these drugs, meaning imported catfish had not been tested for these antibiotics since FSIS assumed responsibility for their safety in April 2016.

As these examples illustrate, neither FDA nor FSIS was aware of MRMs or other testing methods that the other agency was using or developing that might have been helpful for carrying out its oversight program. As we have previously reported, when responsibilities cut across more than one federal agency—as they do for the safety of imported seafood—it is important for agencies to work collaboratively.⁴⁹ Taking into account the nation's long-range fiscal challenges, we noted that the federal government must identify ways to deliver results more efficiently and in a

⁴⁹GAO, *2015 Annual Report: Additional Opportunities to Reduce Fragmentation, Overlap, and Duplication and Achieve Other Financial Benefits*, [GAO-15-404SP](#) (Washington, D.C.: Apr. 14, 2015), [GAO-06-15](#)

way that is consistent with its multiple demands and limited resources. We also identified key practices that can help enhance and sustain federal agencies' collaboration, including identifying and addressing needs by leveraging resources across agencies to support the common outcome. Moreover, in 1984, FDA, FSIS, and the Environmental Protection Agency entered into an MOU committing the agencies, in part, to coordinate their regulatory activities concerning the presence of drug and other residues in food. More specifically, under this MOU, the agencies agreed to exchange information related to analytical methods for identifying and quantifying residues of drugs, pesticides, and environmental contaminants in food, and to cooperate in developing and implementing analytical and statistical methodologies to ensure comparability of results in the examination of food. Thus, by not coordinating on testing methods, FDA and FSIS have not fully met the terms outlined in the 1984 MOU.

Lack of coordination in developing drug residue testing methods has resulted, in some cases, in differences in MRLs for unapproved drugs. These are the levels or thresholds at which the agencies will take regulatory action. In some cases, particularly for an unapproved drug, the MRL may correspond to the limits of detection associated with an agency's particular testing method. In the course of our work, we noted a number of cases where the agencies were using different MRLs for the same unapproved drug. For example, for one antibiotic, the MRL that FSIS considers unsafe is 20 times higher than FDA's level, yet FDA considers anything above its MRL to be a human health concern. In essence, this means that FSIS does not consider catfish with residue levels greater than FDA's MRL, but less than FSIS's MRL, to be adulterated. However, when FDA had oversight of catfish, the same level would have rendered the product adulterated.⁵⁰ We discussed this and other cases with FSIS officials, and they said that FSIS uses FDA's tolerances for drugs that FDA has approved. However, FSIS developed its own MRLs for unapproved drugs, as according to FSIS officials, the agency has the discretion to do so using its own testing methods.

According to FSIS officials, the agency was not aware of FDA's MRLs for unapproved drugs. FSIS officials acknowledged that the agency had not requested information from FDA on its MRLs for unapproved drugs used

⁵⁰This level would render other types of finfish, which FDA still regulates, adulterated as well. Catfish is classified as a finfish.

on finfish, including catfish. For their part, FDA officials said that they do not make public their MRLs for unapproved drugs out of concern that some fish farmers may use these drugs if they believe they can do so in a way that results in residues below FDA's MRLs. Under federal standards for internal control, management should communicate information externally through reporting lines so that external parties can help achieve its objectives. Without coordinating and communicating on their development of drug residue testing methods and corresponding MRLs for imported seafood, including catfish, the agencies do not have reasonable assurance that they are taking a consistent approach to protecting consumer safety from unsafe drug residues.

Conclusions

FDA and FSIS face difficult challenges in ensuring the safety of the U.S. food supply, particularly as that food supply increasingly includes imported foods such as seafood. Because much of imported seafood is raised in confined conditions on farms, drugs are used to prevent or treat disease and increase survival rates. According to FDA, residues of some drugs can cause cancer or allergic reactions when consumed by humans. In addition, some drugs administered to food-producing animals may cause bacteria of human health concern to become resistant to antibiotics used in humans. It is therefore important that federal oversight is effective in ensuring that seafood is free of unsafe drug residues

As required in FSMA, FDA developed a plan in 2013 to expand the capacity of foreign governments and their respective food industries in countries that export foods to the United States. The plan was to include recommendations for formal agreements with other countries that would include provisions to place greater responsibility on these countries for the safety of their seafood exports. However, while FDA has used such agreements for addressing pathogen hazards in molluscan shellfish, it has not done so with respect to drug residues in seafood and has no plans to do so. Without pursuing formal agreements with countries exporting seafood to the United States that commit these countries to test for drugs of concern to FDA and the corresponding MRLs that the agency established for these drugs, FDA will not have reasonable assurance that imported seafood does not contain unsafe drug residues.

FSIS has not decided whether to include, as part of an initial equivalence determination or subsequent verification audits, visits to any foreign catfish farms as part of its on-site audit in another country. However, the 2014 Farm Bill directs FSIS to consider, in part, the conditions under which catfish are raised, and catfish farms are the place where drugs are

introduced. Without visiting at least a sample of farms whose catfish are exported to the United States, such as the farms that supply catfish to the seafood processing facilities that FSIS plans to visit during its on-site audits, FSIS may be missing an opportunity to fully understand the conditions under which the catfish are being raised. In addition, FSIS does not plan to require countries exporting catfish to the United States to test for drugs of concern to FSIS as part of their drug residue monitoring plans. By having countries exporting catfish to the United States include in their national residue monitoring plans the drugs of concern to FSIS and the corresponding MRLs, as a precondition for equivalence determinations, FSIS would have better assurance that U.S. food safety requirements were being met and that U.S. consumers were being protected.

Finally, FDA and FSIS are independently developing drug testing methods and MRLs for use in seafood, and lack of coordination and communication in developing drug residue testing methods has resulted, in some cases, in differences in MRLs—specifically, for unapproved drugs. Without coordinating and communicating on their development of drug residue testing methods and corresponding MRLs for imported seafood, including catfish, the agencies do not have reasonable assurance that they are taking a consistent approach to ensuring consumer safety from unsafe drug residues.

Recommendations for Executive Action

We are making a total of five recommendations, including two to FDA and three to FSIS:

The Commissioner of FDA should pursue formal agreements with countries exporting seafood to the United States that commit these countries to test for drugs of concern to FDA and the corresponding MRLs that FDA established for these drugs. (Recommendation 1)

The Administrator of FSIS should ensure that agency staff doing an on-site audit in another country for an equivalence determination visit at least a sample of farms whose catfish are exported to the United States to determine the conditions under which the catfish are being raised, including the drugs being used. (Recommendation 2)

The Administrator of FSIS should require as part of an equivalence determination that countries exporting catfish to the United States include in their residue monitoring plans the drugs of concern to FSIS and the corresponding maximum residue levels. (Recommendation 3)

The Commissioner of FDA should coordinate and communicate with FSIS in developing drug residue testing methods and corresponding maximum residue levels for imported seafood that may also be applicable to imported catfish. (Recommendation 4)

The Administrator of FSIS should coordinate and communicate with FDA in developing drug residue testing methods and corresponding maximum residue levels for imported catfish that may also be applicable to other imported seafood. (Recommendation 5)

Agency Comments and Our Evaluation

We provided a draft of this report to USDA and the Departments of Commerce, Health and Human Services, and Homeland Security for their review and comment. In written comments, Health and Human Services's FDA agreed with one of the recommendations and partially agreed with the other. FDA also provided technical comments, which we incorporated as appropriate. In written comments, USDA's FSIS partially agreed with two of the recommendations and stated that its current policy already addresses the third recommendation. Copies of Health and Human Services's and USDA's comments are presented in appendixes III and IV, respectively. In an email, the Department of Homeland Security's GAO-Office of Inspector General Liaison Office stated that, because there were no recommendations directed to the department, it would forego a formal management response letter but provided one technical comment, which we incorporated. Likewise in an e-mail, the Department of Commerce's National Oceanic and Atmospheric Administration Audits Office stated that the agency did not have any technical comments.

In its written comments, FDA agreed with our recommendation that it should coordinate and communicate with FSIS in developing drug residue testing methods and corresponding maximum residue levels for imported seafood that may also be applicable to imported catfish. FDA stated that it has a process in place to notify FSIS of new tolerances and changes in tolerances for FSIS-regulated products and that it will extend this process to notify FSIS of concentrations of specific unapproved drugs in catfish over which FDA has public health concerns. In addition, FDA stated that it has contacted FSIS about rejoining the quarterly meetings FDA holds on aquaculture method prioritization and development.

FDA partially agreed with our recommendation that it should pursue formal agreements with countries exporting seafood to the United States that commit these countries to test for drugs of concern to FDA and the corresponding MRLs that FDA established for these drugs. FDA stated

that, while it had not received any requests to establish this type of arrangement, it concurs that the agency could explore pursuing such arrangements. FDA also stated that factors outside its control that could limit robust implementation of this recommendation include the country's ability and readiness to comply with the requirements necessary to have a successful arrangement. FDA added that applicable test methods, analytical capacity and adequate government oversight would be among essential criteria. We recognize that there are external factors that could affect FDA's implementation of this recommendation, but we do not believe such factors should prevent FDA from pursuing formal agreements with other countries related to testing seafood for drugs of concern and the related MRLs for these drugs, as these factors have not hindered the EU and other countries that have successfully pursued such agreements.

In its written comments, FSIS stated that the draft report contains a few either misleading or inaccurate statements that it believes we use to support our recommendations directed at USDA. For example, FSIS points to our statement that "FSIS has not made farm visits a routine part of initial equivalence determinations and verification on-site audits...." According to FSIS, this statement is somewhat misleading, because FSIS has not made any initial equivalence determinations for foreign catfish fish inspection systems;⁵¹ therefore, FSIS has not yet had the opportunity to conduct on-site verification audits of foreign catfish inspection programs for initial equivalence determinations. FSIS stated that it partially agrees with the recommendation that FSIS visit at least a sample of farms whose catfish are exported to the United States to determine the conditions under which the fish are raised. We are aware that FSIS has not yet conducted on-site audits, and we discuss in our report the timing of those audits once the agency receives the required information and documentation from foreign governments. However, we nonetheless believe it is important that FSIS visit at least a sample of catfish farms as a routine matter during its equivalence determination on-site audits, instead of relying on a review of documentation describing a foreign country's fish farm oversight program. We believe that FSIS can best

⁵¹FSIS stated that it is more accurate to use the term Siluriformes fish throughout the report, as it is the order of fish under FSIS jurisdiction, and that by using the term "catfish" throughout the report, it appears to invalidate the clarification in the 2014 amendment (Sec. 12106) in the Agricultural Act of 2014, which GAO may not have intended. Consistent with all of our reports on this issue, we use the term catfish to refer to Siluriformes fish.

understand the conditions under which catfish are raised and obtain information about the drugs actually used on farms through in-person visits to these farms, as FDA and the EU do as part of their seafood oversight efforts. As noted in our report, FSIS will already have its inspectors in the foreign country for on-site audits, so these individuals could also visit the farms that supply catfish to the seafood processing facilities that FSIS plans to visit during its on-site audits. FSIS could also independently verify any foreign country information about its catfish farm oversight program through visits to catfish farms.

FSIS stated that its current policy already addresses our recommendation that it require, as part of an equivalence determination, that countries exporting catfish to the United States include in their residue monitoring plans the drugs of concern to FSIS and the corresponding maximum residue levels. FSIS identifies as misleading or inaccurate our statement that, “while FSIS will test domestic catfish for at least 61 drugs using its multi-residue method and other methods, it is not clear how many drugs or which drugs other countries will test for in catfish exported to the United States.” According to FSIS, this statement is incorrect, as foreign countries are required to provide drug testing information to the agency as part of the Self-Reporting Tool (SRT), which is a requirement for an initial or ongoing equivalence determination. In addition, FSIS stated that it will also have access to information on a foreign country’s testing for drug residues through the SRT and the country’s residue monitoring plan. Further, after reviewing those plans, according to FSIS, the agency can request changes to the plan for testing for drug residues. We disagree that FSIS policy already addresses our recommendation. In our report, we explain the type of information that foreign countries will provide in the SRT as well as the information that foreign countries will be required to include in their residue monitoring plan. However, a foreign country will decide what drugs it will test for. FSIS could question the design of the residue monitoring plan if it identified unsafe drug residues based on its own testing. Nevertheless, FSIS does not plan to test all catfish imports because its reinspection program is not designed to be the primary means by which the agency identifies unsafe drug residues in imported catfish. Rather than address potential testing gaps in a foreign country’s residue monitoring program piecemeal, FSIS should require that foreign countries test for all drugs of concern to FSIS at the outset of the equivalence determination, thus ensuring that foreign countries are demonstrating that their measures are as effective as FSIS’s in addressing the safety of imported catfish.

FSIS partially agreed with our recommendation that FSIS should coordinate and communicate with FDA in developing drug residue testing methods and corresponding MRLs for imported catfish that may also be applicable to other imported seafood. In its comments, FSIS noted that while we found examples where FDA and FSIS officials, including program directors and laboratory officials, were unaware of the other agency's development and use of more efficient methods to detect drug residues in seafood, including catfish, they believe that the characterization of this finding is overstated. FSIS stated that while our audit work may have found examples where officials were unaware of a specific activity, the U.S. Agricultural Research Service, FSIS, and FDA regularly share information related to analytical methods for identifying and quantifying residues of drugs, pesticides, and environmental contaminants. Nevertheless, FSIS stated that it fully intends to implement the provisions of the MOU with FDA on coordinating on testing methods and that it also intends to enhance residue testing coordination through other interagency mechanisms as well, such as the Surveillance Advisory Team and the Interagency Residue Control Group.

As agreed with your office, unless you publicly announce the contents earlier, we plan no further distribution of this report until 30 days from the report date. At that time, we will send copies to the appropriate congressional committees; the Secretaries of Agriculture, Commerce, Health and Human Services, and Homeland Security; and other interested parties. In addition, the report will be available at no charge on the GAO website at <http://www.gao.gov>.

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



Sincerely yours,

Steve Morris
Director, Natural Resources and Environment

Appendix I: Objectives, Scope and Methodology

This report addresses how the Food and Drug Administration (FDA) and U.S. Department of Agriculture's (USDA) Food Safety and Inspection Service (FSIS) ensure the safety of imported seafood from unsafe drug residues. Specifically, this report examines (1) how FDA helps ensure the safety of imported seafood from unsafe drug residues and ways the agency could strengthen its efforts, (2) how FSIS helps ensure the safety of imported catfish from unsafe drug residues and ways the agency could strengthen its efforts, and (3) the extent to which FDA and FSIS coordinate their oversight efforts. Unsafe drug residues may include residues

- from drugs unapproved for aquaculture use in the United States,
- of approved drugs that exceed allowed levels, or
- of drugs that are approved for use on one seafood species but are being inappropriately used on another seafood species.

To review how FDA helps ensure the safety of imported seafood from unsafe drug residues, we examined FDA regulations, including Hazard Analysis and Critical Control Point (HACCP) regulations. We also reviewed information on FDA's primary oversight mechanism—HACCP inspections of seafood importers and foreign country processing facilities—and its seafood import sampling program, including information on the major components and requirements of these mechanisms. We reviewed relevant sections of FDA guidance manuals, including its *Compliance Program Guidance Manual*, *Regulatory Procedures Manual*, *Office of Regulatory Affairs Laboratory Manual*, and *Fish and Fishery Products Hazards and Controls Guidance - Fourth Edition*. We also reviewed plans and other documents detailing FDA's drug residue sampling program and procedures for its import alert and refusal processes. We analyzed FDA mechanisms for protecting imported seafood from violative drug residues. Specifically, we analyzed 74 randomly selected foreign facility (e.g., processing) inspection reports from a total of 318 reports for fiscal years 2013 through 2015. We also analyzed 9 non generalizable, randomly selected importer inspection reports out of 232 total reports for fiscal year 2015.¹

¹One of the 10 reports for New Zealand was omitted because it is not required to identify affirmative steps because it has a systems recognition agreement with the United States. Systems recognition means that FDA identified the country as having a comparable food safety system to the United States. As such, it is subject to different requirements than what the agency has for seafood imports from other countries, according to FDA officials.

To examine the ways FDA could strengthen its efforts to ensure the safety of imported seafood from unsafe drug residues, we reviewed FDA's use of agreements with foreign countries that address FDA requirements regarding drug residues in farmed seafood and their importance, given limitations in other activities FDA undertakes to ensure the safety of imported seafood. We reviewed legal and planning documents regarding the use of agreements by FDA, including the FDA Food Safety Modernization Act and FDA's 2013 International Food Safety Capacity-Building Plan. We reviewed a 2012 agreement with Mexico intended to ensure that all molluscan shellfish exported to the United States from Mexico are safe. In addition, we reviewed FDA's foreign country assessment criteria and reports for Ecuador (2013), India (2010), Malaysia (2011), the Philippines (2015), and Vietnam (2012) and how any FDA-identified deficiencies were resolved. FDA conducts foreign country assessments to provide the agency with a broad view of a foreign country's industry and regulatory infrastructure capacity to control aquaculture drugs. We also compared FDA activities to the activities FSIS and the European Union (EU) undertake as part of their equivalence determinations to determine if there are any elements of their activities that if included in FDA activities, have the potential to enhance FDA's oversight process for imported seafood.

In addition, we analyzed FDA's import refusal data and data on FDA's import drug residue test results for fiscal years 2010 to 2015. For FDA's import drug residue test data, we corrected the product codes for some entries for which the code did not match the product description and two analysts reviewed any changes made to FDA records to ensure that the revised codes were correct. We also reviewed controls for the systems that house these data and interviewed FDA officials regarding these controls and determined that the data were sufficiently reliable for the purposes of our reporting objectives. We analyzed the National Oceanic and Atmospheric Administration's (NOAA) seafood import volume data for 2010 through 2015 that it acquired from the Department of Commerce and U.S. Customs and Border Protection (CBP) to enable us to identify how many millions of pounds were imported for each type of seafood so that we could compare this to FDA sampling data. We reviewed controls related to the reliability of these data and determined that they were sufficiently reliable for the purposes of our reporting objectives. Specifically, we reviewed a document on the data quality assessment of this information by the U.S. Census Bureau and compared the data to import data generated by another federal agency—USDA's Economic Research Service.

The final year selected for FDA data (foreign processing facility and importer inspection reports and import refusal data and data on FDA's import drug residue test results) and NOAA import volume data was the most recent year for which complete data were available at the time of our analysis.

To examine how FSIS helps ensure the safety of imported catfish from unsafe drug residues, we reviewed information on how the agency was implementing its catfish inspection program during the program's transition period from March 1, 2016, to September 1, 2017, and how it planned to implement its equivalence determination process for catfish. Specifically, for the transition period, we reviewed the 2015 final rule that established the catfish inspection program; FSIS notice and other information on the catfish inspection program requirements; sampling and testing guidance during the transition period, including Hold and Test Protocols; FSIS data on sampling and testing and the results; FSIS data on catfish import sampling from May 1, 2016, through July 9, 2017; and FSIS's *Chemistry Laboratory Guidebook*, including the Screening and Confirmation of Animal Drug Residues Method (CLG-MRM1.06). We also reviewed the agency's controls for the systems that house these data and determined that the data were sufficiently reliable for the purposes of our reporting objectives. For example, we interviewed FSIS officials regarding supervisory approvals of test results input into their system and controls included in their efforts to comply with international standards.

For FSIS's plans for implementing its equivalence determination process after the end of the transition period, we reviewed FSIS regulations, guidance, and other documentation related to FSIS's equivalence determination process as currently used for meat, poultry, and processed egg products. Specifically, we reviewed the steps FSIS takes to determine equivalence, including the Self-Reporting Tool that the agency provides to the foreign governments that ask for equivalence determinations, which contains the general information required from the foreign countries. We reviewed FSIS guidance on the agency's periodic audits of countries to verify continued equivalence and two reports resulting from these audits that FSIS conducted of countries that have already been determined to be equivalent for meat and poultry. We also reviewed FSIS's reinspection program for monitoring the effectiveness of exporting countries' inspection systems and overall food safety programs through imported product examinations and residue testing. We reviewed an example of how FSIS places responsibility on foreign governments to take corrective actions when the agency finds that imported products are adulterated because of contaminants such as violative drug residues.

To examine the ways, if any, FSIS could strengthen its efforts to ensure the safety of imported catfish from unsafe drug residues, we reviewed FSIS plans for its on-site equivalence determinations and verification audits and compared these activities to the activities FDA and the EU undertake as part of their foreign country assessments and equivalence determinations, respectively, to determine if there are any elements of their activities that if included in FSIS activities, have the potential to enhance FSIS's equivalence determinations and verification on-site audits. We also reviewed FSIS's proposed requirements for foreign countries' residue monitoring plans. Lastly, we reviewed the EU's requirements for foreign countries' residue monitoring plans as well to determine whether there were any specific EU requirements that could enhance FSIS's residue monitoring plan requirements. We reviewed the EU's equivalence determination process and, in particular, its seafood import program to determine whether its practices for ensuring the safety of seafood imports have the potential to enhance the U.S. agencies' practices. We discussed the EU equivalence determination process and verification audits with EU officials from the Food and Veterinary Office (Grange, Ireland) to gain a better understanding of its programs and oversight controls for seafood imports. We included the EU program in the scope of our work because the EU is the largest importer of seafood in the world.

To review the extent to which FDA and FSIS collaborate and coordinate in imported seafood and catfish safety programs, we reviewed a 1984 memorandum of understanding (MOU) signed by FDA, FSIS, and the Environmental Protection Agency that was developed to help promote more effective, efficient, and coordinated federal regulatory activities concerning drug residues. We reviewed the general activities of the Interagency Residue Control Group and Surveillance Advisory Team, which constitute the primary vehicles through which these agencies coordinate their regulatory activities concerning the presence of drug residues. We reviewed the April 2014 MOU between FDA and FSIS that was developed, in part, to improve interagency cooperation on food safety and fraud prevention with regard to the transfer of catfish inspection from FDA to FSIS. We reviewed steps FDA and FSIS have taken to collaborate on transferring responsibility for the oversight of catfish. We reviewed general information on the multi-residue methods (MRM) FDA is developing to test for drug residues in seafood and the MRM FSIS developed for testing catfish for drug residues. We reviewed a March 2010 USDA Office of Inspector General report on how the Interagency Residue Control Group and Surveillance Advisory Team were established and currently functioning. We compared their

coordination activities to key practices that can help enhance and sustain federal agencies' collaboration that we previously identified, particularly the practice of identifying and addressing needs by leveraging resources when responsibilities cut across more than one federal agency.²

We met with FDA and FSIS officials to discuss information for all objectives, including obtaining their views on the pros and cons of opportunities to strengthen their programs regarding unsafe drug residues in imported seafood. We reviewed past GAO reports relevant to this topic.³

We interviewed CBP officials in headquarters and at selected U.S. ports of entry to gain a better understanding of the agencies' programs. We interviewed CBP officials at the Port of New York in Newark, New Jersey—the largest port of entry for seafood products in the United States—and toured CBP's facilities to observe its examination of seafood. We also interviewed FSIS officials at a reinspection facility in Newark and observed the reinspection process. In addition, we visited and interviewed CBP officials at the Port of Long Beach in Long Beach, California—the second largest port of entry for seafood in the United States. Further, we interviewed CBP officials at the Otay Mesa Land Crossing and Cargo Facility in Otay Mesa, California, to learn about CBP's activities related to ensuring the safety of seafood imports and CBP's interaction with FDA and FSIS, and observed CBP's review process for imported seafood. The Otay Mesa crossing is in proximity to the Long Beach Port. We selected the largest and second largest ports of entry for seafood into the United States and selected a land port that is in close proximity to one of the seaports. We also interviewed FDA officials at the agency's Southwest Import District's Resident Post at Otay Mesa, California, and at the Los Angeles District Office and Pacific Regional Laboratory in Irvine, California, to discuss FDA's testing of seafood imports for drug residues with laboratory officials. In addition, we visited an FSIS import inspection

²GAO, *Results-Oriented Government: Practices That Can Help Enhance and Sustain Collaboration among Federal Agencies*, [GAO-06-15](#) (Washington, D.C.: Oct. 21, 2005).

³GAO, *Seafood Safety: Status of Issues Related to Catfish Inspection*, [GAO-17-289T](#) (Washington, D.C.: Dec. 7, 2016); *Food Safety: FDA Can Better Oversee Food Imports by Assessing and Leveraging Other Countries' Oversight Resources*, [GAO-12-933](#) (Washington, D.C.: Sept. 28, 2012); *Seafood Safety: Responsibility for Inspecting Catfish Should Not Be Assigned to USDA*, [GAO-12-411](#) (Washington, D.C.: May 10, 2012); *Seafood Safety: FDA Needs to Improve Oversight of Imported Seafood and Better Leverage Limited Resources*, [GAO-11-286](#) (Washington, D.C.: Apr 14, 2011); [GAO-06-15](#). Also see Related GAO Products at the end of the report.

establishment in Vernon, California—close to the Long Beach port—to learn about the measures FSIS uses to ensure that imported catfish do not have unsafe drug residues. We also interviewed officials from the National Marine Fisheries Service in the Department of Commerce to gather information on their imported seafood inspection services performed on a fee-for-service basis for private companies, including any data on sampling of imported seafood for drug residues and associated results.

For informational purposes, we spoke with representatives from one large and one medium-sized catfish farm, Tackett Fish Farms and Pentecost Brothers, respectively; one large catfish processor, Heartland Catfish Company; a large feed mill that produces medicated feed, Fishbelt Feed, Inc.; and the National Warmwater Aquaculture Center at the Mississippi State University Extension Service. To gain stakeholders' perspectives on FDA's and FSIS's efforts to address the safety of seafood imports, we also spoke with representatives from the National Fisheries Institute. According to its website, the institute focuses on education about seafood safety and other issues, and includes more than 200 member companies including seafood processors, importers, and exporters. We also spoke with a representative of the Consumer Federation of America. According to its website, the Consumer Federation of America is an association of non-profit consumer organizations that was established to advance the consumer interest through research, advocacy, and education. Today, nearly 300 groups participate in the federation and govern it through representatives on the organization's Board of Directors.

We conducted this performance audit from January 2016 to September 2017 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's Drug Residue Testing for Imported Seafood

Table 1 shows the number of seafood samples that the Food and Drug Administration tested for drugs and the number and percentage of those samples that contained unsafe drug residues, as well as the volume of seafood imported, for fiscal years 2010 through 2015.

Table 2: Numbers of Imported Seafood Samples Tested by the Food and Drug Administration (FDA) and Percentage Found to Contain Unsafe Drug Residues, and Volume of Seafood Imported, Fiscal Years 2010 through 2015

Seafood type	Fiscal year	Volume imported (in millions of pounds)	Samples tested for drugs	Samples containing unsafe drug residues	Unsafe samples as a percentage of total samples
Catfish	2010	137	88	2	2.3
	2011	203	74	1	1.4
	2012	237	134	7	5.2
	2013	259	99	0	0
	2014	237	67	0	0
	2015	250	33	3	9.1
Salmon	2010	515	105	1	1.0
	2011	529	93	0	0
	2012	618	90	0	0
	2013	655	87	1	1.2
	2014	695	68	0	0
	2015	758	86	0	0
Shrimp	2010	1,234	388	9	2.3
	2011	1,269	415	19	4.6
	2012	1,177	336	12	3.6
	2013	1,113	421	18	4.3
	2014	1,251	396	30	7.6
	2015	1,292	550	67	12.2
Tilapia	2010	474	298	14	4.7
	2011	432	316	6	1.9
	2012	503	274	3	1.1
	2013	504	283	4	1.4
	2014	507	200	1	.5
	2015	495	258	28	10.9
Other	2010	3,169	129	17	13.2
	2011	3,086	172	26	15.1
	2012	3,030	168	6	3.6
	2013	3,097	155	11	7.1
	2014	3,106	116	11	9.5

Appendix II: FDA's Drug Residue Testing for Imported Seafood

Seafood type	Fiscal year	Volume imported (in millions of pounds)	Samples tested for drugs	Samples containing unsafe drug residues	Unsafe samples as a percentage of total samples
	2015	3,142	213	14	6.6
Total	2010	5,529	1,008	43	4.3
	2011	5,519	1,070	52	4.9
	2012	5,564	1,002	28	2.8
	2013	5,627	1,045	34	3.3
	2014	5,798	847	42	5.0
	2015	5,937	1,140	112	9.8
	2010-2015	33,974	6,112	311	5.1

Source: GAO analysis of Food and Drug Administration, Department of Commerce, and U.S. Customs and Border Protection data. | GAO-17-443

Note: The number of samples tested by FDA and the associated results are not intended to be statistically valid for projection purposes. Instead, FDA uses a risk-based computerized tool for admissibility screening and determining which products to examine and test based on various factors, such as past violations history and country of origin. In addition, the sample sizes that are particularly small may convey a level of precision that can be misleading because they can greatly change with minor changes in the data.

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



DEPARTMENT OF HEALTH & HUMAN SERVICES

OFFICE OF THE SECRETARY

Assistant Secretary for Legislation
Washington, DC 20201

AUG 30 2017

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

Dear Mr. Morris:

Attached are comments on the U.S. Government Accountability Office's (GAO) report entitled, *"Imported Seafood Safety: FDA and USDA Could Strengthen Efforts to Prevent Unsafe Drug Residue"* (GAO-17-443).

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

Sincerely,

A handwritten signature in cursive script that reads "Barbara Pisaro Clark".

Barbara Pisaro Clark
Acting Assistant Secretary for Legislation

Attachment

**GENERAL COMMENTS OF THE FOOD AND DRUG ADMINISTRATION (FDA) ON
THE GOVERNMENT ACCOUNTABILITY OFFICE'S DRAFT REPORT ENTITLED:
IMPORTED SEAFOOD SAFETY: FDA AND USDA COULD STRENGTHEN EFFORTS
TO PREVENT UNSAFE DRUG RESIDUES (GAO-17-443)**

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

GAO Recommendation

The Commissioner of the Food and Drug Administration (FDA) should pursue formal agreements with countries exporting seafood to the United States that commit these countries to test for drugs of concern to FDA and the corresponding maximum residual levels (MRLs) that FDA established for these drugs.

HHS Response

HHS partially concurs with GAO's recommendation.

While FDA has not received any requests to establish this type of arrangement, we concur that the Agency can explore pursuing formal arrangements with countries exporting seafood to the United States that commit these countries to test for drugs of concern to FDA and the corresponding MRLs established for these drugs. Factors outside the agency's control that could limit robust implementation of this recommendation include the country's ability and readiness to comply with the requirements necessary to have a successful arrangement. Applicable test methods, analytical capacity and adequate government oversight would be among essential criteria. FDA will continue to use its existing tools to ensure the safety of seafood imported into the United States and, in the event an arrangement is signed, may consider appropriate modifications.

GAO Recommendation

The Commissioner of FDA should coordinate and communicate with FSIS in developing drug residue testing methods and corresponding maximum residue levels for imported seafood that may also be applicable to imported catfish.

HHS Response

HHS concurs with GAO's recommendation.

FDA has a process in place to notify the U.S. Department of Agriculture (USDA) Food Safety and Inspection Service (FSIS) of new tolerances and changes in tolerances for FSIS-regulated products. FDA will extend this process to notify FSIS of concentrations of specific unapproved drugs in catfish over which FDA has public health concerns.

In addition, FDA has contacted FSIS about re-joining the quarterly meetings FDA holds on aquaculture method prioritization and development. The primary FSIS personnel who should attend the Aquaculture method prioritization and development meetings are those involved in laboratory residue analysis. At the annual Surveillance Advisory Team (SAT) review of the FSIS United States National Residue Program (NRP) on June 15, 2017, FSIS and FDA agreed to work on better communication about the FSIS catfish program at the monthly Interagency Residue Control

GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S DRAFT REPORT ENTITLED: HIGH-CONTAINMENT LABORATORIES: IMPROVED OVERSIGHT OF DANGEROUS PATHOGENS NEEDED TO MITIGATE RISK (GAO-16-642)

Group (IRCG) meetings. The SAT is an interagency committee comprised of representatives from FSIS, FDA, the Environmental Protection Agency (EPA), USDA Agricultural Marketing Service, USDA Agricultural Research Service, and the Centers for Disease Control and Prevention (CDC). It consists of experts in veterinary medicine, toxicology, chemistry, and public health who provide professional advice, as well as information on veterinary drug and pesticide use in animal husbandry. The purpose of the SAT is to enhance communication, which includes obtaining and evaluating relevant toxicity and exposure information for each compound that supports the NRP. The IRCG is a large meeting with input from many parts of FSIS, other parts of USDA, FDA, EPA and CDC.

Appendix IV: Comments from the U.S. Department of Agriculture



United States Department of Agriculture

Food Safety and
Inspection Service

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20250

Steve D. Morris
Director
Natural Resources and Environment
United States Government Accountability Office
441 G Street, N.W.
Washington, DC

AUG 24 2017

Dear Mr. Morris,

The United States Department of Agriculture (USDA) appreciates the opportunity to review the U.S. Government Accountability Office's (GAO) draft report entitled *Imported Seafood Safety: FDA and USDA Could Strengthen Efforts to Prevent Unsafe Drug Residues* (GAO-17-443).

General Comments

The draft report contains a few either misleading or inaccurate statements that GAO uses to support recommendations directed at USDA. We address these below and provide our planned corrective actions for each of the recommendations for executive action that are directed at USDA.

The draft report (page 25) states the following: "FSIS has not made farm visits a routine part of initial equivalence determinations and verification on-site audits..." This statement is somewhat misleading. FSIS has not made any initial equivalence determinations for foreign Siluriformes fish inspection systems. Therefore, FSIS has not yet had the opportunity to conduct on-site verification audits of foreign Siluriformes fish inspection programs for initial equivalence determinations.

The draft report (page 32) states the following: "However, while FSIS will test domestic catfish for at least 61 drugs using its [Multi-Residue Method] MRM and other methods, it is not clear how many drugs or which drugs other countries will test for in catfish exported to the United States, because FSIS will not have such specific requirements for a foreign country's residue monitoring plan after the transition period." This statement appears to imply that FSIS will not know how many drugs or which drugs other countries will test for in Siluriformes fish exported to the United States. This is incorrect, as these countries are required to provide this information to FSIS as part of the Self-Reporting Tool (SRT), which is a requirement for an initial or ongoing equivalence determination.

The draft report (page 35) states the following: "Nevertheless, during the course of our work, we found examples where FDA and FSIS officials, including program directors and laboratory officials, said that they were unaware of the other agency's development and use of more efficient methods to detect drug residues in seafood, including catfish." We believe the characterization of your findings is overstated.

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While your audit work may have found examples where officials were unaware of a specific activity, ARS, FSIS, and FDA regularly exchange information related to analytical methods for identifying and quantifying residues of drugs, pesticides, and environmental contaminants.

Finally, it is more accurate to use the term Siluriformes fish throughout this report, as it is the order of fish under FSIS jurisdiction. While the explanation that you provided in the official draft report is correct, the purpose of the amendment (Sec. 12106) in the Agricultural Act of 2014 was to clarify that fish of the order Siluriformes are an amenable species, subject to the appropriate provisions of the Federal Meat Inspection Act. By using the term “catfish” throughout the report, it appears to invalidate the clarification in the 2014 amendment, which GAO may not have intended.

USDA Responses to GAO Recommendations for Executive Action

GAO Recommendation:

The Administrator of FSIS, when doing an on-site audit in another country for an equivalence determination, should visit at least a sample of farms whose catfish are exported to the United States to determine the conditions under which the catfish are being raised, including the drugs being used.

USDA Response:

FSIS partially agrees with this recommendation. The Agricultural Act of 2014 (2014 Farm Bill) requires FSIS to take into account the conditions under which Siluriformes fish are raised. FSIS will perform on-site verification audits as part of its initial equivalence process to ensure that the foreign country’s on-farm controls for producing Siluriformes fish and fish products are implemented as documented. This audit may include farm visits as part of the onsite audits. For example, if establishments in a country have produced Siluriformes fish products that the Central Competent Authority (CCA) or FSIS has found positives of chemicals or pesticides, FSIS would include farm visits as part of the audit. In other situations, FSIS might not visit the farm. However, during the audit, the auditor would verify that the CCA has sufficient on-farm controls based on records reviews at the CCA offices and observations of activities and records at establishments and laboratories.

GAO Recommendation:

The Administrator of FSIS should require as part of an equivalence determination that countries exporting catfish to the United States include in their residue monitoring plans the drugs of concern to FSIS and the corresponding maximum residue levels.

USDA Response:

FSIS’ current policy already addresses this recommendation. For a foreign country to be eligible to export meat (which may include Siluriformes fish), poultry, or egg products to the United States, it must show that its inspection system for meat, poultry, or egg products is equivalent to that of the United States. This means that the country must demonstrate that it either employs the same measures as the United States, and many foreign countries take this approach, or that the measures that it employs, while different from those of the United States, provide an

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equivalent level of public health protection as those of the United States. To be equivalent, FSIS requires countries to routinely assess their chemical residue plans to identify potential chemical residue concerns unique to their country and develop a plan that addresses those chemical concerns. Accordingly, FSIS recognizes there to be certain differences in foreign countries' chemical residue programs because of differences in how countries address chemical residue concerns. Countries must demonstrate that their measures are as effective as those that FSIS takes to address a food safety issue. FSIS must find that a foreign country is employing measures that ensure that there are no unsafe residues of the drugs in product that the country wishes to ship to the United States, or that country is not eligible to export to the United States.

Foreign countries that are currently shipping Siluriformes fish or Siluriformes fish product to the United States must submit in their SRTs, by September 1, 2017 (the end of the transitional period), documentation demonstrating that their system for controlling chemical residues provides an equivalent level of protection to that of the United States. No country has been determined yet to be equivalent for Siluriformes fish or Siluriformes fish products. For initial equivalence, the country must provide information about its residue sampling program to support that the program is equivalent. The foreign country is required to describe the design of its chemical residue control program, its basis (e.g., whether it is risk based or statistically based), and the government's role in oversight of the development and implementation of the program. The submission must also include information about the overall design, analytical methods, how the government decides which chemicals to sample and analyze for, and how they react to violative findings. The country must also provide FSIS with a sampling plan that describes the frequency of sampling, number of samples collected, and analyses performed for each sampling location and product.

FSIS conducts an in-depth review of the foreign country's SRT submission, including information submitted about its chemical residue control program to determine whether it is equivalent. Fish exported to the United States may contain residues only within the tolerances set by FDA and EPA at 21 CFR 556 and 40 CFR 180, respectively. FSIS would question the design of a program if compounds are detected at FSIS' point of entry testing that are not addressed by the country's residue plan, or if FSIS has other reasons to believe that the compounds are in active use in the exporting country and the country is not testing for them. If a foreign country does not have a residue program that is equivalent to FSIS' program, it does not have an equivalent inspection system, and thus would not be determined eligible to continue exporting Siluriformes fish and fish products to the United States.

To maintain ongoing equivalence after an initial equivalence determination, the foreign country must submit the following: a complete list of chemical residues that will be sampled and analyzed in the upcoming year, the analytical methods for each chemical compound, the analytical results from the previous year, and a description of how and what changes are made to its sampling plans one year to the next.

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GAO Recommendation:

The Administrator of FSIS should coordinate and communicate with FDA in developing drug residue testing methods and corresponding maximum residue levels for imported catfish that may also be applicable to other imported seafood.

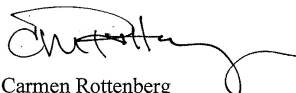
USDA Response:

FSIS partially agrees with this recommendation. FSIS will coordinate and communicate with FDA in developing drug residue methods and corresponding maximum residue levels for imported Siluriformes fish. Extension of either methods or detection levels to other seafood commodities is beyond FSIS' regulatory responsibility. FSIS fully intends to implement the provisions of the Memorandum of Understanding (MOU) with FDA on coordinating on testing methods, and will enhance residue testing coordination and collaboration through the Surveillance Advisory Team (SAT) and Interagency Residue Control Group (IRCG) meetings.

Relatedly, the Agricultural Research Service (ARS) undertakes or coordinates research that addresses FSIS' needs regarding the development and validation of methods for the detection of drug residues, including Siluriformes fish, with one project currently tasked with this effort. Research accomplishments are transferred to FSIS when applicable and technically possible. FDA is also made aware of analytical methods through various means, such as the publication of adopted FSIS methods in the Chemistry Laboratory Guidebook, and at Annual Research Meetings with ARS, FSIS, and FDA.

Again, thank you for the opportunity to review and comment on this draft report.

Sincerely,



Carmen Rottenberg
Acting Deputy Under Secretary
Office of Food Safety

Appendix V: GAO Contact and Staff Acknowledgments

GAO Contact

Steve Morris, (202) 512-3841 or morriss@gao.gov

Staff Acknowledgments

In addition to the contact named above, Anne Johnson (Assistant Director), James R. Jones, Jr. (Assistant Director), David Moreno (Analyst-in-Charge), Beverly Peterson, and Zachary Sivo made key contributions to this report. Important contributions were also made by Kevin Bray, John Delicath, Michele Fejfar, Ying Long, Danny Royer, and Kiki Theodoropoulos.

Related GAO Products

Seafood Safety: Status of Issues Related to Catfish Inspection. [GAO-17-289T](#). Washington, D.C.: December 7, 2016.

Imported Food Safety: FDA's Targeting Tool Has Enhanced Screening, but Further Improvements Are Possible. [GAO-16-399](#). Washington D.C.: May 26, 2016.

2015 Annual Report: Additional Opportunities to Reduce Fragmentation, Overlap, and Duplication and Achieve Other Financial Benefits. [GAO-15-404SP](#). Washington D.C.: April 14, 2015.

Food Safety: Additional Actions Needed to Help FDA's Foreign Offices Ensure Safety of Imported Food. [GAO-15-183](#). Washington D.C.: January 30, 2015.

Food Safety: FDA Can Better Oversee Food Imports by Assessing and Leveraging Other Countries' Oversight Resources. [GAO-12-933](#). Washington D.C.: September 28, 2012.

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

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

Seafood Fraud: FDA Program Changes and Better Collaboration among Key Federal Agencies Could Improve Detection and Prevention.

[GAO-09-258](#). Washington D.C.: February 19, 2009.

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

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

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