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CRS Report for Congress

Seafood Safety: Background and Issues

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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. In the 110th Congress, the farm bill (P.L. 110-234) established new U.S. Department of Agriculture (USDA) catfish inspection requirements. Elsewhere, a Senate committee-approved bill (S. 2688) is intended to strengthen oversight of seafood imports. Other pending bills include H.R. 3077 and S. 2914, also to improve seafood import safety; and H.R. 5219, to increase funding for seafood inspections.

Seafood Safety Risks[1]

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)

[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].

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%).[3] 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.[4] 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.[5] 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.[6]

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

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[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 (cases).

[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/]. 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.

[5] 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].

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

imported from China were contaminated with antimicrobial agents that are not approved for this use in the United States."[7]

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%.[8] 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.[9]

As the 2001 GAO report (see footnote 4) 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

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[7] 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 nitrofuran, 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.

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

[9] 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.

implemented, and to continue to visit each one annually. FDA has indicated that it is inspecting higher-risk seafood firms annually and lower-risk firms every two to three years.

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 (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.

FDA is exploring the potential use of third parties to certify foreign processors of aquacultured shrimp for compliance with FDA's seafood HACCP regulations. FDA has developed a pilot program to collect information for evaluating third-party programs. Phase I of the program will consist of screening requests from third-party certification bodies (private, nongovernmental, other federal government, and state government) to participate in the pilot. In Phase II, FDA will conduct onsite audits of programs by accompanying inspectors during certification inspections. FDA intends to evaluate potential use of the pilot program for augmenting agency efforts and for adjusting the "may proceed" rate for imports of aquacultured shrimp or other food products.[11]

Shellfish Safety. Under provisions of the FFDCA 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.[12] 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.[13]

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

[11] 73 *Fed. Reg*. 39705-39708 (July 10, 2008).

[12] 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.

[13] 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 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 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.[14]

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.[15] 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 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. 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 a report to Congress in 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

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

[15] See CRS Report RL32922, *Meat and Poultry Inspection: Background and Selected Issues*.

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.

2008 Farm Bill. In May 2008, Congress enacted a new omnibus farm law (P.L. 110-234), 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.

Also, §11016(a) 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.

Other Bills. Several other bills are pending in the 110th Congress. The Senate Commerce Committee marked up, on April 24, 2008, the Commercial Seafood Consumer Protection Act (S. 2688). The committee-approved bill would require the HHS and Commerce Departments to cooperate on examining and testing seafood imports; coordinating inspections of foreign facilities; providing for expedited entry for those with good safety records; increasing seafood testing laboratories; and conducting more oversight of problem exporters and their countries, among other provisions. Other bills include S. 2914, on actions to be taken when seafood imports are refused U.S. entry; H.R. 3077, to require seafood imports to come from countries with equivalent safety systems; and H.R. 5219, to authorize appropriations of $6.75 million in FY2009 for implementing an FDA seafood inspection regime. Some changes in seafood regulation might come through broader legislative proposals to improve food safety policies; more than two dozen such bills have been introduced.[16]

In November 2007, the Administration weighed in with its own options, in two separate reports. *Action Plan for Import Safety*, prepared by the Interagency Working Group on Import Safety, covers the safety of most imports. *Food Protection Plan*, prepared by FDA, focuses on food, both imported and domestic. Both plans are oriented toward assessing, prioritizing, and preventing risks — that is, a HACCP-like approach.[17]

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[16] Such non-farm bill proposals are discussed in other CRS reports; see "Food Safety and Nutrition" under the "Agriculture" entry on the CRS home page, at [http://www.crs.gov/].

[17] These plans are at, respectively, [http://www.importsafety.gov/report/actionplan.pdf], and [http://www.fda.gov/oc/initiatives/advance/food/plan.html].