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FOOD SAFETY

FDA's Imported Seafood Safety Program Shows Some Progress, but Further Improvements Are Needed



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Highlights of [GAO-04-246](#), a report to congressional requesters

Why GAO Did This Study

More than 80 percent of the seafood that Americans consume is imported. The Food and Drug Administration (FDA) is responsible for ensuring that imported seafood is safe and produced under sanitation and safety systems comparable to those of the United States. Since GAO reported in 2001 that FDA's seafood inspection program did not sufficiently protect consumers, additional concerns have arisen about imported seafood containing banned substances, such as certain antibiotics. In this review, GAO was asked to evaluate (1) FDA's progress in implementing the recommendations in the 2001 report and (2) other options to enhance FDA's oversight.

What GAO Recommends

GAO recommends that FDA (1) work toward developing a memorandum of understanding with NOAA to use NOAA's resources; (2) make it a priority to establish equivalence or other agreements, starting with countries having high-quality food safety systems; (3) develop a system to track the time involved in processing enforcement actions; (4) give enforcement priority to violations posing the most serious risks; (5) consider accrediting private laboratories; and (6) explore the potential for certifying third-party inspectors. FDA generally agreed with all but the recommendation on making it a priority to establish equivalence or other agreements.

www.gao.gov/cgi-bin/getrpt?GAO-04-246.

To view the full product, including the scope and methodology, click on the link above. For more information, contact Lawrence J. Dyckman at (202) 512-3841 or dyckmanl@gao.gov.

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What GAO Found

Since GAO's January 2001 report, FDA's imported seafood safety program has shown some improvement. FDA inspects more foreign firms, and its inspections show that more U.S. seafood importers are complying with its requirements. FDA also slightly increased the number of seafood products it tests at U.S. ports of entry to just over 1 percent. However, FDA still has not established equivalence agreements with seafood exporting countries as GAO recommended in its 2001 report. Equivalence agreements that commit U.S. trading partners to maintain comparable food safety systems are an efficient way to ensure imported seafood safety. Unlike the U.S. Department of Agriculture, FDA is not legally required to certify that countries exporting food products to the United States have equivalent food safety systems. According to a panel of nationally recognized experts that GAO convened to address this and other issues, establishing these types of agreements would shift some of FDA's burden for ensuring seafood safety to foreign governments. This shift, in turn, would allow FDA to focus its limited resources on seafood products from countries with less advanced food safety systems.

FDA also made little progress regarding the recommendation GAO made in 2001 that FDA communicate to U.S. port-of-entry personnel serious deficiencies identified during inspections so that potentially contaminated imported seafood is examined before it enters the United States. GAO found that FDA continues to experience long delays between finding deficiencies and taking action. For example, GAO's review of foreign firm inspection records found that it took an average of 348 days for FDA to alert port-of-entry personnel about serious safety problems identified at six foreign firms. Moreover, GAO found that FDA does not prioritize enforcement actions when violations that pose the most serious public health risk occur or have an automated system to track the time involved in documenting, reviewing, and processing enforcement actions.

FDA officials acknowledged some of the problems that GAO identified regarding FDA's current imported seafood inspection program, but they also raised concerns about limited inspection resources and competing priorities, such as the recent need to implement provisions of the Bioterrorism Act of 2002. GAO identified several options that FDA could consider to augment its resources and enhance its current program, including (1) commissioning seafood inspectors from the National Oceanic and Atmospheric Administration's (NOAA) Seafood Inspection Program, (2) using state regulatory laboratories and/or private laboratories to augment FDA's testing of imported seafood, and (3) developing a program to use third-party inspectors to augment its program.

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Abbreviations

CCP	critical control point
CDC	Centers for Disease Control and Prevention
CFIA	Canadian Food Inspection Agency
DWPE	detention without physical examination
FDA	Food and Drug Administration
HACCP	Hazard Analysis and Critical Control Point (system)
NOAA	National Oceanic and Atmospheric Administration
USTR	Office of the U.S. Trade Representative

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United States General Accounting Office
Washington, D.C. 20548

January 30, 2004

The Honorable Ernest F. Hollings
Ranking Minority Member
Committee on Commerce, Science, and Transportation
United States Senate

The Honorable Trent Lott
United States Senate

The Honorable John Breaux
United States Senate

More than 80 percent of the seafood that Americans consume is imported from an estimated 13,000 foreign suppliers in about 160 nations.¹ If contaminated, imported and domestic seafood can cause foodborne illnesses, with problems ranging from mild gastrointestinal discomfort to neurological damage. The Centers for Disease Control and Prevention (CDC) estimates that contaminated seafood (finfish and crustaceans) accounted for about 15 percent of the documented foodborne illness outbreaks in the United States—a greater percentage than either meat or poultry, even though meat and poultry are consumed at 8 and 6 times the rate of seafood, respectively.²

The Food and Drug Administration (FDA) is responsible for ensuring the safety of domestic and imported seafood. It implements the Hazard Analysis and Critical Control Point (HACCP) system—a science-based, food safety program introduced for seafood in 1997. The HACCP system is designed to improve food safety by having industry identify and control biological, chemical, and physical hazards in products before they enter the market. Under FDA's food safety regulations, seafood-processing firms must identify hazards that are reasonably likely to occur and must develop and implement plans to control those hazards.

¹According to the National Marine Fisheries Service, National Oceanic and Atmospheric Administration, the percentage of imported seafood is based on live weight.

²CDC derives estimates of foodborne illness from, among other things, reported occurrences of two or more cases of a similar illness resulting from the ingestion of a common food, which is referred to as an *outbreak*. It publishes foodborne disease outbreaks in 5-year increments. These percentages are based on the most recent CDC data available, published in March 2000 and covering 1993 to 1997.

To ensure compliance with its food safety regulations, FDA requires that importers meet one of two conditions. First, importers may obtain seafood from countries that have entered into voluntary agreements with FDA. These agreements may document that foreign countries' seafood safety systems are equivalent to or in compliance with that of the United States. Second, if these agreements do not exist, importers must have records demonstrating that foreign firms' products offered for entry into the United States have been processed in accordance with U.S. HACCP requirements. Such records may include, for example, a copy of the foreign firms' HACCP plan. FDA inspects some U.S. importers and some foreign firms to determine their compliance with HACCP regulations. It also examines and tests selected samples of imported seafood products at U.S. ports of entry to verify their safety. FDA has the authority to hold imported seafood products while it determines if the product is adulterated.³ FDA also has the authority to detain imported seafood products and require importers to demonstrate that the products are not adulterated, a process called detention without physical examination (DWPE).

The Department of Commerce also has a role in promoting seafood safety and quality. The department has statutory authority for providing voluntary inspection services to assist in marketing seafood products. These inspection services are provided through its Seafood Inspection Program, which is located in the National Oceanic and Atmospheric Administration (NOAA).⁴ The Seafood Inspection Program provides fee-for-service safety, sanitation, and/or product inspections for approximately 2,500 foreign and domestic firms annually. Program services include inspections for safety, wholesomeness, and proper handling as well as grading seafood, laboratory analysis, training, and product inspection and certification. The Seafood Inspection Program's services affect 17 percent of the imported and domestic seafood consumed in the United States.

³Among other things, FDA considers a product to be adulterated if it contains bacterial contamination or prohibited chemical substances, or if it has been produced without a HACCP plan.

⁴The Agricultural Marketing Act of 1946 authorized the Seafood Inspection Program. The program was transferred from the Department of Agriculture to the Department of the Interior in 1956 and subsequently to the Department of Commerce in 1970.

In 2001, we reported that FDA's oversight of domestic and imported seafood provided insufficient assurance that the seafood is safe.⁵ With regard to imported seafood, we found that FDA relied on reviews of importers' records, inspections of selected foreign firms, and product examination and testing at the port of entry to ensure seafood safety—but that FDA reviewed records or performed inspections for a very small percentage of products. For example, FDA tested less than 1 percent of all seafood products imported into the United States in fiscal year 1999. 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. Without such equivalence agreements, FDA must rely principally on its reviews of importers' records to ascertain that imported seafood products are processed under an acceptable food safety system. Many importers did not have the required documentation, and, when they did, the documentation often did not adequately demonstrate compliance. We also recommended that FDA communicate to agency personnel at U.S. ports of entry deficiencies identified during its importer and foreign firm inspections because FDA was not scrutinizing products from problem firms at these ports.

Since our 2001 report, questions have persisted about the effectiveness of FDA's seafood safety program and about the adequacy of the agency's inspection and laboratory resources. You asked us to (1) reevaluate FDA's program for ensuring the safety of imported seafood and determine the status of FDA's efforts to implement our recommendations and (2) explore other options for enhancing FDA's imported seafood inspection program, such as using the inspection programs and laboratories of other entities.

In response to your request, we reexamined FDA's program for ensuring the safety of imported seafood, including the status of equivalence agreements, inspections of importers and foreign firms, and product examination and testing at ports of entry. To determine FDA's progress in establishing equivalence agreements with countries that export seafood to the United States, we interviewed FDA officials who are responsible for evaluating other countries' food safety systems. To evaluate FDA's actions to enforce compliance with its food safety requirements, we analyzed FDA's records of inspections for a random sample of U.S. importers and for

⁵U.S. General Accounting Office, *Food Safety: Federal Oversight of Seafood Does Not Sufficiently Protect Consumers*, [GAO-01-204](#) (Washington, D.C.: Jan. 31, 2001).

all of the foreign firm inspections conducted in fiscal year 2002. To explore other options for enhancing FDA's current imported seafood inspection program, we convened a panel of nationally recognized food safety experts. The panel, selected with assistance from the National Academies, discussed the effectiveness of FDA's current approach for ensuring the safety of imported seafood and provided advice on ways to strengthen it. In addition, the panel (1) discussed several other options, such as using NOAA's Seafood Inspection Program and laboratories, as well as those of other entities, to enhance FDA's program and (2) deliberated the advantages and disadvantages of the various options. Appendix I contains additional details of our scope and methodology, and appendix II contains a summer of the expert panel's observations on the safety of imported seafood.

Results in Brief

FDA has made some improvements to its imported seafood safety program since our January 2001 report, but it has not acted on key recommendations we made at that time. In terms of improvements, FDA investigators have found that more importers have the required documentation to demonstrate compliance with U.S. food safety requirements, and FDA now inspects more foreign firms in countries that supply seafood to the United States. FDA also increased laboratory testing of seafood products at ports of entry from less than 1.0 percent in fiscal year 1999 to about 1.2 percent in fiscal year 2002. However, the agency has not addressed our recommendations to improve imported seafood safety. Specifically, FDA has not, as we recommended done the following:

- *Developed goals and time frames for establishing equivalence agreements with seafood exporting countries.* Consequently, FDA continues to rely, in part, on reviewing importers' records to ascertain whether imported products are processed under an acceptable food safety system. Although FDA did not agree with our recommendation, it said that it would continue to assess the equivalency of foreign countries' seafood safety systems and enter into agreements as appropriate. It also said that this effort would be a priority. FDA officials now report that the costs of developing such agreements may outweigh the food safety benefits and, therefore, these assessments are no longer an FDA priority. Furthermore, FDA officials' attention and resources are now more focused on biosecurity issues. Our food safety panel considered these arguments and concluded that FDA should pursue equivalence agreements or other less comprehensive agreements, such as product-specific agreements, in order to shift some of the burden for

HACCP compliance to foreign governments, manufacturers, and processors. The panelists suggested that FDA focus first on establishing agreements with countries that have high-quality food safety systems—an approach that would conserve FDA resources to inspect products from countries with less advanced food safety systems.

- *Communicate to port-of-entry personnel the serious deficiencies identified during importer and foreign country inspections, so that potentially contaminated imported seafood is examined before entry into the United States.* FDA continues to experience long delays in this regard. For example, in 2002, FDA took an average of 348 days to alert port-of-entry personnel about serious safety problems identified with seafood products from six foreign firms. Even when FDA investigators had recommended immediate detention of imported seafood shipments, based on foreign firm inspections, the agency did not take this action because its policy is to first forward all recommendations to headquarters for review. When we brought these delays to headquarters officials' attention, they stated that the agency does not have an automated system for documenting the time involved in reviewing these recommendations but that such delays are unacceptable. This lack of management oversight fails to give priority to taking enforcement action for serious violations, and it increases the likelihood that unsafe products will enter the U.S. market.

Regarding our second objective—to explore other options for enhancing FDA's imported seafood inspection program—we identified four alternatives that can help augment FDA's inspection resources at ports of entry and in foreign countries and also increase the agency's laboratory capacity to test imported seafood products. Given FDA officials' concerns about limited inspection resources and competing priorities, the following options may provide useful alternatives, but they also present some challenges.

- *Use NOAA's Seafood Inspection Program personnel to augment FDA's inspection capabilities.* According to NOAA officials, they could provide FDA with an estimated 22 full-time-equivalent inspectors to, among other things, assist with inspections of U.S. importers and foreign firms and with examinations and sampling of imported seafood at ports of entry. FDA acknowledges that it has the legal authority to commission NOAA employees to conduct inspections and investigations on FDA's behalf by entering into a memorandum of understanding. However, some FDA officials are concerned that this option has the

potential for a conflict of interest because NOAA inspections are based on fee-for-service. FDA also believes that NOAA inspectors would need additional training.

- *Use state regulatory laboratories to augment FDA's capacity for analyzing imported seafood.* FDA is already considering using at least one state regulatory laboratory. According to our expert panel, this option has merit since these laboratories have capabilities and procedures similar to FDA's, but the panel and FDA noted that most state laboratories may not have excess capacity to perform testing.
- *Use private testing laboratories to assist in screening seafood samples.* Our expert panel said, however, that FDA would first need to develop and implement an appropriate accreditation program. FDA recognizes that it would get quicker results if it adopted this option but noted that doing so would require more agency oversight, thereby making this a costly alternative.
- *Develop a program for using private, independent inspectors (third-party inspectors) to inspect foreign processing firms and domestic importers.* Such a program would be similar to one that FDA has just begun to operate for third-party inspections of medical device manufacturers that was specifically authorized by Congress. To implement this option, FDA would need to develop and implement an appropriate certification program. However, FDA has not undertaken a comprehensive review of its legal authorities in this area.

To enhance FDA's ability to ensure the safety of imported seafood, we are making six recommendations, one to the Secretary of Health and Human Services and five to the Commissioner of FDA that are designed to strengthen aspects of the existing program. In commenting on a draft of this report for the Department of Health and Human Services, FDA essentially concurred with five of our recommendations and disagreed with one. FDA disagreed that it should make it a priority to establish equivalence or other agreements. We continue to believe that equivalence agreements are one of the most cost-effective methods for ensuring the safety of imported seafood. We also provided a draft of this report to NOAA, which did not have any comments on the report's findings, conclusions, or recommendations.

Background

CDC estimates that contaminated food causes 76 million illnesses, 325,000 hospitalizations, and 5,000 deaths in the United States each year. On the basis of the number of confirmed outbreaks of foodborne disease in 1997, the latest year for which CDC's data are available, seafood is one of the leading causes of foodborne illness outbreaks in the United States.⁶ Seafood products represented about 15 percent, or 26, of the 169 foodborne illness outbreaks from a confirmed source—a level greater than that associated with meat or poultry products, which are consumed at 8 and 6 times the rate of seafood, respectively. However, as we reported in 2001, CDC officials said that foodborne illness outbreaks are generally underreported and that it is easier to identify the source of some diagnosable illnesses, such as scombroid poisoning from seafood, than illnesses that result from nonspecific gastrointestinal symptoms caused by other foods. Moreover, the actual number of individual cases of illnesses resulting from traced outbreaks were higher for meat and poultry (619 and 353 cases, respectively) compared with 108 cases for seafood. FDA stated that seafood outbreaks may have involved fewer individual cases of illness because seafood has much lower consumption rates than meat and poultry. FDA also noted that some seafood-related illnesses may be caused by recreational or subsistence fishing over which the federal government has little or no control. The Center for Science in the Public Interest, a consumer interest group that works on nutrition and food safety issues, has used CDC data and other sources to track the number of reported food-poisoning outbreaks in the United States and estimates that seafood was responsible for 18 percent of the outbreaks of foodborne illnesses that the center tracked between 1990 and 2002.⁷

Several types of hazards can cause seafood-related illnesses. Specifically:

- Biological hazards—include pathogens, such as *Clostridium botulinum*, *Listeria monocytogenes*, *Salmonella* species, and *Staphylococcus aureus*, and parasites such as roundworms and tapeworms.

⁶According to CDC, only a fraction of foodborne illnesses are routinely reported, and since most foodborne illnesses are sporadic, only a small number of them are identified as being part of an outbreak.

⁷Outbreaks include those that are linked to finfish; other seafood (e.g., crab and shrimp); and seafood dishes, which may include molluscan shellfish (oysters, clams, mussels, and whole or roe-on scallops).

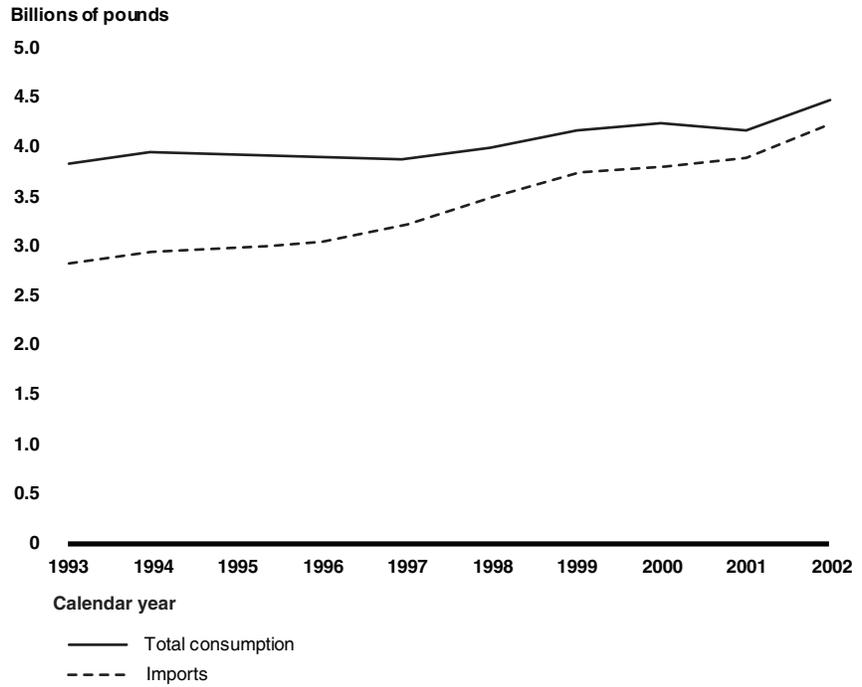
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- Chemical hazards—include compounds such as methylmercury, which can cause illness from long-term exposure; residues from drugs unapproved for use in food animals, such as chloramphenicol and nitrofurans, or overuse of approved drugs that are sometimes used in aquaculture production, which may be carcinogenic, allergenic, and/or cause antibiotic resistance in humans; and marine toxins. According to FDA officials, two marine toxins with potentially serious health effects—scombrototoxin and ciguatoxin—cause most of the reported seafood-related illnesses,⁸ including gastrointestinal and neurological problems. These toxins are heat resistant and cannot be inactivated by cooking.
 - Physical hazards—include foreign objects in food that can cause harm when eaten, such as glass or metal fragments.

Figure 1 shows the steady growth in U.S. consumption and imports of seafood between 1993 and 2002. According to data from the NOAA's National Marine Fisheries Service, the United States imported about 4.2 billion pounds, or more than 80 percent, of its seafood in 2002, as shown in the figure.⁹

⁸FDA noted that a number of illnesses from ciguatoxin are from recreational versus commercial fishing, but the agency did not provide any specific data.

⁹Consumption data are based on edible portions of seafood from imported and domestic sources. Import data are based on both edible and inedible portions of seafood, including bones.

Figure 1: U.S. Seafood Consumption and Imports, 1993 to 2002



Source: National Marine Fisheries Service, National Oceanic and Atmospheric Administration.

In addition, U.S. seafood consumption rose about 25 percent between 1980 and 2002, from 12.5 pounds per person to 15.6 pounds per person.¹⁰ Most seafood consumed in the United States is imported from an estimated 160 countries and 13,000 foreign processors. In 2002, the top 6 seafood exporting countries—Canada, China, Thailand, Chile, Ecuador, and Vietnam—accounted for approximately 63 percent of imported seafood. Imported products include fresh and frozen tuna and salmon as well as crustaceans, such as shrimp and lobsters. Figure 2 shows the proportion of imports to the United States from the 6 leading exporting countries.

¹⁰U.S. seafood consumption data include finfish, shellfish, and other aquatic plants and animals.

Figure 2: Percentage of Seafood Imports to the United States from Major Exporting Countries, 2002



Source: GAO analysis of data from the National Marine Fisheries Service, National Oceanic and Atmospheric Administration.

A large and rapidly growing proportion of worldwide seafood production, including U.S. imports, is produced by aquaculture. In 2000, aquaculture represented about 27 percent of global seafood production, and has increased by an average of 9.2 percent annually since 1970, compared with only an average 1.4 percent increase for captured seafood, according to the Food and Agriculture Organization of the United Nations. As in other animal production systems, aquaculture producers may use antibiotics and other chemicals to prevent or treat disease. Some producers have been found to misuse approved drugs or to use unapproved drugs or chemicals that pose potential human health hazards, such as antibiotic resistance, allergic reactions, or cancer. In recent years, food safety authorities in Europe, Canada, and the United States have begun to detect these substances and are taking steps to control their illegal use.

FDA is responsible for ensuring the safety of both domestic and imported seafood under the Federal Food, Drug, and Cosmetic Act. In 1997,

following recommendations by the National Academy of Sciences and others, FDA adopted a program of preventative controls that are designed to identify hazards during the seafood-production process and minimize the risk of contamination. The HACCP regulations made seafood-processing firms responsible for identifying harmful microbiological, chemical, and physical hazards that are reasonably likely to occur and for establishing critical control points (CCP) to prevent and reduce contamination. The HACCP system is based on the following seven principles that each seafood firm must address:

- *Conduct a hazard analysis.* Identify hazards that are reasonably likely to occur.
- *Identify the CCP.* Identify a point, step, or procedure in the production process where controls can be applied to prevent, eliminate, or reduce to an acceptable level a food safety hazard that is reasonably likely to occur.
- *Establish critical limits for each CCP.* Set the maximum or minimum value at which parameters, such as cooking time and temperature, must be controlled at each CCP to prevent, eliminate, or reduce the hazard to an acceptable level.
- *Monitor each CCP.* Establish monitoring activities that will ensure that the process is under control at each CCP.
- *Establish corrective actions.* Define actions to be taken when monitoring discloses a deviation from established critical limits.
- *Establish verification procedures.* Establish verification procedures to ensure that HACCP plans accomplish their intended goal—that is, ensuring the production of safe products.
- *Establish record-keeping and documentation procedures.* Maintain documentation, including the HACCP plan; CCP monitoring; corrective actions; and verification activities.

Under the HACCP regulations, seafood-processing firms are responsible for conducting a hazard analysis and for developing and implementing HACCP plans for hazards that are determined to be reasonably likely to occur. These hazards may include marine toxins, microbiological contamination, chemical contamination, pesticides, drug residues,

decomposition in certain species, parasites, the unapproved use of food or color additives, and physical hazards. For each hazard identified, the firms must establish CCPs to prevent or reduce contamination. Firms also must establish and monitor sanitation procedures to ensure, among other things, the (1) general cleanliness of food contact surfaces, including utensils, gloves, and outer garments, and (2) control of employee health conditions.

As we reported in 2001, FDA has four approaches to verify compliance with HACCP regulations and ensure the safety of imported seafood. FDA has the authority to enter into voluntary agreements with individual countries on the basis of a determination of equivalence of their seafood safety systems with U.S. HACCP requirements. First, under the provisions of the World Trade Organization Agreement on the Application of Sanitary and Phytosanitary Measures, to which the United States is a signatory, FDA is obligated to enter into consultations with the aim of achieving equivalence agreements upon the request of other World Trade Organization member nations.¹¹ FDA considers other systems to be equivalent when it finds one or more of an exporting country's food safety measures—such as laws, regulations, guidance, and procedures—to be equivalent to our own. U.S. importers can demonstrate HACCP compliance by acquiring seafood from countries with these agreements. Second, in the absence of such agreements, importers are responsible for demonstrating, through documentation, that the seafood they import into the United States is produced under systems that are compliant with U.S. HACCP requirements. During its periodic inspections, FDA reviews this documentation to determine whether importers have met their responsibilities under the HACCP regulations. Third, FDA also inspects a limited number of foreign seafood firms to determine the firms' compliance with HACCP. Lastly, FDA selects a small number of individual shipments at U.S. ports of entry to conduct visual examinations and/or collect and test samples to determine if the seafood is misbranded or adulterated. FDA commented that detaining suspect imported seafood for physical or laboratory examination by the importer is also part of its import control strategy.

If FDA observes HACCP violations during its inspections and testing, it can take several regulatory actions. For example, FDA issues warning letters in cases where violations raise safety concerns that may lead to enforcement

¹¹World Trade Organization Agreement on the Application of Sanitary and Phytosanitary Measures, art. 4, 1994.

action, such as detention, seizure, or injunction—which is a court order to refrain from distributing a product. In the case of foreign firms, a warning letter could advise them of a forthcoming detention, the only enforcement action that is available. Firms that receive warning letters are asked to respond to FDA in writing to indicate what actions they will take to correct the identified problems.

To fund FDA's food safety programs, Congress provided \$393 million for fiscal year 2002. This amount represents a \$106 million increase over FDA's budget for fiscal year 2001, including a \$93 million supplemental appropriation for counterterrorism activities, including those in the Bioterrorism Act of 2002.¹² FDA used some of this increase to enhance its coverage of imported foods, including hiring over 600 new food safety investigators and laboratory personnel; increasing the number of port-of-entry examinations and laboratory testing; and conducting foreign inspections that focused on high-risk foods, including seafood.

FDA's Imported Seafood Safety Program Shows Some Improvement, but Deficiencies Persist

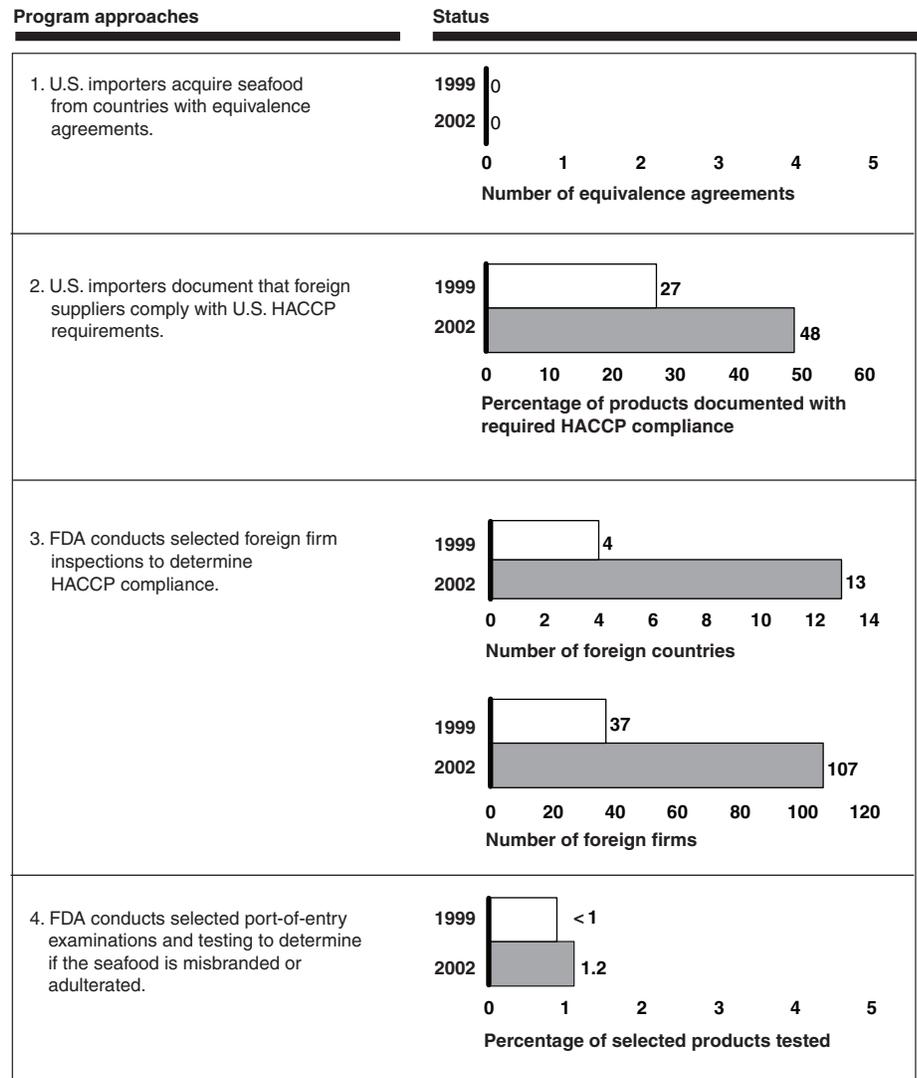
Since our January 2001 report, FDA has made improvements to three of the four approaches it uses for ensuring the safety of imported seafood—importer inspections, foreign inspections, and port-of-entry inspections. FDA has not implemented either of the recommendations we made in our 2001 report regarding establishing equivalence agreements with exporting countries or communicating deficiencies found during inspections to FDA's port-of-entry personnel. Additionally, FDA continues to experience long delays in issuing warning letters or detaining imported seafood at U.S. ports of entry after investigators find serious deficiencies. By not taking timely regulatory action, FDA increases the likelihood that unsafe seafood will enter the U.S. market.

FDA's Program Shows Some Improvement Since Our Last Report

We found that FDA has made some progress in strengthening the efficacy of three approaches for ensuring the safety of imported seafood. However, the agency has made no progress regarding the development of equivalence agreements with seafood exporting countries. Figure 3 summarizes the changes that have taken place in FDA's seafood safety program.

¹²The Public Health Security and Bioterrorism Preparedness and Response Act of 2002, Pub. L. No. 107-188; 116 Stat. 594 (2002).

Figure 3: Status of FDA's Program Approaches for Ensuring the Safety of Imported Seafood, Fiscal Years 1999 and 2002

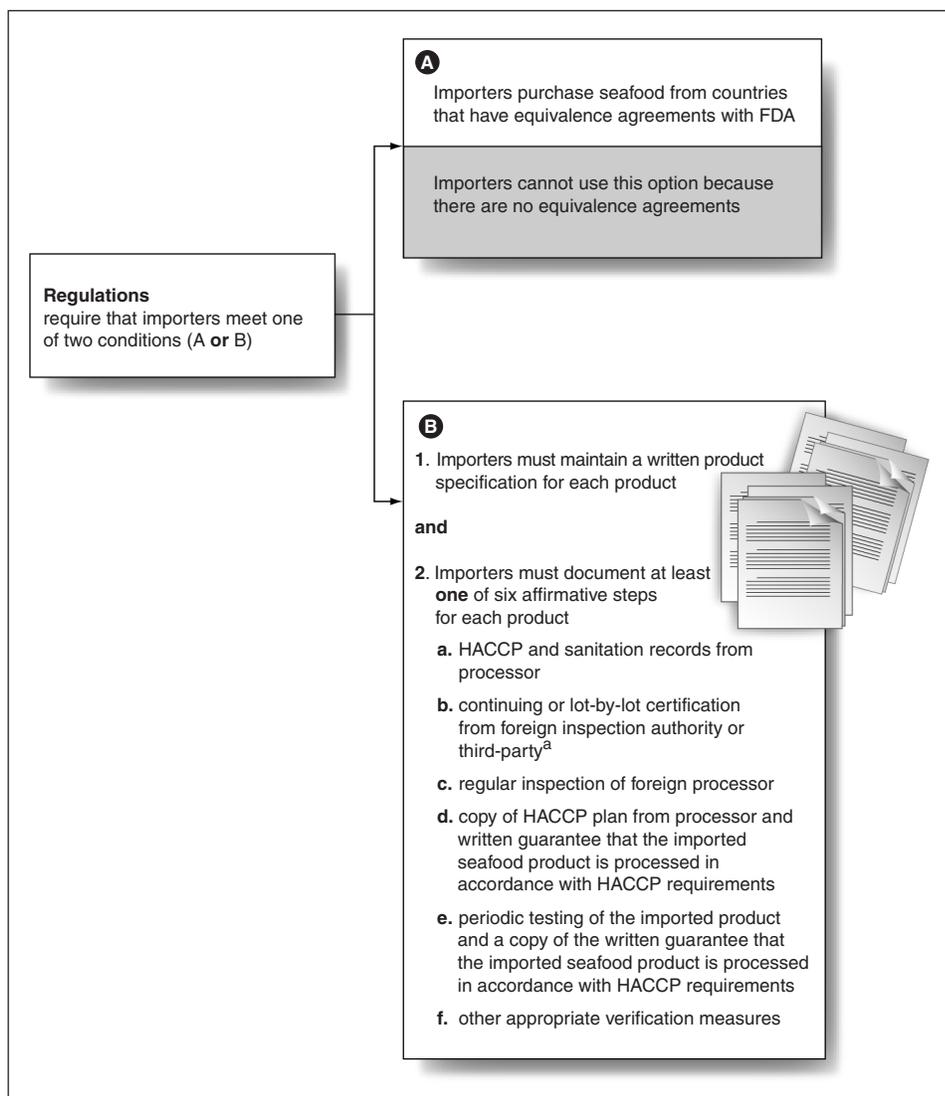


Source: GAO analysis of FDA's seafood safety program.

As we reported in 2001, in the absence of equivalence agreements, U.S. seafood importers are required to maintain written product specifications and take at least one of six affirmative steps to document foreign firms' compliance with U.S. requirements. Figure 4 shows the regulatory

requirements for importers and the documentation that importers can use to demonstrate compliance.

Figure 4: Importers' Regulatory and Compliance Requirements



Source: FDA regulations.

^aApproved foreign processor lists may serve as meeting the continuing certification affirmative step.

While importers have made some progress in maintaining the required documentation, they are still far from full compliance, according to our analysis of FDA's inspection forms for fiscal year 2002. Specifically, on the basis of our random sample of inspections, we estimate that importers had the required documentation for 48 percent of the products they imported, which is up from the 27 percent noted in our 2001 review.¹³ That is, an estimated 48 percent of imported seafood products listed in the FDA inspection forms contained (1) a written product specification document and (2) documentation for at least one of the six possible affirmative steps required by the regulations. In fiscal year 2002, FDA inspected fewer domestic importers—402 (of an estimated 8,500) compared with 644 that the agency reports it inspected in fiscal year 1999.¹⁴ Our analysis shows that FDA investigators made some errors when documenting these 2002 inspections. On the basis of our survey, we estimated that in about 4 percent of the inspection forms, FDA investigators erroneously indicated that the exporting country had an equivalence agreement in place for seafood. Therefore, they did not require the importer to produce the additional documentation required in the absence of an equivalence agreement (written product specifications and at least one affirmative step).¹⁵ FDA officials said the oversight occurred because the investigators had correctly determined that the importers received products from firms on a list of preferred providers developed by the Canadian Food Inspection Agency (CFIA), but the investigators erred in assuming that having the preferred provider list meant that Canada has an equivalence agreement with the United States. FDA officials said they will take steps to clarify the requirement with field personnel to avoid confusion in the future.

¹³To record importer inspection findings, FDA investigators complete a product-specific standardized form after each importer is inspected. The forms indicate whether importers have the required documentation and, if so, whether the documents establish the foreign firm's compliance with U.S. HACCP requirements.

¹⁴As stated in our January 2001 report (GAO-01-204), we obtained and analyzed all of the FDA inspection forms for fiscal year 1999 that were completed at 350 importer firms (covering 432 seafood products). On November 20, 2003, FDA revised the number of domestic importers inspected to 644 during fiscal year 1999 and reported that the agency inspected 676 importers, or about 8 percent of importers inspected during fiscal year 2003.

¹⁵To meet the affirmative step requirement, importers may choose to purchase seafood from firms appearing on lists approved by foreign governments. These governments are assuring FDA that firms on the lists meet U.S. HACCP requirements. FDA acknowledges the approved lists from four foreign countries' inspection authorities: Canada, Japan, New Zealand, and Thailand.

FDA also increased the number of foreign countries visited and seafood firms inspected since we last reported in 2001. FDA visited 13 of an estimated 160 countries in fiscal year 2002 to provide education on the U.S. HACCP requirements and to inspect 108 of about 13,000 seafood firms compared with 4 countries and 37 firms inspected in fiscal year 1999. FDA selects the countries for inspection on the basis of previous compliance problems, the volume of seafood exported to the United States, and the type of product and associated risk. Once it selects a country, FDA selects foreign firms that have a problematic compliance history and works with the country's inspection authority to identify other firms for inspection. According to the Director, FDA's Office of Seafood, FDA plans to inspect about 100 seafood firms in 10 or more foreign countries annually in the future. Although this number represents fewer firms and countries than FDA inspected in 2002, it represents more than FDA inspected in fiscal year 1999. These inspections tend to be targeted on developing countries that are major exporters to the United States.

FDA officials also said they have begun to increase laboratory testing of imported seafood, in particular for aquaculture drug residues, as a result of the increase in staff resources the agency received from the Bioterrorism Act of 2002. According to these officials, in fiscal year 2002, FDA had 310 full-time-equivalent positions for inspections and laboratory testing of all food, with 70 allocated for imported seafood; by fiscal year 2004, FDA estimates that it will have 681 positions, with at least 103 allocated for imported seafood. Furthermore, the proportion of foreign seafood products detained for laboratory testing increased slightly, from less than 1.0 percent in fiscal year 1999 to about 1.2 percent in fiscal year 2002, while imported seafood products increased by 13 percent (from 3.7 to 4.4 billion pounds) over the same period.¹⁶ FDA officials expect laboratory testing to increase to about 1.4 percent of imported seafood products in fiscal year 2004, after the newly hired investigators and laboratory personnel are fully trained.

¹⁶FDA officials commented that the percentage of imported seafood that is tested is higher if the number of samples collected and tested by importers under DWPE is counted. However, the agency provided no data on the amount of testing conducted under DWPE.

FDA Still Lacks Equivalence or Other Agreements with Seafood Exporting Countries

Although FDA stated in January 2001 that it planned to make progress toward accomplishing foreign equivalence assessments and had listed this goal as one of its priorities, the agency has not made progress in this regard. As a result, FDA still has no equivalence or other agreements with any seafood exporting country. At the time of our 2001 report, FDA had not established any equivalence agreements with countries that export seafood to the United States. However, the agency was discussing equivalence agreements with Australia, Canada, and New Zealand and a compliance agreement with Japan.¹⁷ To expedite development of these agreements, we recommended that FDA develop specific goals and time frames for completing them. FDA did not agree with this recommendation, but it stated that accomplishing foreign equivalence assessments would be one of its priorities for fiscal year 2001.

FDA officials now state that developing these agreements is no longer a priority because of several factors. First, they point out that equivalence agreements, as such, do not necessarily contribute to the enhanced safety of imported seafood. Foreign producers are already required to produce seafood products under a HACCP-based system that provides for a high level of assurance of safety, and therefore, an FDA finding of equivalence of a foreign seafood regulatory program or individual seafood safety measures would be unlikely to substantially improve the safety of imported seafood. Second, FDA officials said that the United States does not require a finding of equivalence as a condition for exporting seafood to the United States. Third, the procedures and criteria that are necessary to conduct equivalence assessments have only recently been agreed upon at the international level by the Codex Alimentarius Commission.¹⁸ FDA is working with other U.S. agencies in considering how best to incorporate these international guidelines in situations where equivalence assessments might be helpful for either public health protection or trade facilitation. The Office of the U.S. Trade Representative (USTR), the cabinet agency responsible for developing and coordinating U.S. international trade policy, generally agreed with this view and also said that even with equivalence agreements, FDA would still be required to conduct compliance reviews

¹⁷The compliance agreement being discussed with Japan is for specific seafood products.

¹⁸Codex is an international food standard-setting body under the joint oversight of the United Nations Food and Agriculture Organization and the World Health Organization.

and audits in these countries.¹⁹ Finally, both FDA and USTR said the time and resources required to develop equivalence agreements for seafood may outweigh the benefits.

We agree that establishing equivalence agreements would not automatically result in improved seafood safety. However, by establishing agreements with countries that are able to demonstrate that their safety systems are comparable to ours, FDA could free inspection resources and allow more extensive examination of seafood products from countries with less advanced systems.²⁰ Because FDA does not have equivalence agreements with countries that are exporters of seafood to the United States, FDA principally relies on a review of documentation at importers' offices to attempt to determine whether importers have met their responsibilities and requirements under the seafood HACCP regulations. As we previously discussed in this report, FDA reported inspecting only about 8 percent of domestic importers in fiscal year 2003.

Our panel of experts also concluded that equivalence agreements or less comprehensive alternatives represent an effective approach for ensuring the safety of imported seafood and would also shift some of the burden for ensuring that imported seafood meets U.S. HACCP requirements to exporting countries. Furthermore, the panel suggested that FDA concentrate its efforts on first developing agreements with countries known to have high-quality food safety systems, thereby allowing FDA to focus its limited inspection resources on countries known to have lesser quality food safety systems.

We also acknowledge that time and resources are a necessary factor in negotiating such agreements. However, we note that FDA has entered into similar agreements with several countries that export fresh and frozen shellfish products (fresh and frozen oysters, clams, mussels, and whole or roe-on scallops) to the United States. By reaching agreements through individual memorandums of understanding with Canada, Chile, Mexico, New Zealand, and South Korea, FDA acknowledged that the foreign countries' shellfish sanitation programs meet U.S. standards. If it chose to

¹⁹USTR also told us that guidelines completed by Codex in July 2003 are still too abstract for FDA to use to determine equivalence.

²⁰Under the meat and poultry inspection acts, the Secretary of the Department of Agriculture must certify that exporters of meat and poultry products have equivalent food safety systems before their products can be exported to the United States.

do so, FDA could enter into these types of agreements with countries that export seafood products to the United States as well.

We also note that CFIA has established 14 agreements with foreign exporting countries, including agreements for seafood products. According to CFIA officials, these agreements allow CFIA to decrease the rate of inspection for products from participating countries and direct its resources to higher risk products from countries without such agreements. In addition, CFIA believes that such agreements provide a vehicle for increased communication, thereby allowing the exporting nation to take corrective actions at violating firms discovered during CFIA's verification inspections.

Most FDA Regulatory Actions Are Not Timely

To ensure that FDA takes prompt regulatory action when its investigators find food safety violations during importer and foreign firm visits, we recommended in our 2001 report that FDA communicate deficiencies to port-of-entry personnel so that they can examine potentially contaminated imported seafood before it can enter the United States. Although FDA agreed with this recommendation, we found that it continues to experience long delays between finding deficiencies and taking action, such as issuing a warning letter or detaining a product. As a result, potentially contaminated seafood could be entering the U.S. market.

Once FDA investigators complete an inspection of U.S. importer's documentation or of a foreign firm's processing plant, they submit a recommendation and/or report to headquarters, which decides on regulatory action.²¹ As explained below, FDA issues either *untitled letters* or *warning letters* to inform responsible officials of violations found during the inspection and to afford the officials the opportunity to voluntarily take appropriate and prompt corrective action prior to the initiation of enforcement action. The use of these letters is based on the expectation that a majority of inspected firms will voluntarily comply.

²¹FDA field offices may issue without prior headquarters review warning letters for certain violations found during U.S. importer inspections, such as not having written product specifications.

FDA issues *untitled letters* when the documented violations do not meet the criteria for detention.²² Untitled letters may address, for example, the foreign company's failure to have its HACCP plan list sulfites, an allergen; failure to monitor the safety of water; or failure to maintain the cleanliness of food contact surfaces. These letters do not set time frames for taking corrective action and do not require a response from the firm.

FDA also issues *warning letters* when it finds violations that can directly affect product safety, such as no controls for scrombrotoxin, which is a toxin most commonly found in tuna, mahi-mahi, and bluefish that can cause severe allergic reactions and diarrhea. These letters could lead to enforcement action, such as product detention, if the company does not promptly and adequately correct the problem. To ensure prompt and adequate correction, FDA requires that warning letters be issued within 30 work days—approximately 45 calendar days.

However, FDA is not required to issue letters to firms prior to taking enforcement action. The agency has the authority to take immediate enforcement action, such as detaining a firm's products.²³ Under section 801(a) of the Federal Food, Drug, and Cosmetic Act, FDA can refuse admission of imported products on the basis of information that the product "appears" to be in violation of food safety requirements. When the violations remain uncorrected despite prior warnings, FDA headquarters notifies field offices by listing the firm and product on an Import Alert, ordinarily the next course of action. According to FDA officials, now that the requirements of seafood HACCP are well established, the agency intends to use its refusal authority as the lead action without prior warning to prevent the products of problem foreign processors from entering the country. Our analysis of foreign firm inspections shows that the agency used this authority for one firm in fiscal year 2002.

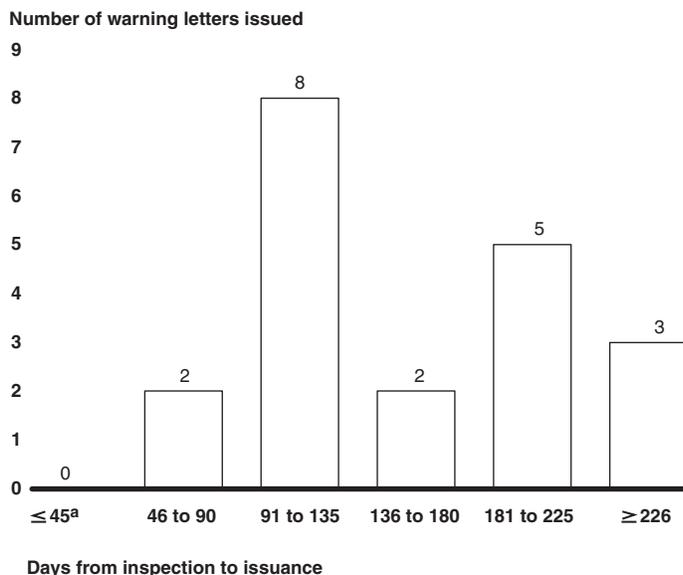
According to our review of inspection records for 99 of 108 foreign firms that the agency visited in fiscal year 2002, FDA is encountering significant

²²As previously noted, under the DWPE process, FDA can also refuse admission of imported products on the basis of information, such as foreign firm inspections, that the product appears to be adulterated. The products are subject to refusal of admission until the violations found during inspection are corrected.

²³FDA classifies inspections as (1) No Action Indicated—no objectionable conditions found, (2) Voluntary Action Indicated—objectionable conditions found but are not sufficient to warrant regulatory action, or (3) Official Action Indicated—serious violations are found that warrant regulatory action.

delays in issuing warning letters when serious violations are identified.²⁴ During its inspections, FDA found that of these 99 foreign firms, 40 had serious violations that warranted regulatory action. For 20 of these 40 firms, FDA decided to issue a warning letter. However, FDA took an average of 157 calendar days to issue these warning letters. As shown in figure 5, all 20 warning letters exceeded FDA's time frame requirement of approximately 45 calendar days.

Figure 5: Number of Days from Inspection to Issuance of Warning Letters for Serious Violations Found at 20 Foreign Firms, Fiscal Year 2002



Source: GAO analysis of FDA data.

^aFDA's requirement is to issue warning letters within 30 work days (or about 45 calendar days).

Fourteen of these 20 warning letters were issued to firms producing high-risk products²⁵—such as semipreserved fish products, including smoked,

²⁴We received and reviewed 107 of the 108 foreign firm inspection records that FDA conducted in fiscal year 2002. Of the 107 files received, we removed 8 inspections because they covered shellfish, which was outside the scope of this assignment.

²⁵According to FDA, high-risk foods are those that may contain hazards that the agency believes present a higher potential to cause harm to humans.

salted, and fermented fish that are susceptible to the growth of bacteria, including *Clostridium botulinum*. This bacteria produces a toxin that can cause gastroenteritis, vertigo, and respiratory failure. For the other 20 firms that did not receive warning letters, FDA issued untitled letters to 14 firms and is considering what action to take for the remaining 6 firms.²⁶ Appendix III provides a more detailed analysis of FDA's foreign firm inspections in fiscal year 2002.

In addition to failing to issue warning letters in a timely manner, FDA encountered significant delays in alerting port-of-entry personnel to detain imported seafood shipments from firms identified with serious safety problems. On average, the agency took 348 calendar days to alert port-of-entry personnel about such products coming from 6 of the 99 foreign firms that the agency inspected in fiscal year 2002. Moreover, 4 of the 6 firms involved were processing high-risk products, which should have caused FDA to take more prompt enforcement action. By not taking timely enforcement actions and communicating these actions to U.S. port-of-entry personnel, FDA increases the likelihood that unsafe products will enter the U.S. market.

Similar delays occurred when FDA investigators found problems with U.S. importers' records. For the 96 inspection forms we reviewed, FDA found that 16 importers had serious violations, such as failure to have the required documentation. The agency issued warning letters to 8 of these importers. The average time elapsed between the date of the inspection and issuance of the warning letter was 103 calendar days; only 2 letters were issued within the required 45 calendar days. Furthermore, 5 of the warning letters covered high-risk products, including scombrototoxin-susceptible seafood, which, if not properly handled, could cause serious health problems requiring hospitalization, particularly for elderly individuals.

FDA officials acknowledged that these delays are excessive and unacceptable and attributed them to a change in personnel responsible for reviewing and issuing these letters. In addition, these officials stated that the time frames were exceeded because the agency has been compelled to give precedence to other public health concerns, such as developing programs to protect the food supply against terrorist threats. Finally, we

²⁶As of October 8, 2003, FDA received adequate responses from 8 of these 14 firms, is considering enforcement action for 5 firms, and has not received a response from 1 firm.

found that FDA does not prioritize enforcement actions when violations that pose the most serious public health risk occur or have an automated system for tracking the time involved in documenting, reviewing, and processing enforcement actions. As a result of increased funding, FDA recently increased the number of personnel responsible for reviewing and issuing these letters and expects to substantially increase its timeliness. Additionally, FDA is in the early stages of developing an automated system that will track the time involved in documenting, reviewing, and processing enforcement actions.

Options Are Available for Enhancing FDA's Imported Seafood Safety Program, but They Present Challenges

Several options could help FDA overcome some of the problems we identified with its current regulatory approach for ensuring the safety of imported seafood. These options could also help to augment FDA's inspections of foreign seafood firms, port-of-entry product examinations, and testing of imported seafood. However, each option presents certain challenges that FDA would need to address. First, NOAA could provide staff from its Seafood Inspection Program to augment FDA's inspections capabilities, and FDA is considering the advantages and disadvantages of doing so. However, some FDA officials are concerned about the cost of using NOAA and about a perceived conflict of interest because NOAA's inspections are fee-for-service. Second, FDA could contract with state regulatory laboratories to augment its current capacity to analyze imported seafood samples, but our expert panel and FDA officials said that most state laboratories might not have excess capacity to assist FDA. Third, FDA could use private laboratories to assist in screening seafood samples, provided that FDA first attests to the laboratories' capabilities to perform the work. Finally, if it has the authority, FDA could use third-party inspectors to conduct HACCP inspections of foreign processing firms and domestic importers; however, FDA would need to certify the inspectors' competency. FDA has not undertaken a comprehensive review of its legal authorities in this area.

NOAA's Seafood Inspection Personnel and Laboratories Could Augment FDA's Regulatory Program

NOAA officials said that they could assist FDA by providing various services to augment FDA's regulatory program for imported seafood. These services include

- foreign firm inspections,
- HACCP training,

-
- domestic importer inspections,
 - port-of-entry inspection and product sampling, and
 - assistance in developing and verifying equivalence or other types of agreements with seafood exporting countries.

NOAA officials also said that they could conduct some domestic seafood inspection services that FDA currently conducts, which would allow FDA to refocus some of its resources on imported seafood. For example, NOAA inspectors could certify domestic seafood products shipped to the European Union and other countries, which is a service that NOAA provided in the past on a fee-for-service basis. Also, FDA and NOAA could agree to recognize NOAA's current inspections of approximately 240 domestic processing firms and authorize NOAA to inspect other domestic firms for compliance with HACCP. NOAA officials estimate that they could provide FDA with up to 22 full-time-equivalent field inspectors as well as additional technical support staff in its headquarters office.

In addition, NOAA and FDA officials are now negotiating the terms of an agreement to use two NOAA laboratories to screen imported shrimp samples for the antibiotic chloramphenicol. FDA is taking this action to increase its testing capacity in response to the detection of the drug in imported shrimp by food safety authorities in Europe, Canada, and some U.S. states. Chloramphenicol is banned for use in food-producing animals because there is no known safe level for human ingestion of this substance. If the negotiations succeed, FDA would increase its screening capacity by 400 samples per year.²⁷

FDA recognizes that it has the authority to use NOAA and is considering the advantages and disadvantages of doing so. While one official raised concerns about a public perception of potential conflicts of interest because NOAA inspections are fee-for-service, others said that this potential problem could be addressed in an agreement between the two agencies. Additionally, NOAA officials said that this concern could be alleviated, in whole or in part, through its receipt of direct appropriations to conduct these activities and/or through contracts with FDA that use

²⁷FDA plans to collect and analyze over 500 shrimp samples for chloramphenicol in fiscal year 2003 using its own laboratories. These laboratories would also be used to confirm the presence of chloramphenicol in positive samples found by the NOAA laboratories.

appropriated funds. Also, FDA-sponsored inspector training and periodic audits of NOAA activities could further address such perceptions. FDA officials also pointed out that it would have to incur costs to provide training to NOAA inspectors and would have to develop an agreement with NOAA specifying how NOAA would conduct inspections and investigations on FDA's behalf. We agree that FDA would need to incur additional costs to use NOAA inspectors and laboratories, but these costs may be less than those FDA would incur if the agency were to hire and train investigators and laboratory analysts without prior seafood experience.

State Regulatory Laboratories Have the Capability, but May Not Have the Capacity, to Assist FDA

FDA is testing only a small fraction of the seafood entering the United States, about 1.2 percent in fiscal year 2002. Our panelists and past GAO reports have stated that port-of-entry laboratory testing is an ineffective "overall" approach for ensuring the safety of imported seafood. Nevertheless, our panelists believed that increased testing is desirable as one approach for verifying the presence of biological, chemical, or drug residues. Therefore, they stated that using state regulatory laboratories to augment FDA's seafood testing, such as state Departments of Health or Agriculture, would be beneficial because

- state laboratories are well equipped for food testing and provide reliable results,
- these laboratories have procedures in place that could meet FDA's standards for compliance testing, and
- FDA's use of state laboratories could improve coordination and information exchange regarding seafood-testing results between state laboratories and FDA.

However, the panelists noted a disadvantage to using state regulatory laboratories. Many states are financially constrained and therefore may not have the excess capacity, equipment, time, or qualified analysts to assist FDA. Furthermore, if FDA were to consider using state laboratories to assist with port-of-entry testing, it would have to ensure that all laboratories are using appropriate sampling and testing methodology.

While FDA laboratory officials agreed that using state regulatory laboratories could be beneficial, they expressed some concerns regarding using the laboratories to support FDA regulatory action. FDA officials agreed that state regulatory laboratories are likely to have established

chain-of-custody procedures—that is, state laboratories control the sample from the time they receive it through the sample analysis so that the sample is not inappropriately altered. Additionally, FDA officials said state laboratories would be required to meet all FDA analysis and data requirements. However, using these laboratories may be a costly alternative because FDA would have to provide training and oversight in addition to the cost required to conduct the analyses. Furthermore, FDA officials noted that states may not have excess capacity to assist FDA.

Despite these concerns, FDA is considering a pilot program with Florida to determine how it could use state laboratory results. This pilot program is similar to FDA's proposed agreement with NOAA for testing imported shrimp for the drug chloramphenicol. Under the proposed pilot program with Florida, FDA would collect the samples and the state laboratory would screen them for traces of chloramphenicol residues. The state laboratory would also perform the more sophisticated confirmation testing on the positive screens, which FDA could then use to take regulatory action. According to FDA officials, the agency must first determine the level of seafood sampling to perform given its other competing public health priorities. They said that considerable funding would be required to establish a meaningful laboratory assistance program with outside sources.

Private Laboratories Could Assist FDA If They Were Accredited

Currently, FDA does not accredit or use any private laboratories to collect or analyze seafood samples. However, for some seafood violations, it does allow seafood firms to use private laboratories to provide evidence that imported seafood previously detained because of safety concerns is now safe and can be removed from the detention list at the port of entry. To assist FDA in analyzing more imported seafood, our panel recommended that FDA accredit private laboratories that comply with FDA's testing methodologies. This option would also provide FDA with greater assurance about the quality of the laboratories importers use to demonstrate that their detained products are safe and can be released into commerce.

FDA officials said that using private laboratories to conduct screenings could result in increased analytical capacity, but this option would require more agency oversight, thereby making it a costly alternative. We note, however, that FDA currently accepts the results from private laboratories that importers provide to the agency to demonstrate that products detained at ports of entry are safe and can be released into commerce. FDA also noted that these private laboratories generally follow the appropriate methodology for sampling, documentation, chain-of-custody, and analysis.

The agency performs a detailed review of the laboratories' sampling and testing methodology for each individual submission to FDA, but this review is not an overall quality assurance review of the entire laboratory and should not be taken as a general endorsement of the submitting laboratory.

As with state laboratories, if FDA were to use private laboratory results to take regulatory action, it would be required to provide training and oversight in addition to funding. However, FDA officials stated that in their view, these laboratories are generally not equipped to perform confirmation testing due to the expense and expertise required. Furthermore, since private laboratories would continue to provide laboratory analysis to the industry that FDA regulates, the agency would have additional responsibilities to eliminate conflict of interest and protect any regulatory testing from bias.

Private Third-party Firms Could Also Assist FDA, If Certified

In the absence of equivalence agreements, FDA could consider developing a program that uses certified third-party firms to conduct HACCP inspections on its behalf, both at foreign processing firms and domestic importers. The Department of Health and Human Services has begun to take this approach by accrediting third-parties to inspect manufacturers of medical devices, as authorized by Congress.²⁸ However, no similar specific legislation exists permitting third-party inspection of seafood firms, and FDA has not undertaken a comprehensive review of its authorities to accredit private third-parties to inspect seafood firms.

Our expert panel believes that industry should pay for the use of these third-parties to shift some of the burden from FDA to support the costs associated with such a service. Following this approach, FDA could inspect more foreign firms and importers without incurring substantial additional costs. However, FDA is concerned that a fee-for-service arrangement for these services would create a public perception of a conflict of interest. According to our panel, to combat this potential problem, FDA would have to implement a system of oversight to ensure that the third-parties are adequately performing their duties. Finally, domestic importers could use

²⁸Congress enacted the Medical Device User Fee and Modernization Act of 2002 on October 26, 2002, Pub. L. No. 107-250, 116 Stat. 1588 (2002). GAO is required to review implementation of the third-party inspection program and submit a report to Congress no later than October 26, 2006. The report is also required to include a recommendation as to whether the program should be continued or terminated.

the accredited third-party firms to demonstrate that their seafood products were processed in accordance with HACCP requirements.

Conclusions

Since FDA first issued the HACCP regulations for seafood safety in 1997, U.S. seafood importers and foreign firms have made some progress in implementing and demonstrating compliance with FDA's seafood safety requirements. However, FDA is still verifying compliance at only a small number of seafood importers and foreign firms. Similarly, FDA's port-of-entry product examination and testing is, and will continue to be, limited. In addition, FDA is no longer making it a priority to negotiate equivalence agreements with seafood-exporting countries, which remains one of the most effective methods for ensuring the safety of imports. Indeed, our panel of seafood safety experts believes that these agreements would help FDA reduce its reliance on importer and port-of-entry inspections and would enable the agency to leverage its staff resources by sharing the responsibility for seafood safety with exporting countries, especially those that are known to produce safe seafood. Coupled with the lack of timely compliance and enforcement action, FDA's efforts to ensure the safety of imported seafood continue to provide insufficient protection to consumers. Unless other options for strengthening these efforts are explored, the risk of unsafe products released into the U.S. market will continue.

Recommendations for Executive Action

To more efficiently and effectively monitor the safety of imported seafood, we recommend that the Secretary of Health and Human Services direct the Commissioner of FDA to work toward developing a memorandum of understanding with NOAA that leverages NOAA's Seafood Inspection Program's resources. The memorandum of understanding should address mutually agreeable protocols and training programs that are necessary to begin using NOAA employees to provide various services. Those services could include inspections of foreign firms, importer inspections, port-of-entry examinations and sample collections, and laboratory analyses.

To strengthen FDA's current imported seafood program and ensure the safety of seafood consumed in the United States, the Commissioner of FDA should take the following five actions:

- make it a priority to establish equivalence or other similar types of agreements with seafood-exporting countries, starting first with countries that have high-quality food safety systems;

-
- develop and implement a system to track the time involved in documenting, reviewing, and processing regulatory and enforcement actions, such as issuing warning letters and detaining unsafe products, so that FDA can identify the reasons for the delays and take actions to address them;
 - give priority to taking enforcement actions when violations that pose the most serious public health risk occur;
 - consider the costs and benefits of implementing an accreditation program for private laboratories; and
 - explore the potential of implementing a certification program for third-party inspectors, which would involve reviewing FDA's legal authorities and considering the costs and benefits, including developing and implementing the standards, controls, and oversight necessary to provide FDA with reasonable assurance that third-party inspectors are qualified and independent.

Agency Comments and Our Evaluation

We provided FDA and NOAA with a draft of this report for review and comment. We received written comments from the Commissioner, FDA, which are presented in appendix IV. FDA also provided technical corrections, which we have incorporated into the report as appropriate. We received a letter from the Chief Administrative Officer, NOAA, stating that the agency did not have any comments. The letter is presented in appendix V.

Regarding the six specific recommendations we made in this report, FDA generally concurred with five and disagreed with one. FDA generally concurred that it should (1) work toward developing a memorandum of understanding with NOAA that leverages NOAA's Seafood Inspection Program's resources; (2) develop and implement a system to track the time involved in documenting, reviewing, and processing regulatory and enforcement actions so that FDA can identify the reasons for the delays and take actions to address them; (3) give priority to taking enforcement actions when violations that pose the most serious public health risk occur; (4) consider the costs and benefits of implementing an accreditation program for private laboratories; and (5) explore the potential of implementing a certification program for third-party inspectors. Since we will be reviewing FDA's implementation of third-party inspections under the Medical Device User Fee and Modernization Act of 2002, FDA could use

the results of this review in assessing the potential to use third-party inspectors for imported seafood.

FDA did not concur with our recommendation to make it a priority to establish equivalence or other similar types of agreements with seafood-exporting countries, starting first with countries that have high-quality food safety systems. In commenting on this recommendation, FDA said the agency is not currently positioned to assign high priority to negotiating equivalence or other types of agreements with numerous countries that export seafood to the United States in light of the pressing priorities associated with implementation of the Bioterrorism Act. FDA also said that establishing these agreements is extraordinarily resource intensive. We agree that the process for creating these agreements is complex and resource intensive; however, we continue to believe that it should be a priority for FDA to negotiate equivalence or other less comprehensive agreements with seafood exporting countries to leverage its limited inspection resources. Additionally, FDA should view the creation of these agreements as a long-term investment in improving imported seafood safety. In the absence of equivalence or other agreements such as memorandums of understanding with seafood-exporting countries, FDA must continue to rely principally on reviews of importer records to determine whether imported seafood is produced under acceptable food safety systems.

FDA also raised some concerns about inferences that could be drawn from the report. For example, FDA said that our draft report implied that seafood has a higher likelihood of causing foodborne illness than other foods on the basis of a comparison of the number of foodborne illness outbreaks in the United States from seafood-related causes than from meat and poultry. FDA also said that our draft report did not acknowledge that foodborne illness outbreaks associated with seafood also include those from recreational and subsistence fishing, over which the federal government has little or no control. We modified this report to include the actual number of cases associated with seafood and meat and poultry outbreaks. We also added CDC's observation that foodborne illness outbreaks are generally underreported and that it is easier to identify the source of some diagnosable illnesses, such as scombroid poisoning from seafood, than illnesses that result from nonspecific gastrointestinal symptoms caused by other foods. Additionally, we added FDA's comment that some seafood-related illnesses may be caused by recreational or subsistence fishing, over which the federal government has little or no control.

As agreed with your offices, unless you publicly announce the contents of this report earlier, we plan no further distribution of it until 30 days from the date of this letter. We will then send copies to interested congressional committees; the Secretary of Health and Human Services; the NOAA Administrator; the United States Trade Representative; the Director, Office of Management and Budget; and other interested parties. We will make copies available to others on request. In addition, the report will be available at no charge on GAO's Web site at <http://www.gao.gov>.

If you or your staff have any questions about this report, please call me at (202) 512-3841. Key contributors to this report are listed in appendix VI.



Lawrence J. Dyckman
Director, Natural Resources
and Environment

Scope and Methodology

To reevaluate the Food and Drug Administration's (FDA) program for ensuring the safety of imported seafood and determine the status of efforts to implement our previous recommendations, we interviewed cognizant government and industry officials. Specifically, we interviewed officials and/or reviewed documents from the following FDA units: Center for Food Safety and Applied Nutrition's Office of Seafood, Office of Compliance, and Office of Constituent Operations; Office of Regulatory Affairs Office of Enforcement, Office of Regional Operations, and Office of Resource Management; Office of Chief Counsel; and Office of International Programs. We also visited the FDA district office in Bothell, Washington, where large volumes of seafood are processed, and we met with FDA officials to discuss relevant regulations, policies, and procedures. We also visited two U.S. importers to observe FDA's importer inspection process firsthand and to discuss their views.

To assess the progress that FDA has made since our 2001 report,¹ we analyzed the agency's inspection records of U.S. importers. Specifically, we randomly selected a probability sample of 117 inspections from a list of 415 importer inspections that nominally represented all importer inspections conducted by FDA for fiscal year 2002. From this sample, 13 inspections were outside the scope of this assignment—for example, they were for molluscan shellfish or the seafood actually was a domestic product. In addition, for 8 additional in-scope inspections, FDA could not locate complete documentation (6 inspections); and FDA did not complete a standardized inspection form (Form 3502) at the time of the inspection (2 inspections).

For the 96 in-scope inspections for which documentation was found, we analyzed the Form 3502 that investigators completed for each imported seafood product² during fiscal year 2002. The 96 inspections were associated with a total of 112 Forms 3502.³

¹U.S. General Accounting Office, *Food Safety: Federal Oversight of Seafood Does Not Sufficiently Protect Consumers*, [GAO-01-204](#) (Washington, D.C.: Jan. 31, 2001).

²To record importer inspection findings, FDA investigators complete a product-specific standardized form (Form 3502) after each importer is inspected. The forms indicate whether importers have the required documentation, and if so, whether it documents the foreign firm's compliance with U.S. Hazard Analysis and Critical Control Point requirements. Investigators may choose to inspect documentation for more than one product and therefore complete more than one Form 3502 during an inspection.

³We removed 5 inspections forms that were incorrectly completed.

Because we followed a probability procedure based on a random selection of inspections (and thereby products), our sample is only one of a large number of samples we might have drawn. Since each sample could have provided different estimates, we express the confidence in the precision of our particular sample's results as 95 percent confidence intervals (e.g., ± 7 percentage points). These are intervals that would contain the actual population values for 95 percent of the samples we could have drawn. As a result, we are 95 percent confident that each of the confidence intervals in this report will include the true values in the study population.

The estimate that 48 percent of U.S. importers' products had the required documentation is surrounded by a 95 percent confidence interval that ranges from 36 percent to 60 percent. We estimated that 4 percent of the FDA inspection forms erroneously indicate that the United States has an equivalence agreement with the exporting country. This estimate is surrounded by a 95 percent confidence interval that ranges from 1 percent to 10 percent.

To assess FDA's progress with regard to inspections of foreign firms, we obtained 107 of 108 foreign inspection reports for fiscal year 2002 for the 13 countries that FDA visited—Brazil, China, Costa Rica, Honduras, Iceland, Jamaica, Mexico, Poland, Taiwan, Thailand, Trinidad and Tobago, Uruguay, and Vietnam. Of these 107 inspection reports, we removed 8 because they covered shellfish, which was outside the scope of our review. We compared FDA's findings for the remaining 99 inspections with FDA's actions at U.S. ports of entry.

For the sample of importer inspections and the entire set of the foreign firm inspections, FDA provided inspection results in hard copy because FDA investigators do not transmit information electronically. FDA also provided us with summary data from the system used to maintain inspection results for our analyses of foreign firm and importer inspections. We conducted a data reliability assessment of the importer and foreign firm inspection information, which indicated that the data and data systems used by FDA were sufficiently reliable and complete to perform our analyses.

To assess the time frames for issuing warning letters and other pertinent information, we analyzed the 20 warning letters FDA issued following its foreign firm inspections and the 8 warning letters FDA issued following its U.S. importer inspections conducted during fiscal year 2002 that FDA determined warranted enforcement action. Recognizing FDA's time frame of 30 work days for FDA to process a warning letter, we did not consider

any warning letter issued within 45 calendar days after the date of inspection as having exceeded FDA's issuance time frame.

In addition, we interviewed and/or received documents from the National Oceanic and Atmospheric Administration's (NOAA) National Marine Fisheries Service, Seafood Inspection Program, and National Sea Grant Program. To obtain industry's views on the Hazard Analysis and Critical Control Point (HACCP) system for seafood and FDA's oversight of seafood firms, we also met with the National Fisheries Institute—a seafood trade association whose membership includes domestic and international firms. We also met with the Center for Science in the Public Interest—a consumer organization focusing on nutrition and food safety—which investigates and reports on outbreaks of foodborne illnesses. Finally, we spoke with officials from the Canadian Food Inspection Agency to discuss their regulations for ensuring the safety of imported seafood and to gain insight on agreements that Canada established with other foreign countries' food inspection authorities. We also received information from the Department of Agriculture about its program for requiring equivalence determinations before allowing exported meat and poultry products to enter the United States. However, the scope of this review did not include exploring whether Agriculture could make inspection or other resources available to augment FDA's seafood inspection program.

To explore other options for enhancing FDA's existing imported seafood safety program, we assembled a panel of recognized experts on the following seafood-related areas: seafood policy, laws, and regulations (including HACCP); public health, epidemiology, and microbiology; risk management and assessment; and international trade policy. With advice from the National Academies, we selected 63 seafood safety experts as potential panelists. From these 63 contacts, we chose the final nine panelists on the basis of the following criteria: (1) recommendations we received from the National Academies and participation on previous academy panels; (2) recommendations from others knowledgeable in the field of seafood safety; (3) the individual's area of expertise and experience; (4) the type of organization represented, including academic institutions, seafood industry, trade groups, and consumer groups; and (5) geographic representation. (The names and affiliations of the panel members are listed in app. II.) On July 2, 2003, we held an all-day meeting with the nine panelists at our office in Washington, D.C. Before the meeting, we provided each panel member with a set of four general discussion questions. At the end of each discussion, we asked the panelists to respond, using an anonymous ballot, to a set of questions that were based on the general

discussion topics. We recorded and transcribed the meeting to ensure that we accurately captured the panel members' statements.

We conducted our review from February 2003 through November 2003 in accordance with generally accepted government auditing standards.

Summary of Expert Panel Observations on the Safety of Imported Seafood

This appendix provides the names and affiliation of our expert panel members and summarizes the discussions held at the all-day meeting. The information presented in this appendix may not represent the views of every member of the panel. Also, this information should not be considered to be the views of GAO.

Members of Our Expert Panel

The following individuals were members of our expert panel on the safety of imported seafood:

- Haejung An, Associate Professor, Department of Nutrition and Food Science, Auburn University;
- Tom Chestnut, Vice President, Total Quality, Darden Restaurants;
- Bob Collette, Vice President, Science and Technology, National Fisheries Institute;
- Cameron Hackney, Dean, Davis College of Agriculture, Forestry and Consumer Sciences, West Virginia University;
- Michael Jahncke, Director, Virginia Seafood Agricultural Research and Extension Center, Virginia Polytechnic Institute and State University;
- Michael Moody, Professor and Head, Department of Food Science, Louisiana State University;
- W. Steven Otwell, Professor, Seafood Technology, Department of Food Science and Human Nutrition, University of Florida;
- Barbara Rasco, Associate Professor, Department of Food Science and Human Nutrition, Washington State University; and
- Caroline Smith DeWaal, Director, Food Safety Approach, Center for Science in the Public Interest.

Summary of Panel Observations

On July 2, 2003, we held an all-day meeting with the nine panelists at our office in Washington, D.C. Before the meeting, we provided each panel member with a set of four general discussion questions. At the end of each discussion, we asked the panelists to respond, using an anonymous ballot,

to a set of questions that were based on the general discussion topics. We recorded and transcribed the meeting to ensure that we accurately captured the panel members' statements. The panelists discussed two overarching themes: (1) changes that FDA has made to improve its ability to ensure imported seafood safety and (2) options for improving FDA's current regulatory approach.

FDA's Recent Changes

Since our last report on this matter in 2001, FDA has made changes to its approach for ensuring the safety of imported seafood. Panelists specifically discussed these changes, including (1) a shift in focus from inspecting foreign countries' entire food safety systems for equivalence to inspecting more foreign firms for HACCP compliance, (2) a slight increase in the number of port-of-entry examinations and laboratory testing of imported seafood, and (3) an increase in testing for aquaculture drug residues. Specifically:

- Panelists suggested that inspecting a small number of foreign firms for HACCP compliance, rather than inspecting foreign countries' entire food safety systems for equivalence, is ineffective because FDA only inspects about 100 seafood firms in 10 countries annually, out of a universe of an estimated 13,000 firms in about 160 countries.
- Panelists believed that increasing the number of port-of-entry examinations and laboratory testing for imported seafood, while desirable, would be ineffective because this approach is not consistent with the preventative HACCP approach.
- Because regulatory authorities around the world are increasingly finding aquaculture drug residues, the panelists believed that more testing for drug residues would be a valuable verification step in an effective HACCP system. Furthermore, panelists believed that FDA should shift its focus to the source of production to prevent the abuse of legal substances or the use of banned aquaculture drugs.

Options for Improving the Current Regulatory Approach

Overall, panelists believed that FDA's approach to ensuring the safety of imported seafood should address problems before products reach U.S. ports of entry. They did not suggest providing FDA with more resources or eliminating any component of the agency's current approach (e.g., port-of-entry examination and testing, foreign firm inspections, and importer inspections). However, the panelists did stress the need for FDA to

rearrange its approach, placing more responsibility for ensuring product safety on foreign governments, and to focus its available resources on ensuring that imported seafood is processed under effective HACCP systems. Therefore, the panelists recommended that FDA explore several options to enhance its regulatory approach, including the following:

Equivalence Agreements

- Panelists recommended that FDA establish equivalence agreements in order to more efficiently utilize its limited resources. They believed that equivalence agreements would be more effective than FDA's direct inspection of foreign firms for ensuring HACCP compliance and would also allow the agency to focus resources on the countries, firms, and products that pose the greatest risk, thereby shifting the burden for HACCP compliance from FDA to foreign governments and foreign firms. Panelists stated that such agreements should not imply that FDA must find a foreign government's seafood safety system "equal" to that of the U.S. system. For example, panelists said that FDA should have flexibility in terms of what it considers equivalent and should also consider alternatives to country-to-country agreements (e.g., product-to-country, company-to-country, and hazard-specific agreements).
- The panel recommended that FDA first consider one-way equivalence agreements, with countries where the United States imports large quantities of seafood but does not export significant quantities. Although panelists noted that two-way agreements are preferred, they believed that using one-way equivalence agreements initially would better ensure that foreign firms are meeting U.S. standards. However, U.S. seafood exporters may object to one-way agreements, arguing that these would favor the foreign countries, which may have barriers to U.S. exports.
- Panelists recommended that FDA establish a timeline for agreements, although there was no consensus on the best way to develop this timeline. Possible suggestions included a phased-in process, based on the quantity of exports to the United States, and the establishment of agreements based on the willingness of participants.
- Panelists believed that Congress should mandate that FDA establish equivalence agreements; however, FDA should be allowed to determine how the agreements are structured and implemented. The panel also expressed concern that our trading partners could view mandating equivalence as protectionist. Additionally, panelists said FDA should

still implement third-party certification and auditing if equivalence is mandated.

- The panel believed that FDA should provide additional training and education to foreign governments and foreign firms on HACCP requirements, and that industry should pay for this training.

Importer Inspections

- Panelists recommended that FDA identify competent inspection authorities to establish lists of preferred suppliers, in which the foreign government inspects firms wishing to export to the United States, to assure the agency that these firms meet HACCP requirements. By adopting this approach, FDA could then target inspection and testing resources to nonpreferred suppliers.
- Panelists recommended that FDA develop an accreditation program for private laboratories that demonstrate compliance with FDA's testing methodologies. FDA could then establish a list of approved, accredited domestic laboratories to augment their port-of-entry testing for compliance and enforcement. Additionally, domestic importers could use the accredited foreign and domestic laboratories to demonstrate, through testing, that their seafood products were processed in accordance with HACCP requirements. Panelists believed that most domestic private laboratories are capable of meeting FDA's standards, such as sample chain-of-custody, laboratory procedure, and qualified analysts, and could provide timely results.

Foreign Firm Inspections

- Panelists recommended that FDA establish a standardized program to certify private, third-party inspectors to conduct HACCP inspections of foreign processing firms and domestic importers. The third-party inspectors would be paid for by industry and monitored by FDA, thereby allowing for more foreign firm and importer inspections at little additional cost to FDA.
- Panelists recommended that FDA place more responsibility on foreign governments to ensure that foreign firms are aware of, and are meeting, their responsibilities under HACCP. Under an effective HACCP system, the panelists felt that FDA's emphasis should be on inspection and testing in the foreign country where the seafood is harvested and processed and where hazards are introduced.
- Panelists recommended that when problems are discovered as a result of inspections of foreign firms or importers, FDA should discuss with

the exporting countries how to prevent these problems from reoccurring.

Port-of-entry Examinations and Testing

- Panelists suggested that state regulatory laboratories (e.g., those operated by the state Department of Health or Agriculture) may be a good option for assisting FDA in testing imported seafood products, particularly in those states with ports and seafood industries. State laboratories provide comparable testing for state regulatory authorities and have procedures in place that could meet FDA's standards for compliance testing. State laboratories are also well equipped for food testing and provide reliable results. Panelists did note, however, that most states are financially constrained, and therefore state laboratories may not have any excess capacity (e.g., qualified analysts, equipment time, or laboratory space) to analyze additional samples for FDA. Furthermore, in order to use the facilities, FDA would need to harmonize testing methodologies.
- Panelists suggested that FDA use the National Marine Fisheries Service laboratories in Pascagoula, Mississippi, and Seattle, Washington, to augment testing at ports of entry. Panel members believed that this was a good option for FDA because these laboratories currently conduct seafood research and testing.
- Panelists did not recommend that FDA use academic laboratories for testing at ports of entry. They stated that most academic laboratories are not structured to do compliance testing and would not meet FDA's standards for chain of custody of the samples or acceptable documentation for compliance or enforcement actions.

Results of GAO Analysis of FDA's Inspections of 99 Foreign Firms, Fiscal Year 2002

Firms	Number of inspections
All firms	
With a HACCP plan as required ^a	93
Not required to have a HACCP plan	5
Processing high-risk seafood	66
Processing high-risk seafood with HACCP plans ^a	65
Found to have serious violations by FDA ^a	40
Placed on detention	6
Firms processing high-risk seafood	
With adequate HACCP plans	10
With inadequate HACCP plans ^a	55
Firms found to have serious HACCP violations	
Issued a warning letter	20
Issued an untitled letter ^b	14

Source: GAO analysis of FDA's inspections of 99 foreign firms.

Note: We received and reviewed 107 of the 108 foreign firm inspection records that FDA conducted in fiscal year 2002. Of the 107 files received, we removed 8 inspections because they covered shellfish, which was outside the scope of our assignment.

^aOne foreign processor did not have a HACCP plan as required.

^bOf the remaining 6 firms found to have serious HACCP violations, 1 firm no longer ships to the United States, 1 firm's case is still being reviewed, and 1 firm's warning letter was never issued; FDA is considering possible reinspection of this firm. For the remaining 3 firms, FDA officials said that they have no record of receiving the inspection reports.

Comments from the Food and Drug Administration

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



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

January 8, 2004

Lawrence J. Dyckman
Director, Natural Resources and Environment
United States General Accounting Office
441 G Street, NW
Washington, DC 20548

Dear Mr. Dyckman:

Please find the enclosed comments from the Food and Drug Administration on the GAO draft report entitled, FOOD SAFETY: FDA's Imported Seafood Safety Program Shows Some Progress but Further Improvements are Needed, (GAO-04-246). The Agency provided technical comments directly to your staff.

We appreciate the opportunity to review and comment on this draft report before its publication as well as the opportunity to work with your staff in developing this report.

Sincerely,

A handwritten signature in black ink, appearing to read "Mark B. McClellan".

Mark B. McClellan, M.D., Ph.D.
Commissioner of Food and Drugs

Enclosure

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General Comments by the Department of Health and Human Service's Food and Drug Administration (FDA) on the General Accounting Office's (GAO) Draft Report, *FOOD SAFETY: FDA's Imported Seafood Safety Program Shows Some Progress but Further Improvements are Needed (GAO-04-246)*

FDA appreciates the opportunity to comment on GAO's draft report that focuses on FDA's imported seafood safety program.

We have some general comments regarding the recommendations, and the overall report, as follows:

General Comments

See comment 1.

- The draft report indicates that headquarters' officials stated that "...the agency does not track the time for reviewing these [Warning Letter and Untitled Letter] recommendations...."

This statement is not accurate. The Agency does track Warning Letter and Untitled Letter recommendations, but currently must manually compute the time it takes to review these recommendations. We anticipate that the recently developed compliance action tracking system, Case Track (referenced below under FDA's comments to Recommendation #3), will provide a more user friendly and efficient database to track this type of information. Additional funding for the continued development and necessary modifications of Case Track will significantly impact the timeframe on when this is to be accomplished.

See comment 2.

- The GAO report implies that seafood has a higher likelihood of causing foodborne illness than other foods based on a comparison of the number of reported outbreaks (i.e., two or more illnesses from a single source) in the United States from seafood-related causes than from meat or poultry. The statement that seafood is riskier than other foods as demonstrated by the Centers for Disease Control (CDC) outbreak data was first aired over a decade ago during public debates over seafood safety and then repudiated by CDC itself. In correspondence to both FDA and to the Congress in 1990, CDC stated that data from its Foodborne Disease Surveillance System alone could not be used to determine whether eating seafood is more or less dangerous than eating other foods.

There are several reasons why CDC data cannot be used in this way. Perhaps the most significant of these is the fact that foodborne illness outbreaks are underreported to CDC, and of those that are reported, they tend to skew in favor of more easily diagnosable illnesses, such as ciguatera and scombroid poisoning from seafood, rather than nonspecific gastrointestinal symptoms caused by other foods. Other factors include the variability of illnesses contained within outbreaks, the fact that most foodborne illnesses occur as sporadic cases rather than as part of outbreaks, and similar factors.

The draft report fails to acknowledge that foodborne illnesses associated with seafood also include those from recreational and subsistence fishing over which the Federal government has little or no control.

There is no reason to believe that commercial seafood is riskier than other commercial sources of animal protein.

See comment 3.

- The draft report states that, in the absence of equivalence agreements, FDA must rely on importer records to determine whether a food in a foreign country has been produced acceptably. That is incorrect. As GAO points out elsewhere in the document, FDA relies on

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See comment 4.

examination and sampling at ports of entry, overseas inspections of foreign processing plants, and detention without physical examination (DWPE), among other things. It is important to recognize that the FDA seafood HACCP requirement that importers take and document "affirmative steps" to ensure that U.S. requirements are met was a novel concept when introduced several years ago. FDA recognized that this concept would take time to implement successfully and therefore has never relied on it exclusively as a way to ensure safety. Rather, it is a relatively new approach that is being integrated into the overall food safety system.

- We do not believe that the GAO report fully captures the basis for issuing Warning and Untitled Letters. We believe a more accurate explanation is as follows:

"Once FDA Investigators complete an inspection of a foreign facility or at a domestic importer, they submit a recommendation and/or report to headquarters for review and a regulatory decision. FDA issues Warning Letters and Untitled Letters to inform responsible individuals of violations found during the inspection. This is consistent with FDA's practice to afford individuals and firms the opportunity to voluntarily take appropriate and prompt corrective action prior to the initiation of enforcement action. The use of these letters is based on the expectation that a majority of individuals and firms will voluntarily comply. The main distinction between the two letters is that a Warning Letter contains a statement that FDA will consider action if corrections are not made and demands a written response within a certain period of time. To ensure Warning Letters address current conditions, current FDA policy requires that Warning Letters be issued within four months from the date that the inspection concludes."

"Untitled Letters do not reference enforcement actions, contain or demand a response. The use of an Untitled Letter rather than the more serious Warning Letter may be for a variety of reasons; such as, the violations observed or deviations at the firm are not of regulatory significance; the evidence is not current or it is inconclusive; it was the firm's first inspection; or new rules have been implemented."

Comments on Recommendations for Executive Action

1. **To more efficiently and effectively monitor the safety of imported seafood, we recommend that the Secretary of Health and Human Services direct the Commissioner of FDA to work toward developing a memorandum of understanding with NOAA that leverages NOAA's Seafood Inspection Program's resources. The memorandum of understanding should address mutually agreeable protocols and training programs necessary to begin using NOAA employees to provide various services. Those services could include inspections of foreign firms, importer inspections, port-of-entry examinations and sample collection, and laboratory analyses.**

FDA Comment

The Food and Drug Administration and the National Oceanic and Atmospheric Administration (NOAA), National Marine Fisheries Service (NMFS), Seafood Inspection Program have had a long, collegial working relationship and have been working for some time to better integrate their programs. We have once again begun a dialog between FDA and NOAA discussing a possible transfer of the Seafood Inspection Program from NOAA to FDA. In lieu of such a transfer, FDA will be working with NOAA to find better ways of integrating its programs with those of the NMFS.

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We currently have three Memoranda of Understanding (MOUs) between the two agencies dealing with seafood safety and inspection operations as well as an MOU on shellfish growing waters that includes three other agencies in addition to FDA and NMFS. We also have had multiple Interagency Agreements that provided joint funding to determine the effects of fish consumption on human mercury toxicity; the Shellfish Safety Assistance Project to provide financial support for the operation of the central office of the Interstate Shellfish Sanitation Conference; as well as jointly funding with USDA and DOD to support the National Advisory Committee for the Microbiological Criteria for Foods. Additionally, the two programs continue to work closely to represent the United States on issues arising from the Codex Alimentarius Committee on Fish and Fishery Products. We agree that it is important to continue to explore if there are additional cooperative activities either under our existing MOUs or additional agreements that can help us better leverage NOAA Seafood Inspection Program resources in order to more efficiently and effectively protect the public health.

The NMFS currently has a program to provide export health certificates for seafood exporters shipping to the European Union, a service that FDA also provides at considerable expense. The major difference is that the NMFS charges the seafood processor who benefits from the service. While some segments of the seafood industry object to paying fees for this service, we have been working to develop a pilot program in which requests for export certificates for live and fresh seafood will be referred to NMFS. By limiting the burden of providing these perishable commodity export health certificates, FDA will be able to free up its limited resources for other seafood activities.

In addition, the recently enacted Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Bioterrorism Act) added a new authority under section 314 to commission other federal officials to conduct examinations and inspections for facilities that are regulated under the Federal Food, Drug, and Cosmetic Act and by another federal agency. We have been reviewing that authority with a number of different federal agencies to determine what kinds of programmatic activities might best be achieved by using this newly established commissioning authority and who might be commissioned. Our first use and highest priority was the use of this new authority to commission personnel from the Bureau of Customs and Border Protection in the Department of Homeland Security to assist with border inspections. However, FDA has also conducted an initial legal review and has determined that, under certain circumstances, we can use the authority under section 314 of the Bioterrorism Act because the Department of Commerce/NMFS jointly regulates these seafood facilities with FDA. Now that we have completed our initial legal review and developed procedures for commissioning, we are in a position to enter more formal discussions to explore the potential for commissioning of NMFS inspectors. We have suggested forming a work group to determine if commissioning could permit NMFS to provide more service to the industry, increase the value of their inspections, and assist FDA in meeting its public health responsibilities.

There also may be other opportunities for us to better leverage with NMFS inspectors where it may be advantageous to get information from NMFS inspectors, who may already be "on site," rather than having an FDA inspector travel to a distant location

Yet another example of increased coordination could be the use of NOAA laboratory capacity to carry out analyses of seafood samples that FDA takes during the normal course of our work, or during "crisis" situations. Specifically for chloramphenicol analysis, we are currently finalizing an IAG with the NOAA Fisheries' National Seafood Inspection Laboratory (NSIL) located in Pascagoula, MS and the NOAA Fisheries' Northwest Fisheries Science Center in Seattle, WA. We hope that such an agreement may help increase our laboratory capacity, with the potential fuller utilization of NOAA capabilities. Discussions between the particular NOAA fisheries

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facilities have resulted in FDA's provisional approval (pending on site review) of these laboratory's methods for sample submission, custody, routing, and accounting and documentation procedures necessary to maintain the regulatory chain of custody and tracking required for import collections. FDA is still awaiting our FY'04 budget to determine if we will be able to fund these proposals.

Finally, FDA has long explored the potential that could be obtained by transfer of the NMFS voluntary, fee-for-service seafood inspection program to FDA. The transfer of the program from one agency to another would require legislation. A bill to transfer this program was transmitted to the Congress in 1999 but a sponsor could not be found and thus the bill was never formally considered. We are not aware of any current Congressional effort to provide for such a realignment.

To strengthen FDA's current imported seafood program and ensure the safety of seafood consumed in the United States, the Commissioner of FDA should take the following five actions:

- 2. Make it a priority to establish equivalence or other similar types of agreements with seafood exporting countries, starting first with countries that have high-quality food safety systems.**

FDA Comment

In light of the pressing FDA priorities associated with implementation of the provisions of the Bioterrorism Act, and for the reasons described below, FDA is not currently positioned to assign high priority to negotiating equivalence or similar types of agreements with the numerous countries that are currently exporting seafood to the United States. However, the agency is aware that in some specific situations, formal agreements with governments of seafood exporting countries can enhance the assurances of safety for seafood exported to the United States. The agency has established a number of such agreements pertaining to seafood safety, six of which are currently operative. All current seafood safety agreements are longstanding "compliance-based" agreements, rather than equivalence agreements, whereby the governments of the exporting countries have agreed to undertake certain regulatory and administrative actions, or to otherwise put safety measures into place, that provide FDA with reasonable assurance that seafood exported to the United States complies with applicable U.S. requirements. Five of these involve raw molluscan shellfish, under which a foreign country agrees to comply with the rather complex requirements of the U.S. National Shellfish Sanitation Program.

Under some circumstances, these types of compliance agreements can be useful components in the overall food safety effort, at least in the control of specific seafood safety hazards. The agency notes, however, that negotiation and establishment of formal compliance agreements with other governments is extraordinarily resource intensive. In general, FDA would not be positioned to accept seafood safety assurances from exporting countries unless and until the agency conducts a credible assessment of the exporting country's seafood safety system, both as it exists "on paper" and as it is being implemented, in practice, specifically to guarantee compliance with U.S. requirements. This process currently requires expenditure of very significant time, personnel and monetary resources by FDA. Nonetheless, FDA intends to review the potential scope(s) of such agreements, targeted toward specific issues and problems, and the extent to which they could be beneficial and provide possible resource efficiencies and savings in the long run. There is no timetable for this review, however, because for the current fiscal year, at least, the agency lacks resources to engage in overseas evaluations of foreign regulatory systems - an essential prerequisite for any agreement.

See comment 5.

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As with compliance agreements, FDA agrees that equivalence agreements, in principle, can be effective in specific cases to enhance seafood safety. However, the agency does not believe that equivalence agreements, applied broadly to many exporting countries, would enhance seafood safety markedly or would be practicable from a resource perspective.

Within the context of the World Trade Organization Agreement on the Application of Sanitary and Phytosanitary Measures (WTO SPS agreement), the concept of equivalence is envisioned as a means for exporting countries to gain otherwise blocked or inhibited market access, if they are able to demonstrate satisfaction of the importing country's "appropriate level of protection". In the case of most seafood exported to the United States, the "otherwise blocked or inhibited" condition is not applicable. Under the laws FDA administers, an affirmative governmental demonstration of either compliance or equivalence for seafood as a precondition for market access is not required. Consequently, governments of exporting countries are not mandated to affirmatively demonstrate to FDA compliance or equivalence of their seafood products as a condition for market access. Thus, there is little apparent market access incentive for exporting countries, in general, to seek an FDA evaluation or finding of equivalence. FDA recognizes, however, that all WTO Members are required to engage in discussions on equivalence if so requested by another Member. In this regard, FDA has discussed and would be prepared to discuss potential seafood equivalence options if so requested by an exporting country's government.

As with compliance agreements, the process by which equivalence agreements are established, even for countries with sophisticated seafood safety systems, is extraordinarily resource intensive. The process of "paper review" and on-site evaluation of an exporting country's seafood safety system or its individual seafood safety measures, may take several years and very large expenditures of staff and monetary resources to complete. Once FDA completes such an equivalence evaluation, and if the agency makes a determination of equivalence, it must, according to provisions of the Uruguay Round Agreements Act, go through notice and comment.

As the United States has stated within the WTO SPS Committee during that Committee's recent deliberations on WTO Members' implementation of the concept of equivalence, the practical benefits of equivalence agreements, in terms of public health protection or trade facilitation, may not be worth the costs associated with the process. In fact, outside of specific situations, such as those bearing on meat and poultry safety, where equivalence is mandated as a condition for market access, very few equivalence agreements have been established by other WTO Members.

As noted by GAO, the Codex Alimentarius Commission (Codex) has very recently established guidelines to facilitate all countries' understanding and practical implementation of the concept of equivalence. The United States, and FDA in particular, was instrumental in developing these important international guidelines which can now be used in those cases where a formal equivalence evaluation process appears to be warranted as a necessary means of trade facilitation. FDA, in cooperation with other U.S agencies, intends to utilize these new international guidelines as a framework for establishing workable FDA equivalence criteria for foods. In so doing, FDA will look carefully for means to make the equivalence evaluation process as efficient as possible, such that it can be used effectively in those situations where it is actually warranted.

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See comment 6.

3. Develop and implement a system to track the time involved in documenting, reviewing, and processing regulatory and enforcement actions, such as issuing warning letters and detaining unsafe products, so that the agency can identify the reasons for the delays and take actions to address them.

FDA Comment

FDA recognizes the need to strengthen its tracking and processing of establishment inspection reviews, and in 2001 began the development of the Compliance Action Case Track System (Case Track) for foreign and domestic case reviews. Case Track is a computerized system which has capabilities that address the areas of concern identified in the GAO Report.

In 2002, FDA initiated a pilot of the computerized system for processing and tracking domestic cases. In 2003, FDA transitioned all domestic cases under the new Case Track system.

FDA is currently working with contractors on the parameters needed to complete the next phase of incorporating foreign case processing and tracking into the system, as well as creating a tickler mechanism that provides notification to the case reviewer when timeframes are approaching. FDA anticipates completion of the imports transitional and implementation phase and tickler system by the Spring of 2004. Additional funding for the continued development and necessary modifications of Case Track will significantly impact whether the projected timeframe is met.

In addition, the agency field components use the Field Accomplishments and Compliance Tracking System (FACTS) to track the time involved in preparing, receiving, and processing regulatory and enforcement actions. FACTS is an FDA agency-wide database that provides the ability to request and manage field work assignments and record work results (from assignments through compliance actions).

The field compliance components use FACTS to record details and events which take place during handling of compliance actions such as Warning Letters and enforcement actions. FACTS provides the ability for the chronological record of a case to be maintained and monitored."

4. Give priority to taking enforcement actions when violations that pose the most serious public health risk occur.

FDA Comment

Because of the limited resources available for foreign seafood inspection, FDA assures that inspectional efforts are generally directed at those firms representing the greatest risk. FDA considers a number of risk factors in identifying firms for coverage. These factors include:

- Firms producing products known to present specific hazards
- Firms in countries that are significant sources of product for U.S. markets
- Firms in countries that may pose safety or security concerns
- Firms in countries with known infrastructure problems
- Firms producing products shipped in large quantities into the U.S. or shipped in smaller quantities but intended for vulnerable populations
- Firms with identified problems.

In this respect, FDA's HACCP-based foreign compliance inspections are prioritized in advance. It is important to recognize that the violations found during these inspections do not typically involve a finding of contaminants in the products being shipped to the United States. Rather, they

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involve a finding that better preventive controls are needed to ensure that there will not be contaminants in the products in the future. For those reasons, FDA has not typically prioritized the results of one inspection over another; rather, the agency believes it is important to take action on all of the findings in a timely manner. FDA acknowledges that it needs to improve in that area. Because HACCP-based foreign compliance inspections are relatively new and are being performed in addition to traditional activities, it has not always been easy to manage the process as expeditiously as the agency would prefer.

Once a firm has been identified for inspection as a high risk, FDA remains committed to taking strong, prompt enforcement when violations are found. In this regard, ORA and CFSAN managers agreed to reinforce with their respective staffs the importance of timely foreign inspection reports and followup. Additionally, FDA is moving towards more use of Detention Without Physical Examination (DWPE) rather than Warning Letters and Untitled Letters. In accordance with FDA guidance implementing section 801(a) of the Federal Food, Drug, and Cosmetic Act (FD & C Act), FDA lists a foreign firm's product(s) on an Import Alert to notify the field that the firm's products are subject to refusal of admission. The products are subject to refusal of admission until the violations found during the inspection are corrected. The use of DWPE in this context is one way of expediting the corrective action to achieve compliance.

5. Consider the costs and benefits of implementing an accreditation program for private laboratories.

FDA Comment

The question of FDA becoming an accreditation body and implementing an accreditation program for non-FDA laboratory testing requires an objective analysis to fully address all the issues, including the costs and benefits. While FDA believes that such a study may be valuable, our current priorities are focused on full implementation of the new food safety and security authorities contained in the Bioterrorism Act. As these priorities permit, FDA will:

- Conduct a preliminary review of the legal authorities relating to the adoption and implementation of an accreditation program for non-FDA laboratory testing of imported seafood. This analysis would identify the applicable legal authorities, if any, that we currently have and whether additional authorities are needed.
- The review would be followed up with a study that would examine a variety of issues including examining the scope of accreditation that could be offered by FDA and attendant costs and benefits, both quantifiable and unquantifiable, of implementing different options. Other legal or administrative obstacles may be identified through these assessments and during the cost/benefits evaluation.

Update on Status of Federal, State Laboratory Testing

FDA currently is evaluating several federal and state laboratory testing initiatives. At this time these initiatives are limited to analysis of import seafood collected by the FDA. FDA is currently negotiating with three outside laboratories to test official FDA imported seafood samples for the presence of chloramphenicol.

Federal Laboratory -- NOAA

Two NOAA proposals have been received, reviewed and are in final stage of approval by the FDA and NOAA authorities. The participating NOAA laboratories will screen import shrimp

**Appendix IV
Comments from the Food and Drug
Administration**

samples collected by the FDA for the presence of chloramphenicol (CAP). The screening test performed by the laboratories is not sufficient to support FDA regulatory action; CAP detected by the screening test will be regarded as presumptive and FDA will perform more definitive confirmation testing before taking regulatory action. The NOAA laboratories are not equipped to perform confirmation testing; the laboratories will enhance FDA testing capacity by identifying import entries free of CAP residues and reducing the testing required by the FDA to confirm a presumptive finding of CAP residues.

The NOAA proposals include funding by the FDA for personnel, equipment, and use of facilities; the agreements will be signed and implemented upon FDA approval of funds. FDA will also assume additional expenses (not identified in the proposals) for training, oversight, and confirmation testing.

The duration of the NOAA proposals are limited to one fiscal year of screening imported seafood; FDA and NOAA will evaluate agreement in final quarter and modify, restructure, or terminate for FY05 as warranted.

State Laboratory -- FDACS

FDA is currently in discussion with Florida Department of Agriculture and Consumer Services (FDACS) to establish an agreement providing state assistance with testing of imported shrimp for CAP residues. FDACS will also receive official FDA collections of imported shrimp for screening and confirmation testing. FDA intends to identify firms for regulatory action based on state testing.

FDACS expects to request funding from the FDA to implement a testing agreement. No testing levels or costs have been identified. FDA will assume additional expenses for oversight and monitoring of the state laboratory testing. The state testing would add additional capacity by permitting regulatory action based on state findings.

6. Review its legal authorities and consider the costs and benefits of implementing a certification program for third-party inspectors.

FDA Comment

FDA believes that a third party inspection and certification program to monitor the safety of imported seafood may hold potential promise to enhance FDA's seafood safety program, but notes that, as with laboratory accreditation, the cost and benefits must be identified and considered. As resources permit, the agency intends to identify and consider the costs and benefits of implementing a certification program for third party inspectors of imported seafood, as well as begin a review of legal authorities relating to the adoption and implementation of such a certification program.

The following are GAO's comments on the Food and Drug Administration's letter dated January 8, 2004.

GAO Comments

1. We modified our report to state that although FDA does not have an automated system for computing the time it takes to review warning letter and untitled letter recommendations, it is in the early stages of developing such a system. This system will enable FDA to track the time involved in documenting, reviewing, and processing enforcement actions.
2. We modified this report to include the actual number of cases associated with seafood and meat and poultry outbreaks. We also added the Centers for Disease Control and Prevention's observation that foodborne illness outbreaks are generally underreported and that it is easier to identify the source of some diagnosable illnesses, such as scombroid poisoning from seafood, than illnesses that result from nonspecific gastrointestinal symptoms caused by other foods. Additionally, we added FDA's comment that some seafood-related illnesses may be caused by recreational or subsistence fishing, over which the federal government has little or no control.
3. As shown in our report, FDA inspects only a small percentage of U.S. importers, examines and samples a very small amount of imported seafood at U.S. ports of entry, and inspects few seafood firms in foreign countries each year. In the absence of equivalence or other agreements such as memorandums of understanding with seafood-exporting countries, FDA must continue to rely principally on reviews of importer records to determine whether imported seafood is produced under acceptable food safety systems. For these reasons, we continue to believe that FDA should develop such agreements as quickly as possible. Moreover, FDA acknowledged in its final HACCP rule, issued in December 1995, that in the absence of significant numbers of agency inspections of foreign processing facilities, a memorandum of understanding can be the most efficient and effective mechanism for ensuring that foreign processing plants are operating in compliance with the requirements of the regulations.¹

¹Procedures for the safe and sanitary processing and importing of fish and fishery products, 60 Fed. Reg. 65096, 65155 (1995). (Codified at 21 CFR Pts. 123.12 and 1240.)

4. We modified this report to include FDA's basis for issuing these letters.
5. We acknowledge that establishing equivalence or other agreements is complex and resource intensive. However, we continue to believe, as supported by our panel of nationally recognized food safety experts, that equivalence agreements or less comprehensive alternatives, such as compliance agreements or memorandums of understanding represent a more effective long-term approach for ensuring the safety of imported seafood and would allow FDA to leverage its staff resources by shifting some of its regulatory burden to exporting countries. Also, U.S. importers would be able to rely on the foreign regulatory authority to ensure compliance with HACCP requirements by foreign processors.

Also see comment 3.

6. Our report recognizes that FDA is beginning to take action to develop an automated system to track the time involved in documenting, reviewing, and processing regulatory actions.

Also see comment 1.

Comments from the National Oceanic and Atmospheric Administration



UNITED STATES DEPARTMENT OF COMMERCE
National Oceanic and Atmospheric Administration
OFFICE OF FINANCE AND ADMINISTRATION

JAN 13 2004

Mr. Lawrence J. Dyckman
Director, Natural Resources
and Environment
United States General Accounting Office
441 G Street, NW
Washington, DC 20548

Dear Mr. Dyckman:

Thank you for the opportunity to review and comment on the General Accounting Office's draft report entitled, "Food Safety: FDA's Imported Seafood Safety Program Shows Some Progress but Further Improvements are Needed," GAO-04-246. The National Oceanic and Atmospheric Administration does not have any comments on the draft report.

Sincerely,

for Mark A. Cato
William F. Broglie
Chief Administrative Officer



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GAO Contacts and Staff Acknowledgments

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