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Hearing on Chinese Seafood: Safety and Trade Issues

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Members of the Commission, thank you for the opportunity to participate in today's hearing entitled *Chinese Seafood Imports: Safety and Trade Issues*. I am pleased to provide testimony for the U.S. Food and Drug Administration (FDA or the Agency) addressing one of your key issues for this hearing, which is to assess the health impact of imported Chinese seafood.

FDA's SEAFOOD SAFETY PROGRAM

FDA has statutory authority and responsibility for the safety of all food, except for most meats, poultry and processed egg products, which are regulated by the U.S. Department of Agriculture.

With respect to seafood, FDA operates a mandatory safety program for all fish and fishery products under the provisions of the Federal Food, Drug and Cosmetic (FD&C) Act, the Public Health Service Act, and related regulations. The FDA program includes research, inspection, compliance, enforcement, outreach, and the development of regulations and guidance. As a cornerstone of that program, FDA publishes the *Fish and Fisheries 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. FDA is finalizing the fourth edition of this guidance document, which has become the foundation of fish and fishery product regulatory programs around the world.

FDA's program for fish and fishery products is comprehensive in its nature and is fully integrated into the food safety structures of FDA's Center for Food Safety and Applied Nutrition (CFSAN) and FDA's field organization, the Office of Regulatory Affairs (ORA). Because of the cold-blooded nature of fish and the nature of the aquatic environment in which they live, fish and fishery products pose unique food safety challenges which are quite different than those posed by land animals. FDA has developed extensive expertise in these areas over decades of regulating this commodity.

CFSAN experts are responsible for evaluating the hazard to public health presented by chemical 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 (NOAA) 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.

Inspections

FDA's field staff is responsible for ensuring 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 food-borne illnesses, and performs other activities designed to ensure the safety of these products. In FY 2007, FDA staff and state contractors conducted approximately 3,600 inspections of foreign and domestic seafood manufacturers, processors, importers, and storage facilities.

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 Seafood Hazard Analysis Critical Control Point (HACCP) Regulation, in 21 C.F.R. Part 123. 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 keep those hazards from occurring.

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. In contrast to historical methods of evaluating processing practices on the day of the inspection, the HACCP 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 ensure that the industry complies.

Every three years, FDA issues compliance programs that outline the Agency's field staff's inspection responsibilities. The Domestic Fish and Fisheries Products Compliance Program (CP 7303.842) and the Import Seafood Compliance Program (CP 7303.844) provide a priority list for inspection coverage based mostly on risk. Examples of high priority products include ready-to-eat products, such as hot or cold smoked fish, scombrotoxin-forming fish, such as tuna or mahi-mahi, aquacultured seafood products, and fish packed in reduced oxygen packages.

Annually, FDA determines a "work plan" for each FDA district office that outlines the Agency's field staff's domestic inspection responsibilities. This work plan focuses on areas that are a priority for the Agency, and allocates available resources.

Even though inspectional coverage is based primarily on product risk, FDA district offices may adjust that coverage to a particular establishment, such as one that may have been associated with a consumer complaint or illness or one with a poor compliance history. For example, the work plan may dictate that a processor be inspected annually, but if during an inspection the processor is found out of compliance re-inspection will occur more rapidly.

The regulatory sanctions that FDA has available to apply to domestic processors of fish and fishery products that are non-compliant are warning letters, seizure of products, injunction against further noncompliant practices, or prosecution of an individual or establishment.

REGULATION OF FOOD IMPORTS

FDA's primary authority over imported food and other products under our jurisdiction derives from section 801 of the FD&C Act, which provides a broad statutory framework to ensure that the products are safe, wholesome, and accurately labeled.

When an FDA-regulated product is offered for import into U.S. commerce, Customs and Border Protection (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 and the right to provide 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 within 90 days unless re-exported by the owner or consignee.

To better manage the increasing volume of imported products that we regulate, FDA currently screens electronically-submitted information on all incoming shipments, and then uses a risk-based approach to target our inspectional resources at products having the greatest potential for causing harm to public health. It is important to note that while FDA is not able to physically inspect a large percentage of import entries, all import entries are electronically screened for a variety of risk factors, using the Operational and Administrative System for Import Support (OASIS). OASIS is an automated system for processing and helping FDA make admissibility determinations for regulated products offered for import.

In 2002, Congress gave FDA significant new authorities to enhance protection of the food supply in the Public Health Security and Bioterrorism Preparedness and Response Act (the Bioterrorism 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 U.S. 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 U.S. and held for further examination. Prior notice can be submitted either through CBP's Automated Broker Interface/Automated Commercial System (ABI/ACS) or FDA's Prior Notice System Interface (PNSI). Currently, FDA receives approximately 33,400 prior notice submissions per business day.

FDA has numerous other tools and authorities that enable the Agency to take appropriate action regarding imported products. The Agency conducts some inspections of food manufacturers overseas. FDA also performs routine surveillance examinations of imported goods to check for compliance with U.S. requirements. Because of the large volume of FDA-regulated foods being exported from a large number of countries, it is

not feasible to routinely inspect every shipment of foreign-produced foods at the point of import. We do, however, work with foreign governments and food producers to help ensure that imported food is produced, processed, and packed in accordance with U.S. requirements.

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 the product does not meet U.S. requirements or is otherwise unsafe. On the basis of that evidence, FDA field personnel may detain the article that is being offered for entry into the U.S. without physically examining the product. When an Import Alert is issued and FDA detains a shipment, the owner or consignee has an opportunity to introduce evidence to demonstrate that the product is not violative.

FDA also performs laboratory analysis on a sampling of products offered for import into the U.S. 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.

Seafood Imports

More than 80 percent of all seafood consumed by Americans is imported. FDA regulates imported seafood products, including those from aquaculture, by conducting foreign manufacturer inspections, inspecting importers, and performing examinations and collecting surveillance samples of imported goods at the time of entry. FDA prioritizes these import-related activities based on the products' risk. High priority products, and foreign processors or importers of high priority products, are assigned higher priority for surveillance activities. Lower priority products, processors, and importers are sampled or inspected less frequently with remaining resources. Examples of high priority imported products are the same as those produced domestically and include ready-to-eat products such as hot or cold smoked fish, scombrotoxin-forming fish such as tuna or mahi-mahi, aquacultured seafood products, and fish packed in reduced oxygen packages.

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. As previously stated, 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.

In fiscal year (FY) 2007, FDA processed approximately 868,000 entries of imported seafood, while our field staff performed more than 14,000 physical examinations of seafood imports and collected over 6,000 samples of domestic and imported seafood for analysis at FDA field laboratories.

CHINESE IMPORTS

China is a major producer, exporter, and importer of FDA-regulated products and it presents a diverse range of issues for the Agency. China is presently one of the world's largest producers and consumers of agricultural products, and a major supplier to the U.S. of seafood, canned vegetables, fruit juices, honey, and other processed foods. In the past, FDA has encountered compliance problems with several Chinese food exports, including lead and cadmium in ceramicware used to store and ship food, and staphylococcal contamination of canned mushrooms. While improvements have been made in these products, the safety of food and other products from China remains a concern for FDA, Congress, and American consumers. While these concerns are not unique to China, recent incidents have focused greater attention Chinese products.

Aquacultured Seafood

Aquacultured seafood is a fast-growing sector of the world food economy, accounting for approximately half of all seafood production worldwide. More than 80 percent of the seafood consumed in the U.S. is imported from approximately 130 countries, and over 40 percent of that seafood comes from aquaculture operations. By volume, China is the largest exporter of seafood to the U.S., and the second largest in terms of monetary value. In particular, China exports significant amounts of shrimp and catfish products, which represent two of the ten most consumed seafood products in the U.S.

As the aquaculture industry continues to grow, concern about the use of unapproved drugs and unsafe chemicals in aquaculture operations has increased significantly. There is clear scientific evidence that the use of unapproved antibiotics and other drugs and chemicals, such as malachite green, nitrofurans, fluoroquinolones, and gentian violet, can result in the presence of residues in the edible portions of aquacultured seafood. Fluoroquinolones are not approved for use in food fish and have been prohibited from extra-label use in the U.S. and many other parts of the world because of public health concern about the development of antimicrobial resistance. Moreover, prolonged exposure to nitrofurans, malachite green, and gentian violet, or their metabolites, has been shown to induce cancer in humans or animals. From a regulatory perspective, FDA has not approved any of these substances for use as drugs in aquacultured fish, nor are they generally recognized as safe or approved as food additives under the FD&C Act.

Since November 2001, FDA has tested shipments of aquacultured seafood products from China and other countries, and when residues of unapproved drugs have been found, has placed individual firms on Import Alert. In 2006, we significantly broadened these restrictions by issuing an Import Alert providing for the detention without physical examination of eel from anywhere in China due to findings of malachite green. In the course of an increased sampling program of imported Chinese aquacultured seafood which ran from October 1, 2006, through May 31, 2007, FDA continued to find residue of unapproved drugs in fish species including catfish, basa, shrimp, dace and eel.

Because the problems were seen in product from many different companies located in various parts of China, FDA imposed a countrywide Import Alert (IA #16-131) on all farm-raised catfish, basa, shrimp, dace and eel from China.

Shipments of products covered by Import Alert 16-131, which went into effect on June 28, 2007, are subject to detention without 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. Such evidence could include appropriate samples of the product properly analyzed for the aquaculture drugs of concern by a third party laboratory and found to be free of drug residues.

A producer that provides evidence that it has the appropriate controls and processes in place to ensure the safety of its product will be considered for removal from detention without physical examination (DWPE). The import alert recommends that the producer provide information in three areas, as follows:

1. Documentation showing that a minimum of five consecutive entries have been released by FDA based on third-party laboratory analysis verifying that the products do not contain the specified substances;
2. Documentation from an appropriate third party demonstrating that an inspection of the processor was conducted and that the seafood was processed in accordance with FDA's Seafood HACCP regulations, including controls for aquaculture drugs; and
3. Documentation that the processor is in compliance with all Chinese government requirements for exporting aquacultured seafood to the United States.

Since imposition of the countrywide Import Alert, FDA has detained 2,964 shipments of aquacultured seafood from China, and through laboratory testing, 1,387 of those shipments have been released into U.S. commerce.

Zhanjiang Guolian Aquatic Products Corporation, Zhanjiang, China (Guolian), one of the largest aquaculture shrimp exporting firms in that country, was the first Chinese company to request removal from DWPE under the Import Alert. The Chinese government's regulatory agency responsible for the export of food, the General Administration of Quality Supervision, Inspection and Quarantine (AQSIQ) certified Guolian's compliance with FDA's Seafood HACCP Regulation with respect to the control of unapproved aquaculture drugs. AQSIQ has expressed its intention to FDA to use Guolian as a model to show other aquaculture companies how to implement preventive controls for aquaculture drugs that will minimize the risk of unapproved drug residues in the product, facilitating their removal from the Import Alert.

FDA's consideration of Guolian's request for removal from DWPE consisted of the following actions.

1. FDA personnel reviewed documentation of the firm's HACCP controls for unapproved aquaculture drugs and performed an on-site audit of AQSIQ's physical

inspection of the firm's processing plant in China, which included a review of the documentation for aquaculture drug process controls. This audit, conducted in August 2007, indicated that AQSIQ's certification that the firm meets the requirements of FDA's Seafood HACCP Regulation with respect to the control of aquaculture drugs was well founded.
2. FDA reviewed reports of third party laboratory analysis of five consecutive shrimp shipments from the firm in which no drug residues were found.
3. FDA reviewed a certification from the Chinese government that the firm is in compliance with Chinese requirements for exporting seafood to the United States.

Based upon our review, we determined that the firm had demonstrated an ability to consistently produce a non-violative product. Therefore, on September 18, 2007, FDA removed Guolian from detention without examination under Import Alert 16-131. The Agency has reviewed reports of third party laboratory analysis from 27 shrimp shipments produced by the firm from the June 28, 2007 effective date of the Import Alert to the present. No unapproved drug residue was found in any of these samples.

Approximately 26 Chinese firms have requested their removal from Import Alert 16-131. To date, none have fully met FDA's expectations for removal from the Import Alert and Guolian remains the only firm exempted. However, AQSIQ has certified compliance for an additional thirteen Chinese firms and FDA has completed its paper review of the materials related to these firms. An on-site audit of AQSIQ's certification inspections of these firms is planned for July 2008. Successful completion of the audit will result in removal of these thirteen firms from the Import Alert and acceptance of future AQSIQ certification for other firms as meeting the second element (listed above) of removal from the Import Alert.

The National Marine Fisheries Service has also submitted a list of firms that they have certified to be incompliance with the Seafood HACCP Regulation with respect to the control of aquaculture drugs. FDA is awaiting materials from these firms to complete a paper review and, ultimately, an on-site audit.

MEMORANDA OF AGREEMENT

In September 2006, President Bush and Chinese President Hu Jintao agreed to create a Strategic Economic Dialogue between the United States and China. Reflecting the growing relationship between the U.S. and Chinese economies, the Strategic Economic Dialogue is designed to be a forum for discussing ways the United States and China can work together to address economic challenges and opportunities as responsible stakeholders in the international economic system. Last May, in conjunction with the 2nd Strategic Economic Dialogue, FDA and others within the Department of Health and Human Services (HHS) initiated discussions regarding the need for stronger agreements with relevant regulatory agencies in China. The agreements are intended to help assure the safety, quality and effectiveness of FDA-regulated products exported from China to the U.S.

In early December 2007, HHS Secretary Leavitt and Chinese officials signed agreements that represent an unprecedented advance in FDA's efforts to ensure the safety and quality of food, feed and medical products imported from China. The documents, which were countersigned by the Minister of the General Administration of Quality Supervision, Inspection and Quarantine (AQSIQ) and the Commissioner of the Chinese State Food and Drug Administration (SFDA), create an incremental, confidence-building system for enforcing compliance with U.S. standards in regulated products before they leave China.

The AQSIQ agreement requires specific actions to be carried out by clear deadlines, and is based on a three-pronged strategy of registration, certification and verification. First, the Chinese manufacturers of the agreed-upon items have to register with AQSIQ. AQSIQ will share the registration data with FDA, and the food producers must agree to regular inspections to ensure their exports meet the U.S. standards. Second, the agreement specifies that AQSIQ will certify food and feed covered by the agreement that meets FDA's standards. Third, to verify compliance, the Chinese are adopting quality-assurance methods to be applied at each step of the production process. For example, Chinese authorities will develop a comprehensive electronic tracking system to follow products from production to exportation. This will help ensure that growers and manufacturers are building quality into their processes and that FDA can take action if they do not.

Another critical aspect of these agreements is information sharing. Chinese authorities have pledged to provide timely notification to U.S. regulators under a wide range of circumstances, including the failure of a facility to meet inspection requirements and the suspension or revocation of a manufacturer's certification status. FDA inspectors will also gain broader access to Chinese production facilities and on an expedited basis.

FOOD PROTECTION PLAN

Going forward, all of FDA's seafood safety efforts will be informed by the Food Protection Plan announced in November 2007. The Food Protection Plan defines a science and a risk-based approach to better ensure the safety of domestic and imported foods eaten by American consumers.

The Plan, which focuses on both domestic and imported food, complements the Import Safety Action Plan that describes how the U.S. can improve the safety of all imported products. The Import Safety Action Plan lays out a road map with short- and long-term recommendations to enhance product safety at every step of the import life cycle. Taken together, the two plans will improve efforts by the public and private sector to enhance the safety of a wide array of products used by American consumers.

The Food Protection Plan is premised on preventing harm before it can occur, intervening at key points in the food production system, and responding immediately when problems are identified. Within these three overarching areas of protection, the plan contains a number of action steps as well as a set of legislative proposals. Taken together, these

efforts will provide a food protection framework that ensures that the U.S. food supply remains safe.

To strengthen its efforts to prevent contamination, FDA plans to strengthen support of food industry efforts to build safety into products manufactured either domestically or imported. The Agency will work with industry, state, local, and foreign governments to identify vulnerabilities and will look to industry to mitigate those vulnerabilities, using effective methods such as preventive controls.

The plan's intervention element emphasizes focusing inspections and sampling based on risk at the manufacturer and processor level, for both domestic and imported products, that will help verify the preventive controls. This approach is complemented by targeted, risk-based inspections at the points where foreign food products enter the United States.

The plan calls for enhancing FDA's information systems related to both domestic and imported foods to better respond to food safety threats and communicate during an emergency.

The Food Protection Plan's three core elements--prevention, intervention, and response--incorporate four cross-cutting principles for comprehensive food protection along the entire production chain by:

- Focusing on risks over a product's life cycle from production to consumption;
- Targeting resources to achieve greatest risk reduction;
- Using interventions that address both food safety (unintentional contamination) and food defense (deliberate contamination); and
- Using science and employing modern technology, including enhanced information technology systems.

CONCLUSION

Ensuring the safety of the food supply continues to be a top priority for FDA and we are working hard to ensure the safety of all human food and animal feed, in collaboration with our Federal, state, local, and international food safety partners. FDA is working diligently to efficiently and effectively use the resources and authorities provided by Congress to protect the public health of the U.S. and to help ensure that imported products are safe for American consumers. Despite the challenges which face us, the American food supply continues to be among the safest in the world. Thank you for the opportunity to provide testimony to the Commission.