

GAO

Report to the Ranking Member,
Subcommittee on Oceans, Atmosphere,
Fisheries, and Coast Guard, Committee
on Commerce, Science, and
Transportation, U.S. Senate

February 2009

SEAFOOD FRAUD

FDA Program Changes and Better Collaboration among Key Federal Agencies Could Improve Detection and Prevention



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Highlights of [GAO-09-258](#), a report to the Ranking Member, Subcommittee on Oceans, Atmosphere, Fisheries, and Coast Guard, Committee on Commerce, Science, and Transportation, U.S. Senate

Why GAO Did This Study

In 2007, Americans consumed almost 5 billion pounds of seafood. Most seafood buyers, at many levels—importers, distributors, supermarkets, restaurants, and individual consumers—assume that the seafood they buy is what the seller claims it is. However, this is not always the case. Sometimes seafood products are mislabeled for financial gain—an activity called seafood fraud. Three federal agencies play key roles in detecting and preventing seafood fraud: the Department of Homeland Security's Customs and Border Protection (CBP), the Department of Commerce's National Marine Fisheries Service (NMFS), and the Department of Health and Human Services' Food and Drug Administration (FDA). GAO was asked to determine (1) the actions key federal agencies take to help detect and prevent seafood fraud and (2) the extent to which these key federal agencies collaborate with each other to help detect and prevent seafood fraud. GAO reviewed data and documents from each agency on actions to detect and prevent seafood fraud, and interviewed agency officials and other key stakeholders.

What GAO Recommends

GAO is making recommendations to CBP, NMFS, and FDA that are intended to help reduce the prevalence of seafood fraud, increase interagency collaboration, improve information sharing, and reduce overlaps. In commenting on a draft of this report, CBP, NMFS, and FDA generally agreed with the recommendations.

To view the full product, including the scope and methodology, click on [GAO-09-258](#). For more information, contact Lisa Shames at (202) 512-3841 or shamesl@gao.gov.

SEAFOOD FRAUD

FDA Program Changes and Better Collaboration among Key Federal Agencies Could Improve Detection and Prevention

What GAO Found

CBP and NMFS conduct several activities to help detect and prevent seafood fraud, but FDA told GAO that it focuses on food safety and undertakes few fraud-related activities. Nonetheless, fraud can result in food safety problems. For example, fish that was mislabeled as a different species for financial gain has caused illnesses due to the presence of a potentially deadly toxin.

- CBP reviews seafood import documentation to detect schemes to avoid paying the appropriate customs duties as seafood products enter the country, among other things.
- NMFS addresses seafood fraud through its voluntary, fee-for-service inspection program, which includes inspecting seafood that retailers, among others, are purchasing to verify its net weight and ensure the species is correctly identified. According to NMFS officials, NMFS inspects approximately one-third of the seafood consumed in the United States.
- FDA examines only about 2 percent of imported seafood annually, and its primary seafood oversight program does not address economic fraud risks, which limits its ability to detect fraud. An FDA seafood fraud-related activity is the maintenance of a publicly available list of seafood names that is intended to help the industry correctly label products. However, until 2009, FDA had not fully updated the list it created in 1993 to reflect over 400 name changes. Finally, FDA's guidance to help seafood processors comply with its seafood oversight program does not reflect the seafood labeling requirement of the Food Allergen Labeling and Consumer Protection Act of 2004 to include the species of fish or shellfish on product labels. Because of the limited scope of FDA's seafood oversight program, its mismanagement of the Seafood List, and its failure to update its guidance to reflect the allergen labeling requirement, consumers have less assurance that the seafood they purchase is correctly labeled.

The federal agencies that share responsibility for detecting and preventing seafood fraud—CBP, NMFS, and FDA—do not effectively collaborate with each other. Specifically, they have not identified a common goal, established joint strategies, or agreed on roles and responsibilities. As a result, the agencies have not taken advantage of opportunities to share information that could benefit each agency's efforts to detect and prevent seafood fraud, nor have they identified similar and sometimes overlapping activities that could be better coordinated to use limited resources more efficiently. For example, each agency has its own laboratory capability for determining seafood species and uses different methodologies for creating standards for species identification. The result is that neither the laboratories nor the data developed in them are shared.

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Abbreviations

CBP	Customs and Border Protection
FDA	Food and Drug Administration
HACCP	Hazard Analysis and Critical Control Point
HHS	Department of Health and Human Services
ICE	Immigration and Customs Enforcement
MOU	memorandum of understanding
NFI	National Fisheries Institute
NMFS	National Marine Fisheries Service
NOAA	National Oceanic and Atmospheric Administration
NTAG	National Targeting and Analysis Group
USDA	U.S. Department of Agriculture

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United States Government Accountability Office
Washington, DC 20548

February 19, 2009

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

Dear Senator Snowe:

In 2007, Americans consumed almost 5 billion pounds of seafood. Most seafood buyers, at many levels—importers, distributors, supermarkets, restaurants, and individual consumers—assume that the seafood they buy is what the seller claims it is. However, this is not always the case. Sometimes people mislabel seafood products for financial gain—an activity called seafood fraud. The most common types of seafood fraud are shipping products through an intermediary country to avoid customs duties (transshipping), adding excessive amounts of water or ice to the seafood to increase its weight (over-treating), substituting a different species of seafood for the species listed on the label (species substitution), including less seafood in a package than indicated by the label (short-weighting), and other types of mislabeling or misrepresenting of seafood products.

Although comprehensive information on the extent of seafood fraud does not exist, seafood industry officials believe that seafood fraud is a problem. The available information suggests that the scope and economic impact of seafood fraud vary widely and can occur at any point in the seafood supply chain, from large-scale, multinational schemes involving importers—with impacts in the millions of dollars—to fraudulent activities at individual restaurants or grocery stores. Seafood fraud can have both food safety and economic consequences. For example, seafood fraud affected food safety in 2007 when imported puffer fish, which contains a potentially deadly toxin, was mislabeled as monkfish, and people became ill. Another example of fraud is including the ice-glaze covering used to freeze and preserve fish fillets in the net weight of the product, which has primarily an economic impact because consumers get less fish than they paid for. Seafood fraud can undermine consumer confidence in the U.S. seafood supply, over 80 percent of which is imported.

Three federal agencies play key roles in detecting and preventing seafood fraud: the Department of Homeland Security’s Customs and Border Protection (CBP), the Department of Commerce’s National Marine Fisheries Service (NMFS), and the Department of Health and Human Services’ Food and Drug Administration (FDA). CBP collects customs duties on imports, including seafood, and seeks to prevent the evasion of customs duties. Goods imported into the United States may be subject to duties on the basis of their product type, value, and country of origin, among other things. In addition, to limit the sale of foreign-made products in this country at less-than-normal value, called “dumping,” some imported goods are also subject to antidumping duties. NMFS provides fee-for-service inspection services on request to the seafood industry, including processors, distributors, and other firms. These inspections can address economic integrity issues, such as the accuracy of a seafood product’s label, as well as seafood safety issues. Finally, FDA is responsible for ensuring that the nation’s food supply, including seafood, is safe, wholesome, and properly labeled. To that end, FDA is authorized to issue regulations to enforce the Federal Food, Drug, and Cosmetic Act. The act prohibits the misbranding or adulteration of food products, which would include the mislabeling and substituting of seafood products that constitute seafood fraud. FDA is responsible for seafood that is imported into the United States as well as seafood that is harvested and processed domestically. FDA inspects U.S. importers and domestic and foreign processors to ensure their compliance with applicable requirements, including labeling requirements and FDA’s Seafood Hazard Analysis and Critical Control Point (HACCP) regulations. The HACCP regulations require seafood processors to identify and develop processes to mitigate biological, chemical, and physical hazards that are likely to occur. FDA also provides guidance to the seafood industry on the naming of seafood products and on food safety hazards. Table 1 shows the types of seafood fraud that these three agencies might detect when performing their authorized roles.

Fraud type	CBP	NMFS	FDA
Transshipment to avoid duties	✓		
Over-treating		✓	✓
Species substitution	✓	✓	✓
Short-weighting		✓	✓
Other mislabeling or misrepresenting	✓	✓	✓

Source: GAO analysis of documents obtained from and discussions with CBP, NMFS, and FDA.

When an issue crosses federal agency lines, as seafood fraud does, the agencies involved must collaborate to deliver results more efficiently and effectively. For the purpose of this report, we define “collaboration” as a joint effort by two or more agencies that is intended to produce a greater public benefit than when the agencies act alone. Our previous work indicated that federal agencies can efficiently and effectively collaborate when they, among other things, (1) identify a common goal, (2) establish joint strategies to achieve that goal, (3) agree on their roles and responsibilities, (4) identify ways to maximize and leverage their resources, and (5) establish procedures and policies for working together systematically across agency lines.¹ When agencies do not collaborate efficiently and effectively, their individual efforts are carried out in an uncoordinated way, thereby limiting the overall effectiveness and efficiency of federal expenditures. For example, in 2007, we added the federal oversight of food safety to our high-risk list because this fragmented system—in which 15 federal agencies collectively administer at least 30 laws related to food safety—has caused inconsistent oversight, ineffective coordination, and inefficient use of resources.²

In this context, you asked us to determine (1) the actions key federal agencies take to help detect and prevent seafood fraud and (2) the extent to which these key federal agencies collaborate with each other to help detect and prevent seafood fraud.

Our research identified CBP, NMFS, and FDA as the key agencies involved in detecting and preventing seafood fraud. To determine the actions these agencies have taken to detect and prevent seafood fraud, we reviewed data and documents from each agency on the amount and nature of seafood fraud that they have identified, actions they have taken to prevent seafood fraud, and actions they have taken against fraud perpetrators. At all three agencies, we reviewed program guidance, inspection operation manuals, and other documentation and interviewed knowledgeable

¹GAO, *Results Oriented Government: Practices That Can Help Enhance and Sustain Collaboration among Federal Agencies*, [GAO-06-15](#) (Washington, D.C.: Oct. 21, 2005). The other three practices discussed in our report on effective collaboration are (1) develop mechanisms to monitor, evaluate, and report on results; (2) reinforce agency accountability for collaborative efforts through agency plans and reports; and (3) reinforce individual accountability for collaborative efforts through performance management systems.

²See our most recent series, GAO, *High-Risk Series: An Update*, [GAO-09-271](#) (Washington, D.C.: January 2009). Also see, GAO, *High-Risk Series: An Update*, [GAO-07-310](#) (Washington, D.C.: January 2007).

officials. We also obtained examples of seafood fraud criminal investigation cases and met with representatives from the major seafood industry trade associations. To determine the extent to which key federal agencies collaborate with each other to help detect and prevent seafood fraud, we reviewed existing federal interagency agreements and spoke with agency officials from CBP, NMFS, and FDA. (App. I provides additional information on our scope and methodology.)

We conducted this performance audit from January 2008 to February 2009, in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Results in Brief

CBP and NMFS conduct several activities to help detect and prevent seafood fraud; however, FDA has taken few actions because it sees food safety as its top priority. These agency activities are described in the following text:

- CBP focuses on detecting schemes to avoid paying customs duties as seafood products enter the country, such as transshipment to avoid antidumping duties. CBP's import specialists review seafood import documentation on product type, value, and country of origin to ensure that importers have paid the appropriate duties. The agency also uses information provided by one of its National Targeting and Analysis Groups to help identify potentially fraudulent seafood shipments. This group analyzes data on foreign producers and importers that may be involved in transshipment schemes to avoid paying antidumping duties and works with port officials to examine these shipments as they arrive. For example, Chinese shrimp have been subject to an antidumping duty since 2005 because producers have set prices on the shrimp that were lower than the normal value. On the basis of this information and allegations from the domestic shrimp industry, a National Targeting and Analysis Group began to scrutinize imports of shrimp from Chinese producers and identified approximately \$6 million worth of Chinese shrimp that had been transshipped through Indonesia in 2005 to avoid antidumping duties.
- NMFS's seafood fraud detection activity consists of a voluntary, fee-for-service inspection program that supports the seafood industry in two ways. First, seafood retailers, such as supermarkets, may ask NMFS to

inspect the seafood products they purchase to ensure the products have not been misrepresented. In such cases, NMFS's inspectors verify a product's net weight and ensure the species is correctly identified. Second, seafood processors may ask NMFS, through its Quality Management Program, to inspect their seafood processing operations to not only ensure compliance with FDA's HACCP regulations but also to identify measures that can help prevent seafood fraud. Such measures may include requiring the processor to weigh all products and compare that information with the stated weight on the package before the product leaves the facility and periodically testing the scales. According to officials in NMFS's Seafood Inspection Program, NMFS inspects approximately one-third of the seafood consumed in the United States.

- FDA sees ensuring the safety of the nation's food supply as a top priority and, therefore, devotes minimal resources to detect and prevent seafood fraud. Nevertheless in the course of conducting its food safety activities, FDA has at times incidentally uncovered seafood fraud. More specifically, as part of its food safety activities to ensure that imports are not contaminated, among other things, FDA examines imported seafood products, which occasionally has resulted in its identifying seafood fraud. However, FDA's opportunities to identify fraud are limited because it examines only about 2 percent of imported seafood. FDA is also limited in its ability to detect seafood fraud because its primary oversight program for seafood processors—HACCP—does not require them to identify and mitigate economic fraud risks that can occur during processing. However, seafood oversight programs operated by NMFS and the Canadian government include such requirements. An FDA seafood fraud-related activity is the maintenance of a publicly available list of scientific and market names of seafood—the Seafood List—that is intended to help the seafood industry comply with FDA's regulations on product mislabeling. However, FDA did not fully update the publicly available list it created in 1993 until January 2009, and does not provide stakeholders with an opportunity to comment on proposed changes before they are finalized. In addition, FDA provides guidance to seafood processors to help ensure that their seafood products are safe. However, this guidance does not reflect the seafood labeling requirements in the Food Allergen Labeling and Consumer Protection Act of 2004, which requires that the species of fish or shellfish be included on product labels to notify consumers who may be allergic to a particular species of fish. According to a senior FDA official, the act's labeling requirements also could help detect and prevent species substitution, since processors would need to verify the species of fish or shellfish to ensure accurate labeling. Because the seafood HACCP regulations do not address economic fraud risks; the Seafood List, until very recently, had not been kept up to date; and FDA's guidance does not

reflect the allergen labeling requirements, the seafood industry may be less vigilant in ensuring their seafood products are correctly labeled and the public may more often encounter seafood products that are not what they are advertised to be. Consequently, we are recommending that FDA improve its ability to detect and prevent seafood fraud by (1) proposing amendments to its HACCP regulations to include measures to identify and mitigate economic fraud risks; (2) providing the opportunity for stakeholder comments prior to formalizing any changes to the Seafood List and routinely updating the public list; and (3) updating its guidance to reflect the seafood labeling requirements of the Food Allergen Labeling and Consumer Protection Act of 2004.

The federal agencies that share responsibility for detecting and preventing seafood fraud—CBP, NMFS, and FDA—do not efficiently and effectively collaborate with each other, which can diminish the efficiency and effectiveness of their efforts. Specifically, these agencies have not worked together to identify a common goal related to seafood fraud, established joint strategies to achieve such a goal, or agreed on their roles and responsibilities. Moreover, they have not identified ways to maximize and leverage their resources or established processes and policies for working together systematically across agency lines. As a result, these agencies are not sharing important information that could be helpful in detecting and preventing seafood fraud. For example, when FDA reviews the labels of imported products to identify potentially fraudulent labeling, it does not systematically share the results of these reviews with CBP. If CBP had access to the results of the labeling reviews, it could compare this information with the labels on products entering the country and better determine whether a product was mislabeled to avoid a customs duty or other import restrictions. In addition, these agencies have not leveraged their resources to address seafood fraud efficiently and effectively. For example, NMFS's voluntary fee-for-service inspection program and FDA's health and safety inspections are similar. However, an FDA official said that the agency is not sure whether it can rely on NMFS inspections, in part due to concerns about potential conflicts of interest, because NMFS is paid by industry to conduct its inspections. FDA raised this same concern to us in 2004 but added that it already had agreements with NMFS to deal with seafood safety and inspections, and that it would look at other ways to better leverage NMFS resources. Nonetheless, FDA does not currently try to determine whether NMFS has already inspected a seafood facility when it is deciding which facilities to inspect. Consequently, some facilities may be "over-inspected," while others are not inspected frequently enough. For example, in fiscal year 2007, FDA inspected 104 seafood facilities that were also inspected by NMFS; while FDA had not

inspected 1,464 other facilities since before fiscal year 2003. In addition, CBP, NMFS, and FDA each has its own laboratory capability for, among other things, determining the species of seafood samples they receive. The agencies also use different testing methodologies and standards for species identification and do not acknowledge each other's laboratory results, nor do they generally share the species standards they have developed. As a result, resources are not used efficiently or effectively. We are recommending that CBP, NMFS, and FDA collaborate to (1) develop goals, strategies, and mechanisms to efficiently and effectively share information and resources related to seafood fraud detection and prevention across agency boundaries and (2) create a federal agencywide library of seafood species standards. In commenting on a draft of this report, the Department of Commerce, representing NOAA; the Department of Health and Human Services, representing FDA; and the Department of Homeland Security, representing CBP, generally agreed with our recommendations. Appendixes II, III, and IV contain reprints of the departments' letters, respectively.

Background

Seafood fraud can include a variety of illegal activities done for economic gain and can occur at any point in the seafood supply chain. The domestic seafood supply chain begins with the harvester—that is, the people who catch or farm the seafood. From there, seafood products are shipped to processors, which then produce fresh, frozen, breaded, or cooked seafood. Processors or distributors then sell the seafood to supermarkets or restaurants. The process is similar for foreign seafood products, with one exception: these products enter the country through an importer and then move on to a distributor. According to the National Oceanic and Atmospheric Administration (NOAA), in fiscal year 2007, over 80 percent of the seafood consumed in this country was imported, and shrimp was the most widely consumed seafood. Seafood imports into the United States most frequently come from Canada, China, and Thailand, according to the U.S. Department of Agriculture's (USDA) Foreign Agriculture Service.

Federal investigations have identified incidents of seafood fraud. For example, the Department of Homeland Security's Immigration and

Customs Enforcement (ICE)³ and NOAA's Office for Law Enforcement investigation that began in 2004 identified seafood fraud that involved smuggling and distributing mislabeled catfish into the United States from Vietnam. According to the indictment, an individual and his companies in Florida aided by exporters in Vietnam imported thousands of pounds of catfish into the United States labeled as grouper to avoid paying antidumping duties that the Department of Commerce had imposed on Vietnamese catfish. The defendant pled guilty and was sentenced to 51 months in prison. The judge also ordered the companies to forfeit property and pay over \$1 million in restitution.

Seafood fraud can include a variety of illegal activities undertaken for economic gain. Such fraud typically involves mislabeling the seafood product and can include the following actions:

- *Transshipment to avoid duties:* Foreign producers may ship seafood products on route to the United States through a third country to avoid import duties by labeling the product's country of origin as the third country and also to avoid regulatory controls such as FDA import alerts.⁴
- *Over-treating:* Processors may, for example, over-bread prepared seafood products, use water-retaining chemicals, or over-glaze with an ice covering to artificially increase the weight of seafood products without indicating the true net weight of the seafood on the label.
- *Species substitution:* Participants in the seafood supply chain may label a species of seafood as another species. Typically, a lower-market-value species is labeled as a higher-market-value species to realize a larger profit. This results in consumers paying too much for the product.
- *Short-weighting:* Participants in the seafood supply chain may label packages of seafood as containing more than they actually contain.

³ICE is the largest investigative branch of the Department of Homeland Security. According to ICE, the agency assigns special agents to, among other things, investigate manufacturers and importers allegedly involved in the duty evasion schemes and uses agents stationed in foreign countries to conduct investigations.

⁴Import alerts are designed to ensure that products from processors covered by the alert are detained and refused entry into the United States until the importer can prove that the imported product is safe and complies with all applicable regulations, generally by providing FDA with the results of third-party laboratory analysis of the product.

-
- *Other mislabeling and misrepresenting:* Participants in the seafood supply chain may provide various types of incorrect information about the seafood product or can commingle two or more different products having different values but sell the entire lot at the value of the highest priced product.

Seafood fraud is an inherently deceptive activity and poses challenges for federal agencies to detect and prevent it while still maintaining the flow of legitimate seafood goods into and within the United States. Some fraudulent activity can even occur openly. For example, seafood companies receive public, written solicitations to purchase fraudulent seafood products. One type of solicitation offers to sell packages of fish fillets that are purposely mislabeled as another fish type to avoid antidumping duties and also capitalize on the higher market value of the falsely labeled fish type. These fish fillets are sold at a discount to the initial buyer, but then can be fraudulently resold for a higher price. Another type of solicitation offers to sell short-weight packages of seafood at a discount that the buyer could then fraudulently resell at the full price on the basis of the labeled package weight.

Federal, state, and local agencies play a role in detecting and preventing seafood fraud throughout the supply chain. In general, federal agencies inspect seafood processors, distributors, and importers and imported seafood products. States also inspect seafood processors either through contracts with FDA or under their own authority. States and local governments inspect and regulate retail establishments such as restaurants and supermarkets.

CBP's trade-related responsibilities include assessing the final customs duties, including antidumping duties, due on imports and collecting those duties. All goods imported into the United States are subject to a rate of duty, which may be free for certain products. The U.S. government has established a duty rate according to the product classification code—for example, fish sticks and other fillets that are breaded or coated with batter have a specific classification code and duty rate.⁵ Antidumping and countervailing duties may also be required on imported products. The U.S. government may impose antidumping duties on products exported to the United States at unfairly low prices (i.e., dumping) and countervailing

⁵Generally, the Congress establishes normal customs duties and authorizes the executive branch to impose special customs duties, such as antidumping and countervailing duties.

duties on products exported to the United States that were subsidized by foreign governments. The Department of Commerce sets these duty rates for specific products, countries or manufacturers, or any combination of these factors.

NMFS provides voluntary fee-for-service inspection services through its Seafood Inspection Program on request to the seafood industry, primarily under the authority of the Federal Agricultural Marketing Act of 1946. NMFS provides its services to domestic and foreign seafood firms to help them ensure compliance with all applicable federal food regulations, including FDA's seafood HACCP regulations. NMFS's services include inspections of a firm's processes and products to identify food safety and economic fraud risks as well as laboratory analyses.

Along with its responsibility for ensuring the safety of other food products under the Federal Food, Drug, and Cosmetic Act, FDA has the primary responsibility for ensuring that the nation's seafood is safe, wholesome, and properly labeled.⁶ To carry out these responsibilities, FDA has created oversight programs designed to, among other things, examine and sample imported seafood products, inspect domestic and foreign seafood processors and importers, and assist state and local governments in their efforts to regulate retail establishments such as restaurants and supermarkets. Under the HACCP regulations, seafood processors are required to prepare and maintain a plan identifying critical points in the processing where contamination is reasonably likely to occur and implement control techniques to prevent or mitigate the contamination. FDA then inspects U.S. importers and domestic and foreign seafood processors to ensure their compliance with these HACCP regulations. When FDA first proposed the seafood HACCP regulations in 1994, the agency recommended that HACCP plans include controls for nonsafety hazards such as economic adulteration. Specifically, FDA recommended that the seafood industry adopt preventive processing measures to help ensure that, among other things, seafood was correctly identified and its weight properly recorded. Furthermore, FDA also proposed guidelines on how a seafood processor could use a HACCP-based approach to ensure that fish and fishery products were in compliance with the economic

⁶The 2008 Farm Bill made catfish subject to mandatory inspection by USDA. The new law requires that USDA continuously inspect domestic catfish, and that imported catfish meet equivalent standards before being imported into the United States. The Secretary of Agriculture in consultation with the Commissioner of the Food and Drug Administration has until the end of 2009 to issue regulations to implement the new law.

adulteration and misbranding provisions of the Federal Food, Drug, and Cosmetic Act. However, in finalizing its HACCP regulations, FDA eliminated these economic fraud controls. In discussing its reasoning for eliminating the economic fraud controls in the *Federal Register*, FDA stated that the seafood HACCP system would need to mature before the agency could determine whether it should address matters other than food safety hazards, such as economic fraud.

The seafood industry also plays a role in detecting and preventing seafood fraud. Seafood industry associations represent various aspects of the industry throughout the supply chain, from harvesters to retailers. They include product-specific associations, such as the Southern Shrimp Alliance in southern states or the Maine Lobster Promotion Council, or business-specific associations, such as the National Restaurant Association. These industry associations work to protect the brand name and quality of their respective products or businesses; monitor issues and legislation that may impact the industry, including fraud and other illegal activities; and work with government agencies and other organizations to promote the health and viability of their industry. Some of these associations have also provided federal agencies with information on potential seafood fraud, such as transshipping schemes to avoid antidumping duties and advertisements for short-weighted seafood products. In addition, the National Fisheries Institute (NFI) also created the Better Seafood Bureau to help its members combat such seafood fraud problems as transshipping to avoid antidumping duties, species substitution, and short-weighting.⁷ According to NFI, the goal of the Better Seafood Bureau is to promote economic integrity in the seafood industry and assure customers of the quality of the institute's members' products. NFI requires a hand-signed contract from each member's Chief Executive Officer that he or she will comply with all U.S. laws and regulations, and has created an accountability system that requires members who break the contract to pay for a third-party audit of its processes.⁸ The Southeastern

⁷NFI is a seafood industry advocacy organization. According to NFI, its mission is to educate the American public about seafood safety, sustainability, and nutrition. NFI's nearly 400 members range from the owners of small, family-owned fishing vessels to large, nationally traded corporations and include representatives of business, education, and government.

⁸The third-party audit of the member's processes is the normal practice NFI uses to hold its member accountable, but it reserves the right to dismiss the member from the Better Seafood Bureau without a third-party inspection or to take a different action, depending upon the type of violation.

Fisheries Association also developed the Seafood Product Quality Code in 1984 to educate any interested harvesters, processors, distributors, wholesalers, retailers, and consumers on standards and measures to promote product quality and build confidence in the seafood industry.

Federal agencies face challenges in achieving their missions, especially if they have limited resources and some elements of their missions are shared with other agencies. Effective collaboration is often key to overcoming these challenges, and our previous work has identified practices that can help enhance and sustain collaboration.⁹ First, collaboration requires agency staff, working across agency lines, to define and articulate the common federal outcome or goal they are trying to achieve. Second, once a common goal is established, agencies need to develop joint strategies. Such strategies help align the partner agencies' individual activities and resources to contribute to accomplishing the common goal. Third, the agencies should work together to agree on their roles and responsibilities. By agreeing on their roles and responsibilities, agencies can clarify who will do what, organize their joint and individual efforts, and determine who will lead the collaborative effort. Fourth, because each agency may contribute different activities and levels of resources toward achieving the common goal, by assessing their relative strengths and weaknesses, collaborating agencies can identify opportunities to leverage each other's resources. This may lead to additional benefits that would not have been available if they were working separately. Fifth, to ensure consistent implementation of their activities and a sustained collaborative effort to achieve the common goal, the agencies should develop compatible policies and procedures for all of the agencies to follow. (App. I includes a list of the three other collaboration practices we previously identified but did not address in this report.)

⁹GAO-06-15.

CBP and NMFS Take a Variety of Actions to Detect and Prevent Seafood Fraud, While FDA Takes Few Actions Related to Seafood Fraud

CBP focuses on detecting schemes to avoid paying customs duties by reviewing import information; targeting and, along with ICE, investigating potential seafood fraud perpetrators; and taking enforcement actions, if warranted. NMFS offers a voluntary, fee-for-service seafood inspection program that can detect seafood fraud, such as short-weighting, and may also help prevent seafood fraud by identifying economic fraud risks during processing. However, NMFS inspects approximately one-third of the seafood consumed in the United States. FDA directs its field staff to minimize work on economic fraud issues because it considers food safety a higher priority than economic fraud. Nonetheless, FDA's health and safety actions, such as examinations of seafood imports, sometimes uncover seafood fraud incidentally. FDA's primary regulatory program for domestic seafood processors—HACCP—does not address the economic fraud risks also associated with processing. In addition, while FDA maintains a list of scientific and market names of seafood that is intended to help the seafood industry comply with FDA's regulations on product mislabeling, until January 2009, FDA had not fully updated the publicly available list it created in 1993, despite having made numerous changes since then. Finally, the guidance FDA provides to seafood processors to help ensure that their seafood products are safe does not reflect the seafood labeling requirements in the Food Allergen Labeling and Consumer Protection Act of 2004, which could incidentally help detect and prevent species substitution, since processors would need to verify the species of fish or shellfish to ensure accurate labeling.

CBP Takes a Variety of Actions to Detect Schemes to Falsify Import Information and Thereby Avoid Paying Import Duties

For imported seafood to enter U.S. commerce, the importer must file for entry with CBP and submit electronic or paper entry documents to CBP. The entry documents include basic information about the imported product, such as its type, quantity, and value. As the first step, port officials select some of these entry documents to review to determine whether to allow the imported product, including seafood, to enter U.S. commerce.¹⁰ However, due to the large number of goods imported into the United States, port officials can only examine a fraction of incoming shipments. For example, from fiscal years 2004 to 2008, CBP officials examined between approximately 1.0 to 2.4 percent of all seafood imports. Importers must file additional documents (known as "entry summary" documents) and pay the appropriate duties, taxes, and fees on imported

¹⁰All imported goods are reviewed for national security purposes in a screening process that occurs prior to the importer filing for entry of the imported goods.

merchandise for consumption, including seafood products, within 10 days after CBP releases them from its custody. CBP's import specialists and other port officials select some entry summary documents to review to ensure accurate duty collection, which includes some seafood. For example, Chinese shrimp and crawfish and Vietnamese frozen fish fillets are subject to antidumping duties. On the basis of these reviews, CBP officials select importers for further review whose documentation indicates that they may be trying to avoid paying the appropriate duties.

In addition, CBP operates a national statistical sampling program, known as the Compliance Measurement Program, which randomly selects shipments of imports by commodity for review or examination to determine the degree to which they comply with customs trade laws and regulations, among other things. The Compliance Measurement Program was designed to identify trade problems or patterns of deception for specific commodities so that CBP officials can then focus their efforts against these illegal or fraudulent activities. Port officials only review a limited number of seafood entries under the program. For example, in fiscal year 2007, import specialists from all ports in the United States examined 766 seafood product entries out of 390,799 such entries and found a high compliance rate, 97.3 percent, for the applicable trade revenue laws. Although the Compliance Measurement Program could uncover seafood fraud or duty evasion, CBP officials noted that in-depth investigative work may be needed to uncover schemes to willfully defraud the U.S. government, which is beyond the scope of the examinations conducted under the program.

Another step CBP takes to detect and prevent seafood fraud is to target shipments that CBP officials suspect are part of a scheme to evade customs duties. CBP has five National Targeting and Analysis Groups (NTAG) that develop criteria to target potentially fraudulent imports. One of these NTAGs develops criteria to target potentially fraudulent shipments of seafood and reviews leads from other CBP officials and external organizations, such as trade associations, on transshipping schemes to avoid paying antidumping and countervailing duties. This NTAG researches and monitors trade trends to identify changes or patterns in trade that may signal potential fraudulent activity. For example, as part of their 2005 inquiry into an allegation of illegal transshipment of Chinese shrimp through Indonesia, the NTAG staff reviewed information on the shippers of Indonesian shrimp before and after the antidumping duty order for Chinese shrimp was put in place. They found a sharp decrease in shrimp imports from China after the antidumping duty order was issued in early 2005 and a concurrent increase

in shrimp imports from Indonesia, among other countries. The NTAG staff enlisted the support of ICE to investigate Indonesian shrimp exporters who they suspected were illegally transshipping Chinese shrimp. They found that some Indonesian firms were importing Chinese shrimp and then shipping them to the United States labeled as Indonesian shrimp. CBP found that, in 2005, approximately \$6 million worth of Chinese shrimp had been illegally transshipped through Indonesia to avoid antidumping duties.

While the illegal transshipment of Chinese shrimp continued through a different transshipping point, this time it also had a health- and food-safety-related effect. In June 2007, FDA announced a countrywide import alert on five Chinese-farmed seafood products, including shrimp. This import alert required that all Chinese shrimp be detained and refused entry, unless the importer could prove the absence of unapproved drugs in the shrimp. On the basis of industry information and CBP and ICE investigations, CBP determined that Chinese shrimp was being transshipped to the United States through Malaysia. Due to this illegal transshipment, importers of Chinese shrimp were able to circumvent not only the 2005 antidumping duty but also FDA's recent import alert. In September 2007, CBP tested shipments of suspected Chinese shrimp illegally transshipped through Malaysia for the presence of unapproved drugs and found some contaminated shrimp. On the basis of CBP's information, in March 2008, FDA issued a new import alert requiring importers of shrimp from one Malaysian manufacturer to prove the absence of unapproved drugs prior to entering future shipments of shrimp into U.S. commerce.

In 2007, the NTAG that works on seafood fraud issues also helped identify another scheme importers were using in their attempt to evade antidumping duties on Chinese shrimp. Under this scheme, importers provided CBP with fraudulent information on the product type to evade antidumping duties. A precursor to breaded shrimp called "dusted shrimp" was exempted by the Department of Commerce from the antidumping duty order on imported Chinese shrimp.¹¹ On the basis of allegations from the U.S. shrimp industry, CBP initiated an intensive examination and

¹¹The Department of Commerce's definition of true, dusted shrimp is that having a coating of rice or wheat flour constituting between 4 and 10 percent of the product's total weight after being dusted, but prior to the shrimp being frozen. In conjunction with subject matter experts, CBP developed a set of characteristics that a product is required to meet to be considered true, dusted shrimp.

sampling operation to determine whether importers were bringing in shipments of falsely declared dusted shrimp to avoid the antidumping duties on Chinese shrimp. Over the course of a 90-day period, CBP found that of the 81 alleged dusted shrimp entries examined and sampled, approximately 64 percent of the shipments did not meet the criteria to qualify as dusted shrimp. The potential loss of trade revenue from these fraudulent dusted shrimp shipments was approximately \$5 million. Extrapolating back to when the antidumping duty order first became effective in 2005, CBP concluded that the importers caught importing these fraudulent dusted shrimp imported approximately \$117 million worth of potentially fraudulent dusted shrimp with a possible loss of trade revenue from the uncollected antidumping duties of \$132 million.

CBP's Office of Regulatory Audit provides additional support with suspected transshipping incidents to determine whether importers are participating in schemes to evade duties. CBP audits importers to ensure that they have reported and paid all trade revenue, such as antidumping duties, as required under trade laws and agreements. They perform two types of audits—a quick-response audit, which focuses on a specific issue, and a focused assessment audit, which evaluates all of a company's CBP activities and controls. The quick-response audits are focused on detecting fraudulent practices, such as unlawful transshipment of seafood to evade antidumping duties. For example, a quick-response audit concluded in 2007 found that an importer did not pay approximately \$2.2 million in antidumping duties on imported Chinese shrimp that was transshipped through Indonesia. The focused assessment audits are comprehensive audits where the auditors review and test the company's management oversight processes or "internal controls" to identify areas of uncollected trade revenue, such as unpaid antidumping duties. The focused assessment audits have included seafood importers, but they have only uncovered one violation since 2005 that was related to seafood fraud.

Finally, in the event CBP identifies violations of laws, it can assess penalties against an importer. The maximum penalty amount that CBP can assess varies, depending upon whether the perpetrator's actions were fraudulent, negligent, or grossly negligent. Penalties can range from two to four times the loss of lawful duties, taxes, and fees to the U.S. government or the domestic value of the merchandise. In addition, CBP may cooperate with other agencies to pursue criminal charges against perpetrators of seafood fraud. For example, in July 2003, CBP cooperated with ICE to investigate a case where, according to ICE officials, one exporter and several importers conspired to evade antidumping duties in excess of \$3 million on freshwater crawfish. According to these officials, the

coconspirators were indicted for smuggling and conspiracy in November 2003, and one defendant was convicted of conspiracy in 2004.

NMFS's Voluntary, Fee-for-Service Seafood Inspection Program Helps Industry Detect and Prevent Seafood Fraud

NMFS offers two types of services to help industry address seafood fraud. NMFS provides these voluntary, fee-for-service inspection services through its Seafood Inspection Program. This program currently serves approximately 375 domestic seafood firms and 63 foreign seafood firms, and, according to senior officials in NMFS's Seafood Inspection Program, NMFS inspects approximately one-third of the seafood consumed in the United States. First, NMFS inspects shipments (known as "lots") of seafood products purchased by its clients that include retailers such as supermarkets. During lot inspections, inspectors take a random, representative sample from the seafood lot and may perform several tests on this sample, including weighing it to ensure that the actual weight matches the labeled package weight. NMFS inspectors have identified instances of seafood fraud, especially short-weighting, in seafood products processed domestically and in foreign facilities. NMFS also may be able to uncover species substitution during a lot inspection in two ways: (1) according to senior officials in NMFS's Seafood Inspection Program, NMFS inspectors are trained to visually differentiate between different types and species of fish and (2) inspectors can use the capabilities of NOAA's National Seafood Inspection Laboratory to test for and identify the species of seafood. However, NMFS does not maintain a comprehensive list of all lot inspections conducted and, thus, does not have the ability to determine the frequency with which it uncovers fraudulent seafood products.

Second, NMFS also offers a Quality Management Program that can help seafood processors decrease the potential for fraudulent seafood by applying HACCP principles to both food safety and economic fraud risks. In 2007, NMFS inspected 202 domestic seafood companies under its Quality Management Program. As part of this program, NMFS inspects seafood processors to ensure their compliance with FDA's seafood HACCP regulations that require processors to identify potential food safety hazards during processing and establish controls to mitigate them. NMFS also goes a step further and requires that seafood processors that choose to participate in the Quality Management Program (1) create a "Defect Action Plan," which identifies potential economic fraud risks during the processing of seafood, such as short-weighting, and (2) develop measures to mitigate those fraud risks. For example, the plan could require that samples of the finished seafood product be removed from the processing line every hour and the weight checked to ensure that the

actual weight and the weight as stated on the package are the same. If any short-weights were identified, then all products since the last check would be weighed again, and the content amounts would be corrected. Also, the scales used in the processing phase would be checked and recalibrated, if necessary. In addition, processors can inspect seafood products upon receipt and compare the processors' species identification with the species listed on the invoices. Through these measures, processors can provide some assurance against short-weighting and species substitution.

FDA Considers Economic Issues a Low Priority Compared with Health and Safety Issues, but It Has Incidentally Identified Instances of Seafood Fraud

FDA is responsible for ensuring that foods are safe, wholesome, sanitary, and properly labeled. To that end, FDA is authorized to issue regulations to enforce the Federal Food, Drug, and Cosmetic Act. The act prohibits the misbranding or adulteration of food products, which would include seafood products that have been mislabeled, substituted, or over-glazed. FDA considers detecting violations like these a low priority and devotes minimal resources to such work, according to published program guidance and senior FDA officials. For example, FDA's program guidance to its field staff on imported and domestic seafood products states that no resources have been allocated for seafood fraud-related work, and that resource expenditures in this area should be kept to a minimum. According to FDA senior officials, the agency does not have the staff or resources to address economic fraud in addition to their food safety responsibilities, which they believe are a top priority and more important.

Nevertheless, in the course of their work examining the safety of seafood imports, FDA inspectors may uncover seafood fraud. FDA inspectors review import entry information, such as the type of seafood being imported and the importer's history of violations, if any; physically examine the imported goods; and collect samples for laboratory analysis to identify those that are potentially in violation of U.S. food regulations and laws. FDA may refuse to allow an imported seafood product to enter U.S. commerce if it appears to be adulterated or misbranded or for other violations of regulations and laws that FDA administers. However, from fiscal years 2003 to 2008, only 1 percent of the refusals of imported seafood products were related to seafood fraud.

FDA also maintains an "import alert" list to detain entries of imported foods that appear to have significant recurring violations. FDA currently has three import alerts related to seafood fraud. One import alert lists 10 foreign firms that were found to have declared an assortment of seafood products under the name of a fictitious, incorrect, or substituted species. The other two import alerts provide information to FDA's field staff about

the potential mislabeling of two specific types of fish—catfish and red snapper. The import alerts inform field office staff of the species of fish that can legally be labeled as catfish or red snapper and guidance on how to handle incoming shipments that may not be accurately labeled. However, FDA officials only physically examine a small percentage of imported seafood—about 2 percent of all seafood entries from fiscal years 2003 to 2008. Of the 2 percent of imported seafood examined by FDA officials, approximately 0.05 percent of these examinations were related to seafood fraud.

FDA's primary oversight program for domestic seafood firms is the HACCP program, but the focus of this program is health and safety not economic fraud. FDA's seafood HACCP regulations require seafood processors to identify and establish controls to mitigate potential food safety hazards. FDA inspects domestic firms involved in the production, storage, and distribution of fish and fishery products to ensure that their HACCP plans are properly designed and implemented. However, FDA inspectors spend very little time looking for seafood fraud. For example, the percentage of domestic seafood firm inspections where investigators conducted seafood fraud work was approximately 0.5 percent from fiscal years 2003 to 2008. FDA also inspects some importers and foreign processors for HACCP compliance because, as the agency noted in publishing its final HACCP regulations, the importer and foreign processor share responsibility in complying with importing regulations. Importers are required either to (1) obtain seafood products from a country that has an active memorandum of understanding or similar agreement with FDA that documents the equivalency or compliance of the foreign inspection system with the U.S. system or (2) implement written verification procedures to show that the foreign processor has complied with the HACCP regulations. Furthermore, FDA inspects foreign fish and fishery processors that export seafood to the United States, but this number of inspections is very limited. For example, in fiscal year 2007, FDA inspected only 61 of 14,569 registered foreign seafood firms.

In its 1994 seafood HACCP proposed rule, FDA recommended that seafood firms use HACCP-like measures to control for economic fraud because, as FDA stated, seafood fraud could also impact food safety. In the proposed rule, FDA stated that the “. . . misidentification of species may also have adverse public health consequences.”¹² The connection

¹²Proposal to Establish Procedures for the Safe Processing and Importing of Fish and Fishery Products, 59 Fed. Reg. 4142 (Jan. 28, 1994).

between economic fraud and food safety can be seen in an incident in 2007 where two individuals became ill after eating puffer fish. According to FDA, the puffer fish was imported into the country mislabeled as monkfish. Unlike monkfish, puffer fish contains a potentially deadly toxin called *tetrodotoxin*. CBP and ICE's shrimp transshipping investigation also highlights the connection between economic fraud and food safety. CBP and ICE's investigation found that foreign manufacturers and importers were not only attempting to circumvent antidumping duties by sending Chinese shrimp to the United States through Malaysia, but these companies were also evading an FDA import alert aimed at stopping adulterated Chinese shrimp from entering the United States. Incidents like these and others have led FDA officials, including a senior official in FDA's Office of Food Safety, to reconsider the agency's limited level of effort regarding economic fraud because they now believe that, if left unregulated, over time, seafood fraud may create food safety problems. Specifically, that same official said that it may be time for FDA to reconsider incorporating nonfood safety hazards, such as economic fraud, in the seafood HACCP regulations. According to senior FDA officials, the agency can still take actions, such as reviewing labels and issuing import alerts to prevent seafood fraud. However, these officials acknowledged that requiring measures in HACCP to address seafood fraud would build prevention into the processing of seafood. In addition, NMFS officials that administer the agency's Quality Management Program believe that amending FDA's HACCP regulations to include measures to address economic fraud risks would require minimal resources for the seafood industry and FDA to implement. Moreover, according to officials in the Canadian Food Inspection Agency, Canada has a program similar to NMFS's program that requires seafood processors to identify and mitigate both food safety hazards and economic fraud risks. However, because FDA inspectors primarily inspect for compliance with HACCP regulations, until the agency amends the HACCP regulations to include measures to identify and mitigate economic fraud risks, its inspectors will continue to spend limited time ensuring against mislabeled products, and seafood processors may be less attentive to protecting against fraud.

Another opportunity for FDA officials to detect seafood fraud is during their review of food labels. According to officials in FDA's Division of Import Operations and Policy, food label reviews sometimes occur during HACCP inspections of domestic seafood processors and examinations of imported seafood products. According to FDA guidance, investigators are to review labels on at least three food products when conducting a domestic or foreign firm inspection. The review entails ensuring that the label complies with all relevant food label laws and FDA regulations. For

example, the Federal Food, Drug, and Cosmetic Act, as amended, prohibits the “misbranding” of food, which includes, among other things, labeling that is false or misleading. In addition, food labels must generally include an ingredients list that identifies the product’s ingredients by their common or usual names in order of predominance by weight. Food labels must also accurately state the contents in terms of weight, measure, or numerical count of the product. However, our September 2008 report found that FDA does not have reliable data on the number of labels reviewed, nor does it track the complete and timely correction of the violations it identifies during the reviews.¹³ As a result, FDA cannot provide reliable information on the number of label reviews that identified seafood fraud, nor on any corrections of the seafood fraud violations it identified.

FDA may also detect seafood fraud through complaints from industry associations. For example, on several occasions during 2008, NFI provided FDA with copies of public, written solicitations from foreign and domestic companies offering to sell packages of seafood packed to 80 or 90 percent of the labeled package weight for a discount. These short-weighted products could then potentially be fraudulently sold in U.S. commerce for the full price on the basis of the labeled package weight. According to an FDA Consumer Safety Officer, FDA wanted NFI to provide additional information on these companies, such as their locations, because some of these companies were not in FDA’s inventory of seafood processors or importers, and FDA could not identify them with certainty. However, we found that some of the companies were listed in FDA’s inventory because FDA had previously inspected them. According to a senior FDA official, FDA is still working with NFI on this matter; however, as of December 2008, the agency had taken no action against any of the companies that sent solicitations.

In addition, FDA may detect seafood fraud from consumers and others who contact FDA field staff, by telephone, to complain about issues such as suspected short-weighted seafood products or species substitution. For example, in one case, a consumer complained to FDA about frozen shrimp mislabeled as a product of Mexico when a second label underneath the first indicated that it was a product of Thailand. Typically, the FDA District

¹³GAO, *Food Labeling: FDA Needs to Better Leverage Resources, Improve Oversight, and Effectively Use Available Data to Help Consumers Select Healthy Foods*, [GAO-08-597](#) (Washington, D.C.: Sept. 9, 2008).

Consumer Complaint Coordinator would field the telephone call, collect information from the consumer, such as the description of the product and the problem with the product, and would attempt to determine the responsible seafood firm. The Complaint Coordinator or other FDA field staff would evaluate the complaint and determine whether immediate action is required or whether the information would be used for surveillance in the next inspection of the seafood firm. However, our 2008 food labeling report found that FDA program managers could not use FDA's data system that captures consumer complaints to track their timely and appropriate resolution because these data were not entered into the system in a manner that would facilitate analysis. Specifically, standard terminology was not used and information on complaint resolutions was captured in different data fields.¹⁴ We found similar issues regarding the follow-up of consumers' complaints of seafood fraud. We reviewed FDA summary data for 105 consumer complaints related to such things as misbranded, mislabeled, and short-weighted seafood products from fiscal years 2004 through 2007. We judgmentally selected and reviewed FDA's internal documents for 5 of 105 consumer complaints and found that for all 5 of the complaints, FDA indicated that it would follow up on the complaints during the next inspection of the firm that had produced the seafood product in question. However, we found no information in FDA's inspection reports to indicate that FDA had followed up on three complaints. There was no inspection report available for the fourth complaint, and for the fifth complaint, there was a report for an inspection that was conducted a few days prior to the filing of the complaint.

There are several actions that FDA can take if seafood fraud is discovered during an inspection of a seafood firm. FDA may issue a warning letter—which is a notice that enforcement actions may be forthcoming if corrections are not made—to firms for serious violations of regulatory significance. For less serious violations, FDA may send an untitled letter, which is an informal communication that corrective actions are needed. However, FDA issued no warning letters or untitled letters regarding seafood fraud from fiscal years 2005 through 2008. Additionally, FDA may initiate enforcement actions against seafood firms, such as seizing and removing seafood from the marketplace; obtaining an injunction to stop a company from engaging in behavior that violates certain prohibitions of the Federal Food, Drug, and Cosmetic Act and regulations; or barring seafood firms from importing goods into the United States. FDA, however,

¹⁴[GAO-08-597](#).

has not taken any of these actions for seafood fraud violations since 2000, according to a senior FDA official. However, FDA's Office of Criminal Investigations has investigated allegations of seafood fraud and provided information to the Department of Justice for legal action against the perpetrators.

FDA helps the seafood industry avoid species substitution by maintaining on its agency Web site a publicly available "Seafood List," which is a compilation that includes the scientific and market names for imported and domestic seafood. The Seafood List is intended to promote uniformity in the use of FDA-acceptable market names by the seafood industry and to provide consistent advice on these names. For example, "catfish" can only be used as a market name for fish that belong to the family *Ictaluridae*, even though there are other species of fish whose vernacular name may include the word catfish. However, before January 2009, the public version of the Seafood List had not been kept up to date. According to an FDA official responsible for the Seafood List, even though over 400 changes have been made to FDA's internal version of the list since 1993, only about 22 changes had been made to the public version of the list as of the end of 2008. However, in January 2009, FDA made the revised and fully updated list available to the public on its Web site.

Other countries, such as Canada and Australia, maintain a similar type of Seafood List. However, their policies and procedures for maintaining these lists differ from those of FDA. For example, Canada publishes on the Internet guidelines and criteria that it uses to assign a new name for a species of seafood. In addition, the Canadian government will not allow a new name for a fish if it is similar or resembles the name of a fish with a higher market value. Also, changes made to Canada's seafood list are disseminated to an e-mail distribution list that interested parties can join. In contrast, until January 2009, FDA did not provide information to the public on the guidelines or criteria that it used to determine acceptable market names for seafood. In addition, stakeholders do not have the opportunity to comment on proposed changes to the Seafood List, unless the change was required by law or regulation. In contrast, Australia allows for a 3-month public consultation period prior to finalizing the change. A senior FDA official told us that stakeholders can write to FDA at any time with comments about the Seafood List, but that there is no formal comment period before changes are made to the list because it is considered guidance, not an agency regulation.

A recent example of a change to the Seafood List illustrates some of these issues. In April 2005, FDA allowed a restaurant to advertise langostino—

with the common names “squat lobster” and “Colorado langostino”—as “langostino lobster.” However, as of December 2008, the publicly available Seafood List had not been updated to reflect this change. According to the list on December 10, 2008, the market name for langostino is “langostino,” and the common names are “squat lobster” or “Colorado langostino.” Furthermore, according to officials from the Maine Lobster Promotion Council, the council wrote to FDA to protest this change to the naming of langostinos because it allows a lower-market-value seafood, langostinos, to take advantage of the higher market value and reputation of the American lobster name.¹⁵ According to officials from the Maine Lobster Promotion Council, FDA did not respond to its inquiries regarding the reasons for the name change for langostinos. An FDA official responsible for the Seafood List told us that FDA responded to the council by e-mail in August 2008 stating that, “we have not objected to use of the term langostino lobster for various species of squat lobsters.”

According to a senior FDA official, seafood labeling requirements from the Food Allergen Labeling and Consumer Protection Act of 2004 may help prevent species substitution, but FDA has not updated its guidance to the seafood industry to fully reflect the act’s labeling requirements. The act requires the product label to contain the name of a food source from which a major food allergen is derived, and, when the major food allergen is fish or Crustacean shellfish, the specific species of fish or shellfish must be listed to notify consumers with food allergies of a particular type of fish species. According to the same FDA official, the act’s labeling requirement may help detect and prevent species substitution, since processors would need to verify the type of fish or shellfish they are processing to ensure accurate labeling. However, these seafood labeling requirements are not reflected in FDA’s guidance to the seafood industry on the development of their HACCP plans to prevent and control the health and food safety hazards associated with seafood—the *Fish and Fisheries Products Hazards and Controls Guidance*.¹⁶ According to a senior FDA official, seafood processors should be aware of the act’s requirements, and FDA can still enforce those requirements, even if they are not reflected in the

¹⁵The Maine Lobster Promotion Council, established by Maine in 1991, markets and promotes the sale of Maine lobster in local, regional, national, and world markets year-round. The council comprises harvesters, dealers, and public members from each of Maine’s three regions.

¹⁶U.S. Food and Drug Administration, Center for Food Safety and Applied Nutrition, *Fish and Fisheries Products Hazards and Controls Guidance: Third Edition* (June 2001). See the following Web address: <http://www.cfsan.fda.gov/~comm/haccp4.html>.

guidance. Even so, senior FDA officials told us that they plan to update the guidance to reflect the Food Allergen Labeling and Consumer Protection Act of 2004 labeling requirements, but they could not provide us with a publication time frame.

Limited Collaboration Exists among the Key Agencies Responsible for Detecting and Preventing Seafood Fraud

Limited collaboration among CBP, NMFS, and FDA to detect and prevent seafood fraud can diminish their efficiency and effectiveness in dealing with this issue. CBP, ICE, FDA and its Office of Criminal Investigations, and NOAA's Office for Law Enforcement have worked together on criminal cases against individuals and companies suspected of committing seafood fraud. CBP, ICE, and FDA are working together to target commodities that pose health and safety risks, and NMFS and FDA have worked on joint laboratory efforts to share standards for seafood species identification. However, CBP, NMFS, and FDA have not established common goals related directly to detecting and preventing seafood fraud or joint strategies to help achieve the goals. In addition, these key agencies have not established policies and procedures to promote effective collaboration and better leverage resources to achieve their common goal. As a result, the agencies have not taken advantage of opportunities to share information that could benefit each agency's efforts to detect and prevent seafood fraud, nor have they identified similar and sometimes overlapping activities that could be better coordinated to use limited resources more efficiently and effectively.

CBP, NMFS, and FDA Have Not Taken Any of the Key Steps to Develop an Enhanced Collaborative Working Relationship Related to Detecting and Preventing Seafood Fraud

CBP, ICE, FDA and its Office of Criminal Investigations, and NOAA's Office for Law Enforcement have worked together on developing and investigating criminal cases against individuals and companies suspected of committing seafood fraud. For example, in one situation, ICE and the Office for Law Enforcement developed a case against an individual and his companies in Florida, who, aided by exporters in Vietnam, imported thousands of pounds of catfish into the United States labeled as grouper and other fish to avoid paying antidumping duties. The case resulted in an indictment and a guilty plea by the defendant. In addition, CBP, ICE, and FDA are working together to target commodities that pose health and safety risks through Operation Guardian, which is an enforcement initiative to deal with imported substandard, tainted, and counterfeit products. Operation Guardian's efforts have led to seizures of such commodities as pharmaceuticals, steel components, honey, shrimp, and toys.

However, despite CBP, NMFS, and FDA having responsibilities related to seafood fraud detection and prevention, these agencies have not implemented key practices our previous work has identified that can enhance and sustain collaboration among federal agencies.¹⁷ Specifically, CBP, NMFS, and FDA have not worked with each other to (1) identify their shared individual goals related to seafood fraud detection and prevention and (2) develop a common overarching goal or goals. Because these agencies have not identified a common goal, they also have not implemented the next practices we identified for effective collaboration and established joint strategies to achieve that goal or agreed on their respective roles and responsibilities in achieving the shared goal. The agencies also have not identified ways to maximize and leverage their resources by agreeing on the resources and activities each agency can commit to accomplishing the common goal, nor have they established procedures and policies for working together systematically across agency lines. Because the agencies have not implemented any of the key practices that enhance collaboration, they have missed opportunities to share data among themselves that could enhance seafood fraud detection and prevention and leverage resources. They also have not identified similar or overlapping activities that could be better coordinated or consolidated so that limited funds would be used more efficiently and effectively.

CBP, NMFS, and FDA Are Missing Opportunities to Share Information to Better Detect and Prevent Seafood Fraud

CBP, NMFS, and FDA each collect information on seafood products to meet their respective responsibilities, but they do not always share information that could be used to detect and prevent seafood fraud. CBP collects information on seafood imports, such as product type, product quantity, and country of origin, through the review and examination of imported goods and import entry documents, audits, and laboratory analysis. NMFS collects information in lot inspection reports that identify short-weighted domestic and imported products. FDA collects information on imported seafood products, such as the accuracy of product labeling, through entry document reviews, food label reviews, product examinations, inspections, and laboratory analysis. Some of the information these agencies collect could be used to identify seafood fraud, such as the names of the importers and the seafood products that were illegally transshipped to avoid customs duties or were mislabeled. However, these agencies have not developed procedures to identify or share useful information. For example, CBP and FDA both find seafood

¹⁷GAO-06-15.

imports with inaccurate product type, weight, and country-of-origin labels. By sharing this information, CBP and FDA would have more data about violative imported products and could target those products with the most violations or greater likelihood to be violative for more frequent inspections. Additionally, CBP and FDA could compare information each agency receives from importers on the product type and country of origin to determine if this information is consistent, which would help ensure that importers were not attempting to circumvent an antidumping duty or an FDA import alert. An official in FDA's Division of Import Operations and Policy told us that while there are no formal mechanisms for sharing this information between FDA and CBP, FDA makes referrals regarding violative imported products to CBP on an ad hoc basis.

In addition to information on seafood products, CBP, NMFS, and FDA also have information on seafood importers that each collects through audits and inspections, respectively, but do not share this information with each other. During an importer audit, CBP ensures that importers have reported and paid all trade duties as required under trade laws and agreements on the basis of the product documentation and labeling. During an inspection of a seafood importer, FDA may review importer documentation and collect samples to identify products not in compliance with the Federal Food, Drug, and Cosmetic Act's labeling requirements. FDA and CBP may both identify discrepancies in product information supplied by seafood importers, such as declaring incorrect information on import documents or having inadequate proof of documentation, when checking for compliance with labeling requirements. Because CBP and FDA do not share the results of their respective audits and inspections, they do not have the most comprehensive information on noncompliant seafood importers that could help identify those with a greater likelihood of problems in the future. In addition, NMFS does not share information with FDA from its lot inspections about importers and processors that produced short-weighted seafood products on a regular basis, so FDA could further investigate this concern during future examinations or inspections.

In investigating illegal transshipment or other schemes to avoid duties, CBP and ICE may require information on foreign seafood producers critical to their investigations. However, CBP and ICE may be denied access to the countries where the problematic seafood producers are located. For example, in 2007, CBP and ICE were denied entry into a country to investigate an alleged transshipping scheme to avoid paying antidumping duties and, thus, could not collect crucial information about the foreign seafood producers in question. CBP could potentially benefit

from information obtained from FDA and NMFS, both of which conduct inspections of foreign seafood producers.¹⁸ According to senior CBP and ICE officials, they would find information from FDA's and NMFS's foreign inspections beneficial, depending on the facts of particular enforcement activities they are pursuing.

Lack of Collaboration by CBP, NMFS, and FDA to Detect and Prevent Seafood Fraud Has Resulted in Overlapping Actions and Inefficient Use of Resources

Not only does the lack of collaboration create inefficient information sharing between the key federal agencies, it also creates overlapping agency efforts and inefficient use of government resources. NMFS and FDA have similar inspection programs—NMFS inspects facilities, on request, for health, safety, and economic integrity issues, while FDA focuses its inspections on health and safety concerns. However, an FDA official said that the agency is not sure whether it can rely on NMFS inspections, in part due to concerns about potential conflicts of interest because NMFS is paid by industry to conduct its inspections. FDA has identified these potential conflicts as an impediment to fully using NMFS inspection efforts in the past. In our 2004 report on FDA's imported seafood safety program, we stated that an official raised concerns about potential conflicts of interest with NMFS inspections, but that other officials thought that these concerns could be addressed in an agreement between the two agencies.¹⁹ We recommended that FDA and NMFS develop a memorandum of understanding (MOU) that, in part, would use and leverage NMFS inspection services to more efficiently and effectively monitor the safety of imported seafood. In response, FDA stated that there were already three MOUs between FDA and NMFS that dealt with seafood safety and inspection operations, but that it would explore additional opportunities to better leverage NMFS inspection resources and more efficiently and effectively protect the public health. Among the three MOUs, the 1974 MOU between FDA and NMFS stated, in part, that NMFS would provide FDA with information on establishments under contract with it, and that such inspections and consultations with FDA should diminish the need for FDA inspections. Despite FDA's statements and the provisions in its 1974 MOU, FDA still does not take into account whether NMFS has already inspected a facility when FDA determines which facilities it will inspect. For example, from 2005 through 2008, NMFS

¹⁸NMFS inspected 63 foreign facilities from 2007 through November 2008, and FDA inspected 112 foreign facilities from October 2006 through June 2008.

¹⁹GAO, *Food Safety: FDA's Imported Seafood Safety Program Shows Some Progress, but Further Improvements Are Needed*, [GAO-04-246](#) (Washington, D.C.: Jan. 30, 2004).

inspected one facility we visited at least four times a year, yet FDA also inspected it in 2005, 2006, and 2008. Furthermore, neither agency found any significant issues during their inspections of this facility. Overall, in fiscal year 2007, FDA inspected 120 facilities that were also inspected by NMFS, while FDA had not inspected 1,464 other facilities since before fiscal year 2003. Also during fiscal year 2007, NMFS inspected 88 facilities that FDA either had not inspected within the same fiscal year or had not inspected at all. In its technical comments to our draft report, FDA stated that it is currently negotiating an MOU with NMFS that is intended to address its concerns about potential conflicts of interest.

Furthermore, CBP, NMFS, and FDA each have their own laboratory capabilities for, among other things, determining the species of seafood samples they receive. Moreover, because these agencies use different testing methodologies and standards for species identification, they do not acknowledge each others' laboratory results, nor do they share the species standards they have developed. CBP uses DNA sequencing to identify a seafood species, and FDA and NMFS use the isoelectrophoresis method.²⁰ While CBP has developed some authenticated DNA samples of fish species, it uses GenBank DNA sequences as a guide to conduct most of its laboratory testing for species identification.²¹ FDA and NMFS do not believe that the GenBank data are sufficiently accurate to use as the basis for a regulatory action, such as providing validated evidentiary support to prove species substitution during a criminal prosecution. As a result, FDA is in the process of developing its own secure database of DNA sequences for seafood species identification. FDA laboratory officials told us the agency has developed DNA sequences for 72 seafood species and is in the process of adding about 100 more species. NMFS has its own library of standards for seafood species identification but has had meetings with FDA regarding sharing species standards and getting DNA analysis approved by an international accreditation agency as an official method for species identification. According to FDA laboratory officials, the

²⁰Isoelectrophoresis is a method of testing that uses an electric field to separate proteins for a species to create a distinct pattern that can be used to compare with and identify a seafood species, among other types of species. This method of testing has been authenticated as an official method for species identification by an international accreditation agency.

²¹GenBank is an open-access DNA sequence database that is maintained at the National Institutes of Health's National Center for Biotechnology Information. GenBank receives DNA sequences from laboratories throughout the world. After being reviewed by National Center staff, these DNA sequences are placed in the public database.

agency would be willing to share its species standards with CBP as well, but neither agency has had any discussions on this matter. According to a senior CBP laboratory official, CBP has no need to access any standards other than those contained in GenBank. Both CBP and FDA could increase the number of DNA sequences they have available to identify species substitution by combining and sharing their standards. However, CBP, NMFS, and FDA have not collaborated with each other to develop a comprehensive DNA database.

Conclusions

Although FDA has tools that it could use to help detect and prevent seafood fraud, the agency is not using them as efficiently and effectively as it could. For example, the agency's primary regulatory program for seafood firms—HACCP—does not require firms to identify and establish controls to mitigate economic fraud risks, only potential food safety hazards. Also, the agency does not provide the opportunity for stakeholder comments prior to making changes to the Seafood List, and it has not routinely updated the public version of the list whenever FDA makes changes to it. This has limited the effectiveness of the list in promoting uniformity in seafood species names and in preventing species substitution. Likewise, not updating the *Fish and Fisheries Products Hazards and Controls Guidance* to reflect the labeling requirements of the Food Allergen Labeling and Consumer Protection Act of 2004 has limited the usefulness of the guidance in preventing species substitution.

Because responsibilities for detecting and preventing seafood fraud are shared among three key federal agencies—CBP, NMFS, and FDA—effective collaboration is important to operating efficiently and effectively and to producing a greater public benefit than if the agencies acted alone. Currently, however, the three agencies are mostly acting alone and have not implemented key practices to begin collaborating more efficiently and effectively, such as identifying a common goal and establishing joint strategies to achieve the goal. As a result, the three agencies are not sharing information that could be used to detect or prevent seafood fraud and are working on creating individual databases of seafood species standards and using different methods to do so. Until these agencies begin collaborating more efficiently and effectively to detect and prevent seafood fraud, duplication of efforts may continue to occur, and the agencies may continue to miss opportunities to use limited federal funds more efficiently and effectively.

Recommendations for Executive Action

To help reduce the prevalence of seafood fraud and improve FDA's actions to detect and prevent seafood fraud, we are recommending that the Commissioner of the Food and Drug Administration take the following three actions:

- propose amendments to FDA's seafood HACCP regulations to include requirements that covered facilities include control points that can be used to identify and mitigate economic fraud risks;
- provide the opportunity for stakeholder comments prior to formalizing any changes to the Seafood List not required by law or regulation and routinely update the public version of the list whenever FDA makes any changes; and
- update the *Fish and Fisheries Products Hazards and Controls Guidance* to reflect the seafood labeling requirements of the Food Allergen Labeling and Consumer Protection Act of 2004.

To maximize the efficiency and effectiveness of each agency's efforts to detect and prevent seafood fraud and to increase interagency collaboration, improve information sharing, and reduce overlaps, we recommend that the Commissioner of Customs and Border Protection, the Under Secretary of Commerce for Oceans and Atmosphere, and the Commissioner of the Food and Drug Administration take the following two actions:

- develop goals, strategies, and mechanisms to share information and resources related to seafood fraud detection and prevention across agency boundaries and
- create a federal agencywide library of seafood species standards.

Agency Comments and Our Evaluation

We provided the Departments of Commerce, Health and Human Services, and Homeland Security with a draft of this report for their review and comment. Commerce, representing NOAA, said that the draft report did a fair and thorough job in assessing and isolating seafood fraud issues and concerns shared by Commerce, HHS, and Homeland Security, and the agency agreed with the two recommendations regarding interagency collaboration that involved Commerce. Commerce also noted that while the draft report emphasized the activities of the Seafood Inspection Program, NOAA's Office for Law Enforcement also plays a pivotal role in

seafood fraud activities when detected. Commerce's specific comments are presented in appendix II.

HHS, representing FDA, said that the draft report raised some important issues regarding FDA's seafood program, and the agency generally agreed with our recommendations. HHS provided additional information about activities that FDA has under way related to specific recommendations. Regarding our first recommendation, HHS said that FDA agrees that it is appropriate to reassess whether to recommend that processors include nonsafety hazards in their HACCP plans but did not say that the agency would propose amending HACCP regulations to require such changes. We continue to believe that the regulations should be amended. Regarding our second recommendation, HHS said that FDA would reassess the mechanism to seek stakeholder comments on changes to the Seafood List but did not commit to providing stakeholders with the opportunity to comment before changes are made to the list, as we recommended. We continue to believe that it is important that stakeholders be able to comment before changes are made to the list. While HHS said that FDA had revised the Seafood List and would post it on its Web site soon, HHS did not say whether FDA planned to routinely update the public version of the list whenever it makes any changes, as we recommended. We continue to believe that this is important. Regarding our fourth recommendation, HHS said that FDA agrees that it should collaborate with the other federal agencies to maximize efficient use of resources, but HHS also said that FDA is currently involved in many collaborative activities related to seafood fraud. We recognize that FDA has collaborative activities under way; however, as this report indicates, we believe that many opportunities exist to improve collaboration, specifically in the detection and prevention of seafood fraud, by following the key collaboration practices our report identifies. These practices can increase the opportunities to identify and share the relevant information and resources necessary for effective and efficient prevention and detection of seafood fraud. HHS provided technical comments that we incorporated into the report as appropriate. HHS's specific comments are presented in appendix III.

Homeland Security, representing CBP, generally agreed with the two recommendations that involved CBP. Regarding our recommendation to create a federal agencywide library of seafood species standards, CBP said that it believes that it would be more efficient for the agencies to work with the National Institutes of Health in the maintenance of GenBank and assist in addressing whatever shortcoming might be associated with that data bank. We are not recommending whether CBP, FDA, and NMFS should agree to use an existing data bank or to create a new one. Rather,

we are recommending that, to improve efficiency and reduce costs, the three agencies collaborate to fully understand each others needs, capabilities, and plans so they can agree on a single species standards library. Homeland Security also provided technical comments that we incorporated into the report as appropriate. Homeland Security's specific comments are presented in appendix IV.

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

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

Sincerely yours,



Lisa Shames
Director, Natural Resources and Environment

Appendix I: Scope and Methodology

The three federal agencies that play key roles in detecting and preventing seafood fraud are (1) the Department of Homeland Security's Customs and Border Protection (CBP), (2) the Department of Commerce's National Marine Fisheries Service (NMFS), and (3) the Department of Health and Human Services' Food and Drug Administration (FDA). We reviewed data and documents from each agency on the amount and nature of seafood fraud that they have identified and any corrective actions they have taken against fraud perpetrators. We also reviewed program guidance, inspection operation manuals, and other documentation and interviewed knowledgeable officials to determine each agency's overall approach and specific actions to detect and prevent seafood fraud—including the priority given to seafood fraud detection and prevention among their other responsibilities. We also observed FDA's and NMFS's inspections of seafood processing facilities. In addition, we obtained examples of criminal investigations of seafood fraud to understand the nature and impact of seafood fraud.

For this report, we relied on the findings of our September 2008 report to assess the reliability of FDA's data.¹ The data we used came from the same data sources used in our 2008 report, in which we found the FDA data to be sufficiently reliable for the purposes of this report. To assess the reliability of CBP and NMFS data, we performed testing for obvious errors in accuracy and completeness and reviewed relevant documentation. We also worked closely with agency officials to identify and resolve any data problems. We determined that the data from these three agencies were sufficiently reliable for the purposes of this report.

Finally, we also met with representatives from six major seafood industry associations to determine their views on the nature of the seafood fraud problem, the actions they have taken to help prevent seafood fraud, and how they interact with the key federal agencies. We interviewed officials from the Catfish Farmers of America, Maine Lobster Promotion Council, National Fisheries Institute, National Restaurant Association, Southeastern Fisheries Association, and Southern Shrimp Alliance.

We visited the Boston, New York/Newark, and Los Angeles/Long Beach ports of entry. During these visits, we observed CBP's process for

¹GAO, *Food Labeling: FDA Needs to Better Leverage Resources, Improve Oversight, and Effectively Use Available Data to Help Consumers Select Healthy Foods*, [GAO-08-597](#) (Washington, D.C.: Sept. 9, 2008).

reviewing import entry documents, discussed local targeting efforts and whether any collaborative efforts related to seafood fraud existed between CBP and FDA, and toured the port facilities. At the Los Angeles/Long Beach ports, we also met with FDA officials to discuss and observe their process for inspecting imported seafood.

We also interviewed officials from four states—California, Florida, New York, and Texas—to determine their roles, responsibilities, and interactions with the federal agencies in detecting and preventing seafood fraud. We selected these states on the basis of their population size and, because of their coastal location, their having a potential port of entry for imported seafood. Additionally, we interviewed officials at Alabama’s Food and Drug Laboratory because of its active efforts in developing laboratory methods for testing seafood products.

To determine the extent that the key federal agencies collaborate with each other to help detect and prevent seafood fraud, we first identified practices that our previous work indicated can help enhance and sustain collaboration among federal agencies.² For the purposes of this report, we focused on the first five of the eight practices we previously identified for enhancing and maintaining effective collaboration among federal agencies: (1) define and articulate a common goal; (2) establish mutually reinforcing or joint strategies to achieve that goal; (3) identify and address needs by leveraging resources; (4) agree on roles and responsibilities; and (5) establish compatible policies, procedures, and other means to operate across agency boundaries. We did not address the following practices: (1) develop mechanisms to monitor, evaluate, and report on results; (2) reinforce agency accountability for collaborative efforts through agency plans and reports; and (3) reinforce individual accountability for collaborative efforts through performance management systems. We did not address these practices because we found that CBP, NMFS, and FDA had not implemented the first five practices. As a result, because limited collaborative activities were under way, we did not expect the agencies to have developed mechanisms to monitor and report on the results of their collaboration, reinforce accountability by preparing reports, or establish performance management systems. We also analyzed agency documents and interviewed officials from CBP, NMFS, and FDA to determine the extent to which they had (1) implemented the first five previously

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

mentioned collaboration practices, (2) identified and shared information that could be beneficial in addressing seafood fraud, and (3) engaged in overlapping seafood fraud-related activities.

We conducted this performance audit from January 2008 to February 2009, in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Appendix II: Comments from the Department of Commerce



UNITED STATES DEPARTMENT OF COMMERCE
The Deputy Under Secretary for
Oceans and Atmosphere
Washington, D.C. 20230

JAN 27 2009

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

Dear Ms. Shames:

Thank you for the opportunity to review and comment on the Government Accountability Office's draft report entitled, *Seafood Fraud: FDA Program Changes and Better Collaboration among Key Federal Agencies Could Improve Detection and Prevention* (GAO-09-78). On behalf of the Department of Commerce, I enclose the National Oceanic and Atmospheric Administration's programmatic comments to the draft report.

Sincerely,

A handwritten signature in cursive script that reads "Mary M. Glackin".

Mary M. Glackin
Deputy Under Secretary
for Oceans and Atmosphere

Enclosure



Department of Commerce
National Oceanic and Atmospheric Administration
Comments on the Draft GAO Report Entitled
“FDA Program Changes and Better Collaboration among Key Federal Agencies
Could Improve Detection and Prevention”
(GAO-09-258/January 2009)

General Comments

In general, the report on seafood fraud detection does a fair and thorough job in assessing and isolating the issues and concerns shared by the named agencies, including the National Oceanic and Atmospheric Administration (NOAA). The report will be used to assist NOAA to determine more effective methods in seafood fraud detection and assist in prioritizing the concerns for correction and implementation. The report and the recommended NOAA solutions will be shared with the proper industry groups to facilitate changes in seafood fraud and its detection.

It should be noted that, while throughout the draft report much emphasis was placed on the NOAA activities relative to the Seafood Inspection Program, NOAA's Office of Law Enforcement also plays a pivotal role in seafood fraud activities when detected.

NOAA Response to GAO Recommendations

“To maximize the efficiency and effectiveness of each agency's efforts to detect and prevent seafood fraud and to increase interagency collaboration, improve information sharing, and reduce overlaps, we recommend that the Commissioner of Customs and Border Protection, the Under Secretary of Commerce for Oceans and Atmosphere, and Commissioner of the Food and Drug Administration take the following two actions:”

Recommendation 1: “develop goals, strategies, and mechanisms to share information and resources related to seafood fraud detection and prevention across agency boundaries”

NOAA Response: NOAA agrees with this recommendation. Such strategies and mechanisms have already been initiated in relation to other areas of seafood inspection and production. The NOAA Seafood Inspection Program, aligned with other NOAA agencies has recently adopted the strategy to research and implement proactive testing and evaluation methods to detect and isolate economic fraud practices to protect the consumer and assist industry in enhanced processing methods. NOAA will certainly work with the Department of Homeland Security's Customs and Border Protection and the Department of Health and Human Services' Food and Drug Administration to further this goal and to reduce seafood fraud in the United States.

Recommendation 2: “create a federal agency-wide library of seafood species standards”

NOAA Response: NOAA agrees with this recommendation. Such a library of documented seafood species standards shared among federal agencies would lead to

**Appendix II: Comments from the Department
of Commerce**

NOAA Response: NOAA agrees with this recommendation. Such a library of documented seafood species standards shared among federal agencies would lead to increased program efficiencies and effectiveness by reducing duplication and creating a more comprehensive collection of species standards. The National Seafood Inspection Laboratory is currently holding discussions with the other agencies on this subject and NOAA's National Marine Fisheries Service will continue to implement this recommendation using existing resources.

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



DEPARTMENT OF HEALTH & HUMAN SERVICES

OFFICE OF THE SECRETARY

Assistant Secretary for Legislation
Washington, DC 20201

JAN 30 2009

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

Dear Ms. Shames:

Enclosed are comments on the U.S. Government Accountability Office's (GAO) report entitled: "Seafood Fraud: FDA Program Changes and Better Collaboration Among Key Federal Agencies Could Improve Detection and Prevention (GAO-09-258).

The Department appreciates the opportunity to review this report before its publication.

Sincerely,

Barbara Pisaro Clark

Barbara Pisaro Clark
Acting Assistant Secretary for Legislation

Attachment

FDA's General Comments to the U.S. Government Accountability Office's (GAO) Draft Report Entitled, *Seafood Fraud – FDA Program Changes and Better Collaboration Among Key Federal Agencies Could Improve Detection and Prevention (GAO-09-258)*

The Food and Drug Administration (FDA) appreciates the opportunity to review and comment on the Government Accountability Office's (GAO) draft report. GAO has raised some important issues regarding FDA's seafood program. FDA strives continually to advance its public health mission, and this includes efforts to improve the safety, sanitation, suitability, and proper labeling of seafood.

FDA's Specific Comments on GAO Recommendations

GAO Recommendation 1:

To help reduce the prevalence of seafood fraud and improve FDA's actions to detect and prevent seafood fraud, we are recommending that the Commissioner of the Food and Drug Administration propose amendments to FDA's seafood HACCP regulations to include requirements that covered facilities include control points that can be used to identify and mitigate economic fraud risks.

FDA Response:

FDA agrees with GAO that it is appropriate at this time to reassess whether to recommend that processors include nonsafety hazards. When FDA proposed the Seafood HACCP Regulation, 21 CFR 122, in 1994, FDA included a recommendation, not a requirement, that HACCP plans include controls for hazards unrelated to safety, such as economic fraud. Approximately 75 comments addressed this provision, the vast majority of which urged that it be eliminated from the regulations. Those that argued for removal stated that 1) HACCP for safety purposes would be a big challenge for both the industry and regulators, and that inclusion of nonsafety hazards might be overwhelming; 2) nonsafety hazards are covered adequately by existing FDA regulations and by industry quality control programs; 3) inclusion of nonsafety hazards deviates from internationally recognized HACCP principles; and, 4) inclusion of nonsafety hazards would dilute and jeopardize a desirable industry focus on safety. Those that argued for inclusion of economic adulteration stated that 1) the same conditions of processing that affect the occurrence of safety hazards affect the occurrence of nonsafety hazards, making the two control systems compatible; 2) an improvement in consumer confidence in seafood cannot be achieved without improvements relative to economic deception; 3) the seafood industry considers economic fraud to be the most significant hazard affecting the marketing of its products; 4) species substitution can be safety related; 5) HACCP controls would likely enhance compliance with existing nonsafety standards; and, 6) inclusion of controls for economic fraud would not significantly increase the costs to industry.

After review of the comments, FDA concluded that the HACCP system would have to mature and FDA would need to learn more before it could determine whether a mandatory HACCP program should include nonsafety matters. Additionally, the agency noted that the statutory provisions that form the basis for the Seafood HACCP regulations are safety provisions.

FDA's General Comments to the U.S. Government Accountability Office's (GAO) Draft Report Entitled, *Seafood Fraud – FDA Program Changes and Better Collaboration Among Key Federal Agencies Could Improve Detection and Prevention (GAO-09-258)*

FDA's application of HACCP is intended for the effective enforcement of sections 402(a)(1) and (a)(4) of the Federal Food, Drug, and Cosmetic Act, which apply to products that contain substances that may render the product injurious to health and to processing conditions that are insanitary and that could render a product injurious to health. Thus, the only issue for FDA to consider in the preparation of the final regulations was whether to retain the recommendation, not requirement, to include nonsafety hazards in processors' HACCP programs. FDA was persuaded by the point raised by some comments that advisory provisions of regulations are often confused with or misapplied as requirements. For these reasons, the recommendation to include economic fraud in HACCP plans was not included in the final regulation.

After more than a decade of implementation, FDA recognizes the Seafood HACCP program as a mature program, and agrees with GAO that this is an appropriate time to reassess whether to recommend that processors include nonsafety hazards, such as economic fraud, in their HACCP plans.

GAO Recommendation 2:

To help reduce the prevalence of seafood fraud and improve FDA's actions to detect and prevent seafood fraud, we are recommending that the Commissioner of the Food and Drug Administration publicize the criteria FDA uses to revise the Seafood List, provide the opportunity for stakeholder comments prior to formalizing any changes to the list not required by law or regulation, and routinely update the public version of the list whenever FDA makes any changes.

FDA response:

FDA agrees with GAO that it should reassess the mechanism to seek stakeholder comments on potential changes in the list of acceptable market names and inform stakeholders of the changes.

The last hard copy version of *The Seafood List* was published in 1993. Since then FDA has made the decision to produce the document only in an electronic version, available on the Agency website. The first and most recent electronic-only version of the document was published in 2002. Between the 1993 and 2002 version, there were market name changes associated with 22 species of fish, all mandated by law or regulation (e.g., catfish and brown king crab). Changes mandated by regulation undergo a public notice and comment period. Since 2002, FDA has accepted new market names for an additional 23 species of fish, none of them mandated by law or regulation.

FDA has recently completed work on the next version of the document and expects that it will be posted on the Agency's website very shortly. This version will include the 23 most recent market name changes (e.g., langostino lobster). It will also include approximately 400 changes in scientific names and additional species names in order to stay current with taxonomic convention. These latter changes do not affect industry's understanding of suitable market names. In addition, the guidance will include a description of the factors that FDA uses in determining acceptable market names.

FDA's General Comments to the U.S. Government Accountability Office's (GAO) Draft Report Entitled, *Seafood Fraud – FDA Program Changes and Better Collaboration Among Key Federal Agencies Could Improve Detection and Prevention (GAO-09-258)*

GAO Recommendation 3:

To help reduce the prevalence of seafood fraud and improve FDA's actions to detect and prevent seafood fraud, we are recommending that the Commissioner of the Food and Drug Administration update the Fish and Fisheries Products Hazards and Controls Guidance to reflect the seafood labeling requirements of the Food Allergen Labeling and Consumer Protection Act.

FDA Response:

The *Fish and Fishery Products Hazards and Controls Guidance* is a set of recommendations from FDA to the fish and fishery products processing industry regarding the hazards that are reasonably likely to occur in such products and providing suitable controls to minimize the risk of occurrence of those hazards. FDA intends to reflect the labeling requirements of the Food Allergen Labeling and Consumer Protection Act in the fourth edition of *Fish and Fishery Products Hazards and Controls Guidance*. The document is currently in Agency clearance.

GAO Recommendation 4:

To maximize the efficiency and effectiveness of each agency's efforts to detect and prevent seafood fraud and to increase interagency collaboration, improve information sharing, and reduce overlaps, we recommend that the Commissioner of Customs and Border Protection, the Under Secretary of Commerce for Oceans and Atmosphere, and Commissioner of the Food and Drug Administration develop goals, strategies, and mechanisms to share information and resources related to seafood fraud detection and prevention across agency boundaries.

FDA Response:

Three key federal agencies share responsibilities for detecting and preventing seafood fraud. According to GAO's report, each Agency mostly acts alone and has not implemented key practices to begin collaborating more effectively. FDA agrees that it should collaborate with the other federal agencies to maximize efficient use of resources and is currently collaborating with National Marine Fisheries Service (NMFS) to develop an inter-agency library of seafood species standards. As mentioned by GAO, FDA also has collaborated, leveraged resources, and shared data with the Department of Homeland Security's Customs and Border Protection (CBP) in efforts such as Operation Guardian and in sharing weekly refusal reports.

In December of 2007, Department of Homeland Security, Immigration, and Customs Enforcement (ICE) implemented Operation Guardian to combat the growth in the importation and distribution of a variety of consumer products, which potentially threaten the health and safety of U.S. consumers. Since the inception of Operation Guardian, several joint enforcement efforts have been initiated against imported food, including seafood, involving ICE, CBP, and FDA. In May 2007, Guardian regional working groups composed of ICE, CBP, and FDA personnel were formed throughout the country. Sixty-one agents from FDA's Office of Criminal Investigations (OCI) are assigned to the ICE-chaired 35 regional working groups.

4

FDA's General Comments to the U.S. Government Accountability Office's (GAO) Draft Report Entitled, *Seafood Fraud – FDA Program Changes and Better Collaboration Among Key Federal Agencies Could Improve Detection and Prevention (GAO-09-258)*

Guardian headquarters representatives and regional working group members generally meet monthly to evaluate ongoing investigations and incoming fraud allegations, and to initiate new enforcement actions. Several of these investigations are targeted at individuals and entities responsible for the fraudulent importation, through transshipment, of seafood subject to CBP anti-dumping duties and FDA import alerts which are intended to prevent seafood containing unapproved antibiotics from entering the United States. ICE and OCI will continue cooperative investigative efforts into such areas as transshipment or adulteration of seafood products. In addition, collaboration between CBP and the FDA has resulted in regulatory actions and import alerts.

Some other specific examples of FDA's collaborative efforts include the following:

- FDA collected a sample of "langostino" meats through the Port of Blaine, Washington that FDA determined were freshwater crawfish instead of langostinos. Freshwater crawfish from China are subject to an anti-dumping duty of 223 percent. An initial review of entries indicated that there were at least 23 entries of "langostino" meat valued at \$2.3 million. FDA's report of these findings to members of the ICE resulted in the collection of \$2.9 million in tariff duties from a Canadian firm that exports seafood to the United States. The firm admitted that it had misclassified tariff duties on freshwater crawfish from China.
- FDA participated in a joint investigation with United States Fish & Wildlife Service (USFWS) and ICE that involved the smuggling of illegal caviar and the sale of adulterated and misbranded product throughout the United States. Marky's Caviar, also doing business as Optimus, Inc., purchased sturgeon caviar smuggled into the United States by couriers inside suitcases without a CBP declaration or USFWS inspection. The investigation determined that the sturgeon caviar and other fish roe sold were adulterated and misbranded. The caviar was adulterated by mixing Beluga caviar with less valuable caviar. The caviar was misbranded because it was labeled as Russian caviar when it was in fact Chinese. On April 15, 2005, the firm was sentenced to pay a \$1 million criminal fine into the Lacey Act Reward Fund, to adhere to a stringent wildlife compliance plan, and 5 years probation. The sentence was imposed for knowingly purchasing sturgeon caviar with false wildlife invoices, knowingly purchasing smuggled caviar, and failing to exercise due care in purchasing smuggled caviar.

GAO Recommendation 5:

To maximize the efficiency and effectiveness of each agency's efforts to detect and prevent seafood fraud and to increase interagency collaboration, improve information sharing, and reduce overlaps, we recommend that the Commissioner of Customs and Border Protection, the Under Secretary of Commerce for Oceans and Atmosphere, and Commissioner of the Food and Drug Administration create a federal agency-wide library of seafood species standards.

FDA's General Comments to the U.S. Government Accountability Office's (GAO) Draft Report Entitled, *Seafood Fraud – FDA Program Changes and Better Collaboration Among Key Federal Agencies Could Improve Detection and Prevention (GAO-09-258)*

FDA Response:

FDA is collaborating with other Federal agencies in developing a library of seafood species standards. FDA held a two-day workshop in January 2008 entitled *Regulatory Applications of DNA-Barcoding for the Species Identification of Fish* which was attended by members of the NMFS National Seafood Inspection Laboratory, the NMFS Northwest Fisheries Science Center, the Smithsonian National Museum of Natural History, the Canadian Center for DNA Barcoding, and the International Consortium for the Barcode of Life. In collaboration with the Smithsonian NMNH and the Canadian Center for DNA Barcoding, FDA published a paper in 2008 entitled *Potential Use of DNA Barcodes in Regulatory Science: Applications of the Regulatory Fish Encyclopedia* in the *Journal of Food Protection*. This paper laid the groundwork for DNA barcoding at FDA and provided a bridge for the new methodology with FDA's established set of reference tissues used in the old protein isoelectric focusing method. FDA also published an FDA Laboratory Information Bulletin method in 2008 entitled, *A Protocol for Validation of DNA-Barcoding for the Species Identification of Fish for FDA Regulatory Compliance*, which is currently in the final stages of a three laboratory inter-lab trial. This trial is the first step necessary for performing a full collaborative study required for international accreditation.

FDA has also established a contract with the Smithsonian National Museum of Natural History for authentication and vouchering of seafood standards collected by FDA. FDA believes that this contract could potentially be the foundation for the GAO-recommended library of seafood species standards, and will be discussing that possibility with NMFS and CBP.

Appendix IV: Comments from the Department of Homeland Security

U.S. Department of Homeland Security
Washington, DC 20528



**Homeland
Security**

January 30, 2009

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

Dear Ms. Shames:

The Department of Homeland Security (DHS) appreciates the opportunity to review and provide comment on the Government Accountability Office's (GAO) draft report titled, *SEAFOOD FRAUD: FDA Program Changes and Better Collaboration among Key Federal Agencies Could Improve Detection and Prevention* (GAO-09-258).

DHS generally concurs with the report's two recommendations. Following are our recommendation-specific comments; technical comments were provided under separate cover.

Recommendation 1: Develop goals, strategies, and mechanisms to share information and resources related to seafood fraud detection and prevention across agency boundaries.

Response: Concur. Customs and Border Protection (CBP) will consider issues related to seafood fraud in its regular assessment of trade risk and its annual planning process in a continuing an ongoing effort to address these matters.

CBP was an active member of the President's interagency work group addressing import safety concerns. The interagency work group developed the Import Safety Action Plan, which acknowledges multiple areas of import safety concerns including information sharing among agencies. The action plan recognizes that agency collaboration, including the International Trade Data System (ITDS), is essential for addressing import safety concerns effectively. ITDS is a single window information integration program that will allow agencies to collaborate in the identification and prioritization of high-risk shipments, including those considered import safety risks and anti-dumping risks, such as those identified in this report.

On the heels of the President's Action Plan for Import Safety, the implementation of interagency workgroups led DHS agencies to conduct special operations and other efforts targeted at addressing health and safety issues. Throughout the report, GAO makes note of these special operations, specifically Operation Guardian, where interagency collaboration is demonstrated.

- 2 -

Recommendation 2: Create a federal agency-wide library of seafood species standards.

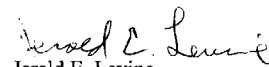
Response: Concur. CBP would not oppose the development of a national agency database provided that CBP be issued the funding and the authority to maintain the database.

CBP currently uses "Gen-Bank" which is a DNA Sequence Library of different species that is maintained by the National Institutes of Health/National Center for Biotechnical Information. This database accepts DNA Sequence Data from around the world and is truly international in nature and wide ranging. Prior to the entry of information into the database the information is reviewed by a panel of NIH DNA specialists. Being international in nature, it is more widely accepted around the world for a number of purposes. CBP frequently uses Gen-Bank and has not identified problems or issues with the data to date.

The proposal to create an agency wide database would appear to be duplicative of the Gen-Bank but only on a smaller National level. CBP would not oppose the development of a national agency database provided that CBP be issued the funding and the authority to maintain the database. However, CBP believes that it would be more efficient for the agencies to work with NIH in the maintenance of Gen-Bank and assist in whatever shortcoming might be associated with that data bank.

Again, we thank you for the opportunity to review and provide comments on this draft report and look forward to working with you on future homeland security issues.

Sincerely,



Jerald E. Levine
Director
Departmental GAO/OIG Liaison Office

Appendix V: GAO Contact and Staff Acknowledgments

GAO Contact

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

Staff Acknowledgments

In addition to the individual named above, Stephen D. Secrist, Assistant Director; Ami Ballenger; Carolyn M. Boyce; Carol Bray; Kevin S. Bray; Nancy Crothers; Winchee Lin; David Moreno; and Matt Sumpter made significant contributions to this report.

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