



STATEMENT OF

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**“WASTE AND DUPLICATION IN THE USDA CATFISH
INSPECTION PROGRAM”**

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INTRODUCTION

Good morning Chairman Pitts, Ranking Member Green, and members of the Committee. I am Bill Jones, Deputy Director of the Center for Food Safety and Applied Nutrition's Office of Food Safety, 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.

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.

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.

As you know, the Agriculture Act of 2014 required the U.S. Department of Agriculture (USDA) to issue final regulations for Siluriformes and Siluriformes products, which includes catfish. As

required by Congress, in May 2014, FDA and USDA's Food Safety and Inspection Service (FSIS) established a Memorandum of Understanding (MOU) intended to move primary regulatory oversight of Siluriformes and Siluriformes products from FDA to USDA/FSIS. Since that time, FDA has worked closely with USDA/FSIS to provide training and technical expertise. For example, during the transition, FDA provided assistance to USDA/FSIS regarding FDA historical inspection and enforcement activities concerning Siluriformes and Siluriformes products; guidance and interpretation on FDA's previously issued Import Alerts related to Siluriformes; facility and firm registration information; lab sampling techniques and species identification; information about inspection and follow-up activities related to facility inspection observations; and technical assistance concerning the harmonized tariff schedule codes used for Siluriformes import shipments submitted to Customs and Border Protection's electronic import entry system. Earlier this year, USDA/FSIS began its primary regulatory oversight of catfish and catfish products. FDA continues to exercise regulatory oversight over all other fish and fishery products, including in dual jurisdiction establishments that prepare, pack, hold, or otherwise handle both catfish and other fish and fishery products.

While USDA/FSIS currently has primary regulatory oversight over catfish, I would be happy to discuss FDA's regulatory framework for overseeing the safety of all other fish and fishery products, both imported and domestic.

FDA'S SEAFOOD SAFETY PROGRAM

Because fish are cold-blooded and live in aquatic environments, fish and fishery products pose food safety challenges different from those posed by land animals. For example, certain fish species, like tuna and mahi mahi, produce toxins upon spoilage. These toxins can cause severe

food poisoning and are not destroyed by cooking. In addition, fish that live in contaminated waters can carry contaminants in their bodies. The contaminants generally do not cause food poisoning but contaminated fish can cause health risks if continually consumed over a long time. Fish raised in aquaculture, particularly if raised in unhealthful conditions, may contain residues of unapproved antibiotics or other chemotherapeutics they received for treatment or prevention of diseases or infections associated with those conditions.

FDA has developed extensive expertise in these areas over decades of regulating seafood. Experts in FDA's Center for Food Safety and Applied Nutrition (CFSAN) are responsible for evaluating the hazard to public health presented by chemical contaminants, 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, to which I serve as the U.S. Delegate.

FDA operates a mandatory safety program for the 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 hazard analysis critical control point, or 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 requires a preventive system 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 hazards that are reasonably likely to occur. Foreign processors who export seafood products to the United States must operate in conformance with the seafood HACCP regulation. In addition, the HACCP regulation requires importers to understand the hazards associated with the products they are importing and to take positive steps to verify that they obtain shipments from foreign processors who comply with the regulation's requirements.

The field staff in FDA's Office of Regulatory Affairs (ORA) are 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 conduct inspections of fish and fishery product processing establishments, conduct follow-up investigations to track foodborne illnesses, and perform other activities, such as sampling, 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 FDA's responsibility to oversee industry compliance.

FDA allocates its inspection resources based primarily on the risk of the product. Examples of high-risk products include ready-to-eat products, such as hot or cold smoked fish, scombrototoxin-forming fish, such as tuna or mahi-mahi, and fish in reduced oxygen packaging. Catfish and related fish species are identified in FDA's Fish and Fishery Products Hazards and Controls Guidance as having the potential hazard of chemical contaminants, which could include industrial chemicals such as heavy metals, and pesticides. Chemical exposure is a concern for fish harvested from aquaculture ponds, freshwater bodies, estuaries, and near-shore coastal waters that may be subject to shore-side contaminant discharges, as opposed to the open ocean. Chemical contaminants and pesticides may also accumulate in aquacultured fish through contaminated feed ingredients. In addition, aquacultured catfish may contain residues of unapproved antibiotics or other chemotherapeutics. Given that catfish typically live in environments that may be affected by unapproved drug residues or other chemical contaminants, when catfish were under FDA's HACCP program, a processor of catfish and related species would have had to address the hazard in its HACCP plan.

Catfish typically pose less of an acute food poisoning risk to consumers than certain other types of fish. This is in part because catfish are generally not eaten raw or packaged in ready to eat form and are neither scombrototoxic nor prone to other natural toxins. Historically, FDA sometimes found violations in domestic catfish product and, when we did, took appropriate regulatory action. Generally, when unapproved antibiotic chemicals were detected in imported catfish, FDA placed these products on Import Alert to prevent contaminated product from entering the country, as described in greater detail later in the testimony.

FDA has a number of regulatory tools that apply to domestic and foreign processors of fish and fishery products that are non-compliant, including 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 foods (other than infant formula, for which FDA already has recall authority) when a company fails to voluntarily recall regulated foods that meet certain criteria, after having been 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. In addition to these new enforcement tools, FDA also has 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. These new authorities enable the Agency to more effectively prevent unsafe food from entering commerce.

For example, in 2016, FDA performed environmental sampling of establishments regulated under the seafood HACCP regulation. The environmental sampling from these establishments resulted in a number of seafood recalls because FDA detected *Listeria monocytogenes*. This also led to the registration suspension of one seafood HACCP establishment, which prevents food from the establishment from entering commerce until appropriate measures are taken to protect food safety.

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.

The Agency has numerous tools and authorities that enable it to take appropriate action regarding imported products. The Agency conducts inspections of foreign food manufacturers and, if FDA requests to inspect a foreign facility but is refused, FSMA gave the Agency the authority to refuse that facility's food admission into the United States.

Besides HACCP inspections of foreign facilities, the Agency also conducts surveillance of food offered for import at the border, referred to as import entries, to check for compliance with U.S. requirements. FDA reviews all import entries electronically prior to the products' being allowed into the country. The Agency has implemented an automated screening tool, the Predictive Risk-based Evaluation for Dynamic Import Compliance Targeting (PREDICT) system, which has significantly improved FDA's screening of all imported entries. PREDICT uses automated data mining and pattern discovery to identify data anomalies with regard to imports. The system utilizes the admissibility history for the firm and/or specific product and also incorporates the inherent risk of the product, facility inspection history, data quality concerns and sample analyses, as well as types of products that the firm offers for entry into U.S. commerce. Based on this electronic screening, the Agency focuses its inspection and sampling resources on those entries with the potential for the greatest impact on public health.

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, importer, geographical region, or country to believe that future shipments of an imported product may be violative. On the basis of that evidence, FDA field personnel may detain future shipments of the article that is being offered for import into the

United States without physically examining or testing the product. The Agency has approximately 50 active Import Alerts that identify a seafood product from a firm and/or country based upon past violations.

When an Import Alert is issued and FDA detains an import entry, the importer has an opportunity to introduce evidence to demonstrate that the product is not violative. The Import Alert shifts the burden to the importer to provide testimony to demonstrate that the product meets FDA regulatory requirements. If the testimony includes laboratory analysis, FDA laboratory staff will review the laboratory report to verify that the results are accurate and had been analyzed using a valid method, and that the sample had been collected properly before accepting the results as a basis to release the entry into U.S. commerce. FDA decisions to remove a product, manufacturer, packer, shipper, grower, country, or importer from detention without physical examination (DWPE) would be based on evidence establishing that the conditions that gave rise to the appearance of a violation have been resolved and on the Agency's having confidence that future entries would be in compliance with the FD&C Act.

In March 2016, FDA provided USDA/FSIS a complete list of firms that process catfish and are subject to DWPE, including under Import Alerts for the presence of unapproved drugs in aquaculture, for seafood products contaminated with salmonella, for misbranded seafood, and one related to uneviscerated fish. FDA also provided USDA/FSIS a list of firms that had imported catfish in the previous three years and continues to provide USDA/FSIS with FDA inspection, testing, and import history for firms that have been identified by their competent country authority as intending to import catfish into the United States. It is FDA's understanding that USDA/FSIS has used this information to identify incoming shipments of catfish products for

testing. For example, in May 2016, USDA/FSIS refused shipments of Siluriformes from two Vietnamese companies that FDA had previously flagged for residues of unapproved drugs.

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.

Working with Foreign Counterparts

It is worth noting that FDA is working globally to better accomplish its mission to promote and protect the public health of the United States. As one example, the Agency has conducted foreign country assessments to evaluate the other 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 planning of foreign seafood HACCP inspections, provide additional evidence for potential regulatory actions, such as Import Alerts, and improve collaboration with foreign government and industry contacts to achieve better compliance with FDA's regulatory requirements.

CONCLUSION

Food safety continues to be a top priority for FDA. The Agency has a strong regulatory program in place for fish and other 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.