



CRS Report for Congress

Seafood Safety: Background and Issues

Geoffrey S. Becker
Specialist in Agricultural Policy
Resources, Science, and Industry Division

Harold F. Upton
Analyst in Natural Resources Policy
Resources, Science, and Industry Division

Summary

Congress is paying renewed attention to the safety of fish and shellfish, some of which have been associated with foodborne illnesses and can contain environmental contaminants. Among the issues for lawmakers is whether current food safety programs are sufficiently protecting consumers, and if not, what changes should be considered. Another complexity is that most U.S. consumption is from imports. Seafood safety is being considered along with a number of broader food safety issues in the 110th Congress, where hearings and legislation are anticipated in the second session.

Seafood Safety Risks¹

Studies and dietary recommendations have suggested that increased consumption of seafood can contribute to a more healthful diet.² Nonetheless, seafood consumption is not without risk.

Although hazards caused by microbes and naturally occurring toxins in seafood have been well characterized, the public health burden has been difficult to quantify or to assess over time due to data limitations. Foodborne illness data are prone to under-reporting, and in many cases the cause of the illness (called the food vehicle) may not be determined. The U.S. Centers for Disease Control and Prevention (CDC) published data for approximately 3,550 reported outbreaks of foodborne illness that occurred during

¹ Sarah A. Lister, Specialist in Public Health and Epidemiology, CRS Domestic Social Policy Division, contributed to this section of the report.

² National Academy of Sciences (NAS), Institute of Medicine, Food and Nutrition Board, *Seafood Choices: Balancing Benefits and Risks*, 2007. The U.S. *Dietary Guidelines for Americans, 2005*, for example, cites limited evidence suggesting an association between consumption of fatty acids in fish and reduced risks of mortality from cardiovascular disease for the general population. Accessed at [<http://www.health.gov/dietaryguidelines/default.htm>].

calendar years 2004 through 2006. A causative food vehicle was reported for about 1,900 of the outbreaks. Of these, seafood (finfish or shellfish) was reported as a vehicle in 310 (16% of the 1,900) outbreaks. In comparison, red meats were reported in 325 (17%) outbreaks, and poultry in about 290 (15%).³ To put these data into some perspective, annual U.S. per capita consumption of seafood was about 16 pounds in 2005, compared with 110 pounds for red meats and 74 pounds for poultry.⁴ Collectively, these data suggest that microbial and toxic hazards from seafood may pose a public health threat comparable to that from meat and poultry.⁵

Naturally occurring toxins were involved in more than half of all seafood-associated outbreaks with known or suspected causes in 2004-2006. Such toxins are primarily ciguatera, from certain tropical reef-dwelling finfish, and scombroid poisoning, which develops in some species after harvest due to inadequate refrigeration. Other common problems are norovirus, the bacterium *Vibrio parahaemolyticus* in raw shellfish, and various other pathogens, such as *Clostridium botulinum*, in processed seafood products.

The Institute of Medicine (IOM) has cited other risks of consuming seafood: that of high levels of chemical and heavy metal pollutants from the environment such as mercury, lead, polychlorinated biphenyls (PCBs), and pesticides. Some of these problems, such as high mercury levels, are more evident in carnivorous fish at the top of the food chain, such as shark, swordfish, and bluefin tuna.⁶ But the IOM also has noted that it has been difficult to quantify the risks of some of these hazards due to incomplete data, the complexity of dietary and nondietary contaminant exposures, and the fact that certain health effects such as cancer develop over a much longer period than microbial illnesses.⁷

Worldwide, half of all seafood now comes from aquaculture, as producers seek to meet rising seafood demand at a time when wild stocks are being depleted by overfishing and environmental degradation. Aquacultured (farm-raised) seafood also may contain high levels of potentially harmful chemicals. This was illustrated on June 28, 2007, when the Food and Drug Administration (FDA, in the U.S. Department of Health and Human Services) issued an import alert on the “Detention Without Physical Examination” of all aquacultured products of certain fish species from China. FDA said it issued the notice

³ CRS analysis of CDC *Summary Statistics for Foodborne Outbreaks*, accessed January 2008 at [http://www.cdc.gov/foodborneoutbreaks/outbreak_data.htm]. An outbreak is an incident involving at least two persons.

⁴ U.S. Department of Agriculture (USDA), Economic Research Service (ERS), *Food Availability (Per Capita) Data System*, accessed at [<http://www.ers.usda.gov/Data/FoodConsumption/>].

⁵ See, for example, General Accounting Office (now Government Accountability Office, or GAO) report, *Food Safety: Federal Oversight of Seafood Does Not Sufficiently Protect Consumers* (GAO-01-204), January 2001.

⁶ In March 2004, FDA and the Environmental Protection Agency, for example, issued a joint consumer advisory about mercury in fish and shellfish, directed at women who might become or are pregnant, nursing mothers, and young children. *Backgrounder for the 2004 FDA/EPA Consumer Advisory: What You Need to Know About Mercury in Fish and Shellfish*, accessed January 29, 2008, at [<http://www.fda.gov/oc/opacom/hottopics/mercury/backgrounder.html>].

⁷ *Seafood Choices: Balancing Benefits and Risks*, 2007; and *Seafood Safety*, 1991, both National Academy of Sciences, Institute of Medicine, Food and Nutrition Board.

after targeted sampling in the prior year “repeatedly found that farm-raised seafood imported from China were contaminated with antimicrobial agents that are not approved for this use in the United States.”⁸

Increased imports, including from many other Asian countries in addition to China, have complicated efforts to protect consumers from unsafe fish and shellfish. In 1995, imports already constituted more than half of U.S. per-capita seafood consumption; by 2006 they reached 87%.⁹ By 2005, more than 150 countries were exporting seafood to the United States, FDA observed.

Current Inspection Programs

FDA Safety Inspection. FDA has primary responsibility for the safety of all domestic and imported foods, including seafood, under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended (21 U.S.C. Sec. 301 *et seq.*). Excepted are most meat and poultry products, which the U.S. Department of Agriculture’s Food Safety and Inspection Service inspects under other statutory authorities. The FFDCA requires that all such foods be safe, nutritious, wholesome, and accurately labeled. FDA-regulated foods may be deemed adulterated or misbranded for a variety of statutorily prescribed reasons. FDA also sets maximum safe levels of unavoidable toxic substances in foods, including fish, and requires that all domestic and foreign food manufacturing facilities adhere to Good Manufacturing Practices (GMPs; 21 C.F.R. Part 110), which address safe handling and plant sanitation. Generally exempt are establishments such as farms, including fish farms, that merely raise and/or harvest a raw commodity.

Seafood is one of the few FDA-regulated food groups further regulated under a system of risk prevention controls known as HACCP, for Hazard Analysis and Critical Control Points. Under HACCP, domestic processors must prepare site- and product-specific plans that analyze potential safety hazards, determine where they are likely to occur during processing, identify control points and how they will be monitored, and hazards controlled. Importers of foreign seafood must take steps to verify that the products obtained from foreign processors are in compliance with the HACCP rules.¹⁰

There are an estimated 5,500 active domestic seafood companies and 13,000 foreign seafood firms shipping to the United States.¹¹ However, as the 2001 GAO report (see

⁸ FDA Import Alert #16-13, accessed January 23, 2008, at [http://www.fda.gov/ora/fiars/ora_import_ia16131.html]. The fish species are catfish, basa (related to catfish), shrimp, dace (related to carp), and eel. The banned agents are nitrofurans, malachite green, and gentian violet, which have been found to be carcinogenic to laboratory animals; and fluoroquinolones, an antibiotic whose use may lead to antibiotic resistance. Under the import alert, FDA detains all covered products until the importer demonstrates, through independent testing, that a representative sample of the product is free of these contaminants. See CRS Report RL34080, *Food and Agricultural Imports from China*, by Geoffrey S. Becker.

⁹ Source: U.S. Department of Commerce, National Oceanic and Atmospheric Administration, *Fisheries of the United States, 2006*, at [<http://www.st.nmfs.noaa.gov/st1/fus/fus06/index.html>].

¹⁰ Seafood HACCP regulations (at 7 U.S.C. Part 123) were published in final form in the December 18, 1995 *Federal Register* and became effective on December 18, 1997.

¹¹ January 25, 2008, personal communication, Seafood Inspection Program, National Oceanic and Atmospheric Administration (continued...)

footnote 5) noted, if a processor determines and FDA inspectors agree that a particular product is of low risk, no plan is needed; therefore not all firms necessarily will have a plan. Moreover, fishing vessels are exempt, unless they do more than minimal processing. Following publication of its HACCP rule, FDA sought to inspect all regulated seafood establishments to ensure that HACCP was being implemented, and to continue to visit each one annually. By 2006, FDA indicated that it was no longer inspecting all seafood processors annually due to resource constraints and to the increased number of domestic processors. However, those deemed to be of higher risk “have the highest priority” for inspection.¹² (FDA now conducts inspections of all food establishments that are not high-risk about once every five years, on average.)

The FFDCA empowers FDA to refuse entry to any food import if it “appears,” based on a physical examination or otherwise, to be adulterated, misbranded, or in violation of the law. In exercising its oversight, the agency relies on a system of bonding and of prior notifications by importers and document reviews at points of entry (ports). From lists of these entries, the agency selects products for physical examination and/or testing to determine whether they contain adulterants. FDA inspected, or tested for contaminants, less than 2% of an estimated 860,000 seafood shipments in 2006.¹³

As noted, foreign seafood processors are subject to the same requirements, including HACCP, as domestic firms, and the U.S. importers of their products must take “affirmative steps” to help ensure that these requirements are being met. FDA conducts inspections to check compliance of these importers and of selected foreign processors (for example, 72 in 10 countries in FY2005), focusing on those that are major exporters to the United States and on developing countries less likely to have sophisticated safeguards.

Shellfish Safety. Under provisions of the FFDCA and Public Health Service Act, FDA cooperates with 23 coastal shellfish-producing states and some foreign countries in a National Shellfish Sanitation Program (NSSP) to promote the safe production of fresh and frozen molluscan shellfish — oysters, clams, and mussels — for human consumption.¹⁴ FDA works through the Interstate Shellfish Sanitation Conference (ISSC), an organization of state shellfish regulators who in turn adopt state and local laws, based on an NSSP “model ordinance,” to ensure that shellfish in their jurisdictions are safe and sanitary. An objective of these laws is to ensure that products can be traced to harvest waters that are safe. Generally, dealers must be listed with their state regulatory agency in order to ship shellfish products commercially.¹⁵

¹¹ (...continued)

Atmospheric Administration, U.S. Department of Commerce.

¹² House Appropriations Committee, *Agriculture, Rural Development, Food and Drug Administration and Related Agencies Appropriations for 2007*, Hearings, Part 5, p. 658.

¹³ Food and Water Watch, *Import Alert: Government Fails Consumers, Falls Short on Seafood Inspections*, May 2007.

¹⁴ FDA is authorized to accept assistance from state and local authorities and others in the enforcement of its laws to assure food safety and to prevent the spread of communicable diseases, at 21 U.S.C. 372 in the FFDCA, and 42 U.S.C. 243 in the Public Health Service Act, respectively.

¹⁵ See FDA, National Shellfish Sanitation Program, *Guide for the Control of Molluscan Shellfish, 2005*, at [<http://www.cfsan.fda.gov/~ear/nss3-toc.html>].

NOAA Voluntary Inspection. Within the Department of Commerce, the National Oceanic and Atmospheric Administration (NOAA) administers a voluntary seafood inspection program under authority of the Agricultural Marketing Act of 1946 (7 U.S.C. Sec. 1621 *et seq.*). The program offers additional levels and types of inspection that exceed the FDA HACCP-based requirements, which program participants also must meet. Examples include continuous on-site NOAA inspection during all production hours, certification that plants or vessels meet specified sanitation requirements, quality inspections of individual product lots, and/or laboratory testing of products, among other services. These services are provided on a fee-for-service basis and entitle participants to use various official grading and labeling marks, which are viewed as making their products more attractive to buyers. In 2006, NOAA reported active Seafood Inspection Program contracts with 377 firms, although the participant number changes constantly. The additional number of foreign participants (currently more than 50) has increased recently due to such firms' desire to comply with requirements of the FDA import alert on aquacultured products from China. The number of participating firms is a small fraction of all seafood facilities, but they produce a significant portion of the total volume: in 2006, the NOAA voluntary program inspected 1.9 billion pounds or 33% of the total seafood consumed in the United States.¹⁶

Selected Issues and Bills in Congress

Until the mid-1990s, many seafood safety proposals involved putting inspection on a par with that of meat and poultry. Specifically, the U.S. Department of Agriculture's (USDA's) Food Safety and Inspection Service (FSIS) is required, under the Federal Meat Inspection Act (21 U.S.C. 601 *et seq.*) and the Poultry Products Inspection Act (21 U.S.C. 451 *et seq.*), to inspect all livestock and poultry both before and after they are slaughtered, and to be present continuously whenever plants are processing meat and poultry products.¹⁷ The most recent such proposal (H.R. 4302), introduced in 1996 during the 104th Congress, would have combined meat, poultry, and seafood inspection authorities within USDA.

Jurisdictional differences were among the reasons previous bills were not enacted. USDA and the House and Senate Agriculture Committees have long been responsible for meat and poultry inspection, while FDA, the Senate Committee on Health, Education, Labor, and Pensions, and the House Committee on Energy and Commerce have primary responsibility for the safety of seafood (and other foods). Other unresolved issues included the potentially higher costs to both taxpayers and industry, the complexities of designing a program covering many more seafood species than are involved for meat and poultry, and questions about the extent to which such a program actually would improve public health.

Seafood safety garnered renewed attention in 2007, following a number of reports of contaminated foods, some from foreign sources, entering the food supply. Numerous congressional hearings and media reports in 2007 brought wider public recognition of the role foreign producers now play in meeting U.S. demand for fish and shellfish.

¹⁶ January 25, 2008, personal communication, Seafood Inspection Program, NOAA. Also see NOAA, USDC Seafood Inspection Program, at [<http://seafood.nmfs.noaa.gov/>].

¹⁷ See CRS Report RL32922, *Meat and Poultry Inspection: Background and Selected Issues*, by Geoffrey S. Becker.

Underlining this awareness was the issuance of the Food and Water Watch report in May 2007 (see footnote 13), and the FDA action on Chinese seafood in June 2007 (see footnote 8).

Among other policy developments in 2007 was the Administration's release, on November 6, of two separate but related reports. The broader of the two is the *Action Plan for Import Safety*, covering the safety of most imports for consumers, including but not limited to food. This was prepared by the Interagency Working Group on Import Safety. The other is FDA's *Food Protection Plan*, which focuses on food, both imported and domestic.¹⁸ Both plans are oriented toward assessing, prioritizing, and preventing risks, regardless of a product's origin — that is, an HACCP-like approach. Many recommendations would need new legislative authority and/or additional funding, which the Administration has promised to request in its FY2009 budget proposal.

Another development was the December 11, 2007, announcement by U.S. and Chinese officials of a memorandum of agreement (MOA) on food and feed safety that states the two countries' intention "to establish a bilateral cooperative mechanism" that "may include current and future registration and certification systems. The mechanism aims to provide the Parties with information to use in judging whether an imported product meets the requirements of the importing country." Among the products to be initially included are those of aquaculture, excluding mollusks. Some stakeholders expressed skepticism about the willingness or ability of the Chinese — and the limited resources FDA has — to meet the objectives of the agreement.¹⁹

During its first session, the 110th Congress enacted wide-ranging FDA legislation (P.L. 110-85) with a provision (Sec. 1006) requiring a report to Congress by late March 2008 that describes the specifics of the seafood inspection program, the feasibility of developing traceability systems for catfish and seafood products to both foreign and domestic processing plants, and an assessment of the risks associated with contaminants and banned substances; HHS may enter into partnerships with states on inspection. Sec. 1007 requires FDA to consult with NOAA on a report on environmental risks associated with genetically engineered seafood products, including the impact on wild fish stocks.

The Foreign Seafood Safety Act (H.R. 3077) was introduced in 2007; it would require seafood imports to come from countries that are certified by FDA as using "reliable analytical methods, and that are at least as protective of human health as such programs in the United States." Most other food safety bills now pending in the 110th Congress are not seafood-specific, but likely would affect fish and shellfish safety programs if enacted.²⁰ A provision in the Senate-passed omnibus farm bill (H.R. 2419, Sec. 10002) would require farm-raised catfish to undergo federal food safety inspection comparable to that conducted for meat and poultry species. It also would establish a grading program for the same products under the Agricultural Marketing Act of 1946. The provision is not in the House-passed version of the bill, which was awaiting a House-Senate conference in late January 2008.

¹⁸ The two can be accessed at, respectively, [<http://www.importsafety.gov/report/actionplan.pdf>] and [<http://www.fda.gov/oc/initiatives/advance/food/plan.html>].

¹⁹ See CRS Report RL34080, *Food and Agricultural Imports from China*, by Geoffrey S. Becker.

²⁰ For other bills with at least a potential impact on seafood, see CRS Report RL34152, *Food Safety: Selected Issues and Bills in the 110th Congress*, by Geoffrey S. Becker.