



Seafood Safety: Background and Issues

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April 3, 2009

Congressional Research Service

7-5700

www.crs.gov

RS22797

CRS Report for Congress

Prepared for Members and Committees of Congress

011173008

Summary

Although seafood consumption can contribute to a healthy diet, some fish and shellfish can cause foodborne illnesses or contain environmental contaminants. Are current food safety programs sufficiently protecting consumers, and if not, what changes should be considered? A complexity is that most U.S. seafood consumption is from imports.

The Food and Drug Administration (FDA) within the Department of Health and Human Services plays the lead role in ensuring the safety of both domestic and imported fish and shellfish, but other agencies, including the National Marine Fisheries Service in the Department of Commerce and the Food Safety and Inspection Service in the U.S. Department of Agriculture, also have notable responsibilities.

In the 111th Congress, the first safety bills specific to seafood are S. 92, aimed at violative seafood imports, and H.R. 1370, authorizing \$15 million annually to strengthen coordination between agencies on seafood safety and quality, particularly regarding imports. Several more comprehensive food safety bills, including H.R. 759, H.R. 875, H.R. 1332, and S. 510, could have significant implications for seafood producers and processors.

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Seafood Safety Risks

Studies and dietary recommendations have suggested that increased consumption of seafood can contribute to a more healthful diet.¹ 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 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%).² To put these data in context, 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.³ However, an average outbreak related to seafood consumption generally affects a smaller number of people (i.e., fewer individual cases per outbreak).

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.⁴ 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.⁵

¹ 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>.

² 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 (cases).

³ 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/>. See also 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.

⁴ 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>.

⁵ *Seafood Choices: Balancing Benefits and Risks*, 2007; and *Seafood Safety*, 1991, both National Academy of Sciences, Institute of Medicine, Food and Nutrition Board.

Worldwide, one-third of all seafood now comes from aquaculture, as producers seek to meet rising seafood demand at a time when wild stock production has leveled off at 90 to 95 million metric tons annually. 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 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.”⁶

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 2007 they reached 84%.⁷ 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 (FSIS) inspects under other statutory authorities. The FFDCA requires that all such foods be safe, 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 are to 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.⁸

⁶ 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.

⁷ U.S. Department of Commerce, National Oceanic and Atmospheric Administration, *Seafood Consumption Declines Slightly in 2007*, at http://www.noaa.gov/stories2008/20080717_seafood.html.

⁸ Seafood HACCP regulations (at 7 U.S.C. Part 123) were published in final form in the December 18, 1995 *Federal Register* (continued...)

As the 2001 GAO report (see footnote 3) 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. The agency recently reported that there are approximately 13,400 domestic seafood processing establishments, and that it had inspected a total of 3,066 in 2004, 2,830 in 2005, and 2,456 in 2006.⁹

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 2006.¹⁰

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 (81 processors inspected in 10 countries in 2004, 72 in 10 countries in FY2005, and 68 in 8 countries in 2006), focusing on those that are major exporters to the United States and on developing countries less likely to have sophisticated safeguards. FDA counted approximately 14,900 registered foreign exporters of seafood to the United States, but observed that “a great many more foreign firms are involved in the processing of the products that eventually are shipped to the U.S.”¹¹

FDA is exploring the potential use of third parties to certify foreign processors of aquacultured shrimp for compliance with FDA’s seafood HACCP regulations. During Phase I of the pilot program, FDA screened requests from third-party certification bodies (private, nongovernmental, other federal government, and state government) to participate in the pilot; it announced six participants in late 2008.¹² During Phase II, which was to run through June 2009, FDA is conducting onsite audits of programs by accompanying inspectors during certification inspections. FDA said it intends to evaluate potential use of the pilot program for augmenting

(...continued)

Register and became effective on December 18, 1997.

⁹ FDA, Center for Food Safety and Applied Nutrition. Report to Congress, Food and Drug Administration Amendments Act of 2006, P.L. 110-85, Section 1006—Enhanced Aquaculture and Seafood Inspection, December 20, 2008. Also as required by Section 1006, the document discusses the feasibility of traceability systems for all catfish and seafood products in order to identify their processing plant of origin, and assesses the risks associated with particular contaminants and banned substances. Accessed March 31, 2009, at <http://www.cfsan.fda.gov/~lrd/seartc08.html>.

¹⁰ Food and Water Watch, *Import Alert: Government Fails Consumers, Falls Short on Seafood Inspections*, May 2007.

¹¹ *Report to Congress on P.L. 110-85, Section 1006*. The report also noted that FDA conducted inspections of 657 seafood importers in 2004, 500 in 2005, and 529 in 2006, out of a total of 2,660.

¹² “FDA Announces Participants of Pilot Program for Third-Party Certification of Imported Aquacultured Shrimp,” December 2, 2008 press release, accessed March 31, 2009, at <http://www.fda.gov/bbs/topics/NEWS/2008/NEW01919.html>.

agency efforts and for adjusting the “may proceed” rate for imports of aquacultured shrimp or other food products.¹³

Shellfish Safety

Under provisions of the FFDCFA and the 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

NOAA Voluntary Inspection

Within the Department of Commerce, the National Marine Fisheries Service (NMFS) of 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 on-site NOAA inspections during 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 number of foreign participants (in 2008, 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

¹³ 73 *Fed. Reg.* 39705-39708 (July 10, 2008). A separate FDA document issued in January 2009 sets forth the agency’s criteria for others’ use of *voluntary* third-party certification for food and animal feeds. More information on, and a link to, the FDA *Guidance for Industry: Voluntary Third-Party Certification Programs for Foods and Feeds* can be found in CRS Report R40443, *Food Safety: Selected Issues and Bills in the 111th Congress*.

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 FFDCFA, 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>.

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

GAO Report on Seafood Fraud

GAO in February 2009 reported that the three principal U.S. agencies that share responsibility for detecting and preventing seafood fraud—Customs and Border Protection (CBP) within the Department of Homeland Security, NMFS, and FDA—“do not effectively collaborate with each other. Specifically, they have not identified a common goal, established joint strategies, or agreed on roles and responsibilities.” GAO observed that “CBP and NMFS conduct several activities to help detect and prevent seafood fraud, but FDA told GAO that it focuses on food safety and undertakes few fraud-related activities. Nonetheless, fraud can result in food safety problems. For example, fish that was mislabeled as a different species for financial gain has caused illnesses due to the presence of a potentially deadly toxin.” The GAO report offered a number of recommendations to improve the detection and prevention of seafood fraud, including the addition of fraud detection provisions to the FDA seafood HACCP regulations.¹⁷

Selected Legislation in Congress

Until the mid-1990s through the 104th Congress, many seafood safety proposals sought to put fish inspection on a par with that of meat and poultry. USDA’s FSIS is required, under the Federal Meat Inspection Act (FMIA; 21 U.S.C. 601 *et seq.*) and the Poultry Products Inspection Act (PPIA; 21 U.S.C. 451 *et seq.*), to inspect all livestock and poultry both before and after they are slaughtered, and to be present whenever plants are processing meat and poultry products.¹⁸ 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 (HELP), and the House Committee on Energy and Commerce have claimed jurisdiction over the safety of seafood (and other foods). Others such as the Senate Committee on Commerce, Science, and Transportation, also have had roles.

Seafood safety began to garner new attention in the 110th Congress, following a number of reports of contaminated foods, some from foreign sources, entering the food supply. Numerous congressional hearings and media reports in 2007 and 2008 brought wider public recognition of the role foreign producers now play in meeting U.S. demand for fish and shellfish. Underlining this awareness was the issuance of the Food and Water Watch report in May 2007, and the FDA action on Chinese seafood in June 2007.

2007 FDA Legislation

Wide-ranging FDA legislation (P.L. 110-85) adopted in 2007 includes a provision (§1006) requiring the report to Congress cited above in this CRS report. HHS also may enter into partnerships with states on inspection, under §1006. Under §1007, FDA must consult with NOAA on a report on environmental risks associated with genetically engineered seafood products, including the impact on wild fish stocks.

¹⁷ *Seafood Fraud: FDA Program Changes and Better Collaboration among Key Federal Agencies Could Improve Detection and Prevention*, GAO-09-258, February 19, 2009. The quotations are from the GAO highlights page, accessed March 31, 2009, at <http://www.gao.gov/highlights/d09258high.pdf>.

¹⁸ See CRS Report RL32922, *Meat and Poultry Inspection: Background and Selected Issues*.

2008 Farm Bill

In June 2008, Congress enacted an omnibus farm bill (P.L. 110-246), with a section (§11016(b)) that newly designates “catfish,” as defined by the Secretary of Agriculture, as an “amenable species”—that is, subject to mandatory inspection under the FMIA. The amendment will apply to companies that process catfish for food. It also directs USDA to “take into account the conditions under which the catfish is raised and transported to a processing establishment,” and to consult with FDA. The inspection provision reportedly was urged by the U.S. catfish industry, which has faced strong competitive pressure from foreign catfish producers, particularly in Asia, where, U.S. interests allege, unacceptable types and levels of veterinary drugs are more frequently used. The conference report states the intent of Congress “that catfish be subject to continuous inspection and that imported catfish inspection programs be found to be equivalent under USDA regulations before foreign catfish may be imported into the United States.” The report also noted that the Secretary already has authority under the FMIA to mandate inspection for other seafood species if he deems it appropriate. (He has not.)

FSIS was reportedly working in early 2009 on a proposed rule to implement the catfish inspection requirement. In 2008, the agency reportedly estimated that it would need \$5.3 million and 91 staff in FY2009, and \$16.5 million and 95 staff in FY2010, to implement the program. FSIS estimated that at least 22 processing plants, primarily in the southern United States, would have to be inspected, and at least 15 foreign countries would have to apply for an FSIS determination that their inspection systems are equivalent to the U.S. safety systems before any of their establishments could ship catfish to the United States.¹⁹

Also, §11016(a) of the farm bill amends the Agricultural Marketing Act of 1946 (7 U.S.C. 1622) to require USDA to establish a voluntary grading program for catfish, which producers could opt into and pay for with user fees (as exists in other USDA quality grading programs authorized by the 1946 act). The section further authorizes producers of other farm-raised fish and shellfish species to apply for voluntary grading services.

Bills in the 111th Congress

As of April 3, 2009, two bills focusing on seafood safety had been introduced. A measure (S. 92) by Senator Vitter would require the HHS Secretary to refuse all imports of seafood or seafood products from a country or exporter that does not meet requirements of the food and drug act (FFDCA) or is not likely to meet the requirements of any other federal food safety law. It also contains notification requirements for shipments that are refused entry. On the House side, H.R. 1370 by Representative Weiner would require the Secretaries of Commerce and HHS to enter into a memorandum of understanding for more cooperation and coordination on seafood safety activities (to include specific provisions listed in the bill), require an increase in laboratories certified to analyze seafood for compliance with federal law, and authorize \$15 million in each of FY2010 through FY2014 to fund these and other activities outlined in the bill.

A number of more comprehensive food safety measures—H.R. 759 (Dingell), H.R. 1332 (Costa), and S. 510 (Durbin)—call for substantial changes to FDA’s food safety programs primarily by

¹⁹ Source: “Details of USDA catfish inspection plan revealed in 5-page memo,” *Food Chemical News*, December 1, 2008.

amending the FFDCFA. Many of these proposed changes could have implications for seafood facilities regulated by FDA. Another bill impacting seafood producers and processors, particularly those participating in the NOAA-NMFS program, is H.R. 875 by Representative DeLauro. The DeLauro bill would create a new, independent Food Safety Administration within HHS but separate from FDA, to which all current food safety functions, personnel, and assets now at FDA would be transferred. Additionally, the DeLauro bill would move to the new agency all personnel and assets used to administer the NMFS seafood inspection program.

For details on these and other food safety bills, see CRS Report R40443, *Food Safety: Selected Issues and Bills in the 111th Congress*.

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Acknowledgments

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