How FDA Regulates Seafood

FDA Detains Imports of Farm-Raised Chinese Seafood

On June 28, 2007, FDA announced a broader import control of farm-raised catfish, basa, shrimp, dace (related to carp), and eel from China. FDA will start to detain these products at the border until the shipments are proven to be free of residues from drugs that are not approved in the United States for use in farm-raised aquatic animals. The agency took this action to protect American consumers from unsafe residues detected in these products. There have been no reports of illnesses to date.

FDA

FDA is taking this strong step now because of continuing evidence that certain Chinese aquaculture products imported into the United States contain illegal substances. Aquaculture, also known as fish farming, involves raising fish in enclosed areas to be sold for food. Almost half of all imported seafood is from aquaculture, according to the U.S. Department of Commerce.

During targeted sampling, from October 2006 through May 2007, FDA repeatedly found that farm-raised seafood from China was contaminated with antimicrobial agents that are not approved for use in the United States. More specifically, the antimicrobials nitrofuran, malachite green, gentian violet, and flouroquinolones, were detected. Nitrofurans, malachite green, and gentian violet have been shown to cause cancer with long-term exposure in lab animals. The use of fluoroquinolones in food animals may increase antibiotic resistance, making it harder for this class of drugs to fight certain infections in people.

"Consumers should know that this is not an immediate public health hazard," says Robert Brackett, PhD, director of FDA's Center for Food Safety and Applied Nutrition. "The levels of contaminants that have been found are very low, and FDA is not advising consumers to destroy or return farm-raised seafood that they may have already purchased and have in their homes. The agency also is not seeking a recall of products already in the marketplace."

FDA is taking this action as a precautionary measure to prevent problems that may occur from long-term exposure to harmful residues. The agency is also concerned about the possible development of antibiotic

FDA, in collaboration with state regulatory counterparts, conducts in-plant inspections that focus on product safety, plant/food hygiene, economic fraud, and other compliance concerns.

resistance. "This action serves to keep contaminated products from entering the country so that they don't reach American consumers," Brackett says.

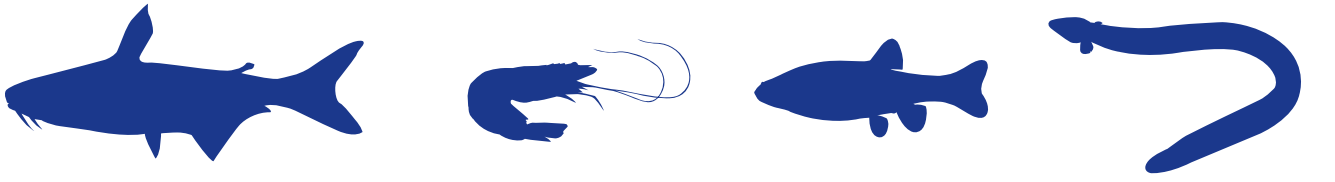
Here's a look at how FDA works to protect consumers from unsafe seafood.

How do drug residues end up in fish?
Some fish are given drugs to treat bacterial and parasitic diseases that cause major mortalities in fish. FDA's Center for Veterinary Medicine (CVM) regulates drugs given to animals. CVM conducts research to improve the drug approval process and expand the number of safe drugs available for fish production. CVM also develops methods to detect unapproved chemicals in fish tissues so that harmful drug residues don't wind up in the fish on your plate.

Is imported seafood required to meet the same standards as domestic seafood?
Yes. Imported foods must be pure, wholesome, safe to eat, and produced under sanitary conditions. FDA requires imported seafood to be free of harmful residues. Importers must comply with regulations under the Federal Food, Drug and Cosmetic Act and the Fair Packaging and Labeling Act. In addition, seafood must be processed in accordance with FDA's Hazard Analysis and Critical Control Point (HACCP) regulations. A 1997 regulation, "Procedures for the Safe and Sanitary Processing and Importing of Fish and Fishery Products," requires seafood processors to identify food safety hazards and apply preventive measures to control hazards that could cause foodborne illness.

What other specific FDA regulatory programs focus on seafood?
- **National Shellfish Sanitation Program:** Administered by FDA, this program provides for the sanitary harvest and production of fresh and frozen molluscan shellfish (oysters, clams, and mussels). FDA conducts reviews of foreign and domestic molluscan shellfish safety programs.
- **Salmon Control Plan:** This is a voluntary, cooperative program among industry, FDA, and the Grocery Manufacturers Association/Food Products Association. It's designed to provide control over processing and plant sanitation, and to address concerns in the salmon canning industry.
- **Low-Acid Canned Food (LACF) Program:** To ensure safety from harmful bacteria or their toxins, especially the deadly Clostridium botulinum (C botulinum), in canned foods, regulations were established to ensure that commercial canning establishments apply proper processing, controls, such as heating the canned food at the proper temperature for a sufficient time to destroy the toxin-forming bacteria. Products such as canned tuna and salmon are examples of LACF seafood products.

How does FDA know when there is a safety concern associated with seafood?
FDA, in collaboration with state regulatory counterparts, conducts in-plant inspections that focus on product safety, plant/food hygiene, economic fraud, and other compliance concerns. FDA also receives notice of every seafood entry coming from a



FDA/Michael Ermarth

After FDA repeatedly found that farm-raised seafood from China was contaminated, the agency announced on June 28, 2007, a broader import control of all farm-raised catfish, basa, shrimp, dace(related to carp), and eel from China.

An import alert identifies products that are suspected of violating the law so that FDA field personnel and U.S. Customs and Border Protection staff can stop these entries at the border prior to distribution in the United States.

foreign country and selects entries from which to collect and analyze samples. FDA laboratories analyze samples for the presence of various safety hazards and contaminants, such as pathogens, chemical contaminants, unapproved food additives and drugs, pesticides, and toxins. Through close collaboration with the Centers for Disease Control (CDC) and state and foreign regulatory partners, FDA also learns of seafood safety concerns that arise through reports of illness potentially associated with seafood products.

What steps does FDA take when problems with seafood are detected?

For imported seafood, FDA has the authority to detain the food at the border to keep it from entering the country. This happens when FDA's analysis of such products indicate that they are not in compliance with the laws and regulations enforced by FDA. FDA can subsequently refuse entries of detained products if evidence of compliance is not provided by the importer or the importer does not correct the problem.

FDA has developed a number of import alerts that address problems found in seafood products in the past. An import alert identifies products that are suspected of violating the law so that FDA field personnel and U.S. Customs and Border Protection staff can stop these entries at the border prior to distribution in the United States. Usually, these import alerts will describe the products or firms that are subject to detention without physical examination. When products are detained without physical examination, the burden for demonstrating compliance of the product falls on the importer. Such compliance must be demonstrated before the product can enter U.S. commerce.

FDA can recommend criminal prosecution or injunction of responsible domestic firms and individuals, as well as seizure of contaminated products in commercial distribution within the U.S. FDA also works with domestic seafood processors to initiate voluntary recalls of contaminated products that may pose a safety concern to consumers.

What kind of research on seafood safety does FDA do?

FDA conducts research to better understand the nature and severity posed by various safety hazards, and other defects which may affect quality and economic integrity and to develop methods to minimize these risks. There are FDA laboratories specializing in seafood research on the Atlantic, Gulf, and Pacific coasts to address regional problems related to toxins and contaminants. FDA also has a facility in Laurel, Md., for conducting state-of-the-art research on drugs used in aquaculture.

What is the consumer's role in seafood safety?

As with any food, consumers should take precautions to reduce the risk of foodborne illness associated with seafood. This includes properly selecting, preparing, and storing seafood. For example, consumers should only buy food from reputable sources and buy fresh seafood that is refrigerated or properly iced. Also, most seafood should be cooked to an internal temperature of 145°F. Some people are at greater risk for foodborne illness and should not eat raw or partially cooked fish or shellfish. This includes pregnant women, young children, older adults, and people with compromised immune systems.

For More Information

Questions and Answers on FDA's Import Alert on Farm-Raised Seafood from China
www.cfsan.fda.gov/~frf/seadwpe.html

Fresh and Frozen Seafood: Serving It Safely
www.cfsan.fda.gov/~lrd/seafsafe.html

Food Safety for Moms-to-Be
www.cfsan.fda.gov/~pregnant/safemea.html

Timeline: Farm-Raised Fish Imported from China
November 16, 2001 - June 28, 2007
www.fda.gov/consumer/updates/fishtimeline062807.html