



TESTIMONY OF

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FOOD AND DRUG ADMINISTRATION

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INTRODUCTION

Good afternoon, Chairman Vitter, Ranking Member Shaheen, and Members of the Committee. I am Dr. Steven Solomon, Deputy Associate Commissioner for Regulatory Affairs at the Food and Drug Administration (FDA or the Agency), which is part of the Department of Health and Human Services (HHS). Thank you for the opportunity to appear before you today to discuss the Agency's ongoing efforts to oversee the safety of the U.S. seafood supply.

In the interest of public health, it is vital that both domestically-processed and imported seafood are safe, wholesome, and properly labeled. FDA has had a strong regulatory program in place since the mid-1990s to ensure the safety of domestic and imported seafood. In fact, the hazard analysis and risk-based preventive controls framework of FDA's seafood-safety program is a basis for the preventive controls requirements for other FDA-regulated foods called for in the FDA Food Safety Modernization Act (FSMA), enacted in 2011. For this reason, FSMA specifically exempts seafood from some of its requirements. However, FSMA also provides the Agency with a number of new authorities that will help improve the safety of domestic and imported FDA-regulated foods, including seafood.

The Agency has a variety of tools to ensure compliance with seafood safety requirements, including inspections of domestic and foreign processing facilities, examination and sampling of domestic seafood and seafood offered for import into the United States, domestic surveillance sampling of imported products, inspections of seafood importers, evaluations of filers of seafood products offered for import, and foreign country program assessments. FDA works closely with our foreign, Federal, state, local, and Tribal partners to share relevant information and ensure that products in U.S. commerce meet applicable FDA requirements.

Seafood is one of the most highly-traded commodities in the world. The Agency recognizes that success in protecting the American public depends increasingly on our ability to reach beyond U.S. borders and engage with its government regulatory counterparts in other nations, as well as with industry and regional and international organizations, to encourage the implementation of science-based standards to ensure the safety of products before they reach our country.

In my testimony today, I will discuss FDA's regulatory framework for overseeing the safety of the U.S. seafood supply, emphasizing the Agency's efforts with regard to imported seafood.

FDA'S SEAFOOD SAFETY PROGRAM

Because fish are cold-blooded and live in aquatic environments, fish and fishery products pose unique food safety challenges, which are quite different from those posed by land animals. FDA has developed extensive expertise in these areas over decades of regulating this commodity. Experts in FDA's Center for Food Safety and Applied Nutrition (CFSAN) are responsible for evaluating the hazard to public health presented by chemical, including toxins, and microbiological contaminants in fish and fishery products. FDA operates the Gulf Coast Seafood Laboratory in Alabama, which specializes in seafood microbiological, chemical, and toxins research. In addition, seafood research is conducted at CFSAN's research laboratory in College Park, Maryland. FDA, in collaboration with the National Oceanic and Atmospheric Administration at the Department of Commerce, also represents the United States at the Codex Alimentarius Commission's Committee on Fish and Fishery Products, the international food safety standard-setting body for this commodity.

FDA operates a mandatory safety program for processing of fish and fishery products. As a cornerstone of that program, FDA publishes the Fish and Fishery Products Hazards and Controls Guidance, an extensive compilation of the most up-to-date science and policy on the hazards that affect fish and fishery products and effective controls to prevent their occurrence. The document, currently in its fourth edition, has become the foundation of fish and fishery product regulatory programs around the world.

Seafood Hazard Analysis Critical Control Point (HACCP) Regulation and Inspections

Processors of fish and fishery products are subject to FDA's Procedures for the Safe and Sanitary Processing and Importing of Fish and Fishery Products, commonly known as the HACCP regulation. In short, this regulation requires both domestic and foreign processors of fish and fishery products to understand the food-safety hazards associated with their process and product and, through a system of preventive controls, to control for those hazards. Every processor is required to have and implement a written HACCP plan whenever a hazard analysis reveals one or more food-safety hazard(s) that is/are reasonably likely to occur. Foreign processors who export seafood products to the United States must operate in conformance with seafood HACCP regulations. In addition, HACCP regulations require importers to take positive steps to verify that they obtain shipments from foreign processors who comply with the regulation requirements. Congress, in FSMA, directed FDA to put in place a similar preventive controls system as the seafood HACCP program for other FDA-regulated foods as a way to prevent problems rather than reacting to them after they occur. The Agency is working to finalize rules to implement these preventive controls for FDA-regulated foods beyond seafood covered by the

HACCP regulation.

The field staff in FDA's Office of Regulatory Affairs (ORA) is responsible for overseeing regulatory compliance for fish and fishery products produced in the United States and for those products imported from abroad. The field staff conducts inspections of fish and fishery product processing establishments, conducts follow-up investigations to track foodborne illnesses, and performs other activities designed to oversee the safety of these products. The HACCP inspection approach is used by FDA during domestic and foreign inspections of seafood processors to focus its attention on the parts of seafood production and processing that are most likely to affect the safety of the product. Specifically, the approach allows FDA to evaluate processors' overall implementation of their HACCP systems over a period of time by having access to the firms' HACCP plans, including monitoring, corrective action, and verification records. In this model, it is the seafood industry's responsibility to develop and implement HACCP controls and the regulatory Agency's to oversee that the industry complies.

FDA allocates its inspection resources based mostly on the risk of the product. Examples of high-priority products include ready-to-eat products, such as hot or cold smoked fish, scombrototoxin-forming fish, such as tuna or mahi-mahi, aquacultured seafood products, and fish packed in reduced oxygen packages. Even though inspectional coverage is based primarily on product risk, FDA district offices may adjust that coverage to inspect a particular establishment, such as one that may have been associated with a consumer complaint or illness or one with a poor compliance history. Domestic seafood processors are inspected at least once every three years. FDA also conducts inspections of foreign seafood processors, and in Fiscal Year (FY) 2014 conducted 303 inspections under the foreign seafood program.

The regulatory sanctions that FDA has available to apply to domestic and foreign processors of fish and fishery products that are non-compliant include Warning Letters, seizure of products, injunction against further non-compliant practices, and/or prosecution of an individual or establishment. FSMA provided FDA with additional tools, such as the authority to issue a mandatory recall for certain foods (other than infant formula, for which FDA already has recall authority), when a company fails to voluntarily recall certain foods that meet certain criteria after being asked to do so by the Agency. In addition, FDA can now order administrative detention of any article of food, if there is reason to believe that it is adulterated or misbranded. These new enforcement tools, combined with FDA's new authority under FSMA to suspend the registration of a facility if the Agency determines that food manufactured, processed, packed, received, or held by such facility has a reasonable probability of causing serious adverse health consequences or death, enable the Agency to more effectively prevent unsafe food from entering commerce. I will describe the Agency's authorities specific to imports later in my testimony.

Working with Government and Industry Partners

FDA also works closely with the states and industry to ensure the safety of the U.S. seafood supply. In addition to the seafood HACCP inspections performed by FDA inspectors, FDA currently contracts with 24 state regulatory agencies to perform seafood HACCP inspections. These state partners operate under equivalent regulatory, operational, enforcement, and compliance protocols, and their inspectors are trained by FDA. There are 929 seafood HACCP inspections scheduled to be performed by our state partners in FY 2015.

The U.S. food safety program that controls molluscan shellfish (oysters, clams, mussels, and scallops) safety is called the “National Shellfish Sanitation Program” (NSSP). The NSSP is a Federal-state cooperative program with oversight provided by FDA in cooperation with state shellfish experts and other members of the Interstate Shellfish Sanitation Conference (ISSC). The purpose of the NSSP is to promote and improve the sanitation of shellfish moving in interstate commerce through Federal/state cooperation and uniformity of state shellfish programs. Thirty-five states have certified shellfish shippers participating in the NSSP. FDA’s Interstate Certified Shellfish Shippers List (ICSSL) is published monthly on FDA’s website for use by food control officials, the seafood industry, and other interested persons. The shippers listed on the ICSSL have been certified by regulatory authorities in the United States, Canada, Korea, New Zealand, and Mexico under the uniform sanitation requirements of the NSSP. Canadian, Korean, New Zealand, and Mexican shippers are included under the terms of the shellfish sanitation agreements FDA has with the governments of these countries. State and local retail food codes modeled after the FDA Food Code contain requirements that make it unlawful for retailers and food service operators to obtain raw molluscan shellfish from sources not included on the ICSSL.

DNA Testing to Address Seafood Fraud

In recent years, there have been reports of seafood in the United States being labeled with an incorrect market name. FDA is aware that there may be economic incentives for some seafood producers and retailers to misrepresent the identity of the seafood species they sell to buyers and consumers. While seafood fraud is often an economic issue, species substitution can be a public health risk (*e.g.*, substituting a scombrotxin- or ciguatoxin-associated fish for a non-toxin-

associated fish). For this reason, the Agency has invested in significant technical improvements to enhance its ability to identify seafood species using state-of-the-art DNA sequencing. DNA sequencing has greatly improved FDA's ability to identify misbranded finfish seafood products in interstate commerce or offered for import into the United States. The Agency has trained and equipped eight field laboratories across the country to perform DNA testing as a matter of course for suspected cases of misbranding and for illness outbreaks due to finfish seafood, where the product's identity needs to be confirmed. FDA also trained analysts from the U.S. Customs and Border Protection (CBP) and the National Marine Fisheries Service in its new DNA-based species identification methodology. FDA has made its protocol for using DNA sequencing for the identification of finfish products as well as its DNA reference standards publicly available through the FDA website. As a follow up to its now established capacity to identify finfish products using DNA, FDA has recently developed a protocol and a DNA reference library to extend these identification capabilities to include commercial species of shrimp, crab, and lobster. The Agency has already posted some of its DNA reference sequences for shrimp, crab, and lobster on its website and anticipates releasing the protocol to the public this year after final peer review, which will enable the seafood industry to monitor and test their products to confirm the species.

With DNA testing capacity in place, FDA has conducted DNA testing on fish that have a history of being misidentified in an effort to determine the accuracy of the market names on their labels. These sampling efforts specifically targeted seafood reported to be at the highest risk for mislabeling and/or substitution, including cod, haddock, catfish, basa, swai, snapper, and grouper. As FDA announced in September 2014, the sampling and testing conducted as part of this project found that the fish species was correctly labeled 85 percent of the time. The Agency

has the authority to take enforcement action against products in interstate commerce that are adulterated or misbranded and refuse admission of products imported or offered for import that appear to be adulterated or misbranded. FDA will use the results from this testing to help guide future sampling, enforcement, and education efforts designed to ensure that seafood offered for sale in the U.S. market is labeled with an acceptable market name for the species. For instance, the Agency is conducting sampling and testing, in cooperation with state and local authorities, to look for mislabeling at the retail level. We also have posted on the FDA website a three-part learning module on proper seafood labeling to help the seafood industry, retailers, and state regulators ensure the proper labeling of seafood products offered for sale in the U.S. marketplace.

REGULATION OF FOOD IMPORTS

FDA's authority under the Federal Food, Drug, and Cosmetic Act (FD&C Act) provides a broad statutory framework to ensure that imported foods are safe, wholesome, and accurately labeled. It is the importer's responsibility to offer for entry into the United States product that is fully compliant with all applicable U.S. laws. Under the seafood HACCP regulation, HACCP controls are required for both domestic and foreign processors of fish and fishery products. Additionally, the regulation requires that U.S. importers take certain steps to verify that their foreign suppliers meet the requirements of the regulation. As mentioned earlier, FDA uses a variety of measures to enforce processors' compliance with seafood HACCP, including inspections of foreign processing facilities, use of a screening system to sample imported products, domestic surveillance sampling of imported products, inspections of seafood importers, evaluations of filers of seafood products, foreign country program assessments, and relevant

information from our foreign partners and FDA foreign office posts.

When an FDA-regulated product is offered for import into U.S. commerce, CBP procedures ensure that FDA is notified. If the product appears to be adulterated or misbranded, based on examination or other information, such as prior history of the product, manufacturer, or country, FDA will give notice advising the owner or consignee of the appearance of a violation under the FD&C Act and the right to provide testimony or evidence (such as a laboratory analysis by an independent laboratory) to rebut the appearance of the violation. In some circumstances, importers may request permission to recondition the product to bring it into compliance with applicable requirements and regulations. If the product is ultimately refused admission, it must be destroyed, unless it is exported by the owner or consignee within 90 days of the date of the notice of refusal.

In 2002, the Congress gave FDA new authorities to enhance protection of the food supply in the Public Health Security and Bioterrorism Preparedness and Response Act. One of the most important provisions is the requirement that FDA be provided prior notice of food (including animal feed) that is imported or offered for import into the United States. This advance information enables FDA, working closely with CBP, to more effectively target food that may be intentionally contaminated with a biological or chemical agent or which may pose a significant health risk to the American public. Suspect shipments then can be intercepted before they arrive in the United States and held for further evaluation. To enhance targeting efforts on commercial imports, FDA participates in the Commercial Targeting and Analysis Center, which consists of CBP and nine other participating Federal agencies.

FDA has numerous other tools and authorities that enable the Agency to take appropriate action regarding imported products. In recent years, the Agency has significantly increased the number of inspections of foreign food manufacturers. For example, FDA conducted 1,336 foreign food facility inspections in FY 2014, compared to 153 inspections in 2008. Looking specifically at seafood, the Agency conducted 303 foreign seafood facility inspections in FY 2014, compared to 95 inspections in 2008. Furthermore, FSMA gave FDA the authority to refuse admission into the United States of food from a foreign facility, if FDA is refused entry by the facility or the country in which the facility is located upon FDA's request to inspect such facility.

Besides physical inspections of domestic and foreign facilities, the Agency's field force also conducts surveillance of food offered for import at the border to check for compliance with U.S. requirements. As part of our surveillance work at the border, FDA utilizes a risk-based approach to allocate resources, with priority given to high-risk food safety issues. FDA screens all import entries electronically prior to the products' entering the country, and a subset of those are physically inspected at varying rates, depending on the potential risk associated with them. Based on the risk ranking, the Agency will direct resources to the more critical activities that have a greater impact on public health. In FY 2014, FDA processed approximately 938,000 entries of imported seafood, while our field staff performed nearly 26,000 physical examinations of seafood imports and collected over 5,600 samples of domestic and imported seafood for analysis at FDA field laboratories.

The Agency has implemented an automated screening tool, the Predictive Risk-based Evaluation for Dynamic Import Compliance Targeting (PREDICT) system, which significantly improves FDA's screening of imported food. PREDICT uses automated data mining and pattern discovery

to identify data anomalies with regard to import and compliance history of a firm and/or a specific product, such as the facility inspection history; results of previous field exams, sample analyses, and facility inspections; and types of products that the firm offers for entry into U.S. commerce. For example, if a firm historically imports fresh seafood and suddenly imports canned seafood, this information is detected by PREDICT and may trigger a decision by the Agency to conduct an examination of the new type of imported product.

Another key tool for screening imported goods is the Import Alert. Import Alerts inform FDA field personnel that the Agency has sufficient evidence or other information about a particular product, producer, shipper, or importer to believe that future shipments of an imported product may be violative. On the basis of that evidence, FDA field personnel may detain the article that is being offered for import into the United States without physically examining the product. The Agency has over 45 active seafood-specific Import Alerts that prevent imports from certain firms and/or countries based upon past violations. When an Import Alert is issued and FDA detains a shipment, the importer has an opportunity to introduce evidence to demonstrate that the product is not violative. Most commonly the existence of an Import Alert shifts the burden to the importer to conduct testing to demonstrate that the product meets FDA regulatory requirements. FDA decisions to remove a product, manufacturer, packer, shipper, grower, country, or importer from detention without physical examination would be based on evidence establishing that the conditions that gave rise to the appearance of a violation have been resolved and the Agency has confidence that future entries will be in compliance with the FD&C Act.

FDA also performs laboratory analysis on a sampling of products offered for import into the United States and performs periodic filer evaluations to ensure that import data being provided to

FDA is accurate. Certain violations relating to imported food may lead to civil or criminal charges.

Working with Foreign Counterparts

FDA is working globally to better accomplish its mission to promote and protect the public health of the United States. The Agency has strengthened and better coordinated its international engagements by establishing permanent FDA posts abroad in strategic locations, such as India and China. The posting of FDA staff in certain overseas regions is a key part of the Agency's strategy for expanding oversight of imported food. An expanded overseas presence allows for greater access for FDA inspections and for greater engagement with foreign industry and foreign counterpart agencies. This all helps to ensure that products shipped to the United States meet applicable FDA requirements.

FDA is working with foreign counterparts in many areas. For example, FDA has worked closely with the Chinese government on inspections, particularly for seafood. FDA imposed a country-wide Import Alert on all farm-raised catfish, basa, shrimp, dace, and eel from China in June 2007, due to the presence of unapproved animal drugs and/or unsafe food additives. Shipments of products covered by the Import Alert may be detained, without physical examination, at the time they are offered for import into U.S. commerce. The shipments can be released by FDA after evidence is provided to overcome the appearance that the products are violative. In October 2014, FDA and representatives from China's General Administration of Quality Supervision, Inspection, and Quarantine visited various facilities along the aquaculture supply chain in two provinces, including shrimp farms, feed stores, feed mills, retail facilities

that sell aquaculture drugs and chemicals, and processing facilities, to better understand China's food safety control systems.

The Agency has conducted foreign country assessments to evaluate the country's laws for, and implementation of, good aquaculture practices. Specifically, FDA evaluates the country's controls, including licensing and permitting, inspections, and training programs for aquaculture products. FDA uses the information from country assessments to better target surveillance sampling of imported aquaculture products, inform its planning of foreign seafood HACCP inspections, provide additional evidence for potential regulatory actions, such as an Import Alert, and improve collaboration with foreign government and industry contacts to achieve better compliance with FDA's regulatory requirements. For example, the country assessments for China in 2006, Chile in 2008, and India in 2010 resulted in increased sampling and testing for aquaculture products from these countries (*e.g.*, eel from China, salmon from Chile, and shrimp from India).

PRESIDENTIAL TASK FORCE ON COMBATING ILLEGAL, UNREPORTED, AND UNREGULATED FISHING AND SEAFOOD FRAUD

As mentioned previously, FDA is aware that there may be economic incentives for some seafood producers and retailers to misrepresent the identity of the seafood species they sell to buyers and consumers, and we have conducted DNA testing on fish that have a history of being misidentified, in an effort to combat seafood fraud. In June 2014, President Obama issued a Presidential Memorandum, "Establishing a Comprehensive Framework to Combat Illegal, Unreported, and Unregulated Fishing and Seafood Fraud." Among other actions, the

memorandum establishes a Presidential Task Force on Combating Illegal, Unreported, and Unregulated (IUU) Fishing and Seafood Fraud (Task Force), to be co-chaired by the Secretaries of State and Commerce. FDA, as a part of HHS, serves on the Task Force. The Task Force released its action plan in March 2015. Among other things, the plan directs the Task Force to identify and develop within six months a list of the types of information and operational standards needed for an effective seafood traceability program to combat seafood fraud and IUU seafood in U.S. commerce. The plan also directs the Task Force to establish, within 18 months, the first phase of a risk-based traceability program to track seafood from point of harvest to entry into U.S. commerce. FDA is working with its government partners to implement these recommendations in order to ensure that imported seafood is properly labeled.

CONCLUSION

Oversight of the safety of the U.S. food supply continues to be a top priority for FDA. The Agency has a strong regulatory program in place for seafood products. FDA will continue to work with our domestic and international partners to ensure the safety of both domestic and imported seafood.

Thank you, again, for the opportunity to appear before you today. I would be happy to answer any questions.